16th Congress of



30 March - 1 April 2011, Vienna - Austria

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¹De Prijck, K, D'Haese E, Vandenbroucke J et al. Microbiological challenge of four protective devices for the reconstitution of cytotoxic agents. Soc. Appl. Microbiol. 2008; 47: 543-548.



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GENERAL INFORMATION

- The poster judging will take place on Thursday, 31 March 2011.
- Poster presenters must check in with the hostesses in the poster area (main entrance area of the congress centre) on Wednesday, 30th March, and they will assist participants with hanging their posters in the proper area.
- The poster prize winners must be present at the closing ceremony on Friday, 1st April in order to win.

DISCLAIMER

EAHP makes no representations or warantees of any kind expressed or implied about the completeness, accuracy, reliability, suitability or availability with respect to the content of the abstracts and related graphics and tables. Any reliance you place on such information is therefore at your own risk. In no event will EAHP be reliable for any loss or dammage arrising from or in connection with the content of these abstracts.

POSTER AWARD

Encouragement prize for investigators

The best abstracts/posters – with regards to aspects like originality, scientific quality and practical applicability – will be awarded with 3 prizes amounting EURO 750, EURO 500 and EURO 250. The winners will be announced at the closing ceremony of the congress. The winner must be present at the ceremony to receive his/her award.



EAHP - EPSA award

Recognising and honouring the best scientific research manuscript authored by an undergraduate student

During its annual congress, EAHP will offer the Student Science Award to one or several European Pharmaceutical Student Association (EPSA) students, hence recognising and honouring the best scientific research manuscript authored by an undergraduate student. This award recognises a student's significant intellectual contribution which promotes the state of the art in hospital pharmacy and pharmaceutical research methods or theories. EPSA students and members are invited, through their organisation to submit manuscripts to an EAHP jury, who will select the best paper. The later will be presented during the congress and published in EJHP.





Nature of the Award:

First author of the winning article will receive free attendance to the 16th EAHP Congress in Vienna, €500 for travel and accommodation expenses, plus official recognition of the winner during the EAHP Congress closing ceremony.

Eligibility Criteria:

Any manuscript under the category of original research, case reports, scientific commentary and review articles, written by any undergraduate hospital pharmacy student(s) submitted for peer review by 15 January 2011 and approved for publication in the EJHP March 2011 issue in either the EJHP Practice or the EJHP Science journal, will be eligible for this competition.

Submission Procedures:

Any EPSA member may submit a manuscript following the **EJHP Guidance for Authors**. The manuscript shall be submitted to **abstract@eahp.eu**. A complete copy of the manuscript must accompany the submission. A cover letter should be provided that states why the article represents an outstanding contribution to the field of hospital pharmacy and describes how it advances hospital pharmacy research, clinical, scientific, technical, economic and social aspects of pharmacy and therapeutics or affects health policy.

Review and Selection:

The EAHP- EPSA Student Science Award Jury serves as the review and selection committee for the Student Science Award. The jury will select the single best manuscript that shows significant insight into hospital pharmacy research from all those submitted based on its scientific quality and societal relevance. The committee has the discretion to not make the award in any given year.

Award Presentation:

The EAHP-EPSA Student Science Award will be presented during the award ceremony at the EAHP Annual Congress in Vienna, Austria on 1 April 2011.

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* RRR 70%; 95% CI, 49 to 82; (P<0.001) in modified ITT population; total VTE: any DVT, non-fatal PE, and all-cause mortality. 1. Eriksson Bl et al. *N Engl J Med*. 2008;358(26):2765–2775. 2. Kakkar AK et al. *Lancet*. 2008;372:31-39

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Qualitative und quantitative Zusammensetzung: 10mg Rivaroxaban. Liste der sonstigen Bestandteile: Mikrokristalline Cellulose, Croscarmellose-Natrium, Lactose-Monohydrat, Hypromellose, Natriumdodecylsulfat, Magnesiumstearat, Macrogol (3350), Titanoxid (E171), Eisen(III)oxid (E172). Pharmakotherapeutische Gruppe: Andere antithrombotische Mittel, ATC-Code: B01AX06 Anwendungsgebiete: Zur Prophylaxe venöser Thromboembolien (VTE) bei erwachsenen Patienten nach elektiven Hüft- oder Kniegelenksersatzoperationen. Gegenanzeigen: Überempfindlichkeit gegen Rivaroxaban oder einen der sonstigen Bestandteile, klinisch relevante akute Blutungen, Lebererkrankungen, die mit einer Koagulopathie und einem klinisch relevannten Blutungsrisiko verbunden sind, Schwangerschaft und Stillzeit. Vorsichtsmaßnahmen und Warnhinweise: Die Anwendung von Rivaroxaban wird nicht empfohlen bei Patienten: - die gleichzeitig eine systemische Behandlung mit starken CYP3A4 und P-gp Inhibitoren, z. B.: Azol-Antimykotika (wie Ketoconazol, Itraconazol, Voriconazol u. Posaconazol) oder HIV-Proteaseinhibitoren (z. B.: Ritonavir) erhalten, - mit einer schweren Nierenfunktionsstörung (Kreatinin-Clearance 15 ml/min), und, da keine Daten zur Sicherheit und Wirksamkeit vorliegen, bei Patienten: - unter 18 Jahren, - die sich einer Operation nach einer Hüftfraktur unterziehen. Die folgenden Patientengruppen weisen ein erhöhtes Blutungsrisiko auf und müssen daher von Beginn der Behandlung an sorgfätig beobachtet werden: Patienten mit einer schweren Nierenfunktionsstörung (Kreatinin-Clearance 15 - 29 ml/min), Patienten mit einer mittelschweren Nierenfunktionsstörung (Kreatinin-Clearance 30 - 49 ml/min), die gleichzeitig andere Arzneimittel erhalten, die zu erhöhten Rivaroxaban Plasmaspiegeln führen können, zirrhotische Patienten mit einer mittelschweren Leberfunktionsstörung (Kreatinin-Clearance 30 - 49 ml/min), die gleichzeitig andere Arzneimittel erhalten, die zu erhöhten Rivaroxaban Plasmaspiegeln führen können, zirrhotische Patienten mit einer mittelschweren Le

konzentration von Rivaroxaban führen und somit seine Wirksamkeit verringern und sind bei gleichzeitiger Einnahme mit Rivaroxaban mit Vorsicht anzuwenden. Besondere Vorsicht ist geboten bei der Anwendung von neuraxialer Anästhesie (Spinal/Epiduralanästhesie) oder Spinal/Epiduralpunktion. Xarelto enthält Lactose. **Nebenwirkungen**: Häufig: Anstieg der GGT, Tiransaminasenanstieg (einschließlich enthölte ALT und AST), Anämie (einschließlich entsprechender Laborparameter), Übelkeit, postoperative Blutungen (einschließlich postoperativer Anämie und Wundblutungen). Gelegentlich: Anstieg von Lipase, Amylase, Bilirubin im Blut, LDH und alkalischer Phosphatase, Tachykardie, Thrombozytose (einschließlich rehöhter Thrombozytenzahl), Synkope (einschließlich Bewusstlosigkeit), Schwindel, Kopfschmerzen, Verstopfung, Durchfall, abdominale und gastrointestinale Schmerzen (einschließlich Oberbauchschmerzen, Magenbeschwerden), Dyspepsie (einschließlich seinschränkung der Nierenfunktion (einschließlich Kreatinin- und Harnstoff-Anstieg im Blut), Pruritus (einschließlich seltener Fälle von generalisiertem Pruritus), Hautrötung, Urtikaria (einschließlich seltener Fälle von generalisierten Pruritus), Hautrötung, Urtikaria (einschließlich Hämatomen und seltenen Fällen von Muskelblutungen), gastrointestinale Blutungen (einschließlich Zahnfleisch- und Rektalblutungen, Bluterbrechen), Hämaturie (einschließlich Müdigkeit, Asthenie), Fieber. Selten: Anstieg von konjugiertem Bilirubin (mit oder ohne gleichzeitigem ALT Anstieg), allergische Dermatitis, Leberfunktionsstörung. Häufigkeit nicht bekannt: Blutungen in ein kritisches Organ (z. B.: Gehirn), Blutungen der Nebenniere, Blutungen der Bindehaut, Hämoptysis, Überempfindlichkeitsreaktionen, Gelbsucht. Inhaber der Zulassung: Bayer Schering Pharma AG, 13342 Berlin, Deutschland. Verschreibungs-/Apothekenpflicht: NR, apothekenpflichtig. Weitere Angaben zu Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln und sonstigen Wechselwirkungen.

gen, schwangerschaft und Sinizert und veerwinkungen sind der veröffentlichten Fachinformation zu entnehmen. **Stand der Information**: Juni 2010. Xarelto Fachkurzinformation, Version Österreich



POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

CPC022 Clinical intervention audits - Why bother?

M. Creed, B. Kehoe, J. Brown, M. McGuirk, C. Meegan

¹Mater Misericordiae Hospital, Pharmacy, Dublin, Ireland (Rep.)

Background

Clinical pharmacy services have been provided to all wards in the MMUH since 1994. Clinical pharmacists frequently make reactive interventions, which are any action by a pharmacist that directly results in a change to a patient's management or therapy (1). However, time and resource constraints have limited the auditing and assessment of this.

Purpose

Categorise day-to-day interventions performed by MMUH clinical pharmacists. Produce a robust, easy-to-use 'Clinical Intervention Audit Tool'. Pilot the tool and estimate annual clinical pharmacist intervention numbers. Compile reports based on information obtained in the audit and to establish what information could be gained from routine intervention recording.

Material and Method

Literature review, cross-sectional study to identify pharmacists' top interventions, design and pilot data collection form, collection of data by each clinical pharmacist for one day during a four-day data collection period, analyse & evaluate data using Microsoft Excel.

Results

The collection tool developed was based on the observation of clinical pharmacists' top interventions: checking patient details, prescription and administration problems, medication enquiries and patient counselling, stock issues and monitoring. The tool can generate reports; top drugs, classes of drugs and specialties involved in pharmacists' interventions. Total number of interventions = 546 (113 patients); Average = 4.83 per patient. Annual number of interventions was extrapolated to be 77,744 based on discharge statistics. 183 interventions related to prescription & administration, involving 108 drugs. Anti-infectives and anticoagulants were the drug classes that required most intervention. Orthopaedics was the specialty that required most prescription & administration interventions.

Conclusion

Information generated from recording clinical pharmacists' interventions is highly valuable and should be performed on a routine basis. It provides information on the impact of clinical pharmacy services on local prescribing and drug administration practices, the educational needs of staff and underscores the need for continuous clinical audit.

No conflict of interest

GRP014 New pharmacogenetic biomarkers for predisposition to toxicity in colorectal cancer patients

L. Cortejoso-Fernández, M.I. García-García, E. González-Haba, P. García-Alfonso, M.N. Sánchez-Fresneda, M.L. Martín-Barbero, M. Sanjurjo-Sáez, L.A. López-Fernández

Background

5-fluorouracil (5-FU) and capecitabine are the *gold standards* in colorectal cancer (CRC) treatment. The objective was to identify genetic biomarkers associated with moderate and severe toxicity of these drugs in CRC patients.

Material and Method

Retrospective study with 116 CRC patients taking 5-FU/capecitabine alone or in combination with other drugs. Clinical data (age, sex, treatment and toxicity) and genotype of the selected *single nucleotide polymorphisms* (SNPs) were recorded. DNA containing these genomes was isolated using PCR Template Preparation Kit (Roche). Based on the *Common Terminology Criteria for Adverse Events* patients were classified into 2 groups depending on the neutropenia: negative (grades 0-I) or positive (grades II-IV). DMET Plus microarray (Affymetrix) was used with 42 samples (22 from patients with grades 0-I neutropenia and 20 from patients with grades II-IV) to identify biomarkers for predisposition to neutropenia. Selected SNPs were genotyped by the SNaPshot technique. Fisher's exact test and linearity by linear association chi-square test (SPSS v.15.0.) were used to study association between polymorphisms and toxicity. p < 0.05 was considered significant.

Results

10 different forms of 9 genes (*GSTT1* (rs2266637), *PPARD* (rs7757196), *ABCC4* (rs4148551 and rs3742106), *CYP2A6* (rs3742106), *CYP2C9* (rs1057910), *DPYD* (rs2297595), *CDA* (rs2072671), *CYP2B6* (rs8192709)and *ABCC5* (rs3805114)) were selected according to 2 criteria: 1) have a role in the metabolism of fluoropyrimidines or 2) imply an important difference in the percentage of patients affected by neutropenia depending on the genotype. Statistically significant associations were obtained between the presence of zero copies in *GSTT1* and the development of asthenia and neutropenia and between the presence of polymorphisms in *ABCC4* and *CYP2C9* and neuropathy.

Conclusions: DMET Plus microarray is a valid approach to find new polymorphisms related to adverse reactions in 5-FU/capecitabine-treated patients. Bigger cohorts are needed to verify the associations obtained between the polymorphisms in *GSTT1*, *ABCC4* and *CYP2C9* and the development of toxicity.

No conflict of interest

¹Hospital General Universitario Gregorio Marañon, Pharmacy, Madrid, Spain

²Hospital General Universitario Gregorio Marañon, Oncology, Madrid, Spain

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POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

PHC011 Treatment of 70 patients in a surgical intensive care unit with posaconazole ñ a single centre experience

T. Hoppe-Tichy, C. Lichtenstern, S. Swoboda, S. Hofer, M.A. Weigand, D. Störzinger

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²University Hospital of Giessen, Department of Anesthesiology, Giessen, Germany

³University Hospital of Heidelberg, Department of Anesthesiology, Heidelberg, Germany

Background

Invasive fungal infections (IFIs) are a rising problem in surgical intensive care units (SICU). Posaconazole, an extended-spectrum triazole, is effective against *Candida* spp. and *Aspergillus* spp. and has a favourable safety and tolerability profile.

Objectives

Aim of this observational, retrospective drug use evaluation (DUE) was to assess the use of posaconazole in SICU patients.

Material and Method

Patients (N=70) were admitted to the SICU between April 2006 and July 2009 and administered posaconazole (via gavage). Posaconazole use was evaluated in terms of demography, co-morbidities, microbiological, clinical infection and mortality data.

Results

Renal replacement therapy (65.7% of patients), transplantation (48.6%), diabetes mellitus (28.6%) and cancer (17.1%) predisposed the majority of the patient population to a higher risk of IFI. Fungal infections were found in 61/70 patients (87.1%), of which 88.5% had *Candida* and 34.4% had *Aspergillus*. The mean duration of posaconazole therapy in the SICU was 8.1 days; 60.0% of patients received prior antifungal therapy (i.e. caspofungin, fluconazole or itraconazole) and 20.0% of patients switched to other antifungal therapy after posaconazole treatment. Conclusions

Posaconazole may be an important and safe treatment option for SICU patients.

No conflict of interest

GRP022 An Audit of Electronic Prescribing in ICU

Casserly M., "Ging P.," Meegan C., "Marsh B., a Fahey L., a Curran MR.

"Pharmacy Department, aIntensive Care Unit, Mater Misericordiae University Hospital (MMUH)

Background

Medication errors in the Intensive Care Unit are common and causes are multifactorial¹. An MMUH ICU audit was carried out in 2007 looking at the number and type of prescribing errors². Electronic prescribing has been shown in various studies to reduce prescribing errors. As a result, both the USA & UK health policies recommend the introduction of electronic prescribing³. In September 2009, the MMUH ICU introduced Philips Intellivue Clinical Information Portfolio® (ICIP) which incorporates computerised physician order entry (CPOE).

Purpose

To compare the number and type of medication errors before and after the introduction of ICIP.

Material and Methods

- Prospective study with consecutive sampling.
- 10-day data collection period.
- · Comparable data collection to previous prescribing audit.
- · Results compared to previous audit.

Results

219 patients (pre-ICIP) vs. 249 patients (post-ICIP).

66 prescribing errors pre-ICIP vs. 43 post-ICIP.

The introduction of CPOE eliminated some common errors associated with handwritten prescriptions e.g. incomplete or illegible prescriptions. The prescribing of drug name, dose, route & frequency are now mandatory fields and cannot be omitted. Every prescription can be traced to the prescriber, as every user of the ICIP system has a unique password-protected identity. The number of patients with incomplete allergy status declined from 37 to 3, as it is a mandatory field. The number of duplicated prescriptions increased with the use of CPOE from 3 to 8. A drug was prescribed for the wrong patient (n=1). IV infusions appear as active although the patient is no longer receiving them (n=20).

Conclusion

Electronic prescribing reduces prescribing errors but it does not eliminate them. It changes the nature of the error and can introduce new errors. This audit has helped identify what modifications and improvements are required for the ICIP system. As a result of this audit, a set of prescribing rules has been drawn up to help improve the safety of CPOE. Each prescriber and every computer now has a laminated list of these rules. Portfolio® (ICIP) which incorporates computerized physician order entry (CPOE).

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POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

GRP051 Prevention strategies for medication errors - which one to pick?

H.M. Seidling, D.W. Bates, W.E. Haefeli, C. Lovis, P. Bonnabry

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⁵Geneva University Hospitals, Pharmacy, Geneva, Switzerland

Background

To minimize patient harm resulting from medication errors, many interventions have been developed. However, these strategies show varying impact on prevention of medication errors. Moreover, most strategies have been implemented in single medical centers and generalizability of the results remains uncertain. We aimed to assess (1) which prevention strategies have been implemented and evaluated, (2) which outcomes have been achieved, and (3) which strategies have been found to be most useful with regard to different constraints.

Material and Methods

We conducted a literature search in Medline including the MESH-term "Medication Errors/prevention and control" and developed a classification schema based on published prevention strategies. Subsequently, distinct literature researches identified studies for each strategy. Controlled or quasi-controlled interventions which assessed prevention of medication errors as primary endpoint were included.

Results

We identified 20 different prevention strategies allocated to three superordinated categories (i.e. persons, processes and structures, and products). Literature research identified 1123 studies, of which 122 met our inclusion criteria. The prevention strategies aggregating most publications were quality improvement programs and computerized physician order entry; the fewest studies were published for electronic health records. About 90% of studies reported a positive effect on at least one type of medication error. 38 studies assessed secondary outcomes, 23 found positive effects, particularly on adverse drug events. Prevention strategies have been assessed primarily for inpatient and outpatient care (N=45 and 21); only 4 studies assessed hospital discharge. Overall, education of professionals and combined interventions showed highest chances to be sucessfull (83% of studies). For paediatrics, quality improvement programs seemed more and clinical pharmacist interventions less promising compared to adults.

Conclusion

In conclusion, despite major variations in methodology, current literature may allow identification of the prevention strategies most appropriate taking into account specific constraints such as setting, patient population and error type.

No conflict of interest

TCH022 Mercaptopurine suspension 10 mg/ml

D.J. Postma, H.W.G. Wagenaar: 1Royal Dutch Pharmaceutical Society, Den Haag, Den Haag, The Netherlands

Background

Internationally, the WHO emphasizes the importance of developing new paediatric medicines. In the Netherlands, this importance is generally recognized. When industry does not provide suitable preparations, formulations should be developed for small scale compounding in public or hospital pharmacies. To this aim, the Royal Dutch Association of Pharmacists (KNMP) cooperates closely with the Special Interest Group on Paediatric Medicine of the Dutch Association of Hospital Pharmacists (NVZA). One of the developed formulations is Mercaptopurine suspension 10 mg/ml.

Purpose

Mercaptopurine is practically insoluble in water. This means that an oral, liquid preparation with mercaptopurine is only feasible as a suspension. Literature1 suggests that ascorbic acid should be added as anti-oxidant, to protect mercaptopurine for oxidation. The need for an anti-oxidant is doubted, because the mercaptopurine will be merely suspended and is not dissolved. A stability study has been performed on two formulations, with and without ascorbic acid. Aim of the study is to find a formulation that yields a stable suspension for at least 6 months.

Materials and methods

Several batches of mercaptopurine suspension 10 mg/ml were prepared in a standard suspension base, with and without ascorbic acid. The batches, packed in PET-bottles, were kept at 25 °C for 6 months. Samples were taken at 0, 1, 3, 6 and 9 months, and were analysed for appearance, pH, viscosity, related substances and content of mercaptopurine. For the assay a stability-indicating HPLC-method was used, based on the Ph.Eur. monograph for the active ingredient.

Results and conclusions

All suspensions show stability for at least 6 months, regarding the content of mercaptopurine. The addition of ascorbic acid has no additional value. On the contrary, ascorbic acid causes a slight colouration of the suspension, while the viscosity decreases in time. This is unwanted in regard to the physical stability. It is concluded that a formulation without ascorbic acid yields the most stable suspension.

Literature

1. Am J Health Syst Pharm 65(2008): 441-7.

No conflict of interest

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POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

GRP004 The pharmacist as a member of a multidisciplinary group to control the use of restricted antibiotics

C. Lopez Martin, B. Tortajada, M. Nieto, A. Gomez, F. Ferrer, J. Arenas, V. Faus

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Background: the inappropriate use of antibiotics results in an increase in antibiotic resistance which should be avoided through programmes that optimise antibiotic treatment.

Purpose

To evaluate the results of an antibiotic advice programme undertaken during 2009 in terms of suitability, acceptance and economic benefit.

Materials and methods

Every day the pharmacist checks the prescriptions for restricted antibiotics (RA). When a prescription for RA is found, a request for information (R) is sent to the Infectious Diseases Service (IDS) which includes, for each RA, patient information, diagnosis, cultures, reason for the request (dose adjustment, evaluation of empirical treatment, duration of treatment or change of antibiotic) and other information (creatinine clearance, neutrophil count or concomitant treatment). The IDS replies to the request, which is noted in the patient's medical history, with a document called Therapeutic Advice Evaluation (TAE). This makes suggestions for compliance with Infections Committee guidelines and recommendations for changes in the duration or treatment. The estimated saving due to changes in the treatment is calculated as (cost of initial treatment x days with the new treatment) – (cost of new treatment x days of treatment).

Results

In 2009, 290 requests were sent to IDS. 252 came from the Pharmacy Service (202 were answered, 41 were not significant). The departments with more RA prescriptions were Internal Medicine (138R), Surgery (41R), Pneumology (36R) and Gastroenterology (29R).

Most-prescribed ARs were imipenem (93R), cefepime (57R) and ertapenem (47R). A change of treatment was recommended in 75% of the TAEs. 37% of the RAs prescribed did not comply with Infections Committee guidelines. 74% of the recommendations were accepted. The estimated saving due to changes in the treatment was 33,731 euros.

Conclusion

37% of RAs prescribed did not comply with Infections Committee guidelines. By controlling the use of RAs, antibiotic treatment was optimised in 74% of cases, which led to savings of 33,731 euros.

No conflict of interest

PHC012 Pharmacokinetic-pharmacodynamic support for a reduction of carboplatin dose in elderly advanced non-small cell lung cancer patients

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⁶Oporto University Pharmacy Faculty, Pharmacology Department, Porto, Portugal

Background In clinical practice, doses of carboplatin are calculated using the Calvert formula, where real glomerular filtration rate of patients is replaced by an estimated value of creatinine clearance, determined by the Cockcroft-Gault (CG) equation. Purpose To analyse whether carboplatin's clearance and haematological toxicity justify the administration to elderly patients with advanced non-small cell lung cancer of a 20 % lower dose than that given to younger patients.

Materials and methods

A total of 33 patients received carboplatin on day 1 and gemcitabine on days 1 and 8, and repeated every 21 days. The Calvert-CG formula was employed to calculate a carboplatin dose with a target AUC of 5 mg·min/mL in younger adults (48.48% of the total study population, aged 44-65) and 4 mg·min/mL in elderly patients (51.52 % of the population, aged 71-81). Three blood samples were collected from each patient and the ultrafiltered platinum plasma concentration was determined. Data from 24 patients were treated for population modelling using the non-linear mixed effect modelling approach. Haematological toxicity was evaluated for the 33 patients.

Results and Conclusions

The final covariate models for clearance (CL) (L/h) and volume (Vc) (L) were obtained by means of the following formula: CL= $[4.87-(Age (years)-70)\cdot0.13+(body weight (Kg)-70)\cdot0.06-(Serum creatinine (mg/dL)-0.9)\cdot0.70]$; Vc= $[6.24+(weight (kg)-70)\cdot0.24]$. The relative error of carboplatin clearance estimated by the Calvert-CG formula was 13.53% for younger adults and 67.97% for elderly patients.

A reduction of 20% in the dose of carboplatin administered to elderly patients did not result in significant differences between rates of grade 3+ of anaemia, neutropenia or thrombocytopenia with respect to younger patients.

No conflict of interest

CALL FOR ABSTRACTS – 2012 MILAN

17th Congress of the EAHP, 21-23 March 2012, Milan, Italy

Original contributions from all fields of hospital pharmacy are encouraged and welcomed for poster presentation.

Deadline for submission: 15 October 2011

During the review process, the award nominees will be selected and the presenting author of the the nominated abstracts will be invited to give an oral presentation after which the final judging will take place.

Please be sure to provide an email address which will not be blocked by spam servers so that we may notify you for modifications and nominations.

(Submit your abstract via the EAHP web site's online submission page.)

IMPORTANT NOTE: The online submission form does not recognise some symbols from various keyboards, therefore, please proof your abstract after entering into the system.

The format and guidelines for the online abstract submissions will be changed. Please visit the EAHP web site at http://www.eahp.eu/Congresses/Abstract-information to view the new guidelines and to submit abstracts for the Milan congress 2012.

One of the changes which will be made is that the abstracts are to be entered into the system by section according to the guidelines. These 5 sections will be as shown below. Abstracts will not be accepted unless they meet the new guidelines which will be posted during the summer of 2011.

Background

Purpose

Material and methods

Results

Conclusion



POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

DGI017 Development of a web-based antimicrobial resource to improve antimicrobial prescribing ñ a two year review

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Our Teaching Hospitals were poorly performing for Clostridium difficile infection (CDI) and MRSA bacteraemia, despite 'CDI-friendly' antibiotics used in patients >80 years

Purpose

The project was to build a web-based infection-management resource to improve antimicrobial prescribing by providing:

- · evidence-based, peer-reviewed guidelines
- educational resource
- audit resources with results
- decision support including calculators

Materials and methods

Templates were developed for each guideline development team of a clinician, microbiologist and pharmacist. Each guideline includes algorithms, investigations, empiric and directed therapy (including special populations), oral switch, duration, specialist referral criteria, references, review dates, and evidence levels. Drafts are peer reviewed for 4 weeks where they are endorsed without changes or with minor revision, or need a major revision. Guidelines are updated based on comments, and repeat peer-review if necessary. Once ratified, uploaded to Antimicrobial Resource website.

- 104 guidelines developed; average 73 draft views; 7 comments per draft (3 had second peer-review)
- >7000 hits/month
- Antimicrobial prevalence decreased from ~35% to ~25%
- CDI decreased from ~80 to ~20 cases/month

Discussion

Many Trusts use pocket-sized guidelines which go out of date. Our pathways focus on diagnosis and investigations, with antimicrobials if necessary. Development processes promotes ownership and subsequent usage. Feedback mechanisms ensure continual update. Less patients are on antimicrobials or develop CDI. Changes in prescribing may have contributed.

Conclusions

Web-based, evidenced-based, peer-reviewed antimicrobial guidelines are an effective method to support prescribers in their diagnosis and treatment of infection. Links to resources such as eBNF, eMC and dose calculators improve patient safety. Feedback processes with regular update ensure that guidelines are always up-to-date. Guidelines designed and delivered in this manner promote usage, and when combined with other elements of antimicrobial stewardship, is associated with a decrease in the prevalence of antimicrobial usage and reductions in some HCAIs.

No conflict of interest

GRP015 Drugs not included in the hospital formulary: Prescription error reduction with computerized prescription order entry M. Vélez, E. Delgado, A.M. Álvarez, C. Pérez, T. Bermejo

Hospital Ramon y Cajal, Phamacy Department, Madrid, Spain

Background: Computerised Prescription Order Entry (CPOE) has been shown to reduce prescription errors, mainly because of Clinical Decision Support (CDS).

Purpose

To evaluate the impact of CPOE on the frequency of errors in the process of CPOE prescription of Drugs Not Included in the Hospital Formulary (DNIHF) versus Manual Prescription (MP).

Material and Method

Prospective, descriptive and observational study among inpatients in a general hospital. Two wards in the Orthopedic-Traumatology department each with 28 beds were selected, one with CPOE and the other with MP. The study period was 45 natural days. MPs are handwritten by the prescriber on multicopy order forms and one copy is sent to the Pharmacy department where pharmacists transcribe and validate the medical order into the *Hospiwin*[®] application *Prescriwin*[®]. In CPOE the physician directly enters the treatment in *Prescriwin*[®] and a pharmacist validates the prescription online. The software provides CDS at the moment of prescription for Drugs Included in the Hospital Formulary (DIHF) checking for example drug-drug interactions, duplicate medicines, drug allergy, maximum and usual dosage, etc. When prescribing DNIFH there is no CDS but prescribers are presented with fields for route of administration, frequency and dose.

Results

- 1,536 prescriptions were written (737 MP vs. 799 CPOE).
- A total of 13 out of 28 (46.4%) of DNIFH-MP prescriptions contained an error compared to 6 of 42 (14.3%) of DNIFH-CPOE prescriptions, a 69% reduction (Odds ratio: 0.06-0.60).
- The most common type of error for DNIFH was the omission of dose and route of administration (92.3% for MP and 50% for CPOE).
- MP errors for DNIFH were statistically more numerous than for DIFH (Odds ratio: 1.78-8.23).

Conclusions: even though no CDS is available for the prescription of DNIFH, CPOE was shown to be an effective tool in reducing prescription errors because it helps the prescriber write a more complete prescription. No conflict of interest



17TH CONGRESS OF THE EAHP, 21-23 MARCH 2012

Preliminary programme

<u>Special patient groups – hospital pharmacists creating standards for care</u> (For more information, please see the 1st announcement in your congress bag)

The limits of treatment **Keynotes:**

Better medicine for children

Pharmaceutical care for geriatric patients

Seminars:

- Methodolgy, development of guidelines & implementation of standards 1.
- 2. Hospital pharmacists in transplantations
- 3. New drugs worth paying for?
- 4. The lean model two practical examples
- 5. Focus on genetic screening by hospital pharmacists
- 6. Clinical trials in geriatrics
- 7. Safe drugs for neonates
- 8. Orphan drugs and off-label medicines
- 9. Chronic infections the involvement of the hospital pharmacist
- 10. Pain management
- 11. State of the art compounding
- 12. National delegates' seminar
- Highlights of Italian Hospital Pharmacy 13.

Workshops:

- 1. How to create a pharmaceutical care plan
- 2. Therapeutic education of patients
- 3. TDM in renal impairment and transplantation



POSTER AWARD NOMINEE ORAL PRESENTATIONS

Wednesday, 30th March, 14.00 – 15.30 and Thursday, 31st March, 08.30 – 10.00, Forum Room

PHC017 Search of genetic polymorphisms associated with severe neurotoxicity in colorectal cancer patients receiving oxaliplatin-based chemotherapy using the DMET genotyping platform

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Background

Explore the role that DMET will play in future pharmacogenetics studies.

Purpose

We performed the Drug Metabolizing Enzymes and Transporters (DMET) platform analyses in a cohort of colorectal cancer patients receiving fluorouracil, folinic acid and oxaliplatin (FOLFOX) adjuvant chemotherapy in order to determine association with severe neurotoxicity.

Materials and methods

This was a retrospective study in which DNA was purified from peripheral blood of colorectal cancer patients starting FOLFOX adjuvant chemotherapy. DNA processing and genotype identification for each patient sample were performed using the Affymetrix DMET platform. Genotypes were determined for every SNP site, reported as homozygous wild-type, heterozygous, homozygous variant or 'no call'. Patients were strict selected by the presence of severe (grade 3) neuropathy due to oxaliplatin. Neurotoxicity was assessed in accordance with NCI CTCAE v3.0. Primary endpoint was the identification of polymorphisms associated with development of severe neuropathy.

Results

DMET offers the ability to scan 1936 variants in 225 genes and only 60 genes were found to be associated with response and toxicity. The rate of earning was around 97%. These data revealed that variants in five genes (that is, GSTP1, GSTM1, GSTT1, NQO1 and ATP7A) were associated with toxicity in all the patients. All of them showed null polymorphisms or rather mutations in the gluthation family (GSTT1, GSTM1, or GSTP1). 2 patients harboured heterozygous variants for NQO1. These genes are involved in detoxification of platinum. And other 3 patients had homozygous variants for ATP7A. This encodes a transporter of copper and has a potential role in platinum efflux.

Conclusions

DMET identifies detoxification and copper transporter pathways as pharmacogenetic targets. Genes in these pathways are responsible for intracellular accumulation of platinum and could play a role in severe neurotoxicity development. DMET adds more information than the simple analysis of polymorphisms previously identified in other studies.

No conflict of interest

GRP065 What can hospital pharmacists do for patient safety when encountering potentially counterfeit medicines purchased by patients over the internet

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Background

The popularity and the number of internationally operated illegal online drugstores that are selling medications without prescriptions or deliver products with unknown origins are rising. As Europeans are spending billions of Euros on the illicit medicines market the chances of accidental overdose, drug interactions and toxicity is increasing.

To estimate the significance of the problem in Hungary and to define adequate methods to assess the quality and potential danger of drugs sold online.

Material and Method

The attitude of more than 500 patients regarding purchasing drugs online was evaluated in our survey implemented in hospital (n=107) and community pharmacy (n=434) setting.

A comprehensive methodology was set up by our institution which allows general and professional quality assessment by:

- · Standardised ranking method of online drugstores
- Documentation, evaluation of distribution process
- Identification of microbiologic contamination
- Measurement of physical properties by pharmacotechnology methods
- Chemical analysis of active substance

Results

Our results show that nearly 5% of the respondents of the questionnaire have ordered drugs or dietary supplements online and about same amount of people are considering this option in the near future. 163 online pharmacies were evaluated and followed for 28 months. Less than 7% of the sites require prior medical prescription and 38% do not exist after two years. Out of the thirteen medications (paracetamol, sildenafil, tramadol) test ordered, 11 arrived (85%). Main components were identified (HPLC, spectrophotometry) in all samples. Compared to original authorized medications, higher chemical contamination was observed, indicating lower quality ingredients. The increased microbiological contamination and the higher standard deviation of pharmacotechnology parameters suggest poor quality control of production.

Conclusion

Our observations not only draw the attention of hospital pharmacists to illegal online drugstores and counterfeit medicines but also suggest a comprehensive methodology for professional pharmaceutical quality assessment of medication ordered online. No conflict of interest

General and Risk Management, Patient safety (including: medication errors, quality control)

GRP001 Pharmacy Education of Medical Undergraduates

M. Kieran, C. Boyle, M. Creed, J. Brown, M. McGuirk, C. Meegan ¹Mater Misericordiae Hospital, Pharmacy Department, Dublin, Ireland (Rep.)

Background

Shortcomings in medical education are a recognised factor in prescribing errors. A previous study of MMUH doctors confirmed there were omissions in medical undergraduate training with respect to pharmaceutical issues such as prescribing and medicines management.

Suggestions given in this study on how undergraduates' training in could be improved, involving amendment of the undergraduate curriculum to include pharmacist-mediated tutorials.

The MMUH is affiliated with the School of Medicine, UCD which introduced a 'Professional Development' module for final year students in 2010, incorporating a pharmacy/prescribing component.

Purpose

To develop a pharmacist-mediated tutorial programme to educate medical undergraduate students on prescribing and medicines management issues.

To evaluate the tutorial programme.

Material and Methods

Pharmacy representatives agreed on learning objectives with the MMUH UCD senior lecturer.

A team of pharmacists developed and delivered the tutorial content in line with these objectives.

Students were asked to complete evaluation forms

Results

Final year medical students were allocated a 3-hour pharmacy tutorial session. Topics covered included prescribing practicalities, the quality use of medicines, hospital pharmacy and medication safety. The tutorials were given on three separate occasions. Didactic lectures formed the backbone of the sessions. These were interspersed with practical and interactive sessions where students had to practice prescription writing and drug calculations.

Student feedback was very positive.

99% agreed they gained practical insights

95% agreed it extended their knowledge of the topic

92% agreed teaching methods were effective

97% rated the overall session good or excellent

The tutorial content was appropriately amended after each session, taking into account relevant student feedback.

Conclusion

A comprehensive pharmacist-mediated tutorial programme was developed for final year medical students to prepare students for prescribing and to improve their knowledge of medicines management issues.

Student feedback indicated the sessions were very well received by the medical students and improved the students' preparation for prescribing.

No conflict of interest.

GRP002 The Need for Needles

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Background

Insulin pens are a patient-friendly manner to administer accurate doses of insulin. They are available as pre-filled disposable units or re-usable pens requiring cartridges of insulin.

An incident involving the inappropriate withdrawal of insulin from a pre-filled insulin pen on a Medicine for the Elderly ward in the MMUH was reported. In collaboration with the Clinical Nurse

Manager (CNM) it was ascertained that nurses were using insulin syringes to withdraw insulin from pens and cartridges, due to a lack of availability of disposable needles on the ward.

Collaboration with the Drug Safety Facilitator identified further investigation of this issue was required.

Purpose

To implement changes to prevent recurrence of this practice.

Material and Methods

- · Root-cause analysis of this issue.
- · Liaison with Diabetes Clinical Nurse Specialist to establish best practice recommendations.

Results & Conclusion

Two causative factors were identified:

- 1. Lack of knowledge that such practice is inappropriate
- Insulin pens are sealed units whose patency may be compromised by the inappropriate withdrawal of insulin.
- 2. Lack of availability of disposable needles

Frequent delays in the supply of disposable needles from the Supplies Department to wards occurred. Discussion with that department highlighted:

- Disposable needles were ordered on an ad hoc basis.
- Brands were not substituted causing extended delays if a brand was unavailable from the manufacturer.

The Diabetes Clinical Nurse Specialist distributed a memo to all wards:

- Highlighting the safety issues associated with this practice.
- The names and codes of the needles stocked in the hospital.

In response to a reported medication variance a ward-based review of the process of insulin administration was undertaken. This highlighted an issue, which was a potential source of error throughout the hospital.

Once the issues were identified, changes were implemented to eradicate the practice of inappropriate insulin withdrawal from all wards. To ensure continuity of supply two brands of disposable needles are now routinely stocked in the Supplies Department.

No conflict of interest.

GRP003 Did someone borrow my pen?!

J. Brown, C. Meegan, M. Creed

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Background

In 2009, the FDA[1] issued an alert warning of the risk of transmission of blood-borne pathogens from the shared use of insulin pens and insulin cartridges. An audit of insulin prescribing, storage and use was undertaken to assess the potential for shared insulin device use in the MMUH.

Purpose

To assess the factors in the MMUH that may potentially contribute to the risk of transmission of blood-borne pathogens.

To highlight system changes which may be necessary including supply, storage, labelling and prescribing of insulin preparations.

Material and Methods

A cross-sectional review to:

Identify practices at ward level for the storage of insulin preparations.

Examine prescribing of insulin on the Diabetic Drug Chart. Examine if patients are using a patient-specific supply of insulin pens/cartridges.

Results

- 32 different preparations of insulin brands were stored on wards.
- Wards had 345 insulin vials/cartridges/pens on stock.
- There were 72 individual prescriptions on 20 wards for insulin.
- 20 (28%) of prescriptions were for Actrapid® sliding scales.
- Of the remaining 52 prescriptions:
 - None (0%) had the device specified on the diabetic drug
 - All (100%) had a dose and frequency specified.
 - Only 28 (56%) had a supply labelled specifically for the patient.
- The results highlight that:
- There is wide variety of insulin preparations in the hospital.
- Many opened insulins do not have a date of opening.
- Many open insulin cartridges/pens do not have patient-specific details. These are the products for which the FDA has issued an alert regarding use.

Conclusions

Practice review is required in the MMUH to introduce processes to:

Ensure that insulin is prescribed by brand name, together with the device to be used. Ensure that there is a process for ready access to the appropriate device required.

Ensure that the appropriate patient details and date of opening are documented when insulin preparations are opened.

Review storage of insulin at ward level.

[1]Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens (2009). Last accessed on 04/03/10

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInform ationforPatientsandProviders/DrugSafetyIn formationforHeathcareProfessionals.gov

No conflict of interest

GRP004 The pharmacist as a member of a multidisciplinary group to control the use of restricted antibiotics

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Background

The inappropriate use of antibiotics results in an increase in antibiotic resistance which should be avoided through programmes that optimise antibiotic treatment.

To evaluate the results of an antibiotic advice programme undertaken during 2009 in terms of suitability, acceptance and economic benefit.

Materials and methods

Every day the pharmacist checks the prescriptions for restricted antibiotics (RA). When a prescription for RA is found, a request for information (R) is sent to the Infectious Diseases Service (IDS) which includes, for each RA, patient information, diagnosis, cultures, reason for the request (dose adjustment, evaluation of empirical treatment, duration of treatment or change of antibiotic) and other information (creatinine clearance, neutrophil count or concomitant treatment). The IDS replies to the request, which is noted in the patient's medical history, with a document called Therapeutic Advice Evaluation (TAE). This makes suggestions for compliance Infections Committee guidelines with recommendations for changes in the duration or treatment. The estimated saving due to changes in the treatment is calculated as (cost of initial treatment x days with the new treatment) - (cost of new treatment x days of treatment).

Results

In 2009, 290 requests were sent to IDS. 252 came from the Pharmacy Service (202 were answered, 41 were not significant). The departments with more RA prescriptions were Internal Medicine (138R), Surgery (41R), Pneumology (36R) and Gastroenterology (29R). Most-prescribed ARs were imipenem (93R), cefepime (57R) and

ertapenem (47R). A change of treatment was recommended in 75% of the TAEs. 37% of the RAs prescribed did not comply with Infections Committee guidelines. 74% of the recommendations were accepted. The estimated saving due to changes in the treatment was 33,731 euros.

Conclusion

37% of RAs prescribed did not comply with Infections Committee guidelines. By controlling the use of RAs, antibiotic treatment was optimised in 74% of cases, which led to savings of 33,731 euros.

No conflict of interest.

GRP005 An evaluation of a pharmacist at a pre-admission clinic on the safety and accuracy of patients' medication on admission to the ward

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³Welsh School of Pharmacy Cardiff University, Pharmacy, Cardiff, United Kingdom

Background

Inaccurate medicines reconciliation at the pre-admission stage of an elective surgical patient-care pathway can lead to medicationrelated incidents on admission and could increase the risk of perioperative complications. The pre-admission stage presents an opportune time for pharmacists to initiate their involvement in patient care.

Purpose

To evaluate the impact of a pharmacist at an orthopaedic preadmission clinic (PAC) on the accuracy and safety of the medicines on admission to the ward.

Material and Methods

The number and type of pharmaceutical interventions made at a PAC and on the ward at admission by the pharmacist were recorded. An intervention was defined as any activity the pharmacist undertook to ensure accurate, appropriate and safe prescription of medication. A comparative analysis of the number and type of interventions recorded for those patients that were seen by a pharmacist in PAC (active arm) and those that weren't (control arm) was then undertaken. The clinical significance of the interventions was assessed by 8 senior healthcare professionals working within the field of elective surgery in the trust.

The number of interventions required for patients on admission to the ward reduced from 89.7% in the control arm to 18.1% in the active arm. In total 248 interventions were made: 131 in the active arm and 117 in the control arm. The majority of the interventions in the active arm (84.7%, n=111/131) were made at PAC and resolved prior to admission. The remaining 15.3% (n=20/131) made on the ward were necessary as the doctor had either not signed, used or made the necessary amendments to the transcribed inpatient drug chart from the PAC. The 248 interventions made during the study were categorised into 28 intervention types and one of the most frequent interventions related to the incorrect/incomplete documentation of the patient's allergies or intolerances which occurred for 13 and 17 patients in the active and control arm respectively. In the active arm, this intervention was made 12 times at the pre-admission stage and only once on the ward; an example of this intervention includes angioedema with

penicillin, not documented for a patient. The omission of patients' regular medication occurred significantly more frequently in the control arm (p=0.001) whereas the provision of advice for the perioperative management of medication occurred significantly more frequently in the active arm i.e. at PAC (p=0.000). Both of these intervention types occurred frequently, each being recorded 25 times. All the interventions were classed to be of clinical significance, ranging from 'somewhat significant' to 'extremely significant' by the majority opinion of the 8 assessors. On average 8.1 and 2.2 minutes was spent per patient on the ward in the control and active arm respectively.

Conclusion

Pharmacy involvement at PAC led to a significant reduction in the number of clinically significant interventions required at admission and therefore improved patient safety. The time spent at PAC significantly reduced the time required per patient at admission.

No conflict of interest

GRP006 EVALUATION OF THE COMPUTERIZED THERAPEUTIC PROCESS IN A HOSPITAL: PILOT STUDY IN AN INTERNAL MEDICINE DEPARTMENT

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Background

This 1000 bed hospital uses a decentralised daily individualised drug dispensing system. > 90% of beds are included. A quality evaluation program has been associated with the therapeutic process since 1997. To take into account the increasing computerisation of the care process, we revised the data collection form. Modifications needed to be tested in one clinical unit, before an extensive trial in all hospital departments. Involvement of a clinical pharmacist was justified to perform this pilot study.

Material and Methods

The data collection form, modified by clinical pharmacists and a specialist clinical nurse, increased from 18 to 29 items in order to evaluate the computerised drug process including medical prescription, pharmacy dispensing and nurse administration. Evaluation was performed for random beds for 8 days by a pharmacy student. One collection form was completed per day and per bed.

Results

Prescription (N=79): missing information: 5.1%, difference between current prescriber and computing code used: 7.6%, incorrect dose unit: 20.3%. Dispensing by the pharmacy: technician identification missing on prescriptions: 5.1%, dosage errors or route of administration: 8 %, non-administration alert to the clinical pharmacist omitted: 100% (16 returns)

Nurse administration: not validated on time: 38%, non-administration alert to the physician omitted: 31.6 %, units of the daily dose dispensed not respected: 20.3 %; no labelling on the infusion bags: 3.8 % (1/26).

Conclusion

Computerisation aims to safeguard the care and therapeutic process; thanks to it, some data appear automatically. Nevertheless, it seems necessary to monitor carefully new risks (increased probability of errors on units and doses) if drop-down menus do not include alarm systems. Other similar risks have been published; consequences for patients are possibly lethal if health professionals are not vigilant.

No conflict of interest

GRP007 Infusion reactions to systemic chemotherapy

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Background

Prospective study in a hospital oncohaematology day unit. The duration of the study was 9.5 months and in total 598 patients were treated

Purpose

To determine the incidence of infusion reactions (IRs) in patients treated. To find out whether any areas of chemotherapy protocols need improvement to minimise the risk of IR.

Material and Methods

Chemotherapy was prescribed, validated, prepared and administered with the support of a computerised closed process with chemotherapy protocol (including supportive drugs). IRs were notified by an intensive surveillance system. The Karch-Lasagna algorithm and National Cancer Institute Common Toxicity Criteria (CTCAE) were applied.

Results

A total of 62 IRs were observed, in 46 patients (7.7%) of a total of 598 patients treated.

Drugs causing IRs: docetaxel 11 / 52 patients (21%), oxaliplatin 20 / 112 patients (18%), etoposide 3 / 20 (15%), paclitaxel 8 / 78 (10%), irinotecan 2 / 24 (8%), rituximab 6 / 66 (9%), cetuximab 2 / 26 (8%), trastuzumab 4 / 67 (6%), carboplatin 4 / 71 (6%) and cisplatin 2 / 82 patients (2%).

Three patients suffered repeated IRs. In this group the imputability algorithm gave "definite" while other cases returned "probable". The IR resulted in the treatment being stopped or changed in 11 patients (24% of those affected).

The IR was considered level 3 of severity by the CTCAE 11 times, and the rest (35 patients) level 1-2 severity.

The rates of occurrence and the kind of IR observed were as described in the literature.

Conclusion

Current chemotherapy protocols have proved relatively ineffective in preventing IRs. Some protocols can be improved, to bring rates of IR to the lower limit described in the literature. Desensitisation protocols should be improved to avoid repetitions of IRs.

No conflict of interest

GRP008 Self induced poisoning with hypoglycemic medication in non diabetic subjects

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Background

The incidence of hypoglycaemia among people without diabetes is unknown. Severe and prolonged hypoglycaemic episodes (level of sugar in the blood below 60 mg/mL) due to a variety of causes can lead to dysfunction of the central nervous system and stimulate the sympathetic nervous system leading to permanent brain damage.

Purpose

The aim of this study was to investigate the incidence of self-induced poisoning with hypoglycaemic drugs in non-diabetic subjects. Overdose with hypoglycaemic agents increases the risk of morbidity, mortality and permanent neurological deficit.

Material and Methods

Aretrospective study was conducted using 10,146 patients assisted for acute exogenous poisoning admitted to the Emergency Department of Clinical Emergency Hospital of Craiova, Romania between 1999 and 2009. Admission criteria were: confusion, seizure, slurred speech, blurred vision, past medical history of psychological illness and alcohol dependence. Data were collected from the Emergency Department's electronic database.

Results

From the total subjects included in this study, only 42 patients (0.41%) were identified with hypoglycaemic drug-induced hypoglycaemia related to attempted suicide. From those, self-poisoning with insulin was found in 22 patients (52%) and with oral diabetes agents (especially sulphonylureas) in 20 (48%) cases. A higher preference for this method was noted in the 18-44 year old age group, with no statistical difference between females and males. Diagnostic difficulties were noted in patients with coma and convulsions. There was a favourable outcome in all cases but one: a subject who took gliclazide and alcohol later developed cardiac complications leading to death.

Conclusions

The study revealed that self-harm with hypoglycaemic drugs is uncommon. Early diagnosis and treatment could prevent neurological deficit and consequently optimise prognosis.

No conflict of interest

GRP009 Application of measures to minimize dispensing errors when filling medication boxes

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Background

Analysing dispensing errors (DEs) allows us to identify weak points of the system, so that new strategies can be developed to prevent them.

Purpose

To compare DE rates between January-April 2009 (P1) and January-April 2010 (P2), after measures to reduce DEs were introduced

Material and Methods

Prospective observational study. The staff and the method used to fill drawers were the same during the two periods. Medicines were checked before being sent to the wards, checking the content of the boxes against the dispensing lists issued by the computer. Errors were recorded.

Otero et al.'s terminology was used to classify DEs.

Measures improved after P1: alerts were made to appear in the dispensing lists for the drugs with a higher rate of errors, stickers were put on the drug drawers to avoid mistakes in drug names, different doses of some drugs stored in the same drawer were strictly separated, staff were invited to meetings and informative sessions about the proceedings.

Results

During P1, 2916 errors were recorded (0.79%), and during P2, 2727 (0.76%) (p>0.05).

During P2 dose omission and wrong dosage (WD) errors were lower (18.32% and 59.78% reduction respectively) compared to P1. However, spare dose and wrong patient errors increased (by 80.61% and 38.14% respectively).

The most frequent error in both periods was dose omission (0.35%

P1, 0.29% P2). The drugs with a higher number of errors were:

- Wrong pharmaceutical form: Metamizol extended release, Primperan (metoclopramide) and Anagastra (pantoprazole)
- WD: Cesplon (captopril), Clexane (enoxaparin) and diazepam extended release.

Conclusions

- The above-mentioned measures may have reduced DEs slightly.
- Although the number of DEs detected in our hospital was smaller than the number reported from other hospitals, checking dispensed medicines drawers daily is necessary since it has been demonstrated to improve dispensing quality.
- New technologies would be useful to reduce spare dose and wrong patient error rates.

No conflict of interest

GRP010 Evaluation of the resolution of drug quality problems reports in a university hospital

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Background

Reporting drug quality problems may provide essential information for minimising patient exposure to unsafe, ineffective and poor quality drugs. Drug manufacturers should provide information about their products readily and resolve drug quality problems.

Purpose

To evaluate the performance of drug manufacturers regarding drug quality problems reported to the Pharmacy Service by the University Hospital of the University of São Paulo (SF/HU-USP). The following criteria were used: type of problem, time to solve the problem (days) since the first contact with the manufacturer, number of replies from the manufacturers and replacement of defective medicines.

Material and Methods

Drug quality problems reported to SF/HU-USP were recorded during the period January 2007 to July 2010. These data were compiled from reporting forms that contained the date of occurrence of the quality problem, the identification of the drug and manufacturer (trademark, generic name, strength, pharmaceutical form, batch number, expiry date, authorisation number, date of acquisition, quantity, supplier), classification of the problem, date of contact with manufacturer/supplier, date of the manufacturer/supplier reply, resolution of the problem and conclusion of the occurrence.

Results

During the study period 221 quality problems were reported with drugs that resulted in 195 occurrences and notifications to 49 Brazilian drug manufacturers. Of this number, 33 manufacturers replied to all the notifications, 2 did not reply and 14 replied partially. The average time to manufacturer reply and problem resolution was 83.2 days varying from 1 to 396 days. Of the 195 notifications, 179 were resolved after the manufacture's reply and 16 were not answered. 36.5% of the notifications were replied to within 7 days, 13.8% took up to 15 days, 10.7% up to 1 month and in 49.5% of notifications the manufacturer's reply and resolution of the occurrence took over 1 month. 141 replacements were made for defective medicines. The highest number of notifications per manufacturer was 21 and the lowest was 1. Injectable pharmaceuticals had the highest number of complaints (60.6%), following by tablets (10.4%) and others (29.0%).

Conclusion

The performance of drug manufacturers measured by drug quality problems and their resolution can be a quality indicator for hospital pharmacists. Brazilian drug manufacturers do not present an effective way to communicate with consumers, specifically with

hospital pharmacists. The time taken to resolve drug quality problems is too long and in many cases a satisfactory conclusion is not achieved.

No conflict of interest

GRP011 Results of pharmaceutical-care-programs in geriatric-populations

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Background

Nursing home pharmaceutical services are provided by the referring Hospital Pharmacy Department.

Objective

To assess the impact of a pharmaceutical care programme in a geriatric population.

Material and methods

A study of 240 patients in two nursing homes from January 2009 to April 2010.

The pharmacist was tasked with validating drug prescriptions daily. When medicines- related problems (MRPs) were found, a physician was notified orally or in writing for review and modification if necessary. The results were analysed with the statistics software SPSS 11.5.

Results

At least one way of improving the treatment was found in 76.3% (187 patients). A total of 207 interventions was made. The median age of the users involved was 80 (49 to 98)

The most frequent MRPs: Unsuitable dose or frequency (25.1%), unsuitable duration of treatment (18.4%), cost-effective alternative (11.6%), medicine not appropriate (6.8%) and duplicated treatment

Central nervous system, blood and blood-forming organs, cardiovascular and antibiotics were the pharmacotherapeutic groups with the most MRPs. Main optimisations performed: stopping the drug (30.4%), changing dose or frequency (25.1%), switching to a drug included in the hospital formulary (11.6%), changing to a safer drug (6.3%), and changing the dosage form (5.8%). Considering the seriousness of impact on the patient, 48.1% of cases required or would have required a change in treatment but no change in monitoring, 46.6% caused or would have caused increased monitoring but no change in vital signs and 5.3% caused or would have caused changes in vital signs and required or would have required additional testing or invasive procedures. Physician acceptance of proposals was 95.2%.

Conclusion

In 2 of 3 institutionalised nursing home patients, at least 1 MRP was identified. Polypharmacy(more than 8 drugs per person) and elderly patients make up a subsidiary group of pharmaceutical care programs, aimed to optimise drug therapy in terms of efficacy, safety and efficiency.

No conflict of interest

GRP012 Analysis of medication errors in a psychiatric hospital

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Medication errors are defined as any preventable events that may cause or lead to inappropriate use of medicines or patient harm.

Purpose

To identify sources of error in order to improve the safety of the medicines use system. In this hospital an electronic checking system is used for daily drug validation.

Material and Methods

From June 2006 to August 2010 medication errors were prospectively collected using a standard report form. They were analysed according to the taxonomy adopted by the National Coordinating Council for Medication Error Reporting and Prevention. For each error, causes were identified in order to set up corrective measures.

Results

A total of 55 medication errors were recorded in four years. 60% were potential and 40% were actual errors. Medication errors occur in storage (21.8%), prescription (20%), drug delivery (36.4%), preparation (10.9%) and administration (10.9%). The most frequent error reports were incorrect dose (30.6%), dose omission (27.8%) and patient identity error (11.1%). 34.5% of reports gave circumstances that may cause error. An error occurred but did not reach the patient in 25.5% of cases or reached the patient without harm in 18.2% of cases. 9.1% of errors required health monitoring. An error resulted in temporary harm to the patient in 3.6% of cases and in prolonged hospitalisation in 9.1% of cases. The analysis shows that errors were due to multifactorial causes. Causes identified were human factors (71%), computer error (23%) or lack of communication (6%).

Conclusion

This study allowed us to set up corrective measures (including reinforcement of pharmaceutical analysis, safe procedures for dispensing drugs, improved data-processing parameter setting and software training and the systematic checking of the patient's identity prior to administration).

Finally, a programme to raise awareness amongst health professionals of the need to prevent harm caused by drugs has been implemented in order to improve the rate of error reporting.

No conflict of interest

GRP013 Assessment of an Oral Compounding Unit in a Haitian Hospital Pharmacy After Earthquake

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Background

In 2009, a preparation unit was created in Saint Damien hospital pharmacy (Haiti) to provide dose-banded oral preparations for paediatric treatment. After the earthquake, an assessment of the pharmaceutical preparation unit was conducted by Haitian pharmacists with the support of voluntary foreign pharmacists to improve the quality of products prepared and assure quality of care at this tragic time.

Material and methods

The PIC/S Guide to Good Practice was selected as the international reference for the preparation of medicinal products in pharmacies and translated chapter by chapter strictly in the form of closed questions by a team of hospital pharmacists in 2007 and updated in 2010. There were 4 levels of answer: positive, partial positive, negative and not applicable. The Haitian pharmacists of Saint Damien hospital made a self-assessment with the support of an independent hospital pharmacist. Recommendations were formulated for medical coordination to improve the quality of preparation.

Results

A total of 130 points were evaluated; 24 were not applicable. Of the 106 relevant questions, 11 fully met the conditions, 54 partially. The acceptable response rate was thus 61% and involved: documentation 65%, premises and equipment 64%; quality control 44% and complaints and product recalls 29%.

Conclusion

This assessmentprovided an inventory of proposals to improve quality and generated more awareness of the critical problems encountered in this time of crisis. The corrective measures adopted were: weight variation control in batch production, batch recall procedures and validation of manufacturing and preparation processes, for which a new pharmacist was appointed.

No conflict of interest

GRP014 New pharmacogenetic biomarkers for predisposition to toxicity in colorectal cancer patients

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Background

5-fluorouracil (5-FU) and capecitabine are the *gold standards* in colorectal cancer (CRC) treatment. The objective was to identify genetic biomarkers associated with moderate and severe toxicity of these drugs in CRC patients.

Material and methods

Retrospective study with 116 CRC patients taking 5-FU/capecitabine alone or in combination with other drugs. Clinical data (age, sex, treatment and toxicity) and genotype of the selected single nucleotide polymorphisms (SNPs) were recorded. DNA containing these genomes was isolated using PCR Template Preparation Kit (Roche). Based on the Common Terminology Criteria for Adverse Events patients were classified into 2 groups depending on the neutropenia: negative (grades 0-I) or positive (grades II-IV). DMET Plus microarray (Affymetrix) was used with 42 samples (22 from patients with grades 0-I neutropenia and 20 from patients with grades II-IV) to identify biomarkers for predisposition to neutropenia. Selected SNPs were genotyped by the SNaPshot technique. Fisher's exact test and linearity by linear association chisquare test (SPSS v.15.0.) were used to study association between polymorphisms and toxicity. p < 0.05 was considered significant.

Results

10 different forms of 9 genes (*GSTT1* (rs2266637), *PPARD* (rs7757196), *ABCC4* (rs4148551 and rs3742106), *CYP2A6* (rs3742106), *CYP2C9* (rs1057910), *DPYD* (rs2297595), *CDA* (rs2072671), *CYP2B6* (rs8192709)and *ABCC5* (rs3805114)) were selected according to 2 criteria: 1) have a role in the metabolism of fluoropyrimidines or 2) imply an important difference in the percentage of patients affected by neutropenia depending on the genotype.

Statistically significant associations were obtained between the presence of zero copies in *GSTT1* and the development of asthenia and neutropenia and between the presence of polymorphisms in *ABCC4* and *CYP2C9* and neuropathy.

Conclusion

DMET Plus microarray is a valid approach to find new polymorphisms related to adverse reactions in 5-FU/capecitabine-treated patients. Bigger cohorts are needed to verify the associations obtained between the polymorphisms in *GSTT1*, *ABCC4* and *CYP2C9* and the development of toxicity.

No conflict of interest.

GRP015 Drugs not included in the hospital formulary: Prescription error reduction with computerized prescription order entry

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Background

Computerised Prescription Order Entry (CPOE) has been shown to reduce prescription errors, mainly because of Clinical Decision Support (CDS).

Purpose

To evaluate the impact of CPOE on the frequency of errors in the process of CPOE prescription of Drugs Not Included in the Hospital Formulary (DNIHF) versus Manual Prescription (MP).

Material and methods

Prospective, descriptive and observational study among inpatients in a general hospital. Two wards in the Orthopedic-Traumatology department each with 28 beds were selected, one with CPOE and the other with MP. The study period was 45 natural days. MPs are handwritten by the prescriber on multicopy order forms and one copy is sent to the Pharmacy department where pharmacists transcribe and validate the medical order into the *Hospiwin*® application *Prescriwin*®. In CPOE the physician directly enters the treatment in *Prescriwin*® and a pharmacist validates the prescription online. The software provides CDS at the moment of prescription for Drugs Included in the Hospital Formulary (DIHF) checking for example drug-drug interactions, duplicate medicines, drug allergy, maximum and usual dosage, etc. When prescribing DNIFH there is no CDS but prescribers are presented with fields for route of administration, frequency and dose.

Results

- 1,536 prescriptions were written (737 MP vs. 799 CPOE).
- A total of 13 out of 28 (46.4%) of DNIFH-MP prescriptions contained an error compared to 6 of 42 (14.3%) of DNIFH-CPOE prescriptions, a 69% reduction (Odds ratio: 0.06-0.60).
- The most common type of error for DNIFH was the omission of dose and route of administration (92.3% for MP and 50% for CPOE).
- MP errors for DNIFH were statistically more numerous than for DIFH (Odds ratio: 1.78-8.23).

Conclusion

Even though no CDS is available for the prescription of DNIFH, CPOE was shown to be an effective tool in reducing prescription errors because it helps the prescriber write a more complete prescription.

No conflict of interest

GRP016 Medical prescripcion by drug name: analysis of factors influencing

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Background

Prescription of medicines by international non-proprietary name (INN) instead of brand name improves quality and safety for the patient. It is recommended by the World Health Organisation. We aimed to increase generic prescribing by means of a printed prescription-administration sheet (PPAS) bearing the generic name, which showed good results in a previous study.

Purpose

To assess the degree of generic prescription (INNP) with this system and identify other factors influencing prescription.

Material and Methods

The first prescription is done by traditional handwritten sheet (HWS) and the next ones are done on PPASs. For one week all the treatment sheets were collected for patients who were discharged in whom this system was used (282 beds). We analysed the prescriptions on both kinds of sheets, handwritten and printed. We assessed the proportion of generically-prescribed drugs according to kind of sheet, medical specialty, whether a physician or surgeon wrote the prescription, and how long this system had been used. The statistical analysis, by Pearson's chi-square test, was done with an Epidat 3.1 program. A difference was considered significant if $p \leq 0.05$.

Results

We analysed the treatments of 181 patients who were discharged in the study period. 1158 prescriptions were written by HWS and 964 by PPAS. The percentage of generically-prescribed medicines was 28.6% in HWS and 35.9% in PPAS (p=0.01). There was no significant difference between surgical (33.5%) and medical (30.5%) services. The frequency of INNP was higher in those areas that had used this system for more than two years (36.5%) compared with those that used this system for one or two years (26.8%; p=0.005) and less than one year (29.7%; p=0.05). The distribution of INNP according to specialty was: psychiatry 43.8%, surgery 35.2%, traumatology 33.2%, internal medicine 29.9%, other medical specialties 24.2%. There was a significant difference between psychiatry and internal medicine (p=0.01), also between psychiatry and other medical specialties (p=0.001).

Conclusion

The use of a PPAS bearing the generic name significantly increased the adherence to this type of prescription. We found one influential factor was the length of time for which the system had been used, highlighting the training work carried out. Medical specialties with large numbers of patients with a lot of medicines, and many ambulatory prescriptions, have more difficulty adhering to this system.

No conflict of interest

GRP017 drugs monitoring with laboratory test: a tool that improve the safety of the patient

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Background

Pharmacological monitoring of hospitalised patients by means of blood tests is very important to decrease adverse drug reactions. This is not always easy to do as it is a lot of work daily for both physicians and pharmacists.

Purpose

To develop a tool to facilitate pharmaceutical intervention and monitoring of hospitalised patients treated with high-risk drugs, using information from blood tests.

Material and Method

We did a literature search in Medline and Embase, using as keywords: drug monitoring, laboratory tests and hospital pharmacy. We also referred to the summary of product characteristics. Then we the most important combinations of drug/blood test to monitor.

Results and Conclusion

This table summarises the results:

	RF									TROLYTES		TH	ALB	ОТ	
	Cr	Ur	AST	ALT	WBC	Pla	Hb	CPK	QT	Na	K	Mg	T3T4		
CLOZAPINE					*1				+						*2
LITHIUM	+	+											+		
CBZ										*3					
DIURETICS	+	+									+				
ACEIs	+										+				
DIGOXIN											+				
AMIODARONE			+	+				*4	+		+		+		
LINEZOLID					+	+									*5
AMG, VAN	+	+													
METFORMIN	+														
STATINS+FIB	+	+	+	+				+							
STATINS+COLCH	+	+	+	+				+							
ESAs							+								
PHENYTOIN														*6	
K, Na, Mg										+	+	+			
ALLOPURINOL	+														
GLITAZONES	+		+	+											

CBZ:carbamazepine; ACEIs: angiotensin-converting enzyme inhibitors; AMG, VAN: aminoglycosides and vancomycin; FIB:fibrates; COLCH:colchicine; ESAs:erythropoyesis-stimulating agents; RF: renal function; LF: liver function; CBC: complex blood count; MD: muscular disorder; CD: cardiac disorder; TH: tyroid hormones; ALB: albumin; OT: others; Cr: creatinine; Ur: urea; AST: aspartate aminotransferase; ALT: alanine aminotransferase; WBC: White blood cells; Pla: platelets; Hb: haemoglobin; CPK: creatine phosphokinase; QT: QT interval.

- *1: The use of clozapine is not indicated if WBC <3500/mm³.
- *2: Neuroleptics generally affect glucose, triglyceride and cholesterol levels.
- *3: CBZ produces hyponatraemia. It should be withdrawn if Na <130 mEq / L.
- *4: Amiodarone increases the levels of CPK, especially when used with simvastatin, so simvastatin doses higher than 20 mg / day are not recommended; it may be replaced with pravastatin whose metabolism is mediated by CYP3A4.
- *5: Avoid use with MAOs due to risk of neuroleptic syndrome.
- *6: Adjusted for albumin levels if there is hypoalbuminaemia, to estimate free fraction.
- +: Monitor

Only appropriate blood tests should systematically monitored in order to increase the quality of the interventions made by the pharmacy department.

No conflict of interest

GRP018 Quality indicators of total parenteral nutrition in a neonatology unit at a Brazilian teaching hospital

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Background

Adequate nutritional support for premature or sick neonates requires daily calculating and ordering of parenteral nutrition (PN). A standardized process for ordering, preparing, administering and monitoring allows the team to calculate PN as well as to check recommended quality indicators.

Objectives

To calculate and evaluate some quality indicators for patients with PN in a Brazilian neonatal ward based on International Life Sciences Institute (ILSI) recommendations.

Material and Methods

Medical records were evaluated by pharmacists of the institution from July 2009 to June 2010. An intranet tool was consulted in order to collect data from laboratory tests. A total of 11 PN quality criteria were defined and examined.

Results

A total of 62 patients were included in this study, 32 male and 30 female, gestational age of (33.1 \pm 6.7) weeks; the duration of PN use was (9.9 \pm 9.0) days, the hospital stay was (35.9 \pm 35.0) days, the suitability of the amount/composition calculated/prescribed was close to 100%. The recovery rate of patients for whom enteral nutrition was prescribed was 88.9% (11.1% died). The death rate correlated negatively with Apgar at birth. The rate of catheter infection was 7.93%. The liver function was affected in 4.7% and renal in 23.8%, this last related to the gestational age. According to ILSI recommendations, ten of the eleven indicators were in the acceptable range.

Conclusion

The definition of quality criteria and standards for them is an efficient method of providing qualitative and quantitative analysis of the clinical care of patients receiving PN. It detects areas for improvement and assists in developing a methodology for efficient working practices. The data generated by this study justified the importance of monitoring these parameters by pharmacists as members of the nutritional therapy team.

No conflict of interest

GRP019 Germany's first national medication error reporting system DokuPIK: establishment, results and clinical assessment

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Background

DokuPIK is the first German online database to report medication errors and pharmaceutical interventions. In 2010, it was established as the standard reporting system in the Department of Orthopaedics at the St. Franziskus-Hospital, Münster. Six months after its establishment, clinical experience enabled a first assessment to be made of the system's relevance for future drug risk management.

Purpose

To assess the clinical value of the DokuPIK drug error reporting system as a safety tool for hospital pharmacists. In addition, a comprehensive analysis of drug error data was conducted.

Material and Methods

In the Department of Orthopaedics, the medicines prescribed for elective patients (n = 712; female: 41%; median age: 63 years) was reviewed by a hospital pharmacist. Errors in the drugs and subsequent interventions were documented via DokuPIK. Data was analysed using multiple endpoints (including error location, type of error, cause of error, error severity). Interventions were stratified according to cause of intervention, impact of intervention, cost benefit and assignment to categories determined by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).

Results

Errors in the medicines occurred in 99 of 712 patients (14%). Most common errors were incorrect dosage (34%), interactions (17%) and inappropriate choice of drug (13%). According to the NCC MERP categories, 75% of errors were categorised Categories A or B (error did not reach patient), and 6% of errors were categorised Category E (temporary harm, need for treatment).

Conclusions

Regarding clinical manageability, the DokuPIK database was found to be a comprehensive tool for the differentiated reporting of drug errors and pharmaceutical interventions. Furthermore, it may function as a tool to strengthen clinical pharmacy: at the St. Franziskus-Hospital Münster, the results of this DokuPIK medication error analysis resulted in the creation of a permanent clinical pharmacist post at the hospital's admission office.

No conflict of interest

GRP020 Drug-related problems and pharmacist interventions in medical and surgical departments

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Background

Hospital clinical pharmacists are crucial in drug therapy optimisation for detecting, solving and preventing drug-related problems (DRPs), which often translate to morbidity and mortality in hospitalised patients.

Purpose

To detect and characterise DRPs in medical and surgical wards (MWs, SWs) and estimate the level of acceptance of pharmacist interventions (PIs) by physicians.

Material and Methods

An epidemiological prospective 12-month study was conducted in 3 MWs and 2 SWs in Fernando Fonseca's Hospital, from January to December 2009. Each day, clinical pharmacists checked prescriptions for drug dosage, adjustment for renal function, interactions, duplication and duration. DRPs detected were classified according to possible negative outcome indicators defined by the Dader Method as: untreated health problem, unnecessary drug, non-quantitative efficacy (wrong drug), quantitative efficacy (sub-therapeutic dosage/duration), non-quantitative safety (allergy, adverse reaction) and quantitative safety problems (extended duration/toxicity). Pharmacists promptly discussed these DRPs with physicians verbally or in writing, providing suggestions for drug optimisation. Pls were classified as accepted (suggestion accomplished within 48 hours) or non-accepted (different physician opinion, patient discharge, death or other reason). All data were recorded in a computer database.

Results

We detected 436 DRPs in MWs and 144 DRPs in SWs, mainly in male, elderly patients (age>65). DRPs were mostly related to drug regimen (57.6%-MW; 50.7%-SW) and unsuitable pharmaceutical form (20.6%-MWs; 9.0%-SWs) and mainly involved enoxaparin and omeprazole on the MWs and gentamicin and piperacillin/tazobactam on SWs. The majority of possible drugrelated negative outcomes were related to quantitative safety (52.5%-MWs; 38.9%-SWs) and quantitative efficacy (18.6%-MWs; 23.6%-SWs). High levels of PI acceptance were observed (80.0%-MWs; 94.4%-SWs).

Conclusion

In both types of ward, DRPs were mostly related to drug regimen and unsuitable pharmaceutical form, differing only in the drugs involved. This study also allowed our Pharmacy to establish quality and activity measurement indicators, in order to optimise drug therapy and justify clinical pharmacist interventions in hospitalised patients.

No conflict of interest.

GRP021 Optimization of treatment in patients with multiple sclerosis

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Purpose

To detect and optimise inappropriate prescriptions (IPs) in patients with multiple sclerosis (MS).

Material and Methods

Observational and prospective study from November 2008 to November 2009 in patients with MS who were monitored in the Pharmaceutical Care to Outpatients Unit in a regional hospital. Data were recorded in a standardised "Medication history" document which included: 1) patient personal and clinical data, pharmacotherapy data, dietary habits and analytical and microbiological data; 2) clinical service data and 3) record of IPs and pharmaceutical interventions. IPs were detected by the validation of manual prescriptions, applying the criteria for interferon beta and glatiramer acetate validation contained in the MS therapy validation guide. These criteria included indications, special precautions and contraindications, drug combination, usual dosage and adjustment in renal/hepatic insufficiency, interactions and usual side effects, duration of the treatment and method of administration. The information used to complete the document was obtained from the patient's medical history and from interviews with the patients. Patients were given oral and written information.

Results

8 patients were included (5 men and 3 women). Most patients received interferon beta-1b (62.5%). Interventions: a total of 29 IPs were identified (3.6 IP/patient). The main problems detected were: unsuitable dose/frequency (34.5%), side effects (27.6%), special warnings ignored (13.8%) and method of administration (10.3%). The most common side effects related were flu-like symptoms, chills, fever and injection site pain. The acceptance rate was 96% by medical staff.

Conclusion

The application of explicit criteria to validate manual prescriptions (e.g. the use of the MS therapy guide) contributed to: 1) the identification of patients with IPs and 2) optimisation of pharmacotherapy. In addition, health education given to the patient contributed to a better knowledge of their disease and its treatment, allowing better adherence to treatment.

No conflict of interest

GRP022 An Audit of Electronic Prescribing in ICU

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Background

Medication errors in the Intensive Care Unit are common and are multifactorial¹. An MMUH ICU audit was carried out in 2007 looking at the number and type of prescribing errors².

Electronic prescribing has been shown in various studies to reduce prescribing errors. As a result, both the USA & UK health polices have recommended the introduction of electronic prescribing³.

In September 2009, the MMUH ICU introduced Philips Intellivue Clinical Information

Portfolio® (ICIP) which incorporates computerised physician order entry (CPOE).

Purpose

To compare the number and type of medication errors before and after the introduction of ICIP.

Material and Methods

- · Prospective study with consecutive sampling.
- 10-day data collection period.
- Comparable data collection to previous prescribing audit.
- Results compared to previous audit.

Results

219 patients (pre-ICIP) vs. 249 patients (post-ICIP).

66 prescribing errors pre-ICIP vs. 43 post-ICIP.

The introduction of CPOE eliminated some common errors associated with handwritten prescriptions e.g. incomplete or illegible prescriptions.

The prescribing of drug name, dose, route & frequency are now mandatory fields and cannot be omitted.

Every prescription can be traced to the prescriber, as every user of the ICIP system has a unique password-protected identity.

The number of patients with incomplete allergy status declined from 37 to 3, as it is a mandatory field.

The number of duplicated prescriptions increased with the use of CPOE from 3 to 8.

A drug was prescribed for the wrong patient (n=1).

IV infusions appear as active although the patient is no longer receiving them (n=20).

Conclusion

Electronic prescribing reduces prescribing errors but it does not eliminate them. It changes the nature of the error and can introduce new errors. This audit has helped identify what modifications and improvements are required for the ICIP system. As a result of this audit, a set of prescribing rules has been drawn up to help improve the safety of CPOE. Each prescriber and every computer now has a laminated list of these rules.

Portfolio® (ICIP) which incorporates computerized physician order entry (CPOE).

No conflict of interest

GRP023 Identification of drugs frequently associated with medication errors

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Background

Medicines errors (MEs) are a major problem for patient safety. Better knowledge of risk factors is necessary to avoid drug errors. It is therefore essential not only to identify drugs that are most often involved in MEs but also drugs that potentially cause the worst harm.

Material and Methods

The study checked 5345 records stored in the DokuPIK medicines error reporting system (MERS) developed by the German Association of Hospital Pharmacists. Data were exported into Excel and screened independently by two hospital pharmacists. Most records already had a reference to the drug that was involved in a ME or the drug involved could easily be identified and entered into the table. Entries were categorised for frequency and the degree of harm caused by the ME.

Results

The DokuPIK MERS is a very useful tool for identifying risky drugs. We identified drugs that were most likely to be involved in MEs as well as the drugs that had the potential to cause most harm to the patient.

A preliminary analysis revealed the following rank order of drugs that were most likely to be involved in a ME: simvastatin (incl. combinations), enoxaparin, diclofenac, ramipril (incl. combinations), phenprocoumon, ciprofloxacin, prednisolone, vancomycin, acetylsalicylic acid and digitoxin. The most frequent causes for the

ME were overdose, wrong dosage, interaction, misinterpretation of the prescription, selection of drug, dose adjustment. Drugs that have the potential to cause the most harm to the patient were identified as: colchicine (death by overdose), vincristine, beta-sympatholytics (asthmatic attacks), glucocorticoids (gastrointestinal bleeding) and simvastatin (rhabdomyolysis).

Conclusion

Based on our present data we are already able to identify a number of drugs that are most likely to be involved in MEs. With this information we can develop strategies to avoid drug errors while making best use of human and financial resources.

No conflict of interest

GRP024 Non-formulary prescriptions and hospital pharmacist's intervention in a Hospital Centre

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Background

It is difficult to correct problems related to how drugs are used by prescribers, pharmacists and patients. Most successful rational drug use activities are based on regulatory, managerial and educational actions. The formulary system is a process by which Pharmacy and Therapeutics Committees (PTCs) evaluate and selects from the available drug products those that are considered most efficacious, safe and cost effective. Normally, only formulary drugs are approved for use in health facilities. However, the therapeutic needs of a small number of patients cannot be met by any drugs in the hospital formulary.

Purpose

To evaluate non-formulary prescriptions and hospital pharmacist interventions

Material and Methods

A six-month retrospective study of non-formulary drug requests (January to June 2010); the PTC had established procedures for evaluating the use of non-formulary drugs. The prescribing physician should complete the Non-Formulary Drug Request Form, designed and approved by the PTC, and forward it to the pharmacy. It may be appropriate for the pharmacist to discuss the use of a formulary drug with the physician. If the prescribing physician determines that a non-formulary drug is required, the hospital pharmacist reviews available evidence on the subject and makes a written report supporting an informed decision. The PTC or the clinic director (urgent situations), may authorise drug use.

Results

We analysed 728 non-formulary drug requests. Non-formulary drug prescriptions were mainly due to toxicity or lack of efficacy of first-line treatment. The majority of these requests were drugs used in the treatment of infections followed by malignant diseases and immunosuppression. The pharmacist's review and report took 2.7 (1-30) days. The pharmacist agreed with the prescription in 97.5 % of cases (710). 725 prescriptions were authorised. We didn't evaluate prescriptions not formalised as the result of previous pharmacy interventions.

Conclusion

The use of medicines is an inherently complex process that requires constant evaluation. Being a part of this process, hospital pharmacists can play a major role in the efficacious, safe, and cost-effective use of drugs.

No conflict of interest

GRP025 Implementation of Quality Risk Management in the Clinical Pharmacy Field

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Background

In Austrian hospital pharmacy Quality Risk Management has been established for working processes such as production and logistics to provide a constant high level of service and safety. In recent years clinical pharmacy has gained in importance in Austria as another considerable service that pharmacists offer to the hospital.

Purpose

The intention of this study is to emphasise the need for a quality assessment system in the clinical pharmacy setting and to demonstrate that the methodology of Quality Risk Management we know from production can be applied to clinical pharmacy too.

Material and Methods

A risk management process for clinical pharmacy was initiated in accordance with the ICH-Q9 Quality Risk Management Guideline for active substances and medicinal products. Failure Modes and Effects Analysis (FMEA) was used to detect critical steps in the working processes of the clinical pharmacist and to categorise them by their risk of potential hazard. Measures for risk reduction were deduced from the results of this risk analysis.

Results

Risk assessment assumes a clearly defined description of workflow. Quality indicators have to be set to avoid inconsistency in working practices and patient harm. Standard operating procedures can provide the basis of a quality system in the clinical pharmacy setting. The risk analysis indicated that it is important to have obligatory specifications and regulations as well as a documentation of pharmaceutical interventions. Using the same quality standard for both clinical pharmacy and production enables clinical pharmacy to be integrated into the established Quality Risk Management system.

Conclusion

It has been proved that risk management strategies and instruments such as risk analyses can be used successfully in clinical pharmacy. The objective of Quality Risk Management in clinical pharmacy is to achieve reproducibility and to avoid patient harm. Standardisation also benefits the clinical pharmacist as validation of his work.

No conflict of interest

GRP026 Specific intervention in patients with therapeutic administration annual zoledronic to avoid duplication

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Background

Zoledronic acid (Aclasta) (annual bisphosphonate) has been given in Spanish hospitals for osteoporosis since January 2009. There is a risk of treatment duplication when the Primary Health Care (PHC) is unaware of the existence of this treatment and continues to prescribe other drugs for the prevention of fractures.

Purpose

To identify patients with treatment duplication (TD) with other bone metabolism drugs to avoid safety problems and check prescription of Calcium and Vitamin D.

Material and Methods

PHCclinical history of patients who had been treated with 5 mg zoledronic acid annual dose in hospital (January 2009-May 2010) were reviewed to detect the concomitant prescription of other drugs for bone metabolism.Patients were contacted by telephone by PHC doctors to cancel duplicated treatment. Clinical practice guides recommend taking calcium (1-1.2 g/day) and vitamin D (80 IU/day). Indicators:

1-% patients with therapeutic duplication drugs and 2- %TD

3-% patients administered zoledronic without prescription of calcium and vitamin D in primary care

Results

- 1) 19 of the 122 patients who had been given zoledronic acid in both settings were excluded because there was no clinical history.
- 2) 11.65% of the remaining 103 patients were continuing to be prescribed another drug for bone metabolism (%) (bisphosphonates (54), raloxifene (15), teriparatide (16), strontium ranelate (15))
- 3) 32.03% patients were not prescribed calcium and vitamin D (72% women, 28% men).
- 4) We designed a zoledronic annual administration sheet for the clinical pharmacist to send to the PHC pharmacist in order to advise to the doctors about patients who receive it.

Conclusion

It is necessary to design interventions between the two levels of care for drugs classified as high risk to promote the correct use of these drugs.

Due to the high percentage of patients without calcium and vitamin D a specific intervention must be performed to increase use.

No conflict of interest

GRP027 Effect of a clinical pharmacist on drug therapy of patients in a long-term care facility

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Background

Due to multiple morbidity and changed pharmacokinetics, elderly patients have an increased risk of adverse drug reactions and other medication-related problems.

Purpose

To assess the effect of a clinical pharmacist on the quality of patient prescribing in a long-term care facility.

Material and Methods

Ongoing prospective clinical pharmacist intervention study. Review of chart data for age, weight, medical history, list of medical conditions, medication profiles and laboratory values and systematic evaluation of each patient for suboptimal drug treatment using the ten criteria of the Medication Appropriateness Index (MAI) by Hanlon et al.

Results

From January to August 2010 368 patient charts were reviewed. After our evaluation according to the MAI 13% had unnecessary medication, 18% of the doses were not correct and clinically significant drug-drug interactions were found for 14% of the prescriptions. 124 patients (34%) presented with known impaired renal function (estimated glomerular filtration rate eGFR < 60 mL/min/1.73 m²) and 12% had to have their drugs adjusted. 24% incorrect directions for administration were discovered, mostly due to crushed drugs for patients with swallowing difficulties or feeding tubes (133 patients i.e. 36%).

To assess the rate of acceptance another review of charts started in September, showing that about 50% of pharmaceutical recommendations were accepted.

Conclusion

Elderly, long-term care patients are a challenging group for the medication process. A clinical pharmacist should regularly evaluate their medicines to improve suboptimal prescribing and to detect drug-related problems as soon as possible. As the acceptance rate is still not satisfying we decided to promote our service by increasing our presence during the ward rounds.

No conflict of interest

GRP028 Streamlining empirical antibiotic prescribing in paediatric intensive care

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Background

Antibiotics are widely used in neonatal and paediatric intensive care units (PICUs) and play an important role in the treatment of critically ill patients. To streamline antibiotic prescription, recommendations for empirical treatment were introduced in our PICU in 2005 and revised in 2008.

Purpose

To analyse the completeness of, and compliance with, the initial and revised recommendations.

Material and Methods

Prescriptions of empirical antibiotics were prospectively evaluated and compared with the recommendations in our PICU (23 beds) for 10 weeks in 2006 and 20 weeks in 2008.

Results

54 and 94 prescriptions for empirical antibiotic treatment were evaluated in 2006 and 2008 respectively. Treatment for 70% (2006) and 84% (2008) of the indications was defined in the recommendations. The choice of antibiotic was consistent with the guidelines in 84% (2006) / 79% (2008). However, 8% and 18% of the choices were too broad. 92% (2006) / 95% (2008) of the dosages were consistent with the recommendations.

In 2008, re-evaluation of empirical treatment after 48-72 h, as indicated in the recommendations, could be analysed in 84 patients staying longer than 72 h. In 45 (54%) cases, treatment was reevaluated. After re-evaluation 13 therapies were left unchanged, 11 therapies were adjusted and 21 were terminated. At discharge from PICU 32 (59%) patients and 52 (55%) patients in 2006 and 2008 respectively were on antibiotic treatment. The duration of treatment was defined in 63% (2006) / 67% (2008) of the cases and it was consistent with the recommendations in 55% for both groups.

Conclusion

The revised recommendations were applicable to more clinical situations than the original ones. The treatment was only reviewed in half the patients and in addition information on the duration of antibiotic therapy at discharge was lacking in one third of patients in our cohort.

No conflict of interest.

GRP029 IMPLEMENTATION OF A SYSTEM OF DRUG SAFETY INFORMATION

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Purpose

With the aim of improving the safety of our patients, to set up a system for obtaining data on drug use, which allows the analysis and dissemination of the monthly results to all staff involved.

Material and Methods

Creation of a multidisciplinary working group to improve the safe use of medicines. Drafting of procedures for prevention and monitoring of medicine errors. The criteria for the new procedures included:

- 1. All drug allergies to be recorded.
- 2. All syringes to administer medicine must be properly labelled indicating the drug they contain.
- 3. The therapeutic effect of analgesics, antipyretics and sedatives administered on demand must be recorded.
- 4. All antibiotics must be administered within the established range for length of course.
- 5. All multi-use drug containers must be properly labelled indicating the opening date and the expiry date after opening.
- 6. All thermolabile medicines must be stored in a fridge.
- 7. There should be no expired drugs in the stores.
- 8. All high-risk drugs that are withdrawn from a store must be recorded together with a double check.
- 9. All vials of concentrated electrolytes to be stored under lock and key.

The quality indicators were defined as the percentage of compliance with each criterion. A monthly assessment system was established for each criterion.

Results

The values obtained are shown in the table:

Indicator		ry % compliance April
	2009	2010
1	70	95
2	50	80
3	75	99
4	82	100
5	33	80
6	95	100
7	95	100
8	13	85
9	33	80

The use of this system has reduced drug-related adverse effects by 95%.

Conclusion

The use of this system of drug safety information has developed a higher level of awareness in health care workers and has improved patient safety.

No conflict of interest

GRP030 drug history: medication reconciliations between patient's usual treatment and hospital prescription

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Backgroung

Since 1995, our pharmacy department has provided a named patient daily distribution system closely supervised by pharmacists.

Purpose

To add to our clinical duties medicines reconciliation between the patient's personal treatment and the hospital prescription in the vascular surgery department.

Material and Methods

Data was collected either from the patient's General Practitioner (GP) prescription or medical reports or the anaesthetic report or by questioning the patient. The drug history was then compared to the hospital's prescription, which was not computerised. Correct names, dosages, doses and substitutions (for non-available products) of the drugs were checked. If discrepancies were found, the pharmacist checked with the prescriber and then classified them as intentional or non-intentional.

Results

The study took place from August to September 2010. During this period, 76 patients were hospitalised and 47 drug histories were recorded at random. Of these, 29 were collected from the patient's GP's prescription, 8 from medical reports, 7 from anaesthetist's reports and 3 from asking the patient. 42 prescriptions showed discrepancies. They were non-intentional in 25 cases. They represented 37 prescriptions for individual drugs out of 377 in total i.e. 9.8%. They were: forgotten drugs (35%), wrong doses (28%), wrong dosages (32%) and wrong substitutions (5%). Among these discordances those with the greatest potential adverse effect on the patient were mainly with cardiovascular drugs. Mistakes in diabetes drugs and lipid-regulating drugs were also likely to harm the patients. All pharmaceutical interventions were discussed with and approved by the prescriber.

Conclusion

The drug history is a key point to correct prescribing (therefore to good dispensing) and needs to be correctly detailed. Clinical pharmacists intend to design a document, available in the patient's medical file, detailing the drug history. This document should improve patient care.

No conflict of interest

GRP031 Introduction of an education, audit and feedback programme to improve the recording of clinical indication and duration on antimicrobial prescriptions.

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Background

Our tertiary teaching hospital trust was identified as underperforming on healthcare-associated infections in 2008. Part of the response was to expand the antimicrobial stewardship programme.

Purpose

To find out whether the introduction of a monthly audit programme with structured feedback improves compliance with antimicrobial prescribing standards

Material and Methods

Every month, all in-patients were audited against standards of duration and indication on antimicrobial prescriptions. The results were reported back using the Trust intranet plus local feedback at all levels. League tables were used to rank the four bed-holding Divisions, plus 43 specialties within them. There is no electronic prescribing so direct measurement of course length was not possible, so the prevalence of antimicrobial prescribing was used as a surrogate.

Results

Baseline compliance in November 2008 for duration was 55%, indication (in notes) 54%. Performance slowly improved until July 2010 when both duration and indication were 90%, and prescriber identification was 89%. Indication dipped in December 2009 from 92% to 81% when recording on the drug chart was required. Percentage of patients on antimicrobials dropped from 35% to routinely less than 28%. Even accounting for seasonal variation in infections, the same month in different years showed an average reduction of 2.1%. Whilst the Trust as a whole has never reached the >95% compliance, many specialties have.

For comparison, an audit of 34 UK Trusts showed an average of 53% for duration (range 12-99%), and 67% for indication from 11

centres (range 36-86%).

Conclusion

Setting the standard of recording the indication and duration on all antimicrobials on the patient's prescription chart with monthly audit and feedback from all patients appears to improve prescribing quality. A range of formats for feedback encourages competition and improvement. When the new High Impact Intervention for antimicrobials is introduced, this approach could help Trusts reach the target.

No conflict of interest

GRP032 Drug dosage adjustment in patients with renal impairment: Analysis of prescriptions for patients at the university hospital of leipzig

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Appropriate dose adjustment and drug selection for patients with renal impairment is important to avoid adverse drug reactions and ensure optimal treatment outcomes.

To identify the use of potentially risky drugs for the kidney and to evaluate whether appropriate dose adjustments were made in patients with severe renal impairment.

Material and Methods

In this study prescriptions for hospitalised patients with an estimated glomerular filtration rate lower than 30 ml/min were analysed for 66 days. The eGFR was estimated using the revised 4-component Modification of Diet in Renal Disease study equation. Hierarchically structured information sources were used to analyse the prescriptions: German drug labelling, international reliable and up-to-date drug information references like Drugdex. Based on these guidelines, each individual drug prescription was rated as "appropriate" or "renal risk drug" ("appropriate dose", "inappropriate dose", "contraindicated", "use with caution").

Results

17,222 records were analysed for a total of 1,308 patients. 63% (n=10,781) were renal risk drugs: Dose adjustments were necessary for 2,964 prescriptions (17%), out of which 801 (27%) were rated as "inappropriate dose". 1,171 (7%) of all prescriptions were rated as "contraindicated" and 6,646 (39%) prescriptions were rated as "use with caution". The total of 801 prescriptions rated as "inappropriate dose" included 44 different drugs, out of which 25 were anti-infective drugs with a total of 416 prescriptions. The most drugs with inappropriate doses were ramipril, metoclopramide and ciprofloxacin. The most frequent anti-infective drugs with inappropriate doses were ciprofloxacin, valganciclovir and imipenem. Antithrombotic and antihypertensive drugs were the most commonly contraindicated prescriptions.

This study points out that physicians do not take patient renal function sufficiently into account when prescribing. Renal risk drugs were widely used in patients with severe renal impairment and dosing errors were quite frequent.

No conflict of interest

GRP033 Patient medication reconciliation at hospital admission. A pilot study. F. Falcao, J. Cabrita, M. Caramona

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Background

Despite the attention being given to the problem of medication safety, little attention has been paid to the medicines problems that are encountered by older patients who are receiving care across settings. Admission to hospital for surgery can be a critical, vulnerable moment for medicines discrepancies. Prior studies suggested that unintended medicinesdiscrepancies are common at the time ofhospital admission. These errors are particularly worthy ofattention because they are not likely to be detected by computerisedphysician order entry systems.

Purpose

In this study we intend to determine the frequency of treatment omissions in the records of elderly surgical patients at admission to

Material and Methods

Observational study conducted on a general surgical ward in a central hospital. The study population consisted of surgical patients aged 65 years and older admitted to the hospital taking at least one drug for a chronic condition. The primary outcome was discrepancies betweenthe physicians' prescriptions at admission and a comprehensive medicines history obtained through an interview.

Results

We studied 30 patients (mean age = 74 years) predominantly females (63%). These patients were taking an average of 4.5 drugs at admission. Drugs for cardiovascular problems were found to be most common (45.5%) followed by drugs used to treat blood diseases (14.2%) and the CNS (12.7%). We found discrepancies betweenthe physicians' prescriptions at admission and interview data in 13 patients (43.3%).

Conclusion

significant percentage of older patients experienced discrepancies in their drug treatment after making the transition from home to hospital. As part of a multidisciplinary team pharmacists can play an important role in implementing a practice model to prevent unintended discrepancies.

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- 2 Baker et al. The Canadian Adverse Drugs Event Study: The incidence of Adverse Events among Hospital Patients in Canada". Canadian Medical Association Journal 170 (11): 1678-86.
- 3 Cohen et al. Variation in medicines information for elderly patients during initial interventions by emergency department physicians. Am J Health-Syst Pharm vol 65 2008: 60-64

No conflict of interest

GRP034 Evaluation of the "restricted" antimicrobial agents' use for the years 2004 and 2009 in a county hospital of Crete,

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Background

"Agios Georgios" Chania General Hospital of Crete is a 465-bed general hospital covering any need for hospitalisation among a 150,000 population of locals and visitors. Infection is a very common diagnosis upon admission and the use of "restricted" (under surveillance) antimicrobial agents is often the first choice, contrary to the CDCP (Centers for Disease Control and Prevention) recommendations for community infections.

Purpose

The administration of restricted antimicrobial agents used to treat hospitalised patients throughout 2004 and 2009 was examined in order to identify therapeutic choices.

Materials and Methods

Third-generation-cephalosporins, synthetic penicillins plus penicillinase inhibitor, glycopeptides, carbapenems, quinolones and streptogramins were the agents evaluated. All data were derived from our Data Information System and were used to estimate the DDD (Daily Defined Dose) per 1,000 patients.

Results

27,254 patients were hospitalised in 2004 and 29,186 patients in 2009 with an average of 4.40 and 4.45 nursing days respectively. The total cost of drugs was € 9,611,262 in the first survey vs. €16,541,035 in the second (an increase of 72.10%, P<0.05).The cost of antibiotics was € 2,782,117 vs. € 3,937,098 (an increase of 41.51%, P<0.05). The total DDDs/1,000 patients were 1,835.42 vs. 2,118.21 for 2004 and 2009 respectively.

The use of ertapenem had gone down by 83.00% (P<0.05), while the use of levofloxacin had increased by 185.98% (P<0.05). Similarly, the use of the ticarcillin+clavanulate went down by 63.40% (P<0.05) and imipenem 61.94% (P<0.05). Seen as a drug category, quinolones have increased 91.00% (mainly due to the increase of ciprofloxacin by 62.37%, P<0.05), while carbapenems have decreased 64.98% comparing the two years for which we have data (P<0.05).

Conclusion

There were statistically significant differences concerning both the cost and the use of advanced antimicrobial agents in 2004 and 2009. Differences concerned each individual substance as well as certain drug categories. Probable causes include a change in resistance between hospital and community microorganisms, accompanied by a change in prescribing habits, during these 5 years.

No conflict of interest

GRP036 Quality in prescribing and dispensing of clinical trials in a tertiary hospital

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Background

The quality of prescribing and dispensing in clinical trials (CTs) was evaluated.

Purpose

To analyse the incidents recorded, as well as the quality of data in the computerised register, in order to design a new application that promotes patient safety and enables us to account for the supplies.

Material and Methods

We looked at the prescribing and dispensing forms that were in the dispensing Access database between January 2009 and April 2010. They were used for active CTs with medicines. Primary variable: Incidents reported referred to the total number of items dispensed.

A form was designed in the database that recorded the point in the process at which the incident occurred, whether it affected the patient or not, when it was detected, the classification that was used to describe the incident and the cause to which it is attributed.

Results

In the study period 3071 dispensed items and prescriptions were evaluated from 136 CTs. We detected 296 incidents affecting 290 dispensed items (9.4%). Of these, only one affected the patient, without causing harm.

The point in the process at which the highest number of incidents was detected was dispensing (44.3%). Incidents also were found at prescription (27.4%) and pharmaceutical validation (16.6%). These incidents were detected during quality control (82.8%) and were classified as dispensing without signing (21.66%), label lost (18.6%), etc. Analysing the impact per CT it was found that a small number of trials (22 CTs) accumulated the majority of incidents detected (80.4%). Complex identification requirements were the biggest source of error.

Conclusion

Paying attention to patient safety and correct recording of the data, the new application was designed to record supplies made and prescriptions dispensed. Each trial is different, so it is possible to adapt the recording system to multiple steps and different procedures for receiving and dispensing: it is now possible to enter the data using a configurable supply form. Once the new system has been implanted, we will analyse the incidents again to find out whether there has been an improvement.

No conflict of interest

GRP037 Knowledge and usefulness of a drug alert-system for patients with kidney disease

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Background

Computer alert systems have been developed over recent years to reduce adverse drug events (ADEs) in hospitalised patients. Inpatients with renal insufficiency are a vulnerable group for ADEs, thus many of these systems have focused on nephrotoxics and drugs eliminated via the kidney. We designed and implemented an application that provided real-time drug prescription decision support to the physicians. It was announced on the hospital website. It gives information about the patient's renal function and provides a list of the prescribed drugs for which caution is needed or which are nephrotoxic for that patient.

Purpose

A year after its introduction we wanted to know what use physicians were giving this system in order to improve it if necessary.

Material and Methods

We designed a questionnaire with 14 multiple-choice questions and distributed it among the prescribing departments. After a month we collected the completed questionnaires.

Results

111 surveys were collected which constituted a representative sample of prescribing departments and medical categories. All but one considered such a system as designed helpful even though only half of them knew of its existence. Among those who were aware of it, 71% checked the patient's renal function and 57% the drug list. 80% looked for alternatives to contraindicated drugs. Four out of five believed the system was helping in the management of their patients because it helped them recognise patients with renal failure and reminded them about the importance of evaluating it at the time of prescribing medicines. Improvements suggested were: making alerts more striking, suggesting alternatives for contraindicated drugs and reporting the specific dosage adjustment when required.

Conclusion

In an electronic prescription system equipped with many applications such as ours, the introduction of a new alert system should be actively communicated. Modifications such as the ones suggested will be made to improve the efficiency of the system.

No conflict of interest

GRP038 Prevention on prescription medication errors: first quantification of pharmacist interventions in a newly opened hospital

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Background and purpose

To describe the clinical interventions made by a hospital pharmacist in surgical and medical wards in a level 3 general public hospital with 120 beds opened in February 2008.

Material and Methods

4 weeks of prospective study in August 2010 including all adults discharged with at least one prescribed drug from the departments of general surgery (24 beds), and medical and internal medicine (28 beds). Every day a pharmacist in the Pharmacy Department checks all the drug charts that use the Selene and Pharmatools CPOE (Computerised physician order entry) available in the hospital, without participating in the ward rounds. All interventions were collected and quantified by Microsoft Excel 2003. The variables collected were: reason for intervention, the drug involved and the acceptance of the intervention by the physicians.

Results

52 interventions were recorded in four weeks (46% surgical wards, 54% medical wards). The most frequent reasons for an intervention were: change of treatment (25%), theduration of treatment (23%), duplicated drug treatment (9.6%), inappropriate doses (7.7%) missing information or clarification (3.8%), the avoidance of allergy (3.8%), a wrong unit of measurement (5.8%), a non-formulary item (3.8%), a drug interaction (3.8%), an inappropriate or wrong drug (3.8%), other reasons (9.9%).

75% of interventions were accepted by the physicians. The drugs involved were heterogeneous, although the majority of interventions included analgesics (34%) and antibiotics (17%).

Conclusion

The pharmacist reviewing drug charts identifies real and potential medication errors in surgical and medical wards. A further study is required to calculate intervention/patient/day, to tabulate standard errors and to design warnings in the CPOE program to improve patient safety.

No conflict of interest

GRP039 "Feeding tube pass" - Information- and documentation-booklet for tube-feeded patients A. Morgenbesser

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Background

We designed the "Feeding tube pass" because of: a) a lack of structure in in the discharge management of tube-fed patients

- b) little or insufficient information for everybody involved: patients, relatives, the extramural facilities and nursing homes that handle tubes (gastric and jejunal tubes)
- c) written information was lacking for handling tube-fed patients

Purpose

To set up a standardised discharge-management system, which guaranteed a high level of safety for the patient at the time of discharge, after discharge and also if the patient is readmitted.

Material and Methods

The project involved an interdisciplinary team that contributed professional experience and skills (pharmacist as head of team together with dietician, nurse and physician).

A booklet was written containing general information about the tube, the kind of tube feeding and advising how the tube feeding should be administered, care of the tube, information about the dressing, personal care and stating which medicine(s) should be given and how they should be administered through the tube. Information about complications concerned tube feeding and sheets for documenting changes in tube feeding and medication also are included.

The booklet is added to the patient record at the time of inserting the tube. At the time of discharge the professionals complete the booklet together with the patient or relatives and clarify the remaining questions with them.

Results

So far more than 20 tube-fed patients have left our hospital with the booklet. For evaluation we created questionnaires and asked the patient/relatives or personnel of nursing homes to complete the questionnaires. The feedback showed approval and satisfaction of 100 %. To keep this level the booklet is updated yearly.

Conclusion

With the interdisciplinarily-designed "Feeding tube pass" it could be shown that the quality of patient treatment and satisfaction has been greatly improved and the information given is much easier to reproduce.

No conflict of interest

GRP040 Non-small cell lung cancer therapy in the Hospital of Parma, Italy: recommendations by "GReFO" (Gruppo Regionale Emilia-Romagna Farmaci Oncologici)

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Background

Lung cancer is a major cause of death in Europe. Non-small cell (NSCLC) histology accounts for 87% of lung cancers with a 10-15% five-year survival. New therapeutic approaches have been proposed recently.

A regional multidisciplinary group (GReFO) was created in Emilia-Romagna to issue recommendations for the use of pemetrexed or bevacizumab plus platinum-derivatives in NSCLC for first-line treatment settings.

Purpose

To evaluate NSCLC treatment schedules used in Parma Hospital in order to implement GReFO recommendations locally.

Material and Methods

GReFO recommendations on NSCLC treatment, published in 2010, were used to identify parameters by which to monitor medical prescriptions.

Since 2008, treatments have been compounded at the Antiblastic Centralised Intravenous Admixtures Unit (UMaCA=Unità Manipolazione Chemioterapici Antiblastici) of the Pharmacy Service. A software application has been used for prescription, compounding and administration.

Treatment schedules in the UMaCA database were analysed and the patients treated in the period Jan2009-May2010 were examined.

Results

Based on GReFO recommendations, 3 monitoring parameters were identified: age, performance status (PS), drug treatment history. 24 NSCLC treatment schedules were in use, of which 8 contained pemetrexed or bevacizumab.

206 patients with NSCLC (age 40-76) were treated during the period examined: 14 (6.8%) received pemetrexed+cisplatin (nobody >70 years), 12 (5.8%) carboplatin in place of cisplatin (6 patients >70y), 33 (16%) pemetrexed monotherapy (11 patients >70y), 4 (1.9%) bevacizumab in association with chemotherapy.

In accordance with the negative recommendations from GReFO, bevacizumab was little used. Pemetrexed with platinum derivatives was used in 12.6% of patients, carboplatin was preferred in elderly patients(>70 years) because of better compliance. Finally, pemetrexed was used less than recommended, with a strict selection of patients.

Conclusion

Cancer complexity requires a restriction in the use of active agents to improve available resources and provide the best treatment. Local implementation of recommendations is a key step in clinical governance.

Our prescription software is a good tool to monitor adherence to the recommendations, but the addition of clinical parameters (PS, tumour histotype) could optimise evaluations.

No conflict of interest

GRP041 Introduction of a comprehensive antimicrobial stewardship process to decrease broad spectrum antimicrobial usage and HCAIs

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Background

In 2008, our large Tertiary Hospitals Centre had excessive rates of *Clostridium difficile* infection & MRSA bacteraemia, despite no cephalosporins being used in elderly patients.

A consultant pharmacist was appointed to support the current team to develop Antimicrobial Stewardship.

Purpose

A strategy was written that aimed to promote prudent antimicrobial prescribing, and included:

- · the development of an "Improving Antimicrobial Prescribing Group"
- · web-based, evidence-based, peer reviewed infection treatment & prophylaxis guidelines
- · a formal audit program with supporting tools and web-based performance feedback
- · formal feedback on antimicrobial usage
- · restriction of broad-spectrum antimicrobials outside of guidelines or microbiology recommendations
- · web-based renal function, drug dosing and oral switch tools
- \cdot a requirement to specify the indication for, and duration of, all antimicrobial prescriptions
- · screen savers and posters to promote better prescribing
- · e-mail feedback mechanisms for poor performance
- an education programme for doctors and nurses, including elearning.

Material and methods

Strategy elements were introduced over a 12-month period. Data was collected prospectively, including monthly prescription-based point prevalence audit on all beds.

Results

96 guidelines were written that get 7000 hits/month.

- · Patients on antimicrobials have decreased from ~35% to ~25% (P=0.11)
- · 117 audits of antimicrobial guidelines or prescribing by specialty have been conducted in the last 18 months
- \cdot Indication and duration on prescriptions rose from 55% and 54% to 92% (p=0.05) and 93% (p<0.01) respectively
- · Broad-spectrum antimicrobial use decreased by 22%
- · Clostridium difficile infections decreased from ~80 to <20/month

Discussion

Strong leadership was needed to successfully deliver the strategy, including reporting performance indicators to Board level. Infection management pathways with a robust development process promoted ownership and subsequent usage. This has probably led to a reduction in patients receiving inappropriate or extended courses of broad spectrum antibiotics, and thus a reduction in healthcare -associated infections.

Conclusion

A comprehensive antimicrobial strategy can reduce antimicrobial prescribing and healthcare -associated infections.

No conflict of interest

GRP042 Detecting adverse drugs events with alarm signals in a convalescence unit

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Background

Adverse drug events (ADEs) happen with alarming frequency when patients are being cared for, representing losses difficult to quantify. The only possible way to act is to know the real extent of the problem.

Purpose

To determine the incidence of ADEs in a convalescence unit; to identify how many of these reactions could have been prevented and establish the cause, origin and severity.

Material and Methods

Prospective observational study lasting eleven months, performed in a 48-bed convalescence unit. Patients in 8 predetermined beds were monitored. Age, hospital stay and prescribed medicines were recorded.

The medical histories were reviewed in order to detect potential ADEs using alarm signals, which are a modification of Otero et al..'s alarm diagnosis, to which were added some risky medicines and some analytic samples.

If an ADE was suspected, the Karch and Lasagna algorithm was used to analyse the coincidence.

The Schumock and Thornton questionnaire was used to evaluate the preventability.

Preventable drug-induced adverse events were classified according to the medication error taxonomy defined by the Ruiz-Jarabo 2000 group.

Results

We included 80 patients, with an average age of 76.6 years, an average hospital stay of 47.1 days and 16 medicines per patient. 57 ADEs were recorded, 19 (33.3%) of which were preventable. Lack of patient monitoring was the main cause, with 14 (73.7%) cases. Lapses were a large cause, with 9 (47.4%) cases. As far as severity was concerned, 18 (94.7%) ADEs contributed to or caused temporary harm and required intervention.

Conclusions

This detection system enables us to obtain better information about the nature and incidence of ADEs in our daily clinical practice. Thus we can promote corrective measures to reduce the incidence, for the safety of patients hospitalised in our unit.

No conflict of interest

GRP043 Prevalence of potentially hazardous drug interactions at hospital discharge

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Background

Up to 21% of adverse drug event-related hospital admissions are due to drug interactions.

Purpose

To assess the prevalence of potentially hazardous drug interactions at third level hospital discharge.

Material and Methods

Data for this retrospective study were obtained from the pharmacy claims database between 1 January and 31 July 2010.

Hazardous drug interactions were defined by at least in three of four international drug interaction references (Vidal, British National Formulary, Drug Interaction Facts and Drug Reax) as major, hazardous, contraindicated or avoidable, depending on the reference. [1]

Results

Between 1 January and 31 July 2010, at least two drugs prescribed at hospital discharge were dispensed at community pharmacies to 9405 patients. On average, patients were dispensed 5.6 pharmaceutical products.

In this seven-month study period, 494 (5.3%) patients had at least one interacting drug pair. The highest prevalence of interacting drug pairs dispensed was methotrexate and an NSAID, occurring in 43% of the 28 patients who were dispensed methotrexate.

For patients who were dispensed gemfibrozil, concomitant use of was common (28%); the co-administration acenocoumarol with anti-platelet drugs was also frequent (25%) or acenocoumarol with NSAIDs (24.1%).

Conclusion

In this retrospective study, 5.3% of subjects were dispensed potentially hazardous interacting drug pairs. Patient prescription at hospital discharge should be reviewed to prevent potentially hazardous drug interactions and to avoid serious adverse drug

(1) Br J Clin Pharmacol 2010;70:252-7

No conflict of interest

GRP044 Analysis of the safety profile of bosentan in a group of patients with cutaneous systemic sclerosis

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Background

Bosentan is an endothelin receptor antagonist used to prevent ulcers in patients with cutaneous systemic sclerosis (SSc). It can cause hepatic and blood toxicity.

Purpose

To analyse the safety of bosentan in patients with systemic sclerosis and to assess the incidence of hepatic and blood toxicity.

Material and Methods

Retrospective observational study (June 2005-May 2010) of patients diagnosed with SSc and treated with bosentan for the management of digital ulcers. We reviewed medical records and collected the following data: age, sex, date of start of treatment, dosage, adverse events (AEs) and other clinically relevant data. If the patient stopped treatment, the end date and reason for suspension were recorded, as were the safety endpoints, namely, liver transaminase values (AST and ALT) and haemoglobin levels.

Results

The study included 27 patients: 22 women (81.5%) and 5 men (18.5%), with a mean age of 58.7 years. Mean (SD) duration of treatment was 22.3 months (14.7 months).

During the study period, 12 patients stopped treatment due to AEs (25%), unsubstantiated indication (25%), lack of response (17%), favourable clinical outcome (17%), and other reasons (16%)

Treatment was changed due to safety problems in 37.5% of patients: in 3 cases (12.5%) treatment was stopped (in 1 case. severe anaemia [Hb 7.6 g/dl]) and in 6 cases (25%) the dose was reduced, leading to improvement or disappearance of the AEs (83.3% of cases).

The most common AEs were decreased haemoglobin (55.5%), elevated ALT and/or AST (22.2%), and intolerance with headache dizziness, fatigue, and malaise (18.5%).

Conclusion

The most common reason for discontinuation was AE with unsubstantiated indications (patients who did not meet the clinical criteria for the drug). The results agreed with the data sheet in terms of AEs. Several patients experienced AEs, most of which were not clinically relevant. All AEs were dose-dependent and usually responded to dose reduction.

No conflict of interest

GRP045 Evaluation of the use of parenteral antibiotics in a neonatal unit

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Background

The majority of antibiotics used in preterm infants are not available in suitable dosage forms. Dissolution and dilution are used to adjust

Our hospital is equipped with a sterile preparation unit which came under pharmaceutical responsibility recently. Parenteral antibiotics were prepared on alternate days.

Purpose

To check the procedure for dissolution and / or dilution of antibiotics and the storage conditions.

Material and Methods

The survey was conducted by direct observation of the preparation of 12 antibiotics under laminar airflow. The preparation methods and storage conditions were noted and compared to the literature data [1, 2, 3].

Results

The percentage of errors found was 42% distributed as follows: type of dilution solvent (62%), type of dissolution solvent (25%) and error in the volume taken for dilution (13%). The correct volumes of dissolution solvent were used.

Literature data showed that 33% of the dilutions should be used immediately, while they were stored at 2-8 °C for 24 hours. 42% of the drugs must be kept in the dark.

A written chart summarizing the of dissolution and dilution

procedures has been created. To avoid refrigerating the preparations, additional staff members have been assigned for daily preparation. In addition, drugs requiring storage in the dark are now covered with aluminium foil.

This study has improved the quality, the efficiency and the safety of care by avoiding the use of under-strength, over-strength drugs and unstable preparations. It has also decreased bacterial resistance and length of hospital stay reducing nosocomial infections and hospitalisation cost respectively.

Conclusion

The active measures used reduced the errors considerably. Our study highlights the importance of pharmacists to improve the quality of treatment.

- 1. University Hospital of Geneva guide to administration of injectable drugs
- 2. Summary of product characteristics
- 3. www.stabilis.org

No conflict of interest

GRP046 Managing change process-oriented by а management: a practical illustration for electronic data management in a hospital pharmacy

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Background

Hospital pharmacists as any health worker are living in an era of change. The Department of pharmacy of Clamart has defined its project's target by value management method as becoming a fully patient focused professional for 2014 rather than being an apothecary". This led the management staff to re-think the organization and way of management. This work presents the design and implementation of the data and documentation management at the pharmacy by a process oriented approach.

Material and Methods

A steering committee composed of the chief-pharmacist, Quality Management Engineer (QME), Assistant Manager, Technician chief defined the goal of the project using the value analysis APTE® method (i.e find a document in less than five minutes). Information meetings were carried out to teach pharmacy staff about some definitions of process by a problem based learning.

Working groups (including pharmacists, pharmacist technicians, technician assistants, secretary) were formed and supervised by the QME to work out the process mapping (PM) of the pharmacy. Validation of the PM was performed by asking 23 different pharmacy staff members to correctly place 27 documents according to the MP definition.

Results

The PM has been designed in 4 months by the different working groups. There are 3 kinds of processes: Steering, Operational and Maintenance. Steering and Maintenance contain processes without customer (pharmacy's processes). Operational ones are constituted of processes from customer to customer. It is represented as a workflow diagram that depicts the sequence of action to build a pharmaceutical product of service. Three main customers have been determined: patient/Clinical Wards, suppliers. University/Media.

Each of the processes includes several Macro-processes and subprocesses. 79 % of pharmacy staff correctly placed existing documents according to the right sub-processes and 75 % were also able to correctly identify the type of quality document. Macroprocesses and processes worksheets have been written and approved.

The former Pharmacist quality manager that was supposed to overlook all the documents has been replaced by 8 steering managers for each macroprocess to better share the responsabilities and improve efficiency.

Conclusion

Process-oriented knowledge management initiatives are designed to provide employees with task-related knowledge in the organizations. This brings forth a clearer understanding of a process or series of parallel processes. The PM is a "customer" vision of an organisation. It emphazises the value of the activities. This is the first step to install the lean management. The MP is currently applied at the pharmacy and all quality documents have a process oriented approach and correspond to what's just needed by the staff.

No conflict of interest

GRP047 External rotation in the intensive care unit of an american hospital: pharmaceutical interventions conducted

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In the USA, the Clinical Hospital Pharmacist (CHP) is fully integrated into the care team, providing pharmaceutical care at the patient's bedside.

Purpose

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To describe the type of interventions carried out during an external rotation of a resident pharmacist in the Surgery Intensive Care Unit (SICU) at a U.S hospital and cost savings with this interventions.

Material and Methods

From September 25th to October 14th 2009, a third-year Spanish resident joined as an "observer" of the CHP in the SICU in a U.S hospital. Early in the morning, the CHP reviewed the treatment profile of the inpatients (about 15-20 daily) and laboratory/ microbiology parameters.

Through the electronic medical records, the CHP checked the inpatients' clinical situation, the changes made during the previous day and prepared for possible interventions.

During the morning briefing with all the medical staff, the pharmacological treatment of each inpatient was discussed, addressing the concerns presented by the medical team and conducting pharmaceutical interventions if necessary. These interventions were recorded and subsequently classified as described below:

Code Intervention type Addition of drug to therapy Α

В Prevention of medication error or adverse

event

С Dosage or frequency adjustment

D Electrolyte recommendations Drug information Duration of therapy G Renal dose adjustment Н Stream lining of antibiotics Therapeutic alternative

Deletion of drug from therapy J Κ IV to PO

Medication administration record

reconcilliation

Wherever appropriate, each intervention was related to a determined number of saved doses, and their consequent economic savings.

RESULTS

The total number of interventions during the rotation was 93. The distribution of these interventions were:

Intervention type	Number of interventions
Н	26 (27,9%)
L	16 (17,2%)
F	10 (10,7%)
J	8 (8,6%)
K	7 (7,5%)
C	6 (6,5%)
A	5 (5,4%)
1	5 (5,4%)
D	4 (4,3%)
В	3 (3,2%)
G	2 (2,2%)
E	1 (1,1%)

All the interventions were accepted, and provided a cost saving of \$ 23.177overall.

CONCLUSION

- The incorporation of a CHP into the care team facilitates the implementation of pharmaceutical interventions to optimize patient drug therapy.
- The documentation and evaluation of interventions made are essential to raising awareness of the importance of the role of the CHP within the health care team.
- The pharmacist's intervention represents a cost reduction, without affecting the effectiveness of treatment, and improved efficiency of pharmacotherapy.

No conflict of interest

GRP048 EVALUATION OF STABILITY OF ORAL MORPHINE SULPHATE IN A REGISTERED TRADEMARK

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Purpose

Evaluate the stability of morphine sulphate solution 6 mg/ml contained in an oral commercial formulation when the vial has been opened for four days at 4 and 25°C.

Materials and Methods

Oral solution of morphine sulphate 6mg/ml contains morphine sulfate and inactive ingredients (edetate disodium, citric acid and purified water) and deionized water as diluent.

UV-1240 spectrophotometer Simatsu has been used to determinate the amount of morphine sulphate and a thermostatic bath (Erweka ZT-41) to keep the vial at 25°C. A calibration curve was prepared at a wavelength λ =281nm (maximum absorption of morphine sulfate) at this wavelength degradation products from, or the excipients contained in the trademark do not interfere in the measurements. A series of dilutions of concentration 0.15, 0.075, 0.0375, 0.01875 and 0.0094 mg/ml were prepared and 5 absorbance measurements were performed for each dilution.

The determinations were made spectrophotometrically by a validated method from a commercial solution 6mg/ml diluted to 0.06 mg/ml for 24, 48, 72 and 96 hours. This operation was carried out at two different temperatures, 4°C (refrigerator) and 25°C (water bath).

Samples were sent to Microbiology Department to ensure the absence of microbiological contamination in the open vial in a refrigerator and a water bath.

Results

The values of the spectrophotometric determinations carried out for 0, 24, 48, 72 and 96 hours at the two temperatures under study indicate that morphine sulphate losses were 4.03±0.12% (temperature environment), and 3.62±0.13% (4°C). In all cases, microbiological results were negatives.

Conclusions

In both cases morphine sulphate losses are below 5% so we can conclude that it is not necessary to discard the commercial vial once opened for a time of 4 days, although we recommend storage in a refrigerator during this period so that losses are lower and there is not microbiological contamination.

No conflict of interest

GRP049 Adherence as a changing process: evolution through time in a cohort of HIV-patients

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Background

High adherence to treatment is needed to achieve the goals of antiretroviral therapy (ART), but adherence is a changing process depending on many factors.

Purpose

To describe changes in adherence behaviour in a cohort of patients treated with ART for more than 5 years.

Material and Methods

Data of adherence to ART were collected from a cohort of HIV-patients who started ART in a third level hospital between 1997 and 1999 and with a continuous follow-up of at least 5 years. Data collection ended in july-2007.

Adherence was measured combining pharmacy refills assisted by a computer program and patient-self-report assisted by a semi-structured interview. Adherence during the first 6 months of treatment was compared with adherence during the last 6 months before last control for each patient. An intake of 90% or more of prescribed drugs was considered good adherence.

Results

360 patients of a cohort of 540 completed a follow-up longer than 5 years (median follow-up 8,3 years). Initially, two groups were obtained: 252 (70%) good adherent patients and 108 (30%) bad adherents. At the end of follow-up, adherence changed as follows: 182 patients (72,2% of good adherents) remained good adherents and 70 (27,8%) worsened adherence, versus 62 patients (57,4% of bad adherents) that remained bad adherents and 46 (42,6%) that improved adherence.

Conclusion

More than half of the patients remained good adherents despite of a chronic treatment.

Less than 30% of good-adherent patients changed to bad adherence, but more than 40% of bad adherents improved their adherence from the beginning to the end of our study. This is probably due to the support of the multidisciplinary team focused on adherence and the better-tolerated and more simplified therapies. Implementation of new strategies is needed in order to reduce the proportion of non-adherent patients.

No conflict of interest

GRP050 Pharmacotherapy situation of HIV positive patients with salvage treatment in our health area

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Purpose

To analyse changes in ART in HIV-positive patients with salvage therapy and assess its relevance to current recommendations.

Material and Methods

Retrospective study of antiretroviral therapy from February 2009 to April 2010 in 232 patients, 41 of whom were having salvage therapy (17.67% of total).

Data source: IANUS (electronic medical records), SILICOM (dispensing program) and the latest update (January 2010) of GESIDA group recommendations.

Results

Sample population: 41 patients, 24 men and 17 women, with a mean age of 42.4 years.

Changes to ART: 15 patients developed multiresistance and / or changed their treatment to once a day (QD), 14 patients suffered side effects (57% lipodystrophy), 5 patients switched because of intolerance to the drug (100% enfuvirtide), 6 cases of drug interaction with other chronic treatments and in 4 of them the changes in the ART were caused by risk factors (low CD4 count, opportunistic infections or other underlying disease)

We performed genotypic resistance tests on 15 patients and a tropism test with positive results on 3.

Conclusion

Most of the changes were caused by adverse effects, multiresistance related to antiretroviral therapy and the choice of a QD regimen to improve adherence to ART. However, although 100% of changes were made individually, fewer than half had recent resistance testing.

In accordance with the GESIDA Consensus Document (Level B) recommendations we propose a standardised protocol including resistance tests to avoid the emergence of resistance to new drugs included in the ART and a medicines record review to detect potential drug interactions and toxicities.

No conflict of interest

GRP051 Prevention strategies for medication errors - which one to pick?

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Background

To minimize patient harm resulting from medication errors, many interventions have been developed. However, these strategies show varying impact on prevention of medication errors. Moreover, most strategies have been implemented in single medical centers and generalizability of the results remains uncertain.

Purpose

We aimed to assess (1) which prevention strategies have been implemented and evaluated, (2) which outcomes have been achieved, and (3) which strategies have been found to be most useful with regard to different constraints.

Material and Methods

We conducted a literature search in Medline including the MESHterm "Medication Errors/prevention and control" and developed a classification schema based on published prevention strategies.

Subsequently, distinct literature researches identified studies for each strategy. Controlled or quasi-controlled interventions which assessed prevention of medication errors as primary endpoint were included.

Results

We identified 20 different prevention strategies allocated to three superordinated categories (i.e. persons, processes and structures, and products). Literature research identified 1123 studies, of which 122 met our inclusion criteria. The prevention strategies aggregating most publications were quality improvement programs and computerized physician order entry; the fewest studies were published for electronic health records. About 90% of studies reported a positive effect on at least one type of medication error. 38 studies assessed secondary outcomes, 23 found positive effects, particularly on adverse drug events. Prevention strategies have been assessed primarily for inpatient and outpatient care (N=45 and 21); only 4 studies assessed hospital discharge. Overall, education of professionals and combined interventions showed highest chances to be sucessfull (83% of studies). For paediatrics, quality improvement programs seemed more and clinical pharmacist interventions less promising compared to adults.

Conclusion

In conclusion, despite major variations in methodology, current literature may allow identification of the prevention strategies most appropriate taking into account specific constraints such as setting, patient population and error type.

No conflict of interest

GRP052 Quality management system ñ application of an audit programme in a hospital pharmacy setting

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Background

Quality management systems (QMS) are integrated into corporate culture. International Organization for Standardization (ISO) Standards are documented agreements containing technical specifications, to ensure that materials, products, processes and services are fit for their purpose. ISO 9001 standards normalize collective and repetitive activities, adopting a set of guidelines applied internationally.

Purpose

The purpose of this study is to determine whether the implementation of an audit program contributes to improve performance of a pharmacy department (PD).

Material and Methods

Documents were drawn up and actions were developed to meet the mandatory requirements of ISO 9001 standards. The QMS was implemented using innovative technology, namely quality management software.

Collaborators were assigned to do specific training in internal audits, and an annual audit programme was designed. The annual programme includes audits to the measurements, analysis and improvement processes (n=5) and to all the key processes (n=11). The audits were developed according to the ISO 19011:2002 and the findings classified as non-conformities (NC) or improvement hypotheses (IH). To all findings, corrective and/or preventive actions were established and causes evaluated.

Results

Until October 2010, 13 internal audits were performed, being identified 118 IHs and 71 NCs, accounting for 51% of all findings recorded in the software program. Of the 189 findings, 52% are closed with 99% effectiveness of corrective and/or preventive actions taken.

The findings were distributed by several PD key processes: medication distribution (24%/ n=46), pharmacy production (43%/ n=81), medication reception and storage (29%/n=54), and also

infrastructures maintenance (19%/n=36). As for the causes, the most prevalent were: non compliance of documented instructions, need for awareness towards new attitudes, deficient process follow-up and collaborator's forgetfulness.

Conclusion

Audit programmes, as part of a QMS, allow rapid detection of NCs and IHs, resulting in quality improvement of provided services and better work organization.

No conflict of interest

GRP053 Medication reconciliation for admission and discharge hospitalized patients

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Background

Drug-related problems (DRP) are health problems resulting from pharmacotherapy, that lead to therapeutic failure or to new undesirable effects. The medication reconciliation is a key point of improvement to the patient care process.

Purpose

The aim of this study is to analyze the process of medication reconciliation initiated 4 years ago in a tertiary hospital

Material and Methods

Study conducted between January-June 2010. Patients admitted to cardiology or cardiovascular-thoracic surgery and stroke neurological unit were included. Data: a. from electronic clinical history: diagnostic, antecedents and allergies; b: from electronic prescription program: hospitalized prescription and c: from patients interview: medication prior to admission (prescription and nonprescription drugs and herbal preparations). Discrepancies were documented and commented with physicians. At discharge, a scheduling of treatment with advises on medication use was delivered to each patient. DRP were classified and registered in the program ATEFARM® 2006.0.0.16 by the IASER methodology (identification, recommendation, therapeutic follow-up, evaluation and outcomes).

Results

713 patients were included in the medication reconciliation program: 55% from cardiology department, 21% thoracic surgery, 16%cardiovascular surgery and 8% stroke neurological unit. 55.5% male and middle ages 65 years. DRP detected (N=101) related to effectiveness (37%), indication (37%), safety (23%) and adherence (4%). Under dosage was the most recurrent problem (17.8%), followed of need of additional treatment (21.8%) and over dosage (13.8%). 85.7% of the recommendations were accepted by the doctors and 75% of them has obtained an improvement of the standard care of the patient.

Conclusion

Medication reconciliation prevented and resolved DRP by optimizing pharmacotherapeutic treatments and the education of professionals and patients. There is increasing evidence that participation and interventions of clinical pharmacists in health care positively influence clinical practice.

No conflict of interest

GRP054 Comprehensive medication history: the need for the implementation of medication reconciliation processes

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Background

Comprehensive medication history (CMH) is of outmost importance for patient evaluation and prescription of drug treatment upon hospital admission.

Purpose

The aim of this study was to assess the need for the implementation of medication reconciliation processes into clinical practice.

Material and Methods

Patients admitted to a teaching hospital in Slovenia were randomly selected and included in the study. For every patient a CMH was obtained by a research pharmacist using different sources of information. Next, medication history in the hospital medical record was reviewed. Prescription of medicines was assessed for completeness of information and discrepancies between both medication histories were recorded and classified.

Results

Overall, 108 patients with a median age of 73 years were included. The research pharmacist recorded the use of 651 medicines, of which 94.9% provided all relevant details for drug identification and administration. Less medicines (464) were recorded in the hospital medical record as compared to the CMH (paired t-test, p>0.001) and only 42.0% of these medicines were evaluated as complete. When comparing the medication history in the medical record with the CMH, at least one discrepancy was detected in 72.4% of medicines and was often present in the medication order on the drug chart (76.2%) and in the discharge letter (69.9%). Discrepancies often arose due to medicine's omission (20.9%) and medicine's commission (6.5%).

Conclusion

The high rate of discrepancies between the recorded drug history and CMH reported in our study shows the need for implementation of medication reconciliation practices. Pharmacists' participation in admission reconciliation, as described in this study, led to more complete and accurate drug histories. In the study hospital, pharmacist-led CMH have been introduced in a research framework within which the benefits of this service for the reduction of medication errors and adverse drug events is being studied against routine practice in a randomised trial.

No conflict of interest

GRP055 Splitting tablets boosts dosing inaccuracyAnalysis of a proprietary medicinal product containing phenprocoumon <u>S. Janowitz</u>, R. Reihs-Zips, S. Rohleder, W.M. Halbmayer, A.E. Henein, A. Palkovits-Obrowsky, A. Wichmann, U. Muster, B. Böhmdorfer

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Background

Abnormal fluctuations in drug geriatric patients taking phenprocoumon, led to considerations about lack of uniformity in shared proprietary product.

Purpose

We wanted to analyse the uniformity of a medical product containing phenprocoumon. Fluctuation in anticoagulation due to inaccurate dosing is a serious problem which can lead to bleeding or insufficient anticoagulation.

There is limited data to medical products containing phenprocoumon in comparison to warfarin.

Material and Methods

For all weighing steps an analytical balance was used Tablets were quartered along both score lines either manually or using a tablet cutter and weighed.

Quarters were manually agitated in the original glass container, in which the tablets are supplied by the manufacturer and weighed. Uniformity of mass of whole tablets and quarters before and after agitation was calculated using a t-test analysis.

Results

Friabilty after quartering tablets was not statistically significant regardless of whether the tablets were quartered manually or by using a tablet cutter.

When phenprocoumon tablets are quartered along both score lines, quarters of variable mass are produced, which can affect dosing accuracy

A statistically significant (p<0,05) loss of mass after agitation could be shown in tablets quartered with a tablet cutter.

Conclusion

The following recommendations were made:

Preference given to therapy schedules where whole or only halved tablets are used- avoiding a further halving step

For manufacturers to increase the tablet diameter, replacing embossed score lines with deeper

Lowering the quantities of active ingredient in the proprietary medicinal product e.g. 1mg Tablets

Consideration to be given to producing phenprocoumon tablets with different strengths, which may be colour coded- similar to warfarin in the UK.

No conflict of interest

GRP056 A case report: Tolerance Test of docetaxel in patient with paclitaxel hypersensitivity

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Background

Hypersensitivity reactions (HSRs) to chemotherapy agents have limited their use for fear of inducing severe reactions or death. There is a 2-5% risk or hypersensitivity with paclitaxel. Crosssensitivity has been reported between taxanes.

Purpose

The purpose is to report a case of patient allergic to paclitaxel that can be treated with docetaxel using a protocol of tolerance. Methods: A descriptive study of a patient allergic to paclitaxel. We collected information from clinical and pharmacotherapeutic history.

A systematic literature about desensitizations and tolerance tests of taxanes was performed. Collaboration with Allergy Unit and Oncology Unit. Evaluation of symptoms related with hypersensitivity of paclitaxel.

Bolsa Nº	Dosis (mg)	Dosis acumulada
1	0,012	0,012
3	0,03	0,042
3	0,06	0,102
4	0,12	0,222
5	0,3	0,522
6	0,6	1,122
7	1,5	2,622
8	2,118	4,74
9	3	7,74
10	7,2	14,9
11	15	29,9
12	35	64,9
13	65	129,9

Results

A 50 year old woman diagnosed of ovarian carcinoma was treated with paclitaxel and she suffered an anaphylactic reaction with dyspnea, glottis edema, and systemic vasodilation. The case was evaluated to make a tolerance test with docetaxel. Firstly, it was performed a skin test with docetaxel and the result was negative, so is possible to apply the tolerance protocol. It consists in a gradual re-introduction of small amounts of drug antigens up to full therapeutic doses. No adverse reactions related with hypersensitivity were described.

Conclusion

Docetaxel has been an alternative treatment for our patient with paclitaxel hypersensitivity after a tolerance test and it's possible the therapy with taxanes.

No conflict of interest

GRP058 Impact of pharmacist interventions on the frequency of medication errors in patients with enteral feeding tubes

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Background

In the last decade, the use of enteral feeding has expanded due to its advantages over parenteral nutrition. The choice and administration of medicines through enteral feeding tubes (EFTs) represents a challenge since it often requires crushing tablets and off-label use which can cause adverse drug events (ADE).

Purpose

To evaluate the prescription, dispensing and administration of medicines to patients with EFTs and to assess the impact of pharmacist interventions on the frequency of drug errors and preventable ADEs.

Material and Methods

A prospective randomised controlled trial including 60 patients with an EFT was performed in July and August 2010 in a general hospital in Lisbon. In the intervention group, the appropriateness of drug therapy was assessed daily by the researcher according to selected literature criteria on medicines administration via EFT and pharmacists intervened if discrepancies were found. Patients in the observation group were subjected to routine drug treatment checks and pharmacist interventions. For both groups, drug errors identified and pharmacist interventions were recorded and compared.

Results

	patients	age (range)	with an	suggested pharmacist interventions	suggested pharmacist	No. of incorrect doses administered
Intervention group		80.5 (36-94)	100/192 (52%)		76/103 (74%)	67
Observation group		80.5 (33-93)	17/183 (9%)	17	12/17 (71%)	139

The intervention group had a significantly higher number of suggested pharmacist interventions (t-test, p<0.001), but not a significantly lower number of incorrect doses administered (t-test, p=0.159) since 27 (26%) interventions suggested in the intervention group were not accepted. The frequency of preventable ADEs is yet to be analysed.

Conclusion

The study shows that patients with EFT need special attention when medicines are prescribed, dispensed and administered. Pharmacist interventions can reduce drug errors and the number of incorrect doses administered to these patients. Construction of a druginformation database and in-depth education of the healthcare team is needed.

No conflict of interest

GRP059 Participation of hospital pharmacists in intensive care units from three Clinical hospitals in FYR Macedonia reduced prescribing errors

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The need to improve patient care by coordinating the activities of various health care professionals had become a topic of increasing interest in the health care community. In a collaborative patient care professionals from multiple disciplines use their specialized training to make significant contributions that improve patient care. Through provision of pharmaceutical care and medication therapy management pharmacist are integral members of health care team. Coordinated care between pharmacists and physicians can improve patient care outcomes.

To investigate whether participation of hospital pharmacists can be an effective approach in reducing prescribing errors and prevents adverse drug events in intensive care unit in three clinical hospitals.

Material and Methods

A prospective study in which we were compared a baseline period with an interventional period in which 12 hospital pharmacists (10 pharmacists and 2 specialist of pharmacoinformatics) reviewed medication orders for patients admitted to ICU (prescribing, recommendations, interactions, ADRs). The pharmacists discussed about these problems during patient review meetings with ICU doctors. We used Medscape model for pharmacist-physician collaborative working relationship.

Results

During the 6 months period hospital pharmacists reviewed 826 orders and made 463 recommendations. During the study period the pharmacists and physicians made 338 consensuses. The prescribing errors were significantly lower in study period, so the ADRs were reduced from 23 to 8 per 1000 monitored patient days.

Conclusion

The participation of the hospital pharmacists in ICU was associated with significant reduction in prescribing errors and related ADRs.

No conflict of interest

GRP060 Improving communication about possible sideeffects to in-patients before discharge

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Background

The 2009 National In-Patient Survey suggested 'patient experience' could improve with better provision of information about side-effects of medicines (1). Written information, such as that provided in patient information leaflets is inadequate; specific individualised verbal communication is needed prior to discharge (2).

Purpose

Traditionally, on discharge from hospital, newly prescribed medicines are explained to patients in terms that encourage concordance (e.g. timing of doses and course length). Though shown otherwise (3), there is a perception that knowledge about side-effects adversely affects attitudes to taking medicines. Our objective was change this attitude in pharmacy staff, signpost access for patients to further information if wanted, and through this demonstrate improvement in patients' experience of side effects counselling by the next National Survey.

Material and Methods

Seminars were held at which the value of side-effects advice was emphasised. Pharmacy staff when counselling, were to use the term 'side-effect' and ask open questions to encourage the patient to ask for specific information if wanted. A business style card giving details of how to contact a pharmacist for further information was then handed to the patient personally.

All wards have a Patient Experience Tracker system on which patients record their satisfaction or otherwise with aspects of their in-patient stay including whether they were given sufficient information about side-effects.

Results

Patients' responses to side-effects questions on the Tracker improved over the study period and are now consistently above 80% 'satisfied' with the information they receive. This appears to be better than the 2009 Survey score of 52% and we await the 2010 results.

Conclusion

An improvement in positive comments from patients regarding sideeffects has been shown. Though the reasons may be multi-factorial, there is a perceived benefit from pharmacy input. A controlled study is needed to assess the true potential for this initiative in improving communications about side-effects.

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- 2.Grime J et al. Health Expectations 2007; 11(5):1-160
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GRP061 Implementing a procedure for aseptic technique validation in parenteral nutrition compounding

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Background

The pharmacist is responsible for ensuring that parenteral nutrient solutions are accurately compounded, stored, and dispensed. Several published guidelines establish universal practice standards for compounding sterile preparations.

Purpose

Development of a procedure for validation and control of the aseptic technique in the total parenteral nutrition (TPN) compounding process, according to international practice recommendations.

Material and Methods

We performed a literature research to find a suitable procedure for validation. We adapted the technique recommended by the United States Pharmacopeia-National Formulary, chapter 797, and established a procedure to validate the aseptic technique. In this procedure we compounded a sterile preparation using a sterile broth (Trypcase Soy Broth TSB-ST, REF 44 011, bioMérieux). This preparation simulates compounding of a parenteral nutrient solution.

The personnel responsible for preparing TPN do so always under the same conditions of cleanliness, garbing, and sterility, following the established procedures. Media bags are incubated at room temperature for 7 days, before being visually evaluated by a pharmacist. The technique was considered successful if the solution was clear and unsuccessful if it was cloudy.

Results

We performed this validation monthly for six months. Each month a different member of the compounding personnel elaborated the sterile preparation. After inspection by the pharmacist, all the results were satisfactory; none of the preparations were contaminated during the compounding process.

Conclusion

The implementation of this validation procedure of the aseptic technique enables the pharmacist to guarantee the accuracy and quality of TPN. Chapter <797> Pharmaceutical compounding-sterile preparations. United States Pharmacopeia/National Formulary. Rockville, MD: The United States Pharmacopeial Convention. Inc; 2008. (http://www.usp.org).

No conflict of interest

GRP062 INTRANET TOOL FOR DOCUMENTING PHARMACEUTICAL INTERVENTIONS

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Background

Pharmaceutical interventions can be a measure of the impact of pharmaceutical activity in the patient care. We developed and implemented an intranet-based tool to collect and analyse pharmaceutical interventions, in order to meet the requirements of our Quality Management System.

Purpose

This project had three objectives: First, to provide a robust, easy-touse tool, acceptable to all pharmacists; second, to document and classify interventions; third, to verify the usefulness of this tool in our daily practice.

Material and Methods

This application was developed, between July and August 2010, by the Pharmacy Department in collaboration with the Information Technology Department. The implementation phase took place in August and September 2010 in two settings: Cytotoxic Unit and Ambulatory Unit. We analyzed the data regarding the number of entries, time spent, intervention type and acceptance by the clinical staff. At the present, we are developing a scoring system to evaluate the intervention significance by pharmacists and physicians.

Results

During the implementation phase, we verified a total of 111 entries. 57,6%(64/111) of them were safety-related interventions (patient id; chemotherapy protocol; drug; dosage; route of administration); 25,2%(28/111) were efficacy-related (chemotherapy anthropometric variables; stability/dilution; periodicity: drug medication schedule); and 17,1%(19/111) were supplementary information. From this period, 9,0%(10/111) of the interventions were not accepted, and most of them (70,3%) were associated with a time spent <15 minutes. The data on the scoring system is being collected and will be available in December 2010. No complains about ease-of-use or breakdowns were reported.

Conclusion

This tool seems to be robust and easy to use. However this system is still undergoing an experimental phase, and some work has to be done regarding standardization. We are looking forward the results of the scoring system, because it will allow us to measure and evaluate the relevance of our daily activity to other important partners and colleagues.

References:

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No conflict of interest

GRP063 Evaluation of pain and its analgesic treatment in oncologic patients

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Background

Cancer can be associated with many symptoms, but pain is one most feared by patients. Patients feel pain at all disease stages and it can be present for an extended time and thus become chronic.

Purpose

The study was designed to determine the proportion of patients with cancer who have substantial pain, its intensity and the treatment received by patients.

Material and Methods

Prospective study of hospitalized patients at oncology ward from January to May 2010.Data collected: age, sex, admission reason, tumor, analgesic treatment and pain intensity.

The patients were asked about the pain they were having at the time of admission, using

Visual Analogue scale (VAS). It was a horizontal row of equidistant number from 0 to 10 with the words "no pain" at the 0 and "the worst imaginable pain" at the 10.

Results and Conclusion

284 oncologic patients were screened (120 women and 165 men). Age range: 18-87 years old. The most frequent reasons for admission were fever (17%), pain (15,6%) and chemotherapy

administration (15%). The tumors more frequents were lung (19,7%), colon/rectal (14%) and breast (12%).37,8% were treated with NSAIDs or acetaminophen, 6,9% with weak opioids(tramadol) and 55,3% with strong opioids (morphine). One patients needed oral administration of ketamin for chronic pain. A ketamin mixture was prepared at Pharmacy Service. Of the 284 patients with cancer, 46,7% had cancer pain (32,6% woman and 67,4% men).55,2% had mild-moderate pain (VAS:3-6) and 44,8% severe- excruciating pain (VAS:>6-10).

Over half the patients had pain; its optimal management can improve quality of life. Pharmacists are in a excellent position to work with prescribers to select the best analgesics to treat cancer pain and to develop drug formulations as an alternative therapy.

No conflict of interest

GRP064 The lack of medicines in inpatient wards before the administration: who is the guilty?

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Background

The inpatient wards may detect lack of medicines just immediately before the administration which should have been dispensed by a pharmacy service. This may cause stress between the teams as they must displace employees to solve such problems.

Purpose

The aim of the present work was to evaluate the reasons that caused this kind of lack of medicines at University Hospital from the University of São Paulo, Brazil.

Material and Methods

We performed a prospective study from June 2009 to May 2010. The complaints on the lack of medicines received by the Department of Pharmacy from University Hospital of University of São Paulo (DP) were evaluated qualitatively and quantitatively.

Results

We received 1,739 complaints due to lack of medicines. 1289 (74.1%) were attributed to problems occurred at the unit ward: 28.6% resulting from the loss of medicines, 19.6% in advance by the delivery of medicines, 16.4% nurse did not timetable, 10.5% changed the schedule of administration of the drug without notify DP, 6.7% related to the transference of patients without notify DP, 6.0% were prescribed a new item and the pharmacy did not receive the new prescription.

Regarding the lack of medicine due to the DP, 450 complaints were received (25.9%): 55.3% DP did not send the medicines, 22% the drugs were packaged in different shifts. It was observed that the medical and surgical wards had the highest average lack of medication at the nursing unit, respectively 28.1% and 27.3%.

Conclusion

These finds indicated that both DP and nursing units have responsibility in the detection and resolution of lack of medication at the time of administration to the patient and further efforts are needed to reduce it. The number of beds per unit, the complexity of patients and their prescriptions might have contributed to the amount of these kinds of errors.

No conflict of interest

GRP065 What can hospital pharmacists do for patient safety when encountering potentially c purchased by patients over the internet counterfeit

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Background

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The popularity and the number of internationally operated illegal online drugstores that are selling medications without prescriptions or deliver products with unknown origins are rising. As Europeans are spending billions of Euros on the illicit medicines market the chances of accidental overdose, drug interactions and toxicity is increasing.

Purpose

To estimate the significance of the problem in Hungary and to define adequate methods to assess the quality and potential danger of drugs sold online.

Material and Methods

The attitude of more than 500 patients regarding purchasing drugs online was evaluated in our survey implemented in hospital (n=107) and community pharmacy (n=434) setting.

A comprehensive methodology was set up by our institution which allows general and professional quality assessment by:

- Standardised ranking method of online drugstores
- Documentation, evaluation of distribution process
- Identification of microbiologic contamination
- Measurement of physical properties by pharmacotechnology
- Chemical analysis of active substance

Results

Our results show that nearly 5% of the respondents of the questionnaire have ordered drugs or dietary supplements online and about same amount of people are considering this option in the near future. 163 online pharmacies were evaluated and followed for 28 months. Less than 7% of the sites require prior medical prescription and 38% do not exist after two years. Out of the thirteen medications (paracetamol, sildenafil, tramadol) test ordered, 11 arrived (85%). Main components were identified (HPLC, spectrophotometry) in all samples. Compared to original authorized medications, higher chemical contamination was observed, indicating lower quality ingredients. The increased microbiological contamination and the higher standard deviation of pharmacotechnology parameters suggest poor quality control of production.

Conclusion

Our observations not only draw the attention of hospital pharmacists to illegal online drugstores and counterfeit medicines but also suggest a comprehensive methodology for professional pharmaceutical quality assessment of medication ordered online.

No conflict of interest

GRP066 The Hospital pharmacist in prehospital emergency care

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Background

Hospital pharmacists are rarely involved in planning for the management of major incidents or events in which the wellbeing of large numbers of people may be threatened.

Purpose

The aim was to test an operating model that included the active participation of a pharmacist in the planning of pharmaceutical care for an event that had the potential for a major incident involving mass casualties.

Material and Methods

On September 11th and 12th, 2010 an air show was held in Rivolto - Udine - Italy to mark the 50th anniversary of the Italian aerobatic team "Frecce Tricolori". About 400,000 people attended ranging in age from 1 to 85. The setting was festive and noisy. On the field in addition to the First Aid Stations, a pharmacy was set upwith a pharmacist manager and a staff of three pharmacists. Information relating to the supply and monitoring of drugs in each medical station were recorded on a paper checklist.

Results

In the planning of resources 85 pharmaceutical products were deemed necessary. In the two days 220 patients (about 6% of the people) requested medical treatment, mostly for minor illnesses. In total only 60% of the 85 drugs available were used at varying doses. The most used drugs were paracetamol tablets (39.5% of patients), metoclopramide (5.9%) and sodium chloride 0.9% bags (7.3%). The pharmacists inspected all 7 medical stations twice daily. There were no errors in the drug storage; the temperature of stocked drugs was always appropriate. There were no adverse drug reactions or medication errors.

Conclusion

Emergency preparedness with the planning of pharmaceutical and medical resources is crucial to saving lives and property during an emergency. In an emergency when the risk of medication errors may be higher, the hospital pharmacist can act as "... expert in the therapeutic use of medicines... source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medicines" [1]

. Reference

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 No conflict of interest

GRP067 Medication Reconciliation in Traumatology Unit<u>A. Alcobia</u>, S. Domingos, P. Santos, N. Craveiro Lopes, A. Goncalves

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Background

The elderly patient's proportion has increased significantly in recent decades, being a group that represents high cost of medication consumption. About 28% of patients admitted in Sort-Stay Medical Unit, in our hospital, presented drug related problems. Poor communication at transition of care is the cause of 50% of medication errors and about 20% of adverse drug events. To hospitalize patients is often prescribed medication that may cause the omission/duplication of drugs that the patient takes regularly. Medication Reconciliation consists in comparing the patient's medication, prior to hospitalization, with hospital prescription, resulting in detection of medication errors, called discrepancies.

Purpose

Identify and resolve discrepancies between the hospital prescription and the patient's current home medication and improve the process of collecting and processing information.

Material and Methods

Prospective observational study that included all patients aged over 65 years, with at least one chronic disease, admitted to the Trauma Unit, in Hospital Garcia de Orta, between March and July of 2010. The selection of patients is done by a pharmacist or a nurse,

24/48h after admission. The pharmacist checks the patient's file in order to collected demographic data, co-morbidities and outpatient therapy. The pharmacist makes the medication reconciliation, detecting discrepancies that are reported to the physician, with some recommendations.

Results

The 5-month study included 89 patients with a mean age of 82.2 ± 7.53 years, 83 patients (93,3%) received an average of 5.58 ± 2.92 medications in an outpatient setting. 191 discrepancies were found in 65 patients, 55,5% of which were unintentional discrepancies. Most of this were due to omission of medications (88,7%), different doses (4,7%) and duplication (4,7%). The pharmacist made 65 recommendations/interventions in 47 patients, mainly related to the prescription of drugs omitted/changed/discontinued, dosage adjustments and monitoring parameters, which were mostly accepted by the physician (93.6%).

Conclusion

Medication Reconciliation, conducted by the pharmacist as part of a multidisciplinary team, is an important strategy for reducing medication related errors, increasing the effectiveness of therapy, reducing the associated costs and improving adherence.

No conflict of interest.

GRP068 Drug Related Problems at Emergency Admission

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Background

Drug related problems are commonly associated with hospital admissions resulting inpatient morbidity and mortality, and increased costs. In Portugal, the available information about hospital admissions due to drug related problems (DRP) is very limited. A literature search showed that about one out of three hospital admissions were caused by DRP.

Purpose

The aim of this study was to identify and characterize DRP in the patients who were admitted in the Short-Stay Medical Unit (SSMU), in Hospital Garcia de Orta.

Material and Methods

Retrospective study including all patients admitted to the SSMU, in Hospital Garcia de Orta, between January and March 2010. The data were collected based on the patient's medical file. The definition and classification of DRP of the Second Consensus of Granada (2002) have been adopted.

Results

This study included 181 patients, 60 males and 121 females. A total of 50 (27, 6%) patients presented DRP at admission (15 males and 35 females). The average age was 75,7 \pm 15,2 years for the patients with DRP and 76,7 \pm 15,2 for the patients without DRP. The patients with DRP had 3,4 comorbidities and received 5,93 different medications. An average of 1,34 DRP was found per patient. From a total of 67 DRP, 26 (39%) were related with the lack of a drug or use of an unnecessary drug; 6 (9%) were related with noneffectiveness and 35 (52%) were associated with safety problems. The average hospital stay was 9,98 \pm 5,35 days for the patients with DRP.

Conclusion

Our data are consistent with the published studies. As a consequence of our results, a medication reconciliation program was proposed in our hospital. The introduction of systems as medication reconciliation, for the early detection of drug related problems may help to reduce problems related to drug therapy. No conflict of interest

GRP069 Pharmacogenetic as a diagnostic tool in osteoporosis-related bone fracture

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Background

Osteoporosis is the most common skeletal chronic disease in developed countries. Hip fracture (HF) is the most threatening osteoporotic fracture due to its high mortality at first year (30%). Moreover, the effectiveness of treatments for osteoporosis is low (48%). Osteoporosis has a strong genetic component but it is not clear whether genetic differences exist in relation to morbidity and efficacy of the pharmacotherapy. For this reason, this review was designed to identify the pharmacogenetic markers associated to bone mineral density (BMD) and osteoporosis fracture risk (FR) in order to create a methodological pharmacogenetic tool to be applied by pharmacists or health professionals in the clinical translational research.

Material and Methods

Pharmacist and specialist physicians reviewed the most relevant candidate gene studies and gene-wide association studies in European/American population related to: BMD and/or osteoporosis FR and antirresorptive treatment in pharmacogenetics databases (PharmaGKB®, Hapmap®). We then collected data related to gene polymorphism (locus, SNP, position change, etc.), genotyping methodology, group patients studied and association achieved (yes/no).

Results

We identified 23 SNPs corresponding to 6 pathways (osteoclastogenesis, Wnt, Vitmin D, Estrogen, Collagen, Mevalonate) and 12 gene (OPG, RANK, RANK-L, LRP-5, LRP-6, ITGB-3, ALOX-15, VDR, ESR- α , ESR- β , COL1A1, FDPS). We implemented an easy genotyping methodology, applying PCR-RFLP in a 74% of work routine protocols and the rest by PCR-Sequencing. Statistic significant association between SNPs, BMD and/or osteoporosis FR and antiresorptive was not achieved in any study performed, showing controversial results, compared to reference results.

Conclusion

There is not a consensus set of SNPs associated to BMD and/or osteoporosis FR and antiresorptive treatment. Validation of these SNPs in every local population is necessary to develop pharmacogenetic diagnostics tools with clinically relevant genetic impact on osteoporosis and its personalized treatment at the hospital level and contribute with this pathology.

No conflict of interest

GRP070 Analysis of pharmaceutical interventions in a unit of Obstetrics and Gynecology

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Background

To record, classify and evaluate pharmaceutical interventions made from Hospital Pharmacy Service at the Department of Obstetrics and Gynecology

Material and methods

An observational, descriptive and prospective study was carried out for 2 months. It was about the pharmacotherapy monitoring of patients admitted to the Obstetrics and Gynecology Unit, where the dispensing scheme is unit dose drug dispensing system without computerized physician order. We recorded and classified pharmaceutical interventions that detect potential medication error.

Results

235 patients were selected, all female, whose mean age was 37.6 + / - 8 years. The main diagnoses were: natural childbirth (102), uterine leiomyoma (18), endometriosis (15), pregnant women to study (14), caesarean section (10), abortion (8), metrorrhagia (8), breast cancer (6), cancer of the cervix (5) and others (49). 289 interventions about potential medication error were performed (1.2 interventions per patient), of which 235 were related to dose or drug regimen and 54 to the route of administration. The interventions were accepted at 100% of cases.

The kind of interventions were: a) Resolution of dosage not specified in the prescription or prescription unintelligible (117), b) adjustment of medication to the presentations available on the hospital's pharmaceutical guide (114), c) sequential therapy(54), d) unsuitable dosage (4).

Pharmacist's interventions avoided 121 drug-related problems, which were related to patient safety

Conclusion

Evaluation, classification, and registration of pharmaceutical interventions allow us to quantify the value added by the unit dose drug dispensing system in the process of drug use and distribution and the contribution of pharmacists to the quality of prescribing in inpatient units.

No conflict of interest

GRP071 Antibiotic Therapy Evaluation In Elderly Nursing Home Residents

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Background and purpose

Evaluation of the use and effectiveness of antibiotic treatments in clinical practice in elderly nursing home residents, who were given individualized pharmaceutical care by the hospital pharmacy service reference.

Material And Methods

Prospective observational study of one year (2008), 164 patients (41 men and 123 women) mean age (83.2 \pm 8.9 years) diagnosed empirically on some type of infection.

We conducted a follow-up treatments initiated at the beginning of the infectious process until the remission, using the computer application of the pharmacy department (SINFHOS®). The variables analyzed were: 1) sex, 2) infectious episodes, 3) type of infection, 4) antibiotic used by type of infection and 5) recurrence of antibiotic treatment.

Results

The cumulative incidence of infection during the study year was 92.7%. 100% of males and 90.2% of women had an infection. We observed a total of 409 episodes, 67.7% were female with an average duration of each infection of 8.7 days (range: 1-42)

EPISODES/INFECTION	%
BUCODENTAL(B)	0,98
GASTROINTESTINAL(GI)	0,73
URINARY(U)	22,25
OCULAR(OC)	23,96
OROPHARYNGEAL(OR)	1,47
OTIC(OT)	0,98
RESPIRATORY(R)	42,05
SOFT TISSUE(ST)	3,91
VAGINAL(VA)	2,93
VIRAL(VI)	0,73

TREATMENT	%
B-LACTAMS	33,33%
FLUORQUINOLONE	31,18%
POLYMYXIN	15,91%
MACROLIDES	6,67%
AMINOGLYCOSIDES	4,30%
IMIDAZOLE	2,80%
TRIAZOLE	2,37%
SULPHONAMIDES	2,15%
ANTIVIRAL	0,65%
GLYCOPEPTIDES	0,43%
NITROFURAN	0,22%

44 episodes (10.76%) required administration of a second treatment to resolve the infectious process, 3(0.73%) required three treatments and only 1(0.24%) required four treatments. The cure rate to a first empirical treatment was 88.26%.

Conclusion

The study population has a high incidence of infection, showing that males are more likely to have any infectious process, predominantly respiratory, eye and urinary tract in that order.

The use of antibiotics was successful, according to the protocols of empirical therapy. The majority of the infections were resolved after the introduction of only one single treatment.

No conflict of interest

GRP072 Outpatient medication usage during hospitalization in a French hospital

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Background

In France inpatients receive prescribed drugs necessarily from hospital pharmacy. However all medications are not available in pharmacy as it is rule to promote drug substitution and avoid redundant marketed drugs.

Therefore some patients bring their own outpatient medications despite the regulation. It can lead to adverse events and have iatrogenic consequences.

Purpose

To study the frequency and circumstances of use of outpatient medications in 7 care units (CU) and 4 surgery units (SU).

Material and Methods

A questionnaire with 7 items was developed by pharmacy team and validated in Committee of Drug and Medical Device (COMEDIMS).

During one week pharmacy team interviewed each inpatient admitted the day of study about the type and amount of medications they brought with them and the type and amount they used.

Results

During study 122 patients were interviewed. Before their hospitalisations 80% had medications prescribed by their general practitioners. 61% brought their medications with them (80% in SU, 38% in CU). 22% used them without informing medical staff. 160 medication boxes were found in units and 29% were not prescribed (34% in SU, 23% in CU). 50% of them were not used by patient or medical staff. 34% were used by patients with medical agreement but without nurses monitoring. Main kinds of medications were pain and heart medications.

Discussion / Conclusion

Although some differences exist between SU and CU, this study provides evidence that outpatient medications are used during hospitalisation and hospital practitioners don't prescribe all of them. Measure of improvement will consist in designing and diffusing local pocket guideline that provides all information for hospital practitioners related to prescription of medications, including outpatient medications.

No conflict of interest

GRP073 Improving the medication pathway ñ Implementation of unit dose medication system in the internal medicine departments

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Background

The medication pathway is a complex processes that incorporates abundant clinical risk issues as well as tangled logistics aspects. When reviewing the literature one can identify four main areas where medication errors might occur during this process: prescribing, transcribing, preparation, dispensing and administration. In order to improve and overcome problems encountered in this process it was decided to implement a unit dose (UD) system for the internal medicine departments in the Hillel Yaffe Medical Center, Hadera, Israel. UD is a system whereby the patients receive prescribed medications, in a personalized tailored manner, on a daily basis, or according to average length of stay, as opposed to bulk dispensing.

Purpose

The following were the objectives of the new system:

- 1. Improving logistics; concentrating on "Just in Time" (JIT) concept.
- 2. Decreasing and preventing medications errors.
- 3. Cost savings.

Material and Methods

In order to implement the above changes it was decided to use 'Demings' quality circle, also known as the 'PDCA': "Plan, Do, Check and Act" and focus on preparing and administering medications in the medical departments.

Results

- Logistics: JIT was achieved in full 280 nursing hours were saved monthly.
- Risk management To detect, prevent and decrease medications errors. Approximately 1000 near misses and mistakes are prevented and aborted annually.
- Financial issues The annual direct cost savings for the UD system was approximately 75,000 NIS (measured in nursing time and medication utilization). Indirect cost, although not measured, was achieved due to prevention of errors and improving quality of care.

Conclusion

The UD system has been successfully operational since 2007, leading to substantial improvements in logistics, risk reduction and cost savings. This process will be upgraded with the introduction of electronic medication records and its link to an online medication decision support system, increasing pharmacy involvement and monitoring of this process.

No conflict of interest

GRP074 Improving the intranet management ٥f chemotherapy-related policies, protocols and guidelines in an Irish cancer centre

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Background

The large cancer centre in which this change project took place is heavily reliant on the availability of Intranet-based policy, protocol and guideline documents (protocols) to guide chemotherapy management. However, a number of errors and anomalies had been noted in the filing of protocols on the Intranet system, in addition to complaints from clinical staff of difficulty in locating protocol documents.

The above issues were viewed as a safety concern in terms of active failures and latent conditions which compromised the medication error defence of protocol availability. This project was thus instigated with the aims of reducing difficulty in locating protocols and reducing the risk of error in protocol filing activities.

Material And Methods

Kotter's Eight-Stage Process was employed to manage the change. The existing system was analysed to determine change needs, which included a transfer of responsibility for protocol management to Pharmacy, the introduction of a standardised system for protocol filing, and a complete layout redesign of all protocol-containing Intranet webpages.

Results

Transfer of protocol management responsibility was achieved at an early stage and significant stakeholder input informed the restructuring of Intranet webpages and the removal of obsolete or inappropriate protocol content. Protocol location supports including 'disease subcategory tables' and a protocol index document were introduced to the Intranet and electronic filing templates were introduced to the protocol management system to reduce filing error. A standardised filing system was implemented along with a quality control log of protocol management activities. Stakeholder satisfaction, and level of ease in locating Intranet-based protocols, were both found to increase following the introduction of the changes.

Conclusion

The chosen change model proved effective in guiding the change process, which was successful in meeting the identified change needs to the satisfaction of all stakeholders.

No conflict of interest

GRP075 IMPACT IN THE USE OF **INFLIXIMAB¥S OPTIMIZATION PROGRAM: PRELIMINARY RESULTS**

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Background

Infliximab is an ant-inflammatory agents that work by blocking the action of the pro-inflammatory cytokine TNF-α. It is increasingly being used to treat a number of autoimmune diseases.

Purpose

To evaluate the impact of infliximab's program protocol in our Pharmacy Service (PS). This program focuses on the clinical effectiveness use to control health care resources and reduce

Material And Methods

A prospective study was carried out during 10 months (July 2009 -May 2010). We included all patients with infliximab treatment at the Elche University General Hospital. A list of the patients was sent to the PS weekly, informing about each patient's weight and dose regimen of infliximab. The drugs was reconstituted and diluted by the intravenous unit. The vials were adjusted very accurately, avoiding an unnecessary expense for partially used vials. The preparation process was safe as a laminar flow hood was used every time. A triple control of the entire process was carried by the pharmacist, reviewing all prescription, transcription and preparation to minimize potential errors, assuming a standard deviation's dose of +/- 10% per patient.

Results

104 patients were included in our study: 75% rheumatoid arthritis, 22% ankylosing spondylitis, 2% psoriasis, 1% Crohn's disease. 793 preparations were made, with an average of 3.44 vials per patient. A total of 12 incidents were registered: a patient unscheduled (an extra dose were prepared, discarding the remaining of the vial), a transcription error in dosage by outpatient unit, a change dosage without new prescription from the doctor, a case of adverse reaction during intravenous infusion, five patients who did not attend to the appointment day and three patients who were late. A noteworthy decrease in the expense of 40036.32 € was achieved.

Conclusion

The establishment of an optimization infliximab's program is an effective strategy to control health care resources and reduce cost.

No conflict of interest

GRP076 20% Oral sucrose solution for neonatal analgesia L. Sánchez-Pacheco Tardón, R. Pardo Sánchez, L. Canadell Vilarrasa, T. Aguilella Vicente, L. Sánchez Parada, L. Castillo

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Background

Newborns undergoing painful procedures need help in pain relief. Clinical studies have shown a reduction of changes in physiological parameters and measurements of pain scores after the administration of preventive painkillers such as sucrose in situations where the neonate is suffering pain or stress.

Purpose

To describe a standardised neonatal analgesia protocol with a 20% oral sucrose solution in invasive procedures for low and medium intensity, to design a typified formula in the Pharmacy Service for the prevention of medicine errors associated with its administration in the hospital neonatal unit care and to acquire some data about its effects on new-born babies.

Material and Methods

Clinically relevant studies were reviewed in order to establish a standardised pain-reduction procedure for invasive procedures in

The Pharmacy Service prepared re-packaged unit-dose capsules of 0.9 g sucrose and wrote a protocol in order to prepare a 20% extemporaneous aqueous oral sucrose solution and simplify its administration in the hospital unit by nurses.

The solution is dosed by weight of the baby, in a dose range of 0.1 to 2 mL (from 0.02 g to 0.4 g of sucrose). A single dose is administered orally (not by nasal or oral tube) followed by nonnutritive sucking two minutes before the procedure.

Heart rate was measured just before administering the sucrose solution and immediately after and 1 minute after heel lancing, as were duration and intensity of cry.

Results

The typified formula was followed properly in two cases during one month. Both of them were full term babies whose weights were 3090 g and 3600 g and who received 0.4 g of sucrose (2 mL of 20% sucrose) via syringe 2 minutes before heel lancing for blood tests.

A heart rate reduction of 8% and 9.94% respectively was observed one minute after heel lancing. Both babies stopped crying and became calm and quiet 30 and 38 seconds respectively after heel lancing.

On the same day two other babies who did not receive sucrose cried for 5 minutes and 30 seconds and 4 minutes and 50 seconds after heel lancing.

Conclusion

The standardisation of this formula and protocol has improved sucrose administration in the neonatal unit care and errors were minimised after the neonatal analgesia protocol was introduced.

The administration of sucrose seem to be associated with a reduction of heart rate, intensity and duration of cry and other indicators of pain such as facial expressions.

However, further studies are needed to identify the optimal dose of sucrose and the effects of repeated use.

No conflict of interest

GRP077 Integrated software decreases errors in cytotoxic therapies

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Background

Medication process errors during chemotherapy could create several problems for the patient. The common strategy to decrease drug errors is the use of computerised physician order entry (CPOE). CPOE is highly effective in reducing errors when cytotoxic drugs are prescribed but is ineffective during the preparation and administration phases.

Purpose

To improve the safety of the work flow, an integrated system that manages the prescription, preparation and administration phases using barcodes is recommended. Several studies have proved that bar codes are efficacious in reducing errors during drug preparation and on the wards during administration.

This study was carried out in two Italian hospitals - the Ospedali Riuniti of Ancona and La Maddalena Hospital of Palermo - which use similar systems of computerised checking of oncology treatment from prescription to administration.

Material and Methods

FMECA is a method that was initially used in industry to study the probability of error during production. In hospitals, the FMECA method can help to investigate how changes in the workflow reduce potential errors.

In our study the oncology treatment workflow from prescription to administration was evaluated before and after the introduction of the integrated system in both hospitals.

Results

In Ancona hospital, the probability of error was reduced by 0% during prescription (which was already using CPOE), 58% during

preparation and 60% during administration. In Palermo hospital the figures were 86% during prescription, 69% during preparation 60% during administration. On average the probability of error was reduced by 39% and 71% respectively.

Conclusion

Integrated software is very effective in reducing errors during the prescription, handling and administration of cytotoxic drugs. The CPOE system should be extended so that preparation and administration are also checked.

No conflict of interest

GRP078 Quality management system applied to clinical pharmacy activities

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Background

Quality management systems are integrated into corporate culture. ISO 9001 standardises collective and repetitive activities, providing a set of guidelines for international application.

Purpose

Our Hospital Centre integrates three hospitals with one combined pharmacy department (PD). Since there was a wide variation in practice in the original PDs, the purpose was to standardise procedures in Clinical Pharmacy (CP), establishing indicator targets and quality objectives for each process.

Material and Methods

Key processes were defined for the PD: selection of medicines (SM), pharmacovigilance, pharmacokinetics, drug information, pharmacotherapy follow-up (PFU) and nutritional therapy (NT). Indicators, targets and quality objectives were established for each process and measured during the first half of 2010.

Results

For the SM, the indicator was the percentage of restricted drugs that took more than five days to be prepared by a pharmacist, which was 9.98%. (Standard: < 20%).

Regarding the PD's pharmacovigilance activities we notified 22 adverse drug reactions (ADRs). An active pharmacovigilance programme was implemented for new drugs introduced into the hospital. During the study period 58.6% (standard > 60%), of the introduced drugs were included, 26 patients monitored and 2 ADRs reported. The indicator set for pharmacokinetics is the percentage of therapeutic levels obtained, which was 72.9% (standard >70%). To improve our results, we established training and discussion of clinical cases.

We recorded 379 requests for drug information. To ensure good quality information, we requested collaboration from a Centre for Drug Information to assess the agreement of responses.

We are still in the implementation phase for the PFU and NT processes. The indicators are respectively: percentage of inpatients/outpatients who are followed up by a pharmacist and number of patients in whose treatment a pharmacist intervenes.

Conclusion

Indicators allow review and adaptation of clinical pharmacy activities. The standardisation and implementation of procedures enables clinical pharmacy activities the documented and improved.

GRP079 Application of customer's satisfaction inquiries and complaint treatment in a hospital pharmacy setting

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Background

Quality management system (QMS) standards such as ISO 9001 provide a model for setting up and operating a management system. One of the ISO 9001 principles is that organisations depend on their customers, therefore should focus on their needs. The implementation of a QMS ensures that the Pharmacy Department (PD) objectives are linked to customer needs and expectations, by measuring customer satisfaction.

Purpose

To find out whether inquiries about satisfaction and a complaint handling system contribute to improving the PD's performance.

Material And Methods

The QMS was implemented using innovative software, which allows satisfaction surveys to be recorded and customer complaints analysed. Different categories of customer were identified, satisfaction surveys were drawn up and distributed, and spontaneous complaints were notified and recorded by any collaborator of the PD.

Results

In the first half of 2010, 384 inquiries were completed, 275 by outpatients, 12 by physicians, 34 by nurses and 63 by other healthcare professionals, with a satisfaction rate of 77.2%, 85.4%, 75.1% and 83.2% respectively, with a global satisfaction average of 80.2%. Analysis of the surveys suggested as areas for improvement: waiting time, restocking and individual unit dose distribution. These aspects were considered, and improved practices were adopted.

Of all the complaints recorded in the PD (n=70), 39 were made by outpatients, 6 by physicians; 22 by nurses and 3 by other healthcare professionals. In 54.2%, the PD was responsible for the problem, and measures were taken for its correction.

Conclusion

The use of customer satisfaction surveys and the implementation of a complaints handling system as part of QMS allow aspects in need of improvement to be identified, resulting in action being taken to answer customers' needs.

No conflict of interest

GRP080 Influenza A (H1N1) virus vaccination in HIV patients

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Background

Patients infected with HIV were considered by the health authorities to be at risk of influenza A, and were therefore expressly recommended to have a vaccination.

Purposes

To evaluate the results of the official vaccination campaign against H1N1 virus in HIV-positive patients taking highly active antiretroviral treatment (HAART) in our health care area. To evaluate the incidence of influenza A in this population.

Material and Methods

We conducted a survey about the influenza A vaccination with HIV patients who collected medicines from our pharmacy department from 1 March to 15 April 2010. All patients were asked whether they

had had any symptoms that would make them suspect a bout of flu during the risk period. All vaccinated patients were asked whether they had had any side effects. We also compared the antivirals dispensed with the influenza A database. The results were recorded in the pharmacotherapy follow-up sheet for each patient.

Results

Of the 171 patients surveyed (47 women, 124 men) with a mean age of 45.5 years, 57 (33.3%) had received the influenza A vaccine. Side effects were attributable to the vaccine in four patients and in all cases were mild and disappeared soon afterwards (pain at the injection site, headache, flu-like syndrome, fever). No patients vaccinated against the H1N1 virus had previously had influenza A, and one patient was treated for 1 month with a diagnosis of influenza A. The patients who chose not to be vaccinated for A flu did so because of uncertainty surrounding the safety of the vaccine.

Conclusion

- Despite the influenza vaccination being recommended for HIV patients, the number of patients who were vaccinated was low.
- The incidence of influenza A was negligible, with only one recorded case.
- The use of HAART in HIV patients reduces the risk of flu, aligning this risk with that of the general population.

No conflict of interest

GRP081 A quality control study in the preparation of medical treatments in a pharmacy service of nursing homes

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Purpose

To analyse and evaluate the quality control in different steps of preparing medical treatments in a pharmacy serving nursing homes.

Material and Methods

An observational prospective study (duration: 11 months) with 1504 elderly patients from 18 nursing homes. Treatments are prepared and provided in unit-dose packs weekly through two dispensing systems: medication tray and blister lidding.

Each system has a checking procedure: in the blister lidding system, an assistant checks every blister, so errors cannot pass unnoticed (full checking system).

On the other hand, in the medication tray system, an assistant only checks 10 medication treatments prepared on every tray (partial checking). If no errors are found, the checking is correct. If an error is found, the assistant proceeds to check another 10 treatments. If more than one error is found at any step of the procedure, every treatment must be checked.

Variables noted: number of treatments prepared, number of errors detected, type of error and drug involved.

Results

35536 treatments where checked (53.86%; Cl95%: 53,50-54,24) in which 956 errors were detected (2.70 %; Cl95%: 2.52- 2.86). The type of errors were: 276 "missing full medicines" errors (28.93%; Cl95%: 26.07- 31.92); 180 "missing medicine units" (18.87%; Cl95%: 16.43- 21.50). Drugs that caused more errors were: omeprazole (6.98 %; Cl95%: 5.37- 8.89) and salicylic acid (4.89%; Cl95: 3.6-55.55). 73.85% of errors were detected in the blister lidding system (Cl95%: 70.94-76.61), and 26.15% of errors were identified in the medication tray system (Cl95%: 23.40-29.06). The average of errors detected was 0.95 (Cl95%: 0.85- 1.06).

Conclusion

The full checking system increases the quality of the healthcare process ensuring greater security for the professionals, since the medicines mistakes are not likely to reach the patients.

No conflict of interest

GRP082 Analysis of drug interactions associated with outpatient treatment in elderly patient

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Background

Drug-drug interactions are of great concern, as they are known to be related to adverse drug reactions and hospitalisations.

Purpose

To determine the prevalence of clinically relevant potential drug interactions (PDIs) associated with chronic treatment of elderly patients at hospital admission, as well as factors related to their appearance.

Material and Methods

Cross sectional study (three months, October 1st to December 31st, 2009) performed in university general hospital of 350 beds. We recruited a random sample of 382 patients aged ≥ 65 years who were admitted to hospital. At hospital admission a clinical pharmacist took a medication history of the usual drug treatment.

We used the drug database of the General Council of Colleges of Pharmacy (BOT) to identify PDIs. The level of severity was determined according to Stockley's Interaction Alerts and the Hansten and Horn criteria.

We evaluated the relationship between polypharmacy, comorbidity, age and gender with the presence of interactions. Statistical analysis was performed with SPSS version 15.0.

Results

Nearly half of patients (41.6 %) were at risk of suffering an adverse event secondary to a PDI, of whom 59.5% had comorbidities and 95% had been prescribed five or more drugs. We found 272 PDIs. The seven drug groups accounting for 80.6% of the interactions were the following: antiplatelet agents (15.5%), proton pump inhibitors (PPI) (15%), diuretics (13.9%), bronchodilators (13.3%), anticoagulants (10.1%), digoxin (7.0%), and statins (5.9%).

The most common types of interactions, together with the recommendations and the level of severity, are given in Table 1:

Interaction	%	Recommendation
diuretics -bronchodilator	17.3	avoid association
antiplatelet - PPI	15.1	avoid association
antiplatelet - statin	10.3	monitor patient
diuretic - digoxin	9.6	monitor patient
anticoagulant - PPI	9.2	monitor patient
anticoagulant -antiplatelet	7.7	avoid association
bronchodilator -theophylline	5.1	monitor patient
benzodiazepine - PPI	4.8	avoid association
beta blocker -bronchodilator	3.7	monitor patient
Ca antagonist - digoxin	3.3	monitor patient
others	14	•

1: Stockley, 2: Hansten and Horn

We found 27 different PDIs, for which the recommendation for 48.1% was to avoid association and for 51.9% it was to monitor the patient.

Comorbidity and greater number of drugs were positively associated with interactions (p<0.001).

Conclusion

The high percentage of patients with PDIs (41.6%) highlights the size of the problem. The results suggest the desirability of prioritising interventions in the groups responsible for most of the PDIs. Patients with multiple comorbidities and taking more medicines are at increased risk of PDIs.

No conflict of interest

GRP083 Can we count on you?

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Background

The weight of children on the paediatric ward ranges from 500 g to 100 kg. The size of each dose is therefore highly variable and that increases the risk of calculation errors. Medication errors account for approximately 1/3 of all reported adverse events [1]. It is therefore very important that physicians and caregivers calculate the dose of children's medicines correctly.

Purpose

To improve patient safety, we wanted to develop an e-learning course on how to calculate the correct dose of medicines.

Materials and methods

A multidisciplinary team (a pharmacist, two nurses and a multimedia programmer) prepared a course consisting of a series of exercises for calculating the dose of medicine together with a final test. The examples were constructed from the actual daily drug prescriptions on the paediatric ward.

Results

The course gives background knowledge, including model solutions, explanations of units, symbols and useful formulas, a calculator, where the findings apply to the result field in each exercise and a notepad for the results of the intermediate calculations. Once an exercise has been solved, the response will be evaluated and there will be feedback in terms of explanatory comments, formulas and a model solution.

The structure of the course consists of 5 modules for calculations concerning solid drugs, liquid medicines, dilutions, infusions and composite tasks. In the final test there will be two questions from each module.

The final test must be taken annually and all the answers must be correct to pass the test. 20% of the physicians and 46% of the caretakers have passed the test this year.

Conclusion

The course is in operation on the children's ward and is mandatory for all physicians and caregivers. An evaluation of the course will decide what needs to be done to raise the pass rate.

1. Annual Report 2009, DSPS, National Board of Health, Denmark

No conflict of interest

GRP084 Reconciliation errors affecting nursing home patients M.S. Albiñana, <u>L. Fuster</u>, R.J. Taboada, I. Rodríguez ¹ferrol health care area, pharmacy, ferrol, Spain

Background

in 2005 the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) established medicines reconciliation as a key initiative to reach National Patient Safety Goal #8.

Purpose

To identify medicines discrepancies affecting elderly nursing home (NH) patients: intended discrepancies and reconciliation errors (REs). Type, frequency and care transition point with REs. Medicines involved in REs.

Material and methods

Prospective study between January 2009 and September 2010 at two NHs with 295 resident beds. Home medicines list at NH admission, outpatient specialist physician prescriptions and hospital admission and discharge prescriptions were compared with current NH drug chart to identify discrepancies. Medicines discrepancies notified were considered RE if intervention was accepted or intended discrepancy if intervention was not accepted. REs were classified as: omission of medicine, different dose/route/frequency, incomplete prescription, different medicine and added medicine. Medicines involved in REs were classified by ATC classification system group.

Results

We identified 79 discrepancies: 7 intended discrepancies and 72 REs (91.14%). 58 patients had at least one RE (19.66%); 11 of them had two (3.73%).

		Care transition point with RE				
		NH admission	Outpatient specialist physician visit	Hospital	Hospital discharge	TOTAL (%)
Type	Omission	14	3	1	0	25.00
RE	Different dose/route /frequency	17	17	0	1	48.61
	Incomplete prescription	2	0	0	0	2.78
	Different medicine	2	0	0	1	4.17
	Medicine added	7	6	0	1	19.44
TOTA	AL (%)	58.33	36.11	1.39	4.17	100

Forty-six drugs were involved in REs, 56.94% were classified as group N (nervous system), 15.27% group C (cardiovascular system) and 9.72% group B (blood and blood forming organs).

Conclusion

- Most errors were different dose, route or frequency and drug omissions.
- Although REs were identified primarily on admission, we found them at every care transition point.
- The high percentage of interventions accepted shows that pharmacist involvement in medicines reconciliation is important in reducing medicines errors in the elderly population.

No conflict of interest

GRP085 INCIDENTS AND NEAR MISSES WITH MEDICAL DEVICES: RESULTS FROM THE REPORTING SYSTEM IN AN ITALIAN HOSPITAL

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Background

Incidents may occur not only in the administration of drugs, but also during the use of medical devices. To ensure patient safety, healthcare professionals are required to report not only unexpected side effects of drugs, but also incidents that may occur during the use of medical devices. In the last years, the level of awareness

about incident reporting has increased. In Italy the Legislative Decree implementing European Directive 2007/47/EC required post-market surveillance of medical device to be instituted.

Purpose

We performed a retrospective analysis to evaluate the adherence to ministerial recommendations, identify the most common sources of risk and facilitate learning about problems and preventing them from (re-)occurring in the future.

Material and Methods

The Italian Minister of Health provided a form to be completed by healthcare professionals: in our hospital, an incident reporting system has been established, and professionals have been requested to report incidents and near misses that might have impaired a patient's safety.

A database was created, containing all incidents reported from 2005 to 2010: to determine the prevalence and characteristics, a retrospective review was conducted.

Results

From 2005 to September 2010, 30 events involving medical devices were reported (14 were near misses). The specialties reporting the highest number were: General Surgery Division (5), Oncology Department (5), Ophthalmic Department (5) and Intensive Care Unit (4).

In 13% of cases a surgical intervention was required; in 17% an appropriate medical procedure was necessary. Only 1 death was reported. Most of the incidents involved patients, but in 3 cases healthcare professionals were also injured.

Conclusion

Incident monitoring is useful to prevent or minimise the effects of incidents. Current reporting rate is low: further research and improvement of the reporting system is required to assess potential severity and ensure patient safety.

No conflict of interest

GRP086 Errors prevention in drugs management with information technology

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Background

Drug management-related incidents are a significant problem in healthcare organisations. However, information technology, single dose delivery (SDD) and involving pharmacists in clinical pathways can contribute to preventing these incidents.

The Reggio Emilia Health Authority (Italy) introduced drug management information technology called "Programma Somministrazione Controllo Farmaci" (PSC). Although use of information technology did reduce many potential dangers (incomplete/ unintelligible prescriptions, misidentification of patients), other dangers and errors are still lurking.

Purpose

To identify the main critical points of drug management using PSC-SDD, to monitor the type and frequency of events and near misses and to enhance good drug management safety practice at the San Sebastiano Hospital of Correggio (RE), Italy.

Material and methods

A team of 10 healthcare professionals, coordinated by the Nursing Risk Manager, employed the FMECA (Failure Mode and Critical Effect Analysis) tool to identify and evaluate critical issues in drug management. We then used an incident reporting form (IR) for 40 days, which allowed us to monitor the type and frequency of main events and near misses observed.

Results

The FMECA analysis highlighted the following critical areas: patient identification, drug prescription and dispensing. IR confirmed this, with 230 reports (199 near misses and 31 events). The main issues were drug prescription, dispensing and provision (132 total reported events, including 13 dispensing failures and 7 errors in dispensing dosage). Other incidents reported concerned computer breakdown, defective tools (26), delays (11) or errors in drug delivery (19).

Thanks to the team's research and analysis we were able to achieve the following results:

Improved communication among team members in terms of sharing problems and finding solutions; Enhanced staff awareness of the critical steps of drug management; Increased use of identification wristband; A number of audio warning signals introduced in bar code readers in whole or half dose dispensing (tablet, vial); Increased number of bar code readers available for clinical data entry in database, resulting in safer drug management (insulin, anticoagulants) and elimination of paper-based treatment forms on the ward; Change in drug prescription scheme based on phoning in prescriptions to the pharmacist for quick dose preparation, thereby reducing delays.

Further, more detailed, analysis will allow us to identify other major safety barriers.

Conclusion

FMECA and IR have proved to be effective tools that allow us to identify critical areas in the complex process of drug management. Involving staff in project design, critical issue identification and improvement actions have led to achievements both in patient safety and in staff awareness. These achievements will result in a safer service and in continuing improvement in health care.

No conflict of interest

GRP087 Study of the use of thromboprophylaxis at the start of treatment with lenalidomide plus dexamethasone in patients with multiple myeloma

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Background

Patients with multiple myeloma (MM) have a high risk of thrombotic episodes (3-15%). Several studies report an increased risk in patients treated with lenalidomide combined with dexamethasone, which requires the use of thromboprophylaxis at the start of the treatment. In our hospital, to get the best efficacy/security profile, patients are classified according to risk factors. Literature recommends aspirin for patients at low or no risk and low molecular weight heparin (LMWH) for patients at high risk.

Purpose

To evaluate the use of thromboprophylaxis in patients with MM at the start of treatment with lenalidomide and dexamethasone.

Material And Methods

Retrospective observational study. We collected data for two years from patients diagnosed with MM who started the treatment with lenalidomide and dexamethasone. Variables: age, sex, thrombotic risk factors (individual, associated diseases, resulting from the MM and concomitant treatments) and thromboprophylaxis. Patients were classified according to whether they had none, one or at least

two additional risk factors. It was confirmed whether the thromboprophylaxis for each patient was adequate based on risk. Data were collected with the Prescriplant electronic prescribing and patient history application.

Results

In the period between 01/10/2008 and 30/09/2010 28 patients diagnosed with MM were treated with lenalidomide, 15 women (53.6%). Median age: 69.5 (41-84). Two of them were excluded in the absence of any historical pharmacotherapy data (N = 26). Five patients (19.2%) had no risk factors and none of them had thromboprophylaxis. Two patients (7.7%) had one risk factor and both had aspirin. Nineteen patients (73.1%) had two or more risk factors, of which 16 (84.2%) had LMWH and 3 (15.8%) had aspirin.

Conclusion

1 - Thromboprophylaxis was adequate in 18 of 26 patients (69.2%) 2- It is necessary to include a review of the thrombotic risk in our pharmaceutical care programme in patients treated with lenalidomide plus dexamethasone.

No conflict of interest

GRP088 Quality of medication ordering for investigational antineoplastic agents

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Background

Incorrect use of antineoplastic agents can produce biased results in clinical trials as well as toxicity in patients. Thus, special precautions are necessary to prevent antineoplastic drug-related errors.

Purpose

To evaluate the quality of medicines prescriptions for investigational antineoplastic agents (PIAAs) in the onco-haematological section of a European general teaching hospital with a population coverage of 700,000 inhabitants.

Material and Methods

A descriptive and prospective study from February to May 2010 in onco-haematological outpatients enrolled in clinical trials.

Investigational antineoplastic chemotherapy prescriptions were recorded. Data collected included demographics, pathology, and medical service. The pharmacists recorded the date of administration, patient's name, body surface area (BSA), dosage, investigator's name, cycle number, and study name-protocol number (PN) and whether antineoplastic drugs were prescribed or omitted. PIAAs were considered correct when all of the above fields were completed. Then, descriptive statistics were calculated.

Results

During the study, 102 PIAAs were recorded and 32 patients (19 of them men) with an average age of 64 (47-81) were involved. Patients had an average of three PIAAs. The pathologies of these patients were colorectal (n=76), gastric (n=9), pulmonary (n=9), breast (n=3), lymphoma (n=4) and prostate (n=1) cancer.

All prescriptions were clearly dated and identified. BSA was omitted in 91%, PN in 48%, investigator's name in 31%, chemotherapy cycle number in 20%, and dosage in 8%.

Conclusion

The main area of PIAA that needs improvement is inclusion of patient's BSA and PN in the chemotherapy prescription in order to prevent drug-related errors. To improve safety in onco-haematological patients enrolled in clinical trials, the present standardised forms should be changed to include the most frequently omitted data. Physicians must be informed of the importance of recording all data in the PIAA. No conflict of interest

GRP089 Retrospective study of the use of darbepoetin in oncologic patients

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Background

Darbepoetin is authorised for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. However, during the last few years, it has been associated with reduced survival and/or poorer tumour outcomes in patients with cancer. Cancer patients with potentially curable disease should not be treated with darbepoetin. Additionally, patients with haemoglobin (Hb) values above 12g/dL were at higher risk.

Purpose

To describe the population treated with both chemotherapy and darbepoetin between January and March 2010, to identify patients with curable disease receiving darbepoetin and to quantify the patients on darbepoetin whose haemoglobin values exceeded 12g/dL.

Material and methods

The following data were collected for each patient: darbepoetin starting date, nearest Hb value before (previous fifteen days), number of red blood cell transfusions (including 21 days before and after darbepoetin treatment) and oncologic diagnosis.

Results

A total of 122 patients were investigated; 93 of them had solid tumours: 20.4% colorectal, 19.4% lung, 14.0% gynaecological, 11.8% breast, 8.6% pancreatic, 4.3% head and neck, 1.1% bladder and the rest of them had another solid tumour. In addition, 29 had haematological disease: 31.1% multiple myeloma, 58.6% lymphoma and 10.3% had another haematological disease. Before the first administration of darbepoetin 74.5% of the patients had an Hb<10g/dL, 23.9% 10-10.9g/dL and 1.6% >11g/dL. 31 patients received a total of 45 red blood cell transfusions, most of them during darbepoetin treatment (only 7 before it). During treatment period 19 patients had an Hb>12g/dL in 27 measurements. In 18 patients the intention of treatment was curative: 2 adjuvant breast, one adjuvant bladder, one adjuvant lung, one limited lung disease, one adjuvant colorectal, 10 high grade lymphoma, one T-lymphoma and one pre-transplant multiple myeloma. In this group, darbepoetin was started with Hb>10g/dL in 4 haematological patients; three of them reached Hb>12g/dL during the treatment.

Conclusion

The percentage of patients with potentially curable disease was high and some of their Hb values exceeded 12g/dL. Pharmacist should verify diagnosis and Hb level before dispensing darbepoetin and recommend the lowest effective dose avoiding the need for transfusion.

No conflict of interest

GRP090 Analysis of medication errors occurred during the process of preparation of antineoplastic admixtures

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Background

In our hospital the preparation of antineoplastic admixtures for intravenous administration is centralised in the Pharmacy Department. These drugs are included within high-risk drugs, i.e. those which improperly used can cause serious injury or death of patients. Due to the high number of processes involving use of drugs, drug-related errors (DREs) are inevitable.

Purpose

To identify and analyse drug-related errors caused during the preparation of high-risk drugs by a qualified nurse of the Pharmacy Department. This information may help us to apply corrective measures to avoid or minimise the errors identified.

Materials and Methods

We conducted an observational, prospective study from January 15 to April 15, 2010. We included all ready-to-administer antineoplastic mixtures prepared by a qualified nurse in the Pharmacy Department and prescribed by the Oncology or Haematology Department. Antineoplastic admixtures were prepared for each patient individually.

Quality control was performed routinely, prior to preparing the mixtures. The parameters measured were: correct identification of the tray, correct drug, number of vials, solvent and correct diluent. Drug-related errors detected were corrected.

A second check was made after preparation: that the mixtures were correctly identified and the number of mixtures prepared was correct.

Results

16 DREs were detected: two incorrect drugs, two incorrect number of vials, four incorrect solvent, four incorrect diluent and four admixtures incorrectly identified. There was no tray misidentified. Error rates were: 0.29% incorrect drug, 0.29% incorrect number of vials, 1.05% incorrect solvent, 0.83 % incorrect diluent and 0.58% incorrectly identified.

Conclusion

The detection and analysis of DREs enables the reasons that contribute to its appearance to be investigated. This may help us to minimise the number of DREs.

No conflict of interest

GRP091 Chemotherapy Side Effects: Patients Report E. Laguna. C.E. Hernández. B. Núñez. R. Díez

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Background

Side effects are the most important handicap of chemotherapy. They can worsen adherence and effectiveness of treatment and affect patients' quality of life. If they are known they can be prevented or minimised.

Purpose

The aim of the study was to find out how many of the side effects experienced by oncology patients are reported to physicians in a routine medical visit.

Material and Methods

Observational prospective study between 30April 2010 and 30 May 2010. All patients with solid tumours receiving second or subsequent chemotherapy cycles were included.

An individualised questionnaire was made for each protocol, including all side effects with an incidence higher than 1%. All patients were asked to fill in the questionnaire on their second and following chemotherapy cycles. Answers were then checked against the patient's medical records.

Results

A total of 111 patients were included in the study, 45.5% male and 54.5% female. Median age was 64 years old. Only 23.25% of side effects were recorded in the clinical record. Side effects reported more frequently in the medical records were: fatigue, skin reactions, nausea, muscle pain, hypersensitivity, cough, diarrhoea, tingling, appetite loss and mucosity. According to the questionnaires the most frequent side effects were: fatigue, nausea, appetite loss, taste disorders, constipation, diarrhoea, tingling, cough, nail disorders and alopecia.

Conclusion

The reporting of fewer side effects to physicians may be caused by a variety of reasons. Patients may not remember all side effects that occurred or they may consider them as normal effects of treatment that are not necessary to report. The lack of information about side effects may reduce the quality and effectiveness of chemotherapy. For this purpose an individualised questionnaire could be a useful tool to identify side effects in an exhaustive way.

No conflict of interest

GRP092 DokuPIK - Clinical Pharmacists' Interventions in Germany (AG Dokumentation und Evaluation pharmazeutischer Interventionen, ADKA, Germany)

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Background

Clinical pharmacists have shown to improve the quality of drug treatment and to reduce morbidity and mortality of patients. In 2008 the internet-based database DokuPIK (www.adka-dokupik.de) was developed, with which German clinical pharmacists can document and classify pharmacist interventions (PIs).

Purpose

To evaluate PIs documented and classified in DokuPIK from 1.1.2009 to 31.12.2009 using descriptive statistics.

Results

5272 Pls – from 370 registered users - were evaluable, with the majority in the specialities of surgery (37%), internal medicine, neurology and haematology/oncology (10% each). The most frequent causes of interventions - multiple selections were possible – were classified as procurement/costs (27.4 %), incorrect dosing or failure of dose adjustment (18.9%), inappropriate use of drugs (11.8%) and advice or selection of drugs (10.8%). The categories interaction (10.5%) and incomplete prescription/transcription error (10.0%) were next. Interventions due to adverse events, duplications, contraindications or incorrect use each accounted for less than 3%.

The four most common categories of PI were: improvement of patient safety (24.6%), cost reduction (23.1%), an error occurred that reached the patient, but did not cause patient harm (NCC-MERP C) (14.8%) and an error occurred but did not reach the patient (NCC-MERP B) (13.2%). In 15 cases (0.28%) an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation (NCC-MERP F).

Suggested interventions (n=3878) were implemented in 3149 cases (95.1%). In 568 cases the response was not known. In the vast majority (92%) the pharmacist was the initiator of the PI, indicating the high level of active pharmaceutical support in German hospitals.

Conclusion

These results show that the clinical pharmacist is an important member in the health care team and can contribute to improving the quality of drug treatment.

(Co-authors contributed equally; listed in alphabetical order)

No conflict of interest

GRP093 Pharmaceutical intervention in the setting of antimicrobials glomerular filtration

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Background

Scientific societies recommend estimation of GFR as the best index for the assessment of renal function and dosage adjustment of drugs. The choice is due to its sensitivity and simplicity.

Purpose

To evaluate the impact of pharmaceutical intervention on the suitability of antimicrobial regimens during impaired renal function and to identify antibiotics often incorrectly prescribed.

Material And Methods

Retrospective observational study from May to September 2010. 1649 prescriptions for antimicrobials (except aminoglycosides and vancomycin) were reviewed. Variables: 1. Percentage of inappropriate prescriptions of all antibiotic prescriptions per month. 2. Percentage of inappropriate prescriptions of each antibiotic per month (of the four most commonly prescribed antibiotics.) Inappropriate prescribing: Not adjusted for GFR. Statistical analysis: Difference in percentages, statistical significance: p <0.05.

Results

Total percentage of prescriptions with inappropriate dosage in the month of May (baseline): 24.5%; the following months, respectively, 14.8%, 9.0%, 10.3% and 6.6%, p <0.01 for all the deviations from baseline. Percentage of inappropriate total prescriptions of levofloxacin in May: 32%; the following months, respectively: 24%, 15%, 18.9% and 9.3%. For ciprofloxacin the base rate was 25%, in subsequent months, 17.3%, 2.4%, 2.2% and 3.6%. Amoxicillinclavulanic acid the base rate was 8.1%, the subsequent months 5.9%, 5.5%, 7.2% and 5.7%. For imipenem base percentage was 27.8%; the following months, respectively 25.0%, 16.7%, 12.5% and 13.3%. The differences in percentages from baseline were significant in all months for levofloxacin and in the last three months for ciprofloxacin. For all other antibiotics no significant differences were found.

Conclusion

The pharmaceutical intervention recommending dose adjustment for patients with renal impairment improved the quality of antibiotic prescription. For levofloxacin, imipenem, ciprofloxacin and amoxicillin-clavulanic acid, greater control is necessary because there is a high degree of inappropriate prescribing.

No conflict of interest

GRP094 Adherence to an established protocol on prothrombin complex concentrate prescriptions in the emergency department of an Universitary Hospital

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Background

In 2007, a consensus guideline for reversing oral anticoagulant treatment was introduced in our hospital. In this recommendation, the use of prothrombin complex concentrate (PCC) is restricted to cases of very urgent surgery and major haemorrhage with clinical compromise with INR≥1.6. The administration of PCC must be accompanied by vitamin K.

Purpose

To determine the adherence to the protocol for PCC prescription in the emergency department.

Material and Methods

Retrospective study. Sample: 100% patients treated with PCC in the emergency department between February-September 2010. Data: age, sex, dosage, INR before PCC administration, concomitant administration of vitamin K and diagnostic indication for which PCC was used. Data were gathered by pharmacists from the clinical histories and controlled medicines record of the Pharmacy Department.

Results

65 patients were given PCC (26% female, median age 77.1 years (±9.13). Dosage: 600 IU/20 patients, 1200 IU/44 patients, 1800 IU/1 patient. Median INR before PCC administration: 4.1. Dose was correctly adjusted depending on INR in 25/65 patients (28.5%). Concomitant vitamin K was used in 34/54 patients (no data were recorded in 11/65 patients). Diagnostic indication was appropriate in 44/65 patients (67.7%) (16/44 very urgent surgery, 26/44 major haemorrhage, 2/44 both). In the other 21/65 patients (32.3%) PCC prescription was incorrect (16/65 patients did not have very urgent surgery or major haemorrhage and in 5/65 patients previous INR<1.6).

Conclusion

We detected low adjustment to the new protocol (diagnostic indication, concomitant vitamin K, dose adjustment). We suggest providing more information to physicians before dispensing PCC for anticoagulant reversal in the emergency department.

No conflict of interest

GRP095 Nevirapine-induced exanthema in HIV patient: a case report

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Background

Nevirapine is a non-nucleoside reverse transcriptase inhibitor of HIV-1. The recommended dose is 200 mg daily for the first 14 days (this lead-in period should be used to reduce the frequency of rash), followed by 200 mg twice daily, in combination with at least two additional antiretroviral agents. Rash reactions occur in 13.6% of patients. A 53-year-old man was diagnosed with HIV/HCV coinfection in 1997. In June 2010, he had good response with undetectable viral load, receiving tenofovir/emtricitabine, atazanavir and ritonavir. In order not to worsen his lipodystrophy it was decided to switch to tenofovir/emtricitabine and nevirapine.

Purpose

To describe the role of the pharmacist in the detection of an outpatient's adverse reactions.

Material and Methods

The patient's medical history was reviewed. The patient was prospectively monitored during hospital pharmacy visits.

Results

The patient took 200 mg of nevirapine daily for five days and then increased to 200 mg twice daily. In July 2010 the patient visited the emergency department presenting dyspnoea, vomiting, dizziness and rash. The emergency physician prescribed antihistamines. In August 2010 his wife went to the hospital pharmacy to pick up more nevirapine and reported that he continued to have oedema and rash on his face, difficulty urinating and depression.

The pharmacist noticed a clear relationship between the patient's deterioration and the introduction of nevirapine so she phoned the Internal Medicine physician to get information about it. The physician replaced nevirapine with atazanavir and ritonavir, getting an excellent response and the toxicity disappeared.

Conclusion

The first 18 weeks of treatment are critical as a severe and life-threatening rash may be caused or a rash accompanied by constitutional symptoms including cases of Stevens-Johnson syndrome, toxic epidermal necrolysis and serious hepatitis/hepatic failure. In such cases nevirapine must be discontinued permanently. Continuing collaboration between physicians and pharmacists is important to minimise toxicity of antiretrovirals.

No conflict of interest

GRP096 Implementation of IV drugs compatibility chart in paediatrics

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Background

Parenteral drugs in simulated Y-site administration is a daily occurrence in clinical practice. Drug incompatibilities may occur if no written information is available.

Purpose

To create and introduce a compatibility chart in the paediatrics department to reduce the number of drug-related errors due to incompatibilities.

Material and Methods

Literature review of IV drug compatibility in simulated Y-site administration using Trissel 13th Ed, BC Cancer and Micromedex2.0. The chart was created in an Excel table that included 13 antibiotics, 12 cytostatics, 4 antifungals, 4 types of serum, 4 analgesics, 2 antiulcer drugs, 2 corticosteroids, 2 antiemetics, 1 antiviral, 1 antituberculosis drug, 1 immunosuppressant, 1 benzodiazepine, 1 antihistamine, total parenteral nutrition and other 4 agents (rasburicase, mesna, folic acid and immunoglobulin). Each agent was indexed against 52 others and a colour code was used to indicate non-compatible drugs (red), compatible (green), no available information (yellow), and different compatibility depending on drug concentration (white).

Results

The IV drug compatibility chart includes 66 (4.79%) non-compatible combinations and 14 (1.02%) concentration-dependent drug combination incompatibilities. In 997 (72.35%) combinations no available information has been found. Six incompatibilities were detected in 2009, mainly related to ondansetron, sodium bicarbonate and vancomycin. After the introduction of the IV drug compatibility chart no incompatibilities were recorded from January to October 2010.

Conclusion

The creation and implementation of a compatibility chart reduced the number of incompatibilities in a paediatrics department.

No conflict of interest

GRP097 Analysis of medication errors in an oncology department with computerized physician order entry

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Purpose

To identify and analyse the drug-related errors (DREs) with cytostatic drugs (CDs) after the introduction of Computerized Physician Order Entry (CPOE) in the Oncology Department (OD) and to suggest improvements.

Material and Methods

Retrospective study (January 2009 - September 2010) of the DREs recorded in the CPOE System (Farhos) in a general hospital. Medical prescriptions and pharmaceutical validations were performed according to standardised protocols. Parenteral CDs were prepared by nurses of the Pharmacy Department and were administrated to patients by nurses of the OD. DREs were discussed in weekly multidisciplinary meetings.

Results

During the period of study, 15,088 prescriptions for CDs were validated and prepared for 1,315 patients.

A total of 63 DREs were recorded (0.4% of the total prescriptions):

- 62%: physician prescription (28% overdose, 6% underdose, 11% incorrect therapeutic interval, 11% incorrect drug or omission, 6% incorrect route of administration).
- 11%: pharmaceutical validation (5% miscalculation of infusion volume).
- 19%: preparation (5% wrong duration of infusion, 5% incompatible solvent).
- 8%: administration.

89% of DREs were detected before reaching the patient: 2% in physician prescription, 56% in pharmaceutical validation, 10% in preparation and 21% before administration in the OD.

The remaining DREs were not detected and reached the patients: 6% by errors in the administration (extravasation). Grade 2 erythema was caused in 2 patients despite symptomatic treatment. The DREs involved 28 different drugs, most frequently trastuzumab (17%), fluorouracil (15%), cetuximab (11%) and carboplatin (6%).

Conclusion

The number of DREs recorded was lower than in the literature thanks to CPOE, pharmaceutical intervention in multidisciplinary teams and communication in weekly meetings.

The identification of weak points in the use of CDs facilitates improvements. It is important to implement measures at the critical point of administration to patients to improve the quality of patient care.

No conflict of interest

GRP098 A computerized chemotherapy prescription programme evaluation in an oncology department

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Background

We implemented a computerised chemotherapy prescription program (CCPP) in which oncologists prescribe electronically and pharmacists validate electronically for both day-patients and inpatients treated by the Oncology Department.

Purpose

To evaluate user satisfaction with the program.

Material And Methods

9 months after the introduction of the CCPP (Chemotherapy Module of "FarmaTools" by Dominion Healthcare), we gave a questionnaire to the 6 oncologists who used the CCPP. The questionnaire consisted of 38 items including its simplicity, fluency, safety, utility as a clinical information tool, satisfaction level about the implementation process, about the Pharmacy and Information Technology departments.

Results

The questionnaire was answered by all the oncologists.

They all evaluated CCPP as an easy tool in different subjects. There were different opinions about the utility as a clinical information tool; even that it was preferable to manual prescription. Most of them considered that it was more time consuming, due to

the slowness of the program and technical faults. Opinions about its effect on patient waiting time or nursing time were variable. They all agreed that the CCPP was safer than the manual prescription system.

Regarding future improvement possibilities, alerts related to doses, allergies and interactions were considered the most useful strategies, followed by integrating laboratory data, the patient's usual drugs and antiemetic therapy.

They all declared a high satisfaction level with the Pharmacy Department in resolving emerging problems and a lower satisfaction level with the IT Department.

Conclusion

Safety was considered the main advantage against manual prescription.

The learning process is key to optimising the CCPP.

Improving fluency and implementing alerts should be future options. A fluent relationship between the Pharmacy and Oncology Departments made the implementation possible.

No conflict of interest

GRP099 Sodium Thiosulfate treatment of choice in calciphylaxis

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Background

Calciphylaxis is a rare complication of chronic renal failure associated with high morbidity and mortality. It is characterised by the appearance of ischemic necrosis and skin ulcers as a result of the accumulation of calcium in the dermoepidermal arterioles. A number of case reports have identified some risk factors associated with the development of calciphylaxis: hyperparathyroidism, treatment with oral anticoagulants, vitamin D supplements, hyperphosphataemia and high calcium levels. These factors are not enough to explain the appearance and severity of calciphylaxis.

Purpose

Sodium thiosulfate is not widely used to treat calciphylaxis, because it is little known. Therefore, we think it is very important to publicise this case, for future application in clinical practice.

Material and Methods

We checked the patient's medical history and the Spanish Society of Nephrology recommendations.

Results

A 75-year-old woman presented ulcerated and necrotic lesions and pain in both legs. Skin biopsy and other imaging tests showed calciphylaxis. The patient did not have elevated serum calcium; however she had other associated risk factors: anticoagulation and hyperparathyroidism. The following care was established: stop treatment with warfarin and start treatment with bisphosphonates and cinacalcet. However, the lesions responded poorly, so after consulting the Pharmacy Department, who reviewed the literature, it was decided to start treatment with sodium thiosulfate IV. 25 g of sodium thiosulfate was administered as a 25% solution in 250 mL of 0.9% saline infusion for one hour after each haemodialysis, 3 times per week. In the end, the patient received 13 administrations.

Conclusion

The treatment with sodium thiosulfate was effective and safe. Further studies are needed to establish the correct use of this drug in this pathology.

GRP100 Polypharmacy in the Diabetology, Dyslipidemia and Rheumatology outpatients of Coimbra University Hospital

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Background

Polypharmacy, although useful in many areas, is associated with an increased risk of adverse drug reactions, drug-drug interactions, noncompliance with treatment and hospitalisations. Awareness of drug use patterns is an important tool in promoting the rational use of drugs and minimising the potential risks.

Purpose

To quantify and characterise polypharmacy in the Diabetes, Dyslipidaemia and Rheumatology outpatient departments.

Material And Methods

Descriptive cross sectional study in outpatients aged over 18. The pharmacist conducted an interview, between May 2007 and February 2008, collecting data on medicines, morbidity and demographic characteristics. Polypharmacy was defined as the concurrent use of five or more drugs.

Results

Of the 253 subjects, 153 (60.5%) were women. The mean number of drugs taken varied according to patient characteristics, between 3.58±2.45 and 6.89±3.03. Mean drug use per patient was 5.3, this number being higher in women. Polypharmacy was observed in 61% of the population, of whom 45% were aged > 65 years.

Outpatients from the Rheumatology Department used more drugs than the other patients. The number of drugs used increased with age in both men and women.

Analysing the drugs consumed, 72.3% of the population used drugs for the cardiovascular system, 49% drugs for diabetes, and 38% drugs for blood and blood forming organs. Women took more drugs for the nervous system, musculoskeletal system and hormonal preparations, sex hormones and genital system modulators.

Conclusion

These results express the high frequency of polypharmacy. Female gender and older age are predictors of a higher number of drug treatments. The results are in line with national and international trends regarding the greater use of medicines in women and the elderly, together with the most consumed drug groups.

No conflict of interest

GRP101 Pure red-cell aplasia associated with chronic hepatitis C treatment: a case report

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Background

The current treatment of chronic hepatitis C is based on the combination of pegylated interferon (Peg-Inf) plus ribavirin. Many side effects are associated with the administration of Peg-Inf plus ribavirin, mainly haematological in nature such as anaemia, neutropenia, thrombocytopenia and others. The frequency of pure red-cell aplasia remains uncertain.

Purpose

We report a case of severe anaemia due to acute pure red-cell aplasia during Peg-Inf alpha-2b plus ribavirin treatment.

Material and Methods

A 45-year-old man with no relevant medical history was diagnosed in January 2010 with chronic hepatitis C (genotype 3a) and viral load of 57900 IU/mL. By the end of February 2010 he began treatment with Peg-Inf alpha-2b 120 mcg weekly and ribavirin 1000 mg daily (variable dose by weight). At baseline, laboratory data were normal except for alanine aminotransferase, which was slightly higher than normal.

Results

Eight weeks after the treatment started, the haemoglobin level had decreased from 16.6 g/dl to 11.4 g/dl. In the 12th week, the patient went to casualty with a haemoglobin level of 5.7 g/dl, so the treatment of Peg-Inf plus ribavirin was suspended. During four months after the treatment stopped the patient was given 12 erythrocyte transfusions. In this period, the haemoglobin level never exceeded 7 g/dl. On September 16th 2010, after a bone marrow biopsy, the patient was diagnosed with pure red-cell aplasia requiring high doses of deflazacort (60 mg q8h). After the second weeks of deflazacort treatment the haemoglobin levels increased to 9.6 g/dl.

Conclusion

Pure red-cell aplasia is a possible complication in patients who receive Peg-Inf plus ribavirin. This information should be considered when anaemia develops during the treatment of chronic hepatitis C.

No conflict of interest

GRP102 Are standard recommendations for therapeutic use of human normal immunoglobulin being followed? A review of clinical practice in a portuguese oncology hospital

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Background

Human Normal Immunoglobulin (IVIg) is a safe preparation, made from the plasma of thousands of healthy human donors. Since immunotherapy has become an integral part of modern treatment in oncology, the complexity of the immune system has given rise to different treatment approaches.

Purpose

The present study was designed to compare the product use with the approved indications.

Material And Methods

A retrospective observational study was performed at the pharmacy by reviewing medical prescriptions for IVlg (model n^{o} 1804 - Portuguese Health Ministry) between 1 June and 11 September 2009. The following data were collected: diagnosis, dose and frequency of administration. The main outcome measure was the compliance of medical prescriptions with the summary of product characteristics.

Results

A wide variation in practice was found. Only 61% of prescriptions followed the clinical recommendations for the therapeutic use of IVIg: 26.4% in bone marrow transplantation, 18.7% in chronic lymphoid leukaemia (CLL) and 11.5% in immunological deficiency syndromes (IDS). 3.3% of this data referred to paediatric patients. 39% of the prescriptions did not conform to the approved indications: 31.3% in Hodgkin's/ Non-Hodgkin's Lymphoma, 3.8% in Chronic Inflammatory Demyelisation Polyneuropathy (CIDP), one patient with myasthenia gravis and another with dermatomyositis.

Conclusion

Most of the therapeutic use of IVIg followed the approved specifications (replacement therapy in IDS and CLL). However in the paediatric population further information should be required.

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Although published scientific information supports the drug's administration in other pathological conditions such as myasthenia gravis and dermatological lesions, we considered these off-label uses. The major limitation of our study relies on the lack of patient clinical data such as weight, diagnosis and dosage interval. For future pharmaceutical interventions this information should be added to the prescription.

Conflict of interest

GRP103 Medication errors found in the ambulatory care pharmacy prescriptions of a university hospital

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Introduction

A medication error is any preventable event that may cause or lead to inappropriate use of medicines or patient harm while the medicine is under the control of the health care professional, patient, or consumer, and can have many causes and be done in different ways.

Purpose

To identify and quantify medication errors in the ambulatory care pharmacy prescriptions.

Material And Methods

One-month evaluation of the pharmacotherapeutic profile of patients attending ambulatory care at Coimbra University Hospital. We attempted to identify and quantify non conformities (NC) (prescriptions not fulfilling legal requirements) and prescribing errors (PE) by descriptive statistics.

Results

Out of 2,665 prescriptions, 332 had NC and/or PE (118 in the manual system (MS) and 214 in electronic support (ES)): 113 were NC; 210 had PE; and 8 were both.

Regarding MS prescriptions, 116 were NC (111 were NC; 5 were both NC/PE) and 7 presented PE (2 with PE; 5 with both PE/NC). Concerning the number of NC/prescription, we identified 2 with zero NC, 9 with 1, 38 with 2, 37 with 3, 21 with 4, 9 with 5 and 2 with 6 NC. Most common NC problems were the absence of: International Non-proprietary Name (INN) prescription (27.5%); administration route (21.0%); health sub-system (13.6%); dosage (11.2%); and Regarding the number of PE, we've dosage form (11.2%). identified 111 prescriptions with zero PE and 7 with 1. Each PE was of a different type. Concerning ES prescriptions, 5 had NC (2 with NC; 3 with both NC/PE) and 211 presented PE (208 with PE; 3 with both PE/NC). Regarding the number of NC/prescription, we identified 209 with zero NC and 5 with 1. Most common NC problem was the absence of physician's signature (80.0%). Concerning the number of PE, we identified 3 prescriptions with zero PE. 167 with 1. 39 with 2. 3 with 3 and 2 with 4. Most common PE were: two different administration frequencies for the same drug (64.1%); errors of administration frequency (9.9%); and prescribed frequency different from the one explained to the patient (6.5%).

Conclusion

12.5% of prescriptions presented NC and/or PE. The large number of NC in the MS prescriptions reveals a lack of compliance with legal requirements, compared with ES prescriptions, due, in this case, to the inherent computer-preformatted elements. In the ES prescriptions there was a higher number of PE due to the non-appropriate use of the computer system. Although the ES prescriptions contributed to the decrease of errors related to legal requirements, ensuring the correct dispensing and administration of drugs, there was an increase in PE related to incorrect frequencies of administration, which requires future study to adjust the system.

No conflict of interest

GRP104 Adherence to darbepoetin alfa treatment in outpatients with chronic kidney disease

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Background

Adherence to treatment problems is observed in all situations in which medicines have to be administered by the patient, regardless of the type of disease. A lack of adherence to darbepoetin alfa in patients with chronic kidney disease (CKD) will promote haemodynamic imbalance. The advanced age of these patients and changes in treatment regimens may be the main causes of lack of adherence.

Purpose

To analyse adherence to darbepoetin alfa treatment in out-patients with CKD in a general hospital.

Material And Methods

Retrospective observational study of patients with CKD who received darbepoetin alfa treatment in August 2010, through the Pharmaceutical care Consulting Room, using DIPEX vs. 2.0. We rejected patients who started or changed treatment during the study. The percentage adherence was calculated by the formula: ADH=[(no. of medicines dispensed/ no. of medicines per administration x no. of administrations per day) / (no. of days between two dispensing dates)] x 100. Patients with an average adherence lower than 80% were considered non-adherent.

Results

29 patients were included, 72.4% female. Average age: 72.4 years (29-95). Darbepoetin alfa doses used were: 10 mcg (3.5% of patients), 20 mcg (13.8%), 30 mcg (44.8%), 40 mcg (20.7%), 60 mcg (3.5%), 80 mcg (6.9%), 100 mcg (3.5%) and 150 mcg (3.5%). 37.9% of patients were considered non-adherent to darbepoetin alfa treatment. Collected adherence rates ranged from 29 to 100%. 63.6% of non-adherent patients had a weekly treatment regimen; the other 36.4% had a biweekly regimen. All patients with monthly treatment regimens were found to be adherent to it.

Conclusion

- -Monitoring of adherence is needed to improve the efficacy of darbepoetin alfa, owing to the high percentage of therapeutic failure.
- Pharmaceutical care for patients with anaemia secondary to CKD should include strategies to ensure adherence to treatment, especially for patients receiving weekly treatment, as most of them are not adherent.
- The role of Hospital Pharmacist is fundamental for assessing adherence and to inform nephrologists of the adherence of patients to treatment.

No conflict of interest

GRP105 A pocket clinical guide for the management of drugdrug interactions in HIV patients

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Background

Drug-drug interactions (DDIs) related with HIV treatment are common because of the increase of age-related comorbidities, the development of new drugs and more complex antiretroviral regimens.

Purpose

To create a clinical guide for managing HIV patients: a useful, reliable, comprehensive, up-to-date, evidence-based DDI resource for healthcare workers (physicians and pharmacists).

- To cooperate with clinicians in the choice and maintenance of

effective and safe pharmacotherapy to improve quality of life in HIV patients.

Material and methods

We evaluated the antiretroviral drugs most often prescribed in our HIV population with the Pharmacy database and analysed pharmacological treatment for other clinical conditions.

General and specific DDI databases were consulted (UptoDate, HIV Drug Interactions and Interaccioneshiv.com).

Results

The antiretroviral drugs most used were:

Reverse Transcriptase Inhibitors:

- nucleoside analogues: abacavir, emtricitabine, lamivudine
- non-nucleoside analogues: efavirenz, etravirine, nevirapine
- 2. Protease İnhibitors: atazanavir, darunavir, fosamprenavir, lopinavir/ritonavir.ritonavir
- 3. CCR5 inhibitor: maraviroc
- 4. Integrase Inhibitor: raltegravir

Therapeutic groups selected to treat other clinical conditions were: analgesics, antiarrhythmics, antibiotics, anticonvulsants, antidepressants, antidiabetics, antifungals, antihistamines, antihypertensives, antimigraine and antiplatelet agents, and anticoagulants, antipsychotics, antivirals, anxiolytics/hypnotics, bronchodilators, erectile dysfunctional agents, gastrointestinal agents, herbal remedies, lipid-lowering agents, oral contraceptives, steroids and tuberculostatics.

A pocket clinical guide was made with all this information. DDIs were classified as safe or contraindicated.

Conclusion

Our pocket clinical guide is a useful and necessary tool for the physicians of University Hospital, Guadalajara, to manage DDIs in HIV patients. It is different from Flockhart's table because it only shows the DDIs between the most often prescribed antiretroviral drugs in our HIV population and pharmacological treatment for other clinical conditions in these patients without analysing the enzymes involved.

The information described in the guide should be updated periodically and expanded to new drugs and DDIs.

No conflict of interest

GRP106 MEDICATION RELATED PROBLEMS OF OVERDOSING DETECTED BY THE VALIDATION OF THE MEDICAL PRESCRIPTIONS.

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Background

The aim of pharmaceutical care is to optimise the use of drugs. Limited resources make it necessary to prioritise effort on drugs most likely to cause medicines-related problems (MRPs).

Purpose

To investigate MRPs of overdosing detected in a 2^{nd} level hospital by the validation of prescriptions.

Materials and Methods

A retrospective study from July 2009 to July 2010. We analysed the problems by therapeutic group, drugs most involved and type and relevance of the pharmaceutical interventions (PIs). Climente Martín's classification was used to describe the relevance of the PI.

Results

156 MRPs were detected. 153 of them were due to overdose, 1 to inadequate duration, 1 to inadequate administration rate and 1 to errors in conversions. The drugs most frequently involved were: cardiovascular drugs 25%, highlighting digoxin (11 interventions),

antibiotics 24.3% highlighting aminoglycosides (12) and vancomycin (4).

nervous system drugs 14.1% highlighting metamizole (5) and paracetamol (3).

The PI made was a recommendation to reduce the dose in 87.2% of the cases and to stop the treatment in 12.8% of the cases. 40 of the MRPs would have caused reversible harm with additional treatment necessary and a prolonged stay in hospital (25.6%). Of these 40 MRPs, 25% were due to aminoglycosides, 12.5% to digoxin, 10% to antineoplastic therapy and 7.5% to potassium solutions.

Conclusion

Drugs that act on the cardiovascular systems caused the majority of MRPs, mainly digoxin, while antibiotics (aminoglycosides and vancomycin) are also potentially harmful in overdose. Of the total MRPs detected almost a quarter may have required additional treatment and an extended hospital stay, and again aminoglycosides and digoxin were the source of most problems. Therefore, we found these drugs the most important to validate for dose if safer treatment is required with limited resources.

No conflict of interest

GRP107 Analysis of the pharmaceutical interventions carried out through the validation of the medical prescriptions

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Background

Pharmaceutical care means the active participation of pharmacists in patient care, in dispensing and monitoring drug treatment. With customised pharmaceutical care the pharmacist is responsible for detecting, preventing and solving problems related to medicines, so that drugs are effective and safe in use.

Purpose

To investigate the pharmaceutical interventions (PIs) carried out in patients admitted to a second-level hospital when validating the medical prescriptions. We analysed the types of PI and the therapeutic groups (TGs) in which the greatest number of medicines-related problems (MRPs) were detected.

Material And Methods

Descriptive and retrospective study from July 2009 to July 2010. Included in the study were the PIs made when validating manual and electronic prescriptions in the area of unit doses; the MRPs detected were classified according to Cipolle's method.

Results

2,266 Pls were performed, of which 1,745 (77%) were connected with alternative administration (sequential therapy (ST)) and 521 (23%) with other MRPs. The classification of the Pls in ST identified 1,439 cases (82.8%) for omeprazole and 299 cases (17.2%) for levofloxacin. The Pls performed for the remaining MRPs were divided into the categories:

a) 172 MRPs of indication (33%) (27 by non-treated indication and 145 by unnecessary medicine). The MRPs of indication by unnecessary medicine (145) were divided into: non-indicated (29), alternative more cost-effective (12), inappropriate duration (11), treatment to prevent an adverse reaction (AR) (1) and duplicate treatment (92),

b)121 MRPs of effectiveness (23.2%) (20 due to inappropriate medicine and 101 due to sub-therapeutic dosage). The MRPs of lack of efficacy due to under dosing are divided in turn into: inappropriate doses (55), inappropriate duration (2), inappropriate administration (2), and interactions (42).

c) 228 MRPs to do with safety (43.8%) (72 due to ARs and 156 to over-dosage). The MRPs to do with safety due to ARs were classified, in turn, into: allergy (24), inappropriate administration (13), adverse effect (5), interaction (5) and contraindicated because

of risk factors (24).

With regard to the TGs in which the greatest numbers of MRPs were detected, three stood out: group A (digestive system) 66.3%, group J (anti-infectives) 19.3%, group C (cardiovascular system) 6%.

Conclusion

The most frequent PIs were to do with the sequence of treatment and within this, omeprazole. From the remaining MRPs, PIs to do with safety stand out, in the first place, and within these, first was overdose, followed by allergies and contraindications due to risk factors.

The 2nd type of PI was to do with indication, with a high rate of duplicated treatments standing out. Finally, the PIs to do with effectiveness were mainly due to under-dosing. The TG in which most MRPs were detected was group A, the ST of omeprazole standing out, followed by group J. These groups deserve special attention in the validation of prescriptions.

No conflict of interest

GRP108 OFF-LABEL USE OF INTRAVENOUS IMMUNOGLOBULIN IN A GENERAL HOSPITAL

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Background

Although intravenous immunoglobulin (IVIg) has only seven uses approved by the Spanish health authorities, the literature contains descriptions of more than 150 off-label uses with various degrees of scientific support.

Purpose

To review the scientific support for off-label uses made of IVIg in the authors' institution.

Material And Methods

The electronic clinical records of our institution were searched for retrospective reviews of cases in which IVIg treatment was given between January 2009 and March 2010. In each case found, the condition treated was noted and the scientific support for this use was evaluated.

Results

Forty-six cases of IVIg treatment were identified. In 14 (30.4%), approval of the use made was indicated in the summary of product characteristics (SmPC), while in 32 (69.6%) the use was off-label. Of the 46 cases of use, 67.4% were potentially beneficial and 32.6% of little probable benefit to the patient according to the following condition-based criteria:

- a) Uses included in the SPC idiopathic thrombocytopenic purpura (ITP), Guillain-Barré syndrome and common variable immunodeficiency were assumed to be acceptable and potentially beneficial.
- b) Off-label use in the following conditions was likewise deemed to be acceptable and potentially beneficial: immunodeficiency secondary to surgery or illness; pemphigus vulgaris; Lambert-Eaton myasthenic syndrome; myasthenia gravis; myositis; autoimmune haemolytic anaemia; autoimmune acute hepatitis; Miller-Fisher syndrome.
- c) Off-label use in the following conditions was deemed to have been of little probable benefit: amyotrophic lateral sclerosis; lower motor neuron syndrome; paraneoplastic cerebellar degeneration; thrombocytopenia not responding to platelet transfusion; antiphospholipid syndrome and immunothrombocytopenias other than ITP; wound infection.

Conclusion

IVIg is used in our institution in a wide variety of approved and offlabel situations. In about one-third of cases, IVIg is not in principle expected to be of substantial benefit to the patient.

No conflict of interest

GRP109 Effectiveness of pharmacotherapeutic protocols in Urology

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Purpose

To assess the effectiveness of analgesia that is used in the treatment of urology. To assess administration errors.

Material and Methods

This was designed as a 6-month observational, descriptive and retrospective study in a tertiary hospital with 360 beds. All patients who were treated were included.

We first reviewed the procedures for prescribing and administering medicines connected with the most frequent procedures in urology (bladder tumour transurethral resection (TUR), prostate TUR, laparoscopic radical nephrectomy, open nephrectomy, radical prostatectomy and radical cystectomy with ileal duct). We then reviewed patients' clinical histories to obtain the record of administration, Visual Analogue Scale (VAS) values at every shift and additional analgesia requirements. The VAS was used to assess how much pain was experienced by the patients.

Results and conclusion

We evaluated a total of 28 patients (71.4% having prostate/bladder TUR, 25.6% laparoscopic radical nephrectomy and 7.1% radical cystectomy with ileal duct).

98% of the possible VAS scores were recorded. All the agreed VAS scores were recorded in 78% of the patients.

92.8% of patients reported VAS scores of 0-3 (26 patients) at some point. 35.7% (10 patients) had VAS scores of 3-6 at some point and 28.6% (8 patients) had scores of 6-10 at some point. All VAS values > 3 coincided with the lack of administration of the standard analgesia.

334 drugs administrations were made. 87.7% of the administrations were correct in all respects while in 12.3% there were administration errors. 95% of patients presented ≥ 1 administration error. The errors were made as follows in percentage terms: omeprazole 32.5%, metamizole 27.5%, dexketoprofen 20%, 15% paracetamol and 5% bemiparin.

A better system for administering the drugs might improve the effectiveness of drug treatment.

No conflict of interest

GRP110 Implication of Failure Mode and Effect Analysis on Medication Management Process

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Background

Errors throughout the medicines management process are one of the most crucial problems in hospital pharmacies. The failure mode and effect analysis (FMEA) technique defines a contemporary approach to improving complicated processes, and eliminating risks and possible errors in these processes. FMEA has recently been widely used to deal with risks and potential errors in complicated processes. Previous literature (see the references) provides successful examples of the use of FMEA on the medicines management process. FMEA is a systematic approach to determining the dragging or failing parts of a process and the

necessary precautions to be taken to make those processes safer. The aim is to determine the possible errors in a process and to redesign the process and take safety measures to prevent these errors. The impact of a specific error on the performance of whole system is examined.

Purpose

To find opportunities to decrease potential errors in the medication process (prescribing, dispensing, and transferring medicines) by using FMEA.

Material and Methods

A multidisciplinary study group was constructed for this research. The steps of prescribing, dispensing and transferring medicines were defined. Then, all possible errors throughout all these steps were identified. A risk priority number (RPN) was calculated for each defined error by multiplying the severity, occurrence and detection. The riskiness of the processes was calculated by adding the RPNs of all possible errors in that process. The severity of possible errors was evaluated by the committee according to the possible hazard it might result in. For instance, lack of dosage information is an error, which might result in different problems with different severity levels. If it results in treatment with wrong dosage, it has a severity level of 8. If it is detected, it only results in a delay until the correct dosage is learned, then the severity level will only be 5. The frequencies of these errors were calculated using occurrence statistics, which had been collected since 2007. Next, the errors were ranked according to their RPNs to observe the more worrying errors, and the reasons behind these errors were examined.

Results

Using the results of these calculations, an improvement plan and solutions to these problems were developed. The changes in RPNs in the redesigned processes were recorded and checked. The total RPN decreased from 2967 to 1495 after the FMEA project. The medication error reports of near-miss incidents have declined 43% since the start of the project.

Conclusion

The guidelines, policies and teaching of the medication management process were revised. The new quality management technique was successfully implemented by the contributions of different disciplines and the potential risk of the medication management process has fallen by 50%.

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No conflict of interest

GRP111 Medication Reconciliation: an Italian pilot project to improve patient safety at transitions of care

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Background

Many international studies have shown that medicines reconciliation is an effective strategy to reduce medication errors as patients move from one care setting to another.

Purpose

The purpose of this pilot project was to implement a comprehensive programme of medicines reconciliation (from admission to discharge) in order to increase patient safety and to improve communication at the interface between hospital and primary care.

Material and Methods

This two-year project aims to enrol 400 patients, admitted to the Internal Medicine ward of a 44-bed hospital in the Region Emilia-Romagna (Italy). A pharmacist is assigned to the project for the entire study. This pharmacist collects the medication history from multiple sources (interviews with the patient/caregiver, assessment of packages, communication with the general practitioner - GP); detects, documents and communicates any medication errors or unintentional discrepancies; participates in ward rounds and checks drug treatment during hospital stay; provides medication counselling to medical doctors and patients. All the data are collected in personalised forms and processed in a database.

Results

From July 2009 to July 2010, 341 patients were enrolled, with 268 (79%) of them interviewed within 24 hours of admission. The mean number of medicines per patient at admission was 5.9 (0-15). 75 patients (22%) at admission and 41 (12%) during hospitalisation had at least one medication error (omission, extra medicine, discrepancies in dose or frequency, change of drug). 20 cases were considered clinically important by the ward's medical staff. The pharmacist detected 40 (12%) unintentional discrepancies in the GP medical records, 53 (15%) in admission orders, 23 (7%) in inpatient prescription charts, 52 (15%) in discharge letters.

Conclusion

The analysis of preliminary data confirms that discrepancies at transitions of care are common and that medicine reconciliation performed by a pharmacist reduce the likelihood of medication errors and the potential for patient harm.

No conflict of interest

GRP112 Focus on Patient Safety: designing a check-list to improve medication reconciliation process

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Background

Admission to or discharge from hospital are critical transition points in patient care that are especially important for elderly and other high-risk patients. The aim is to develop a medicines reconciliation (MR) checklist.

Material and Methods

Exploratory qualitative exercise 18 months after the introduction of an MR programme in an Internal Medicine Short Stay Unit in a level-2 hospital.

A working group was created to do thiscomposed of pharmacists who previously documented the current state of MR. The literature was reviewed and *brainstorming* used to bring out the key points to consider during this process.

Results

Admission

- Review medical record (MeRe).
- Create a current drug history (DH) using the most recent and accurate sources.
- Interview patient/family to confirm DH against patient's home medication list (HML): dosage, frequency, route.
- Record patient's drug allergies/ adverse drug events.
- Ask for self-medication habits, homeopathy, over-the-counter medication, herbal remedies, etc.
- Consult primary care physician, CPOE (Turriano®) or nursing home.
- Confirm drugs dispensed from hospital pharmacy department using Medicines Management Software (Farhos®, Dipex®).
- Update the MeRe with DH collected and submit to physician.
- Compare medicines prescribed in hospital with accurate DH, making pharmacotherapeutic recommendations.
- Require a physician to review MeRe: continue or stop HML depending on the new clinical situation of the patient.
- Enter the HML into Infowin® (management software for drug information).

Discharge

- Physician must revise the HML and update it as appropriate.
- After physician has prescribed the discharge medicines, the pharmacist prints out a Discharge Medicines Form using Infowin®.
- The pharmacist reviews the medicines with the patient/family, explaining what is on the form.
- A copy of the discharge prescription is placed in MeRe

Conclusion

MR policies are effective in improving patient safety. The finalised checklist is a comprehensive tool and we consider it necessary for optimal MR.

No conflict of interest

GRP113 Out of hours Pharmaceutical care in a third level Hospital

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Purpose

To evaluate and classify calls received on the on-call pager between 10 p.m. and 8 a.m.

Material and Methods

Three-month prospective study on in-patient drug-related queries during the night.

A data collection form was created, stating: time and date, ward, caller details, reason for the call, level of emergency (high, medium or low) and answer to the problem.

Results

A total of 77 calls were received, 19 of which were made by a clinician and 58 by the on-call supervising nurse.

The allocation by wards was: pneumology 12 calls (15.6%), paediatrics 12 (15.6%), A&E 11 (14.3%), internal medicine 6 (7.8%), intensive care units 6 (7.8%), haematology 4 (5.2%), general surgery 4 (5.2%), traumatology 3 (3.9%), cardiology 3 (3.9%), paediatric ICU 3 (3.9%), neurology 3 (3.9%), nephrology 2 (2.6%), gastroenterology 2 (2.6%), gynaecology 2 (2.6%) and 1 call (5.2%) each of the following wards: urology, otolaryngology, neurosurgery and post-surgery reanimation unit.

The emergency level was high for 26 (33.7%) calls, medium for 34 (44.1%) and low for 17 (22%) calls. The degree of emergency was defined depending on the drug involved, risk to the patient and the physician's question. Drugs involved were: antimicrobials (35), blood products (7), anti-epileptics (4), antidotes (3) and others (27). The queries that resulted in the calls were: 75.3% (58) on dispensing, 9% (7) about drug information, 7.7% (6) on product

location within Pharmacy Department, 6.5% (5) for help with extemporaneous preparation and 1.3% (1) drug intoxications.

The queries were resolved satisfactorily with 100% acceptance by the clinicians.

Conclusion

A high percentage of emergency calls (33.7%) justifies the continuous physical presence of a pharmacist to resolve drugrelated issues, so that drugs can be used correctly and safely.

No conflict of interest

GRP114 Evaluation of antineoplastic drugs prescriptions and the risk factors related to medication errors

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Background

The prescription is the first step in the drug use sequence and is recognised as an important contributor to the global problem of medication errors. The prevalence of medication errors associated with antineoplastic drugs is not precisely known, but any mistakes in the use of these drugs consistently produces serious adverse effects in patients. The aim of this study was to evaluate the prescription of antineoplastic drugs and prescription risk factors related to medication errors.

Material and Methods

In April 2007, a cross-sectional and descriptive study was conducted in a university hospital. Prescriptions for 100 cytostatic drugs were studied and 11 variables were analysed: use of trade name, use of acronyms or abbreviations, anthropometric data (weight, height, body surface area), dosage, clinical protocol, route of administration, electronic or manual prescription, identification of the prescriber and clinical stage.

Results

The total number of errors found was 377. Among those errors, 6 were potentially serious: in 3 cases the dosage was 25% too high and in another 3 cases the dosage was 25% too low. There was a lot of missing information on the prescriptions, such as: anthropometric data: weight (80%), height (80%) and body surface area (65%); route of administration (3%); clinical protocol (38%); prescriber's identification (22%) and clinical stage (44%). In the prescriptions, the brand name was present in 37%, acronyms and abbreviations in 2% and 54% were manual prescriptions; these represented 59.2% of total errors found.

Conclusion

The most frequent error was lack of information, making it more difficult for the pharmaceutical team to validate the prescription, jeopardising patient safety.

The results reinforced with the team the importance of a clear, complete and accurate prescription, along with the need to implement an electronic prescription system for antineoplastic drugs; this is currently under development.

GRP115 Progressive multifocal leukoencephalopathy in a patient treated with natalizumab. Clinical case report

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Background and purpose

A case of progressive multifocal leukoencephalopathy (PML) occurred in a patient treated with natalizumab. The efficacy of the treatment with cidofovir and mefloquine was evaluated.

Material and methods

The patient's clinical history including the pharmacology and the clinical monitoring of the entire illness was reviewed. An exhaustive literature search was made of the treatment of PML and the relation between natalizumab and PML.

Results

In 1996, a 49-year-old woman was diagnosed with recurrent/relapsing multiple sclerosis. In February 2008, after several unsuccessful treatments (including an autologic medullary transplant), she started treatment with natalizumab (300 mg/month). Despite this treatment, she continued to have serious ataxia and dysarthria. In April 2009, in a check-up magnetic resonance image (MRI) scan, major damage was discovered in the frontal region suggesting PML. The results were positive for PML diagnosis after a confirmed PCR for JC virus DNA. Two months later, it is decided to suspend the natalizumab as a possible cause of the PML developing. The relation between natalizumab and PML was classified by Naranjo's algorithm as "possible".

In August 2009, although its efficacy had not been proved, treatment with cidofovir was initiated, which promised better control of viral replication. In September 2009, as no improvement had been seen, it was decided to start treatment with mefloquine (250 mg/day for 3 days, followed by 250 mg/week for six months). The patient's clinical progress was favourable, as confirmed in the last MRI scan, in March 2010.

Conclusion

PML is an adverse effect associated with the treatment of natalizumab. In 2010, "The Spanish drugs and health products agency" notified the high risk of PML developing after two years of treatment with natalizumab. At present, though mefloquine is being studied as an important therapeutic alternative, no treatment has proven efficacy against PML. Finally, there is undoubtedly an urgent need to monitor the adverse effects of recently marketed drugs.

No conflict of interest

GRP116 Pharmaceutical Care in Bone Marrow Transplantation (BMT) at Sultan Qaboos University Hospital (SQUH)

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Background

The Bone Marrow Transplant (BMT) centre in Oman was opened at SQUH in 1995 as a single-bed unit expanded to 4 beds in 2008. So far 180 patients have had a transplant for leukaemia and a variety of hereditary disorders. Allogeneic transplantation from matched siblings is the most common type.

Given the complexity of pharmacotherapy, BMT patients represent a population at a high risk of drug-related problems. Few studies have described pharmaceutical care issues and interventions of a clinical pharmacist in a BMT unit [1] and to our knowledge; no such studies had been conducted in our region.

Purpose

To evaluate the pharmacist's interventions in a combined adult and paediatric BMT unit.

Material and Methods

Clinical interventions were compiled over 30 non-consecutive days using the Clinical Pharmacy Intervention Form. Data concerning patients, drugs, types of interventions, outcomes and the clinical significance were compiled.

Results

Over the 30-day period, 82 interventions were noted. The interventions were mainly for drug regimen (40%) followed by monitoring (30%), drug choice (12%) and patient counselling (10%). Antineoplastics and immunosuppressants were the drug class with highest number of interventions (39%). 90% of the interventions were accepted without any change. In 40% of interventions the drug efficacy was improved and in 23% the toxicity risk was avoided. These interventions were of major clinical significance in 10% and of moderate significance in 25%. One of the key interventions was the preparation of a drug manual for all routinely prescribed drugs with patient-specific calculated doses, volumes to be measured and minimum volume dilutions. This had clear advantages for prescribers, nursing staff and patients.

Conclusion

Clinical pharmacists' interventions data are useful to describe pharmaceutical care issues and are comparable to those reported in other studies.

References:

Port-Labarthe et al: Pharmaceutical care in an inpatient pediatric hematopoietic stem cell transplant service. J Oncol Pharm Practice 2008:14: 147-152

No conflict of interest

GRP117 Implementation of a process to improve the system of distribution of drugs in Unit Dose Area

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Background

In the transcription process, many discrepancies occur between the Pharmacy Service (PS) and the ward.

Purpose

To analyse the discrepancies between drugs prescribed and the transcriptions of the prescriptions to the computer system in PS and the nurses' transcriptions on the wards.

Material and Methods

A prospective study, in a hospital of 485 beds, 400 of which use a unit dose drug distribution system (UDDDS). First, the nursing staff transcribe prescriptions into the Farmasyst computer program in the PS. Later, a printed copy of the patient's current treatment is checked on the ward with the nurse transcription, in her dispensing record. This is done in the afternoon, three times a week, for all patients admitted to the different wards in the UDDDS. Possible causes of discrepancies are classified as: P (prescription missing in PS), C (prescription correct but different dose administration regimen), F (PS transcription error) and HU (transcription error in the ward). The errors identified are resolved during this check.

Results

From April 2009 to April 2010, we reviewed 91881 treatments for a total of 14941 hospitalised patients (6.15 different drugs per patient).

The total discrepancies were 7461 (8.12% of the treatments reviewed): 1645 type P (1.79%), 3947 type F (4.30%), 936 type C (1.02%) and 933 type HU (1.02%). After evaluation, any errors were rectified in the PS and the ward.

Conclusion

The use of a system to detect discrepancies in the transcription process in PS and the wards enables errors to be evaluated, analysed and subsequently corrected, improving the quality of the UDDDS process.

No conflict of interest

GRP118 Cisapride on pediatrics. Evaluation of safety after a pharmacovigilance alert.

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Background

Cisapride is a prokinetic drug with proven effectiveness for treatment of gastro-oesophageal reflux disease (GERD). In June 2000, the *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS) published a safety alert warning about the risk of appearance of serious ventricular arrhythmias during treatment with cisapride. From 1 January 2005, AEMPS only allows treatment with cisapride on a named patient basis for treatment of proven pathologicalGERDafter failure of other treatment options in

Purpose

To evaluate the safety of cisapride in the paediatric population being treated with it.

neonates, infants and children up to 36 months of age.

Material and Methods

Retrospective observational study in a third-level hospital (January 2005-September 2010). Information was obtained from the computerised clinical history (Clinic®) and pharmacy dispensing records. Data collected: age, sex, dose, duration of treatment, adverse events. Safety was evaluated by the appearance of cardiac arrhythmias.

Results

62 children were treated (28 girls and 34 boys), all under 36 months of age, 5 of them being considered as high-risk patients due to some previous cardiopathy.

All patients were given an electrocardiogram by the cardiology service, before the beginning of the treatment and 15 days after.

The dosage of cisapride was the same for every patient: 1.5 mg/kg/day. Daily doses were divided between alternate feeds/meals.

The average duration of treatment was 2 months.

No episodes of arrhythmia were related to cisapride.

Conclusion

Cisapride is a safe treatment for GERD in paediatric patients when the indication and monitoring plan are well established.

No conflict of interest

GRP119 Impact of a pharmaceutical intervention program in renal impairment patients with antibiotic prescription

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Background and purpose

It is estimated that nearly 30% of patients admitted to hospital have renal impairment [Glomerular Filtration Rate (GFR) < 60ml/min]. When GFR is < 50 ml/min, many antibiotics need dosage adjustment to avoid side effects and renal toxicity. The pharmacist is able to detect patients with antibiotic drugs and renal impairment. We have evaluated the impact of renal impairment in antibiotic therapy, through a pharmaceutical intervention program.

Material and Methods

From March 2009 to September 2010, we conducted a pharmaceutical intervention programme for patients with renal impairment in a 500-bed hospital. A pharmacist systematically reviewed all serum creatinine values analysed in hospital for inpatients. Estimated GFR (eGFR) was calculated for each patient by the MDRD4 formula. We studied the complete treatment (including antibiotics) in all patients hospitalised in wards with electronic prescribing with an eGFR < 50ml/min. We selected those patients who required dosage adjustment according to the eGFR. The pharmacist relayed the suggested adjustment to the physicians electronically. We calculated the impact of our intervention.

Results

A total of 1,614 interventions were performed. Nearly half of them (719, 44.5%) involved an antibiotic. In 455 of these 719 interventions (63.3%) the physician agreed with the suggested change. The table summarises the number of interventions involving antibiotics:

Drug	Nº Interventions (%)	Intervention: dose reduction	Intervention: interval extension	Total patients with the drug
Levofloxacin	301 (41.9%)	x	-	2,307
Amoxicillin/ Clavulanic acid	122 (17.0%)	x	x	2,843
Meropenem	47 (6.5%)	x	х	575
Imipenem	43 (6.0%)	x	х	524
Ciprofloxacin	39 (5.4%)	x	х	1,236
Piperacillin/ Tazobactam	33 (4.6%)	x	x	745
Others	133 (18.5%)	-	-	-
Total	718 (100%)	-	-	-

Conclusion

Antibiotics were involved in nearly half interventions. More than half of them were related to levofloxacin and amoxicillin + clavulanic acid. Pharmacy departments can contribute to optimal dose prescriptions of antibiotics in patients with renal impairment and therefore, to patient safety. Future studies should evaluate the clinical and economic impact of these intervention programmes.

No conflict of interest

GRP120 Retrospective study on adverse drug reactions in a general hospital

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Background

The benefits of drugs should outweigh any risks that they may generate. Some Adverse Reactions (ADRs) result in longer hospital stays or admission to hospital. ADRs are an important clinical problem with an unknown impact on the hospital.

Purpose

To describe and analyse ADRs that cause hospitalisation, the sociodemographic characteristics and outcomes of the patients, the drugs most frequently involved, and the action taken after ADRs are detected.

Material and Methods

Retrospective study from January 2008 to December 2009. Patients were identified by the hospital statistics centre (SC) as having had an ADR. The pharmacy department reviewed all reports on the pharmacotherapeutic history of patients provided by the SC.

Results

During the study period, 414 ADRs were reported in the hospital, affecting 215 males (51%) and 199 females (49%). The mean age was 59 yrs. There was access to the complete report for 312 (75%) patients, of whom 213 had a mean hospital stay of 14 days. The mean duration of ADRs was 11 days; 96% of ADRs were considered mild/moderate and 4% severe. Blood (35%), gastrointestinal tract (7%), skin (3%) and heart (3%) were the organs most frequently involved. The drug responsible was withdrawn in 156 patients (50%) and continued in 129 (41%). The drugs most frequently involved in an ADR were antineoplastics (53%), antimicrobials (8%), anti-inflammatories (7%), anticoagulants (6%) and antiarrhythmics (3%).

Conclusion

ADRs represent a public health problem that led to the hospital admission of 52% of these patients. The drugs most frequently involved were antineoplastics (53%); 47% of the drugs are widely prescribed in clinical practice, so greater control of treatment is required to prevent ADRs.

No conflict of interest

GRP121 Epoetins: pharmacotherapeutic monitoring patients with renal chronic disease in dialysis

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Background

In June 2008 the Health Ministry and the Spanish Medicines Agency published an alert about the risks associated with the use of epoetins, recommending that haemoglobin (Hb) levels be kept between 10-12 g/dL and that 12 g/dl not be exceeded because of safety concerns.

Purpose

We wanted to evaluate epoetin treatment of patients with chronic renal disease (CRD) having dialysis in a private centre linked with our hospital, to which we dispense drugs.

Material and Methods

Medicines for all patients with CRD in dialysis are supplied every month according to individual prescriptions. From January 2010 the prescriptions stated the last Hb value in order to monitor epoetin doses according to a protocol established between Pharmacy and Nephrology Departments.

We retrospectively studied the epoetin prescriptions and Hb values from January to September 2010 of the patients who had dialysis in the private linked centre.

Results

We studied 25 patients and recorded 225 Hb values. 92 (40.89%) of them were > 12 g/dl: in 42 cases (45.46%) the dose was lowered, in 7 cases (7.70%) epoetin was suspended and in 43 cases (46.74%) the dose was not modified. 17 cases (7.56%) had Hb values < 10 g/dl: in 9 cases (52.94%) the dose was increased, in 5 cases (29.41%) the dose was not modified (patients with anaemia in a study), in one case (5.88%) the patient received a transfusion without the dose changing, in another case the patient required a higher dose of iron and the outcome was unknown for one patient.

Conclusion

A large percentage of patients had Hb values higher than the highest value of the range according to the alert (12 g/dl). Monitoring the dose of epoetins compared with the Hb levels can improve patient safety.

No conflict of interest

GRP122 Pharmaceutical intervention is needed in patients with liver and kidney failure

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Background

Renal and/or liver failure is common in hospitalised patients and the doses of antibiotics that are eliminated by the kidney or liver have to be reduced. The aim of this study was to adapt the dosage size and interval to the renal and/or hepatic function through pharmaceutical intervention and to determine to what extent the intervention was acceptable.

Material and Methods

A prospective study was conducted from the pharmacy department of a hospital of 1100 beds between June and August 2010 through the electronic prescription programme. Patients were chosen who were prescribed antibiotics eliminated via the kidneys or liver. Inclusion criteria were: 1) Patients with creatinine levels exceeding 1.1 mg/dl and creatinine clearance (CrCl) <50 ml/min (Cockroft-Gault formula). 2) Patients with elevated liver enzymes and bilirubin during the treatment period and liver cirrhosis.

Results

in

1458 patients were identified who had been prescribed antimicrobials eliminated by the kidney and/or liver, of whom 1327 (91%) had renal impairment (RI) and 131 (9%) had hepatic impairment (HI). It was noted that 160 (12%) patients were receiving too much medicine because they had RI while 5 (4%) were having too much because of HI. Of all patients RI recommendations were made in 61 (38%) patients, of which 36 (22%) requested dose reductions, 23 (14%) requested increasing the interval between doses, 2 (1%) both and 6 (4%) requested withdrawal/substitution of the antimicrobial. In patients with HI, we requested only 1 change in the medicine (20%), the withdrawal/substitution of the antimicrobial. Of all the recommendations, 35 (57%) were accepted in patients with RI and 1 (100%) in patients with HI.

Conclusion

Although the number of patients requiring a pharmaceutical intervention for a drug for renal elimination was greater than that of hepatic elimination, the percentage of interventions in the latter is high enough to warrant a daily review by the hospital pharmacists.

No conflict of interest

GRP123 Do the potencially innapropriated prescriptions have a higher risk of causing adverse drug reactions in elderly patients?

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Background

Potentially inappropriate medicines (PIM), drugs or doses not recommended for elderly patients, interactions and unsuitable dosages can lead to adverse drug reactions (ADRs). However, most ADRs occur in patients who are prescribed treatment within the limits of accepted clinical practice. Our objectives were to describe hospital admissions due to ADRs among older people and analyse whether the main suspect drugs (SD) were being prescribed inappropriately (PIM).

Material and Methods

Descriptive, retrospective study over 3-year period (2007-2009) in a 400-bed hospital. Source: Pharmacy Department Database (Access) of ADRs coded at the time of the discharge report. Date

collected: age, sex, clinical unit (CU), SD, therapeutic group (ATC Classification), clinical manifestation [System Organ Class (SOC)]. PIM evaluation: Beers' Criteria (BC).

Results

518 ADRs that required hospitalisation were recorded, 422 of them in patients \geq 65 years. Dismissing 33 ADRs due to lack of information, we included 389 patients (55.3% female, 79 \pm 6.8 years). Major CUs: Internal Medicine (75.6%), Cardiology (6.9%), Digestive (4.4%), Oncology (3.6%). Frequent therapeutic groups were: oral anticoagulants [OA] (19%), antineoplastics (10.8%), NSAIDs (9.5%), antibiotics (8.5%), digitalis (9%), antidiabetic agents [AA] (5.7%), diuretics (5.7%). The most frequent ADRs were from the following SOCs: metabolism and nutrition disorders (12.3%), blood and lymphatic system disorders (11.1%), gastrointestinal disorders (9.5%), cardiac disorders (5.7%), infections and infestations (33%).

Finally, it was found that 18. 8% of SDs were included in BC. Nevertheless, in a considerable number of them, such as digoxin, benzodiazepines, etc. we could not assess whether the patient had been given a PIM because the exact posology/drug/kind of NSAID was not specified. So, only 27 prescriptions were confirmed PIM: for amiodarone (10), diclofenac (10), digoxin (5), ketorolac (1) and alprazolam (1).

Conclusion

This study showed that many PIMs had a much smaller risk of causing ADRs at admission than other drugs, such as OAs, antineoplastics, AAs, etc., some of which were high-alert medicines that required appropriated monitoring.

No conflict of interest.

GRP124 Non conformity indicator among clinical trial related activities

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Background

According to Good Clinical Practice, a pharmacist manages investigational products (IPs) for clinical trials. In our large teaching hospital, 350 clinical trials are running, representing about 3000 items dispensed and 300 trials being monitored a year. There is a turnover of technicians who perform tasks in the clinical trials such as receiving IPs, dispensing, returning IPs and recording all stages for accountability purposes. Pharmacists are involved in all stages and monitoring. To ascertain the quality level, it is very important to evaluate non-conformity at each stage.

Purpose

To estimate the quality of recording of the various stages by monitoring, to establish a base line for continuing quality improvement and to take a stock inventory.

Material and Methods

For one month, all clinical trials monitored were included in an internal audit calculating non-conformity rates. As each was monitored, the pharmacist counted records of IPs received, dispensed and returned. Errors or missing records on accountability forms were counted. With these data, nonconformity rates were calculated at each stage.

Results

Fourteen clinical trials were monitored during the study period. For these, 299 records were listed: IPs were received 57 times, dispensed 162 times and 80 IP returns were made. Twenty one (7%) erroneous or missing records were detected: 6 (10%) concerned IPs received, 9 (5.5%) IPs dispensed, 6 (7.5%) IPs returned. No errors or missing records were noted for 7 trials (50%). Most of the erroneous or missing records concerned only 2 trials, which had complex arrangements.

Conclusion

An internal audit enabled us to measure the quality of recording and detected studies that were not being well managed, probably because of complex IP dispensing schemes. This enabled us to take corrective action during staff training. It would be interesting to plan regular audits, two months a year for example, with the aim of keeping non-conformity rates of each stage below 5%.

No conflict of interest.

GRP125 POTENTIAL INTERACTIONS BETWEEN ANTIRETROVIRAL THERAPY AND HERBAL PRODUCTS

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Background

There is increasing interest in the health risks related to the use of herbal products (HPs), which are not subject to specific health checks. Most consumers think that HPs are safe and without side effects.

Purpose

To quantify and analyse potential interactions between antiretroviral therapy (ART) and HPs in HIV patients. To ascertain patients' opinions on the effect of HPs in their treatment.

Material and Methods

A survey was made of HIV patients with ART, from 12/01/2009 to 30/01/2009, to find out which HPs patients were taking regularly or occasionally. We asked their opinion of the action of HPs and their effect on ART. To detect and investigate possible interactions between HPs and ART we consulted interaccioneshiv.com and the BOT-plus database. We recorded the interactions categorised as contraindicated/not recommended and potential interaction with clinical relevance.

Results

252 patients were included, 70.2% men, average age 44.25 (±9.04) years, 78% with viral load <50copies/mL, and median CD4 count of 480 (0-1920) cells/mm3. The most commonly used therapy was Tenofovir+Emtricitabine+Efavirenz (17.9%)and tenofovir+emtricitabine+lopinavir/ritonavir (10.3%). At least one protease inhibitor was included in 50% of the ART, an inhibitor analogue reverse transcriptase in 40.5% and both in 5.6%. 35.3% of patients were polymedicated. 49 patients (19.44%) were taking HPs; of these, 24 interactions or contraindications were found in 8 patients caused by Echinacea (9), Ginseng (8), Uncaria tomentosa (4), Hypericum perforatum (2), and Evening Primrose (1). 20.83% of interactions could reduce the effectiveness of ART and 79.17% could increase the toxicity. 57.7% of patients thought that HPs didn't have similar effects to drugs and 27.6% thought that HPs could not affect their treatment.

Conclusion

It is necessary to involve pharmacists in the overall patient treatment and for them to inform the physician about the possible interactions and educate patients about the risk of using herbal products without supervision.

GRP126 Impact of four months pharmaceutical notifications in anticancer drugs production unit

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Background

Software is helpful for prescribing, checking prescriptions and drug preparation. Pharmacists routinely check prescriptions and contact physicians. In 2010, our cytotoxic reconstitution activity increased strongly (from 20000 to 30000 units per year). In this context, we activated a specific functionality of our prescription software to systematically trace physician notifications PNs.

Purpose

To retrospectively analyse these PNs and to study their relevance and impact.

Material and Methods

We use the CHIMIO application from Computer Engineering. PNs are issued while validating prescriptions and transmitted by phone to clinicians and/or nurses. The pharmaceutical analysis concerned the patient's characteristics (weight etc.), the nature of the drug, posology, time period between courses, relevance of the prescription and the nature of the vehicle, volumes and medical devices.

These PNs concerned all our clinical departments (medical, digestive, neuro-oncology, paediatric haematology, paediatric oncology and onco-haematology).

Results

258 PNs were made in four months on 6004 analysed prescriptions (4.3%). Our interlocutors were mainly clinicians (86%), and nurses (7%). 61 protocols, both adult and paediatric, were involved in our PNs. The main problems were related to abnormal posology (P:55.0%), dilution volumes (D:16.3%), misuse of protocol (MP:8.5%), time period between courses (DC:14.7%), medical devices (MD:3.2%), chronology and duration of administration (CDA:2.3%). Our PN led to a modification of the prescription in 23.6% of the cases, with respective modifications of P:12.0%, D:58.5%, MP:45.5%, DC:5.3%, MD:50%, CDA:66.7%.

Conclusion

Our PNs led to a limited number of prescription modifications. The low level can be explained by the computerised prescription process that prevents calculation errors. Nevertheless modifications resulting from our PNs were able to prevent-treatment induced problems.

The next step will be for us to maintain this systematic NP analysis, to better identify the origin of currently observed abnormalities in prescriptions. In addition, we will evaluate more precisely the economic impact of these PNs.

No conflict of interest

GRP127 Conciliation of medication in a Traumatology Department in a tertiary hospital

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Background

Previous studies suggest that unintended medicines discrepancies that represent errors are common at the time of hospital admission. Medicines reconciliation involves comparing the patient's current list of medicines against e.g. the physician's prescriptions upon admission, transfer, and/or discharge.

Purpose

To compare the home medicines list and medicines prescribed when patients are admitted to a traumatology ward to identify and resolve possible unintended discrepancies. To assess the types of errors identified.

Material and Methods

Prospective study conducted from October 2009 to March 2010 with patients admitted to the traumatology ward. Patients over the age of 55 with at least one chronic illness in addition to the reason for hospitalisation were selected. Pharmacists reviewed the treatments 24-48 hours after hospitalisation. A pharmacotherapeutic history was compiled by collecting data from different sources (emergency admission record, nursing assessment chart, review of previous admissions, patient and / or family interview and written information provided by the patient). The physician's prescription on admission was compared with the patient's pharmacotherapeutic history.

Results

Over a six-month period, 153 patients were included (23% of all the patients admitted). The average age was 75.4 ± 9.6 years and the average number of chronic medicines was 6.7 ± 2.8 per patient. 42% (230) of discrepancies detected were not justified by the clinical condition of the patient (1.5 unjustified discrepancies/patient). Among the unjustified discrepancies, the majority were due to the omission of a drug (8.4%), followed by incomplete prescription (6.7%). 2.3% of the non-justified discrepancies were dosing, frequency or route errors. The acceptance rate of the pharmaceutical recommendation was 74.5%.

Conclusion

The high number of discrepancies identified shows that medicines reconciliation is a necessary process in clinical practice. The action of the pharmacist, as part of the multidisciplinary team, can be a useful tool to improve the safety and effectiveness of drug treatment.

No conflict of interest

GRP128 IMPLEMENTATION OF CLINICAL PHARMACY SERVICES IN THE EMERGENCY DEPARTMENT TO IMPROVE THE MEDICATION RECONCILIATION PROCESS

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Purpose

To identify drug-related problems (DRPs) in the reconciliation process, the accuracy of admission prescriptions written for our emergency department (ED) and the analysis of pharmaceutical interventions (PhI). Secondary objectives were to classify and evaluate the potential clinical impact of DRPs.

Material and Methods

Cross-sectional observational study lasting one month. A dedicated emergency medical pharmacist (Eph) recorded in a ClinDoc database Monday to Friday from 9 to 15h, the daily interventions performed in the ED.

The variables analysed included age, sex, DRPs, number and type of PhI according to the Pharmacy Services own coding. To compare means we used the Kolmogorov-Smirnov test.

Results

From 15 April to 15 May 2010,159 patients were evaluated, the mean age was 69 (16-93),53% were men. The average number of home medicines was 5.85 ± 3.84 . The average number of drugs prescribed in the ED was 6.22 ± 2.8 . 22.1% patients had at least one DRP; 22.1% had 2; 8.8% 3 and 14.5% over 3 DRPs.

Patients with \leq 10 prescriptions had a mean of 0.74 \pm 1.22 DRPs, between 10-20, 1.93 \pm 1.68 and those with >20, 3.33 \pm 2.67 (p <0.001).The clinical impact of DRPs was classified according to the Consensus of Granada: indication (75.21%), effectiveness (14.29%) and safety (10.5%).These are a modification of the four given by Cipolle et al. 238 PhI were performed in 101 patients (63.5%), representing 2.4 PhI per patient. Of these, new treatment was suggested in 38.24%, change of treatment 32.35% and dosage adjustment suggested in 19.33% were the main PhI.

Conclusion

The high prevalence of DRPs detected in the reconciliation process, as well as the resulting PhIs justify the need for pharmaceutical care in the ED.

The patients with more DRPs detected were those with the greatest number of active prescriptions, so these patients with polypharmacy should be considered as an at-risk group.

No conflict of interest

GRP129 Evaluation of hospital pharmacy-based pharmaceutical care and services

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Background

The health strategy of the Republic of Macedonia, adopted in 2007 and projected to 2020, is focused on: organisation of health protection, (quality, planning and human resources), financing and pharmaceutical services. Considering the last priority, general principles in establishing pharmacy services are defined as well as the role of pharmacists in therapeutic drug management, self-medication, health promotion and pharmacoeconomics.

Purpose

To identify the quality and standards of hospital pharmacy based on pharmaceutical care and services in the hospital pharmacies in Macedonia in respect to the Basel statements for the future of hospital pharmacy.

Material and Methods

A structured questionnaire was prepared and delivered electronically, by mail and/or directly to the pharmacists from 15 hospital pharmacies, of which 11 were central and 5 satellite pharmacies. The questionnaire was arranged in 7 sections, namely: access to patient data and role of the pharmacist in therapeutic drug management; access to drug information, availability and communication with the drug information centres; risk management and communication with the centre for adverse effects and medical errors; drug purchasing and planning; communication tools in drug ordering; staff competency, teaching, continuing education and professional development; and patient education and counselling. Questions were answered by entering one of three options: A (implemented), B (partially implemented) and C (not implemented).

Results

for the first two sections the majority of answers were B, the third section was C, fourth, fifth were A, sixth and the last one were B.

Conclusion

Good pharmacy practice and pharmaceutical care is partially implemented in the hospital pharmacies. However, the need to improve hospital pharmacy is evident, especially in the domains of staff competency, teaching and professional development, with increasing numbers of specialists needed in all fields of pharmacy.

No conflict of interest

GRP130 Survey for the detection of sound and look alike drugs included in the pharmacotherapeutic guidebook

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Purpose

To identify look-alike and sound-alike drugs (LADs /SADs), evaluate the risk of medication errors (MEs) due to this similarity and invite suggestions to avoid MEs.

Material and Methods

A survey intended for the hospital health staff distributed through the supervisors. The survey was composed of two parts, one for LADs and another for SADs. They were designed to make people aware of what drugs were easily mistaken and the actions to take to reduce the risk of MEs. Descriptive statistics were used to analyse the results.

Results

132 surveys were collected. The staff members involved were nursing staff, nurse aides/technicians and others. The wards involved were: Internal Medicine, Intensive Care Unit, Respiratory, Traumatology, Emergency, Urology, Neurology, Digestive, Paediatrics, Oncology, Pharmacy, Gynaecology, Vascular and Surgery.

The main LADs detected were: Ciprofloxacin IV G.E.S./Paracetamol IV G.E.S (7.1%), Budesonide Inh Aldo/Salbutamol Inh Aldo (4.4%), Adrenaline Braun/Atropine Braun (3.1%), Enantyum amps/Digoxin amps (3.1%), Digoxin amps/Haloperidol amps (3.1%) and Noradrenaline amps Braun/Solinitrina fuerte amps (3.1%). The highest risk of MEs was for Digoxin amps/Sinogan amps (9%).

The main SADs

were:Ceftriaxone/Cefotaxime/Cefazolin/Ceftazidime (45.1%), Lorazepam/Lormetazepam (20.59%), Prepar/Propess (4.9%), Adalat/Aldomet (3.9%) and Metamizol/Methimazole (2.9%), this one having the highest risk of ME (8.5%). Only 16 MEs reached the patient. To avoid MEs caused by LADs, 50% of those polled suggested adding colour to the boxes containing the medication (22.7%), separating these boxes or double checking (18.2%). To help distinguish SADs 67% of those polled commented that the doctor almost never included the clinical indication on the prescription.

A special bulletin was written regarding LADs and SADs.

Conclusion

The LADs/SADs included in the Pharmacotherapeutic Guidebook are potential and real causes of MEs. It is important to have an updated list of them and to take measures to avoid MEs.

No conflict of interest

GRP131 Impact of high-alert medication on the risk associated with the pharmacotherapeutic process

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Background

Risk assessment is a quality improvement strategy that quantitatively and qualitatively evaluates the likelihood of medication errors. The aim of this study was to analyse the impact of high-alert drugs on the overall risk associated with the pharmacotherapeutic process.

Material and Methods

A retrospective, observational study of drug-related problems (DRPs) recorded from January to December 2009.

Data collectedwere thenumber of DRPs, the drug involved, the

severity and likelihood of detection. All scores were set between 1 and 5 according to the <code>laser</code>© methodology. Risk was estimated through the <code>risk index</code> (RI), which provides information about the individual level risk, and the <code>risk priority number</code> (RPN), which reports on the risk at the system level. They were calculated as follows:

RI= (2 x severity) + likelihood of detection [+1 if severity>3]. RPN= RI x frequency.

Drugs were classified in two subgroups: high-alert (HA) (according to *The Institute for Safe Medication Practices*) and low-alert drugs (LA). The two groups were compared by mean values of RI and the percentage attributable risk: %AR= (RPN_{total} – RPN_{HA/LA})/ RPN_{total}

Results

889 DRPs were identified and 838 were suitable for analysis. The median values of RI and RPN were 7 (Range: 3 to 12) and 77.49 (Range: 7 to 2637), respectively. The highest RI was found for digoxin, potassium and antineoplastic drugs while the greatest RPN corresponded to antimicrobials, digoxin and other cardiac agents. The mean RI was 7.4 (7.28-7.52) for HA drugs and 6.1 (6.01- 6.19) for LA drugs. The difference was statistically significant (p<0.05). The risk attributable to HA drugs represented 27% of NPRtotal whereas LA drugs accounted for 73%.

Conclusion

There is a greater risk of harm in patients taking high-alert drugs; nevertheless, given the high rate of problems related to other drugs, risk management requires interventions at both the individual and system level.

No conflict of interest

GRP132 Safe use of hospital medication in Primary Health Care

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Background

Some medicines dispensed through Hospital Pharmacy Outpatients require subcutaneous (SC) or intramuscular (IM) administration. Many patients have difficulty in handling the medicine (rheumatoid arthritis, multiple sclerosis, elderly patients and children), or they are nervous of self- administration and consequently they go to Primary Health Care (PHC) to solve this problem.

Purpose

To provide information to nurses in PHC who are faced with unfamiliar hospital drugs and to evaluate the results of the intervention.

Material and Methods

Review of drugs dispensed with intramuscular and subcutaneous administration in our Outpatient clinics. We prepared a simple pamphlet containing photos, method of administration (SC, IM), handling (dilution, stability), indications, common posology and adverse effects immediately after administration. Information was disseminated to community pharmacies that surround our Hospital with the collaboration of the Coordinator Centre. We distributed the pamphlets and used a survey to evaluate nurses' opinions of the utility and the use of the information.

Results

We found different pharmaceutical presentations: prefilled syringes, vials, cartridges and pens. The main drugs involved were etanercept, adalimumab, darbepoetin alpha, beta epoetin, beta interferon (1a, 1b), glatiramer acetate, pegfilgrastim, filgrastim, peginterferon alpha-2a and ertapenem. The main diseases involved were rheumatoid arthritis, multiple sclerosis, hepatitis, anaemia, infections and neutropenia secondary to chemotherapy or to chronic kidney failure. The survey was conducted in 10 PHCs. It contained questions about the administration, stability and

indications of the 11 drugs. We received replies from 16 nurses. Comparing knowledge before and after, we improved it in an average of 80% of participants.

Conclusion

Work in connecting PHC and Hospital makes for safer IM and SC administration of hospital medicines. Nurses consider this information very useful for their job and it's a benefit for patients.

Technology (including: robots for production, Incompatibilities, drug production and analytics, CRS)

TCH001 Electronic prescribing and robotic dispensing: evidence of errors reduction

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Background

Sunderland Royal Hospital has approximately 1,000 beds and has operated an integrated electronic prescribing system (EP) since 2001. In September 2009, a robotic dispenser directly linked to EP was installed into the main pharmacy.

Purpose

To assess the impact of EP (Meditech) and robotic dispensing (ARX- Rowa Robots) combined. The number of dispensing errors was measured pre and post installation.

Material and Methods

The main dispensary at Sunderland issues around 800,000 items per annum. The dispensing errors were logged monthly and analysed for the cause.

Results Table 1 Month errors Jun-08 0 Jul-08 0 Aug-08 3 Sep-08 5 Oct-08 3 Nov-08 2 Dec-08 4 Jan-09 Feb-09 Mar-09 Apr-09 May-09 Jun-09

Jul-09 Aug-09

Sep-09 Oct-09

Nov-09 Dec-09 1

Jan-10 0 Feb-10 Mar-10

0 Apr-10 May-10 0 Jun-10 0 Jul-10 total 37

1.653435 1.423077 mean

Table 1 shows a spike in errors just after installation in September 2009. On analysis, these were found to be errors caused by dispensing those packs *not in the robot*. This spike was due to the disruption of the dispensary post-instillation.. Sept 2009 = date robot operational with EP

Types of error identified in DEAS (Drug Error Analysis Stu categories:

Type of error

wrong strength of correct drug supplied

wrong quantity

wrong warnings or directions

wrong drug name on the label

wrong strength on label

wrong form

wrong patient name on label

Others

Conclusion

The number of errors is small compared to the DEAS study (1). Examination of error showed all post robot installation errors were not made using EP and robot, but using EP and hand picking items from the shelves, allowing human error to occur. EP plus Robot eliminates main DEAS error types. Reliance on these systems potentially 'de-sensitises' the workforce to the risk of error for items not included in EP-robotic system.

References

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Key words: electronic prescribing, dispensing robot, error rate

No conflict of interest

TCH002 Long-term stability of esomeprazole in dextrose 5% polyolefin bags at 5 ± 3*C after freeze thaw treatment

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Background

Advance preparation of intravenous solutions could improve quality assurance, safety, time management and save drug delivery costs.

To investigate the stability of esomeprazole 0.4 mg/mL and 0.8 mg/mL in 5% dextrose in polyolefinbags after freezing, long-term storage and microwave thawing.

Material and Methods

The stability of five polyolefin bags (Viaflo, co-extruded layers of polyethylene, polyamide, polypropylene, Ph Eur compliant) containing approximately 0.4 mg/mL of esomeprazole and five other bags containing approximately 0.8 mg/mL both in 5% dextrose prepared under aseptic conditions was studied after freezing for 1 month at -20°C, thawing in a microwave oven with a validated cycle, and storage at 5±3°C. Esomeprazole concentration was measured by HPLC using a C8 reversed phase column, a mobile phase consisting of 35% acetonitrile and 65% Na₂HPO₄ buffer at pH 7.59 with H_3PO_4 (2 M) and NaOH (0.5 M), and detection with a diode array detector at 280 nm. Visual inspection, microscope observation, spectrophotometric measurements and pH measurements were also performed.

Results

No precipitation occurred in the preparations but a slight change of colour was observed. No microaggregates were observed with optical microscopy or revealed by a change of absorbance. Based on a shelf life of 90% residual potency, esomeprazole solutions (0.4 and 0.8 mg/mL) were stable for at least 30 days after freezing and microwave thawing, a period during which the 95% lower confidence limit of the concentration-time profile remained superior to 90% of the initial concentration. During this period, the pH values of drug solutions did not change.

Conclusion

Within these limits, esomeprazole (0.4 and 0.8 mg/mL) in 5% dextrose infusions may be prepared and frozen in advance by a centralized intravenous admixture service, thawed and stored at least 30 days at 5±3°C before use in clinical units.

TCH003 Long-term stability of temocillin in dextrose 5% and in sodium chloride 0.9% polyolefin bags at 5±3*C after freeze thaw treatment.

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Background

Advance preparation of intravenous solutions could improve quality assurance, security, time management and save drug delivery costs.

Purpose

To investigate the stability of a mixture of temocillin 20 mg/mL in 5% dextrose and in 0.9% sodium chloride in polyolefin bags after freezing, microwave thawing and long-term storage at 5±3°C.

Material and Methods

The stability of ten polyolefin bags (Viaflo, co-extruded layers of polyethylene, polyamide, polypropylene, Ph Eur compliant) containing 20 mg/mL of temocillin, five bags in 5% dextrose (D5) and five bags in 0.9% sodium chloride (S), prepared under aseptic conditions was studied after freezing for 1 month at -20°C, thawing in a microwave oven with a validated cycle, and storage at 5±3°C. For 30 days, temocillin concentrations were measured by HPLC using a C18 reversed phase column, a mobile phase consisting of 15% acetonitrile and 85% ammonium acetate at pH 4 with acetic acid, and detection with a diode array detector at 235 nm. Visual inspections, microscope observation, spectrophotometric and pH measurements were also performed.

Results

No precipitation occurred in the preparations but a slight change of colour was observed. No microaggregates were observed with optical microscopy or revealed by a change of absorbance. Based on a shelf life giving 90% residual potency, temocillin infusions were stable for at least 23 days in D5 and 25 days in S after freezing and microwave thawing, corresponding to the period where 95% lower confidence limit of the concentration-time profile remained above 90% of the initial concentration. During this period, the pH values of drug solutions were observed to decrease without affecting chromatographic parameters.

Conclusion

Within these limits, temocillin in D5 and in S infusions may be prepared and frozen in advance by a centralised intravenous admixture service, then thawed before use in clinical units.

No conflict of interest

TCH004 How to reasonably project in use dates? - A study of the literature

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Background

Individualised drug therapy increases the need for extemporaneous compounding. If a new formulation is prepared or a modification is made to a commercially available dosage form, the pharmacist must estimate a reasonable in-use date. Most compounding pharmacies do not have a fully equipped quality control laboratory available.

Purpose

To establish strategies and guidelines on how to predict in-use dates for extemporaneous preparations based on the available literature.

Material and Methods

A comprehensive literature search (PubMed, Google, tertiary literature) was performed on sources addressing in-use dates and stability. Additional information was obtained from the pharmaceutical industry.

Results

Relevant information on the stability of extemporaneous preparations and how to predict in-use dates was mainly derived from scientific books (n=9) and scientific journals (n=2). Thirty-six pharmaceutical companies were contacted to obtain data on commercial products (n=88), used as sources for compounding. Four different ways to assess in-use dates were identified [see refs].

The synopsis contains guidance on legal regulations, definitions, factors influencing product stability, and data on the stability of extemporaneous preparations based on the available literature. An easy-to use flowchart to assess in use dates for individually compounded products was developed.

Conclusion

A collection of relevant data on the topic of in-use dates was generated and a general strategy drawn up that enables compounding pharmacists to estimate in-use dates. This estimates the stability of preparations for the duration of their administration with a view to improving patient care and enhancing the efficiency, safety and quality of preparations compounded by pharmacists.

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No conflict of interest

TCH005 Development of a steril sodium citrate 30% solution for hemodialysis patients

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Background

Vascular access is one of the biggest problems of haemodialysis treatment. It is known that an arteriovenous fistula provides the best vascular access, but creating it is not always possible. Other solutions, such as the insertion of a central venous catheter, are then required. Adequate protection of such catheters by filling between dialyses with locking solution affects the frequency of haemodialysis-related complications. The frequency of infection is statistically reduced when 30% sodium citrate is used to fill the catheter. Sodium citrate has antibacterial and anticoagulant properties that are confined to the catheter when used as a catheter lock. Studies of its use as a catheter lock have suggested that it is effective in preventing infection and bleeding complications.

Purpose

To find suitable conditions for the small scale production of sterile sodium citrate 30% solution.

Material and Methods

A literature search was made and the monographs obtained were examined practically.

Results

The plan of the process finally adopted included three steps: one strictly dedicated to preparing the solution and the other two to the physical chemistry quality control of the raw material (sodium citrate) and the final product (sterile solution of sodium citrate 30%). The formulation must be prepared in a LF cabinet, using aseptic techniques plus sterile filtration to filter to the sterile primary packaging. The solution is sterilised by autoclaving. The final solution is then submitted to quality control, for which a set of selected assays was defined that ensure that both raw material and final product are of assured quality.

Conclusion

It was possible to meet this challenge and create the conditions to start the small scale productions of our first batch of this formulation: a sterile solution of sodium citrate 30%. A preliminary validation process is in progress to ensure the physical chemistry stability as well as microbiological control of a pilot batch.

No conflict of interest

TCH006 Measure of chemical cross-contamination during the preparation of injectable cytotoxics

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Background

The chemical contamination of injectable cytotoxics during their preparation is an issue for healthcare workers. Cross-contamination between consecutive preparations is poorly studied but may potentially affect the patient.

Purpose

To evaluate the spread of contamination during the preparation of injectable cytotoxics from the surface of vials to the surface or the interior of the infusion bags (external contamination) from the interior of a vial to the surface of the final preparation (internal contamination)

Material and Methods

Quinine dihydrochloride (QdHCI) was used as a tracer and analysed by spectrofluorimetry.

External contamination:

- Content of each vial transferred with a needle to an infusion bag.
- Contaminated vials (immersed in 0.25M QdHCl solution, burden: 7mg/vial) and non-contaminated vials were used.
- Cross-contamination: two successive preparations (n=10): the first one was performed with a contaminated and the second with a non-contaminated vial.
- Accumulation of the contamination: ten successive preparations with contaminated vials.
- Analysed items: surface and content of bags and gloves. *Internal contamination*:
- Vials containing 200 mg of QdHCl, reconstituted with 5 mL of WFl.
- Contents of 10 vials transferred to 10 bags.
- Accumulation: contents of 3 vials transferred to a bag (10 \times consecutively).
- Analysed items: surfaces of bags and gloves.

Results

External contamination: no transfer of contamination inside the second bags, but on the surface of the preparations bags without quinine (38 mg \pm 21). The accumulation was only observed on the preparation gloves (193 μ g).

Internal contamination: absence of QdHCl on the surface of the final preparations and low rates on the gloves (26 µg±31). No

accumulation observed on the bags, but on the preparation gloves (12 μ g).

Conclusion

Cross contamination exists during the preparation of injectable cytotoxics, but without evidence of any transfer inside the second bags. The accumulation on the preparation gloves demonstrates that the cleaning procedures must be improved.

No conflict of interest

TCH007 PREPARATION OF BRILLIANT BLUE G 0,05% FOR STAINING THE INTERNAL LIMITING MEMBRANE AND TO FACILITATE ITS EXTRACTION IN INTRAVITREAL SURGERY

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Background

Due to the amount of macular surgeries carried out nowadays it is important to develop new formulations with stains less toxic to dye the internal limiting membrane. We propose the development of a formulation with a dye (Brilliant Blue G 0,05%) which is less toxic than others stains used nowadays. This dye allowes color to stay for few seconds in the internal limiting membrane (MLI) and to falicitate handiling.

Material and Methods

Brilliant Blue G-250 mg; NaCl 0.9% c.s.p. 500 ml.

Method of preparation: 250 mg of Brilliant blue G are weighed in sterile glass and dissolved in 50 ml of NaCl 0.9%. Volume is risen up with NaCl 0.9% in a 500 ml flask. Final concentration is 0.5 mg / ml. The solution is filtered by a Millipore filter 0.22 μ m into a 1 ml syringe. Only 0.5 ml are dispensed in one syringe.

Microbiological controls are done to check any relevant microbiological contamination.

Results

We were able to develop a formula useful in eye surgery that provides a better staining, it facilitates macular level visibility for optimal handling of the internal limiting membrane, in addition it has a lower toxicity than other dies.

Conclusion

Staining with Brilliant Blue G is shown as an interesting alternative to macular surgery and it is better, in terms of resolution, than other alternatives such as indocyanine green or blue tripan.

No conflict of interest

TCH008 Microbiological and physicochemical validation of stock solutions of ganciclovir in paediatric patients

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Background

Because of its mutagenic properties, preparation of ganciclovir is centralised in the pharmacy department. In a paediatric hospital, syringes are used more than bags in order to reduce fluid intake for patients. Syringe compounding takes longer than bag compounding.

Purpose

To reduce the compounding time of ganciclovir by using stock solutions. Our purpose was to validate our process using microbiological and physicochemical assays.

Material and Methods

Stock solutions of 1 and 5 mg/mL were reconstituted in polypropylene bags of 5% dextrose in water or 0.9% sodium chloride and coupled to a secure connection bidirectional system.

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From a microbiological point of view, (1. A) a sterility test and (1. B) mediafill test were performed. All admixtures were incubated and checked for bacterial growth.

The physicochemical validation was carried out using (2. A) a visual inspection at each sampling, (2. B) degradation content controls, a forced degradation test (2. C) content determination with a previously validated HPLC-UV method.

Results

- (1. A) The sterility test was not contributive: ganciclovir is bacteriostatic thus no growth was detected after seeding. (1. B) Our process passed the media fill test.
- (2. A) Visually, all samples were clear, no precipitate appeared. (2. B) After forced degradation with HCl, a reduction in the peak area was observed and a new peak was detected (revealing an unknown product).
- (2. C) During content control, 100% of the samples showed less than 10% loss of ganciclovir after 3 months.

Conclusion

The growth control and sterility were inconclusive, the media fill test proved the quality of the aseptic manufacturing process and multiple sampling. Physicochemical stability was proven for up to 3 months. This protocol is applied in our hospital and a pharmacoeconomic study (workload and material cost) will be performed.

No conflict of interest

TCH009 Implementation of software for non-sterile compounding in a pharmacy service

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Background

New software for the management of non-sterile compounding was implemented to comply with current Spanish regulations

Purpose

To describe and evaluate the implementation of Compliance and IT Services Formulation Management and Weighing Cabinet (CITS Form) for non-sterile compounding.

Material and Method

The CITS Form includes:

- Databases: raw materials and packaging (type and description), non-sterile individual and batch-prepared formulations (SOPs).
- Raw materials and packaging management tools: origin, stocks, batches, check-out, shelf-life, batch status. Barcode labels identify raw materials taken away.
- Reports.
- Formula planning: compounding materials and methods are described in the SOPs. A precision scale connected to the software provides automatic verification of the correct dosage within established safety limits. Formulation components are identified by barcode scanning. Automatically, once all components have been weighed, a certificate is edited and printed. Finally, to achieve total traceability, the formula identifying label displays all relevant data including a registry number. All steps and who performed them are recorded. 2008 and 2009's formulation records were reviewed to evaluate the use of CITS Form. Prescriptions for non-sterile formulations were compared with their corresponding CITS Form elaboration certificates. Average preparation time was calculated comparing among application-assisted and traditional formulations.

Results

The software contains 147 raw materials and 75 SOPs.

Non-sterile formulations prepared in 2008 and 2009 were 759 and 870 respectively. In 2009 CITS Form assisted preparations accounted for 70.9% of the total compared to 67.7 % in 2008, being

mostly liquids (98.5%). Only 1.3% were semi-solids and 0.2%, solids.

No discrepancies were found between the prescriptions and the elaboration certificates.

Mean preparation time per formulation increased by 3.8 minutes (13.3 vs. 9.5 min)

Conclusion

The CITs form improves safety of non-sterile compounding, minimising human error, thus guaranteeing that the final preparation and the original prescription match and the final composition is within the established limits.

- The CITs form allows monitoring and recording of all the activities, ensuring traceability through thorough documentation of the entire process.
- The CITs form's main drawback is the longer preparation time required.

No conflict of interest

TCH010 Boric acid vaginal capsules for triazole-resistant Candida vulvovaginitis: a case report

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Background

Approximately 50% of the vulvovaginitis produced by *Candida glabrata* do not respond to triazoles. As an alternative treatment, boric acid for vaginal administration has an estimated effectiveness of 65-70%.

Purpose

We describe the preparation, quality controls, adverse effects, storage conditions, recommended posology, effectiveness and tolerance of these vaginal capsules.

Material and Methods

Our patient was a 44 year old woman with vulvar pruritus and history of recurrent vulvovaginal candidiasis that did not respond to triazole treatment. Fluconazole and itraconazole-resistant *C. glabrata* was found in vaginal discharge. The gynaecologist requested our service for the preparation of boric acid vaginal capsules. This formulation must be elaborated in the pharmacy service because it is not commercially available.

Results

Boric acid powder was over-encapsulated into empty, hard gelatine capsules (size 00). Each capsule contained 600 mg boric acid (with an added 2% loss) and lactose as excipient until final volume 0,94 mL each. After the formulation, a sample of 20 capsules was used for the control weighing. The recommended intravaginal dose was 600 mg at night for 14 days and, if recurrence, continue the treatment with one capsule two days a week. The capsules were dispensed with an information leaflet including: composition (active ingredient and excipients), posology, duration of treatment, route, method of administration, adverse effects (vaginal burning, erythema), storage conditions (at room temperature, protected from light) and expiration date (one year).

Our patient had a good tolerance to this formulation and the symptoms were totally resolved. After 9 months *C. glabrata* was isolated in vaginal discharge so the treatment was repeated. One year later no more infection recurrence has been notified.

Conclusion

Intravaginal boric acid capsules were well tolerated with satisfactory clinical outcome. Although it is not considered first-line therapy, it may be an alternative for vulvovaginitis due to triazole-resistant *C. qlabrata*.

TCH011 Assessing cross-contamination and air contamination in a robotic IV compounder

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Background and Purpose

The Robotic IV Automation robot (RIVA™) is an ISO 5 primary engineering control for sterile compounding passing all applicable engineering control certification requirements including Canadian Good Manufacturing Practices Guidelines. This study examines drug cross-contamination of preparations compounded in RIVA™ to validate that drug A is not found in doses of drug B. Air contamination generated during compounding was also examined to determine worker exposure while interacting with RIVA™.

Material and Methods

Due to its low level of detection in solution and air, Naproxen sodium (NAPna), packaged as 1gm power vials, was compounded. A robust compounding protocol was undertaken to include reconstitution; fluid transfer to syringes; multiple vial punctures and concentration-specific, exact-volume bags. RIVA™ compounded for 23.5hrs divided over 3 days. Doses of NAPna were compounded simultaneously or sequentially with doses of normal saline (NS). During compounding, NS was transferred from infusion bags to empty vials, by RIVA™ to duplicate the NAPna process more precisely. RIVA™ compounded 5ml syringes containing 4.5ml of NAPna or NS; 45ml in 60ml syringes; and 55ml in 275ml exactvolume bags. The contents of the NS doses were analyzed for cross-contamination. Air sampling of personnel and the RIVA™ cell was also done. All samples were analyzed by an independent laboratory using HPLC with an NAPna level of detection of 0.020ng/ml. Compounding was conducted at Intelligent Hospital Systems, Winnipeg, Canada.

Results

No NAPna was detected in any NS doses: 30/30 5ml syringes; 24/24 60ml syringes and 12/12 275ml bags. All air samples taken from the cell (8/8) and from personnel (6/6) were below the target of $1ng/m^3$

Conclusion

RIVA $^{\text{TM}}$ can compound multiple ingredients concurrently with no cross-contamination. Air samples demonstrate no potential worker exposure due to inhalation during RIVA $^{\text{TM}}$ compounding. Study results show RIVA $^{\text{TM}}$ is an effective tool in compounding sterile preparations.

Conflict of interest: yes; Advisory board:: Author Power is a member of the IHS Scientific Advisory Board and a consultant to IHS. The financial relationship is not related to sales of product. Authors Erickson and Mlodzinski are employees of IHS.

TCH012 Assessing drug residue in a robotic IV compounder L. Power, B. Erickson, T. Doherty

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Background

Studies have documented drug residue on surfaces following manual sterile compounding. Reduced surface contamination should result in lower incidents of worker exposure. The Robotic IV Automation robot (RIVA $^{\text{TM}}$) is an ISO 5 primary engineering control for sterile compounding passing all applicable engineering control

certification requirements including Canadian Good Manufacturing Practices Guidelines. This study was conducted to evaluate surface contamination generated by RIVATM during compounding.

Material and Methods

Naproxen sodium (NAPna), a non-potent active pharmaceutical ingredient, was compounded as it behaves aggressively as a powder; is water soluble and can be detected at low levels. NAPna, packaged as 1gm powder vials, was diluted to 20mg/ml. A robust compounding protocol was devised to include RIVA™ functions: reconstitution; fluid transfer to syringes or bags; multiple vial punctures and concentration-specific bags of exact volume. RIVA™ compounded for 23.5hrs over 3 days. Seventy-five grams of NAPna were loaded, compounded and disposed of.

Surface wipe sampling was done on bags, syringes, and specific areas in the RIVA™ to recover NAPna residue. All samples were analyzed by an independent laboratory using HPLC with a NAPna level of detection of 0.000078 ng/cm². Compounding was conducted at Intelligent Hospital Systems, Winnipeg, Canada.

Results

NAPna doses	900mg/1liter bags	90mg/5ml syringes	900mg/60ml syringes	1100mg/275ml bags
Sampled	24	8	24	12
Above target	1*	none	none	none

Target: 1 ng/cm² *1.28 ng/cm²

RIVA areas	Floor	Sub-systems	Outp
Sampled	34	65	
Above target	none	3	r

^{**} included in total sub-system samples

Conclusion

Limited residue was detected on surfaces during robust compounding by RIVA $^{\text{TM}}$ of 75grams of NAPna. Some studies of manual compounding of less than 40grams of drug have reported levels of 10-40 ng/cm² on surfaces. RIVA $^{\text{TM}}$ is superior to manual compounding in reducing surface contamination.

Conflict of interest: yes; Advisory board:: Author Power is a member of the IHS Scientific Advisory Board and a consultant to IHS. The financial relationship is not related to sales of product. Authors Erickson and Doherty are employees of IHS.

TCH014 Set up and validate a method to measure the plasmatic concentration of ribavirin by chromatography liquid high performance (CLHP)

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Background

Ribavirin is an antiviral used for chronically infected hepatitis C patients. But its use is limited by its haematological toxicity. It results in anaemia which is reversible when the treatment is discontinued. The ribavirin plasmatic concentration is strongly correlated to the patients's viral response to the drug and to its haematological toxicity.

Purpose

The purpose of the study was to set up and validate a method to measure ribavirin plasmatic concentration by chromatography liquid high performance (CLHP) after a solid-liquid extraction (S/L). We aim to use this method for the follow-up of hepatitis C patients receiving ribavirin treatment.

Material and Methods

The method developed uses a solid-liquid extraction on phenyl boronic acid columns followed by a CLHP using a C18 column and a liquid phase composed of phosphate buffer (10mM, pH 2.5) and a UV detection at 210 nm.

Results

The fidelity, accuracy and linearity of this method have been validated. In terms of specificity, we have proven that the use of other antiretroviral drugs in association with ribavirin (for HIV and Hepatitis C co-infected patients) does not cause any interference to the measurement of ribavirin concentration.

Conclusion

Our method can be used for the treatment follow-up of patients treated with ribavirin. It has two advantages in comparison to previously published studies : a low threshold detectable concentration 75ng/ml vs 200ng/ml and a low sample volume 500 μL vs 1000 μL .

No conflict of interest

TCH015 Anticancer drugs handling: A Training program for linstitut Salah AzaÔz staff

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Background

The handling of anticancer drugs is a high risk procedure for the patient and the manipulator. Therefore, it has to be performed by a trained and qualified staff. The aim of this study is to initiate an appropriate staff training program for the preparation of anticancer drug in the cytotoxic centralized preparation unit (CCPU), Institute Salah Azaiz (ISA).

Material and Methods

The training was carried out at the CCPU by the pharmacist, and concerned the staff assigned to this unit. First was a theoretical training that was validated by an exam. The second stage involved a practical training on the work bench and the third stage was a practical training carried out in the isolator. Any transition from one stage to the other had to be assessed and approved by the pharmacist in charge. In each stage of the practical training, anticancer drugs were simulated by a solvent. The manipulator has been evaluated using a dye: methylene blue. The ability of staff to achieve an aseptic preparation was evaluated by the Media Fill Test. A standard protocol was developed by the pharmacist. After performing the last practical stage, liquid culture media were incubated at 35°C for 14 days. This test was performed three consecutive days for each manipulator.

Results

Each technician passed successfully every test. No microbiological growth was observed in culture broths within 14 days. Using an internal protocol for Media Fill Test wasn't the best way to evaluate the aseptic filling but we have used this protocol because of the unavailability of Media Fill Test Kit.

Conclusion

The staff training program for anticancer drugs handling proved to be efficient as the staff achieved a good level of understanding of the risks associated with anticancer drugs and a compliance with the requirements sat up for anticancer drugs preparation according to Good Manufacuring Practice.

No conflict of interest

TCH017 Stability of 25 mg/mL azacitidine suspensions stored in polypropylene syringes at -20*C

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Background

The manufacturer of azacitidine (Vidaza®) indicates a stability of 45 minutes at room temperature and 8 hours at 2-8°C. The aim of this study was to look for a longer period of stability.

Purpose

We investigated how freezing at -20°C affects the stability of azacitidine suspension 25 mg/mL in polypropylene syringes. This could allow to prepare suspensions in advance.

Material and methods

Azacitidine was manipulated under aseptic conditions: reconstitution with sterile water for injection and preparation of syringes. The stability was studied after freezing for 8 days at -20°C, defrosting at room temperature and storage for 8 hours at 2-8°C. Samples were analysed by a stability-indicating high-performance liquid chromatographic method using a reversed-phase column, a mobile phase consisting of phosphate buffer 10 mM pH 6,5, and detection wavelenght at 200 nm. Visual inspection was also performed.

Results

No modification of suspension or coloration was visually observed in any syringes. Azacitidine concentrations were always above 95 % of the initial concentration during the study period. Three degradation products were observed at the beginning of the study. They represented approximately 5 % of the total of the peaks surfaces. At the end of the study, only one degradation product has slightly increased and no other degradation products appeared after 8 days of freezing.

Conclusion

Azacitidine suspension 25 mg/mL was stable for 8 days at -20°C. After thawing at room temperature, suspension was stable for 8 hours at 2-8°C. Azacitidine syringes can be prepared in advance.

No conflict of interest

TCH018 Contribution of microcalorimetry in the early identification of different species of Staphylococcus

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Background

Microcalorimety is an experimental technique which allows us to determine, with high sensitivity, the energy liberated during any process or transformation.

Purpose

To assessing the contribution of microcalorimetry as an early identification method for Staphylococcus species.

Material and Methods

A Calvet type microcalorimeter, which maintains a constant temperature of 37 degrees centigrade, was used.

Samples of S. aureus(ATCC 25213), S. epidermidis(ATCC 35983), S. hominis (CECT 234) and S. warneri(CECT 236) at different concentrations (10^6 , 10^5 , 10^3 and 10UFC/ml) were prepared. Half digested Soy-casein liquid culture was used as a culture

medium. A 7 ml sample of culture medium was injected into the test cell together with 1 ml of physiological saline, and 7 ml of culture medium was injected into the control cell. Both cells were placed in the microcalorimeter and left to stabilize for approximately an hour

and a half. At this time 1 ml of the test concentration was injected into the test cell.

Graphs were obtained at various concentrations for four different bacterial species representing the difference of heat potential over time. In these graphs the different phases of growth can be identified: lag, log, stationary and death. The thermograms obtained show certain characteristics that are repeated for each bacterial species at all concentrations, and which allow us to identify species in less than 15 hours. In the case of S. aureus, the most virulent species studied, signal detection time is less than for coagulasenegative species (S. epidermidis, S. hominis and S. warneri). Likewise, the plots obtained present greater intensity in the case of S. aureus.

Conclusion

Microcalorimetry allows us to measure the growth of different species of Staphylococcus by measuring the energy released during metabolism. Although it is necessary to complete the study, it seems possible to identify different species based on the characteristics of the calorimetric curves, and therefore start treatment adjusted to the sensitivities of the micro-organism in a few hours.

No conflict of interest

TCH019 Preparation guide for intravenous admixtures ready for administration with electronic ambulatory pumps

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Background

Electronic ambulatory pumps allow delivery of intravenous drug therapies in outpatient setting. This type of administration require from drug admixtures at least 24 hour stability at room temperature.

Purpose

To develop a preparation guide within hospital pharmacy service for intravenous admixtures ready to delivery through electronic ambulatory pumps.

Materials and methods

Drugs candidates were selected according the following criteria:

- Drugs requiring more than one daily dose.
- Drugs with at least 24 hour stability at room temperature.
- Drugs requiring complex handling (e.g. transfer the content of many vials into the IV bag).

A bibliographic review was performed to determine the drugs physico-chemical characteristics:

- Concentration range to guarantee a secure administration and stability of the admixture for at least 24 hours at room temperature.
- Stability of drug admixtures refrigerated.
- Compatible diluents.
- Packaging material. - Dilution osmolarity.
- Infusion time.

The preparation guide for selected drugs was developed, standarizing admixtures concentrations following dosage schedule and physico-chemichal as well as microbiological stability.

Results

The following drugs were selected to be included in the guide: acyclovir, ampicilin, ceftazidime. clindamicine, piperaciline/tazobactam, cloxaciline, vancomycin, penicilline G, tigecycline, aztreonam and human inespecific immunoglobulin. For each drug different parameters were defined: usual dose and posology, total dose, infusion time, type and volume of diluent, concentration range, osmolarity and stability at room temperature and refrigerated.

Conclusions

Through standarization and centralization in the pharmacy service we can elevate security and quality levels as well as make easier elaboration and administration processes. This guide requires a continuous actualization to include new drugs candidates to delivery through electronic ambulatory pumps.

No conflict of interest

TCH021 New technologies used to improve drug stock control by Pharmacy Department

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Background

According to current legislation, management of drug stocks in Clinical Units is responsibility of Pharmacy Department (PD), but its control becomes difficult and it usually falls on nursing staff.

To Justify the necessity of Automated medicines Dispensing Systems (ADS) in Clinical Units in a 1212 beds Hospital to provide a higher control by the PD.

Material and Methods

2 reviews in 2 consecutive years of 24 drug stocks in Clinical Units including operating rooms. Variables recorded were: order, drug identification and conservation, refrigerator, photosensitive and narcotic drugs and amount of medication. After data analysis in first revision, an action plan was carried out to improve critical points.

Results

In first and second review, we found similar negative results. With

ADS implementat		itical points could be solved:
	Negative results with traditional stocks:	with SAD implementation:
Alphabetical order of drugs	75% ordered by trademark, increased risk of errors in trademark changes	Available search by active substance and trademark, lower risk of errors.
Identification and conservation	46% are wrongly identified (cut blisters with no name neither expiration date). Expired drugs in 63% of drug stocks	Perfectly identified drugs, unit repackaged, more control in expiration date
Refrigerators	5% of thermolabile drugs not refrigerated. Drinks and food in 41% of them. Only 50% with thermometer.	All thermolabile drugs refrigerated, more control, integrated thermometer with automatic temperature recording
	Negative results with traditional stocks:	with SAD implementation:
Photosensitive drugs	80% not properly protected from light	Proper protection in closed boxes
Narcotic drugs:	Traceability not achieved in 17% of drug stocks	Traceability through electronic registration
Amount of medication	Excessive	Rationalization of resources

Conclusions

ADS are needed because they increase drug control by the PD. they minimize the risk of medication errors, improve storage drug conditions in Clinical Units and achieve a better rationalization of resources.

No conflict of interest

TCH022 Mercaptopurine suspension 10 mg/ml

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Background

Internationally, the WHO emphasizes the importance of developing new paediatric medicines. In the Netherlands, this importance is generally recognized. When industry does not provide suitable preparations, formulations should be developed for small scale compounding in public or hospital pharmacies. To this aim, the Royal Dutch Association of Pharmacists (KNMP) cooperates closely with the Special Interest Group on Paediatric Medicine of the Dutch Association of Hospital Pharmacists (NVZA). One of the developed formulations is Mercaptopurine suspension 10 mg/ml.

Purpose

Mercaptopurine is practically insoluble in water. This means that an oral, liquid preparation with mercaptopurine is only feasible as a suspension. Literature suggests that ascorbic acid should be added as anti-oxidant, to protect mercaptopurine for oxidation. The need for an anti-oxidant is doubted, because the mercaptopurine will be merely suspended and is not dissolved. A stability study has been performed on two formulations, with and without ascorbic acid. Aim of the study is to find a formulation that yields a stable suspension for at least 6 months.

Material and methods

Several batches of mercaptopurine suspension 10 mg/ml were prepared in a standard suspension base, with and without ascorbic acid. The batches, packed in PET-bottles, were kept at 25 °C for 6 months. Samples were taken at 0, 1, 3, 6 and 9 months, and were analysed for appearance, pH, viscosity, related substances and content of mercaptopurine. For the assay a stability-indicating HPLC-method was used, based on the Ph.Eur. monograph for the active ingredient.

Results and conclusion

All suspensions show stability for at least 6 months, regarding the content of mercaptopurine. The addition of ascorbic acid has no additional value. On the contrary, ascorbic acid causes a slight colouration of the suspension, while the viscosity decreases in time. This is unwanted in regard to the physical stability. It is concluded that a formulation without ascorbic acid yields the most stable suspension.

Literature

1. Am J Health Syst Pharm 65(2008): 441-7.

No conflict of interest

TCH023 Stability of 25mg/ml methotrexate solution in polyethylene syringes

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Background

Methotrexate is a folinic acid antagonist widely used to treat early diagnosed ectopic pregnancy. Methotrexate acts by stopping trophoblastic cell growth and is administered locally by a single intramuscular injection at the dose of 50 mg/m². In our hospital, as all cytotoxic drug preparations are centralised in the pharmacy

department, three standard methotrexate doses prepared in advance under aseptic conditions (75, 85 and 95 mg) are available in syringes to treat patients as quickly as possible in case of emergency.

Purpose

To determine the physical-chemical stability of the methotrexate solution repackaged in polyethylene syringes in order to set a shelf life for the preparation.

Material and Methods

Polyethylene syringes were prepared from marketed 25mg/mL MTX solution, protected from light and stored between 2 and 8°C. Methotrexate was assayed by an HPLC method with previously validated UV detection. We used a diode array detector to compare methotrexate UV absorption spectrum obtained between 220 and 500 nm, for syringes and reference solution. 18 syringes were prepared at day 0. Triplicate samples were visually inspected for colour change and were quantified by HPLC immediately after preparation and at day 8, 15, 30, 60 and 120. Methotrexate concentration at day 0 was considered as 100% and methotrexate concentration in subsequent samples greater than 90% were considered stable. Sterility testing was performed throughout the 3 month study period.

Results

During the study period, no colour change and/or precipitation were observed and all syringes tested for sterility were found sterile. All UV absorption spectra were strictly similar to the reference solution. From day 8 to 120, methotrexate concentrations were not significantly different from the reference solution and no degradation peaks appeared in samples studied. According to these results, there was no significant drug loss during storage in polyethylene syringe was shown during the study period.

Conclusion

Under our storage conditions, the 25 mg/mL methotrexate solution repackaged in polyethylene syringes was seen to be stable for at least 120 days, which enabled us to fix a shelf life of 3 month for the preparation.

No conflict of interest

TCH024 Sterile multidose Lidocaine 2 % anesthetic gel galenic preparation as a replacement of the coomercial

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Background

Facing the problem of a lack of a commercial pharmaceutical dosage form of lidocaine 2% anaesthetic gel we decided to supply hospital wards with an in-house sterile multidose 2% preparation as a replacement for the industrial commercial preparation. In fact, at the time of our decision there was (and currently is) a deficiency of licenced commercial pharmaceutical dosage forms of that product, which is widely used in most hospital wards.

Purpose

To prepare lidocaine 2% anaesthetic gel as a galenical preparation and research its microbiological and content integrity.

Material and Methods

After extensive research of the tertiary and primary literature and various online compendium formulations we developed our own composition according to our ingredients and hospital wards' needs. Ingredients used for this preparation were: powdered lidocaine HCl (Sigma-Aldrich, USA, USP), Carboxymethyl-cellulose Na, high viscosity (Sigma-Aldrich, USA, USP), Aqua sterillisata (our hospital Department for production of infusion solutions,

Ph.Eur.).We prepared the gel in the galenical laboratory in the pharmacy. Then we extemporaneously sterilised the prepared gel according Ph.Eu. 3rdEd (by autoclave sterilisation in the Department for the production of infusion solutions in our hospital) and in the same department we packed it according to pPh.Eu.3rdEd requirements, using aseptic procedures, into 10 mL sterile syringes (BD and Co. Discardit).Tests (following USP 31.Ed, Chemical tests and assays (541) regulations) of the lidocaine HCl content in this preparation were performed in the microbiological department of Centre for Public Health, Bitola. We are currently performing assays of the content of lidocaine HCl in the test samples to determine the shelf life.

Results

Analysis of the lidocaine HCl content confirmed that the preparation met the requirements (average content=19.90 mg lidocaine HCl/1 g gel). Average pH=6.7 met the requirements too. Sterility control tests also confirmed the sterility and agreement of the preparation with the pharmacopoeia requirements. The formulation of the preparation will be presented on the poster at the congress.

Conclusion

We devised our own formulation and production process for sterile multidose anaesthetic lidocaine 2% gel. To start with we prepared a small amount i.e. small series of the product, on which all tests were performed. Based on the results we produced a large quantity and packed it as a multidose preparation. The whole procedure for preparing this product was: 1. compound a suitable formulation; 2. produce the gel; 3. sterilise the gel by autoclaving; 4. pack; 5. test for content of the active substance; 6. determine pH; 7. sterility test.

Once we had done the compounding, preparation and testing, we prepared sterile multidose lidocaine 2% anaesthetic gel in the hospital pharmacy of the Clinical Hospital in Bitola and we overcame the problem of a lack of the commercial pharmaceutical dosage form in our country.

No conflict of interest

TCH025 Preparation and quality control of unpreserved Dexamethasone sodium phosphate eye drops in hospital pharmacy

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Background

Dexamethasone eye drops are used to treat eye inflammation caused by infections, injury, surgery or other conditions. All eye preparations are sterile when issued. They should be preserved and used with care to prevent contamination of contents. For some purposes, dexamethasone sodium phosphate eye drops must not contain chemical preservatives. In hospital practice, single use drops should be used whenever possible. Unpreserved drops should be stored in the refrigerator and discarded after 7 days.

When it is not possible to buy single dose eye drops they must be

When it is not possible to buy single dose eye drops, they must be prepared in the pharmacy.

Purpose

to investigate the possibility of preparing and checking the quality of multidose dexamethasone sodium phosphate eye drops without preservative.

Material and Methods

Multidose (5 mL) dexamethasone sodium phosphate eye drops 0.1 % were prepared in the hospital pharmacy, following an established procedure for ophthalmic preparations and the content of dexamethasone sodium phosphate (spectrophotometric method), pH of solution (potentiometric method) and sterility (Ph.Eur) were examined. Eye drops from the batch examined were stored in the refrigerator.

Results

According to the standard operating procedure dexamethasone sodium phosphate eye drops 0.1% were prepared, sterilised by passing through a bacteria-retentive membrane with nominal pore size 0.22 μm (Ph.Eur. 6.0, 5.1.1) under aseptic conditions, in a laminar air flow cabinet. Content, pH and sterility complied with pharmacopeia (USP 26) demands at the moment of preparation. In repeated, simulated hospital conditions, stored refrigerated at 2 to 8°C, eye drops were sterile for 30 days. The dexamethasone sodium phosphate content and pH of the eye drops also remained stable for this period.

Conclusion

With the appropriate technology and procedures, it is possible to prepare preservative-free dexamethasone sodium phosphate eye drops of the required quality in the hospital pharmacy, and they can be stored at 2 - 8°C, for 30 days.

No conflict of interest

TCH026 Incompatibility of intravenous amiodarone with a Swan-Ganz catheter

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Background

Patients in intensive care units (ICU) often receive many continuous infusions of drugs on a limited number of intravenous lines. In our ICU, one frequent combination of drugs administered together is dobutamine-norepinephrine-amiodarone (DU-NE-AM). During a 24-hour *in vitro* simulated Y-site administration of DU-NE-AM through a Swan-Ganz catheter [SGC], the measured concentration of AM at the extremity of the SGC was abnormally low until 2 hours after start and thereafter returned to normal. This phenomenon was more obvious when the administration rate was low. Based on literature data, we suspected an incompatibility of AM with the SGC, made of a mixture of PVC and plasticizer and internally coated with heparin.

Purpose

To find the cause of this low AM concentration and compare the results when administered through a SGC with or without heparin.

Material and Methods

Simulation of Y-site administration of AM (Cordarone 12.5 mg/mL in dextrose 5%) with glucose-saline (3.3% dextrose and 0.3% NaCl) at a rate of 1 mL/h each, through

1) a heparin-coated SGC

2) an uncoated SGC.

AM concentration at the end of the SGC was measured by HPLC after 2, 3 and 4 hours. It was considered as "expected" if it reached 90-110% of the theoretical concentration (6.25 mg/mL).

Results

With the uncoated SGC, the AM concentration measured was as expected. However, it took 3 hours for AM administered through the heparin-coated SGC to reach the expected concentration.

So the PVC seems to play no role, while AM seems to interact with the heparin coating the inside of the catheter.

Conclusion

Literature reports incompatibility between AM and PVC as well as heparin. Our results show that there was no significant interaction with PVC whereas the heparin contained in SGC can interact with administered drugs, such as AM. Close attention must be paid to this risk.

Drug supply / logistics (including: computer-aided drug dispatching and ward pharmacies)

DSL001 Study To Improve Quality In A Unit Dose Distribution System

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Purpose

- 1. To study the quality in a Unit Dose Distribution System (UDDS) by examining Medicines Claims (MCs) received from the wards.
- 2. To detect the weak points of the UDDS and suggest strategies for improvement.

Material and Methods

A prospective, observational study, of one month's duration, was undertaken (October 2009) in a General Hospital with 717 functioning beds. A total 1,699 patients were included in the study. They were hospitalised in 542 beds with UDDS spread over 15 wards (Cardiology, Heart Surgery, Gastroenterology/Internal Medicine, General Surgery, Urology, Neurology, Neurosurgery, Traumatology, Vascular Surgery, and Infectology). The pharmacists classified, checked and recorded the MCs. Pharmacists met up with ward sisters to improve and check distribution systems and timetables. Manuals were given out with the information.

Results

1,048 MCs were received at the hospital pharmacy department. The averages were: 33.0 MCs/day, and 1.93 MCs/bed.

72.324 medication lines were transcribed and 137.933 units of medicine were dispensed. On the wards with traditional UDDS, 1.917 Traditional Medications Orders (TMOs) were transcribed. An average of 0.166 MCs/TMOs were transcribed. On the wards with UDDS, with Computerised Medical Orders (CMOs), 9,450 CMOs were transcribed. An average of 0.077 MCs/CMO were transcribed.

MCs by category

Already sent/wrong medicine, in the medication trolley	48%
Ward stock medicine	24%
Medicine omitted at MO	14%
Medicine substituted for by a therapeutic equivalent	7%
Medicine contributed by the patient	4%
Medicine for a patient for which no MO was received the pharmacy	at _{1%}
Medicine prescribed as "if needed"	1%
Error interpreting the MO by nursing staff	0%

Conclusion

The analysis of the MCs enabled medication errors to be detected and prevented, making better patient security possible. The quality control development team has enabled the following improvement actions to be planed: Daily medicines trolley revisions, Get better communication with the people working on the ward. Introduce new technologies

No conflict of interest

DSL002 Development of a validated managing model for pharmaceutical products management

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Background

In the present Italian background, which is of debates regarding National Health System inefficiencies, waste, clinical risk and clinical governance, it is very important to balance patients' requirements with the health services budgets by remembering to monitor processes involving pharmaceutical products (prescription, storage, distribution, administration). In 2009 ASP Messina attempted to improve professional and management awareness of the need to manage pharmaceuticals in a safer, cheaper and more suitable way, thus encouraging a dialogue and the involvement of

hospital and territory stakeholders. To do this, the management model was externally validated and ISO 9001:2008 certificated by Bureau Veritas. *ASP Messina* was supported by *OPT* S.r.l., with the unconditional support of *Novartis*, to manage this activity.

Purpose

To report how ASP Messina achieved its goal.

Material and methods

After 2 months of training, monthly meetings followed to obtain both optimal operation of services and processes. For each process, critical situations, ways of improvement, pointers and quality standards were analysed. The model is now verified by internal human resources, trained under *OPT* supervision.

Results

Since the beginning of this project, the results obtained were the use of shared rules for hospital and territorial pharmacists and the design of shared methods and tools for good management of pharmaceuticals by the users (single treatment sheet, ward handbook of commonly used pharmaceuticals, rules for the good management of supplies). Furthermore, the project effectively linked the *Dipartimento del Farmaco* to the *ASP* General Management to improve the allocation of resources.

Conclusion

The creation of an easy, measurable and usable managing model is a key to overcoming the problems of pharmaceutical management. This method proved very useful in looking for strong or weak areas to improve the pharmaceutical operation of *ASP Messina*

Conflict of interest

DSL003 Investigational medical products in clinical trials

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Background

We studied the supplies we receive for clinical trials (CTs) in order to introduce a new computer database to allow proper recording and counting of supplies, and to improve safety so we are prepared for new patients.

Purpose

To prepare for a new CTs database by analysing the different kinds of investigational medicinal products (IMPs) used in CTs.

Material and Methods

Using an Access database we obtained the information concerning IMPs of all CTs approved from January 2005 to September 2010 in which medicinal products were received.

IMPs were classified according to the different routes of administration and the identification system currently employed.

Results

Route of administration	Number of items	%
Oral	708	60.5
Intravenous	393	33.6
Medical devices/accessories	40	3.4
Medical gases	1	0.1
Implants	1	0.1
Others (topical, inhaled, etc.)	28	2.4

Identification of IMP	Number of items	%
Identified by patient number/visit number	61	5.2
Identified by kit number	351	30
No system of identification	759	64.8

We analysed the 422 CTs for which we received medicinal products during the study period. A total of 1171 different items was supplied, approximately 2.8 types of IMPs per CT. IMPs classification is reflected in the results table. As shown, 35.2% of the supplies are identified numerically by patient number (5.2%) or by kit number (30%). These medicinal products require proper identification during the dispensing process. We also counted the number of identified IMPs blinded with placebo, supplies that could be active medicine or placebo. We found that 250 items were blinded (60.7%).

Conclusion

Knowledge of the complexity of IMPs has been essential in the design of the new application for CTs. We have designed a system to record the entry and dispensing of all items supplied; it adapts to each trial, continuing to record reception or dispensing and enabling us to input data correctly using a configurable form. Once we have implemented the new system, we will check whether there has been an improvement.

No conflict of interest

DSL004 Impact of implementation of an automated dispensing device on medications costs in nursing units

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Background

Automatic drug cabinets constitute a safe dispensing system, which makes it possible to avoid errors in the administration of medication. Likewise, they save on costs because they only supply specific patient required dosage, and also they enable us to improve drug management given that they record all the daily operations, ensuring drug stock availability. Pyxis Medstation 3500 Automated drug dispensing systems are installed in some hospital areas. These cabinets are connected with Presel electronic prescription software and Sinfhos management pharmacy software.

Purpose

To analyze the impact of automated drug dispensing cabinets connected to electronic prescription installed in Neurology and Obstetrics nursing units reducing the expenditure on medicines.

Material and Methods

Medication costs in Neurology and Obstetrics nursing units was examined for a given period by the Pyxis Medstation 3500 automated dispensing system implantation. In Neurology from February 2009 to January 2010, and Obstetrics from November 2009 to August 2010. They were compared with the equivalent previous period. Cost data was obtained from the management Sinfhos software. This computer application differentiate among: manual data input (great volume intravenous solutions and emergency medication ordered out of dispensing hours), barcode scanners data input (nursing units medicines store dispensing), and Pyxis automated cabinets drug replacement data which are transferred from Pyxis information system to Sinfhos management application.

Results and conclusions

Drugs dispensed by automated device represent respectively a 73,79% and a 57,86% of total medicines consumption in Neurology and Obstetrics infirmary units. For the study period, costs of medicines in Neurology nursing units decreased by 17,35% and in Obstetrics by 27,67%. According to this results, the investment cost in dispensing system (Neurology 63.405€, and Obstetrics 46.611€) will be recovered in an average period of 33 months (Neurology 30 months and Obstetrics 37 months). Implementation of an automatized drug dispensing system reduces medication cost in the nursing units. Also it is a profitable measure from budget perspective.

No conflict of interest

DSL005 Heart Transplantation: Immunossupressive maintenance regimens in 88 heart transplant recipients from Hospital de Santa Cruz, Portugal

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Background

Immunosuppressive drugs are undergoing major changes in the current context of Hospital Pharmacy, requiring medical and pharmaceutical monitoring.

Purpose

Characterize immunosuppressive maintenance regimens evolution in heart transplant recipients (HT) outpatients to evaluate prescribing trends.

Material and Methods

Retrospective study of immunosuppressive agents dispensed to outpatients HT, during January 2006 -July 2010, in Hospital Santa Cruz Pharmacy.

Data were obtained from software hospital pharmacy and medical data base.

Results

Eighty-eight HT outpatient were included - 80% male; mean age at transplant date 44,5 ± 16,2 years (range 2-69). Were evaluated 1642 distribution registry (mean drug/distribution 1,59±0,83; mean distribution/patient 4,94±2,19). Drugs dispensed mycophenolate mofetil (MMF), everolimus (EVL), sirolimus (SRL) and tacrolimus (TAC). In this group all HT had MMF prescribed (HT de novo or with previous switch from azathioprine. TAC was prescribed to 34% HT vs 49% CYA (cyclosporine), an inverse proportion to that reported in ISHLT 2010 Registry, although a 19% increase in TAC prescription and a 24% decrease in CYA, during 2006-2010. Tacrolimus is not included in national legislation so prescription/distribution to HT requires Pharmacy evaluation and Hospital Administration Council authorization, being limited to HT with high risk of rejection. Currently mTOR inhibitors (EVL/SRL) are prescribed to 20% HT.

Most common regimens were: MMF+CYA (59,09%), MMF+TAC (29,55%) and MMF+EVL/SRL (10,23%); 23 HT had alterations in their regimen: CYA was converted into EVL or SLR due to cardiac allograft vasculopathy (21.74% HT), serum creatinine >2 mg/dl (13,40%) and tumors (4.35%).The introduction of TAC formulation for once daily administration promoted a switch in 13 of 22 HT previous prescribed with TAC bid.

Conclusion

Immunosuppressive agent's prescription and respective distribution depends not only of patient characteristics, as well as guidelines and national legislation. This study provided insights into prescriptions trends and will be helpful for future protocol elaboration and clinical outcomes evaluation.

No conflict of interest

DSL006 Inhibitors of tyrosine kinase: hospital dispensing M. Gayoso Rey, E.Y. Romero, E. Pedrido, A. Mucientes, B. Leboreiro, A. Regueira

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Purpose

To assess the economic impact of dispensing inhibitor of tyrosine kinase in the hospital (ITK) for oncohaematological patients, following its inclusion as a special program in our hospital.

Material and methods

After the implementation of the special dispensing program for ITK we performed a 2-year retrospective study from January 2008 to December 2009. We analyzed the dispensing of the 6 ITKs

included in the Pharmaceutical Guide (PG) in our hospital: imatinib, erlotinib, sorafenib, sunitinib, dasatinib and nilotinib.

We used an integrated computer application in the pharmacy service, analyzing the number of patients under treatment, the dispensing carried out within the ITK program and the total number of units dispensed.

For economic analysis, we used a computer management tool, which records the average value of each drug to the pharmacy services and in which we used the recommended retail price (RRP) as the reference cost.

Results

The number of patients included in the ITK program was 195. The distribution of patients being treated with each drug was the following: imatinib 53 (27.2%), erlotinib 89 (45.6%), sorafenib 21 (10.8%), sunitinib 25 (12.9%), dasatinib 6 (3%), nilotinib 1 (0.5%). The total number of prescriptions dispensed was 963, with a total of 43,271 pharmaceutical units dispensed.

Economic savings over these 2 years have been 51,048.6 €. The average time available for the pharmacist to attend each patient is 2.5 min. so the estimated savings for the ITK program would be achieved in 8 working days of the pharmacist.

Conclusions

- 1. Savings thanks to the outpatient ITK dispensing program, have been 51.048.6 € over 2 years.
- 2. The dispensing of oral cytostatic and other supporting drugs, along with pharmaceutical care in the Pharmacy Outpatients srevice, allows greater pharmacotherapy follow-up of the oncohaematological patients optimizing the cost of treatment.

No conflict of interest

DSL007 Evaluation of antibiotic consumption in a neonatal unit and implementation of a traceability system

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Background

The Neonatal service benefits from a Sterile Preparation Unit (SPU) which came under pharmaceutical responsibility recently. Antibiotics were prepared by nurses according to a standard list overestimating daily consumptions.

A traceability system was created by the pharmacy staff in order to determine the antibiotic doses needed for hospitalised newborns.

The aim of this study is to evaluate the utility of this traceability system in terms of treatment adequacy to newborns needs and in terms of cost.

Material and Methods

Each patient prescription was reported on a notebook detailing the date, patient name, weight, prescribed drug and posology.

The data is introduced in an excel file enabling to calculate daily SPU needs for each antibiotic. 13 from the most prescribed antibiotics were retained for this study.

Consumption has been estimated over three months according to prescriptions. For each day and each antibiotic, it has been checked whether standard treatment was adapted to hospitalized newborns needs and the antibiotic consumption was compared to same period's consumption if standard treatment had continued to be applied

Result

Standard treatment was insufficient in more than 50% of ampicilline and cefotaxime cases (respectively 60% and 74%), in 4% of cases for imipeneme/cilastatine and in 6% of cases for ciprofloxacine. It has been in excess for 100% of cases for ceftazidime and ofloxacine, in more than 90% of vancomycine, amikacine and erythromycine cases and in more than 60% of colimycine, piperacilline/tazobactam ciprofloxacine, metronidazole, rifampicine cases.

The cost comparison between both methods underlines that the traceability system has enabled to achieve an average saving of about 1200 € per month.

Conclusion

This study confirms the safety and profitability interest in determining SPU needs according to prescriptions before being able to set up a pharmaceutical analysis system of prescriptions. It represents a preliminary step versus the instauration of a daily nominative individual dispensation system

No conflict of interest.

DSL008 Pharmacoeconomic evaluation of a commercial methadone versus an extemporaneous preparation

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Background

The treatment for opioid dependence is based on substitutive use of methadone which decrease illegal drug use, increase treatment adherence and reduce the risk of contracting and transmitting infective diseases associated to the use of parenteral drugs.

The goal is the abstinence from all opioid drugs, including methadone, which is obtained by the progressive reductions in the doses of methadone administered. To make easier the dosage and correct administration is needed an oral solution. Until 2008, no commercial oral-solution methadone existed, so it was necessary the preparation in pharmacy services.

Our objective was to evaluate the commercial methadone purchase costs in front of its preparation in our service costs.

Material and Methods

We recollected the data of unitary methadone doses manufactured in our laboratory from January to August of 2010 and cost of production and bottling were calculated (table 1), the cost from commercial methadone were estimated with the price gave by Gebro Pharma Laboratory.

	L.naracteristics		Water cost	Elaborati on cost	Packing material cost	Total cost
Eptadone®	5mg/ml vol					57,04
Preparation	10 mg/ml vol	7,708	1,102	1,185	1,64	11,64

Table 1 Cost in euros by 1L

During the period evaluated, 821 unitary doses were manufactured which mean 54,8g of methadone. Beside we supplied 130g as 10 mg/ml solution for a chronic hospital dependent of our pharmacy. We had to prepared 18,5 L to cover this dispensations which meant a cost of 215€. The cost of the commercial methadone in that case would be 2108 €. The annual cost estimation for preparation is 322,5 € and for commercial, 3162,11 €.

Conclusion

The cost that mean use commercial methadone is greater than manufacture it and it does not contribute with any advantage in the hospital pharmacy service.

DSL009 A preliminary italian study for the development of a departement's pharmacy

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Background

The philosophy of ward pharmacy was born in Italy recently. It is very important to act as fixed point of reference for doctors, as is already the case in the United States and Spain.

Purpose

To reduce the overall cost of the ward, increase the appropriateness of prescriptions and reduce mistakes on the ward.

Material and Methods

The first phase of this project was to select a ward with suitable organisational characteristics. The second phase was to install a pharmacist on the ward with the task of writing a ward manual, to help in preparing and examining pharmaceutical protocols and to provide advice when needed.

Results

The first ward selected was the oncology ward. As the result of placing a pharmacist on the ward, pharmaceutical expenditure was reduced by 20%. This result was possible thanks to the ward manual, the result of a fruitful collaboration between the ward pharmacist and the staff of the ward selected. Furthermore, the quality of care has improved through more rational prescribing and the opportunity to personalise treatment with individualised doses. The presence of the ward pharmacist has drastically reduced the number of errors made on the ward.

Conclusion

The pharmacy is at the heart of a properly operating hospital. Our idea is to bring it closer to doctors, putting a pharmacist on all wards, in order to tie pharmacists in to clinical activities as fixed advisers while keeping our role in the internal distribution of medicines.

No conflict of interest

DSL010 Computerization of pharmaceutical prescription at the Hospital Moscati of Avellino Italy

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Background

In recent years our hospital has developed a policy of total computerisation of all processes to do with drugs: the patient is entered right at the beginning and the drugs are distributed directly from the first cycle of therapy.

Purpose

To involve the pharmacy in designing the final phases: making it possible to prescribe and dispense drugs for the first course of home therapy, and making the link with the Hospital Therapeutic Handbook.

Material and Methods

To achieve these objectives we used a network application server installed at our hospital that was able to interface with the terminals of all departments. If the doctor prescribes treatment at home, the software automatically detects patient data previously entered by the booking centre.

The doctor can choose the type of prescription and prescribe the necessary drugs. In this particular phase the role of the pharmacy management software is decisive, because the application allows only approved medicines to be shown as available for prescription,

which are in the Hospital Therapeutic Handbook.

The doctor can then print and sign the prescription, with which drugs can be obtained from the hospital pharmacy.

Results

The system developed has now been installed in almost all departments, enabling correct prescriptions to be compiled rapidly. Errors to do with the patient's details have all but disappeared. In addition, prescribing now aligns perfectly with what is allowed by the Hospital Therapeutic Handbook. At the same time, consultation over the contents of the Handbook has been improved, and any changes made to the Handbook can now be updated in real time.

Conclusion

The integrated system has finally computerised all processes connected with drugs, simplifying the work of the hospital pharmacist whilst enabling all departments to be consulted about prescribing practices. It has also greatly simplified the work of the doctor to create a path allowing simple yet effective compilation of prescriptions.

No conflict of interest

DSL011 Economic and asistencial impact of dispensing antineoplasic drugs from hospital pharmacy

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Background

Following the statement of 9 February 2010 from Department of Health of Aragon Government (SALUD), some drugs which were dispensed from Pharmacy now have to be dispensed from outpatients Unit from Hospital Pharmacy. These drugs are: omalizumab, deferasirox, temozolomide, capecitabine, anagrelide, imatinib, nilotinib, lapatinib, dasatinib, sunitinib, sorafenib, erlotinib, bexarotene, miltefosine, ustekinumab and gefitinib.

The aim of this study is to describe and assess the economic and activity impact in the Outpatients Unit.

Material and Methods

The study period was the first three months, from april to june of 2010. We analyzed the increase in the number of patients, number of dispensations and activity in the outpatients Unit; cost of these drugs in outpatients Unit, and savings for SALUD.

Results

These drugs were dispensed to 286 patients (12,22% of total patients). The increase over last year was 25%. The cost was 801.639,62 € (18,54% of total cost of drugs dispensed in outpatients Unit). The major economic impact (75%) of these drugs were due to: erlotinib, imatinib, sorafenib, sunitinib and capecitabine. When comparing the cost of acquisition by the Hospital Pharmacy with retail price, the savings obtained by SALUD were 43.011,53 €.

Conclusion

Dispensing these drugs from Hospital Pharmacy improves quality and monitoring of patients apart from saving an important amount of money.

DSL012 Pharmacist interventions in the internal medicine area <u>I. González Perera</u>, M. Cháfer Rudilla, F. Gutiérrez Nicolás, M.M. Viña Romero, I. Plasencia García, J.A. Martín Conde, M.A. Gomez Ocaña, J. Merino Alonso

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Backgroung

Documentation of interventions is vital to a patient's continuity of care and demonstrates the value of clinical pharmacy. The aim of this study was to describe and quantify the pharmaceutical interventions in the Internal Medicine Area.

Material and Methods

Prospective longitudinal study from June 2009 to September 2009 in the Internal Medicine ward in an 800-bed university hospital. Interventions made during this time were recorded in an Access® database. The pharmacist interventions were classified in four groups: System Improvements; Preventive Actions; Educational Pharmacist Interventions and Pharmacotherapy Recommendations.

Results

During the study period, 341 pharmacist interventions were performed (4.26 intervention/day):

- 3 % of the interventions allowed system improvements; like a software implantation for the automatic dosage adjustment in renal failure.
- 30 % were pharmaceutical preventive actions (82 % prevented possible adverse effects or therapy failures and 18 % were useful to clarify medical prescriptions).
- 24 % were educational interventions (88 % for doctors and nurses; and 12 % for patients).
- Finally 43 % were pharmacotherapy interventions (79 % related to an inappropriate dose, 14 % to clarify home medication and 7 % were pharmacokinetic monitoring).

Conclusion

The presence of the pharmacist in clinical units represents an improvement in clinical outcomes and a lower incidence of drug related problems, making a medication use more effective and safe. Therefore, the record of pharmaceutical intervention is a useful tool for documenting and evaluating their contribution to the hospital patient care.

No conflict of interest

DSL013 Patient oriented intravenous medication supply in a German intensiv care unit ñ challenges and unmet needs <u>M. Hug</u>, G. Häckh

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Background

Patients in an intensive care unit (ICU) receive a variety of drugs most of which are prepared on site by the nursing staff. While some hospitals have managed to establish uniform standards for the management of drug supply and administration others have not. Aim of our present study was to assess the current state of medication preparation and administration in four selected medical and surgical ICUs at our University Medical Center.

Material and Methods

To obtain data on the way infusable drugs are handled, experienced nurses were observed by a pharmacist and the time needed to prepare the respective infusion was measured. In addition an onsite survey was performed to collect information on the compostion and total number of parenteral solutions that were mixed by the nurses during a representative day.

Results

The observation revealed marked differences between the four

ICUs. Neither a standard for the individual drug concentrations nor a uniform technique by which drugs were prepared or administered could be identified. Striking differences were also observed in the time required to prepare parenteral solutions. On average the preparation of a 50 ml perfusor required 4.6 min (ranging from 90 s to 9 min). The four ICUs had a daily demand of 664 perfusor syringes. An analysis of the type of solution administered by perfusor revealed that 49% of the contents had a physical chemical stability of more than 3 months while only 9% were stable for less than 7 days. For all the ICUs at our hospital this implicates that more than 1,000 perfusor syringes per day could potentially be prefabricated in a central facility.

Conclusion

Our data show that standardisation and pre-production of perfusor syringes for intravenous administration save a considerable amount of time for the nursing staff while quality and safety of these products could be increased.

No conflict of interest

DSL014 The creation of an on-line galenic formulary network: the Italian experience

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Background

Galenic formulation represents an important heritage in pharmacy; however it is a complex procedure that demands significant resources of professional ability and time. The idea of an on-line galenic formulary arises from pharmacists' growing need to devise formulations that are not commercially available and the opportunity afforded by the Internet to compare and share old and new compounded formulations. The hope is to provide hospital pharmacists with a useful instrument for examining differences in preparation methods and improving their technical and pharmaceutical knowledge.

Purpose

To investigate and create an on-line Galenic Formulary Network, available to all Italian hospital pharmacies accustomed to compounding medicines and willing to join in sharing experiences and new ideas in this field.

Material and Methods

A web-based Galenic Formulary was developed in Hypertext Preprocessor (PHP), PHP is a server-side scripting language based on open-source tools. This system was embedded in the web site of the Burlo-Garofolo hospital of Trieste and then constructed according to the requirements and the needs of the clinical pharmacists of several Italian hospitals. The Galenic Formulary is based on a WAMP (Windows Apache MySQL PHP) platform working on an internal virtual server. It consists of a database loaded with galenic formulations; only authorised hospital pharmacists can add galenic formulations to the database using a secure and personal authentication method in order to guarantee their identity.

Result

The new on-line Galenic Formulary Network was set up in April 2010. During the period April-October 2010, 100 users have subscribed and 87 hospitals have included their formulations. In 6 months more than 150 formulations have been added, with more than 800 on-line visits from April 2010.

Conclusions

An on-line network for sharing galenic preparations could have strong appeal for hospital pharmacists and represents an initial step in establishing a network through which pharmacists can consult formulations any time they are needed or collaborate in developing new preparations for different pathologies.

No conflict of interest

DSL015 Improvement of the pharmaceutical management in a pharmacy service of nursing homes

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Purpose

To improve the pharmacotherapeutic management in a pharmacy service within nursing homes by encouraging adherence to the Pharmaceutical Guide (PG).

Material and Methods

A prospective cohort study of 22 months in a pharmacy service of nursing homes for the elderly. In the first period (2008), the degree of adherence to the PG was quantified as an indicator of pharmacotherapeutic management after developing a "medicine not included in the PG" programme (MNIPG). In the second period (2010), we re-evaluated the degree of adherence.

Results

In 2008, the average number of prescriptions per drug not included in the PG was 4.13 (Cl95% 2.33-5.82) and in 2010 it was 2.84 (Cl95%: 2.01-3.68); the difference between the means was not significant (p=0.185). The percentage adherence to the PG in 2008 was 96.95%, and in 2010 was 97.99%; the difference between the two periods was significant (p=0.00002). The number of non-included drugs of low therapeutic utility required decreased by 9.25% (p=0.0014), and the prescription of drugs with equivalents in the PG by 30.04% (p<0.0001). The acquisition of drugs without therapeutic alternatives increased by 39.29% (p<0.00001). The drugs not included in the PG most frequently prescribed were in 2008: citalopram (15.63%), pantoprazole (8.9%) and citicoline (8.59%). In 2010 they were: atorvastatin (12.12%), rasagiline (7.9%) and atenolol (6.67%). In both periods, the main therapeutic group was metabolic and cardiovascular systems. The acceptance of recommendations was 82.26%.

Conclusion

The implementation of the PG's pharmacotherapy management programme has led to an increase in the adherence to the PG and a decrease in the number of prescriptions with the MNIPG programme. On the other hand, the acquisition of excluded drugs without alternatives has increased significantly while the use of alternative drugs with equivalent treatment in the PG has significantly reduced.

No conflict of interest

DSL016 The main causes of refusal of requested medicines from the Pharmaceutical Assistance Specialized Component of Brazilian Ministry of Health

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Background

The evaluation of health services is a type of management process. It supports the decision-making process, which may alter the initial situation identified as a problem. Process management is essential to guarantee the public's access to properly prescribed medicines.

Purpose

The aim of this study was to identify the processes for requesting medicines and the main causes of refusing requests for medicines from the Pharmaceutical Assistance Specialized Component.

Material and Methods

In August 2009, a cross-sectional descriptive study was conducted into requests refused by Outpatient Pharmacy Section of the University Hospital and data were collected through a structured form

Results

Of 4,989 requests for medicines received during the study period, 486 were refused (9.7%), of which 55.8% were new cases and 44.2% were renewed requests. Prescriptions written for the entities Dyslipidemia (30%) and Refractory Schizophrenia (12%) were the health conditions for which prescriptions were most often rejected. Each rejected request had an average of 1.4 problems (min. 1, max. 6), and the main causes were: lack of examinations indicated by the protocol (58.0%), necessity for a detailed medical report (17.5%), requesting document incorrectly filled in (12.3%), inadequacy of prescription (12.1%), informed consent of patients missing or incorrectly filled in (10.7%), lack of information about previous treatments (7.6%), treatment not included in the protocol (7.4%) and the amount of requested medicine above that allowed by the clinical protocol (7.2%). The high percentage of refused requests demonstrates the importance of communication management. The lack of documented tests was highlighted as the main problem in drug release and incorrect processes.

Conclusion

These results show strong evidence that action plans should be defined for those causes of refusal. The interaction between pharmacy professionals and prescribers should be improved in order to disseminate information about the administrative procedures for dispensing medicines from the Pharmaceutical Assistance Specialized Component.

No conflict of interest

DSL017 Automation and safety: Error incidence filling medication carts using automated and manual system

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Background

Manual filling systems (MFSs) are being replaced by automated dispensing systems (ADSs) - Kardex - when unit doses are delivered via medicines carts. These automated processes can involve errors that could directly affect patient safety.

Purpose

1/ To qualify and quantify errors in the filling of medicines carts with unit doses using ADSs. 2/ To compare the error incidence and filling times using ADSs with our historical control (HC) of the MFS.

Material and Methods

Prospective, observational study with HC in a tertiary hospital with 500/600 beds using a unit dose system. 9360 lines corresponding to 26208 units of medicine dispensed by an ADS were reviewed. Discrepancies between the unit dose program and the ADS software were found. The errors were classified in seven types: 1/ Kardex validation without taking the correct units of medicines; 2/ unknown cause for missed or extra medicines; 3/ put medicines in incorrect patient box; 4/ out of Kardex medicines missed; 5/ failure to withdraw medicines when a patient was discharged; 6/ Kardex medicines taken from an incorrect box; 7/ medicines changes not updated. Filling time was recorded and compared with HC.

Results

165 errors were detected by processing 9,360 lines (incidence = 1.8%; IC95%=1.5-2.1): 1/ 24.2% (IC95%=17.9-31.5), 2/ 22.4% (IC95%=16.3-29-5), 3/ 18.2%,(IC95%=12.6-24.9), 4/ 13.9%, (IC95%=9.0-20.1), 5/ 13.3% (IC95%=8.5-19.4), 6/ 4.8% (IC95%=2.1-9.3) and 7/ 3.0% (IC95%=1.0-6.9). Filling time by ADS was 312 min (IC95%=300-324 min) while that required for the MFS was 295 min (IC95%=273-317 min).

Conclusion

The incidence of filling errors with ADS was 1.8% (IC95%=1, 5-2, 1) which was double the estimated rate in the MFS (0.7%) (IC95%=0, 4-1, 0). Filling time with the ADS was similar to that required for the MFS.

Drug information (i. Anti-infectives, ii. cytostatics, iii. others)

DGI001 Home parenteral nutrition: Patients¥ satisfaction to the attention given by the Hospital Pharmacy Service

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Background

Patients requiring home parenteral nutrition should have the opportunity to express their degree of satisfaction with the attention given by the whole nutrition team.

Purpose

The aim of this study was to evaluate patients' and carers' satisfaction with the hospital pharmacy service involved in the preparation and management of their nutrition.

Material and Methods

A questionnaire was sent to patients receiving home parenteral nutrition. It was arranged in six different parts: patients' demographics, carers' information, pharmacy facilities and management, pharmacist experience and patient supplies. All these aspects were ranked on a scale of 1 to 5 (5 was the highest score).

Results

The percentage of respondents was 100% (n=9). The mean age was 60.10 years (range 12.91-84.20). The carer was either the patient himself (n=4) or a relative (n=5) and only one patient did not feel qualified to administer the treatment, despite the teaching programme.

Time spent waiting (score 4.77) and items related to the pharmacist (written and oral information given when the patient was discharged (4.76), the pharmacist's interest in the patient (4.88) and a telephone number to contact directly with the pharmacist (5.00)) were the most positive aspects.

On the other hand, the frequency of trips required to pick up their nutrition and supplies (4.44), hours of opening (4.44), and aspects related to pharmacy facilities (degree of comfort and cleanliness (4.33), privacy (4.44) and accessibility (4.44)) were marked less highly, but nevertheless scored well.

Conclusion

All patients and relatives were satisfied with the attention given by the hospital pharmacy service. Only one patient did not feel qualified to administer his parenteral nutrition. Consequently, the pharmacy department decided to work together with the rest of the nutrition team group in order to discuss a way to help him.

No conflict of interest

DGI002 Study of the use of linezolid in outpatients and patients admitted in the hospital, except in intensive care unit <u>V. GOITIA RUBIO</u>, I. CAMARON ECHEANDIA, R. HERNANZ CHAVES, L. GUISASOLA RON, B. SANCHEZ NEVADO, M. NOGALES GARCIA, A. QUINTANA BASTERRA, C. MARTINEZ MARTINEZ

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Purpose

To assess the use of linezolid in hospital inpatients, excluding intensive care unit (ICU), and / or outpatients.

Material and Methods

Retrospective study of patients treated with linezolid who were admitted, except in ICU, and / or were treated as outpatients in 2009. The data collected were department, gram positive bacterial isolated previous to treatment and its antibiogram, as well as plasmatic creatinine, antibiotic allergics and duration.

Results

Total prescriptions with linezolid were 55 (52 patients). The departments that prescribed more linezolid and the average duration of treatment was: hematology 40% of prescriptions / 10 days, traumatology 16,4% / 33 days, vascular surgery 9,1% / 15 days and pulmonology 7,3% / 11 days. The treatment was empiric in 56,4% occasions, mainly hematology with 23,6% traumatology 9,1% of all prescriptions. It was isolated 27 gram positive bacterials in 23 prescriptions (48,8%), being the most frequent Staphylococcus epidermidis (8), metilicin Staphylococcus aureus (MRSA) (7) and Enterococcus (6). There was one case of hepatotoxicity to tuberculostatic who required linezolid. In 3 cases there weren't antibiogram. The others microorganism were susceptible to vancomycin (except an enterococo susceptible to ampicillin, not tested to vancomicyn) and resistant to beta-lactam antibiotics (except in 3 prescriptions, but the patients were allergic to penicillins). Linezolid was the first antibiotherapy in 30% of the cases, only in 4 was confirmed the susceptibility. The 20% of prescriptions had used a glycopeptide previously. Almost all vancomycin treatments had pharmacokinetic monitorig. The 83,7% of prescriptions had plasmatic creatinine less than 1,4 mg/dl previous to linezolid.

Conclusion

The treatment of linezolid has been empiric in a high percentage of the prescriptions. The antimicrobial therapy with vancomycin had been a good alternative to the treatment with linezolid, due to the excelent susceptibility to vancomycin and the normal kidney function of most of the patients.

No conflict of interest

DGI003 Analysis of empirical antibiotic therapy in emergency department and follow up in general medicine department

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Purpose

To know treatment continuation and switching in general medicine department (GMD) admitted patients with empirical antibiotic therapy (EAT) indicated in emergency department (ED).

Methods

Prospective, observational study from November 2009 to March 2010 in a 500-bed university hospital. The study included adult patients admitted in GMD with prescription of EAT from ED.

Data collected included demographics, infection aetiology, EAT, treatment duration, and EAT changes in GMD: addition or antibiotic withdrawal, dosage changes, substitution or discontinue antibiotic treatment.

Results

226 patients were included, 121 were men with an average age of 78 (±15.1). Lung infection was registered in 69.9% cases, urinary tract infections in 15.1%, dermatological 4.4%, bloodstream 3.5%, gastroenterology infection 3.5% and other aetiologies 3.5%. Penicillines were the 51.3% prescriptions amoxicillin/clavulanic), 18.2% quinolones (16.8% levofloxacine), 11.9% cephalosporines (11.1% ceftriaxone), 5.7% carbapenems (2.2% meropenem) and 12.9% antibiotic associations (azitromicine and ceftriaxone were the main of it with 4.4%). The average duration of EAT was 5.9 days. EAT was maintained after GMD admission in 129 patients (57.1%), was modified in 75 (33.2%) and was removed in 22 (9.7%). EAT complete substitution carried out in 58 patients (25.7%), in eight patients (3.5%) one of the antibiotics was removed and in nine (4%) dose was changed, six of them due to renal failure. In any case another antibiotic was added. The causes of EAT changes were isolated microorganism in 30 of the 75 cases, in nine of them because of antibiogram results. The mean treatment duration until changes was three days.

Conclusion

EAT was maintained in a high percentage of cases. Modifications were basically carried out 72 hours after admission, however just 52% analyzed cases were based on culture results.

It is necessary sensitizing physicians to the importance of antibiogram and culture results.

No conflict of interest

DGI004 Zoledronic acid: Evaluation of drug use in a general hospital

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Background

Zoledronic acid (ZOL)is a bisphosphonate used to prevent skeletal-related events (SREs) in patients with bone metastases and to treat tumour-induced hypercalcaemia (TIH).

Purpose

To evaluate ZOL prescribing and safety in patients with bone metastases.

Material and Methods

Observational retrospective study of patients treated with ZOL over 2 months in our hospital. Information was collected from patients' clinical histories and the Farmatools 0902 software. Data collected: SREs (pathological fractures, spinal compression, bone radiation or surgery, bone pain or tumour-induced hypercalcaemia), diagnosis, indication, doses received, calcium and vitamin D supplemental therapy, chemotherapy treatment, serum calcium and creatinine levels (creatinine clearance was calculated for those patients with serum creatinine > 1.4 mg/dL) and adverse effects.

Results

49 patients were treated with ZOL during the period studied (22 male and 27 female). Median age was 70 years (range 34-88). Median doses received was 14 (range 1-44). The average cost per patient was 3,732 €, with a total cost of 183,967 €. Incidence of SREs was: 74% bone pain, 20% bone radiation, 16% pathological fractures, 6% spinal compression, 4% hypercalcaemia and 4% bone surgery. The main indication was prevention of SREs (98% of patients) and two of them also suffered from TIH. In one patient, the prescription did not conform to authorised indications because there were no bone metastases or TIH. 46% of patients had multiple myeloma, 37% breast cancer, 14% prostate cancer and 4% another type (lung, renal cancer). 60% of patients received calcium and vitamin D supplements. None of the patients presented osteonecrosis of the jaw during the study period and ZOL was well tolerated. In three of the patients only, the dose of ZOL needed to be reduced due to renal impairment.

Conclusion

The treatment of a high percentage of patients did not comply with the package leaflet recommendations, especially regarding calcium and vitamin D supplementation. The dosage was correct in all patients. Adverse events were consistent with those described in the literature.

No conflict of interest

DGI005 Efficacy and safety of intravenous fentanyl in a palliative care unit

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Background

Fentanyl may be the opioid of choice in cases of renal failure, intestinal obstruction or when other opioids cause side effects.

Purpose

To investigate the analgesic efficacy and safety of fentanyl in continuous intravenous perfusion (CPfentanyl) for treatment of severe cancer pain in a palliative care unit.

Material and Methods

Retrospective study. Sample: 100% patients. Inclusion criteria: patients admitted to the palliative care unit with CPfentany during the period March/2009 – February/2010. Data collected: age, sex, diagnosis, prior analgesic treatment, reason for changing to CPfentanyl, initial conversion of dose (initial conversion ratio: fentanyl by transdermal delivery (TDfentanyl)/CPfentanyl 1:1; morphine/fentanyl 100:1; methadone/fentanyl 20:1; tramadol/morphine 10:1), duration and reason for ending CPfentanyl treatment. Data extraction: software for management of narcotic drugs and clinical history.

Results

17 patients were identified (10 men, median age: 64 years; range: 39-88). 100% of the diagnosis was terminal cancer (5/17 gastrointestinal, 3/17 lung, 2/17 pancreatic, 2/17 tongue, 2/17 gynecological, 3/17 others). Pretreatment: 11/17 TDfentanyl, 4/17 morphine, 1/17 methadone, 1/17 tramadol+amitriptyline. Reason for changing to CPfentanyl: 5/17 uncontrollable pain, 10/17 clinical instability (fever, poor peripheral perfusion, increase in the number of analgesic rescues, delirium), 2/17 gastrointestinal dysfunction. For initial conversion of dose, 3/17 patients remained at equianalgesic dose, 5/17 increased the dose and 9/17 reduced the dose. Median duration of treatment: 6 days (range: 1-30 days). Reason for ending treatment: 11/17 death, 3/17 good control of pain, 1/17 hyperalgesia (increased sensitivity to pain), 1/17 neurotoxicity.

Conclusion

Initial conversion TDfentanyl/CPfentanyl 1:1 is effective and safe. CPfentanyl allows rapid control of pain. CPfentanyl allows the calculation of an effective fentanyl dose and a later change to TDfentanyl, if necessary. In cases where it was necessary to use a fentanyl dose that was lower than that calculated, opioid-induced hyperalgesia/pain could be postulated.

No conflict of interest

DGI006 Parenteral nutrition suplemented with glutamin in haematological patients undergoing peripheral blood stem cell transplant

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Background

Glutamine is an essential amino acid in hypercatabolism and plays an important role in protein metabolism, the immune system, intestinal function and the response to oxidative stress.

In April 2009 a new parenteral nutrition (PN) protocol was approved in our hospital that recommended the use of glutamine in the PN of patients undergoing a peripheral blood stem cell transplant (PBSCT).

Purpose

To describe the results of using glutamine in the PN of patients undergoing PBSCT after 17 months' monitoring.

Material and Methods

Prospective study from April 2009 to September 2010 including haematological patients undergoing PBSCT on glutamine-supplemented PN for 7 or more days. Glutamine was administered at the rate of 0.2–0.5 g/kg/day for 3 weeks maximum. Demographic data, weight on admission, days on PN, hospital stay, total amount of protein in PN, glutamine as a percentage of the total protein input, liver profile (GOT, GPT and GGT), glycaemia and nutritional parameters (albumin, prealbumin, and retinol binding protein) prior to PN and 7 days later were gathered for each patient. Data was analysed with SPSS v.17.

Results

5 patients were included, 3 women, mean age 54.5 years, mean weight 68.5 Kg. Mean stay in hospital 33.2 days. The average number of days on PN was 9.8, mean total protein 89.6 g and mean glutamine percentage of the total protein input was 17.6%. No statistically significant results were found when comparing liver, nutritional and glycaemia parameters prior to and after 7 days on glutamine-supplemented PN.

Conclusion

The addition of glutamine to PN in patients undergoing PBSCT did not improve the variables studied. Comparative studies with a control group and bigger sample size need to be done to be able to achieve conclusive results and determine the potential advantages of adding glutamine to PN in these patients.

No conflict of interest

DGI007 Stability study of doripenem for continuous infusion <u>S. Mosnier-Thoumas</u>, F. Xuereb, C. Chapouly, M.C. Saux, D. Breilh ¹Clinical Pharmacy Haut-Lévêque Hospital, EA 2968 Clinical Pharmacokinetic, Pessac, France

Background

Doripenem, the latest carbapenem, like other β -lactam antibiotics, inhibits synthesis of the bacterial cell wall. It is indicated in the treatment of adults with complicated intra-abdominal and urinary tract infections and nosocomial pneumonia. To optimise the clinical response rate, doripenem can be delivered by continuous infusion after dilution but continuous infusion may be limited by the physicochemical stability of the antibiotic.

Purpose

To investigate the stability of doripenem infusion solutions under a variety of conditions.

Material and methods

Two different concentrations of doripenem commonly used in treatment (6 and 10 mg/mL) were prepared in 0.9% sodium chloride (NaCl 0.9%), 5% glucose (G5%) or H_2O solutions in PVC (Poly Vinyl Chloride) syringes and placed in different conditions (+4°C, 25°C, 25°C in the dark and 37°C). Doripenem was measured using a validated high-performance liquid chromatography method coupled to ultraviolet detection.

Results

The stability of doripenem was satisfactory when solutions are stored at +4°C for 48 hours and at room temperature for 12 hours in NaCl 0.9% and H_2O . At 25°C and 37°C, a yellow colour developed depending on the solvent and temperature. The strength of colour did not affect the stability of solutions. The main factor that affected the stability of doripenem was the storage temperature.

Conclusion

This in vitro study reports on the possibility of preparing doripenem in NaCl 0.9% at 6 and 10 mg/mL in PVC syringes for continuous

infusion and to keep them safely at 25°C for at least 12 hours. For continuous infusion of standard doses of doripenem (1.5 g per day) we recommended preparing syringes containing a dose of 10 mg/mL, to be changed every 8 hours. Having obtained these results it is now essential to conduct a pharmacokinetic/pharmacodynamic optimisation study of doripenem by continuous infusion.

No conflict of interest

DGI008 ANTIBIOTIC PRESCRIBING IN CLINICAL HOSPITAL CENTER OSIJEK DURING THE PERIOD 2004-2009

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Background

The frequency of antibiotic use in hospital is recognised as possibly the most important factor for antimicrobial resistance.

Purpose

To show the use of ATC-J01 drugs in our hospital for the years 2004-2009.

Material and Methods

The data presented were obtained by analysing antibiotic consumption recorded by the computer in the Pharmacy Department. Antibacterial consumption is shown as defined daily doses (DDDs) per 100 occupied bed days (OBD).

Results

The financial cost of antibiotics for systemic use, ATC-J01, for 2004-2009, grew steadily from 5.9 million Croatian Kunas (Euro 804,000) in 2004 to 11 million (Euro 1.5 million) in 2009. Compared with total drug use, ATC-J01 drugs were 16.71% in 2004 and 14.03% in 2009. Use of ATC-J01 drugs oscillated from 40.96 DDDs per 100 OBD in 2004 to 43.4 in 2005, 42.95 in 2006 and 41.83 in 2007 followed by an increase to 50.54 in 2008 and 56.67 in 2009. Penicillins were the most prescribed antibiotics, increasing from 13.59 DDDs per 100 OBD in 2008 to 20.09 in 2009. The most prescribed drug was amoxiclav (ATC-J01CR02), given intravenously and orally, with the largest decrease in use across the four years studied; 15.03 in 2004 to 1.89 DDDs per 100 OBD in 2007, followed by an increase in use to 13.38 DDDs per 100 OBD in 2009.

Consumption of cephalosporins grew from 6.82 DDDs per 100 OBD to 11.3 in 2009. The consumption of cefuroxime ranged from 5.18 2004 to 11.3 DDDs per100 OBD in 2009. The use of ceftriaxone grew from 0.58 in 2004 to 1.35 DDDs per 100 OBD in 2009. Consumption of aminoglycosides decreased and the use of carbapenems, macrolides, fluoroquinolones and vancomycin grew. Ciprofloxacin consumption grew from 1.57 in 2004 to 5.23 DDDs per 100 OBD in 2009.

Conclusion

The consumption of antibiotics increased in the period observed. Introduction of strict control of prescribing antibiotics is required.

The use of amoxiclav has been rationalised by placing it on a reserve list. Urgent control of the prescription of some cephalosporins and ciprofloxacin is needed, the consumption of which grew more than three-fold in the given period.

DGI009 HIV-positive patients clinical and therapeutic path: a multidisciplinary team in Amedeo di Savoia hospital

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Background

"Amedeo di Savoia" Hospital is the regional centre in Piedmont for HIV infection diagnosis and treatment and approximately 3,500 patients are cared for. Since their life expectancy is increasing, it is necessary to monitor the efficacy and tolerability of the antiretroviral therapy, treatment adherence, drug resistance and the cost of HAART.

Purpose

- To create a multidisciplinary team including infectivologists, pharmacists and nurses;
- To standardise the dispensing and monitoring of HAART, in order to improve patient care quality
- To investigate interactions between HAART and other drugs and treatment adherence
- To save money

Material and Methods

2 pharmacists work together with infectivologists and nurses and they dispense HAART to HIV-positive patients.

Physicians and pharmacists record the patient's therapeutic and clinical history using a particular software application; Pharmacists, instead, monitor treatment and costs using File F software.

Interactions analysis is based on http://www.hiv-druginteractions.org/ and Micromedex.

Adherence is calculated on the frequency of dispensing repeat prescriptions and is defined as: days supplied between refill dates/(duration of interval + 60 days) x 100.

Results

Over 10 months (1/11/2009-31/08/2010), pharmacists dispensed HAART to 1650 patients every two months, working with 9 infectivologists.

Interactions between HAART and other drugs were checked in 112 patients: an interaction occurred in 50% of patients.

Adherence was measured for 1514 patients in therapy with NNRTI or NRTI: 54% of patients had >95% adherence, only 1% with <40% adherence.

HAART dispensed by pharmacists saved 5%, equal to Euro 200,000.

Conclusion

As shown above, a multidisciplinary HIV infection team has improved (98% of patients are satisfied), simplified (patients have to wait less time to take therapy) and standardised (therapy every two months) the clinical and therapeutic path of HIV-positive patients. Other studies are needed to compare adherence measured by pharmacy-refill with HIV viral load or CD4+ cell count.

No conflict of interest

DGI010 BORTEZOMIB FOR MULTIPLE MYELOMA: RESULTS OF 2 YEARS OF MONITORING

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Background

The first-in-class proteasome inhibitor was bortezomib, used in treatment of multiple myeloma(MM).

Purpose

Our purpose was: to describe therapeutic regimens with bortezomib, the response to them and to analyse the efficacy and safety of this agent used in clinical practice in our hospital.

Material And Methods

Descriptive and retrospective study of patients with MM treated with bortezomib between January 2008 and December 2009. Demographics and clinical parameters were collected from: clinical history, consultation prescription software cytostaticos (Oncofar®3.3) and clinical history software(Selene®). Response criteria for assessment of MM were according to Blade criteria(EBMT) and International Myeloma Working Group: complete response(RC), very good partial response(VGPR), partial response(PR), minimal response(MR), stable disease(SD) and progressive disease(PD).

Results

We studied fifty-nine patients(25 males and 34 females), average of age 63 years[30-82]. 34 patients(57,63%) were diagnosed of IgG MM, 14(23,73%) of Bences-Jones MM, 9(15,25%) of IgA MM, 1(1,69%) nonsecretory MM and 1(1,69%) of plasma cell leukaemia. The median number of therapeutic regimens pre-bortezomib was 2[1-5]. Patients received the following regimens with bortezomib: A)Bortezomib alone(22); B)Bortezomib-dexametasone(19); C)Bortezomib-cyclophosphamide-dexametasone(14);

D)Bortezomib-melphalan-prednisone(12);E)Bortezomib-oxorubicin-melphalan-prednisone/thalidomide-cyclophosphamide-

dexametasone(9). The responses to these regimens were: A)3-RC, 1-VGPR, 13-PR, 1-MR, 2-SD, 2-no data; B)5-RC, 2-VGPR, 7-PR, 4-MR, 1-no data; C)4-RC, 2-VGPR, 3-PR, 2-MR, 1-PD, 2-no data; D)2-RC, 1-VGPR, 6-PR, 2-MR, 1-SD; E)5-RC, 1-VGPR, 2-PR, 1-SD. Thirty-five patients(59,32%) experienced adverse events, predominantly: 17(48,57%) peripheral neuropathy(PN), 12(34,29%) gastrointestinal toxicity and 3(8,57%) infections. 11 patients(31,43%) required dose reductions due to PN and 7 patients(20%) discontinued therapy,3 by PN.

Conclusion

Most patients diagnosed with MM were middle-age women and more than half of cases were IgG MM. Patients achieved PR with most regimens containing bortezomib, RC was achieved with regimens C and E. The PN and gastrointestinal toxicity were the predominant toxicities in more than 50% of patients; PN was responsible of reducing the dose in most cases and some of them the final withdrawal of treatment.

No conflict of interest

DGI011 Guide for handling queries about administration of drugs through enteral tubes developed by The Medicine Information Centre.

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Background

As hospitalised patients are often incapable of swallowing ordinary tablets and capsules, quite a large percentage of the medicines-related inquiries received by the Medicine Information Centre concern the administration of drugs via enteral feeding tubes. To ensure consistent, balanced, standardised and high-quality counselling when presented with this type of inquiry the Medicine

Information Centre wrote a guideline for answering enquiries.

Purpose

To secure clinically relevant and safe medicines delivery through *enteral* feeding *tubes*.

Material and Methods

Inquiries concerning *drug* administration through *enteral* feeding *tubes* involve consideration of several factors. Inspiration from a presentation at ASHP 2009, as well as relevant literature studies,

has been used as background material to the guideline.

Results

In recent years approximately 9% of all inquiries received by the Medicine Information Centre have been concerning drug administration through *enteral tubes*. In order to assess the pharmaceutical situation in these inquiries, it is essential to receive all relevant background information in each individual case.

Whenever these inquiries are made, there are always several factors to be addressed, so the guideline serves as a checklist of factors to be considered. The guideline contains disclosing questions such as: what medicines is the patient taking, dispensed in what form, does patient receive nutrition via the tube/feeding regime, type of feeding tube, placement of the tube, etc. Only when these issues are fully identified can further questions be asked.

Conclusion

The guideline reviews all relevant information that is required to provide a professional pharmaceutical assessment and give competent medical advice to clinical staff.

The poster will present the guideline questions.

No conflict of interest.

DGI012 Accidental subcutaneous administration of intravenous infusions: An inquiry answering guideline

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Background

Occasionally, the Medicine Information Centre receives inquiries concerning accidental subcutaneous administration. Key questions in this type of inquiry include: "What happens when a particular intravenous infusion has accidentally been administered subcutaneously?"; "How should the incident be handled?"

Often a quick answer is needed. Because of the time issue, the complexity and the relatively few inquiries of this type, an inquiry-answering quideline on this subject was deemed necessary.

Purpose

To ensure all relevant information needed to answer an inquiry is available and to obtain a full overview of the incident.

Material and Method

Dealing with the paravenous administration of IV infusions involves consideration of numerous factors. Relevant literature on these factors has been studied and used as background material to produce the guideline.

Results

The guideline contains a list of factors to remember when encountering inquiries on accidental subcutaneous administration. These include:

- · which patient data should be collected;
- what characteristics of the given drug require further examination. The quideline also indicates possible interventions.

Only when a full overview on the incident is achieved is it possible to provide a professional pharmaceutical assessment, and give competent medical advice for possible interventions (if any) to be performed by the clinical staff in hospitals.

Conclusion

So far the guideline has only been used in a few cases. In the future, the guideline will be used on every occasion the Medicine Information Centre receives inquiries concerning accidental subcutaneous administration.

The poster will present the guideline.

No conflict of interest

DGI013 Correlation between case-mix and antibiotic consumption in a tertiary hospital

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Background

Antibiotic consumption monitoring commonly reflects variations in usage due to different rates of infection or outbreaks. It is also useful to identify situations of inappropriate usage that carry risk of drug-resistant microorganisms and increase treatment costs. However, possible confounders may explain antibiotic consumption variations.

Purpose

To assess the relationship between case-mix index and antibiotic use indicators.

Material and Methods

Ecological study conducted in a 275-bed tertiary care hospital in Spain. Data were collected annually from 2004 to 2009. Antimicrobial in-hospital consumption was calculated in terms of number of defined daily doses (DDD) per 100 patient-days. Groups included were J01 (Antibacterials for systemic use) and J02 (Antimycotics for systemic use). DDD provided by the ATC/DDD system of the WHO collaborating centre of drugs statistic and methodology in 2009 were used.

Variables calculated were length of stay (LOS) and the case-mix index. The case mix is estimated by assigning a relative weight to each Drug Related Group (DRG) that reflects the predictable cost compared to the median cost of a hospitalised patient. The median value of the DRG relative weight estimated annually is multiplied by the number of admissions to get the total weight (TW) of the patients admitted yearly. TW reflects the severity of the hospitalised patients. Simple regression analysis was used to evaluate the correlation of TW and LOS with the antibiotic use.

Results

From 2004 to 2009 total systemic antibiotic use increased (118, 121, 124, 135, 139, 139 DDD/100 patient-days respectively) with a remarkable percentage increase of 8.7% between 2006 and 2007. LOS did not change significantly (4.66, 4.61, 4.40, 4.80, 4.66 and 4.60 days). A progressive increase in the case-mix severity was also observed (TW 33333, 34898, 36449, 39277, 40508, 37999). A strong correlation was found between TW and DDD/100 patient-days (correlation coefficient (r) 0.927), while r between LOS and DDD/100 patient-days was low (0.318).

Conclusion

The patient severity index provides meaningful information to facilitate the interpretation of quantitative hospital antibiotics use and allow more reliable comparisons among different health care institutions.

No conflict of interest

DGI014 ADEQUACY OF EMPIRICAL ANTIBIOTIC TREATMENTS IN CLINICAL PRACTICE

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Background

The rational use of antibiotics in clinical practice aims to guarantee maximum efficacy and lowest toxicity of antibiotic treatment.

It is essential that each hospital have strategies for the dissemination of, and compliance with, protocols to ensure the rational use of antibiotics.

Purpose

To assess the suitability of restricted antibiotic treatments prescribed empirically to hospital protocols.

To ascertain the rate of acceptance of the recommendations for change of treatment when the prescribed antibiotic does not comply with the protocols.

Material and Methods

A prospective study conducted between March 2009 and March 2010. Through the electronic management system for hospital patients, all the prescriptions for restricted antibiotics prescribed during the last 24 hours were assessed. The treatments prescribed in medical intensive care units and in infectious diseases were excluded. An internal medicine physician specialising in infectious diseases and a resident of the pharmacy service assessed the adherence of the treatment to the protocols according to the patient's clinical situation. If the antibiotic treatment was not suitable, a recommendation to change the antibiotic was made to the physician in charge of the patient. The treatment was checked 24 hours later to find out the recommendation had been accepted. All this information was recorded in an Access database for subsequent statistical analysis.

Results

During the study period 276 patients with prescriptions for restricted antibiotics were evaluated (63.40% men, mean age: 72). 312 antibiotics were assessed (26.60% imipenem, 18.59% levofloxacin, 15.71% cefepime, 13.46% piperacillin-tazobactam, 10.58% ertapenem, 6.73% vancomycin, 6.09% linezolid, 0.96% meropenem, 0.64% daptomycin, 0.64% aztreonam). 140 (44.87%) treatments did not comply with the protocols. The causes of unsuitability were 48 (34.29%) for inappropriate indications, 39 (27.86%) for unsuitable route of administration, 36 (25.71%) for excess spectrum, 9 (6:43%) for insufficient spectrum and 8 (5.71%) for existence of a more cost-effective treatment. 141 recommendations were made, 85% of which were accepted.

Conclusion

The adherence to protocols of empirical antibiotic treatments should be improved to achieve maximum efficiency in health care. The assessment of the prescribed therapies ensures greater compliance of the protocols and therefore a more rational use of antibiotics.

No conflict of interest

DGI015 Reduction of bevacizumab infusion time

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Background

The Spanish label of Avastin (bevacizumab) states that from the third cycle forward it can be administered in 30 minutes but this rate of administration is not proportional to the dosage employed. We follow the recommendations of a previous American study.

Purpose

To reduce the bevacizumab infusion time from 30 minutes to 20, 15 or 10 minutes according to the dosage, from the fourth cycle onward, monitoring the safety of our intervention.

Material and methods

An administration sheet was drawn up for day hospital nurses in order to determine the safety of the intervention. It contained 2 parts; a part for the pharmacist to fill in (patient demographic data, patient identification number, chemotherapy regimen and cycle number) and another part for nurses to fill in (including transfusion reactions if they occurred, adverse reactions and their treatment). The study period was six months from February to July 2010. According to the literature, bevacizumab 5 mg/kg infusions can be

administered over 10 minutes; 7.5 mg/kg over 15 minutes and 10 mg/kg over 20 minutes.

Results

The mean age of the patients in our study was 55 years. We had 90 infusions; 48 were for men and 42 for women. 66 were administered over 10 minutes (5 mg/kg) colorectal cancer, 22 over 15 minutes (7.5 mg/kg) non-small cell lung cancer and 2 over 20 minutes (10 mg/kg) breast and brain cancers. This saved 1670 minutes. There were no reactions to the transfusions in the period studied.

Conclusion

The infusion time of bevacizumab was reduced safely in our hospital. It enabled day patients with bevacizumab in their chemotherapy regimens to leave hospital more quickly. The pharmacist helps scarce resources to be used efficiently whilst maintaining safety standards.

No conflict of interest

DGI016 use of bevacizumab and cetuximab in colorectal cancer treatment in a Portuguese general hospital

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Background

Colon and rectal carcinomas are the 3rd most common type of cancer worldwide, with an overall survival of 10% at 5 years in patients with metastatic disease. The increase in survival rate over the past years is mainly due to the introduction of targeted therapies with monoclonal antibodies, including bevacizumab and cetuximab.

Purpose

To investigate cetuximab and bevacizumab use in the treatment of colorectal carcinoma in a general hospital.

Material and Methods

Retrospective study of bevacizumab and cetuximab use pattern in colorectal carcinoma between 2006 and 2009.

Results

Between 2006 and 2009, 40 patients received treatment with cetuximab and 72 with bevacizumab. In the group on cetuximab (35% female and 65% male), 35 had a colon cancer diagnosis and 5 rectal cancer, the mean age was 64 years. Regarding metastases location, 27 patients had 1 site, 9 had 2 sites and 4 had 3 or more sites. Hepatic metastases were common (87.5%). Of the 40 patients investigated only 1 had prolonged therapy over one year. With regard to bevacizumab (44.4% female and 55.6% male), 63 had colon cancer and 9 rectal cancer, the mean age was 59 years. Regarding metastases location, 54 patients had 1 site, 11 had 2 sites and 7 had 3 sites. Hepatic metastases were common (87.5%). Of the 72 patients investigated 3 remained on treatment over two years. Of the 112 patients on monoclonal antibody therapy, 15.2% received treatment first with bevacizumab followed by cetuximab and only one patient started with cetuximab.

Conclusion

The majority of patients presented colon cancer with liver metastases. More patients were treated with bevacizumab than cetuximab. The treatment lasted longer with bevacizumab than with cetuximab, a fact which can be explained by the use of cetuximab after progression.

DGI017 Development of a web-based antimicrobial resource to improve antimicrobial prescribing \tilde{n} a two year review

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Background

Our Teaching Hospitals were poorly performing for Clostridium difficile infection (CDI) and MRSA bacteraemia, despite 'CDI-friendly' antibiotics used in patients >80 years.

Purpose

The project was to build a web-based infection-management resource to improve antimicrobial prescribing by providing:

- · evidence-based, peer-reviewed guidelines
- · educational resource
- · audit resources with results
- · decision support including calculators

Material and Methods

Templates were developed for each guideline development team of a clinician, microbiologist and pharmacist. Each guideline includes algorithms, investigations, empiric and directed therapy (including special populations), oral switch, duration, specialist referral criteria, references, review dates, and evidence levels. Drafts are peer reviewed for 4 weeks where they are endorsed without changes or with minor revision, or need a major revision. Guidelines are updated based on comments, and repeat peer-review if necessary. Once ratified, uploaded to Antimicrobial Resource website.

Results

- 104 guidelines developed; average 73 draft views; 7 comments per draft (3 had second peer-review)
- >7000 hits/month
- Antimicrobial prevalence decreased from ~35% to ~25%
- CDI decreased from ~80 to ~20 cases/month

Discussion

Many Trusts use pocket-sized guidelines which go out of date. Our pathways focus on diagnosis and investigations, with antimicrobials if necessary. Development processes promotes ownership and subsequent usage. Feedback mechanisms ensure continual update. Less patients are on antimicrobials or develop CDI. Changes in prescribing may have contributed.

Conclusion

Web-based, evidenced-based, peer-reviewed antimicrobial guidelines are an effective method to support prescribers in their diagnosis and treatment of infection. Links to resources such as eBNF, eMC and dose calculators improve patient safety. Feedback processes with regular update ensure that guidelines are always up-to-date. Guidelines designed and delivered in this manner promote usage, and when combined with other elements of antimicrobial stewardship, is associated with a decrease in the prevalence of antimicrobial usage and reductions in some HCAIs.

No conflict of interest

DGI018 Intraocular recombinant tissue plasminogen activator: a case report

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Background

The formation of intraocular fibrin is a potentially serious

complication of cataract surgery that may lead to surgical failure. Intracameral injection of recombinant tissue plasminogen activator (r-TPA) has been advocated for treatment of postsurgical fibrinous membrane formation in adults following cataract surgery.

Purpose

To describe a case report of a patient that required an intracameral injection of r-TPA due to the formation of intraocular fibrin following uncomplicated cataract surgery.

Material and Methods

Medical record review. Bibliography research about intracameral r-TPA (elaboration, dosage, effectiveness).

Results

66-year-old female presented to the Emergency Service with loss of visual acuity (20%). Eleven days before, she had undergone a routine uncomplicated right eye cataract surgery, with the use of topical antibiotics and corticoids postoperatively. She was diagnosed of anterior uveitis, with corneal edema, intraocular pressure elevation and fibrin membrane formation on the intraocular lens. Eighteen days after topical ophtalmic treatment (with prednisolone, apraclonidine, cyclopentolate and timolol) and oral acetazolamide, the acute phase improved but persisted a dense fibrin plaque on the intraocular lens, for what the ophthalmologist decided to ask the Hospital Pharmacy Department for intracameral r-TPA elaboration, as "off-label" use. After develop the Normalized Procedure, intracameral r-TPA injection of 25 mcg/0,1 ml was prepared in a sterile area with an horizontal laminar flow cabinet in order to guarantee product sterility. After the intracameral administration, the fibrin membrane rapidly dissolved (in 24-48 hours) without any complication. Also, intraocular pressure decreased reaching normal levels and visual acuity increased (80%).

Conclusion

- The prompt resolution of the fibrin membrane is important since it may cause a reduction in visual acuity
- The use of r-TPA may supplement the use of steroidresistant fibrin membrane dissolution with minimal side effects. r-TPA might have its own place in ophthalmologic therapy.

No conflict of interest

DGI019 Compliance of the antibiotics policy in a general hospital

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Background

Establishing a good policy for the use of antibiotics at hospital level is essential in clinical practice to optimise their use and to reduce the occurrence of antimicrobial resistance.

Purpose

To evaluate compliance with the antibiotics policy established by the pharmacy and therapeutics committee and infections committee for the use of cefotaxime, linezolid and meropenem.

Material and Methods

A retrospective review of all treatments with cefotaxime, linezolid and meropenem between March 2009 and March 2010. The protocols for use of these antibiotics and the patient's clinical histories were reviewed to verify their correct use.

Results

Cefotaxime was used in 19 cases, only 13 of them (68.42%) matched the indications approved by the committees: in central nervous system infections when quick action is needed (7 cases) or infections in newborn infants to prevent bilirubin encephalopathy (6

cases). Linezolid was used in 31 patients. The treatment matched the protocol in 23 of the 31 cases (74.19%). Linezolid is approved in our hospital in pneumonia and skin infections caused by vancomycin-resistantMRSA (7 cases) or when vancomycin is contraindicated (16 cases). As for meropenem, there were 18 treatments. It was noted that 12 of the 18 treatments (66.67%) were prescribed according to hospital antibiotic policy, which approves the use of meropenem in brain abscess, meningitis in immunocompromised patients, when there is risk of seizures (10 cases), or when seizures have appeared associated with treatment with imipenem (2 cases). If we evaluate the 3 antibiotics globally, 70.58% of the treatments were in line with the committee-approved indications.

Conclusion

The prescription of antibiotics complies with hospital antibiotic policy in a high percentage of cases. However, we should insist on dissemination of the committee's decisions to ensure the proper use of antibiotics

No conflict of interest

DGI020 Effectiveness and safety of azacitidine in the treatment of patients with myelodysplastic syndromes and acute myeloid leukemia

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Background

Azacitidine is a hypomethylating agent and represents a new approach to treatment with important benefits for patients with myelodysplastic (syndrome MDS) and a related condition called acute myeloid leukaemia (AML).

Purpose

To evaluate the efficacy and safety of using azacitidine in our hospital.

Material and Methods

A retrospective study of all patients treated with azacitidine from February 2008 to August 2010. Data source: clinical history and computerised records from the cytostatic unit.

The following variables were analysed: sex, age at diagnosis, diagnosis, previous treatment received, number of cycles, dose and dose reduction, response, need for transfusions and colony stimulating factor.

Safety was evaluated by the appearance of adverse reactions.

Results

10 patients (8 men, 2 women) with mean age 71.8 years old (range 57-78) were investigated. 6 patients had MDS (1 subtype RAEB-1 (anaemia with excess blasts), and 5 RAEB-2) and 4 AML with previous MDS, in first remission after induction chemotherapy. Patients received azacitidine 75 mg/m² subcutaneously for 7 days every 28 days. A dose reduction (60 mg/m²) was required in 3 patients with AML. All patients required transfusions during the treatment; 1 (RAEB-1) required colony-stimulating factor.

Of the 4 AML patients: 2 were still continuing with the treatment after 12 and 6 cycles respectively; 1 died after 5 cycles; 1 maintained complete response up to 6 cycles. Of the 6 MDS patients: 1 was still continuing with the treatment after 12 cycles; 1 progressed to AML after 6 cycles; 3 died (after 6 and 4 cycles) and in 1 patient treatment was suspended (after 10 cycles) due to pancytopenia. The main side effects were haematological (80%) followed by nausea (20%) and local erythema (only in the first cycles).

Conclusion

Azacitidine has shown efficacy in 4 of 10 patients. Haematology toxicity was the main adverse effect observed, according to current evidence.

No conflict of interest

DGI021 Bevacizumab in recurrent glioblastoma

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Background

The use of bevacizumab in patients with glioblastoma is an off-label therapeutic option, not recommended by the Committee for Medicinal Products for Human Use, but supported by phase II clinical trial results.

Purpose

To assess treatment use, initiation criteria and adverse events related to bevacizumab, in patients with glioblastoma.

Material and Methods

We retrospectively analysed a series of patients with glioblastoma who were being considered for treatment with bevacizumab. All medical records were reviewed and the monitoring was conducted from June 2010 to September 2010.

Results

Treatment was sought for eight patients with a median age of 57 years (range 7-62). Three of them were not candidates to receive bevacizumab, two patients because of bad performance status and one patient due to thromboembolic disease.

Five patients underwent treatment in a first or second relapse. The eligibility criteria were similar to those found in clinical trials: they had previously received external-beam radiotherapy and oral temozolomide. Disease progression after chemotherapy was confirmed by magnetic resonance imaging and all patients showed good performance status. Four patients received bevacizumab plus irinotecan (10 mg/kg, 125 mg/m²) and one patient received bevacizumab plus temozolomide (7.5 mg/kg, 75 mg/m²) once every two weeks. Currently, four patients are continuing treatment with an average of four administrations (range 1-6).

One patient had rapid disease progression and died two months after starting treatment. In another patient, the dose of bevacizumab was reduced from 10 mg/kg to 7.5 mg/kg and irinotecan was decreased 10 percent because of grade I asthenia and abdominal pain. Other patient had grade I neutropenia, and the remaining patients had no adverse events.

Conclusion

The eligibility criteria were adjusted to the most representative studies reported in the literature. Bevacizumab is a therapeutic option, with acceptable toxicity, in patients refractory to standard treatment, but it is advisable to perform more trials with a larger population.

No conflict of interest

DGI022 Safety of azacitidine in patients with myelodysplastic syndromes

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Background

Azacitidine is a demethylating agent recently introduced for myelodysplastic syndrome.

Purpose

to evaluate safety of azacitidine in patients with myelodysplastic syndrome.

Material and Methods

a retrospective observational study in patients treated with azacitidine from January 2009 to April 2010. Data were collected from clinical histories and from the electronic prescription program.

Results

azacitidine is approved by the EMA for subcutaneous use and for both subcutaneous and intravenous by the FDA. 12 patients, 10 men and 2 women, with an average age of 74, were treated with azacitidine. Three patients received azacitidine subcutaneously, seven intravenously and two patients began with subcutaneous injection and changed to intravenous route to prevent from hematoma. Injection site reactions were registered in 4 patients (subcutaneous administration): hematoma (4), blushing (3), pain (2), inflammation and induration (2). There were 20 admissions (10 patients), with an average of 1.7 per patient. The reasons were: febrile neutropenia (5), anaemia (4), respiratory infection (3), fever (3), thrombocytopenia (2), pancytopenia (1), hypotension (1), epistaxis (1), local skin infection (1), septic shock (1) and hypocalcemia with paralytic ileus (1). Two admissions were for reasons unrelated to their pathology. Six patients died during the hospitalization: 2 febrile neutropenia, 2 anaemia and fever and 2 unrelated. Most of these complications occurred before the third cycle. Hypotension was also evaluated with blood pressure data of 8 patients, 6 of whom presented hypotension (<90/60mmHg) or decreases of more than 20mmHg after azacitidine administration. Two cycles had to be delayed due to hypotension. Four of these patients were with antihypertensive treatment. No differences were seen between administration routes.

Conclusion

adverse reactions overlap with the complications of the disease itself, so it is difficult to assess if they are therapy-related or part of natural course of the disease. Further studies would be necessary to determine frequency and severity of adverse reactions and, in case of hypotension, if antihypertensive treatment should temporary be discontinued.

No conflict of interest

DGI023 L-asparaginase from Erwinia chrysanthemi: an alternative in patients with hypersensitivity to L-asparaginase from Escherichia coli

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Background

L-asparaginase (L-ASA) is an effective antineoplastic agent, which is an integral part of combination chemotherapy protocols for adult acute lymphoblastic leukaemia (ALL). Its antitumor effect results from the depletion of asparagine, an amino acid essential to leukaemia cells, and subsequent inhibition of protein synthesis leading to cytotoxicity.

Purpose

To identify and analyse the adverse reactions associated with administration of L-ASA from *E. coli* and to show the benefit of L-ASA from *E. chrysanthemi* in those patients.

Material and Methods

Observational, descriptive and retrospective study of adult patients with ALL treated with *E. coli* L-ASA from January 2008 to June 2010 who showed adverse reactions to the drug. The data were obtained from the hospital's electronic clinical history and FARMIS software. All adverse reactions were recorded and reported by "yellow card" to the Pharmacovigilance Autonomic Center.

Results

Of the 17 patients treated with E. coli L-ASA during the study. 8 showed hypersensitivity reactions (47%). The average age of these patients was 31.8 (16-66) years and the assignment to different treatment protocols was made according to age, number of leukocytes present in the blood and cytogenetic abnormalities. Thus, 5 patients were classified as intermediate risk and 3 as high risk and the dosage of L-ASA ranged between 10,000 and 25,000 IU/m². In all patients the administration of E. coli L-ASA was discontinued when adverse reactions appeared. Four patients showed a mild allergic skin reaction and corticosteroid or antihistaminic treatment was prescribed. The other 4 patients presented anaphylactic shock and were treated with adrenaline, oxygen and corticosteroids. After recovery, six patients continued with the same oncologic scheme, replacing the L-ASA from E. coli by one derived from E. chrysanthemi, adjusting the dose according to the phase of the protocol when the adverse reaction appeared (mean dose 20,000 IU/m²) and changing from intravenous to intramuscular administration. Only in one patient was the L-ASA removed and in another the whole scheme was changed.

Conclusion

- The intramuscular administration of L-ASA derived from E. chrysanthemi was safe in all patients with initial sensitivity to L-ASA from E. coli, constituting a useful option for continuing with the established treatment in patients with ALL. - Exhaustive monitoring of adverse reactions can lead to corrective measures to ensure minimum risk and more effective treatment.

No conflict of interest

DGI024 Study concerning the antibiotic resistance phenotypes of some bacterial species with nosocomial potential

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Background

The nosocomial infections, through their frequency and consequences, represent a prior problem for the human pathology. These infections are more and more difficult to restrain as a result to the apparition of "hospital supergerms" with increased virulence and multiple antibiotics resistances. The present research is important in identifying the antibiotic resistances of bacteria which can be involved in nosocomial infections. The resistance phenotypes detected can be used in establishing the preventive post-surgery antibiotic therapy in order to avoid the transmission of hospital infections.

Material and methods

We analyzed 1620 biological samples (blood, pus, cervix secretions, urines, pharyngeal and nasal swabs) taken from the Obstetrics and Gynecology and Intensive Care patients from the Regional Emergency Hospital of Craiova, Romania. By classical bacteriological diagnosis we isolated 380 pathogens. The antibiotic susceptibility testing was performed by disk diffusion Kirby-Bauer method.

Results

The results allowed us to establish some resistance phenotypes of important pathogens groups which can be used in antibiotic therapy. We identified for Escherichia coli a high percentage of the PAZA betalactam resistance phenotype (50,48%), but for aminoglycosides the wild phenotype was predominant (40,71%). Also Escherichia coli had a sensitive phenotype (69,48%) to

quinolones. For Klebsiella pneumoniae the most frequent aminoglycosides resistance phenotype was ESBL (48,48%). Also, we detected a high resistance (32,23%) of Staphylococcus aureus strains to penicillin and methicillin (MRSA), and almost equal frequency of sensitive (36,24%) and KGT (30,24%) aminoglycoside resistance phenotypes.

Conclusion

Our study is of great importance in monitoring the circulation of bacterial strains which can be involved in nosocomial infections and in choosing the right therapy needed to prevent the phenomena of selecting multi-resistant strains.

No conflict of interest

DGI025 Effectiveness and safety of Entecavir and Tenofovir in patients with chronic hepatitis B

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Background

To evaluate effectiveness and safety of Entecavir (ETV) and Tenofovir (TNF) in patients with chronic hepatitis B (CHB) who had not previous been treated with a nucleo(t)ide analogue.

Material and Methods

Retrospective descriptive study of patients treated with TNF or ETV who had not previous been treated with a nucleo(t)ide analogue from January 2009 to May 2010. The information was obtained from medical records, recorded the following data: age, sex, laboratory diagnosis, treatment, dose, test (alanine aminotransferase (ALT)), DNA HBV, HBeAg, HBsAg, anti-HBs and anti-HBe. Measure of response consists of normalization of ALT levels (5-31 IU/I) and decrease in serum DNA HBV level, loss of HBeAg (in patients HbeAG positive) and loss of HBsAg in patients HBeAg negative. The safety profile was evaluated by type of side effects.

Results

6 patients were treated with TNF (4 men and 2 women); average age of 45.2 (29-63) years; the dose was 300mg/day, and the treatment duration was of 4.6 5 patients were HBeAg negative. One patients had severe acute hepatitis B .To achieve virological and biochemical response in 8.3% of patients. One patient showed gastrointestinal intolerance. 7 patients were treated with ETV (5 men and 2 women), average age of 46.1 (39-61) years; the dose was 0.5 mg /day and the treatment duration was of 8.4 6 patients were HBeAg negative and one patient had severe acute hepatits B.To achieved virological and biochemical response in 85,7% of patients. One patient showed gastrointestinal intolerance,

Conclusion

Both treatments were effective in normalizing ALT levels and lower HBV DNA levels. The safety profile of the two agents was similar. Based on these results, the choice between these two possibilities in HBC should be in terms of cost-effectiveness.

No conflict of interest

DGI026 Assessment of lung cancer treatment

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Objective

To review the treatment of lung cancer patients (LC) and to assess compliance with Clinical Practice Guidelines (CPG) established for this disease.

Material and Methods

A retrospective observational study of patients with LC in July December 2009. Data were obtained from a review of pharmacotherapeutic history. The variables were: sex, age, tumour stage at diagnosis, histological classification, chemotherapy (CT) received and number of lines.

Results

63 patients, 49 males and 14 females with a median age of 58 years (range: 38-82). LC (NSCLC)was diagnosed in 51 patients (68.6%) 35 were classified histologically adenocarcinomas, 13(25.6%) as squamous cell carcinoma, and 3 (5.8 %) as large cell carcinoma. LC(SCLC) was diagnosed in 12 (19%). TNM staging system was used for NSCLC. According to this system, 5.8% of patients (3) were classified as stage IA, 1.92% (1) stage IB, 5.8%(3)as IIA,5.8%(3) and IIIA, 21.5%(11) and IIIB and 58.8% (30) and IV. SCLC uses a different classification: limited disease(LD), 25% (3) and extensive disease (ED), 75%(9). With regards to the CT received, patients with adenocarcinoma and stage I, II and III (14), 35.7% received CT (cisplatin and docetaxel)and radiotherapy as the first-line treatment, and as the second-line pemetrexed alone (21.4%) or erlotinib (14.3%). Most patients with adenocarcinoma and stage IV (21) received a combination of cisplatin and pemetrexed as the first-line treatment (13, 61.9%). As the second line, 14.3% received erlotinib. Patients with squamous cell NSCLC, 38.5% received as the first line cisplatin and docetaxel and as the second line (15.4%), gemcitabine and vinorelbine. Of the 3 patients with large cell NSCLC, 2 (66.6%) were treated with the combination of cisplatin and pemetrexed as the first-line treatment and one (33.3%) received pemetrexed alone as the second line. Of the 12 patients diagnosed with SCLC, 10 received as the first-line a combination of carboplatin / cisplatin and etoposide. Gemcitabine plus irinotecan was administered in 2 out of 12 (16.6%) patients as the secondline.In NSCLC, 53% (27) received one line of treatment, 27.4% (14) two, 15.7% (8) three, two patients (3.92%) were given five and six lines of treatment, respectively. In the SCLC, 83.3% (10) received one line and 16.6% (2), two. 84% of patients with LC received two lines of treatment.

Conclusion

The establishment of CPGs is a necessary element to standardize CT received by patients. Compliance with the CPGs in the treatment of LC is high, which means greater efficiency and quality improvement.

No conflict of interest

DGI027 Prevention of bronchiolitis in an infant with congenital heart disease: the effectiveness of palivizumab.

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Purpose

To study the effectiveness and toxicity of palivizumab for immunoprophylaxis of bronchiolitis in infants with congenital cardiopathy (CC).

Material and methods

We performed an observational and retrospective study of patients with haemodynamically significant CC that had been treated prophylactically with palivizumab between the 5-month periods of October to February in the years 2008-2009 and 2009-2010. Data were collected from the revision of the medical records corresponding to these periods.

Patients were treated with 15 mg/kg/month palivizumab. As a measure of effectiveness we used: hospitalization rate, days of hospitalization, time in the ICU and need for mechanical ventilation. As a security measure we measured the incidence of adverse reactions.

Results

We recorded 15 patients, 10 men and 5 women ≤ 24 months of age (mean: 12.4 months) suffering from CC. The distribution per period was as follows: 4 children were treated in the 2008-2009 5-month period, 9 in 2009-2010 and 2 in both periods. Two patients (13.3%) were born preterm at 32 weeks. We recorded 8 patients (53.3%) that were operated surgically prior to the period. Five doses monthly during the corresponding periods were administered in 80% (12) of the patients. One (6.6%) child suffered an episode of bronchitis while undergoing treatment. Positivity for respiratory syncytial virus (RSV) was confirmed in the nasal discharge, which required admission to the paediatric ICU for 12 days. For the first 48-72 hours the patient needed oxygen due to the presence of oxygen desaturation although there were no signs of cardiovascular decompensation. They did not require mechanical ventilation. The respiratory symptoms improved favourably. One patient (6.6%) presented skin pallor and generalized macular rash which was probably related to the administration of palivizumab.

Conclusion

Compliance to the recommendations set forth in the technical data sheet was observed in 80% of the patients, and 93.3% did not suffer any outbreak of disease in the lower respiratory tract. Only one patient suffered a rash as an adverse reaction, so we may conclude that palivizumab is a well tolerated drug.

No conflict of interest

DGI028 Clinical use of linezolid:Retrospective study at the University Hospital of Limoges (France)

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Background

Faced with a significant increase in the use of linezolid observed in 2009 in the University Hospital of Limoges, a study was carried out to estimate the relevance of its use with regards to the recommendations made by its marketing authorization and to optimize its therapeutic follow up.

Linezolid is used to treat bacterial GRAM positive infections: pneumonia and soft tissue infections. It is an expensive antibiotic prescribed as a last resort.

Material and Methods

Retrospective study performed in patients treated with linezolid between January and April 2010.

The collected data concerned the conformity of prescription, implementation and monitoring of the antibiotic therapy.

Results and discussion

Forty two patient's records were analyzed. In 78% of the cases, linezolid is prescribed out of marketing authorization indications. The listed indications are:

Septicemia	29%
Fever syndrome	19%
Central catheter infections	14%
Skin and soft tissue infections	12%
Pneumonia and lung infections	12%
Urinary infections	7%

Ascitic fluid infections	2%
Prothesis infections	2%
No indication	2%

In the context of the proper use of antibiotics and in order to supervise the use of linezolid, a protocol will be set up by the hospital. The protocol will be based on scientific recommendations and will be validated by the anti-infective committee. It will permit the justification of the prescription of linezolide in relevant indications not mentioned in its marketing authorization and inadequate use which could be at the origin of an apparent resistance will be avoided.

Conclusion

This work allowed us to describe clinical use of linezolid in our hospital. The actions taken will improve its use. The recommendations established will be distributed to all care units and will provide a tool for prescribing and monitoring this antibiotic. A revaluation will be made after one year to verify the efficiency of actions implemented.

No conflict of interest.

DGI029 Safety experience with lenalidomide in multiple myeloma

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Background

Lenalidomide is a potent analogue of thalidomide with improved safety profile. It is indicated for the treatment of multiple myeloma (MM) in patients who have failed one prior therapy.

Purpose

The aim was to evaluate toxicity and tolerance of lenalidomide in patients with MM.

Material And Methods

Retrospective observational study of patients with MM treated with lenalidomide from January 2008 to May 2010.

Data were collected from the cytostatics software Oncofarm^a, clinical histories, out-patient dispensing software Farmatools^a and analytics registration software Omega3MIL^a.

Results

A total of 18 patients were included in the study (7 men, 11 women). Average age at the time of diagnosis: 64.7 years.

Treatment interruption was needed in 10 patients (55.5%): due to haematological toxicity (1), death (1), lack of response (5) and disease progression (3).

The most common adverse effects observed in these patients were those associated with haematological toxicity: 14 patients (77.8%) developed anemia, grade III anemia ocurred in 6 patients; 9 patients (50%) developed neutropenia, grade III neutropenia occurred in 2 patients and grade IV in 2 patients; 10 patients (55.5%) developed thrombocytopenia, grade III thrombocytopenia ocurred in 7 patients and grade IV in 2 patients. Upper respiratory tract infection occurred in 8 patients (44.4%). 1 case (5.6%) of deep vein thrombosis was reported although thromboembolic prophylaxis was made. 6 patients (33.3%) suffered from gastrointestinal side effects. 1 patient (5.6%) developed neuropathy. Fatigue occurred in 2 patients (16.7%) and peripheral oedema ocurred in 1 patient (5.6%)

10 patients (55.5%) required blood products transfusions and 3 patients (16.7%) growth factors.

Conclusion

The most common adverse effects were those associated with haematological toxicity and upper respiratory tract infections. Careful monitoring of those serious adverse effects is essential to prevent life-threatening complications.

Only 44.4% of patients did not require any support therapy during the treatment with lenalidomide.

No conflict of interest

DGI030 Evaluation of patients' knowledge on medication dispensed in an outpatient pharmaceutical care unit

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Background

Patients' knowledge on drug therapy is one of the bases for compliance. The ability of patients to adhere to a medication regimen is imperative for achieving optimal outcomes.

The aim of this study is to assess patients' knowledge on the drug therapies they are prescribed which are dispensed in an outpatient pharmaceutical care unit (OPCU).

Material and Method

This is a cross-sectional study using a 24-item, self administered questionnaire, offered to patients who were attended in an OPCU between July 2009 and October 2009. Two of the questions were about drug brand name and medication purpose. Age, sex, educational level and medical origin were registered.

A total of 240 patients completed the questionnaire (response rate was 35.3%). The participants had a mean (SD) age of 52.1 (17.4) years and 51.3% were men. 188 patients (78.3%) knew medication name and 186 patients (77.5%) knew drug indication. Of the 165 (68.8%) patients with satisfactory knowledge (drug name and indication) 52.7% (87/165) were men (NS), 52.5% (83/158) had basic educational level (p<0.01), and had a mean (SD) age of 48.8 (15.0). Medical specialities with a higher average of patients with good knowledge of their medication were pneumology (100% of patients included in this group), dermatology (85.7%) and rheumatology (82.5%). Lower scores belonged to nephrology (only 35.3% of the patients in this group had a good medication knowledge) and haematology (44.4%) patients.

Special attention should be addressed to those patients with low educational level and to specific treatments (nephrology and haematology medication). An integrated and multidisciplinary education program may improve the patient's knowledge on medication as well as patient's compliance.

No conflict of interest

DGI031 Dutch standardised reference work on manipulation of oral dosage forms

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Background

Patients are often not able to swallow tablets/ capsules which results in manipulation of oral dosage forms by the patient or a care giver. Mostly it concerns elderly patients, children and/ or patients with enteral feeding tubes. Lack of knowledge results in medication errors, like crushing modified release tablets. Several hospital pharmacies made reference works for other care givers to support right decision making and manipulation methods. These have

shown increase in quality of pharmaceutical care. Initiative was taken by the Royal Dutch Pharmacists Association and the Dutch Hospital Pharmacists Association to develop a nationwide standardised reference work on manipulation of oral dosage forms.

The purpose of the project was to give standardised information on specific medicine to support the pharmaceutical care process from prescribing to administration in order to reduce medication risks, intended for every type of care giver concerned with any of the steps in this process.

Material and methods

A multidisciplinary working group was set up, consisting of hospital pharmacists, community pharmacists, a pharmacy technician, nurse practitioner and dietician. The process from prescribing to administration was described and the information need in each moment of this process determined. Existing knowledge, experience and further information demands were also determined. Where needed, new knowledge was gained and experts were consulted. Standard operation procedures were made to ensure constant quality of information. Texts were tested by the intended users on workability and comprehension.

Results and conclusion

An electronic reference work was made with information on 500 active ingredients and their oral dosage forms. Tablets and capsules were evaluated on technical aspects and occupational health hazards when manipulating tablets and capsules. This resulted in the conclusion on whether a specific drug could be manipulated. Separate manipulation methods were given in case of swallowing difficulties and enteral feeding tubes, each method accompanied by detailed instructions and animated video's on manipulation and administration techniques. In case of enteral feeding extra instructions were given on avoiding drug- enteral feeding interactions. A patient information leaflet was made with information on swallowing difficulties, swallowing techniques and explanation on medication risks when manipulating tablets and capsules.

No conflict of interest

DGI032 MANAGEMENT INNOVATIONS THE IN PHARMACOTHERAPY OF MEDICAL ONCOLOGY UNIT ATTACHED IN A GENERAL HOSPITAL BASIC

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Background

The hospital under study has not recognized the Medical Oncology Unit, although in its portfolio of services is seen as providing care for patients of cancer treatment area in three diseases: breast, lung and colorectal established as priorities by the Directorate Management hospital admission and hospital oncology unit of reference. The protocols are made in December 2005 between hospital pharmacy and oncology service reviewed. The provision is made by two oncologists care activity of the reference center for two days a week, not persisting continuity of prescribers, but changes are taking place regularly optional. In the absence of computer application, the prescription is made in sheet prepared for the purpose of completing manual.

Analyze the evolution of pharmacotherapy for Medical Oncology Unit in a general hospital dependent on a core referral hospital.

Material And Methods

Design: Longitudinal retrospective study over a period of four years (January 2006-December 2009), performing requirements analysis and review of the preparations made. Validated and recorded by the pharmacist on sheet designed by the service itself.

Results

Analysis of all prescriptions:

2006,42 patients (PT): breast cancer (22) lung cancer (14), colorectal cancer (6).

2007,30 patients: breast cancer (19) lung cancer (8), colorectal cancer (3).

2008,47 patients: breast cancer (24) lung cancer (15), colorectal cancer (8).

2009,30 patients: breast cancer (14) lung cancer (9), colorectal cancer (7).

Conclusion

1^a. There is no upward trend in the number of pharmacotherapeutic treatments performed.

2ª. Although the unit is operating properly, the three parties involved (Medical Oncology Service, Pharmacy and Nursing), calls for the daily care continuity and achievement of computer applications that facilitate clinical activity in the area while maintaining the security and quality in the whole circuit, all aimed at getting the safety and welfare of the patient.

No conflict of interest

DGI033 ECONOMIC ANALYSIS OF THE MANAGEMENT OF MEDICAL ONCOLOGY UNIT ATTACHED IN A BASIC GENERAL HOSPITAL

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Background

The hospital under study is not recognized Medical Oncology Unit, so you do not have a budget level of economic pillar for the purchase of drugs needed for this unit. However, in its service portfolio referred as health provision for patients of area oncological treatment of three pathologies: breast cancer, lung and colorectal, established as priority by management hospital of our hospital and the reference hospital's oncology service.

Purpose

Analyze the evolution of the economic impact of a Medical Oncology Unit in a general hospital dependent on a reference hospital.

Material And Methods

Design: A retrospective study was longitudinal over a period of four years (January 2006-December 2009). The acquisitions are made by the study hospital while consumption is charged to the reference hospital, performing a cost analysis by software application pharmacy.

Results

Cost analysis. Consumption:

2006: € 142,033.11. Patients treated: 42.

2007: € 115,992.41. Patients treated: 30.

2008: € 156,515.72. Patients treated: 47.

2009: € 193,661.13. Patients treated: 30.

Conclusion

There is a cost increase to the number of patients treated during 2006, 2007 and 2008, increasing significantly in 2009, when not in line with the treatments but increased with the incorporation of new drug protocols of particular economic importance.

No conflict of interest

DGI034 Darunavir/ritonavir monotherapy for the treatment of HIV infection

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Background

Darunavir/ritonavir (DRV/r) monotherapy was recently included in European and Spanish guidelines as alternative treatment in HIV infection. This strategy represents an option in patients with intolerance to nucleoside reverse transcriptase inhibitors (NRTI) or for treatment simplification. Such strategy applies only to patients without history of failure on prior protease inhibitor (PI) based therapy and who have had viral load < 50 c/ml in at least the past 6 months.

Purpose

The aim of this study is to analyze HIV patient treated with DRV/r monotherapy in a tertiary hospital and to evaluate its efficacy.

Material and methods

Retrospective study of all patients treated with DRV/r monotherapy from January 2009 to September 2010. Medline/Pubmed search using keywords: darunavir, HIV, monotherapy. Data were obtained from the clinical histories, outpatients' computer files and laboratory reports. Variable studied: age, sex, previous treatment, reason for change treatment and duration of new treatment.

Efficacy was measured as the average of current viral load and CD4 T-cell count.

Results

The study included 20 patients (80% men, 20% women). Mean age was 49±8 years. Patients were previously treated with: Pl/r monotherapy (40%); 2 NRTIs+1Pl/r (20%); 1NRTIs+1 Pl/r+1NRTIt (15%); 1NRTIs+1NRTIt+1NNRTI (5%); 1 Pl/r+ RAL (10%); 1NRTIs+RAL+1 Pl/r (5%); 1NNRTI+RAL+1IP/r (5%).

Reasons for treatment modification were classified as: treatment simplification (30%), adverse events (50%), treatment resistance (15%) and non-adherence to antiretroviral therapy (5%).

The average duration of treatment with DRV/r was 5±3 months. Currently 75% of patients achieved undetectable viral load and CD4 T-cell count 618±306 cell/µL.

Conclusion

DRV/r monotherapy has demonstrated efficacy maintaining continuous plasma HIV-RNA suppression in a large proportion of patients. It is an alternative option for those patients with toxicity related to NRTI, or for trying to avoid such toxicities in virologically controlled patients without previous failure to PI. In addition it is also a good strategy to reduce complexity and improve treatment adherence.

No conflict of interest

DGI035 Lopinavir/ritonavir monotherapy as a simplification strategy in the treatment of HIV infection

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Background

Guidelines for the use of antiretrovirals for HIV infection recommend combining at least three agents. But, as recommended by GESIDA and EACS guidelines, lopinavir/ritonavir (LPV/r) monotherapy could be considered in patients without prior failure of protease inhibitor, with undetectable viral loads for prolongued periods (<50 copies/ml more than 6 months) or with signs or symptoms of nucleoside/nucleotide toxicity as a strategy to reduce toxicity and costs of antiretroviral therapy in the long term while also preserving other therapeutic options.

Purpose

Review the reasons for change to LPV/r monotherapy and evaluate its efficacy.

Material and Methods

Retrospective observational study from January 2008 to September 2010 of clinical and pharmacotherapeutic history of HIV patients treated with LPV/r monotheraphy. The following data were collected: age, sex, reasons for simplifying to monoteraphy and months of treatment with LPV/r. Moreover, efficacy was measured as percentage of patients with indetectable plasma viral load (<50 copies/mL) and their CD4-T cell count.

Results

1508 active patients with HIV during study period of which 83 (5.5%) were in treatment with LPV/r monotherapy. 59 (71.08%) men and 24 (28.91%) women, with a mean age of 46±8 years. Reasons for simplifying to monoteraphy were: simplification because of poor adherence (54.22%), previous triple therapy related toxicity (20.48%), liver disease (liver transplantation, cirrhosis or hepatitis C virus coinfection) (8.43%), previous antiretroviral drug resistance (7.23%), kidney disease and/or dialysis (6.02%) and explicit wish of patients (3.61%). Average time with LPV/r treatment was 19±14 months. Percentage of patients with undetectable plasma viral load was 76.74%, and their average CD4 cells count is 541.70±271.54 cells/µL.

Conclusion

LPV/r monotheraphy has demonstrated efficacy maintaining continuous plasma HIV-RNA suppression in a high proportion of patients with remarkable CD4 cells counts. It is an alternative option mainly for patients with intolerance to nucleoside/nucleotide analogues, and to reduce complexity and improve treatment adherence.

No conflict of interest

DGI036 Pemetrexed as second-line treatment of advanced non-small-cell Lung Cancer

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Background

An increasing number of patients with advanced non-small cell lung cancer (NSCLC) progress after front-line chemotherapy. Pemetrexed is a multitargeted antifolate agent registered in second-line treatment of NSCLC.

Purpose

To describe efficacy and safety of pemetrexed as second-line treatment in a cohort of patients in a teaching hospital.

Material and Methods

Retrospective observational study of all patients with NSCLC treated with pemetrexed since January 2007 and December 2008 for second-line therapy. From medical records and pharmacy database we collected: sex, age, previous chemotherapy, metastatic sites, Status performance, number of cycles received, response rates, time to progression, 1-year survival rate and safety profile

Results

In this two-years period, 30 patients received second-line treatment for NSCLC of whom fifteen patients (13 men, 2 women), mean age 51 years-old (43-70) received pemetrexed 500 mg/m² every three weeks as single agent. All patients had received platinum-based chemotherapy as front line. Most common metastatic sites were: bone (2), brain (2), and the liver (2). Histology was predominantly non-squamous (66%) and the mean ECOG Status Performance score was 2. Mean number of cycles received was 3 (1-8) It was reported partial response in one patient, stable disease in 4 patients (26%), 8 patients with early disease progression (53%), one patient

was considerer no responder and there is no information from other patient. Mean time to progression was 2.3 months (0,6-5) and the 1-year survival rate was 60%. Most common adverse events were grade 2 mucositis and asthenia (3 patients). Two patients experienced haematological toxicity (grade 1–2 anaemia and thrombocytopenia) that required blood transfusions and the use of Erythropoiesis-Stimulating Factors

Conclusion

For patients with advanced NSCLC who progress following first-line platinum-based chemotherapy, data collected support the use of pemetrexed in second-line treatment as an efficacious option with a manageable toxicity profile.

No conflict of interest

DGI037 Restricted Antibiotics Management

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Background

Antibiotics have been tried to be restricted and controlled worldwide, because of raising concern on antibiotic resistance problems. Frequent unnecessary and inappropriate use of these drugs give rise to disease-causing microbes that are resistant to drug therapy.

Purpose

The purpose of this research is to develop policies and guidelines of the process to determine the patients who use restricted antibiotics and plan their treatment under the supervision of the infection control specialist.

Material and Methods

To start the project, a multidisciplinary committee which consists of the members of the infection control committee was constructed. The committee first listed the restricted antibiotics in the hospital formulary and found that 13% of all drugs in the list were restricted antibiotics. Then, the antibiotics using instruction was revised and it became obligatory that all patients who used restricted antibiotics more than three days were to be treated under the supervision of infection control specialist. The drug orders consisting a restrictive antibiotic were stamped by the pharmacy department when they reviewed the order, and the physicists who saw the order stamped were expected to consult the infection control specialist if the drug was to be used more than three days. The revision wasn't very successful, because the physicians were reluctant to inform the infection control specialist although they saw the restricted antibiotics stamp. To resolve this problem, information technology has been used. Pyxis drug consoles are programmed to provide a batch report every morning which lists all the patients who use restricted antibiotics and these lists are submitted to the infection control committee to inform them about these patients.

Results

It has been observed that 75% of the patients on restricted antibiotics have been treated under supervision of the infection control specialist. The list of antibiotics which have been used inappropriately is determined and classified according to the department using tehm. These departments have been encouraged to follow the restricted antibiotics policies. The appropriate use of antibiotics has been recorded as a performance measurement to evaluate the success of the project.

Conclusion

The multidisciplinary approach has increased the awareness of the health care professionals on the antibiotic resistance problem. The insufficient involvement of the physicians has been resolved using the information technology. Not only the ratio of the inappropriate use restricted antibiotics is lowered, but also the departments which are less interested in this issue could be determined and they have been encouraged to follow the policies defined.

DGI038 Analysis of medical prescriptions containing highcost antibiotics to treat pneumonia in hospital with the aim of assuring community-hospital continuity

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Purpose

To trace a picture of high-cost antibiotic (HCA) requests in two hospitals of ASL-CN2 to identify correct decisional paths in the choice of treatment and create a shared path of community-hospital continuity.

Material and Methods

During the period of March-April 2010 we recorded the information contained in HCA request forms (RFHCAs): drug (imipenem + cilastatin, meropenem, teicoplanin, piperacillin + tazobactam, cefepime, levofloxacin), diagnosis, treatment, microbiological documentation, reason for choice of antibiotic.

Results

RFHCAs for pneumonia represent more than a third of the total (185/518 requests, 107/261 patients). RFHCAs for nosocomial pneumonia (NP) are the most frequent (40%), followed by "community acquired pneumonia" (CAP)(29%) and "nosocomial by ventilator" (NPV)(10%).

Levofloxacin (mean dose: 500 mg/day for 8 days) is the most popular drug in the treatment of CAP (60%) and represents one third of requests for NP. Carbapenems (mean dose: 1700 mg/day for 5-6 days) are mostly used for the treatment of NP (42%).

Piperacillin + tazobactam (mean dose: 13.2 + 1.6mg/day for 7 days) is widely used in the NPV (68%) and represents one quarter of CAP requests. The sensitivity profile is only recorded in 14% of cases (most often in the NPV). Few drug combination therapies are reported (40/185): 28% in CAP (piperacillin + tazobactam and levofloxacin) and 8% in NPV. Few drug switches are recorded (8/97 patients).

Conclusion

TheRFHCA is useful for tracing trends in prescriptions: there is a preference for empirical therapy, proper division between oral and parenteral therapy, use in 1st and 2nd choice of carbapenems and piperacillin + tazobactam (usually reserved for special cases or targeted therapies).

This study is preliminary to the work of a multidisciplinary group that aims to share best-practice recommendations for empirical treatment of respiratory infections, both at hospital and community level. This study shows the need to:

- find out how community prescriptions affect local hospital prescriptions for CAP,
- monitor pneumonia treatment in hospital by clinical audit.

No conflict of interest

DGI039 ANALYSIS OF THE 'PROTOCOLES OF TOXICITY PROPHYLAXIS' OF CHEMOTHERAPY SCHEMES USING TAXANES

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Purpose

To review the modifications to, or deviations from (MoDs), the protocols established for the prevention of toxicity associated with chemotherapy (CT) schemes that contain taxanes, with a view to identifying opportunities for improvement.

Material and Methods

A retrospective observational study of the CT prescriptions (approved and off-label indications) in the month of June 2010 of

schemes using taxanes. The following data were compiled: medical history number (MHN), diagnosis, CT scheme, number of prescriptions reviewed, number of prescriptions modified and type of modification made. This information was sifted using an Excel database.

Results

We reviewed:

- 141 prescriptions for CT including docetaxel (42 patients). The predominant diagnosis was breast cancer (78.6%). We found 35 (24.8%) MoDs: 77.2% using the cyclophosphamide-adriamycin-docetaxel scheme (in 55.5% dexamethasone had been removed, ondansetron had been added to 33.3%, 11.11% had added aprepitant and removed dexamethasone), 14.90% using the docetaxel alone scheme (80% had added dexamethasone and 20% ondansetron), 5.7% were using the docetaxel-cyclophosphamide scheme (100% added aprepitant) and 2.9% used the docetaxel-trastuzumab scheme (100% removed dexamethasone).
- 182 prescriptions for CT with paclitaxel (54 patients). The predominant diagnoses were breast cancer (63%), ovarian cancer (14.8%) and lung cancer (13%). All modified schemes corresponded to paclitaxel-carboplatin (72.7% added iron, 9.1% added furosemide, 18.2% added aprepitant).

Conclusion

Theresults obtained showed that a review of the steroids and antiemetics protocols is needed in docetaxel schemes. On the other hand, very few patients treated with paclitaxel experience modifications in toxicity prophylaxis treatment.

No conflict of interest

DGI040 Lenalidomide: adverse events review after two years of experience

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Background

Lenalidomide has been authorised by the EMA since 2007 in combination with dexamethasone for the treatment of multiple myeloma (MM). Its adverse events (AEs) often cause modifications or cessation of treatment.

Purpose

To describe lenalidomide-related AEs detected within our hospital-based patients.

Material and Methods

Retrospective descriptive study of patients treated with lenalidomide by reviewing Pharmacy Department records, electronic medical records and Haematology Department records. We noted: age, sex, diagnosis, number of lenalidomide cycles, associated drugs, posology, dosage, toxicity, dose modifications, treatment delays, suspension due to toxicity, filgrastim, erythropoietic stimulating agent (ESA), bisphosphonates and comorbidities.

Results

60 patients began treatment with lenalidomide from 1/3/2007 to 31/12/2009 for MM, myelodysplastic syndrome, myelofibrosis, non-Hodgkin's lymphoma and POEMS syndrome. Median age was 71 (45-90). Median number of cycles was 4 (1-20). In 141 cycles dose was 25 mg, 15 mg in 65, 10 mg in 77, 5 mg in 35 and 1 cycle 5 mg q48h. AEs were: neutropenia (47%, needing filgrastim in 61% of cases), thrombocytopenia (25%), rash (8%), asthenia (7%), deepvein thrombosis (5%) (not related to ESA administration), cardiac insufficiency (3%), neuropathy (2%), and peripheral oedema (2%). AEs caused treatment cessation in 7 cases (12%), dose modifications in 19 (32%) and delays in 23 (38%).

All patients received thromboembolic prophylaxis and 12 (20%) also received ESA. Among MM patients, 17 (36%) received zoledronic acid.

Conclusion

The most frequently reported AEs and those requiring dose reduction or discontinuation of treatment in different studies regardless of diagnosis, were neutropenia and thrombocytopenia. Our results, 46.67% and 25% respectively, are at an intermediate level compared to literature data. It is mandatory to monitor patients at initiation and throughout treatment. Monitoring should be multidisciplinary through protocols for the correct use of prophylaxis and support treatments (GCSF, ESA, zoledronic acid or thromboprophylaxis).

No conflict of interest

DGI041 ANALYSIS OF THE 'PROTOCOLES OF TOXICITY PROPHYLAXIS' OF CHEMOTHERAPY SCHEMES USING PLATINUM

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Background

A review of the modifications of or deviations from (MoD) the protocols established for the prevention of toxicity associated with chemotherapy (CT) schemes that include platinum, with a view to identifying opportunities for improvement.

Material and Methods

A retrospective observational study of the CT prescriptions (standard and off-label indications) in the month of June 2010 of schemes using platinum. The following data were compiled: medical history number, diagnosis, CT scheme, number of prescriptions reviewed, number of prescriptions modified and type of modification carried out. This information was recorded using an Excel database.

Results

We reviewed:

173 prescriptions withcarboplatin (38 patients). The predominant diagnoses were lung cancer (31.7%), ovarian cancer (28.9%) and breast cancer (18.5%). 24 (13.9%) MoDs were found: 29.2% to the carboplatin-etoposide scheme (anti-emetic was added in 75% of the cases), 25% to the carboplatin-paclitaxel scheme (50% iron preparations, 33.3% aprepitant and 16.7% furosemide), 20.8% carboplatin-gemcitabine (60% iron preparations, 20% ranitidine and 20% antihistamines), 12.5% monotherapy (100% paracetamol), 8.3% carboplatin-pemetrexed scheme (100% aprepitant + vitamin B12) and 4.2% carboplatin-5-fluorouracil (5-Fu) /cetuximab scheme (100% aprepitant).

210 prescriptions withoxaliplatin (65 patients). The predominant diagnoses were colon and rectal cancer (81.5%). 14 (6.7%) MoDs were found: 35.7% to the oxaliplatin-gemcitabine scheme (aprepitant was added in 100% of cases), 21.5% oxaliplatin-capecitabine scheme (66.7% dexamethasoneand 33.3% aprepitant), 14.3% oxaliplatin-capecitabine/bevacizumab scheme (100% dexamethasone), 14.3% oxaliplatin-irinotecan-capecitabine/cetuximab scheme (100% ondansetron), 7.1% oxaliplatin- 5-Fu scheme (100% aprepitant) and 7.1% oxaliplatin-epirubicin-capecitabine scheme (100% aprepitant).

Note that 57.1% of schemes modified contained capecitabine. 53 prescriptions with cisplatin (22 patients). The predominant diagnosis was lung cancer (50%). 2 (3.8%) MoDs were found: 50% were made in schemes in which cisplatin was combined with vinorelbine (100% ondansetron) and 50% with bleomycin and etoposide (100% aprepitant).

Note that carboplatin, oxaliplatin and cisplatin schemes needed anti-emetic in 45.8%, 100% and 100% of cases, respectively.

Conclusion

In view of the results obtained it will be necessary to review CT protocols that use platinum, especially for anti-emetic prophylaxis.

No conflict of interest

DGI042 INTRAVENOUS INMUNOGLOBULIN: USE IN PAEDIATRIC PATIENTS

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Background

The different mechanisms of action of intravenous immunoglobulin (IVIG) make this agent useful as replacement therapy in the treatment of primary and secondary immunodeficiency and in a wide range of autoimmune and inflammatory processes. In recent years the use of IVIG has increased.

Purpose

to describe the conditions of use in paediatric patients at a University Tertiary Hospital in Madrid (Spain).

Material and Methods

A retrospective, descriptive use study conducted among paediatric outpatients and inpatients treated with IVIG during June-July 2009. Clinical parameters were collected from the clinical history and pharmacy record: age, sex, weight, diagnosis, prescribing hospital service, dose of treatment and serum IgG levels before and after treatment. Suitability for use was checked against the therapeutic indication authorised by the Spanish Medicines Agency.

Results

A total of 29 patients were prescribed IVIG (mean age=8); 17 were outpatients. The indications were: primary immune deficiency (51.72%), immune idiopathic thrombocytopenic purpura (10.34%), transplant (6.8%), kidney transplant thrombocytopenia (3.44%) liver transplant (3.44%), intractable epilepsy (3.44%), toxic epidermal necrolysis immunotolerance in haemophilia (3.44%), cortical blindness (3.44%) and infection in preterm infants (3.44%). IVIG was prescribed by five different paediatric units: Immunology (55.17%), Oncohaematology (20.68%), Intensive Care (10.34%), Neurology (6.8%), Nephrology (3.44%), Neonatology (3.44%). 31.1% of the use was off-label. The mean serum IgG levels before and after infusion were 677 mg/dL and 780 mg/dL respectively.

Conclusion

In most paediatric patients, IVIG replacement therapy is used in the treatment of immunodeficiency. It also has an immunomodulatory effect which is the basis for use in autoimmune and inflammatory processes, although it is not always used for the approved indications. Clinical monitoring is recommended to individually match the dosage for each patient depending on the levels of pre-infusion serum IgG to achieve the recommended levels (IgG= 400 mg/dL)

No conflict of interest

DGI043 Experience of the use of trabectedin in a teaching hospital

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Purpose

The aim of this study was to describe our experience with trabectedin, in particular the overall survival (OS) and adverse events (AEs) profile.

Material and Methods

Retrospective study of patients treated with trabectedin between October 2006-2010. Data collected: diagnosis, previous types of treatment, dose, cycles, AEs and OS (defined as time from starting treatment with trabectedin to death).

Results

12 women and 3 men were treated with trabectedin. Median age was 46 years [21-65]. 11 patients were diagnosed with soft tissue sarcoma (STS) and 4 with relapsed ovarian cancer. In the case of STS: 8 patients died while undergoing treatment, 1 patient completed the treatment and 2 patients are still on treatment. Median number of previous lines of treatment received was 2.5 [2-5], 1, and 2.5 respectively. For the 9 patients who finished treatment median cycles received was 2 [1-8] and OS was 49.5 days [5-187]. The dose was 1.5 mg/m2 over 24 hours of intravenous infusion every 3 weeks. In the recurrent ovarian cancer: 2 patients are currently on treatment with trabectedin plus pegylated liposomal doxorubicin (PLD) (5th and 6th line therapy). The other 2 patients were treated with trabectedin as monotherapy: one patient died after the first cycle (8th line therapy) and OS was 10 days. The other one discontinued therapy after 3 cycles due to lack of response (4th line therapy). The trabectedin monotherapy dose was 1.3 mg/m² and trabectedin plus PLD dose was 1.1 mg/m² every 3 weeks.

The most common AEs were grade 1-2: nausea/vomiting, fatigue, neutropenia, anaemia, thrombocytopenia, and transaminase elevations. 2 patients had hematologic toxicity grade 3-4, which in one case led to a delay in the schedule and to discontinuation of treatment in the other case.

Conclusion

Trabectedin does not seem to improve OS in these heavily pretreated patients with poor prognosis and very limited therapeutic options. This drug was generally well tolerated.

No conflict of interest

DGI044 study of use of raltegravir in HIV patients

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Purpose

Todescribe the efficacy and profile the use of raltegravir, the first integrase inhibitor, in the treatment of multi-treated HIV patients.

Material and Methods

Retrospective observational study performed from January 2008 to April 2010 which included HIV patients treated with raltegravir for at least 12 weeks. We excluded all patients who did not follow the treatment.

Data was obtained from the Pharmacy Service computerised dispensing application (Paciwin), and the Infectious Diseases Unit's monitoring program (Eviha). We created an Excel database in which we collected the following variables: age, gender, disease stage, HCV or HBV co-infection, number of previous antiretroviral drugs, current antiretroviral treatment, viral load and CD4 cell count.

Results

The study included 71 patients; the mean age was 45.8 ± 7.4 years, and 28.1% (20) were women. 76.1% (54) of the patients had AIDS symptoms. 2.8% of the patients (2) presented HVB and 33.8% (24) had HCV. The number of previous antiretroviral drugs per patient was 10.40 ± 3.51 .

During the study, 47.8% (34) of the patients had regimens that included nucleoside reverse transcriptase inhibitors (NRTIs), 56.3% (40) non-nucleoside transcriptase inhibitors (NNRTIs), and 77.4% (55) protease inhibitors (PIs). Of the NRTIs the most used were tenofovir; 38% (27) patients, and emtricitabine; 25.3% (18) patients.

Of the NNRTIs, etravirine was the most used in combination with raltegravir; 53.5% (38) of the patients, and of the PIs darunavir was the most prescribed with 57.7% (41) patients. 94.4% (67) of the patients presented an undetectable virus load. The mean CD4 cell count was 513.77 ± 307.1 .

Conclusion

The introduction of raltegravir as part of the antiretroviral treatment is an efficacious alternative in patients with treatment failure, achieving virological response in a high percentage of patients. As it acts on a different treatment target the incorporation of raltegravir into the already available therapeutic options could be a treatment option in those multi-treated patients with virological failure.

No conflict of interest

DGI045 Study of Cetuximab's uses in a general hospital N. Sala-Vilajosana, J. Pastor Cano, J. Leon-Villar, M.D. Najera-Perez, J.C. Titos-Arcos

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Background

Nowadays, the incorporation of monoclonal antibodies into chemotherapy is standard practice. The use of cetuximab has been extended to new targets. During the last four years, European indications have grown (in colorectal and head&neck cancer).

Purpose

To analyse the prescriptions of cetuximab for patients from our hospital.

Material and Methods

A retrospective observational study was carried out for 20 months in a general hospital. The selected patients had received at least one dose of cetuximab during 2008. Data was obtained from chemotherapy prescriptions and an oncologist pharmacy program (Oncofarm).

Results

The population studied (n=68) contained 72% males and 28% females. The age ranged from 28 to 81 years old. Diagnoses were colorectal cancer (72%), head&neck (25%) and cervix and oesophagus (2%) the latter being off-label use. Distribution by treatment lines was first line (10%), second line (38%), third line (37%) and ≥fourth line (15%). 47% were in the 1st-15th week of treatment and 53% in at least the 16th week within clinical trials. 41% of patients had suffered postponement of their treatment, either one (50%), two (29%), three (14%) and >three delays (7%). In 21% of patients, the cause was notified to pharmacy department.

One of the adverse effects was hypomagnesaemia. Magnesium levels were reported in 19% of patients, 10% of them presented at least one low level, as is indicated in the product information.

Conclusion

Although cetuximab is often used for established indications in Europe, we still have to establish the real effectiveness of this new treatment in most of our patients.

We should also consider the delays during their treatment, which were in part generated by the product's adverse effects.

DGI046 Erlotinib monotherapy as first-line treatment for stage IV lung adenocarcinoma

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Background

Erlotinib is an optional second-line therapy in stage IV lung adenocarcinoma; it is administered orally and the most common side effects are skin reactions and diarrhoea.

Purpose

To assess the use of erlotinib monotherapy as a first-line treatment for stage IV lung adenocarcinoma in our hospital.

Material and Methods

Retrospective observational study in a general hospital of 700 beds. All patients diagnosed with unresectable stage IV lung cancer were included who started treatment with erlotinib from January 2007 to March 2009. The information was obtained from Silicon (Pharmacy department software) and medical record application IANUS.

The following data were collected: age, sex, non/smoker, overall survival at 12 months, dosage, duration of treatment and reason for suspension.

Results

13 patients were included, 62% female, mean age 76.7 years, 5 of whom were former smokers. The overall survival at 12 months was 69%. All patients began treatment with erlotinib 150 mg once daily and in 5 patients (38%) it was necessary to reduce the dose (4 to 100 mg and 1 to 75 mg) due to intolerance (3 skin toxicity, 1 diarrhoea, 1 impairment of functional status). 46% of patients were treated for over 1 year. The treatment was ended due to disease progression (1 case), intolerance (2 cases) and the patient's death (4 cases).

Conclusion

The profile of patients being treated with erlotinib first-line in our health area is that of elderly women with no history of smoking. The survival data suggest that this drug should be considered as an option. The good tolerability profile and the ease of administration make erlotinib a useful antineoplastic in elderly patients who are not candidates for more aggressive chemotherapy. However, its use is not authorised in our country so these cases require special management.

No conflict of interest

DGI047 Study concerning the efficiency of antibiotics in treatment of suppurative ear infections produced by Staphylococcus aureus

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Background

Infectious ear pathology represents an important health concern, due to the possible complications, because it is close to the brain. *Staphylococcus aureus* is a pathogen frequently involved in suppurations of the ear, which require immediate antibacterial treatment plus an anti-inflammatory.

Purpose

Our study aimed to evaluate the efficacy of antibacterial therapy in the treatment of ear infections due to *Staphylococcus aureus*.

Material and Methods

We studied 520 inpatients with ear infections, admitted to the otorhinolaryngology clinic from the Regional Emergency Hospital of Craiova, Romania, between 1.01.2008 - 31.05.2010. Ear swabs were taken and a bacteriological diagnosis was made. After the bacteria were isolated they were identified by their morphological, culture, biochemical and pathogenicity characteristics (with a BD Phoenix automated analyser). Antibacterial susceptibility was tested using the Kirby-Bauer standardised disk diffusion method and the results were interpreted according to NCCLS/CLSI standard.

Results

We isolated 165 strains of *Staphylococcus aureus*, from which 32 were positively identified as MRSA. The strains isolated were sensitive to beta lactams (amoxicillin with clavulanic acid and ampicillin with sulbactam – 87.5%), cephalosporins (cefuroxime-cefuroxime - 83.3%, latamoxef – 80%), aminoglycosides (gentamycin – 88.2%, amikacin – 87.5%), quinolones (ofloxacin – 73.3%), rifampicin – 84.6% and sulfamethoxazole -trimethoprim (68.8%). All the strains isolated were sensitive to vancomycin. Multi-resistant strains were also identified.

Conclusion

Antibiotic susceptibility testing is required to direct the treatment of ear infections. The tests and recommendations must be performed on antibiotic groups from classes A, B, C, O and Inv, according to the NCCLS/CLSI standard.

No conflict of interest

DGI048 Study concerning the antibiotic therapy in suppurative ear infections caused by Pseudomonas aeruginosa

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Background

Nosocomial infections are presently a serious health issue, due to the involvement of hospital strains of bacteria with increased virulence and resistance to antibiotic treatment.

Purpose

To establish the resistance to antibiotics of *Pseudomonas (Ps)* aeruginosa strains isolated from patients with ear infections and the resistance phenotypes.

Material and Methods

We identified the bacteria responsible for 511 samples of ear suppuration, collected from patients with ear infections, hospitalised in the Otorhinolaryngology clinic of the Clinical Regional Hospital of Craiova, Romania, between 1.01.2009 – 1.09.2010.

Results

Ps. aeruginosa was identified in 240 (46.96%) of cases analysed. We observed co-infection Ps. aeruginosa with Proteus (7.08%), Escherichia coli (2.08%) and Staphylococcus aureus (1.25%). Antibiotic susceptibility testing showed sensitivity to beta lactams (imipenem 89%, meropenem 90%), cephalosporins (cefoperazone 66%, cefepime 54%, ceftazidime 53%), aminoglycosides (tobramycin 85%, netilmicin 81%, amikacin 73%), quinolones (norfloxacin 79%, ofloxacin 67%, ciprofloxacin 61%), colimycin 100%.

In choosing the antibiotic therapy we recommend using antibiotics according to the NCCLS/CLSI system: group A - ceftazidime, gentamycin, ticarcillin; group B - imipenem, amikacin, cefepime; group C - netilmicin, cefoperazone.

The strains of Ps aeruginosa isolated belonged to the following

resistance phenotypes: CAZA, ESBL, RN, IMPD, PAZA, (for beta lactams), GnToNetA, GnANet, GnA (for aminoglycosides) and DNA gyrase and IMPD (for quinolones).

Conclusion

Multiple resistance of *Pseudomonas aeruginosa* strains to antibiotics is largely due to wide scale use of antibiotics. The strains that produce nosocomial infections are extremely virulent and are an important cause of the chronic evolution of ear infections.

No conflict of interest

DGI049 Utilization of study granulocyte-colony stimulating factor in onco-haematologic outpatient

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Background

In the onco-haematological context, administration of granulocyte colony stimulating factor (G-CSF) for primary prophylaxis of febrile neutropenia (PPFN) in outpatients allows the chemotherapy dose and regimens to be maintained, an important clinical goal especially in curative tumour settings.

Purpose

To analyse the use of G-CSF in approved indications in our centre.

Material and Methods

Outpatients to whom G-CSF was dispensed from July 2009 until December 2009 were identified and their medical records reviewed. Variables recorded: demographic, onco-haematological diagnosis, indication for the prescription and chemotherapy cycle they were receiving.

Results

7509 QTs were prescribed during the study period, 6308 corresponding to Medical Oncology (ONC) and 1201 to the Haematology Service (HCL).

7% of prescribed chemotherapy cycles required support with G-CSF. G-CSF was dispensed 529 times, for a total of 197 patients (39% men, 61% female) whose mean age was 54 years [range 23-83]. 72% of prescriptions were from ONC, while the remaining 28% were from the HCL (Table 1).

Table 1. Indications and services

	PPFN	Secondary	prophylaxis	of	Mobilisation	in R
		febrile neutro	penia (SPFN)		autologous HSCT	рє
ONC	255	125			0	0
HCL	28	49			26	20

PPFN may be required in breast cancer (BC) and lung cancer (LC) chemotherapy (Table 2) and with docetaxel chemotherapy.

Table 2. Diagnoses requiring PPFN

ONC					
ВС	LC	Oesophageal-gastric cancer	Head and neck t		
48%	16%	15%	12%		

Conclusion

The main prescriber of G-CSF in outpatients was ONC, responsible for 72% of prescriptions during the study period, which was also the main service prescribing chemotherapy, with 84% of the total. The main indication for G-CSF in ONC was PPFN and in HCL it was SPFN. The need for PPFN was mostly associated with BC and LC and an incidence of neutropenia >20%.

No conflict of interest

DGI051 Delayed introduction at reduced dose of prolonged release tacrolimus in kidney transplants treated with quadruple immunosuppressive therapy

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Background

Organ transplantation from expanded criteria donors (ECDs) increases the risk of delayed graft function. In our hospital, in this kind of transplantation quadruple therapy is used: basiliximab, mycophenolate, corticosteroids and tacrolimus in deferred introduction at half dose (0.1 mg/kg/day).

Purpose

To assess the clinical course of patients who have followed this immunosuppressive regimen.

Material and Methods

We included all kidney transplants from ECDs treated with quadruple immunosuppressive therapy from March 2009 to March 2010. The following data were obtained: age of donor and recipient, incidence of delayed graft function and acute rejection, creatinine clearance and glomerular filtration rate (GFR) at discharge and length of hospital stay. We also obtained data about the treatment with prolonged release tacrolimus (PRT): day first administered post-transplant, initial dose, dose at discharge and plasma levels. The tacrolimus dose was adjusted to achieve target blood levels of 8 ng/mL.

Results

We investigated 40 kidney transplants from ECDs: mean age of donor 60 +/- 13 years, mean age of recipient 58 +/- 11 years, 47% of recipients were male. PRT was started 4 days post-transplant day +/- 1.5, the initial dose was 0.11 +/- 0.03 mg/kg/day and dose at discharge was 0.15 +/- 0.08 mg/kg/day. Tacrolimus levels were: in the first determination 6.9 +/- 4.5 ng/mL, at 14 days 7.7 +/- 2.3 ng/mL and at discharge 8.0 +/- 2.3 ng/mL. In 26 patients (65%) the initial dose of PRT was increased. In 13 patients (32%) the graft function was delayed, one episode of acute rejection was presented and the average hospital stay was 22 +/- 9 days. Creatinine at discharge was 2.15 +/- 0.93 mg/dL, creatinine clearance (Cockroft-Gault 43.4 +/- 17.2 mL/min) and GFR (MDRD) mL/min/1.73m², 3 patients with

Conclusion

Target plasma levels can be achieved with the delayed introduction at half dose of PRT, although moderate increases of dose are frequent. The clinical results were favourable, so it may be a valid strategy to avoid the nephrotoxicity of calcineurin inhibitors, which can be introduced later and at lower doses due to the coverage provided by the induction of immunosuppression obtained with basiliximab.

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Pharmacotherapy: Pharmacokinetics and Pharmacodynamics (including: ADE, TDM, DUE)

PHC001 Antibiotics Monitoring by Pharmacokinetics Unit in a Pharmacy Service

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Background and purpose

To analyze vancomycin and aminoglycoside monitoring by pharmacokinetics unit. In this area pharmacist selects the patients for monitoring according to: advanced age, renal impairment, obesity, no response to treatment, and report results by electronic prescription program. Evaluate acceptance degree of pharmacokinetic reports by clinicians.

Material and Methods

Retrospective study of antibiotics monitoring interventions from January/09 to April/10. The information was obtained from pharmacokinetic reports. We collected the following data: age, sex, clinic ward, antibiotic monitoring, concomitant therapy (other antibiotics or nephrotoxic drugs ...), culture and antibiogram, leukocyte count, CRP, urea, creatinine and acceptance or not by the clinicians.

Results

233 patients were monitoring, 80 women and 153 men. Average age was 63.4 years. 51% had renal impairment and 49.7% of the patients had culture and antibiogram. Clinic wards with more interventions were Cardiovascular Surgery (33.2%), Hematology (11%) and General Surgery (8.3%). There were 361 interventions of these 227 of vancomycin, 45 of amikacin, 50 of tobramycin and 25 of gentamicin.268 interventions were accepted (74.2%) and 15.2% were not accepted, the rest of cases (10.5%) discontinued treatment by discharge, death or treatment change. In reports we suggested dosage increase (23.8%), dosage decrease (28.8%), dosage range increase (12.7%) and the same dosage (34.5%). There is an increase in the acceptance degree from 66.6% in the first month to 92.6% in the last one.

Conclusion

The recommendations in pharmacokinetic reports have a high acceptance degree by clinicians. It has been increasing since the beginning. Monitoring of antibiotics by the pharmacy service is a good control of infectious process, avoiding toxic levels and adverse effects, and allowing individualization dosage of each patient.

No conflict of interest

PHC002 Study of the durability of antiretroviral monotherapy with boosted protease inhibitors.

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Background

Strategies to simplify human immunodeficiency virus (HIV) treatment are conceived to avoid lipodystrophy and cardiovascular complications, to improve lifelong adherence and to reduce HIV multidrug resistance. It has been demonstrated that after a phase of maximal suppressive high activity antiretroviral therapy (HAART), the same level of viral suppression can be maintained by fewer drugs.

Purpose

To evaluate in clinical practice the durability of antiretroviral monotherapy with boosted protease inhibitors (MBPI).

Material and Methods

Retrospective analysis (from January 2008 to June 2010) of MBPI prescriptions recorded in the Outpatient Pharmacy Department (ATHOS-APD drug prescription database) in a teaching general hospital.

Previous HAART combination, time of HIV-RNA suppression, MBPI regimen and demographic data were collected. Statistical methods for survival data analysis (Kaplan-Meir) and descriptive statistics were powered by SPSS 12.0 for Windows.

Results

A total of 30 patients (mean age = 43.4 ± 8.5 years, 56.6% (17) male, 43.4% (13) female) had MBPI (83.3% (25) LPV/r (lopinavir/ritonavir) 400 mg-100 mg /24h and 16.7% (5) DRV/r (darunavir/ritonavir) 800 mg-100 mg /24h). Previous HAART combinations were: a) tenofovir (TDF) + emtricitabine (FTC) + lopinavir boosted (LPV/r) (63.4% (19)) b) zidovudine (AZT) + lamivudine (3TC) + LPV/r (20.0% (6)) c) TDF + AZT+ LPV/r (10.0% (3)) d) didanosine (ddl) +AZT + LPV/r (6.6% (2)). The mean time of HIV-RNA suppression was 25.96 ± 10.52 months.

To calculate survival time we only included patients on LPV/r because of the high level of censored data with boosted darunavir (DRV/r) and its recent use as MBPI in our hospital. The mean survival time was 17 months (CI 95% = 15-19) and the cumulative survival at the fifth month 0.8625 (standard error = 0.0754).

Conclusion

Despite our low number of patients, our results suggest that the MBPI strategy with LPV/r seems to maintain acceptable continuous plasma HIV-RNA suppression in patients already suppressed on a standard triple combination. It is important that MBPI provides continuous high effectiveness because of the HIV resistance.

No conflict of interest

PHC003 Study of Drug-Drug Interactions in prescriptions of general practitioners and specialists in Iran during 2007-2009

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Purpose

Prescriptions written by general practitioners and medical specialists were studied and compared to determine the type, time of onset and clinical importance of drug-drug interactions (DDIs) in an aim to reduce further complications.

Material and Methods

Prescription processing software was used to evaluate prescriptions recorded in 33 Medical Universities of Iran. In this cross-sectional study all data from 21 March 2007 to 21 December 2009 were analysed. After analysis, DDIs were recorded for general practitioners and 14 different medical specialists. Due to the greater clinical significance of major DDIs, moderate and minor DDIs were not considered in this study.

Results

In 44,567,550 prescriptions, the percentage of clinically significant interactions was higher in prescriptions of medical specialists and of those, cardiologists and internists were at the top of the list. The percentage of prescriptions with rapid onset interactions was highest among cardiologists. The percentage of prescriptions with delayed onset interactions was the highest in the psychiatrists in 2007-2008 and the highest in the neurologists in 2008-2009. The interactions found most frequently were: digoxin plus furosemide, captopril plus triamterene, gemfibrozil plus atorvastatin, enalapril plus triamterene, cimetidine plus codeine, gemfibrozil plus lovastatin and haloperidol plus propranolol. The study of DDIs in the present population showed that the DDIs with highest clinical significance were the antihypertensive drugs such as beta blockers and calcium channel blockers followed by ACE inhibitors. In comparing general practitioners and medical specialists, it was evident that more major DDIs were found in the prescriptions of medical specialists. It seems that medical specialists deal with more potent drugs with a low therapeutic index, which might be a reason for greater DDIs in their prescriptions.

Conclusion

Potential drug interactions are frequent among outpatients prescribed several medicines. The rate of such interactions increased with the number of drugs prescribed.

No conflict of interest

PHC004 Oral Hormone therapy undesirable effects in breast cancer patients of Fernando Fonseca Hospital

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Background

Undesirable effects associated with oral hormone therapy in breast cancer patients, like with any other available medicine, are, on the one hand, discovered during clinical trials, on the other hand, discovered following marketing.

Trying to identify and systematise these undesirable effects in a restricted setting, such as our hospital, will help us to direct our work towards minimising the consequences of those undesirable effects.

Purpose

To describe the undesirable effects of oral hormone treatment on Fernando Fonseca Hospital breast cancer patients. In addition, to identify measures taken by patients in response to those effects.

Material and Methods

This was an observational, transversal, non-randomised, prospective study. An undesirable effect sheet was designed, the "Undesirable Effects Diary", for each medicine dispensed in our Oral Chemotherapy Dispensing Outpatient Department. This sheet contained the most frequent undesirable effects of the medicine in question, according to Summary of Product Characteristic. a space for patient to note which undesirable effects they felt and also a space for the pharmacist to note measures taken by patients regarding possible undesirable effects. Medicines investigated were: anastrozole, exemestane, letrozole, tamoxifen. Sheets were handed to patients, with an explanation, while they were picking up medicines and collected on their next visit to our Oral Chemotherapy Dispensing Outpatients. This prospective survey started in June 2009 but we are still handing out and collecting sheets for all new patients. Our sample represents all breast cancer patients on oral hormone treatment with Oncology and Gynaecology medical appointments. Data are processed in an Excel database.

Sources of bias: patients' difficulties in relating particular undesirable effects to the administered medicine even in monotherapy; patients' difficulties in perceiving particular physiological signs and matching them to a particular undesirable effect of the medicine; patients' inability to complete the given "Undesirable Effects Diary".

Results

We have collected 213 sheets. We have observed that the most common undesirable effects in anastrozole patients (n=29) were joint pain (63%) and thinning hair (52%); exemestane patients (n=19) reported hot flushes and sweats (64%) and joint pain (53%); letrozole patients (n=34) reported fatigue (56%) and musculoskeletal effects; and tamoxifen patients (n=131) reported hot flushes (63%) and fatigue (50%). 70% of patients did not take any action regarding undesirable effects they felt.

Conclusion

Results were in accordance with the Summary of Product Characteristics. We had expected a more pro-active approach by patients regarding the undesirable effects they experienced.

No conflict of interest

PHC005 Identification of opportunities for improvement in the adjustment of drugs in renal failure

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Background

Drug dosing errors are common in patients with renal impairment and can cause adverse effects and poor outcomes.

Purpose

To determine the need for dosage adjustment of drugs in hospitalised patients with impaired renal function.

Material and Methods

Descriptive cross-sectional study conducted in hospitalised patients. In February 2010 we selected randomly among all patients admitted those who had had a creatinine level check in the last 15 days. To calculate the glomerular filtration rate (GFR) we used the Modification of Diet in Renal Disease (MDRD4) formula. It analysed the drugs prescribed for patients with GFR< 60mL/min/1.73m² to determine which drugs needed adjustment to renal function.

Results

526 patients were included in the study, 56.4% men and 43.6% women. The mean age was 74.8 ± 12.9 years.

14.8% of patients had a GFR <60 mL/min/1.73 m² and all of them had been prescribed a drug that required dosage adjustment. We classified the patients into 3 groups according to GFR: a) 6.5% of the patients had GFR <15 mL/min/1.73 m² b) 33.3% had GFR 15-29 mL/min/1.73 m², of which 9.8% had a narrow therapeutic index drug c) 60.2% of the patients had GFR: 30-59 mL/min/1.73 m², of which 12.2% had a narrow therapeutic index drug.

1437 drugs were prescribed, of which 24% required adjustment to renal function. 17.8% of these were antibiotics, and 8.1% of them had a narrow therapeutic range; 17.3% were low molecular weight heparin (LWMH), 15% were analgesics, 11.3% were angiotensin-converting enzyme inhibitors and 10.7% were ranitidine.

Conclusion

- The proportion of hospitalised patients who needed dose adjustment due to renal function of prescribed drugs was 14.8%, which justifies routine pharmaceutical care in this area.
- The group of drugs on which pharmaceutical intervention must focus are antibiotics, as these are often used, and LWMH, which is a high-risk agent.

No conflict of interest

PHC006 Adverse drug reactions in HIV patients with hospital income

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Background

Adverse drug reactions (ADRs) are common among HIV patients. A previous study in our hospital showed up to 45% treatment changes due to ADRs to antiretrovirals (ARTs).

Purpose

To assess ADRs and related risk factors in HIV patients admitted to hospital.

Material and Methods

5-year observational cohort study in hospitalised HIV patients. Cohort 1 and 2: patients with and without ADRs. Sample: 100% patients in cohort 1; simple random sampling in cohort 2. Inclusion criteria: diagnosis of "adverse drug effects, biological and medicinal substances for therapeutic use" according to ICD-9 (E930 to E949). Exclusion criteria: paediatric patients. Risk factors assessed: sex, age and CD4+ count. Data analysis test: Pearson's chi-square and Student's-t.

Results

1/82 ADRs, in 63 HIV patients, with 72 hospital admissions. 2/ Incidence of ADRs in HIV patients was 13.7/1,000 patient-years vs. 3.1/1,000 among non-HIV patients (p<0.001).

3/ Risk factors analysis (cohort 1 vs. 2):

3.1.- 71.4% vs. 69.4% males (p=0.38);

3.2.- 41.8 vs. 41.6 years (p=0.86);

3.3.- 172 vs. 195 CD4+/mL (p=0.36).

41 Distribution of ADRs:

- 4.1.- Drug therapeutic classification: 45% ARTs, 27% antibiotics.
- <u>4.2.-</u> Drugs: 16% co-trimoxazole, 15% lopinavir/ritonavir, 10% zidovudine.
- 4.3.- System: 24% endocrine, nutritional, metabolic and immune, 22% digestive, 21% blood and haematopoietic organs, 20% CNS.
- 4.4.- Adverse reactions: 15% anaemia, 13% dermatitis.
- **5/** 1 patient required ICU admission. 84% were solved without sequels, 13% with sequels and 3 patients died of causes unrelated to ADRs.

Conclusion

- 1/ We observed a higher incidence of ADRs in HIV patients than in non-HIV patients.
- 2/ No risk factors (sex, age or immunosuppression) showed a relationship with ADR incidence among HIV patients.
- 3/ Antiretrovirals were the therapeutic group that caused more ADRs.
- **4/** The system most affected by ADRs was "Endocrine, nutritional, metabolic and immune" and anaemia was the main ADR.
- **5/** ADRs, although severe in some cases, are mostly solved without sequels and no deaths resulted.

No conflict of interest

PHC007 Palonosetron use evaluation

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Background

Palonosetron was first included in the hospital's pharmaceutical guide in November 2009.

Purpose

To assess the efficacy and safety of palonosetron in the handling of chemotherapy-induced nausea and vomiting in our hospital.

Material and Methods

Evaluation of the use anti-emetic drugs for cancer from November 2009 to April 2010.

Results

35 patients (0.8% of all cancer patients treated within 6 months) were included. Only 2 of them were given palonosetron as the first option; the rest were refractory to the standard antiemetic treatment in our hospital (ondansetron-based). 77% were women and median age was 52 ± 8 years (range 34-65). 50% had cancer of the breast, 15% of the head and neck, 12% colorectal cancer, 8% ovarian, lung and 4% oesophagus and unknown origin. The most commonly used chemotherapy regimens were cisplatin-based (19%); TAC (taxotere, adriamycin and cyclophosphamide) (15%) and cisplatin in monotherapy (12%). The rest were combinations of these and other

agents. Average number of cycles given was 6 \pm 4 (range 1-15). 6 patients (17%) had anticipatory emesis. In all of them, except for the 2 cases of first-line palonosetron, ondansetron 8 mg IV was used on day 1 plus IV dexamethasone (20 mg or 12 mg if also aprepitant was also given). Dexamethasone was given orally on days 2, 3 and 4 in 23% of patients. Other treatments resulted in small variations in the dose of dexamethasone. The absence of emesis reported by patients was 73% day 1; 50% day 2; 58% day 3; 65% day 4 and 73% day 5. Absence of nausea: 57.7% day 1; 11.5% day 2; 23% day 3; 38.4% day 4 and 57.7% day 5. The antiemetic treatment was generally well tolerated. Adverse reactions described as frequent: 35% had constipation and there were cases of headache.

Conclusion

Palonosetron may be an option for patients refractory to conventional therapy. The small number of cases and their heterogeneity does not allow a more conclusive result to be established

No conflict of interest

PHC008 POSACONAZOLE USE FOR PROPHYLAXIS OF INVASIVE FUNGAL INFECTION IN HEMATOLOGICAL PATIENTS

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Background

In the last year the hospital has added posaconazole for the prophylaxis of invasive fungal infection in patients with graft-versus-host disease (GVHD) on immunosuppressive treatment who have undergone an allogeneic hematopoietic transplant and in patients diagnosed with acute myeloid leukaemia (AML) or myelodysplastic syndrome (MDS) on induction chemotherapy.

Purpose

To investigate the use of posaconazole after its recent inclusion in the hospital's therapeutic guide.

Material and Methods

Retrospective observational study. Period: September 2008 to March 2010. Setting: Tertiary general hospital. Inclusion criteria: Neutropenic patients treated with posaconazole. Exclusion criteria: Duration of treatment < 5 days. Sources of information: Clinical history and pharmacy record of posaconazole dispensed.

Results

Thirty-seven episodes were recorded of prophylaxis with posaconazole in 30 patients (13 women, 17 men) of average age 56 (25-82) and a diagnosis of AML (n= 24), MDS (n= 1) or GVHD (n=5). Median duration of treatment was 25 days (5-168). Patients received 200 mg of posaconazole g8h at meals or with enteral nutrition. The plasma concentrations of posaconazole were not measured. Posaconazole administration was never interrupted due to adverse effects. Serum galactomannan levels were checked twice weekly, all samples being negative. No fungi were isolated in patients' microbiological cultures. One case of pulmonary aspergillosis was diagnosed by high resolution computed tomography and required combined antifungal treatment. In 12 episodes prophylaxis was changed to another antifungal agent for empirical treatment of persistent fever. Seven patients died during prophylaxis with posaconazole due to the underlying disease. In 17 episodes prophylaxis was maintained satisfactorily until the neutropenia resolved.

Conclusion

- 1. Posaconazole was used according to the guidelines.
- 2. No adverse reactions were observed during the study period.
- 3. Prophylaxis with posaconazole did not prevent elevated use of empirical antifungal therapy.

PHC009 Cost-savings of a pharmacokinetic consultation service in patients treated with aminoglycoside and vancomycin in Thailand

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Background

Clinical pharmacy interventions have been shown to result in significant clinical outcomes and are associated with cost savings. However, the impact of interventions, especially those related to pharmacokinetic consultation and cost saving have been little studied in Thailand.

Purpose

To study the cost saving on aminoglycoside and vancomycin treatment of a pharmacy-based pharmacokinetic consultation service.

Material and Methods

An 18-month prospective study was conducted in a 500-bed tertiary care private hospital on the effects of medicine costs and charges from the pharmacokinetic consultations. Interventions made by the clinical pharmacist were documented. Physician acceptance and cost savings were also calculated. The effects of the service were measured in terms of charges for drug products and solvents, changes in drug costs based on altered dosing intervals throughout the treatment and laboratory costs and charges for serum drug evaluations.

Results

Of the total 558 interventions performed, 97% of the interventions were accepted and followed by physicians. 73% of the interventions resulted in the confirmation of appropriate dose and increasing the dose and dosing interval. Of the 27% interventions that required dose modification to reduce toxicity, 16% were evaluated for cost savings because the dosing interval was increased and drug administration temporarily withheld, since many of the patients had renal impairment. The potential cost savings of the pharmacokinetic consultation service was Euro 14,120 (593,055 Thai Baht). The vancomycin dosage adjustment accounted for the larger economic impact. In the meantime, drug assay charges were Euro 6,313 (265,165 Thai Baht) for these interventions.

Conclusion

In our study direct cost savings of drugs to the patient correlated positively with this pharmacy-based pharmacokinetic consultation service. The effect of the service on adverse drug event cost avoidance and indirect cost savings of the intervention increasing doses should be further studied.

No conflict of interest

PHC010 Vitamin D monitoring during oral bisphosphonates treatment

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Background

due to recent reports of links between low vitamin D levels and risk of breast cancer, non-Hodgkin's lymphoma and colorectal cancer we conducted a survey of vitamin D levels in a population treated with oral bisphosphonates which a priori should have vitamin D levels over 30 ng/mL (normal range 30-100 ng/mL).

Purpose

To evaluate Vitamin D level control among hospitalised patients treated with oral bisphosphonates, in order to pursue further studies and to establish multidisciplinary corrective measures if needed.

Material and Method

From 7/09/2010 to 21/09/2010 we included in our study every patient admitted to the hospital regardless of their clinical situation who had a prescription for an oral bisphosphonate. We reviewed electronic medical files (Clinic application) and the hospital laboratory internal database which records all vitamin D levels for the hospital-based population.

Results

patients treated with oral bisphosphonates: 22 (19 osteoporosis, 3 other causes)

Patients with vitamin D measurements: 8 (36%)

Patients without any vitamin D measurement ever: 14 (63%)

Patients with Vitamin D over 30 ng/mL: 5 (22%)
Patients without vitamin D supplementation: 10 (45%)
Patients without calcium supplementation: 6 (27%)

Conclusion

Only 22% of patients showed the correct vitamin D levels but worse, 63% had never had a test and despite current recommendations for necessary supplementation with calcium (1000 mg/d) and vitamin D (400-800 IU/d) when starting treatment with oral bisphosphonates, only half of our patients were correctly treated. We need to analyse the problem detected and establish urgent corrective measures.

No conflict of interest

PHC011 Treatment of 70 patients in a surgical intensive care unit with posaconazole ñ a single centre experience

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Background

Invasive fungal infections (IFIs) are a rising problem in surgical intensive care units (SICU). Posaconazole, an extended-spectrum triazole, is effective against Candida spp. and Aspergillus spp. and has a favourable safety and tolerability profile.

Purpose

Aim of this observational, retrospective drug use evaluation (DUE) was to assess the use of posaconazole in SICU patients.

Patients and Methods

Patients (N=70) were admitted to the SICU between April 2006 and July 2009 and administered posaconazole (via gavage). Posaconazole use was evaluated in terms of demography, comorbidities, microbiological, clinical infection and mortality data.

Results

Renal replacement therapy (65.7% of patients), transplantation (48.6%), diabetes mellitus (28.6%) and cancer (17.1%) predisposed the majority of the patient population to a higher risk of IFI. Fungal infections were found in 61/70 patients (87.1%), of which 88.5% had Candida and 34.4% had Aspergillus. The mean duration of posaconazole therapy in the SICU was 8.1 days; 60.0% of patients received prior antifungal therapy (i.e. caspofungin, fluconazole or itraconazole) and 20.0% of patients switched to other antifungal therapy after posaconazole treatment.

Conclusion

Posaconazole may be an important and safe treatment option for SICU patients.

PHC012 Pharmacokinetic-pharmacodynamic support for a reduction of carboplatin dose in elderly advanced non-small cell lung cancer patients

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Background

In clinical practice, doses of carboplatin are calculated using the Calvert formula, where real glomerular filtration rate of patients is replaced by an estimated value of creatinine clearance, determined by the Cockcroft-Gault (CG) equation.

Purpose

To analyse whether carboplatin's clearance and haematological toxicity justify the administration to elderly patients with advanced non-small cell lung cancer of a 20 % lower dose than that given to younger patients.

Material and Methods

A total of 33 patients received carboplatin on day 1 and gemcitabine on days 1 and 8, and repeated every 21 days. The Calvert-CG formula was employed to calculate a carboplatin dose with a target AUC of 5 mg·min/mL in younger adults (48.48% of the total study population, aged 44-65) and 4 mg·min/mL in elderly patients (51.52 % of the population, aged 71-81).

Three blood samples were collected from each patient and the ultrafiltered platinum plasma concentration was determined. Data from 24 patients were treated for population modelling using the non-linear mixed effect modelling approach. Haematological toxicity was evaluated for the 33 patients.

Results and Conclusion

The final covariate models for clearance (CL) (L/h) and volume (Vc) (L) were obtained by means of the following formula: CL= [4.87-(Age (years)-70)·0.13+(body weight (Kg)-70)·0.06-(Serum creatinine (mg/dL)-0.9)·0.70]; Vc= [6.24+(weight (kg)-70)·0.24]. The relative error of carboplatin clearance estimated by the Calvert-CG formula was 13.53% for younger adults and 67.97% for elderly patients.

A reduction of 20% in the dose of carboplatin administered to elderly patients did not result in significant differences between rates of grade 3+ of anaemia, neutropenia or thrombocytopenia with respect to younger patients.

No conflict of interest

PHC013 complementary therapy for hepatitis c treatment <u>S. Fernandez-Espinola</u>, D. Marin Garcia, C. Galan Retamal, R. Garrido Fernandez, V. Padilla Marin ¹HOSPITAL ANTEQUERA.AREA SANITARIA NORTE DE MALAGA, Pharmacy, Malaga, Spain ²HOSPITAL ANTEQUERA.AREA SANITARIA NORTE DE MALAGA, Gastroenterology, Malaga, Spain

Background

The current standard in hepatitis C treatment consists in combination regimens of pegylated interferon-alfa (Peg-INF- α) with Ribavirin (RBV) for 24/48 weeks. PEG-INF- α -induced neutropenia is a cause of dose reduction. Ribavirin-induced hemolytic anaemia is a common cause of dose reduction or discontinuation.

Purpose

The objective of this study is to demonstrate the usefulness of growth factors such as Filgrastim (granulocyte stimulating factor) and Darbepoetin-alfa (erithropoiesis stimulating factor) as an alternative for managing these haematologic side effects without reducing the optimal dose of the combination antiviral regime, increasing the probability of achieving sustained viral response (SVR).

Material and Methods

Observational and retrospective study performed in Hospital Comarcal de Antequera, Spain. Patients were under standard VHC treatment and had been treated with haematopoietic growth factors such as filgrastim and darbepoetin-alfa due to anaemia (Hb<9gr/dl) and/or neutropenia (neutrophils < 0,5x10⁹/l) between January 2009 to June 2010 (18 months).

Data were obtained from the pharmacy outpatient dispensation program and the Clinical Analysis laboratory program of our hospital.

Written informed consent was obtained from all patients before the off-label use of haematopoietic grown factors.

Results

During the follow-up period, seven patients received complementary treatment with haematopoietic growth factors. Three patients were treated with Filgastrim 30 MU/twice/week and four patients were treated with Darbepoetin-alfa 30 mcgr/week. In the last group two patients needed to increase the dosage up to 60 mcrgr/week. SVR was obtained in all patients that received Filgastrim, but only in one patient who had received Darbepoetin-alfa.

Conclusion

Filgastrim has shown to be beneficial in the treatment of PEG-INFalfa induced neutropenia. Darbepoetin-alfa may be beneficial in the treatment of ribavirin-induced anaemia to obtain SVR. Additional studies will be required to expand these observations.

No conflict of interest

PHC014 Effectiveness of empirical anti-infective treatments in urinary tract infections in elderly institutionalized patients <u>M. Rodriguez Jato</u>, X. Martinez Casal, J. Gonzalez Lopez, M. Touris Lores, C. Crespo Diz, M.E. Concheiro Nine ¹Complejo Hospitalario Universitario de Santiago de Compostela, Pharmacy, Santiago de Compostela, Spain

Background

Symptomatic and uncomplicated lower urinary tract infections (UTIs) are among the most frequent pathologies in elderly institutionalised patients.

Purpose

To analyse the impact of UTIs and to evaluate the effectiveness of empirical anti-infective treatments.

Material and Methods

Descriptive study in historic cohort of one year with 154 institutionalised patients in a long term care (average age 83.57±7.22). Inclusion criteria: patients diagnosed uncomplicated lower urinary tract infection. Exclusion criteria: complicated urinary tract infections and those that required hospitalisation. Data sources: conventional and electronic clinical history (IANUS) and pharmacotherapy management electronic (SINFHOS) applications. Variables analysed: 1) number of infectious episodes (episode: UTI that needed one or more consecutive anti-infectious treatments until remission), 2) antiinfective drugs used, 3) treatment effectiveness. The statistical analysis was performed using the chi-square (χ^2) test using the SPSS 13.0 package for Windows.

Results

UTI incidence was 29.2%; this yields 45 patients with an infection, over a total of 68 episodes. 66.7% of patients presented one episode of UTI; the remaining 33.3% presented more than one episode. Two episodes need to be retreated resulting in a total of 70 treatments. Profile of anti-infective use was: 51.3% guinolones (ciprofloxacin and norfloxacin), 37.2% beta lactams (amoxicillin clavulanic acid and cefuroxime axetyl). 11.5% had co-trimoxazole and nitrofurantoin. The resulting effectiveness was 84.3%. There were two groups of anti-infective drugs with similar sensitivity: (a) quinolones and amoxicillin- clavulanic acid with effectiveness over 90% and (b) effectiveness around 60% for co-trimoxazole and cefuroxime-axetyl (66.7%).

Conclusion

The incidence of UTIs in the group of patients studied was similar to that of previous research. The empirical treatment of UTIs in this group of patients is an appropriate clinical practice, due to its high effectiveness (more than 80%). Amoxicillin- clavulanic acid, ciprofloxacin and norfloxacin are highly effective, near 90%.

No conflict of interest

PHC015 Evaluation of gentamicin initial therapeutic regimen in the newborn in a general portuguese hospital

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Background

Gentamicin is an aminoglycoside commonly used to treat neonatal infections caused by Gram negative. The potential risks associated with its use justify the monitoring of this drug. In order to better tailor therapy to this population, gentamicin pharmacokinetic (PK) parameters were characterized, and an initial therapeutic regimen considering the birth weight (BW) and gestacional age (GA) was adopted. This study aims to validate the initial regimen in order to ensure the achievement of initial serum samples within the therapeutic range (TR).

Material and Methods

A preliminary retrospective study was performed between 2009/2010 in 156 newborns of the Neonatal Intensive Care Unit (95 males and 61 females) undergoing treatment with IV gentamicin for suspected or confirmed infection with Gram negative. Data collection was performed consulting PK data sheet, and included BW, GA, postnatal age (PNA), sex, initial therapeutic regimens, serum creatinine and peak and trough concentrations.

Results

The GA ranged between 25 and 41 weeks; 83,4% had less than 34 weeks. The BW ranged between 485 and 5010 grams.

Of the 312 initial serum concentrations obtained, 206 (66%) were within the TR (58.3% peak, 41.7% trough). The population was divided by groups according to the newborn main stages of maturation. The group analysis, regarding concentrations within the TR, found that the newborns with GA ≤30 weeks had 27,2% of levels within the TR, with 30>GA≤34 weeks 25,7% and with GA> 34 weeks had 47.7%.

For the different subgroups values are consistent when compared with the literature. These results show the importance of individualize doses of gentamicin in newborns with low GA as well as the characterization of PK of the population described.

Accordingly, it's necessary to adapt the initial dosing regimen for gentamicin in low GA, establishing relationship with various clinical descriptors and their influence on pharmacokinetic parameters.

No conflict of interest

PHC016 Club Orange Æ - it's the bits inside that made the Ciclosporin levels high!

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Background

We present a case of probable interaction between ciclosporin and an orange juice-based soft drink.

A transplant patient, with previously satisfactory ciclosporin troughs, had a steep rise in levels when her oral intake changed entirely to a Club Orange soft drink during a norovirus infection. Levels rose from a baseline of 158 nanograms/mL to a peak of 464 nanograms/mL over a period of 3 days despite ciclosporin doses being withheld. When the drink was stopped her ciclosporin levels returned to normal. Her serum creatinine remained stable throughout.

Material and Methods

Literature review

Results

Numerous studies and reports link ingestion of grapefruit juice with raised ciclosporin levels[1]. It is considered that the most likely components of grapefruit juice to be responsible for these effects are the furanocoumarin derivatives bergamottin and 6', 7'dihydroxybergamottin (DHB) [2]. There is one case report in the literature of raised ciclosporin levels in a patient who took his doses with a similar orange soft drink[3]. However a subsequent single dose study in healthy volunteers failed to show any interaction [4]. Club Orange contains 11% orange juice from concentrate. The varieties of oranges used both contain bergamottin and DHB[5,6]. Ciclosporin levels are usually reduced by diarrhoeal illness[7,8].

Conclusion

- 1. We believe that drinking Club Orange was responsible for the rapid threefold rise in ciclosporin levels in our patient.
- 2. We have shown a plausible mechanism for this interaction. This only the second time that such an interaction has been reported. The absence of an alternative explanation and the fact that dechallenge led to a decline in levels means that the interaction would be considered "probable".
- 3. This case underlines the importance of considering interactions with food when trying to explain fluctuations in ciclosporin levels. We advised the patient to avoid this and similar citrus-based products in the future.

PHC017 Search of genetic polymorphisms associated with severe neurotoxicity in colorectal cancer patients receiving oxaliplatin-based chemotherapy using the DMET genotyping platform

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Background

Explore the role that DMET will play in future pharmacogenetics studies.

Purpose

We performed the Drug Metabolizing Enzymes and Transporters (DMET) platform analyses in a cohort of colorectal cancer patients receiving fluorouracil, folinic acid and oxaliplatin (FOLFOX) adjuvant chemotherapy in order to determine association with severe neurotoxicity.

Material and Methods

This was a retrospective study in which DNA was purified from peripheral blood of colorectal cancer patients starting FOLFOX adjuvant chemotherapy. DNA processing and genotype identification for each patient sample were performed using the Affymetrix DMET platform. Genotypes were determined for every SNP site, reported as homozygous wild-type, heterozygous, homozygous variant or 'no call'. Patients were strict selected by the presence of severe (grade 3) neuropathy due to oxaliplatin. Neurotoxicity was assessed in accordance with NCI CTCAE v3.0. Primary endpoint was the identification of polymorphisms associated with development of severe neuropathy.

Results

DMET offers the ability to scan 1936 variants in 225 genes and only 60 genes were found to be associated with response and toxicity. The rate of earning was around 97%. These data revealed that variants in five genes (that is, GSTP1, GSTM1, GSTT1, NQO1 and ATP7A) were associated with toxicity in all the patients. All of them showed null polymorphisms or rather mutations in the gluthation family (GSTT1, GSTM1, or GSTP1). 2 patients harboured heterozygous variants for NQO1. These genes are involved in detoxification of platinum. And other 3 patients had homozygous variants for ATP7A. This encodes a transporter of copper and has a potential role in platinum efflux.

Conclusion

DMET identifies detoxification and copper transporter pathways as pharmacogenetic targets. Genes in these pathways are responsible for intracellular accumulation of platinum and could play a role in severe neurotoxicity development. DMET adds more information than the simple analysis of polymorphisms previously identified in other studies.

No conflict of interest

PHC018 Vancomycin Pharmacokinetics in preterm neonates E. Marques, A. Rodolfo, P. Silva, A.S. Cardoso, A.P. Carrondo ¹Hospital de Santa Maria, Serviço de Gestão Técnico-Farmacêutica, Lisbon, Portugal

Background

Vancomycin is an antibiotic often prescribed for suspected and confirmed Gram-positive infections. In late-onset sepsis the most commonly reported pathogens are coagulase-negative staphylococci.

The increased incidence of methicillin-resistant *Staphylococcus* aureus has led to an increased use of vancomycin. Over recent years, interest has increased in refining dosing regimens for neonates in order to improve efficacy and decrease toxicity.

Purpose

To determine vancomycin pharmacokinetics parameters in this population.

Material and Methods

A retrospective cohort study was conduct in paediatric intensive care units, academic hospital, between January 2007 and September 2010. Population pharmacokinetics were estimated in 52 preterm neonates (95 observations). Patients with at least one available vancomycin serum concentration value were included in the study. Demographic and laboratory data, as well as the vancomycin dosing history, were recorded from the patient's Therapeutic and Drug Monitoring data sheet. Fluorescence polarisation immunoassay was used for plasma vancomycin measurements. A 1-compartment model was used, with trough values only, and the kinetic parameters were estimated using the AbbottBase Pharmacokinetic Systems 1.0 software. Patients were distributed into 3 groups which differed significantly in terms of mean postconceptional age (<30 weeks in group I; 30-34 weeks and <1.2 kg in group II; 30-42 weeks and ≥ 1.2kg in group III).

Results/Conclusion

Neonates with a gestational age of 24-39 weeks, a postconceptional age between 26-40 weeks and a weight of 0.492-3.400 kg were treated. Daily doses between 3.53 and 58.82 mg/kg/day of vancomycin were used. The population estimated mean pharmacokinetics values were: Group I – Vd=0.49L/kg \cdot Cl=0.054L/kg/h \cdot T1/2=7.5h; Group II – Vd=0.56L/kg \cdot Cl=0.055L/kg/h \cdot T1/2=8.0h; Group III – Vd=0.56L/kg \cdot Cl=0.070L/kg/h \cdot T1/2=6.5h.

Effects of age (postnatal and gestational) and weight are the major contributors to clearance variability in premature neonates.

No conflict of interest

PHC019 The QT-interval as a matter of heart. What risk comes from drugs?

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Background

Prolongation of the QT interval is a serious adverse effect of various drugs. Some drugs, on the other hand may cause concomitant cardiac problems through bradycardia or changes in the patients' serum electrolytes.

Purpose

To identify and point out the existing risks that may lead to QT prolongation in geriatric patients through interdisciplinary cooperation between the clinical pharmacist and geriatricians.

Material and Methods

In 100 consecutive patients admitted to our department of geriatric acute care we retrospectively analysed the admission ECGs for QT-interval prolongation and the patients' history of use of drugs potentially causing QT-interval prolongation, hypokalaemia, hypomagnesaemia and bradycardia.

Results

We analysed ECGs taken at admission of 100 patients consecutively admitted to our department for prolongation of the QTc interval – it was prolonged in 26 of the patients. 12 of these patients were admitted to the department with drug(s) that can lead to prolongation of the QT interval.

Hypokalaemia was found in 18% of the patients (n=100), hypomagnesaemia in 44% of the patients (n=27, it was not possible to get the magnesium levels of all patients) - thus they presented an additional risk factor for torsade de pointes.

The list of drugs with a QT risk was established using several databases. It encompasses a broad spectrum of pharmacological agents. The list was adjusted according to the current use of these substances in the department, allowing the creation of a compact (pocket card format) ward-specific list of drugs with QT-prolonging potential.

Conclusion

QT prolongation is a serious yet preventable adverse event of drug therapy. A compact ward-specific list of potentially QT interval prolonging drugs established in interdisciplinary cooperation between the clinical pharmacist and geriatricians helps highlight this aspect of drug therapy. It is planned to expand this approach to other wards in our hospital.

No conflict of interest

PHC020 Evaluation of the prescription profile of injectable proton pump inhibitors in the emergency department of a central hospital

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Background

Proton pump inhibitors (PPIs) are widely prescribed for acid-related disorders. However, as they are often used chronically and in patients taking several medicines, they have the potential to trigger drug interactions and adverse effects.

Purpose

To determine the prescription profile of injectable PPIs (IV PPIs) in the emergency department of Hospital Geral do Centro Hospitalar de Coimbra -Entidade Pública Empresarial. Specific objectives: To identify clinical conditions and criteria for the use of an IV PPI; to evaluate the consistency of the prescriptions with the indications approved in the Summaries of Product Characteristics.

Material and Methods

Clinical records were assessed for a retrospective observational study of drug use, prescription and type of indication, during the month of February 2008 in the emergency department.

Results

A total of 317 patients were included, with a mean age of 63.59 years (SD =20.81); 52.7% were female. IV PPIs were prescribed in "approved diagnoses" in 11.4% and for 24.6% the use was "appropriate".

A percentage of 22.1 had already brought prescribed PPIs from home; 43% received a prescription upon discharge from the

emergency services. There were prescribers from 15 medical specialties: internal medicine 53.3%; pneumology 9.8 %; surgery and gastroenterology 8.2%. Epigastric abdominal pain accounted for 33.3% of the approved final diagnoses. For the prescriptions without "appropriate use", 65 patients had a diagnosis related to the respiratory system, 7.5% diagnoses of nonspecific abdominal pain and nonspecific chest pain; 17% were concomitant prescriptions with corticosteroids.

Conclusions

In most cases the use of an IV PPI was not appropriate. Prescriptions within the "approved diagnosis" were a minority. These results demand further studies and pharmacist intervention.

No conflict of interest

PHC021 Comparison of different formula to calculate GFR R. Juvany, E. Leiva, S. Cobo, A. Figueras, A. Padulles, J.M. Cruzado, R. Jódar

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Background

A variety of GFR equations exist to identify patients in need of drug dosing adjustments, leading to variability in this process.

Purpose

To select the most appropriate GFR equation to reduce variability and improve drug dosing adjustments.

Material and Methods

Patients with GFR<60mL/min were included and stratified by body mass index (BMI) into overweight/obese (BMI≥25 kg/m²) or non-obese. GFR prediction equations used were: Cockroft-Gault with ideal (CGi) or real body weight (CGr), Salazar-Corcoran (SC) and Chronic Kidney Disease Epidemiology Collaboration Group (CE), all expressed in mL/min and Modification of Diet in Renal Disease (MDRD-4) expressed in mL/min/1.73 m² (M) and in mL/min (MA).

Percentage differences (PDs) between GFR values obtained by different equations were calculated. The accuracy was considered acceptable when >90% of PDs fell within $\pm 30\%$ (PD $\pm 30\%$). Passing-Bablok regression was used to compare different equations exhibiting constant and proportional precision over the measurement range.

Discrepancies between clinical decisions leading to drug-dosing adjustments were evaluated at two drug dosing thresholds: <30 and <50 mL/min.

Results

267 patients were studied (125 females). In the overweight/obese group (n=138), the proportion of PD±30% were 97.8% for CE vs SC, 94.2% for MA vs SC and 100% for CE vs MA and M vs MA. In non-obese patients, PD±30% was 89.9% for CE vs MA and 99.2% for M vs MA. When compared with CGi or CGr the accuracy was unacceptable.

According to Passing-Bablok regression, in both groups, CE and MA differences were not constant and proportionally significant. The lowest percentage of patients with discordant clinical decisions was detected in MA and CE independently of BMI.

Conclusion

Standardising the use of MA or CE independently of BMI for drug dosing purposes could be a useful tool to improve variability of drug dosing adjustments. M could be a good alternative in the absence of anthropometric data.

PHC022 Intravenous chemotherapy dosing in obese patients in the Portuguese Institute of Oncology of Coimbra Francisco Gentil, EPE

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Concerns about toxicity have led clinicians to use empirical dose reductions in obese patients.

To check the dose of intravenous chemotherapy for obese patients at the IPOCFG, EPE. The chemotherapy dose for real body surface area (BSA) was calculated and then compared with the actual dose received. The renal function was evaluated.

Material and Methods

Obese patients with IMC ≥30 receiving intravenous CT at our institution from January 2009 to July 2010. The data was collected using the Oncofarm application. To evaluate renal function, creatinine clearance (CLCr) was calculated using the Cockcroft-Gault (CG) equation for obese patients.

Results

Of 1690 patients, 28.9% were obese: 78.2% grade I, 16.3% grade II and 5.5% grade III. The average age was 61 years (28-90). Of all the obese patients, 75.9% were female and 1.4% had a BSA > 2m². BSA-based dosing is standard practice at our institution, using actual body weight to calculate BSA that is capped at 2m2. In grades II and III no significant difference was found between these doses and the doses calculated with real BSA. In grade I, 3.9% patients presented differences of 10-25% and 3.4% differences of 25-50%. In grade I, 5.1% presented CLCr>60mL/min; 72.7% CLCr 30-60mL/min; 21.4% CLCr 15-30 mL/min, 0.8% CLCr<15mL/min. In grade II, 8.1% presented CLCr 60mL/min; 78.4% CLCr 30-60mL/min and 13 .5% CLCr 15-30mL/min. In grade III, 8% presented CLCr>60mL/min; 17.7% CLCr 30-60mL/min; 20% CLCr 15-30mL/min, 4% CLCr<15mL/min.

Conclusion

Empiric strategies for dose adjustments in obese patients should be discouraged because they may compromise efficacy. The scarcity of information demonstrates that additional prospective studies are required. The CLCr obtained with the CG formula for obese patients was inferior. This is important for dose adjustments in elderly patients.

No conflict of interest

PHC023 Profile of albumin prescription at a University Hospital

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Although albumin is widely used, the risks and benefits of its use in clinical practice remain inconclusive, resulting in unnecessary expense. Studies of prescription profile and drug use are key tools to promote rational use.

Purpose

To analyse the prescription profile of albumin for six months at a University Hospital.

Material and Methods

Retrospective study of Human Albumin 20% prescription, January-June 2010 by clinical record review. Data collected: serum albumin (SA), duration of treatment (DT), daily dose (DD), number of units/prescription and cost/prescription. Descriptive statistics were

calculated (mode; mean ± standard deviation).

Results

The study included 878 patients with a total of 1515 prescriptions and 12226 prescribed units of albumin. Patients were aged between 1-96 years with 868 aged over 18 years old.

Albumin was prescribed by 27 wards mainly surgery (24.4%), gastroenterology (15.9%) and internal medicine (12.3%).

Albumin was used mostly in hypoalbuminaemia (50.6%), liver disease (8.3%) and massive oedema (4.0%).

The SA was 2.38±0.69g/dL [1-5.1], number of units/prescription was 8.07±4.32 [1-36], DD was 28.6±14.51g [10-180], DT was 3.21±1.53days [1-13], and cost/prescription was 110.17±205.70€ [25.49-458.92], with a total expense of 311,640.74€.

The SA of 1g/dL was found in a 70-year-old patient, prescribed a DD of 30 g in the emergency room for hypoalbuminaemia, while the value of 5.1 g/dL was found in a 50-year-old patient prescribed 30g DD for hypoalbuminaemia in surgery. In 421 prescriptions patients had SA >2.5 g/dL. Most frequent values (mode) were: SA 2.4 g/dL, DD 30 g and DT 3 days.

Discussion/Conclusion

The main goal of treatment is to maintain adequate intravascular filling. Some cases showed no clear benefit of using albumin instead of artificial colloids, a less expensive alternative. In this study we found cases of prescription profiles not in accordance with quidelines and identified the need for more rational use.

No conflict of interest

PHC024 Evaluation of medium-term effectiveness of a pharmaceutical care program in patients with antiretroviral therapy

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Background

Pharmaceutical care (PC) programmes represent a useful tool to prevent and resolve drug-related problems (DRPs). Antiretroviral treatment presents special difficulty for adequate compliance, due to the large number of interactions and adverse drug events involved as well as the high rate of adherence needed to be effective.

Purpose

To evaluate the medium-term effectiveness of a PC programme to optimise antiretroviral therapy. To determine the needs of the population involved and the information provided during this period.

Material and Methods

We analysed the PC records (Access 2007) of the outpatients treated with antiretroviral therapy in a University Hospital between October 2005 and September 2010. The variables examined were: number of patients and visits made, adherence to treatment measured by questionnaires (SMAQ, Simplified Medication Adherence Questionnaire) and half-yearly record of drugs dispensed. DRPs identified and information provided pharmacists.

Results

2,518 visits from 663 patients (87.7% of the population) were made over five years. On average 300 patients/year with 1.67 visits/patient/year were spoken to by pharmacists, who carried out 1.54 interventions/visit. There was an increase in the proportion of well-adherent patients, as shown by both the SMAQ and the pharmacy record of dispensed prescriptions. According to this, the percentage of compliant patients (adherence > 95%) increased from 62 to 74%. It's worth noting the declining number of DRPs detected over this period, dropping from 0.79 to 0.24 PRMs/visit. As

a result of the decrease in DPRs, the percentage of interventions to resolve them was reduced by 30%. At the same time, there was an increase in the percentage of interventions to prevent adverse drug events (Δ = +8.9%), promote healthy diets (Δ = +10.7%) and resolve patients' questions (Δ = +22%).

Conclusion

The PC programme significantly reduced the DPRs of antiretroviral therapy and increased the percentage of patients with good adherence. This activity is still very necessary as a preventative tool and is useful for patient education.

No conflict of interest

PHC025 Hepatotoxicity caused by the association of sildenafil and bosentan, a clinically significant interaction?

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Purpose

To evaluate the liver toxicity caused by the simultaneous administration of sildenafil and bosentan in patients suffering from pulmonary hypertension. To investigate how this interaction is described by different drug interaction sources.

Material and Methods

Retrospective observational study of all the patients treated at the same time with sildenafil and bosentan from 2007 to the present. By reviewing the electronic clinical history the values for GOT, GPT and GGT were obtained, before and after the coadministration till the 37th week. GOT 0-37, GPT 0-40 and GGT 7-50 were considered normal ranges for men and for women GOT 0-32, GPT 0-35 and GGT 7-32.The drug interaction sources consulted were: My optimum health.com, Drugdigest, Medscape (Drug Interaction Checker), BOT plus and Micromedex.

Results

During the study, 8 patients took both drugs at the same time. In 4 out of the 8 patients no change in transaminase levels was found. In 2 of them, the GOT level was raised but not over the normal range. In 3 patients the GPT level was raised but only one over the normal range. In 2 patients the GGT level raised, just one over the normal range. Only in one patient were both GPT and GTT levels outside the normal range, but they returned to normal values in a few weeks. In any case it was not necessary to stop the treatment because of hepatotoxicity. The drug interaction sources consulted classify this interaction as moderate risk except Medscape which does not classify it and BOTplus which defines it as potentially important.

Conclusion

Although this interaction is classified as moderate risk by different sources and potentially important by one of them, we did not see any significant events in the patients we studied.

No conflict of interest

PHC026 Results from a retrospective and prospective study use of tigecycline

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Background

Within this hospital there is a significant lack of communication of clinical data (such as comorbidities), analytical, microbiological data (such as antibiotic sensitivity) and therapeutic response (progress of the infection).

Purpose

Given the potential use of tigecycline in infections due to multiresistant microorganisms, it seemed appropriate to evaluate the use adjustment and effectiveness, according to hospital's Pharmacy and Therapeutics Committee (PTC) recommendations.

Material and Methods

Tigecycline prescriptions were evaluated for 6 months, both retrospectively and prospectively, to see if they matched the indications authorised by the PTC. At the beginning of the treatment and later we monitored the patient's progress, by means of computerised data (microbiological parameters of laboratories, cultures, antibiotic resistance, diagnosis tests, clinical and pharmacotherapeutic record).

Results

24 patients were evaluated with a median age of 68.5 years [89-14]. 95.8% of requests were authorised either because they satisfied the PTC's recommendations (79.2%) or because there was no therapeutic alternative (16.6%). The main diagnoses were infection of a surgical wound (78.3%), skin or soft tissue infection (12.5%), respiratory tract infection (8.5%), recurrent sepsis of urinary origin (4.2%). Sixty-six percent (n=16) of the patients had a history of allergy to penicillins or beta lactam derivatives . Among the patients with positive cultures, the germs most frequently isolated were Enterobacteriaceae 42.1%, Enterococcus spp 26.3% and Acinetobacter baumannii 21.1%. 62.5% of the patients displayed a favourable evolution of the infection during the treatment with tigecycline and concomitant antibiotic therapy. Two patients showed intermediate sensitivity to tigecycline and one patient, resistance. During the time of study there were 4 deaths

Conclusion

The changed PTC recommendations for the use of tigecycline enable rational use. It is a therapeutic alternative in patients with multi-resistant microorganisms who are allergic to penicillins.

No conflict of interest

PHC027 Experience of the use of vancomycin in continuous intravenous perfusion in neutropenic patient, report of a case <u>M. Muros Ortega</u>, A. Pareja Rodriguez de Vera, C. Bonillo García, J. Velasco Costa, R. Olmos Jimenez, A. De la Rubia Nieto ¹University Hospital Arrixaca, Farmacia, murcia, Spain

Background

Coagulase-negative Staphylococci bacteraemia is one of the major causes of morbidity and mortality in immunocompromised patients, and is related to subcutaneous central catheters. According to the guidelines of the Infectious Diseases Society of America patients with neutropenic fever are at greatest risk, and must be treated with vancomycin plus cephalosporin or carbapenem. The optimal plasma vancomycin level is from 5-15 µg/ mL if given normally to 15-20 µg/ mL in continuous intravenous perfusion.

Purpose

The aim is to describe our experience with monitoring the plasma vancomycin level in hematologic patients with neutropenic fever.

Material and Methods

Prospective study monitoring the plasma vancomycin level in hematologic patients from the pharmacokinetics unit in the pharmacy service. Data were collected from the medical history and the Laboratory and Microbiology Services database.

Results

17 year old man (weight 146 kg) was diagnosed with acute lymphoblastic leukaemia in 2008. He was given salvage chemotherapy (FLAG-IDA) for a relapse of the disease due to a subcutaneous reservoir. During hospitalisation, he had pain in the reservoir area, sweating and fever. Staphylococcus epidermidis was obtained from a blood culture and treatment with vancomycin 1

g twice a day was started. After 2 days, the plasma vancomycin level was suboptimal (0.8 μ g/ mL). We recommended increasing the vancomycin to 1 g every 6 hours but this only resulted in a suboptimal plasma level too (1.2 μ g/ mL). Finally we recommended changing to vancomycin 4 g in continuous intravenous perfusion obtaining an optimal plasma vancomycin level of 14.9 μ g/ mL. After 8 days the fever resolved.

Conclusion

- Neutropenic patients with fever are an at-risk group. Through drug monitoring pharmacists can collaborate in safe and effective treatment
- The administration of high dose vancomycin in continuous infusion can be an effective alternative in young neutropenic patients.

No conflict of interest

PHC028 INFLUENCE OF DOCUMENTED VANCOMYCIN MIC IN THE TREATMENT OF MRSA BACTEREMIA

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Background

Glycopeptides have been the reference drugs for treating bacteraemia and endocarditis due to MRSA but recently, questions have arisen about their limited success in isolates with vancomycin 1.5µg/mL≤MICs≤2µg/mL.

Purpose

To discover whether a knowledge of the MIC affects the decision to treat MRSA bacteraemia or endocarditis with vancomycin.

Material and Methods

Retrospective observational study with 2 periods: period 1, when the MIC was not available on the hospital's intranet and period 2, when microbiology reports contained the MIC. Data source: Microbiology records of MRSA-positive blood cultures and patient medical records. Data recorded: age, gender, antibiotics used, documented vancomycin MICs, microbiological report of vancomycin susceptibility and outcomes.

Results

34 patients were investigated, (61.8% men), with a median age of 64±15. 6 patients were excluded because they did not receive treatment (5 died, 1 recovered). MICs and patient treatment in the two periods are shown in the table below:

the periods are entern in the table below.	Period 1
No contract of the Contract	
Number of patients	18
Vancomycin MIC	
	7
≤1µg/mL	(38.8%)
≥2µg/mL	10 (55.6%)
Unknown	1 (5.6%)
	,
Patients treated	14
Treated with v comycin	8 (57.1%)
2 nd line linezolid	2
2 nd line daptomycin	1
Treated with linezolid	2 (14.3%)
Treated with daptomycin	2 (14.3%)
Treated with teicoplanin	2 (14.3%)
Outcome	
cure	11
died	6
other	

Conclusion

According to the Spanish recommendations for the treatment of bacteraemia caused by MRSA isolates with vancomycin MIC≥ 1.5 mg/dl, vancomycin should not be used if alternatives are available.

If vancomycin is used in these cases, the dose must be adjusted to obtain a trough serum concentration of 15-20 mg/L.

Vancomycin use is not monitored at our hospital and this appears to mean that it is not used in a systematic way. The results of this study suggest that documenting vancomycin MIC is important to decide the treatment and when MIC≥2µg/mL other treatments seem to be preferable.

No conflict of interest

PHC029 Drug use evaluation of romiplostim in a series of patients with idiopathic thrombocytopenic purpura

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Background

Romiplostim is a *thrombopoietin* receptor agonist that stimulates megakaryopoiesis in patients with chronic idiopathic thrombocytopenic purpura (ITP) refractory to standard treatment.

Purpose

To evaluate the use, effectiveness and tolerance of romiplostim and to find out whether results are consistent with recommendations of the summary of product characteristics.

Materials and methods

Retrospective observational study for 16 months in a university hospital. Data collected: clinical, haematological and pharmacotherapy records.

Evaluation criteria:

- a. Correct indication: percentage of splenectomised or non-splenectomised (where surgery is contraindicated) refractory ITP patients with platelet count (PC) <50x10E9/L.
 b. Treatment characteristics: initial dose (1 mcg/kg); dose
- b. Treatment characteristics: initial dose (1 mcg/kg); dose adjustment depending on weekly PC: PC<50x10E9/L, increase 1 mcg/kg; PC>200x10E9/L for 2 weeks, decrease 1 mcg/kg and PC>400x10E9/L, discontinue.
- c. Effectiveness: sustained platelet response (SPR): PC≥50x10E9/L for at least 6 of the last 8 weeks of treatment; transient platelet response (TPR): PC≥50x10E9/L for at least 4 consecutive weeks; median of percentage of weeks with PC≥50x10E9/L of total treatment weeks.
- d. Tolerance: undesirable effects (UEs) and discontinuation of treatment.

Results

We investigated 7 patients:

- a. Six patients (85.7%) achieved the treatment criteria (50% splenectomised, 50% contra-indicated splenectomy). 100% of patients started treatment with PC<50x10E9/L.
- b. One patient was started at doses >1 mcg/kg. 71.4% of the dose adjustments fitted the established criteria.
- c. SPR was achieved in 3 patients (42.9%); TPR in 2 other patients (28.6%). Median of percentage of weeks was 47.1 (range: 5-68).
- d. In one patient the onset of UEs led to discontinuation.

Conclusion

Although the indication, dosage and initial PC criteria followed the recommendations in more than 85% of patients, it appeared that they were not managed properly because of incorrect dose adjustments. Therefore, we consider a more comprehensive validation necessary. With moderate effectiveness and good tolerance it seems necessary to conduct studies with greater numbers of patients to obtain more conclusive results.

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PHC030 Non-biological complex drugs: how to show therapeutic equivalence ñ the Leiden proposal1

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Background

For classical small molecules, generics are authorised after the patent expires upon documentation of therapeutic equivalence; that is, pharmaceutical equivalence (same API and dosage form) together with comparable pharmacokinetics (bioequivalence) investigated in a cross-over volunteer study. This paradigm cannot be applied to complex drugs, such as the biologicals, for which a (bio) similar pathway was introduced by the EMA in 2004 that requires clinical trials to demonstrate therapeutic equivalence. There are non-biological complex drugs that share characteristics of the biologicals.

Purpose

To become acquainted with expert opinion based upon existing evidence, regarding appropriate requirements to guarantee therapeutic (and safety) equivalence and possible interchangeability of non-biological complex drug. To define criteria for consideration in a regulatory framework of authorisation to copy complex drugs.

Material and Methods

The scientific rationale for the appropriate means of authorising generic versions of original complex drug products was explained in a workshop attended by experts from academia, pharmaceutical scientists and regulatory authorities involved with non-biological complex drugs (e.g. LMWH, liposomal drugs, iron-sugar drugs and glatiramoids).

Results

	Conventional Drugs	Complex Drugs
Size	Small (single molecule)	Large (mix)
Structure	Simple, defined	Complex, defined by the exact manufacturing process
Modification	Well defined	Many options
Manufacturing	·Predictable chemical process · Identical copy can be made	Difficult to control from starting material to final API Impossible to ensure an identical copy
Characterisation	Easy to characterise fully	Cannot be characterised fully (mixture of related molecules)

Conclusion

Complex molecules cannot be fully identified. Even slightly different manufacturing processes can vary the safety and efficacy of the product. Only a 'biosimilar approach' with non-clinical and clinical testing requirements can ensure therapeutic equivalence and finally interchangeability between complex drugs.

1. Paper accepted and in print in Regulatory Toxicology and Pharmacology

Conflict of interest

Other Hospital Pharmacy topics (including: medical devices)

OHP001 Developing consensus guidance to facilitate service redesign involving pharmacist prescribing in secondary care in Scotland

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Pharmacist prescribing was introduced in the UK in 2003. Previous research indicated a gap in the implementation of pharmacist prescribing (PP) in secondary care in Scotland with no single strategy for implementing PP [1,2].

Purpose

To develop consensus guidance to facilitate service redesign involving PP in secondary care.

Material and Methods

Using evidence generated from focus groups conducted previously[3], statements were formulated on service management and role development. These formed the basis of a questionnaire for a consensus research method using the Delphi technique. Key stakeholders (strategic and practising professionals) involved in PP in Scotland were invited to participate and rank their level of agreement or disagreement with the statements on a five-point Likert scale, and list any additional statements. Two rounds of Delphi were conducted. Ethical approval was obtained.

Results

71 individuals were invited with 40 consenting, representing 11/14 health boards. 87.5% completed Round 1 and 72.5% completed Round 2. Agreement (70 - 100%) was reached with 27/30 statements. Agreement was highest in areas related to succession planning rather than those relating to role development. Comments were provided that helped to inform Round 2 where 6 statements were provided for ranking. Agreement was reached with one further statement in Round 2. All statements where agreement was reached were included.

Conclusion

The high level of agreement in succession planning may reflect the strategic cohort within this group. Areas where there was a lack of included educational and training competencies and particularly the future orientation of the service. The high rate of participation among pharmacist prescribers and pharmacists involved in developing non-medical prescribing policies indicates interest and possibly need for such guidance. This is the first research aimed at developing a tool to guide the implementation of pharmacist prescribing in secondary care. References

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No conflict of interest

OHP002 hospital pharmacy in the field of clinical nutrition: a study on patients after percutaneous endoscopic gastrostomy

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Background

Although percutaneous endoscopic gastrostomy (PEG) is frequently performed in our hospital, routine follow-up of patients has not been established. Therefore, the evolution of the nutritional status is unknown and necessary interventions possibly missed.

Purpose

To provide monitor patients after PEG. The aim was to investigate the nutritional status and to evaluate the benefits of a reinvestigation three months later. Additionally, complications and quality of life were examined.

Another intention of this study was to expand the role of the hospital pharmacist as a member of the nutrition support team from a mainly logistic function to active participation in the management of nutrition.

Material and Methods

Blood parameters (C-reactive protein, albumin, prealbumin, vitamins (A, E, B₁₂, D₃ and folic acid), cholesterol, triglycerides, iron, ferritin, cholinesterase, zinc and selenium were analysed to identify nutritional deficiencies. Body mass index (BMI) calculations assessed the risk of malnutrition. Bioelectrical impedance analysis (BIA) visualised body composition.

A questionnaire investigating various aspects of life after PEG was designed; a standardised instrument measured health- related quality of life.

Results

24 patients were recruited, only six of these were aged under 65. 45% died within three months of PEG.

Blood parameters, BMI and BIA parameters revealed considerable nutritional deficiencies.

Follow-up investigations were well received and highly beneficial, resulting in 50% tube replacements, frequent changes in enteral nutrition, routine dietary counselling and management of swallowing dysfunctions.

The questionnaire revealed no major problems after PEG (gastrointestinal functions, drug use, wound healing). In general, quality of life was improved after three months.

Conclusion

The study established the collaboration of hospital pharmacy in clinical nutrition management and revealed interesting aspects for aftercare. Patients after PEG tube placement clearly benefit from well-thought-out nutrition. A follow-up investigation should be performed routinely.

No conflict of interest

OHP003 Spinal cord stimulators : an evaluation in Paris **University Hospitals**

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Background

Spinal cord stimulation, or neurostimulation, inhibits pain messages by sending pulsed electrical signals to the spinal cord. It is indicated in the treatment of neuropathic pain resistant to usual analgesic treatments. Spinal cord stimulators (SCSs) are active implantable medical devices and consist of a pulse generator with remote controls, implanted stimulating electrodes and conducting wires connecting the electrodes to the generator.

The aims of this study were to review the types of SCS used and to estimate the economic impact of these devices in Paris University Hospitals.

Material and Methods

This study was performed using the product data sheets, a literature review and the manufacturer's sales records.

Results

In 2010, six types of SCS were available in France. Three were identified in the treatment of chronic neuropathic pain resistant to standard analgesic treatment and and the treatment of peripheral ischemic pain: the Genesis (Saint Jude), Itrel3 and Prime Advanced (Medtronic). An estimated 550 to 1100 implantations are performed in France per year, with 50 (average price 8,000 euros) in Paris University Hospitals. Three refillable SCSs are indicated in the treatment of patients requiring a high level of stimulation: the Eon (Saint Jude), Precision (Boston) and Restore (Medtronic). An estimated 80 to 165 implantations of this type of SCS are performed in France per year, with 15 (average price 18,000 euros) in Paris University Hospitals. The SCSs were assessed by the French National Authority for Health, and are reimbursed in addition to the DRG tariffs and as such are listed on an "add-on list". In France, the refillable SCSs are subject to a check of prescriptions and numbers dispensed.

Conclusion

Six types of SCS were identified for two different uses. These innovative medical devices represent major progress in the management of chronic pain. Further similar studies are needed in order to check the impact of the cost, although it is at present negligible in Paris University Hospitals despite the high cost of new stimulators.

No conflict of interest

OHP004 Activity and related cost of the outpatient dispensing pharmacy unit in a second-level hospital in Spain: A three-year retrospective analysis

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Background

The Outpatient Dispensing Unit (ODU), with 70% of the total hospital spending on drugs, has been one of the fastest growing fields in hospital pharmacy in recent years. Describing current trends is essential for future decisions.

Purpose

To examine care activities developed in the ODU and their cost in a Spanish second-level hospital over 36 months in order to set up priority action groups.

Material and Methods

A retrospective three-year investigation was performed. Data regarding number of patients(A), items dispensed (B), cost(C), distribution per group (according to pathology) and Average Time per Patient (ATP: average time spent in the ODU by the patients) were collected.

Results

Overall increases in A, B and C values were 23.05%, 13.62% and 22.61%, respectively. This was accompanied by a decrease in ATP estimated at over 26%. Per group, the highest increases were and 61.31%(C), corresponding to the group Haemophilia, followed by anti-TNF (rheumatology patients with biological therapy) with 33.67% and 20.38% and Multiple Sclerosis (31.07% and 41.97%); increases for HIV (13.86% and 22.77%) and CHV (5.88% and 3.86%) were also observed. The Others Group (which brought together patients from different pathologies) increased by 26.92% and 31.78%; however, more than 60% of this increase was due to patients suffering from chronic renal disease who were prescribed α-darbepoetin. In addition, patients belonging to the groups Haemophilia, anti-TNF, Multiple Sclerosis and HIV, together with the group Metabolic Disorders (Gaucher's, Pompe's, Hurler's, Hunter's and Fabry's diseases) representing about 40% of patients, accounted for more than 75% of total expenses.

Conclusion

A substantial growth in all parameters was observed, especially in certain pathologies. Such an increase has led to impairment of the assistance provided to patients. As nearly 40% of patients consume approximately three quarters of economic resources, future efforts should focus on the aforementioned groups, implementing cost-containing strategies without harming care quality (price negotiation, opening hours and staff expansion, long-term dispensing, etc.). No conflict of interest

OHP005 Use of systems of continuous infusion of analgesics and local anesthetics prepared at the pharmacy service M. Rabuñal Álvarez, S. González Piñeiro, L. Elberdín Pazos, M. Calvín Lamas, C. Seco Vilariño, I. Martín Herranz ¹Complejo Hospitalario Universitario A Coruña, Pharmacy, A Coruña, Spain

Background

Elastomeric devices and cassettes for patient-controlled analgesia (PCA) pumps are an effective alternative for drug administration in acute postoperative pain and palliative care.

Purpose

To describe and analyse the use of infusers/cassettes of analgesics and local anaesthetics.

Material and Methods

Retrospective study, period 2006-2009. Source of data: record of infuser/cassette preparation by the Pharmacotechnical Section of the Pharmacy Service (PS). Nine types of infuser/cassette are in use: 0.25% levobupivacaine, 0.2% ropivacaine, 0.15% ropivacaine +1 mcg/mL fentanyl, 0.18% ropivacaine +1 mcg/mL fentanyl, 0.125% bupivacaine, 0.5 mg/mL morphine +1.2 mg/mL ketorolac and infusers of variable doses of morphine, bupivacaine + fentanyl, morphine + bupivacaine. Data recorded: drug, type of infuser/cassette prepared, amount measured for each clinical unit. To calculate the total cost, the cost of the drug, device and infusion system (if applicable) were considered. Staff costs were not considered.

Results

Total number of infusers/cassettes prepared: 4430: 387(2006), 554(2007), 1071(2008) and 2418(2009), showing annual increases of 43.15% (2007), 93.32% (2008) and 125.78% (2009). The overall increase was 525%. The cost in 2006 was 20021€ and in 2009 116575€ (482% increase). Preparations: 37.71% ropivacaine 0.15%+1 mcg/mL fentanyl, 15.82% bupivacaine at variable doses, 13.92% morphine (variable doses), 12.8% bupivacaine + fentanyl, 19.75% others. Systems were used for postoperative patients, deliveries, Caesarean sections, short-stay surgery and analgesia in palliative care. <u>Postoperative patients</u> 1318: 495 epidural bupivacaine 0.125%, 362 morphine 0.5 mg/mL +1.2 mg/mL ketorolac and 273 infusers of 50 mg morphine (all cases for analgesia). Deliveries/Caesareans 2311: 1858 0.15%+1 mcg/mL fentanyl (epidural analgesia), 239 bupivacaine 0.125%+1 mcg/mL fentanyl and 63 levobupivacaine 0.25%(surgical wound). Patients who had short-stay surgery: 119 bupivacaine 0.125% and 38 levobupivacaine 0.25%. Palliative care: 338 infusers of variable doses of morphine (270/338 hospital-at-home care).

Conclusion

The great increase observed in the number of infusers/cassettes of analgesics and local anaesthetics prepared in the PS reflects the new approach taken for the treatment of pain and its prevention in clinical practice. This has a significant economic and additional workload impact for PS, which is explained by the extension of this activity and the allocation of human and technological resources needed. Infusers/cassettes developed in the PS allow the safe combination of drugs, ensuring asepsis and stability of the mixture.

OHP006 Consumption and effectiveness of Filgastrim and Pegfilgastrim in a Oncology Service

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Background

Recombinant human granulocyte-colony stimulating factors (rhG-CSFs) are used to reduce the duration and severity of neutropenia in patients undergoing myelosuppressive chemotherapy (ChMT) and to mobilise peripheral blood progenitor cells. Their high cost forces us to use them correctly.

Purpose

To analyse the consumption and the effectiveness of Filgrastim (Filg) and Pegfilgastrim (PFilg) on the oncology ward from January 2009 to August 2010.

Material and Methods

A retrospective study. Records were obtained from the outpatients database of those taking the medications in pharmacy and analytical laboratory. The following data were collected: age, gender, diagnosis, ChMT schedules, Filg or PFilg, indication and neutrophil values before and after the rhG-CSFs. The indication was classified as primary prophylaxis (1P), secondary prophylaxis (2P) and treatment (T: neutrophil values<1.5x10⁹/L.).

Results

We reviewed 144 treatments. The mean age was 61 (DE 10.3), 59% were women and there was no difference between the use of the two drugs: Filg 51% and PFilg 49%. 53% of pharmacy prescriptions for Filg were for 5 units.

The indications analysis revealed that 14% were 1P, 37.8% 2P and 48.3% T. There was no difference in the use of rhG-CSFs as regards indications.

Renal neoplasia was the condition most treated with rhG-CSFs (37.5%). Apart from that, 41% of rhG-CSFs consumption was due to breast cancer (higher incidence). FOLFOX ± bevacizumab was the most used ChMT schedule with these drugs (23.6%).

The mean increase of neutrophil value in P and in T was statistically significant (2504x10⁹/L. p=0.000 and 6642x10⁹/L. p=0.000 respectively).

Conclusion

The consumption of the two rhG-CSFs is similar and there are no differences related to the indications. More of the products were used for breast cancer, but renal neoplasia was the condition most treated.

Filg and PFilg achieved their objective, to statistically increase the neutrophil count in treatments or to maintain them in prophylaxis.

No conflict of interest

OHP007 Management of standard instrumentation ir university hospital of Montpellier by the unit of sterilisation <u>E. guiller</u>, S. Pourtalié, C. vagner, J. cantoni, P. Rambourg ¹University hospital of Montpellier, Pharmacy, Montpellier cedex 5, France

Background

In University Hospital of Montpellier, the sterilisation unit handles the standard equipment for 101 units (11 major divisions of the hospital). The sterilisation unit is responsible for the repurchase of reusable standard materials "lost" by the units. This standard equipment is the object of a call for tender and can be distinguished from special equipment, mainly ordered by surgical units.

Purpose

To evaluate the costs engendered by the loss of standard equipment from the units in 2009 and to propose approaches for minimising this.

Material and Methods

In January 2010, assistant managers undertook an inventory in the care units. Besides posting the losses, this annual inventory allows us to adjust allocations as needed. The costs of the losses concerned at the inventory are added to those met all year round in 2009. These are one-off losses from the care units reported to the sterilisation unit by phone call or on the index cards used for communication.

Results

The spending limit for the losses, for which the pharmacy is responsible, represents a total budget of 25 816€, of which 70% follows the inventories. The most overdrawn divisions are: "birth and pathology of the woman" (24.53%), "Emmbrun": kidney, high blood pressure, metabolic endocrinology, "Burns" (21.80%) and "Emergencies" (12.82%).

Discussion

The cost supported by the pharmacy represents 2.6% of the budget assigned to instruments (standard and special). To educate the care units and simplify the ordering of equipment, the sterilisation unit has suggested that standard equipment be ordered from the supplier by Purchasing. The standard and special equipment would then be ordered in the same way. The cost would be immediately charged to the requesting major division.

Conclusion

To empower care units, transferring the budget seems inevitable, if the standard instruments are to be better managed.

No conflict of interest

OHP008 Centralized compounding services for monoclonal antibodies in a regional hospital: a pharmacoeconomical analysis

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Background

Due to the absence of a hospital pharmacy in the Judenburg/Knittelfeld regional hospital (Upper Styria), monoclonal antibodies (MABs) for inpatient treatment were prepared by nursing staff.

To protect operators and improve the costs /benefits a centralised hospital pharmacy-based compounding service was introduced in the nearest larger Leoben/Eisenerz regional hospital.

Purpose

To describe the financial efect of implementing a MAB compounding service for a small 297-bed regional hospital over six months.

Material and Methods

The number of original packages of four MABs (bevacizumab, panitumumab, rituximab and trastuzumab) needed for centralised preparations (the remainder of containers are used) was compared to the number needed for decentralised preparation (assuming no remainders are used). Total costs and resultant net savings were calculated.

The compounding was done in an isolator (clean room class A), which is located in a clean room class D.

Results

A total of 170 preparations for 41 patients were compared. Bevacizumab, panitumumab, rituximab and trastuzumab accounted for 46, 6, 32 and 16% of all preparations, respectively. Data and selected parameters are shown in table 1.

Table 1

Total		No. packages		Drug costs* (€)			Total
MAB	Total dose (mg)	centrai	Decentral- ised	central	Decentral- ised	Preparation costs**(€)	saving s (€)
b	U	50.7 at 400 m	14 at 100 mg 49 at 400 mg	107.60 8	116.346	4.000	4,738
Panitumuma b	4.137		41 t1 0 mg	17.595	17.425	513	-683
Rituxima	9.58	100 mg 61.6 at	53 at 100 mg 60 at 500 mg	120.26 3	123.499	2.770	466
Trastuzumab	12.37 0		101 at 150 mg	56.794	69.690	1.436	11,460

^{*} selling price ex factory

No savings could be proved by the centralised preparation of panitumumab, because no more than one preparation a day was made at the Leoben/Eisenerz regional hospital (no residues were reused).

Through the centralised preparation of the monoclonal antibodies bevacizumab, panitumumab, rituximab and trastuzumab at the Leoben/Eisenerz hospital pharmacy, the total savings for the Judenburg/Knittelfeld hospital amount to 15,981€ within a period of six months.

Conclusion

The implementation ofcentralised MAB compounding leads to a reduction of direct drug costs compared to former decentralised compounding.

No conflict of interest

OHP009 Reducing medication costs by implementing recommendations in hospitals- A description of a successful implementation in Region Zealand, Denmark

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Background

The five regions of Denmark are each responsible for recommending drugs that are effective, safe and inexpensive for use within hospitals and primary care. The challenge however is to implement such recommendations, where the goal is to ensure that the majority of the prescriptions are for the recommended drugs, and thereby reduce the medicines costs considerably. The Hospital Pharmacy of Region Zealand has met this challenge by various approaches. A successful approach regarding recommendations on Proton Pump Inhibitors (PPIs) is described.

Purpose

To implement the recommendation of PPIs, and thereby

- reduce medicines costs
- unify the prescriptions for PPIs in the region

Material and Methods

The implementation was made through intervention on three levels; hospital, ward and prescriber, in a top-down approach.

- 1. Current use of PPIs were recorded, and portrayed in diagrams
- 2. The Regional Drug and Therapeutics Committee's recommendations on PPIs were communicated through Newsletters to all clinical personnel at the hospitals
- 3. To have a dialogue regarding the recommendations and use of PPIs, the ward managements were contacted personally by a clinical pharmacist
- 4. Oral presentations of the recommendations were made to

doctors at the wards with considerable PPI use

- 5. Suggestions for changing non-recommended PPIs at prescriber level were made by pharmacy assistants
- 6. A 3-month follow-up was made on the use of PPIs (type and amount) and the wards that were still not complying with recommendations were exposed to the relevant steps again

Results

The use of non-recommended PPIs before and after the implementation was respectively 44729 and 17088 (DDD/6 month). After the implementation described the cost of PPIs were reduced by 64%

Conclusion

The top-down approach described was more successful than previous bottom-up approaches (step 1-6 in opposite order) for implementing the recommendations made by the Regional Drug and Therapeutics Committee.

No conflict of interest

OHP010 Pharmacists' well-being at work: evaluating a tool to aid decision making

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Background

The Health and Safety Executive (HSE) conclude that a preventative population-based risk assessment approach to staff well-being can be more effective than a case-based approach [1]. The HSE define six management standards and have developed a validated tool to aid performance benchmarking against 136 UK organisations [2].

Purpose

To evaluate the utility of an HSE tool in assessment of hospital pharmacists' well-being.

Material and Methods

The HSE tool, using a weighted five-point Likert scale (1=poor; 5=good), was administered to NHS hospital Pharmacists using an on-line survey tool (Surveymonkey). Data was aggregated from participating Trusts and sorted into four categories: Green (>80th percentile of national data), Blue (>= 50^{th} but $<80^{th}$), Amber (>= 20^{th} but $<50^{th}$) and Red ($<20^{th}$).

Results

200 pharmacists (75%) from 11 Trusts responded. Mean scores benchmarked against each management standard are shown (Table 1). There are interesting differences in performance between study and benchmark comparator groups that are worthy of further investigation. Significant differences were found between junior and more senior pharmacists for 'demands' (p<0.001) and 'control' (p<0.001). The method used was simple, reliable and required minimal time and effort to deploy.

Table 1: Results from pharmacists' survey

	A 11		
Stressor	All Pharmacists	'Junior' Band 6&7*	'Senior' Band 8+
Demands	2.93(R)	3.18(B)	2.82(R)
Control	3.44(A)	3.21(R)	3.53(B)
Manager's Support	3.41(A)	3.36(A)	3.44(A)
Peer Support	3.72(A)	3.82(B)	3.69(A)
Relationships	3.81(A)	3.94(B)	3.77(A)
Role	3.97(R)	3.96(R)	3.98(R)
Change	3.04(A)	2.90(A)	3.11(B)

^{**51.29€} per preparation including staff, storage, maintenance, facilities, disposable articles, protective clothing etc.

*NHS pay scales – band 6/7 staff are typically more junior and less experienced than band 8+ staff.

Conclusions

The tool allows benchmarking of Pharmacist's well-being and highlights areas for targeted improvement effort. The methodology used has potential significant utility for either single or multiple organisations.

References

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No conflict of interest

OHP011 Relationship of polypharmacy in functional status and cognitive impairment among elderly

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Background

Polypharmacy is common in older patients, causing adverse drug effects, drug-drug interactions and other drug-related problems. Complex medication regimens are difficult for patients to understand. Mild cognitive impairment and disability are common in elderly people, and these may also affect medicines compliance. Those patients with cognitive impairment and difficulty with instrumental activities of daily living are target subpopulations for polypharmacy intervention.

Objective

Todetermine the association between functional and cognitive impairment with polypharmacy in elderly outpatients.

Patients and methods

The setting was a community-based geriatric assessment unit located in Hospital de La Ribera (Valencia, Spain). Newly admitted and regular patients were recruited during clinic visits. During the assessment each patient (or caregiver) was asked by a pharmacist to report his/her medicines. Cognitive status was assessed with the Short Portable Mental Status Questionnaire (SPMSQ) (0-10). Disability was measured by modified Rankin scale (0-6). Upon completion of each patient's assessment, data were entered into a patient register and included the following: personal information, result of cognitive test, and medication data.

Results

The study group comprised 63 patients. The participants had a mean (SD) age of 80 (7.3) years and 63.5% (40/63) were women. Only 26 patients (41.3%) managed their own medication. Median number of prescription medicines was 6.7 (range 1-12). 15 participants (23.8%) reported taking one or more self-medication products (analgesics, vitamins or herbal products). Patients had a mean SPMSQ score of 3.8 (2.9), and modified Rankin score of 1.5 (1.3). Patients who were treated with a higher number of drugs had better cognitive function test scores (r=0.025; p=0.43)) but a greater disability level (r=0.25, p=0.04).

Conclusion

Polypharmacy seems to be associated with cognitive and functional status but more research is needed to further delineate the consequences associated with drug use in elderly patients.

No conflict of interest

OHP012 sodium cromolyn 0.21% cream for patients with cutaneous mastocytosis

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Background

Cutaneous mastocytosis (CM) is a disease limited to skin characterised by an abnormal proliferation and accumulation of mast cells. The skin lesions are most common from the first month to 2 years of age and the treatment used is cromolyn sodium 0.21% cream (CSC).

Purpose

To evaluate the medicines dispensed, patient profile and cost of CSC in our hospital.

Material and Methods

Retrospective and descriptive study of CSC prepared and dispensed to patients with CM by the Pharmacy Service in a secondary hospital from January 2007 to April 2010. Demographic data, number of CSC units dispensed/patient were recorded.

Results

A total of 251 CSCs were prepared, at a cost of \in 630.01 for a total of 144 patients with CM: 63 (43.7%) women and 81 (56.3%) men. Fifty four (37.5%) patients were aged 0 to 2 years; 37 (25.7%) 3 to 5 years, 30 (20.8%) 6 to 8 years; 15 (10.4%) 9 to 11 years and 8 (5.6%) older than 12 years.

	2007	2008	2009	2010
Number of patients (%)	35 (24.3)	46 (31.9)	57 (39.6)	6 (4.2)
Number of CSC units dispensed (%)	50 (19.9)	85 (33.9)	101(40.2)	15 (6)
Number of CSC units dispensed/patient	1.43	1.85	1.75	2.67

Conclusions

Demand for and production of CSCs dispensed/patient has increased since 2007 to date. Patients from birth to 2 years use the cream most, similar to what is reported in the literature, where the incidence of this condition is more common.

No conflict of interest

OHP013 Dispensing of tyrosine kinase inhibitors by the pharmaceutical care consulting room in a Hospital Pharmacy Service

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Background

Before August 2007, in the region of Galicia, Spain, the tyrosine kinase inhibitors were dispensed in community pharmacies with medical prescriptions. The Gallego Health Service's order 12/07 required these drugs to be dispensed by hospital pharmacies.

Purpose

To assess the impact in the Hospital Pharmacy Service of the Gallego Health Service's order 12/07 relating to the definition, use and dispensing of the group of drugs tyrosine kinase inhibitors.

Material and Methods

retrospective study from September 2007 to February 2010 of the patients who started treatment with tyrosine kinase inhibitors and continued treatment at the pharmaceutical care consulting room. We use the Silicon and the Dipex programs, report monthly resources consumed by the consulting room and a daily record of pharmaceutical care activity (general patient information, items dispensed and pharmaceutical interventions).

Results

In the study period 83 patients started treatment with tyrosine kinase inhibitors and 18 patients continued treatment initiated previously. These patients constitute 19.6% of monthly expenditure of pharmaceutical care consulting room, with a total of 899 items dispensed. These treatments impose on the hospital an average cost of 106000€/ month, with an annual increase of 11.2%. Of total expenditure on these drugs, 73.5% corresponds to imatinib, 10.4% to sunitinib, 6.74% sorafenib, 6.76% erlotinib, 2.33% dasatinib and 0.51% lapatinib.

Conclusion

A great increase in pharmaceutical spending by the Hospital Pharmacy Service has been imposed by the increased use of tyrosine kinase inhibitors. The appearance of erlotinib and sunitinib in this health area has enabled many treatments to be simplified and treatment to be dispensed to outpatients. We consider the dispensing of this group of drugs at the hospital level very important, both as regards economics and welfare.

No conflict of interest

OHP014 THE INFLUENCE OF THE HOSPITAL PHARMACIST ON PRESCRIBING MEDICATIONS

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Background

In the past few years pharmacists have been more often involved in the provision of rational pharmacotherapy and prevention of drugrelated problems (DRP).

Purpose

To measure the influence of pharmacists on medicines prescribing and to evaluate cooperation between pharmacists and physicians.

Material and Methods

The research was conducted from December 2009 to April 2010 in the Emergency Centre, Clinical Centre of Serbia. Every pharmacist action related to medicine use was noted. Communication with physicians was personal (in the pharmacy or on the ward) or by telephone.

Results

There were 85 conversations with physicians; most of them were done with anaesthesiologists (26), surgeons (24) and neurologists (11). The pharmacistshad influence on the choice of medicines (100 times), and on the dose of medicines (63 times). Physicians were asked for help about choice of medicine 70 times, 39 times about choice of anti-infective agents. The pharmacist suggested a change of treatment 26 times, 23 times suggesting a change of antibiotics. Advice about dosage was asked 54 times, 36 of them were about dosing of antibiotics. Pharmacists changed the proposed dose of medicines 9 times.

Conclusion

The research showed that pharmacists do influence medicines prescribing, that physicians have confidence in pharmacists' opinions and that they consult them about the treatment. The record of the most frequent interventions indicates that pharmacists should focus on usage of antibiotics in their future work. No conflict of interest.

OHP015 Influence of international antiretroviral guidelines on hospital protocols and pharmacy budget

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Background

Antiretroviral treatment (ART) for HIV patients has changed in recent years in accordance with international guidelines (European AIDS Clinical Society, US Department of Health and Human Service). It has led to hospital treatment protocols and pharmacy budget modifications with earlier initiation of therapy in treatmentnaïve HIV-infected patients, initial regimens and switching strategies for virologically non-suppressed patients.

Purpose

To analyse the impact of HIV treatment guidelines on antiretroviral treatment and pharmacy budget in a 1450-bed university hospital.

Material and Methods

Retrospective observational study for 5 years (2005-2009). Patients: 100% HIV, adults. Data source: Outpatient Dispensing Pharmacy Department and Budget Monitoring databases.

Results

Evolution of antiretroviral treatment

	2005	2006	2007	2008	2009
Nº patients	483	520	533	587	647
Annual increase	-	7.7%	2.5%	10.1%	10.2%
NRTI:	269	258	225	176	121
zidovudine/lamivudine	4	33	71	91	116
abacavir/lamivudine	0	49	187	340	442
tenofovir/emtricitabine					
PIS/R	187	191	191	205	187
lopinavir/ritonavir	66	97	136	156	229
atazanavir/ritonavir	-	-	9	26	47
darunavir/ritonavir					
Rescue therapy (Raltegravir, enfuvirtide, etravirine, maraviroc)		14	13	17	66

NRTI: nucleoside reverse transcriptase inhibitors; PI/r: protease inhibitors/ritonavir

Evolution of the antiretroviral budget

COSTS (€)	2005	2006	2007	2008	2009
Annual	3,547,842	3,890,218	4,349,622	,170,790	6,321,237
Annual increase	-	9.7%	11.8%	18.9%	22.2%
% of total budget	9.69%	9.62%	9.69%	9.74%	10.61%
Cost/patient- year	7,345	7,481	8,161	8,809	9,770
NRIT	1,832,895	1, 47,026	2,195,793	2,546,174	3,105,846
PI/r	938,970	1,117,051	1,357,719	1,658,416	2,026,527
Rescue therapy	115,482	165,279	127,703	294,817	512,525

Conclusion

Our hospital protocols derived from new antiretroviral guidelines led to an increased number of patients on treatment. They also led to an increased consumption of abacavir/lamivudine or tenofovir/emtricitabine vs.zidovudine/lamivudine,atazanavir/ritonavir or darunavir/ritonavir vs. lopinavir/ritonavir and rescue treatment.

The higher price of these new treatments has an incremental effect on the Pharmacy budget, so hospital pharmacists must cooperate with clinicians and hospital directives in antiretroviral therapies protocols for treatment-naïve and experienced HIV patients and with budget monitoring.

No conflict of interest

OHP016 Cost analysis of anemia treatment with erythropoiesis-stimulating agents in cancer patients receiving chemotherapy

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Background

Spaepen et al. (The Oncologist 2008;13:596–607) published a cost analysis on the treatment of chemotherapy-induced anaemia with erythropoiesis-stimulating agents (ESA) darbepoetin alfa (n=429), epoetin- α (n=1584) and epoetin- β (n=380), using data from the Belgian Hospital Disease Database.

Purpose

To assess the applicability of the Belgian analysis to the Austrian setting, and to evaluate differences in costs between ESAs.

Material and Methods

To adapt Belgian data for the Austrian setting, discrepancies in cancer epidemiology, treatment patterns and cost of medical care between countries were adjusted using a mixed-effects model stratifying for propensity score quintiles (as in Spaepen 2008), using data from Eurostat, Austrian cancer statistics, IMS sales data, reimbursement and treatment guidelines and reimbursement lists (Euro, 2010).

Results

Similarities were found in mean age and gender (41.01 vs. 40.72 years; 39.48% vs. 39.39% male) between Austrian and Belgian patients. Overall cancer incidence was somewhat lower in the Austrian population (0.45% vs. 0.52%). Differences were found in the prevalence of haematological, female breast, lung, female genital cancers, which were less prevalent in Austria. Weight of those cancer types was reduced in the original dataset. No major differences were found regarding the use of ESAs or blood transfusions. Total costs were $\{8,825\pm970\}$ for darbepoetin alfa vs. $\{11,693\pm871\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ and $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoetin- $\{13,776\pm997\}$ for epoet

Conclusion

The cost of ESA treatment was lowest in patients receiving darbepoetin alfa compared to patients receiving epoetin- α or epoetin- β . The findings for Austria were in line with those from the Belgian analysis, accounting for patient characteristics and treatment costs.

Conflict of interest: Yes; Advisory board:consulting; This study was sponsored by Amgen (Europe) GmbH

OHP017 monoclonal antibodies compounded medication:manufacturing evaluation

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Background

Pharmacists are committed to the development of appropriate drug dose for each patient and must manage the resources at their disposal

Purpose

To demonstrate the importance of pharmacists on the preparation of monoclonal antibodies and the great deal of work this implies for the service.

Material and Methods

observational study in a general hospital (August 2009-July 2010). The production records of the sterile compounded medicines department collected at the Pharmacy during the study period were evaluated as well as the number of vials used in their preparation.

Results

The number of sterile compounded medicines prepared was 2878; half of them (1450=50.38%) were monoclonal antibodies.

702 units (48.1%) were prepared as pre-filled syringes, and 652 (44.96%) were prepared in perfusion bags.

Talking about the monoclonal antibodies prepared in syringes, 447 were doses of ranibizumab, with a consumption of 289 vials and a cost of 303068.52€.

Intravitreal syringes of bevacizumab were prepared. To achieve this, 4 vials were used to prepare 170 doses with a cost of 5527.8€. Finally, 181 doses of palivizumab were prepared using 177 vials (173 vials of 100 mg and 4 50 mg vials, 165287.29€). Without the intervention of pharmacists expenditure would have been 268 (160 100 mg vials and 108 50 mg vials, or 214432.36€).

On the other hand, perfusion bags of infliximab were prepared. 652 doses were obtained for the cost of 2,078 vials and a cost of 1279798.74€.

Conclusion

- The preparation of pre-filled syringes turns out to be profitable as we obtain several doses using only one vial.
- Individualized doses entail a better management of economic resources and higher cost savings, but it means a bigger workload for pharmacists in preparation.

No conflict of interest

OHP018 Assessment of postoperative pain in the most prevalent surgical interventions

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Background

Postoperative pain (POP) is due to nocciceptive stimulation during surgical interventions, and it is one of the most prevalent symptoms in hospitalisation wards (HW).

Purpose

To analyse POP control of the most prevalent surgical interventions in our hospital to know how effective the new anaesthesia protocol (AP) is.

Material and methods

Prospective observational study carried out from October 2009-March 2010. We evaluated POP intensity of every patient admitted to hospital after a surgical intervention, using the Visual Analog Scale (VAS). For each patient, we registered 3 VAS measures: at resuscitation ward (immediately after surgery) (1REA), one hour (h) after arrival at HW (2REA), and 13h after arrival at HW (3REA). We differentiated between patients without pain/mild pain (VAS≤3) and patients with moderate/severe pain (VAS>3).

Results

The total number of VAS assessments was 1425 (50.8% men). Mean age was 58.6 (SD 17.6)

Our results are related to the most prevalent surgical interventions. Those were: inguinal hernia (11%), laparoscopic colecistectomy (9.1%), arthroscopy (7.2%), other hernias (7.1%) and knee prosthesis (6.6%).

The percentage of patients that showed a VAS>3 was: 3.1% in 1REA, 5.7% in 2REA and 7% in 3REA.

Related to pain intensity and type of intervention, statistical differences were found only in 2REA: while 13.8% of the group of knee prosthesis showed VAS>3, only 1% of the arthroscopy group showed it (x^2 =16.7 p=0.002).

We found statistical differences in 2REA between the type of anaesthesia and pain intensity. Intradural anaesthesia produced more pain (7.6%) than general anaesthesia (2.7%) (p=0.024).

Duration of surgical interventions was longer in patients belonging to VAS>3, with statistical significance in 2REA (p=0.030) and 3REA (p= 0.001).

Women showed more pain, with statistical significance in 3REA (p=0.023).

Conclusion

- The AP established in our hospital provides a satisfactory pain control compared to previous data available.
- However, it needs to be reviewed for the most painful surgical interventions and, above all, in 2REA.

No conflict of interest

OHP019 Going paperless; A new work and communication method in the Intensive Care Unit

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Background

The MMUH ICU/HDU complex introduced the Philips Intellivue Clinical Information Portfolio (ICIP) system in September 2009. ICIP is an integrated patient information system that directly interfaces with the patient's mechanical ventilator, assist devices, physiological data, arterial blood analysers, haematological, microbiological, biochemical and therapeutic drug monitoring laboratories. All medicines, fluids, Total Parenteral Nutrition (TPN), enteral feeding are prescribed electronically. All documentation of nursing and medical notes is carried out electronically on the ICIP system.

Post implementation of ICIP, the clinical pharmacy review of the ICU patient required swapping between many different screens to retrieve the relevant information, which was very labour intensive. In addition, laboratory results & the patient's medicines were still recorded on the pharmacy paper record sheet to facilitate audit, drug supply handover and to record interventions made.

Purpose

To fully integrate the Clinical Pharmacist's workflow and method of multidisciplinary communication with the ICIP system.

Material and methods

v A review of the daily activities of the clinical pharmacist in the ICU/HDU complex was carried to establish if it was feasible so eliminate the use of paper for; drug supply, recording of pharmacist interventions and facilitating handover to other clinical pharmacists. v Consultation with Clinical Pharmacist's from other hospitals that

v Consultation with Clinical Pharmacist's from other hospitals that use ICIP.

v A tab was developed that pulled all the information of pharmacy relevance into the one screen.

v An electronic pharmacy worksheet was developed to incorporate the daily clinical pharmacy activities in the ICU and for multidisciplinary communication.

Results

Pharmacy Tab

The pharmacy tab provides at a glance the relevant blood results, drug infusion rates, heart rate & rhythm, blood pressure, enteral & TPN feeding rates and gastric aspirates

Pharmacy ICIP Worksheet

The Pharmacy ICIP Worksheet represents the systematic review of the ICU patient. The pharmacy work sheet includes the following patient details, to mention a few:

- · Allergy status
- · Abnormal blood results that may impact on the patient's drug therapy.
- · Tick boxes to indicate: renal replacement therapies, nutritional status, Gastrointestinal &

Anti-coagulant prophylaxis

- · Pre ICU admission medicines
- · Drop-down box for therapeutic drug monitoring
- · Handover sections for annual leave cover.

Communication

Ø Recommendations for nursing & medical staff are recorded electronically on the pharmacy work sheet. This information is easily accessed, traceable and is a record of any interventions made.

Ø The ICIP flow sheet has a password protected tick box to indicate that the patient has been reviewed & that recommendations have been left for the nursing or medical staff.

Conclusion

The clinical pharmacist in the ICU now carries out all clinical activities using the ICIP system in a time efficient manner and is fully integrated with the ICIP system. It allows the clinical work of the pharmacist to be fully traceable and audited more easily. This process has eliminated the paper documentation of daily activities and it provides a permanent and easily accessible record of recommendations for medical and nursing staff.

No conflict of interest

OHP020 Knowledge Management: a key tool to improving Pharmaceutical Care

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Background

The objective was to set up and assess a Knowledge Management System in a Pharmacy Department of a General Hospital with 717 functioning beds.

Material and methods

In March 2004, before setting up the Knowledge Management System:

- Data and information was audited.
- The information audited was classified according to the Management Guide published by the Spanish Society for Hospital Pharmacy.
- Standard Operating Procedures were elaborated to standardize the data registration process.
- The computer system was selected and located on the computer

network of the Information Technology Department.

- All Pharmacy Department computers were connected to the Knowledge System
- A Knowledge Manager was appointed.

In April 2004, the Knowledge Management System was set up. The added value of the information introduced into the Knowledge System from April 2004 to April 2009 was assessed.

The information that did not match any category of the Management Guide was moved to the Knowledge Transfer folder, which mainly includes:

- Interesting website addresses
- Useful bibliography in PDF format
- Clinical sessions from the Pharmacy Department
- Current legislation

Results

The electronic documents included in the study are quite numerous but the following points can be highlighted:

- 28 procedures were created that contain the "Know-How" of the Hospital Pharmacy Department.
- A Normalised Hospital Procedure for Therapeutic Exchange was created
- A Hospital Formulary were included
- 76 drug-evaluation reports were drafted
- 37 drug-administration protocols were drafted for nurses
- 165 medication-error reports were included
- 292 complex enquiries from the Drug Information Centre were solved

Conclusion

- 1. Knowledge Management improves pharmacists' work and prevents information gaps.
- 2. Knowledge Management turns information into knowledge which is of strategic value in decision making.
- 3. A Pharmacy Website has been created to support the Knowledge Management System.

No conflict of interest

OHP021 Pharmaceutical attention to the discharge o paediatric patients in treatment with magisterial formula M. Cólogan, M.A. Ocaña, O. Pedreira, I. Plasencia, J. Merino Hospital Ntra. Sra. de Candelaria, Farmacia, Santa Cruz de Tenerife, Spain

Background

The range of pharmaceutical specialities available is increasingly wide, but there is a continuing real need to formulate medicines, especially in areas of dermatology and paediatrics. The majority of medicines lack appropriate dosage forms for treating children.

Purpose

To avoid mistakes associated with the prescription of paediatric medicines that have to be compounded.

To establish coordination between the hospital and community pharmacy shops in order to facilitate continuation of the treatment when the patient leaves hospital.

Material and Methods

We have designed a "patient information leaflet" for every medicine of our own formulation. We detailed the qualitative and quantitative composition, concentration, recommendations for administration, indication, adverse reactions, storage conditions and expiry date. It is accompanied by an individualised form stating the name of the patient, dose, frequency and duration of the treatment. The telephone number of the pharmacy laboratory is included and the name of the responsible pharmacist for any explanation. At discharge, the pharmacist delivers the verbal and written information directly to the patient's relatives, to accompany the medicine.

Results

The patients leave hospital with the treatment, which it will last as minimum one week, which is sufficient time to locate a community pharmacy from where to obtain further suplies. The community pharmacists have the information about the prescription and the formula such as we prepared it in the hospital.

Conclusion

Coordinating the efforts between hospital pharmaceutical and ambulatory care, we must fill the therapeutic gap that exists in paediatrics, to assist the patients as much as possible. This is the weakest point of the system. We hope this avoids possible mistakes arising from the change of welfare level and the lack of information to the patients.

No conflict of interest

OHP023 Treatment of geriatric depression in clinical practice at a general hospital.

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Background

Geriatric depression causes suffering and increases medical comorbidity and disability among elderly individuals. Recent studies have shown a high prevalence of depression in medically ill older adults (65 years and over).

A growing number of drugs are available for clinicians to choose from in the treatment of depressive disorders. The aim of our study is to describe treatments of geriatric depression used at a general hospital.

Material and Methods

A retrospective observational study of two months duration was undertaken (August-September 2010) in a hospital with 450 functioning beds. All patients admitted to the Internal Medicine ward during the study period were included.

Information was collected from the pharmacotherapeutic history: age, gender and antidepressant therapy.

Results

A total of 215 patients were included in the study (52.1% women, 47.9 % men); of all patients, 161 (74.9%) were \geq 65 years old. During the time of the study 31 patients (14.4%) were treated with antidepressants; of these 31 patients, 26 (83.9%) were \geq 65 years old and 5 (16.1%) were younger.

Antidepressant drugs prescription was higher in patients aged 65 years and older (16.1%) than in younger patients (9.2%).

9 different drugs were prescribed in older patients: Trazodone (37.9%), Escitalopram (27.6%), Fluoxetine (6.9%), Paroxetine (6.9%), Mirtazapine (6.9%), Sertraline (3.45%), Citalopram (3.45%), Mianserine (3.45%) and Duloxetine (3.45%). The main antidepressant groups prescribed were: serotonin reuptake inhibitors (SSRI) (48.3%), atypical antidepressants (48.25%), and serotonin and norepinephrine reuptake inhibitors (SNRI) (3.45%). Tricyclic antidepressants and Monoamine Oxidase Inhibitors were not prescribed.

Conclusion

There is a high prevalence of antidepressant pharmacotherapy prescribing in older adults admitted to a general hospital. Antidepressants prescription in geriatric patients was higher than in young patients.

The SSRIs and the atypical antidepressants were the top-rated drugs for depression in patients aged 65 years and older.

OHP024 The italian project: iperpto

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Background

The hospital drug formulary is a very important decision-making tool, which allows the doctor to have simple and complex medicines that are useful to ensure effective diagnosis, treatment and rehabilitation. SIFO, the Italian Hospital Pharmacy Society, wishes to have available online a hypertext formulary (IperPTO) based on guidelines as a tool of clinical governance.

It is only possible to add active ingredients to the IperPTO if they are accompanied by a guideline that indicates the drug's "place in therapy". The guidelines adopted follow the WHO's International statistical classification of diseases and related health problems (ICD). At present there is an ongoing critical evaluation of the guidelines already in use. The assessment tool used for the validation of the guidelines is the AGREE instrument. The AGREE II consists of 23 key items organized within 6 domains followed by 2 global rating items ("Overall Assessment"). Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.

Purpose

To create a hypertext formulary based on guidelines as a tool of clinical governance.

Material and Methods

IperPTO is available at

www.laboratoriosifofarmacoeconomia.org/iperpto.htm and new compounds can be added by logging in to www.laboratoriosifofarmacoeconomia.org/ptolg.htm.

The database contains about 395 active agents and 180 guidelines. Of these 84% are management, 14% prevention, 2% management and prevention. The guidelines included about 30% active ingredients used in cancers (ICD 140-239), followed by a 11% diseases of the circulatory system (390-459) and 10% Infectious and parasitic diseases (ICD 001-139), the other equally distributed in the other classes ICD.

The next step will be to invite all the colleagues to start the quality assessment of the guidelines already placed in the database.

Conclusion

The ongoing project is potentially very useful for both local and national health.

No conflict of interest

OHP025 Use of atosiban and estimated cost savings of a protocol with nifedipine as tocolytic therapeutic alternative R. Garcia Ramos, R. Veiga Gutierrez, E. Espino Paisan, J.M. Giraldez Montero, M.E. Concheiro Nine

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Background

Atosiban is a safe tocolytic agent but expensive. Recently nifedipe is used "off label" and seems to be at least as effective in treating preterm labour (PL) as well as having a much lower cost and oral administration.

To analyze current use and cost of atosiban in women admitted to hospital with PL and estimate cost savings in case of alternative use of nifedipine in women no associated with risk factors.

Material and method

Observational study of women with preterm labour admitted for 8 months who received atosiban. Pharmacy databases and electronic medical records were revised. Variables studied: age, pregnancy, inhibition time, delivery gestational age, risk factors. Treatment applied cost was 1221 euros for atosiban (383.75 mg) and 1.2 euros for nifedipine (190 mg). Cost-minimisation analysis was conducted on the basis of similar effectiveness.

We studied 77 patients with mean age 30.8 years (SD:5.36), 14.2% were readmitted. Patients received a mean of 401.5 mg (SD: 251mg) of atosiban. Gestational age at the time of receiving the first dose was 29.6 weeks (SD:2.97). Labour was inhibited by more than 48 hours in 91%. Regarding risk factors for 84.1% had none, 6.8% had diabetes, 2.2% change in blood pressure, 2.3% hydramnios, 4.5% multiple pregnancy, no heart disease, hyperthyroidism or uterine infection.

Cost of nifedipine for those without risk factor was found to be 88 euros compared to 93860 euros for atosiban, which can offer in savings per year 120605 (1267 per patient).

Conclusion

Results indicate that atosiban is used mainly according to indications, however patients studied had few risk factors. For this reason use of nifedipine in our environment would be a very significant cost savings in addition to the convenience of administration. Difference would be much higher if the material for administration and time nursing care were included.

No conflict of interest

OHP026 Descriptive study on the use of the complete enteral nutrition in a general hospital

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Background

To describe the use of enteral nutrition in patients who only receive nutritional support.

Material and Methods

A descriptive study lasting one year (January-December 2009) was carried out in a general university hospital. We included all patients with complete enteral nutrition (CEN) registered in the unit dose area (400 beds). An Access® data base was designed, this included: patient identification, height and weight, route of enteral administration, patient history (diabetes, kidney failure, heart disease, etc), current disease, and nutritional history (formula type and volume).

Results

146 CEN episodes were registered (0.4/day) which corresponded to 118 patients, 56% men. The mean age was 71.6 years. The height and average weight was 66.5Kg and 164cm, respectively. The clinical services distribution was: Internal Medicine 42(28.8%), Neurology 31(21.2%), Oncology 18(12.3%), Infectious Disease Unit 15(10.3%), Otorhinolaryngology 10(6.8%), others 30(20.6%). The administration routes were: nasogastric tube jejunostomy 16(11%), gastrostomy 14(9.6%), by mouth 11(7.5%), nasojejunal tube 7(4.8%). CEN were administrated for an average of 11 days and a volume of 1350mililitres/day. The more used formulas were: to diabetics 48(32.9%), standard 46(31.5%), standard with fiber 27(18.5%), hyperproteinic 19(13%). Personal histories registered were: hypertension 48(32.9%), diabetes 41(28.1%), neurological diseases 26(17.8%), heart disease 22(15.1%). The 22.9% patients with diabetic formula were not registered in their history and 14% of diabetic patient not received special formulas. In 103 episodes (70.5%), the treatment duration was greater than or equal to 5 days; and of witch, 18(17.5%) received dietary fiber.

Conclusion

CEN was only 1.2% of hospital stays. Most representative services were Internal Medicine, Neurology and Oncology. All patients with associated pathologies were not administered special diet.

This kind of nutrition was well tolerated, only the low utilization of dietary fiber in long-term CEN, can lead to appearance of constipation.

No conflict of interest.

OHP027 Evaluation of the work developed by the Technical Working Group for Immunotherapy of Multiple Sclerosis M.S. Rivero Cava, L. Romero Soria, S. Martin Clavo, J.F. Rangel Mayoral, P. Gemio Zumalave, F.J. Liso Rubio

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Background

In the year 2008, the Technical Working Group for the Immunotherapy of the Multiple Sclerosis (GTTEM) is constituted in our region for the need of a control system that assures a rational use of the treatments for this pathology.

Purpose

The aim of this study is to evaluate the work developed by the GTTEM.

Material And Methods

Descriptive and retrospective study of the treatments evaluated by the GTTEM in our hospital, from his creation, in the year 2008, to September 2010. Data were collected from the prescription document and from the dispensing program of outpatient unit in pharmacy service.

Results

Since the creation of the GTTEM, 80 treatments (78 patients with multiple sclerosis (MS), 32% men and 68% women, mean age of 39 years (14-69)) has been evaluated in our hospital. Diagnostics: first clinical episode 2 patients (2,5%), relapsing-remitting MS 58 patients (72,5%), MS secondary progressive 7 patients (8,75%), severe relapsing-remitting MS 9 patients (11,25%) and refractory relapsing-remitting MS 4 patients (5%).

It was evaluated 51 treatments initiated (64%), and 29 treatments modified (36%) -20 because of inefficiency, 8 because of adverse reactions (5 influenza-like symptoms, 1 depression, 2 rash) and 1 because of both (inefficiency and adverse reaction: depression). The drugs prescribed were: Interferon beta 1-a: 47.5%; Glatiramer acetate: 20%; Interferon beta 1-b: 17.5%; Natalizumab: 15%.

Conclusion

- The creation of this working group represents an advance in the rational use of drugs in the immunotherapy of the MS, very important because of the characteristics of these treatments (drugs indicated for specific clinical forms of the disease, ability to produce severe adverse reactions, high cost) with an active participation of the pharmacist, who validates the prescriptions depending on the clinical characteristics of the patient.
- The GTTEM has evaluated effectively all treatments initiated or modified since it was created.

No conflict of interest

OHP028 COMPARISON OF HARRIS-BENEDICTÍS AND MIFFLIN ST JOERÍS EQUATIONS IN SURGICAL PATIENTS

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Background

Indirect Calorimetry is the Gold Standard for predicting resting energy expenditure (REE) in hospitalized patients because of his

accuracy, but estimation by Harris Benedict's (HB) and Mifflin-St Joer's (MSJ) equations are more commonly used for being faster and economical. HB is recommended in elderly patients and MSJ in obese patients.

Purpose

To compare REE estimated by HB and MSJ equations in surgical patients with PN.

Material and Methods

Prospective observational study carried out during 6 months in surgical patients with PN. REE was calculated by HB and MSJ equations and corrected with the stress factor adapted from Ireton-Jones. We compared the estimated REE requirements obtained by both equations using SPSS statistical analysis. Patients were categorized according to gender, age and body mass index (BMI).

Results

Data were collected from 73 patients: 47 males (mean age 69.0 ± 11.6 years) and 26 females (mean age 73.9 ± 12.8 years). Measured REE was 1542.1 ± 233.7 kcal/day for HB and 1489.3 ± 255.9 kcal/day for MSJ (t=5.95, P<0.005).

In males, there were no statistical differences between HB (1628.1 \pm 222.5 kcal/day) and MSJ (1622.4 \pm 184.9 kcal/day). In females, REE estimated by MSJ was significantly lower than the value calculated by HB (1248.6 \pm 179.2 kcal/day and 1386.7 \pm 165.1 kcal/day, respectively) (t=22.63, P<0.005). Their multiple linear regression analysis revealed that firstly weight, after height and latest age significantly influence on these differences (R-squared = 0.957, P<0.005). We found significant differences between HB and MSJ in both BMI \leq 25 and BMI > 25 kg/m² patients and \leq 65 and >65 years too.

Conclusion

We could use either HB or MSJ in our male patients. For the other analyzed groups, we should compare REE calculated by HB and MSJ with those predicted by Indirect Calorimetry to choose the most appropriate equation.

No conflict of interest

OHP029 CALORIC ADJUSTMENT BY STANDARD PARENTERAL NUTRITION PREPARATIONS

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Background

Total parenteral nutritions (TPN) can be prepared individualized or from standard parenteral nutrition preparations called Three-Compartment Bags (TCB). These TPN systems available generate a debate about whether it is better standardization or individualization of TPN. TCB provide safety and are cost-effective cause they require less manipulations, items and manpower.

Purpose

To compare real energy supply and calculated resting energy expenditure (REE) by Harris Benedict equation (HB). To assess the adequacy of caloric intake using TCB.

Material and Methods

Prospective and observational study for 6 months in surgical patients with TPN. REE was calculated by HB and corrected with the stress factor (critical patient, peritonitis and fistula 1.3; else 1.1) and then compared with real intake provided by TCB at day 5. All analyses were performed with SPSS software.

Results

This study included 70 patients, 3 of them were excluded (TPN duration <5 days). Final data were collected from 67 patients; mean

age 70.7 \pm 12.3 years, 65.7% men. The most common indications for TPN were colon cancer (25.4%) followed by bowel obstruction (16.4%) and gastric cancer (13.4%). Mean duration of TPN was 10.4 \pm 6.5 days. The 76.1% of all TPN were TCB at day 5.

There were no significant differences between calculated REE by HB and real energy supply at day 5 in all TPN (1581.7 \pm 259.6 kcal/day and 1590.9 \pm 252.4 kcal/day, respectively) (t=0.240, P<0.811). There were also no significant differences between calculated REE by HB and real caloric intake using TCB at day 5 (1584.0 \pm 266.6 kcal/day and 1659.1 \pm 219.8 kcal/day, respectively)(t=1.872, P<0.67).

Conclusion

In all TPN systems, there is a correct degree of concordance between real energy supply at day 5 and predicted REE by HB. TCB prescribed in our hospital fit the calculated requirements in most of the patients.

No conflict of interest

OHP030 Generics promotion $\tilde{\mathbf{n}}$ analyzing differences between the hospital and out-patient sectors

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Background

In the European scenery, the extent of generic promotion measures varies between the countries, resulting in different levels of generics uptake. Surveys on generic promotion seem to focus on the outpatient sector.

Purpose

To analyze the differences in generic promotion practices between the out-patient and in-patient sectors.

Material and methods

- Survey on the regulatory framework for generic promotion, in particular generic substitution and INN prescribing, for the outpatient sector (coverage: all EU Member States, data as of July 2010)
- Investigation of generics promotion practices in the in-patient sector (coverage: 20 European countries, data as of spring 2010)

Results

In the out-patient sector, INN prescribing and/or generic substitution is allowed in many European countries but is not obligatory (e.g. CZ, ES, FR, HU, IT, NL, SK). In hospitals, the use of generics is influenced by the compilation of the hospital pharmaceutical formulary, whose extent differs among countries. There are countries where generic substitution is not allowed in the out-patient sector (e.g. UK), but generic substitution is practiced in hospitals. Furthermore, examples of hospital pharmacists promoting generics use were identified: E.g. in Denmark hospital pharmacists assist hospital wards by directly substituting with a (cheaper) generic product.

Conclusion

In general, generic promotion in the out-patient sector has been well advanced in Europe but several countries have only started with generic substitution within the last ten years. However, benefiting from generics use has been a tradition in hospitals for decades, even in countries where generics promotion in the out-patient sector is still not encouraged.

The analysis stresses the importance of the hospital pharmacists as a guarantor of a rational use of medicines and as communication focal point about such practices in the hospital.

No conflict of interest

OHP031 Use of topical lidocaine patches

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Background

Transdermal lidocaine patches are not commercially available in Spain. To obtain them, they have to be requested as foreign medication (if used as indicated in data sheets) or as a compassionate use programme (for non indicated uses)

Purpose

To analyze the use of transdermal lidocaine patches in a third level hospital.

Material and methods

A retrospective and descriptive study has been conducted based on a review of clinical histories of patients who were attended in our ambulatory patient unit care and who were using transdermal lidocaine 5% (December 2008 - April 2010).

Results

A total of 40 requests for treatment were handled (22 women and 18 men, with a median age of 62 years).

15% of the patients (6) used the patches as indicated in the data sheet, i.e., for post-herpetic neuralgia. 85% of them (34) used the patches following a different indication such as neuropathic pain, no post-herpetic neuralgia, (64.7%), mechanical pain (14.7%), muscle pain (8.8%) and complex regional pain syndrome (2.9%).

Regarding the treatment of postherpetic neuralgia, 20% of the patients discontinued the use of the patches due to an important adverse skin reaction. For all other indications, 33% of the patients discontinued the treatment (50% improvement, 40% no therapeutic efficacy and 10% by dermal intolerance).

The usual dose was one patch of lidocaine 700 mg/day (83% of patients), although there were patients with 2 patches/day (11.4%), three patches/day (2.8%) or half patch/day (2.8%).

The average annual cost per patient was 1,310 €, which represents 35% of total billed foreign medication from the ambulatory patient unit care.

Conclusion

The use of transdermal lidocaine in our hospital is mostly for unapproved indications (85%).

68% of patients starting treatment continue treatment with good tolerance and 6% discontinued treatment for major skin reactions. While waiting for its marketing in Spain, the number of patients benefiting from lidocaine patches has significantly increased the annual cost of our outpatient dispensing area.

No conflict of interest

OHP032 Hospital pharmacists and the new challenge of implantsë procurement

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Background

In Austrian hospitals implantable medical devices are normally administrated by general purchasing departments.

Reorganisations led to incorporation of implants' procurement into the pharmacy department of the largest Austrian tertiary care hospital.

Purpose

To analyse and describe the rationale for and benefits achieved by restructuring implants' procurement during 5 years. To emphasise the role of the hospital pharmacist and difficulties in this new field of work

Material and methods

Analysis of the restructuring process and description of key figures.

Posulte

The process of implants' procurement was implemented and relevant SOPs were integrated into the existing hospital pharmacy's quality management system, leading to transparency and simplification of purchasing and supply. Cost reduction was achieved by reducing stock holding costs, price negotiations and issuing calls for tenders, independently or in cooperation with the Viennese Hospital association for cardiac and orthopaedic implants. The number of implants in the computerised catalogue could be reduced by 20%. It now comprises 16.000 implants in 39 different categories with a financial volume of € 20 million. Data on MRI compatibility was systematically collected for 7.615 implants. 480 consignment contracts, of which 210 are test runs, were established, guaranteeing a high degree of innovation and economic efficiency. Specially trained hospital pharmacists perform evidence-based evaluations for special implant committee meetings and offer scientific and economic advice to other health care professionals.

Conclusion

The incorporation of implants' procurement into the hospital pharmacy led to cost reduction and process simplification and is well appreciated by other health care professionals and the hospital management. Transparency and cost awareness could be increased. Hospital pharmacists working with implants need a high degree of expertise and therefore require appropriate training. This can only be guaranteed by allocating sufficient resources for this new field of work.

No conflict of interest

OHP033 Establishment of a protocol for use os sugammadex. Evaluation of results

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Background

The five regions of Denmark are each responsible for recommending drugs that are effective, safe and inexpensive for use within hospitals and primary care. The challenge however is to implement such recommendations, where the goal is to ensure that the majority of the prescriptions are for the recommended drugs, and thereby reduce the medicines costs considerably. The Hospital Pharmacy of Region Zealand has met this challenge by various approaches. A successful approach regarding recommendations on Proton Pump Inhibitors (PPIs) is described.

Purpose

To implement the recommendation of PPIs, and thereby

- reduce medicines costs
- unify the prescriptions for PPIs in the region

Material and Methods

The implementation was made through intervention on three levels; hospital, ward and prescriber, in a top-down approach.

- 1. Current use of PPIs were recorded, and portrayed in diagrams
- 2. The Regional Drug and Therapeutics Committee's recommendations on PPIs were communicated through Newsletters to all clinical personnel at the hospitals
- 3. To have a dialogue regarding the recommendations and use of PPIs, the ward managements were contacted personally by a clinical pharmacist

- 4. Oral presentations of the recommendations were made to doctors at the wards with considerable PPI use
- 5. Suggestions for changing non-recommended PPIs at prescriber level were made by pharmacy assistants 6. A 3-month follow-up was made on the use of PPIs (type and amount) and the wards that were still not complying with recommendations were exposed to the relevant steps again

Results

The use of non-recommended PPIs before and after the implementation was respectively 44729 and 17088 (DDD/6 month). After the implementation described the cost of PPIs were reduced by 64%.

Conclusion

The top-down approach described was more successful than previous bottom-up approaches (step 1-6 in opposite order) for implementing the recommendations made by the Regional Drug and Therapeutics Committee.

No conflict of interest

OHP034 Influences of policy rules on the development of costs of in-hospital drugs.

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Background

There are concerns about the rising costs of healthcare and medicines, because the absolute costs of hospital drugs are increasing disproportionally. Little is known about how policy decisions of 3rd party payers or governments are affecting the inhospital drug budget.

Purpose

We observed significant differences in the development of budgets depending on how national policies affected different classes of medicines. In order to compensate hospitals in 2006 the Dutch government created two policy rules. For high cost drugs the reimbursement is 80% while for very expensive orphan drugs the reimbursement is 100%. This study demonstrates how policy rules affect costs of medicine in a priority class

Material and Methods

The purchase data of three hospitals; a small local hospital, a regional teaching hospital and a university hospital in the Netherlands were collected over a 9 year period (2000 and 2008). In the data a distinction was made between traditional drugs, designated high cost drugs, orphan drugs (Dutch).

Results

The cost of traditional medicines stayed remarkably equal (1.95%), however the increase in the costs of high cost and orphan drugs (NL) is striking, respectively 21% and >100% per year. The rise of costs of high cost and orphan drugs is increasing since 2006. The increase in cost is due both to increased prices and higher drug consumption.

Conclusion

This study demonstrates how reimbursement policies affect the inhospital drug cost over a 9 years period. We conclude that open end reimbursement policies for high cost medicines, neglecting the countervailing power of interested market parties, lead to uncontrollable cost expansion. We therefore advise that governments and 3rd party payers should design reimbursement policies for expensive medicines exploiting countervailing powers with proper incentives that already have proven their value in traditional medicines.

OHP035 Drug therapy optimization due to in-patient pharmaceutical care

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Background

The five regions of Denmark are each responsible for recommending drugs that are effective, safe and inexpensive for use within hospitals and primary care. The challenge however is to implement such recommendations, where the goal is to ensure that the majority of the prescriptions are for the recommended drugs, and thereby reduce the medicines costs considerably. The Hospital Pharmacy of Region Zealand has met this challenge by various approaches. A successful approach regarding recommendations on Proton Pump Inhibitors (PPIs) is described.

Purpose

To implement the recommendation of PPIs, and thereby

- reduce medicines costs
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Material and Methods

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- 1. Current use of PPIs were recorded, and portrayed in diagrams
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- 3. To have a dialogue regarding the recommendations and use of PPIs, the ward managements were contacted personally by a clinical pharmacist
- 4. Oral presentations of the recommendations were made to doctors at the wards with considerable PPI use
- 5. Suggestions for changing non-recommended PPIs at prescriber level were made by pharmacy assistants
- 6. A 3-month follow-up was made on the use of PPIs (type and amount) and the wards that were still not complying with recommendations were exposed to the relevant steps again

Results

The use of non-recommended PPIs before and after the implementation was respectively 44729 and 17088 (DDD/6 month). After the implementation described the cost of PPIs were reduced by 64%.

Conclusion

The top-down approach described was more successful than previous bottom-up approaches (step 1-6 in opposite order) for implementing the recommendations made by the Regional Drug and Therapeutics Committee.

No conflict of interest

OHP036 Successful lenalidomide desensitization

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Background

Lenalidomide, a thalidomide analogue, was authorised by the European Commission in 2007. It is available as Revlimid in capsules of 5, 10, 15 and 25 mg. Because of its antiangiogenic, antineoplastic and immunomodulatory properties and its more potent activity compared to thalidomide, it is considered an effective alternative in the treatment of Multiple Myeloma (in combination with dexamethasone 40 mg). The reported prevalence of rashes among patients with multiple myeloma and lenalidomide treatment is 29%.

Purpose

To devise a suitable lenalidomide extemporaneous formulation in the necessary concentrations and volumes so that desensitisation can be attempted in Multiple Myeloma patients with allergic reactions.

Material and Methods

Two patients, a 57-year-old man and a 77-year-old woman diagnosed with Myeloma Multiple started treatment with lenalidomide; on the second day both of them presented itching and generalised erythema.

The Allergy Unit started a lenalidomide desensitisation protocol.

In both cases, the Pharmacy Service prepared a suitable extemporaneous formula: a suspension of lenalidomide in low-density sodium carboxymethylcellulose 1.5% at concentrations of 0.025 - 0.25 -2.5 mg/mL. These concentrations allowed the oral administration of an initial dose of 0.0025 mg of lenalidomide, increasing it every 15 minutes to a cumulative dose of 20 mg. The total time for this procedure was 3 hours.

Results

The response to increasing the doses was satisfactory, with no adverse reactions, so the patients subsequently completed the 21 days of treatment with lenalidomide with no evidences of recurrent hypersensitivity.

Conclusion

Our extemporaneous formula was shown to be useful, safe and effective for performing a lenalidomide desensitisation process.

No conflict of interest

OHP038 OFF-LABEL USE OF MYCOPHENOLATE MOFETIL IN OUTPATIENTS UNIT IN A GENERAL HOSPITAL

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Background

Mycophenolate mofetil (MMF) is commonly used to prevent rejection following solid organ transplantation an has proven effective in the treatment of autoimmune diseases, renal disorders and other off-label indications

Purpose

To evaluate the use of MMF in off-label indications

Material and Methods

Retrospective study involving all the patients (10) treated with MMF in off-label indications between January 2008 and September 2010. The data of each patient were obtained from "off-label" prescriptions, outpatients software and from the review of clinical history.

Results

The 10 patients received different doses of MMF (1-2 g /day) for the treatment of: atopic dermatitis (3 cases), ANCA vasculitis (2), lupus nephritis (1), systemic lupus erythematosus (2) and autoimmune interstitial lung diseases (2). The duration of MMF treatment ranged from 2 to 19 months. MMF was used in off-label indications to treat patients without other alternative treatment. Most of them were previously treated with corticosteroids, calcineurin inhibitors and other immune suppressive drugs. After the treatment with MMF the 3 patients with atopic dermatitis achieves complete clearance and only in 1 case of systemic lupus MMF was effective. We observed that MMF was associated with significant clinical improvement in patients with ANCA vasculitis, lupus nephritis and autoimmune interstitial lung diseases. Serum ANCA decreased in 40 % patients and the 2 patients with autoimmune interstitial lung diseases had symptoms. The adverse effects were: (2) and elevated aminotransferases (1). improvement in thrombocytopenia

Conclusion

- Off label use of MMF in the treatment of patients with autoimmune diseases refractory to conventional therapy is safe and effective.
- The great variety of "off label" uses of MMF, observed in our hospital, make it necessary the implementation of a multidisciplinary protocol for use of MMF in patients with refractory autoimmune diseases.

No conflict of interest

OHP039 Supporting specialisation in hospital pharmacy in Finland

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Background

A new postgraduate hospital pharmacy specialisation programme was launched at the University of Helsinki in 2010. The programme was developed in collaboration with stakeholders in the healthcare sector through an e-survey (1), open seminars and field visits to university and district hospitals, and with pharmacy education experts in all three schools of pharmacy in Finland, using international benchmarking.

Purpose

The purpose of this unique programme is to support competency development of hospital pharmacists, and to establish and improve clinical pharmacy services in Finland.

Material and Methods

Five pharmacists with a BSc (Pharm) degree and six with an MSc (Pharm), working in hospitals or health centres, started their studies in 2010. The part-time programme takes three years to complete for the BSc (Pharm) and four years for the MSc (Pharm) pharmacists. The programme comprises compulsory and optional courses, a research project (BSc (Pharm)) or a licentiate/MPhil research project (MSc (Pharm)) and periods of work experience on the wards or in other hospital pharmacies. International work experience and other studies are encouraged.

Results

Two courses, Clinical pharmacy and patient care in hospitals and Research and evaluation methods in hospital pharmacy, have started this year. New courses are being developed in areas of Medicinal products and compounding, Medicines information, Medication safety, Management, organisation and economics in healthcare, and Outcomes assessment and rational drug therapy. Initial student feedback has been positive; the course outcomes and feedback will be evaluated at the end of the academic year and the specialisation programme.

Conclusion

This hospital pharmacy specialisation programme is aimed to support competency development of hospital pharmacists, evaluation of the programme outcomes and feedback are required in the future.

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No conflict of interest

OHP040 Genus Candida in Clinical Hospital Center Osijek during the period 2005-2009

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Background

Candida fungi are normal flora of human bodies, but in immunocompromised patients they become invasive pathogens.

Purpose

To report the occurrence of Candida yeast in Clinical Hospital Centre, Osijek, in the period 2005-2009.

Material and Methods

A retrospective analysis of the Candida fungus isolates obtained from the Microbiology Laboratory of our hospital. A pharmacist from the Pharmacy Department checks dispensing of antifungal drugs against attached lab reports on a daily basis.

Results

The number of isolates of Candida fungi from specimens received from the clinics and wards of our hospital in 2005 was 304, in 2006 - 278, 2007- 285, in 2008 - 391, and in 2009 - 482. 98 samples were isolated from urine in 2005, 106 in 2006, 117 in 2007, 168 in 2008 and 272 in 2009; 83 from blood cultures in 2005, 48 in 2006, 34 in 2007, 44 in 2008 and 33 in 2009. Other isolates were obtained from sputum, throat smears, tracheal aspirate, cervical smears, wound smears, catheter tip and the stomach contents. Isolated fungi were: C. albicans, C. famata, C. guillermondi, C. krusei, C. parapsilosis, C. spp, C. tropicalis and C. glabrata. Isolates appear mostly on Department of Anaesthesiology, on Haematology, Clinic for Infectious Diseases, Neurosurgery, Neurology, Paediatrics, Surgery Clinic, and Gynaecology. At other clinics/ wards smaller numbers of Candida yeasts were isolated.

Conclusion

C. albicans was the leading Candida fungi isolated in clinics and wards of our hospital. It was mostly isolated from urine, followed by blood culture. During the study period for isolates from blood, C. albicans and C. glabrata decreased by almost 50%, and C. parapsilosis by almost 90%. Most of the isolates appeared at the Department of Anaesthesiology and Haematology, which was expected, because patients monitored in this department are on combination antimicrobial treatment and are highly immunocompromised.

No conflict of interest

OHP041 DEVELOPMENT OF A SOFTWARE FOR MONITORING OF RESTRICTED USE DRUGS

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Background

The pharmacy and therapeutics committee established criteria for dispensing and use of certain drugs which were being overused.

Purpose

To describe the design of a software application that allows us to record comprehensive, effective and safe medicines for restricted use (MRU).

Material and Methods

Retrospective study from 1 January to 30 April 2010. The computer application was developed with the Access 2003 database manager. The drugs controlled by classification as restricted use were: antibiotics (linezolid, tigecycline, daptomycin, ertapenem), next-generation antifungals (caspofungin, anidulafungin, voriconazole), erythropoietin (darbepoetin beta), granulocyte-

monocyte colony stimulating factors (GM-CSF) (Filgrastim, Pegfilgrastim) activated drotecogin alfa, albumin and eplerenone. The database included the following modules:

- Patient's personal data: name, medical record number, prescribing physician, service, primary and secondary diagnosis.
- Pharmacotherapy: allows event data processing to be recorded (drug, dose, loading dose, dosage, number of units a day, number of days accumulated units, start date, date range) and previous episodes to be viewed.
- Management: enables daily listings to be printed of service, drug and patient, speeding the delivery and control of the MRU.

The system of work was to issue a special request for individualised prescription at the beginning of treatment. After assessing the suitability of treatment with respect to the criteria established it was dispensed and recorded in the database.

Results

We analysed a total of 1102 items dispensed for restricted use, for 260 patients. The percentage of inpatients who were treated with different MRU was 0.75%. The distribution of the main services (76% of the total) was: 49.64% UCI, 9.71% Haematology Resuscitation 9.71%, 7.46% nephrology-cardiology. The spending on MRU per patient was EUR 1301.5. The total cost was 338,401 euros.

Conclusion

- This new system is presented as a practical working tool that enables restricted medicines to be recorded and controlled, optimising their rational use.
- Facilitates the daily work enabling improved patient care.
- Streamlines the use of information, facilitating studies of drug use.

No conflict of interest

OHP042 IMPACT OF EQUINOCANDIN'S THERAPEUTIC INTERCHANGE

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Background

Before the therapeutic substitution of echinocandins, there was an overuse of voriconazole and underuse of caspofungin. Anidulafungin was approved by the Pharmacy and Therapeutic Committee in May 2009 and was included in the Hospital Formulary as a therapeutic substitute for caspofungin.

Purpose

To investigate the use of voriconazole and echinocandins after the introduction of a therapeutic substitution program.

Material and Methods

We performed a retrospective comparative study to observe the consumption of these antifungals between June 2009 and May 2010 in comparison to the previous period. The data we used in the study were obtained through the Pharmacy Department Multibase v.3. Program (Dominion). The unit of measurement we used was DDD (Defined Daily Dose) per 100-stay (DDD/100S) provided by the WHO Collaborating Centre for Drugs Statistics methodology 2009 version. The DDD for each drug was 50 mg for Caspofungin, Anidulafungin 100 mg and 400 mg for Voriconazole. The data were processed in an Excel spreadsheet.

Results

The use of voriconazole was 0.990 and 0.874 DDD/100S for the first and second periods, respectively, 0.260 and 0.150 DDD/100S for caspofungin, and for anidulafungin DDD/100S 0.027 versus 0.426 (1st and 2nd period respectively). There was a decrease of 11.7% for voriconazole and 42.6% for caspofungin, as well as an increase of 1508.6% for anidulafungin. The systemic antifungal drug with the highest consumption was anidulafungin.

Conclusion

The introduction of echinocandins as therapeutic substitutes has increased the quality of the prescription, regulating the use of antifungal agents. The introduction of substitution for very expensive drugs allows rational use of them. These drug use studies should be conducted systematically, using standard units, to identify consumer trends thus allowing the hospital to influence them.

No conflict of interest

OHP043 Checking Parenteral Nutrition support in a secondary hospital versus European recommendations

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Background

Parenteral Nutrition (PN) can be a safe and effective method of nutritional support when is used on carefully selected patients and appropriately monitored.

Purpose

To report the experience of PN support in a Secondary Hospital and check if it follows the European directives.

Material and Methods

Retrospective, descriptive study of patients with PN support between April 2010 and August 2010. Data collected:

- -Demographic data.
- -Route of administration: Central (CR) or Peripheral (PR).
- -Standard or individual formulations.
- -Indication for PN: Diseases unrelated to the digestive system (URDS): Hypercatabolic States (H), preterm infants of very low birth weight (PI), visceral failure (V) and Oncology (On). -Duration of PN.

Results were pooled and analysed in an Excel database. We evaluated the results according with the European Society of Parenteral and Enteral (ESPEN) recommendations (Clinical Nutrition 2009; 28:359-479).

Results

92 patients with PN (45 male).

Distribution of diagnosis and duration of treatment according to the different route of administration and type of formulations of PN:

NP		Individual Formula	tions
Diagnosis		Central route (adult patients)	Central route (preterm infar
	S	8	
RSD	M	1	
	0	1	
	H	1	
URSD	PI		4
UKSD	V	3	
	On	3	
Number of PN		17	4
Duration of NP (D	ays)	12.35 (2-31)	5 (4-7)

The majority of PN was administered by PR (n=54) for an average of 6.5 days. Standard Formulations (n=71) were mostly used. Patients with pathologies related to the digestive system (n = 62) were more frequent and most of them were due to cancer (O) (n = 20)

The ESPEN recommendations according our patients groups are:
-RSD: PN is mandatory in case of intestinal failure, at least in the acute period. Postoperative PN is beneficial in undernourished patients but no specific substrate composition of PN is required. CR and PR may be selected according to the expected duration of PN. -URSD: Patients with Hypercatabolic States who receive PN should receive a complete formulation to cover their needs fully. CR is often required to administer the high osmolarity (if PR does not

allow full provision of the patient's needs then PN should be CR). The majority of cancer patients requiring PN for only a short period of time do not need a special formulation.

Conclusion

There was a high adherence to ESPEN recommendations. For optimal Nutrition therapy

Results

Access for parenteral feeding is traditionally a central vein, but the peripheral route can be used for short-term feeding and should be considered for most patients. Standard formulations are possible, always considering the individual nutritional status and each particular clinical situation.

No conflict of interest

OHP044 Comparison of two methods for measuring adherence to treatment in HIV patients

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Background

The lack of adherence to antiretroviral therapy (HAART) leads to treatment failure, resistance, cross-resistance and transmission of resistant viruses to other patients. Thus, the measurement of adherence is an essential part of HAART.

Purpose

To determine adherence to HAART of outpatients using two methods.

Material and Method

HARRT treatments were divided into 3 groups:

- Preferred therapy (PT)
- Alternative therapy (AT)
- Alternative therapy when PI (protease inhibitors) or NNRTI (non-nucleoside reverse transcriptase inhibitors) are not possible (ATNP) Adherence was measured by two methods:
- The SMAQ questionnaire (SQ). This is a quick test to measure adherence to HAART, validated for Spanish population by GESIDA/SEFH/PNS (AIDS Study Group/Spanish Association of Hospital Pharmacy/National AIDS Plan). It consists of 6 questions and, depending on patient's answer, we differentiate between adherent patients (ADs)/non-adherent patients (NADs).
- Drug consumption data obtained from database of outpatients who take the medicine in the pharmacy (DCD). Depending on when the patients came to collect the treatment, we could know if they took it correctly (ADs) or if they missed any doses (NADs).

Results

During September-October 2010, 47 outpatients came to pick up HAART treatment: 29 were taking the PT (20 patients taking 2 nucleoside reverse transcriptase inhibitors (NRTI)+1 NNRTI; 9 patients taking 2 NRTI+1PI/r), 15 the AT and 3 the ATNP. The percentage of NADs was: SQ 30.6%, DCD 25%. The two methods were concordant (Kappa index=0.862). A statistical difference was observed between the number of drugs and AD and NAD patients. With SQ, the average number of drugs was: ADs 1.40 (SD=0.577), NADs 2.27 (SD=0.905) (p=0.001). DCD showed similar results ADs 1.41 drugs (SD=0.572), NADs 2.44 (SD=0.882) (p=0.000). The same differences were obtained related with frequency of administration/adherence and number of pills/adherence.

Conclusions

The percentage of NADs agrees between the methods and with data obtained from other studies.

- As the number of drugs, number of doses and number of pills decreases, patient adherence improves.
- It is necessary to find strategies to improve patient adherence to HAART. No conflict of interest.

OHP045 fusion proteins and monoclonal antibodies off-label utilization. evaluation of a ten-year period¥s use in a tertiary hospital

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Background

The use of fusion proteins and monoclonal antibodies is growing, not only in terms of their official indications, but also for unauthorised indications. The procedure for off-label drug use carries a clinical and administrative burden.

Purpose

To describe the use of these biological drugs for unauthorised indications in a 1400- bed tertiary hospital.

Material and Methods

Retrospective, observational study of all the patients on off-label biological treatments was conducted using the database held in the Pharmacy Department for the last 10 years.

Results

18 biological drugs were used in 518 prescriptions (7.27% of the total hospital off-label prescriptions) for 107 indications:

OFF-LABEL INDICATIONS						
Drugs	Nº Prescriptions	Nº Ir	ndications			
			(2010/06/30: Still u			
Basiliximab	175	7	(6)			
Rituximab	94	24	(22)			
Infliximab	65	16	(10)			
Bevacizumab	47	13	(13)			
Daclizumab	41	5	(5)			
Adalimumab	21	11	(8)			
Etanercept	15	8	(5)			
Trastuzumab	13	3	(0)			
Anakinra	8	2	(1)			
Gemtuzumab	8	3	(3)			
Omalizumab	8	3	(2)			
Cetuximab	7	2	(0)			
Alemtuzumab	6	5	(4)			
Efalizumab	5	2	(2)			
Others (4)	4	5	4			
TOTAL	518	107	(84)			

Prescriptions were mainly written in four clinical areas: transplantation (47%), rheumatology (14%), haematology (12%), oncology (10%), others (17%).

Conclusion

Significant off-label use of fusion proteins and monoclonal antibodies is observed, mainly in very complex clinical areas such as transplantation, oncohaematology and rheumatology.

Only a small percentage of total off-label indications have been approved during this decade.

Considering this complexity and also their high cost, all efforts to improve their use are needed. Hospital pharmacists can play a key role as specialists to be consulted regarding these drug treatments.

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OHP046 Multiperforated catheter in post-operatively pain therapy: a report of 13 cases

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Before using multiperforated catheters in our hospital, we conducted a prospective observational study to evaluate the usefulness of this new medical device. The main argument in favour of using this medical device is to significantly reduce the consumption of opioids and the side effects associated with them.

Material and Methods

We recorded all catheter insertions in the abdominal surgery ward. Various items were recorded: indication, duration of exposure, rate of ropivacaine administration, multiple analgesic administration, opioid use, Visual Analogue Scale (VAS) score for each patient.

Results

In 1 month, 13 catheters were placed after laparotomy. Among these 13 patients, 1 patient died on Day 1.

For the remaining 12 patients, the average duration of catheter placement was 53 hours. There was one technical problem (leak) leading to the premature removal of the catheter on day 1. Administration of multiple analgesics was necessary for all patients (paracetamol 4 g/24h + tramadol 300 mg/24h). 6 patients were given nefopam, 3 patients received morphine IV (4 to 20 mg/24h) and 1 received subcutaneous morphine (8 x 5 mg). No signs of overdose or infection were reported. The average VAS was 2.

Conclusion

Using a multiperforated catheter creates a significant additional cost, but all patients undergoing this procedure had a relevant indication. All seemed to have had pain relieved with the amounts of ropivacaine administered (VAS low). Before multiperforated catheters, morphine (10 to 60 mg/24h) was use to manage postoperative pain in visceral surgery. In this observational study, we found a reduction in consumption of morphine (4 patients out of 13), and improvement in the postoperative rehabilitation of patients. Given these results, the benefit / risk of multiperforated catheter versus thoracic epidural injection in postoperative laparotomy via the umbilicus will be discussed in our hospital. Following this study, protocols for pain management with a catheter will be reassessed.

No conflict of interest

OHP047 Cost saving of intravenous drugs used Rheumatology Day Unit ward

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Background

Current management of rheumatoid arthritis is mostly focused on biological response modifiers such as adalimumab and etanercept administered subcutaneously, as well as tocilizumab, infliximab, rituximab and abatacept administered by intravenous infusion at our Rheumatology Day Unit (RDU).

Purpose

To evaluate the cost saving achieved due to vial optimisation by our Pharmacy Service.

Material and Methods

Data were collected daily from patients attending the RDU over a 10-month period (December 2009 - September 2010) from our management system software (SAP): number of patients, number of infusions prepared and number of vials used. In the economic analysis, we only considered the cost of purchasing the drugs. Cost saving was calculated as the difference between the theoretical and real number of vials used.

Results

During the 10-month period of data collection a total of 138 patients attended our RDU: they were given tocilizumab (26), infliximab (81), rituximab (19) and abatacept (12). Total number of infusions prepared reached 644: tocilizumab (193), infliximab (343), rituximab (41) and abatacept (67).

Infusions were prepared using aseptic technique in a horizontal laminar airflow hood. The minimum number of vials was used by reducing wastage. Total number of vials used was: tocilizumab 488 vials of "200 mg/10 mL" (349 €) and 97 vials of "80 mg/4 mL" (139.6 €) which meant a cost reduction of 11,237.8 €, and Infliximab 1,154 vials of "100 mg" (494.57 €) with a cost saving of 42,038.45 €. With regard to rituximab and abatacept the number of vials used was 79 and 214, respectively which did not assume any cost saving as the dose prescribed was adjusted to complete vials.

Conclusion

Preparation of intravenous infusions used at the RDU in our Pharmacy Service achieved a cost saving of 53,276.25 € during the period analysed. By rationalising the number of vials used the Pharmacy Service contributed to drug cost containment and optimisation of the available resources.

No conflict of interest

OHP048 BACTERIAL SURVEILLANCE AND MONITORING OF THE CONSUMPTION OF FLUOROQUINOLONES IN THE AULSS 21 OF LEGNAGO (ITALY)

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Background

Antibacterial consumption is increasing in many countries around the world, and it is increasingly recognized as the primary reason for the emergence of resistance.

To analyse the evolution of antimicrobial resistance to ciprofloxacin and levofloxacin from the 1st semester 2009 to the 1st semester 2010 in some wards of AULSS21 of Legnago (545 beds) and compare it with the consumption of the same antibiotics in the same period the previous year.

Material and Methods

The study involved the collection of all first isolates in blood, urine and trans-tracheal samples between the 1st semester 2009 and the semester 2010. Four microorganisms were chosen: Enterobacteriaceae, Pseudomonas aeruginosa, S. aureus and S. epidermidis.

Microorganism lab tests concerned Medicine, Geriatrics, Infectious Diseases, Intensive Care Unit (ICU) and Surgery. The antibiotics consumed in the hospital were transformed into DDD which isthe assumed average maintenance dose per day for a drug used for its main indication in adults.

Results and Conclusion

Enterobacteriaceae resistance to fluoroquinolones was found to have reached alarming values (>25%); R (resistance) + I (intermediate sensibility) varied from 29% in Medicine and ICU to 49% in Geriatrics. Pseudomonas resistance to fluoroguinolones has increased further in medical departments. There are no particular problems of resistance to commonly used drugs for S. aureus and epidermidis.

The consumption of ciprofloxacin did not increase in any of the units and in some cases decreased. The consumption of IV

levofloxacin increased in every unit and particularly in ICU (+192 doses) and in Medicine (+221 doses). The consumption of oral levofloxacin increased particularly in Medicine (+590 doses) and Geriatrics (+525 doses). The consumption of fluoroquinolones has continued to increase in Italian hospitals. At the same time, increasing resistance in clinical isolates towards the same antibacterial agents has been observed. This study has highlighted some critical elements which will be analysed by the local Hospital Infections Committee in order to identify possible corrective actions.

No conflict of interest

OHP049 Quality of external prescription indicators in a terciary hospital

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Background

External hospital prescription directly conditions primary care prescription and costs for patients and society.

To ensure the proper use of medicines, three prescription indicators have been established: Percentage of prescriptions written by active substance (%PA) to guarantee the efficient use of economic resources, the percentage of prescriptions for drugs marketed in the last 5 years that do not involve a major therapeutic efficacy and / or safety (%NTNR) and percentage of prescriptions for drugs whose efficacy and safety have not been demonstrated in clinical trials (%VINE).

Purpose

Toanalyse the evolution of external prescription indicators and verify the necessity for improvement strategies.

Material and Methods

The study included all groups of drugs. Data were obtained (July 2009 to July 2010) from a software application that collects all hospital physician prescriptions. Improvement strategies have been implemented since July 2009: prescription reports are sent monthly to each service, physicians, and hospital director.

Results

Data collected were:

	jul09	ago09	sep09	oct09	nov09	dec09	jan10
PA(%)	58.5	57.57	57.33	56.66	56.79	57.81	58.37
NTNR(%)	1.48	<u>1.44</u>	<u>1.45</u>	1.76	1.83	<u>1.67</u>	1. <u>66</u>
VINE(%)	8.08	6.91	8.3	7.69	7.25	7.12	7.79
	feb10	mar10	apr10	may1	0 jun10	jul10	
PA(%)		mar10					_
PA(%) NTNR(%)	61.64	63.3		64.22	65.6	65.71	_

%PA has increased positively: from 58.52% in July 2009 to 65.71% in July 2010 (within objectives, \geq 65%). Regarding %NTNR and %VINE, values have remained within the objectives (<2% for NTNR and <9% for VINE).

Conclusion

The successful evolution of indicators has shown that improvement strategies are effective. To further improve these values, new interventions will be performed: specific clinical sessions, briefings, delivery of written information about newly-marketed drugs and systematic reviews of relevant clinical trials.

No conflict of interest

OHP050 The hospital pharmacist involved in the continuity of care: an experience of multidisciplinary domiciliary assistance in Italy.

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Background

In Italy, Hospital Pharmacists (HP) can be involved in some activities related to patient care also at discharge from the hospital in order to ensure the best continuity of care when the patient returns home. Besides providing information on the correct use of the medicines, analysing the reports of ADRs and monitoring the physicians' prescriptions, in recent years HPs have become part of a multidisciplinary team involved in Domiciliary Assistance (called ADI) for oncology patients in the terminalperiod. The team is also composed of oncology clinicians, nurses, psychologists, rehabilitative therapists and social workers. Only the HPs don't receive any further fee because they operate during their daily working hours.

Purpose

To collect data about ADI over one year. A specific domiciliary programme supplying supportive andpalliative care for patients hasbeen developed by the HPs of the Pharmaceutical Services and Department of Primary Care of Trapani since 2003.

Material and Methods

We analysed the prescriptions entered in our database and the distribution of solutions for infusion, drugs and medical devices in all the province of Trapani in Sicily (approximately 474,000 inhabitants) from 01/09/2009 to 31/08/2010.

Results

Over one year we received 550 prescriptions related to 111 adult patients and 1 child (58 male, 54 female). The median age in the group of adult patients was 72 years for male (range 84-52) and 71 for female (range 99-36). In accordance with a formulary compiled by the HP and the oncologist for this service, the hospital pharmacy provided 16 classes of medical devices, 9 different IV solutions included in ATC B05, 4 dietetic supplements and 8 classes of drugs, such as diuretics, heparin, intravenous PPIs, antibiotics and so on.

Conclusion

Oncology represents a clinical setting where domiciliaryassistance is necessary for the patients and also for their families, who receive from the HP and the team all the support and the information about the therapies required. ADI is indeed consideredadvantageous both in terms of quality of care and reductionin costs of inappropriate hospitalisation and the hospital pharmacists play an important role giving their appropriate professional contribution.

No conflict of interest

OHP051 Classification and elaboration of San Filippo Neri Hospital Repertory of sutures

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Background

In Italy recent regulatory focus more attention has been paid to medical devices (MDs) and the need for their rationalisation. One of the main difficulties is the absence of a common language mainly due to insufficient knowledge of these pharmaceutical goods. Faced with the necessity to discharge normative regulations the team of pharmacists of San Filippo Neri Hospital decided to classify the MDs used in the Hospital according to the National Classification of Medical Device (CND) approved by Health Ministry and to create a Hospital Compendium.

Material and Methods

In 2009 we focused our attention on sutures; these were divided into different types and each was associated with the description of the material, the features of the needle and the thread, the trade name, the product code and each was also associated with its CND classification and description. Sutures in the CND are classified into category H (suturing device), group 01 (sutures) and at the fourth level of detail they differ by the material of the thread. For the Hospital Compendium it was decided to maintain this system of classification.

Results

Sutures in 2009 accounted for 2.48% of the expenditure incurred by the hospital for MDs. In the Hospital we have 12 different types of suture threads, the most widely used (48.44%) of the total threads used are polyglycolic acid with lactic acid (H0101010202) with an economic impact of 23.62%. This is followed by diffusion sutures (11.56%) in polypropylene (H0102010104) but with a bigger impact (35.52%). Polyester monofilament sutures (H0102010102) are the least used (0.18%).

Conclusion

The Hospital Compendium, in addition to giving an opportunity for economic assessments, has proved a valuable tool for healthcare professionals to know what MDs are used in the hospital so everyone is speaking the same language.

No conflict of interest

OHP052 Hospitalisation rates in systemic lupus erythematosus

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Background

Systemic lupus erythematous (SLE) is a chronic systemic autoimmune disease characterised by acute periods of disease activity (flares). Its prevalence on average is 4.3per 10,000 people in Europe. Cost studies in Germany and UK calculate (direct) SLE costs of €3192, and approx. € 2666 per patient/year respectively (in 2002), attributing 35-48% to inpatient care.

Purpose

To explore the SLE burden of disease on hospital care across 5 countries (France, Spain, Italy, Germany, UK).

Material and Methods

Data on SLE patients were obtained by the Adelphi Lupus Disease Specific Programme (DSP). Adelphi's DSP is an observational cross-sectional dataset involving rheumatologists (180) and nephrologists (75), who were asked to complete questionnaires on 5 consecutive SLE / Lupus nephritis patients seen by them at their centres.

Results and Conclusion

Patients (1270) were primarily female (85%), median age of 40; 60% had mild, 35% moderate and 5% severe disease. The overall mean number of flares per year was 0.65; with 0.94 in patients with moderate and 1.52 in patients with severe disease. Sixteen percent of all SLE patients experienced one hospitalisation; of these 63% were patients with severe disease. Only 0.04% of admissions included a stay in intensive care. Mean rates of hospitalisation were similar across all countries (range 17-25%), with some variation in average length of stay (range 9-17 days). The rate of hospitalisation of SLE patients is high which may be driven by a combination of disease activity, organ damage, infection and planned surgery. However, further analysis is needed to better understand the cause. Hospitalisations are likely to be one of the key drivers of cost for SLE; ways to reduce their frequency and duration may help reduce SLE-related costs. No conflict of interest

OHP053 Comparison of two equations to estimate the glomerular filtration rate in people aged 75 or older

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Background

The use of Cockcroft-Gault (CG) or simplified MDRD (Modification of Diet in Renal Disease) functions result in a useful tool to estimate the Glomerular Filtration rate (GFR), considered the best index in the evaluation of renal function.

Purpose

To compare the GFR of patients aged 75 and older, without known renal disease by the MDRD-4 formula, CG formula and urine 24h creatinine clearance (CrCl 24h), obtained by using Jaffe's method (colorimetric assay).

Material and methods

An observational, retrospective study in a general hospital with 630 beds. 50 patients aged 75 and older without prior renal disease were included (27 men and 23 women). They were hospitalised in the Surgery Unit between January and September, 2010.

We compared and correlated the GFR estimation obtained by CG and MDRD formulas against the result achieved by CrCl 24h We studied the existing mismatch by means of Kappa Index.

Results

Means of GFR were: CrCl 24h: 99.14 mL/min/1.73 m^2 and CG: 75.55 mL/min/1.73 m^2 , significantly lower than with MDRD: 109.93mL/min/1.73 m^2 .

GFR	CrCl	CG	MDRD-4				
>130	7	1	10				
100-130	17	6	19				
70-100	15	22	16				
40-70	8	19	4				
<40	3	2	1				

TABLE 1. Patients' classification into different degrees of agreement of GFR depending on the different formulas.

The agreement obtained by Kappa Index was 0.291 (CI 95%: 0.1203-0.4614) between CG and CrCl 24h and 0.563 (CI 95%: 0.3918- 0.7348) between MDRD and CrCl 24h.

Conclusion

Mean GFR values show that CG tends to underrate the result while MDRD overrates the GFR value if compared with CrCl 24h. The statistical analysis shows that, at best, the degrees of agreement over random is 29.1% between CG and CrCl 24h and 56.3% between MDRD and CrCl 24h.

According to the scale proposed by Landis and Koch (1977) these results are classified as fair and moderate agreement respectively. We consider that the MDRD and CG formulas to estimate the GFR in people aged 75 and older are not interchangeable. Specific studies in old people are needed to establish the most accurate formula.

No conflict of interest

OHP054 Analysis of drugs returned in outpatients unit of hospital pharmacy

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Background

In Spain many drugs are dispensed only from Hospital Pharmacies. Sometimes patients return them for many reasons, but we cannot always use them again.

Purpose

To evaluate drugs returned from outpatients: types of drugs, reason why they are returned, cost involved.

Material and Methods

A retrospective study from January 2009 to June 2010. Data source: computerised records from the Hospital Pharmacy. Data collected: drugs returned, reason, quantity and cost; drugs reused, drugs not reused (cause and cost).

Results

147 outpatients returned drugs of 78 different medicinal products, totalling 12,909 units. 92.67% of returned drugs were reused. Drugs were returned for the following reasons: treatment changed or finished (82.29%), death (6.77%) and treatment discontinued (2.60%). Total cost of returned drugs was 109,496.15 €. 25.15% had to be rejected as they had to be stored at 2-8°C (17.74%) and the packaging of the drug (3.29%). Drugs rejected with major economic impact were: adalimumab, etanercept, icatibant, peginterferon α-2a and peginterferon α-2b, glatiramer acetate and interferon β-1a.

Conclusion

A high percentage of drugs returned from outpatients to Pharmacy Service can be used again, but those drugs that are not candidates for reuse due to unknown storage or their packaging should be closely monitored. We are going to change the prescription form, adjusting it to the medical appointment, in an attempt to avoid returned drugs because of treatment change or finish.

No conflict of interest

OHP055 Occlusion alarms during administration of lipid emulsion with vitamins in neonates: in vitro evaluation

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Background

Lipid emulsion syringes with vitamins stable for one week are used in the neonatology unit of our hospital[1]. An increased incidence of occlusion alarms are reported by nurses compared to lipid emulsion syringes without vitamins prepared daily.

Purpose

To compare experimentally the occurrence of occlusion alarms when infusing lipid emulsion with or without vitamins.

Material and Methods

Smart pump (Module DPS, Fresenius Kabi, pressure alarm at 300 mmHg), 10 ml BD syringes, in-line filter (1.2 μm Lipipor NLF, PALL Medical), catheter 27 G (Deltec, Smith Medical). Lipid emulsion (Lipofundin MCT/LCT) tested with or without vitamins (Cernevit), and stored for 2 hours or 7 days at +2-8°C. Flow rate started at 1 mL/h with 1 mL/h increments every 25 min, pressure determined on the pump. Kinematic viscosity (Ubbelohde viscometer, Schott-Geräte, capillary 0.63 mm) and apparent pH measured at 25°C. Results expressed as mean \pm SD.

Results

At 2h: mean pressure (n=2) was higher at each flow rate in syringes with vitamins compared to syringes without vitamins (1 mL/h: 71 \pm 70 mmHg vs 35 \pm 7; 2 mL/h: 150 \pm 85 vs 100 \pm 14; 3 mL/h: 260 \pm 71 vs 200 \pm 28). Occlusion alarm was observed at 4 mL/h in syringes with vitamins. At 7 days: mean pressure was higher at 1 mL/h in syringes with vitamins (220 \pm 57 vs. 20 \pm 7) and occlusion alarm occurred at 2mL/h. No alarm was observed until 4 mL/h in syringes without vitamins. At 2h, viscosity (n=3) was higher (0.258 mm²/sec \pm 0.001 vs. 0.237 mm²/sec \pm 0.003) and pH lower (6.15 vs. 7.23) in syringes with vitamins but no changes were observed at 7 days.

Discussion / Conclusion

The addition of vitamins to lipid emulsion and 7-day storage increased the risk of occlusion alarm. Higher viscosity may explain differences observed at 2h. Emulsion destabilisation and/or syringe sticking due to extraction of silicone oil should be evaluated as possible causes to explain the increase in pressure observed after 7 days.

References:

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No conflict of interest

OHP056 Project of Pharmaceutical Centralisation of injectable medication in a neonatal intensive care unit

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Background

Licenced medicines in appropriate dosages for newborns are limited, thus requiring adjustments of pharmaceutical dosage forms. The preparation of parenteral drugs regularly leads to errors because of complex doses and calculations.

Purpose

To evaluate the case for centralisation of injectable drugs within the pharmacy.

Material and Methods

A prospective survey by direct observation was conducted in the neonatal intensive care unit. It allowed us to assess the practices during the preparation of parenteral drugs. Preparation error was defined as an error of dose, product, dissolution / dilution, a physico-chemical incompatibility, an error of stability or hygiene. This survey was followed by an FMECA risk analysis and proposals for corrective measures.

Results

The survey allowed us to observe 16 preparations of solutions under laminar airflow hood (HFLA) by a nurse and 10 preparations of doses to be administered by other nurses. No errors of dose or product were found. However, 66.6% of the preparations were not compliant with the procedures of dissolution / dilution. No stability data of were found for 33% of the preparations. Concerning hygiene, the environment of HFLA was inadequate, and hand washing was not sufficient. The different risk factors were identified.

The FMECA analysis identified 7 failure modes. The criticality indices were calculated for the current situation and for the various corrective measures proposed. Only centralisation in the pharmacy would enable indices of the parenteral preparations to be obtained below the fixed thresholds of acceptability. A CIVAS project was consequently suggested with the following objectives: to improve the quality, safety, protection of the staff and the environment and cost reduction.

Conclusion

Evaluation of the current situation and risk analysis are the preliminary steps before any plans for centralisation within the pharmacy. Centralisation of drug preparation allows the highest quality levels to be reached among the corrective measures.

OHP057 Opportunity of switching to single-use dental examination trays in an out-patient Stomatology Department

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Background

In order to anticipate possible outsourcing of the sterilisation work, the Pharmacy Department has been aiming to reduce the range of reusable devices.

Purpose

To assess the possibility of switching the reusable dental examination trays (including a mirror, tweezers and a dental probe) to single use.

Material and Methods

The real-life consumption of the kit components was first discussed individually with the practitioners. The quality of the disposable devices offered by several suppliers was then evaluated. Finally, a cost-minimisation analysis comparing single-use to reusable devices allowed us to choose between these two options.

Results

In 2009, 2100 dental examination trays were sterilised. We estimated following a four-day evaluation, that the mirror is used by itself in 1650 of the exams, the tweezers in 350 cases and all of the three elements only in 100 cases. It was also noticed that mirrors are mainly used as tongue depressors. The professionals agreed to use wooden tongue depressors instead of single-use mirrors, which were estimated to be not solid enough. Seven sterile kit suppliers were subsequently evaluated. Kits that were not supplied in a rigid tray were discarded. Taking these choices into account, the yearly acquisition cost for the single-use option (450 kits and 1650 tongue depressors) would add up to 402€ and the increment of waste disposal to 2.5€ only. On the other side, the yearly cost of the sterilisation process was estimated at 4679€. All in all, the switch to single-use trays would allow 4275€ to be saved every year in the out-patient Stomatology Department. That would represent about 10% of the annual spending on medical device in this Department.

Conclusion

A switch to single use often aims to simplify the handling of medical devices and reduce the risk of infection transmission. In our study, this action proved to be economically advantageous as well.

No conflict of interest

OHP058 CLINICAL AND ECONOMIC IMPACT OF MULTIPLE SCLEROSIS

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Background

Multiple sclerosis (MS) is a disease with a high impact on the public health budget. It also has a great effect on the quality of life of patients.

Purpose

to describe the treatments for MS and its cost.

Material and Methods

An observational study investigated patients diagnosed with MS in July 2009. The programs used were Farmatools 2.3 PB and IMED. The variables were: type of MS (RRMS (relapsing remitting MS) PPMS (primary progressive MS), SPMS (secondary progressive), RPMS (relapsing progressive), Expanded Disability Status Scale (EDSS), age, treatment, annual flare-ups and cost of drug acquisition.

Results

410 patients were studied. The female/male ratio was 3:1. 66% were treated with disease-modifying drugs.

The monthly drug cost was 238,991€, with an average cost per patient of 885€/month. RRMS represented 80% of cases, costing 181,562 €/month for drugs. The mean age was 28 years, the number of flare-ups/year was 1.54 and had a mean score of 1.54 EDSS. SPMS represented 16.2%, with drug cost of 51,407€. The mean age was 28 years, the number of flare-ups 1.50, EDSS of 5.61. PPMS was suffered by 2.2%. The monthly total drug cost was 5,207€. The average age of these patients was 38, flare-ups of 1.42 and 3.66 EDSS. RPMS was present in 1.5% of patients. The monthly total drug cost was 815. The mean age was 35, flare-ups of 0.5 and EDSS of 2.75.

Conclusion

Despite the increased spending generated by the RRMS drugs, the clinical pattern at a higher cost per patient is the SPMS. The large variability of treatments in MS makes pharmacist monitoring important in this disease, helping to identify adverse effects and adherence. This is essential for efficacious treatment and improved quality of life of patients.

No conflict of interest

OHP059 Analysis of the prescription of antipsychotics in a tertiary hospital

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Background

The emergence of new neuroleptic drugs in recent years may have changed the prescribing pattern of atypical antipsychotics.

Purpose

To examine the evolution of external prescriptions for antipsychotics in the Psychiatry Service (PS) of a tertiary hospital.

Material and Methods

Data from external prescriptions were obtained from a self-management programme, from 2004/01 to 2009/12. For neuroleptic drugs, number of prescribed daily doses (PDDs) was obtained annually (PDD=mg/DDD (defined daily dose)). Global prescription, prescription drug groups (typical antipsychotics=TAP, atypical antipsychotics=AAP and lithium) and individual prescription drug were analysed.

Results

The annual global prescriptions is shown in table 1.

	2004					
PDDs	19952	16448	23305	24028	22787	22770
TAP (%)	11.42	8.19	8.77	11.35	6.66	5.65
AAP (%)	66.53	72.05	73.69	68.88	78.19	80.96
Lithium (%)	22.05	16.76	17.54	19.77	15.14	13.39

During the study period, the number of PDDs prescribed increased by 14.1%. The most important variation occurred in the period 2005-2006 with an increase of 42.1%, followed by later stabilisation. AAPs and lithium increased in 2007 compared with 2006 (33.03% and 15.85%) and decreased in 2008 (-44.32% and -27.37%) and 2009 (-15.32% and -11.39%) over the previous year. By contrast, TAPs increased in 2008 and 2009 compared to 2007 by 7.65% and 11.38%.

Individual analysis showed that the prescription of 5 drugs (clozapine, lithium, olanzapine, quetiapine and risperidone) represented over 80% of total prescriptions between 2004 and 2007. The marketing of paliperidone and increased use of aripiprazole made all these 7 drugs 91.5% and 93.7% of total prescription in 2008 and 2009. From 2004 to 2009, the use of lithium reduced by 30.68%. By contrast, quetiapine use has doubled between 2004 and 2009 (263.76%).

Conclusion

The prescription of neuroleptics during the study period shows an overall increase in use of these drugs. Despite the increased use of AAPs, they have not totally replaced the first generation whose level of use is still high.

No conflict of interest

OHP060 Implementation of a cardiopulmonary resuscitation protocol: pharmacist¥s role on an interdisciplinary team <u>M.P. Sierra Muñoz</u>, M. Mejía Recuero, D. Barreira Hernández, S. Canales Ugarte, M.A. Garijo Catalina, D. Barreda Hernández ¹Hospital Virgen de la Luz, Pharmacy Department, Cuenca, Spain ²Hospital Virgen de la Luz, Intensive Care Unit, Cuenca, Spain

Background

Cardiopulmonary resuscitation (CPR) is a vital emergency procedure and must be performed according to international guidelines to reduce the incidence of injures or premature death as a result of an in-hospital cardiopulmonary arrest.

Purpose

To describe the CPR protocol introduced at the Hospital and evaluate the usefulness of pharmacist intervention in order to improve CPR drugs.

Material and Methods

A multidisciplinary group from a secondary level hospital examined the resuscitationguidelines of the Spanish Society of Intensive Care, Critical and Coronary Units and the Spanish Association of Critical Care Nurses published in 2005 to determine a general CPR protocol.

The Intensive Care Unit collaborated with other medical services, nurses and pharmacists in making it. The CPR protocol was introduced to the hospital in December 2009.

Results

The new CPR protocol includes: Hospital risk map, general equipment of each area, life support equipment, hygiene training, In-hospital CPR data, ethical considerations and other references and annexes.

The function of the pharmacist and the Pharmacy and Therapeutics Committee was to review the pharmacologic management of adult and paediatric CPR and adjust the drugs to the hospital's pharmacotherapeutic guide. CPR pharmacotherapy is grouped according to: Anaesthetic/ Sedative (Midazolam, Propofol). Muscle relaxant (Vecuronium). Vasopressor (Adrenaline). Cardioactive (Atropine, Lidocaine, Amiodarone) and other drugs.

Fluid therapy is included. 6/16 drugs need special precautions for storage (light protection, cold storage, narcotic storage cabinets).

Conclusion

* Doctors, hospital pharmacist's and nurses' roles were described in this protocol focused on reducing premature death and neurological damage as a result of an in-hospital cardiopulmonary arrest.

*In emergency medical care, drug therapy plays a critical role that places the pharmacist in a position to improve the quality of CPR assistance. It is the pharmacist's responsibility to maintain suitable product specifications, replace drugs used and store medicines appropriately.

*It will be necessary to evaluate CPR pharmacotherapy in all hospital areas according the drugs available in the hospital's pharmacotherapeutic guide.

No conflict of interest

OHP061 Secondary hematological malignancies to imnunosuppressive therapy.

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Background

We report the case of a patient with immunosuppressive therapy who developed myelodysplastic syndrome (MDS).

Secondary haematological malignancies are a complication in transplant patients with immunosuppressive therapy. Lymphomas or lymphoproliferative syndromes appear most frequently than MSD.

Purpose

To examine the possible relationship between the use of immunosuppressants and the development of MDS with progression to acute myeloid leukaemia (AML).

Material and Methods

A 60-year-old patient with chronic renal failure secondary to nephrolithiasis, received a kidney transplant in 1990. Induction of immunosuppressive therapy consisted of anti-thymocyte globulin / anti-lymphocyte globulin, prednisone (PD), ciclosporin (CsA) and azathioprine (AZA).

After induction treatment continued with PD 7.5 mg /day, CsA 75 mg/12h and AZA 75 mg /day. AZA was suspended in 2002 due to pancytopenia. In 2006, the patient presented severe pancytopenia (haemoglobin (Hb) 6.9 g / dl, WBC 1500/mm 3 , platelet 100,000/mm 3).

Results

- She was diagnosed with MDS, with trilineagedysplasia with excess of blasts and with high probability of leukemic transformation. Complex karyotype (> 3 chromosomal abnormalities) indicating poor prognosis. The immunosuppressive treatment was modified (PD 5 mg / day, CsA 50 mg at breakfast and 25 mg at dinner).
- In February 2007 clinical progress was favourable (Hb: 10.5 g/dl; WBC: 3500 mm³, platelet 90000/mm³). The karyotype was still complex but with a decrease of cells with abnormalities.
- In May 2007, the complete blood count showed: Hb 11.1 g/dl, WBC 1200/mm³, Platelets 35.000/mm³ and complex karyotype with the appearance of new clones. She started treatment with idarubicin 19 mg (1-3 days) and cytarabine 160 mg (1-7 days). After this treatment the patient developed respiratory failure which led to her death.

Conclusion

- The use of multiple immunosuppressive drugs could be considered a factor in the increased susceptibility to secondary hematologic malignancies.
- The secondary MDSs tend to be more aggressive than primary with progression to AML. The complexity of the karyotype corresponds to the evolution of the disease and does not usually appear in "novo MDS".
- Secondary haematological malignancies are a complication in transplant patients with immunosuppressive therapy. These patients should be monitored and treatment individualised.

OHP062 HORIZON SCANNING: THE EXPERIENCE OF SIFO LABORATORY OF PHARMACOECONOMICS

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Background

Osservatorio Innovazione (OI) Pharmacoeconomics Laboratory is a project started three years ago in the field of horison scanning (HS). This project involves a team of experts in clinical and economic evaluation of innovative products (drugs and medical devices). Its main objectives are to monitor innovative drugs and medical devices and producebrief and original filecards on innovative products based on a simplified cost-Valutazione effectiveness evaluation (VES Economica Semplificata).

Purpose

The main objective of this contribution was to analyse the HS results produced by the OI from January to September 2010.

Material and Methods

To systematically identify the most relevant innovative products, OI examines all original articles published in 6 very authoritative peerreviewed journals. The most prominent studies are firstly classified according to their therapeutic area and then according to the subgroup that meets our criteria for undertaking pharmacoeconomic evaluation. This evaluation is then carried out according to our VES methodology. The endpoints suitable for a VES are in most cases restricted to survival, progression-free survival, disease free survival or major events avoided.

During the first 9 months of 2010, our HS activity identified 188 comparative studies. Among these, 32 studies met the criteria for undertaking a VES.

The finding for 29 of these studies was the superiority of the new product; in these cases the VES was therefore developed as an incremental cost-effectiveness analysis. In the remaining 3 studies, the innovative therapy produced no advantages in comparison with the comparator; hence, the VES was carried out as a cost minimisation analysis.

Conclusion

The activities of the OI team are made available to Italian hospital pharmacists via a website. The next step of this experience is to promote the use of the findings generated by our VES in the assessment activities carried out by local Drugs and Therapeutics Committees.

No conflict of interest

OHP063 Impact of a weight control programme in a psychiatric long-term care Hospital

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Previous epidemiological nutritional studies in elderly populations have demonstrated that overweight and obesity, using the WHO classification, are the main health problems. If we also consider one additional factor as mental illness, we find out that there is a special interest to develop weight control programs to avoid an increase in personal cardiovascular risk among this population.

Material and Methods

We present a transversal prospective observational study undertaken in two periods of one week with the same sample of inpatients: First period was in 2007 (first week of May), Second period was in 2009 (first week of May). We used the body max index (BMI) and WHO classification to classify our chronic psychiatric inpatients. Between the first and second period we changed some important rules in relation with the diet: Diets were prescribed on an individual basis; distribution was also individualised, and there was a diet review to adjust calorie content to a maximum of 2,500 Kcal/day.

Results

Sample patients were 148 inpatients (81 male and 67 female). First period distribution was as follows: underweight 0%, normal 26%, overweight 36%, obese 37%. Data from the second period results are: underweight 1%, normal 32%, overweight 36%, and obese 32%. The average loss of weight was around 2 kg per patient.

Conclusion

Dietary reengineering can help to maintain nutritional status without great changes over time, improving slightly the distribution of the inpatient psychiatric population, increasing the normal weight group, and reducing the obese group. The overweight group showed no change. The weight control program has achieved partial results but the dietary approach was not enough for this population, and the programme should be expanded to include more physical activities, even sports adapted to individual skills.

No conflict of interest

OHP064 Cost-efficacy analysis of pemetrexed in first-line treatment of non-small cell lung cancer

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In a phase III trial, which included 1725 patients and compared pemetrexed-cisplatin to gemcitabine-cisplatin in first-line treatment of non-small cell lung cancer (NSCLC), pemetrexed showed similar clinical efficacy. This drug was recently approved by the European Medicines Agency (EMA) for this therapeutic indication. The histology of NSCLC is known to affect the efficacy of treatments.

Purpose

To evaluate the cost-efficacy relation of pemetrexed, in the first-line treatment NSCLC patients, considering the different histologies, and using published data from the clinical trial and cost data from our hospital. This study was required in order to assess treatment options in our hospital.

Material and Methods

Based on the above- mentioned phase III trial, the efficacy of pemetrexed or gemcitabine, plus cisplatin, in the first-line treatment of NSCLC was evaluated. We considered overall survival and cancer histology. Treatment costs were calculated based on the direct cost of the drugs in 2010. This study was conducted from an institutional perspective - the hospital perspective.

Results

The overall survival of the NSCLC patients treated in our first-line setting with pemetrexed + cisplatin was: 1.05 years in adenocarcinomas, 0.78 years in squamous cell carcinomas; 0.87 years for large cell carcinomas and 0.72 years for other histologies. The overall survival of the NSCLC patients treated in our first-line setting with gemcitabine + cisplatin was: 0.77 years in adenocarcinomas, 0.90 years in squamous cell carcinomas; 0.56 years for large cell carcinomas and 0.77 years for other histologies. The associated costs for the two treatments were calculated considering 5 treatment cycles (the average number of cycles indicated in the clinical trial for each treatment scheme) and a body surface of 1.7 m². The cost associated with the use of granulocyte colony-stimulating factors (G-CSF), was also considered based on the frequency of neutropenia described for the two therapeutic options.

For adenocarcinomas and large cells carcinomas, the incremental cost-efficacy ratios (ICER) calculated for pemetrexed + cisplatin versus gemcitabine + cisplatin were 31.514€ and 28.959€ respectively. In the squamous cell carcinomas and other histologies, the gemcitabine + cisplatin option was more effective and less expensive.

Conclusion

In the histologies of NSCLC in which the pemetrexed + cisplatin option was more effective than gemcitabine + cisplatin, the calculated ICER was higher in adenocarcinomas. In squamous cell carcinomas and other histologies gemcitabine + cisplatin were more cost effective, even when G-CSF use is considered.

No conflict of interest

OHP065 Clinical, etiological and treatment modalities for urinary tract infection in immune compromised patients

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Background

The evolution of urinary tract infections in immune-compromised patients remains a problem at national level in many countries including Romania.

Purpose

To evaluate the clinical, etiological and the rapeutic aspects of urinary tract infections in immune-compromised patients due to severe evolution, which can be potentially lethal in some of these cases.

Material and Methods

A retrospective study of 131 patients who were immune compromised and diagnosed with urinary tract infections. Patients were admitted and treated in the Intensive Therapy Unit of Clinical Emergency Hospital Craiova, Romania between 1.09.2009 - 1.09.2010. All cases were selected according to immune status and protocol. The criteria included: demographic information, comorbidities, clinical and pathology details. Data were analysed with EPI Info 2002.

Results

There was an equal distribution between the sexes (51% males, 49% females) with a predominance of those living in urban areas (72%) and varying age of 30 to 90 years. In most cases (81%) we identified at least 2 criteria of immune compromise: age >60 years (68%), chronic urinary infection (21%), kidney stones (19%) and diabetes (18%). Where established (56%), the aetiology of the infection was due to *Escherichia coli* (46%), and *Pseudomonas aeruginosa* (16%). First-line treatment was given according to sensitivity and +/- clinical evolution. Monotherapy was used in 45.80% cases, a combination of 2 antibiotics in 49.62% cases and 3 antibiotics in 4.580% cases. Classes of antibiotics used: beta lactams antibiotics, quinolones, aminoglycosides, III/IV generation cephalosporins, carbapenems.

Conclusion

Urinary tract infections in immune-compromised patients are still common and difficulties in treatment and prognosis are increasing. This can lead to a high cost per treatment.

No conflict of interest

OHP066 Results of the smoking cessation program in which our pharmacy service takes part

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Background

Since 2007 our Pharmacy Service has been participating in a financed pharmacology smoking cessation programme, providing information leaflets, dispensing treatment and compiling statistics.

Purpose

To analyse the effectiveness and cost of this programme during 2007.

Material and Methods

Primary care doctors report the number of patients who began treatment in 2007, treatment received and response when just finishing this, and after 6 and 12 months. Hospital pharmacists determine the cost per patient and per treatment, and the total cost using the Athos database.

Results

In 2007 treatment was prescribed to 2,418 patients. Follow-up information was sent about 418 patients (17.3%): 19.4% were treated with nicotine patches; bupropion 47.4%; varenicline 33.2%. When finishing treatment 62.9% did not smoke; after 6 months 41.1%; after one year 34.9% continued not to smoke. Success with the 3 different approaches breaks down as follows:

Treated with nicotine patches: 58% had stopped smoking just after the treatment; this fell to 37.0% after 6 months; 34.6% after one year. Bupropion: 63.1% had stopped just after the treatment; 39.4% after 6 months; 34.3% after one year. Varenicline: 65.5% just after the treatment; 46.0% after 6 months; 36.0% after one year.

The total cost amounted to 251,817 \in . The cost per patient treated with nicotine patches was 57 \in ; with bupropion 104 \in , and with varenicline 205 \in .

Conclusion

The three drug treatments showed similar efficacy. Varenicline showed better results, but the differences were not statistically significant (p>0.05). The results might be biased because the follow-up data was sent only by the more involved doctors.

The cost of treatment per patient with varenicline (205 \in) is double that of bupropion (104 \in), and is more than three times that of nicotine patch therapy (57 \in).

If all patients who started treatment in 2007 had been treated with nicotine patches, 113,023.6 euro would have been saved, achieving the same efficacy.

No conflict of interest

OHP067 Users' satisfaction evaluation of an ambulatory pharmacy service in a University Hospital: intervention analysis

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Background

The level of user satisfaction regarding a service offered could reflect its quality.

Purpose

To evaluate the impact of interventions conducted in the ambulatory pharmacy service, in order to identify existing problems and to develop and implement practical solutions to those problems.

Material and Methods

The present quantitative and interventional study was approved by the Institution's Ethics Committee. Satisfaction was evaluated through an interview with users who received medicines dispensed by the ambulatory pharmacy. Structured interviews were conducted in three periods: period 1 (March 2008, N = 81), period 2 (September 2008, N = 113); period 3 (March 2009, N = 109). The interventions made consisted of administrative changes and plans for continuing education. Statistical evaluation was performed using correspondence analysis.

Results

Satisfaction with the general pharmacy care increased (period 1: 79.1%; period 2: 87.6%; period 3: 90.8%; related to excellent and good satisfaction). In specific topics analysed, initial dissatisfaction improved regarding to waiting time for care (30.9%; 47.8%; 63.3%), number of employees (38.3%; 69.9%; 64.2%) and waiting area (56.8%; 77.0%; 78.9%). In every period, satisfaction with information about the dispensed medicine was 100%, although after the end of the study, information was provided to a maximum of 26% of users interviewed. Through correspondence analysis, it was observed that most answers were concentrated closer to the satisfaction levels, 70.7% of the data were around excellent and good.

Conclusion

The present study observed that there is a great level of satisfaction with the ambulatory pharmacy service and it increased as the interventions were made. However, professional continuing education was only beginning and may not reflect on counselling. In conclusion, more continuing education must be encouraged for professionals responsible for dispensing.

No conflict of interest

OHP068 Study of dermatologic side effects of patients treated with Cetuximab from 2008 to 2009

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Background

Cetuximab is a chimeric monoclonal antibody, an epidermal growth factor receptor (EGFR) inhibitor, for treatment of metastatic colorectal cancer (MCC) and head and neck cancer (HNC). EGFR is involved in the proliferation of skin keratinocytes, which explains the appearance of dermatologic side effects in 80% of the patients.

Purpose

To investigate the dermatological side effects of cetuximab in patients diagnosed with MCC and HNC who received this treatment during the period from January 2008 to December 2009.

Material and Methods

Patients were listed, and the dosage, frequency and line of treatment were reviewed using the Oncogest computer program. In addition, the Selene program was used to review the medical records, and dermatological side effects were identified.

Results

73 patients were given cetuximab from January 2008 to December 2009 (71.2% male). 37% were diagnosed with HNC (88.9% male), and 63% with MCC (60.9% male). Average age: 63 years old, (range: 35-81 years old). Side effects on the skin were described in 80.8% of the patients; of whom 67.8% presented an acneiform reaction, 23.7% dry skin, 16.9% rash, 15.3% nail disorders (paronychia), and 8.5% pruritus. 13.7% of the total (60% male) had to suspend cetuximab due to dermatological side effects; average age: 65; all these patients had MCC. 60% of these had previously tried a dose reduction. The dose had to be reduced in 11% of the patients (62.5% male); average age: 67 years; 87.5% with MCC. Dose reduction range: 10-40%. 75% of these subsequently had to

suspend cetuximab because of dermatologic side effects.

Conclusion

-80.8% of the patients showed dermatologic side effects, mainly acneiform reaction, which matches with current literature.

-13.7% had to suspend Cetuximab because of dermatologic side effects while 11% required a dose reduction.

No conflict of interest

OHP069 effectiveness of inhaled antibiotics in patients with bronchiectasis colonized by multiresistant microorganisms M.T. Acin Gerico, M. Garcia Palomo, J.M. Martinez Sesmero, A.R. Rubio Salvador, J.J. Cia Lecumberri, P. Moya Gomez ¹Hospital Virgen de la Salud, Pharmacy, Toledo, Spain

Background

Bronchiectasis colonized by multi-resistant Gram-negative microorganisms (BCMR) is a frequent disease with an increasing prevalence in the world. Inhaled antibiotics (IAs) tobramycin and colistin can be useful because of scanty systemic absorption, which avoids the appearance of resistance and side effects.

Purpose

To examine the effectiveness of IAs in patients with BCMR.

Material and Methods

Observational retrospective study (2007-2010) of patients with BCMR treated with IAs in a third-level hospital. Demographic, clinical, microbiological information were obtained from electronic clinical records. The consumption of IAs was recorded by APD Athos-Prisma from 2-9 September 2010. Effectiveness was evaluated by sputum culture. One cycle of colistin treatment (TC) means 30 days of continued treatment and one cycle of tobramycin treatment (TC) means 28 days of continued treatment with 28 days off

Results

Thirty-four patients (17 males and 17 women), mean age 65.9 years (SD: 18.3), were treated with IAs. Twenty seven (79.4%) were treated with colistin; Seven (20.6%) were treated with tobramycin. Six (17.6%) died because of exacerbations of BCMR.

N° of (%)	patients	Microorganism			
32 (94)		Pseudomonas a	eruginosa	1	
1 (3)		Pseudomonas baumannii	putrida	and	Acinetobacter
1 (3)		Escherichia coli.			
	_	N 10 6		0/1	

1	T	
Drug	N° of patients (%)	TCs
	1 (3.7)	<1
Colistin	17 (63)	1-3
Consum	5 (18.5)	4-6
	4 (14.8)	>6
Tobramycin	5 (71.4)	1
Tobianiyen	2 (28.6)	2

In four (14.8%) patients colistin eradicated the infection after 1, 2, 6 and 7 TCs. Eight (29.6%) presented recurrences. One (3.7%) presented intolerance. Two (25 %) changed to another colistin administration system. In one (14.3%) patient tobramycin eradicated the infection after 2 TCs. None presented recurrences. The rest of patients continued in treatment at the end of the period of study.

Conclusion

No patients presented recurrences with tobramycin, which might suggest better effectiveness compared with colistin. Because the eradication rate was similar, it would be appropriate to repeat the study with a larger patient sample.

OHP070 Prescription order at hospital discharge. Checking with qualitative indicators

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Background

The quality of prescribing is becoming a social and political concern as efficiency and pharmaceutical expenditure in the care process are more widely discussed.

Purpose

To assess the quality of discharge prescription writing in a general hospital.

Material and Methods

Retrospective descriptive cross-sectional study (March-August 2010). Selection criteria: ≥65-year-old patients discharged from Internal Medicine Short Stay Unit and included in a Pharmaceutical Care Programme in which the pharmacist performs medicines reconciliation and explained the discharge medicines to the patient. Information source: Infowin (management software for pharmacotherapeutic information). Data collected: sex, age, drugs and therapeutic groups (according to ATC classification).

Qualitative indicators:

- a) General:
- -Prescription completed with International Non-proprietary Names (INN)
- -Adherence to Pharmacotherapeutic Guide in Primary Care (PGP) -Potentially Inappropriate Medicine (PIM) in elderly patients (Beers
- -Low-therapeutic Utility Drugs (LUD)
- b) Specific:

Criteria)

. /				
Indicator	Formula description			
Omeprazole	[Omeprazole prescriptions / total Proton Pump Inhibitors (PPI) prescriptions]*100			
Oral Antidiabetic Agents (OAAs)	[OAA included in PGP/ total OAA prescriptions]*100			
Angiotensin-II receptor antagonist (ARA-II)	[ARA-II included in PGP/ total ARA-II prescriptions]*100			
First-choice NSAIDs	[lbuprofen, naproxen and diclofenac prescriptions/ total NSAID prescriptions]*100			
Simvastatin	[simvastatin prescriptions /total lipid-lowering prescriptions]*100			

Database: Excel.

Results

122 patients were included (67 women), mean age 81 years (65-98). 898 drugs were prescribed at discharge [7.3 (1-18) drugs/patient], which corresponded to the following major therapeutic groups: PPI (9.1%), sulphonamides alone (6.5%) and antiplatelet agents (5.1%). The results of indicators were:

General	Prescription completed with INN
	Adherence to PGP
	PIM
	LUD
Specific	Omeprazole
	OAA
	ARA-II
	NSAIDs
1	Simvastatin

Conclusion

The use of these indicators at different levels allows us to identify opportunities for interventions in order to improve prescribing. If the pharmacist adopts strategies to improve discharge prescribing, we will get to promote rational drug use in the National Health System.

No conflict of interest

OHP071 Establishment of a mentoring program and control of antimicrobial treatment in general surgery

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Background

The data comparing antimicrobial consumption in the hospital between 2008 and 2009 showed a 37% increase in economic income and 3.85% in the number of DDD/100 stays.

Purpose

To establish a mentoring and control of antimicrobial therapy (PACTA) programme between the departments of pharmacy and infectious diseases, and analyse the impact of the PACTA on consumption trends.

Material and Methods

The pharmacy service established a daily collection of data from all patients hospitalised in the general surgery department who were prescribed: antimicrobials with a greater effect on drug costs; antibiotics administered intravenously or prescribed orally for more than 5 and 10 days respectively; 2 or more antibiotics prescribed simultaneously. A comparative analysis of consumption data was carried out comparing 2010 data with the same period in the previous year.

Results

The total number of patients in the general surgery service prescribed an antibiotic with a major economic impact during the follow-up period was 109: aminoglycosides (11%), antifungals (7.3%), tigecycline (4.5%), daptomycin (2.75%), quinolones (2.1%), carbapenems (1.1%) and linezolid (1.1%). Patients who were given antibiotics for more than 5 and 10 days corresponded to 33% and 1%. Patients who were given 2 or more antibiotics simultaneously accounted for 27%. The comparison with 2009 consumption data shows an increase in the consumption of antibiotics of 49%, with the carbapenem group having the greatest increase (99%). The number of DDD/100 stays fell by 4.89% over the same period of 2009, however the consumption decreased as the percentage of DDD/100 stays shows (-1.42).

Conclusion

Pharmaceutical costs resulting from the use of antibiotics in the general surgery department has increased in spite of the PACTA. It was concluded that this increase was due to the increased use of carbapenems. Therefore new strategies are required aimed at fundamentally improving the monitoring and prescribing of this group of antimicrobials.

No conflict of interest

OHP072 Carbapenems selection by means of the SOJA method

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Background

Rational drug selection for formulary purposes is extremely important. In the System of Objectified Judgement Analysis (SOJA) method, selection criteria for a given group of drugs are defined and the extent to which each drug fulfils the requirements for each criterion is determined. To each criterion is given a relative weight, and the more important a given selection criterion is considered, the higher the relative weight. In 1998, a study[1] was published that compared the carbapenem antibiotics by means of the SOJA method. There were only two carbapenems at the time: Imipenem/cilastatin and meropenem. Since then, two more drugs have become available: ertapenem and doripenem. In this study, the selection criteria used were adapted from the study mentioned, and applied to the four drugs.

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Purpose

To evaluate the carbapenem group for a Pharmacy and Therapeutics Committee informed decision.

Material and Methods

The SOJA method was applied to the four available carbapenems: imipenem/cilastatin, meropenem, ertapenem and doripenem. The evaluation criteria were selected, and all information used in drug scoring was collected, by literature search. The exceptions were resistance data and acquisition costs, where specific information from our hospital was used.

Results

The following selection criteria and relative weight were used: number of formulations (20); number of approved indications (30); pharmacokinetics (60); antimicrobial spectra (110); efficacy (175); development of resistance (120); general side effects (100); severe side effects (100); drug interactions (75); dosage frequency (45); acquisition cost (105) and experience/documentation (60).

Meropenem showed a higher total score. The order obtained was: meropenem, doripenem, imipenem/cilastatin and ertapenem.

Conclusion

These results allow the Pharmacy and Therapeutics Committee to decide based on more information. The added therapeutic value of a drug can only be evaluated when several criteria are compared with the alternatives.

1) Janknegt R. et al. Carbapenem antibiotics: drug selection by means of the SOJA method. EHP 1998;4(1):5-12

No conflict of interest

OHP073 Implementation of a protocol of use of botulinum toxin type A in focal hyperhidrosis

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Background

Hyperhidrosis is characterised by excessive sweating (palms, axillae, soles). It has an important impact on social relationships. Treatment options (antiperspirants, anticholinergics, iontophoresis, clonidine and benzodiazepines) are often ineffective and sympathectomy could be considered an alternative but with serious complications. Thus, botulinum toxin type A (BTX-A) could be a valid option.

Purpose

- To review the efficacy and safety of BTX-A in hyperhidrosis, from the scientific literature.
- To draw up a protocol in these indications in collaboration with the Dermatology Department.
- To perform a retrospective analysis after the introduction of this protocol in our hospital.

Material and Methods

Systematic review of scientific literature in PubMed and Embase with the terms "hyperhidrosis" and "botulinum toxin type A".

The literature data were evaluated according to effectiveness, safety and cost; especially in off-label indications (palmar and plantar hyperhidrosis)

Retrospective observational study of the use of BTX-A in hyperhidrosis from protocol approval (July 2009-September 2010).

Results

The literature gave us sufficient experience of BTX-A in hyperhidrosis. The protocol was designed with the Dermatology Department, (informed consent and application form with indication and number of vials).

After authorisation of the protocol, 37 patients were treated [75.68%

(28/37) axillar; 21.62% (8/37) palmar; 2.7% (1/37) plantar]; average age: 31 years; 81% female. 24.3% of patients were treated for off-label indications (average age: 29 years; 87% female).

Effectiveness was 95% (measured with Minor Test and 10-question validated questionnaire of quality of life (DLQI) in a periodic dermatological follow-up). No adverse effects. Only one patient needed a new injection after 12 months.

Total cost: 13900.32€ (off-label indications were 34.5%). Average cost per patient: 533.21€.

Conclusion

BTX-A is a suitable, effective and safe therapy for focal hyperhidrosis according to the scientific literature.

Protocols of compassionate use allowed the most efficient management in processing documents and dispensing drugs.

The effectiveness and safety of BTX-A in our patients agreed with that of the literature.

Clinical pharmacy and clinical trials (including case series)

CPC001 Bevacizumab in the treatment of epithelial ovarian carcinoma which is resistant to platinum therapy

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Purpose

To evaluate the efficacy and safety of bevacizumab in patients with epithelial ovarian carcinoma who have progressed after a platinum-based therapy.

Material and Methods

Retrospective observational study (November 2005 - April 2010). It includes patients with advanced epithelial ovarian carcinoma who, after a platinum-based chemotherapy, received bevacizumab 10 mg/kg/day IV every 2 weeks and cyclophosphamide 50 mg/day PO until progression or unacceptable toxicity. Efficacy and safety information, demographic and clinical characteristics were obtained from the review of medical records and Farmis software. Descriptive statistical analysis was performed by calculating frequencies and proportions for qualitative variables and mean (standard deviation) or median (range) for quantitative variables. Progression-free survival (PFS) was studied using the Kaplan-Meier method.

Results

Data collection comprised results from 23 patients with stage III epithelial ovarian carcinoma and a median age of 60.56 years (32- $\dot{80}$). 65.21% had a family history of ovarian carcinoma. Before bevacizumab, patients received a mean of 3.7 different chemotherapy schedules. They received a mean of 8.2 cycles of bevacizumab. 60.9% of patients died, and 39.1% remained under study; 26% of them continued in treatment with bevacizumab, the rest required a change of treatment after disease progression. The median PFS was 3.7 months (1-14). At the beginning of bevacizumab therapy, 70% of patients had ECOG 1 and 2, after several cycles, they achieved ECOG 0. 65.2% experienced adverse events: asthenia grade 1 in 66.6% and grade 2 in 33.4%, hypertension grade 1, 2 and 3 in 62.5%, 25% and 12.5%respectively; deep venous thrombosis grade 3 in one patient; bleeding gums grade 1 and 2 in 2 patients; 2 cases of mucositis grade 2 and several cases of grade 1 toxicity such as haematuria, constipation, diarrhoea, dyspnoea and alopecia.

Conclusion

Bevacizumab moderately improves quality of life and may involve clinical benefit in patients with poor prognosis platinum-resistant epithelial ovarian carcinoma. Although it is well tolerated, patients should be closely monitored to avoid potentially serious events such as bleeding and venous thromboembolic events.

No conflict of interest

CPC002 The evaluation of alternative therapies used by patients with known chronic liver disease by a clinical pharmacist

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Background

Many patients with chronic liver disease use various alternative therapies either overtly or in a hidden manner believing that they are safe and have no adverse effects. The varying types and degree of such therapies is still largely unknown in Romania.

Purpose

For a clinical pharmacist to identify the types of alternative therapies used and to gather in-depth information about these

treatments. It has been demonstrated that trainee doctors do not pay much attention to this area of medicine due to a lack of training in this direction.

Material and Methods

Structured interviews were conducted by a clinical pharmacist on 100 patients with known chronic liver disease over a two month period. Patients were seen in an outpatient clinic of Emergency Hospital Craiova, Romania and a purpose- designed questionnaire was given. Data was collected and analysed using Student's t-test.

Results

The primarydiagnoses were: chronic hepatitis C (n 26), chronic hepatitis B (n 24), fatty liver (n 18), and cirrhosis (n 32).

From the total of 100 patients 44 were female and 56 were male with the average age being 52 +/- 8 years. 68 patients co-operated and stated that their treatment ranged from homeopathic treatment 9 (13%) to herbal remedies 55 (81%) amnd energetics therapy 3 (4%). 23 patients were reluctant to cooperate.

Conclusion

The data showed a significant use of alternative therapies, especially herbal remedies in patients with chronic liver disease. Furthermore, it underlines the importance of and the need for a clinical pharmacist in counselling those patients to make sure they understand the possible interactions of alternative therapies with standard medical treatment. A lack of understanding can lead to serious adverse effects and poor management in patients with chronic liver disease.

No conflict of interest

CPC003 Desensitization for hypersensitivity reactions to liposomal doxorubicin: a case report

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Background

Hypersensitivity reactions (HSRs) to chemotherapy agents are uncommon and associated with certain antineoplastic categories (taxanes, epipodophyllotoxins, asparaginase, platinums and others). HSRs limit their use, but rapid desensitisation allows patients to be treated without changing the first-line treatment.

A 75-year-old woman with Hodgkin's lymphoma, started <u>ABVD</u> (with liposomal doxorubicin due to heart problems) <u>chemotherapy regimen</u> as first-line treatment. The patient developed shivers during the first doxorubicin infusion, and rash and fever during the second one. The infusion was immediately stopped, dexchlorpheniramine and hydrocortisone were administered. The same reactions were observed with a slow infusion rate.

Purpose

To evaluate the safety and efficacy of the liposomal doxorubicin desensitisation protocol designed for this patient.

Material and Methods

The patient was premedicated the night before and 30 minutes before the beginning of the doxorubicin infusion. The desensitisation protocol designed for intravenous infusion consisted of a 10-step protocol with 0.012 mg as initial dose and consecutive increasing intravenous doses every 10 and 30 minutes. Altogether 10 different doses were administered. The target dose (23.6 mg) was completed in 3.2 hours.

Resul

The patient completed 6 cycles of treatment without complications. Anti-allergic drugs were not required after the desensitisation.

Conclusion

The 10-step protocol in 3.2 hours for liposomal doxorubicin was safe and effective for this patient.

CPC004 The use of antibiotics in treatment of acute COPD exacerbations does not adhere to national guidelines

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Background

Acute exacerbation of chronic obstructive pulmonary disease (COPD) is a serious condition with a mortality of 10%. The condition often requires treatment with antibiotics.

Purpose

1) to ascertain which antibiotics the physicians prescribe in first line treatment to patients with acute COPD exacerbation 2) to compare the treatments given with national guidelines.

Material and Methods

The study included 100 randomly selected patient charts; 25 from each of the 4 emergency wards in Zealand Region. Data were collected retrospectively from electronic charts August-December 2009. Inclusion criteria were COPD patients older than 18 years with acute exacerbation of COPD, need for antibiotics, no concurrent treatment with chemotherapy or immunosuppressive drugs admitted to the emergency wards. The national guidelines included guidelines from the Danish Society of Respiratory Medicine, Medicin.dk, Institute for Rational Pharmacotherapy and the Danish College of General Practitioners.

Results

The study showed that cefuroxime, benzyl penicillin and amoxicillin in combination with clavulanic acid were the most frequently used antibiotics. 82% of the patients received intravenous antibiotic treatment exclusively. Of these patients, 73% were treated with cefuroxime and 27% with benzyl penicillin. Oral antibiotics were used in 17% of the patients. Of these, 88% were treated with amoxicillin in combination with clavulanic acid and 12% with phenoxymethylpenicillin. The national guidelines recommend cefuroxime as first choice drug in hospital treatment of acute exacerbation of COPD.

Conclusion

Cefuroxime was the most commonly used antibiotic in the treatment of acute COPD exacerbation. According to national guidelines, benzyl penicillin is not recommended for the treatment. However, benzyl penicillin was used for 27% of the patients. The results indicate a need for a regional guideline composed in co-operation with specialists in Infectious Disease, Clinical microbiology and pulmonary disease. This will help the physicians choose the right treatment, and contribute to standardised treatment of patients with acute COPD exacerbation in Zealand Region.

No conflict of interest

CPC005 Duration of Highly Active AntiRetroviral Treatment (HAART) lines in clinical practice.

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Background

Several factors are involved in the maintenance of the diverse lines of HAART. Transmission had been via drug addiction in 49.5%, heterosexual relations in 30.5% and homosexual relations in 11.7%.

Purpose

To determine the length of time patients not included in clinical trials

spend in different treatment lines.

Material and Methods

A cohort of 632 patients was followed from January 1997 to 7July 2010. We recorded the duration of different HAART regimens. Patients were classed in two groups depending of the dates of treatments, A) from 1997 to 2005, and B) from 2006 to 2010. The reasons for changing treatment were: any adverse effect, virological failure (considering the definition of European and Spanish guidelines), abandon (suspension of treatment for at least 3 months and another treatment was started), simplification (lower dose or length of treatment or substitution by fixed dose combinations), and others (treatment interruptions, HCV treatment, pregnancy, death, etc.)

Results

88.3% of the patients were on HAART. 69% were men, median age was 44 and 32.1% were CDC-C stage. The median number of treatment lines was 3 and the duration averaged 25.23 months. Reasons for changing in group A were: adverse effects in 30.2% (n: 309), virological failure 17.8% (n: 182), abandon 18.9% (n: 193), simplification 15.2% (n: 155) and others 17.9% (n: 183) In group B the reasons were: adverse effects in 34.6% (n: 112), virological failure 10.5% (n: 34), abandon 12.9% (n: 42), simplification 28.1% (n: 91) and others 13.9% (n: 45)

Conclusions

1) Although HIV infection is a chronic disease, the length of time patients receive that same treatment line is relatively short. 2) Simplification has become a more common reason for modification of treatment in recent years. 3) Adverse effects are the biggest reason for changing treatment.

Acknowledgements

We are grateful to the Internal Medicine department for its help in this study.

No conflict of interest

CPC006 Efficacy and safety of antiangiogenic therapy for macular degeneration associated with age

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Purpose

To evaluate the use of antiangiogenics authorised for the treatment of exudative macular degeneration (AMD), and their safety and efficacy.

Material and Method

One year retrospective study in patients with AMD treated with pegaptanib or ranibizumab. We studied the visual acuity (VA) measured by a visual scale of optotypes (the Snellen E test) in the affected eye before treatment and after the third dose. Vision is considered normal when the VA is 0.4 to 1.

Results

In this period we treated 93 patients, 73 (78.5%) with ranibizumab and 20 (21.5%) with pegaptanib. Of them we assessed 53 (57%) patients and 54 eyes as having received three or more doses of anti-angiogenic. 60.4% were women and 39.6% men, mean age 77.9 years (57-91 years). Of the 54 eyes treated, 53.7% had received 3 doses, 40.7% received 4 doses and 5.6% 5 doses. After the third dose the VA had improved in 46.3% of the treated eyes, remained unchanged in 5.5% and got worse in 48.2%. Of the eyes whose VA worsened, 8 (30.8%) received a fourth dose, and one of them was coming to get the 5th dose. As for the presence of exudative signs, it appears that after the third dose 38.9% of eyes had no vascular exudation while those signs persisted in 61.1%. Of these, 23 (69.7%) received a fourth dose and three were receiving a fifth dose. None of the patients had serious adverse events such as uveitis, endophthalmitis or retinal detachment.

Conclusion

- The effectiveness following administration of three doses of antiangiogenesis agent was limited, also if we evaluate the improvement in VA in terms of signs of bleeding.
- Given the high cost and limited efficacy of treatment, there should be criteria for selecting appropriate patients.
- The period of study should be extended
- Intravitreal injection of pegaptanib and ranibizumab is considered

No conflict of interest

CPC007 Development of a pharmacist-designed painformation leaflet for clozapine with increased readability.

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Background

The benefits of educating a patient are clear, but a patient must understand the information they are receiving in order for it to benefit their healthcare [1]. Health Literacy (HL) has been defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [2]. Users of psychiatric services are more likely to have an impaired reading ability [3].

Purpose

To design a user-friendly patient information leaflet (PIL) on clozapine that is appropriate to the health literacy level of the clozapine population.

Material and Methods

All patients receiving clozapine in the Mercy University Hospital (MUH) were eligible for inclusion unless deemed clinically too unwell. The Rapid Estimate of Adult Literacy in Medicine (REALM)[4] screening instrument was administered and scored out of 66. A new PIL was designed for patients using the National Adult Literacy Agency (NALA) approved guide to plain English [5]. This PIL was compared with the manufacturer's PIL and both were assessed for readability using the Flesch Reading Ease Score (FRES) [7] and Flesch-Kincaid Grade Level (FKGL [7].

40 patients completed the REALM with an average score of 60.58 (±8.7). Table 1 shows the results of the readability score for PILs: Table 1: Comparison of readability of the PILs .

	FRES*	FKGL
Company-designed PIL	49.7	10.3**
Pharmacist-designed PIL	62.0	8.1***

*The higher the score, the easier the document is to understand.

**A FKGL of 10.3 equates to an approximate reading age of 15

**A FKGL of 8.1 equates to an approximate reading age of 13 years.

Conclusion

The pharmacist-designed PIL was found to be an easier document to read than the company-produced PIL.

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No conflict of interest

CPC008 Pharmacist-led interventions improve patient's knowledge of clozapine

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Background

Clozapine is an effective antipsychotic used in treatment-resistant schizophrenia [1]. It is considered a last and best option for patients who have responded to, or tolerated, little else [2]. We know that patient knowledge of medication is positively correlated to adherence and hence health outcomes [3] and that pharmacists represent an accessible health professional uniquely qualified to deliver key information and counselling to patients [4].

To improve knowledge amongst schizophrenic patients receiving clozapine through a pharmacist intervention.

Material and Methods

All patients receiving clozapine in the Mercy University Hospital (MUH) were eligible for inclusion unless they were deemed to be clinically too unwell. A questionnaire was designed and administered, by a clinical pharmacist, assessing clozapine knowledge. Questions included: "Do you know why you need to have regular blood tests?" Patients were scored out of 13. A pharmacist-developed patient information leaflet (PIL) on clozapine was provided to all of the participants in addition to advice and counselling on clozapine treatment. Patients were reassessed to determine whether the intervention had improved their knowledge of clozapine. The Statistical package for the Social Sciences (SPSS) Version 15 was used for data analysis. Descriptive statistics include frequencies, percentages and mean values. Means are reported with standard deviation (SD) where appropriate. Bivariate analyses were conducted to determine any statistically significant relationships between varying parameters. A paired samples T-test was used to describe the correlation between the scores obtained at first and second interviews.

Results

Forty four patients (66% male, 70% smokers, 95% unemployed) took part in the study. The average age of the population was found to be 39 years (±11.6). The average score in the questionnaire preintervention was 8.16 which increased to an average of 9.57 post intervention. This improvement was statistically significant (p<0.001).

The pharmacist's intervention led to improved knowledge amongst schizophrenic patients on clozapine.

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No conflict of interest

CPC009 An audit of antifungal prescribing in haematology patients in St. Vincent's Ward, Mater Misericordiae University Hospital

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Background

Invasive fungal infections (IFIs) are a major cause of morbidity and mortality in immunocompromised patients. Antifungal agents are used routinely in haematology patients in the prophylactic, empiric and targeted treatment settings.

Comprehensive evidence-based guidelines on the diagnosis and management of IFIs have been published in recent years. The guidelines in place in MMUH for the use of antifungals in haematology patients were very limited.

Purpose

To investigate the appropriateness of current antifungal prescribing practices in haematology patients in MMUH, with a view to implementing evidence-based guidelines for their appropriate use.

Material and Methods

The audit, which was retrospective in nature, included all haematology patients who received any form of antifungal treatment from January - June 2008 and all those who received empirical or targeted treatment from June - December 2008. All aspects of antifungal treatment were reviewed including indication, dose, route of administration, timing of initiation and duration of treatment. Data was collected using a specifically designed Data Collection Form to record information obtained from patient medical notes and drug charts.

Results

54 haematology patients were included in the audit. These patients had received 150 courses of antifungal treatment.

Areas of prophylactic treatment that were associated with non-adherence were indication (58%), dose (29%) and dosage form (13%).

Areas of empirical treatment associated with non-adherence were indication (10%) and timing of initiation of treatment. In the targeted treatment setting, the duration of antifungal treatment was extended beyond that recommended in a small number of cases.

The total cost associated with inappropriate use amounted to €43,560 in 2008.

Conclusion

Evidence-based guidelines have now been produced in conjunction with Clinical Microbiology and Haematology for the use of antifungal agents in the prophylactic, empirical and targeted treatment settings in MMUH haematology patients.

These guidelines were implemented at ward level in December 2009. Further study will serve to complete the audit cycle in order to assess the impact of the guidelines on antifungal prescribing, associated costs and most importantly haematology patient care.

No conflict of interest

CPC010 Use, effectiveness and toxicity profile of sorafenib in hepatocellular carcinoma

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Background and purpose

Our aim is to analyze use, effectiveness and toxicity of sorafenib in patients diagnosed with hepatocellular carcinoma (HCC) in the Gastroenterology department.

Material and Methods

Patients who started treatment with sorafenib between August and April 2010 were selected. Medical records were checked: BCLC and Child-Pugh scores, etiology of the disease, previous treatments, dose, starting and withdrawal dates of treatment with sorafenib and safety variables. The proportion of patients who complied with the protocol approved by the Pharmacy and Therapeutics Committee was calculated: advanced HCC (BCLC stage C) and preserved liver function (Child-Pugh A and B < 7 points).

Results

27 patients were included to analyze use and toxicity and 32, to calculate overall survival. 88,9% complied with the protocol established by the Committee. Hepatitis C in combination or not with alcoholism was the most common cause of the disease (29,6 and 25,9% respectively). 22,2% had not been previously treated and 40,7% had undergone surgical resection. 40,7% of patients had to stop definitely the treatment due to toxicity (63,6%) and lack of efficacy (36,4%). There was one temporary withdrawal (3,7%) and 29.6% required dose reduction. Diarrhea occurred in 55.6% of patients and skin toxicity, in 66,7%. Transaminase and bilirubin elevations were common (55,6 and 33,3%, respectively). 14,8% of patients developed thrombocytopenia; 14.8%, anemia and 3,7%, leukopenia. 66,7% required antihypertensive and/or diuretic drugs to control hypertension. Overall survival was 83,1% after the first year of treatment and 60,9%, after the second one. 23 patients were still alive at the end of the study.

Conclusion

Palliative chemotherapy in HCC with sorafenib meets largely the protocol proposed by the Pharmacy and Therapeutics Committee. A significant proportion of patients survived when the study was concluded. The toxicity profile matches with the one described in the Summary of Product Characteristics of the drug.

No conflict of interest

CPC011 Evaluation of a pharmaceutical care program in patients with chronic hepatitis B

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Background

Viral hepatitis is a major cause of chronic liver disease and a worldwide public health problem. It is estimated that over 350 million people are infected with hepatitis B virus.

Purpose

To detect, prevent and resolve drug-related problems (DRs) while monitoring patients with chronic hepatitis B (CHB).

Material and Methods

Observational and prospective study from January to December 2009 in patients with CHB who were being monitored in the

Outpatients Pharmaceutical Care Unit in a regional hospital. The data was recorded in a standardised document named "History of Pharmaceutical Care" which included: 1) personal and clinical data from patient, pharmacotherapy data, dietary habits, lifestyle, and analytical and microbiological data; 2) data of the medical staff and clinical service and 3) record of DRPs, their possible causes and the seriousness (Schneider scale), the pharmaceutical interventions and the clinical suitability of those interventions. The information used to complete the document was obtained from the patient's medical history and from the interviews with the patients. Patients received oral and written information. After three months, the patients completed a survey on therapeutic adherence and satisfaction.

Results

21 patients were included (14 men and 7 women). Two patients with CHB presented chronic hepatitis C. Most patients were taking adefovir dipivoxil. Were identified a total of 27 DRPs (1.3 DRP/patient). Types of DRP: safety (62.9%), mainly because of an unsuitable dose/interval and side effects; indication (29.6%), mainly because of therapeutic duplication and effectiveness (7.5%), mainly due to inappropriate drug. Three serious DRPs were detected (asthenia and raised creatinine). The therapeutic adherence was 98%. The degree of satisfaction of the patients was very good at 93%.

Conclusion

The individualised monitoring of patients with CHB made it possible to detect, resolve and inform about a variety of DRPs. In addition, health education given to the patient contributed to a better knowledge of his/her disease and its treatment, encouraging better therapeutic adherence and degree of satisfaction.

No conflict of interest

CPC012 Characterization of the use of intravitreal Bevacizumab in diabetic retinopathy in a central hospital L. Fétal, A. Parola, H. Farinha, F. Falcão

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Background

Bevacizumab is an anti-VEGF (vascular endothelial growth factor). The most studied is VEGF-A, crucial to angiogenesis and vascular permeability and considered harmful to the eye.

Favourable results are reported in patients treated with intravitreal injections of bevacizumab in diabetic retinopathy (DR). Off label use of 1,25mg intravitreal bevacizumab (IB) raises the need for assessment of patients treated.

Purpose

Assessment of the off label use of Bevacizumab in DR.

Material and Methods

Retrospective observational study. Data collection from clinical files and pharmacy records of patients proposed for treatment with IB during the first semester of 2010.

DR patient's descriptive analysis of: demographics, diagnostic eye exams, previous treatments, clinical outcome, and complications.

Results

We evaluated 25 patients, mean age 64.4 years, of which 60% were male. Of the 25 patients proposed to IB, 44% (n=11) had DR. This subpopulation had mean age 64.7 years and 55% were male. In 73% IB was performed.

Eight patients (8/11) have record of performing eye diagnostic exams prior and 7/8 post to IB administration: 55% (n=6) had record of previous panretinal photocoagulation (PRP) and 36% (n=4) of previous intravitreal triamcinolone due to macular oedema (ME) associated with DR. The visual acuity (VA) pre-administration was determined in 88% (7/8) of the patients, and intraocular

pressure in 63% (5/8) of the patients.

During post-administration follow-up, only one patient didn't have any record of VA assessment. Improvement in VA and ME was reported in 50% (4/8) of the patients. Reduced neovascularisation was noted in one patient (1/8) and reduced ME in another patient (1/8). Two patients (25%) showed no improvement after IB. No complications following IB were notified.

Conclusion

The favourable short-term results suggest further study is needed in a larger group of patients with a wider (1year) post-administration follow-up period. No short-term safety concerns were revealed.

No conflict of interest

CPC013 Impact study of the collaboration between pharmacists and emergency physicians in hemorrhagic accidents due to oral anticoagulant therapy (OAT)

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Background

Haemorrhagic accidents due to oral anticoagulant treatment (OAT) are an emergency situation that requires specific and timely treatment with prothrombin complex concentrate (PCC) and vitamin K. It is well described in the literature that adherence to clinical recommendations is not optimal.

Purpose

To describe the management of haemorrhagic accidents due to OAT and evaluate the impact on collaboration between pharmacists and emergency physicians in those situations.

Material and Methods

We conducted a multicentre retrospective analysis of the prescription of PCC in a first period running from 1 January 2007 to 31 April 2008 in four hospitals (3 university and 1 tertiary). In the tertiary hospital, the pharmacists created a new standardised prescription sheet in collaboration with emergency physicians including recommendations. We prospectively analysed the new prescription of PCC in the tertiary hospital in a second period running from 1 May 2008 to 31 December 2009.

Data collected were: demographic characteristics, type of haemorrhage, indication for OAT, reversal therapy (dose and time delay) and patient outcomes.

Results

During the first period, data concerning 256 patients were processed (76±12 y, 53% men). Atrial fibrillation and pulmonary embolism were the main indications for OAT concerning 157 (62%) and 28 (11%) patients respectively. Bleeding was major in 179 (70%) patients, with intracranial bleeding. PCC was prescribed for minor bleeding and elevated INR (without haemorrhage) in 36 (14%) and 10 (4%) cases respectively. Appropriate reversal treatment using PCC (> 20 IU/kg) and vitamin K was used in only 66 (37%) patients with major haemorrhage. In-hospital mortality reached 30%. During the second observational period, data concerning 63 patients were processed (74±9 y, 60% men). Major haemorrhages were observed in 27 (43%) patients, with 13 (20%) intracranial bleeding. The treatment used was significantly improved for 38 (60%) patients (p<0.01). In-hospital mortality occurred in 10 (16%) cases.

Conclusion

To our knowledge, this is the largest patient cohort describing the management of haemorrhagic accidents due to OAT. Collaboration between clinical pharmacists and emergency physicians has greatly improved adherence to clinical recommendations which is so valuable in those emergency situations when lives are at stake.

CPC014 Outcome measures in the treatment of Rheumatic Diseases with biological drugs

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Background

Rheumatic diseases have a large social impact because of their high incidence, economic costs and reduced patient quality of life: the WHO and the UN devoted the decade 2000/2010 to the prevention and treatment of musculoskeletal diseases and rheumatic disorders. For some years now drugs that act on the pathogenesis of the disease (DMARDs or Disease-modifying antirheumatic drugs) have been in clinical practice, in order to try to change the course and to slow down the progression of the disease.

Purpose

This study, conducted by the University Hospital Pharmacy San Martino (Genoa), in collaboration with the Rheumatology Clinic, is part of the monitoring that aims to assess the appropriateness of prescribing biological DMARDs (infliximab, etanercept, adalimumab, anakinra, rituximab, abatacept). Clinical data collected were used primarily to assess the outcome indicators of treatment with biological agents and the result of switching from one biological DMARD to another.

Material and Methods

We examined the Departmental cards (SD), sent to the pharmacy at the beginning of the treatment with biological agents and during the follow-up visits (observation period: 2006-2009), belonging to a sample of 146 patients (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis). In particular, we analysed the values of DAS28 (Disease Activity Score), against the EULAR (European League Against Rheumatism) response criteria.

Results

The mean DAS28 at the start of treatment was 5.74. The mean reduction in DAS28 values between the beginning of the treatment and the last follow-up paper on the card sent to the pharmacy (data available for a total of 81 treatments), was 2.8 points. Switching treatment appears to be a fairly common practice, especially from one anti-TNF to another, due to lack of efficacy or poor tolerance.

Conclusion

The implementation of this prescribing path is an example of pharmaceutical care by enabling interaction with the clinical pharmacist to ensure the patient has effective and safe care.

No conflict of interest

CPC015 Pivotal study on the appropriateness of prescribing antiretroviral therapy

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Background

With limited resources, the pharmacist and the physician have the responsibility to do their ethical and professional best to safeguard patient health, but also to optimise the use of public resources.

Purpose

To assess the appropriateness of prescribing combination antiretroviral therapy (cART). In particular we wanted to monitor the prescribing of High Cost Drugs (HCDs), evaluating whether it was in line with the official therapeutic indications and with the DHHS and / or EACS guidelines.

Material and Methods

The San Martino University Hospital Pharmacy, in cooperation with the Clinic for Infectious Diseases (approximately 800 patients followed), defines the treatment criteria and criteria for collecting the data. These limit infectious disease physicians to prescribing 2 tabs high-cost ARVs for treatment-naive or -experienced patient care. HCDs: darunavir, tipranavir, etravirine, raltegravir, maraviroc and enfuvirtide.

Results

Patients enrolled February - July 2010	Number	HCD	% HCD
Treatment - naïve	15	4	26
From other centres	5	0	0
Recovery from interruption	13	0	0
Switch for tolerability	11	5	45
Switch to simplify	22	4	20
Switch failure	10	7	70
Total	76	20	26

The cART HCD prescribed off-label to the 4 treatment-naive patients was raltegravir + protease inhibitor, because of renal and/or cardiovascular disease. The most frequently prescribed HCDs to treatment-experienced patients were: 9 darunavir, 5 raltegravir, 3 etravirine and 2 maraviroc. Ten patients had virological failure (1.25% of total patients followed).

Conclusion

The Patient Register is a quick way to collect data on the more frequently prescribed treatment. It is a very useful tool suitable for creating a dialogue between doctor and pharmacist. Our intention is to expand the initiative throughout the Region to create a Regional Registry. This will make possible to monitor the therapeutic strategy in such a specialised area, for which Liguria Region has spent approximately EUR 24 million (source: IMS).

No conflict of interest

CPC016 Patient with visceral Leishmania resistant to all treatments used

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Background

A woman aged 27, a native of Colombia, returned to the emergency room with fever and diarrhoea with enteroinvasive characteristics, with very liquid green stools with explosive beginning, and bilious vomiting. The patient had been diagnosed 2 years ago with serious haemophagocytic syndrome of unknown cause (bone marrow and Leishmania antigen negative), after ruling out infection, malignancy and autoimmune diseases. Because of this her spleen was removed and she was given ciclosporin and etoposide.

Purpose

To evaluate the efficacy of treatment in visceral leishmaniasis.

Results

In May 2010 malaise, fever and anaemia continued so it was decided to perform a new bone marrow biopsy and intestinal wall biopsies, this time finding Leishmania. For this reason, ciclosporin and etoposide were suspended and treatment begun with liposomal amphotericin B (5 mg / kg). But after 2 weeks febrile peaks and anaemia were maintained. The anaemia was treated with darbepoetin 300/15 days with good result. Because the response to amphotericin B was poor it was decided to initiate treatment with pentavalent antimony and miltefosine. After 3 weeks, the patient

recovered and the fever, diarrhoea and anaemia disappeared. A new bone marrow aspirate was negative. However the idea is to keep to a monthly dose of pentavalent antimony.

Conclusion

- 1- Treatment with pentavalent antimony appears to be effective in cases of visceral leishmaniasis resistant to amphotericin B.
- 2- It is possible that the haemophagocytic syndrome was secondary to visceral leishmaniasis. It seems less likely that it was an infection due to immunosuppressive treatment as leishmaniasis explains the initial symptoms.

No conflict of interest

CPC017 Role of clinical pharmacist in anticoagulation management

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Background

The use of anticoagulant treatment is expanding among the elderly population. A better understanding of the drugs may lower dose requirements, which may reduce the risk of unanticipated overtreatment and haemorrhage.

Purpose

To identify the most frequent warfarin interactions in hospital drug prescribing and analyse the effects of interactions on the warfarin dose for elderly heart patients.

Material and Methods

In this study patients (age >65) with indications for warfarin treatment from the cardiology department were included from May 2008 to September 2008.

Results

A total of 100 patients (60 male, 40 female) met the study inclusion criteria. The mean age was 69 ± 3 years. Patients received warfarin treatment for the following indications: atrial fibrillation (n = 43), other rhythm disorders (n = 29), cardiomyopathy (n = 21) prosthetic valve (n = 7).

Concomitant other drugs were analysed that were known either to prolong the prothrombin time or international normalised ratio (INR) or interact with warfarin such as amiodarone (25%), statins (13%), anti-inflammatory drugs (aspirin (4%)), proton pump inhibitor (omeprazole (4%)).

In this study we found an inverse correlation between the starting dose of warfarin and the maintenance dose of amiodarone ($r^2 = 0.94$, p < 0.005). When we calculated the dose of anticoagulant for these patients, there seemed to be a maximum 32% mean decrease in the warfarin dose required by the elderly population being treated at the same time with warfarin and amiodarone (200 mg/d).

Conclusion

- Clinical pharmacist collaboration with physicians is important to:
- recognise, analyse and manage potential warfarin drug interactions during admissions;
- prescribe other medicines or change the dose of warfarin based on changes of INR.
- Clinical pharmacists have an important role in educating elderly patients about the potential adverse consequences due to other drugs used with warfarin.

No conflict of interest

CPC018 Visualization of tumor tissue with 5-aminolevulinic acid in malignant glioma

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Background

Malignant glioma is an aggressive tumour of neuroepithelial tissue, with a high recurrence rate and unfavourable prognosis.

Purpose

To describe the experience of using 5-aminolevulinic acid (5-ALA) in 14 patients with malignant glioma, for the display of malignant tissue during their surgical resection.

Material and Methods

A descriptive study was performed in 14 patients with malignant glioma who were given 5-aminolevulinic acid, to distinguish the tumour more clearly and aid its removal. 5-ALA is metabolised to fluorescent porphyrins, especially protoporphyrin IX (PPIX). The formation of PPIX induced by 5-ALA is significantly higher in malignant tissue than in normal brain tissue. Upon excitation with blue light (λ = 400-410 nm), the PPIX is strongly fluorescent and can be viewed with a neurosurgical microscope. The fluorescence emission can be red (corresponding to strong and established tumour tissue) or soft pink (corresponding to infiltrating tumour cells).

Results

Of all patients, 7 were younger than 40 years. Nine were men and five women. Of these, 2 patients were diagnosed with anaplastic astrocytoma, 2 with anaplastic oligodendroglioma and 10 patients with glioblastoma multiforme. All patients were given 5-ALA (20 mg / kg) orally from 2 to 4 hours before induction of anaesthesia. The use of 5-ALA allowed more complete removal of brain tumour during surgery. Brain imaging performed after surgery did not show any visible tumour in any patients. All patients had favourable results, without postoperative complications and most of them did not require a hospital stay exceeding 10 days.

Conclusion

Standard treatment of glioma includes surgical resection, radiotherapy and chemotherapy. Fluorescence induced by 5-ALA was used as an intraoperative marker for malignant glioma tissue in order to improve surgical resection of these tumours, since the more extensive the resection, the greater the chances of survival.

No conflict of interest

CPC019 OFF-LABEL USE OF OCTREOTIDE IN INTESTINAL ANGYODISPLASIA

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Background

Intestinal angiodysplasia is a degenerative lesion of blood vessels of the intestines that can cause gastrointestinal bleeding. Octreotide LAR, a long-acting synthetic somatostatin analogue that reduces splachnic blood flow has seen to be effective in a few cases. Off-label treatments, once approved, can be dispensed from outpatient's pharmacies at Spanish Hospitals.

Purpose

To evaluate Octreotide effectiveness, safety and cost of treatment for patients diagnosed with Angyodisplasia.

Material and Methods

We conducted a retrospective study including patients diagnosed with Angiodysplasia and collected Octreotide LAR at the Pharmacy department, from 2008 to 2010. Data were collected from revision

of clinical history and from the out-patient database prescription program: demographic data, blood requirements, bleeding episodes, haemoglobin (Hb) levels and cost. Also, the pharmaceutical care given to these patients was classified into first appointment and its successive appointment, in which the treatment was monitored.

Results

During the follow-up period, 6 patients with a mean age of 71 years (85% women) received at least 5 doses of Octreotide (10 to 20 mg), administered subcutaneously once a month. At the beginning of the treatment, all patients had Hb level bellow lower normal range and a medical record of serious gastrointestinal bleeding. After treatment with Octreotide. There were significantly decreased blood requirements in 4 of them, as well as the frequency of bleeding episodes. No side effects developed in any subject. In all our patients where octreotide was effective, the treatment is ongoing. The average cost per patient/month is $964,5 \in$.

Six first appointments and 76 follow-on appointments were made from the Pharmacy department.

Conclusion

Octreotide seems an effective and safe drug in treating angiodysplasia. Pharmacist contribute to the follow-up of these offlabel treatments (specially when duration recommended for the drug is still undetermined), therefore to its efficiency.

No conflict of interest

CPC020 evaluation of the necessity of total parenteral nutrition in patients undergoing autologous hematopoietic stem cell transplantation

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Background

Total parenteral nutrition (TPN) in often needed as supportive treatment for patients undergoing autologous hematopoietic stem cell transplantation (AuHSCT).

Purpose

Toevaluate the need for and the cause of TPN initiation in patients undergoing AuHSCT in the immediate post-transplant period, considering the type of haematological pathology and preparative treatment received.

Material and Methods

Retrospective study of patients undergoing AuHSCT from January 2006 to December 2009. Clinical histories, electronic medical files (Clinic) and pharmacy nutrition records were reviewed.

Results

During this period, 99 AuHSCTs were performed.

Diagnosis: 38 Multiple Myeloma, 38 Non-Hodgkin's Lymphoma, 13 Hodgkin's Disease, 1 Acute Lymphoblastic Leukaemia, 2 Acute non-Lymphoblastic Leukaemia, 1 Chronic Lymphoblastic Leukaemia, 3 Ovarian germ cell tumour, 1 Primitive neuroectodermal mediastinal tumour, 1 Neuroblastoma, 1 Medulloblastoma.

Median age at transplant: 53 years (3-65).

38 AuHSCT (38.4%) required TPN, average duration: 11.8 days. In all cases, the main reason why TPN was necessary was mucositis: 8 degree I-II (mucositis + moderate digestive toxicity), 8 degree III, 22 degree IV.

Treatment regimens associated with TPN:

23 BEAM: carmustine 300 mg/m² + etoposide 800 mg/m² + cytarabine 800 mg/m² + melphalan 140 mg/m² (incidence 49%: 23/47 of patients treated), 7 melphalan 200 mg/m² (23%: 7/30), 1 melphalan 100 mg/m² (50%: 1/2), 1 Total Body Irradiation (TBI) 12 Gy + cyclophosphamide 120 mg/Kg (50%: 1/2), 2 carboplatin AUC<4 x 5 days + etoposide 1500 mg/m² + ifosfamide 10000

 mg/m^2 (100%: 2/2), 1 etoposide 60 $mg/Kg + melphalan 140 <math>mg/m^2$ (100%: 1/1), 1 busulfan 480 $mg/m^2 + melphalan 140 <math>mg/m^2$ (100%: 1/1), 1 thiotepa 900 mg/m^2 (100%: 1/1).

Conclusion

In clinical practice, TPN is started when the development of gastrointestinal toxicity interferes with regular oral nutrient intake, and continues until toxicity resolves. Its use has been higher in allogeneic compared to autologous transplantation due to complications. It is estimated that TPN can be indicated in 37% of AuHSCT without previous TBI and 50% of AuHSCT with irradiation. The results obtained with our study population confirm these literature data.

No conflict of interest

CPC021 Pharmacists and ophthalmologists in the treatment of autoimmune ocular inflammatory diseases. Example of the collaboration in the Hospital of Parma

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Background

Autoimmune disorders can give rise to sight-threatening ocular inflammation, often chronic or recurrent. Steroidal anti-inflammatory treatment has serious side effects and therapeutic options are limited, especially for uncontrolled phases of disease. Combined immunosuppressive agents can be used in a steroid-sparing regimen.

Purpose

To evaluate the safety and efficacy of steroid-sparing intravenous treatments compounded at the Pharmacy Service to control severe or recurrent ocular inflammation in patients with autoimmune disorders.

Material and Methods

Since 2008 treatments have been compounded at the Antiblastic Centralised Intravenous Admixtures Unit (UMaCA) of the Pharmacy Service. Software has been used for the prescription, compounding and administration.

Treatment schedules for autoimmune ocular disorders in the UMaCA database contain methotrexate (T3), cyclophosphamide (T4), rituximab, infliximab, combined with steroids if needed, administered intravenously in a stepladder sequence and discontinuously to minimise toxicity, according to disease severity. Patients were referred by the Inflammatory and Autoimmune Diseases Service of the Ophthalmology Institute. Patients treated in the period Oct 2008 - May 2010 were examined.

Results

In the period analysed, 44 patients (2.6% of the total) with inflammatory ocular involvement were treated (median age 43 years, range 20 - 80y, 19 males and 25 females).

28 patients received cyclophosphamide (12 combined with methotrexate), 15 methotrexate alone, 3 patients were given rituximab and 1 infliximab. A total of 432 treatments were compounded for these patients. The absolute percentage (1.9% of the total in UMaCA) of these therapies was low compared to antitumor treatments, but it was significant, given the rarity of these diseases. In 43/44 patients treatment was effective in achieving inflammatory quiescence (control of inflammation, visual acuity; only 1 patient did not experience an improvement.

Conclusion

Pharmacist and ophthalmologist collaboration in Parma make possible an immunomodulating intravenous treatment that is safe

and effective. The number of patients coming from other regions of Italy and even from foreign countries (67%) underlined the importance and uniqueness of compounding treatments in a centralised pharmacy service not only for onco-haematological patients.

No conflict of interest

CPC022 Clinical intervention audits ñ Why bother?

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Background

Clinical pharmacy services have been provided to all wards in the MMUH since 1994. Clinical pharmacists frequently make reactive interventions, which are any action by a pharmacist that directly results in a change to a patient's management or therapy (1). However, time and resource constraints have limited the auditing and assessment of this.

Purpose

Categorise day-to-day interventions performed by MMUH clinical pharmacists.

Produce a robust, easy-to-use 'Clinical Intervention Audit Tool'.

Pilot the tool and estimate annual clinical pharmacist intervention numbers.

Compile reports based on information obtained in the audit and to establish what information could be gained from routine intervention recording.

Material and Methods

Literature review.

Cross-sectional study to identify pharmacists' top interventions.

Design and pilot data collection form.

Collection of data by each clinical pharmacist for one day during a four-day data collection period.

Analyse and evaluate the data using Microsoft Excel.

Results

The collection tool developed was based on the observation of clinical pharmacists' top interventions: checking patient details, prescription and administration problems, medication enquiries and patient counselling, stock issues and monitoring.

The tool can generate reports; top drugs, classes of drugs and specialties involved in pharmacists' interventions.

Total number of interventions = 546 (113 patients); Average = 4.83 per patient.

Annual number of interventions was extrapolated to be 77,744 based on discharge statistics.

183 interventions related to prescription & administration, involving 108 drugs.

Anti-infectives and anticoagulants were the drug classes that required most intervention.

Orthopaedics was the specialty that required most prescription & administration interventions.

Conclusion

Information generated from recording clinical pharmacists' interventions is highly valuable and should be performed on a routine basis.

It provides information on the impact of clinical pharmacy services on local prescribing and drug administration practices, the educational needs of staff and underscores the need for continuous clinical audit.

No conflict of interest

CPC023 Clinical experience with once-a-day pill administration of erlotinib in Non Small Cell Lung Cancer patients

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Background

Erlotinib, an orally available inhibitor of Epidermal Growth Factor Receptor, is approved for treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) following failure of initial chemotherapy[1].In our study, the most common histology was adenocarcinoma (73.9%). 91% were non-smokers.

Purpose

To describe our experience with erlotinib use in NSCLC, its safety and effectiveness, contributing to the information presented by large randomised clinical trials.

Material and Methods

Descriptive and retrospective analysis of all patients treated with erlotinib for NSCLC from October 2008 to June 2010. The information was collected from the patients' clinical files.

Results

Twenty-three patients were included. Median age was 72 years (range 50-86). All patients presented with stage IV disease. Erlotinib (150 mg/day) was given first-line in 6 (26.1%), second-line in 2 (8.7%) and third-line in 15 (65.2%) patients. Median duration of treatment was 14 weeks (range 1.0-47.4). Fifteen (65.2%) patients stopped treatment due to disease progression, 5 (21.7%) died during treatment, 2 (8.7%) stopped taking erlotinib because of treatment-related adverse events (AE) and 1 (4.3%) are continuing on the treatment. Seventeen patients (73.9%) experienced treatment-related AEs. Skin rash and diarrhoea were reported the most (70.6% and 64.7% respectively). Median overall survival from initiation of erlotinib was 6.3 months (range 0.5-16.3). By the end of the study period 15 patients were alive.

Conclusion

The decision to use erlotinib first-line in 6 patients was due to their age (all except one were ≥82 years old) and limiting co-morbidities. As in other studies[3], AEs related to erlotinib were responsible for dose reduction and treatment interruption/ discontinuation so clear information must be given to patients before they start treatment. Median overall survival was similar to results found in the literature [1,2]. New therapeutic options are still needed for patients who progress rapidly after first-line therapy or have poor performance status. No conflict of interest

CPC024 Patients with malignant tumors of the larynx, pharynx and esophagus: analysis of nutritional status during hospital stay

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Background

In cancer patients, poor nutritional status is associated with a decreased quality of life and survival. Vomiting caused by chemotherapy may lead to nutrient losses and the neoplastic processes cause increased energy needs. Patients with tumors of larynx or esophagus are at increased risk of malnutrition because the location of the tumor causes dysphagia and odynophagia. In many cases the patient has a total inability to swallow solid foods, so it reduces the intake of nutrients. The aim of this study was to detect possible cases of malnutrition in these patients and determine the participation of the Nutrition Area of the Pharmacy Service.

Materials and Methods

During 4 months, we selected those patients admitted to the hospital with tumors of the larynx, pharynx and esophagus. For each patient were analyzed biochemical parameters for nutritional assessment (albumin, lymphocytes and total cholesterol) and body mass index (BMI) was calculated. Three scales of nutritional status were established: mild malnutrition (albumin: 3'5-2'8 g/dL; lymphocytes: 2000-1200 n°/mm³; cholesterol: 179-140 mg/dL), moderate malnutrition (albumin: 2'7-2'1 g/dL; lymphocytes: 1200-800 n°/mm³; cholesterol: 139-100 mg/dL) and severe malnutrition (albumin: <2'1 g/dL; lymphocytes: <800 n°/mm³; cholesterol: <100 mg/dL).

Results

A total of 26 patients were recorded. Analyzing the values of the nutritional parameters it was found that all patients fulfilled at least one criterion of mild malnutrition, 77% showed criteria of moderate malnutrition and 23% showed levels of severe malnutrition. Only 54% of patients were treated with specialized nutritional support receiving an average of 1800 kcal per day.

Conclusion

There is a high rate of malnutrition during the hospital stay. It should establish better nutritional screening tools at hospital entry, and a complete nutritional support to all patients requiring it. The Pharmacy Service management would be useful to achieve an optimal nutritional status of these patients.

No conflict of interest

CPC025 Alcohol-free Benzydamine mouth gel recommendations and experiences in oral mucositis

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Background

Chemotherapy- and radiotherapy-induced oral mucositis (OM) represents a therapeutic challenge frequently encountered in cancer patients. More than 40 different substances were evaluated in terms of prevention and treatment of mucositis. The implementation of an alcohol-free benzydamine mouth wash in pharmaceutical care is discussed. Benzydamine is one option supported by an evidence base.

Material and Methods

A mouth gel with 0.15% benzydamine hydrochloride has been developed, which is in line with recommended requirements (alcohol-free preparation, no growth factor, easy to use oral, pleasant taste and consistency, moderate price) and has been analyzed concerning its safety and effectiveness, using both subjective and objective measures.

Results

Its lead compound alcohol mouth gel contains benzydamine HCl, sodium hydrogen carbonate, saccharine sodium, polysorbate, polyvidone, glycerol and hydroxyethyl cellulose. The evaluation of OM by longitudinal survey in the Head and Neck Clinic (n=10;20 % female, 48-65 y) was recorded before cytotoxic therapy (T0) and at day 7 (T1). The Brief Pain Inventory pain intensity score decreased (T0:12.6 \pm 4.1; T1: 9.4 \pm 3.0). The pain during a 24-hour recall period was reduced by 36.5 \pm 9.4 %. Patients reported less use of analgesic medications (non-opioid medications). The mouth gel was applied undiluted on average 4 times per day (Min: 3, Max: 5). Patients developed mostly OM-degree 1 (WHO, 80%).

Conclusion

Health-related quality of life is improved by reducing pain. This new intervention for the prevention and treatment of OM could ultimately lead to reduced patient suffering and improve cancer treatment outcome. The 0.15% alcohol-free benzydamine mouth wash can be produced easily from any pharmacy. No conflict of interest.

CPC026 Pharmaceutical care in Cardiology

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Background

Heart failure (HF) is a severe chronic condition that requires close monitoring and polymedication. Therefore, a clinician pharmacist (CP) may play an important role in supervising the treatment.

Purpose

- · To develop pharmaceutical care in Cardiology.
- To optimise HF treatment in close collaboration with the general practitioner (GP).

Material and Methods

Role of the CP:

- · Complete drug anamnesis upon admission
- Proactive analysis of treatment and preparation of discharge plan during admission
- At discharge: ambulatory care setting, educate patient in treatment schedule, dietetic rules and lifestyle principles.
- Follow up one month after discharge to assess changes of treatment.

Variables studied:

Patients and GPs participated in phone interviews and filled in questionnaires to assess adherence to the CP's recommendations and level of satisfaction.

Results

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Population

Between 11 February and 7 October, 104 patients with a diagnosis of HF were hospitalised, of whom 78 (75%) agreed to participate in the study. Recovery rate for ambulatory follow up was 80.1% for patients and 66.6 % for GPs.

Adherence

All patients but only 1/3 of GPs reported following the recommendations established by the pharmacist in terms of drug doses, schedule of intake and any other relevant adaptation of the treatment.

Satisfaction

Patients reported a better understanding in the treatment strategy, drug-specific information, and appreciated the availability of the CP. Likewise, GPs found the CP's interventions valuable complete with improvement of patient's adherence in half of the cases.

Conclusion

The integration of a CP and the development of pharmaceutical care in a specialised HF Clinic improves HF management through better adherence to treatment. This supports the need for a specific CP consultation.

No conflict of interest

CPC027 Comparative effectiveness of XELOX versus XELOX plus Bevacizumab as first-line chemotherapy for metastatic colorectal cancer

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Background

The addition of bevacizumab to chemotherapy based on fluoropyrimidines and oxaliplatin regimens has shown to improve progression-free survival (PFS) in patients with metastatic colorectal cancer (MCRC) ¹.

Purpose

The aim of our study is to evaluate effectiveness of bevacizumab added to first-line chemotherapy based on capecitabine and oxaliplatin (XELOX) in patients with MCRC.

Material and Methods

Retrospective observational study of patients with MCRC treated with XELOX or XELOX plus Bevacizumab (XELOX-AV) between January 2009 and December 2009 in a general teaching hospital. Data were recorded from the medical report and oncology pharmacy software (Oncobass® software database). Age, sex, diagnosis date, metastasis location, previous drug use and number of cycles received were analysed.

Effectiveness was measured as PFS. Monitoring response to treatment was based on medical imaging techniques and biochemistry analyses. Statistical analysis was performed with SPSS.

Results

11 patients with MCRC were prescribed XELOX. Male/female ratio: 7/4; median age=73 years. Median number of cycles received: 7 (range 1-8).

16 patients were prescribed XELOX-AV. Male/female ratio: 10/16; median age=63,5 years. Median number of cycles received: 6,5 (range 1-9).

Dose reduction or stopping therapy was necessary in 27,27% of patients in XELOX arm, and in 37,50% of patients in XELOX-AV arm. In both arms, most of these cases were attributable to oxaliplatin-induced peripheral neuropathy or capecitabine-induced gastrointestinal toxicity.

The Kaplan-Meier analysis was used to estimate survival. The median PFS duration was 181 days (range 14-365) with XELOX versus 133 days (range 53-337) with XELOX-AV.

Log-rank, Breslow and Tarone-Ware tests were used to compare data for PFS between the two arms of treatment. No statistically significant differences were observed.

Conclusion

In our study, both treatment options have shown similar effectiveness and, contrary to other authors' conclusions, our results cannot demonstrate that the addition of bevacizumab to a XELOX regimen improves PFS in patients with MCRC.

No conflict of interest

CPC028 Effectiveness of antiretroviral therapy and prophylaxis with zidovudina in the vertical transmission of HIV E. Lacalle Fabo, S. Berisa Prado, M.T. López Mancha, E. Pellejero Hernando, A. Fero Urigüen, G. Elizondo Rivas, J.J. Elizondo Armendáriz, F. Marcotegui Ros

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Background

According to GESIDA the risk of HIV vertical transmission (VT) from mother who had taken prophylaxis for HIV is about 1.5% of newborns.

Purpose

Evaluate the effectiveness of antiretroviral therapy (ART) during pregnancy and delivery prevention of VT in a maternal hospital.

Material and Methods

Retrospective observational study on all HIV-positive patients who received prophylaxis with intravenous zidovudine at the delivery, from January 2009 to February 2010 (13 months). The data was obtained from electronic clinical history.

Results

We collected a total of nine patients with a median of 34 years old. In one patient infection was diagnosed at the time of pregnancy, the others patients were already receiving ART. CDC clasification: Grade A2 55.5%, Grade B2 22.2% Grade A3 11.1% and grade C3 11.1%. Viral load (VL) at the time of pregnancy: 6 undetectable, 5 of them remained undetectable until the time of delivery. The VL median (range) of the other 3 patients was: 70102 copies/ml (106-167975 copies). All patients had undetectable VL at the time of Following the recommendations SPNS/GESIDA/SEGO/AEP 4 patients were treated with 2 NAs plus 1 IP, 5 patients with 2 NAs plus 1 NN. In one patient EFV was changed to NVP for its contraindication in pregnancy.The proportion of vaginal delivery vs cesarean section was 5 - 4. All patients were treated with intravenous ZDV according to current recommendations, as well as newborns with oral ZDV during the first 6 weeks. At this moment all children virological test are negative.

Conclusion

An appropriate monitoring of ART is necessary during pregnancy to minimize the VL at the time of delivery to avoid VT. In our study it has been achieved 100% effective in virological tests, although we must wait until children are 18 months for confirmation of HIV antibody negative (serological).

No conflict of interest

CPC029 Multidisciplinary approach of the team haematologist - clinical pharmacist for the treatment of idiopathic thrombocytopenic purpura with romiplostim

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Background

Italy

Romiplostim is a fusion protein analogue of thrombopoietin and could represent a treatment option for patients with idiopathic thrombocytopenic purpura (ITP) refractory to standard treatment.

Purpose

To describe the efficacy and safety of romiplostim in 4 patients with ITP in our centre.

Material and Methods

We report the cases of 4 patients with ITP refractory to corticosteroids and immunoglobulin, treated with romiplostim to achieve a platelet count of at least 50 x $10^9/L$ (threshold count – TC). The treatment protocol contemplates a dose escalation phase (range: 1-10 mcg/kg, with weekly increments of 1 mcg/kg) followed by a custom constant dose phase once the TC has been achieved. Pharmacists collected effectiveness and safety data and collaborated in organising administration schedules and drug reconstitution procedures, in order to optimise the number of vials used.

Results

All patients were treated according to the protocol.

Patients 1 and 2 have reached their constant dose phase.

Patient 1 responded well to 1 mcg/kg weekly or fortnightly after splenectomy reaching normal platelet count (total treatment weeks, TTW 30). Patient 2 needed to increase dose to 10 mcg/kg weekly to reach and maintain the TC (TTW 30).

Patients 3 and 4 are currently in their dose escalation phase.

Patient 3 at TTW 7 has not yet achieved the TC and is still increasing the dose. Patient 4 at TTW 17 is showing a discontinuous response even with doses of 9 mcg/kg weekly.

Romiplostim was well tolerated in all cases. Patient 1 had thrombocytosis after administration of romiplostim concomitantly with splenectomy and was treated with Low Molecular Weight Heparin and acetylsalicylic acid.

Conclusion

In our experience, romiplostim could be an effective and safe treatment for ITP. Haematologists and pharmacists will follow up to detect late adverse reactions and confirm long-term maintenance of response.

No conflict of interest

CPC030 Obstructed nasal breathing after propranolol intake in infants

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Background

Propranolol is a nonselective beta-blocker, used for various indications in infants such as long QT syndrome or blue spells in tetralogy of Fallot.

Two different parents reported on an adverse effect (AE) under propranolol treatment which is not described in the Swiss summary of product characteristics (SSPC).

Case Reports

Case 1: Female (6 weeks), with long QT syndrome and congenital hypertrophic cardiomyopathy treated with propranolol mg/kg/day). Her parents described an obstructed nasal breathing sounding like a snore that occurred always shortly after propranolol intake and lasted for several minutes.

Case 2: Female (3 months), with tetralogy of Fallot treated with propranolol (5 mg/kg/day). Her parents reported on raspy breathing because of nasal congestion that occurred immediately after administration of propranolol and lasted for about 30 minutes. After repair of her heart defect, propranolol was discontinued and the symptoms disappeared.

Conclusion

The clinical observations in these two infants suggest a possible relation between propranolol intake and obstructed nasal breathing. In both patients the symptoms were limiting for the patients and impressing for the caregivers. Progressive nasal obstruction in infants may result in respiratory distress because breathing depends on nasal patency at that age. This clinically important AE is not mentioned in the SSPC which is possibly due to the irrelevance of the symptom in adults and the lack of safety studies in children. We suggest an opening of the reporting system through pharmacovigilance by including also mild AE in infants in order to recognize drug toxicity in this vulnerable patient population.

No conflict of interest

CPC031 FAILURE TO REACH NUTRITIONAL GOALS: CAUSES AND EFFECTS

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Background

There is a high prevalence of hospital malnutrition associated with increased morbidity and mortality

To determine why and how many patients do not reach their nutritional goals (NG) in a group of hospitalized patients receiving enteral nutrition (EN).

Material And Methods

Cohort study including all patients who started EN between January and May 2010. Using the following variables: age, sex, height, initial weight/final, initial BMI/end balances, disease history, type of nutrition, mode and method of administration of nutrition, days of nutrition, reasons for beginning/ending and changes in nutrition, laboratory, cultures, diagnostic tests and concomitant medication. The NG was set to reach 25-30 kcal/kg/day for three days with nutritional support. We excluded patients who received nutrition for fewer than 5 days.

Results

Of the 30 nutritional cases reviewed, 19 (63.3%) were analyzed. Age, weight, height and BMI at the beginning of nutrition (standard deviation = SD) were respectively 65 (SD=16), 69 kg (SD=12.85), 167.1 cm. (SD=7.9) and 24.9 kg/m2 (SD=3.9). The average NG was 1725-2070 kcal/day. The most prevalent pathology was cancer (31.5%) followed by gastrointestinal problems (21.05%). Low intake, presence of dysphagia and episodes of pancreatitis were the most common nutritional causes. All patients started continuous infusion of EN and only 13% continued via a bolus. 63.1% of patients achieved their NG and out of these 50% maintained it. 54.54% discontinued the nutrition in a timely manner prior to interventions or different diagnostic tests and therefore did not achieve their set NG. For 30.8% of the patients who reached the NG but did not maintain it, this was due to the onset of diarrhea. 21% of patients in the study died during the course of it. Of these, 75% were critically ill patients, and only 50% reached their NG.

Conclusion

The interruption of nutrition for the purpose of testing/interventions is the most common reason for not reaching the NG. Not reaching the NG may be associated with worse clinical development for the patient. This problem can be solved by being aware of its existence and preventing its occurrence by following protocols that define the fasting time required for each procedure.

No conflict of interest

CPC032 Higher doses of Vitamin C may be needed to affect outcome in severe head injury

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Background

Increased production of free radicals and reactive oxygen species leading to oxidative stress appears to play an important role in the pathogenesis of ischemic, hemorrhagic and traumatic brain injury. Although effectively proven in experimental animal studies, no controlled randomized clinical trials have evaluated effectiveness different dosages of the most-available antioxidant, vitamin C, on outcome of brain injury. In this study, we tried to evaluate the effect of two dosages of this compound on mortality, patient outcome, and evolution of peri-lesional edema in severely head-injured patients.

Material and Method

We performed a multicenter, randomized, double blind, placebocontrolled trial including adult patients with severe head injury (GCSs=8 or less) and with the radiologic diagnosis of diffuse axonal injury. Eligible patients were randomized into four groups receiving any of the following protocols for seven days: Group A: low dose vitamin C (500 mg IV daily); group B: high dose vitamin C (10g IV on admission day and the forth day, followed by a 4g IV daily for the remaining three days); Group C: placebo. All patients were managed based on an ICP-targeted strategy. Multiple parameters including daily level of consciousness, diameter of the peri-lesional edema/infarction, length of hospitalization, Glasgow outcome scale on discharge and after two and six months of follow-up were registered.

Results

Seventy-five patients (62 male, 13 female) were randomized (25 in each group) and 91% attended the follow-up session at 2 and 6 months. There was no significant difference in mortality rate (28% the overall mortality rate). Outcome at discharge and follow-up were not different in any groups (P=0.14). Length of hospitalization was non-significantly prolonged in the placebo group (P=0.08). High-dose vitamin C stabilized or reduced the diameter of peri-lesional edema/infarct in 68% of patients (P=0.01). No adverse effects related to the vitamin dosing and administration occurred.

Conclusion

We could also find a beneficial effect of high dose vitamin C on stabilization of the peri-lesional edema in these patients.

No conflict of interest

CPC033 NATALIZUMAB: EFFECTIVENESS AND SAFETY AFTER TWO YEARS OF USE

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Background

Natalizumab seems to reduce risk of progression of disability and frequency of relapses in patients with relapsing-remitting multiple sclerosis (RRME)

Purpose

The aim is to evaluate the effectiveness and safety of natalizumab's treatment after two years of use

Material and Methods

We conducted a retrospective observational study for 24 months. Several variables were studied, including age, previous treatments, number of doses, nuclear magnetic resonance (NMR) images, EDSS (Expanded Disability Status Scale) and adverse reactions during and after infusion were studied. The effectiveness was quantified through appearance of relapses and evolution of NMR and EDSS scale. Safety was analyzed by intolerance to the infusion and other adverse effects

Results

11 patients, between 24 and 58 years old, RRME diagnosed with high activity or quick progression were treated. Patients have previously used interferon beta 1A, 1B or glatiramer, and had 2 to 6 in EDSS scale before the starting of natalizumab. Patients received a dose of 300 mg q4w by 60 minutes infusion; monthly analytical control and NMR after 12 months were made. 190 doses were administered, with an average of 17,2 administrations per patient (range 11-22).

During the treatment a new outbreak was detected in two patients and the evolution of the EDSS and NMR showed neurological stabilization in 10 patients. An hypersensitivity reaction was seen in a patient, but it was solved and not was repeated in following doses using a slower rate of infusion (90-120 minutes). Other adverse effects were fatigue, erythema, transient rising in transaminases, immunosuppression and leukocytosis

Conclusion

Absence of relapses (with two exceptions) and stabilization of the disease were shown during natalizumab's use. Nevertheless, experience is poor to know the real therapeutic place of natalizumab in RRME's treatment yet.

Hypersensitivity associated to infusion was seen in one patient, and it was solved reducing the administration rate to 90-120 minutes

No conflict of interest

CPC034 Drug use and drug interactions as potential cause of gastro-intestinal haemorrhage

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Background

Many drugs are known to cause gastro-intestinal (GI) haemorrhage. This risk increases if two or more of these drugs are combined

Purpose

To check whether patients who were treated for GI bleeding in a 1000-bed hospital had taken such medications, and to prove the role of gastric acid reducing drugs.

Material and Method: the records of 130 patients who had been admitted to hospital due to GI haemorrhage were checked retrospectively for the following risk factors: older age, sex, smoking habit, alcohol consumption, insufficient kidney and/or liver function, impaired coagulation and intake of drugs known to cause GI bleeding (as nonsteroidal anti-inflammatory drugs, platelet aggregation inhibitors, oral anticoagulants, serotonin reuptake inhibitors, glucocorticoids, preparations containing ginseng, gingko or garlic) prior to hospital admission. The bleeding localization, any other gastro-intestinal impairment or diseases in the patients' anamnesis as well as drugs used to inhibit or reduce gastric acid secretion were also taken into account.

Results

The haemorrhage incidence increased with age, correlating with reduced function of kidney and/or liver but no gender differences were found. 32% had GI diseases, 30% were smokers. 47% of the patients were treated with gastric acid reducing drugs. 79% took "risk drugs" prior to the incident; 55% of these patients even received a combination of two or more of these drugs. In contrast to other authors who showed that in 80% bleeding is localized in the upper GI tract, 47% of our investigated patients had haemorrhage in the lower GI tract. In nearly half of the patients who had taken gastric protection drugs, the bleeding localization was found in the lower GI tract.

Conclusion

Patients under therapy with drugs known to cause bleedings should be closely monitored for signs of GI damage. Pharmacists should give advice how to substitute potentially harmful drugs in patients showing any other risk factor for GI haemorrhage.

No conflict of interest

CPC035 Off-label plasma derivates use in a general hospital: retrospective study

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Background

The clinical use of plasma derivates is a current practice in an hospital institution. The hospital center (CHLO) does not have instituted guidelines concerning the prescription of this drug class, which might benefit the prescription act. The aim of our study was to determine the proportion of off-label prescriptions in plasma derivates in one of the three hospitals that constitute the center - S. Francisco Xavier.

Material and Methods

All the prescriptions of plasma derivates were evaluated over a 30-month period (January 2008 to June 2010) to determine whether they were used in an "approved" or "off-label" condition according to the summary of product characteristics (SPC).

Of all available plasma derivates, only albumin and Immune Globulin Intravenous (Human) (IGIV) were considered for this study.

Results

A total of 1321 plasma derivate prescriptions were analyzed, corresponding 1050 to albumin and 271 to IGIV. The albumin and IGIV off-label prescriptions were 403 (38%) and 48 (18%), respectively. In a global evaluation, over a third of all prescriptions – 451 (34.19%) – did not followed the terms of marketed authorization (SPC).

Conclusion

The study main limitation concerned the difficulty in understanding the uncompleted clinical justifications. However, it showed that off-label use of plasma derivates was frequent in this hospital. The final results also revealed a higher off-label utilization of albumin compared with IGIV. In order to overcome the well-known disadvantages of off-label drug uses, guidelines implementation should be considered, once it would help to identify the clinical conditions where these drugs have a well established risk-benefit ratio. With therapeutic rationalization both patient and institution will benefit.

No conflict of interest

CPC036 Genetic variation in renin-angiotensin system genes and cognitive defect in dialysis patients

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Background

Neurocognitive defects have been documented in dialysis patients (Murray et al., 2006). Such effect may affect a patient's decision regarding medical therapy and dialysis process, as well as medication compliance.

Renin angiotensin antagonist drugs (RAA) such as angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor II antagonist (AIIA) may have cognitive improving properties in dialysis patients. Limited studies have been carried out to investigate the role of renin-angiotensin system (RAS) gene polymorphisms in depression (Saab et al., 2007) but none in cognitive impairment.

Purpose

The aim of this study is to replicate own earlier finding that chronic kidney disease patients have improvement in neurocognitive performance when RAA drugs are used as opposed to other antihypertensives and to investigate the possible contribution of RAS polymorphisms in this improvement.

Material and Methods

A total of 53 (18-60y) Saudi dialysis patients and 42 healthy blood donors were examined for RAS gene polymorphisms. RAS genes tested were AT $_1$ R (A1166C), AT $_2$ R (C3123A), ACE I/D, AGT (M268T), and AGT (T207M) using polymerase chain reaction and agarose gel electrophoresis.

Of 53 dialysis patients, 13 patients were using RAA drugs (RAA group) and 40 patients were on other type of antihypertensives (non-RAA group). Dialysis patients were also examined neurosychologicaly using battery of 5 cognitive tests: the Rey Auditory-Verbal Test, the Rey-Osterrieth complex figure, semantic verbal fluency, letter cancellation, and digit symbol substitution.

Results

The genetic distributions among dialysis patients and healthy control as well as RAA and non-RAA group were similar. Furthermore, within dialysis patients, RAA patients appeared to score more highly on neurocognitive tests than the non-RAA group

although the differences failed to achieve statistical significance. Among all covariables (RAS genotypes, age, sex, education, RAA drugs, DM, and smoking) the reported significant association to cognitive function was only with education (OR 1.35 [1-1.8]).

Conclusion

This study was unable to find a significant association between RAS genotypes and cognitive performance in dialysis patients treated with RAA and non-RAA antihypertensives.

References

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No conflict of interest

CPC037 Abatacept and Rituximab in rheumatoid arthritis refractory to TNF therapy: a one-year overview of the prescriptions.

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Background

Rituximab (Rtx) and Abatacept (Abt) are both indicated in active rheumatoid arthritis (RA) after failure of TNF therapy.

Purpose

To assess (i) their clinical use and (ii) the feasibility of an economic study.

Material and Methods

Retrospective and systematic review of all first administration of Abt or Rtx for RA, in one rheumatology department over 12 months. Patients were considered in a single group.

Results

22 patients received Rtx and 15 Abt. During the first six months, the Rtx/Abt ratio was 14/5 and during the last six months 7/10. Median age was 52 years [28-75] in the Rtx and 50 years [32-81] in the Abt group.

Median period with RA was 13 years in both groups; DAS28 were 5.3 [3.9-7.7] and 5.4 [3.7-8.7] in the Rtx and Abt groups respectively.

Prednisone was added at 6.5 mg and 6.8 mg/ day with Rtx and Abt. Three [1-6] versus 4 [2-6] DMARDs on average and at least 2 anti-TNFs had been tried in 81.8% vs.. 86.6% of patients in the Rtx and Abt groups. The choice of therapy was defined as: decision of patient and/or physician (40.9% for Rtx versus 6.7% for Abt), associated auto-immune pathology (23% vs. 0%), prior intolerance to or failure of the other biotherapy (4.5% vs. 73.3%); other reason (27.3% vs. 20%).

Conclusion

Three patients per month were initially treated with Rtx or Abt. The characteristics were similar between the groups. The more recent license of Abt explains the imbalance. It was first used as an alternative in patients who were in therapeutic failure including Rtx. Today, its efficacy and safety were well known explaining the Rtx/Abt ratio in recent months.

Thus, comparative studies are justified. Due to the chronicity of the disease and dissimilar pharmacological actions, the prior use of Rtx probably does not affect Abt response. Therefore, a cost-effectiveness analysis is reasonable in this cohort.

CPC038 Assessment of overall cost treatment of abatacept and rituximab in arthritis rheumatoid

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Background

Rituximab (Rtx) and abatacept (Abt) are both licensed in rheumatoid arthritis (RA) refractory to anti-TNF. Rtx is administered by infusion every 6 months and Abt every month.

Purpose

The aim of this study was to evaluate the one-year cost of each treatment considering effectiveness.

Material and Methods

Patients were from a prior study[1]. Briefly, all patients with RA treated for first time with Rtx (n=22) or Abt (n=15) were selected retrospectively over one year. At baseline, characteristics were similar in the two groups.

The overall cost was determined by codification of the medical actions undertaken and the cost of the drugs. Treatment responses were categorised using the European League Against Rheumatism (EULAR) definitions.

Results

Table 1 shows EULAR responses at 6 and 12 months in the two groups

RTX	(n=22)AB	T (n=15)
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EULAR Response at 6	months `	, ,					
Responders	68.1%	53.0%					
Non Responders	27.2%	47.0%					
Disruption or Lost from	view4.7%	0.0%					
EULAR Response at 12 months							
Responders	36.4%	53.3%					
Non Responders 27.2% 47.0% Disruption or Lost from view4.7% 0.0% EULAR Response at 12 months Responders 36.4% 53.3% Non Responders 40.9% 26.7%							
Disruption or Lost from view22.7% 20.0%							

Table 2 shows the management of care and the costs in the two groups

	RTX (n=22)	ABT (n=15)
Mean number of admissions to the rheumatology ward	9 7	12
Traditional hospitalisation	64.0%	14.5%
(mean length of stay in hospital)	(4.6 days)(2.1 days)
One-day hospitalisation	15.5%	53.0%
Hospitalisation but little treatment required	0.0%	28.0%
Consultation	20.5%	4.5%
Mean duration of treatment in months [min max]	9 [5-12]	11 [7-12]
Cost of one vial (€)	1417	419
Overall cost (management + vials) pe patient per month (€)	r ₁₂₅₀	1530

Discussion, Conclusion

This finding is consistent with similar efficacy and cost in the two groups. Abt is associated with more frequent but shorter hospitalisations Moreover with Abt we noted hospitalisation that did required a low level of treatment (administration arranged automatically by a nurse according to predefined parameters).

Thus, day-patient or outpatient treatment should be considered because it might save the hospital money.

1 J.Finzi et al. Abatacept and Rituximab in rheumatoid arthritis refractory to TNF therapy: a one-year overview of the prescriptions. *submitted 2010*

No conflict of interest

CPC039 Evaluation of a drug dispensing at discharge program in a surgical service

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Background

The Drug Dispensing at Discharge Program is a project whose aim is to achieve the reconciliation of treatment at hospital discharge with home treatment.

Purpose

To evaluate a program of drug dispensing at discharge in the urological surgery service by analyzing pharmacoeconomic and pharmacologic implications.

Material and Methods

We performed a four-week prospective study of drug dispensing at discharge in patients admitted to the urology service.

We used a computer intra-hospital management application to assess the economic impact of the treatments dispensed.

We used the pharmacological dispensing records at discharge for the pharmacotherapy profile analysis. The circuit for pharmaceutical care is as follows: the pharmacist dispenses specific quantities of individualized prescribed drugs whose duration is finite. These are accompanied by a written report indicating dosage, duration of treatment, and additional information. Furthermore, each patient is told which drugs should be suspended after the intervention, and which need to be restarted and when.

Results

Pharmacological products were dispensed 46 times on discharge during the study period. This assumes an average of 2.3 times per day and involves approximately 1 hour of work during normal working hours for the pharmacist. A total of 88 drugs, of which 42 (47.7%) were antibiotics, 24 (27.3%) pain relievers, 11(12,5%), stomach protectors, 4 (4.5%) low molecular weight heparins, 3 (3.4%) antispasmodic urinals, 2 (2.3%), 2 (2.3%) α -adrenoreceptor antagonists and the remaining 2 (2.3%) alkalizers were dispensed. With this program, the pharmacist required 20 hours of work, generating savings 821.71 €, which would save 10,641.15 € annually.

Conclusion

The Drug Dispensing at Discharge Program improves reconciliation of treatment at the time of discharge and has proven to be economically profitable for the health system.

It also allows us to reduce the number of drugs at medicine destruction points, since each patient is only given the quantity of drugs required to complete treatment.

No conflict of interest

CPC040 Adverse reaction after ammonium tetrathiomolybdate treatment for a case of Wilson's disease

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Background

Wilson disease is a rare inherited disorder that lead to an abnormal metabolism of copper resulting in an accumulation of this element, mainly in liver and brain. Currently, there are 4 drugs being used as anticopper agents: zinc, which blocks intestinal absorption of cooper; D-penicillamine and trientine, both of which are chelators that increase urinary excretion of cooper, and ammonium tetrathiomolybdate (TTM), which forms a non-toxic tripartite complex. TTM has the advantage of rapid onset of action, apparently without producing an accute agravation of neurological symptoms. Unfortunately, its use is restricted based on limited clinical experience and commercially unavailability.

Purpose

We report a case of reversible marrow depression secondary to treatment of Wilson's disease with the copper-chelating drug TTM and its management.

Material and Methods

A 22-year-old male with Wilson's disease was initially treated with D-penicillamine 250 mg/8h and zinc 50 mg/8h for 15 days. Due to D-penicillamine intolerance it was prescribed trientine 300 mg/12h.2 months later a neurological examination showed a poor response to trientine. Then, this drug was changed for TTM 160 mg/24h (40 mg q.i.d), which was elaborated as an extemporaneous formulation after authorisation as a compassionate use by the national regulatory agency.

Results

After 1 month on this treatment the patient developed haematological toxicity; (baseline: Haemoglobin 13.5 g/dl, neutrophils 2690/mcL, platelets 149000/mcL; on TTM treatment: Haemoglobin 9.2 g/dl, neutrophils 590/mcL, platelets 95000/mcL).TTM was withdrawn and a granulocyte colony-stimulating factor was prescribed. A week later, blood cell counts were at normal limits. The patient completed his treatment with zinc.

Conclusion

The probable agent causing reversible marrow depression in this case was TTM (Naranjo's algorithm score:6 = probable). A rapid resolution of bone marrow functions was observed after withdrawal of TTM. The haematological toxicity was pharmacologically manageable

No conflict of interest

CPC041 Treatment of MELAS syndrome. Case report and literature review

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Background

Mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) is a maternally-inherited, multisystem mitochondrial disorder.

Material and Methods

Case report of a patient diagnosed with MELAS syndrome and literature review in PUBMED in order to assess the best options for treatment. The search terms were: MELAS, mitochondrial disorders, stroke-like episodes, L-Arginine.

Results

A 56-year-old man was diagnosed with MELAS syndrome in July 2010. He had a quickly-progressing neurodegenerative disorder with widespread cerebral involvement observed by EEG, with epileptogenic foci, and a 5% of ragged red fibres in the muscular biopsy. Analytical parameters showed CK total (565 U/L), LDH (106 U/L) and AST (42 U/L) altered, with a normal value of lactate. Although there have been no controlled clinical trials for the treatment of this syndrome, the literature review highlighted the use of the following drugs: coenzyme Q10, menadione, ascorbate, idebenone, riboflavin, nicotinamide, L-Arginine among others, and recommended avoidance of others such as valproic acid, phenytoin, some anaesthetics, statins, antidiabetics and others. In this particular patient the recommended treatment was coenzyme Q10 100 mg/8h, L-carnitine 900 mg/8h, both given orally, and L-Arginine 0.5 g/Kg in continuous intravenous administration over 24 h, followed by 0.2 g/Kg/day orally indefinitely. Further treatment included levetiracetam and ascorbic acid. The treatment was well tolerated; the patient only had hypotension during the intravenous administration of L-Arginine. 24 h after initiating the treatment with L-Arginine, the patient was re-evaluated; a slight improvement in the EEG was observed but without clinical improvement. Three days later, the patient was discharged and since then he has continued with this treatment, with the result that the disease is controlled at the moment.

Conclusion

Based on the idea of this is a mitochondrial disorder, the treatment of the MELAS syndrome tries to compensate for the lack of metabolites involved in the metabolic cascade.

The use of L-Arginine is based on the hypothesis that stroke-like episodes in MELAS are caused by impairment of vasodilation in some segments of intracerebral arteries.

No conflict of interest

CPC042 DAPSONE IN DERMATITIS HERPETIFORMIS

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Background

Dermatitis herpetiformis is an autoimmune blistering disorder associated with gluten-sensitive enteropathy.

Purpose

To undertake a retrospective observational study of patients undergoing treatment with dapsone from the time of diagnosis to the present day.

Material and Methods

Data were collected from the medical records and personal questionnaires; to assess the efficacy of dapsone treatment (disappearance of the skin lesions).

We assessed two patients, a man and a woman, 44 and 29 years old respectively. They were diagnosed due to the presence of intensely pruritic papulovesicular rashes on the elbows, knees and gluteal regions.

The diagnosis was confirmed by histopathological examination of the lesions, which included direct immunofluorescence, the finding of granular IgA deposits, and pathognomonic signs of the disease. The patients followed a treatment consisting of a gluten-free diet and oral dapsone at a dose of 100 and 50 mg respectively.

Levels of glucose 6-phosphate dehydrogenase enzyme were measured for both patients prior to the initiation of therapy with dapsone. Regular complete blood counts and general biochemical analyses (liver and kidney profile) were performed during treatment.

Results

In both cases dapsone was and still is effective, since itching and skin lesions improved within 24-48 hours. In the case of the male patient, a gluten-free diet was enough to control the disease, with lesions reappearing when gluten was reintroduced in his diet. Diet alone was insufficient to control the disease in the case of the female patient with injuries reappearing 3-4 days after stopping treatment. With respect to secondary adverse effects, Dapsone is well tolerated.

Conclusion

Dapsone is an effective drug for controlling the symptoms of dermatitis herpetiformis, although it does not cure the disease. Its use must always be complementary to a gluten-free diet, and it should be reserved for those individuals who do not respond to diet only or those with severe cutaneous manifestations that require quick symptomatic relief.

CPC043 Change in nutritional and metabolic parameters of obese patients undergoing a cycle of enteral protein nutrition (EPN)

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Background

For the treatment of severe obesity there are many scientific publications on oral protein diets, while there are no publications that use enteral protein nutrition. Obese patients are difficult to treat with oral diets due to poor compliance; these people need at certain times to receive treatment under a comprehensive liability, without obligation to respect patient dietary rules. For this reason in our hospital, we have tried a new treatment: a very low-calorie and carbohydrate enteral nutrition (EPN).

Purpose

To verify the compliance with, efficacy and safety of EPN

Material and Methods

124 patients were treated for a 14 day cycle. An enteral solution of amino acids, whey proteins, minerals, alkalising substances and fibres was administered. Vitamins and herbal diuretics were administered orally. Great attention was given to solubilisation, in order to enable administration by 8-CH nasogastric tube.

Results and conclusion:

Results after 14 days of EPN	
Weight loss	7.43 ± 1.91 kg
waist circumference decrease	5.77 cm ± 2.13
reduction of average blood glucose	mg / dL 18.93
reduction of baseline fasting insulin	9.95 mcIU/ ml
HOMA index	from an average of 4.92 to 2.05
mean blood urea nitrogen	stable
creatinine	stable
reduction in total cholesterol	44.19 mg / dL ± 33.24
LDL cholesterol reduction	26.12 mg / dL ± 27.53
reduction of triglycerides	80.60 mg / dL ± 34.78
	From an average of 49.83 mg/dL to 43.02 mg/dL

It is interesting to note a significant increase in growth hormone (with initial average of 1.29 ng / ml and final of 2.29 ng / ml) and the reduction of visceral adipose tissue, assessed by ultrasound. With the safety protocol that we developed side effects have been rare and of little significance when we achieved an improvement in all clinical and metabolic parameters that determine vascular risk.

No conflict of interest

CPC044 Neurotoxic effects induced by the topical administration of cycloplegics in a pediatric patient

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Background

Cycloplegic drugs are frequently used in ophthalmology examinations. Although they are administered topically, their absorption could produce neurotoxicity.

Purpose

To report the risk of neurotoxicity associated with cycloplegic eye drops.

Material and Methods

Review of the available literature about neurotoxicity and cycloplegic eye drops, and report of a case that happened in the Paediatric Department during the pharmacist training period.

Paculto

A 4-year-old girl was admitted to the Emergency Department presenting a confusional episode with incoherent speech, unresponsive bilateral mydriasis, agitation, unsteady gait, visual hallucinations, spatial disorientation and lack of recognition of her family. Her parents revealed that two hours before an ophthalmologist had administered to her one drop of tropicamide and one drop of cyclopentolate eye drops for a fundus examination. The patient was admitted and was kept under observation, considering that the half-life of these eye drops is around 6 h for tropicamide and 24 h for cyclopentolate. During the first 24 h the patient evolved favourably. No drugs were administered to resolve the clinical status. The neurotoxicity was resolved progressively although nonreactive bilateral mydriasis persisted 3 days after intoxication. This case was reported to Madrid's Pharmacovigilance Centre, which replied that these side effects are described for these drugs: they are dose dependent, and if administration is not stopped there could be risk of coma with cardiovascular collapse, even death.

A review carried out about the neurotoxic effect of these drugs reported 75 cases of neurotoxicity in patients exposed to cycloplegic drugs: 29 cases were due to cyclopentolate, 19 to atropine, 18 to homatropine, 7 to scopolamine and 2 to tropicamide. Many of the patients reported were children or elderly people.

Conclusion

Topical administration of drugs must not be underestimated. In our patient the neurotoxicity was resolved without sequelae but some cases of death have been reported. Moreover, neurotoxicity induced by cycloplegic drugs should be considered in order to make a differential diagnosis of acute confusional syndromes.

No conflict of interest

CPC045 Romiplostim in the treatment of immune thrombocytopenic purpura

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Background

Immune thrombocytopenic purpura (ITP) is an autoimmune disorder that is usually characterized by platelet destruction caused by antiplatelet autoantibodies.

It is a rare disease recognized by de National Organization of Rare Diseases, as well as the FDA.

Romiplostim is a thrombopoietin receptor agonist used in ITP and it is administered weekly as a subcutaneous injection.

Purpose

Analyze the use and effectiveness of romiplostim in our hospital.

Material and Methods

Prospective observational study on all patients treated with romiplostim until August 2010.

Data were obtained from: bibliography research, product information document, clinical histories, and laboratory data (platelets level).

The parameters evaluated were:

- Previous drugs used
- Number of weeks with platelet response (WPR): Number of weeks with platelet counts $\geq 50 \times 10^9 / L$.
- Stable dose of Romiplostim: When the patient has received the same dose of romiplostim for 8 consecutive weeks.
- Subject non-responder: Platelet count \leq 20x10 9 /L for 4 consecutive weeks who has received the maximum dose (10 mcg/Kg).

Results

8 patients (4 men and 4 women, mean age 55,13±8,59 years old) were treated with romiplostim.

Only one of them had been splenectomized.

There were 2 non-responder subject (patients 3 and 4)

	Weeks into treatment	WPR	Stable dose of romiplostim
Patient1	66	27	6
Patient 2	61	15	10
Patient 3	20	6	-
Patient 4	16	2	-
Patient 5	69	28	4
Patient 6	30	28	1
Patient 7	17	0	9
Patient 8	19	4	3

One patient (number 6) finished treatment with romiplostim because platelets levels were stable and normal.

Previous treatments received were: corticosteroids, 8 patients (100%); intravenous immunoglobulin G, 6 patients (75%); rituximab, 4 patients (50%); danazol, 1 patient (13%) and azathioprine, 1 patient (13%).

Conclusion

75% of patients have successfully maintained a stable dose and the 87.5% have achieved platelet counts ≥50x10⁹/L.

Romiplostin may be an alternative in patients with ITP who do not respond to previous treatment.

No conflict of interest

CPC046 Standard parenteral nutrition for preterm infants : impact on amino acid intake

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Background

Early and aggressive amino acid supplementation (3-4 g/kg/day since birth) is recommended in preterm infants to prevent catabolism and long term adverse consequences¹. Inadequate early nutritional intake was suspected in our institution with individualised parenteral nutrition (IPN) due to prescribing and compounding delay. Ready-to-use standard parenteral nutritions (SPN) for the first 5 days of life were developed² and implemented to improve nutritional support.

Materials and Methods

Retrospective case (SPN) - control (IPN) study in a neonatal and paediatric intensive care unit between April 2008 and February 2010. SPN : glucose 10.8%, amino acids 3%, +/- electrolytes. Inclusion criteria : preterm infants with birth weight \leq 1500 g and gestational age \leq 32 weeks. Outcome: cumulative amino acid intake during the first 5 days of life (Mann-Whitney and linear modelling by GEE)

Results

64 preterm infants were included (23 SPN– 41 IPN). Cumulative amino acid intake was significantly higher during the first 5 days of life in the SPN group (day 0: 1.1 \pm 0.7 g/kg/day vs 0.0 \pm 0.1 g/kg/day; day 1: 2.9 \pm 0.9 vs 0.8 \pm 1.0; day 2 : 5.2 \pm 1.0 vs 2.7 \pm 1.6; day 3 : 7.9 \pm 1.3 vs 5.5 \pm 2.2; day 4: 11.0 \pm 1.7 vs 8.7 \pm 2.7, p < 0.001 for all days). The supplementary intake of 2.1 g/kg/day at day 1 in the SPN group remain constant over the time (no day effect, p = 0.699). Intake of 3 g/kg/day was reached at day 4 in both groups (3.1 \pm 0.7 vs 3.21 \pm 1.0, p =0.47).

Discussion/Conclusion

Cumulative amino acid intake was improved by SPN during the first 5 days of life of preterm infants due to earlier nutritional supplementation. However, European recommendations being reached only at day 4, an increase of amino acid concentration in the formula should be considered.

References:

- 1. Koletzko B. ESPGHAN Guidelines. J Pediatr Gastroenterol Nutr. 2005; 41 Suppl 2:S1-87.
- 2. Bouchoud L. Clin Nutr. 2010 May 18 [Epub ahead of print]

No conflict of interest

CPC047 Interdisciplinary team effort leads to guideline and rationalisation af opioid use

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Background

Use of opioids varies remarkably between various regions of Denmark. The use is espe-cially high in the North Region (NR) which might imply an irrational use. In particular use of "none-recommended" opioids constitutes a problem.

Purpose

The aim was to develop and implement a cross sectional guideline on "how-to-use" opioids. It was anticipated that the guideline would help reduce overall use of opioids and "none-recommended" opioids in the primary and secondary health care system in NR.

Material and Methods

- Drug formularies (DF) in the primary and secondary health care system in NR were streamlined.
- An interdisciplinary group developed an "easy-to-use" guideline, to assist when pre-scribing opioids. The guideline complies with DF.
- The guideline was distributed to all doctors in NR during January-March 2010, and was made available online.
- Ward lists in hospital units were adjusted to recommendations in the guideline.
- A press release on development and implementation was made to increase focus.
- Hospital staff meetings were conducted introducing the guideline and emphasising importance of correct treatment of pain and use of opioids.
- · Use of opioids is currently monitored.

Results

- Development of a guideline on "how-to-use" opioids"
- A cross sectional implementation strategy insuring same message to all doctors in NR.
- Preliminary results in secondary health care system might imply

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changes in the use of opioids. A 17 % reduction of the total use of opioids (DDDs) was observed compar-ing October-December 2009 to April-June 2010. Use of opioids shifted toward a higher use of recommended opioids. For example use of oxycodone ("nonerecommended") decreased 42 % (DDD) in the same period.

Conclusion

The study showed that interdisciplinary team effort, led to implementation of the guideline. It substantiates that it is possible to influence use of opioids, and hopefully in the future it will result in a rational prescription pattern.

No conflict of interest

CPC048 Rare diseases: epidemiology and treatment of a patient cohort

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Background

European Union estimates diseases to be rare when they affect no more than 5 over 10.000 persons. Adequate treatments for most rare diseases don't exist. This lack of treatment is due to various causes (high research cost, large number of diseases, few patients for many rare diseases). Lacking a single aetiological treatment for most rare diseases, their management involves an approach to symptoms treatment. In Italy, a number of provisions to facilitate access to drugs has been issued (off-label use of drugs, coverage for approved interventions, etc.).

the purpose of this paper was to characterize the cohort of patients affected by rare diseases, resident in the District of S.Agata di Militello (Messina), with a population of 76,078 inhabitants and retrieve information about their treatment.

Material and Methods

9 patients (5 males, 4 females) were analyzed and their prescriptions in the period 01/01/2009 and 30/09/10 were assessed. All drugs were dispensed by the Hospital Pharmacy. All data were recorded in an Access database where sex, age, disease and drugs were recorded.

Results

patients are affected by Wilson's disease (2), glycogenosis (1), pyridoxine-dependent epilepsy (1), deficit of L-citrulline (1), Behcet syndrome (1), Wolfram syndrome (1), relapsing polychondritis (1), Rett syndrome (1). The affections were from severe to very severe, chronic and life-threatening. All prescribed therapies are in according to international protocols, but in some cases they were used to improve life quality only.

Discussion

Rare diseases epidemiology is a new action field still largely unexplored. New epidemiologic data allows to upgrade guidelines and share guidelines and therapeutic protocols.

No conflict of interest

CPC049 Influence of tumor necrosis factor inhibitors on

hospitalisation: a ten years experience

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Background

Tumor necrosis factor inhibitors (TNFI) are associated with several adverse reactions. Some could be so severe that require hospitalisation.

Purpose

The aim of this study is to describe the use of TNFI in a third level hospital and to analyze the hospital admissions of the patients treated with TNFI (infliximab, etanercept and adalimumab) since January 2000 to December 2009.

Material and Methods

Descriptive and retrospective study based on the review of clinical histories of patients treated with TNFI and the register of Outpatient Pharmacy Department. The minimum period of treatment was 4 months, namely, when the treatment with the TNFI was assessed as efficient.

Results

There were 301 patients treated with TNFI, 144 men and 157 women. The diagnoses were: rheumatoid arthritis (44,1%), ankylosing spondylitis (16,3%), psoriatic arthritis (14,9%), Crohn's disease (10,0%), ulcerative colitis (6,0%), psoriasis (5,0%), juvenile idiopathic arthritis (1,7%) and others (2,0%). During this period, there were 203 hospital admissions, and these were classified in three categories: 49,3% of admissions were related with the disease itself, 23,6% could be related with the drug and 27,1% were unrelated to disease or drug. Of all admissions, 107 patients were in treatment with infliximab, 60 with etanercept and 36 with adalimumab. For admissions related with the drug, 42 of 48 were due to infection (bacterial, fungal or viral), 2 due to fever, 2 due to hematological alteration and 2 due to cardiac alteration.

Conclusion

TNFI are mainly used in rheumatic diseases, like rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis. Despite some limitations of this study, TNFI seem to be involved in a significant number of admissions, especially bacterial infections.

No conflict of interest

CPC050 Use of inhaled antibiotics against Pseudomonas Aeruginosa infection in noncystic fibrosis bronchiectasis A. López-Vizcaíno Castro, J. Gulín Dávila, P. Sempere Serrano, A. Perez Castro, P. Castellano Copa, F. Fernández Ribeiro ¹Complexo Hospitalario Xeral-Calde, Pharmacy, Lugo, Spain

To analyze the use of inhaled antibiotics against Pseudomonas Aeruginosa infection in noncystic fibrosis bronchiectasis.

Material And Methods

Retrospective observational study. Study period: January 2007-January 2010. There were included all patients noncystic fibrosis diagnosed with Pseudomonas aeruginosa infection who had started the treatment with inhaled antibiotics during the study period. From the medical record data (IANUS) the following were assessed: cultures of sputum, drug susceptibility and etiology of bronchiectasis. The data were evaluated according to the regulation of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR) on diagnosis and treatment of bronchiectasis.

Results

There were included 18 patients, 5 women and 13 males, with an average of age of 74 years (CI) (58-91). In 78 % of the patients the etiology of the bronquiectasis was in relation with other pulmonary pathologies (EPOC, asthma, chronic bronchitis) and in 22 % associated with other diseases like rheumatoid arthritis and ELA. 83 % of the patients received treatment with tobramycin inhaled as therapy of beginning, 11 % with ceftazidime and 6 % with colistimethate sodium. It was necessary to make change of treatment in 2 patients because of intolerance and in 1 patient because of resistances. As for the cultures of sputum, all Ps. Aeruginosa isolates were resistant to cefotaxime and 50 % to ciprofloxacin. Among patients exposed to the treatment during the study period, 22% developed resistance to one or more antibiotics.

Conclusion

The management of patients with bronchiectasis and chronic bronchial infection by Pseudomonas aeruginosa in our hospital is according to the recommendations of the SEPAR. However the high level of resistance to ciprofloxacin in our area determines the choice treatment in COPD exacerbations.

No conflict of interest

CPC051 Physician's adherence to a new antibiotic guidelines in the course of time

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Background

Development of guidelines is one of the main strategies in antimicrobial stewardship. Only a few studies have evaluated the circumstances that may affect the physician's adherence to guidelines.

Purpose

To assess the time trend of non-adherent prescriptions with the hospital protocol after the introduction of tigecycline in a university hospital.

Material and Methods

A retrospective observational audit was carried out in a 450-bed acute-care university-affiliated hospital. All patients treated with at least one dose of tigecycline between February 2007 and May 2009 were included in the audit.

The inclusion in the drug formulary was preceded by the creation and distribution to all physicians of a laminated-card protocol describing its approved indications, doses, routes of administration and salient characteristics. This protocol was also made available via the hospital's intranet.

Another educational intervention was performed 18 months after the introduction of tigecycline.

The correlation of non-adherence prescriptions grouped by 14 2-month periods was analysed with the Spearman correlation coefficient. Statistical tests were two tailed, performed using a 0.05 significance level and using SPSS, v. 12.0.

Results

A total of 197 patients were included in the audit. In 173 (82.7%) patients, tigecycline was administered according to the protocol. The percentages of prescriptions non-adherent with the protocol rose from February 2007 - July 2008 (Spearman's rho coefficient 0.741; P = 0.022).

After an educational intervention, the percentages of prescriptions non-compliant with the protocol declined between July 2008 - May 2009 (Spearman's rho coefficient -0.876; P = 0.022).

Conclusion

An increase in physician non-adherence to the protocol over time since its introduction in the hospital was detected.

The results of the audit had to be communicated to physicians as a reminder of the guidelines in order to improve adherence to the protocol. This proved to be an effective corrective measure.

No conflict of interest

CPC052 Impact of Implementation of One-Pharmacist-One-Client Counseling Method on Abstinence Rate in Smoking Cessation Clinic in Teaching Hospital

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Background

Different interventions and counselling methods employed by different smoking cessation clinics in various settings may affect abstinence rates among smokers.

Purpose

To identify defaulter rate, abstinence rate at month 6 and continuous abstinence rate at month 12 post-quit date before and after the implementation of the One-Pharmacist-One-Client counselling method among smokers.

Material and Methods

At the start of the cessation programme, the nicotine dependence of each client was identified using the Fagerstrom Questionnaire. Pharmacotherapy in the form of Nicotine Replacement Therapy or varenicline was given. Blood pressure, weight, breath carbon (CO), withdrawal symptoms, side effects of monoxide pharmacotherapy were monitored on each follow-up visit. However before October 2007, 2 pharmacists in each clinic session saw clients on a weekly rotation basis resulting in each client seeing a different pharmacist as counsellor throughout the entire 24-week programme. Starting October 2007, a One-Pharmacist-One-Client counselling method was introduced resulting in each client seeing only 1 pharmacist as counsellor throughout the 24-week programme. Expired Carbon Monoxide (CO) levels were recorded at Month 6 and Month 12 post-quit date. Abstinence was defined as CO level below 10 ppm and self-reported abstinence from cigarette smoking since quit date. Default was defined as failing to attend 3 consecutive follow-up sessions with intention of withdrawing from programme.

Results

A total of 58 subjects were recruited, predominantly male with mean age of 43.3 ±14.5 years. Defaulter rate before, 1 year and 2 years after implementation of One-Pharmacist-One-Client counselling method were 53.2%, 67.5% and 54% respectively. Abstinence rate at month 6 post-quit date before, 1 year and 2 years after implementation of the One-Pharmacist-One-Client counselling method were 31.8%, 61.5% and 60.9% respectively.

Continuous abstinence rate at month 12 post-quit date before, 1 year and 2 years after implementation of One-Pharmacist-One-Client counselling method were 27.3%, 30.8% and 47.8% respectively.

Conclusion

the One-Pharmacist-One-Client counselling method has been proved to positively increase the abstinence rate and continuous abstinence rate among smokers recruited. However, the defaulter rate was not altered by the type of counselling method used.

This finding may support the supposition that inability to successfully use coping skills when faced with stressors will reduce the chances of abstaining from tobacco (Raymond Niaura et al 2002)

CPC053 Clinical pharmacy services in the largest Austrian tertiary care hospital

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Background

Clinical pharmacists (CPs) take part in ward rounds on three standard care units (SCUs): department of nephrology (NE, daily), cardiac surgery (CS, twice weekly) and hematology (HE, twice weekly), and on three intensive care units (ICUs) weekly: department of infectious diseases (ID), gastroenterology (GE) and neonatology (NN). In the psychiatric clinic (PC) a CP is available for consultations daily.

Purpose

To detect and analyse pharmaceutical care issues (PCIs) and evaluate the CPs' contributions on the SCUs, ICUs, and in the PC, respectively.

Material and Methods

Study period 22 weeks. PCIs, the CP's recommendations and the acceptance rate (excluding solely informational and organisational issues) were documented according to an adapted classification system¹.

Significance of CPs' contributions was rated on a six-point-significance rating scale (-1 – adverse significance – 4 extremely significant)².

Results

A total of 478 PCIs were addressed during 138 ward rounds. The five most common PCIs were related to specific information (30.1%), organisational advice (14.2%), medical chart errors (7.7%), untreated indications (7.5%) and drug use without indication (6.9%). The three most frequent CPs' recommendations were related to general information (42.9%), addition of new drugs (13.4%) and dose adjustments (12.6%).

The mean acceptance rate of CPs' interventions was 54.7%. The majority of PCIs (75.3%) was rated to be somewhat to extremely significant. Results per ward are shown in Table 1.

Table 1							
	NE	PC	cs	ΗE	ID	GE	NN
Average number of PCIs per ward round	5.5	1.1	3.8	1.3	3.7	3.5	2.9
Overall acceptance rate (%)	60.9	40.9	65.8	91.7	30.6	25.8	46.7
Percentage of somehow significant interventions (rating 1-4)	70.8	84.6	86.5	61.1	64.3	87.8	74.0

Conclusion

This first systematic evaluation of clinical pharmacy services highlights on areas with a potential need for improvement of care. Although acceptance rate was average, proportion of somehow significant interventions was high.

References:

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- 2 Hatoum HT et al. Evaluation of the contribution of clinical pharmacists: inpatient care and cost reduction. Drug Intell Clin Pharm 1988; 22(3):252-9

No conflict of interest

CPC054 Pharmaceutical interventions on parenteral nutrition support

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Background

Documentation of interventions is vital to a patient's continuity of care and demonstrates the value of clinical pharmacy.

Purpose

To describe and quantify the pharmaceutical interventions in the parenteral nutrition area.

Material and Methods

Prospective longitudinal study from July 2009 to September 2009 in the parenteral nutrition area in an 800-bed university hospital. Interventions made during this time were recorded in an Access database. The pharmacist interventions were classified in four groups: System Improvements; Preventive Actions; Pharmacist Educational Interventions and Pharmacotherapy Recommendations.

The interventions were based on standard references cited in the guide "Standardisation of nutritional support" made by the Working Group on Nutrition, SEFH (Calvo MV, *et al.* 2009).

During the study period, 978 administrations of nutrition were made to 118 patients, and pharmacists made 261 interventions (3.95 interventions/day; 2.2 interventions per patient).

- 4% of the interventions suggested system improvements; such as a Standard Process.
- 61% were pharmaceutical preventive actions; 73% prevented possible adverse effects or treatment failures.
- 17% were educational interventions, mainly (80%) addressed to the medical staff.
- Finally 18% of the interventions were recommendations regarding a drug; 60% related to an inappropriate dose or treatment.

Conclusion

Pharmaceutical interventions are a useful tool for hospital patient care. The presence of the pharmacist in clinical units represents an improvement in clinical outcomes and a lower incidence of drugrelated problems, making the use of medicines and parenteral nutrition more effective and safer.

No conflict of interest

CPC055 PRESCRIPTION PROFILE, GENDER DIFFERENCES AND CLINICAL ANALYSIS OF POTENTIAL PHARMACEUTICAL INTERACTIONS OF CLOPIDOGREL: A CASE-CONTROL STUDY WITHIN THE ITALIAN HOSPITAL

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Background

Clopidogrel is a prodrug metabolised by CYP2C19. Drugs inhibiting this enzyme might reduce its therapeutic activity. In order to reduce gastrointestinal bleeds, PPIs are usually prescribed in association with clopidogrel.

Purpose

To find out whether there is a gender difference in the response to clopidogrel. In addition to assess the clinical importance of interactions between clopidogrel and CYP2C19 inhibitor drugs.

Material and Methods

A retrospective case-control observational study carried out by the University Hospital of Ferrara.

The study focused on clopidogrel prescriptions from 01/01/2008 to 31/12/2008. The group of cases included patients who experienced

secondary cardiovascular or cerebrovascular events while taking clopidogrel. The group of controls included patients who did not experience such secondary events in 2008.

Results

The study focused on 781 patients, 20.1% of which (n.157) experienced secondary effects. The mean age was 70 years old. Men (67% of the population investigated) experienced secondary events more than women (OR 1.54; IC 95% 1.04-2.28; p<0.03). 70% of patients took PPIs and we noticed that the risk of secondary events increased by 2.2% with respect to the remaining patients (20.77% vs. 18.57%; OR 1.15; IC 0.78-1.70; p>0.05). Among PPIs, lansoprazole was the most used. For this subgroup the risk was 5.2% higher (risk for exposed patients: 23.75%; risk for non-exposed ones: 18.57%; p>0.05). The interaction with PPIs is particularly interesting only among women, with a risk 6.3% higher (17.46% exposed, 11.11% non-exposed). The risk remains the same among men.

Conclusion

The gender differences we highlighted could be explained on the basis of CYP2C19 genetic polymorphisms. Poor metabolisers are much more frequent among men than among women. Analysed data show an increase in cardiovascular or cerebral secondary events for patients exposed to PPIs. However, it was not possible to rule out differences between cases and controls being purely due to coincidence.

No conflict of interest

CPC056 Introduction of Clinical Pharmacy to a Dermatology Ward

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Background

Clinical pharmacy services are an essential component of medical care in today's hospitals. In order to develop and implement clinical pharmacy services in a large Austrian general hospital a routine medicines review by a clinical pharmacist was initiated on a dermatological ward.

Purpose

To evaluate the need for, and acceptance of, pharmaceutical care by determining the number of drug-related problems and the rate of physician interventions.

Material and Methods

The medicines of inpatients on a dermatological ward of a general hospital were assessed prospectively on a twice-weekly basis over a three-month period (March-June 2010). The pharmacotherapy review was performed using a standardised data collection form recording patient data (age, sex, renal function, abnormal laboratory parameters and comorbidities), current medicines, drugrelated problems and physician interventions. Information was obtained from the drug charts and recommendations to the physician were given during a twice-weekly meeting. Data collected was analysed by SPSS.

Results

A total of 172 drug-related problems were found in 86 of 186 evaluated patients (46%). The drug-related problems identified were classified into 7 categories with the following distribution: indication (14%), dosage (35%), dose frequency (13%), contraindication (2%), drug duplication (1%), drug-drug interaction (17%) and laboratory, i.e. dose adjustment required due to renal or hepatic impairment (18%). The drug classes causing most problems were antihypertensive drugs, anticoagulants, antibiotics and antidepressants. Of the 172 recommendations 124 (72%) led to an intervention by the physician.

Conclusion

The project demonstrated the potential of a routine medicines review by a clinical pharmacist in order to optimise drug therapy and improve patient safety and resulted in the introduction of a continuing, systematic clinical pharmacy service on the dermatological ward.

No conflict of interest

CPC057 Pharmaceutical care in Emergency Area

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Background

Drug-related problems (DRPs) are responsible for morbidity in health care facilities.

Purpose

To estimate the suitability and effectiveness of a pharmaceutical care programme at the observation room of a hospital Emergency Area.

Material and Methods

This prospective study was performed from 20 July to 20 September at the observation room of the Emergency Area.

DRPs were classified into different categories: indications, effectiveness and safety, and were entered in a computer programme.

DRPs were identified by two pharmacists, during one hour per day, from Monday to Friday, by monitoring pharmacological-therapeutic profiles.

The variables used to measure the work done were the number of pharmaceutical interventions per patient and day.

The economic variable was the Relative Value Unit (RVU), defined by the TECNO group of the Spanish Society of Hospital Pharmacy, for individualised patient follow-up.

The value of the first pharmaceutical intervention was 39.58 RVU and the following interventions were 13.19 RVU.

Results

116 patients were included in the study (53% women, 47% men). Average patient age was 75 (33-103). The average number of interventions per day was 3.5. 17% of the patients had two or more DRPs. A total of 147 DRPs were recorded during the study. Of these, 7% were in the indications category, 87% in effectiveness and 5% in safety.

77% of pharmaceutical interventions in effectiveness were therapeutic exchanges for prescription drugs from the Hospital Formulary. The calculated RVU was 5,000 RVU.

Conclusion

- 1. The therapeutic exchange rate was significant in interventions related to effectiveness.
- 2. The study results, expressed by the number of preventive or corrective interventions per daily hour of pharmacist presence, suggest the extension and consolidation of the experimement.

CPC058 Parenteral nutrition "all-in-one" in the pediatric unit.

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Background

Parenteral nutrition (PN) is necessary for the development of preterm infants.

Purpose

To describe the introduction of a new process of "all-in-one" PN preparation in order to reduce the handling involved in administration.

Material and Methods

All-in-one nutrition needs to contain at least 5% glucose, 2% amino acids and 1.5% of lipids. When these requirements were not met, the lipids were given separately in a lipid formulation stable for 12 hours. All nutrition solutions were filtered through membranes with pore size of 1.2 microns.

The content of nutrition prescriptions were analysed by pharmacists to detect inconsistencies and recommend the best solution: variation in the amount of any component or increase in the solution volume.

The stability criteria were obtained from Standardisation of nutritional support, developed by the Nutrition Working Group, SEFH (Calvo MV, et al. 2009).

Results

During the study period, one year (2009), 604 PN solutions were prescribed:

- 490 (80%) met the requirements for all-in-one PN.
- In 114 PN solutions the concentrations were insufficient: 50 (44%) low concentrations of amino acids.

34 (30%) low levels of lipids.

22 (20%) insufficient amounts of lipids and amino acids Finally 8 (6%) contained low concentrations of glucose.

Pharmaceutical intervention were required to adjust the nutrient levels in 41 (36%) of these solutions, changing the content and/or volume to adjust to the stability requirements.

Conclusion

The introduction of "all in one" PN has reduced the number of solutions to be administered and thus reduces the risk of infection. All PN solutions are now able to supply the daily nutritional requirements for preterm infants.

No conflict of interest

CPC059 Clinical pharmacist's medication reviews at a rheumatology ward

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Background

Outpatients often present great challenges for information transfer. Particularly in the case of patients with complex medical needs, the responsibility of care is often shared.

Purpose

To evaluate a medicines review service provided by a clinical pharmacist (CP) for outpatients at the rheumatology department at Viborg Regional Hospital, Denmark.

Materials and Methods

Patients were randomly assigned to an intervention group (IG) or a control group (CG). In the IG the patients were invited to discuss their medicines with the CP shortly before their consultation. The medicines as documented in the Electronic Patient Journal (EPJ)

(and other available sources) were reviewed and updated together with the patient. The CP recommended medicines interventions either to the rheumatologist or to the general practitioner (GP).

The CG followed normal procedure as outpatients. The number of changes to medicines made by the rheumatologist and the number of times the GP was contacted were noted after the consultation.

Results

	Intervent
Patients	296
Average age	60
Distribution of males	39
Pharmacist interventions	1335
Rheumatologist interventions	-

On average, IG patients received 1.3 interventions on rheumatology medicines, while CG patients only received 0.7 during the project period. Interventions recommended to the rheumatologists were 47 (acceptance rate 51%) and to the GP 42 (24%).

Conclusion

The medicines reviews by the CP in the IG led to significantly more interventions than in the CG. The interventions were primarily made in collaboration between the patient and the CP. Only a few recommendations were made to the rheumatologists and the GPs, however, room for improvement exists regarding implementation of those interventions.

No conflict of interest

CPC060 effectiveness and safety of sorafenib in advanced hepatocellular carcinoma

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Background

Sorafenib is indicated for the treatment of advanced hepatocellular carcinoma (HCC). It is the first systemic treatment to prolong survival in HCC patients.

Purpose

To determine the effectiveness and safety of sorafenib in advanced HCC in clinical practice.

Material and Methods

Retrospective study from June 2007 to September 2010. Demographic parameters, duration of treatment, progression date, survival time, dose reductions and adverse events were obtained from the pharmacy's electronic records and clinical records. The analysis included only patients who received sorafenib for more than 1 month.

Results

26 patients were treated with sorafenib for HCC. 15 of them were investigated (12 male (80%), 3 female (20%), with mean age 61 years (41-81)). 8 patients (53%) had previously been treated with transarterial chemoembolisation. In addition, 9 patients (60%) therapy after received another systemic The median time on treatment was 4.3 months (2.5-14). At the time patient still analysis, one was on Median progression-free survival was 4 months (2-14). Median overall survival was 10 months (2.5-15). At the end of the study, 4 patients were still alive. One was still on treatment and the other 3 survived after starting sorafenib for 24, 30 and 31 months. Finally, 12 patients (80%) required dose reduction or temporary interruption of treatment due to adverse events. Asthenia (8, 53%), dermatological toxicity (8, 53%) and diarrhoea (8, 53%) were the most frequent side effects.

Conclusion

Overall survival and progression-free survival observed in this study were similar to those described in the pivotal trial (SHARP*). The

most frequent adverse events were consistent with those described in literature, and required dose reduction and interruption of treatment in a high number of patients.

* N Engl J Med 2008;359:378-90.

No conflict of interest

CPC061 PERFORMANCE EVALUATION OF A PHARMACY CLINICAL TRIALS UNIT

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Background

Pharmacists as drug experts have a crucial role to play in the conduct and management of clinical trials (CTs). The extent of pharmacy service involvement in CTs varies according to the individual trial protocol and design and must focus on ensuring that the pharmaceutical aspects of a CT are managed in accordance with the legislation and good clinical research practice.

Purpose

to identify key issues of pharmacy involvement in CTs, to propose quality indicators for monitoring performance and test their reliability in practice. Quality measures are needed to document the quality of performance, make comparisons and determine priorities, support accountability and support quality improvement. However little has been published in this field.

Material and Methods

the role of pharmacists in CTs was retrieved from the published literature and discussed with the stakeholders of pharmacy in clinical trials. Relevant process steps and outcomes were signalled during this phase and resulted in the definition of quality indicators. The reliability of such indicators was tested across one or four months of pharmacy unit clinical trials activity

Results

75 CTs were active and recruiting patients during the period evaluated. Quality indicators defined and corresponding data are shown:

Indicator	Definition	One month result
Supplies not compliant	Non-compliant supplies/total supplies	1/31
Medicine out of stock	Number of stock outs/number of active CTs	1/75
Storage temperature out of accepted range	Number of incidents/total determinations	4/3888
	Number of system failures/number of active CTs with IVRSs	4/68
Patients asking for additional information on CT	Number of consultations/number of leaflets given directly to patients	2/81
Indicator	Definition	Four months result
patients as expected	% CT fulfil/CT active	53.3%
Medication errors		
prescription	Prescription errors/total prescriptions	11/572
preparation	Preparation errors/total IV preparations	1/145
dispensing	Dispensing errors/total items dispensed	0/572

Conclusion

Using quality indicators for performance measurement is one way of monitoring the quality of services offered by pharmacy clinical trials units

No conflict of interest

CPC062 Intrathecal liposomal cytarabine use

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Background

Liposomal cytarabine (LC) is a sustained-release formulation of cytarabine effective in the treatment of lymphomatousmeningitis. Its main adverse effect is arachnoiditis.

Purpose

To analyse the use and safety of LC in hematologic patients in our hospital.

Material and Methods

Retrospective observational study of LC use (January 2008 - April 2010).

Data obtained from: Clinical histories, product information document (PID), literature search and hospital oncology software. Demographic data, underlying disease, indication, posology, pretreatment symptomatology and adverse reactions were evaluated.

Results

6 patients (3 men), 28±8.27 years old.

Underlying disease: acute lymphocytic leukaemia (4 patients), non-Hodgkin's lymphoma (1) and acute myeloid leukaemia (1).

Indication: relapse of disease with central nervous system (CNS) blast infiltration (5 patients, 1 of which had meningitis) and prophylaxis of CNS relapse (1).

All patients received 50 mg of LC, except the prophylaxis (25 mg). Number of doses received: between 1 and 6 (3±1.9).

Two patients received only 1 dose. In 2 other patients administration was every 2 weeks, (induction and consolidation phases).

The patient with prophylactic medication received treatment monthly. Only 1 of the patients reached the maintenance phase, with 2 doses every 2 weeks and monthly since the third dose.

Four patients had previous symptoms upon intrathecal administration: headache (4 patients), fever (1), nausea and/or vomiting (1) and facial paralysis (1).

Headache (83% of patients), fever (17%), nausea and/or vomiting (17%), dizziness (17%) and facial paralysis (17%) were observed after administering the drug.

None of patients were diagnosed with arachnoiditis, a common adverse event specified in PID.

Dexamethasone was used as arachnoiditis prophylaxis: intravenous route (4 patients) and intrathecally (2).

Conclusion

Usually LC is well tolerated, since after its administration there were no serious adverse effects.

Headache was the most frequent adverse reaction observed.

Symptoms following administration are not attributable to the drug, because in most cases previous similar symptoms were observed that could be due to the disease itself.

Also, the number of patients treated was small, making it impossible to establish a clear causal link.

Simultaneous administration of dexamethasone might have contributed to the good tolerance of the drug.

CPC063 Impact of agalsidase beta shortage in two patients with Fabry disease

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Background

Fabry's disease is an inherited disorder caused by a deficiency of a-galactosidase A activity leading to lysosomal accumulation of globotriaosylceramide (GL-3), which can cause tissue damage throughout the body. GL-3 level is the most sensitive parameter for monitoring and can be measured in plasma and in urine. Treatment is based on enzyme replacement using 2 approved drugs: agalsidase b (Fabrazyme) and agalsidase a (Replagal). A shortage of agalsidase b since June 2009 led the European Medicines Agency (EMA) to recommend lowering the dose from 1 mg/kg/2 wk to 0.3 mg/kg/2 wk.

Purpose

To assess the response in 2 patients whose doses of agalsidase b were reduced

Material and Methods

We describe the outcome of 2 patients who started having agalsidase b. Data were obtained from the clinical history, as follows:

- Clinical parameters (neurological, cardiac, gastroenterological, renal, respiratory, ocular, and dermatological).
- Laboratory parameters (GL-3, serum creatinine, uraemia and urinary protein excretion).

Results

Before starting agalsidase b, the first patient was diagnosed with heart injury due to Fabry's disease. After 9 months of treatment with the reduced dose of agalsidase b the urine GL-3 level rose from 130.65 to 160.53 GL-3/mmol creatinine. The second patient had proteinuria caused by kidney damage due to Fabry's disease. He was treated with the reduced dose for 11 months and the urine GL-3 level increased from 135.50 to 243.56 GL-3/mmol creatinine. Neither patient showed significant changes in clinical or laboratory parameters, except in GL-3 levels.

Conclusion

Although clinical manifestations remained unchanged, increasedGL-3 levels were observed at lower doses. These results are consistent with the EMA update (July 2010), i.e. patients treated with a dose of agalsidase b <1 mg/kg/2 wk should be evaluated for switching to an alternative, such as agalsidase a, or return to the full dose of agalsidase b.

No conflict of interest

CPC064 Thyroid dysfunction during antiviral treatment for chronic hepatitis C

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Background

Thyroid dysfunction is a complication of pegylated interferon alfa (Peg-INF α) and ribavirin combination treatment for chronic hepatitis C virus (HCV).

Purpose

To determine the incidence and long-term outcome of thyroid dysfunction in HCV-infected patients receiving combination antiviral treatment.

Material and Methods

Patients treated for chronic HCV between October 2006 and July 2010 were analysed retrospectively. All patients received Peg-INF α and ribayirin.

Patients underwent screening for thyroid disease by means of TSH levels every 12 weeks during treatment and at weeks 12 and 24 after treatment.

Overt hyperthyroidism was defined as a low TSH level (<0.4 mIU/L) along with elevated levels of T4 (>1.42ng/dL) whereas subclinical hyperthyroidism as a low TSH level (<0.4 mIU/L) on two separate occasions with reference-range levels of T4.

Overt hypothyroidism was defined as an elevated TSH level (>4mIU/L) along with low levels T4 (<0.7ng/dL) whereas subclinical hypothyroidism as an elevated TSH level (>4 mIU/L) on two separate occasions with reference-range levels of T4.

Results

76 patients were included, 49 (64%) men, medium age (range): 43 (21-58), average length of treatment 39 weeks (12-72).

The overall incidence of thyroid dysfunction (overt and subclinical) in our population was 14 patients (18.4%, 50% men).

During treatment, overt thyroid disease was diagnosed in 5 patients (6.6%), including hypothyroidism in 3 (3.9%) and biphasic thyroiditis (hyperthyroidism followed by hypothyroidism) in 2 (2.6%). They were treated with levothyroxine or carbimazole according to the diagnosis.

In addition, 9 patients (11.8%) were diagnosed with subclinical thyroid disease, including subclinical hypothyroidism in 5 (6.6%) and subclinical hyperthyroidism in 4 (5.3%). No treatment was needed in those patients.

During the 6-month follow up after the HCV treatment, thyroid dysfunction did not develop in 13 patients. In one patient thyroid function took 11 months to return to normal.

Conclusion

Hypothyroidism is the most frequent form of dysthyroidism during antiviral treatment.

Thyroid dysfunction is reversible in most individuals within 6 months after treatment.

No conflict of interest

CPC065 Severe biochemical and virological breakthrough in patients with chronic hepatitis C treated with Pegylated interferon alfa and Ribavirin

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Background

About 15% of chronic hepatitis C (CHC) patients with complete response to Peg-INF α and ribavirin develop mild elevations of aminotransferases (ALT) and viral load (VL) during follow up (relapser patients). However, severe abnormalities in these parameters are unusual.

Purpose

To determine the incidence and long-term outcome of severe biochemical and virological breakthrough in relapser patients with CHC treated with Peg-INF α and ribavirin.

Material and Methods

Descriptive retrospective study including patients treated between October 2006 and September 2010. The data was obtained from the Electronic Clinical History.

Results

69 patients were included, 46 (67%) men, mean age (range): 42 (21-75), VL: 4,603,507 IU/ml (1013-51,200,000), genotype: G1 52%, G2 3%, G3 38%, G4 7%, ALT levels before treatment (upper limit normal value (ULN)): 2.7 ULN (0.5-10.6).

After treatment, 49 (71%) patients had a complete response, 39 (56%) sustained virological response^{##} and 10 (14%) experienced virological breakthrough (relapsers), 3 (4%) with severe elevation of ALT (table).

These 3 patients were male, G1, with high VL and 1.3 -2.5 ULN ALT levels before treatment. During follow up, only patient 1 showed mild increase of bilirubin levels (2.3 mg/dl (0-1.1)). All patients remained asymptomatic after treatment apart from patient 1 with asthenia and mild jaundice.

Treatm	eatment			Biochemical and virological breakthrough		Follo	w up	
Patient			Virological Response ^{###}	Week	(IU/ml)	ALT levels (ULN)		ALT levels (ULN)
1	39		Rapid (week 4)	12	69 mill	22	64	2-3
2	45	48	Early (week 12)	11	1.2 mill	7-8	38	2-3
3	51	72	Early (week 12)	14	3.2 mill	14	21	4-5

^{*} Complete virological response: viral load <15 IU/mL plus normal ALT levels at the end of treatment.

Treatment		Biochemical and virological breakthrough			Follow up			
Patient			Virological Response ^{###}	Week	(IU/mI)	ALT levels (ULN)	Week	ALT levels (ULN)
1	39	48	Rapid (week 4)	12	69 mill	22	64	2-3
2	45	48	Early (week 12)	11	1.2 mill	7-8	38	2-3
3	51	72	Early (week 12)	14	3.2 mill	14	21	4-5

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Conclusion

Severe biochemical and virological breakthrough is relatively frequent in patients treated with Peg-INF α and ribavirin, usually without relevant clinical consequences.

No conflict of interest

CPC066 Safety of epoetin beta methoxy-polyethylene glycol in the treatment of anaemia in chronic kidney disease

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Background

High target haemoglobin (Hb) levels (Hb>13 g/dl) achieved with erythropoiesis-stimulating agents (ESAs) in the treatment of anaemia in patients with chronic kidney disease (CKD) may be associated with an increased cardiovascular risk. The long half-life of the newest ESA, methoxy polyethylene glycol-epoetin beta (Mircera) which is a Continuous Erythropoietin Receptor Activator (CERA) could make haemoglobin levels more difficult to manage.

Purpose

To describe prescription of ESAs to treat anaemia in pre-dialysis patients with CKD and to assess the safety related to haemoglobin levels reached with different kinds of ESA, especially CERAs.

Material and Methods

We conducted a retrospective observational study of adult predialysis outpatients with CKD who collected ESAs from the Pharmacy Department between 24/05/2010 and 06/06/2010. We recorded the following data: patient identification, kind of ESA (epoetin alfa, epoetin beta, darbepoetin alfa, CERA), prescribing hospital service and laboratory parameters. Primary endpoint: percentage of patients with Hb>13 g/dl.

Results

We included 208 patients (53.4% men; median age, 76.0 years). The Nephrology Unit prescribed 85.1% of treatments. Median baseline parameters were Hb=11.5 (10.5-12.5) g/dl, serum creatinine=2.06 (1.54-2.96) mg/dl, uraemia=102.5 (74.0-133.5) mg/dl, albumin=4.0 (3.7-4.3) g/dl, C-reactive protein =0.40 (0.20-1.94) mg/dl, and fibrinogen=502 (410-608). The only statistically significant differences were that patients treated with CERA had lower CRP than patients treated with epoetin alfa and darbepoetin alfa, and patients treated with CERA were younger than those treated with epoetin beta and darbepoetin alfa. There was no significant difference in the percentage of patients with Hb>13 g/dl (epoetin alfa, 15%; epoetin beta, 13.6%; darbepoetin alfa, 15.4%; and CERA, 22.6% [p=0.544]).

Conclusion

There was no significant difference in the percentage of patients with Hb>13 g/dl treated with different kinds of ESA. However, a higher percentage was found in patients treated with CERA.

Pharmacists could play an important role in controlling laboratory parameters and doses of ESA in order to reduce the number of patients with Hb>13 g/dl.

No conflict of interest

CPC067 Use of erythropoiesis-stimulating agents in outpatients from the Oncohaematology Unit

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Background

Treatment with erythropoiesis-stimulating agents (ESAs) aims to increase haemoglobin levels. In oncohaematology, these drugs are used to treat anaemia caused by a variety of disorders.

Many indications are off-label, and the Summary of Product Characteristics only authorises treatment of chemotherapy-induced anaemia.

Purpose

Our objective was to describe prescriptions of ESA to oncohaematology outpatients and to compare the efficacy of the different types of ESA.

Material and Methods

We conducted a retrospective observational study of oncohaematology outpatients who collected ESAs from the Pharmacy Department between 24/05/2010 and 06/06/2010. We recorded the following data: patient identification, type of ESA (epoetin alfa, epoetin beta, darbepoetin alfa), indication, dosage, and laboratory parameters (uraemia, serum creatinine, haemoglobin, albumin, and C-reactive protein). The primary efficacy endpoint was haemoglobin.

^{##} Sustained virological response: viral load <15 IU/mL plus normal ALT levels 6 months after the end of treatment.

^{****} Virological response: viral load <15 IU/ml

Results

We included 42 patients (52.4% men); mean age was 73.9 years. The means (SD) of the laboratory parameters were as follows: haemoglobin, 11.2(1.8) g/dl; serum creatinine, 1.07(0.52) mg/dl; uraemia, 48.8(24.0) mg/dl; albumin, 4.05(0.8) g/dl; and C-reactive protein, 3.81(5.02) mg/dl. There were no statistically significant differences in any of the parameters between the groups of patients treated with the different types of ESA (p>0.05). ESAs were prescribed as darbepoetin alfa in 71.4% of patients (monthly mean dose 538 μ g [353]), epoetin alfa in 21.4% (monthly mean dose, 160000 IU [0]), and epoetin beta in 7.1% (monthly mean dose, 94 666 IU [81057]). The indications were chemotherapy-induced anaemia (33.3%), myelodysplastic syndrome (28.6%), multiple myeloma (19.0%), others (9.5%), and unidentified (9.5%).

Conclusions

There was no difference in efficacy between the 3 types of ESA prescribed by the Oncohaematology Unit. Darbepoetin alfa was the most commonly prescribed agent. The most common indication was chemotherapy-induced anaemia, although the prescriptions were off label in 57.1% of cases. Consequently, monitoring indications and laboratory parameters, especially haemoglobin, is an essential task of the pharmacist in the delivery of ESA.

No conflict of interest

CPC068 Assessment of a first group of patients operated to brain malignant tumours with 5-aminolevulinic acid at a central hospital

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Background

5-aminolevulinic acid (5-ALA) is indicated for improving visualisation of malignant tissue in adult high-grade glioma surgery. These tumours have a poor prognosis, particularly if they recur. 5-ALA given orally 3h before surgery causes an intracellular accumulation of fluorescent porphyrins. Fluorescent-guided surgery allows an easier intra-operative identification of tumour-infiltrated tissue enabling extended removal of the tumour and its margins.

Purpose

To investigate the efficacy and safety of 5-ALA in intra-operative tumour identification and the use of a constant 1500 mg dose (for patients over 75 kg weight) as well as the cost impact.

Material and Methods

A retrospective study was performed from February to September 2010. Data was collected from the computer information system. Patients were included in a pharmacovigilance active process (PAP) managed by hospital pharmacists and received a 20 mg/kg dose under 75 kg weight. Above 75 kg weight, with the surgeon's agreement, they were given a 1500 mg dose (1 ampoule).

Results

Thirteen patients were included (6 males, 7 females). Mean age was 53 (range 26-70). Histology findings were: 62% glioblastoma multiforme, 23% anaplastic oligodendroglioma and 15% others. 5-ALA was administered in 7 cases (54%) of redo surgery and in 6 cases (46%) for primary surgery. The average hospital stay was 25 days (7-55). The mortality was 0%. Nine patients (69%) were included in PAP. Three adverse reactions were reported. In twelve patients (92%) the fluorescence achieved was appropriate including the 4 patients over 75 kg who received only 1500 mg. The procedure failed in one patient probably due to a schedule administration error.

Hospital cost saving through using the minimum dose was 4,152 €.

Conclusion

These short-term results are encouraging. As an adjuvant in surgery, the advantages of 5-ALA are considerable. Side effects reported are not severe. A dose of 1500 mg is appropriate for patients over 75 kg weight representing a significant cost saving.

No conflict of interest

CPC069 Desensitization for hypersensitivity reactions of gemcitabine

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Background

Gemcitabine is one of the most useful and well-tolerated cytotoxics drugs, but has a remarkable incidence of allergic skin rashes (25%) and pruritus (10%).

Purpose

To report a case of parenteral desensitisation to gemcitabine in a patient with a previous hypersensitivity reaction.

Material and Methods

Desensitisation was performed on a 63-year old patient with urothelial carcinoma of the renal pelvis. In the second administration of the first cycle of treatment following relapse she manifested a hypersensitivity reaction to gemcitabine.

The patient had previously been treated with gemcitabine for three cycles (six administrations of gemcitabine) with reduction of masses and adenopathy.

The patient developed intense urticaria forty-eight hours after administration of gemcitabine.

For desensitisation, dilutions of 0.04 mg/ml, 0.4 mg/ml and 4 mg/ml of gemcitabine were administered in sequence. In order to achieve the total dose of gemcitabine required (2100 mg) dilutions were administered with a progressive increase in the rate of administration up to 6.5 hours.

The administration was conducted in the Intensive Care Unit to address any hypersensitivity reaction in the patient.

Results

Desensitisation of the patient resulted in the successful administration of the drug, with minimal side effects being seen (facial flushing, no pruritus, bronchospasm or dyspnoea) at 7 hours after the end of administration.

Afterwards, she received gemcitabine cycles with the same dose at normal speed without any incidents.

Conclusion

This protocol achieved the desensitisation of a patient with previous hypersensitivity to Gemcitabine in a safe and effective way, maintaining the most appropriate treatment for her.

No conflict of interest

CPC070 The role of hospital pharmacist in Haematology outpatients' department

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Background

Pharmaceutical counselling aims to educate patients in the conscious management of disease and treatment. This study describes the collaboration between the Haematology and Pharmacy Departments in an outpatients' clinic for elderly patients affected by refractory lymphoma, treated with oral chemotherapy.

Purpose

To highlight the efficacy and safety of treatment and satisfaction of patients with pharmacist counselling.

Material and Methods

Haematologists and pharmacists identified six low-dose oral protocols: NIET (procarbazine, idarubicin, etoposide, dexamethasone), NET (procarbazine, etoposide, dexamethasone), FC (fludarabine, cyclophosphamide), F (fludarabine), L (chlorambucil), D (dexamethasone).

Each appointment is followed by a counselling session with the pharmacist to explain the treatment, deliver simple informative material and assess quality of life through questionnaires.

Cost Minimisation Analysis for oral and IV FC was performed based on equivalent efficacy data from the literature.

Results

From January to September 2010, the outpatients' department accepted 23 patients. The choice of protocols was: FC (7 patients), NIET (6 patients), L (5 patients), F (4 patients), D (1 patient).

Six cases of haematological toxicity G2-3, 1 of cardiac toxicity G3 and 1 of neurological toxicity G2 were identified and treated. Patients treated with NIET required more frequent monitoring and management of adverse events; 2 of them needed switching to NET or idarubicin alone.

Seven patients discontinued treatment after 3-6 cycles following a good response from the disease.

A high level of compliance was observed and quality of life was found to be acceptable.

CMA for FC showed that oral administration provides an economic benefit of $\in\!$ 160.28/cycle/patient, which increases to $\in\!$ 458.34/cycle/patient if reduced doses are compared to IV administration.

Conclusion

Initial results confirmed the efficacy, tolerability and acceptance of oral chemotherapy. Pharmacist counselling was found to be a good instrument to improve compliance. The study will be extended to incorporate pharmacoeconomic analysis into other protocols.

No conflict of interest

CPC071 Gender-specific aspects of adverse drug events (ADEs)

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Background

Important risk factors for drug-related problems in hospital are polypharmacy, female sex, age >65 years and use of anticoagulants or diuretics [1]. Gender-specific differences in pharmacodynamics and pharmacokinetics have been described [2].

Purpose

To evaluate the incidence and nature of adverse drug events (ADEs) at hospital admission with special consideration of gender-specific aspects in an Austrian internal hospital.

Material and Methods

In an observational prospective study, 3190 medical records of newly-admitted internal ward patients were assessed over a period of six months. Potential ADEs were identified. Cases were evaluated by a clinical pharmacist and specialist in internal medicine by means of a computer tool.

Results

ADEs were identified in 242 patients (8%). Significantly more women than men were affected by an ADE (10% versus 6%, p < 0.005). However, when analysing by age group, the difference was only significant in patients of \geq 81 years of age (76% females in the

ADE group versus 62% females in the control group). The most common ADEs were 1) electrolyte imbalances, 2) overanticoagulation and bleeding complications, 3) renal insufficiency and dehydration or 4) syncope/arrhythmia. Women were mainly affected by electrolyte imbalances and over-anticoagulation. According to the "Common Terminology Criteria for Adverse Events", 62% of ADEs were either severe, life-threatening or fatal. In women, a significantly higher proportion of life-threatening and fatal ADEs occurred in comparison to men (23 versus 12%, p=0,031).

Conclusion

ADRs are fairly common in an Austrian hospitalised population. Women were significantly more frequently and seriously affected than men, especially at an age of \geq 81 years.

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No conflict of interest

CPC072 Natalizumab in Multiple Sclerosis

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Background

Multiple sclerosis is a demyelinating disease of the Central Nervous System that assumes a particular role by affecting and disabling young people. The most common clinical form is relapsing-remitting Multiple Sclerosis (RRMS), characterised by relapses (also known as exacerbations), during which new symptoms can appear and periods of remission, in which the patient partially recovers from deficits acquired during the relapse. Natalizumab is a humanised recombinant monoclonal antibody approved for the treatment of patients with RRMS with rapidly evolving severe relapsing remitting multiple sclerosis and who have failed to respond to a full and suitable course of beta interferon.

Purpose

To evaluate the clinical use of natalizumab in patients with RRMS, in Garcia de Orta Hospital.

Material and Methods

Retrospective observational study of patients diagnosed with RRMS and treated with natalizumab, between August 2008 and July 2010. Natalizumab effectiveness was evaluated based on the EDSS (Expanded Disability Status Scale), number of relapses and the results of magnetic resonance imaging (MRI).

Results

Our study included 11 patients with RRMS (5 males and 6 females), the mean age was 36.6±9.4 years [23-56 years]. Before natalizumab treatment all the patients were previously treated with beta interferon and 5 patients were additionally treated with glatiramer. Median time of disease evolution was 8.0±4.5 years [1-16 years].

The 11 patients were treated with the recommended dosage of natalizumab: 400 mg once every 4 weeks and they received an average of 12.9 ± 5.3 infusions [8-21 infusions].

The patient with the longest treatment (21 infusions) stopped the treatment due to the lack of response; all the other patients are still on treatment.

In 7 patients (63.6%), the initial EDSS was equal to or greater than 5. Considering the EDSS score, 7 patients improved and 6 maintained the initial value (initial average value: 4.4±1.8 [1.5-6.5] versus final average value: 3.2±1.9 [1-6.5]) Only 1 patient presented an exacerbation during natalizumab treatment, with an MRI showing new lesions. During the relapse, the EDSS worsened, and the patient recovered after a course of methylprednisolone. The patient did not develop anti-natalizumab antibodies.

The patients who completed 12 months of treatment (5 patients), had a check-up MRI that found no new lesions. There were no reports of side effects associated with natalizumab treatment.

Conclusion

This study allows us to conclude that natalizumab is an effective and safe drug for the patients we observed. There is the need to establish criteria for proper use and careful selection of patients, as well an appropriate follow-up in order to guarantee rational use.

No conflict of interest

CPC073 Terlipressin in Hepatorenal Syndrome

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Background

Hepatorenal syndrome (HRS) is a life-threatening medical condition that consists of rapid deterioration in kidney function in individuals with chronic liver disease. Two forms of hepatorenal syndrome have been defined:

Type 1 HRS entails a rapidly progressive decline in kidney function, with an increase in serum creatinine and a substantial decrease in the glomerular filtration rate, while type 2 HRS is characterised by a steady and progressive decline in the renal function. Terlipressin is a vasopressin analogue used in type 1 HRS, which acts on vasopressin vascular (V1) smooth-muscle cell receptors, acting like a vasoconstrictor and improving systemic and renal perfusion. Literature data indicates that type 1 HRS is reversed in about half of the patients treated with terlipressin, with an associated immediate survival of 30-40%.

To evaluate terlipressin use in type 1 HRS patients, in Garcia de Orta Hospital.

Material and Methods

Retrospective observational study of patients diagnosed with type 1 HRS and treated with terlipressin, between January 2008 and August 2010.

Our study included 12 patients with type 1 HRS treated with terlipressin (11 males and 1 female), median ages 59.2 ± 11.0 years [45-76 years]. All patients were treated simultaneously with

Terlipressin's approved posology is 3-4 mg per 24 hours, divided into 3 to 4 administrations. Four of the patients studied received 1 mg terlipressin every 6 hours (4 mg/day). The rest of the patients received terlipressin every 4 hours, with daily doses of between 3 and 12 mg.

The average length of treatment was 4.1±2.4 days [1-9 days]. Ten patients died while on terlipressin and 2 stopped treatment due to toxicity. Of the two patients who experienced toxicity, the HRS was reversed in one and the other died. The HRS reversal rate observed for terlipressin, and the immediate survival, was 8.3%. None of the patients received the standard 10 days' treatment indicated for terlipressin.

Conclusion

The HRS reversal rate and the immediate survival observed in this study were less than the published studies. Terlipressin use in HRS patients requires careful selection of patients and closer monitoring, in order to ensure rational use.

No conflict of interest

CPC074 Sorafenib evaluation in advanced hepatocellular carcinoma

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Background

Hepatocellular carcinoma (HCC) is the 6th most common cancer in the world and the third leading cause of cancer-related death. Hepatitis B virus is the most frequent underling cause and other risk factors include alcohol use, non-alcoholic fatty liver disease, smoking and inherited liver disease. The associated mortality rate is high, with fewer than 5% alive five years after diagnosis. Sorafenib, an oral multiple kinase inhibitor, was the first systemic therapy approved for advanced HCC treatment. The phase III trial, which led to its approval, produced an overall survival of 46.4 weeks. In that trial, 97% of the patients were classified as Child-Pugh class A.

To evaluate sorafenib effectiveness in patients with HCC, in Garcia de Orta Hospital.

Material and Methods

Retrospective analysis of advanced hepatocellular carcinoma patients treated with sorafenib, from August 2009 to August 2010.

This study included 8 HCC patients (6 males and 2 females), with a median age of 57.0 \pm 5.7 years [50-68 years]. All patients received sorafenib 400 mg twice daily.

At the beginning of the treatment, 7 patients presented Child-Pugh class B and only 1 patient Child-Pugh class A. The patient with Child-Pugh class A is the only one still on treatment.

The median treatment duration was 12.6 weeks ± 9.0 weeks [2-29] weeks]. Seven patients stopped treatment and 5 of them died. The median overall survival, since the beginning of treatment was 18.2 weeks ± 12.8 weeks [3-29 weeks].

The more frequent adverse events were diarrhoea, abdominal pain and weight loss, leading to dose reductions in 3 patients.

Conclusion

Since hepatocellular carcinoma develops mainly in patients with cirrhosis, it is very difficult to select patients with well-preserved liver function (Child-Pugh class A), in which sorafenib could have a more beneficial therapeutic effect. The median overall survival of the patients analysed was less than in the published studies, mainly because the majority of these patients are Child-Pugh class B.

No conflict of interest

CPC075 Rapid infusion of rituximab over 60 minutes

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Background

Standard administration of rituximab over 2 to 3 hours requires considerable healthcare resources and is uncomfortable for patients. There is interest in reducing rituximab administration times and although infusion over 90 minutes has proved safe, there is limited data about safety of 60-minute infusions.

Purpose

To assess the safety of second and subsequent rituximab administrations over a 60-minute constant rate infusion.

Material and Methods

All patients received rituximab (375 mg/m2 in 500 mL of 0.9% normal saline) and premedication with intravenous hydrocortisone (100 mg), paracetamol (1000 mg) and dexchlorpheniramine (5-10 mg). Rituximab was administered at a constant rate infusion (500 mL/hour). Patients were eligible for rapid rituximab infusion if they had not showed severe reactions during their first rituximab infusion. The variables assessed to quantify the safety were rash, bronchospasm, fever or hypotension.

Results

130 rapid infusions of rituximab over 60 minutes were administered to 41 patients between May 2009 and September 2010. The median age was 61.5 years (range 18-85) with patients receiving a median of 3.17 rapid rituximab infusions (range 1-7). Rapid infusion over 60 minutes was well tolerated with no patients having significant reactions to the rapid administration rate.

Conclusion

Second and subsequent rituximab infusions can be safely administered over 60 minutes without risk of significant infusion reaction. The new protocol should be considered for most patients in normal clinical practice. If implemented correctly this finding has considerable beneficial implications, since it could save a significant amount of patient time and healthcare resources.

No conflict of interest

CPC076 Haemodialysis: analysis of profitability

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Background

Public hospitals in France have become increasingly profitorientated due to changes in the National Health financial System (NHS). Costs of haemodialysis sessions are in fact not difficult to calculate, because coverage is well codified by the NHS with an easily identified profit/loss margin. We decided to choose this model for our study.

Purpose

To determine whether haemodialysis activity was profitable in 2008 and 2009.

The second objective was to identify the primary and the increasing expenditure items of this type of medical service.

Material and Methods

All the receipts and expenditures, apart from lab tests, were determined by creating exhaustive monitoring tables. Thus, we could subsequently calculate profits and accurately analyse the expenditure.

Results

Profit per haemodialysis session was 50 euros in 2008 and 32 euros in 2009. A session therefore remained profitable between 2008 and 2009, despite a decrease of 26 euros in the reimbursement price.

During the two years, the main expenditure items were staff costs (approximately 150 euros per session) and pharmaceutical costs (approximately 100 euros per session).

Medical sterile devices, erythropoietin, parenteral nutrition and catheter lock solution represented the major pharmaceutical costs. However, whereas medical device costs decreased between 2008 and 2009, drug cost increased. This is explained by the increase in fibrinolytic agents (+100%), parenteral nutrition usage (+111%), iron supplement costs (+32%) and catheter lock solution costs (+27%). These results led to a coordinated programme with physicians to find less expensive alternatives, while at the same time maintaining quality medical care. For example, an economy of 3,000 euros per year will be made by substituting urokinase for alteplase. Similarly, a substitution of citrate plus taurolidine solution by a citrate solution should save 5,000 euros per year.

Conclusion

Haemodialysis is a cost-effective activity. The study permitted collaboration between pharmaceutical and medical teams and led to action with a change in some care practices. It was a pilot programme which can be usefully applied to other medical departments.

No conflict of interest

CPC077 Standarized parenteral nutrition.ls it suitable for everyone? Our experience.

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Background

Nutritional status is a relevant factor contributing to the recovery of surgical patients.

Purpose

To evaluate whether the current Standard Parenteral Nutrition (SPN) protocols adopted are varied enough to supply suitable nutritional support according to the ASPEN 2009 consensus.

Material and Methods

Data were collected from medical reports between January-March 2010 in a tertiary hospital. The selected parameters were age, sex, BMI, comorbidities, days of hospitalisation, duration of SPN, energy and protein requirement and type of SPN. The types of SPN available in our centre are:

Name of SPN	N 7	N 10	N 16
g Proteins	45.6	72	103.1
Total Kcal	1215	1900	2000
Volume ml	2000	1875	2000
Electrolytes	Yes	No	No
Vitamins & Trace Elements	No	No	No

Results

A total of 37 patients were included. The median age was 64 years (SD 17) and 72.9% were men. The patients were given SPN for 10.6 days (SD 6.6), and had median hospital stays of 29.9 days (SD 21.7) BMI and comorbidities are shown in the next table:

	DM	HT	CRD
BMI>40		1	
BMI>30	4	1	1
BMI>24	1	8	
BMI 20-24	2	4	
BMI <20		1	
Total	7	15	1

DM Diabetes mellitus HT Hypertension CDR Chronic Renal Disease, Dyslipidaemia; COPD Chronic Obstructive Pulmonary Disease.

We found that a total of 55.7% patients did not receive the correct caloric support, being 42.3% overfeeding. The protein intake was not suitable for 46.1% of the patients, 34.6% of patients were not given sufficient protein. Moreover SPN was not supplemented with vitamins and trace element in an 86%, of whom 41.6% also lacked electrolytes.

Conclusion

It seems that the available SPN in our centre does not cover the energy-protein needs of hospitalised patients. New SPN protocols based on internationalguidelines should be written so that patients obtain appropriate nutrition.

CPC078 Pharmaceutical interventions realized in internal medicine service.

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Background

Clinical pharmacists as members of the health care team play an important role in patient care.

Purpose

To describe activities and interventions performed during a fourthyear clinical rotation on an internal medicine ward and to validate a new Accessdatabase to record them.

Material and Methods

Three months of pharmaceutical care was carried out on a 48-bed internal medicine ward. For recording in the database, clinical pharmacy activities were divided into: medicines reconciliation (MR) on admission, pharmacotherapeutic follow-up (PF), medicines information for discharged patients (MIDP). Pharmaceutical interventions (PIs) were classified as medicine-related problem (MRP), therapeutic interchange (TI), drug interaction (DI) or others. The information database was used to edit a pharmacotherapeutic report directly.

Results

57 patients received PI during their admission. 40.4% were male and 59.6% female. The average age was 80.8 years. 137 PIs were documented. MR on admission was recorded in 39 patients (68.4%), showing an average of 10.3 medicines/patient: 36.5% of ambulatory medicines were discontinued. Also 1 DI, 22 TIs, 37 MRPs were reported and 3 classified as others. 95.3% of PIs in reconciliation were accepted by physicians. PF reports were made on all 57 patients, with an average of 1.3 interventions/patient. These were divided into 7.9% DIs, 5.3% TIs, 69.7% MRPs and 17.1% others. PF acceptance was 80.3%. At discharge, 22 patients (38.6%) received MIDP showing an average of 13.45 medicines/patient.

Conclusions

Through medicines reconciliation on admission, clinical pharmacists in internal medicine increased prescription by the formulary.

The pharmaceutical interventions presented were accepted in a large percentage of cases.

Increasing medicine information for discharged patients is an important target because patients are older and the average number of medicines/patient is 3.15 higher than at admission.

The design of this database was perfectly suited for a daily clinical pharmacy activity in internal medicine, facilitating the recording and providing the most relevant data with which to study new skills or to improve less common ones.

No conflict of interest

CPC079 Effects of Shared Medication Record at admission

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Background

In order to facilitate congruent information about patients' medicines throughout the complete patient path, to reduce errors related to transition and improve patient outcome, a Danish national registry of all citizens' currently prescribed medicines - a Shared Medication Record (SMR) - has been developed. SMR is to be updated at all encounters with the family doctor, at discharge after hospitalisation, and at consultations in out-patient clinics.

The SMR has been incorporated into the Electronic Health Record System in Sjaelland Region, OPUS Medicine (OM) and was studied at a ward receiving acute patients admitted to Koege Hospital.

Purpose

To check that incorporating the SMR into OM facilitates medicines reconciliation upon admission and saves time.

The primary efficacy parameter was time used to resolve the medicines history. Among secondary parameters were information source congruence, discrepancy between SMR and actual medicines, and clinicians' workload.

Material and Methods

Consultations were randomised to be performed with OM and the usual information sources on patient medicines or to SMR plus the other sources. Consultation time was recorded (h:min). After each consultation the doctor rated workload score on a visual analogue scales (VAS; 0-10), and a short supplementary VAS questionnaire was answered upon finishing the study.

Results

62 consultations were observed. Total consultation time was 1:10 h:min (0:32-2:40) with OM and 1:05 h:min (0:30-2:25) with SMR. Time used to resolve medicines history was 4:43 min:sec (1:15-15:37) with OM [+ 1:30 (0:30-2:40) after access to SMR], and 5:27 min (2:15-12:52) with SMR. Time used to resolve medicines history for the 16 patients without data in OM were 4:02 min:sec (1:15-10:12) for OM and 2:47 min:sec (2:00-2:47) with SMR.

The doctors judged SMR very helpful in resolving the medicines history.

Conclusion

SMR does not shorten the consultation time or the time to resolve medicines history. However SMR is useful for medicines consolidation and does not increase work load.

No conflict of interest

CPC080 Evaluation of the Efficacy and Safety of Conversion From Calcineurin Inhibitors to Everolimus in Renal Transplant Recipients

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Background

The introduction of the calcineurin inhibitors (CNIs), ciclosporin (CsA) and tacrolimus (TAC) into clinical practice, and later, their association in protocols with new and more potent drugs, resulted in a significant decrease in acute rejection and an improvement in short-term graft survival with most centres now achieving 90% 1-year graft survival. Despite short-term success, the rate of long-term attrition in graft survival has remained surprisingly constant, and survival does not exceed 10 years. This fact has two major causes: graft chronic dysfunction (chronic allograft nephropathy and chronic rejection), and patient death (with functioning graft) due to cardiovascular lesions. Calcineurin inhibitor (CNI) nephrotoxicity is one of the many factors that may be contributing to long-term damage in transplant kidneys. The possibility of withdrawing or avoiding CNIs, using non-nephrotoxic protocols, becomes a clear aim in order to prevent late graft loss and get better long-term results

Purpose

To evaluate the efficacy and safety of conversion from CNI-based treatment to everolimus in maintenance renal transplant recipients.

Material and Methods

Between February 2009 and July 2009, 63 renal transplant recipients were converted from a CNI-based immunosuppressive protocol to everolimus, according to clinical criteria: stable patients, without proteinuria and serum creatinine < 2.5 dl. CNI suspension was abrupt, everolimus doses (between 2.25 and 3 mg/day) were chosen in order to achieve target trough levels between 3 and 8 ng/ml. No other changes were made in the immunosuppression regime. The efficacy was analysed according to renal function, biopsy-proven acute rejection, graft loss and death. The safety was evaluated based on reported adverse events.

Results

63 patients were included, 43 (68.8%) were male and 20 (32.2%) female with a mean age 50.1 ± 12.2 (range: 20 to 68) years. Follow-up of 3.3 ± 1.7 (range: 1 to 6) months. No biopsy-proven acute rejection, graft losses or deaths were observed. Six months after conversion we observed a tendency to improved renal function (pre-conversion 1.4 \pm 0.31 mg/dl; post-conversion 1.2 \pm 0.35 mg/dl). 4 of the 63 patients suspended the drug and were switched back to CNI (6.3%): 1 patient, CMV infection; 1 patient, BK nephropathy; 1 patient, hepatic toxicity; and 1 patient, serious oral ulcers. Only 6 patients (9.5%) had proteinuria at the end of 6 months. After conversion, 17 of the 63 patients experienced haematological drugrelated toxicity (27%): 5 patients, anaemia; 6 patients, leukopenia; and 6 patients, thrombocytopenia. These adverse reactions were transient and of mild intensity, with rapid recovery to the baseline. 8 patients (12.7%) had aphthous ulcers. The levels of cholesterol and triglyceride increased slightly but remained within acceptable limits.

Conclusion

Conversion from CNI to everolimus is a simple and safe procedure that has proved effective and well tolerated by renal transplant patients. The conversion should always be individualised, and the patient evaluated more frequently. A longer study of these patients will corroborate these results, giving you greater consistency.

No conflict of interest

CPC081 Local evaluation of methoxy polyethylen glycol epoetin beta therapy before introduction to hospital formulary: clinical pharmacist and physician collaborative approach G. Leonardi, A. Lavacca, <u>F. Cattel</u>, S. Boffa, T. Paone, E.J. Pennone, M. Scaldaferri, E. Sciorsci, G.P. Segoloni, S. Stecca ¹A.O.U. SAN GIOVANNI BATTISTA, Department of Internal Medicine - Division of Nephrology Dialysis and Transplantation, Turin, Italy

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Background

From January 2009 methoxy polyethylene glycol epoetin beta, a continuous erythropoietin receptor activator (CERA) became available as treatment to stimulate erythropoiesis in chronic kidney disease.

Purpose

For physicians and clinical pharmacists to perform a local evaluation of the drug in terms of efficacy, safety and cost-saving in order to assess the introduction of the drug into the hospital formulary and ward health care management. Literature data were used.

Material and methods

Monocentric prospective phase IV study involving 20 patients on haemodialysis (n=19) or peritoneal dialysis (n=1) on stable erythropoietin treatment. Inclusion criteria evaluated stability of haemoglobin (Hb) (range 11-12 g/dl or more), erythropoietin, iron, folic acid and vitamin B12 treatment, inflammatory status in the 3

months prior to the study. After a 4 week run-in period during which standard treatment continued, all the patients were switched to the CERA once monthly for three months. Haematological parameters were measured monthly.

Results

Treatment before switch was: erythropoietin α (n=7) or β (n=7) or darbepoetin (n=5) once to three times weekly. 4 patients dropped out for reasons not related to drug use (1 of them before starting the CERA). Treated population: n=19. During CERA treatment we observed stable haemoglobin mean values vs. standard EPO (Hb 11.1±0.6 g/dl vs. 11.2±0.7 g/dl (p:0.8)). No differences were found in any other parameters evaluated.

89% of patients had a dose adjustment (58% reduction, 31% increase).

There were 7 adverse events; 2 serious adverse reactions (probably none of them treatment-related).

In our population switching from standard erythropoietin to CERA resulted in an increase in mean monthly drug-associated costs of 36%. We didn't consider administration requirement and staff-associated costs.

No substantial advantages in our working procedures were seen.

Conclusion

In accordance with the study results, at the moment the CERA has not been added to the hospital formulary.

Further and exhaustive economic evaluation should be performed to assess possible cost saving on a wider population or longer treatment duration.

No conflict of interest

CPC082 Contribution of maraviroc and raltegravir in the antiretroviral therapy outcomes in patients with human immunodeficiency virus infection

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Background

Raltegravir and maraviroc are new antiretroviral agents indicated in case of resistant mutations by European Guidelines.

Purpose

To evaluate the virological and immunological response in patients with human immunodeficiency virus (HIV) infection treated with maraviroc and/or raltegravir, and their contribution to the antiretroviral therapy (ART) outcomes of our HIV population.

Material and Methods

An observational, retrospective study was carried out with patients on ART with maraviroc and/or raltegravir from February 2008 until September 2010. We recorded from the selected patients: demographic information, current antiretroviral treatment, reason for change to these drugs and adherence (by record of dispensed items). To evaluate efficacy we included the plasma HIV RNA (VL) and CD4 T-cell counts before the change, duration of treatment with these drugs and current values of VL and CD4. Undetectable VL (<20 copies/ml) or decrease >1 log₁₀ was regarded as virological response, and CD4 increase as immunological response. In addition, we recorded the current VL and CD4 count of our HIV population in treatment.

Results

13 patients (77% men) were included, median age 51.38 years, from 260 HIV patients on ART. The average duration of treatment was 14.46 months. 11 (84.6%) of the patients included were treated with these drugs due to virological failure and the response obtained was ideal in 8 (72.7%). In 1 patient, who was treated for immunological failure, CD4 count increased to 68 cells/ml supporting undetectable VL, and in 1 patient with renal failure

virological and immunological response was maintained. 9 patients (69.23%) presented adherence ≥95%. The response obtained in these patients increased from 180 (69%) to 188 (72%) the patients with virological control in our HIV population.

Conclusion

The introduction of new drugs such as maraviroc and raltegravir to ART has helped to improve virological and immunological benefit in the HIV population. Pharmaceutical care helps to optimise ART and improves patient adherence.

No conflict of interest

CPC083 Vinflunine in the treatment of adult patients with transitional cell carcinoma of the urothelial tract: drug utilization review

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Background

Vinflunine is indicated in monotherapy for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen.

Purpose

To review the effectiveness of vinflunine in the treatment of adult patients with carcinoma of the urothelial tract.

Material and Methods

Medical record review and retrospective analysis (January to September, 2010) of prescriptions recorded in the Outpatient Pharmacy Department (ATHOS-APD drug prescription database) and in the Clinical Oncology database (ONCOBASS) in a general teaching hospital. Clinical conditions, previous drug use, dose, line of chemotherapy, number of cycles administered, Progression-free Survival (PFS) were analysed.

Results

A total of 6 patients with metastatic transitional cell carcinoma of the urothelial tract were prescribed vinflunine. All patients were male, median age 65 (53-74).

Two patients died before receiving treatment.

In the group of the four patients who received treatment, two (50%) received vinflunine as a second-line treatment after failure of a platinum-based regimen, one (25%) received vinflunine as a third line after two regimens containing platinum and one patient (25%) was prescribed vinflunine as a fourth alternative after treatment with three different regimens based on platinum.

Mean number of chemotherapy cycles received per patient was 3. Only one patient (25%) received all planned cycles of chemotherapy (6).

During treatment, one patient (25%) died, two patients (50%) showed progression of the disease before complete treatment and one patient (25%) had progression after completed treatment.

All of three patients whose disease progressed (75%) continued treatment with other lines of chemotherapy. Median PFS was 3.5 months.

Conclusions

Vinflunine failed to demonstrate effectiveness in the treatment of transitional cell carcinoma of the urothelial tract in our patients, although data from more patients and longer-term studies are required.

No conflict of interest.

CPC084 Posaconazole tolerance and efficacy in cystic fibrosis lung disease children with fungal refractory infection

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Background

The lung disease cystic fibrosis is frequently associated with invasive, chronic and refractory fungal infections in children. Thus, an effective and, if possible, oral antifungal treatment is required to improve patient quality of life. Posaconazole is an extended-spectrum triazole used for the treatment and prophylaxis of refractory invasive fungal infections in adult patients. It has favourable pharmacokinetic properties, a good safety profile and documented preventive and therapeutic clinical efficacy in adults

Purpose

to evaluate posaconazole use in children with cystic fibrosis for whom standard antifungal treatment has failed.

Material and Methods

We studied 4 paediatric patients (6-15 years old) with cystic fibrosis and an invasive fungal infection.

Results

In all patients, strains of *Aspergillus fumigatus* were isolated in bronchial secretion samples. In one patient, initial resistance to flucytosine, itraconazole, caspofungin and amphotericin led to posaconazole use in first intention. In the other patients, posaconazole was used in second or third intention after oral treatment had failed or adverse effects had appeared with other antifungal drugs. Three patients received an adult dose (400 mg bd) and the fourth received 300 mg bd after plasma concentration measurement and dose adjustment. Posaconazole improved the general status in all patients and all bronchial samples were negative after treatment completion.

Conclusion

In our study, the tolerance and efficacy profile of posaconazole justified its paediatric use in invasive refractory fungal infections associated with cystic fibrosis. Nevertheless, the posology was adjusted to posaconazole plasma levels and its pharmacokinetic properties in children should be investigated to improve the treatment of these patients.

No conflict of interest

CPC085 Use of methoxy polyethylene glycol-epoetin beta (MirceraÆ) in peritoneal dialysis patients

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Background

Study using a new formulation of epoetin that has the advantage of being administered monthly.

Purpose

To evaluate the effectiveness of methoxy polyethylene glycolepoetin beta (Mircera) in patients on peritoneal dialysis (PD) who had previously received alpha epoetin (alpha EPO) treatment.

Materials and Methods

Retrospective observational study of five months performed in a university hospital. Patients included in the study were those with chronic renal failure treated by peritoneal dialysis (PD) who began treatment with Mircera after previous treatment with alpha EPO. Demographic and clinical data were collected from medical records. Data about the Mircera treatment, dosage and previous treatments were obtained from the database of patient pharmaceutical care.

The initial dose of Mircerawas calculated according to the previous weekly dose of alpha EPO and based on previous clinical experience in PD patients: 1000-4000 IU alpha EPO/week: 30-50 μ cg Mircera/month; 5000-8000 IU alpha EPO/week: 75-100 μ cg Mircera/month; 9000-12000 IU alpha EPO/week: 120-150 μ cg Mircera/month; 13000-16000 IU alpha EPO/week: 200-250 μ cg Mircera/month.

Results

A total of 27 patients were included (70.4% men) with an average age of 62.7 \pm 14.4 years. The average haemoglobin (Hb) at baseline was 11.17 \pm 1.17 g/dl and after 5 months was 10.76 \pm 0.97 g/dl. The dose of fourteen patients was increased during the treatment while in two patients it was reduced. At the beginning 40.8% of patients had Hb levels <11 g/dl, 25.9% between 11-11.99 g/dl, 33.3% between 12-12.99 g/dl and no patients had Hb>13 g/dl. The values, for these Hb ranges, after five months were 53.4%, 33.3%, 13.3% and 0% respectively. The Hb average of patients between 12-12.99 g/dl was reduced statistically significantly after four months of treatment in relation to the average Hb at baseline (p=0.034).

Conclusion

Mircera was able to increase the number of patients with Hb <12g/dl which is recommended in the guidelines. The equivalence established between alpha EPO and Mircerashould be checked and the patients followed up for longer.

No conflict of interest

CPC086 Gaucher disease treatment with low dose: a case report

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Background

Gaucher's disease (GD) is an inherited lysosomal storage disease that results from an autosomal recessive deficiency of glucocerebrosidase with consequent accumulation of glycolipids in macrophages of the mononuclear phagocyte system, particularly in the spleen, liver, bone marrow and lung.

Purpose

To determinate the clinical outcomes and cost effectiveness of enzyme replacement therapy (ERT) with imiglucerase in the treatment of symptomatic type 1 GD after a dose reduction because of shortages by the laboratory.

Material and Methods

A case report, between January 2009 and September 2010, of a 41-year-old, non-splenectomised patient, in treatment with ERT with two different doses of imiglucerase: 60 IU / kg or 15 IU / kg every 14 days. The patient's clinical history and analytical data were reviewed and the following therapeutic goals were collected: haemoglobin count, platelet count and chitotriosidase activity.

Results

The patient received 19 administrations at 60 IU / Kg (4,400 IU) and 20 administrations at 15 IU / Kg (1,200 IU). The haemoglobin has increased progressively from baseline of 12 mg / dL to 15-15.8 mg / dL. Platelet counts remained below normal levels throughout the study period, between 40,000 to 70,000 cells / mcL. Chitotriosidase activity decreased since the start of the ERT; before the treatment (October 2008) it had a value of 14.938 nmol/mL/h and the last value was 1.939 nmol/mL/h (July 2010).

The dose reduction resulted in savings of \in 11,164.24 for each dose of 15 IU /kg administered, with a total of \in 223,284.80 in 20 administrations.

Conclusions

Dose reduction did not result in a worsening of therapeutic

achievements or clinical course; in addition, lower-dose treatment led to significant savings. We concluded that treatment with lower doses was cost effective.

No conflict of interest

CPC087 Off-label medicine use: two cases that saved lives

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Background

The off-label use of drugs is frequently considered to be 'state-of-the-art' treatment. Because of lack of legal information, hospital pharmacists are frequently asked to collaborate in the resolution of treatment-related questions.

Purpose

Description of clinical off-label uses (colistin and sodium thiosulfate) that saved patients' lives.

Material and Methods

Retrospective analysis of medical and pharmacy records on two different patients and from the Drug and Therapeutic Committee support data.

Results

A 42-year-old woman, with history of renal failure, on haemodialysis treatment and who had been in hospital many times, developed skin ulceration due to calciphylaxis (a morbid syndrome of vascular calcification). Standard treatment did not result in sufficient clinical improvement and the patient's parathyroid glands were removed. The responsible physician suggested the use of intravenous sodium thiosulfate (off-label indication). The clinical pharmacist provided evidence-based information to guide the treatment. Sodium thiosulfate therapy was started and rapid early clinical improvement was observed and no new calcifications have been A 39-year-old man, with a history of recorded during treatment. cranio-encephalic trauma and hydrocephalus, requiring a ventriculoperitoneal shunt and several operations, developed fever despite standard antimicrobial therapy. Pseudomonas aeruginosa isolated in the cerebral spinal fluid presented susceptibility to meropenem, ceftazidime, amikacin and colistin. After treatment failure with IV meropenem and IV amikacin, the clinical pharmacist suggested intrathecal administration of colistin (off-label use of route of administration), resulting in the patient's recovery.

Conclusion

Off-label use is practiced despite lack of legal information. This is often done in the absence of adequate supporting data. Although our clinical cases were supported by low-evidence case reports only, patients had positive lifesaving clinical outcomes, which sustains the off-label use. More consistent literature data based on drug use evaluation is required in this area to prevent serious safety problems. Clinical pharmacists can play an important role in this area, providing information on clinical-based evidence and patient follow-up.

No conflict of interest

CPC088 ASSESSMENT AND MONITORING THE CONTRIBUTION OF ORAL ZN IN PATIENTS UNDERGOING BARIATRIC SURGERY.

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Background

Zinc absorption is decreased in patients with morbid obesity undergoing bariatric surgery. Zn is a trace element that plays important roles in the body.

Purpose

To analyse serum Zn values in these patients evaluating the impact of oral supplementation of Zn.

Material and Methods

Zn levels in the serum of patients undergoing bariatric surgery from 2002 until September 2010 were followed up by examination of all analytical information available during this period of time in the electronic health record (lanus) and the Central Laboratory computer application Tecnidata v03.54.a version.

We collected all records of oral zinc sulphate dispensed in the Pharmacy Department (Master Formula: Capsules of 50 mg zinc sulfate heptahydrate, which provide 11.4 mg of elemental zinc per capsule and a commercial formula: capsules of 37 mg of Zn, which provide 15 mg of elemental zinc per capsule from June 2008) from the "Dypex" outpatient dispensing program during the study period.

Results

157 women underwent bariatric surgery between April 2002 and February 2010. Only 14 patients received oral zinc sulphate in this time period. In only 2 of 14 patients were Zn levels in the last lab test requested within normal values. The first lab test that included the parameter serum Zn was requested 530 days after surgery on average, with a range [27-1718 days]. In 42.86% of patients the Zn serum value in the first test was within the normal range (65-140 µg/ml). The first oral Zn supplement dispensed from the pharmacy occurred 1225 days after surgery on average, range [107-1883 days].

Conclusion

A protocol for oral Zn supplementation in patients with morbid obesity undergoing bariatric surgery should be developed, to try to get Zn levels within the physiological range.

No conflict of interest.

CPC089 ERYTHROPOIETIN USE IN THE MANAGEMENT OF RIBAVIRIN INDUCED ANEMIA IN HEPATITIS C VIRUS INFECTED PATIENTS

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Background

Anaemia may be the leading cause of premature discontinuation of combination treatment with ribavirin and interferon. Both contribute to the development of anaemia. Certain patient populations appear more susceptible to anaemia such as liver transplant recipients or cirrhotic patients.

Purpose

To study the use of erythropoietin (EPO) in the haemolytic anaemia induced by ribavirin (RBV) in the course of hepatitis C treatment.

Material and Methods

Aretrospective analysis all patients infected with hepatitis C who received EPO (off- label use) to treat haemolytic anaemia caused by RBV from January 2008 to March 2010. The data were obtained from the information systems of the Pharmacy Department, Central Laboratory and the electronic medical records (IANUS).

Patients included in the study were those being treated with interferon (IFN) and RBV and receiving some form of EPO during treatment.

Results

Of the 220 patients treated with RBV and IFN since January 2008, we selected 21 who were being treated with EPO, of which 12 (57.1%) had had a liver transplant. Mean treatment duration with EPO was 187.8 days. During EPO treatment the initialmean Hb was 7.97 g/dL and final Hb was 10.95 g/dL. In 14 patients Hb levels increased by 34.8% while in 7 patients Hb levels decreased by

15.5%. The mean dose of EPO at the beginning was 4190 IU/day and at the end 6782 IU/day. Mean treatment duration with RBV was 323.2 days. The optimal dose of RBV was maintained in 12 patients throughout the treatment. 9 patients required dose reduction, one of whom had to suspend the RBV for 1 month, restarting after that time.

Conclusion

The addition of epoetin improved the haemolytic anaemia caused by RBV and allowed ribavirin treatment to continue. It would be useful to have standardised criteria for erythropoietin dosing in these patients because without EPO treatment it is necessary to suspend ribavirin, which leads to disease progression.

No conflict of interest

CPC090 Use of Rituximab in a patient with Devic's Disease (Neuromyelitis optica). A case report

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Background

Devic's disease or neuromyelitis optica (NMO) is an uncommon autoimmune disease with inflammation and demyelination of the optic nerve and spinal cord with high morbidity and mortality.

Purpose

To describe a patient with NMO and evaluate the efficacy and safety of rituximab treatment.

Material and Methods

A descriptive study was made by reviewing the medical and pharmaceutical records of a 32-year-old patient diagnosed with NMO secondary to tuberculosis treatment.

Results

In December 2009, the patient was admitted due to pulmonary tuberculosis and treated with ethambutol. While in hospital, the patient suffered optic neuritis with associated paraparesis. Once investigated, she was diagnosed with NMO due to tuberculosis treatment, so ethambutol was withdrawn and treatment for NMO was started. The patient was given high-dose corticosteroids (methylprednisolone 1 g IV/24 h, for 5 days) and was discharged with partial improvement of visual deficits and total sensory recovery. Three weeks later, the patient suffered a flare-up consisting of paresthesias, lower paraplegia and impaired sphincter control. Immunomodulatory treatment was administered (5 bolus doses of methylprednisolone followed by 10 alternating cycles of plasmapheresis) but no improvement was evident. Due to the seriousness of the illness, aggressive immunosuppressive therapy recommended: azathioprine, cyclophosphamide, mycophenolate mofetil or rituximab (RTX) were suggested. Finally, it was decided to start RTX because it acts more quickly than than the other options and was less likely to exacerbate the tuberculosis. This use of RTX was an off-label indication, so after permission from our Health Authorities, the patient was treated with RTX 600 mg weekly. After a month of treatment, the patient did not have any adverse effects from the infusion of RTX and experienced a progressive clinical improvement of her motor and sensory deficits, including sphincter control. She was sent to a paraplegic centre for rehabilitation, where, currently, she is continuing to improve.

Conclusions

The goal of NMO treatment is to control symptoms, so in our case, after the failure of conventional therapy, treatment with RTX was an effective alternative treatment .The patient had clinical improvement, still in progress. It was also well tolerated without any significant adverse reactions.

CPC091 Management of blood pressure in patients with depression and hypertension

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Background

There is speculation that depression raises the risk of hypertension or that low blood pressure causes depression or that depression may cause low blood pressure.

Purpose

This study focused on the increase in blood pressure in patients being treated with antidepressants that acted on noradrenergic and/or serotonergic, dopaminergic (bupropion, duloxetine) and with antihypertensives.

Material and Methods

281 subjects from the Psychiatry Hospital of Craiova, Romania were included in the current clinical study, aged between 25 and 65. Data was collected in a computerised database containing data about the patient, blood pressure measurements and medical history. The results were statistically analysed using the ANOVA test and χ^2 test.

Results

Some increased blood pressure measurements were recorded in patients taking tricyclic antidepressants, but also in patients being treated with antidepressants that worked on the noradrenergic and/or serotonergic, dopaminergic systems (bupropion, duloxetine). Subjects treated with tricyclic antidepressants had higher systolic blood pressure values (p=0.003<0.05) and higher diastolic blood pressure values (p=0.00031<0.05). Subjects treated with antidepressants that selectively inhibited norepinephrine reuptake only had higher diastolic blood pressure values (p=0.00041<0.05).

Conclusion

Patients treated with antidepressants that selectively inhibit norepinephrine reuptake had double the risk of hypertension, even if they were also being treated with an antihypertensive. Further study is desirable to find out why we found only higher diastolic blood pressure values, not higher systolic blood pressure values; this might be related to the balance between sympathetic overactivity and parasympathetic underactivity.

No conflict of interest

CPC092 SODIUM OXYBATE IN NARCOLEPSY ASSOCIATED TO CATAPLEXY: A SERIES OF FIVE CASES

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Background

Sodium oxybate (γ -hydroxybutyrate, GHB) has been demonstrated to be effective in reducing symptoms of narcolepsy with cataplexy (NC), a rare chronic sleep disorder characterized by excessive daytime sleepiness and sudden muscular weakness.

Purpose

To test the efficacy and safety of GHB plus modafinil compared to the standard therapy with modafinilin non-responding patients suffering from NC.

Material and Methods

Five patients diagnosed with long-standing NC (mean 12 years since onset) and refractory to standard treatment (modafinil 200 mg OD) were prescribed GHB at progressively-increasing doses (from 2.25 g up to 4 g BID). Primary efficacy outcome (A) was the reduction in the number of daily episodes of hypersomnia and sudden muscular weakness. Second efficacy outcome (B) was the

number of episodes of sleep fragmentation. Other subjective aspects (interest in daily activities, mood, etc.) were also evaluated. Primary safety outcome (C) was neurological (migraine, dizziness) and digestive (nausea) adverse effects.

Results

4 female and 1 male patients, mean age 63.2 years (range 48-70). Average time since start of GHB: 15 months (4-22).

- **A**: All patients showed a significant decrease in daytime sleepiness (82%, 74-90). Cataplexy required maximum doses to achieve low to moderate remission.
- **B**: Sleep fragmentation: reduction from 7-15 interruptions to 1-4. Emotional state, motivation and interest in everyday tasks also evidenced a considerable improvement.
- **C**: Mild-to-moderate hypertension (treated with irbesartan 300 mg/day) (one case), transient episodes of headaches (one case) and modafinil dose-dependent anxiety (one case). No alterations were observed at the cognitive level.

Conclusion

In modafinil-refractory patients, the addition of GHB achieved a noteworthy decrease in the cardinal symptoms, leading to a significant improvement in quality of life. Despite mild adverse effects being relatively common, tolerance at therapeutic doses was acceptable. As first-line drug in the treatment of NC, this study corroborates previous results supporting the efficacy and safety of oxybate.

No conflict of interest

CPC093 The use of tacrolimus enema in inflammatory bowel disease: a report of two cases

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Background

Tacrolimus is a potent immunomodulator. Many studies show that it is effective in systemic treatment of inflammatory bowel disease (IBD). High toxicity limits its use. Local administration seems to be an effective and safe practice.

Purpose

To describe our experience with tacrolimus enemas (TEs) in IBD.

Material and Methods

We reviewed the clinical histories using the Seleneâ program.

- 1)A 80-year-old male with refractory left-side colitis for 12 years. Hevisited the emergency department, due to persistent anal pain and several stools per day. The initial colonoscopy evidenced severe proctosigmoiditis. The drug treatment was intensified with corticosteroids and mesalazine. He did not respond properly and started daily TEs. The use of infliximab was not possible due to a previous allergic reaction.
- 2) A 42-year-old male with Crohn's disease for 20 years. He suffered a severe flare-up. He received intravenous corticosteroids and rectal mesalazine. As the patient did not improve, he started with TEs.

The Pharmacy Service (PS) made a protocol for preparing TEs in appropriate asepsis and sterility conditions. The method consisted of diluting 4 mg of tacrolimus in 150 ml sodium chloride 0.9% and its subsequent packaging in sterile bags. Then, systems for rectal administration were connected to these bags.

The enema must be in contact with anal mucosa for 1-3 hours (approximately).

Results:

1). Ten davs after TE

1 <u>1</u> . Tell days aller T⊑				
Clinical results				
Anal pain	Continued			
Daily stools	Continued			
Endoscopic signs				
Ulcers	Not observed			
Pseudopolyps	Improvement but remained			
Oedema	Improvement but remained			
Safety				
Side effects	Not observed			
Physical tolerance	Good			

The doctor asked the PS if the patient could continue treatment at home. The low stability (24 hours) requires daily dispensing and he did not want to continue the treatment. Therefore, it was stopped.

2) After two TEs, the treatment had to be stopped. The tolerance was very bad and the patient rejected it. As there were no more drugs for disease control, a surgical intervention was necessary.

Conclusion

- 1. The use of TEs might be an effective alternative.
- 2. They seem to be safe.
- 3 More studies are required to determinate the optimal dosage and duration of treatment. Perhaps smaller volumes would improve the tolerance.

No conflict of interest

CPC094 Muscular toxicity from docetaxel in HIV-patient treated by ritonavir

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Background

In hospital patients are treated in different care units for their cancer and for their chronicles diseases. Interactions between their treatments can lead to iatrogenic consequences.

Purpose

To report a case of a docetaxel-ritonavir interaction in a HIV-patient with breast cancer

Material and Methods

Informations including HIV treatment have been obtained from patient clinical history. Chemotherapy treatments were obtained from CHIMIO.

Results

A 36-year-old HIV-positive woman was diagnosed with breast cancer in February 2010. The HIV-infection was diagnosed in 1996. Since 2007 eighth line treatment contains atazanavir (boosted with ritonavir), tenofovir and emtricitabine.

Neoadjuvant chemotherapy contains four cycles of Epirubicine-Cyclophosphamide followed by four cycles of docetaxel.

Patient received four cycles of EC without important side effects. Three days after her first docetaxel cycle she was admitted to emergencies for muscular pains interesting her legs.

Docetaxel-ritonavir interaction was supposed because docetaxel was metabolized by CYP450-3A4 and ritonavir inhibited CYP450-3A4. HIV treatment couldn't be changed because infection was well controlled with viral load below the limit of detection. So docetaxel dose was reduced from 100mg/m² to 65mg/m². However seven days after the second cycle patient was again admitted for muscular pains. Docetaxel was definitely stopped. Another possible choice was to use vinorelbine but review of literature has showed vinorelbine is also metabolized by CYP450-3A4. Thereby patient

received two more cycles of Epirubicine-Cyclophosphamide before mastectomy.

Conclusion

This case report highlights severity of potential interaction between docetaxel and ritonavir. Concomitant administration of these medications may increase docetaxel blood concentration probably due to the inhibition of CYP450 by ritonavir. So docetaxel must be avoided in HIV-patient treated by ritonavir.

While these interactions are well known to clinicians treating HIV, they are probably less obvious to the clinician prescribing chemotherapy. The optimal care for cancers requires that practitioners attend multidisciplinary meeting around the file of the patient.

No conflict of interest

CPC095 Clinical experience with acid alpha-glucosidase in two paediatric patients

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Background

Acid alpha-glucosidase (Myozyme) has been authorised in the EU since March 2006 for long-term enzyme replacement treatment in patients with a confirmed diagnosis of Pompe's disease, a rare inherited disorder.

Pompe's disease is a metabolic myopathy caused by a deficiency of acid alpha-glucosidase (GAA), an enzyme that degrades lysosomal glycogen. It is characterised by progressive muscle weakness and loss of respiratory function.

Purpose

To review the efficacy and safety of GAA in two paediatric patients and calculate the cost of using for one year of treatment.

Material and Methods

We report the cases of two paediatric patients with Pompe's disease who were treated with intravenous infusions of GAA 20 mg/kg given once every two weeks. The patients received routine premedication consisting of dexchlorpheniramine 1 mg intravenously.

Results

Both patients were 14 years old and were diagnosed with Pompe's disease at two years of age. At present, patient 1 needed a dose of 800 mg and patient 2, 500 mg of GAA. Infusion-associated reactions occurred at the second dose in patient 1. These reactions were urticaria, hypotension and shock. GAA was suspended and intravenous dopamine administered with rapid recovery. The reactions resolved with no need to withdraw the treatment. The distance walked in the 6-minute walk test and percentage of the predicted forced vital capacity (FVC) in the upright position improved significantly in both patients. After four years in patient 1 and two years in patient 2, our patients respond well to the treatment.

The treatment cost 201,600 €/annum for one patient and 126,000 €/annum for the other patient.

Conclusion

GAA could be an effective and safe treatment in the long term for Pompe's disease. The progression of the disease appeared controlled associated with an improved walking distance and stabilisation of pulmonary function. Despite the high cost of the drug, its use is justified in this disease by the patients' marked improvement.

CPC096 Immune reconstitution inflammatory syndrome: a case report

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Background

Potent combination antiretroviral therapy (ART) has dramatically reduced the morbidity and mortality associated with HIV infection but its use can be complicated by immune reconstitution inflammatory syndrome (IRIS). In most case reports about IRIS in patients starting ART they have opportunistic infections (OIs).

Purpose

To describe IRIS in a treatment-naive HIV patient without Ols.

Material and Methods

Retrospective CD4-cell count and HIV viral load data were collected from the therapeutic history. Antiretroviral therapy was reviewed using the pharmacy database.

A literature search in PubMed and Medline was carried out with the following search terms: HIV infection, immune reconstitution inflammatory syndrome.

Results

The case of a 48-year-old treatment-naive male HIV patient is described. The HIV was diagnosed in 2005 and ART treatment with emtricitabine (FTC) + tenofovir (TDF) + nevirapine (NVP) began in May 2010. Within ten days of treatment he reported limited rash, severe fever (excluded other causes), jaundice, nausea and vomiting. The viral load dropped sharply, CD4-cell count increased disproportionately (more than twice from baseline) and transaminase levels also increased. ART was withdrawn due to hepatic toxicity and 15 days later the situation was improved. He was diagnosed with early IRIS.

In August 2010, after transaminase levels had normalised, ART was started with emtricitabine (FTC) +tenofovir (TDF) + lopinavir/ritonavir (LPV/r). At the moment, he is continuing the treatment

The levels of CD4, HIV viral load and GOT/GPT are shown in the table below:

DATE	VIRAL LOAD	CD4-CELL	GOT/GPT
	(copies/mL)	(cells/µL)	(U/L)
27/04/2010	234900	307	18/43
14/06/2010	859	828	129/418
25/06/2010			18/64
09/09/2010	903	278	31/42

Conclusion

This is an atypical case of IRIS. The pathophysiology of IRIS is still poorly understood and biomarkers for diagnosis and prediction of IRIS remain to be identified. We have reviewed the available scientific literature about this issue and we are working on a protocol with the infections department because careful monitoring for the development of IRIS during HIV treatment is essential to minimise the associated morbidity and mortality.

No conflict of interest

CPC097 Evaluation of daptomycin use according to restricted indications

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Background

Our antimicrobial stewardship program restricts the availability of drugs such as daptomycin, which require prior approval.

Purpose

to evaluate the appropriateness of daptomycin use in terms of the restrictions established by the Pharmacy and Therapeutic Committee (PTC) in a 1200-bed Hospital.

Material and Methods

6-month retrospective study reviewing medical records. Data collected: age, gender, renal function, prior antibiotic treatment, infection details, culture results and laboratory values. Daptomycin is restricted to the treatment of some serious infections (bacteraemia, right-sided endocarditis, etc.) when standard treatment is not possible due to resistance and/or patient intolerance.

Results

57 patients (32 men) with a mean age of 60 years received daptomycin. The median final dose was 6.9 mg/kg. The median duration of treatment was 11.9 days. The dosing interval was extended to 48 hours in 8 patients with severe renal insufficiency but in 3 it was administered daily. Prior antibiotic treatment had been given to 29.8% of patients (76.5% glycopeptides). Concomitant antibiotics were given to 32 patients (68%). Of the 32 patients (56%) with a positive culture, common pathogens were coagulase-negative staphylococci (CNS) in 21 and 11 S. aureus (MRSA 28%) (7 with decreased susceptibility to vancomycin (MIC ≥2)).

Daptomycin was used for some approved indications: complicated skin and soft tissue infections (16), *S.aureus* bacteraemia (9) and right-sided infective endocarditis (10), and non-indicated infections: 8 CNS bacteraemias (susceptible to other antibiotics), 1 osteomyelitis, 5 left-sided endocarditis and 6 sepsis. (5%) of the 57 patients experienced adverse events or abnormal laboratory value changes possibly related to daptomycin. Clinical success was reported for 48 patients (84%).

Conclusion

These data suggest that daptomycin is an effective and well-tolerated alternative to current treatment options, but prescription does not always follow the advice of the PTC. A proactive strategy of prospective auditing with direct advice and feedback to the prescriber appears more useful than a prior approval method alone.

No conflict of interest

CPC098 Audit of surgical prophylaxis in neurosurgery and surgery services

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Purpose

To evaluate the degree to which surgical prophylaxis protocols established in our hospital by the Infection Committee are followed. To revise and update an audit in order to assess the adherence.

Material and Methods

A prospective observational study was conducted over a period of two months. In the biliary surgery ward only patients operated on for cholelithiasis through laparoscopic cholecystomy were included. A data collection sheet was devised indicating: sex, age, type of operation. To evaluate adherence to the surgical prophylaxis protocols, the following parameters were evaluated: antibiotic/dose, treatment duration.

Results

NEUROSURGERY: 43 patients were analysed, of which 21 were men (48.9%) and 22 women (51.1%)with an average age of 47.3. The types of intervention included in the study were laminectomy (62.8%), discectomy (18.6%), craniotomy (16.2%) and insertion of shunts (2.4%). Appropriate prophylaxis was observed in relation to antibiotic/dose in 100% of the cases. With regard to the duration, this was correct in 30 of the cases (69.8%) and incorrect in 13

cases (30.2%). The cause of the failure was extension of the post-surgical prophylaxis. DIGESTIVE SURGERY: 30 patients were studied, of which 18 were women (60%) and 12 were men (40%), with an average age of 59.8. According to the protocol established by the Infection Committee, the prophylaxis was only correct in 10 cases (33.3%) and incorrect in 20 cases (67.70%). The reason for failure was administering the antibiotic although the existing gallbladder did not break.

Conclusion

Observance of the rules for antibiotic prophylaxis, of great importance in the prevention of hospital infections, was inadequate in 67.7% of cases on the digestive surgery ward, while on the neurosurgery ward the protocol was observed more strictly, 69.7%. It is important to analyse the data of each ward separately and to highlight what has worked in order to establish corrective measures and to reduce the effect and cost of infection.

No conflict of interest.

CPC099 How to ensure continuity of care in medication management at discharge from hospital? : a prospective study in a french hospital

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Background

Inappropriate medicines management and drug-related problems are common following hospital discharge, especially for the elderly. It has been shown [1] that when communication between hospital and community pharmacists improves, patients face fewer problems with their medicines after their discharge.

Purpose

To find out whether a programme to improve continuity of care in medicines management at discharge could be implemented in our hospital.

Material and Methods

This study was conducted in the internal medicine ward of the military hospital in Brest (France) for 4 months. Eligible subjects were patients aged 65 years or over who were discharged home. Before the discharge, we provided explanations to the patients concerning the changes in medicine made during the hospitalisation and we gave them a written summary. We also sent a pharmaceutical discharge plan to the community pharmacies.

Results

39 patients were included in our study. During hospitalisation, the patients had a mean of 3.5 drug therapy changes. 95% of the patients used the same community pharmacy on a regular basis and were able to give the name of their community pharmacist. They all agreed to the direct exchange of information between the hospital and the community pharmacy. All the community pharmacists contacted agreed to participate in the study.

We needed a mean time of 35 minutes to fill in the document for the community pharmacy and 25 minutes to explain the medicines to the patient.

Conclusion

These results highlight that this process is time consuming. They also show that all the community pharmacists and patients included in the study were receptive to our project. This study permitted us to establish communication with the community pharmacists regarding our common patients. The next step will be to evaluate their satisfaction with a questionnaire.

[1] Pharm World Sci. 2003 Apr;25(2):41-2.

No conflict of interest

CPC100 Simultaneous CYP2D6 and CYP2C19 geno- and phenotyping in a sample of the Hungarian population : initial experiences with AmpliChip CYP450 test

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Background

In clinical practice CYP2D6/CYP2C19 genotyping is relevant to the degree that it predicts the individual's metabolic activity. Before a genotyping method is initiated it is essential to obtain a population-specific allele database and to evaluate the performance of the method applied in phenotype prediction.

Purpose

The research objectives were 1) to first investigate the CYP2D6 and CYP2C19 allele frequencies and genotype distribution in a sample of the Hungarian population; 2) to evaluate the performance of AmpliChip CYP450 test in CYP2D6 and CYP2C19 phenotype prediction in the target population.

Material and Methods

A total of 112 unrelated healthy Hungarian volunteers participated in simultaneous CYP2D6/CYP2C19 geno- and phenotyping. The AmpliChip CYP450 test was used for genotyping and a single-time point, 3-hour post-dose phenotyping method with metoprolol and omeprazole was applied to determine CYP2D6 and CYP2C19 phenotypes.

Results

The five most frequent CYP2D6 alleles in our population were *1 (39.8%), 4* (20.4%), 2* (15.1%), 35*(8.5%) and *41 (8.0%). Rare CYP2D6 alleles, such as *7, *9, *41, gene deletions and duplications were also determined. The prevalences of the predicted CYP2D6 phenotypes were the following: 1.9% ultra-rapid metaboliser (UM), 6.5% intermediate metaboliser (IM), 8.3% poor metaboliser (PM) and 83.3% extensive metaboliser (EM). Among CYP2C19 alleles tested the most frequently were *1 (82.6%), then *2 (16.5%) and *3 (0.9%), consecutively. The prevalences of the predicted CYP2C19 phenotypic groups were 98.2% EM and 1.8% PM. The distribution of the measured CYP2D6 phenotypes were 2.67% UM, 7.14% IM, 7.14% PM and 83.0% EM, respectively. Prevalences of the measured CYP2C19 phenotypes were 6.8% PM and 93.2% EM.

Conclusion

CYP2D6 and CYP2C19 allele frequencies and genotype distribution were similar to those reported in other European countries. CYP2D6 phenotype prediction of AmpliChip CYP450 test was reliable for PM, IM and EM although a low sensitivity of UM prediction was observed.

No conflict of interest

CPC101 Epidemiological and clinical characteristics in HIV-naive patients

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Background

The CD4 cell count at which antiretroviral therapy (ART) should be started is an unresolved issue in HIV patients. The present Spanish Guidelines recommend starting at CD4 counts <350 cells/ μ l.

Purpose

To describe the demographics, epidemiological and clinical characteristics of HIV-naive patients who start ART in a Spanish hospital. To describe the antiretroviral combination regimen used and to check its agreement with the latest Spanish guidelines.

Material and Methods

Retrospective observational study from 01/01/2008 to 31/12/2009. Data source: Medical history and pharmacy department's database (SAVAC). Data recorded: age, gender, place of origin, risk of HIV transmission, timing from diagnosis to start of ART, CD4 count, viral load, first antiretroviral combination regimen and daily dosing. Statistical analysis using SPSS 15.0.

Results

We analysed data from 105 treatment-naive patients, 74.3% were men. By origin, 61.9% were Spaniards and 38.1% were foreigners. 88.3% had been infected by sexual contact and 16.2% by injecting intravenous drugs, according to HIV Spanish Cohorts data. Timing from diagnosis to ART was 28.9 months (95% CI 17.9-40.0), average age at initiation was 39.5 years (95% CI 37.9-41.0), lower in women than men (35.7 vs. 40.8, p=0.034), as other studies reported. Baseline CD4 cell count was 219.9 cells/µL (95% CI 194.1-245.7); 86.6% patients were \leq 350 cells/µL , 9.6% were 351-500 cells/µL and 3.8% were > 500 cells/µL. Average viral load was 1041580.5 (SD 5879115.4).

The antiretroviral regimen was 61.0% non-nucleoside reverse transcriptase inhibitor-based, 38.1% protease inhibitor-based and 0.9% nucleoside reverse transcriptase inhibitor-based regimen. Tenofovir/ emtricitabine was used in 86.6% of combinations, the most frequent third drug was efavirenz in 53.3%, 79.0% once-daily dosing regimen. Preferred regimens were used in 98.1%.

Conclusion

Timing initiation and first regimens complied with HIV Spanish Guidelines and Cohorts.

The most frequent therapy isa tenofovir/emtricitabine and a non-nucleoside reverse transcriptase inhibitor-based regimen.

This study offers additional information about the current epidemiological and clinical status profile of HIV infection in Spain.

No conflict of interest

CPC102 Exhaustive monitoring of serum and urinary levels of ethylene glycol after massive ingestion

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Background

Poisoning with ethylene glycol (EG) has become an increasingly frequent medical emergency due to EG being drunk by alcoholics and requires early diagnosis and aggressive treatment.

Purpose

We report a case of successful clinical recovery despite a "lethal" serum EG concentration after a massive intake of EG.

Material and Methods

A 46-year-old obese woman with a history of chronic alcoholism and a depressive disorder made repeated suicide attempts between 2006 and 2010. In June 2010, she came to the emergency area 12 h after ingesting 800 ml of antifreeze (30% EG) simultaneously with alcohol and a large number of prescription drugs. The patient was admitted to the intensive care unit (ICU) with severe metabolic acidosis (pH=7.10) and fluctuating consciousness level. No oxalate crystals were detected. Initial

serum and urine EG concentrations were 2091 mg/L and 179 mg/L, respectively. Intensive therapy was started with sodium bicarbonate, intravenous 10% ethanol, and haemodialysis; the ethanol dose was 0.6 g/Kg within 60 min followed by 0.175 g/Kg/h. At 33 h post-EG intake, EG concentrations reduced to 69.53 mg/L in serum and 221 mg/dL in urine, but the ethanol treatment was maintained for a further 24 h. Frequent measurements were made from the start of treatment to ensure serum ethanol levels were 100-200 mg/dL (the recommended antidote dose). These levels rose from 125 mg/dL at 5 h after the infusion was started to 370 mg/dL at 23 h after the start of the infusion, mandating a reduction in infusion rate to 0.088 g/Kg/h; an optimal level (124 mg/L) was observed at 29 h after start of treatment. A hospital pharmacist monitored the serum and urine levels. The pH began to recover at 15 h after the treatment was started.

Results/Conclusions

We underscore the importance of early and aggressive treatment, antidote therapy, and, above all, the strict monitoring of serum concentrations of EG and its antidote to prevent permanent disability or death.

No conflict of interest

CPC103 Biological impacts of intravenous iron supplementation on haemodialysis patients

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Background

Intravenous (IV) iron is required by almost all haemodialysis patients to optimise erythropoiesis-stimulating agent (ESA) therapy. The recent DRIVE study showed an increase of haemoglobin levels (Hb) when patients received IV iron therapy.

Purpose

To examine two different IV iron administration protocols in our haemodialysis centre. First, from July 2008 to January 2009, the dose of iron was adjusted according to the ferritin level. Then, from February 2009 to December 2009, the dose of iron was adapted to reach a target value for transferrin saturation (TSAT≥20%), whatever the ferritin level. The effects of this protocol modification on the iron test and hepatic function were then analysed.

Material and Methods

182 eligible patients were involved: entry criteria were haemodialysis for at least one year and no more than 3 months of absence after inclusion in the study. Blood tests included a monthly iron test and a liver function test every six months.

Results

In the first period, the average TSAT level reached 27.3%, ferritin 602 $\mu mol/L$ and Hb 114 g/L. Then, for the second period, we obtained 33.2%, 961 $\mu mol/L$ and 117g/l for these levels. Regarding hepatic function, the average ALT level increased from 19.9 (July 2008) to 20.3 IU/L (December 2009), with a maximum of 23.1 IU/L in January 2009. PAL increased from 82.5 to 93.7 IU/L, GGT from 46.2 to 63.9 IU/L, and total bilirubin from 10.6 to 13.3 $\mu mol/L$. Throughout this study, C-Reactive Protein (CRP) was <20 mg/L.

Conclusion

A major increase in iron load was observed, but it had little effect on haemoglobin rates (maybe due to an acceptable rate in the beginning). Despite high ferritin levels, no major disorders of hepatic function were demonstrated in either protocol, CRP remained stable. The long-term consequences of iron overload remain to be evaluated, notably cirrhosis and risk of fibrosis.

No conflict of interest

CPC104 Analysis of initial treatment duration in hepatitis B virus patients

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Background

The duration of initial therapy in the treatment hepatitis B virus (HBV) is affected by several factors including resistance and antiviral efficacy. There are a small number of studies about the duration of initial therapy.

Purpose

To assess the initial duration of treatment in a group of HBV patients and to analyse the clinical variables that can affect it.

Material and Methods

We conducted a retrospective and observational study of treatmentnaïve HBV patients who started treatment between 1st July 2004 and 31st July 2010 in a general teaching hospital. Data were collected from the medical record and the pharmacotherapeutic database (ATHOS). Descriptive statistics and survival analysis (Kaplan-Meier and Cox regression) were performed with SPSSver. 17.0. Independent variables in the regression model (before treatment): age, sex, initial anti-HBV drugs, hepatitis B and antigen (HB Ag), HBV DNA and alanine aminotransferase (ALT) (normal range: 5-40 IU/L); and treatment duration.

Results

We identified 93 patients, mean age 53±14 (33.3% women); 19.3% were HB Ag-positive and 78.5% HB Ag-negative (not determined in 2.2%). The most often prescribed drug was entecavir (38.7%), followed by adefovir (35.5%), lamivudine (17.2%) and other drugs (8.6%). ALT elevation >40 IU/L was detected in 72.04%. HBV DNA in serum was >38,000 IU/mL in 63.4% of patients, <38.000 IU/mL in 25.8%, undetectable in 3.1% and not determined in 7.5% of cases. The Kaplan-Meier analysis estimated mediantreatment duration of 28.8 months(95% CI: 18.67- 38.93). The only variablestatistically significant by Cox regression was initial anti HBV drug (p=0.031), the adefovir Odds Ratio (OR) was 3.69 (CI 95% 1.25-10.93) and lamivudine OR: 10.53 (CI 95% 2.93-37.76). No statistically significant differenceswere found for other treatments analysed.

Conclusion

The initial anti HBV drug is an important factor associated with a higher risk of premature treatment interruption, leading to a shorter duration of treatment than recommended, especially if the initial treatment is lamivudine or adefovir.

No conflict of interest

BEAM SUMMIT 2011

BEAM001 BEAM Summit 2010: The CytoHilton Project

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Background

The CytoHilton Project 'Cytotoxic compounding – Moving from ward to Pharmacy' was one of the eight group results at the BEAM Summit 2010 on Compounding.

Purpose

To develop and present a coherent business case on the topic of cytotoxic compounding within 48 hours with a group of hospital pharmacists from around Europe.

Materials and Methods

Using the expertise of a group of 7 European hospital pharmacists a business case was made to build and validate a clean room suite in an existing building adjacent to the day care facility, in 6 months. The basic idea was to switch from ward preparation to centralized pharmacy preparation of all cytotoxic agents. The new facility is aiming for a 95% delivery of the cytotoxic agents within 60 minutes of receipt of the completed and confirmed prescription. Within the business case different aspects, such as the location, ventilation system, necessary equipment, risk management and cost and financing are discussed.

Results and Conclusion

A business case was developed for the theoretic proposition of the annual preparation of 24,000 units of intravenous cytotoxic agents. The patient group consists of mainly day care patients (70%), combined with in-patient treatments (30%). Electronic prescribing and a closed system in aseptic manipulations are part of the applied system. Details on the validation regime, validation master plan, staff numbers, facility layout (using three separate class D background isolator rooms), process description (from prescription to dispatch and administration), as well a process simulation and environmental monitoring is provided. Finally, the general aspects of this project are projected on a specific drug, azacitidine, to provide clear information on the major advantages and necessity of this project.

No conflict of interest

BEAM002 The establishment of new compounding process for small scale nonsterile solutions in hospital pharmacy: the propranolol oral solution

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Background

TheEAHP BEAM Academy Summit 2010 on the subject "Aspects of compounding" <u>attracted attendees</u> from most EAHP member countries. We were put in mixed groups, assigned a topic and given a facilitator. Group work alternated with lectures presented by experts. The group work resulted with presentations in a

competitive environment. Group D described the propranolol oral solution (POS) formulation presented in this abstract.

Purpose

To establish a compounding area with a controlled environment for small-scale non-sterile oral solutions in our hospital pharmacy. To draw up a business plan by which to present the feasibility of POS to the hospital management.

Materials and Methods

The following aspects were covered in our presentation:

- mission and strategy
- assessment of the necessity of compounding POS
- biopharmaceutical properties of propranolol
- batch size and projected total annual preparation of POS, as well as overall capacity of the facility
- product design (formulation with packaging)
- site master file containing human resources and technical infrastructure
- quality management system with appropriate quality assurance incorporating GMP, quality control and validation master plan based on the risk evaluation
- business plan (potential market; customer needs; trends; competitors; facility and equipment status and requirements; competence and resources available and required; logistic available and required; procurement; costs; proposal of financing of investments in facilities adaptation, additional equipment, education, return of investment)

Conclusion

This workshop taught us how to give an overview of our everyday work in hospital pharmacy in a way that is more understandable to hospital managers, as well as how to transparently indicate which resources are crucial in order to safely and efficiently compound the preparations. During the workshop, we noticed the great differences in resources that each national healthcare system provides to its hospital pharmacy sector. This helped us appreciate how valuable it is to know how to present our work in financial terms.

No conflict of interest

BEAM003 Development of Warfarin an oral liquid suspension a 200mikrog/ml for children

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Background

Warfarin sodium is an anticoagulant, coumarin derivative, which acts by inhibiting vitamin K dependent coagulation factors (II, VII, IX and X). Chemically, it is 3-(α -acetonylbenzyl)-4-hydroxycoumarin and is a racemic mixture of the R-and S-enatiomers. Crystalline Warfarin sodium is an isopropanol clathrate. The crystallization of Warfarin sodium virtually eliminates trace impurities present in amorphous warfarin. Its empirical formula is C19H15NaO4.

Crystalline warfarin sodium occurs as a white, odorless, crystalline powder, discolored by light and very soluble in water. It is prescribed for the prophylaxis and treatment of trombosis, atrial fibrillation, and embolism.

Materials and Methods

The minimum conditions required for the small scale compounding of a non sterile preparation for individual patients, oral liquid suspension of Warfarin were researched, including the necessary bibliographic research and the sequential elaboration of the required monographs.

Results

The plan adopted for the final process included three steps: first-physical chemistry quality control of the raw material (warfarin sodium crystalline); second-strictly dedicated to preparing the oral liquid suspension and third-the physical chemistry quality control of the final product (warfarin oral liquid suspension 200mikrog/ml). The formulation must be prepared in dedicated non sterile preparation facility (clean room), using an aseptic technique for preparation and then packaging and labeling. The final suspension is then submitted to quality control, where a set of selection assays has been defined that ensured that both raw material and final product are of assured quality.

Conclusion

It was possible to accomplish this challenge, established the clinical need, and creates the conditions to start the small scale compounding for individual patients of our first batch of this formulation: an oral liquid suspension of warfarin 200mikrog/ml. Also to reduce technical risks using simple approach to formulation and preparation and to close liaison required with clinical colleagues to monitor effectiveness of formulation to ensure patient safety.

No conflict of interest

BEAM004 Risk assessment in paediatric TPN compounding: a European perspective

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Background

Total parenteral nutrition (TPN) formulations are considered highrisk sterile products because of the large number of components and the complex nature of TPN admixing. It is recommended that TPN solutions should be manufactured by specialized pharmacy staff within dedicated aseptic preparation units.

Purpose

To develop a state of the art procedure for the preparation of TPN solutions for neonates regarding the current best preparation practices across Europe.

Material and Methods

- Focus groups working on the subject "Aspects of compounding" during the EAHP academy BEAM summit using input lectures and workshops to evaluate a European perspective for paediatric TPN compounding.
- TPN production was split into the following stages: prescribing, transmission to pharmacy, pharmaceutical validation, calculations, compounding, labelling, storage, distribution and administration. Failure mode and effect analysis (FMEA) was used to identify the potential risks in the TPN production process. A quality assurance system for TPN production was finally developed.

Results

According to the performed FMEA analysis, critical risk factors include: prescription errors, calculation errors, compounding

mistakes and microbiological contamination. According to best practices in Europe to manage the risks detected, TPN should be aseptically compounded in a laminar flow cabinet class A located in a class B environment. To assist in prescription and compounding, electronic prescription linked to an automated mixing device with bar code technology is the best way to minimize the risk. Only qualified and well-trained personnel should be involved in TPN compounding. Moreover other measures of a quality assurance system like pharmacist validation of prescription, double-check control during preparation, a validated microbiologic control system, and auditing should be implemented.

Conclusion

Pharmacy-based compounding in compliance with the procedures described above, will lead to the production of safe, high-quality, individualized TPN for neonates.

No conflict of interest

BEAM005 Preparation of extemporaneous drugs - a comparative analysis through Europe (Working Group C - BEAM Summit Aspects of compounding)

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Background

The need for extemporaneously prepared drugs in Europe is usually provided through small scale compounding. The European Pharmacopoeia gives a base for this work but local guidelines for small scale compounding can vary. Hence we wanted to examine the differences in seven European countries with examples of small scale compounding.

Materials and Methods

The European Association of Hospital Pharmacists has an ongoing project to interact with its members through several summit sessions focusing on important areas of hospital pharmacy. In September 2010 a summit with regard to aspects of compounding took place in The Hague, The Netherlands. Our working group was formed during this summit under the topic - small scale compounding. During this session we started by comparing our small scale compounding practices with regard to types of spironolactone preparations and the shelf life of an oral liquid of clonidine hydrochloride for children.

Results & Discussion

Seven hospitals serving in total more than 7500 (250-2000) beds in Austria, Finland, Hungary, Ireland, Italy, Norway and Sweden were included in the analysis. All hospitals undertake small scale compounding during week days. For the provision of spironolactone different practices were recorded including capsules, sachets and suspensions. As for the preparation of an oral liquid of clonidine hydrochloride the shelf life varied between the participating countries depending on local practices and type of preservation methods. Although not all participating hospitals carry out these preparations at present, we discussed our approach to solve the difficulties by way of these two substances.

Conclusion

Critically, many products are not standardized and little data to their compatibility and stability are available. Therefore, this survey highlights the need for a European database for preparations in small scale compounding. The database suggested should not strive to contain all drugs, rather give a format based on the

principles of Wikipedia where all participating nations can collect, compare and share their methods of compounding.

BEAM006 Business plan for the preparation of cytotoxic

No conflict of interest

therapies at a central hospital pharmacy unit and its benefits K. Nikou, I. Larsson, K. Saliniece, N. Spiric, P. Csonka, S. Durante General Hospital of Chest Diseases "SOTIRIA", Pharmacy, Athens, Greece Amgros I/S, Amgros I/S, Copenhagen, Denmark Riga East Clinical Teachin Hospital, Pharmacy, Riga, Latvia General hospital prim. dr Abdulah Nakas, Pharmacy, Sarajevo, Bosnia - Herzegovina Mátrai Gyógyintézet Mátraháza, Pharmacy, Gyöngyös, Hungary Hospital of Palermo, Pharmacy, Palermo, Italy

Background

Cytotoxic drugs are therapeutic agents increasingly being used in a variety of healthcare settings. Their toxicity dictates that the exposure of health-care personnel to these drugs should be minimized. At the same time, the requirement for maintenance of aseptic conditions must be satisfied.

Purpose

The aim of the study is to provide safe, high quality cytotoxic drugs for individual treatment of patients, while ensuring the safety of production and delivery of cytotoxic formulations at the lowest possible cost of chemotherapy.

Materials and methods

Using the experience of every team member, during the workshops of the EAHP Academy BEAM Summit 2010 "Aspects of Compounding", a facility of $100m^2$ for the needs of a 600-bed hospital was designed. The output of cytotoxic preparation for the pharmacy unit is 250 per day (i.e. 50 IV bags and 200 syringes) with the work of 8 employees.

Results

With the appropriate business plan one can benefit from the knowledge, skills and experience of hospital pharmacists, the controlled environment, the systematic documentation, the ongoing risk management and the quality assurance. As a result, the risk of product microbiological and environmental contamination could be minimized, on the one hand, and the patient, on the other, could receive the appropriate treatment with financial benefit and patient – staff safety.

Conclusion

It is possible to prepare cytotoxic drugs for individual hospital patients and ensure the delivery of right drugs for right patient in right time, while benefiting from the centralization of cytotoxic drug preparation an amount of approximately 120.000EURO/year for 600-bed hospital.

No conflict of interest

BEAM007 The conception of a compounding unit for the preparation of parenterals \tilde{n} a report from the EAHP BEAM Summit 2010

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Background

Compounding of medication is one of the most important services of a hospital pharmacy. Due to drug shortages, orphan drug status or neglected patients, compounding of medication in a hospital pharmacy is often the only way to procure the appropriate therapy for those patients. The aim of this project was to present a compounding unit of an European hospital pharmacy, having the task to produce high quality ready-to-use parenterals for a limited number of patients.

Materials and Methods

The presented product is an epidural analgesic solution. A site master file was developed describing products to be prepared, personnel and their responsibilities, premises and equipment as well as documentation. Based on the PICS/S-PE010, national GMP Guidelines for hospital pharmacies and general quality management system for the pharmacy department (e.g. ISO 9001), a quality management system (QMS) was established. The QMS incorporates quality control and risk management as well as validation of processes and training of personnel.

Results

The product is an epidural analgesic solution of levobubivacain 1.25 mg/ml, morphine 0.02 mg/ml and clonidine 0.375 µg/ml, prepared in polypropylene bags. The batch size of 80 bags is prepared in a laminar airflow cabinet located in a clean room classification C. Product validation is conducted beforehand and the stability data for 2 months at room temperature is available. Quality control consists of double check, environmental monitoring, sterility test of 3 randomly sampled bags and visual checking. With regard to risk analysis, dosage error and microbiological contamination are identified as high risks (risk-scores 5 and 15). The latter could be reduced by increasing the frequency of personnel training.

Conclusion

Compounding of high quality preparations is an essential task in a hospital pharmacy to ensure an optimum patient care, especially for those patients who need individual, prompt and flexible care.

No conflict of interest

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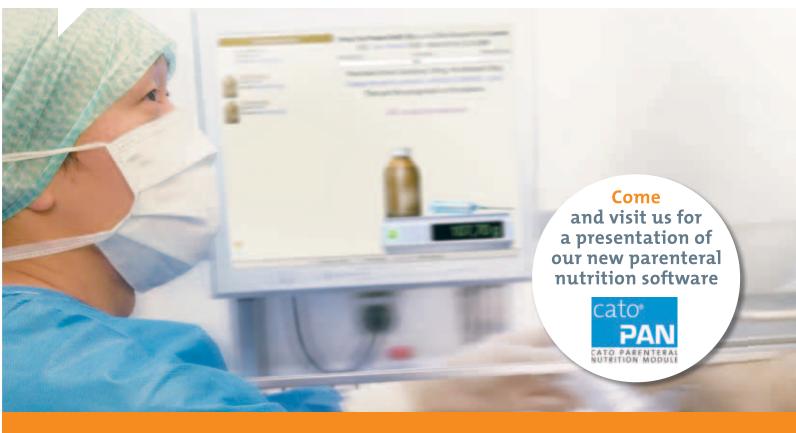
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