VIE15-0723Does the Computerised Physician Order Entrysystem reduce prescribing errors for inpatients ?A before-after study

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Keywords : medication errors, risk management, pharmaceutical intervention, electronic prescribing

BACKGROUND

The Health institution recommends the use of Health Information Technology to reduce the risk of iatrogenic errors. While many publications highlight the benefits of Computerised Physician Order Entry (CPOE) system, others worry about the unintended consequences of such a system on the health care quality. **OBJECTIVE**

To measure the computerisation impact on the quality of drug prescriptions.

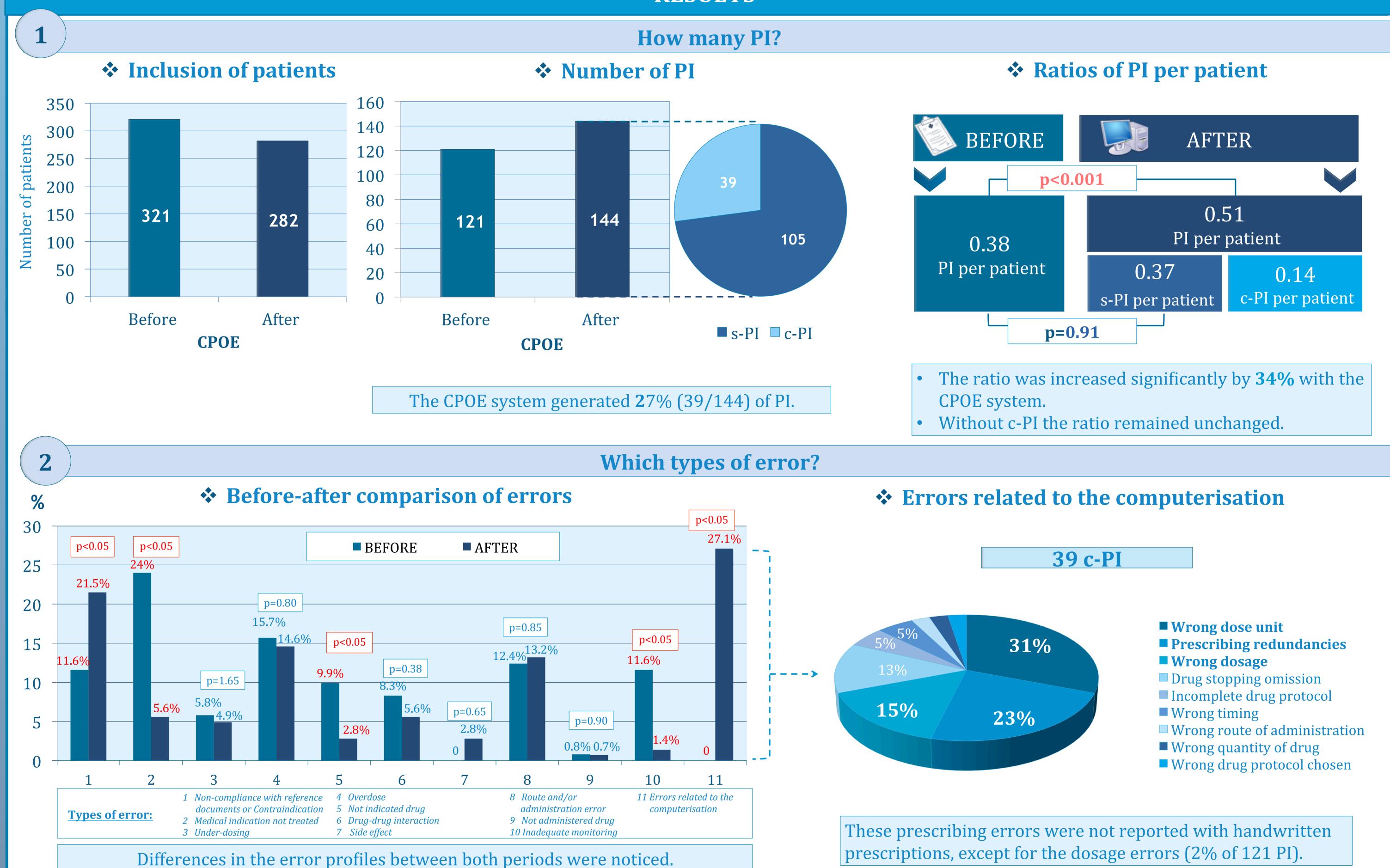
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METHODS

Observational study conducted before and after the CPOE system implementation

		CPOE in		
		BEFORE	AFTER	PI = s-PI + c-PI
St	udy periods	30 days in 2014	30 days in 2015	$\mathbf{FI} = \mathbf{S}^{-}\mathbf{FI} + \mathbf{C}^{-}\mathbf{FI}$
Ι	nclusion of	In 2 medical units (card	liology and diabetology) \approx 41 beds	• PI = Pharmaceutical
	patients	All admitted patients	All admitted patients	Intervention :
		Pharmaceutical analysis of dr	ug prescriptions by unit pharmacists	Prescribing error
STUDY	Collection	 → Pharmaceutical Interventions: Number and types* 	Computerised prescriptions → Pharmaceutical Interventions: Number and types*	 identified and notified by pharmacists s-PI =Standard PI c-PI= PI related to the
	Analysis	 Quantitative analysis : ratios PI per patient = <u>(number</u>) (number of p Qualitative analysis: types* of PI/error 	Before- after	computerisation (CPOE)
		* According to the categorisation of the SFPC (So	ciété Française de Pharmacie Clinique : French Society of Clinical Pharma	<i>cy</i>)





DISCUSSION-CONCLUSION

With the use of the CPOE system, the iatrogenic risk seems to increase. A new kind of errors has been observed: the errors related to the CPOE system. These errors can be due to a lack of software ergonomics (poor readability of the prescriptions, complex functionality) or a misuse of it by the physicians. However, they are avoidable. In order to reduce them, it is important to raise the level of awareness of the prescribers, to improve their training and to promote the vigilance of the pharmacists and the nurses. A partnership with the software publisher is essential to secure the CPOE system and make it evolve.

Acknowledgements: We thank the pharmacists of Rangueil Hospital, physicians and nurses of the diabetology and cardiology departments.

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Children's Research Center CRC

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www.kispi.uzh.ch

Abstract Number: DI-008

Apps for paediatric dosing – an evaluation

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Objectives

Thousands of medical apps can be found in the apple app store and google play. This huge amount makes it difficult to find an appropriate app and to ensure quality and accuracy of an app.

Since we are interested to see whether the available apps are safe to use and to identify areas for possible improvement, we evaluated their quality and content. This evaluation was done in accordance with the European Statements of Hospital Pharmacy to be involved in eHealth/mHealth procedures and to decrease the risk of medication errors (statements 1.7, 5.5).1

Our website www.kinderdosierungen.ch provides paediatric dosages in two languages, German and French (the English version will be published soon). To increase usability, we aim to develop a mobile version whereby the results of our evaluation might be useful.

Methods

Search for paediatric dosing apps

- Keywords such as paediatric, medical, app, dosing (in English or German)
- Perform a google search and search the apple app store and google play
- Search between April and June 2015

Inclusion criteria

- Part I: Selection of apps in either English or German containing structured paediatric dosages (preselection)
- Part II: Selection of apps with a dosage calculator and either more than 70 active ingredients or a calculator specific for preterm infants (in-depth evaluation)

Conclusion

- Several high quality paediatric dosage apps are available.
- The apps Epocrates, Lexicomp and Safe Dose reached the highest scores in our evaluation, followed by AGN Emergency Booklet and EMRA Peds Meds.
- The calculator is the feature that could be improved in all five top apps.
- It is important to keep in mind that the appropriate medical app depends on the contents and features that are relevant for the individual user.
- We recommend that prior to using an app, a short evaluation is performed.

Category (weight)

Quantity (10%)

Calculator (20%)

Features (15%)

Usability (15%)

Additional professional information (5%)

Quality/Content (35%)

Evaluation

Preselection: 43 paediatric dosage

- Six main categories containing a total of 73 criteria were chosen (Table 1)
- Category weights chosen according to importance for usage by healthcare professionals (Table 1)
 - Criteria and weights defined by two experts

Results &	Discussion
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App

Epocrates

Lexicomp

Safe Dose

AGN Emergency Booklet

EMRA Peds Meds



Figure 1: Paediatric dosing app selected for in-depth evaluation²

Quality Conten

3 3 15 3 3 3 1

1 1

2 5

6 6 8 4

10 7

apps Eighteen apps fulfilled criteria for indepth evaluation Top five apps: Epocrates, Lexicomp, Safe Dose, AGN Emergency Booklet, EMRA Peds Meds Table 2: Ranking of top five apps within the 18 included apps for each of the six categories Table 3: Summery of different details

Table 2: Ranking within categories for the top five paediatric dosing apps

18

2 9

> 5 7

together with strengths and weak-

professiona information Additional

13

17

5 2 1

7 13 Rank

1

4

5

nesses of the top five apps Table 3: Details of the top five paediatric dosing apps Languages Operation system Price (CHF) Calculator Strengths Weaknesses Epocrates English integrated manual calculation calculator Android free differentiation usability iOS not integrated 75 Lexicomp English Android quality calculator German iOS quantity further language Safe Dose Enalish Android free (limited number integrated features missing galenic German iOS of medications) automatic calculation usability forms further language 100 (all medications) AGN Emergency Booklet integrated automatic calculation hard to find additional professional information administrative features (FAQ Germar Android 24 informations' iOS EMRA English 3 additional professional integrated calculator Peds Meds automatic calculation inform nation differentiation*

References: 1. The European Statements of Hospital Pharmacy. Eur J Hosp Pharm 2014 21: 256-258. 2. Ralf Müller (2016), AGN Emergency Booklet (Version 11.6.4); David Alden (2014), Critical Peds (Version 1.3); EMRA (2015), EMRA Peds Meds (Version 1.1.0); Epocrates (2016), Epocrates (Version 15.12.1); logicmanta (2013), Kids Drug Dosage Calc - Paed Rx (Version 1.0); Dr. Steve-Oliver Mueller (2015), Kinderanashesie XS (Version 1.1.1); Lexi-Comp (2015), Lexicomp (Version 2.3.3); ITDCS Ltd (2015), Neonatology (Version 1.4); Guy's and ST Thomas' NHS Foundation Trust (2015), NICU (Version 2.3); Caduceus Digital Systems (2014), PedDrugDose (Version 1.1.2); Vargo Anesthesia (2016), Pedi Anesthesia (Version 2.3); DEOD Child (2011), Pedi Daddi Systems (2010), Pedi Idea (Version 2.3); Caduceus Digital Systems (2014), PedDrugDose (Version 1.1.2); Vargo Anesthesia (2016), Pedi Anesthesia (2015), Deel Pocket Series LCC (2010), Pedi Idea (Version 2.3); Caduceus Digital Externation (2011), Pedi Idea (Version 2.3); Caduceus Digital Systems (2014), PedDrugDose (Version 1.1.2); Vargo Anesthesia (2016), Pedi Anesthesia (2015), Deel Pocket Series LCC (2010), Pedi Idea (Version 2.3); Caduceus Digital Externation (2011), Pedi Idea (Version 2.3); Caduceus Digital Systems (2014), PedDrugDose (Version 3.1); theinviter (2014), Pedi Idea (Version 2.3); Caduceus Digital Systems (2013), Pedi Idea (Version 2.3); Caduceus Digital Systems (2014), PedDrugDose (Version 3.1); theinviter (2014), Pedi Idea (Version 2.4); Pedi Idea (Version 2.4); Pedi Idea (Version 2.4); Pedi Idea (Version 4.5); Skyscape Medpresso Inc (2015), Skyscape Medical Library (Version 2.4); Pedi Idea (Version 2.4); Pedi Idea (Version 4.5); Skyscape Medpresso Inc (2015), Skyscape Medical Library (Version 2.4); Pedi Idea (Version 2.4); Pedi Idea (Version 4.5); Skyscape Medpresso Inc (2015), Skyscape Medical Library (Version 2.4); Pedi Idea (Version 4.5); Skyscape Medpresso Inc (2015), Skyscape Medical Library (Version 2.4); Pedi Idea (Version 4.5); Pedi Idea (Version 4.5); Skyscape Medical Library (Version 2.4); Pedi Idea (Version 4.5); Pedi Idea (Version 4.

Suggestions for improvements

- Calculators, especially regarding integration of preterm infant calculations
- Data presentation: Large amount of information to be presented

Table 1: In-depth evaluation of selected paediatric dosage apps

references

Criteria (examples out of 73 criteria)

different routes of administration

therapeutic categories

compatibility

Data presentation, efficiency

Updates, maximum dose, different dosages

for different indications, accuracy of dosage

Number of active ingredients and preparations,

Integration, plausibility check weight/age, pre-term calculations

Add bookmarks, calculation of volumes (liquid forms) or tablets (solid forms), different

Adverse events, drug-drug interactions,

Important to know

- No danger to use any of the 18 evaluated apps
- Quality of the dosages of seven randomly chosen active ingredients from different drug groups (e.g. amoxicillin, furosemide, paracetamol) were evaluated and displayed correct dosage ranges

Limitation of the evaluation

- Evaluation is based on criteria/weights that two experts defined
- End result could be different depending on criteria/weights chosen

^{*}Differentiation: several indications, different dosages for different age groups



IMPROVING PHARMACOLOGICAL TREATMENT: REAL-TIME SAFETY AUDITS

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Objectives

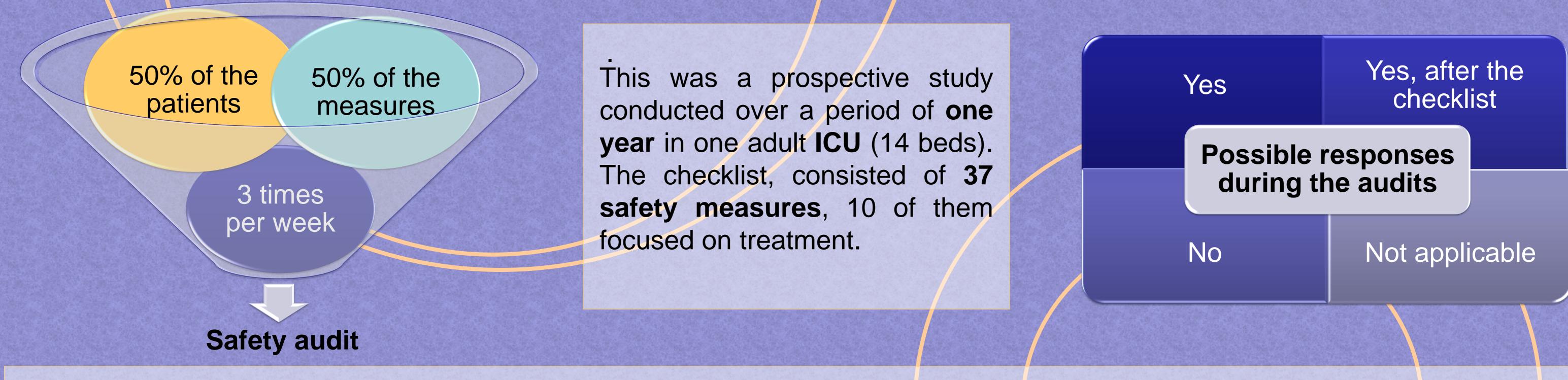
Patients admitted to intensive care units (ICU) are characterized by their need for a more advanced level of care and a higher risk of patient safety-related incidents. Errors in pharmacological treatments may occur due to an unintended act or by omission. Present a checklist designed to improve the pharmacotherapeutical care process

HJ23

Hospital Joan XXIII

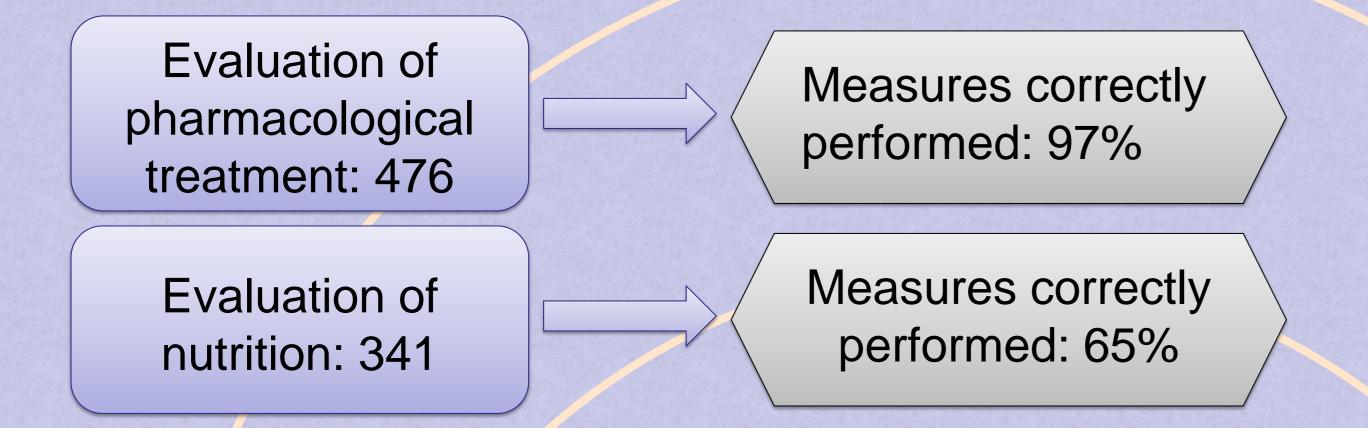
Present the results obtained with this tool in our ICU

Methods



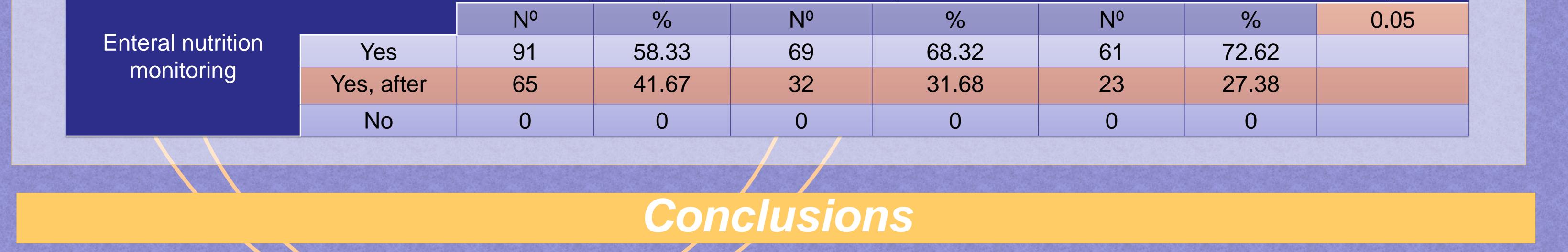
The evaluated **pharmacological treatment** and **nutritional measures** were: allergies, correct prescription, indication and dosage, verbal orders, prophylaxis of thromboembolic disease, gastrointestinal hemorrhage, glycemic control, antibiotic adequacy, enteral nutrition monitoring and parenteral assessment.

Results



Multivariate analyses didn't demonstrate significant changes in the pharmacological care process when variables were analyzed quarterly, except for **improving lack of verbal prescription** (26% to 2.2% p<0.05) and improving **management of nutrition** (58,33% to 72.62% p<0.05). Furthermore, audits were useful to detect errors of omission and to correct them promptly in 8.3%.

		Februar	y – May	June – S	September	Octubre	- Enero	р
Prescribed threatment		Nº	%	Nº	%	N°	%	<0.0001
administred correctly.	Yes	143	73.71	125	85.62	133	97.79	
Verbal orders	Yes, after	0	0	0	0	0	0	
	No	51	26.29	21	14.38	3	2.21	p <0.0001
		Febrary	– May	June – S	September	Octubre	- Enero	p



Real-time safety audits in medication help to verify the adequacy of pharmacological orders and can increase safety awareness. The tool has been useful to improve the nutrition management. 21st Congress of the EAHP



Materiovigilance ex ante risk management



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PAN Sante, Recherche, Risques et vignances des nospices civils de Lyon - nopital neury Gabriene - vina Ance - zo route de vouries - 69230 St Gen

Background

Since the publication of **the April 6th 2011 Decree** on the quality management of medicinal treatment and drugs in health institutions, it has become a priority in hospitals. In addition, in version 2010 of the **High Authority of Health certification manual**, criterion 8d deals with the evaluation requirements and risk prioritization based on defined methods, implementation of preventive, mitigation or recovery actions, staff training in risk analysis, and monitoring and measuring the effectiveness of implemented actions.

It is in this context that the Organization, Quality, User relations Directorate of our health institution has requested medical device vigilance service to

Objectives

• initiate a project on quality management.

• develop a materiovigilance ex ante risk assessment tool.

The chosen quality tool was a **risk mapping**, based on the FMEA method (Failure Mode Effects Analyses) which allows to **prioritize risks**, to **identify actions for improvement** and to **develop an action plan**.

1. A **multidisciplinary group** was created by the project learder.

2. An inventory of the service documentary system was performed.

3. The development of the risk mapping was started. (Fig. 1 Risk mapping development stages)



Methods

4. Through this work, priority risks were identified.

Results & Discussion

Five major activities (bottom-up alerts, top-down alerts, staff, documentary system and computer resources management), about **fifty associated risks** and **many scenarios** were identified.

Due to the risk mapping, three priority actions (Net criticality \geq 18) have been identified to be implemented :

- reinforce staff training,
- raise awareness on reporting,
- write fallback procedures.

Those three actions were included in the action plan 2016.

Score	Level	Description				
Frequency score						
1	Rare	Maximum 1/year				
2	Occasional	< 1/month				
3	Frequent	> 1/month				
Acceptability score						
1	Minor	Acceptable				
2	Serious	Less acceptable				
3	Major	Unacceptable				
	Mast	ering score				
1	Excellent	Action already set up and efficient				
2	Bad	Action difficult to implement				
3 Good Action to enhance or easy to implement						
Fig 2. Risk scoring model						

Activities	Stages	Risks	Causal factors	Impact on global process	Frequency	Acceptability	Gross criticality	Actions for improvement	Mastery	Net criticality
								Enhance HCL staff training	3	27
Bottom-up alerts	Reporting	Not reported event	People : lack of knowledge, omission Method : processes	Ignorance of an event. No analysis of the event.	3	3	9	Promote awarness on reporting among HCL staff	2	18
management			Material : reporting tool ineffective Environment : lack of time	Risk of reoccurrence.				Publication of procedures on intranet portal	l 1 9 1 9	
								Dematerialization of reporting	1	9
			People :omission					Archiving of reception notice	1	6
Top-down alerts management	Sending alert	Not sent alert	Method : processes Material : fax damaged, inbox overload	Referent person is not informed	2	3	6	Redaction of fallback procedures	3	18
			Decode : Jack of involvement					Enhance the organization of HCL Staff training	3	18
		Insufficient number of trained person	People : lack of involvement Method : poor communication Environment : lack of time	HCL staff is unfamiliar with materiovigilance	2	3 6	6	Improvement of communication on staff training	3	18
Staff			Environment . lack of time					Development of E-learning for HCL staff	1 9 1 9 1 9 1 6 3 1 3 1 2 1 1 6 3 1	12
management	Trainning	Inadequate training for	People : lack of involvement Material : inadequate training tools,		2	3		First training lead by the local correspondent of materiovigilance	1	6
		students and residents	inadequate skills assessment tools	Alerts mismanagement	2	3	6	Develop skills assessment tool (questionnaire)	3	18
			Environment : lack of time					Double control by a pharmacist	1	6

Fig 3. Risk mapping (abstract)

Conclusion

The development of this quality tool is made in the context of the certification of health institutions as well as in the context of a comprehensive approach to improve quality management and patient care in hospitals.

Acknowledgements

Arrêté du 6 avril 2011 relatif au management de la qualité de la prise en charge médicamenteuse et aux médicaments dans les établissements de santé, Légifrance. Manuel de certification des établissements de santé, Version 2010, Juin 2009, Haute Autorité de Santé (HAS). OMEDIT Basse Normandie, OMEDIT Ile-de-France SOFGRES Health-Related Quality of Life and its associated factors among South Asian and Middle Eastern patients with chronic diseases in the UK

F. Alhomoud^{1,2,4}, Z. Aslanpour², S. Dhillon³, F. Smith⁴.

¹ Department of Clinical and Pharmacy Practice, School of Clinical Pharmacy, University of Dammam, Dammam, Saudi Arabia. ² Department of Pharmacy, ³ School of Life and Medical Sciences, University of UCL SCHOOL OF PHARMACY Hertfordshire, Hertfordshire, United Kingdom. **BRUNSWICK SQUARE** ⁴ Department of Pharmacy Practice and Policy, School of Pharmacy, University College London, London, United Kingdom. Abstract Number: OHP-001

Background

- Ethnic minority groups (EMGs) including South Asians (SA) and Middle Easterners (ME) in the UK are rising.^[1,2]
- These groups often experience a higher than average prevalence of chronic diseases.^[1,2]

Results

Participants (61% male) had mean (SD) age 58 (13.4) years and on a mean (SD) of 8 (4) medicines. Based on the EQ-5D-3L, the most significant problems reported by respondents were pain/discomfort (70%), followed by mobility (61%), usual activities (48%), anxiety/depression (47%), and self-care (33%) (i.e. where some and extreme problems of each dimension were combined), Figure 1. The mean EQ-5D visual analogue self-rating scale (VAS) score for SA and ME patients was 60.0 (SD \pm 23.8).

- People from different cultural backgrounds may experience language barriers, demonstrate different beliefs, needs and experiences which may affect their ability to use medicines and access services effectively.^[1,2]
- This may lead to poor chronic disease management and health outcomes. Thus, describing EMGs Health-Related Quality of Life (HRQoL) is an important point of interest.

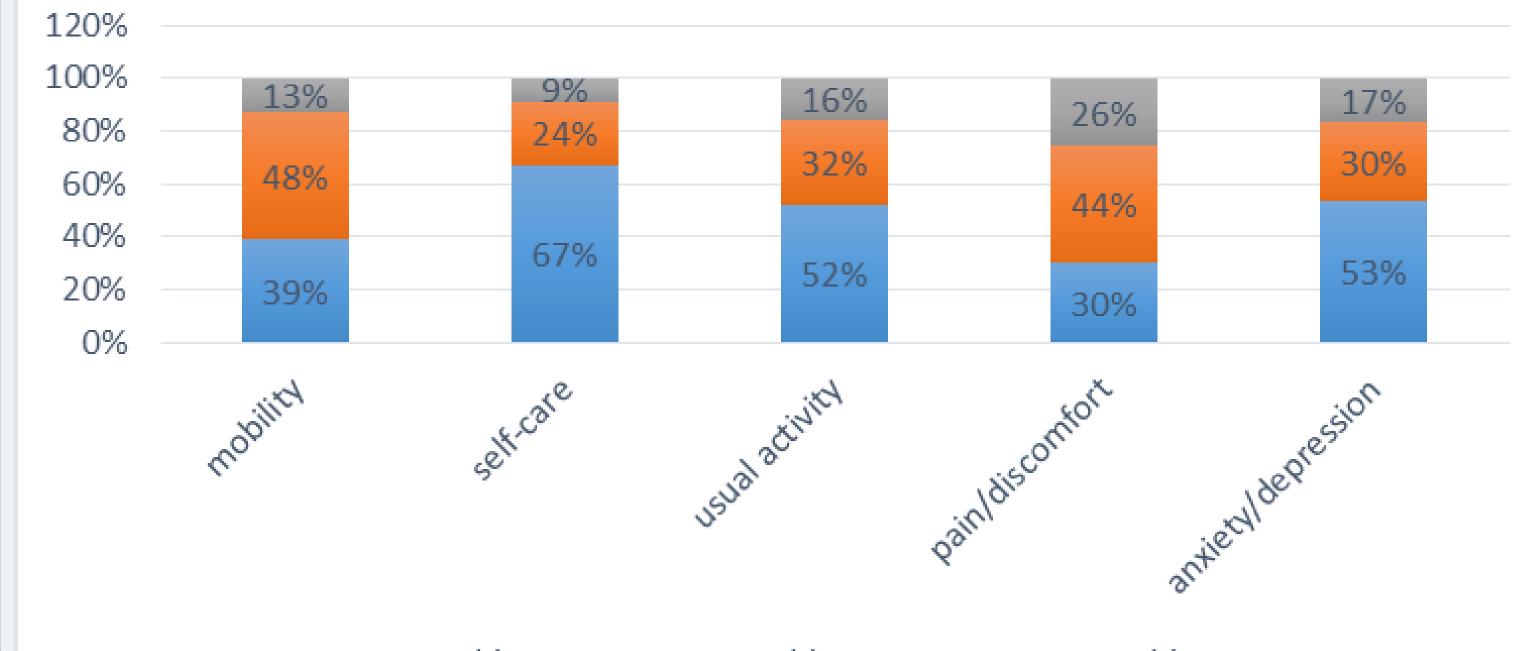
Purpose

To assess the quality of life among SA and ME patients with chronic diseases in the UK and to investigate factors associated with lower EuroQol five-dimension (EQ-5D) visual analogue scale (VAS).

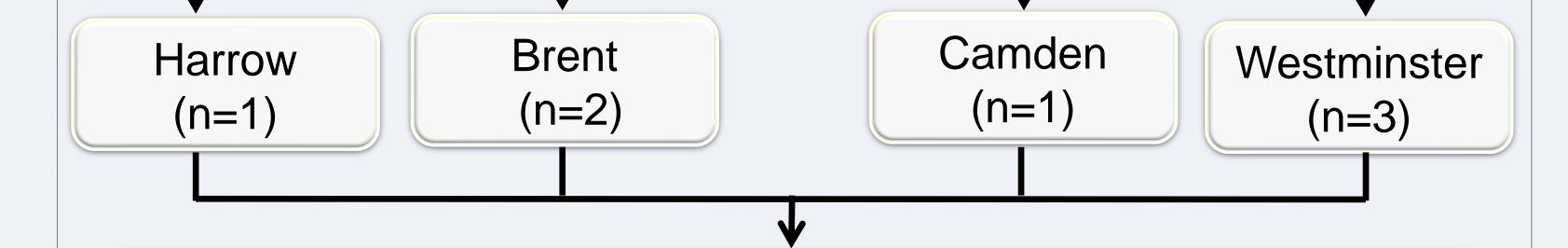
Materials and Methods

The study was conducted with seven community pharmacies in:

Figure 1: EQ-5D self-reported health states of SA and ME patients



extreme problems some problems no problems



Patients from :

- SA and ME origins in the UK,
- aged over 18,
- and prescribed three or more regular medicines for chronic diseases were invited to participate in the study.

Patients were identified when presenting with a prescription

If the informed consent was obtained, the data were collected in faceto-face structured interviews in community pharmacies using EQ-5D-3L.

Information about patients' characteristics, healthcare of the participants, number and type of prescription and non-prescription medicines used by respondents was collected and quantitative procedures were conducted with Software package used for Statistical Analysis (SPSS) 21.

Lower EQ VAS score were associated with the female gender, ME ethnic origin, lower level of education, high number of A&E consultations and emergency GP consultations, Table 1.

Table 1: Factors influencing the EQ-5D visual analogue score in SA and ME patients.

Parameter		EQ VAS Mean (SD)	P value
Gender*	Male	64.06 (24.12)	0.041
	Female	53.92 (22.11)	
Ethnicity*	South Asian	65.51 (23.92)	0.026
	Middle Eastern	54.38 (22.65)	
Education level*	Above high school	71.67 (19.76)	0.001
	High school or below	53.75 (23.58)	
Number of A & E	None	69.21 (22.26)	0.001
consultations*	≥ 1	51 (22.31)	
Number of	None	65.61 (24.59)	0.003
emergency GP consultations*	≥ 1	50.17 (19.66)	

Reference

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- 2. Alhomoud F, Dhillon S, Aslanpour Z, Smith F. South Asian and Middle Eastern patients' perspectives on medicine-related problems in the United Kingdom. International Journal of Clinical Pharmacy, 2015; DOI 10.1007/s11096-015-0103-6.

*Mann-Whitney U test; a p value of <0.05 was taken as conferring statistical significance.

Conclusions

The results add to the volume of knowledge regarding SA and ME patients' health status. Medical, policy and individual attention should be given to the management of chronic diseases and improvement of QoL in EMGs. Longitudinal studies must be performed to monitor changes in QoL and to permit evaluation of the outcomes of chronic disease intervention programs.

University of Hertfordshire





INNAPPROPRIATE PRESCRIBING IN ELDERLY PATIENTS ATTENDING THE EMERGENCY ROOM

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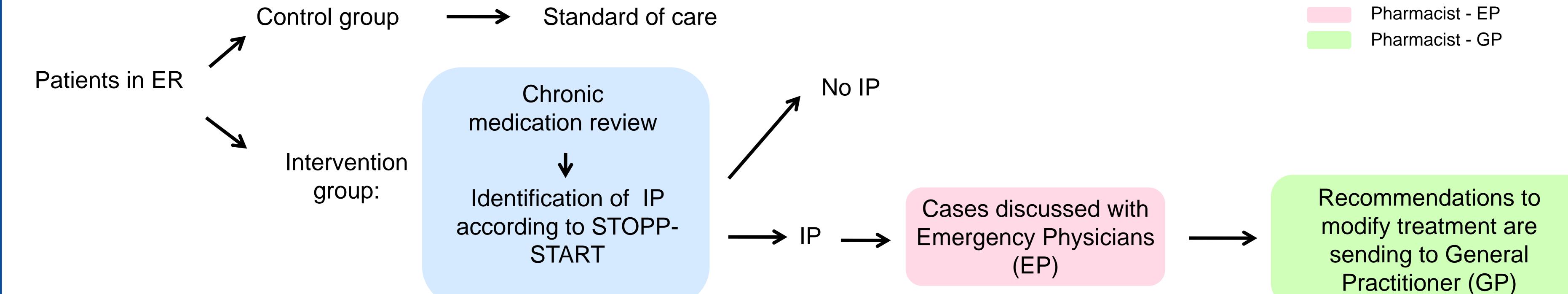
To measure the prevalence of inappropiate drug prescriptions (IP) in elderly patients who attend the emergency room (ER).
 To assess the influence on emergency visits and hospitalizations of a multidisciplinary health care team project designed to identify and resolve them.

Study design

Objetives

Multicentric randomiced controlled trial.





Outcomes:

- Prevalence of IP in elderly patients (final results reported).
- Differences in the rate of hospitalization and emergency visits after one year of follow up (on going).

Results

Patients included: 665

CHARACTERISTICS	CONTROL GROUP(n=342)	INTERVENTION GROUP(n=305)	Р
Gender:			0,614

Prevalence:

262/323 patients with IP in the intervention group

Woman	183 (53,5%)	166 (51,6%)	
Man	159 (46,5%)	156 (48,4%)	
Mean age (SD)	78,2 (7,82)	78,99 (7,59)	0,129
Origin:			0,445
Home	327 (95,6%)	313 (97,5%)	
Social health center	13 (3,8%)	7 (2,2%)	
Charlson ajusted to the mean age (SD)	2,85 (2,3)	3,05 (2,15)	0,077
Number of drugs: median (ICR)	8 (5)	9 (6)	0,008

STOPP CRITERIA	Nº IP	%
Benzodiazepines for \geq 4 weeks.	111	36,63
Any duplicate drug class prescription.	25	8,25
Long-term aspirin at doses greater than 160 mg per day.	24	7,92
ACE inhibitors or Angiotensin Receptor Blockers in patients with	15	
hyperkalaemia.		4,95
Any drug prescribed without an evidence-based clinical indication.	10	3,30
Use of regular opioids without concomitant laxative.	9	2,97
Thiazide diuretic with current significant hypokalaemia, hyponatraemia,	6	
hypercalcaemia or with a history of gout.		1,98
Sulphonylureas with a long duration of action with type 2 diabetes	6	
mellitus.		1,98
Loop diuretic for treatment of hypertensión with concurrent urinary	5	
incontinente.		1,65
NSAID and vitamin K antagonist, direct trombin inhibitor or factor Xa	5	
inhibitors in combination.		1,65
Digoxin at a long-term dose greater than 125 mcg/day if eGFR < 30	5	
ml/min/1.73m ² .		1,65
NSAID if eGFR < 50 ml/min/1.73m ² .	5	1,65
Long-term NSAID or colchicine (> 3 months) for prevention of relapses of	5	
gout.		1,65
Hypnotic Z-drugs increase the risk of falls in older people.	5	1,65

(81,1%; IC 95%: 76.8 – 85.4).

3243 medication reviewed:

- 303 (9.3%; IC 95%: 8.3 10.4) according to STOPP criteria.
- 278 (8.6%; IC 95%: 76.8 85.4) according to START criteria.

START CRITERIA	Nº IP	%
Pneumococcal vaccine according to national guidelines.	134	48,20
Statin therapy with a documented history of coronary, cerebral or peripheral	26	
vascular disease.		9,35
Seasonal trivalent influenza vaccine annually.	24	8,63
ACE inhibitor with systolic heart failure and/or ischaemic heart disease.	16	
		5,76
Laxatives in patients receiving opioids regulary.	14	5,04
Calcium and vitamin D supplement in patients with known osteoporosis and previous fragility fracture(s) and/or Bone Mineral Density T-scores more than	9	
multiple sites.		3,24
Vitamin D supplement in older people who are housebound or experiencing	9	
falls or with osteopenia.		3,24
Antiplatelet therapy with a documented history of coronary, cerebral or peripheral vascular disease.	7	2,52
ACE inhibitor with congestive heart failure or documented coronary artery	7	2,52
disease.		2,52
Beta-blocker with ischaemic heart disease.	5	1,80
Regular inhaled beta 2 agonist or antimuscarinic bronchodilator for mild to	5	.,
moderate asthma or COPD.		1,80

Discussion and conclusions

High number of patients in the ER had IP (prevalence= 81.1%). These data are higher than the data found in other studies (35.9% - 61.3%). In our study a high number of recommendations to modify drug treatment in older people have been done. The final results of the study will clarify if these interventions improve clinical outcomes.

This study is promoted and financed by the REDFASTER group of the Spanish Society of Hospital Pharmacy.

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Agence nationale de sécurité du





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lôpitaux de Lyc

Background: Off-label and unlicensed (OLUL) drug use is a dominant practice in paediatrics. Recent observational studies suggest that OLUL drugs are more likely to be responsible for adverse drug reactions (ADRs) in children than licensed medicines (Santos 2008; ADRIC 2014).

Purpose: EREMI study prospectively assess the relationship between OLUL drug use in children (0–15 years, \geq 3 hospital days) and ADRs occurrence. This EREMI intermediate report describes ADRs detected over 19 months (September 2013 to March 2015) in our children's hospital.

Materiel and Methods: ADRs were detected by the EREMI team (physicians/pharmacists) analysing data extracted from the Hospital Information System (e-HIS):

patient medical records, drug administrations, physiological parameters and biological outcomes. Suspected ADRs were validated with the clinical team.

RESULTS

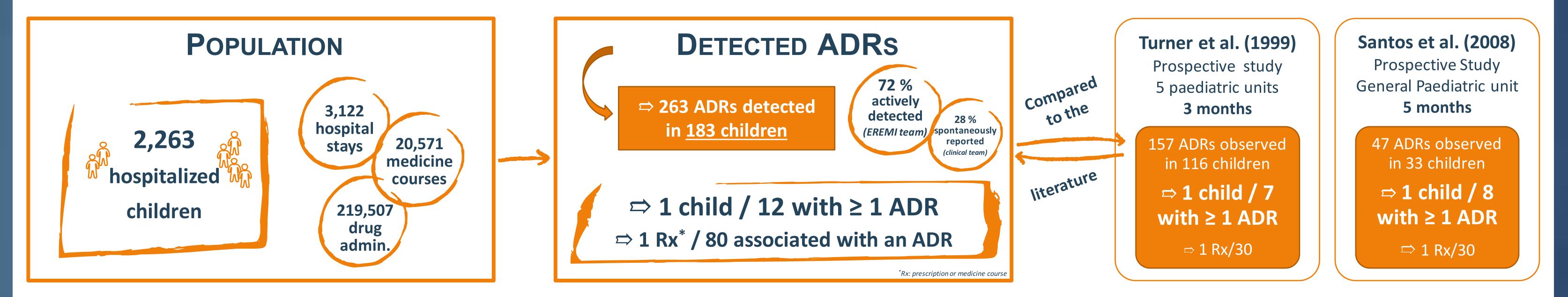


Table 1 – Frequency of observed ADRs within the 7 participating paediatric units.					
Paediatric unit	Mean No. of Rx/child	Total No. of ADRs	Proportion of children experiencing ≥ 1 ADRs	Incidence of ADRs based on No. of children	
1. Paediatric resuscitation	16	134	29 %	45 %	
2. Nephrology / Rheumatology	15	32	10 %	15 %	
3. Developmental psychopathology	1	19	9 %	12 %	
4. Hepatogastroenterology	15	16	8 %	10 %	
5. Neurology / Epileptology	11	25	8 %	9 %	
6. Pulmonology	9	31	4 %	8 %	
7. Endocrinology, General paediatrics	4	6	1 %	1 %	

System organ class	Examples of ADRs No. ADR		% of ADRs
1. Metabolism and nutrition	hypokalaemia, decrease appetite	58	22 %
2. Nervous system	somnolence, extrapyramidal syndrome	28	11 %
3. Psychiatric	discontinuation syndrome, irritability	26	10 %
4. Vascular	blood pressure disorders, thrombosis	24	9 %
5. Hepatobiliary	increased transaminases	21	8 %
6. General and administration site	allergic reactions	19	7 %
7. Gastrointestinal	diarrhoea, pancreatitis	18	7 %
8. Blood and lymphatic system	anaemia, neutropenia	16	6 %
10. Skin and subcutaneous tissue	skin reaction	13	5 %
11. Renal and urinary	renal failure, urinary retention	13	5 %
12. Infection and infestations	opportunistic infections	9	3 %
13. Cardiac	cardiac rhythm disorders	8	3 %
14. Respiratory, thoracic and mediastinal	hypoxia	7	3 %
17. Musculoskeletal and connective tissue	tendinitis	2	1 %
19. Eye	corneal ulcer	1	0 %

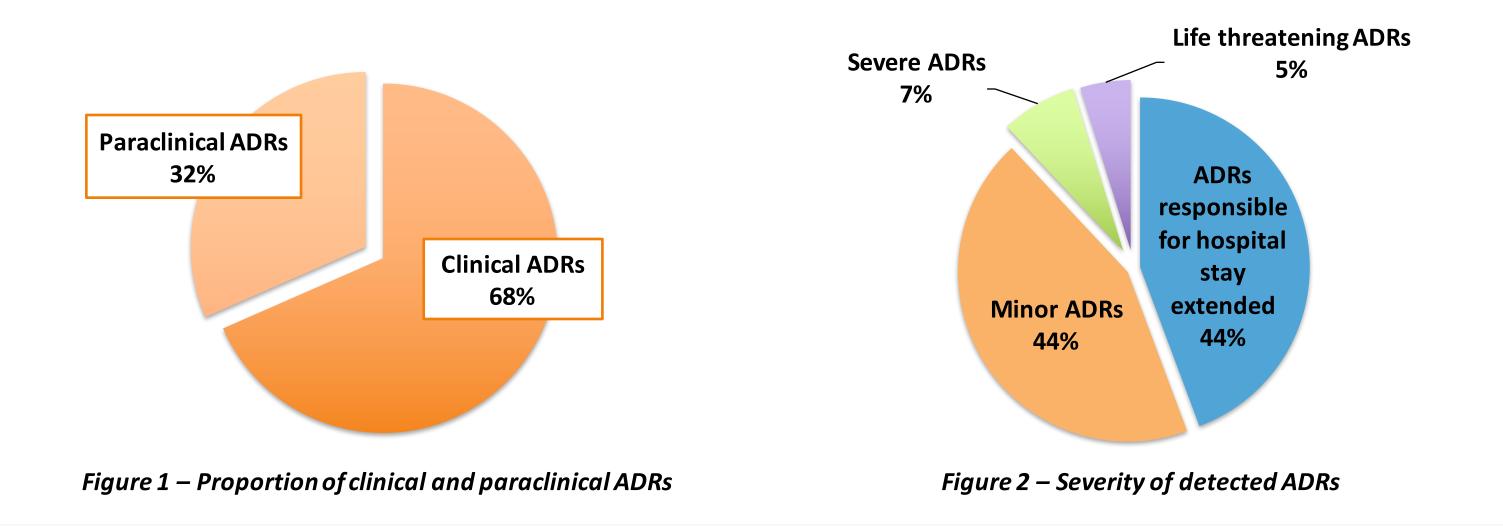


Table 3 – Most commonly observed ADRs.

ADRs	No. of ADRs	%	Suspected drugs
1. Hypokalaemia	27	16 %	diuretics, topiramate, methylprednisolone, nalbuphine
2. Discontinuation syndrome	19	7 %	morphinics, ketamine
3. Somnolence	16	6 %	cyamemazine, nalbuphine, levetiracetam, vigabatrin
4. Cytolysis and cholestasis	16	6 %	mycophenolate, methotrexate, rituximab
5. Hypotension	15	6 %	diuretics, clonazepam, phenobarbital, midazolam
6. Skin reactions	14	5 %	vancomycin, lamotrigine + VPA

Table 4 – Examples of ADRs responsible for hospital stay extended (44%)ADRsSuspected drugsAcute pancreatitis (2)⇔ hydroclorothiazide, VPAAllergic reactions (4)⇔ vancomycin, piperacillin/tazobactam, tocilizumabInterstitial tubulopathy (1)⇔ carbamazepine

Table 5 – Examples of severe of life threatening ADRs (12%)

ADRs	Suspected drugs
Hypokalaemia (12)	⇔ diuretics
Corneal ulcer (1)	⇔sufentanil+ midazolam + Nimbex® + Ketamine
Diabetes (1)	⇔tacrolimus

Discussion and Conclusion:

- ARDs in EREMI compared to the literature:
 - ✓ Almost twice as much children with ≥ 1 ADR;
 - Twice as much medicine courses per child;
 - ✓ Different units, longer ADR detection period in EREMI;
- As expected, great incidence od ADRs within the resuscitation ward (1 child/3 experiencing ≥ 1 ADR).
- Unanticipated high frequency of ADRs occurrence using **psychiatric drugs** in children.

Perspectives:

- Detected ADRs are being reviewed by our Regional Centre of Pharmacovigilance and the EREMI independent committee.
- Majority of ADRs were preventable (e.g.: hypokalaemia, discontinuation syndrome):
- Systematic warning of clinical staff for ADR risks would help in preventing ADRs.
 - Collected information will be used to develop an
- automated tool for the detection of preventable ADRs.

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