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european association
of hospital pharmacists

SIG SPECIAL INTEREST GROUP | FINAL REPORT

Working towards eliminating avoidable harm

January 2024

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The work of this Special Interest Group (SIG) was financially supported by Baxter.

Foreword by the President

The delivery of healthcare is changing quickly and requires a constant adaptation of the safe and efficient patient care that hospital pharmacists provide every day. Especially, since avoidable harm can occur frequently along the entire supply chain of medicinal products in hospitals ranging from provision over dispensing to administration. Addressing problems in a dynamic work environment whilst accommodating increasing and diversifying demands of the healthcare system can be challenging for healthcare professionals and requires a robust design of processes.

To better understand the many factors that can impact the supply, preparation, and administration of medicines in Europe, the European Association of Hospital Pharmacists (EAHP) created a Special Interest Group (SIG) Working Towards Eliminating Avoidable Harm (financially supported by Baxter). The work of the SIG focused on matching different sets of measures with medication error root causes and advocating for their implementation to drive forward change in European hospitals.

On behalf of EAHP, I would like to thank all SIG members for their valuable contributions and their engagement.

András Süle
President of the European Association of Hospital Pharmacists

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Executive Summary

This report presents the findings of the Special Interest Group (SIG) Working Towards Eliminating Avoidable Harm set up by the European Association of Hospital Pharmacists (EAHP).

Background and aim

In 2017, the World Health Organization launched its "Medication without harm" challenge to reduce avoidable medication-related harm by 50% within five years. The focus was set on patients, healthcare professionals, medicines, therapy systems and practices. The work of the SIG aimed at identifying root causes of medication errors, proposing a set of indispensable measures needing to be implemented, recommending accompanying these approaches with an appropriate just culture and supporting the implementation of evidence-based measures driven by hospital pharmacists and advocating for policy change.

Methods

Critical incidences, GMP-inspections, and literature cases were analysed for their most likely root causes and classified into latent system errors and active individual errors. A set of measures related to handling medicinal products was elaborated.

Results

System-level errors accounted for 30/89 incidences. Their root causes were composed of 7 organisational/governance pitfalls, 6 bad human and 17 bad technical resources. CEOs, Boards, inspectorates, as well as governmental and political authorities, but no license-holding hospital pharmacists were identified as risk owners.

Among the 59/89 active inevitable individual errors, 8/59 root causes were arising from slips or lapses (i.e. errors in the schematic behaviour) and 51/59 from mistakes (i.e. errors in the attentional behaviour). 6 mistakes occurred at supply, 19 at order entry, prescription, or dose calculation (e.g. wrong dose), and 26 at dose administration (e.g. wrong medicinal product, wrong patient). Engaging (conscious) patients in their medication is suitable to avoid lapses on administering medication. For this, patients must be able to verify intact blisters.

Conclusion

Discrepancies between legal requirements and missed implementation in hospitals need to be troubleshot. Current critical incidences in hospitals are rarely arising from central hospital pharmacies

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but from system errors leading to circumstances favouring medication errors on the ward. Thus, coping strategies require system-reengineering and designing robust GMP compliance in ward environments. System thinking is even suitable to minimise so-called “inevitable” individual failures of schematic and attentional behaviour.

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Background

Hospital pharmacists play a critical and varied role in the delivery of safe and efficient patient care. With the introduction of novel medicines such as biologics, the adoption of new technology like artificial intelligence and a shift to delivering care in settings outside of the hospital, the environment is changing quickly as are the demands placed on this group of professionals.

While such innovations present huge potential benefits to patients, improving patient and healthcare professional safety in this dynamic environment whilst accommodating increasing and diversifying demands on the healthcare system will be challenging and require new ways of working. Critical incident reporting systems (CIRS) play an important role in the elimination of avoidable harm since they support the structured reporting, collation and analysis of incidents. In addition, they help with identifying clinical risks in hospitals. However, not all hospitals in Europe are equipped with CIRS and those that use them might not exploit their full potential.

EAHP has established a SIG Working Towards Eliminating Avoidable Harm within the supply, preparation and safe administration of medicines in Europe. The work of EAHP's SIG is sponsored by a grant from Baxter. The decisions and outcomes delivered by this working group remain independent of this financial support. The activities of the SIG Working Towards Eliminating Avoidable Harm align largely with the efforts of the World Health Organization (WHO) which aims at globally reducing the level of severe, avoidable harm related to medications by 50% over 5 years.[1]

The SIG set out to develop an educational piece focused on the elimination of avoidable harm, policy recommendations detailing potential mechanisms to improve patient safety and a guidance document for advocacy by hospital pharmacists. The discussions of the SIG and the outcomes of these were summarised in this comprehensive report. In addition, a publication for the European Journal of Hospital Pharmacy (EJHP) was prepared by the group.

European Statements of Hospital Pharmacy

In 2014, EAHP adopted the European Statements of Hospital Pharmacy[2] that express commonly agreed objectives which every European health system should aim for in the delivery of hospital

[1] WHO Global Patient Safety Challenge. Medication Without Harm. Guideline. 2017. Available at: https://www.who.int/publications/i/item/WHO-HIS-SDS-2017.6 (last visited on 20 February 2023).
[2] The European Statements of Hospital Pharmacy. European Journal of Hospital Pharmacy. 2014. 21:256-258. Commented Version of the European Statements of Hospital Pharmacy. 2021. Available at: https://statements.eahp.eu/sites/default/files/Commented%20version%20of%20the%20European%20Statements%20.pdf (last visited on 20 February 2023).

pharmacy services. The use of prefilled medicine syringes is linked to a number of Statements in the European Statements of Hospital Pharmacy cited verbatim, below:

SECTION 1 Introductory Statements and Governance

Statement 1.1

The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working collaboratively within multidisciplinary teams in order to achieve the responsible use of medicines across all settings.

Statement 1.2

At a European level, 'Good Hospital Pharmacy Practice' guidelines based on the best available evidence should be developed and implemented. These guidelines will include corresponding human resources and training requirements and assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services.

Statement 1.4

All hospitals should have access to a hospital pharmacist who has overall responsibility for the safe, effective and optimal use of medicines. Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with appropriate working experience in the hospital setting, and explicit demonstration of competence in hospital pharmacy.

SECTION 3 Production and Compounding

Statement 3.3

Before making a pharmacy preparation, the hospital pharmacist must undertake a risk assessment to determine the best practice quality requirements. These must consider premises, equipment, pharmaceutical knowledge and labelling.

SECTION 5 Patient Safety and Quality Assurance

Statement 5.2

Hospital pharmacists should ensure the development of appropriate quality assurance strategies for medicines use processes to detect errors and identify priorities for improvement.

Statement 5.5

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Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.

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Risk assessment and eliminating avoidable harm

As outlined by the third Global Patient Safety Challenge tackling medication safety by WHO, a considerable amount of harm is avoidable.[3] Similar findings were reported by the European Collaborative Action on Medication Errors and Traceability (ECAMET), a patient safety initiative developed by a group of healthcare professionals and stakeholders, that reported on medication errors caused by the lack of consistency and harmonisation of processes and the low implementation of medication traceability systems.[4]

To contribute to the elimination of avoidable harm within the supply, preparation and safe administration of medicines, EAHP SIG drew inspiration from these initiatives and started its work by looking at risks that exist within hospitals. News reports evaluated by the group at their first meeting showed that system and/or human failure were frequently the causes of harm. When looking closer, the group concluded that harm centres around the traditional treatment of failures caused by inadequate knowledge or skills of individuals and problems in the system linked to poor design.

To catch errors before their occurrence, the SIG reflected on different risk management approaches, including the creation of risk strategies and quality management systems which seek to lower risk through high quality. Linked to the interdependence of risks, incidents and harm, the group collected the following:

- Structure / Process / Outcomes Quality (Donabedian)
- Deming's Reiterating circle (Plan – Do – Check – Act)
- FDA Risk Classification
    - Class I (low, not invasive)
    - Class IIa (moderate, short term invasive)
    - Class IIb (high, long term invasive)
    - Class III (critical, long term invasive)

[3] WHO Global Patient Safety Challenge. Medication Without Harm. Guideline. 2017. Available at: https://www.who.int/publications/i/item/WHO-HIS-SDS-2017.6 (last visited on 20 February 2023).
[4] White Paper Call to Action developed by the ECAMET Alliance on The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm. 2022. Available at: https://ecamet.eu/wp-content/uploads/2022/05/ECAMET-White-Paper-Call-to-Action-March-2022-v3.pdf (last visited on 20 February 2023).

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- Inspections according to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) – leads to harmonisation
- Corrective and Preventive Actions (CAPA)
    - Corrective Action (analytical skills wanted)
    - Preventive Action (anticipative skills wanted)
- Risk Management according to EAHP Statements
    - Production and Compounding (Statement 3.3)
    - Patient Safety and Quality Assurance (Statements 5.3 - 5.6)

The impact of the Good Manufacturing Practice (GMP), PIC/S and guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) were further analysed. Linked to GMP quality requirements the SIG highlighted that these are comprehensive, but not all are suitable for implementation in hospital pharmacies nor fulfillable. The discussion also included the identification of relevant ICH guidelines and PIC/S guides.

- ICH[5]
    - Q2 - Validation of Analytical Procedures
    - Q7 - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
    - Q9 - Quality Risk Management
    - Q10 - Pharmaceutical Quality System
    - E2C - Periodic Benefit-Risk Evaluation Report
    - E6 - Good Clinical Practice (GCP)
    - S6 - Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
- PIC/S[6]

[5] Guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Available at: https://ich.org/page/ich-guidelines (last visited 20 February 2023).
[6] Pharmaceutical Inspection Co-operation Scheme (PIC/S). Publications. Available at: https://picscheme.org/en/publications?tri=gmp#zone (last visited 20 February 2023).

- PIC/S GMP Guide (Introduction) PE 009-15
- PIC/S GMP Guide (Part I: Basic requirements for medicinal products) PE 009-15 (Part I)
- PIC/S GMP Guide (Part II: Basic requirements for APIs) PE 009-15 (Part II)
- PIC/S GMP Guide (related annexes) PE 009-15 (Annexes)
- PIC/S GMP Guide (ZIP) PE 009-15

ICH Q9 - Quality Risk Management and ICH Q10 - Pharmaceutical Quality System were looked at more closely. ICH Q9 provides guidance on the principles and some of the tools of quality risk management that can enable more effective and consistent risk-based decisions, both by regulators and the industry, regarding the quality of drug substances and drug (medicinal) products across the product lifecycle.[7] The SIG reflected on the steps of risk management process that include defining the problem, assembling information, identifying the leader and resources, and specifying the timeline.

[7] European Medicines Agency. ICH guideline Q9 on quality risk management. 2015. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-3.pdf (last visited 20 February 2023).

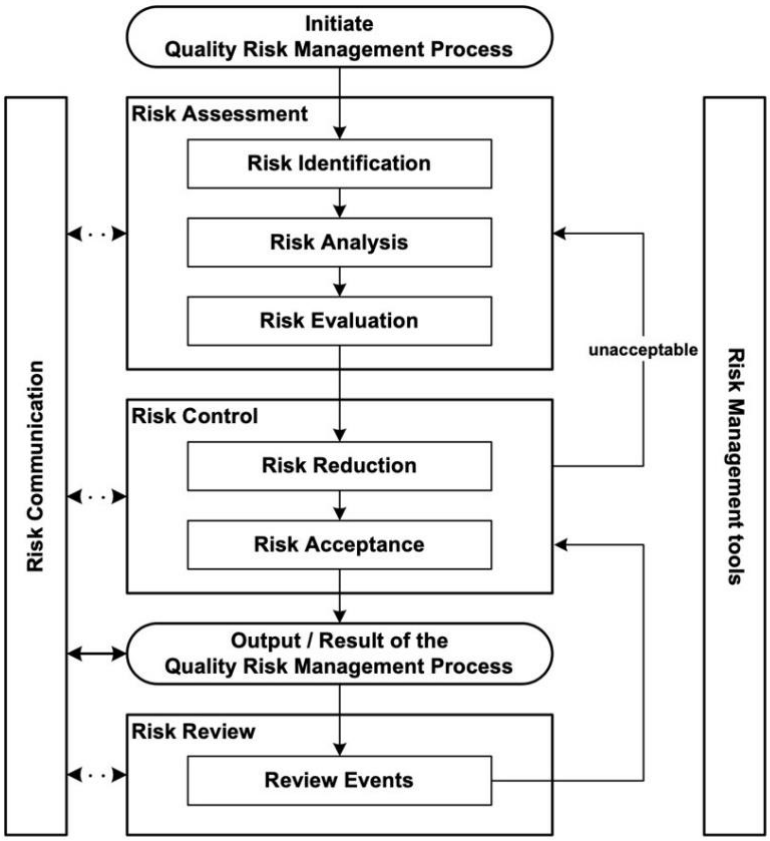

Image 1: Overview of a typical quality risk management process included in ICH Q9.

Also, the basic risk management facilitation methods and tools covered by ICH Q9 – such as Failure Mode and Effects Analysis (FMEA), Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP), Preliminary Hazard Analysis (PHA), Risk ranking and filtering and Supporting statistical tools – were elaborated on. Concerning ICH Q10[8] the SIG concluded that risk management is one of the enablers of a high-quality system.

After looking at existing risk minimisation tools, the SIG elaborated on the eight most common causes of medical errors.[9] These include:

- Communication problems (between different members of the healthcare team, e.g. physician, nurse, pharmacist, patient or others)

[8] European Medicines Agency. ICH guideline Q10 on pharmaceutical quality system. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human_en.pdf (last visited 20 February 2023).
[9] Anne Carrie. The 8 most common causes of medical errors. Agency for Healthcare Research and Quality. 2021. Available at: https://alwaysculture.com/hcahps/communication-medications/8-most-common-causes-of-medical-errors/ (last visited 20 February 2023).

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- Inadequate information flow within different services areas (e.g. lack of seamless care due to poor coordination of medication orders for the transfer of care)
- Human problems (e.g. standards of care, policies and procedures are not being followed properly; poor documentation and labelling of specimens; knowledge-based errors; etc.)
- Patient-related issues (e.g. inappropriate patient identification; inadequate assessment; failure to obtain consent; insufficient education; etc.)
- Organisation transfer of knowledge (caused by insufficiencies in training and inconsistent or inadequate education, especially critical for the training of new employees or temporary support)
- Staffing patterns and workflow (e.g. inadequate staffing in situations can increase the likelihood of mistakes)
- Technical failure (e.g. complications or failure of medical devices, implants, grafts, or pieces of equipment)
- Inadequate policies (e.g. poor documentation and non-existent, or inadequate procedures)

When occurring consecutively the different causes can exacerbate a situation and create a domino effect. To stop the domino effect of a series of concatenated unfortunate events, the SIG applied the "Swiss Cheese Model". Switzerland's virus pandemic defence measures were used as an example to outline how different measures can help avoid that hazards slip through the cracks. Individually none of the measures would have led to preventing the spread of the virus, but taken jointly, different measures ensured that harm caused by the virus is minimised.

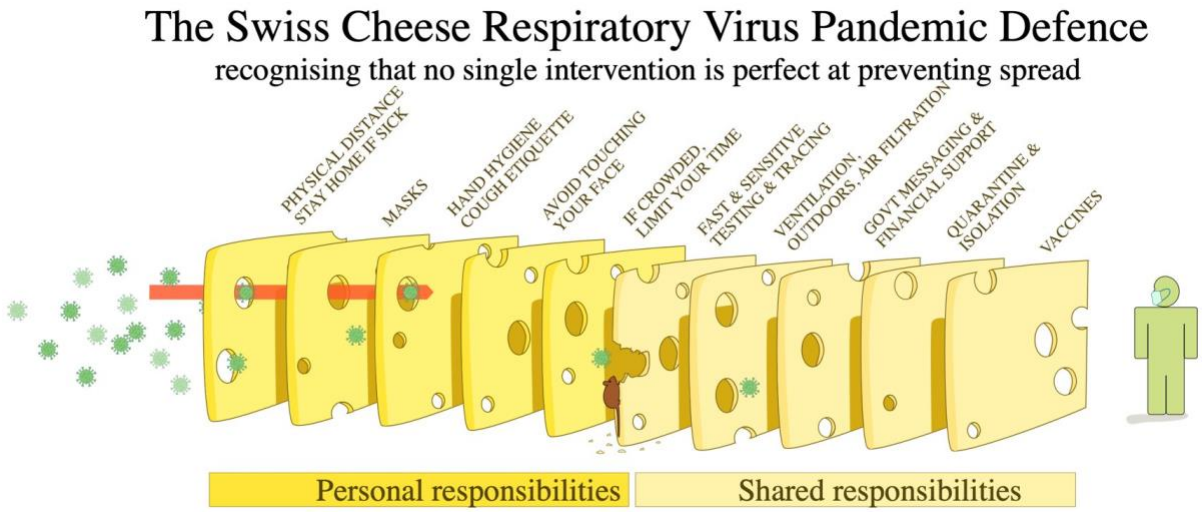

Image 2: "Swiss Cheese Model"[10]

Another model that was discussed, included the CAPA (corrective and preventive action) which focuses on catching errors before they occur.[11] To establish this system, a retrospective analysis of incidents needs to be carried out. These case reviews should involve different (healthcare) professionals with different backgrounds and experience levels. The error should be reviewed with the help of the following cognitive and systematic factors:

Cognitive factors	Systematic factors
• Medical knowledge • Diagnostic reasoning • Therapeutic choice • Clinical assessment	• Materials/machines • Personnel/people • Communication • Processes • Environment

In preparation for the incident reporting exercise, the SIG conducted a root cause analysis for the hospital pharmacy supply chain. Different risks (ranging from low to medium and high) and responsibility levels were attributed. Distribution in accordance with GMP, Good Storage Practice (GSP) and Good Distribution Practice falls within the responsibility of the hospital pharmacy. This responsibility shifts towards clinics, departments and wards for the distribution of pill boxes/blisters to patients and the administration on the wards. Both administration and dispensing in clinics, departments and wards should be carried out with Good Clinical Practice (GCP) guidelines and guidelines of the European Directorate for the Quality of Medicines & HealthCare (EDQM). Based on the discussion the following diagram was created:

[10] Ian M. Mackay. Infographic Swiss Cheese Model. 2020. Available at: https://figshare.com/articles/figure/The_Swiss_Cheese_Respiratory_Virus_Defence/13082618 (last visited 20 February 2023).
[11] Patient Safety Network. Systems Approach. 2019. Available at: https://psnet.ahrq.gov/primer/systems-approach (last visited 20 February 2023).

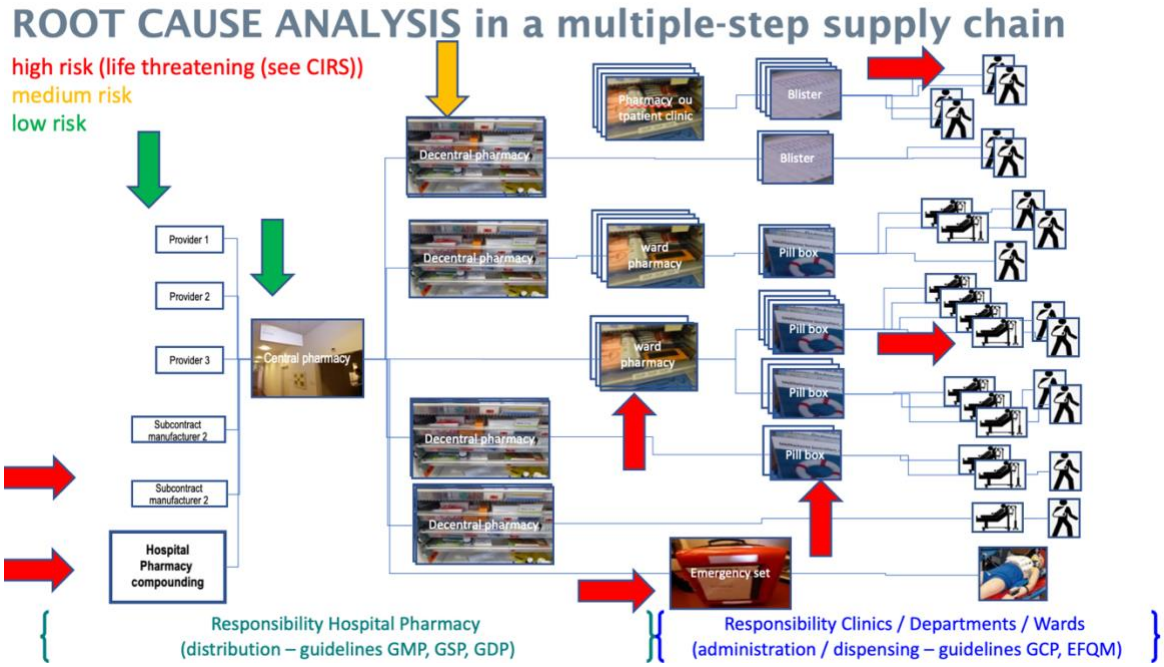

Image 3: Multi-step supply chain linked to the hospital pharmacy

For risk prevention and the reduction of risks in practice, the SIG spoke about policies implemented by a hospital in Switzerland. The measures taken were based on reports from the Critical Incident Reporting System (CIRS). Different task forces – focused on addressing aggression by patients towards personnel and vice-versa, lowering medication/medicinal errors and dealing with intoxications and allergies/intolerances – were established. The task force looking at medical errors in diagnostics, treatment and therapy, and medication errors was chaired by a pharmacist. Some risks, like financial risks, intentional criminal acts, unapproved abandonment by patients of closed wards and the neglected duty to inform were not addressed by the risk reduction policy.

When dissecting the approach of the Swiss hospital that was used as an example, the SIG concluded that risks could be categorised as either system errors or individual errors.[12]

System errors *(caused outside direct patient care)*	Individual errors *(may cause harm when administering treatment)*
Caused by:	Caused by:

[12] Anne Carrie. The 8 most common causes of medical errors. Agency for Healthcare Research and Quality. 2021. Available at: https://alwaysculture.com/hcahps/communication-medications/8-most-common-causes-of-medical-errors/ (last visited 20 February 2023).

• Institution (e.g. policy, organigram, management, regulatory pressure) • Work environment (e.g. staffing, design of a device, equipment, fixed and mobile installations) • Team environment (e.g. workload, safety culture, task)	• Slips – failure of schematic behaviour (e.g. fatigue, stress, lapses in concentration, multitasking) • Mistakes – failure of attentional behaviour (e.g. lack of experience, incorrect choices, insufficient training, negligence)

Linked to this classification the prevention of active errors, such as slips, near misses and mistakes was further elaborated on. A mind map was created to outline the different factors that influence the prevention of active errors.

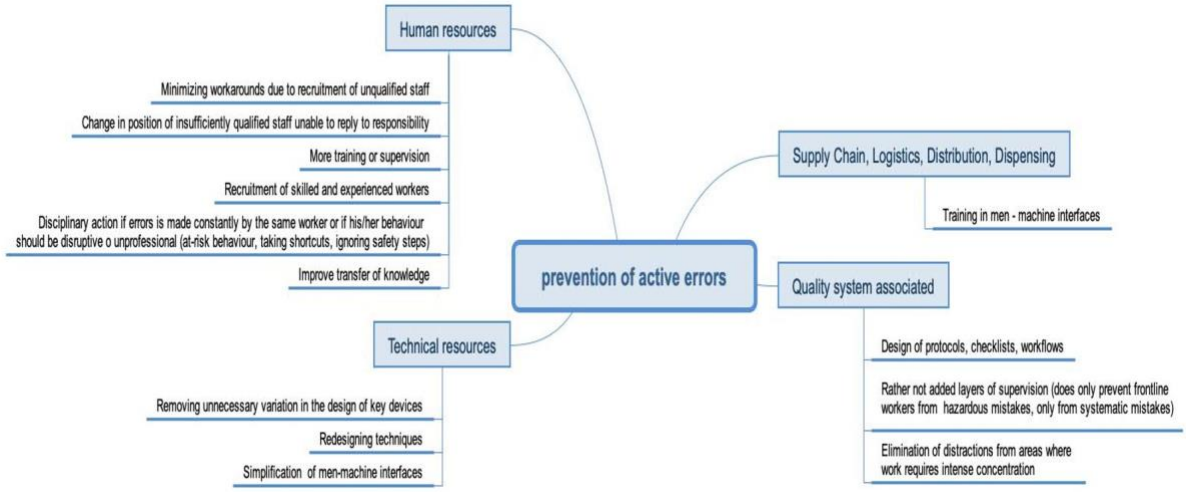

Image 4: Mind map focused on the prevention of active errors

A similar exercise was carried out for latent errors.

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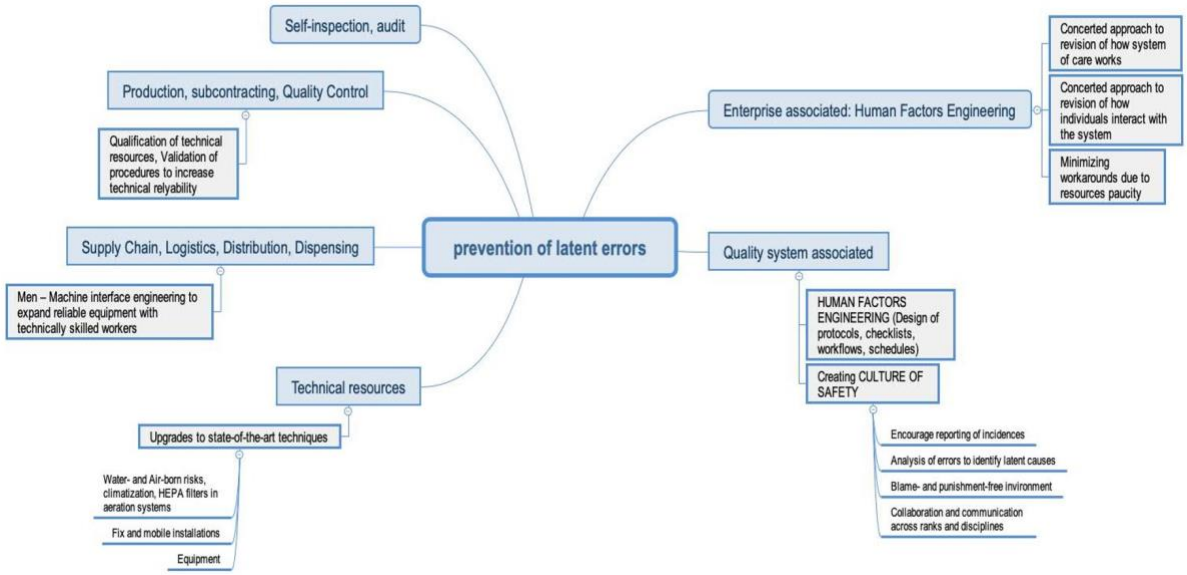

Image 5: Mind map focused on the prevention of latent errors

Both activities aimed at preparing the SIG members for the incident reporting exercise that was carried out in parallel with the discussion on national minimum quality requirements in hospital pharmacies.

Also, the basic risk management facilitation methods and tools covered by ICH Q9 – such as Failure Mode and Effects Analysis (FMEA), Healthcare Failure Mode and Effect Analysis (HFMEA), Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP), Preliminary Hazard Analysis (PHA), Risk ranking and filtering and Supporting statistical tools – were elaborated on.

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National Minimum Quality Requirements

Given the differences that were identified by the SIG members, the group decided to discuss national minimum quality requirements present in the countries represented within the SIG. SIG members from Austria, Italy, North Macedonia, Portugal, Slovakia and Switzerland shared details on the minimum quality requirements in their countries.

Austria

In Austria, the hospital pharmacy is the functional unit of a hospital to which the proper supply of medicinal products in accordance with § 36 of the Pharmacy Act, pharmaceutical care and the proper supply of medical products and other hospital-specific goods in accordance with the hospital's internal organisation is attributed to.

Theoretically, the operation of a hospital pharmacy is regulated by the Austrian Pharmacy Operations Regulation. However, it is not binding by the law that a hospital of a certain size (based on the number of patient beds) has to have a hospital pharmacy. It is still customary in Austria to only have a medical depot run by pharmacy technicians or other personnel with no pharmaceutical education and knowledge in hospitals. The depot is checked quarterly by either a community pharmacist or a hospital pharmacist. This ensures low costs for hospitals but also decreases patient safety in the hospital.

At the moment only 15,8% of all hospitals in Austria have a hospital pharmacy. A clinical pharmacy service is implemented in only a small portion of these hospitals. There are rules defining the nature and size of the hospital pharmacy premises (at least 200m², a dispensary, a storage room, a laboratory and sanitary facilities; a duty room only if on-call duties are performed during the night), the devices, aids and testing equipment for the manufacture and testing of medicinal products, the scientific reference works and other resources, the stock-keeping in the hospital pharmacy, the dispensing by the hospital pharmacy, the pharmaceutical care in the hospital, the general regulations on the manufacture and testing of medicinal products and medical devices, the extemporaneous compounding (formulation) and the extemporaneous compounding stock.

There is however a lack of laws for when there is a need for a hospital pharmacy. For clinical pharmacy, at the moment it is merely stated in the law that “sufficient clinical pharmacists” should be provided. There is still no concrete number to define what the term “sufficient pharmacists” entails and there is much room for interpretation within the different Austrian counties.

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Italy

There are several ministerial recommendations relating to medicines which are relevant for setting minimum standards in Italy. These include:

- 1 Correct use of concentrated solutions of potassium chloride – KLC and other concentrated solutions containing potassium
- 7 Recommendation for the prevention of death, coma or severe harm resulting from errors in drug therapy (01/03/2008)
- 12 Prevention of errors in drug therapy, look-alike and sound-alike (01/08/2010)
- 14 Recommendation for the prevention of errors in therapy with antineoplastic drugs (01/11/2012)
- 17 Recommendation for the reconciliation of drug therapy (01/12/2014)
- 18 Recommendation for the prevention of errors in therapy resulting from the use of abbreviations, acronyms, and symbols (01/09/2018)
- 19 Recommendation for the handling of solid oral pharmaceutical forms (01/11/2019)

Once per year, the hospital risk manager needs to report to the Ministry of Health on their application in hospitals. There is, however, a lack of measurable quality indicators.

The Good Preparation Rules - Official Pharmacopoeia 2003 apply to preparations, including compounding therapies in the pharmacy. They are mandatory, but the control and monitoring system (e.g. a special team dedicated to the control) is missing. For this reason, it is not clear if the Good Preparation Rules are applied fully by all pharmacies in Italy.

Provision Of Law - 1999: Centralization of Antiblastic Drugs at Pharmacies is mandatory for those who perform sterile preparations and for the protection of health workers. Not all hospitals have an antiblastic drugs unit. This is often caused by the lack of pharmacists and personnel with suitable training and lack of dedicated spaces. Hospitals are old and require high economic investments.

ISO 9001 2015 on quality management systems is applied. Certification is still a voluntary and not mandatory act for the pharmacy. Certification in accordance with this standard is mandatory in the haematology unit performing transplantation. The standards for the accreditation of pharmacies are outdated since they stem from 1997. More up-to-date requirements would be needed in relation to the evolution of the pharmacy service in Italy.

In hospitals with a Molecular Tumour Board – a dedicated team working on the evaluation of genomic tests and tumour mutations to identify experimental studies or available drugs – pharmacists are part

of this multi-professional team. Many regional Pathology Diagnostic Therapeutic Paths require the presence of a compounding unit for their establishment. For pharmacists, it is only possible to work in Italy in a hospital with a specialisation in either hospital pharmacy or pharmacology. To improve the training it would be necessary to include a clinical risk course in both the hospital pharmacy specialisation curriculum and the pharmacy degree course.

North Macedonia

Some of the hospitals are standardised by ISO standards in North Macedonia. But this is not the case for most of them. Standardisation of all hospitals would be needed as well as standardisation of all hospital pharmacies. The latter would entail requiring that hospital pharmacists would need to be employed in the hospital pharmacies and that their tasks should not be carried out by nurses or other medical staff. Their work should be supported by an adequate number of pharmacy technicians.

Also, specialised hospital pharmacists would be needed in particular those trained in clinical pharmacy, pharmacoinformatics, pharmaceutical technology for the reconciliation of antibiotics, cytotoxic medicines and parenteral nutrition. Furthermore, protocols for medical treatment are lacking in North Macedonia as well as Therapeutic Committees in hospitals and medicine safety strategies. For increasing patient safety, better IT systems, electronic prescribing and barcoding technology should be implemented.

Norway

A majority of hospitals have a hospital pharmacy in-house. Most hospital pharmacies have pharmaceutical services such as medication reconciliations and med review, discharge conversations with the patient. Pharmacists do not have the mandate to make changes in patients' prescriptions without these changes being approved by a physician. Clinical pharmacist inclusion in the hospital wards is not required by law but most hospitals have pharmacists on selected wards and value their clinical services. Several municipalities have a municipal pharmacist working across nursing homes and homecare facilities

Due to an update in the "Regulations on the requisition and delivery of medicinal products from pharmacies 2021/2022":

- Pharmacists are allowed to administer immunisations.

- Pharmacists can prescribe a limited number of medications (flu vaccines, COVID-19 vaccines and vaccines in the national immunisation program which are administered in the pharmacy).

The regional health organisations own hospital pharmacy companies that take care of specialist health services needs for pharmaceutical services. The hospital pharmacy companies are organised as health companies and are covered by the Health Business Act. The hospital pharmacy companies are separate legal entities.

The hospital pharmacies are perceived as far as it is possible as an integrated part of the health institutions' operations. Organisation with a hospital pharmacy as a separate health enterprise can entail some legal and management challenges. Some hospitals have employed their own pharmacists who take care of parts of the hospital's pharmaceutical services in collaboration with the hospital pharmacy.

There is a long tradition of drug committees in the hospitals. The medication committees are interdisciplinary and are advising the hospital management about pharmaceutical issues. The medication committees overall mandate is to promote rational, safe and cost-effective drug use and ensure efficient drug supply and proper drug preparedness the health institutions. Pharmacists are usually the initiators of drug committee work and often hold positions as the secretarial function.

Portugal

Improvements would be needed in relation to patient health records since electronic access to these records is not yet a reality in all Portuguese hospitals, which makes an informed/appropriate pharmaceutical intervention difficult. The inclusion of pharmaceutical reports in the electronic clinical process is also not yet possible in most Portuguese hospitals, which makes communication and the registration of pharmaceutical interventions difficult. By increasing the inclusion of pharmaceutical reports in the electronic clinical process medication errors could be minimised.

Changes to the pharmacy career in Portugal (covering genetic, clinical pathology and hospital pharmacy) brought structural problems. Hospital pharmacists were not put into a proper position, corresponding to their responsibilities and function in carrying out the training of others. This resulted in pharmacists with 20 to 30 years of experience being demoted and leaving hospitals to work in the industry or in clinical trials.

Minimum staffing requirements linked to the number of hospital beds exist in Portugal. These requirements are a recommendation that is not being followed for hospital pharmacies. Inspections

and audits are carried out. For inflictions, recommendations are provided but no funding is allocated to implement the changes required in the recommendations.

Positive developments in Portugal include that for the composition of Pharmacy and Therapeutic Committees it is required, by law, that physicians and pharmacists participate in an equal number. Also, the hospital pharmacy specialisation was relaunched in 2023, requiring now an exam like in Spain. By law, a pharmacist must work in each hospital since psychotropic medicines and blood products can only be supplied by a pharmacist. Also, a hospital formulary exists in all hospitals.

To improve the hospital pharmacy service in Portugal, additional changes would be needed. Pharmacists should be involved in the creation of all protocols involving medicines. To provide clarifications on medication preparation and information in real-time, pharmacists should be integrated into each team working on the ward. For the management of medication errors, it would be crucial to place a pharmacist in the hospital risk management team and/or the quality and safety department. Also, clinical pharmacy services and reconciliation interventions should be provided by pharmacists in Portugal.

Slovakia

Three different acts and ordinances provide minimum requirements in Slovakia. Act 578/2004 defines that a pharmacist is a healthcare professional and that continuing education is mandatory for all pharmacists. In accordance with Act 362/2011 hospital pharmacies are being established in Slovakia. They form an integral part of an institutional healthcare facility. Hospital pharmacies are tasked with preparing and delivering human medication, medical devices and dietetics based on a written or electronic order from departments and ambulances of the healthcare facility of which it is a part or of a different healthcare facility. It is possible for a community pharmacy to supply a healthcare facility if it doesn't possess a hospital pharmacy. Due to lower costs, this practice is becoming more and more common.

Ordinance on Good Pharmaceutical Practice 129/2012 details the composition of hospital pharmacies. It contains size requirements and minimum staffing requirements. A hospital pharmacy with less than 400 beds needs to employ 2 pharmacists and 3 pharmacy assistants. The number increases by 1 pharmacist and 1 pharmacy assistant with every 200 beds and each additional department included in the hospital pharmacy. Mandatory departments in a hospital pharmacy include the department of individual preparation, the department of medical devices and the department of clinical pharmacy which in reality is the department responsible for medicine logistics. Ordinance on Good

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Pharmaceutical Practice 129/2012 also outlines that the chief hospital pharmacist needs to be a member of the Commission for rational pharmacotherapy and pharmacoeconomics, the Commission for rational anti-infective therapy and antibiotic stewardship and the Ethics Committee. Controls on the wards should be carried out by a pharmacist at least once every 6 months. Also, the drug formulary is a part of the quality assurance system. It has to be updated at least once per year. The clinical pharmacologist in collaboration with the chief hospital pharmacist elaborates on the drug formulary.

The aforementioned acts and ordinances do not define the responsibilities of hospital and clinical pharmacists. Nor do they provide for the reimbursement of hospital pharmacy services. The minimum staffing requirements are a good step in the right direction, but the requirements are too low to ensure that all services can be provided fully. Also, automation and the use of technology are not mandated by law. An increase in technology would however improve patient safety in Slovakia.

Spain

In Spain, it is determined by law, RDL 16/2012, that any hospital, socio-health care centre, or psychiatric centre with 100 beds or more, will require a hospital pharmacy service.

It is not mandatory, but it is common that hospitals in Spain have ISO certifications, being the ISO 9000 the most frequent series of standards. There is a small number of hospital pharmacies accredited by the Joint Commission.

Pharmacists require to complete the hospital pharmacy specialisation to be able to work in hospitals. In addition, hospital pharmacists are active members of the Pharmacy and Therapeutics Committee and Infections Committee. It is relevant that increasing number of hospitals include hospital pharmacists in their Programs for Optimizing the use of antibiotics (PROA). Molecular Tumour Boards are slowly involving pharmacists as part of their multidisciplinary teams.

Hospitals have an electronic medical record system but better integration with primary care is needed. Hospitals have an electronic prescribing system available in most of the areas but better integration with a clinical decision support system and with other systems is needed.

Clinical Incident recording systems (CIRS) are commonly used to record medication errors (ME). Medication errors are investigated and discussed at regular quality meetings. However, heavy workload is a common barrier to registration of ME. The high risk areas of ME identified are paediatrics, oncohaematology, emergency services, intensive care and surgical services.

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In order to improve patient safety, procedures such as medicines reconciliation and improvements in transfer of care would need to be implemented. Investment and use of technology are also needed to reduce ME. Some examples are implementation of traceability systems, use of smart infusion pumps and barcoded medication administration (BCMA).

Switzerland

Minimum quality assurance requirements exist in Switzerland for hospital pharmacies. These are defined in the Therapeutic Products Act and the Medicinal Products Licensing Ordinance. The Therapeutic Products Act ensures that a pharmacy in a hospital establishment is run by a pharmacist and that manufacturing is carried out in conformity with the recognised rules of the good manufacturing practice. The Federal Council is tasked with specifying the recognised rules of the good manufacturing practice. In doing so, it is required to take into account internationally recognised guidelines and standards. Public pharmacies and public hospitals must hold a manufacturing licence. This does not extend towards physicians working in institutions for the elderly and other establishments.

The Medicinal Products Licensing Ordinance outlines requirements for the qualified person. This person is for example responsible for the quality of the supply of medicinal products, is part of the enterprise and figures in the organigram hierarchically subordinated to the directory of the institution and is independent in professional affairs. In addition, the qualified person is authorised to issue directives to all persons handling medicinal products and medical devices and he/she receives all necessary competencies and rights to fulfil his/her tasks.

It was also clarified in Switzerland that a ward pharmacy is not an independent hospital pharmacy. It is not capable to be licensed, therefore no dispensing point of the hospital, but belongs to the infrastructure of a hospital pharmacy, and is therefore, a part of the hospital pharmacy.

Based on the discussion of the SIG, it was concluded that European-wide minimum standards linked to the European Statements of Hospital Pharmacy would be needed across Europe to lower the differences between hospital pharmacy services. Ensuring minimum standards, including for example adequate minimum staffing requirements for pharmacies, requiring their presence in hospitals and

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providing for better equipment, including automation and enhanced IT systems, would not only improve hospital pharmacies but in turn also increase patient safety.

Similar findings were reported by the ECAMET project which calls for the introduction of technical tools, including for example medication traceability and electronic prescribing systems. Barcode medication administration (BCMA) that compares the barcode of the patient's bracelet, the healthcare worker's identification and the medication would also be a tool aiming at increasing medication safety in hospitals. Also, investments into automated drug cabinets and electronic preparation/compounding systems as well as digitalised medication inventory management and dose error-reduction software (e.g. smart pumps) could be useful.

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Incident reporting

After reflecting on different root causes of harm, the SIG started with the identification and classification of incidents. To this end, the group collected examples from their practice. The risks/incidents/harm were described and classified. The following categories

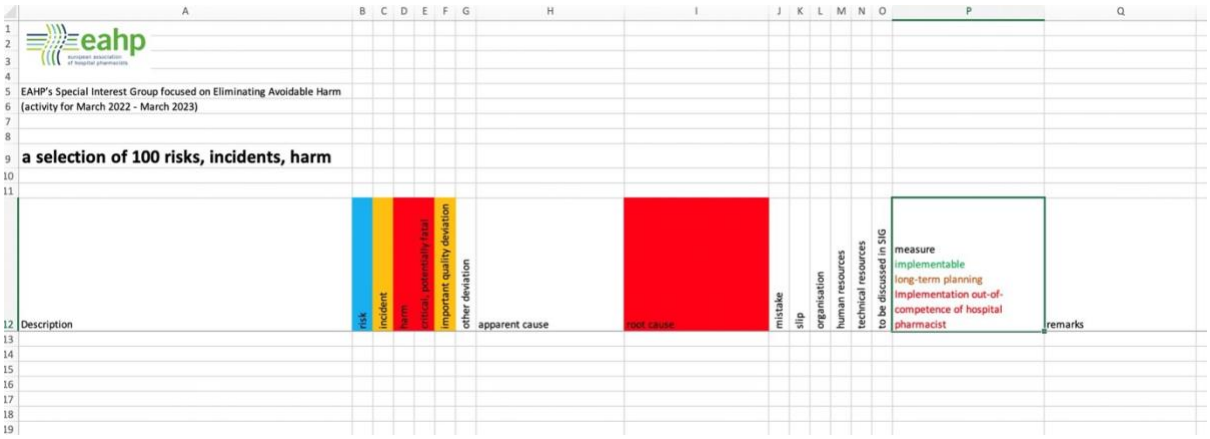

Image 6: Incident reporting sheet created by the SIG

89 incidents were collected by the SIG. System-level errors accounted for 30 of the 89 incidents. Their root causes were composed of 7 organisational/governance pitfalls, 6 human resource problems and 17 bad technical resources. CEOs, boards, inspectorates, as well as governmental and political authorities, but no license-holding hospital pharmacists were identified as risk owners for the 30 system-level errors.

Among the 59 active inevitable individual errors identified within the 89 incidents, eight root causes were arising from slips or lapses (i.e. errors in the schematic behaviour) and 51 from mistakes (i.e. errors in the attentional behaviour). The mistakes could be broken down further. Six of them occurred at supply, 19 at order entry, prescription, or dose calculation (e.g. wrong dose), and 26 at dose administration (e.g. wrong medicinal product, wrong patient). Engaging (conscious) patients in their medication is suitable to avoid lapses in administering medication. For this, patients must be able to verify intact blisters.

Linked to the 89 incidents the SIG members developed measures to address the root causes of the system-level errors and the individual errors identified. The measures were included in an outline

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developed by a Swiss hospital. The SIG members elaborated the measures in small groups focused on the following aspects:

- Individual errors (mistakes)
    - Supply chain
    - Order entry, prescription and dose calculation
    - Dose administration and 5R rules
- Individual errors (slips)
- System errors (teams)
- System errors (institutional)
- System errors (work environment)

Different measures to address root causes at the institutional level and linked to human and technical resources were identified by the group. These include the following:

Measures to address root causes at the institutional level comprise

- Assigning responsibility and independent decisional power to license-holding hospital pharmacists (see Swiss TPA, SR 812.21, art 4 and MPLO, SR 812.212.1, art 2-6)
- Illustrating the responsibilities of the license holder in the organigramme
- Defining ward pharmacies as part of the hospital pharmacy
- Implementing blaming- and punishment-free safety culture
- Standardising PICS PE 010-4 guidance (“GMP guide for healthcare establishments”)
- Abrogating all quality stipulations not released by the license holder
- Standardising CAPA to correct quality deviations
- Implementing Medicines Reconciliation and Medication Review

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Measures to address root causes at the human resources level comprise

- Allocating sufficient qualified HR (for staffing disparities see HIQA[13])
- Limiting work overload, time pressure, and staff fatigue
- Excluding unqualified staff from preparing and administering medicines
- Shifting tasks from overcharged nursing staff to pharmacy technicians and clinical pharmacists

Measures to address root causes at a technical resources level comprise

- Revising working conditions
    - Subordinating all preparation activities to the production-license holder ([CM/Res[2016)1] and [CM/Res[2016)2])
    - Stopping critical processes if 4-eye-principles cannot be applied
    - Designing distraction- and interruption-free working places dedicated to critical handling and high-risk medicines
- Automating processes
    - Optimising communication and information flow
    - Synchronising pharmacy and clinical information systems
    - Predefining electronic workflows
    - Standardising men-machine-interfaces
    - Omitting manual transcribing for electronic prescribing and order-entry with plausibility testing)
    - Implementing clinical decision support systems (CDSS)
    - Investing in robotic systems and electronic dispensing cabinets
    - Introducing barcode labelling and bedside scanning

[13] Health Information and Quality Authority. Medication safety reporting programme in public acute hospitals. 2018. Available at: https://www.hiqa.ie/reports-and-publications/key-reports-and-investigations/medication-safety-monitoring-programme (last visited 20 February 2023).

Conclusion and recommendations

Human errors are inevitable. However, system errors – like latent errors and errors of planning can be minimised through investments. In order to identify avoidable harm both retrospective methods of analysing errors (e.g. root cause analysis) and prospective methods (e.g. FMEA etc.) should be used. Also, ICH-GMP and PIC/S guidelines provide a number of risk management coping approaches.

Discrepancies between legal requirements and missed implementation in hospitals need to be troubleshot. Current critical incidences in hospitals rarely arise from central hospital pharmacies but from system errors leading to circumstances favouring medication errors on the ward. Thus, coping strategies require system-reengineering and designing robust GMP compliance in ward environments. System thinking is even suitable to minimise so-called “inevitable” individual failures of schematic and attentional behaviour.

Also, harmonisation is key for working towards eliminating avoidable harm. Different initiatives have been carried out to achieve European-wide harmonisation, but these have failed for different reasons. Compliance with PICS pushed for by the Council of Europe is supportable but has so far not been achieved due to the lack of mandatory requirements.

Barriers to change identified include the lack of enforceability of existing quality management aspects, the lack of governance (e.g. the lack of individuals taking the lead on addressing harm in institutions) and the fact that some measures cannot be implemented at the national level and thus would require standard setting by a higher instance, e.g. at the EU level.

Inspiration for eliminating avoidable harm could also be drawn from primary care. As outlined in the comparison of the national minimum quality requirements, hospital pharmacists are not a mandatory group of professionals working in hospitals. When comparing this to the primary care sector, the picture looks different. In primary care, a pharmacist is always necessary for dispensing/receiving medication.

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Appendix I – SIG membership

The SIG was comprised of the following members:

Name	Role/Country	Country
Renata Barbosa	Hospital Pharmacists at the Centro Hospitalar Universitario S. Joao in Porto	Portugal
Matthew Greening	Senior Pharmacy Professional Advisor - Infusions and Special Medicines Board	United Kingdom
Sonja Guntschnig	Clinical Pharmacist at the Tauernklinikum in Zell am See	Austria
Jennifer Hayde	Medication Safety Manager (Chief II Pharmacist) at the Tallaght University Hospital in Dublin	Ireland
Helene Heery (until summer 2022)	Senior Clinical Pharmacist at the Portiuncula University Hospital in Ballinasloe, Co. Galway	Ireland
Maria Cristina Iglesias Serrano	Senior Clinical Pharmacist at NHS hospitals. Hospital pharmacist in training, University Hospital Son Espases	United Kingdom/Spain
Helena Jenzer *Chair of the SIG*	Former Chief Pharmacist at Psychiatric University Hospital Zurich (retired)	Switzerland
Kristína Lajtmanová	Hospital Pharmacist at the National Institute of Cardiovascular Diseases	Slovakia
Alma Mulac (joined in September 2022)	Postdoctoral researcher, Department of Pharmacy, Faculty of Mathematics and Natural Sciences, University of Oslo	Norway
Elisabetta Rossin	Simple Structure Manager of the Antiblastic Drugs Unit (UFA) of the ASST Valle Olona	Italy
Slagjana Tentova-Peceva (joined in October 2022)	Chief Hospital Pharmacist, Public Health Care Institution University Paediatric Clinic - Skopje	North Macedonia
Lorraine M Trainor (from March 2022 to summer 2022)	Senior Manager, Medical Affairs at Baxter	United Kingdom
Rebecca White (September 2022 to January 2023)	Senior Manager, Worldwide Medical | Clinical Nutrition | Global Medical Affairs at Baxter	United Kingdom
Pritha Singh (joined in January 2023)	Senior Medical Manager UKI – Baxter Medical Affairs	United Kingdom

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The following observer member participated:

Name	Role/Country	Country
Chris Tilley	Associate Director, Marketing - Compounding, OPAT & RTU drugs Europe at Baxter	United Kingdom

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Appendix II – Incident Reporting Templates

Individual errors (mistakes) – supply chain

Risk:	Individual Errors – Mistakes	
Responsibility:	Risk Owner: CEO, QP, authorized persons,…	Classification: clinical risk > active risk > individual errors > mistakes
Label of the measure(s):	Prevention of active errors – mistakes (Failure of attentional behaviour) - Supply chain	
Measure *Description*	• «root» causes 1. **RootCauses_IE_Mistake1: Inaccurate Storage Work / Handling of infusion containers** In 2010, at the University Medical Center, Mainz, Germany, 3 paediatric patients died after having received parenteral nutrition (PN) admixtures prepared in the hospital pharmacy department. Bacterial growth was diagnosed in the dummy samples analysed by for microbiological contamination. derived from the aqueous admixtures during the night and reported to the pharmacy staff on Saturday morning. Bacterial growth was detected in all aqueous admixtures and in media that had been inoculated with the parent amino acid solution. Thereby it was obvious that the culprit amino acid solutions got contaminated most probably months before the PN admixtures were prepared. The source and the reason for the contamination remain unknown. However, the infusion bottle harboured a crack that may have offered a portal of entry for the microbes. t can be concluded that a mistake in the storage and/or transportation process occurred, most likely detected but not properly treated by unexperienced staff. Classification: Mistake (failures of attentional behaviour). 2. **RootCauses_IE_Mistake22: Distribution error standard infusion** **Delivery** of wrong medicine from a hospital pharmacy: an operation unit ordered 1000 ml bags 0,9 % NaCl for irrigation that is used for the washing of blood in a cell saver machine. A pharmacy assistant mistakenly got ready 1000 ml bags water for irrigation (look alike medicine), the second Pharmacy assistant responsible for a control of delivering medicines allowed the delivery of a medicine to the operation unit without signalling a mistake. The nurse did not check the accuracy of obtained irrigation solution, 1000 ml bag water for irrigation was administered into the cell saver machine that caused the haemolysis of blood.	

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3. **RootCauses_IE_Mistake23: Distribution error even after having performed 4-eye-principle**
   Delivery of wrong medicine from a hospital pharmacy: a department ordered NEODOLPASSE solution for infusion (diclophenac + orphenadrin), the original package was open and 2 bottles were delivered. NEPHROTEC solution for infusion was delivered instead of NEODOLPASSE (look alike medicine). Neither 2 Pharmacy assistants nor Pharmacist realized a mistake. A wrong medicine was not administered to a patient, a Pharmacist noticed a discrepancy in stocks another day.
4. **RootCauses_IE_Mistake26: Inaccurate Storage of look-alikes**
   Near miss accidents with similar looking preparations. For example Ibuprofen and Midazolam children's preparations (suspension, solution) almost mixed up in children's ambulance. Ibuprofen was stored next to Midazolam without outer packaging. Accident prevented by four-eye check. Preparations are licensed to be stored only in their outer packaging. This must be ensured at all times. Similar looking preparations are not to be stored next to one another. Cross-check before administration should be performed. Inappropriate storage. Sloppiness.
5. **RootCauses_IE_Mistake38: SALAD (sound-alikes – look-alikes)**
   Reporting of medication with identical packaging and labelling, facilitating the occurrence of error/harm: ex. Morphine/pethidine. The constant change of supplier due to drug shortage makes it difficult to update safety measures.
6. **RootCauses_IE_Mistake40: Importation risk leading to misunderstandings of medicines information in a foreign language**
   Drug shortage lead to medication import with labelling/information in foreign languages (information gaps). Urgent provision as soon as medicine is available. No time for relabelling nor translation of leaflets. Lack of time/pharmacists for proper labelling/information in Portuguese.

- Risk and measures

1. **Measures_IE_Mistake1: Inaccurate Storage Work / Handling of Infusion Containers**
   a. Continuing inspections of industrial manufacturing sector due to higher risks as compared to unlicensed medicines
   b. Staff training: sensibilisation of team members of hidden risks such as dropped parcels
   c. CAPA measures for improvement of transportation practices and processes
   d. Automation
   e. Safer secondary packaging resilient against damage from dropping down

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f. The transport and delivery of the therapies set up or the distribution of drugs / medical devices / infusion solutions must be carried out by adequately trained personnel, using safety containers (if required) and following procedures to guarantee the traceability of the transport temperature, preventing alterations of the contents and environmental contaminations as well as for the personnel
g. the most resistant packaging and the most technologically advanced formulations should be preferred for the safety storage
h. Management of **experimental drugs**: they must be stored in dedicated cabinets and separated from other the drugs, according to Good Clinical Practice rules and clinical research specifications

2. **Measures_IE_Mistake22 and _Mistake23: Distribution errors**
   a. Standard Operating Procedure (SOP) to be written and trained even to unqualified team members
   b. Double control to be strictly considered
   c. Individual updating knowledge of medicinal products
   d. Combined with systematic errors: Staffing and internal organisation of pharmacy
   e. Automation to be implemented
   f. Barcode scanning recommended
   g. Omitting competing distractions
   h. pay special attention to the preservation of the drugs (including those on the therapy trolley): set up separately or highlight the similarity of the drugs with similar names and / or packaging
   i. avoid verbal or telephone requests/orders for drugs. If this is absolutely necessary, clearly repeat or spell out letter by letter, the name of the drug, the dosage, route of administration;
   j. Specify the pharmaceutical form and route of administration in the prescriptions: in case of doubt, consult the prescriber or pharmacist
   k. avoid the use of abbreviations, especially if the prescriptions and requests/orders for drugs are handwritten
   l. provide for an independent double check of preparations, especially for drugs with a high level of attention;
   m. during discharge, provide information to patients (also in writing and in capital letters), about home therapy: interactions (including with food), intake, storage, contraindications, side effects, safety precautions use.
   n. Re-organize in-hospital logistics oriented to the safe management of the drugs, medical devices, concentrated solutions, drugs with a high level of attention;

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	o. drug storage should be organized in ATC -ANATOMICAL THERAPEUTIC-CHEMICAL order to reduce the possibility of error with LASA drugs p. implement the use, where possible, of automated distribution systems and the distribution in "unit dose"; q. Use the barcode or RFID tracking systems r. introduce computerized technologies for the correct management of the drug; 3. **Measures_IE_Mistake26: Inaccurate Storage of look-alikes** a. Training on the ward: No replenishing or repackaging allowed outside official manufacturing site b. Task shifting from unqualified staff and from nurses to pharmacy technicians 4. **Measures_IE_Mistake38: SALAD (sound-alikes – look-alikes)** a. Need for pharmaceutical staff exclusively dedicated to drug safety/quality process b. Supplier qualification should include assessment of fidelity and reliability of the supplier 5. **Measures_IE_Mistake40: Importation risk leading to misunderstandings of medicines information in a foreign language** a. Need for pharmaceutical staff exclusively dedicated to drug safety/quality process b. Supplier should provide in each case information in English, at least for hospital used medicinal products (responsibility of drug use carried by physicians and pharmacists). If used in retail pharmacy, the information should be given in the local language (responsibility after dispensing carried by patient himself / herself) c. Harmonisation throughout Europe needed d. the availability of information on drug reconstitution, compatibility with diluents and the drugs storage after reconstitution; e. the absence of risk situations (the same colour of the packs for different dosages of the same pharmaceutical form or the similar name); f. the presence of safety devices for the correct preparation and / or administration of the drugs. g. Minimize imported products h. Make local language translation available or request it from the manufacturer i. Disseminate the information about the name of the product that has been replaced with the foreign one and its indication of use	
Time schedule	**Schedule and Milestones**	**Requires resources / involved persons**

Individual errors (mistakes) – order entry, prescription and dose calculation

Risk:	Individual Errors – Mistakes at Order Entry and Prescription Level	
Responsibility:	Risk Owner: CEO, QP, authorized persons,…	Classification: clinical risk > active risk > individual errors > mistakes
Label of the measure(s):	Prevention of active errors – mistakes (Failure of attentional behaviour) - Dose Calculation, Order Entry and Prescription Level	
Measure *Description*	• «root» causes 7. **RootCauses_IE_Mistake4: No interaction check, no INR check** Patient on warfarin was prescribed clarithromycin in the community. Patient was also on warfarin therapy. Admitted to hospital with a high INR. Subsequent multiorgan failure and patient passed away. Pharmacist was censured by the Pharmacy regulator in Ireland for failure to advise the patient to get an INR check within 3days. 8. **RootCauses_IE_Mistake5: No Interaction check sildenafil combined with clarithromycin** Patient on sildenafil po 20mg tds for pulmonary hypertension was prescribed clarithromcyin. Sildenafil dose was not reduced and patient continued taking 20mg sildenafil tds. Patient was hospitalised due to increased sildenafil levels. Clarithromycin is a potent CYP3AR enzyme inhibitor that is involved in many significant drug interactions. Lack of awareness of this interaction and of the need to reduce sildenafil dose (to 20mg once daily) during concomitant therapy with potent CYP3A4 inhibitors. 9. **RootCauses_IE_Mistake6: No interaction check ciprofloxacin combined with tizanidine** Patient due for discharge was prescribed ciprofloxacin po as per microbiologist (recommended po switch from IV piperacillin-tazobactam. Patient also taking tizanidine. Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of tizanidine. Co-administration of ciprofloxacin and tizanidine is contraindicated. The patient experienced excessive sedation and hypotension after 2 doses due to increased tizanidine levels. Delay was discharged and patient was switched back to IV piperacillin-tazobactam.	

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10. **RootCauses_IE_Mistake7: No interaction check meropenem in combination with valproate**
    Patient prescribed meropenem as per microbiogist advice. Patient also on sodium valproate. Patient subsequently developed seizures. Most likely due to reduced valproate levels as expected from concomitant meropenem therapy.
11. **RootCauses_IE_Mistake18: Dose Calculation Error Entresto**
    Experienced Pharmacist received prescription for preparation of 20 mg sacubitril/valsartan (ENTRESTO) divided powders for paediatric patient (off-label use in EU). According to US SmPC starting paediatric dose for less than 40kg is 1,6mg/kg of the combined amount of both sacubitril and valsartan. Pharmacist without knowledge of English language did not check the right dose with clinician neither asked for double control the other colleagues. Pharmacist prepared divided powders calculating only the amount of sacubitril. Prepared dose was too high. Patient manifested hypotension. Lack of cooperation between clinicians and pharmacists, lack of pharmacist education (language barrier - publications in English language). Lack of standardised procedures for each individual preparation.
12. **RootCauses_IE_Mistake19: No interaction check ritonavir – simvastatin**
    Lack of knowledge about drug interaction. Prescribing simvastatin to a patient taking ritonavir during hospitalisation: initialisation of simvastatin treatment in patient with an allergy to atorvastatin and long-life treatment with antiretrovirals consisting of ritonavir. Drug combination ritonavir - simvastatin is contraindicated due to the risk of rhabdomyolysis (CYP3A4 inhibition by ritonavir increases the level of simvastatin). The pharmacist warned a clinician about this drug interaction, recommended fluvastatin or rosuvastatin instead of simvastatin. Patient took only 1 - 2 doses of simvastatin without any harm. There is no requirement of confirmation of prescriptions by Pharmacist in Slovakia. Medication review was done coincidentally.
13. **RootCauses_IE_Mistake20: No interaction check ivabradin - ritonavir – betablockers**
    Prescribing ivabradin to a patient taking ritonavir and betablockers. Ivabradin - ritonavir is contraindicated combination (inhibition of CYP3A4 by ritonavir, increased level of ivabradin). Patient hospitalised with bradycardia, ivabradin stopped by a clinician.
14. **RootCauses_IE_Mistake24: Metamizol prescription although allergy history in patient's record**
    Metamizol stated in inpatient's allergy record. Novalgin (active ingredient: Metamizol) prescribed "as needed" and administered. Massive drug related exanthema occurred. Mistake not detected until days after administration when pharmacist went on the ward round. Lack of knowledge of junior doctors, lack of staff, lack of automated allergy-alert in electronic system; no four-eye check before prescription and administration.

15. **RootCauses_IE_Mistake25: Prescription of too much anticoagulant**
    Pradaxa for AF wrongly underdosed at 110mg 1-0-1 with a GFR of 90 and 73 yo. No reason for dose adjustment. Patient developed DVT under running Pradaxa-therapy. Lack of clinical pharmacy staff to check prescriptions and to provide education. Not sufficient HR for prescription review.
16. **RootCauses_IE_Mistake29: inversion of weight and height in the computerized chemotherapy prescription**
    In calculating the dosage in function of the body surface, the doctor does not notice the error because the body surface does not vary; when the doctor prescribes another drug in which the patient's dosage is a function of weight, this is calculated by finding the height in the computer field: therefore trastuzumab 8 mg / kg x 167 (height) and not x 60 kg (weight). Wrong total dosage of 1336 mg instead of correct 480 mg.
17. **RootCauses_IE_Mistake30: Neglection of patient's weight**
    Prescribing a very different dose between two closely spaced therapies for the same patient: between the two prescriptions. There was a weight difference of about 15 kg over a week. The patient had not been weighed for a long time and the prescription had not been recalculated according to the patient's updated weight (risk of over / underdose if weight is not considered). Neglected both by physician and by nurse.
18. **RootCauses_IE_Mistake34: Loading dose not prescribed**
    Prescription of trastuzumab 6 mg / kg iv - maintenance dose instead of trastuzumab 8 mg / kg - iv loading dose. Some doctor often forgets to prescribe the first loading dose or forgets that six weeks have passed since the last administration and must re-prescribe the loading dose of the drug as required by the drug data sheet. Therefore not a slip, but negligence.
19. **RootCauses_IE_Mistake35: Dose prescription error cytarabine**
    Hematologist asks pharmacist to insert in the software in order to carry out the computerized prescription, a protocol containing cytarabine with a dosage 10 times lower than expected. Haematologist gives the pharmacist a pre-printed form showing the dosage of cytarabine; in the acronym it is indicated 100 mg / m2 and in the description of the protocol instead it is reported 1000 mg / m2; after contacting the haematologist, the pharmacist requests bibliographic support to verify the correct dose of the drug (which is 1000 mg / m2). Urgent request without rechecking chemotherapy protocol with literature protocols / references.
20. **RootCauses_IE_Mistake36: Unclear insulin prescriptio**n
    Patient with unusual insulin regimen, prescribed in an unclear way (without units) causes administration error: blood glucose value assumed as the value of insulin units to be administered. Unclear prescription; Lack of knowledge/training; Lack of communication.

21. **RootCauses_IE_Mistake39: Unclear methotrexate prescription**
    Oral methotrexate dose error: weekly administration of 5 tablets instead of 5 mg (2 tablets); unclear prescription (information in observations; inappropriate use of electronic prescription); combined with unfavourable men-machine interface. Insufficient training on electronic/software prescribing and its possibilities.
22. **RootCauses_IE_Mistake45: lack of knowledge of inexperienced junior prescribers**
    Errors in fluid prescribing are common and can lead to harm. The extent of harm from inappropriate fluid prescribing is difficult to quantify because it is under-reported. A 1999 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report highlighted that a fifth of perioperative patients receiving IV fluids suffered complications. In recognition of the issues surrounding IV fluid prescribing and the lack of standardised guidance, NICE published guidelines for the intravenous fluid therapy in adults in hospital in 2013 and updated them in 2017 - although guidelines are poorly adhered to.
23. **RootCauses_IE_Mistake46: Sodium overload**
    Unphysiological amounts of sodium, surpassing normal dietary intake - are commonly administered to hospitalized patients through ill-considered maintenance fluid therapy and fluid creep. The notoriously difficult renal handling of this sodium overload leads to potentially harmful fluid retention. Lack of awareness. Requires increased attention to this avoidable source of harm - literature suggests the use of low-sodium maintenance fluids and recommend avoiding NaCl 0.9% as the diluent for medication.
24. **RootCauses_IE_Mistake50: Prescription of wrong infusion speed**
    93 mg of noradrenaline was prescribed at a rate of 1 microgram/kg/minute instead of 9.3 mg at a rate of 0.1 microgram/kg/minute. Source - UK National Patient Safety Agency report.
25. **RootCauses_IE_Mistake51: Unclear prescription leading to bolus injection instead of diluted solution injection**
    A 500 mg dose of the antibiotic clarithromycin was administered to a patient as an IV bolus injection instead of diluted in 250 ml of sodium chloride 0.9 per cent infusion. The patient complained of severe irritation in arm above the site of injection and became sweaty. Inappropriate undiluted administration (bolus v infusion) - too high a concentration causing irritation. human error - knowledge or procedure. Source - UK National Patient Safety Agency report.

- Risk and measures

6. Measures_IE_Mistake4, _Mistake5, _Mistake6, _Mistake7, _Mistake19_ Mistake20: No interaction checks...

a. Medicines reconciliation at patient admission compulsory

b. Regular medication reviewing to be implemented
c. Blocking OE/prescribing until medicines reconciliation is performed
d. Clinical Information System to require interaction check at the moment of prescription entry (if not done as part of an automation). Ciprofloxacin increases Tizanidine levels.
e. Raising awareness and sensibilisation for interactions of all qualified pharmacotherapy team members
f. Staff interaction identification and tackling training
g. Electronic prescribing alerting prescribers to interactions to be implemented
h. Attribution of responsibilities as related to regular interaction checking
i. If tight HR then concentration of patients at high risk
j. List medicines in the formulary which are metabolised extrahepatically without the CYP450 isoenzymes (if feasible)

7. Measures_IE_Mistake18, _IE_Mistake25: Dose Calculation Error

a. Standard Operating Procedure (SOP) to be written and trained
b. Double control to be strictly considered
c. Individual updating knowledge of CV medicinal products
d. Combined with systematic errors: Staffing and internal organisation of pharmacy
e. In paediatric / geriatric dosages, high-risk drugs, drugs with a low therapeutic index, experimental drugs, concentrated electrolytes, the calculations must be carried out independently by two operators before preparation and administration
f. It is necessary to leave a written document on how the calculations and the dilutions / reconstitutions of the drugs were made
g. If it is not possible to centralize preparation in the Pharmacy for high-risk drugs, ask for a pharmacist as a consultant in the ward or outsource the preparation until all safety and personnel measures, local and operating procedures are available
h. adopt pre-printed forms and /or introduce, if possible, the electronic prescription, which helps to eliminate handwriting errors.
i. The computerized prescription system must provide warning signals when the dose is out of the therapeutic range, especially for some classes of drugs and / or patients (for example, paediatrics), in case of allergic reactions , drug interactions, duplication of therapy and other aspects on the use of the drug and on any ongoing or discontinued therapies;

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j. Insert computer blocks / ALERTS where risks of parameter inversion or insertion could impact on patient safety
k. Medicines reconciliation and medication review to be implemented with adaption of needed HR.

8. **Measures_IE_Mistake24: Metamizol prescription although allergy history in patient's record**
   a. Electronic prescribing system with integrated plausibility check needed. Should be activated in a way between switched-off position and over-alerting.
   b. Review of entries of junior doctors by superior physician / head of clinic
   c. Clinical decision support system to be evaluated and implemented to help prevent individual errors (mistakes and slips)
   d. carry out reconciliation during inpatient period (even during different or transition care settings, including patient discharge)
   e. evaluate the overall variations, also in patient's changes conditions: evaluate changes in posology, allergies, enzymatic deficits, changes in clinical and anthropometric parameters (weight, clearance), fluid balance, intolerances, interactions with other drugs or medicinal herbs/ over-the-counter products, alcohol and the patient's eating habits, clinical conditions that advise against the use of drugs or require dosage changes (liver / kidney function) and all the conditions or factors that could impact on the patient safety
   f. Provide hospital courses or other training sessions/meeting on little-known or underestimated topics such as fluid balance, infusion solutions, pharmacokinetics, pharmacodynamics ...
   g. The reconciliation and evaluation must be tracked and carried out through software for the identification of all interactions, including plant/natural drugs
   h. Each ward should define a list of interactions / associations and identify the relative risk (to be avoided, not recommended, fatal ...)
9. **Measures_IE_Mistake25: Prescription of too much anticoagulant**
   a. Medicines reconciliation and medication review to be implemented with adaption of needed HR.
   b.
10. **Measures_IE_Mistake29: inversion of weight and height in the computerized chemotherapy prescription**
   a. Plausibility checking to be implemented in CDSS and OE systems, e.g. by predefinition of ranges of entries
   b. Working conditions to be checked: Prevention of distraction, concentration loss, interruptions by phone calls

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c. Technical issue: men-machine interface to be reviewed
d. 4-eye principle also in e-prescribing if no plausibility check is implemented
e. Medication reviews by clinical pharmacists
f. Confirmation of patient's physical parameters at each consultation
g. Diagnoses: Confirmation of clinical chemical values

11. Measures_IE_Mistake30 and _Mistake34: Neglection of patient's weight, loading dose not prescribed

a. Obligation to re-evaluate patient's physical and clinical-chemical values (physicians and nurses!)
b. Adapt IT to alert if weight is not explicitly confirmed at the moment of new prescriptions or dose entries
c. Medication review by clinical pharmacist at least for medicines with small therapeutic range
d. Latest prescription to be checked before updating treatment plan
e. Double checks needed also for physicians' activities

12. Measures_IE_Mistake35 and _Mistake36, _Mistake39, _Mistake45: Dose prescription errors ...

a. Double checks needed also for physicians' activities
b. Fluid prescribing should be made clear in terms of prescription of volumes or amounts or drop-counts
c. Respecting international chemotherapy protocols to be standard (drugs, sequence, frequency, dosage)
d. Implementation of a Cytotoxics Therapeutic Committee in order to approve all protocols and standards of care involving antiblastic medicines
e. Insulins need a highly precise communication
f. Insulin is suitable to involve the patient in the 4-eye-principle
g. Sensibilisation, awareness and training on prescribing errors especially for internes
h. The correct and appropriate use of drugs reduces the risk of error
i. All uses, especially off-label ones, must be supported by scientific literature and consequently the dosages must coincide with those prescribed
j. The request for drug therapy must always be carried out by the prescribing physician in writing, possibly electronically ;
k. Verbal prescriptions should not be accepted, except for the immediate discontinuation of therapy, which must still be transcribed as soon as possible. New prescriptions or changes must also be made in writing, possibly electronically
l. Do not proceed with the preparation and /or administration of a drug if, in case of doubt or unclearness, these have not been clarified: if necessary, request a new prescription or ask for a change

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	with countersigned by the Doctor or write down the time, date, person and content of the call, if the clarification or modification was made verbally or by telephone. 13. **Measures_IE_Mistake46, _Mistake50, _Mistake51: Sodium overload, Prescription of wrong infusion speed, or Unclear prescription leading to bolus injection instead of diluted solution injection** a. Solvents used in parenteral infusions need to be supervised carefully for UE b. Sodium overload by infusions should be prevented and handled by substituting dextrose 5% for NaCl 0.9% **c.** Double checks needed also for physicians' activities d. At least 1 of all nurses involved in a 24-hours-care of the patient should be attentive enough to detect an infusion speed error as compared to treatments of the same kind e. Preparation of injectables ready-for-administration should be double checked also on the ward f. CIVAS (central intravenous additive service by the pharmacy could prevent these kinds of errors	
Time schedule	**Schedule and Milestones**	**Requires resources / involved persons**

Individual errors (mistakes) – dose administration and 5R rules

Risk:	Individual Errors – Mistakes	
Responsibility:	Risk Owner: CEO, QP, authorized persons,…	Classification: clinical risk > active risk > individual errors > mistakes
Label of the measure(s):	Prevention of active errors – mistakes (Failure of attentional behaviour) - Violation_5R_Rules_Administering Medicines	
Measure *Description*	• «root» causes **26. RootCauses_IE_Mistake2: Compilation of Mistakes related to compliance to the 5R rules** a. medicines omitted	

b. medicines given to the wrong patient
c. wrong doses administered
d. mistake in liquid drug amounts (number of drops or number of mL or number of mg?)
e. unintended administration of extra doses
f. wrong route of administration
g. wrong time
h. erroneous picking of look-alikes (similar presentations of different dosages)
i. Treatment of non-responders

2. **RootCauses_IE_Mistake47: Compilation of medication errors from the Norwegian Incident Reporting System**
Overview of frequency, stage and types of medication errors in Norwegian hospitals - emphasis on the most severe and fatal medication errors. 3557 medication errors reported in 2016 and 2017 obtained from the Norwegian Incident Reporting System, bas ed on reports from 64 hospitals (used WHO classification for patient safety) Medication errors most commonly occurred during medication administration. Dosing errors were the most common error type. The substantial number of severe and fatal errors causing preventable patient harm and death emphasises an urgent need for error-prevention strategies.
3. **RootCauses_IE_Mistake3: Wrong Dose administration** 1st case
Inpatient was administered another patient's medication. Patient reviewed by team, was monitored closely, no adverse effects apparent. Not checking patient's wristband prior to medications being administered.
4. **RootCauses_IE_Mistake8: TPN running too long**
A patient's TPN bag ran continuously for 30 hours. It should have been stopped after 20 hours, patient given a four hour break and new TPN bag hung. Failure to do this posed a risk of infection to the patient. A new agency nurse was on duty that evening and was not aware of the protocol.
5. **RootCauses_IE_Mistake9: Wrong TPN looking and sounding alike**
The wrong bag of TPN was hung for the patient. Smofkabiven 16 Electrolyte Free was hung but the intended regimen was Smofkabiven 16 with electrolytes. The incident occurred at the weekend. Lack of familiarity with PN bags.
6. **RootCauses_IE_Mistake10: Wrong solvent infusion**
Patient received incorrect IVF solution (was on 0.45%NaCl + 5% Dex instead of 0.9%NaCl + 5% Dex). Look-alike problem. Errors of this kind increased under high workloads

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7. **RootCauses_IE_Mistake11: Crushing solid medicine**s
   Palliative patient, medicines being crushed inappropriately- Uniphyllin is not suitable for crushing. Patients medications be reviewed in line with STOPP Frail criteria in light of patients disease progression. So theophylline, memantine and statin were all discontinued. Lack of awareness that some medications are not suitable for crushing and that. Alternative formulations are available e.g. oral solution.
8. **RootCauses_IE_Mistake12: Overdosage 10-fold of Pregabalin**
   Patient charted for and received 3 doses of Pregabalin 250mg instead of 25mg as per preadmission. This was brought to the attention of the nurse looking after the patient who reported that she was drowsy. The team were alerted to same. Pregabalin 250mg was discontinued, and 25mg was charted but held and the patient monitored. Classical mistake, eventually staff shortages, time pressure, lapse in concentration.
9. **RootCauses_IE_Mistake13: Opiate overdosing**
   Patient admitted to hospital with drowsiness and confusion secondary to opiates was still charted for and receiving Oxycontin 20mg BD. Patient only recently started on opiates post a procedure in another hospital. His daughter reported that the drowsiness and confusion coincided with the doubling of the dose of Oxycontin on discharge. This was brought to the teams attention and the dose was reduced. Lack of consideration of known side-effect of opioid. Lack of Medicines reconciliation on admission.
10. **RootCauses_IE_Mistake14: Incorrect frequency of enoxaparin**
    Warfarin clinic patient with metallic MVR was in ICU for several days with collapsed lung. Warfarin was held and he was bridged with therapeutic enoxaparin 1mg/kg BD until transfer to a different hospital under Cardiothoracic team. He was off warfarin for a total of 2 weeks. Post procedure this team restarted his warfarin at usual dose with sub-therapeutic bridging with enoxaparin 1mg/kg OD. His INR was only 1.3 when he returned to the warfarin clinic 2 days later. His kidney function was normal so the enoxaparin dose was queried with the discharging physician. It was agreed that BD dosing would be more appropriate and a member of his team agreed to prescribe same until his INR was back in range. The patient was counselled and the prescription faxed to their community pharmacy. Incorrect frequency of enoxaparin. Unlikely to be lack of awareness of the high risk of clotting in this particular patient or lack of awareness of the correct dosing of enoxaparin as cardiothoracic team prescribed. Unknown. Query for ease of administration once daily enoxaparin was chosen?
11. **RootCauses_IE_Mistake15: No anticipation of CNS undesirable effects of ciprofloxacin**
    Patient with history of epilepsy and recent seizure charted for Ciprofloxacin as per microbiologist, but team had not relayed epilepsy/seizure history. The team were asked to contact microbiology again and the patient

was switched to co-trimoxazole. Initial communication between team and microbiologist inadequate. Microbiologist not on site, lack of awareness that patient's history of epilepsy and recent seizure would be relevant to microbiologist. Disjointed care.

12. **RootCauses_IE_Mistake16: Medicines omitted**
    Several preadmission medications omitted in error : Bumetanide, Mebeverine, Perindopril, Venlafaxine, Alprazolam, Alfacalcidol. Aspirin prescribed as per previous admission but this had been since discontinued. And Rosuvastatin (renally cleared and so not licenced if CrCl<30ml/min & note cholesterol and LDL low at 2.2 and 0.5mmol/l), and allopurinol at higher than recommended dose for level of renal function (Crcl 16ml/min). Domperidone charted regularly in spite of only being licenced for prn use and contraindications (renal impairment and heart failure). All of this was brought to the teams attention. Domperidone and Rosuvstatin were discontinued, Allopurinol was dose reduced and the omitted preadmission medications were charted appropriately. Poor medication history on admission. Time pressures, staff shortages.
13. **RootCauses_IE_Mistake17: Pharmakokinetic and phyrmakodynamic considerations neglected**
    Patient has known HFrEF. On admission was prescribed both ACEi and ARNI, however ACEi had been discontinued some months ago by Cardiology when commenced on ARNI as per recommendations. Serious risk of angioedema and renal impairment when both drugs prescribed together. Not flagged as inpatient. Had 4 night stay and was discharged yesterday. On review of medical record today, day 1 post discharge, error noted by Heart Failure CNS. Patient only taking ARNI (Entresto) preadmission. Poor medication history on admission. Lack of awareness of the risks of combining and ACEi with an ARNI. Lack of awareness of the risks of combining ACEi and ARNI. Failure to note error during inpatient stay or on discharge. No clinical pharmacy review done.
14. **RootCauses_IE_Mistake21: Wrong Dose administered** 2nd case
    Administration of a drug to a wrong patient: unexperienced nurse gave a dose of warfarin to a wrong patient. She entered a room, said the patient's name and she gave the dose to a patient who has responded to her (in our hospital, 2 - 3 patients are in the same room). She did not identify the patient by another way (in our hospital we do not have identification bracelets). A clinician realised the dose of warfarin was administered to a patient with planned surgery the next day and should have been administered to a patient with heart valve replacement.
15. **RootCauses_IE_Mistake27: Compilation of wrong dosing: Double dose administered or dose omitted**
    Preoperative antibiotics: Transfer of care from ward to surgery does not work properly. Antibiotics double-administered or forgotten. Implementation of a checklist and holding area for transfer personnel. Checklist

sometimes not functional and needed many educational measures. Holding area understaffed and not regularly available.

16. **RootCauses_IE_Mistake28: Bad practice on patient admission**
    Transfer of care documentation problem. Home medication not accurately transferred into inpatient notes. Not enough resources used to document medication; home medication changed without documented reason; undocumented discrepancies. Allergies documentation inaccurate and discrepancies between allergy documentation and prescriptions. Unqualified staff does medrec.
17. **RootCauses_IE_Mistake31: Wrong patient, wrong medicine, wrong route of application**
    Intrathecal (rather than subcutaneous) administration of bortezomib to wrong patient instead of methotrexate INTRATHECAL: PATIENT, DRUG AND ROUTE ERROR. Support nurse mistakenly gives the neurologist the unlabelled (!) syringe containing the drug bortezomib IV INTENDED FOR ANOTHER PATIENT instead of the prescribed and required one, methotrexate. The chemotherapy drugs are extracted from the envelope that contains / identifies them together with the accompanying sheet describing the therapy. Everything is placed on the therapy trolley almost indistinctly; for this reason the syringe is exchanged and IV bortezomib is administered intrathecally. Patient died after a few days in intensive care.
    - Mistake chain 1st step: Administration of the drug by a different doctor (neurologist) than the one who gave the prescription (oncologist)
    - Mistake chain 2nd step: Possible error induced by the support operator who does not prepare the therapies in relation to the patients, but places them all on the therapy trolley without distinction; organizational disorder
    - Mistake chain 3rd tep: the unpacking of the therapy does not occur at the time of administration with the patient in front
    - Mistake chain 4th step: intrathecal administration of a drug intended for the intravenous route
    - Mistake chain 5th step: failure to recognize the patient
18. **RootCauses_IE_Mistake32: Anti-infective infused to wrong patient**
    Nurse partially administers IV antibiotic therapy (clindamycin 900 mg in 100 ml of saline) to the wrong patient. Approximately 30 ml of diluted drug was infused. Suspended as soon as she realized the mistake. Fatigue, stress. Obviously no patient ID checked.
19. **RootCauses_IE_Mistake33: Wrong dose administration** 3rd case
    Prescription to prepare: "metoprolol 5mg in saline 100ml IV". A student prepares a 100 ml physiological

infusion with 5 metoprolol ampoules of the composition 1mg / ml in a 5 ml ampoule. Incorrect understanding of the doses. Application intercepted by the tutor with a second check.

20. **RootCauses_IE_Mistake37: Wrong infusion administered** 4th case
    29 weeks pregnant in the emergency obstetrics service. Acetaminophen metoclopramide was prescribed. A bag of ropivacaine was administered instead of acetaminophen by a trainee nurse. Medicine incorrectly stored; nurse assumes she didn`t read the bag label before administration. Lack of staff; Lack of knowledge/training: Lack of supervision of trainee nurse.
21. **RootCauses_IE_Mistake41: Wrong immunoglobulin administered**
    1500IU of varicella-specific immunoglobulin were prescribed (prophylaxis post-contact with a patient with varicella in pregnant women with dubious IgG) and 1500IU anti-D immunoglobulin were administered by the nurse. Anti-D immunoglobulin is usually administered in obstetrics; the fact that it was the same prescribed dose - 1500UI) led to a mistake by failing to verify the complete prescription (as well as having an anti-D immunoglobulin unit for another patient). Non-compliance of the SOP for blood products.
22. **RootCauses_IE_Mistake42: I.v. administration of p.o. syringe prepared in advanc**e
    Advance preparation of oral medication in syringe without proper labelling; intravenous administration of the oral solution. Inadequate advance preparation. Inadequate labelling/storage of non-administered medication. Paediatric nurse's report on drug safety training.
23. **RootCauses_IE_Mistake43: Risk of severe harm and death from errors in total parenteral nutrition infusions in babies**
    NHS England Patient safety alert : https://www.england.nhs.uk/wp-content/uploads/2019/12/Patient_Safety_Alert_-_TPN_in_babies_FINAL.pdf . The administration set primed with lipid was threaded through the infusion pump intended for the aqueous component and vice versa. Lipids were therefore infused at the rate intended for the aqueous solution and the aqueous solution at the rate for the lipids. A key factor underlying this error appeared to be near identical protective outer covers on the two infusion bags as the contents for both need to be protected from ultraviolet light. The incorrect infusion rate was entered into the administration pump. Miscalculation of volumes when fluid or pump related changes were made.
24. **RootCauses_IE_Mistake44: review of error reports in the use of TP**N
    Published review of error reports from the Institute for Safe Medication Practices' Medication Errors Reporting. Program that are associated with the PN use process over 10 year period. Compiled errors in TPN

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use in prescribing, orders, compounding, dispensing, administration. Impact and risk of TPN errors & harm is underrecognized and likely underreported. Nutr Clin Pract. 2017;32:826-830).

25. **RootCauses_IE_Mistake48: Wrong route of administration of omeprazole**
    Patient was prescribed omeprazole to be given via a nasogastric line. The dose was prepared in a syringe which was inadvertently connected to the central (intravenous) line. The patient became bradycardic and hypotensive but was resuscitated and recovered without immediate ill effect. Source - UK National Patient Safety Agency report.
26. **RootCauses_IE_Mistake49: Wrong route of administration of concentrated electrolytes**
    A concentrated infusion of 40 mmol potassium chloride in 100 ml sodium chloride 0.9 per cent was inadvertently given through a peripheral line rather than a central line. Source - UK National Patient Safety Agency report.

- Risk and measures

14. Generic Measure

a. Carry out a contextualized risk / self assessment during the design phase of the workspaces or in case of environments or working conditions changes. This evaluation must take into account the personnel (NUMERICAL ADEQUACY), the instruments / technologies, the environments and the procedures. Where the risk is not acceptable, provide for appropriate containment measures.
b. Provide, according to the risk assessment, the minimum safety requirements that must be applied and identify the person in charge for the periodic check of the application of these requirements
c. CUSTOMIZED TRAINING, CONTINUOUS UPDATING, PROCEDURES WITH DOUBLE INDEPENDENT CONTROL IN THE HIGHEST RISK PHASES; periodic re-verification of knowledge and re-training planning for each new employee, including trainees or in case of changes in the setting / workflow.
d. REDUCE THE SOURCES OF DISTRACTION OR DROP IN ATTENTION: telephone interruptions, faxes, doorbells, relatives of patients ...
e. Implement multidisciplinary teams and periodic meetings also to discuss the non-conformities detected and implementation of the consequent improvement actions (CAPA)
f. PROCESS OWNER: Identify a Quality, Risk and Safety Manager for the INPUT AND OUTPUT control of products - distribution and reception / storage (with measurement and random checks, including visual inspection before the "release / use" of the product)
g. Monitor and evaluate the correct use of drugs in relation to the frequency of adverse events that have occurred and disseminate relative knowledge

h. Include a pharmacist among the hospital risk managers
i. Provide periodic ward visits - safety walk around with a team of health professionals; these moments could be included in a hospital training plan.

15. **Measures_IE_Mistake2 and Mistake47: Compilation of Mistakes related to compliance to the 5R rules**
    a. Inter-/multi-professionality and –disciplinarity (clinical pharmacologists, nursing staff, further qualified staff)
    b. Electronic order entry system combined with plausibility check by operators
    c. Clinical decision support system combined with plausibility check by operators
    d. Improvement of men – machine interface
    e. Personalised Medicine (Genetic profiling to identify responders and non-responders, individualised therapy)
    f. Expand diagnostic use instead of economisation
    g. Revise old therapy paradigms (e.g. treatment of all infections by monotherapy)
    h. Monitoring (TDM)
    i. Medicines reconciliation
    j. Medication review / Identify inappropriate medication
    k. Training of staff according to individual need
    l. Vigilances (pharmaco-, haemato-, materio-, etc)
    m. Eliminate disturbances in working environment (e.g. no pager/phone if a person prepare medication)
    n. ensure the correct **identification of the patient** even in the presence of coded procedures (bar code and bracelet);
    o. **involve the patient**, where possible, in the act of his identification before administration and inform the patient, if possible, about his prescribed therapy, including side effects, and encourage him to ask questions about the therapy administered: the correct information to the patient increases his compliance.
    p. ask before each administration for the presence of any allergies (and reconcile with the Medical Record), and changes in anthropometric parameters such as weight, even during different care settings, including patient discharge
    q. check the correspondence between what is indicated in the prescription and what is actually on the therapy chart

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r. **read carefully before administration**: the dosage, the concentration, the route of administration, the expiration date, the drug label, the infusion pump speed and check the connection lines;
s. make available to the nurse **drug information and any changes in patient therapy**; information on the time and route of administration (central or peripheral, IT, IM ..) based on the concentration of the drug or its osmolarity, special warnings on storage, on any other devices necessary for administration;
t. provide the automated production of the doses and the **check administration through computerized technology,** that allows to verify and also trace the sequence and timing of administration of the drugs
u. make **dosage tables** available to facilitate dose adjustments;
v. do not leave patient's **medicines unattended**;
w. provide for the **double check** of preparations by nurses and / or doctors before administration, especially for drugs with a high level of attention;
x. make sure that the **administration has taken place** and put the signature or initials to trace it;
y. pay special attention in case of administration of drugs through a **nasogastric tube**.
z. ask to the pharmacist before proceeding with any **manipulations on oral pharmaceutical forms** (crushing, opening the capsules ...)
aa. Periodic reconciliation of therapy must take **genetics aspects** into consideration
bb. periodic reconciliation of the therapy must take into account **genomic profiling** to customize the therapy with available and / or innovative drugs, even in the experimental phase (especially in the oncology field)
cc. Reconciliation must also include a **re-assessment of therapies** that are no longer necessary or that could lead to drug interactions or whose co-administration could be contraindicated
dd. All set up therapies must have a **label** on the **primary and secondary packaging** that undoubtedly identifies the content and destination
ee. when preparing intravenous mixtures, pay special attention to aseptic techniques, to compliance with dose procedures that guarantee dosing accuracy, to the solutions used to reconstitute the products and to the CHEMICAL-PHYSICAL AND MICROBIOLOGICAL stability of the prepared solutions. Whenever is possible, set up immediately before administration.

16. **Measures_IE_Mistake3 and _Mistake21: Wrong Dose administration**
    a. Alarm by Clinical Information System if bedside barcode scanning was not executed
    b. Definition of electronically checked workflow for administration of medicines

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c. Patient identification process to be reviewed
d. Low income health care systems: double identification of a patient need – in case of conscious patient identified by the full name and visual check of the label on a bed

17. **Measures_IE_Mistake8, _Mistake9, _Mistake43, _Mistake44: TPN ...**
    a. Adequate coaching of new staff members needed
    b. Systematic error human resources combined with mistake: Training on the job to be improved
    c. TPN are among the most risk-prone galenic forms used as medicines. Prevention of UE in patients must be anticipated in terms of physico-chemical and microbiological instabilities
    d. Hospitals should implement a multidisciplinary nutrition support team to supervise at least all patients receiving parenteral nutrition. A nutrition support team is a specialised drug and therapeutics committee to support the general drug and therapeutic committee
    e. Clear protocol describing type, differences, mode of administration should be available
18. **Measures_IE_Mistake10 and _Mistake11: Wrong solvent, inappropriate crushing...**
    a. IT aided identification of right medicine mainly in case of look-alikes
    b. 4 eye-principle to strictly consider
    c. Review of human resources
    d. Even in time constraints, staff is to ask pharmacist. Additional time loss is small.
19. **Measures_IE_Mistake12, _Mistake13, _Mistake 27 and _Mistake28: Bad practice on patient admission, overdosages or omitted doses ...**
    a. 5R rules to be strictly followed
    b. Qualified staff to be employed
    c. Task shift from work overloaded nurses to pharmacy technicians
    d. Seamless care and interface communication to be improved
    e. Medicines reconciliation at admission, at discharge and at transition between wards/intensive care unit to be implemented. These entries will have to be read before additional prescriptions are added.
    f. Task shifting from nurses to pharmacy technicians
20. **Measures_IE_Mistake14 and _Mistake17: Pharmacokinetics and Pharmacodynamics**
    a. Training and additional education of various team members in pharmacokinetics
    b. Medication reviews to be implemented
21. **Measures_IE_Mistake15: No anticipation of CNS undesirable effects of ciprofloxacin**
    a. Seamless care to be practised to avoid disjointed care

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<table>
<tr><td></td><td colspan="2">
b. Communication to be improved
c. Multidisciplinary to be implemented
d. Everyday medication (even the day of discharge) review for highly risk medicine
22. Measures_IE_Mistake16: Medicines omitted
a. Medicines Reconciliation and Medication Review to be implemented
b. Multidisciplinary to be practised
23. Measures_IE_Mistake31, Mistake32, _Mistake33, _Mistake41, _Mistake48, _Mistake49: Wrong patient, wrong medicine, wrong route of application
a. High-risk of unlabelled syringes must be overridden: All passing of medicines to further staff members has to assume that medicine is labelled and declared.
b. Procedures to be defined in SOPs
c. Labelling philosophy: labels to be put on primary container and on secondary container (cave unpacking unlabelled syringes from secondary containers)
d. 5R rules and 4-eye-principle to be strictly considered. Alternative would only be full automation.
e. Preparation of multiple medications on one try to be prohibited
f. Implementation of bar code scanning for patient ID and medicine ID from bracelet
g. Patient to be involved in medicines control and administration (communication of name, birth date, medicine dose etc)
h. Highlight at least route of administration if intrathecal, central venous etc
i. Personnel in training: need of periodic verification of knowledge and skills of the trainee. Sufficient supervision mandatory.
24. Measures_IE_Mistake42: I.v. administration of p.o. syringe prepared in advance
a. Implementation of the European recommendation Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use
b. Use of clearly distinguishable syringes for parenteral use and for oral liquids
c. Label should highlight route of application
</td></tr>
<tr><td>Time schedule</td><td>Schedule and Milestones</td><td>Requires resources / involved persons</td></tr>
</table>

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Individual errors (slips)

Risk:	Individual Errors – Mistakes	
Responsibility:	Risk Owner: CEO, QP, authorized persons,…	Classification: clinical risk > active risk > individual errors > slips
Label of the measure(s):	Prevention of active errors – slips (failures of schematic behaviour)	
Measure *Description*	• «root» causes 27. **RootCauses_IE_Slip1: Handling of patient-owned medicinal products brought in** Patient brought in medication from home. Patient was on PO augmentin at home and was started on IV augmentin in hospital. Medication with patient in the room and he was asked if he had taken any tablets of his stock. He had taken steroids + Po Augmentin. Patient advised not take his own tablets in hospital. Patient's own medications not stored away in locked press in treatment room. Patient not familiar with hospital protocol. Combined slip (primary as no reconciliation performed) and systematic error in the organisation. (secondary) 28. **RootCauses_IE_Slip2: Handling of patient-owned medicinal products (antihypertensives and more)** On admission some of the patients antihypertensives were held, however the patient continued to take her own supply during her inpatient stay. It came to light on Day 3 of her admission and the patient was informed that in this hospital we do not use patient's own medications and the nurses will administer her medications throughout the stay. The patient was fine and her BP was fine taking her usual antihypertensives so her regular medications were recharted. The patient was also started on enoxaparin s/c 1mg/kg bd during her inpatient stay for new onset AFib. As per the patient notes anticoagulation was to be continued however her discharge prescription did not include anticoagulation. It was after regular working hours so the on call doctor kindly reviewed and added apixaban 5mg bd to the discharge prescription. Potassium supplement was also prescribed for a month on discharge and this was reduced to a few days on discharge. Patient's own medications not stored away in locked press in treatment room. Patient not familiar with hospital protocol. Inadequate discharge prescription written. Patient not informed of hospital protocol. Poor discharge planning, rushed, poor communication.	

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29. **RootCauses_IE_Slip3: Patient developing addiction**
    Patient formed an addiction to Nurofen Plus which contains Ibuprofen and Codeine. Induced AKI and multiorgan failure necessitating ICU admission. Over the counter availability of codeine-containing compound analgesics in Ireland. Purchased in a wide number of community pharmacies. No way to track or flag multiple purchases as there is no unique national patient identifier/ identity card to facilitate restricting supply across multiple pharmacies.
30. **RootCauses_IE_Slip4: Hypernatremia following dilution of anti-infective with NaCl 0.9%**
    Wrong dilution ingredient used for anti-infectives administered on the ward. Fosfomycin 8g 1-1-1 was prescribed in Sodiumchloride solution 0.9% 250ml. Patient developed major Hypernatremia. Anti-infectives dilutions was reviewed by pharmacy and an E-mail was sent out to inform staff about the mistake and how to prevent. Lack of knowledge, lack of education. Doctors on wards not aware of the fact that fosfomycin should not be administered diluted in NaCl-solution. Nurses had been misinformed. Lack of clinical pharmacy staff. Wrong list of solvents for infusion dilution created on ward by unqualified staff.
31. **RootCauses_IE_Slip5: Dose adaption only on 1st day of a serious of consecutive days**
    in protocols involving the administration of fluorouracil on two consecutive days, when dose reduction is prescribed on the first day, it is often not maintained even on the second day and not on the entire course of therapy.
32. **RootCauses_IE_Slip6: Dose prescription before consultation (revlimid)**
    Therapy with revlimid 15 mg is prescribed; upon delivery of the drug the patient refuses because the discharge letter in his possession reports therapy with revlimid 10 mg cpr. Error intercepted by the patient; possible urgent request for the drug with modified dosage and simultaneous return of the therapy with an outdated dosage. Possibility that the patient has to return to hospital again for drug withdrawal. Impact on all organizations (nurses, doctors, pharmacists, patients, care givers ...). Doctor prescribed the therapy in progress at a different time (prior) to that in which he visits the patient in order to have the drug available from the pharmacy when he visits the patient; during the visit, the dosage may vary and reports it on the discharge letter that he gives to the patient for the subsequent withdrawal of the drug at the front-office of the Oncology department. The nurse delivers the drug available without knowing that the dosage could be been changed.
    - Mistake chain 1st step: doctor's prescription not contextual and updated with the patient's hospital visit; Negligence of the doctor in lack of prescription's re-check and post-treatment therapy adjustment
    - Mistake chain 2nd step: Nurse's negligence on drug delivery without cross-checking with the patient's hospital letter discharge

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7) **RootCauses_IE_Slip7: Failure to flush the line**
Residual anaesthetic or sedative drugs may be left in intravenous (IV) lines and cannulae unless they are effectively flushed at the end of the procedure. If they are not, the residual drug can be later inadvertently introduced into the patient's circulation causing muscle paralysis, unconsciousness and respiratory and cardiac arrest. Equipment variation, lack of appropriate documentation (including sign-out checklists), lack of clear guidance, training deficits, likely under-reporting. NHS Patient Safety Alert 2017 "Confirming removal or flushing of lines and cannulae after procedures" at https://www.england.nhs.uk/2017/11/confirming-removal-or-flushing-of-lines-and-cannulae-after-procedures/ Also see HSIB Residual drugs in intravenous cannulae and extension lines, March 2021. Contributary factors: Institutional equipment variation, lack of appropriate documentation (Including sign-out checklists), lack of clear guidance, training deficits, likely under-reporting.

8) **RootCauses_IE_Slip8: Failure to open the clamp on the line**
Fluorouracil elastomeric pump did not infuse, discovered 46 hours later when patient returned to have pump removed (which should have been empty at this point). No checklist nor signature required for nursing staff to have opened the clamp, lack of patient education that the bubble should slowly get smaller over time.

- Risk and measures

25. Measures_IE_Slip1 and _Slip2: Handling of patient-owned medicinal products ...

a. Implementation of medicines reconciliation on patient admission
b. Implementation of medicines reconciliation as part of the discharge planning
c. Storage of patient-owned medicines in the ward office or in a lock press or in bedside lockers for compliant patients
d. Policy of using patient owned medicines or not to be reviewed in the hospital: An SOP (Procedure, internal policy) for handling patient's own medication needs to be in place. Engaging patient in own medication plan: patient education!
e. Rushed discharge only when prescription is validated

26. **Measures_IE_Slip3: Patient developing addiction**

a. National register of addicts for confidential communication to medicinal and health professionals
b. Local alerting between pharmacies
c. Communication to hospitals in case of admission
d. Medicines reconciliation (alternative opinion: this slip case is disqualified as slip – this is a policy problem)

e. Medication reviews: Plan – Do – Study – Act Cycle as suggested by SPSP. Periodical auditing of medication administration, preparation, admission and discharge processes, …

27. **Measures_ IE_Slip4: Hypernatremia following dilution of anti-infective with NaCl 0.9%**
    a. Identification of unofficial lists on wards edited by unqualified staff and never reviewed
    b. Systematic error of organigramme: Wards are part of a hospital pharmacy and should therefore be supervised by the qualified person. Therefore: Delivering ready to use medications to the ward. Limit compounding on the ward. Less resource intensive measures: SOPs (plus appropriate reviews), raising awareness about risks of medication errors – staff education.
    c. Unqualified and untrained staff on wards should be discharged of duties that never can be fulfilled. This can be done by task shifting to pharmacy technicians.
    d. Information policy to be reviewed: bring principle for all official communication (with acknowledge of reception and of lecture), fetch principle for nice-to-have information.
    e. Communication and training of clinical standard operating procedures and of product lists in use
28. **Measures_IE_Slip5: Dose adaption only on 1st day of a serious of consecutive days**
    a. Provide for checking the last prescription for the same patient or pay attention to the Doctor's notes in the prescription to confirm the drug's dosage
    b. Provide a double check on the prescription by a different doctor (other that is not the Prescriber) -> 4-eye principle
    c. Schedule periodic meetings with doctors to discuss the most frequent errors and, if necessary, to review the software functions together.
    d. Request prescription's verification by a pharmacist for high level of attention drugs - antiblastic drugs
    e. Patient to be involved in medicines control and administration (communication of name, birth date, medicine dose etc)
    f. Pharmacist validation of prescriptions, esp. for high-risk meds. Evaluation of technology after implementing the technology (patient safety, functionality, practicality).
29. **Measures_IE_Slip6: Dose prescription before consultation (revlimid)**
    a. require drug prescription only with updated blood test
    b. require drug delivery by the doctor during the visit and only after doctor filled out the discharge letter
    c. Medicines reconciliation at discharge: provide double check with the patient on the drug delivered and prescribed and further comparison with the discharge letter

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d. provide Active involvement of the patient on the therapy to be taken, side effects and any dosage changes during therapy.

30. **Measures_IE_Slip7: Failure to flush the line**
    a. According to https://www.england.nhs.uk/2017/11/confirming-removal-or-flushing-of-lines-and-cannulae-after-procedures/
        i. Identify a named individual to take responsibility for co-ordinating the delivery of the actions required by this alert
        ii. Amend the Sign Out section of the WHO Checklist or equivalent in local use to include confirmation that before a patient leaves the procedural area:
            1. All IV administration sets and extension sets without active flow have been removed.
            2. Any multi-lumen connector without active flow through all its arms is removed; or, if this is not possible because a patient cannot tolerate even brief interruptions to essential drug or fluid delivery, that all arms have been adequately flushed.
            3. All cannulae have been identified and either removed or adequately flushed.
        iii. Include in local documentation for handover from procedural area to recovery, and recovery to the subsequent place of care, the requirement for documented and verbal confirmation that lines not in active use have been removed and multi-lumen connectors and cannulae removed or flushed.
        iv. Establish ongoing systems of audit to ensure these barriers are maintained.* *This may be part of existing audit systems to support the implementation of the WHO checklist and NatSSIPs
    b. Hospital pharmacy to provide ready-to-use syringes or licenced devices to flush lines
    c. Active involvement of the patient has prevented error. Negligence. Better explanation of the case needed: we are unsure how this problem came to be.
    d. Posiflush (or similar) needs to be available. Checklists, DETAILED adequate description of SOP (education films, e-learning).
31. **Measures_IE_Slip8: Failure to open the clamp on the line**
    a. 5R rules to be respected mandatory
    b. Patient instruction and integration in therapy objectives and control
    c. Checklist, double-check (four eyes), patient engagement

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Time schedule	**Schedule and Milestones**	**Requires resources / involved persons**

System errors (teams)

Risk:	System Errors Institution (work environment, technical resources)	
Responsibility:	Risk Owner: Minister for Health, Owner/HR Unit of hospital, QP, Inspectorates	Classification: non-clinical risk > latent risk > system errors > human resources
Label of the measure(s):	Prevention of system errors on the human resources level (including Harmonisation of variation in aseptic production standards across Europe)	

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Measure *Description*	• «root» causes (examples) **1. Combined Root Causes Mistakes – Human Resources** a. Many mistakes could be traced back to staffing and HR pitfalls **2) RootCauses_SE_HR1: Variation of standards across Europe (aseptic production)** a. Almost zero sanitisation of hands by Operators in a Grade A environment directly performing aseptic manipulations Compounding high risk TPN products b. No transfer sanitisation of items placed into a Grade A Laminar Flow Cabinet (Horizontal) – Compounding high risk TPN products c. Operators in Grade B cleanrooms without goggles, poorly fitting masks, gloves riding down/sleeves riding up exposing wrists and skin d. Excessive amounts of paper in Grade B cleanrooms e. Standard keyboards, computers and devices in Grade B cleanrooms f. Use of what appears to be personal mobile phones in Grade B cleanrooms g. Excessive number of occupants and no occupancy limit in Grade B cleanrooms h. Obvious omissions or less than optimal practices in Operator techniques (touching surfaces in fluid pathway such as septum, touching items and areas outside of Grade A then immediately compounding, placing hands directly in path of airflow and preventing clean air from surrounding point of manipulations, touching the filter face of cabinet, far too many components in Grade A zone and risks of mix up etc) i. Poorly designed airflow/inlet/extract, with inlet almost above boundary of Horizontal Laminar Flow cabinet, extract under cabinets on the wall creating vortex and counter to use of HLFs j. No routine use of Environmental Monitoring and very little to zero data k. No Media Fill qualification of Operators (technique), Process or Equipment l. No monitoring of Operator gowns or qualification process for entry into Grade B rooms beyond observation by an experienced member of staff (were using sterile garments but no data collected on the process and how staff donned garb without contaminating) m. Poorly designed sanitisation programme with no understanding of bioburden and organisms present, no rotation of biocides, no use of sporicidal agents etc n. Process flows counter to good practice – same inflow used for outflow of finished products and waste, crossing of products and workflows within a room, poor segregation etc o. No sanitisation of Transfer Hatches when moving items from one Grade to higher Grade (i.e. Grade D to Grade B) or the reverse

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p. No routine monitoring of pressure cascades, airflows or temperatures in cleanrooms (or one time review of pressure gauge in the morning but no alarms of ongoing monitoring during the actual compounding day)
q. Poor finish to surfaces, obvious potential areas for contamination/bioburden to accumulate, difficult to clean rooms and layouts, obvious dead spaces for poor airflow in the room
r. Qualification standards poor and not fully documented adequate performance of the cleanrooms (i.e. no smoke tests, air volume measurements, air change rates, DOP testing of HEPA integrity). Temperature controlled areas not mapped and qualified.
s. Very limited or zero periodic requalification of equipment and plant
t. No use of interlocks or alarm system, allowing two doors from 2 or more Graded areas to be open at once and complete loss of pressure cascade and protection of outflow from aseptic core

3) **RootCauses_SE_HR2: Gaps in curriculum of staff members**
Preparation (dilution) of eye drops out of the box with laminar air flow (clean space). Pharmacist asked pharmacist assistant to dilute eye drops (PAMYCON powder for solution - neomycine/bacitracin), without specifying the exact location of the preparation. Pharmacy assistant did not dilute eye drops under the box with laminar air flow, the preparation took place in the laboratory of divided powder preparation (the regular laboratory was unavailable at that time because of the reconstruction, however the laminar air flow was available). Lack of knowledge of the pharmacist.
4) **RootCauses_SE_HR3: Missing sufficient number of pharmacists for medication review**
Due to a lack of clinical pharmaceutical staff not every patient's prescriptions can be reviewed which can lead to late (un-)detected medication errors, interactions, DrP. Example: Linezolid prescribed concomitantly with Escitalopram and Fentanyl leading to fever, delir, serotonin syndrome, hypernatremia. Lack of staff, lack of knowledge about what clinical pharmacists do. No governmental strategies visible; lack of knowledge of stakeholders; inept competitiveness of medical staff. Linezolid can cause serotonin syndrome when administered in combination with other serotoninergic medicines. E-prescribing tool in place but automated alerting not activated.
5) **RootCauses_SE_HR4: Set-up of cytotoxic infusion bag by unqualified staff**
During the set-up, a nurse, recently hired and in training, inserts an infusion set with a filter into the therapy bag that does not allow the therapy to be administered. The nurse is unable to administer paclitaxel albumin prepared by the Antiblastic Drugs Unit. A pharmacist, after having inspected the therapy set up and checked

the contents of the technical data sheet of the drug, realizes that the infusion set with the filter should not have been added and re-prepares the therapy with the correct infusion set.

6) **RootCauses_SE_HR5: Staffing disparities across publicly funded institutions**
Inspection findings: Staffing disparities: No national standard. It was found that the level of clinical pharmacy services was not standardised, and in some cases was reactive only. Connected to this the level of medicines reconciliation at transitions of care varied considerably.

7) **RootCauses_SE_HR6: Verbal communications: no read back. Deference to more senior colleague "they must be right"**
Rivaroxaban dosing error: 15mg BD advised by senior specialist clinician over the phone, heard as and interpreted as 50mg BD. Patient received 1 dose. No electronic prescribing system with clinical decision support, which would potentially have flagged this overdose. No clinical pharmacist verification step prior to administration. Knowledge gap amongst many staff when it comes to DOACs.

- Risk and measure
  1) **Combined Measures Mistakes – Human Resources**
     a. For measures to prevent this kind of errors see mistakes, slips and lapses
     b. Humans can easily be overburdened due to huge amounts of laws, norms, guidelines, requirements. Pressure needs to be taken away to prevent illnesses and burning-outs
     c. Mandatory European measures and inspections that require the implementation of actions can decrease the pressure on professionals to make decisions outside of their expertise.
        a. Humans can easily be overburdened due to regulatory frameworks, guidelines, and technical requirements. Burden can be reduced through system and process prompts rather than reliance on the individual recalling the procedure.
        b. As quality guidance exist sufficiently, inspectorates are responsible to require implementation of all necessary measures to fulfil these norms.
        c. Governments of European countries are required to implement in their countries harmonised standards
     d. Revision of staffing policies and recruiting procedures
        a. Revision of recruiting policy

	b. National programme to increase visibility and value of professions with workforce number challenges to encourage new trainees and retention c. Hospitals to implement sufficient HR for all situations e.g., holidays, illnesses, ... d. Staffing disparities across publicly funded institutions to be highlighted (benchmarking) e. Recruitment of qualified personnel only for key tasks – utilisation of alternate workforce f. To improve human resources basis through nationally supported and recognised training programmes g. Local measure - Ensure the availability of a pharmacist 24hours a day (in person or on a preventive basis, depending on the characteristics of the institution) h. Strengthen workforce capacities to improve safety: it is necessary to strengthen human resources by training a set of generalist workers for support functions (the exhaustion, fatigue and stress of professionals can negatively affect patient safety) e. Review of function, definition of guidelines for assigning error reduction tasks to pharmacists a. Task shifting from nurses to pharmacy technicians b. Identifiable appropriately qualified resource available for each area as appropriate c. Political measures to be implemented to consider hospital and clinical pharmacists needs d. Attribute tasks to pharmacists, e.g., medicines reconciliation, medication review, clinical trials' GMP support, supervision of entire supply chain of medicinal products e. Verification step prior to administration to be assumed by clinical pharmacist f. European-wide review and standardization of the hospital pharmaceutical career: definition of training, specialization, functions, functional and remuneration repositioning of stagnant careers for decades a. Inadequate career positioning compared to high responsibility demotivates professionals. b. Inadequate training for specific responsibilities/functions/areas g. Monitoring compliance with European recommendations (like Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients e [CM/Res(2016)2] on good reconstitution practices in European hospitals). a. GMP quality guidance for all staff and domains where medicines are handled, combined with deactivation of internationally unapproved quality systems

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b. Deactivation of Quality-SOPs issued by nursing staff / not issued by pharmacy, as long as they concerned medicines handlings
c. Implementation of CIVAS (Central venous additive services).

h. Need for adequate training
   a. Including in the specific institution SOPs
   b. Educational and training measures to be assigned to low qualified team members by qualified person
   c. Education and specialisation as well as training on the job to be entirely reviewed
   d. Health care workers in training should always be supervised by qualified staff
   e. Adequate theoretical training first before candidates are allowed to work practically
   f. Training should include basic knowledge of best practices and 5R rules
   g. Teaching hospitals to assume their responsibility to attribute enough teaching staff in the education of new staff members
   h. Education and training on the job to be entirely documented
   i. Life-long learning for handling new devices and galenic forms
   j. Teaching of special consideration of tools for injectables
   k. Ongoing assessment of knowledge and skills. Use of feedback and incident review to improve training and systems support.
   l. Investment in support for clinical pharmacy management staff within Pharmacy Departments, through structured training and peer support, to fully realise any potential benefits that might be expected

i. Effective Communication
   a. Support adequate communication between professionals, remove barriers to interaction, communication skills training
   b. Communicate effectively with patients and their families: patient engagement – enable opportunities for direct patient contact
   c. Improve medication literacy

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d. Provide resources to support the provision of written information to patient, whenever relevant to reinforce verbal information.

j. Adopt/generalise the best practices of other instruction/ countries
   a. Example: Transforming NHS pharmacy aseptic services in England - GOV.UK (www.gov.uk)
      i. Transforming pharmacy aseptic services in England will deliver:
      ii. improved patient experience by enabling care closer to home
      iii. increased patient safety by reducing errors in the manipulation and administration of these medicines
      iv. free up the time of 4,000 nursing staff for patient care
      v. increase productivity from the medicines budget
      vi. increase the resilience of the sector
   b. Focus on people most at risk of experience security incidents: some people are at greater risk of experiencing incidents: children, the elderly, people in homecare or in long-term care facilities, are some examples. Focused work on the high-risk groups can improve the quality and safety of care, providing more personalized attention and ensuring safer transitions between services.
   c. Celebrate successes and share learning with others: knowing what worked well can stimulate brainstorming and help keeping the work safer.

k. Promote measures to avoid interruptions
   a. Use of visual signals such as vests with a warning message, for example: “Do not interrupt. I am administering medication”, to inform that that professional should not be interrupted. Or in strategic locations, such as medication preparation, dispensing and administration areas, warning: “Do not disturb”, “Do not disturb” or “Do not talk”
   b. Use of checklist of important points of the activity in execution. If the professional needs to leave the task and return later to complete it, the checklist will help you remember the moment of interruption.
   c. Appropriate use of mobile devices: - manage the appropriate use of mobile devices, such as cell phones, identifying which resources can be used and what measures should be taken to ensure their safe use

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	d. Educate employees about the risk of using mobile devices, such as cell phones, as a factor in interrupting assistance e. Educate professionals, patients, and family members about the risks of interruption in the event of medication errors f. Treat any inattentive behaviour related to the personal use of mobile devices, such as social networks, instant messaging applications and others, as risky behaviour. g. Definition of the appropriate moments for interruptions: define that, when it is necessary to interrupt a professional in full execution of an activity, this must be done during the break or transition of the task, avoiding interruptions during the most complex moments that require concentration h. Identify common interruptions causes and fix system problems. i. Provide ready-to-administer drugs, minimizing interruptions associated with drug reconstitution and dilution (example: centralization of processes with the highest risk of errors like implementation of CIVAS: Central venous additive services. j. Establish forms of communication between different professionals to resolve routine problems that do not require frequent interruptions. k. Ensuring appropriate sizing human resources to the institution's needs - Restrict the frequency of computer alerts and device alarms to critical information and minimize noise from unnecessary conversations in clinical areas. l. Implementation of a safety culture a. Embed safety and no-blame culture into organisation b. Highlight marking on those medicines that need special handling (process not HR) c. Electronic prescribing (Technical/process not HR) d. Clinical decision electronic support (combined with plausibility testing) (Technical/process not HR) e. Drug safety training: raise awareness of the specific risks of medicines (poor perception of risks) f. Allow early detection and prevention of the occurrence of medication errors g. Improve understanding of measures to reduce the frequency and severity of medication errors h. Streamline the recording of medication errors

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i. Provide information to health professionals, patients, and their caregivers.

m. Provide clinical and emotional support to professionals
   a. Provide human resource framework to proactively identify individuals requiring additional support.
   b. Provide local mentoring and support structure

2) Measures_SE_HR1: Variation of standards across Europe (aseptic production)

a. Staffing policies and recruiting procedures to be reviewed
b. Training needed
c. As quality guidance exist sufficiently, inspectorates are responsible to require implementation of all necessary measures to fulfil these norms.
d. Governments of European countries are required to implement in their countries harmonised standards

3) Measures_SE_HR2 and HR3: Quantitatively and qualitatively insufficient human resources

a. Revision of recruiting policy
b. Educational and training measures to be assigned to low qualified team members by qualified person
c. National programme for valorisation of professions suffering from lack of sufficient number of qualified professionals
d. Task shifting from nurses to pharmacy technicians
e. Wards to be supervised by qualified person, as well as to be adequately illustrated in organigramme
f. Political measures to be implemented to consider hospital and clinical pharmacists' needs
g. Attribute strength tasks to pharmacists, e.g. medicines reconciliation, medication review, clinical trials' GMP support, supervision of entire supply chain of medicinal products
h. Education and specialisation as well as training on the job to be entirely reviewed
i. GMP quality guidance for all staff and domains where medicines are handled, combined with deactivation of internationally unapproved quality systems
j. Deactivation of Quality-SOPs issued by nursing staff / not issued by pharmacy, as long as they concern medicines handlings

4) **Measures_SE_HR4: Set-up of cytotoxic infusion bag by unqualified staff**

a. Health care workers in training should always be supported by a tutor, even in the control of the simplest operations.
b. Adequate theoretical training first before candidates are allowed to work practically

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	c. Training should include basic knowledge of best practices and 5R rules d. Teaching hospitals to assume their responsibility to attribute enough teaching staff in the education of new staff members e. Hospitals to implement sufficient HR for all situations e.g. holidays, illnesses, ... f. Education and training on the job to be entirely documented g. CIVAS (Central venous additive services) to be implemented h. Life-long learning for handling new devices and galenic forms i. Teaching of special consideration of tools for injectables j. Highlight marking on those medicines that need special handling 5) **Measures_SE_HR5: Staffing disparities across publicly funded institutions** a. See HIQA at https://www.higa.ie/reports-and-publications/key-reports-and-investigations/medication-safety-monitoring-programme a. significant investment in support for clinical pharmacy management staff within Pharmacy Departments, through structured training and peer support, to fully realise any potential benefits that might be expected b. Recruitment of qualified personnel only for key tasks c. To improve human resources basis by national education of graduated and post-grad potential staff **6) RootCauses_SE_HR6: Verbal communications: no read back. Deference to more senior colleague "they must be right"** a. Verification step prior to administration to be assumed by clinical pharmacist b. Fill knowledge gaps amongst staff when it comes to DOACs c. Electronic prescribing to be implemented d. Clinical decision support to be implemented (combined with plausibility testing)

Time schedule	**Schedule and Milestones**	**Requires resources / involved persons**

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System errors (institutional)

Risk:	System Errors Institution (Organigram, Responsibility, Competence, Legislation)	
Responsibility:	Risk Owner: Minister for Health, Regulatory Bodies, CEO, QP, supervising authority	Classification: non-clinical risk > latent risk > system errors > institution
Label of the measure(s):	Prevention of system errors on the institutional level	
Measure • *Description*	• «root» causes 1. **RootCauses_SE_institution1: Organigram: Legal Incompatibility of delegation of responsibility and competence of medicinal products supply:** There is a legal requirement stipulated for institutions having inpatient to employ a hospital pharmacist as authorisation holder for the medicinal products' supply chain. The Qualified Person's responsibility must be illustrated in the organigram. Some hospitals do not fulfil this requirement. It hinders the hospital pharmacist to manage medicines supply in the whole hospital and thus to conform to the responsibility attributed. Thus, risk for medicines errors increases. 2. **RootCauses_SE_institution2: Critical incidences (cf. CIRS) caused by errors on the ward** Many critical incidences (cf. CIRS) are caused by errors on the ward produced by unqualified staff activity. There is no recognised pharmacological (advanced or continuing) education of staff members mandated with preparing and/or dispensing patient doses. On the ward, medicines are handled outside best GMP-practices. The hospital pharmacist is not officially declared a being competent and responsible for medicines supply to the patient also on wards. 3. **RootCauses_SE_institution3: Unqualified personal is preparing and/or dispensing patient doses.** Obviously for economic reasons and for dry market of nursing staff, Unqualified personal is preparing and/or dispensing patient doses. HR tolerates unqualified personnel substituting for lacking qualified human nursing resources. These persons do not have any certified professional specialisation to fulfil this task in handling medicinal products. Patient doses are not transparently documented: Preparing person, double-controlling	

person, dispensing person could not be identified for every patient treated. Fluids prepared just-in-time of application were not double-controlled..

4. **RootCauses_SE_institution4: Medicines reconciliation (transition of care) and Medication review not implemented**
   Due to inaccuracies in GP referral letter 95 year old lady charted for and received regular paracetamol and codipar (which contains paracetamol) in error. was only taking CODIPAR PRN prior to admission. Also received Escitalopram and Duloxetine in error. GP had recently switched patient from Escitalopram to Duloxetine but both were listed as current regular medications and so both were charted and administered. This was brought to the attention of the team who discontinued Escitalopram and Codipar. Inaccurate list of medications on GP referral letter.
5. **RootCauses_SE_institution5: Governance deficits**
   Inspection findings: Governance deficits: lack of functioning Drugs and Therapeutics Committee, lack of medication safety strategy, lack of hospital formulary.
6. **RootCauses_SE_institution6: Lacking adequate Risk Management for injectables use in hospitals**
   Publication proposing need for review of preparation and administration of injectable medicines administered in European hospitals. hospitals are frequently associated with medication errors - proportion of which cause preventable severe harm and deaths. Errors most likely to occur during administration and preparation - especially if ward-based. Cousins DH, Otero MJ, Schmitt E. Time to review how injectable medicines are prepared and administered in European hospitals. Farm Hosp. 2021;45(4):204-9.
7. **RootCauses_SE_institution7: Preventable harm in medical care**
   Published systematic review and meta-analysis of observational studies to compare the prevalence of preventable medication harm (2020). Hodkinson et al. BMC Medicine (2020) 18:313. One in 30 patients are exposed to preventable medication harm in medical care, and more than a quarter of this harm is considered severe or life-threatening. All stages implicated - The highest rates of preventable medication harm were seen in elderly patient care settings, intensive care, highly specialised or surgical care and emergency medicine. Highest prevalence rates of preventable harm were at the prescribing and monitoring - but crossed all areas.

- Risk and measures
  1. **Measures_SE_institution1: Organigram: Legal Incompatibility of delegation of responsibility and competence of medicinal products supply:**
     a. Leadership and governance's responsibility to be assumed

i. Appropriate governance structure to be installed: Suggest an appropriate governance structure and responsibility profile that can be adopted internationally as best standards.
ii. Established Drugs & Therapeutics committee/Medicines safety groups against internationally agreed standards to support ongoing monitoring and action against medication errors.
iii. Ensuring appropriate policies, standard operating procedures and, guidelines for the administration of medicines are available

b. WHO source: medication without harm (Chart "Action Areas")

c. Risks of avoidable medicines errors arising from non-conform organigrams can be fixed by
i. Amendment of organigram according to official authorisation attributed to the Qualified Person (or responsible person) of the Hospital Pharmacy (note: in Switzerland a QP is called *"fachtechnisch verantwortliche Person"*, meaning a person responsible as stipulated in the laws. This is the one being authorised by the supervising authority, not necessarily the head of the hospital pharmacy.)
ii. Recognition of independence of QP from any directives related to medicinal products management

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iii. Subordination of wards under QP's responsibility (CH therapeutic agents act art 4 abs 1 and art I abs 2)

2. **Measures_SE_institution2 and _institution6: Critical incidences (cf. CIRS) caused by errors on the ward – often with injectables**
    a. Potential harm by medication errors arising from unqualified ward staff can be fixed by
        i. Officialisation of function of Qualified Person for the entire medicines supply chain in the hospital according to legislation in force in Switzerland and in European countries, e.g. ….)
        ii. Transfer of responsibility for ward staff recruiting to the hospital pharmacist still attributed to the clinical and nursing structures. Unawareness of the problem in the company's Management Board. Laws not implemented.
        iii. Automation of dose preparation (blister preparation et cetera)
    b. Education and training/capability at point of care
        i. Suggest a level of appropriate competency in medication administration
        ii. Use this competency structure to form job descriptions allowing for identifiable roles with appropriate specialist input where necessary
        iii. Nationalize the training to ensure ease of relocation of staff
        iv. Ensure appropriate clinical systems and resources (i.e. smart pumps and administration libraries, injectable medicines guides, epma linked with other clinical systems), availability and access for all staff involved in medication handling at ward level
        v. Utilise tools to prioritise high risk medicines for aseptic compounding to reduce the risk of calculation or handling errors at ward level (NPSA20) - (bonus of reducing burden on nursing staff to release them to caring for patients – which will have a further reduction in errors).
        vi. Ensuring appropriate policies, standard operating procedures and guidelines for the administration of medicines are available
        vii. Multimedia-aided training and simulation rather than reading large amounts of printed paper
3. **Measures_SE_institution3: Unqualified personal is preparing and/or dispensing patient doses**
    a. Staff policy (human resources) policy to be implemented
    b. Tasks of unavailable nursing staff although recruiting efforts are undertaken fulfilled by other professions
        i. Task shift: discharge nurses from medicines handling on the ward, substitute pharmacy technicians for unqualified nursing staff

4. **Measures_SE_institution4: Medicines reconciliation (transition of care) and Medication review not implemented**
    a. Medicines Reconciliation (and Medication Review) to be implemented
    b. HR to be reviewed in terms of quantitative and qualitative skills to prevent mistakes and slips from work overload
    c. Capability at point of care/Prescribing, preparation and dispensing/Patient Engagement/Medication Literacy
        i. Suggest a model for meds rec that increases staffing around key areas (admissions etc)
        ii. Working to top of license – i.e. Technicians doing meds rec with appropriate training/competence and escalating risk
        iii. Ensure adequate IT infrastructure and access to those tools needed to perform at the top of their license.
        iv. Ensure flow of information is available across all levels of care (primary, secondary, tertiary) and to all involved in the patients care. (i.e. GP & associated staff, Hospital, parents/carers, patients)
        v. Ensure adequate suitably competent staffing to allow for appropriate counselling on medication when a patient transitions across care boundaries.
5. **RootCauses_SE_institution5, _institution7: Governance deficits – preventable harm in medical care**
    a. As recommended by the Health Information and Quality Authority during hospital inspections. See HIQA at https://www.hiqa.ie/reports-and-publications/key-reports-and-investigations/medication-safety-monitoring-programme
        i. All hospitals to have a functioning Drugs and Therapeutics Committee to strengthen their governance arrangements and drive improvement in medication safety
        ii. Harmonising of disparities in clinical pharmacy services to be nationally planned to ensure consistency in baseline clinical pharmacy service
        iii. Significant investment in support for clinical pharmacy management staff and in the key player technology ensuring safety for patients
        iv. Cooperation between hospitals
        v. Use of technology to reduce human error in busy, complex and challenging environments
    b. Governance deficits, e.g. safety culture to be implemented

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	c. Stop blame and punishment culture, implement permanent quality improvement according to Deming and Donabedian d. Enlarge tasks of Drugs and Therapeutics Committees from poor selection to policy agreements as related to medicines supply and use e. Learning methodology for HR are highly inefficient and should be completely revised. More guidelines to be limited, better learning on the job with IT support should become more current	
Time schedule	**Schedule and Milestones**	**Required resources / involved persons**

System errors (work environment)

Risk:	System Errors Institution (work environment, technical resources)	
Responsibility:	Risk Owner: Minister for Health, Regulatory Bodies, Owner/Builder of hospital, architects, project group, QP, …	Classification: non-clinical risk > latent risk > system errors > technical resources
Label of the measure(s):	Prevention of system errors on the technical resources level	

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Measure *Description*	• «root» causes (examples) 2. **RootCauses_SE_TR1: Error in design of Infrastructure and fix installation (sterile production)** A newborn baby died at the ICU of Bern Children's Hospital (Switzerland) he received a parenteral nutrition bottle containing a 2.5% calcium chloride solution instead of 20 percent dextrose. Two different unlabelled badges were left in the same room after heat sterilisation. Some bottles of the two badges were mixed up and thus erroneously labelled leading to an identity error of the contents. This error could have been prevented if the autoclaves exits would not direct to the same room. 3. **RootCauses_SE_TR2: Men-Machine-Interface-Risk_Error in prescription of dose unit** Psychopax®(Diazepam) was electronically prescribed as 3-3-3-3 MG corresponding to 9 drops per administration. It revealed that the doctor had intended to prescribe 3-3-3-3 drops (and not mg) per administration. 4. **RootCauses_SE_TR3: Error in infrastructure renovation – maintaining manufacturing while construction activities.** Renovation of the hospital pharmacy building resulted in increased contamination of products by Burkholderia cepacia, even in sterilised infusion solutions and in chlorhexidine cleansing solutions. Hospital patients were affected by lung infections, even causing death in some individuals. Its increased detection required many additional manufacturing and analytical steps before a batch could be released. 5. **RootCauses_SE_TR4: Dispensing omitted** Preadmission medications charted as per recent discharge but team unaware that patient had not had this prescription dispensed. Patient had been newly diagnosed with heart failure on recent admission (early November) and initiated on Furosemide, Digoxin, his Rivaroxaban was changed to Apixaban and Bisoprolol dose increased from 2.5mg to 10mg. However, the patient did not understand that his medication regimen had been altered and he continued to take medication from the blister pack he had at home. The team was unaware of this when he was readmitted and so his regimen was altered further to account for the reoccurrence of symptoms. 6. **RootCauses_SE_TR5: bugs in synchronisation between IT applications** SAP stock and electronic prescribing system stock not aligned which results in inaccurate prescribing of medication; Augmentin instead of Curam, Anaerobex instead of Metronidazole, etc. aut idem not legal in Austria, therefore inaccurate prescribing habits. Sometimes this is not addressed and accurately changed in the course of the inpatient stay, sometimes it is administered and changed in e-kardex later. Lack of IT support and upgrades. lack of IT-staff; lack of training for IT-staff; lack of education for medical staff.

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7. **RootCauses_IE_TR6: Misuse of non-personal IT login and/or password**
   Apparently, doctor prescribed carboplatin AUC 5 significantly different from last entry. Nurse, with the doctor's credentials, had sent the prescription to the antiblastic drugs unit and had forgotten to enter the creatinine value, essential for the automatic computerized calculation of the carboplatin dosage which was first of 125 mg and then of 427 mg (exact dose according to patient parameters).
8. **RootCauses_SE_TR7: Lack of national, networked electronic prescribing systems and of barcode technology**
   Staff are forced to handwrite prescriptions due to lack of electronic prescribing systems, and there is a lack of barcode assisted dispensing and administration systems. Mix-ups have occurred in maternity care between progesterone (Cyclogest) and misoprostol (Cytotec), and between progesterone and Prostin E2 (dinoprostone). This has happened with both prescribing errors and drug selection errors at the dispensing & administration steps. SALAD. Knowledge gaps. Handwritten prescriptions widely in use - lack of electronic prescribing systems. Use of brand name rather than generic name while prescribing. Lack of independent double-checks. Lack of barcode assisted dispensing and administration. Contributory factors: Attentional failure of prescriber and/or dispenser; use of brand name rather than generic name while prescribing; institutional policy- lack of independent double-checks. See IMSN alert at https://imsn.ie/cyclogest-cytotec-errors-in-pregnancy/
9. **RootCauses_SE_TR8: Continuing domination of Paper-based handwritten systems**
   Use of smart technology and electronic prescribing systems is not yet the standard nor is it commonplace in Irish hospitals. Paper-based handwritten systems dominate.
10. **RootCauses_SE_TR9: Multiple failure of the 4-eye-principle at etoposide prescription, preparation and administration**
    The etoposide dose was correctly prescribed but there was a prescription error regarding the dilution; this resulted on a crystallization of the solution. (There was a double signature made by another doctor, preparation by the pharmacy - with double-check procedure - administration by the nurse and even then the error occurred). Apparent cause: Lack of staff; Lack of knowledge/training. Root cause: lack of technical and human resources: electronic prescription of standardized protocols.
11. **RootCCauses_SE_TR10: Undetected confounding of cytarabine with cladribine**
    Cytarabine should have been administered and, due to an error in drug selection/compounding, cladrabine was administered. LASA/incorrect selection. Eventually lack of staff.
12. **RootCauses_SE_TR11: Erroneous replenishing a Pyxis automat**e
    Error loading medication into pyxis system: tacrolimus 0.5mg LP instead of tacrolimus 0.5mg. Lack of knowledge/training; Routine procedures cause distraction. Men-machine interface not been carefully

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considered. Delicate mixing of many human activities with automated system. The automation should go further. Barcode use?

13. **RootCauses_SE_TR12: SALAD L-Thyroxin medicinal products**
    Different doses of levothyroxine are available on the market. The physician prescribed the hospital formulation and the dose he takes at home: levothyroxine 0.1mg: 0.137mg; clinical pharmacist records information to the physician suggesting dose adjustment to 0.125mg (1cp 0.1mg + 1cp 0.25mg), available at the hospital or the use of patient`s medication (home: 0.137mg). Physician opts for home medication, but the patient undergoes medication duplication for a few days. Accompanying risks: Lack of communication, lack of barcode scanning.
14. **RootCauses_SE_TR13: Vancomycin overdosag**e
    Vancomycin suspension in a patient with toxic levels. Lack of monitoring to detect toxic plasma levels.
15. **RootCauses_SE_TR14: Men-Machine Interface _ Inappropriate parameterization electronic prescription**
    Electronic prescription with dose presented as follows: .1mg, which led to a reading error for 1mg (dose multiplied by 10); the same can happen with 1.0mg, with wrong reading for 10mg (especially relevant in paediatrics and neonatology). Misperception/lack of knowledge. Paediatric nurse's report on drug safety training. Also described in the bibliography, as well as the use of units (mcg instead of µg, not to be confused with mg, for example | Incorrect parameterization of the units in the online prescription.
16. **RootCauses_SE_TR15: Overdose caused by weighing error although double validation performed**
    Clonidine oral suspension preparation with powder weighing error: 0.024g instead of 0.0024g; double validation procedure was performed. The error was identified after reporting an adverse reaction (bradycardia) in a child after one dose. Distraction/Induction by colleague. Awareness of a careful double validation. Could be slip, however some used to balances would not commit this kind of error.
17. **RootCauses_SE_TR16: confounding risk DCI prescription versus misleading brand names**
    Same names of different drugs between different countries: can cause important errors when you are studying the pharmacotherapeutic profile of patients coming from another country. Examples: MONOCID (clarithromycin) in Austria and Cefonicid in Portugal and Spain; SERENASE is lorazapam in Belgium and haloperidol in Italy. Similar trademarks names of different drug between different countries can cause errors of duplication, for example. Same examples: EFEROX is levothiroxine in Germany and EFEXOR is venlafaxine is Switzerland and Portugal; PRAZAC is prazosin in Denmark and PROZAC is fluoxetine in Spain and Portugal. Misleading trade name use. Lack of European/global supervision (or legislation): attribution of commercial names of medicines (?). Described in bibliography: - Errores de prescripción: Ejemplos de errores de prescripción frecuentes y su posible prevención. CedimCat.

https://www.cedimcat.info/index.php?option=com_content&view=article&id=192:errores-de-prescripcion-ejemplos-de-errores-de-prescripcion-frecuentes-y-su-posible-prevencion&lang=es .

18. **RootCauses_SE_TR17: Multiple error sources in the course of not-IT supported medication process on the ward**

    Multiple error sources in the course of medicines prescription, preparation and dispensing on the ward:

    a) Clinical information system does not display the most important information in one window
    b) too many persons involved at different times from preparation, to control and dispensation or administration. No state-of-the-art of communication is defined. Each person relies on the other's "having well done"
    c) pill organisers are too small for the number of medicines prescribed. Blisters are opened and tablets prepared without identification nor protection. Source of cross-contamination. Unidentified can be transferred into other units of the box at every movement of the box.
    d) the clinical information system does not alert about doses not ticked as prepared, controlled, distributed, dispensed. The single dose is set as "administered" by default. Thus, doses can be given more than just once or be omitted if nurses are not attentive enough.
    e) liquids are prepared just before administration, often without respecting the 4-eye-principle, e.g. in the night when one nurse is alone. Confounding of labelled lids have occurred repeatedly
    f) no barcode support by the clinical information system

- Risk and measure

4) Measures_SE_TR1: Error in design of Infrastructure and fix installation (sterile production)

a) An autoclave should not direct into the same room as another one as unlabelled containers (of the same kind) are a high risk of confounding. Such a room should be divided into smaller rooms preventing mixing up of unlabelled sterile goods.
b) Omit errors in constructional strategies. Newly constructed infrastructure must be clearly separated into production lanes. A proper project design involving users must be implemented.
c) Line clearance must be performed before production processes start and material from a recent production taken away.
d) Production of different solutions in the same containers must be timely separated.
e) Test badges (e.g. for qualifications) must be recognisable by coloured solutions (recent GMP guideline changed in this term).

f) Other unlabelled containers from former badges should be packed into boxes or protected by packaging hoods preventing manipulations with unlabelled material. Unable bottles of different products are therefore a high risk for harm to patients.

5) Measures_SE_TR2, _TR14, _TR17: Men-Machine-Interface-Risks

a) Technical issue at the men-machine-interface: Amendment of the order entry system, opening an alert system to precise a dose unit as soon as the dose exceeds alarm threshold
b) Develop and include a decision support system to detect unusual prescriptions
c) Omit any distraction when working at the Clinical Information System
d) Plausibility checks
e) Awareness that an IT aided CDSS is only as good as the developers of the application are
f) Implementation of a clinical information system with sufficient technical aid and predefined workflow to release pressure from overburdened staff. The clinical information system must permit a full and logic parametrisation of the workflow according to the need of harm prevention.
g) Task shift to pharmacy technicians needed, accompanied by complete redesign of the prescription, preparation and administration procedures on the ward and subordination of nursing staff under the qualified person as long as it concerns the medication process

6) **Measures_SE_TR3: Error in infrastructure renovation – maintaining manufacturing while construction activities.**

a) Maintaining production when premises reconstruction activities are running must be avoided.
b) Outplacements or sub-contracting for such periods must be organised rather than maintaining current activities in production.

7) **Measures_SE_TR4: Dispensing omitted**

a) IT clinic information system to verify whether patient received prescribed discharge medication
b) Medicines reconciliation at patient's discharge to be implemented
c) HR to be reviewed in order to prevent mistakes and slips arising from work overload
d) Check of patient's literacy to understand new medications

8) **Measures_SE_TR5: bugs in synchronisation between IT applications**

a) Review of entire IT software running
b) Improvement of communication between software applications (pipelines properly defined)
c) Interprofessional project team to resolve problems and implement needs of all stakeholders using common clinical software

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9) **Measures_IE_TR6: Misuse of non-personal IT login and/or password**
   a) Never let unqualified staff to enter prescriptions!
   b) Safety culture to be implemented
   c) Nonpersonal credentials, login, passwords to be prohibited in the entire enterprise
   d) Prevent document falsification and counterfeiting in the whole enterprise
   e) Examination why nurse did this kind of exceeding his/her competence (Lack of resources?)
   f) Omit under diagnostics: Confirmation of clinical chemical values ideally at every consultation
   g) Request prescription's verification by a pharmacist at least for high potent drugs with small therapeutic range
10) **Measures_IE_TR7: Lack of national, networked electronic prescribing systems and of barcode technology**
   a) According to: CycloGESTCytoTECA2019.pdf (imsn.ie)
      i) Short-Term Strategies
         (1) Implement current IMSN recommendations to reduce the risk of SALAD errors3
         (2) Provide induction training for new staff to highlight the risk of these SALAD errors
         (3) Use tall man lettering to distinguish CycloGEST from CytoTEC
         (4) in prescribing and dispensing systems
         (5) Ensure that prescriptions are complete and legible, spelling 'microgram' in full
         (6) Prescribe progesterone supplements both generically and by brand name, including an indication for use e.g. "For maintenance of pregnancy"
         (7) Hospitals should review their processes for the storage and supply of prostaglandin analogues
         (8) Pharmacies and clinical areas should segregate prostaglandin analogues to reduce the risk of SALAD errors
         (9) Implement a robust checking process during the administration or dispensing of progesterone, misoprostol or other prostaglandin analogues. If an independent second person check is not feasible, technical solutions such as barcode verification of the selected product should be considered
         (10) Health professionals must be aware of the indication for use of a prostaglandin analogue or progesterone supplement

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(11) Submit any near misses, medication errors or adverse drug reactions to local incident reporting systems, to the Health Products Regulatory Agency (www.hpra.ie) and the State Claims Agency.

ii) Longer-Term Strategies

(1) Introduction of electronic health records across all 19 maternity hospitals in Ireland will enable printed inpatient and discharge prescriptions; however prescribers need to be aware of the risk of product selection errors in drop-down menus at the point of prescribing

(2) Introduction of barcode scanning at the dispensing and administration stage of the medication use process would enable positive patient identification and ensure that product selection errors are detected

(3) Electronic transmission of prescriptions would facilitate direct import into pharmacy dispensing systems, removing the risk of transcription errors.

8) **Measures_SE_TR8: Continuing domination of paper-based handwritten systems**

a) See HIQA at https://www.hiqa.ie/reports-and-publications/key-reports-and-investigations/medication-safety-monitoring-programme

i) To introduce smart technology and eHealth to the medication management process such as

(1) electronic prescribing

(2) electronic medication reconciliation

(3) automated dispensing

(4) information communication technology (ICT) solutions to stock control and ordering of medicines at ward level

(5) efficiency and improved safety through innovative use of technology

9) Measures_SE_TR9, _TR10, _TR11, _TR12, _TR15, _TR16: Multiple failure of the 4-eye-principle ...

a) General absence of automation and plausibility checking

b) Trusting is good, checking is better: Introduction of barcode scanning at the dispensing and administration stage of the medication use process would enable positive patient identification and ensure that product selection errors are detected

c) Implementation of a cdss, however combined with barcoding and awareness of the staff, that an IT aided CDSS is only as good as the developers of the application are

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	d) Replenishing a Pyxis system corresponds to a manufacturing activity. Medicines are to be checked by barcode scanning whether the right medicine is put into the drawers. e) DCI prescribing may be clearer in many cases than prescription of brand names f) Delimitation of storage system at hospital pharmacy (e.g. SAP, basing on brand names) versus clinical information system (e.g. KISIM, basing on therapeutic agents' names) with clear and 1:1 biunique linkage g) Pop-up alerting in case of sound-alikes and look-alikes h) Training of operators on newly acquired and qualified equipment i) Balances must have printers connected to proof weights. Release could be stopped by release officer or qualified person. j) Lookalikes and soundalikes are highly challenging tasks for qualified staff and need undisturbed working environments 10) **Measures_SE_TR13: Vancomycin overdosag**e a) Pharmacokinetic monitoring lead by the pharmacy to be implemented b) Monitoring to be assumed by multi-professional team c) Human resources to be adapted to the need of such a monitoring care team	
Time schedule	**Schedule and Milestones**	**Requires resources / involved persons**

SPECIAL INTEREST GROUP | FINAL REPORT

Working towards eliminating avoidable harm

COVER DESIGN > www.biographia.it

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website | www.eahp.eu
email | info@eahp.eu
phone | +32 (0) 2/699.25.16

eahp
european association of hospital pharmacists