

SIG - FINAL REPORT

Special Interest Group for The Investigation of Medication Errors in Intensive Care Units



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Foreword by the President

As stewards of patients' medication safety, hospital pharmacists are the key stakeholders ensuring the safe, effective and rational use of medicines by upholding the "rights" of patients. This includes improving the safety of using medications through their close surveillance as well as advising on the most appropriate use of medicines. In particular medication errors, which occur when a medicine has been inappropriately prescribed, prepared, dispensed or administered to a patient, are a key concern for hospital pharmacists.



To address some of the problems caused by medication errors, the European Association of Hospital Pharmacists (EAHP) created a Special Interest Group (SIG) for the Investigation of Medication Errors in Intensive Care Units (financially supported by BD). This SIG was tasked with determining the prevalence of medication errors in intensive care units, their causes or contributing factors, and strategies to improve medication safety and prevent medication errors.

On behalf of EAHP, I would like to thank all SIG members for their valuable contributions and their engagement throughout the past 1,5 years. I sincerely hope that the 32 policy recommendations put forward by the SIG will help to decrease medication errors in intensive care units across Europe. My thanks also extend towards the healthcare professionals across Europe and EAHP's member associations that contributed to the survey activity and that inputting during the focus group discussions.

A handwritten signature in blue ink, which appears to read 'András Süle'.

András Süle
President of the European Association of Hospital Pharmacists

Executive Summary

This report presents the findings of the Special Interest Group for the Investigation of Medication Errors in Intensive Care Units set up by the European Association of Hospital Pharmacists (EAHP). The Special Interest Group (SIG) carried out an investigation into developing and prioritising policy recommendations to support medication safety improvement in ICUs across Europe.

Background

Medication Errors (MEs) are a leading cause of morbidity and mortality in the healthcare system. Patients admitted to Intensive Care Units (ICUs) are potentially more susceptible to MEs due to the complexity and intensity of treatments they receive. Previous studies have identified risk factors contributing towards MEs, and strategies that could prevent them and improve medication safety. However, little is known about which ME prevention strategies are currently in use, or planned, in ICUs across Europe, or what variability exists between these units.

Aim

The aims of this study were to determine the prevalence of MEs, to identify potential contributing factors to MEs, to identify ME prevention strategies in use in ICUs, to explore patient safety culture and medication safety within ICUs, to explore prevention strategies for improving medication safety in the ICU environment, and to develop and prioritise policy recommendations to support medication safety improvement in ICUs across Europe.

Methods

This study comprised four parts: a literature review; a survey; focus group discussions; and a Delphi panel. Ethical approvals were sought for the survey (University College London) and focus group discussions and the Delphi panel (University of Helsinki); participation was voluntary and confidential.

Three literature reviews with systematic searches were undertaken in September-November 2021 to identify relevant literature on the prevalence of MEs, the potential sources, causes and contributing factors to MEs, and prevention strategies for improving medication safety in the ICU environment.

An online cross-sectional descriptive survey was developed based on the reviewed literature, and questions were designed through a collaborative and iterative process. Anonymous responses to the questions were recorded using a five-point Likert scale. In March-April 2022, the survey with reminders was distributed electronically to healthcare professionals (HCPs) working in ICUs across

Europe. Descriptive analysis was used to identify the medication safety practices most commonly used or planned for implementation in ICUs, using Microsoft Excel® (version 2016 or newer).

A topic guide for the focus group discussions was developed based on the reviewed literature and the initial findings of the survey. The main topics included: patient safety culture and medication safety in ICU; and ME prevention strategies and their implementation. Invitations to participate in the focus group discussions were distributed electronically to HCPs working in ICUs or as medication safety officers across Europe. In May 2022, 90-minute focus group discussions were conducted and recorded, using an online video-conferencing facility. The discussions were transcribed verbatim and entered onto an Atlas.ti (version 9) database. The framework analysis was inductive, systematic and transparent and was completed through a collaborative and iterative process.

The reviewed literature, the findings of the survey and the focus group discussions were utilised to develop the initial policy recommendations for medication safety development within the ICU environment across Europe. An online survey for the Delphi panel was developed. The expert panel, consisting of 21 members of the SIG (HCPs with expertise in ICU or medication safety), ranked the policy recommendations anonymously according to their priority for implementation, using a nine-point Likert scale. The recommendations were presented to the panel at Delphi Round 1 in October 2022. At subsequent Delphi Round 2a and 2b in November-December 2022, only those recommendations where consensus had yet to be reached were included. The median and inter-quartile range (IQR) for each recommendation was calculated using Microsoft Excel® (version 2016 or newer) and the data were analysed for the degree of consensus and priority.

Results

A total of 20 original studies on the prevalence of MEs in ICUs published between 2011 and 2021 were included. Nine studies, exploring the prevalence of MEs in multiple stages of the medication use process in ICUs, have estimated the prevalence of MEs in ICUs to be in the range of 38.2 to 363 MEs/100 patients, 9.2 to 967 MEs/1000 patient-days, 10 to 98 MEs/100 medication orders, or 12 to 69.7 MEs/100 doses. Potential contributing factors to MEs in ICUs were identified in 22 original studies between 2016 and 2021. These were often related to systemic issues such as: poor management and organisation, high workload, lack of staff, and fatigue, inadequate guidelines, or design of systems or protocols, distractions, interruptions, and lack of attention, lack of knowledge and education, poor communication and interaction, poor environment and lack of material resources.

ME prevention strategies for improving medication safety in the ICU environment were described in 38 original studies between 2003 and 2021. Many ME prevention strategies have been shown to reduce MEs such as: audit, feedback, education and training, integrating clinical pharmacists in ICU team, standardised prescriptions, electronic prescribing (EP) systems or computerised prescriber-order entry (CPOE).

In total, 587 usable responses to the survey were received from HCPs from 32 different European countries. Supporting the safe use of medicines, many ME prevention strategies were in use in ICUs. Having a standardised process in place for taking medication histories for all patients in the ICUs was reported by 31% of the respondents; 53% reported that EP systems or CPOE were fully implemented for all orders and all patients. A critical care pharmacist was reported by 31% of the respondents of being fully allocated to their ICUs. An independent double-check process was in use for both the preparation and administration of all high-risk medication in the ICUs of 21% of the respondents. While standardised concentrations of regularly used intravenous infusions (IV) were used in the ICUs of 56% of the respondents, smart infusion pumps and oral/enteral syringes that are incompatible with IV lines were fully implemented for all patients and medications in the ICUs of 21% and 55% of the respondents, respectively. Barcode scanning for the verification of medications was reported by 5% of the respondents to have been fully implemented for all medications. Medication review at discharge was reported to occur fully for all patients in the ICUs of 19% of respondents. Use of a fully or partially implemented incident reporting system was reported by 77% of the respondents.

Three nurses and 11 pharmacists participated in the focus group discussions; they worked in seven different European countries, representing Northern, Southern and Western European regions. They expressed their views on how blame culture and 'good' open culture may influence patient and medication safety. Blame culture is seen as still being prevalent amongst the more senior ICU staff and hospital managers. It was perceived that members of staff might be willing to discuss medication related issues with pharmacists but not necessarily with other colleagues due to fear of blame. As facilitators for medication safety, its development and improvement, the participants most often mentioned: engaging and communicating with HCPs in improving medication safety, providing feedback to them on MEs and ME prevention strategies (n=31), interprofessional working in an environment without hierarchies (n=27), and having a 'good' culture and environment (n=25). Lack of engagement of HCPs and their attitudes towards medication safety, and an existing blame culture were mentioned most often as barriers (n=37 and n=34, respectively) to medication safety and its development and improvement. The participants reported 25 different ME prevention strategies in

use in their ICUs, most often assessing knowledge and auditing practice and learning, teaching and training (n=34), incident reporting (n=31), and pharmacists working in ICU and participating in ward rounds (n=30).

In total, 32 policy recommendations were developed. At Delphi Round 1, 19 HCPs participated; consensus was achieved on most recommendations and partial consensus on six. At Delphi Round 2, 18 HCPs participated. After two Delphi rounds, consensus was achieved on all 32 recommendations. All recommendations were considered 'high priority' except one that was considered 'medium priority'.

Conclusion

Through this study it was possible to develop and prioritise policy recommendations to enhance medication safety, which may contribute to reducing MEs in ICUs across Europe. All recommendations were considered 'high priority' for implementation except one, indicating the perceived value of these recommendations in improving medication safety through preventing MEs from occurring in ICUs.

Definitions

In the field of medication errors there are many terms that describe or are closely related to the term 'medication error'. The EAHP Special Interest Group for the Investigation of Medication Errors in Intensive Care Units agreed to adopt the following definitions for the terms connected to medication errors:

A medication error (ME) is '*an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient: such a failure in the drug treatment process does not refer to lack of efficacy of the drug, rather to human or process mediated failures*' (EMA 2015). The error could have caused harm (a near-miss) or has caused harm (an error) to a patient.

The definition of an ME by the European Medicines Agency (EMA) is broad and includes any *preventable mistake or failure*, at any stage of the medication use process; prescribing, dispensing, storing, preparation for administration, and administration of a medicinal product by all persons involved (EMA 2015). It is conceptually very similar to other definitions, such as by the US National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP 2022): 'a medication error is any *preventable event* that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer', which has been advocated by the World Health Organization (WHO 2016).

An adverse event – a broader term – is defined as '*any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment*' (EMA 2015). An adverse event can be further described as '*any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product*' (EMA 2015).

An adverse drug event (ADE) is a term used to differentiate a medication related adverse event from other types of adverse events, e.g. retained foreign object post procedure or falls (EMA 2015); i.e. 'a medication related adverse event resulting either because of a pharmacological reaction to a normal dose, or because of a medication error' (WHO 2002).

An adverse drug reaction (ADR) is '*a response to a medicinal product which is noxious and unintended (Directive 2001/83/EC, Article 1 (11)) and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function*' (Council of Europe 2006). In contrast to an adverse event, an ADR is denoted

by a suspected causal relationship between the medicinal product and the occurrence (EMA 2017). Thus, a difference between a ME, an ADE and an ADR is that an ADE and an ADR, by definition, cause harm to a patient, whereas a ME does not necessarily cause harm to a patient (Figure 1). There is also a difference in preventability: an ME is, by definition, preventable, and an ADE may be preventable whereas an ADR is non-preventable.

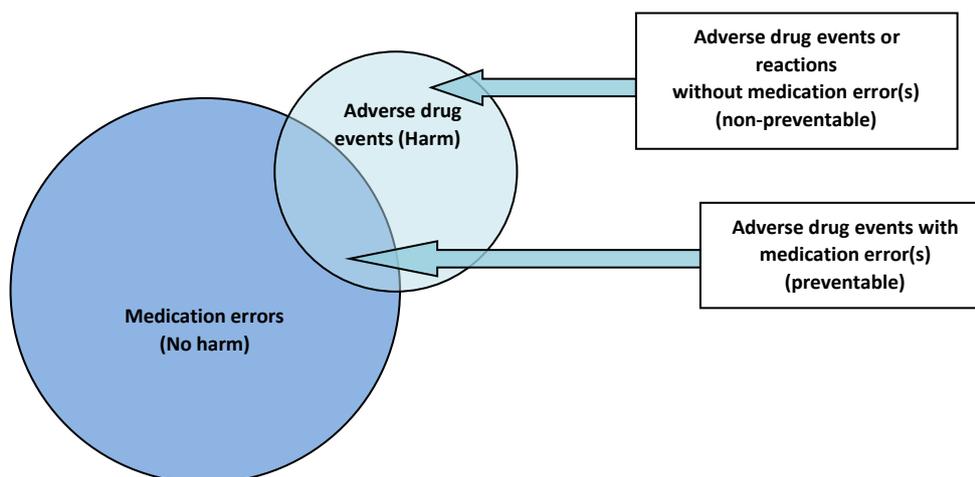


Figure 1. Relationship between adverse drug events (ADEs), adverse drug reactions (ADRs) and medication errors (MEs) (modified from, and based on, EMA (2015) and Morimoto et al. (2011)).

A Drug-Related Problem (DRP) is an event or circumstance involving drug or medicine therapy that actually or potentially interferes with desired health outcomes (Basger et al. 2014).

Background

MEs are considered one of the major causes of morbidity and mortality in the health care system (Kohn 2000). Patients admitted to intensive care units (ICUs) are more susceptible to MEs due to the complexity and intensity of treatments they receive (Kane-Gill, Jacobi & Rothschild 2010). Factors related to the patient, e.g. scarce physiological reserve of the critically ill patients, may increase the potential for harm from MEs; ICU patients are also generally incapable of identifying MEs by themselves because they are sedated and/or intubated (Hussain, Kao 2005, Kane-Gill, Jacobi & Rothschild 2010). The nature of error causation may vary between the different types of ICUs and the age of the patient (neonate, paediatric, adult or elderly) receiving care (Krzyzaniak 2016). Factors related to the medications, e.g. the higher number of medications, increased use of high-risk medications, administration of parenteral medications (mainly prescribed as continuous infusions, where the doses are calculated on a patient-specific basis determined by variables such as patient's weight, renal and hepatic function), and environmental factors, e.g. distractions, occurring in the ICUs, may be contributing factors to MEs (Kane-Gill, Jacobi & Rothschild 2010).

Although MEs in patients admitted to ICUs can happen at any phase of the medication use process (prescribing/ordering, transcribing/documenting, preparation, dispensing, administration, and monitoring) (Kane-Gill, Jacobi & Rothschild 2010), MEs have most frequently been reported at the administration stage (9.8 to 63%) (Paixão Nunes et al. 2013, Escrivá Gracia et al. 2021, Eslami et al. 2019, Krzyzaniak 2016, Agalu et al. 2012, Vazin, Delfani 2012, Haghbin et al. 2016), followed by prescription (6.8 to 43%) (Haghbin et al. 2016, Escrivá Gracia et al. 2021, Schellack et al. 2017, Vazin, Delfani 2012), transcription (3.3 to 18.4%) (Haghbin et al. 2016, Escrivá Gracia et al. 2021, Krzyzaniak 2016, Vazin, Delfani 2012) and dispensing stages (0.78 to 2.3%; up to 25% in the neonatal ICU) (Haghbin et al. 2016, Krzyzaniak 2016, Schellack et al. 2017, Vazin, Delfani 2012).

A series of error prevention strategies have been shown to reduce medication errors, e.g. computerised prescriber order entry (CPOE), clinical decision support systems (CDSS), bar-code medication administration (BCMA) technology, smart infusion pumps, the presence of clinical pharmacists in ICUs, medication reconciliation, education on appropriate medication use and communication at transfer of care (Krzyzaniak 2016, Santesteban et al. 2015, Rice et al. 2021). Additionally, an existing patient safety culture may influence medication safety: a positive patient safety climate is linked to a reduced rate of MEs. While "patient safety culture" comprises the shared beliefs, values, attitudes, and behaviours regarding safety within an organisation (Singer, Vogus 2013), its components can be measured as "patient safety climate". A positive response score of 75% or

above has been used as an indicator of a positive patient safety climate (Profit et al. 2012, Abdi et al. 2015, de Lima Silva Nunes et al. 2021, Vitorio, Tronchin 2020, Al-Mugheed, Bayraktar 2020, Lira et al. 2020, Zenere et al. 2016, Tawfik et al. 2019), but, globally, the patient safety climate in ICU settings varies widely. In the UK and the US, a more positive climate has been reported (France et al. 2010, Tarling et al. 2017, Thomas, Lomas 2018), however, while most studies have reported scores above 50%, they did not reach the 75% threshold (France et al. 2010, Vitorio, Tronchin 2020, de Lima Silva Nunes et al. 2021, Lira et al. 2020, Abdi et al. 2015, Profit et al. 2012, Tawfik et al. 2019, Zenere et al. 2016). The nursing perspective has been studied, and the nurses' perception of patient safety climate has been reported to have been lower than that reported by physicians or other professional groups (Abdi et al. 2015, Thomas, Lomas 2018, Dunstan 2020, Profit et al. 2012).

In studies conducted within Europe, themes that tended to score lowest were work environment, in particular staffing (Tarling et al. 2017) tiredness at work (Thomas, Lomas 2018, Al-Mugheed, Bayraktar 2020) and stress recognition (Al-Mugheed, Bayraktar 2020). In some central European countries, scores for punitive response to error, and error reporting, suggested that a blame culture may still exist (Gurkov et al. 2019) and in Italian NICUs, the lowest domain scores were related to the perception of management and highest to stress recognition (Zenere et al. 2016). Globally, the issues negatively affecting patient safety climate perspectives also included perceptions of management (Dunstan 2020, Lira et al. 2020, Vitorio, Tronchin 2020) and teamwork climate (Abdi et al. 2015). While previous studies have identified contributing factors to MEs and strategies that could prevent them, little is known about ME prevention strategies currently in use or planned in ICUs across Europe, as well as which facilitators or barriers to the implementation of these ME prevention strategies exist. Evidence on patient safety culture as experienced by different healthcare professionals (HCPs) working in ICUs across Europe is also limited.

Special Interest Group for the Investigation of Medication Errors in Intensive Care Units

The European Association of Hospital Pharmacists (EAHP) set up a Special Interest Group (SIG, Appendix I) for the Investigation of Medication Errors in ICUs, which was tasked with developing recommendations for reducing MEs in ICU settings across Europe. Becton, Dickinson & Co. financially supported the work of the SIG; the SIG's work, decisions and outcomes were independent from this financial support. The members of the SIG were HCPs working within ICUs or working as medication safety experts across Europe and may be viewed as representatives of prospective research

participants. The SIG contributed to the design of the research to develop and prioritise policy recommendations to support medication safety improvement in intensive care settings across Europe.

The SIG started its work in summer 2021, with the first meeting taking place in September 2021, and concluded its activities in January 2023. During this period, the SIG conducted literature reviews to determine the prevalence of MEs, to identify potential sources, causes and contributing factors to MEs, and to identify prevention strategies for improving medication safety in the ICU environment. The SIG then developed and conducted the research, utilising quantitative (an e-survey with ICU HCPs) and qualitative (focus group discussions with ICU and medication safety HCPs) methods to collect information on medication safety strategies in use and patient safety culture and medication safety across ICUs within Europe. Lastly, the SIG utilised a Delphi panel to prioritise policy recommendations for medication safety development within the ICU environment developed based on the findings of the literature review, the survey, and the focus group discussions. This report summarises the findings of the SIG's work.

European Statements of Hospital Pharmacy

In 2014, EAHP adopted the European Statements of Hospital Pharmacy that express commonly agreed objectives which every European health system should aim for in the delivery of hospital pharmacy services (EAHP 2014). The work of EAHP's SIG for the Investigation of Medication Errors in Intensive Care Units links to the following Statements:

Statement 4.2

“All prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist. Whenever the clinical situation allows, this review should take place prior to the supply and administration of medicines.”

Statement 4.3

“Hospital pharmacists should have access to the patients' health record. Their clinical interventions should be documented in the patients' health record and analysed to inform quality improvement interventions.”

Statement 4.4

“All the medicines used by patients should be entered on the patient’s medical record and reconciled by the hospital pharmacist on admission. Hospital pharmacists should assess the appropriateness of all patients’ medicines, including herbal and dietary supplements.”

Statement 4.5

“Hospital pharmacists should promote seamless care by contributing to transfer of information about medicines whenever patients move between and within healthcare settings.”

Statement 5.1

“The “seven rights” (the right patient, right medicine, right dose, right route, right time, right information, and right documentation) should be fulfilled in all medicines-related activities in the hospital.”

COMMENT – Ensuring there is comprehensive recording of allergies is a responsibility of all professionals within the multidisciplinary team. Hospital pharmacists should share this responsibility where there is no allergy record for a patient.

Statement 5.4

“Hospital pharmacists should ensure the reporting of adverse drug reactions and medication errors to regional or national pharmacovigilance programmes or patient safety programmes.”

Statement 5.5

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

Aims and objectives

The aims of this study were to explore medication safety within ICU environment across Europe and to develop policy recommendations to enhance medication safety.

Objectives

- To determine the prevalence of MEs, to identify potential contributing factors to MEs, and to identify prevention strategies for enhancing medication safety in the ICUs;
- To identify ME prevention strategies in use in ICUs across Europe;
- To explore patient safety culture and medication safety in ICUs across Europe;
- To explore factors influencing implementation of ME prevention strategies in ICUs across Europe;
- To develop policy recommendations for medication safety improvement in ICUs across Europe; and
- To prioritise the policy recommendations for enhancing medication safety in ICUs across Europe.

Study design

The mixed-methods prospective cross-sectional study comprised four phases. In the first phase, previous literature was utilised to identify the prevalence of MEs, contributing factors to MEs, and implemented ME prevention strategies within the ICU environment. In a second phase, a survey was employed to identify MEs prevention strategies both currently in use and being planned in ICUs across Europe. In a third phase, focus group discussions were used to explore patient safety culture and factors influencing implementation of ME prevention strategies in ICUs across Europe. Based on the literature review, the findings of the survey and the focus group discussions, in a fourth phase, the SIG developed policy recommendations for medication safety improvement in ICUs across Europe. A Delphi panel was utilised to agree upon, and prioritise the implementation of, the developed policy recommendations.

Literature review

Materials and methods

To complete the literature review, the SIG undertook three systematic literature searches as part of the study: the first to determine the prevalence of MEs, the second to identify potential contributing factors to MEs, and the third to explore strategies used to prevent MEs in the ICU environment. Two working groups (WG) of the SIG completed the searches and the reviews. WG 1 was formed by five HCPs of which four were hospital pharmacists practising in ICUs and one was a critical care physician. WG 2 was formed by four pharmacists of which two were actively working in the ICUs of their university hospitals, one was a medication safety pharmacist, and the fourth member was a pharmacist working in academia for whom medication safety and patient safety are areas of research. The members of the two groups were based in different European countries.

The systematic literature searches were conducted with key words (Tables 1, 2, and 3) between October 2021 and November 2021 following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline. The following electronic databases Web of Science, PubMed, Medline, Embase, CINAHL and Google Scholar were searched for original studies. Records were identified using MeSH and Boolean terms by title and abstract screening.

Table 1. Key words used in the systematic literature searches to identify original studies on the prevalence of medication errors in ICU settings.

Error related terms
<i>ME OR medication error OR preventable adverse drug event</i>
AND Intervention related terms
<i>prevalence OR frequency OR risk OR incidence</i>
AND Setting related terms
<i>intensive care unit OR ICU OR critical care unit OR NICU OR PICU</i>

Table 2. Key words used in the systematic literature searches to identify original studies on the potential threats to medication safety in the ICU environment, i.e. contributing factors to medication errors.

Error related terms
<i>ME OR medication error OR preventable adverse drug event</i>
AND Intervention related terms
<i>causes OR risk factors OR contributing factors</i>
AND Setting related terms
<i>intensive care unit OR ICU OR critical care unit OR NICU OR PICU</i>

Table 3. Key words used in the systematic literature searches to identify original studies on the strategies used to prevent medication errors in the ICU.

Error related terms
<i>“medication error” OR “drug error” OR “treatment error” OR “therapeutic error” OR “drug safety” OR “medication safety” OR “medical error” OR “patient safety” OR “incident report” OR “medication related harm” OR “drug related adverse event” OR “adverse drug event” OR “potential adverse drug event” OR “adverse medication event” OR “adverse drug incident” OR “adverse drug effect” OR “adverse drug outcome” OR “adverse drug complication” OR “adverse medication incident” OR “adverse medication reaction” OR “adverse medication effect” OR “adverse medication outcome” OR “adverse medication complication” OR “near miss” OR “medication incident” OR “drug incident” OR “prescribing error” OR “prescription error” OR “inappropriate prescribing” OR “administration error” OR “dispensing error” OR “transcription error” OR “drug-related problem”</i>
AND Intervention related terms
<i>“CCU” OR “ICU” OR “intensive care unit” OR “paediatric intensive care unit” OR “paediatric intensive care unit” OR PICU OR “child intensive care unit” OR “neonatal intensive care unit” OR “new-born intensive care unit” OR “NICU”</i>
AND Phenomenon of interest
<i>“trial” OR “quality improvement” OR “program*” OR “intervention*” OR “quasi-experimental” OR “before-after study” OR “literature review”</i>

The inclusion criteria for all three searches were: only events defined as MEs and preventable ADEs (including potential events); ICU environment (including NICU and PICU); all stages of medication use process; in English language. Concerning the strategies for ME prevention, an inclusion criterion was studies that have evaluated interventions used to prevent MEs. The time frame for the searches were:

2011-2021 for prevalence studies; 2016-2021 for studies about potential threats to medication safety; and from 2001 to present day for studies about strategies of ME prevention.

The exclusion criteria for all three searches were: non-preventable ADEs (adverse drug event); ADR (adverse drug reaction); DRP (drug related problem) where preventable ADEs or MEs could not be extracted; articles where only ICU data were not extractable; studies with exclusively voluntary reporting or incident reports; studies with special type of medication or specific treatment. For prevalence literature review: studies without prevalence data expressed as numerical results and with denominators (for instance: patient-days, number of patients, admissions, administrations, charts). In pre/post intervention studies, only data from pre intervention were used. For articles describing errors at transition of care, only data that originated from ICU were used. Concerning the strategies for prevention, exclusion criteria were systematic reviews; studies that only reported on epidemiology of MEs; studies only containing qualitative information or research; studies of ADRs that did not allow data on preventable ADEs to be studied separately; studies where ICU data were not extractable.

Results

Altogether, 20 original studies on the prevalence of MEs in ICUs were selected (setting ICU (n=16), NICU (n=1) and PICU (n=3)). Threats to medication safety, i.e. contributing factors to MEs, in intensive care settings were identified in 22 original studies (setting ICU (n=12), NICU (n=6), PICU (n=1), and NICU/PICU (n=3)). Finally, 38 original studies presenting strategies used to prevent MEs in the ICU (n=22), NICU (n=9), PICU (n=6) and NICU/PICU (n=1) were found. The identified literature (Tables 4, 5 and 6) was reviewed.

Prevalence of medication errors in intensive care settings

While 20 original studies exploring the prevalence of MEs in ICUs between 2011 and 2021 were identified (Table 4), various study designs (prospective, retrospective, direct observation, chart review studies) were employed in these studies making comparisons across the studies difficult. Eight of the studies explored the prevalence of MEs in only one stage of the medication use process (Agalu et al. 2012, Tully et al. 2019, Sada et al. 2015, Al-Jaghbeer et al. 2016, Horri et al. 2014, Kadmon et al. 2020, Paula et al. 2014, Jones and Cowley 2021). Nine studies, exploring the prevalence of MEs in multiple stages of the medication use process in ICUs, have estimated the prevalence of MEs in ICUs to be in the range of 38.2 to 363 MEs/100 patients (Escrivá Gracia et al. 2021, Aljadhey et al. 2013), 9.2 to 967 MEs/1000 patient-days (Carayon et al. 2014, Jennane et al. 2011, Morimoto et al. 2011, Aljadhey

et al. 2013), 10 to 98 MEs/100 medication orders (Paixão Nunes et al. 2013, Jennane et al. 2011) or 12 to 69.7 MEs/100 doses (Escrivá Gracia et al. 2021, Vazin and Fereidooni 2012).

Table 4. Prevalence of medication errors (ME) in intensive care settings (intensive care units (ICU), neonatal intensive care units (NICU) and paediatric intensive care units (PICU)) in literature identified between 2011 and 2021.

Primary author, year and country	Method used	Type of ME or preventable ADE	Outcomes Prevalence of Medication errors in intensive care settings
ICU			
(Jennane et al. 2011) Morocco	Prospective observational cohort study (voluntary and verbally report; chart review of prescriptions and transcriptions by trained nurses, pharmacist, and physicians)	prescription, ordering, transcription, dispensing, administration, and monitoring MEs and potential ADEs	10 ME/ 100 orders and 967 ME/ 1000 patient-days and 2.28 potential ADE/ 100 orders and 222 potential ADE/ 1000 patient-days (1 ICU (12 beds); 63 patients (509 patient-days, and 4942 prescriptions))
Morimoto et al. 2011, Japan	Cohort study (reviews of charts, laboratories, incident reports, and prescription queries by on-site reviewers)	prescription, ordering, transcription, dispensing, administration, and monitoring	17 ME / 1000 patient-days (in ICU) (3 ICU wards; 459 patients)
(Agalu et al. 2012), Ethiopia	Prospective observation based cross-sectional study, direct observation and chart review	administration	51.8 ME / 100 administrations (1 ICU, 54 patients)
(Vazin, Delfani 2012), Iran	Disguised direct observation method (trained pharmacist)	prescription, administration, transcription, and dispensing	7.6 ME /100 opportunities for error 442 errors per 5785 opportunities for error (1 ICU, 11 beds, 38 shifts)
(Vazin and Fereidooni 2012), Iran	Disguised direct observation method (trained pharmacy student)	prescription, transcription, and administration	69.7 ME / 100 doses (307 doses (observations))
(Aljadhey et al. 2013), Saudi Arabia	Prospective cohort study (Pharmacists reviewed medical records for ADE and ME)	ordering, transcription, dispensing, and administration	38.2 ME / 100 patients (admissions) and 36.2 / 1000 patient-days (2 ICU; 175 patients)
(Paixão Nunes et al. 2013), Brazil	Retrospective analysis (review of medical orders by trained pharmacist and nurse)	prescription, transcription, checking and administration	98 ME /100 orders (in ICU) (233 patients)
(Carayon et al. 2014), USA	Cross-sectional study	ordering, transcription, dispensing, and administration	0.4 events per patient-day. Preventable or potential ADEs occurred in 2.6% of the medication orders. The rate of potential ADEs per 1,000 patient-days was 276 and the rate of preventable ADEs per 1,000 patient-days was 9.2 (2 ICU, 630 patients)
(Paula et al. 2014), Brazil	Retrospective database review (ICU admissions)	administration	4.8 ME / 100 patients (admissions) (1 ICU; 1067 patients (admissions))

(Cuesta-Montero et al. 2015), Spain	Prospective observational study (review of medical records)	prescription, transcription and administration, monitoring	38.6 ME / 100 observations (634 observations)
(de Azevedo et al. 2015), Brazil	Retrospective cross sectional study (review using data collection tool, checked by two experts)	prescription, ordering, transcription, dispensing, administration and monitoring	97.4 ME-hospitalisation/ 100 hospitalisations (116 patients (hospitalisations))
(Sada et al. 2015), Ethiopia	Retrospective cross-sectional analysis of patient cards and medication charts	prescription	40 ME per 100 orders (359 ME) (220 patient charts, 1311 patient-days, 882 prescription episodes)
(Al-Jaghbeer et al. 2016), USA	Retrospective review of hospital readmission following ICU discharge (medical chart)	MEs at discharge from ICU	1 ME/ 136 patients readmitted in ICU (1 ICU; 136 patients)
(Tully et al. 2019) USA and the Netherlands	7-day point prevalence study during transition of care	prescription	45.4 ME/ 100 patients (985 patients transferred)
(Zirpe et al. 2020), India	Prospective observational study (medication chart review method)	prescription, transcription, indenting, dispensing, and administration errors	6.11 ME/ 100 medication charts or patients (1 ICU; 6,705 patients (medication charts))
(Escrivá Gracia et al. 2021), Spain	Descriptive, longitudinal and retrospective study (systematic analysis of the prescription, transcription and administration records)	prescription, transcription, and administration	12 ME/100 doses; with an average of 0.6 errors per day of stay and 3.63 per patient (87 patients; 2634 dose units of medications)
NICU			
(Horri et al. 2014), France	Retrospective study (chart review manually prescribed drug dosages)	dosage prescription	31 ME and 38 ME/ 100 prescriptions (2 NICU: together 224 newborns)
PICU			
(Haghbin et al. 2016), Iran	Prospective direct observational study (trained pharmacist observed prescription, administration, transcription, and dispensing)	prescription, administration, transcription, and dispensing	48.8 ME/100 orders (41 patients)
(Kadmon et al. 2020), Israel	Retrospective review (electronic prescriptions; by a computerized physician order entry with clinical decision support system)	prescription	1.6 ME/ 100 electronic prescriptions with clinical decision support system (1 PICU (12 beds); 292 patients; 6250 prescriptions)
(Jones and Cowley 2021), UK	Prospective data collection (transcription chart review by pharmacist)	transcription	35 ME (one or more)/ 100 transcription charts (29 patients (PICU discharge transcription charts))

Contributing factors to medication errors in intensive care settings

Contributing factors to MEs in ICU settings were identified in 22 original studies between 2016 and 2021 (Table 5). These studies provide evidence of potential contributing factors to MEs that should be minimised to improve medication safety. The studies employed various cross-sectional or longitudinal, prospective or retrospective study designs, including action research, chart review, direct observation, intervention and interview studies.

Several commonly identified contributory factors to MEs have been reported (Table 5). These were related to poor management and organisation (Eltaybani et al. 2019, Alghamdi et al. 2021, Duarte et al. 2020, Farzi et al. 2017a, Arboit et al. 2020, Gao et al. 2019, Khoo et al. 2017, Truter et al. 2017), high workload, lack of staff (Eltaybani et al. 2019), and fatigue (Duarte et al. 2020, Zhang et al. 2017, Arboit et al. 2020, Chalasani, Ramesh 2017), inadequate guidelines, or design of systems or protocols (Alghamdi et al. 2021, Arboit et al. 2020), distractions, interruptions (Eltaybani et al. 2019), and lack of attention (Duarte et al. 2020, Farzi et al. 2017a, Suclupe et al. 2020, Sasaki et al. 2019), lack of knowledge and education (Escrivá Gracia et al. 2021, Zhang et al. 2017, Arboit et al. 2020, Gao et al. 2019, Khoo et al. 2017, Truter et al. 2017, Eltaybani et al. 2019), poor communication (Eltaybani et al. 2019) and interaction (Farzi et al. 2017a, Chalasani, Ramesh 2017, Gao et al. 2019, Farzi et al. 2017b, Moudgil et al. 2021, Vafae Najar et al. 2016), poor environment and lack of material resources (Farzi et al. 2017a, Zhang et al. 2017, Duarte et al. 2020, Eltaybani et al. 2019), insufficient information (Zhang et al. 2017, Vafae Najar et al. 2016) and lack of interest (Arboit et al. 2020).

Additionally, patient related factors (Alghamdi et al. 2021, Chalasani, Ramesh 2017, Palmero et al. 2019) such as number of medications (Bharathi et al. 2020, Escrivá Gracia et al. 2021, Kadmon et al. 2020, Palmero et al. 2019, Tully et al. 2019) type of medications or treatment (Alghamdi et al. 2021, Tully et al. 2019) length of stay (Bharathi et al. 2020, Escrivá Gracia et al. 2021, Kadmon et al. 2020) patient transfer between units (Bharathi et al. 2020, Tully et al. 2019), and low health literacy, including altered level of consciousness, or communication difficulty of patients (Eltaybani et al. 2019), may contribute to the occurrence of MEs in ICU environment.

Table 5. Contributing factors to medication errors (MEs) in intensive care settings (intensive care units (ICU), neonatal intensive care units (NICU) and paediatric intensive care units (PICU)) in literature identified between 2016 and 2021.

Primary author, year and country	Method used	Healthcare professionals (HCPs) and processes involved	Contributing factors to medication errors (Mes)
ICU adult			
(Chalasan, Ramesh 2017), India	Prospective, voluntary, open, anonymous, and stand-alone surveillance	<u>HCPs</u> : medical staff <u>Processes involved</u> : prescribing, distribution, and administration	Excessive workload, fatigue, unclear interpersonal communications, and patient-related factors, which accounted for 37.6%, 13.1%, 9.6% and 7.7%, respectively.
(Farzi et al. 2017a), Iran	Descriptive qualitative method (interviews)	<u>HCPs</u> : members of the healthcare team (a physician, a nurse, and a clinical pharmacist) <u>Processes involved</u> : all medication process	Low attention, lack of communication, environment, management.
(Farzi et al. 2017b), Iran	Descriptive qualitative method (semi-structured interviews)	<u>HCPs</u> : members of the healthcare team (a physician, a nurse and a clinical pharmacist) with at least 1 year of work experience in intensive care units <u>Processes involved</u> : all medication process	“Weak interprofessional interaction (physician and nurse)”, “weak intraprofessional interaction (among physicians)”, and “weak interaction of physician as well as nurse with the patient and family.”
(Rezaianin et al. 2018), Iran	Descriptive-analytical study: self-administered questionnaires). Work commitment (the extent to which nurses felt responsible for care on their unit) measured using scale by Minick & Harvey 2003.	<u>HCPs</u> : nurses <u>Processes involved</u> : all processes	Low work commitment in ICU nurses correlated with high number of MEs.
(Eltaybani et al. 2019), Egypt	Qualitative study (semi-structured interview)	<u>HCPs</u> : nurses <u>Processes involved</u> : all processes	80.7% of nurses had no skill or professional development activities before the time of the error. One-quarter of nurses had a combined role (direct patientcare and supervisory role) at the time of the error. Patients with low health literacy and communication difficulty were involved in 54.0% and 38.7% of the reported errors, respectively. System factors were involved in 84.3% of the reported errors, with managerial and environmental factors involved in 64.3%

			and 38.3% of the errors, respectively. More errors occurred during the evening shift (2–8 p.m.) than the night (8 p.m.–8 a.m.) and morning (8 a.m.–2 p.m.) shifts: 42.7% versus 28.7% and 16.7%, respectively, with a mid-evening shift peak and two additional peaks in the middle of the night and morning shifts. The highest rate of death-associated errors (4.3%) occurred in the middle of the night shift.
(Escrivá Gracia et al. 2019), Spain	Mixed (multi-method) study with three phases that combined quantitative and qualitative techniques (before and after study)	<u>HCPs:</u> nurses <u>Processes involved:</u> administration	Knowledge. The main risk areas were errors in the interval of administration of antibiotics; high-risk medication dilution, concentration, and infusion-rate errors; and errors in the administration of medications via nasogastric tubes.
(Gao et al. 2019), China	Observational study design (Incident report system)	<u>HCPs:</u> medical staff <u>Processes involved:</u> all medication process	<u>Human factors:</u> inexperienced operation and violation in standard operation procedure, the complexity of operative care itself. <u>Medical procedure incidents:</u> poor communication and unclear lines of authority among medical personnel.
(Tully et al. 2019), USA and the Netherlands	Multicentre, retrospective, 7-day point prevalence study	<u>HCPs:</u> pharmacists <u>Processes involved:</u> transition of care (ICU to non-ICU)	Renal replacement therapy during ICU stay and number of medications ordered following transfer from ICU to non-ICU.
(Arboit et al. 2020), Brazil	Descriptive-exploratory study with a qualitative approach (data collection: semi-structured interviews)	<u>HCPs:</u> nurses (ICU) <u>Processes involved:</u> all medication process	Institutional/organisational factors: work routine, patients' complex medical records, fragmentation of care, physical structure, and the number of nursing staff members. Human factors: lack of attention, shortage of employees, tiredness, lack of knowledge, distraction, workload, and lack of interest were highlighted.
(Suclupe et al. 2020), Spain	Retrospective, observational, analytical, cross-sectional and ambispective study (+review of medical records)	<u>HCPs:</u> nurses <u>Processes involved:</u> administration	The most frequent error was interruption during drug administration. Admission to the intensive care unit, nurses' morning shift and workload perception were risk factors associated with interruption.
(Escrivá Gracia et al. 2021), Spain	Descriptive, longitudinal and retrospective study (systematic analysis of the prescription, transcription and administration records)	<u>HCPs:</u> medical staff and nurses <u>Processes involved:</u> prescription, transcription, and administration	Number of medications; number of days of admission; association between causes of errors that were identified in the prescription and the subsequent errors made during the transcription.

(Moudgil et al. 2021) India	Prospective analysis involving purposeful sampling (review of medical records)	<u>HCPs</u> : medical staff and nurses <u>Processes involved</u> : prescribing	Prescription errors, which were due to illegible handwriting; the use of lookalike drugs; and incomplete dose, dosage, and frequency information.
NICU			
(Vafaei Najari et al. 2016), Iran	Descriptive cross-sectional study qualitative (action research) and quantitative (descriptive cross-sectional research) methods.	<u>HCPs</u> : two nurses (recommended by a head nurse), one physician, one Failure Mode and Effects Analysis (FMEA) expert (group leader), a group consultant in charge of risk management, and one person in charge of hospital quality improvement with a minimum of two years of clinical experience in the ICU. <u>Processes involved</u> : prescription and administration	Failure Mode and Effects Analysis (FMEA) technique identified five high-risk modes: Errors in prescription method; Incomplete comment in physician order; Allergic reaction of the patient to the prescribed drug; Prescription of drugs based on another patient's physician order; Errors in use of drugs with similar packages.
(Zhang et al. 2017), China	Grey Relational Analysis (self-incident reports from nurses)	<u>HCPs</u> : nurses <u>Processes involved</u> : prescription, transcription, distribution, administration and monitoring	Human factors; environmental; knowledge. The highest systemic risk factors were critical drug information missing; environmental, staffing, and workflow problems; and lack of staff education.
(Palmero et al. 2019) Switzerland	Voluntary incident report and direct observation (to determine rate of MEs and risk factors).	<u>HCPs</u> : pharmacists and caregivers <u>Processes involved</u> : all medication process	Significantly related to the occurrence of MEs were gestational age <32.0 week (p=0.04) and number of drugs prescribed (p<0.01)
(Sasaki et al. 2019), Brazil	Cross-sectional descriptive study using the observational method	<u>HCPs</u> : nurses and nursing technicians <u>Processes involved</u> : medication rounds (preparation, administration, and documentation)	Interruption: main causes of interruption, the most frequent being: information exchange, 54 (42.4%), conversations, 28 (22.1%), and alarms, 15 (11.8%). All occurred mainly during the medication preparation phase.
(Bharathi et al. 2020) India	Observational study (prospective observation and questionnaire (for mother))	<u>HCPs</u> : NICU staff <u>Processes involved</u> : prescribing, administration, risk factors e.g. length of stay	Polypharmacy, length of stay, transferred from another unit.
(Duarte et al. 2020), Brazil	A quantitative-qualitative, descriptive study (self-reporting and individual interviews)	<u>HCPs</u> : nurses <u>Processes involved</u> : all medication process	Work overload (tiredness and inattention), quantitative of human resources, lack and low quality of material resources, and problems related to leadership.
PICU			

(Kadmon et al. 2020), Israel	Retrospective review (electronic prescriptions; by a computerized physician order entry with clinical decision support system)	<u>HCPs</u> : paediatric intensive care physicians <u>Processes involved</u> : electronic prescribing	The error rate was twice as high in patients older than 12 years than in children 6-12 and 0-6 years old. Compared with patients without errors, patients with errors had a significantly higher score on the Paediatric Index of Mortality, longer PICU stay, and higher number of prescriptions per patient. Patients with errors were more likely to have a neurologic main admission diagnosis and less likely to have a cardiologic diagnosis than patients without errors.
NICU / PICU			
(Khoo et al. 2017), Malaysia	Cross-sectional multicentre study (chart review)	<u>HCPs</u> : pharmacists <u>Processes involved</u> : prescription	Most of the errors were attributed to human factors, i.e. performance or knowledge deficit. The most common contributing factors were due to lack of supervision or of knowledge.
(Truter et al. 2017), South Africa	Prospectively observational, quantitative, descriptive design with review of medication charts.	<u>HCPs</u> : medical staff, pharmacists and nurses <u>Processes involved</u> : prescription, dispensing, administration	Type of ME: prescribing error rate of 43% (95% confidence interval (CI) 39.6 – 46.9); administration error rate of 47.3% (95% CI 43.6 – 50.9); dispensing errors (2%). The causes of these MEs were mostly due to miscalculation (26%), failure to monitor (15%) and procedures not followed (15%).
(Alghamdi et al. 2021), UK	Mixed-methods analysis of anonymized medication safety incidents reports	<u>HCPs</u> : physicians, pharmacists and nurses. <u>Processes involved</u> : prescribing, documenting/transcribing, dispensing, administering, and monitoring	Staff-related factors (68.7%), such as failure to follow protocols or errors in documentation, which were often associated with working conditions, inadequate guidelines, and design of systems and protocols. The most commonly implicated error types were drug omission (n = 4812 [18.8%]) and dosing errors (n = 4475 [17.5%]). Anti-infectives (n = 6483 [25.4%]) were the medications most commonly associated with incidents and commonly involved neonates. Contributing factors by PISA (Patient SAFETY 26classification) system: factors related to patients (n = 62/1765 [3.5%]), medical staff/individual factors (n = 1212 [68.7%]), and organizational factors (n = 482 [27.3%]).

Strategies used to prevent medication errors in intensive care settings

ME prevention strategies used in ICU were identified in 38 original studies between 2003 and 2021 (Table 6). Many ME prevention strategies have been shown to reduce ME such as audit, feedback, education and training (Thomas et al. 2008, Taxis et al. 2013, van der Sluijs et al. 2019, Simpson et al. 2004, Nguyen et al. 2014, Mohan et al. 2019, Melia, Saha 2014, Martinez-Anton et al. 2012, Konda et al. 2021, Ford et al. 2010, Chedoe et al. 2012, Campino et al. 2008, Booth et al. 2012, Alagha et al. 2011, Smith, V. et al. 2021), the presence of clinical pharmacists in ICUs (Ibrahim et al. 2021, Sullivan et al. 2013, Otero et al. 2008, Malfara et al. 2018, Kessemeier et al. 2019, Maaskant et al. 2018, Michalets et al. 2015, Lee et al. 2007, Kucukarslan et al. 2013, Klopotoska et al. 2010, Campino et al. 2008) standardised prescriptions, electronic prescribing (EP) or CPOE (Hogden et al. 2005, Dabliz et al. 2021, Colpaert et al. 2006, Bourdeaux et al. 2014, Otero et al. 2008, Ibrahim et al. 2021, Martinez-Anton et al. 2012, Melia, Saha 2014, Mohan et al. 2019, Alagha et al. 2011, Khammarnia et al. 2017), CDSS (Morriss et al. 2009), rapid response system based on electronic medical records (You et al. 2021), computerised automated drug dispensing system (Chapuis et al. 2010), double-check (Douglass et al., 2017), bar-code medication administration (BCMA) or bar-code scanning technology (Morriss et al. 2009), smart infusion pumps (van der Sluijs et al. 2019), medication reconciliation (Bosma et al. 2018), standardised operating procedures (Melia, Saha 2014) and communication at transfer of care (Bosma et al. 2018).

There were different strategies used in PICUs and NICUs in order to achieve error reductions in these two settings, e.g. educational strategies including pocket tables with dosing guidelines, updated prescription protocols (Simpson et al. 2004, Chedoe et al. 2012, Martinez-Anton et al. 2012, Alagha et al. 2011, Campino et al. 2009), as well as quality measurements, e.g. Plan-Do-Study-Act quality improvement cycles (Konda et al. 2021). Some studies investigated interventions to modify the prescribing process; implementation of specific prescribing recommendations, improving environmental conditions, direct staff supervision and active interaction with pharmacists during rounds (Otero et al. 2008) and feedback provided by pharmacists to physicians (Sullivan et al. 2013). A wide range of HCPs were involved in these activities i.e. pharmacists, nurses, and doctors at all levels from consultants to trainees. All these approaches were shown to be effective in reducing ME rates, to varying extents.

Table 6. Strategies used to prevent medication errors (ME) in intensive care settings (intensive care units (ICU), neonatal intensive care units (NICU) and paediatric intensive care units (PICU)) in literature identified between 2001 and 2021.

Primary author, year and country	Strategy used	HCPs involved	Outcomes
ICU			
(Pronovost et al. 2003), USA	Discharge survey implemented as part of medicines reconciliation process	nurses, ICU residents	Pre-intervention: 94% of discharges had errors, reduced to 0% most weeks post intervention.
(Colpaert et al. 2006), Belgium	Controlled comparison of computerised prescriber order entry (CPOE) versus paper-based units	Physicians, pharmacists, nurses	ME rate significantly lower in computer-based unit (3.4%) versus paper-based unit (27%).
(Lee et al. 2007), USA	Clinical pharmacist participation (CPP)	Pharmacists	Increased error detection and recording. Averted MEs were higher in the phase involving the pharmacist.
(Thomas et al. 2008), UK	Education and audit tool	Physicians	Reduction of % ME over 3 months: pre 22%, post 13.3%, final audit 5%.
(Ford et al. 2010), USA	Controlled comparison of simulation-based versus didactic lecture educational interventions	Nurses	Simulation-based: 30.8 to 4%. No significant effect in error rates in didactic lecture group and increased over time. Both groups showed improvement in quiz scores post-intervention.
(Chapuis et al. 2010), France	Computerised automated drug dispensing system	Nurses, pharmacy technician, pharmacist	Difference in error rate of control – 18.6%, Intervention – 13.5%. Reduction in preparation and storage errors, but no significant effect on picking and administration errors.
(Klopotowska et al. 2010), the Netherlands	Clinical pharmacist participation (CPP)	Pharmacist (ICU staff via interventions)	Reduction in all prescribing errors from 190.5 to 62.5/100 patient-days. Reduction in prescribing errors that resulted in ADERs from 4 to 1/1000 patient-days. Reduction in potentially harmful prescribing errors from 53.1 to 16.1/1000 patient-days. Reduction in prescribing errors with no patient harm from 132.9 to 45.4/1000 patient-days. Cost savings between 26-40 euro per patient-day.
(Kucukarslan et al. 2013), USA	Clinical pharmacist participation (CPP)	Two pharmacists, critical care physician	Reduction of ADEs from 28 to 10/1000 patient-days. No significant differences between groups for cost and length of stay.
(Taxis et al. 2013), Vietnam	Training programme	Nursing staff	Error rate reduced 62.7% to 52.5% on intervention ward, no change in control ward 73.8% and 73.1%.
(Bourdeaux et al. 2014), UK	Computerised prescriber order entry (CPOE) – to increase prescribing of chlorhexidine mouthwash (CH) and	Physicians	Patients receiving HES: 54.1%, 3.1%. Patients receiving CH: 55.3%, 90.4% (pre, post). Improvement in adherence to prescribing guidelines.

	reduce inappropriate prescribing of hydroxyethyl starch (HES)		
(Nguyen et al. 2014), Vietnam	Training programme led by clinical pharmacist	Nurses	Reduction of errors: 64% to 48.9% study, 57.9% to 64.1% control. Intervention ward 2.6 times less likely to have an error. Error rate remained high post intervention.
(Melia, Saha 2014), UK	New standard operating procedures (SOP), standardised prescription sticker with common pre-printed infusion prescriptions, education how to use stickers	All staff	70% improvement in safe prescribing, 24% before and 94% after intervention fulfilled best practice criteria. (Cost-effective intervention: £20 for 6200 stickers).
(Michalets et al. 2015), USA	Clinical pharmacist participation (CPP) on ward increased from 1 to 3	Pharmacists	75% reduction in prescribing related ADEs, 29% increase in cost savings, 37% reduction in ADEs classified as category D or higher.
(Backman et al. 2018), Canada	'SafetyLEAP' programme; 1: leadership and engagement, 2: Audit and feedback, 3: planned improvement intervention	All ICU staff	Inconsistent results across 3 units; 2 ICUs completed the programme and demonstrated positive safety changes, however ICU 3 showed a lack of 'effort and determination' and led to limited deployment. Success was directly dependent on level of engagement.
(Douglass et al. 2018), USA	'Double check' method.	Nurses	54% of participants detected errors in control but 100% in study group where double check occurred.
(Khammarnia et al. 2017), Iran	Computerised prescriber order entry (CPOE)	Physicians	Before: error rate of 19.1%, 14.7% in intervention and control ICU respectively. After: 0.3%, 14.9%. Decrease in illegible error, no drug forms and no drug route error, but increase in wrong dose and form.
(Bosma et al. 2018), the Netherlands	Clinical pharmacist participation (CPP): Medication reconciliation at ICU admission and discharge	Pharmacist	ME at admission: 45% to 14.6%, on discharge 73.9% to 41.2%. Savings of 103 euro per patient
(Kessemeier et al. 2019), Germany	Clinical pharmacist participation (CPP). Phase 1 - pharmacist screening of medical records. Phase 2 - pharmacist screening of medical records and presence for ward rounds.	Pharmacists	Error rate reduction from 14.1% pre-intervention to 5.1% and 3.3% in Phase 1 and Phase 2 respectively.
(Mohan et al. 2019), India	Error sensitization programme, including education and changes to medication chart, and blame-free tool to report errors.	Physicians, nurses	ME incidence reduction from 9.1% to 3.5%.

(van der Sluijs et al. 2019), the Netherlands	Using the 'Lean' team to improve smart infusion pumps	Three ICU nurses, three senior ICU nurses and two intensivists (LEAN team)	Errors decreased from 17.7% pre-intervention to 2.3%.
(Dabliz et al. 2021), Australia (You et al. 2021), South Korea	Electronic medication management system (to support transfer of care) Rapid response system (RRS) based on electronic medical records, with/without automated alerting system (AAS)	Physicians Physicians, nurses	After an initial increase, error rate reduction of 20% at end of phase 2, with a further reduction of 95% in phase 3. In-hospital mortality decreased from 15.1 to 12.9 per 1000 admissions after RRS implementation. Severity of patient condition calculation increased from 2.5 in RRS without AAS to 3.6 with AAS
NICU			
(Simpson et al. 2004), UK	Pharmacist led education programme	Pharmacist, nurse, physicians	Error reduction from 24.1 to 5.1/1000 patient-days.
(Hogden et al. 2005) USA	Pre-printed prescription order form	Physicians	Increased compliance with prescription requirement guidelines.
(Campino et al. 2008) Spain	Observation (audit) by a clinical pharmacist	Nurses, prescribing physicians, pharmacists	Error reduction from 32.8% pre- to 19.2% post-intervention. Rates of incorrect dose fell from 13.6% to 5%, and lack of dose specification fell from 3.3% to 0.5%. No significant change in transcription errors.
(Campino et al. 2009) Spain	Comprehensive preventative educational strategy	Physicians	ME rate and % of registers with error went from 20.7% to 3% and 19.2% to 2.9% respectively. Correct identification of prescribing physician went from 1.3% to 78.2%.
(Morriss et al. 2009), USA	Barcode medication administration (BCMA) system (in addition to pre-existing computerised prescriber order entry (CPOE) and clinical decision support system (CDSS))	Nurses	Reduction of preventable ADEs by 47%
(Chedoe et al. 2012), the Netherlands	Educational intervention	Nurses	Post intervention 0% 'severe' errors (0.3% before). Total error incidence decreased from 49% - 31% - improvement but 'insufficient to achieve an adequate level of safety'.
(Sullivan et al. 2013) USA	Feedback provided biweekly to physicians by pharmacists.	Physicians, pharmacists	83% reduction in narcotic prescribing errors.
(Ibrahim et al. 2021) United Arab Emirates	1. Clinical pharmacist participation (CPP), 2. computerised prescriber order entry (CPOE), 3. smart infusion pumps (SIP), 4. NICU formulary	Neonatologists, clinical pharmacists, neonatal nurses, IT specialist	Error reduction from 25.7 to 6.7/1000 patient-days, sustained results in subsequent years.
(Konda et al. 2021) India	Plan-Do-Study-Act (PDSA) quality improvement cycle	Doctors at all levels from consultants to trainees	Reduction in inappropriately prescribed antimicrobials from 61 to 27% after 5 PDSA cycles.

PICU			
(Alagha et al. 2011) Egypt	1. provision of point of care drug use assists, 2. structured combined order and admin chart, 3. orientation for new residents, 4. Feedback	Nurses, physicians.	Baseline error rate: 78.1% after 35.6%. Parameters and results for different types of errors provided. 'error rate...is still considerable'
(Booth et al. 2012) 2012, UK	Zero tolerance prescribing (ZTP), daily error feedback	Nurses, physicians	Reduction in prescribing errors from 892 to 635/1000 patient-days, further reduction to 447/1000 patient-days with feedback.
(Martinez-Anton et al. 2012), Spain	1. standardisation of sources, 2. pocket tables with dosing guidelines, 3. updated prescription protocol, 4. education	Physicians	Error rate decreased from 34.2% to 21.7%. Identified legibility as an issue – 4.1% of prescriptions had at least one illegible component, reduced to 0.2% post intervention.
(Maaskant et al. 2018), the Netherlands	Clinical pharmacist participation (CPP)	Pharmacist	Reduction of errors from 2.27 to 1.74/100 prescriptions. Immediately after the start of the intervention, a nonsignificant decrease of 0.61/100 prescriptions; a 23% reduction of MEs.
Malfará et al. 2018, Brazil	Clinical pharmacist participation (CPP)	Pharmacist	Cost savings of US\$ 4828. 97% of recommendations accepted by physicians.
Smith et al. 2021, UK	1. daily round to prepare and administer opioid and sedation infusions. 2. development of medication safety workshop 3. increased access to resources	Nursing staff	The number of reported harmful errors, and errors that required monitoring or intervention to ensure no harm, decreased post intervention. The staff confidence attending the medication safety workshops significantly increased in all areas of medication safety.
NICU / PICU			
(Otero et al. 2008), Argentina	1. Modification in the process of prescription of medications, improving environment conditions and direct staff supervision, 2. Clinical pharmacist participation (CPP), and 3. implementation of the "10 steps to reduce medication errors" checklist	All ICU staff: nurses, physicians/physicians and pharmacists	Error rate reduction of 4.1%

Summary of the literature review

Three literature reviews with systematic searches were completed. In total, 20 original studies on the prevalence of MEs in ICUs were included between 2011 and 2021. Nine studies, exploring the prevalence of MEs in multiple stages of the medication use process in ICUs between 2011 and 2021, have estimated the prevalence of MEs in ICUs to be in the range of 38.2 to 363 MEs/100 patients, 9.2 to 967 MEs/1000 patient-days, 10 to 98 MEs/100 medication orders, or 12 to 69.7 MEs/100 doses. Potential contributing factors to MEs in ICUs were identified in 22 original studies between 2016 and 2021. These contributing factors to MEs were often related to systemic issues such as poor management and organisation, high workload, lack of staff, and fatigue, inadequate guidelines, or design of systems or protocols, distractions, interruptions, and lack of attention, lack of knowledge and education, poor communication and interaction, poor environment, and lack of material resources. While ME rates and their contributing factors vary between studies and ICU settings, the problem is real, and solutions are needed.

Solutions, or ME prevention strategies, for improving medication safety in the ICU environment were identified in 38 original studies between 2003 and 2021. Several ME prevention strategies tailored to the setting have been shown to reduce ME such as audit, feedback, education and training, integrating clinical pharmacists in ICU team, use of standardised prescriptions, CPOE or electronic medication management systems.

A survey of medication error prevention strategies in European intensive care units

Materials and methods

To identify ME prevention strategies in use in ICUs across Europe, one working group (WG 3), of the SIG conducted a survey. WG 3 was formed by three intensivists currently working in ICUs, one nurse formerly working in ICU and four pharmacists of which three were actively working in the ICUs of their University hospitals, and the fourth was a pharmacist working in academia for whom medication safety and patient safety are areas of research. The members of this group were based in different European countries.

Study design

An online cross-sectional descriptive survey was distributed via relevant professional networks across Europe to working HCPs in ICUs. This study is reported according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Eysenbach 2004).

Participant recruitment

Participants were invited through the EAHP, and other relevant national and European professional networks with which the SIG had connections, using emails, social media and promotion via the EAHP Congress 2022 (Appendix II). All HCPs in ICUs of all specialities, including adult, paediatric and neonatal, medical and surgical or a specialist medication safety role in their organisation within Europe, were eligible to take part. Sample social media invitations to take part are provided in Appendix II. Due to this 'open' method of dissemination, it was not possible to limit responses to one per organisation, and for this reason it was not possible to calculate a response rate. The recruitment took place between 25th March and 8th May 2022. Participation in the survey was voluntary and anonymous; the participants were asked to provide their informed consent to participate in this research.

Survey instrument

Survey questions were designed through a collaborative and iterative process among WG3, drawing on previous similar surveys (Matti et al. 2018, Otero et al. 2008, Kane-Gill, S. L. et al. 2017). The final draft of the survey was piloted amongst several HCPs with experience working in critical care, and minor changes were made to aid clarity. The survey questions were then uploaded to the online

'easyfeedback.com' platform before being tested again to ensure usability. Using a process of translation, followed by back-translation by two different bilingual speakers for each language, the survey was translated from English (Appendix III) into Estonian, French, German, Italian, Slovenian and Spanish, to provide access to the survey in some other languages spoken across Europe.

The survey invited respondents to review a list of about 40 practices for ME prevention and to indicate whether these were in use or being planned for use in their unit. These practices included (Appendix III) medication history and reconciliation processes, standardised procedures, implementation of EP, use of guidelines and restricted formularies, provision of pharmacy services in critical care, automated medication storage, independent double checks, smart infusion pumps, barcode scanning technology, medication review on discharge, and incident reporting. Some questions were 'nested' so that respondents were only asked more detailed questions where a particular system was in use e.g. questions regarding safety-related features of EP systems if they stated that they had EP in place. The survey also contained a 'free text' response section for participants to add any additional strategies in use that were not listed. The survey was presented using a template on the online platform that was designed to optimise completion on both desktop and mobile devices over about 15 online pages.

Responses to the questions were recorded using a 5-point Likert scale (Appendix III), allowing respondents to select whether a practice was 1) fully implemented for all patients, medication orders, medications or staff, 2) fully implemented for some patients, medication orders, medication or staff, 3) partially implemented for some/all patients, medication orders, medication or staff, 4) planned to be implemented within the next five years of the survey, 5) not implemented. Respondents could also select the option 'Unknown', if they did not know about the extent to which a practice or procedure was implemented in their ICU; none of the questions were mandatory. Respondents were able to review and change their answers at any time, by navigating through the survey using 'Back' and 'Forward' buttons, prior to submitting their survey.

The survey questions also included demographic data, including the profession and gender of the respondent, the type and size of the ICU they worked in, and the country in which they worked. The names of respondents or their organisations were not recorded.

Analysis

Anonymous survey responses were collated, reviewed, and cleaned if necessary. All data were translated into English by members of the SIG prior to analysis. Responses that did not meet the

inclusion criteria were excluded as part of the data cleaning process. Reasons for excluding data from analysis included:

1. Practising in a location outside of Europe;
2. Not providing consent to participate in full knowledge of the information in the participant information leaflet; and
3. Non-response to all survey questions relating to practices for ME prevention.

Surveys received from respondents that did not state a country of practice were retained since the survey had been actively promoted only in Europe; hence, these respondents were thought likely to practise in Europe. Partial responses to the survey were included.

Descriptive analysis was used to identify the medication safety practices most commonly used or planned for implementation. Responses to each question were analysed by the WG3 using Microsoft Excel® (version 2016 or newer) to calculate the overall response rate for each medication safety practice as a percentage. For a selection of key medication safety practices selected by WG3, responses were also analysed by European region. Countries were grouped as Northern, Southern, Eastern and Western Europe using a standard classification (United Nations 2022), and by specific country. Due to smaller numbers of responses for some regions and countries, these data were presented showing numbers rather than percentages. For the 'free-text' question on additional safety practices in use, responses were grouped and summarised thematically.

Ethical considerations

Ethical approval was obtained by UCL Research Ethics Committee (Project ID: 15283.003). The 'easyfeedback.com' platform is General Data Protection Regulation (GDPR) compliant, does not store IP addresses and stores all data within Europe. No personally identifiable data were collected, and the data obtained contained no information that would have reasonably allowed identification of any of the participants. No incentives were provided.

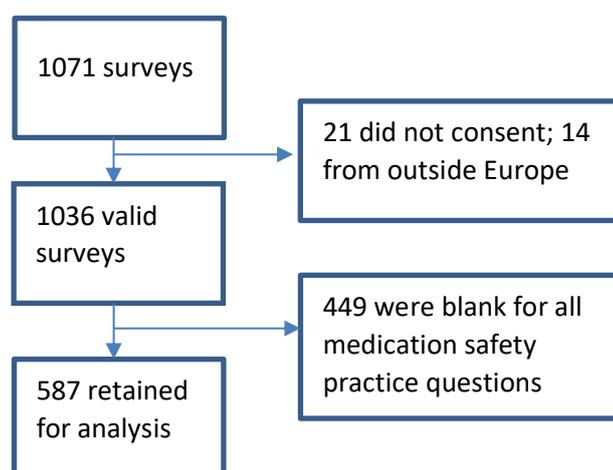
The first page of the survey contained an explanation of the study, how long the survey would take to complete, how the data would be stored and used, who was organising the study, who to contact with any questions, and a 'tick box' for participants to indicate that they had read this information and provide their consent to participate (Appendix II).

Results

Survey Responses

The survey received a total of 1,071 responses, of which 35 were removed during the data cleaning process: 21 participants did not tick “yes” to having read the patient information leaflet and/or did not tick “yes” to indicate consent; 14 further respondents had specified a country outside of Europe. A total of 443 (43%) of the remaining responses did not contain any answers for the questions relating to medication safety practices, and so these were also removed. Twelve responses gave no indication as to in which country the respondent was working but were retained as we assumed they were from Europe. The total number of responses after the data cleaning process and removal of blank surveys was 587, representing a completion rate of 57% of 1,036 (Figure 2).

Figure 2: Flow chart of the selection of survey participants included in the study.



Respondent demographics

Of the 587 respondents, 394 (67%) identified themselves as female, 182 (31%) as male, and one as non-binary. Four preferred not to indicate their gender, and six respondents did not answer this question. The profession of the respondents varied, with 157 (27%) identifying themselves as a doctor or anaesthetist, 107 (18%) as a nurse, midwife, student nurse or nurse anaesthetist, and 317 (54%) as pharmacists, pharmacy managers or chemists. Two respondents identified themselves as ‘other’ professions (unspecified) and four respondents did not answer this question. The countries with highest numbers of responses (Table 7) were Spain (n=99), France (n=79), Germany (n=43), United Kingdom (n=43), Estonia (n=42), Republic of Ireland (n=42) and Finland (n=38).

Table 7. Valid responses to the questionnaire, presented by country and grouped by region (n=587).

European regions and their countries	Number of responses
Northern Europe	202
Denmark	3
Estonia	42
Finland	38
Iceland	1
Latvia	4
Norway	3
Republic of Ireland	42
Sweden	26
United Kingdom	43
Eastern Europe	21
Bulgaria	2
Czech Republic	4
Hungary	2
Romania	10
Slovakia	3
Western Europe	167
Austria	8
Belgium	12
France	79
Germany	43
Luxembourg	3
Netherlands	3
Switzerland	19
Southern Europe	185
Bosnia and Herzegovina	1
Croatia	3
Greece	3
Italy	30
Malta	3
North Macedonia	1
Portugal	6
Serbia	3
Slovenia	28
Spain	99
Turkey	8
Not stated	12
TOTAL	587

Medication safety practices in intensive care settings across Europe

In the following sections, the medication safety practices most commonly used or planned for implementation in intensive care settings across Europe are presented. Additionally, responses to some of the medication safety practices are shown by European region. A more detailed breakdown of the responses to medication safety practices by country are provided in Appendix IV.

Questions omitted from surveys

On analysis it was identified that questions 22 and 23 (Appendix III) were omitted from the published Slovenian survey. These questions were nested within question 15 and only formed part of the survey if respondents selected 'Unknown', 'There has been no activity to implement this' or 'This is planned for implementation in the next 5 years'. Responses to questions 22 and 23 were therefore omitted for 10 respondents. The German questionnaire translation and, thus, the published survey, did not include questions 22, 25 and 30 (affecting 43 respondents). The French questionnaire translation and, thus, the published survey, did not include question 44 (affecting 79 respondents).

Medication history and medication reconciliation practices

Overall, the most widely reported patient safety practice across all ICUs was having patient allergies clearly visible to all HCPs who are involved with prescribing, reviewing, or administering medication, with 65% of respondents indicating that this practice was in place for all patients in their ICUs (Figure 3). In contrast, on admission to the ICU, only 31% of respondents reported having a standardised process in place for taking medication histories for all patients, 23% reported having a clear medication reconciliation process, and 22% that patients and carers were routinely involved in establishing medication histories for all patients.

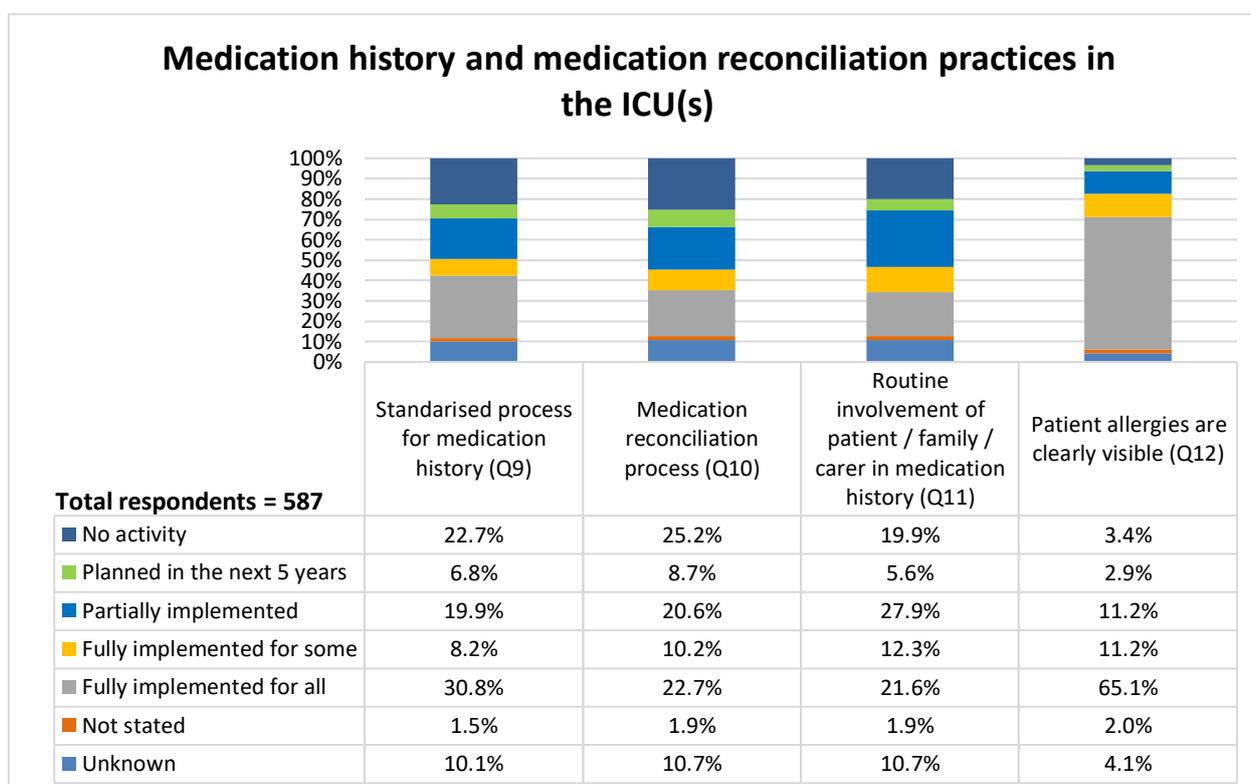


Figure 3 Responses to Questions 9-12 of the survey regarding medication history and reconciliation practices.

Overall, 53.5% of respondents reported having some form of medicines reconciliation process in use, whether that be fully or partially implemented (Figure 4). However, 66% of the respondents working in Northern Europe, 56% in Southern Europe, 40% in Western Europe, and 38% in Eastern Europe reported having some form of medicines reconciliation process in use.

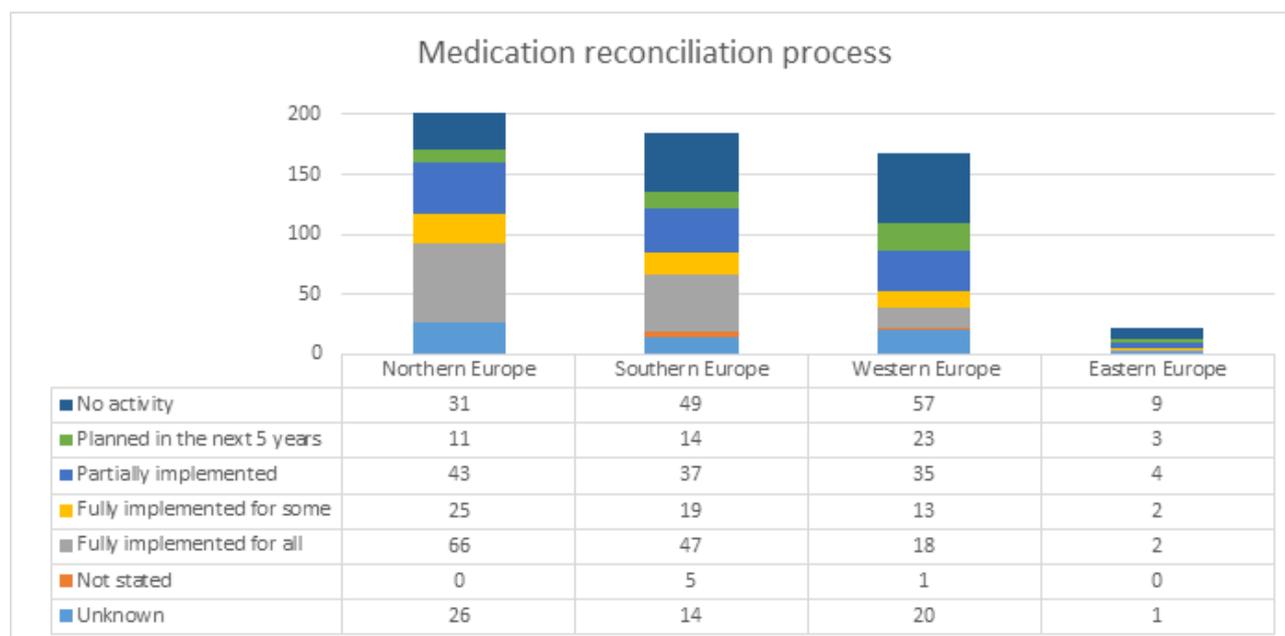


Figure 4. Responses to Question 10 of the survey regarding medication reconciliation process by region.

Standardised procedures and practices

The use of standardised concentrations for regularly used IV infusions was fully implemented within the ICU for 56% of the respondents' organisations (Figure 5). Overall, standardisation of concentrations for common infusions was used to some degree (fully implemented for some or partially implemented) for 85% of respondents' ICUs. Standardised procedures for verbal emergency orders, including retrospective documentation of the medication administered were fully implemented in 35% of the ICUs, and implemented to some degree in 65%. Only 4% and 14% of respondents indicated that there was no plan for their ICUs to use standardised concentrations for common infusions or implement a standardised procedure for verbal orders given in an emergency.

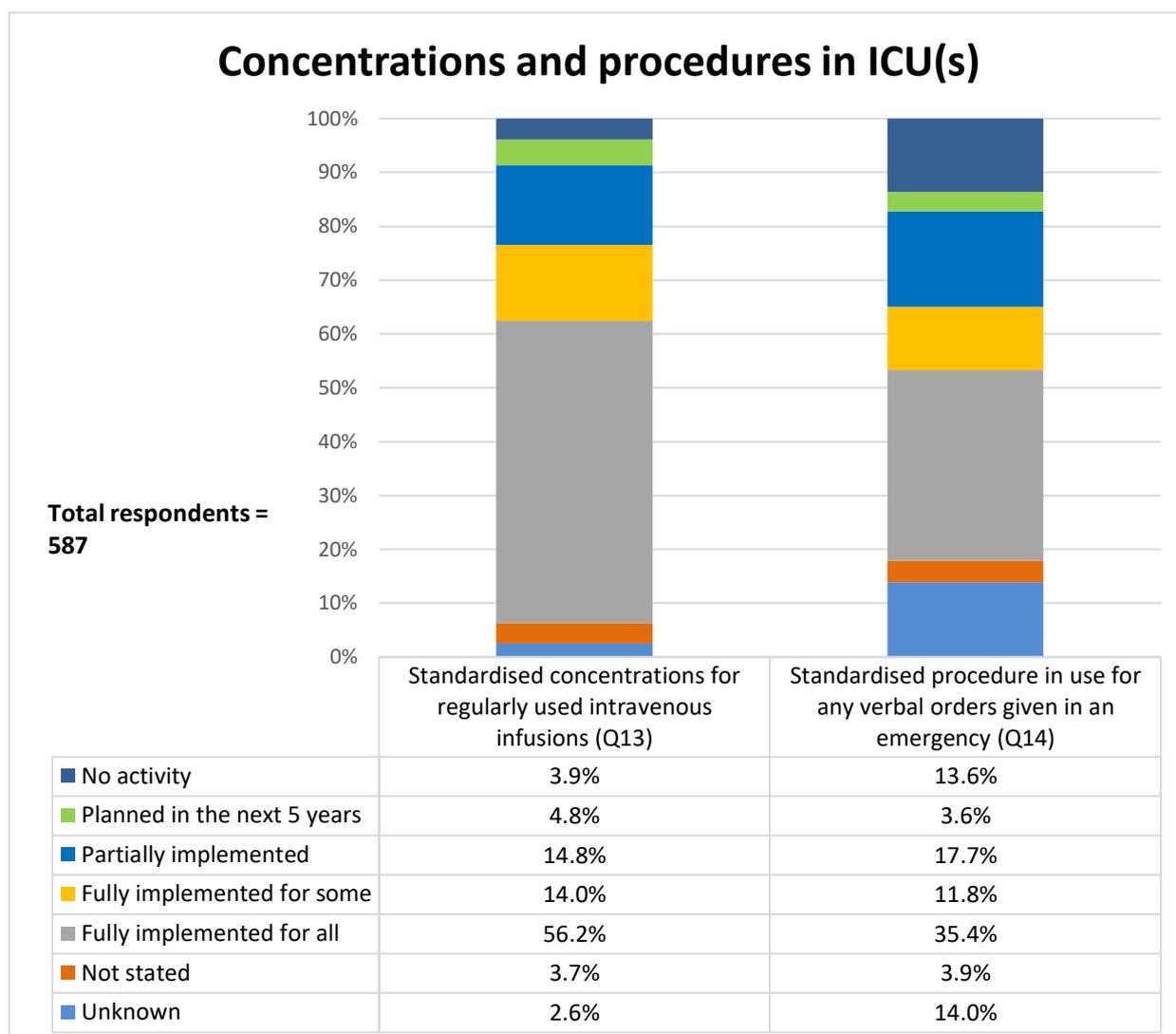


Figure 5. Responses to Questions 13 and 14 of the survey regarding standardised concentrations and procedures for verbal orders.

In Northern Europe, 71% of respondents stated that using standardised concentrations for regularly used intravenous infusions was fully implemented in the ICU (Figure 6). This practice was reported to be fully implemented by 55% of the respondents from Southern Europe, 46% of the respondents from Western Europe, and 29% of the respondents from Eastern Europe.

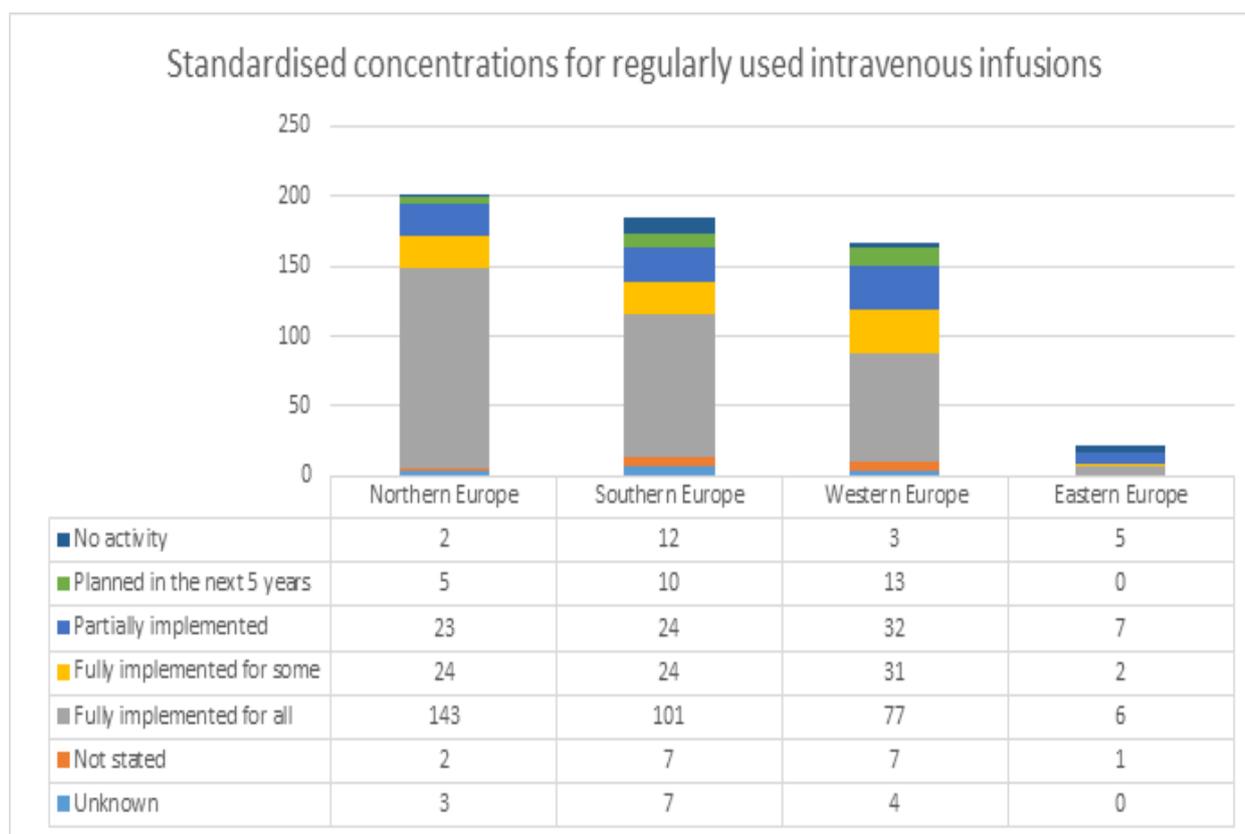


Figure 6. Responses to Question 13 of the survey regarding standardised concentrations for regularly used intravenous infusions by region.

Electronic prescribing and computerised prescriber order entry

EP systems or CPOE were fully implemented for all orders and all patients in 53% of the respondents' ICUs, fully implemented for some orders/patients in 7%, and partially implemented for some or all orders/patients in 5% (Figure 7).

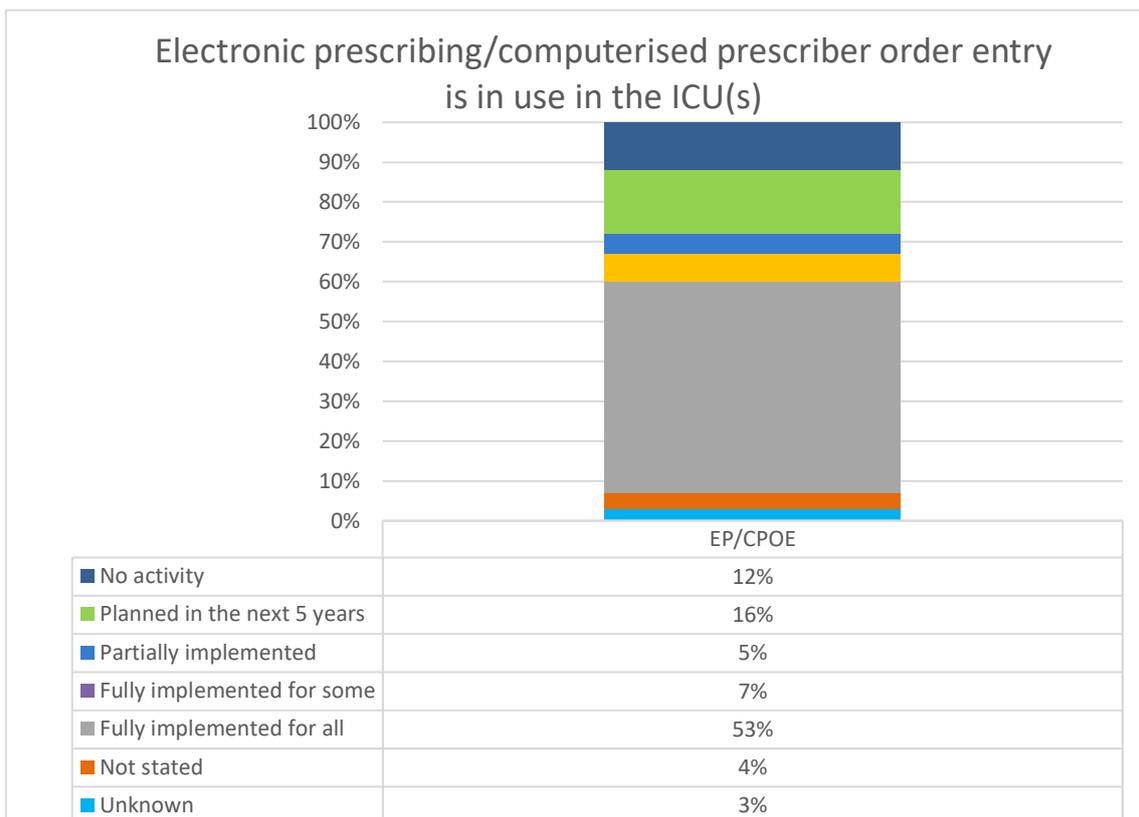


Figure 7. Responses to Question 15 of the survey regarding use of electronic prescribing (EP) and computerised prescriber order entry (CPOE) in ICU(s).

Eastern Europe had the highest percentage of respondents (76%) stating they had some form of EP/CPOE fully or partially implemented (Figure 8), but numbers of respondents were low for this region (n=21). On the other hand, 74% of the respondents from Western Europe reported that their ICU(s) had some form of EP/CPOE implemented, lower proportions of the respondents from Southern Europe (64%) and Northern Europe (59%) reported that their ICU(s) had some form of EP/CPOE implemented.

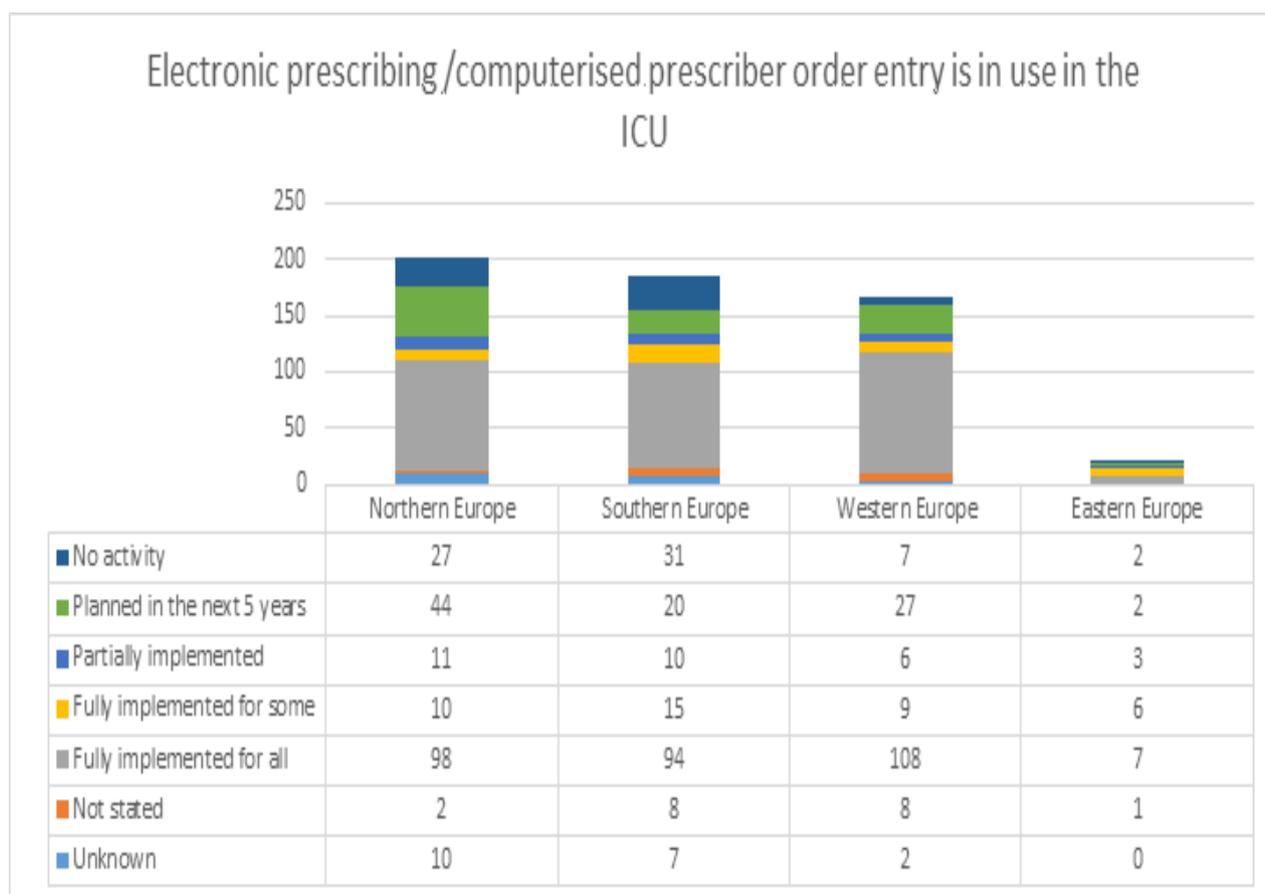


Figure 8. Responses to Question 15 of the survey regarding the use of electronic prescribing (EP) and computerised prescriber order entry (CPOE) in the ICU(s) by region.

Respondents who had answered that EP/CPOE was fully implemented for all patients, orders, medications, or staff (Figure 9), fully implemented for some patients, orders, medications or staff (Figure 10), or partially implemented for all or some patients, orders, medications or staff (Figure 11) in their ICUs were subsequently asked about the extent to which different functions were implemented. Alternatively, those who reported not having CPOE/EP implemented were asked about the extent to which their paper prescribing systems included certain elements (Figures 12 and 13).

Electronic prescribing / computerised prescriber order entry is fully implemented in the ICU for all patients, orders, medications, or staff in our ICU(s)

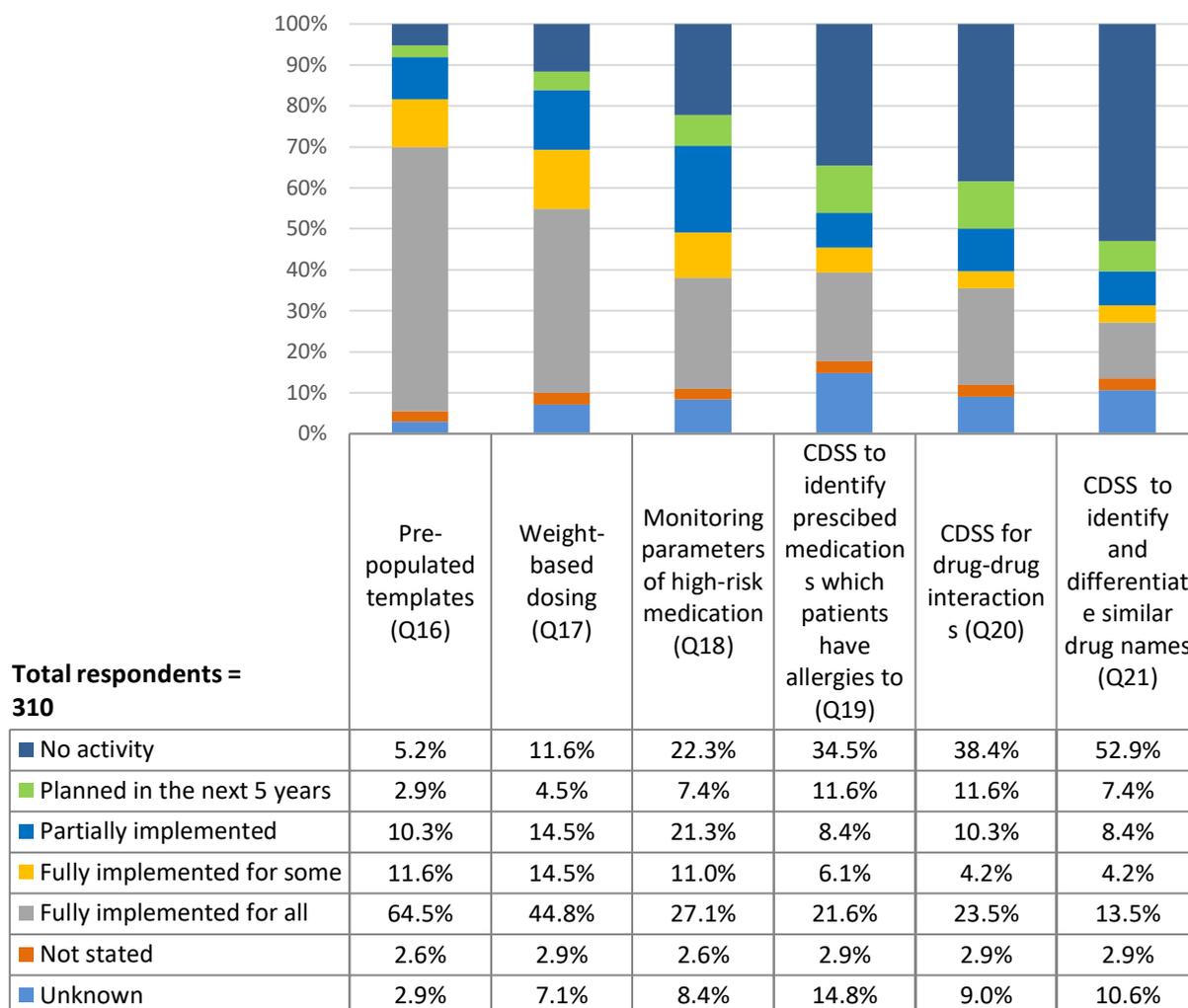


Figure 9. Responses to questions 16-21 of the survey regarding the different functions of EP/CPOE in use where EP/CPOE is fully implemented for all patients/orders/medications or staff. CDSS: clinical decision support system(s).

Electronic prescribing / computerised prescriber order entry is fully implemented in the ICU for some/all patients, orders, medications, or staff in our ICU(s)

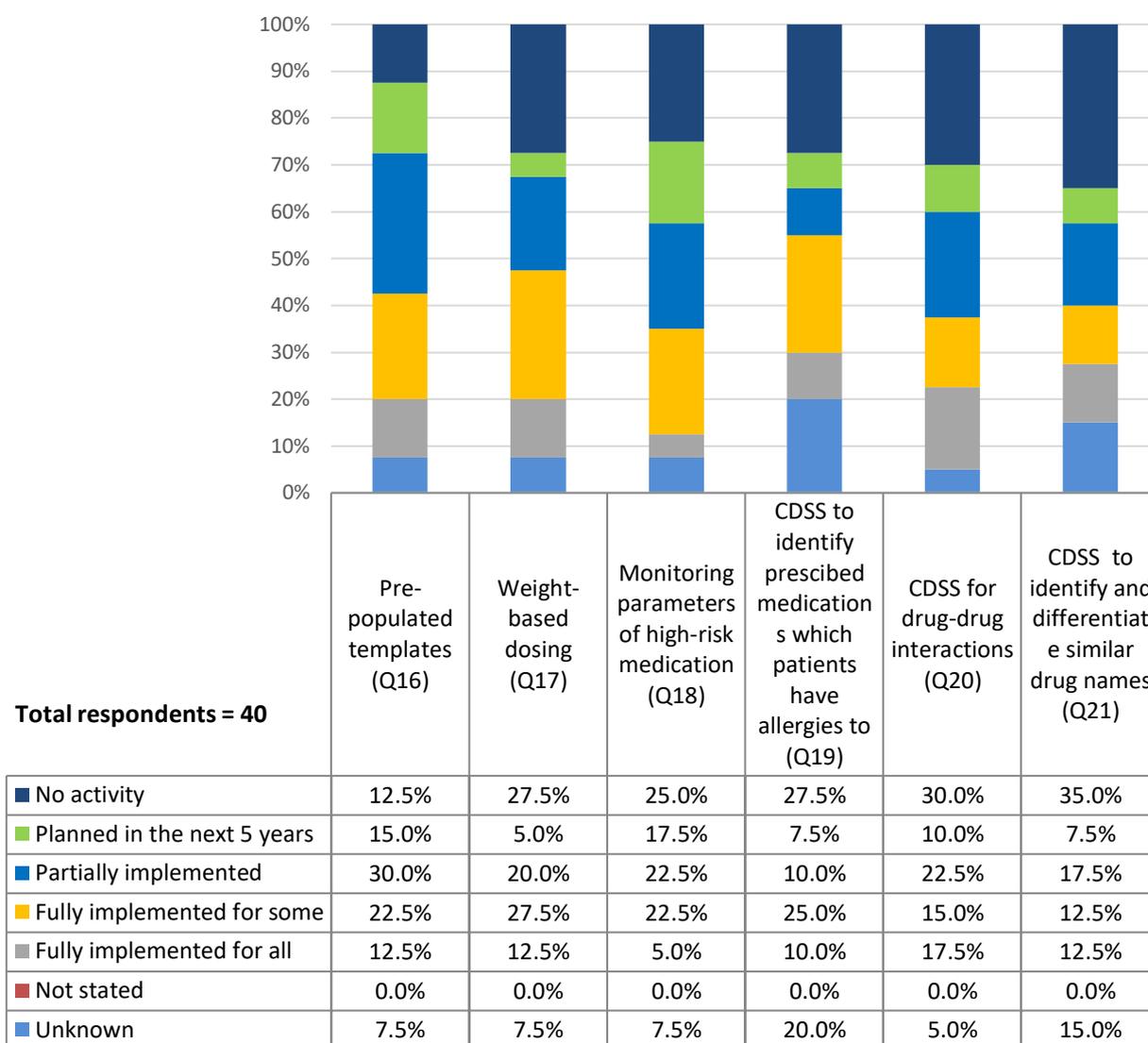
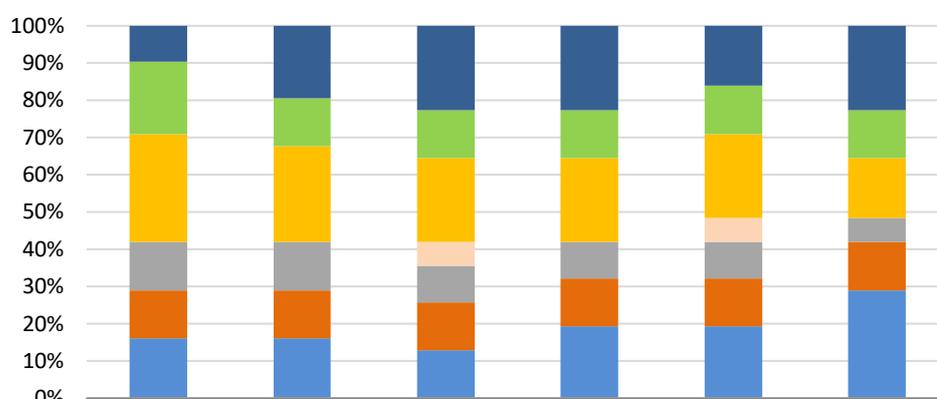


Figure 10. Responses to Questions 16-21 of the survey regarding the different functions of EP/CPOE in use where EP/CPOE is fully implemented for some or all patients, orders, medications, or staff. CDSS: clinical decision support system(s).

Electronic prescribing / computerised prescriber order entry is partially implemented in the ICU for some/all patients, orders, medications, or staff in our ICU(s)



Total respondents = 31

	Pre-populated templates (Q16)	Weight-based dosing (Q17)	Monitoring parameters of high-risk medication (Q18)	CDSS to identify prescribed medications which patients have allergies to (Q19)	CDSS for drug-drug interactions (Q20)	CDSS to identify and differentiate similar drug names (Q21)
■ No activity	9.7%	19.4%	22.6%	22.6%	16.1%	22.6%
■ Planned in the next 5 years	19.4%	12.9%	12.9%	12.9%	12.9%	12.9%
■ Partially implemented	29.0%	25.8%	22.6%	22.6%	22.6%	16.1%
■ Fully implemented for some	0.0%	0.0%	6.5%	0.0%	6.5%	0.0%
■ Fully implemented for all	12.9%	12.9%	9.7%	9.7%	9.7%	6.5%
■ Not stated	12.9%	12.9%	12.9%	12.9%	12.9%	12.9%
■ Unknown	16.1%	16.1%	12.9%	19.4%	19.4%	29.0%

Figure 11. Responses to Questions 16-21 of the survey regarding the different functions EP/ CPOE in use where EP/CPOE is partially implemented for some or all patients, orders, medications, or staff. CDSS: clinical decision support system(s).

Electronic prescribing / computerised prescriber order entry activity unknown - Paper prescribing systems

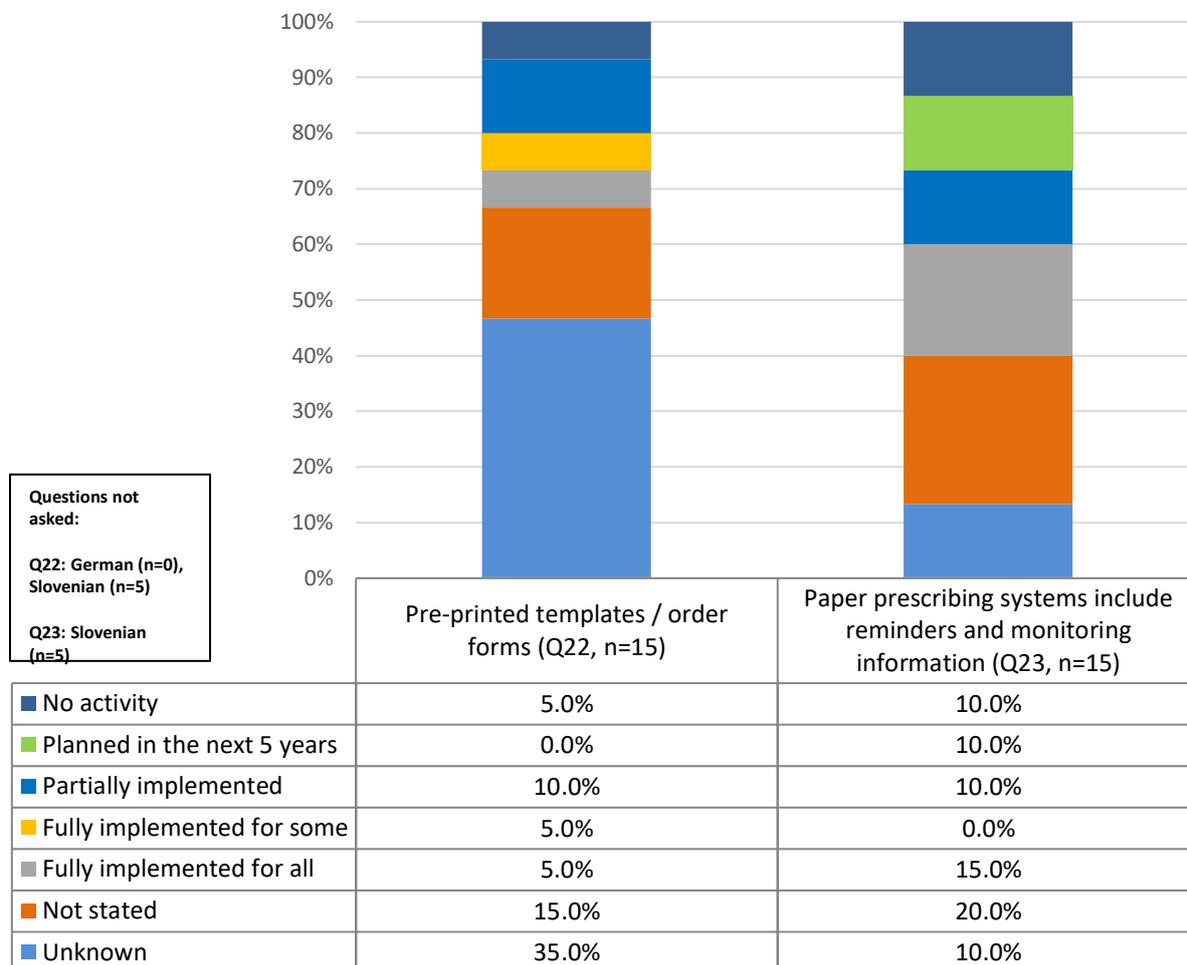


Figure 12. Responses to Questions 22 and 23 of the survey regarding paper prescribing systems where EP/CPOE ‘activity was unknown’ in the ICU(s).

Electronic prescribing / computerised prescriber order entry activity planned in the next five years - Paper prescribing systems

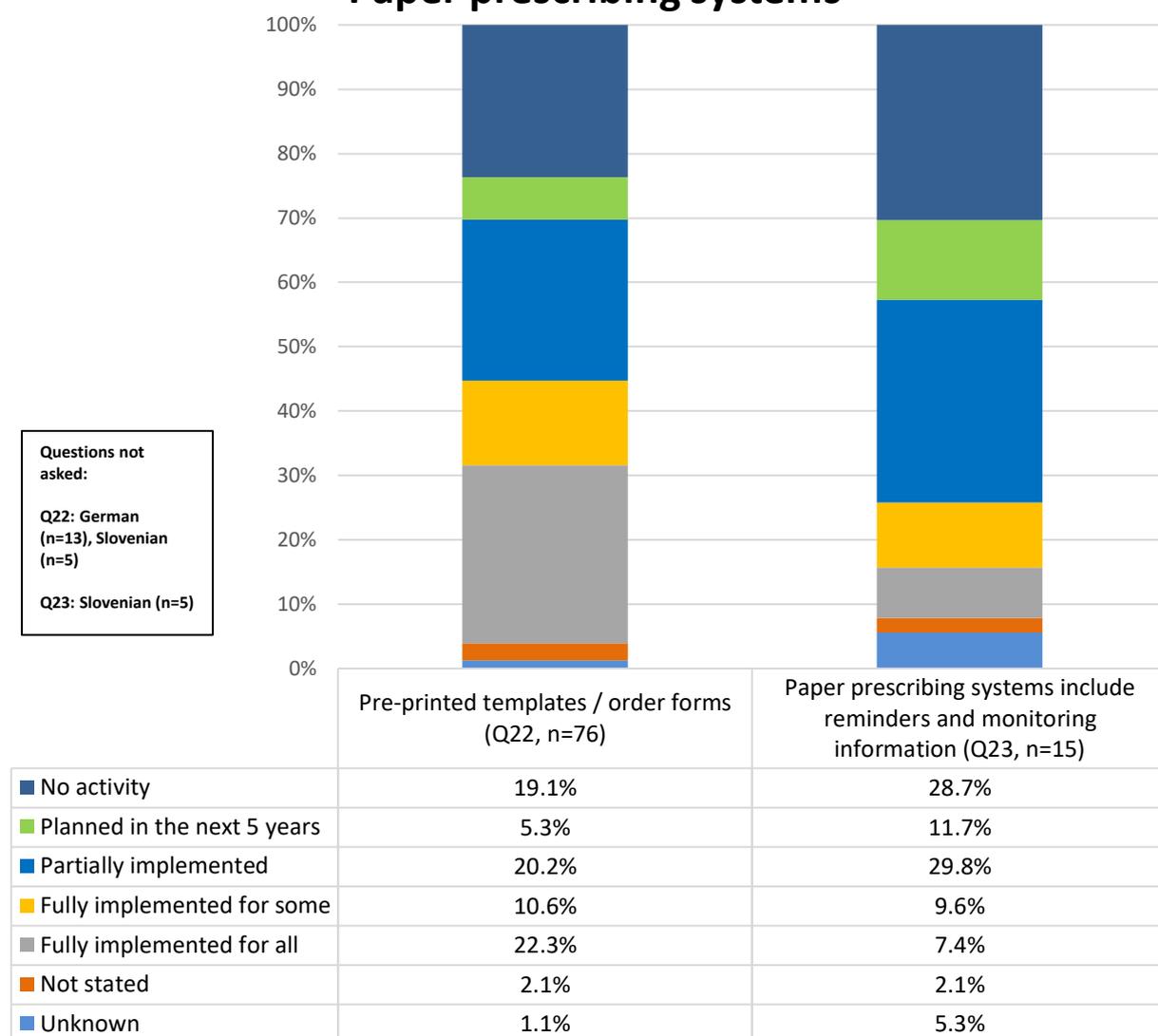


Figure 13. Responses to Questions 22 and 23 of the survey regarding paper prescribing systems where EP/CPOE 'activity was planned in the next five years' to be implemented in use in the ICU(s).

Guidelines and restricted formularies

Almost a fifth of respondents' ICUs (18%) had fully implemented guidelines or templates for all antidotes, reversal and rescue agents (Figure 14). This strategy was fully implemented for some of these agents in 10% of ICUs, and partially implemented for all/some of these agents in 22%. Of 522 respondents who were asked question 25, 21% stated that restricted formularies and guidelines were fully implemented for all ICU-specific medications (e.g. neuromuscular blocking agents), 7% stated that these resources were fully implemented for some ICU-specific medication, and 13% that these

resources were partially implemented for some/all ICU-specific medication (Figure 14). Templates for antidotes, reversal and rescue agents were not implemented in 21% of ICUs, and 31% of respondents did not report having restricted formularies or guidelines for ICU-specific medication. There were plans to have these strategies implemented in the next five years in 4% and 3% of ICUs, respectively.

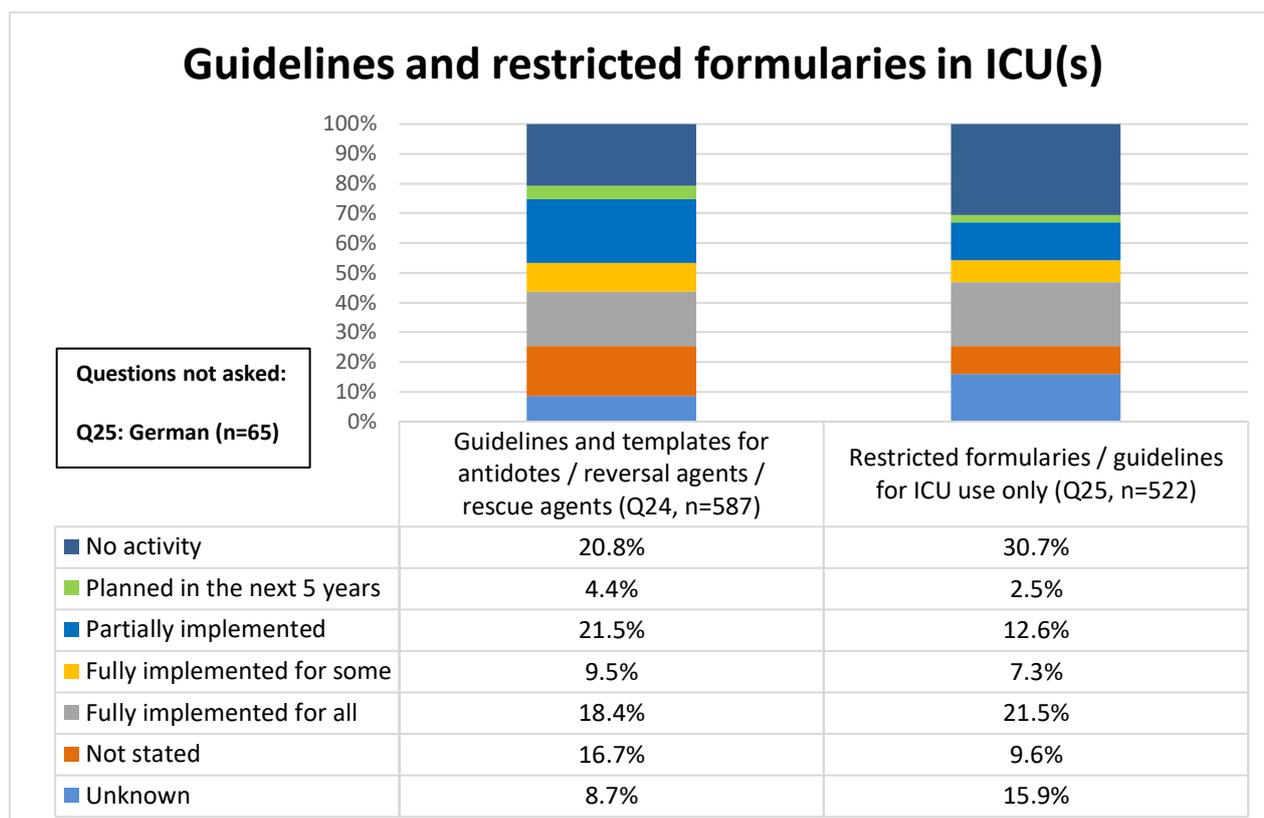


Figure 14 Responses to Questions 24 and 25 of the survey regarding the use of guidelines and restricted formularies in ICU(s).

Critical care pharmacist and pharmacy services

There was considerable variation in critical care pharmacists' inclusion in the multi-disciplinary team in the respondents' ICUs (Figure 15). A critical care pharmacist was fully allocated to 31% of respondents' ICUs with 30% of ICUs having a pharmacist review all ICU patients' medications five days of the week, and 27% having a pharmacist attend ward rounds at least once a week. Only 7% of respondents' ICUs had a 7-day pharmacist review service and of all respondents; the majority (58%) stated that this service was not available in their ICUs.

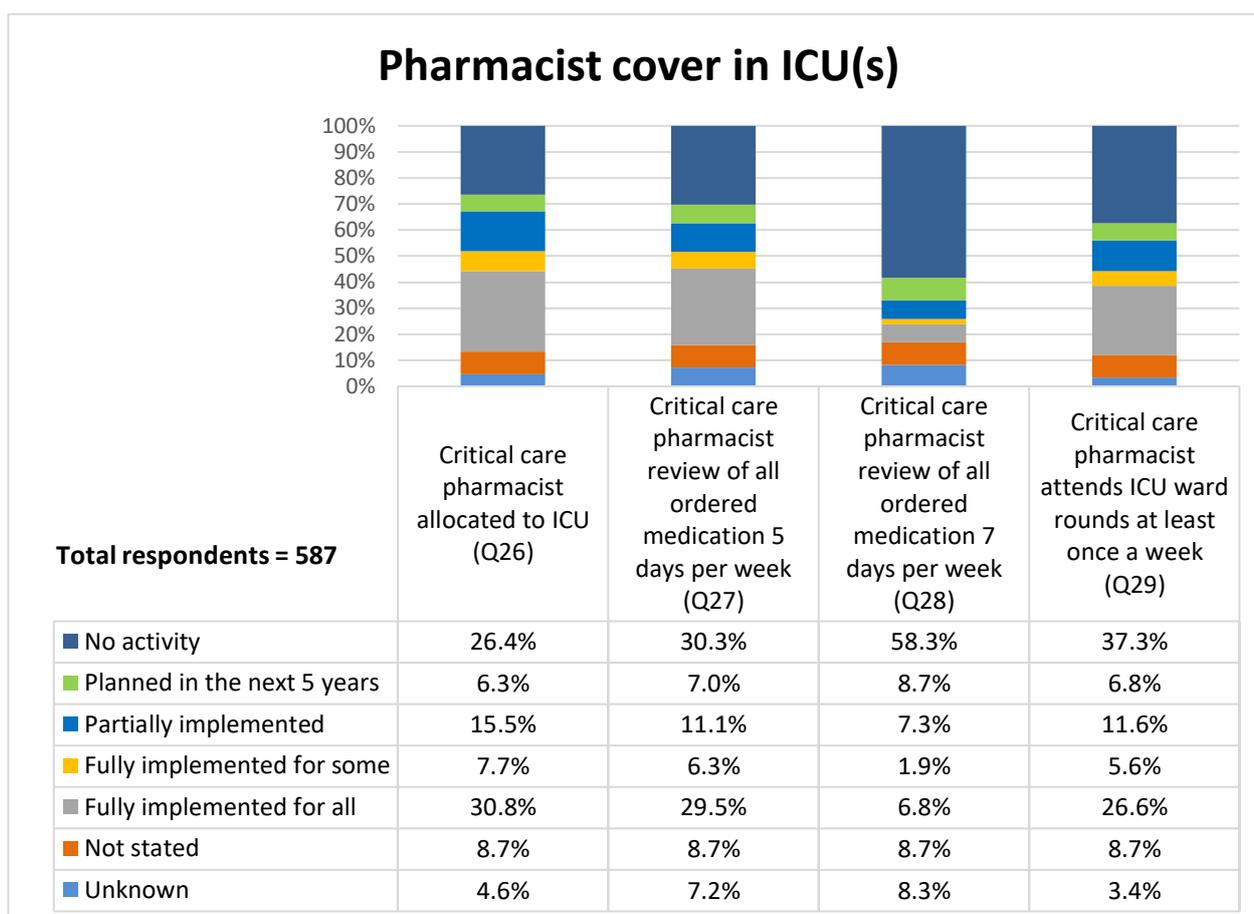


Figure 15. Responses to Questions 26-29 of the survey regarding Critical care pharmacist allocation to ICU(s) and level of service provision.

In Northern Europe, 50.5% of respondents (Figure 16) stated there was a critical care pharmacist allocated to their ICU in some capacity (fully or partially implemented). Of the respondents from Western Europe, 45.5% had a critical care pharmacist in some capacity, followed by 43.2% from Southern Europe, and 28.5% from Eastern Europe.

Similarly, pharmacy service provision in the ICUs also varied (Figure 17). The most commonly reported fully implemented pharmacy service was pharmacy top-up of medications (50%). However, only 4% of respondents stated that all IV medications were prepared by the pharmacy department on a patient-specific basis, and only 4% reported that pharmacist authorisation was required for every medication before a dose could be administered. These services were not implemented for 48% and 66% of respondents' ICUs, respectively.

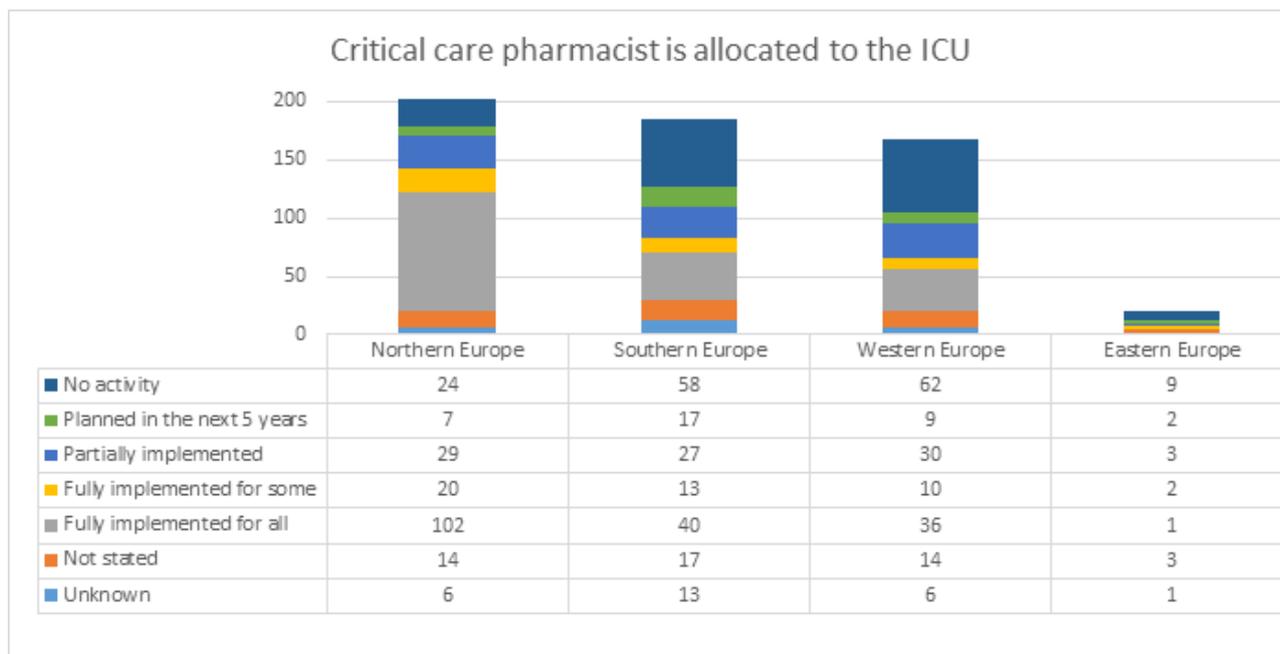


Figure 16 Responses to Question 26 of the survey regarding critical care pharmacist allocation to the ICU(s) by region.

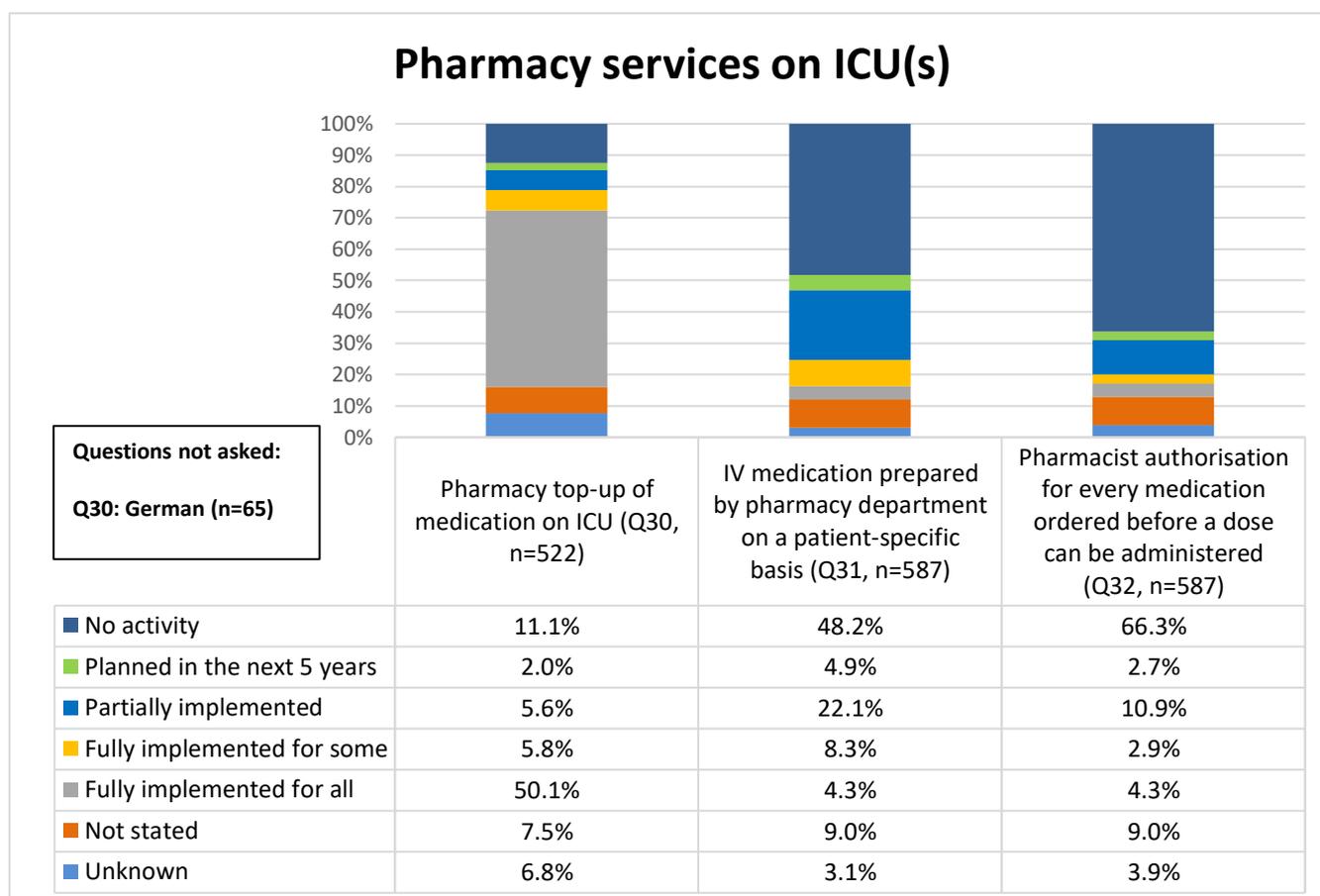


Figure 17. Responses to Questions 30-32 of the survey regarding pharmacy services to the ICU(s).

In Southern Europe, 43% of respondents stated there is either a fully implemented or partially implemented system for patient-specific IV medication preparation (Figure 18). Of those from Northern Europe, 35% had fully or partially implemented this, followed by Western and Eastern Europe (28% and 19%, respectively).

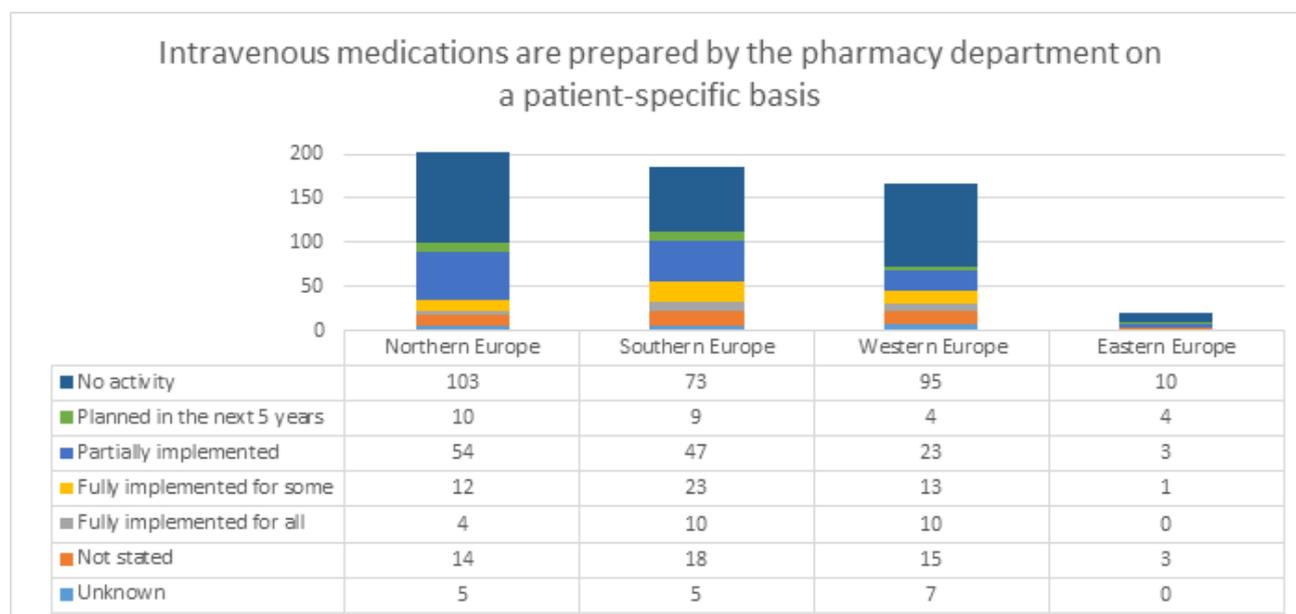


Figure 18. Responses to Question 31 of the survey regarding preparation of IV medications by pharmacy department on a patient-specific basis by region.

Medication storage

All high-risk medications were locked away from other medications in 32% of respondents' ICUs (Figure 19). Processes to mitigate the risk of confusing medications that look alike or sound alike (e.g. unique labels or 'tall-man' lettering) were fully implemented for all types of these medications in 18% of ICUs. All standardised emergency medications were stored in a fixed place in 57% of the respondent ICUs and 19% of ICUs had fully implemented automated dispensing cabinets for all medications used. Nearly half of respondents (48%) stated that automated dispensing cabinets were not used. In Northern Europe, 43% of respondents (Figure 20) stated that all high-risk medication was locked away from other medication in ICU(s). In Southern Europe, all high-risk medication was locked away in 36% of ICUs, followed by 19% in Western Europe and in Eastern Europe (low number of respondents).

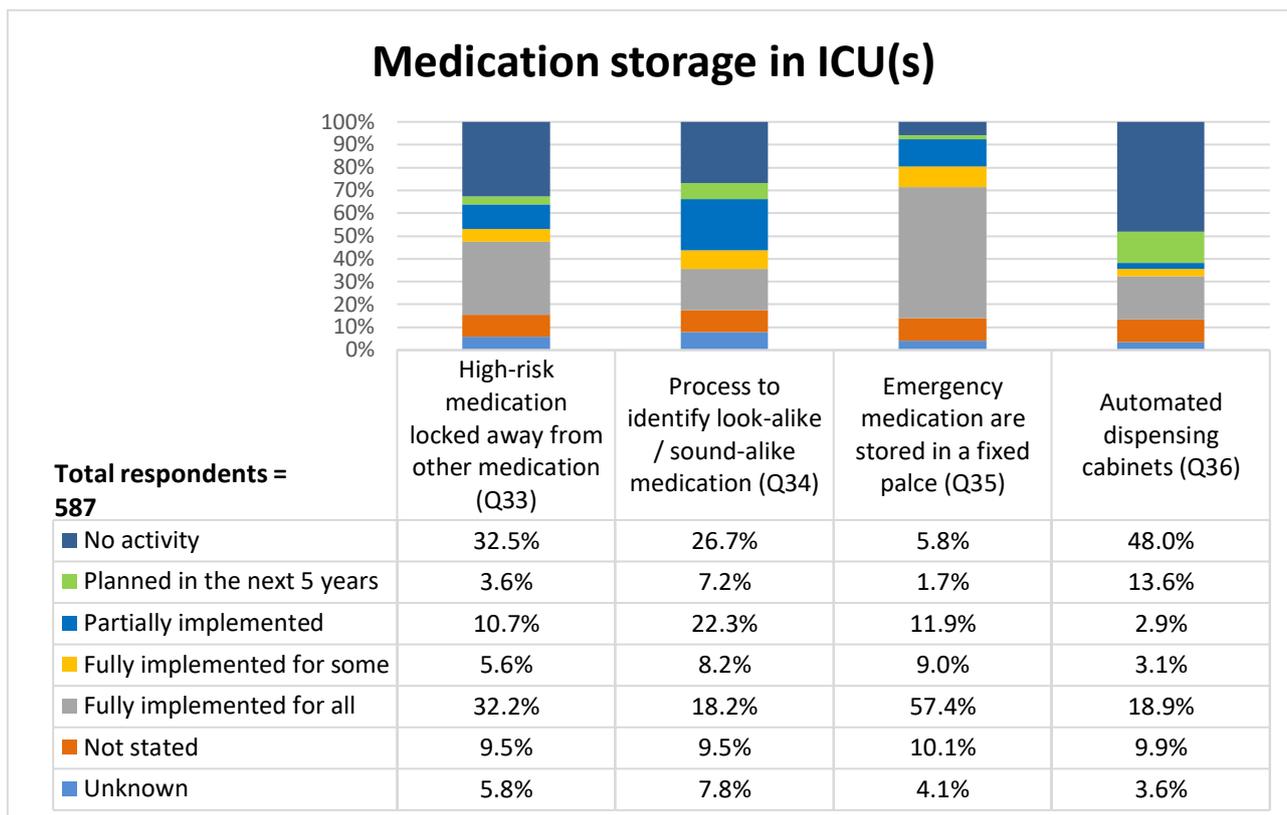


Figure 19. Responses to Questions 33-36 of the survey regarding medication storage in the ICU(s).

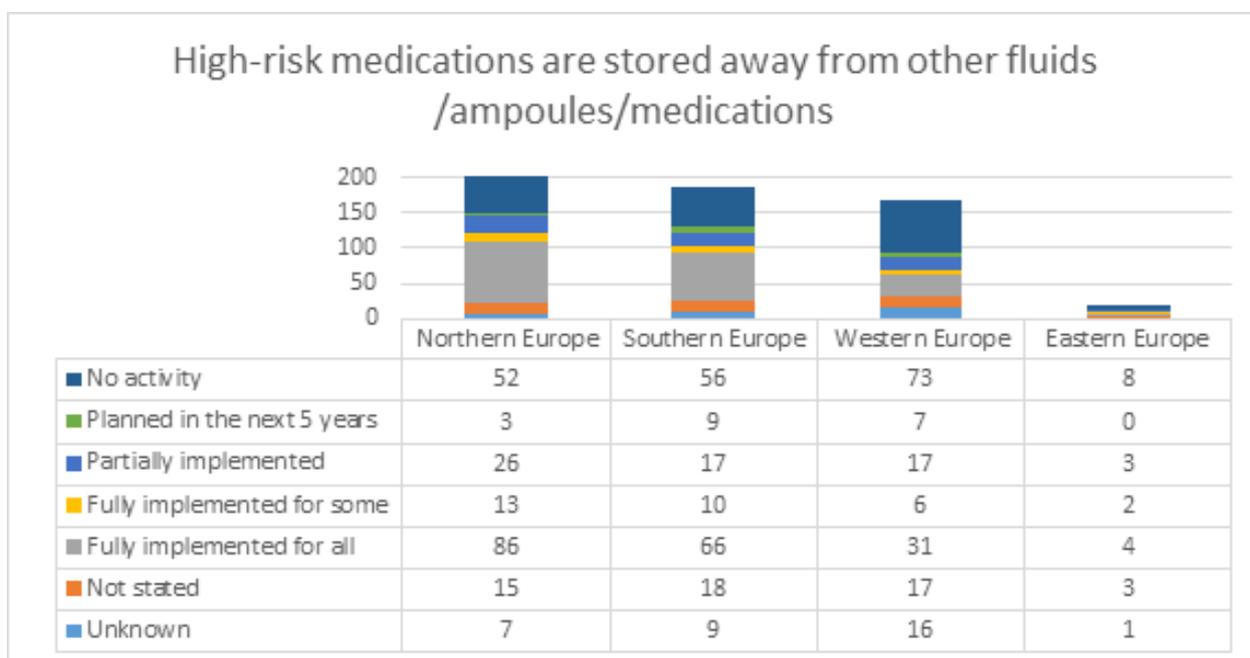


Figure 20. Responses to Question 33 of the survey regarding storing high-risk medications away from other medications by region.

Independent double-check for preparation and administration of medication

In total, 21% stated that there was an independent double-check process used in their ICUs for both the preparation and administration of all high-risk medication. An independent double-check process for the preparation of all medication was fully implemented in 14% of ICUs, and for the administration of all medication in 13% of ICUs (Figure 21).

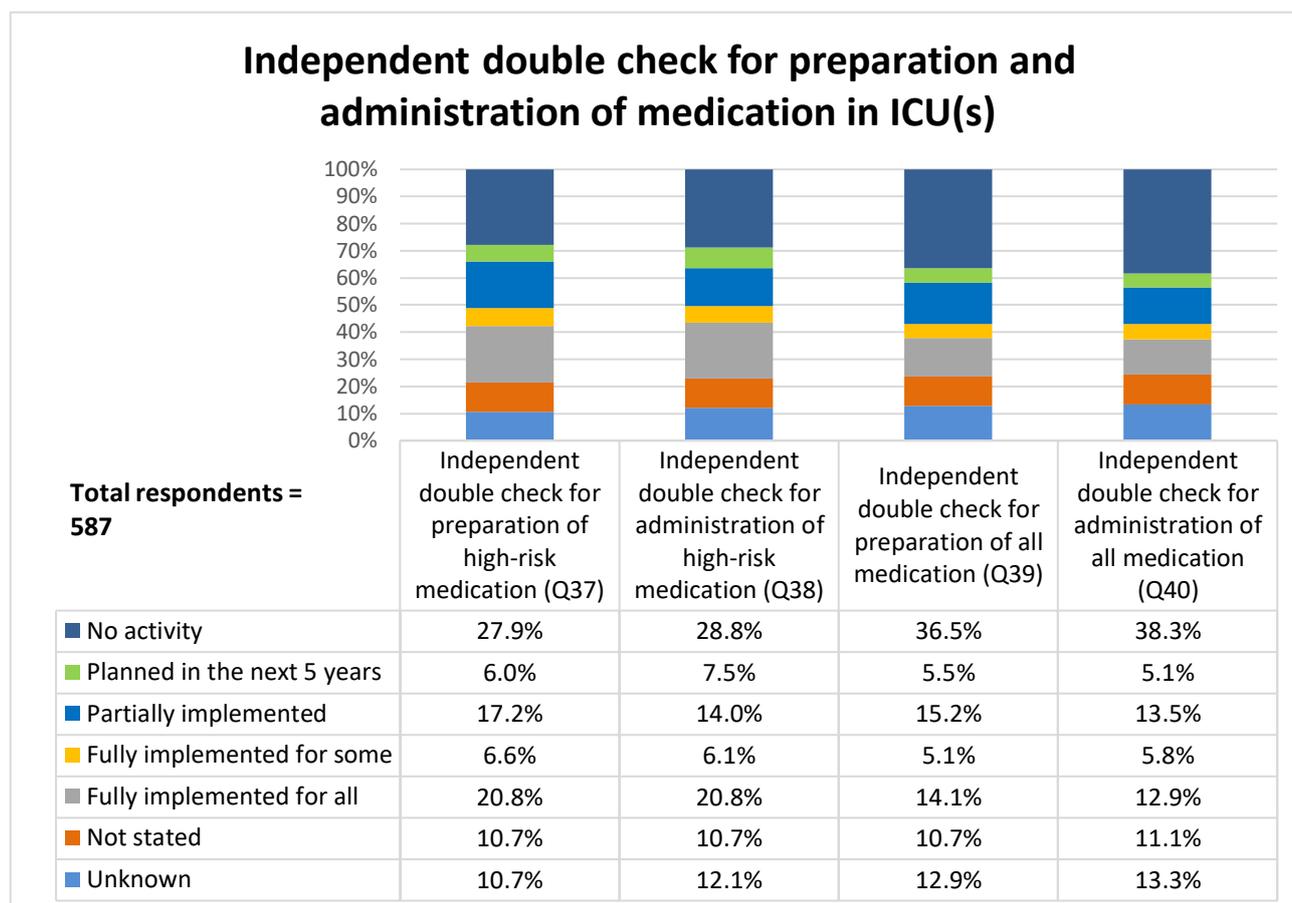


Figure 21. Responses to Questions 37-40 of the survey regarding double checking of the preparation and administration of medication in ICU(s).

In Northern Europe, 33% of respondents stated they had a fully implemented independent double-check for administration of high-risk medications (Figure 22). In Eastern Europe, 24% stated a fully implemented double-check system was in place (low number of respondents), followed by 18% of respondents from Southern Europe and 10% from Western Europe.

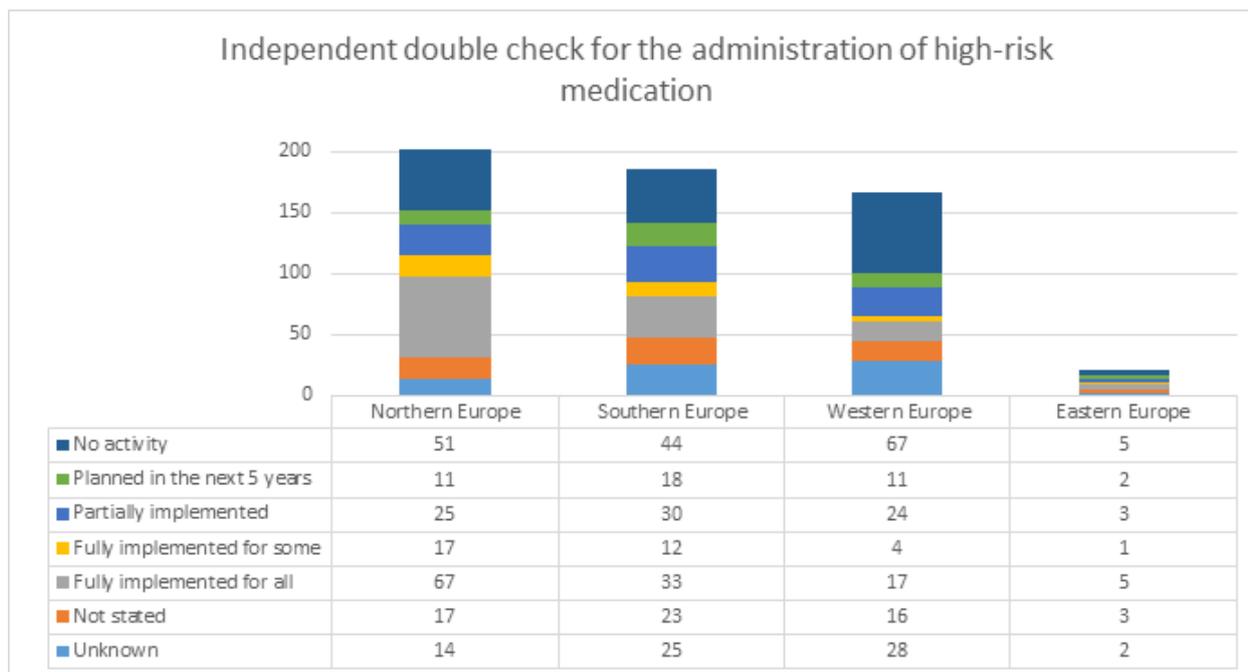


Figure 22. Responses to Question 38 of the survey regarding Independent double check for administration of high-risk medications by region.

Intravenous lines, barcode-scanning technology and 'smart' infusion pumps

Line labels were used for all patients and medications to prevent identification and disconnection errors in 36% of respondent ICUs (Figure 23). Similarly, smart infusion pumps and oral/enteral syringes that are incompatible with IV lines were fully implemented for all patients and medications in 21% and 55% of ICUs, respectively. Barcode scanning technology was not implemented in 50% of ICUs for the verification of patients, or medications.

IV lines, barcode-scanning technology and 'smart infusion pumps' in ICU(s)

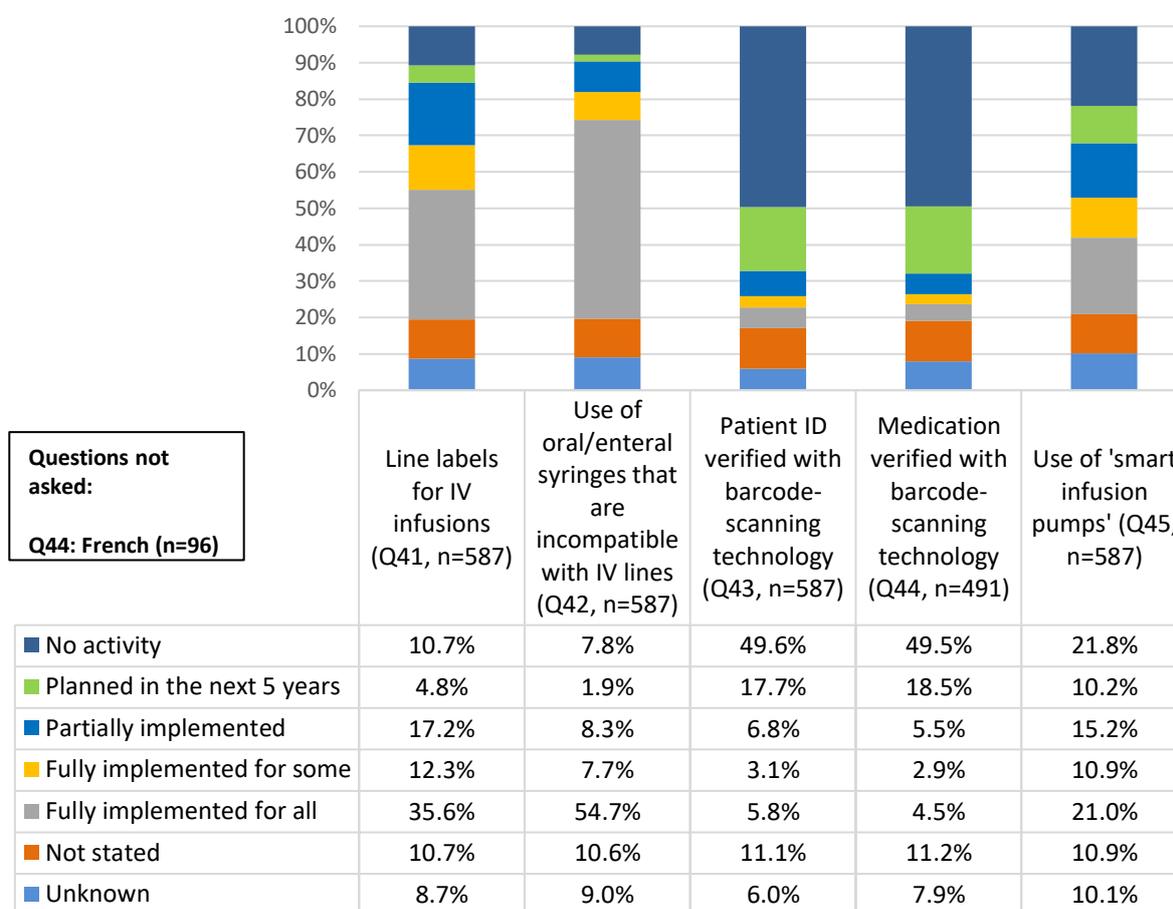


Figure 23. Responses to Questions 41-45 of the survey regarding the use of line labels for, or oral or enteral syringes that are incompatible with, intravenous lines, barcode-scanning technology and 'smart infusion pumps'.

For Northern Europe, 27% of respondents stated that use of smart infusion pumps was fully implemented for all patients on their ICU(s) (Figure 24). These figures were 18% for Western Europe, 12% for Southern Europe, and 10% for Eastern Europe.

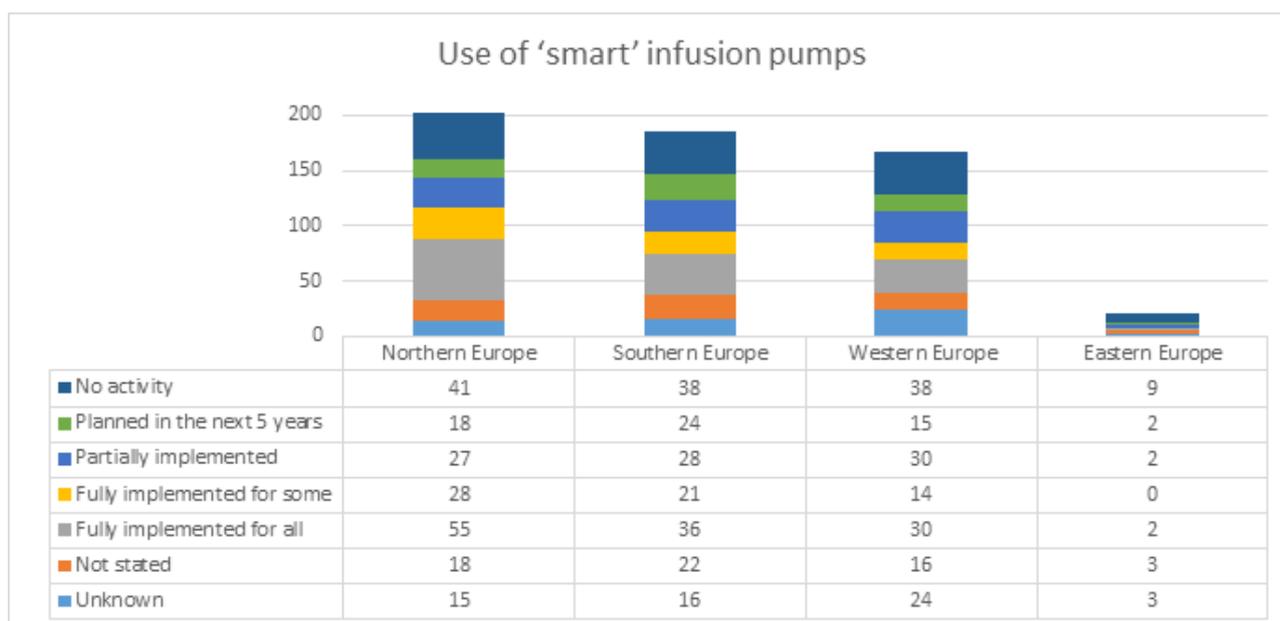


Figure 24. Responses to Question 45 of the survey regarding the use of smart infusion pumps by region.

Medication review on discharge from ICU

Review of medication at the point of patient discharge from the ICU to avoid ICU-specific medication being continued inappropriately occurred fully for all patients in only 19% of respondents' ICUs (Figure 25). This process was not implemented at all in 23% of ICUs, while there were plans to implement this in the next five years in 11% of ICUs. Similarly, a medication review process at the point of ICU discharge to restart any pre-admission medication that may have been withheld occurred fully for all patients in only 16% of ICUs. This process did not occur at all in 25% of respondents' ICUs and was planned to be implemented in the next five years in 10% of ICUs.

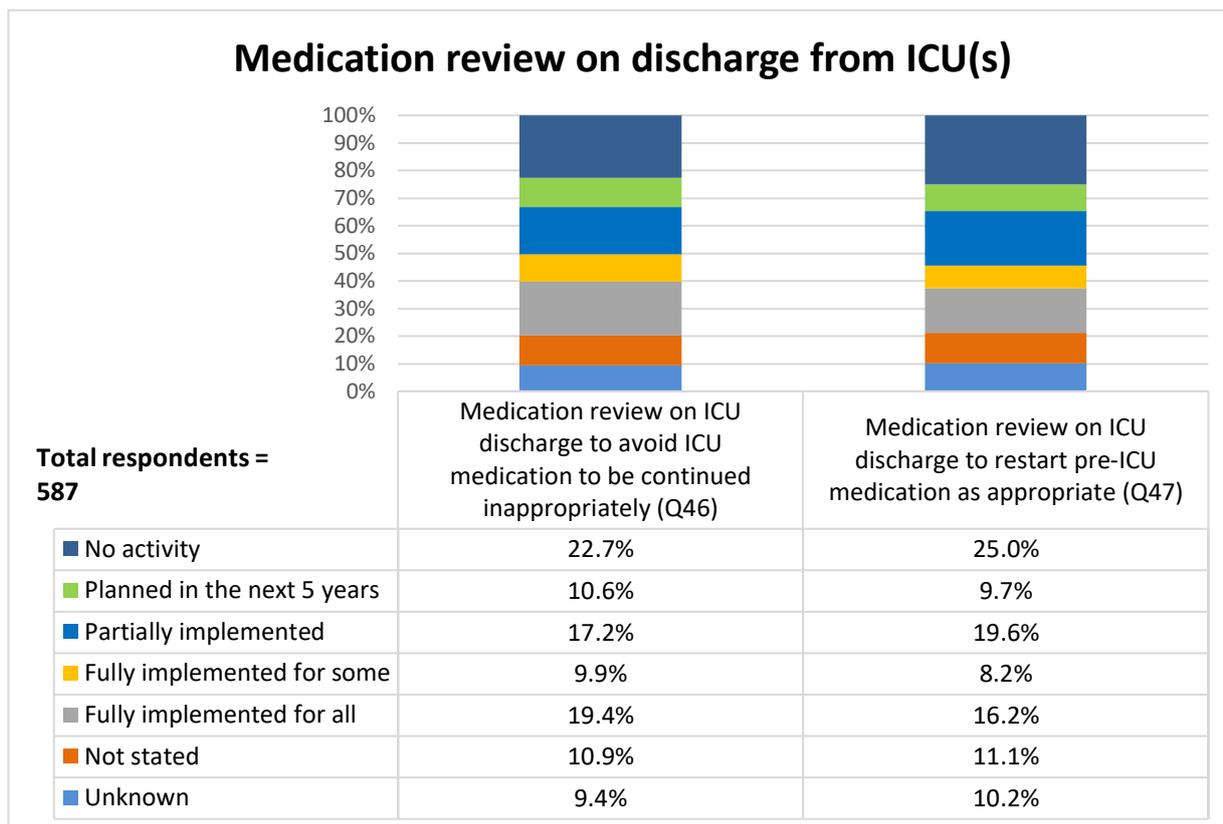


Figure 25. Responses to Questions 46 and 47 of the survey regarding medication review practices on discharge from ICU.

Of the respondents from Eastern Europe (Figure 26), 24% stated there was a fully implemented medication review to avoid inappropriate use of ICU medication on discharge from ICU (low number of response). This figure was 23% for Northern Europe, 21% for Southern Europe, and 14% for Western Europe.

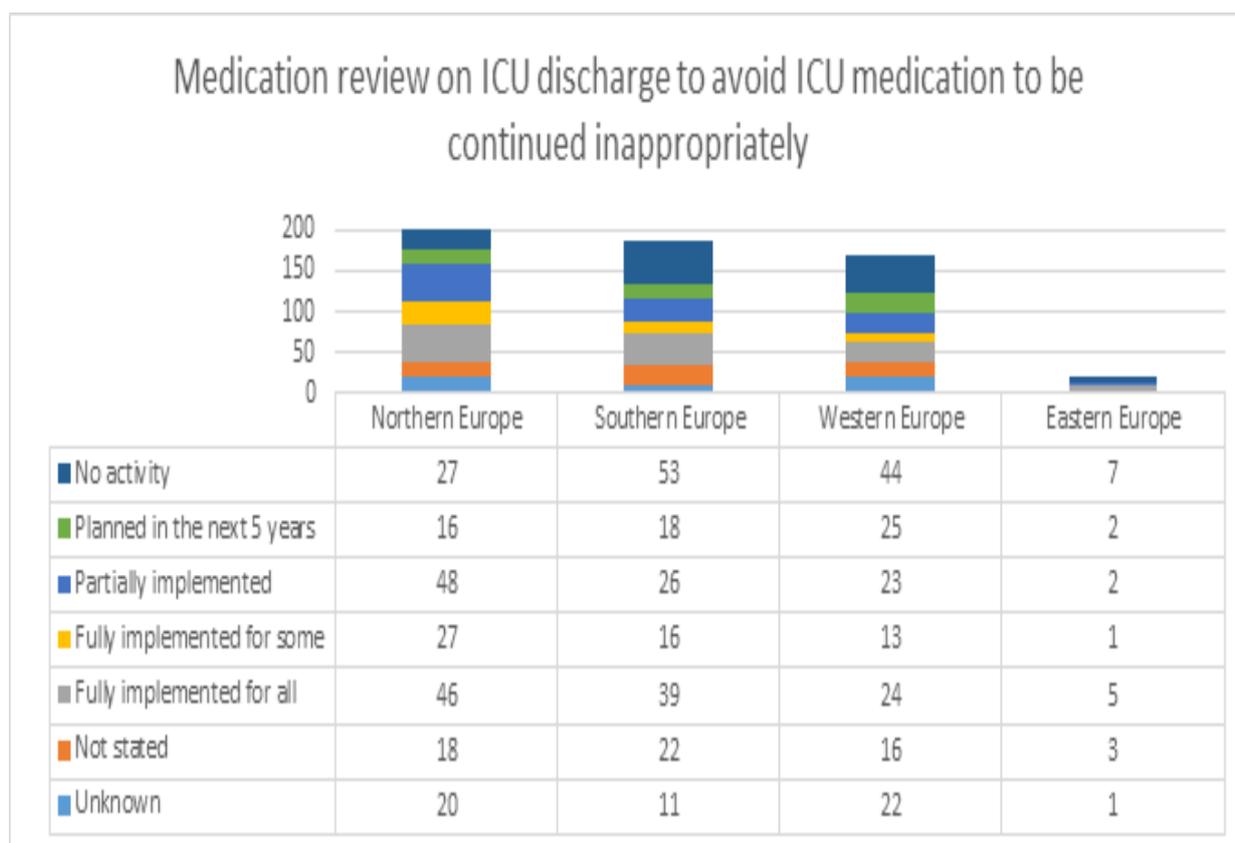


Figure 26. Responses to Question 46 of the survey regarding medication review to avoid ICU medication to be continued inappropriately on ICU discharge by region.

Incident reporting and medication safety

Use of a fully or partially implemented incident reporting system was reported by 77% of respondents (Figure 27), and 71% had regular discussions of medication incidents and the identification of corrective actions to some degree (either fully or partially). The provision of standardised introductions for all new employees such as medication-related processes, protocols, instructions, and checklists was fully present in 26% of respondents' ICUs. Regular medication safety audits occurred to some degree (fully or partially) for 48%.

Incident reporting and medication safety in ICU(s)

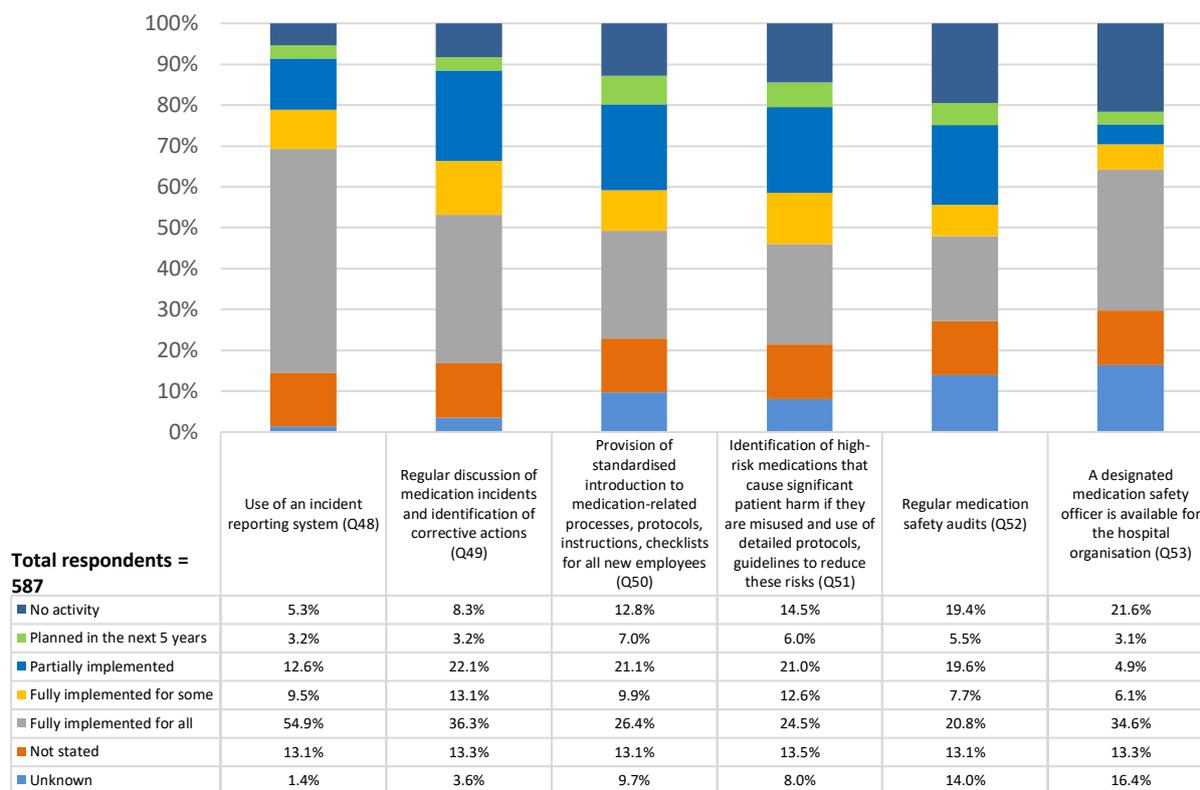


Figure 27. Responses to Questions 48-53 of the survey regarding the use of incident reporting systems and medication safety practices in ICU(s) and availability of a medication safety officer for the hospital.

Of the respondents from Northern and Western Europe, 62% reported a fully implemented incident reporting system (Figure 28). Of those from Southern Europe, 45% reported a fully implemented incident reporting system, followed by Eastern Europe (24%).

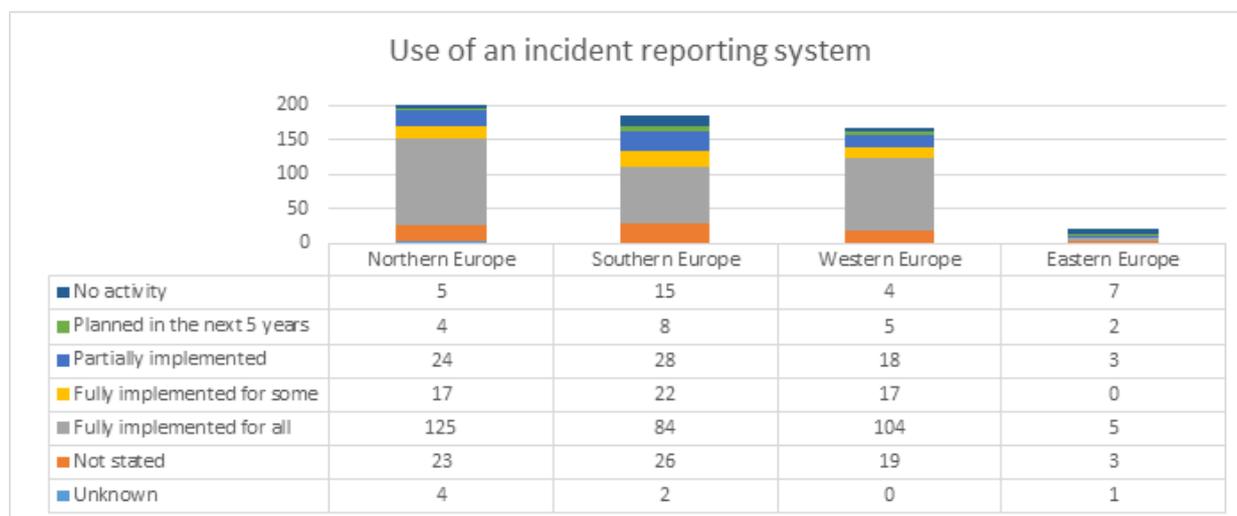


Figure 28. Responses to Question 48 of the survey regarding the use of an incident reporting system by region.

Other strategies to aid medication safety

The main other strategies used in the respondents' ICU(s) to aid medication safety described in 'free-text' responses (n=68) and identified during analysis were resources, pharmacy involvement, technology, safety groups, education, and practices. A brief overview of each theme is presented to summarise these responses.

Resources

Use of various resources to aid standardisation and safety of medication use were described, including both national guidelines and standards. Other resources included were unit- or hospital-specific and included hospital formularies, ICU formularies/ prescribing booklets, Do/Do-not crush lists and standardised guidelines/drug concentrations. In addition to this, the use of Y-site compatibility charts was stated as a method for ensuring only compatible drugs are given concurrently through a Y-site, as well as the use of the Institute for Safe Medication Practice (ISMP) questionnaires to assess practices and processes related to medication use.

Technology

Mobile applications for formularies, guidelines and drug libraries, and interoperability among CPOE systems, smart infusion pumps, barcode medication administration systems, electronic health records, and syringe labelling systems were examples of technologies identified as ways of improving medication safety. Additionally, NRFit® (neuraxial) connectors, unit dose dispensing, use of 'computers on wheels' and electronic tablet computers were reported.

Safety groups

Respondents reported the use of safety groups involving the multi-disciplinary team, risk huddles and an incident management team that reviewed all serious medication incidents. Additionally, respondents reported having a multi-disciplinary medicines safety committee in place and strategies such as 'nurse safety pauses' to highlight certain safety concerns of issues in a particular day or week.

Pharmacy involvement

Pharmacy involvement was identified as playing a role in medication safety through a number of mechanisms including screening all high-risk medications, developing information sheets, and involvement in therapeutic drug monitoring. Pharmacists were also noted to attend ward rounds, lead multi-disciplinary medication safety teams, and take a lead on plans for analgesia and sedation. Other strategies included provision of a 7-day pharmacy service and pharmacy technicians dispensing

medications in medication trollies, as well as having a specialist antimicrobial pharmacist and pharmacist prescribers who can correct prescriptions if needed. Finally, pharmacists conducting the final review of antibiotic medications before administration was identified as a strategy for medication safety.

Education

Education of staff, through several strategies, was identified by a number of participants. Some participants identified memos on certain medications being sent to clinicians and using 'watch out' notices to disseminate learning. Other practices included use of a medication safety newsletter, videos to role-model good practice and private social media groups for ICU staff to share medication information and updates. Additionally, some participants had practice development nurses involved in the training of ICU nursing staff.

Practices

Several standardised practices were identified, including medication storage, and handling audits, completing medicines reconciliation for all inpatients over 70 years of age, and advance preparation of certain medications. Other examples were the use of pre-printed labels for paper medication charts including optimum concentrations and rates, ready-to-use medications and a centralised IV service, and pharmacy preparation of all medicines and parenteral nutrition for neonatology. Other strategies included the minimisation of medications in ICU ward cabinets, preparation of IV medications in a dust-free safety cabinet and double-checking infusions when handing over between two staff shifts. Additionally, some respondents identified a strategy to minimise interruptions or distractions by wearing a red apron, when undertaking tasks requiring concentration, to make others aware that they are not to be interrupted. Other visual aids included labelling syringes, infusion bags and lines using colours, ISO (International Organization for Standardization) labels and flags, as well as storing medications according to ATC (Anatomical Therapeutic chemical) code. Respondents also identified specific nursing roles such as having a lead clinical risk nurse and drug-dedicated nurse resuscitation teams, and a dedicated nurse for medication preparation.

Discussion

In this survey, we obtained 587 usable responses from 33 different countries across Europe. We identified wide variation in the use of medication safety practices, both within and among countries, suggesting there may be some scope for learning from 'best' practice. Findings also suggest that there may be some geographical variation in the approaches taken to support medication safety in critical

care, with technological solutions more common in some areas, and solutions based on pharmacy staff presence in the ICU being more common in others.

Strengths and limitations.

The strengths of this study include translation of the survey into different languages to facilitate responses from a wide range of European countries, as well obtaining as a relatively high number of usable responses overall. A limitation is the high number of respondents who stopped answering the survey after completing the initial demographic questions; we suspect this may reflect individuals who started completing the survey and then realised that they did not have the requisite knowledge to complete the questions concerned. Other limitations include the possibility of having more than one response from the same ICU and/or hospital, and that a small number of questions were omitted from the French, German, and Slovenian surveys. We also acknowledge the limitations of analysing data by region, as countries may be close geographically but very different in terms of healthcare systems and practices. Numbers of responses for some countries and some regions are also lower than others, limiting the conclusions that can be drawn. As with any survey of this type, there may be some response bias such as individuals with greater interest or expertise in medication safety being more likely to complete the survey. There may also be potential variation in responses due to the profession of the respondent which we were unable to formally explore. Finally, there were some practices that we did not explore in the survey such as the use of unit dose drug distribution systems.

Focus group discussions on patient safety culture and medication safety in European intensive care units

Materials and Methods

To explore patient safety culture and advancement of medication safety in ICUs across Europe through focus group discussions, and to explore factors influencing implementation of ME prevention strategies in ICUs across Europe through focus group discussions, one working group (WG4) supplemented by two members of WG2 of the SIG conducted focus group discussions. This working group was formed by six pharmacists of which three were actively working in the ICUs of their University hospitals, one was a medication safety pharmacist, and the other two members were pharmacists working in academia for whom medication safety and patient safety are areas of research. The members of this group were based in different European countries.

Study Design

Online focus group discussions were conducted with HCPs working within adult, paediatric, neonatal ICU environments and within all ICU specialities, for example, cardiac and surgical, or working as medication safety experts, across Europe. This study is reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al. 2007).

Participants and Sampling

Participants were recruited through the EAHP, and other relevant national and European professional networks with which the SIG had connections, using e-mails, and social media. A sample recruitment e-mail, i.e. a cover letter (Appendix V), together with an information sheet (Appendix VI) and an informed consent form (Appendix VII) were forwarded to potential participants. All HCPs working in adult, paediatric, neonatal ICUs with different specialities, for example, cardiac, medical, and surgical, or as medication safety experts in their organisation within Europe were eligible to participate. Due to the international nature of the study, all participants were required to have a suitable level of fluency in English to participate.

The number of focus group discussions was set: there could be a maximum of four focus group discussions. The participants were recruited using purposive sampling to ensure expression of diverse experiences and perceptions. Whilst in face-to-face focus group discussions it is possible to involve up to 12 participants, recruitment was limited to up to eight participants in each discussion to

accommodate online facilitation and participation. With 15-20 participants in total in the focus group discussions, it could be possible to reach thematic saturation (Ritchie et al. 2014), i.e. no new experiences or perceptions emerge from the data during the last focus group discussion.

The recruitment took place between 2nd and 23rd May 2022. During this period, reminders were sent to potential participants and those who had already expressed their interest. Participation in the focus group discussions was voluntary and confidential; the participants were asked to provide their informed consent to take part in this research (Appendix VII). As taking part to the focus group discussions was confidential, the participants were also asked to respect the principle of confidentiality.

Focus Group Topic Guide

Previous literature on patient safety culture and ME prevention strategies was utilised to develop the focus group topic guide (Appendix VIII) through a collaborative and iterative process among WG4 and involving the members of the SIG. The final topic guide was developed after initial quantitative analysis of the survey to HCPs working in ICUs across Europe. Thus, to ensure credibility of the research, potential participants were involved in developing the data collection tool. The main topics included: patient safety culture and medication safety in their ICU; and ME prevention strategies and their implementation. The use of the topic guide was not piloted as, if necessary, it was possible to clarify the topics and prompts during the focus group discussions.

Conducting the Focus Group Discussions

The online focus group discussions were conducted in May 2022. Four potential dates for the focus group discussions were agreed; the participants confirmed their availability by e-mail. Three focus group discussions were arranged on 17th, 18th and 23rd May 2022. As the discussions were conducted in English, which was not the native language for all the participants, the topics of the focus group discussion were sent in advance to the participants.

The focus group discussions were conducted using an online video-conferencing facility, Zoom, to allow participation from different countries simultaneously. While the online videoconferencing facility used in this research was a licensed product of Zoom Inc., all audio and video data were transferred only between servers in the Nordic countries. The names, email addresses and IP addresses of the participants were transmitted to servers within the EU. These were not collected by the researchers through Zoom.

When the participants had joined the online meeting room, the facilitator (RL), who has expertise in qualitative research, including focus group discussions, introduced the SIG and its aim, the research topic, the role of the facilitator in introducing the topics and moving the discussion along, and gave the participants practical instructions. The roles of two other members of the SIG present in the online meeting room were also introduced. An assistant facilitator (MH, SMc or VS) undertook field notes and was prepared to continue the facilitation had the online connection of the main facilitator failed. A record-keeper (GML or SK) took notes of the proceedings to support the transcription. The participants introduced themselves to each other; these demographic data, including the profession and gender of the respondent, and the country in which they worked, were collected for research purposes.

The participants were reminded that their participation was voluntary, and they could leave at any time without giving a reason. However, due to the nature of a focus group discussion, it would not have been possible to erase their contribution to the discussion before their departure. While the topics discussed were not envisaged to be sensitive or distressing, any distressed participant could have withdrawn to a separate online meeting room, where they would have been able to discuss their experiences with the other facilitator (MH, SMc or VS), before returning to the discussion or leaving altogether.

Prior to starting each focus group discussion, consent of all participants was sought for audio and video recording the session, to ensure that the collected data were genuine and for the record-keeper to take notes. These verbal consents were audio recorded. A digital recorder was used to audio record the focus group discussions. As a back-up, the videoconferencing facility, Zoom, was also used to audio and video record the discussions; the video recording was deleted immediately after each discussion, only the audio recording was kept for transcription.

During the focus group discussion, the participants were asked to keep their cameras on if possible, so that they could see each other when discussing the topics. However, if they preferred, they could have kept their cameras off. In this case, the participants were instructed to raise virtually their hand, when asking for their turn to speak. The facilitators and the record-keeper switched off their cameras to let the participants discuss the topics amongst themselves. However, if necessary, the facilitator was prepared to encourage more participation in this online focus group discussion.

To take into account online facilitation and participation, each focus group discussion was planned to last a maximum of 90 minutes. Each topic was allocated enough time for discussion so that everyone was able to participate. The facilitator introduced the topics and encouraged everyone to share their views. This might have meant drawing quiet participants to the discussion and asking dominant participants to give room to others. The focus group discussions were run in a structured way to ensure the objectives were met.

Handling and Storing the Collected Focus Group Discussion Data

This research produced pseudonymised data to be analysed and a register containing personal data (the name, country of work, profession, and contact details, i.e. email address, of the participants). Individual codes for the focus group discussions and the participants of these discussions were created and employed during the analysis.

The digital back-up audio recordings of the discussions, made by using Zoom, were sent to a transcriber (GML and SK) via email, using secure connection and *vice versa*. The discussions were transcribed verbatim, ensuring that the collected data were accurate. However, participants' names or other identifiable information, if used during the discussions, were removed from the transcripts, pseudonymising the data. As another layer of ensuring the trustworthiness of the research, the participants were offered the opportunity to verify the accuracy and completeness of the transcripts of their focus group discussion. After the transcripts were confirmed to be correct and complete, all the audio recordings were deleted. All materials recorded on paper and all data recorded electronically will be securely stored for 24 months after the publication of the research, after which they will be destroyed safely.

Analysing the Collected Focus Group Discussion Data

The transcribed discussions and notes were entered onto an Atlas.ti (version 9) database for storage, coding, and retrieval. A framework approach (Ritchie et al. 2014) was used to explore issues relating to patient safety culture and medication safety within ICUs across Europe. The analysis was inductive, systematic, iterative, and transparent. The analysis was started after all focus group discussions had been conducted and transcribed. All data underwent similar rigorous processes of analysis. The main researcher (RL) read and re-read the transcribed focus group discussions to identify recurring themes that were used as the initial codes of the framework that could be modified during the later phases of the analysis. By using the framework approach, it was possible to record all the phases of the analysis and to preserve links to the individual focus group discussions, thus, making it possible to confirm

interpretations. As part of rigorous analysis, other researchers (AB, JL, VS and SMC) of WG4 checked and confirmed the coding and the trustworthiness of the interpretations in the analysis.

Ethical considerations

Ethical approval was obtained by The University of Helsinki Ethical Review Board in Humanities and Social and Behavioural Sciences (Statement: 18/2022). The Zoom videoconferencing facility stored all data within Europe. The research is General Data Protection Regulation (GDPR) compliant; all collected data were pseudonymised. No incentives were provided.

The cover letter (Appendix V) and the participant information (Appendix VI) contained an explanation of the study, how long the focus group discussion would take, how the data would be stored and used, who was organising the study, who to contact with any questions. A separate consent form was provided for participants to indicate that they had read this information and provide their consent to participate (Appendix VII).

Results

Altogether, 20 HCPs indicated that they were interested in participating in the focus group discussions; 13 participated in three discussions and one provided a written response in May 2022. Three of the participants were nurses and 11 pharmacists. Ten were women and four men. The participants worked in Estonia (n=3), Republic of Ireland (n=3), Spain (n=2), Switzerland (n=2), the UK (n=2), France (n=1) and Italy (n=1), representing Northern (Estonia, Ireland and the UK, n=8), Southern (Italy and Spain, n=3) and Western (France and Switzerland, n=3) European regions. There were no participants from Eastern European region. For the purposes of this study, the findings related to the focus group discussions and the written response are reported as the findings of the focus group discussions.

Patient safety culture

The participants (n=14) discussed their perceptions of the patient safety culture prevalent in their intensive care or hospital setting. They expressed their views on how blame culture and 'good' open culture may influence patient and medication safety. While one participant reported that open patient safety culture had prevailed in both hospitals where they had worked and another reported that blame culture prevailed in a whole country, most participants perceived that both blame, and open culture were prevalent in the hospitals and ICUs where they worked. One of the participants reported that open patient safety culture had prevailed in the ICU in the past, but this had turned into blame

culture after a supportive senior member of staff had left the ICU. However, others mostly perceived that patient safety culture had improved over the years or was currently improving or was even actively being improved.

Influence of blame culture on patient and medication safety

The participants (n=14) thought that if blame culture was prevalent in their working environment, it existed especially amongst the more senior staff within the ICU environment and the managers of the hospitals. As such blame culture was perceived to influence the more junior staff. In the ICU environment, blame culture might be demonstrated by members of staff being blamed, judged, or even punished for committing mistakes. In one ICU, in the past, members of staff, who had been working in the same ICU for a longer time, had not wanted to work with more junior members of staff. The fear of being blamed or even punished may have led members of staff not to admit or report their own mistakes or near-misses or not to report mistakes or near-misses of others or to even cover up mistakes as a mean of protection.

While few of the participants reported that pharmacists could blame other members of staff for committing mistakes, others thought that pharmacists were seen as impartial and supportive. Similarly, some reported that nurses and doctors, especially in senior positions, could blame other members of staff for committing mistakes, rather than considering that particular circumstances had led to an incident or a near-miss. On the other hand, it was perceived that members of staff might be willing to discuss medication related issues with pharmacists. However, at the same time, it was thought that they might not be willing to do so with their other colleagues, doctors, or nurses, as they were believed to have a fear of being judged incompetent; thus, training that would have improved practice might not have been sought or provided. Indeed, the participants described hierarchical structures in the intensive care environment which may foster blame culture further.

The participants perceived that while some HCPs in some ICU environments may believe that individual members of staff are responsible for committing a mistake or a near-miss – others in other places may perceive that the circumstances or the system may be defective and lead to MEs. If mistakes go unnoticed or are not reported, questions are not asked, or issues about the safe use of medicines are not discussed, it is difficult to improve patient and medication safety. Without the support of the senior staff and the management for open culture, blame culture may continue to influence the people working within the ICU environment and the patients they are caring for: patient and medication safety improvement requires a 'good' environment where mistakes are reported, root causes for incidents are found, lessons are learnt, training is provided, and medication safety is improved at the system level.

Developing and improving an open patient and medication safety culture

The participants (n=14) thought that there is a need to develop or improve the existing open culture and to get rid of any remains of blame culture so that members of staff would feel safe reporting and discussing incidents or near-misses and even changing the medication safety language and calling near-misses 'good catches'. Creating such an open culture was, on the other hand, thought to be dependent on senior members of staff within the ICU environment, but also on everyone who works within ICU. An open culture could be achieved if there was a 'good' teamwork atmosphere, where everyone has their role, instead of a hierarchy, and more experienced members of staff and more junior members of staff work together and support each other.

To achieve an open patient safety culture, it was thought important that any fear of blame and any anxieties were removed, so that members of staff could communicate openly and voice their opinions as well as being able to discuss if things had gone well or not so well. Such a step was perceived to require moving towards system-based patient and medication safety thinking, where causes of incidents and near-misses are sought in the working processes and the environment. The participants perceived that in an open environment, where there is a positive attitude to patient safety, involving members of staff in finding solutions to potential concerns in the medication process and acting on suggested improvements, would improve patient and medication safety.

The participants perceived that when an open culture existed in ICU environment, members of staff would trust each other and actively ask for medication related advice, when necessary, and their colleagues would provide the required advice, training and even mentoring. Interprofessional collaboration and working together for the best of the patient were perceived important. On the other hand, in situations when 'things had not gone well', i.e. there had been a medication related incident, a member of staff would be offered support. This support could include a debriefing, opportunities to voice concerns, and feeling comfortable about talking about the incident. In this environment, the debriefing could include thinking about the circumstances that had led to 'not an ideal situation', which was thought preferable to thinking that 'things had gone wrong'. While a debriefing should be offered for those closely involved in any incident, it was perceived that safety briefings should be offered to all members of staff. The participants thought that when an open culture existed, with the involvement of members of staff, it would be possible to identify the 'root causes' of incidents within the system, and learn from them, improving the medication processes and structures. Furthermore, in such an environment, members of staff would want to be involved in improving practice, looking actively for processes that are not working well and monitoring improvement.

Changes in the processes and structures were perceived to constantly require raising awareness of members of staff to keep the momentum of safety initiatives, and support and allocated resources from the hospital management. In addition, national patient and medication safety initiatives were perceived as supportive for such changes. To further support the open culture, it was thought that communication between the hospital management and staff should be improved, and that the management of the hospital should ensure that feedback is provided on patient and medication safety improvements. To foster open culture and the development of patient and medication safety, it was perceived that being aware of relevant strategies on how to improve patient and medication safety was crucial as well as forming a good strategy for these improvements, including, for example, implementing an electronic incident reporting system, whose reports would be reviewed independently by a clinical risk or safety team.

Factors influencing the implementation of medication error prevention strategies

Barriers to medication safety

The participants (n=14) discussed various issues that they perceived to influence medication safety and the implementation of ME prevention strategies as barriers. Thirteen themes of perceived barriers to medication safety emerged from the discussions (Figure 29), one of which had been the recent COVID-19 pandemic. They mentioned most frequently a lack of engagement of HCPs and their attitudes towards medication safety (n=37), and an existing blame culture (n=34) as barriers to medication safety and to developing it.

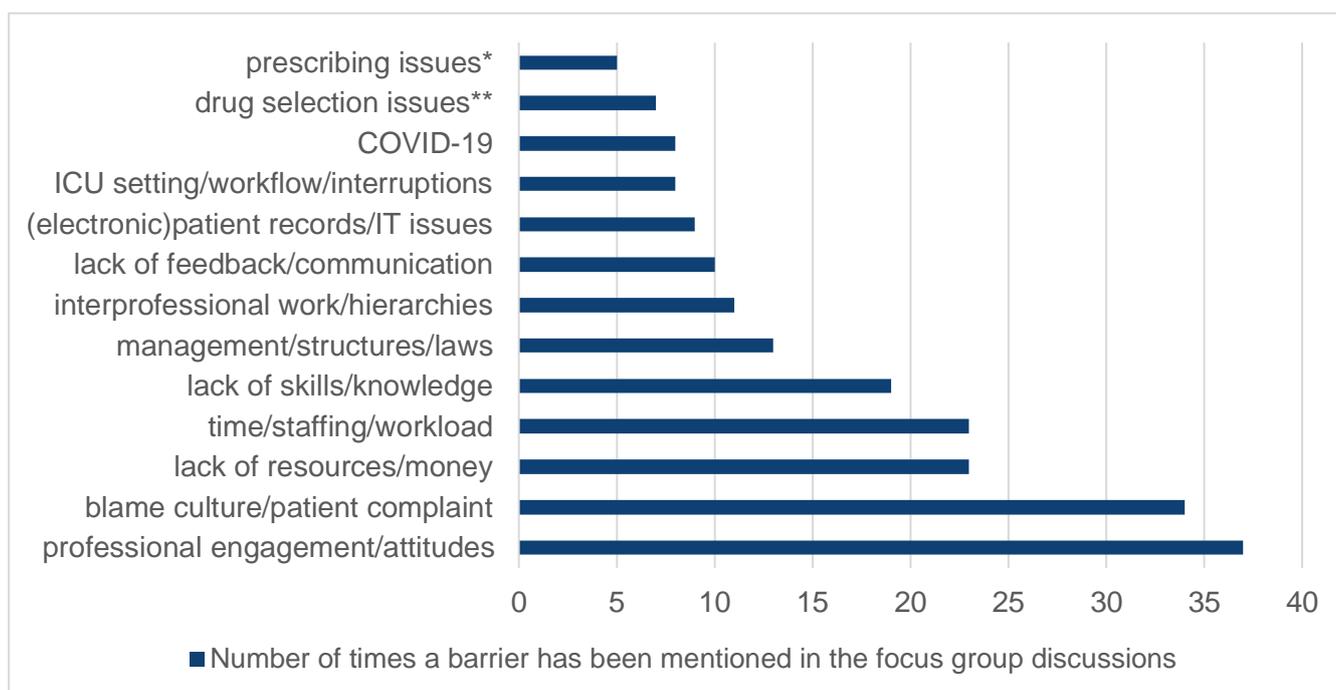


Figure 29. The number of times a certain issue was mentioned as a barrier to medication safety by the focus group discussion participants.

*Prescribing issues included: use of verbal and hand-written prescriptions, and lack of medicines reconciliation.

**Drug selection issues included: drug shortages and look-alike sound-alike (LASA) drugs with their similar sounding names and similar looking packaging.

Facilitators of medication safety

The participants (n=14) discussed various issues that they perceived to influence medication safety and the implementation of ME prevention strategies as facilitators. Sixteen themes of perceived facilitators of medication safety emerged from the discussions (Figure 30). They mentioned most frequently engaging HCPs in improving medication safety, providing feedback to them on MEs and ME prevention strategies, and communicating with other HCPs (n=31), working interprofessionally in an environment without hierarchies (n=27), and having a 'good' culture and environment (n=25) as facilitators for medication safety.



Figure 30. The number of times a certain issue was mentioned as a facilitator for medication safety by the focus group discussion participants.

Medication error prevention strategies

Finally, the participants (n=14) discussed ME prevention strategies that were in use, not in use, planned to be implemented in the next five years, were perceived to be ineffective, or had been rejected in their intensive care units.

Medication error prevention strategies in use

The participants (n=14) reported 25 different ME prevention strategies that were in use in their ICUs (Figure 31). They mentioned most frequently assessing knowledge and auditing practice and learning, teaching and training (n=34), incident reporting (n=31), and pharmacists working in ICU and participating in ward rounds (n=30) as ME prevention strategies in use.

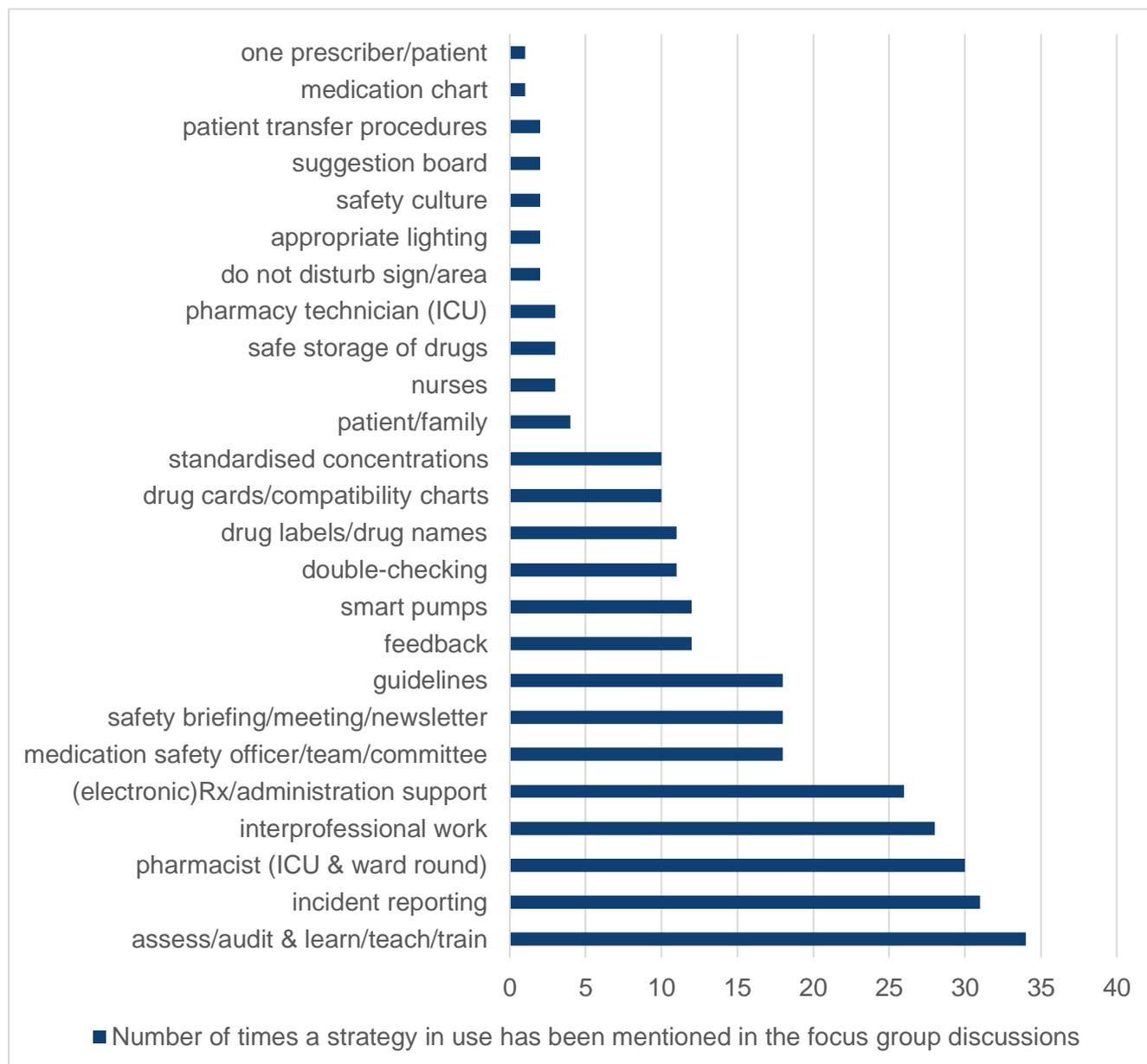


Figure 31. The number of times a medication error prevention strategy in use was mentioned by the focus group discussion participants. Rx = prescribing.

Medication error prevention strategies not in use

The participants (n=14) reported six different ME prevention strategies that were not in use in their ICUs (Figure 32). They mentioned most frequently EP and administration support (n=7) as a ME prevention strategy not in use.

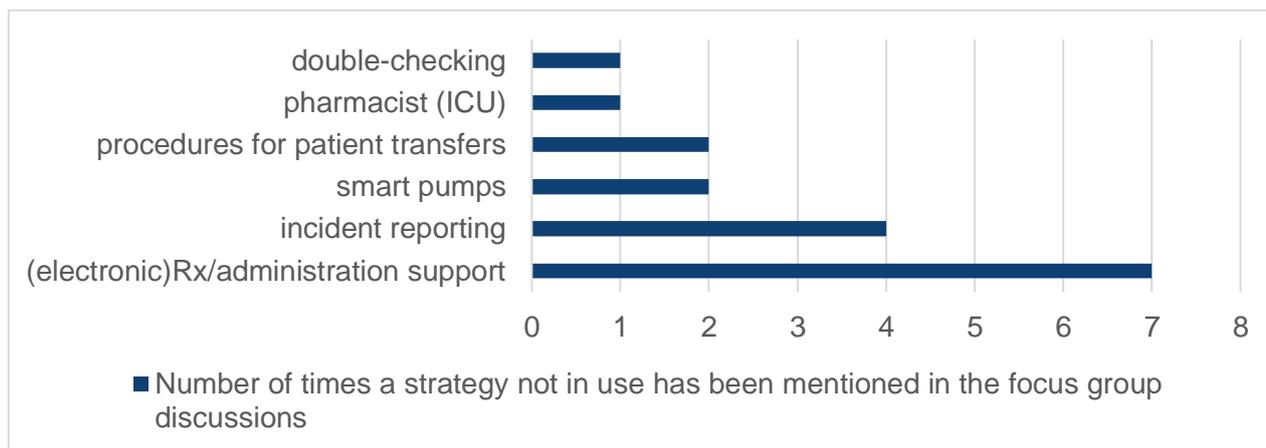


Figure 32. The number of times a medication error prevention strategy not in use was mentioned by the focus group discussion participants. Rx = prescribing.

Medication error prevention strategies planned to be implemented

The participants (n=14) reported 11 different ME prevention strategies that were planned to be implemented for use in their ICUs in the next five years (Figure 33). They mentioned most frequently EP and administration support (n=24) as a ME prevention strategy planned to be implemented.

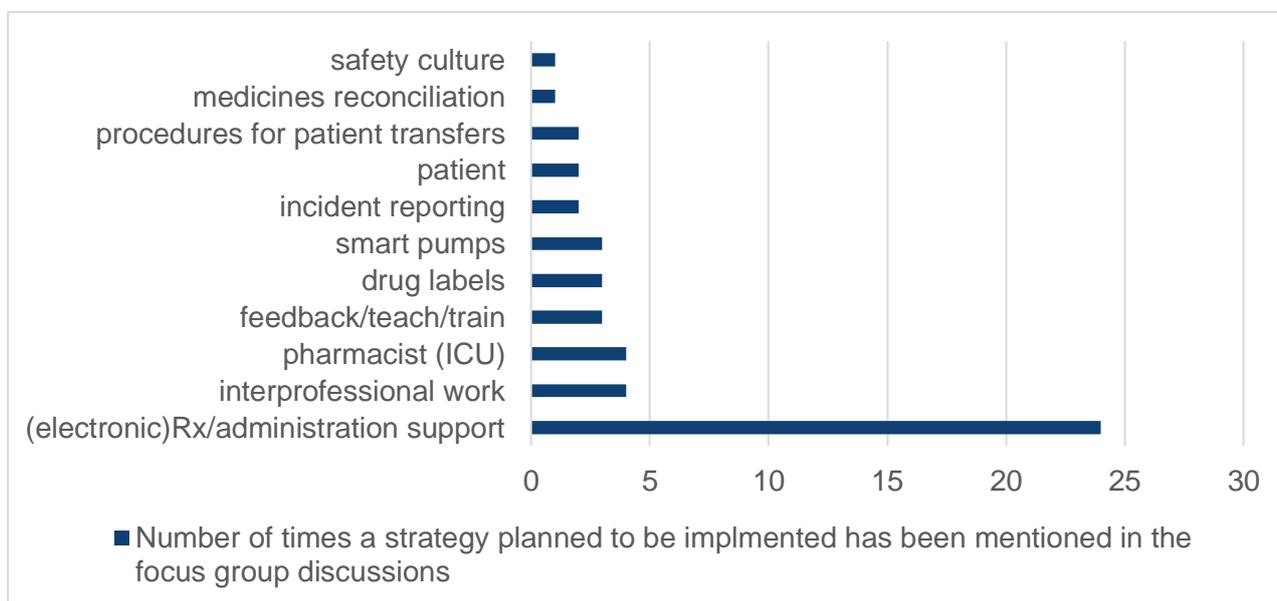


Figure 33. The number of times a medication error prevention strategy planned to be implemented for use was mentioned by the focus group discussion participants. Rx = prescribing.

Medication error prevention strategies that are perceived to be ineffective

The participants discussed seven different ME prevention strategies that they perceived to be ineffective in their ICUs (Figure 34). They mentioned most frequently double-checking (n=10), EP and administration support (n=7), and incident reporting (n=7) as ME prevention strategies perceived as ineffective.

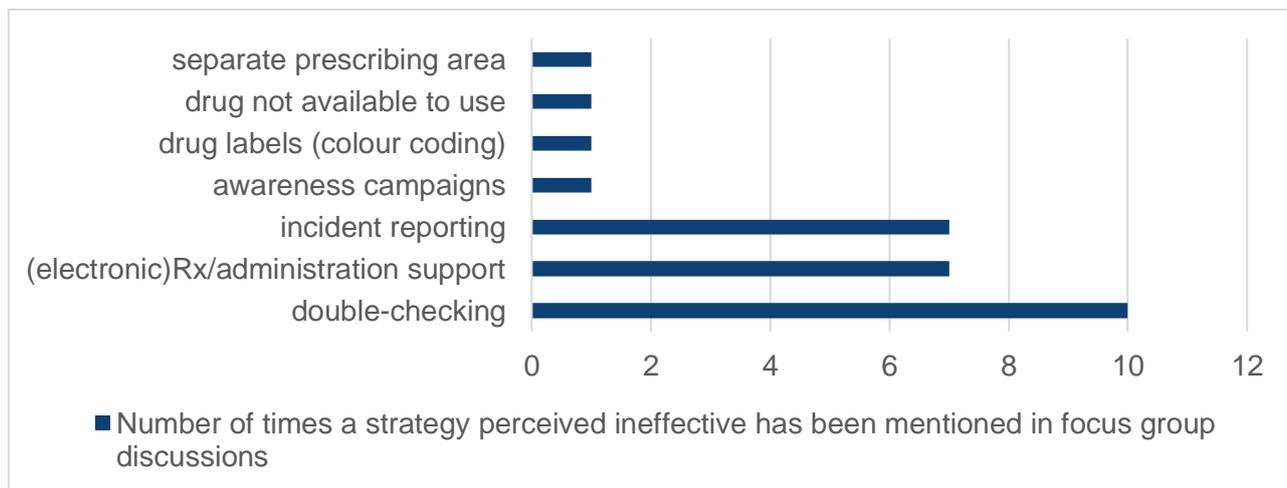


Figure 34. The number of times a medication error prevention strategy perceived as ineffective was mentioned by the focus group discussion participants. Rx = prescribing.

Medication error prevention strategies that have been rejected

The participants reported six different ME prevention strategies that had been rejected from implementation or use in their ICUs (Figure 35). They mentioned most frequently EP and administration support (n=3) as a rejected ME prevention strategy.

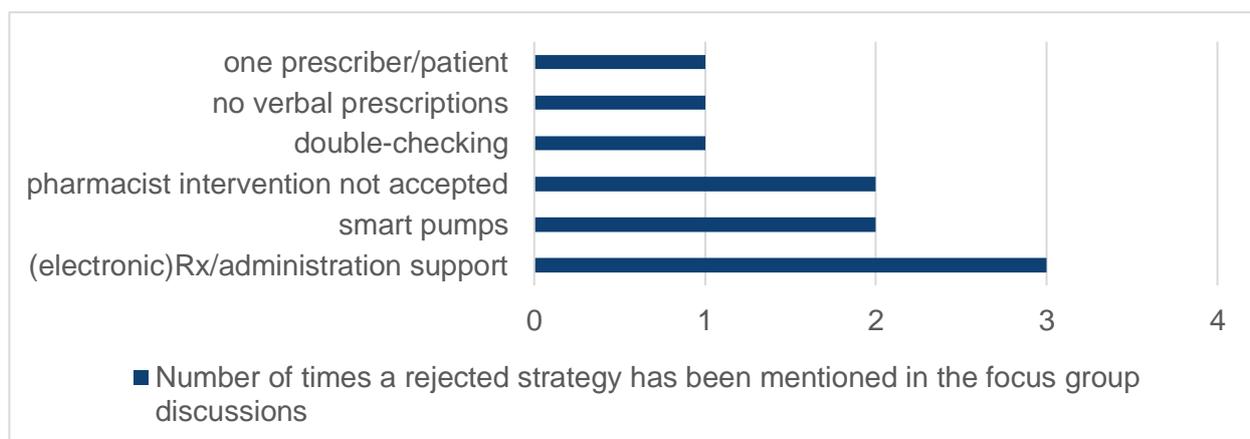


Figure 35. The number of times a medication error prevention strategy rejected from implementation or use was mentioned by the focus group discussion participants. Rx = prescribing.

Discussion of the focus group discussions

In these focus group discussions, 14 healthcare professionals participated from seven different countries, representing Northern, Southern and Western European regions (United Nations 2022). They expressed their views on how blame culture and 'good' open culture may influence medication safety, indicating that there may be scope for improving patient safety culture to enable enhancement of medication safety. In addition to having a 'good' culture and environment, interprofessional working in an environment without hierarchies, engaging, and communicating with HCPs in improving medication safety, may facilitate medication safety improvement. There was variation in the use of ME prevention strategies, suggesting there may be some scope for learning from 'best' practice.

Strengths and limitations.

The strengths of this study include participation from a range of European countries, representing Northern, Southern and Western European regions. The participants were recruited using purposive sampling to ensure expression of diverse experiences and perceptions; the analysis showed both similarities and differences in experiences and perceptions. A limitation is the low number of expressions of interest to participate, and a lack of participation of HCPs from Eastern European region. The requirement of having a suitable level of fluency in English to participate may have influenced participation. Other limitations include a lack of participation of medical practitioners, perhaps due to a high workload, lack of engagement or interest in, or knowledge of, medication safety practices. As with any focus group discussion study, there may be some response bias such as individuals with greater interest or expertise in medication safety being more likely to participate. Saturation of data might have required 15-20 participants; the timing and the number of the focus group discussions were limited, and it was not possible to continue the recruitment. There may also be potential variation in responses due to the profession of the respondents which we were unable to formally explore.

Delphi panel for developing and prioritising policy recommendations for medication safety improvement for European intensive care units

Materials and methods

Working group (WG4) of the SIG, supplemented by three members from WG2 and WG3, undertook a formal consensus process to develop and prioritise policy recommendations for medication safety improvement in ICUs across Europe. This working group was comprised of seven pharmacists, three of which were actively working in the ICUs of their university hospitals, one was a medication safety pharmacist, and the remaining three members were pharmacists working in academia for whom medication safety and patient safety are areas of research. The members of this group were based in different European countries.

Study design

A commonly used consensus methodology known as a Modified Delphi Consensus Study was utilised to develop and prioritise the list of policy recommendations. This method involves use of a panel of experts who provide their opinion in an anonymised and highly structured manner and functions on the premise that group opinion is more valid than that of an individual.

The classical Delphi Study involves the use of a series of questionnaires issued to an expert panel in an iterative manner. A summary of results from the previous round is then provided as controlled anonymous feedback, with the aim of converging opinion and reaching consensus (Jones, Hunter 1995, Keeney et al. 2010). The term 'modified' Delphi has been applied where face-to-face or online meetings, in tandem with the iterative rounds of consensus, are used (Boulkedid et al. 2011, Keeney et al. 2010). Other modifications include the research team, rather than the expert panel, defining the issues requiring consensus during the initial phase of the process (Keeney et al. 2010). This process has previously used to produce best practice and international patient safety recommendations and was utilised by the SIG for the purposes of this study; (Howell et al. 2017, Smith, Z. R. et al. 2019); the working group developed the list of policy recommendations based on the earlier phases of this study as described above, and the initial stage of the study was conducted online. This study is reported according to the Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review (Jünger et al. 2017).

Participants and sampling

All members of the SIG (n=21) from 13 European countries, representing Northern, Southern and Western European regions (United Nations 2022), were invited to participate in the Delphi panel. Convenience sampling was employed, however, the SIG provided a panel comprised of a diverse representation of HCPs with suitable expertise in ICU or medication safety based on their selection for SIG membership.

Although anonymity is commonly preserved with the identity of other Delphi panel members not known to participants, this was not possible in this study due to the composition of the panel and the fact that participants were known to each other through their SIG membership. However, the identity of those SIG members who ultimately participated in the panel was not known. Moreover, the panel members were not aware of how other panel members scored each recommendation, nor any comments submitted to the survey tool by them.

Each SIG member received an e-mail, a participant information sheet (Appendix IX) inviting them to participate; participation was voluntary. The potential panellists were informed that all their responses would be submitted onto a GDPR-compliant web-based online survey tool (easy-feedback.com) that does not register IP-addresses; participation was also anonymous as it was not possible to know who decided to opt out and not participate. The participants were also informed that submission of their responses via this online survey tool would be considered as proof of informed consent to participate. They were also informed that they could withdraw from the study at any stage of the process. However, as all responses were submitted anonymously, they were informed that it would not be possible for their submitted scores to be withdrawn. No incentives were offered.

Handling and analysing the collected consensus data

This research produced anonymised data to be analysed and a register containing personal data (the name, country of work, profession, and contact details, i.e. email address, of the participants). Anonymous submitted responses were exported from the online survey tool for further analysis by the supplemented WG4 using Microsoft Excel® workbooks (version 2016 or newer). The median and inter-quartile range (IQR) for each recommendation was calculated and the results analysed for the degree of consensus. The following pre-determined consensus definitions were applied (Howlett et al. 2018):

- ‘Consensus’ was considered to exist if the interquartile range of the participants’ responses fell within any three-point range;

- ‘Disagreement’ was considered to exist if the interquartile range span both the 1–3 range and the 7–9 range; and
- If neither consensus nor disagreement existed, ‘Partial Agreement’ was considered to have occurred.

Where consensus existed, it was considered that the recommendation was a ‘high priority’ if the median score fell within the 7–9 range, a ‘low priority’ if it fell within the 1–3 range, and a ‘medium priority’ if it fell within the 4–6 range.

Ethical considerations

Ethical approval was obtained by The University of Helsinki Ethical Review Board in Humanities and Social and Behavioural Sciences (Statement: 18/2022). The ‘easyfeedback.com’ platform is General Data Protection Regulation (GDPR) compliant, does not store IP addresses and stores all data within Europe. No personally identifiable data were collected through the Delphi survey, and the data obtained contained no information that would have reasonably allowed identification of any of the participants. No incentives were provided.

The cover letter (Appendix IX) and the participant information (Appendix X) contained an explanation of the study, how long the Delphi survey would take to complete, how the data would be stored and used, who was organising the study, who to contact with any questions. The participants were also informed that submission of their responses via the online survey tool would be considered as proof of informed consent to participate.

Developing the Delphi panel survey and conducting the Delphi panel

Stage 1: Identification of Recommendations

The findings from the following earlier phases of the study were gathered and reviewed by the supplemented WG4 to develop an initial list of potential policy recommendations to be presented to the Delphi panel:

- ME prevention strategies used to improve medication safety in the ICU environment as identified through the literature review;
- ME prevention strategies both currently in use and being planned in ICUs across Europe as identified through the conducted survey; and
- ME prevention strategies that emerged from the focus group discussions with HCPs working across Europe.

A number of additional key references sources were then reviewed to provide supporting references and to identify any further recommendations which may have been omitted. These included standards, statements, guidelines, policy positions and action plans from: the EAHP, the Institute for Safe Medication Practice (ISMP), the American Society of Health-System Pharmacists (ASHP), the WHO, relevant professional organisations from the European Union or its individual member countries, Australia and Switzerland, a recently published list of recommendations about medication error prevention in ICUs in Spain (EAHP 2014, ISMP 2022a, ASHP 2018, WHO 2021, HSE 2021, PSA 2017, PREVEMED 2022, SwissASP 2020, RPS 2022, ASHP 2010, ASHP 2009, ASHP 2019, EAHP 2020, European Commission 2021, ISMP 2015, ISMP , ISMP 2022b, WHO 2014). Where required, a small number of peer-reviewed publications were also referenced to supply supporting evidence.

A final list of proposed recommendations was then agreed with input from all members of the supplemented WG4 over a number of meetings. A summary of the supporting evidence was incorporated into the list of proposed recommendations to be shared with the expert panel in Stage 2. The survey for the use in the consensus round was constructed in the online survey platform ('easyfeedback.com') which comprised of a background, instructions, and a series of questionnaires to allow individual scoring for each policy recommendation. The supplemented WG4 tested the survey to ensure usability prior to finalisation.

Stage 2: Iterative consensus rounds

A multi-stage modified Delphi process with a number of iterative rounds was conducted. The first round (Delphi Round 1) was conducted as a virtual presentation during one of the scheduled SIG meetings. It was estimated this would require 60-90 minutes, requiring no additional time commitment from the participants. Subsequent Delphi consensus rounds included only those recommendations where consensus, or dissent had yet to be reached were included. These were conducted by e-mail in consideration of geographical diversity and time constraints of individual Delphi panel members. It was estimated that completion time for Round 2, and any subsequent rounds, would not exceed 30 minutes. No further time commitment was asked of the participants.

During each round, participants were to be asked to independently score each recommendation using the online survey tool. A 9-point Likert scale was utilised, where a score of 1 indicated 'definitely not a priority' and a score of 9 indicated 'a key priority'. Participants were also to be invited to record any comments on individual recommendations within a dedicated section on the online survey. These comments provided a better understanding of the rationale behind the responses provided at each

round and were used to modify the recommendations as appropriate. Each panel member was asked to save and download their own responses from the online survey instrument on completion of each round.

After each round, feedback was provided to all panel members. This comprised of the distribution of the panel's response and the list of comments from that round. This provided panel members access to the responses of the rest of the panel without knowing the identity of the individuals providing the scores or comments. They were asked to review these group responses in conjunction with their own recorded responses. Participants were instructed that they need not to conform to the group view.

Delphi Panel Round 1

A virtual presentation was delivered to the Delphi panel by one of the members (MH) of WG4 in a SIG meeting on 13th October 2022. A few days prior to the meeting, the final list of recommendations and the supporting evidence for each was sent to the Delphi panel and they were invited to review this material in advance of the meeting. During the presentation, participants were provided with an overview of how the recommendation list had been developed in Stage 1 and the consensus process about to commence. Participants were then sent a link to the online survey by email during the meeting. A brief description of each individual recommendation was then provided, with a short interval between each to allow participants time to consider their response, enter their score using the 9-point Likert scale, and record any comments the online survey tool as described above. After a small number of recommendations were presented, participants were invited to continue the process working independently, with the presenter and supporting WG members remaining accessible on the remote meeting should assistance be required. On completion of the meeting, two separate reminder emails with a link to the Delphi survey were sent to all members of the panel at two weekly intervals.

Delphi Panel Round 2

On completion of Round 1, all data was extracted from the online survey platform and analysed for level of consensus and level of priority. Those recommendations for which consensus, or dissent, was not reached during Delphi Round 1 were identified and collated for inclusion in Round 2. Any comments received during Round 1 were reviewed by the WG and a number of minor modifications were made to the phrasing of the Round 2 recommendations. As for Round 1, the survey for Round 2 was constructed in the online survey platform ('easyfeedback.com') and tested for usability prior to finalisation.

On completion of Delphi Round 2, a discrepancy in the calculation of the interquartile range of two recommendations in Delphi Round 1 data was identified. As a result of this, a further supplementary consensus round using the same online survey tool was required to achieve consensus on these two recommendations. This was referred to as Delphi Round 2b, with the original Round 2 being renamed as Delphi Round 2a.

A link to the online Delphi Round 2a survey was provided in an email sent on 15th November 2022; the participants were asked to submit their scores and comments by 21st November 2022. In Round 2a, each participant was provided with a data sheet containing: the Delphi Round 2 recommendations; the median and inter-quartile range (IQR) of the panel's scores; and any comments provided by individual panel members from Delphi Round 1. The participants had the option to amend or retain their own Delphi Round 1 score after having considered the group results. As in the previous round, participants were asked to save their Delphi Round 2a scores to allow them to compare their individual corresponding scores to those of the panel.

A link to a supplementary Delphi Round 2b survey was provided in an email sent on 6th December 2022; the participants were asked to submit their scores and comments by 12th December 2022. One reminder email (Delphi Round 2a and 2b, respectively) was sent to all members of the panel. Consensus was determined after Delphi Rounds 2a and 2b; thus, a planned third round was not conducted.

Results

Developing initial policy recommendations

In total, 32 initial policy recommendations on how to improve medication safety in ICUs across Europe were developed (Table 8) based on the literature, and the previous phases of the study. These were divided into eight categories:

1. Organisational Safety Culture & Working Environment (n=7);
2. Technology (n=7);
3. Clinical Pharmacy (n=2);
4. Education & Training (n=1);
5. Intravenous Medication Management (n=5);
6. High-Risk Medications (n=2);

7. Medication History & Reconciliation (n=4); and
8. Access to Medication and Resources (n=4).

Developing and prioritising policy recommendations through a Delphi panel

All 21 members of the SIG received the invitation to participate in Round 1 of the Delphi panel in October 2022 and in Round 2 in November and December 2022. One of the members of the SIG had a nursing background, four a medical background and 17 a pharmacy background. Four were men and 17 were women. Due to the anonymous participation, it is not possible to describe the backgrounds of the respondents.

Delphi panel round 1

Altogether, 19 healthcare professionals participated in Delphi Round 1; one of the participants did not provide their opinion to one of the policy recommendations (recommendation 28). Consensus on most of the recommendations was achieved (Table 8), and partial consensus on six recommendations (recommendations 5, 6, 8, 13, 27 and 30); there were no disagreements, or dissent. All but three recommendations (recommendations 4, 8 and 30) were considered as 'high priority'.

Table 8. Delphi Round 1 Consensus and Priority Levels

Number	Recommendation	Median (Q1-Q3; IQR)*	Consensus & Priority
1	Create and maintain an open, transparent and non-hierarchical 'no blame' culture supported by the ICU management to support staff in identifying, sharing, reporting and learning from incidents and near misses.	9 (9-9;0)	Consensus High Priority
2	Implement an effective system to support the reporting of (medication-related) incidents and near misses, including mechanisms to provide feedback on reports to ICU staff.	8 (8-9;1)	Consensus High Priority
3	Undertake routine, systematic and multi-disciplinary review of all ICU related incident reports to identify medication safety areas of risk, opportunities for improvement and provide feedback to ICU staff e.g. use of risk huddles.	8 (8-9;1)	Consensus High Priority
4	Nominate a Medication Safety Lead within the ICU setting to work closely with the organisational Medication Safety Officer (or equivalent) where such a role exists on the implementation and promotion of medication error prevention strategies.	6 (6-8;2)	Consensus Medium Priority
5	Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU to monitor medication safety within the ICU.	7 (5-8;3)	Partial Consensus

Number	Recommendation	Median (Q1-Q3; IQR)*	Consensus & Priority
			High Priority
6	Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	8 (6-9;3)	Partial Consensus High Priority
7	Ensure a safe working environment is provided for ICU staff to practise in a safe and efficient manner e.g. adequate lighting, avoidance of interruptions.	8 (7-9;2)	Consensus High Priority
8	Implement Automated Dispensing Cabinets for the storage of medications in the ICU.	6 (4-7;3)	Partial Consensus Medium Priority
9	Replace paper-based prescriptions with electronic prescribing systems e.g. computerised physician order entry, with associated clinical decision support appropriate to the ICU setting.	9 (7.75-9;1.25)	Consensus High Priority
10	Implement the use of Barcoded Medication Administration to reduce medication administration errors and support complete documentation.	7 (6-8;2)	Consensus High Priority
11	Administer all medication infusions via programmable infusion pumps utilising 'Dose Error Reduction Software' or 'Smart-pumps', which contain a complete and regularly reviewed and updated drug library.	8 (6-8;2)	Consensus High Priority
12	Ensure policies are in place to reduce workarounds and over-rides in the use of implemented technology e.g. bypassing smart-pump drug libraries, barcode medication administration workarounds and automated dispensing cabinet over-rides.	7 (6-8;2)	Consensus High Priority
13	Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, supporting the '5 rights' of medication administration.	7 (5-8;3)	Partial Consensus High Priority
14	Provide dedicated resources to facilitate the implementation, optimisation, maintenance and regular updates to all systems involved in medication management within the ICU.	8 (7-9;2)	Consensus High Priority
15	Provide a dedicated and specialised clinical pharmacy service to the ICU at a staffing level sufficient to ensure regular review and verification of all medications, attendance at multi-disciplinary rounds and input into the development of policies, procedures and guidelines.	9 (8-9;1)	Consensus High Priority
16	Adopt formal antimicrobial stewardship with multidisciplinary input to ensure appropriate use of antimicrobials and reduce antimicrobial resistance.	9 (8-9;1)	Consensus High Priority
17	Provide staff with protected time during working hours and access to a range of education and training opportunities in safe medication use to include new staff from all disciplines, new equipment/medications, refresher training and competency assessment.	8 (7-9;2)	Consensus High Priority
18	Standardise and reduce the range of available/recommended medication infusion concentrations.	9 (8-9;1)	Consensus High Priority

Number	Recommendation	Median (Q1-Q3; IQR)*	Consensus & Priority
19	Provide supporting protocols and guidelines on preparation of IV medications as appropriate to the setting and availability of "ready-to-administer" infusion solutions.	9 (8-9;1)	Consensus High Priority
20	Minimise 'bedside' preparation of intravenous medications and replace with procured and centrally prepared 'ready-to-administer' or 'ready-to-use' medications wherever possible.	8 (7-9;2)	Consensus High Priority
21	Ensure ease of access to information on intravenous compatibilities.	8 (7-9;2)	Consensus High Priority
22	Ensure processes are in place to support safe intravenous medication administration to include: appropriate labelling of medications and administration lines utilising targeted risk reduction strategies e.g. use of colours, TALLman lettering; administration line checks; infusion pump checks.	8 (7-9;2)	Consensus High Priority
23	Maintain a high-risk medication list that is reviewed regularly and is context-specific e.g. paediatrics, with a robust set of associated risk mitigation processes for all stages of the medication use process.	7 (6-8;2)	Consensus High Priority
24	Ensure targeted and risk assessed organisational policies and procedures are in place to support checking procedures for the preparation and administration of high-risk medications e.g. items requiring independent double-checking, specific labelling requirements.	8 (7-9;2)	Consensus High Priority
25	Employ standardised procedures, including patient, family and carer involvement as appropriate, to obtain and document an accurate and complete list (best possible medication history) of each patient's current medication on admission to the ICU.	8 (7-9;2)	Consensus High Priority
26	Implement a formal and thorough medication reconciliation process on both admission to, and discharge from, the ICU to ensure accurate and comprehensive medication information is communicated consistently.	8 (7-9;2)	Consensus High Priority
27	Promote interdisciplinary communication across entire medication use process, utilising a range of mechanisms and structures e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice boards, memos.	8 (6-9;3)	Partial Consensus High Priority
28 (n=18)	Minimise the use of verbal orders with provision of defined supporting processes e.g. pre-printed templates, order sets.	8 (7-9;2)	Consensus High Priority
29	Provide a pharmacy-led service to ensure consistent, appropriate and safe access to a full range of medications appropriate to individual ICUs e.g. stock lists, regular top-up service, drug shortage management, defined storage locations, segregation of high-risk and sound-alike/look-alike medications.	9 (8-9;1)	Consensus High Priority
30	Source and supply medications in 'unit-dose' form with individual barcode where possible to support barcode medicines administration and closed-loop medication management.	6 (4-7;3)	Partial Consensus Medium Priority
31	Ensure all appropriate antidotes, reversal agents, rescue agents and relevant protocols are readily available.	9 (7-9;2)	Consensus

Number	Recommendation	Median (Q1-Q3; IQR)*	Consensus & Priority
			High Priority
32	Maintain a comprehensive and easily accessible suite of up-to-date guidelines and reference sources, which are: approved at an organisational level; made available in digital format where possible; and with robust governance and version control measures in place.	8 (7-9;2)	Consensus High Priority

* Q1- Quartile 1; Q3 – Quartile 3; IQR – Interquartile Range

The feedback received during Delphi Round 1 (Table 9) was used, as appropriate, to modify the six recommendations (recommendations 5, 6, 8, 13, 27 and 30; Table 9) that had received partial consensus for Delphi Round 2. All but two (recommendations 6 and 30) were reworded.

Table 9. Recommendations modified for Delphi Round 2 based on the feedback given by the Delphi panel of experts (n=19) in Delphi Round 1.

Number	Recommendation	Feedback in Delphi Round 1
5	Delphi Round 1: Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU to monitor medication safety within the ICU.	I think that it is important to undertake regular audits but would wonder specifically what is being audited and how the audit data is fed back to ensure quality improvement. Sometimes audits are done but there's no follow up or changes apparent. I'm not sure how one would audit patient safety climate? (Score 7)
	Delphi Round 2 modified : Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU, to inform improvement of medication safety within the ICU.	People get tired of the enormous amount of surveys and only the extremes will be answered (very good versus very bad). People always assess themselves as "perfect" so I do not feel that this will lead to genuine improvement opportunities. (Score 3) Not sure how effective this would be compared to the effort involved. (Score 4)
6	Delphi Round 1: Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	This is really important - without sustained appropriate resources, it is very difficult to invest in ways that support patient safety. (Score 9) IT programming takes time and needs updating regularly. This is costly. (Score 8)
	Delphi Round 2 (unchanged): Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	What is "appropriate technology" depends on the context, the ability to maintain good use of technology is as important as "starting" new technology intense processes. (Score 7) What is "adequate"? This is potentially an open-ended sum of money! We will always need more staff... (Score 6)

Number	Recommendation	Feedback in Delphi Round 1
8	Delphi Round 1: Implement Automated Dispensing Cabinets for the storage of medications in the ICU.	Especially useful for medications that are "look-alike" or "sound-alike". Less useful for bulk medications (norepinephrine, insulin, etc.). (Score 8)
		ADC is one tool to promote safe storage. It is not always a good solution. (Score 2)
	Delphi Round 2 (modified): Implement Automated Dispensing Cabinets for the storage of medications in the ICU, <u>ensuring adequate resources for training, monitoring of usage and optimisation</u> .	Very difficult to comment on this - one it depends how they are implemented - "the devil is in the detail" - if well used and well-implemented, they may benefit patient safety. If not well used, they may make it worse. (Score 4)
		Personal experience with this has not been good. Limited benefit for such a large input of capital and personnel. (Score 3)
13	Delphi Round 1: Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, <u>supporting the '5 rights' of medication administration</u> .	Ultimately this would be the goal to ensure all technology is integrated to support closed loop med management. (Score 7)
		Difficult question! I did not understand the "5 rights" part. However, fully automated closed loop medication management is the next step if we can measure biomarkers or effects continuously. (Score 3)
	Delphi Round 2 (modified): Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, <u>minimising opportunities for error at each stage of the medication use process</u> .	Closed loop in the ICU differs from closed loops in other wards. Patients need differ very fast in the ICU. Closed loop might not always be the way of doing things. If you focus on handling all the different steps in the closed loop you might not be able to focus on the current needs of the patient. This is not easy. (Score 1)
		Very nebulous - hard to implement consistently. (Score 3)
		I think that this recommendation is worded in a way that would make it difficult to measure its implementation in practice. (Score 4)
		Perhaps medication use instead of medication administration? (Score 9)
27	Delphi Round 1: <u>Promote</u> interdisciplinary communication across entire medication use process, <u>utilising a range of mechanisms and structures</u> e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice-boards, memos.	Communication is essential to promote patient safety. Clear channels of communication are important to avoid errors occurring - all staff should be aware of how and who to communicate medication safety issue with. (Score 9)
	Delphi Round 2 (modified): <u>Ensure clear policies and processes are in place to support</u> interdisciplinary communication across entire medication use process, e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice boards, memos.	An automated handover of medications from the ICU to the step-down ward is very convenient but carries the danger that the physicians and nurses from the step-down unit do not critically appraise those prescription. Rather than "prescribing" for the step-down unit I would want to "suggest" medication to be continued at discharge from the ICU. That makes the physicians and nurses of the step-down unit responsible for really starting that medication. (Score 6)

Number	Recommendation	Feedback in Delphi Round 1
		Sorry, what is this???What does it say? (Score 4)
		This is quite a general recommendation - not sure what this means in practice. (Score 5)
		Too nebulous. (Score 5)
30	Delphi Round 1: Source and supply medications in 'unit-dose' form with individual barcode where possible to support barcode medicines administration and closed-loop medication management.	Often these medications are not a "one pill kill" and medication errors are only near-misses. However, if you want a real PDCA-cycle this is important. This is quite expensive and laborsome for the pharmacy because all medications need to be newly packaged and barcoded. Not really consistent with a "green ICU". One of the last steps in the entire medication safety process. (Score 5)
	Delphi Round 2 (unchanged, but capitalised): Source and supply medications in 'unit-dose' form with individual barcode where possible to support Barcode Medicines Administration and closed-loop medication management.	Not sure about this. (Score 4)
		Depends how it's done - and is there evidence to support the benefits in ICU? (Score 4)
		...Barcode Medicines Administration... (Score 9)

Delphi Panel Round 2

Altogether, 18 healthcare professionals participated in prioritising recommendations 8, 13, 27 and 30 in Round 2a (Table 10); however, one of the participants did not provide their opinion to recommendation 30. 17 healthcare professionals participated in Delphi Round 2b for the prioritisation of recommendations 5 and 6 (Table 10); participants classified all recommendations as 'high priority' (Table 10) with 'consensus' in Delphi Round 2.

Table 10. Delphi Round 2a and 2b Consensus and Priority Levels

Number	Original recommendation	New recommendation	Median (Q1-Q3; IQR)*	Consensus & Priority
5 [#]	Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU to monitor medication safety within the ICU.	Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU, to inform improvement of medication safety within the ICU.	7.5 (6-8; 2)	Consensus High Priority
6 [#]	Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	8 (7.5-9; 1.5)	Consensus High Priority
8	Implement Automated Dispensing Cabinets for the storage of medications in the ICU.	Implement Automated Dispensing Cabinets for the storage of medications in the ICU, ensuring adequate resources for training, monitoring of usage and optimisation.	7 (5-7.25; 2.25)	Consensus High Priority
13	Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, supporting the '5 rights' of medication administration.	Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, minimising opportunities for error at each stage of the medication use process.	7 (6.75-8.25; 1.5)	Consensus High Priority
27	Promote interdisciplinary communication across entire medication use process, utilising a range of mechanisms and structures e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice boards, memos.	Ensure clear policies and processes are in place to support interdisciplinary communication across entire medication use process, e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice boards, memos.	8 (6.75-9; 2.25)	Consensus High Priority
30 (n=17)	Source and supply medications in 'unit-dose' form with individual barcode where possible to support barcode medicines administration and closed-loop medication management.	Source and supply medications in 'unit-dose' form with individual barcode where possible to support barcode medicines administration and closed-loop medication management.	7 (4.5-7; 2.5)	Consensus High Priority

* Q1- Quartile 1; Q3 – Quartile 3; IQR – Interquartile Range

Delphi Round 2b (all others = Delphi Round 2a)

Final policy recommendations on medication safety improvement in intensive care

After two Delphi panel rounds, consensus was achieved on all 32 policy recommendations (Table 11). All but one (recommendation 4; medium priority) were considered as 'high priority'. Further Delphi panel rounds were not required.

Table 11. The final policy recommendations on medication safety improvement for intensive care after two Delphi panel rounds.

Number	Recommendation	Priority
1	Create and maintain an open, transparent and non-hierarchical 'no blame' culture supported by the ICU management to support staff in identifying, sharing, reporting and learning from incidents and near misses.	High
2	Implement an effective system to support the reporting of (medication-related) incidents and near misses, including mechanisms to provide feedback on reports to ICU staff.	High
3	Undertake routine, systematic and multi-disciplinary review of all ICU related incident reports to identify medication safety areas of risk, opportunities for improvement and provide feedback to ICU staff e.g. use of risk huddles.	High
4	Nominate a Medication Safety Lead within the ICU setting to work closely with the organisational Medication Safety Officer (or equivalent) where such a role exists on the implementation and promotion of medication error prevention strategies.	Medium
5	Undertake regular audits and self-assessment questionnaires, including measurement of patient safety climate in the ICU, to inform improvement of medication safety within the ICU.	High
6	Ensure adequate budget allocation to support sustained improvements in medication safety, including investment in human resources and appropriate technology in the ICU setting.	High
7	Ensure a safe working environment is provided for ICU staff to practise in a safe and efficient manner e.g. adequate lighting, avoidance of interruptions.	High
8	Implement Automated Dispensing Cabinets for the storage of medications in the ICU, ensuring adequate resources for training, monitoring of usage and optimisation.	High
9	Replace paper-based prescriptions with electronic prescribing systems e.g. computerised physician order entry, with associated clinical decision support appropriate to the ICU setting.	High
10	Implement the use of Barcoded Medication Administration to reduce medication administration errors and support complete documentation.	High
11	Administer all medication infusions via programmable infusion pumps utilising 'Dose Error Reduction Software' or 'Smart-pumps', which contain a complete and regularly reviewed and updated drug library.	High
12	Ensure policies are in place to reduce workarounds and over-rides in the use of implemented technology e.g. bypassing smart-pump drug libraries, barcode medication administration workarounds and automated dispensing cabinet over-rides.	High

Number	Recommendation	Priority
13	Identify and optimise all opportunities to integrate existing and future systems with the aim of providing 'closed loop' medication management, minimising opportunities for error at each stage of the medication use process.	High
14	Provide dedicated resources to facilitate the implementation, optimisation, maintenance and regular updates to all systems involved in medication management within the ICU.	High
15	Provide a dedicated and specialised clinical pharmacy service to the ICU at a staffing level sufficient to ensure regular review and verification of all medications, attendance at multi-disciplinary rounds and input into the development of policies, procedures and guidelines.	High
16	Adopt formal antimicrobial stewardship with multidisciplinary input to ensure appropriate use of antimicrobials and reduce antimicrobial resistance.	High
17	Provide staff with protected time during working hours and access to a range of education and training opportunities in safe medication use to include new staff from all disciplines, new equipment/medications, refresher training and competency assessment.	High
18	Standardise and reduce the range of available/recommended medication infusion concentrations.	High
19	Provide supporting protocols and guidelines on preparation of IV medications as appropriate to the setting and availability of 'ready-to-administer' infusion solutions.	High
20	Minimise 'bedside' preparation of intravenous medications and replace with procured and centrally prepared 'ready-to-administer' or 'ready-to-use' medications wherever possible.	High
21	Ensure ease of access to information on intravenous compatibilities.	High
22	Ensure processes are in place to support safe intravenous medication administration to include: appropriate labelling of medications and administration lines utilising targeted risk reduction strategies e.g. use of colours, TALLman lettering; administration line checks; infusion pump checks.	High
23	Maintain a high-risk medication list that is reviewed regularly and is context-specific e.g. paediatrics, with a robust set of associated risk mitigation processes for all stages of the medication use process.	High
24	Ensure targeted and risk assessed organisational policies and procedures are in place to support checking procedures for the preparation and administration of high-risk medications e.g. items requiring independent double-checking, specific labelling requirements.	High
25	Employ standardised procedures, including patient, family and carer involvement as appropriate, to obtain and document an accurate and complete list (best possible medication history) of each patient's current medication on admission to the ICU.	High
26	Implement a formal and thorough medication reconciliation process on both admission to, and discharge from, the ICU to ensure accurate and comprehensive medication information is communicated consistently.	High
27	Ensure clear policies and processes are in place to support interdisciplinary communication across entire medication use process, e.g. handover procedures and documentation, multidisciplinary rounds/meetings, use of notice boards, memos.	High
28	Minimise the use of verbal orders with provision of defined supporting processes e.g. pre-printed templates, order sets.	High
29	Provide a pharmacy-led service to ensure consistent, appropriate and safe access to a full range of medications appropriate to individual ICUs e.g. stock lists, regular top-up service,	High

Number	Recommendation	Priority
	drug shortage management, defined storage locations, segregation of high-risk and sound-alike/look-alike medications.	
30	Source and supply medications in 'unit-dose' form with individual barcode where possible to support barcode medicines administration and closed-loop medication management.	High
31	Ensure all appropriate antidotes, reversal agents, rescue agents and relevant protocols are readily available.	High
32	Maintain a comprehensive and easily accessible suite of up-to-date guidelines and reference sources, which are: approved at an organisational level; made available in digital format where possible; and with robust governance and version control measures in place.	High

Discussion of the Delphi panel

In total, 32 initial policy recommendations on medication safety improvement for intensive care were developed. In this Delphi panel study, 21 HCPs could have participated from 13 different countries, representing Northern, Southern and Western European regions (United Nations 2022). 19 participated in Delphi Round 1, 18 in Delphi Round 2a and 17 in Delphi Round 2b. After two Delphi rounds, consensus was achieved on all 32 recommendations. All recommendations were considered 'high priority' except one that was considered 'medium priority'.

Strengths and limitations.

The limitations of this study include the inability to consider the relative differences in ease of implementation of these recommendations. As with any Delphi panel study, the increased likelihood of participation from individuals with greater interest or expertise in medication safety has potential to introduce response bias.

The strengths of this study include participation from a range of European countries, representing Northern, Southern and Western European regions, although there was a lack of participation of HCPs from Eastern European region. The participants were recruited using convenience sampling but participation by healthcare professionals with various backgrounds in ICU settings or medication safety was achieved and high response levels were achieved during the iterative rounds. A further strength is that the recommendations are based on previous literature, and on identified ME prevention strategies in use in ICUs across Europe, and perceptions of HCPs working in ICUs and within medication safety across Europe on patient safety culture and factors influencing implementation of medication error prevention strategies.

Conclusion

Through this study it was possible to develop and prioritise policy recommendations to enhance medication safety, which may contribute to improving medication safety and reducing medication errors in ICUs across Europe. All recommendations were considered 'high priority' for implementation except one, indicating the perceived value of these recommendations in improving medication safety through preventing MEs from occurring in ICUs.

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Appendix I – SIG Membership

Name	Role	
Angela Amigoni	Deputy Director of Paediatric Intensive Care Unit, University Hospital of Padova	Italy
Irene Aquerreta	Clinical Consultant, Clínica Universidad de Navarra	Spain
Božena Bürmen	Clinical Pharmacist, University Medical Centre, Ljubljana	Slovenia
Andrea Burch (joined in October 2021)	Deputy Head of Clinic Care, Cantonal Pharmacy of Zürich	Switzerland
Claire Chapuis	Hospital Pharmacist, CHU Grenoble Alpes	France
Suzanne Cooper	Medication Safety Officer and Principal Pharmacist for Medicines Governance and Safety, The Dudley Group NHS Foundation Trust (DGFT)	United Kingdom
John Dade	Advanced Pharmacist Clinical Care, Leeds Teaching Hospitals NHS Trust	United Kingdom
Bryony Dean Franklin	Director of the Centre for Medication Safety and Service Quality (CMSSQ), Imperial College Healthcare NHS Trust, London / Professor of Medication Safety, UCL School of Pharmacy / Theme Lead, NIHR Imperial Patient Safety Translational Research Centre, London	United Kingdom
Dylan De Lange	Intensive Care Unit and the Dutch Poisons Information Center (DPIC), University Medical Center Utrecht	the Netherlands
Samuel Garcia	Medical Affairs Europe Becton Dickinson	Spain
Anne Hiselius	Clinical Pharmacist, Jönköping County Hospital	Sweden
Moninne Howlett	Chief Pharmacy Information Officer, Children's Health Ireland (CHI), Dublin	Ireland
Minna Kurttila	Hospital Pharmacist, Kuopio University Hospital	Finland
Raisa Laaksonen Co-chair of the SIG	Adjunct Professor in Clinical Pharmacy, University of Helsinki	Finland
Chiara Lamesta	Hospital Pharmacist, University Hospital of Parma	Italy
Jana Lass	Hospital Pharmacist, Tartu University Hospital	Estonia
Maria Cruz Martin	Head ICU Hospital 12 de Octubre Madrid Associate Professor Complutense University of Madrid	Spain
Suzanne McCarthy	Senior Lecturer in Clinical Pharmacy Practice at the School of Pharmacy, University College Cork	Ireland
Virginia Silvani Co-chair of the SIG	Hospital Pharmacist, Cork University Hospital	Ireland
Inese Sviestina	Clinical Pharmacist, Children's Clinical University Hospital, Riga	Latvia
Andreas Valentin	Head of the Department of Internal Medicine, Kardinal Schwarzenberg Klinikum	Austria
Emily Whittome (was replaced by Andrea Burch)	Clinical Pharmacist, Cantonal Pharmacy of Zürich	Switzerland

Appendix II – Survey of medication error prevention strategies in European intensive care units | Sample invitations incl. social media

Invitation Email for Organisation

The European Association of Hospital Pharmacists (EAHP) Special Interest Group for the Investigation of Medication Errors in Intensive Care Units (ICU) is conducting research on medication error prevention strategies in intensive care settings across Europe. We hope that the research we are conducting can be used to develop policy recommendations for medication safety improvement in ICUs around Europe.

We would ask if you would kindly facilitate this research by forwarding on the invitation below to your staff to consider participation in this online survey. This survey has received ethical approval from University College London Research Ethics Committee.

If you have any further queries on the survey, please email info@eahp.eu.

Invitation for Participants

The European Association of Hospital Pharmacists (EAHP) Special Interest Group for the Investigation of Medication Errors in Intensive Care Units (ICU) would like to invite you to take part in an online survey.

The aim of this survey is to explore medication error prevention strategies in intensive care settings across Europe. We hope that the results of this survey, along with other research we are conducting, can be used to develop policy recommendations for medication safety improvement in ICUs around Europe. This survey has received ethical approval from University College London Research Ethics Committee.

Healthcare professionals working in any intensive care setting involved with medicines can take part in this study.

This survey is completely voluntary, and you can stop completing it at any time. You do not have to answer any questions you don't want to. Please read the information on the study which provides further detail on the research. The survey will remain open until Sunday, 8th of May 2022.

To find out more and to complete the survey, please use one of the following links:

- Access the English version of the survey <https://easy-feedback.de/SIGSurveymedicationerrors/1449652/2x88c0>
- Access the Estonian version of the survey <https://easy-feedback.de/SIGsurveymedicationerrors/1453544/8LHzg3>
- Access the French version of the survey <https://easy-feedback.de/SIGMedicationerrorsFrenchtranslation/1453156/7hV7uR>
- Access the German version of the survey <https://easy-feedback.de/SIGsurveymedicationerrorsGermantranslation/1453554/vqStyC>

- Access the Italian version of the survey <https://easy-feedback.de/SIGsurvey Medication errors Italian translation/1453682/Nq2UwR>
- Access the Slovenian version of the survey <https://easy-feedback.de/s/1453648/Bb28RA>
- Access the Spanish version of the survey <https://easy-feedback.de/SIGsurvey Medication errors Spanish translation/1453331/z7Qec9>

If you have any further queries on the survey, please email info@eahp.eu.

Launch of survey & general promotion

Are you a #HospitalPharmacist, #Nurse or #Physician working in the #ICU? Share your views on medication error #prevention and help us identify strategies that are in use and/or being planned in European ICUs! Participate in the #EAHPsurvey by 24/04 *[insert link]*

We recently launched the latest #EAHPsurvey focusing on medication error prevention strategies. If you are working in an #ICU as #HospitalPharmacist, #Nurse or #Physician share your views with us by 24/04 *[insert link]*

Do you want to share examples of strategies in use and/or being planned in European #ICUs? Participate in the latest #EAHPsurvey focusing on this topic and share your opinion by 24/04. The survey is available in English, Estonian, French, German, Italian and Spanish! *[insert link]*

Have you already participated in the #EAHPsurvey focusing on medication error prevention strategies? Don't wait to share your feedback via one of the different language versions of the survey. Contribute in English, Estonian, French, German, Italian or Spanish! *[insert link]*

Last week of survey

Time is ticking. If you have not yet responded to the ICU Medication Error Prevention Strategies Survey, make sure that you submit your response by 24/04. To facilitate participation, the survey is available in English, Estonian, French, German, Italian and Spanish!

Last day to participate in the ICU Medication Error Prevention Strategies Survey! If you are a #HospitalPharmacist, #Nurse or #Physician working in the #ICU don't forget to share your feedback by the end of the day! *[insert link]*

Appendix III – Survey of medication error prevention strategies in European intensive care units | English language version

Participant Information (first page of online survey instrument)

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

What is the purpose of the study?

Patient safety is a priority for healthcare organizations worldwide. Due to the complex nature of the intensive care unit (ICU) setting, specific strategies for improving medication safety are likely to be particularly important. We are looking to identify medication error prevention strategies both in use and being planned in ICUs across Europe, in order to develop policy recommendations for medication safety improvement.

Why have I been invited?

You have been invited to participate as you are a healthcare professional working in an ICU setting in Europe.

Do I have to take part?

Participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to indicate your consent online. As your responses to the questionnaire will be anonymous, once you have submitted your responses you will be unable to withdraw. Your right to decline or withdraw from the study will in no way influence or adversely affect you. You can withdraw by closing your browser before submitting your responses, and they will not be included.

What will happen to me if I take part?

If you agree to participate, you will be invited to proceed to complete the survey, which will ask you about medication safety practices currently in use and being planned within the ICU(s) in which you work. We will also ask for some basic demographic information about you (such as your gender and profession) and about your ICU (such as number of beds, ICU specialty and country).

The survey should take approximately 10-20 minutes to complete. There will be no further involvement expected from you.

All information you provide will be confidential and your anonymity will be protected throughout the study. We are not asking participants for their names, or the names of their organisations. Computer IP addresses will not be collected at any point, meaning the data that you provide cannot be traced back to you or your organisation.

The raw data will be kept on password-protected computer systems at University College London for five years after publication of the study in a peer-reviewed journal or a maximum ten years after completion of the study, whichever is first.

What are the possible benefits of taking part?

There will be no immediate benefit to you from participating, but we hope that the information we receive will help us to inform policy recommendations for medication safety improvement in ICUs around Europe.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks from participating in this study. The only disadvantage is the time you need to take to complete the survey.

What if something goes wrong?

If you have a concern about any aspect of this study, please contact the Principal Investigator Professor Bryony Dean Franklin (email: bryony.deanfranklin@ucl.ac.uk).

What will happen to the results of the research study?

It is anticipated that the findings of the research study will be disseminated via a number of avenues, such as through a peer reviewed research paper and presentations at academic conferences. It will not be possible to identify participants from any reports or outputs of the study.

Who is organising and funding the research?

This research is organised by the Special Interest Group for the Investigation of Medication Errors in Intensive Care, as part of the European Association of Hospital Pharmacists (EAHP). The EAHP has received funding support from BD (Becton, Dickinson and Company) for the running of this project. The researchers are independent of BD and EAHP. The Principal Investigator of this study is from UCL School of Pharmacy. The findings of the study will be made available on the EAHP website in due course.

Who has reviewed the study?

The Principal Investigator has obtained approval by UCL research ethics committee (reference number Project ID: 15283.004).

Contact for Further Information

If you would like further information on any aspect of the study, then do not hesitate to contact the Principal Investigator: Professor Bryony Dean Franklin on bryony.deanfranklin@ucl.ac.uk

CONSENT TO TAKE PART

I have read and understood the above participant information

I consent to take part in this study and understand that continuing to complete and submit the rest of the survey indicates this consent

SURVEY QUESTIONS

Before asking you about the medication safety strategies in use in your intensive care unit (ICU), it would be helpful to know a bit about you.

What is your profession?

- Nurse

- Pharmacist
- Physician
- Other (please state)

What is your gender?

- Female
- Male
- Non-binary / other
- Prefer not to say

What is the speciality of the main ICU that you work in?

- Adult medical
- Adult surgical
- Adult mixed medical / surgical
- Adult cardiology / cardiothoracic
- Paediatric
- Neonatal
- Other

How many inpatient beds (including ICU) does your hospital have?

How many beds does your ICU have (excluding any additional beds added due to the COVID pandemic)?

In what country is the hospital you practice/work in located?

RESPONSE CATEGORIES FOR ALL REMAINING STATEMENTS WILL BE AS FOLLOWS:

- A. There has been **no activity** to implement this.
- B. This is being **planned for implementation** in the next 5 years.
- C. This has been **partially implemented** for **some or all** patients, orders, medications, or staff in our ICU(s).
- D. This is **fully implemented** for **some** patients, orders, medications, or staff in our ICU(s).
- E. This item is **fully implemented** for **all** patients, orders, medications, or staff in our ICU(s).
- F. Unknown.

For each of the following items, please indicate the extent of activity in your ICU(s).

Note that there are no 'right' or 'wrong' answers – we recognise that practices differ around the world and will be different in different units.

ADMISSION TO CRITICAL CARE

- Use of a standardised process to obtain a complete list of the medication that the patient was taking prior to admission to the ICU (medication history).
- Systematic comparison of this list of medications with the patient's current prescribed medication and ensuring that any intentional changes have been documented (medication reconciliation).
- Routine involvement of patient / family / carers in establishing the patient's medication history whenever possible.
- Patient drug allergies are clearly visible to all healthcare professionals involved with prescribing, reviewing, or administering medication.

PRESCRIBING

- Use of standardised concentrations for regularly used intravenous infusions.
- Standardised procedure in use for any verbal orders given in an emergency, including a process for retrospectively documenting the medicines and doses given.
- Electronic prescribing / computerised prescriber order entry (CPOE) is in use in the ICU

Branched question only if respondent answers C, D or E to the last question above in relation to CPOE:

- The CPOE system includes pre-populated templates for commonly used critical care medications
- The CPOE system includes support for weight-based dosing.
- The CPOE system includes reminders and/or information about monitoring parameters for high-risk medications (e.g. potassium chloride, inotropes, narcotics, sedatives, insulin, anticoagulants) that are included in the CPOE system.
- The CPOE system includes clinical decision support to identify medications prescribed to which the patient has a documented allergy
- The CPOE system includes clinical decision support to identify drug-drug interactions
- The CPOE system includes clinical decision support to identify and differentiate similar drug names (for example, using "tallman" lettering)

Branched question only if respondent answers A, B or F to the last question above in relation to CPOE:

- Pre-printed paper templates / order forms are in use for commonly used medications.
- Paper prescribing systems include reminders and information about monitoring parameters for high-risk medications.

For all respondents:

- Guidelines or templates in use to ensure appropriate antidotes, reversal agents, and rescue agents are prescribed when necessary.
- Restricted formularies or guidelines in place to allow only intensive care prescribers to prescribe certain medications (e.g. for neuromuscular blocking agents).

PHARMACY SERVICES

- A critical care pharmacist is allocated to the ICU
- There is critical care pharmacist review of ordered medications 5 days per week
- There is critical care pharmacist review of ordered medications 7 days per week
- A critical care pharmacist attends ward rounds on the ICU at least once a week
- There is pharmacy top-up of medication stocked on the ICU.
- Intravenous medications are prepared by the pharmacy department on a patient-specific basis
- Authorisation by a pharmacist is required for every medication order before any dose can be administered

STORAGE OF MEDICATION ON THE ICU

- High-risk medications, such as high concentration potassium chloride, are stored in a separate locked cupboard or automated storage unit away from other fluids /ampoules/medications.
- There is a process for identification of look-alike / sound-alike medicines and the use of strategies to prevent mix-ups such as unique labels or 'tall-man' lettering.
- Standardised emergency medications are stored in a fixed place.
- Automated dispensing cabinets (electronic storage cabinets to control and track medications) are in use on the ICU.

ADMINISTRATION TO THE PATIENT

- Organizational policies and procedures are in place to ensure independent double check for the **preparation of high-risk medications**.
- Organizational policies and procedures are in place to ensure independent double check for the **administration of high-risk medications**.
- Organizational policies and procedures are in place to ensure independent double check for the **preparation of all medications**.
- Organizational policies and procedures are in place to ensure independent double check for the **administration of all medications**.
- Line labels are in use for intravenous infusions to prevent identification and disconnection errors.
- Routine use of oral/enteral syringes that are incompatible with intravenous lines for administration of liquid medications via the oral or enteral routes
- Verification of **patient identity** using barcode-scanning technology prior to medication administration
- Verification of **medications** using barcode-scanning technology prior to medication administration

- Use of 'smart' infusion pumps with standardised libraries and dose error reduction software to check infusion rates against pre-set limits for each medication.

TRANSFER FROM THE CRITICAL CARE UNIT

- A standardised process for review of medication on discharge from ICU to avoid **ICU medications** being continued inappropriately
- A standardised process for review of medication on discharge from ICU to ensure that **pre-ICU medications** are restarted as appropriate

SAFETY CULTURE AND PRACTICES

- Use of an **incident reporting** system to learn from medication incidents (both errors and near misses)
- Regular discussion of medication incidents (both errors and near misses) and identification of corrective actions
- Provision of **standardized introduction** to medication-related processes, protocols, instructions, checklists for all new employees (nurses, physicians, and pharmacy staff) in the unit
- Identification of **high-risk medications** that have an increased risk of causing significant patient harm if they are misused (e.g. potassium chloride, inotropes, narcotics, sedatives, insulin, anticoagulants) and use of detailed protocols, guidelines to reduce these risks.
- Regular **medication safety audits** as a part of the unit's quality monitoring.
- A designated **medication safety officer** is available for the hospital organisation

OTHER

- Other medication safety strategies in use or planned that are not mentioned above:
_____ (space for free text responses)
- Any other comments _____

Appendix IV – Analysis by countries

Figure 1: Medication reconciliation process by country (Question 10)

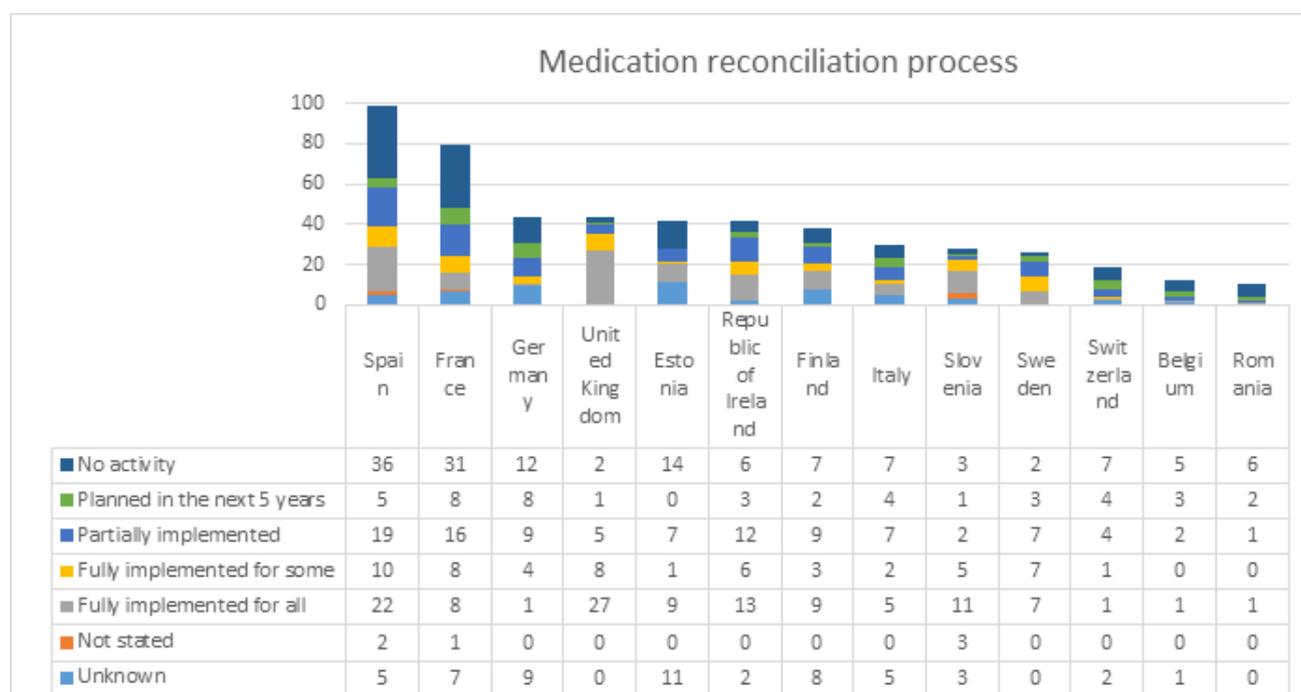


Figure 2: Standardised concentrations for regularly used intravenous infusions by country (Question 13)

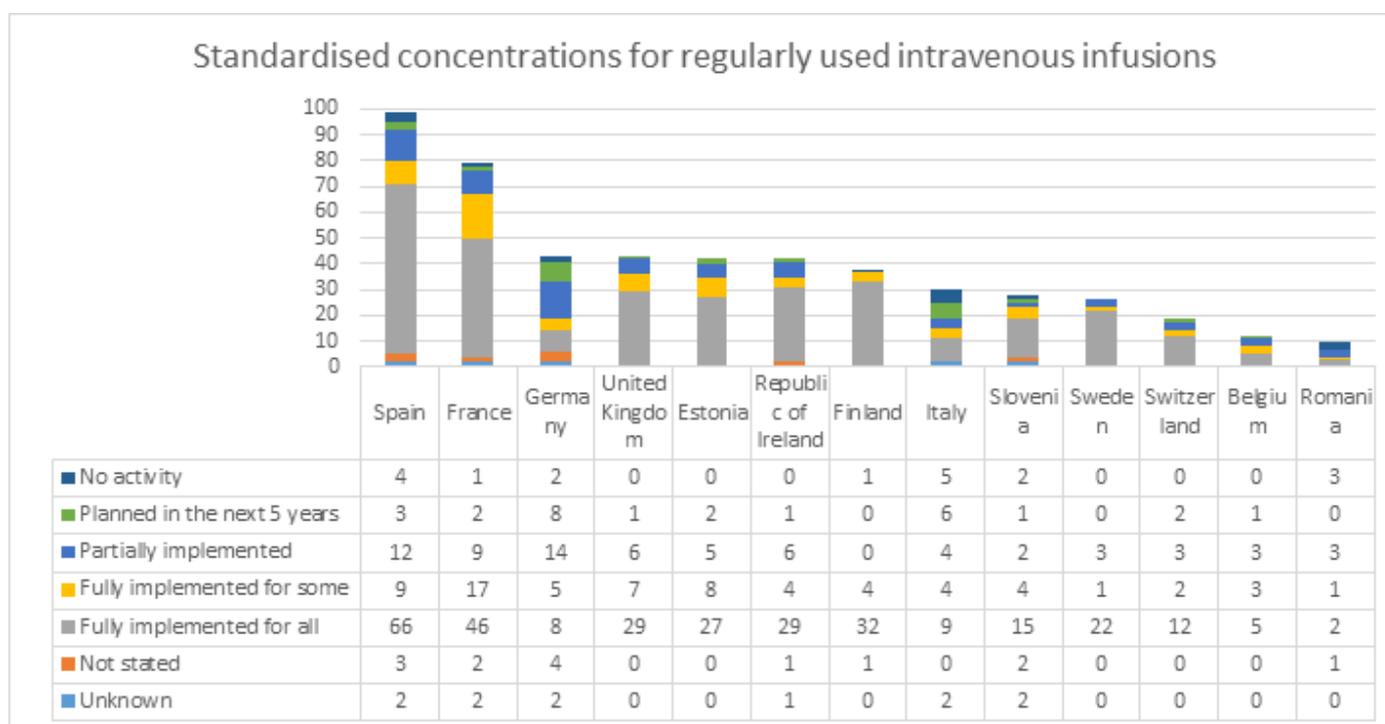


Figure 3: CPOE is in use in the ICU by country (Question 15)

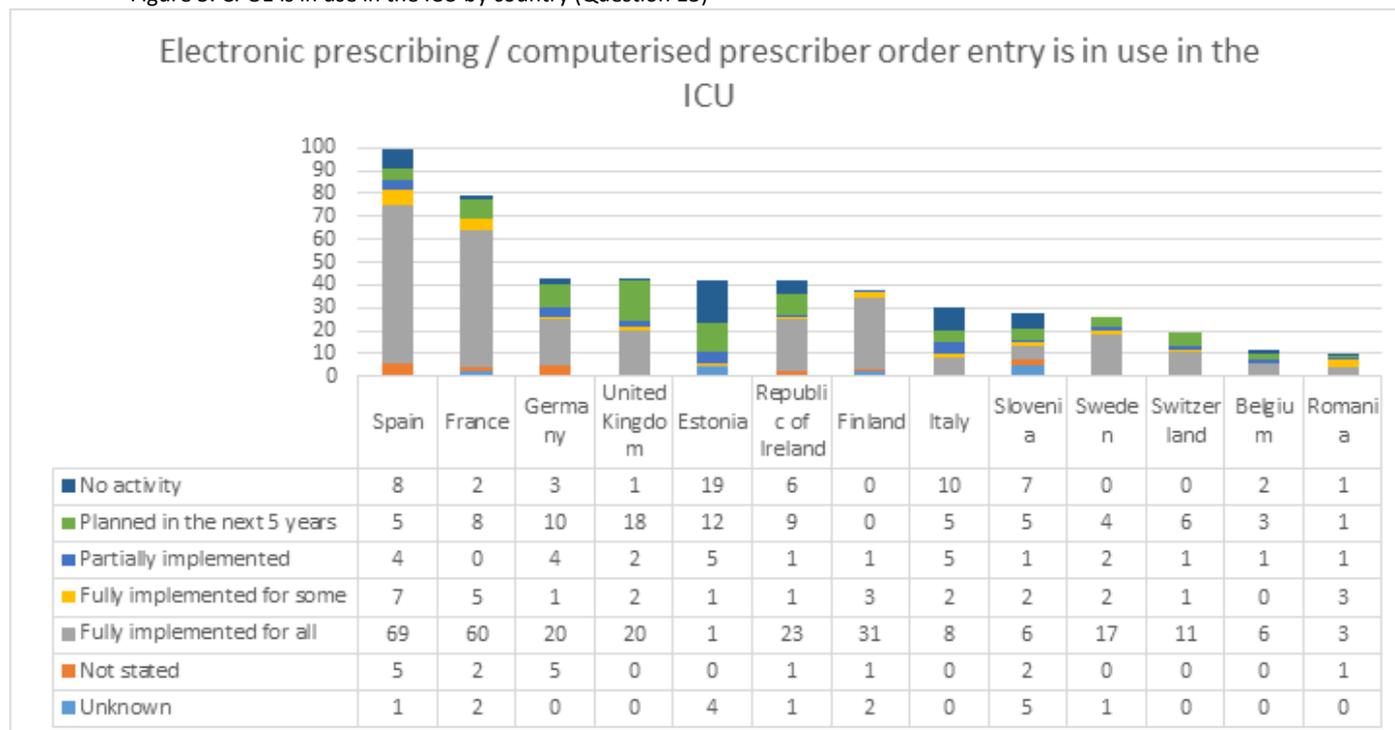


Table 1: Fully implemented for all patients: pharmacist cover in ICUs (Questions 26 to 29)

Pharmacist cover in ICU(s) by country (fully implemented for all)				
	Critical care pharmacist is allocated to the ICU (fully implemented for all) (%)	Critical care pharmacist review of ordered medications 5 days per week (fully implemented for all) (%)	Critical care pharmacist review of ordered medications 7 days per week (fully implemented for all) (%)	Critical care pharmacist attends ICU ward rounds at least once per week (fully implemented for all) (%)
Spain (n=99)	28	39	17	11
France (n=79)	24	29	8	10
Germany (n=43)	16	5	0	51
United Kingdom (n=43)	67	81	2	65
Estonia (N=42)	29	10	2	36
Republic of Ireland (n=42)	62	62	5	48
Finland (n=38)	63	39	0	21
Italy (n=30)	0	7	10	3
Slovenia (n=28)	18	14	4	21
Sweden (n=26)	35	15	8	0
Switzerland (n=19)	16	0	0	53
Belgium (n = 12)	17	0	0	25

Figure 4: Critical care pharmacist allocated to ICU by country (Question 26)

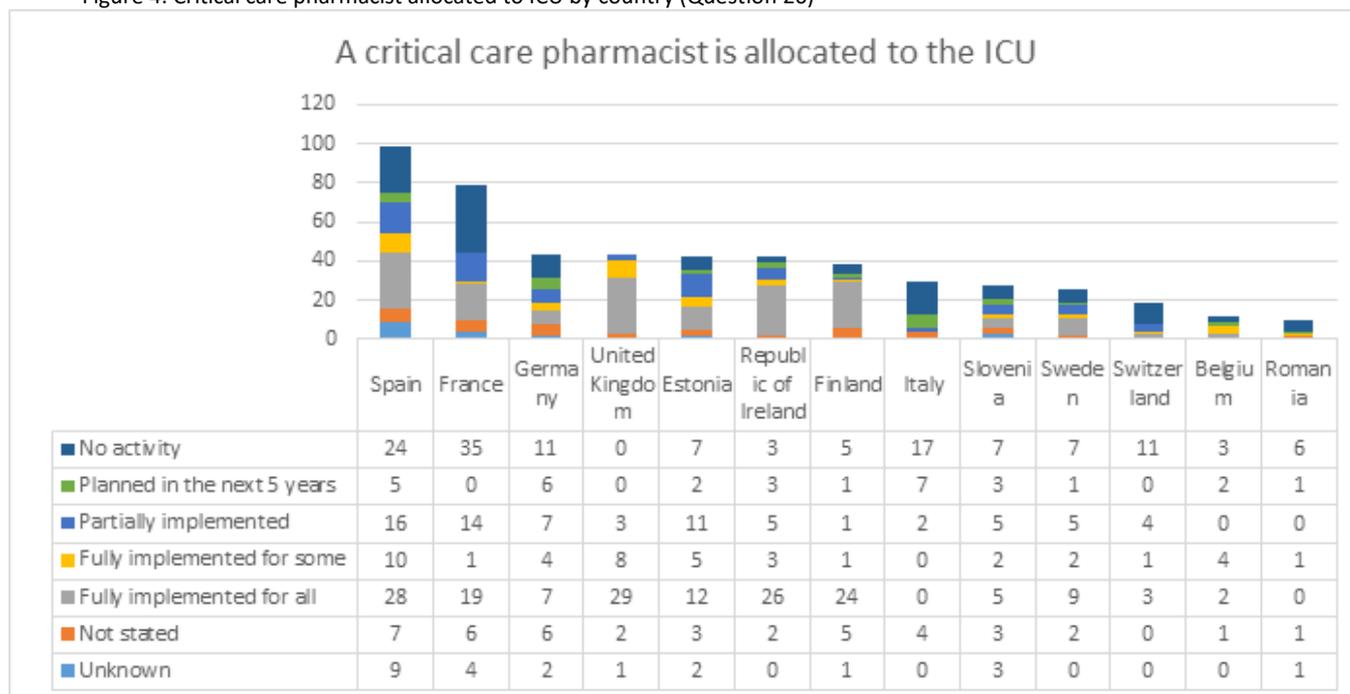


Figure 5: Critical care pharmacist review 7 days per week by country (Question 28)

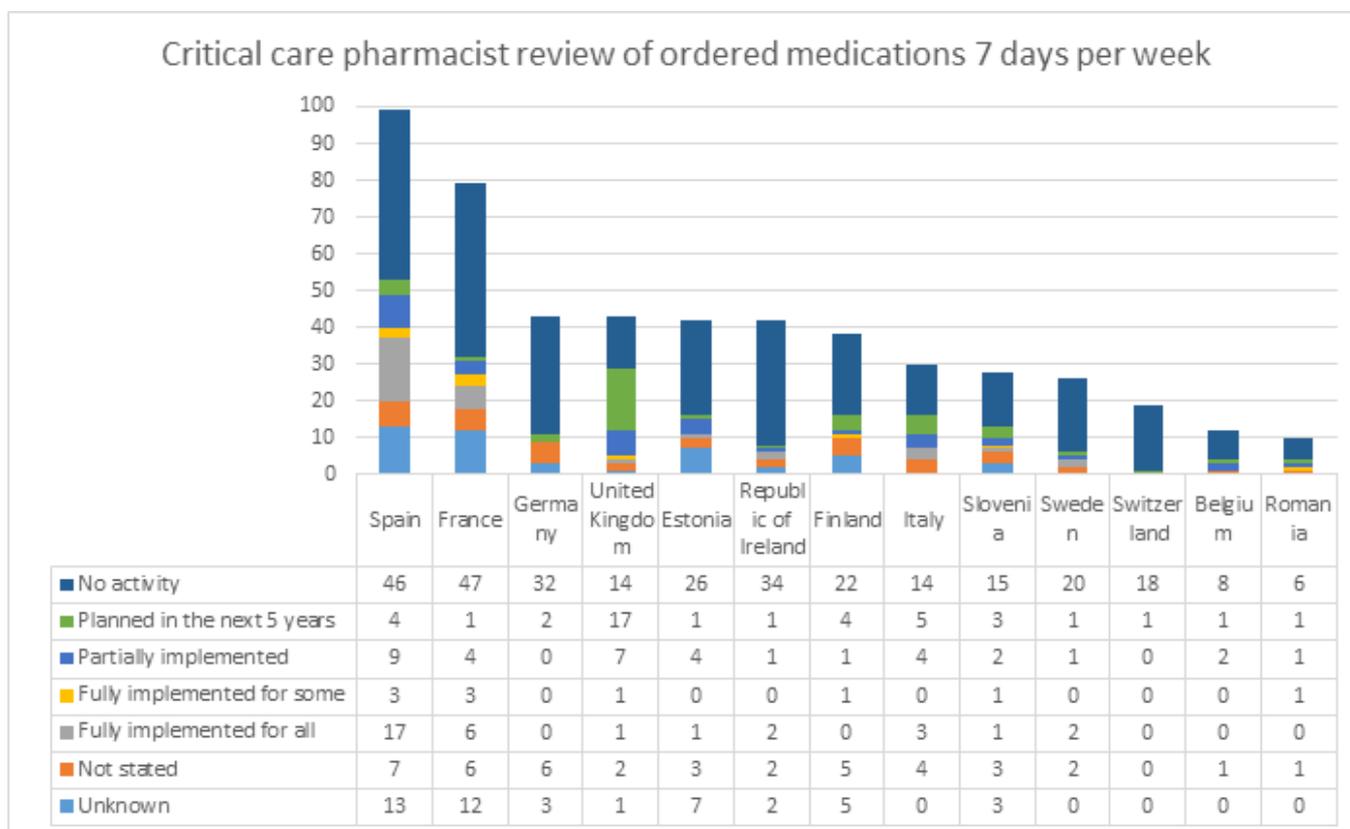


Figure 6: Critical care pharmacist attends ward rounds on the ICU at least once a week by country (Question 29)

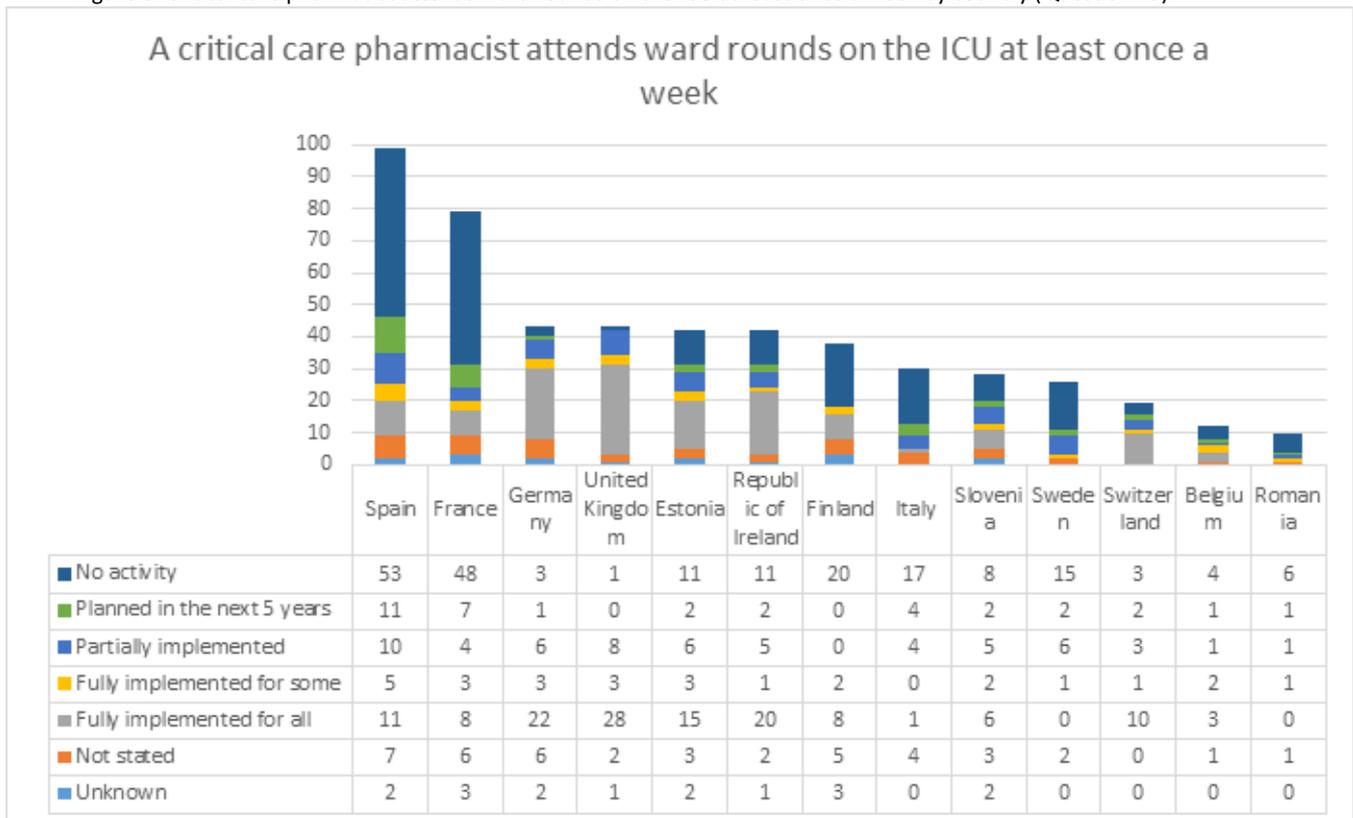


Figure 7: Intravenous medications are prepared by pharmacy department on a patient- specific basis by country (Question 31)

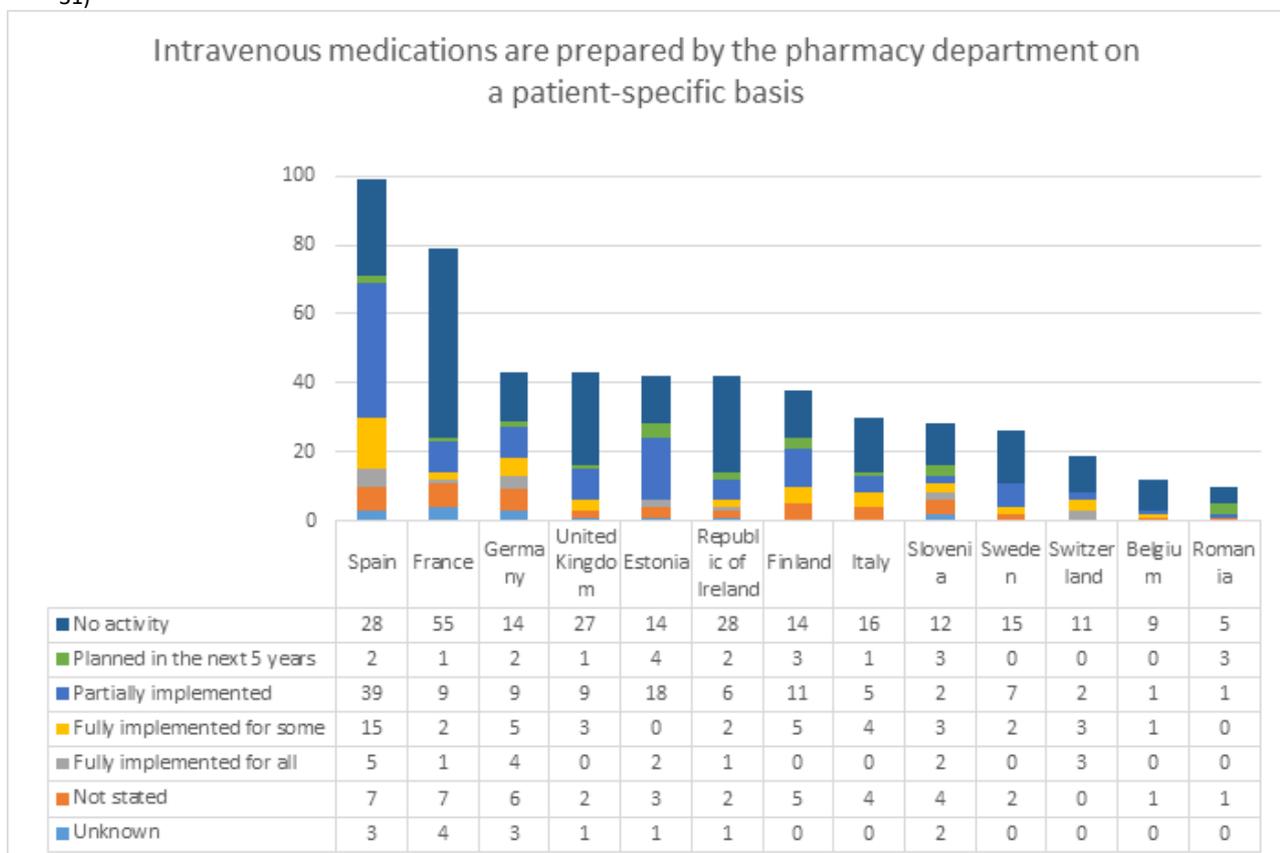


Table 2: Medication storage in ICU(s) by country (fully implemented) (Questions 33-36)

	Medication storage in ICU(s)			
	High risk medication locked away from other medication (fully implemented for all) (%)	Process for identifying look alike sound alike medications (fully implemented for all) (%)	Emergency medications stored in a fixed place (fully implemented)(%)	Automated dispensing cabinets (fully implemented) (%)
Spain (n=99)	24	18	66	48
France (n=79)	28	11	52	35
Germany (n=43)	2	5	40	0
United Kingdom (n=43)	81	14	63	12
Estonia (N=42)	10	2	64	5
Republic of Ireland (n=42)	76	24	69	0
Finland (n=38)	26	32	61	26
Italy (n=30)	60	33	40	7
Slovenia (n=28)	46	18	64	0
Sweden (n=26)	8	27	65	4
Switzerland (n=19)	0	11	47	5
Belgium (n = 12)	25	33	58	33
Not stated (n=12)	17	0	25	8

Figure 8: Independent double check for administration of high risk medications by country (Question 38)

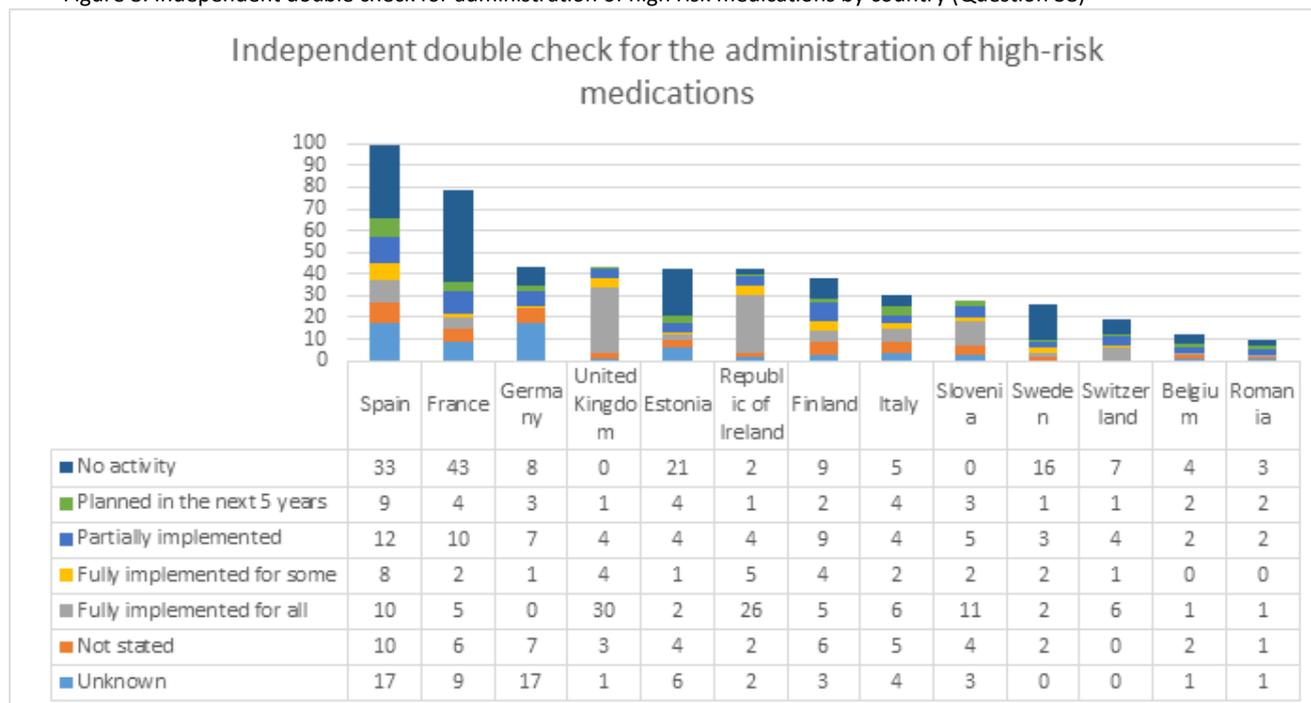


Table 3: Independent double check for administration of high risk medications by country (Fully implemented) (Questions 37 to 40)

Independent double check for preparation and administration of medication				
	Fully implemented an independent double check for preparation of high-risk medication (%)	Fully implemented an independent double check for administration of high-risk medication (%)	Fully implemented an independent double check for preparation of all medications (%)	Fully implemented an independent double check for administration of all medications (%)
Spain (n=99)	11	10	10	6
France (n=79)	8	6	4	5
Germany (n=43)	2	0	2	2
United Kingdom (n=43)	67	70	37	37
Estonia (N=42)	5	5	0	2
Republic of Ireland (n=42)	62	62	43	38
Finland (n=38)	11	13	8	11
Italy (n=30)	17	20	17	13
Slovenia (n=28)	43	39	29	32
Sweden (n=26)	8	8	4	4
Switzerland (n=19)	26	32	11	5
Belgium (n = 12)	8	8	0	0
Not stated (n=12)	0	0	8	0

Figure 9: Use of smart infusion pumps by country (Question 45)

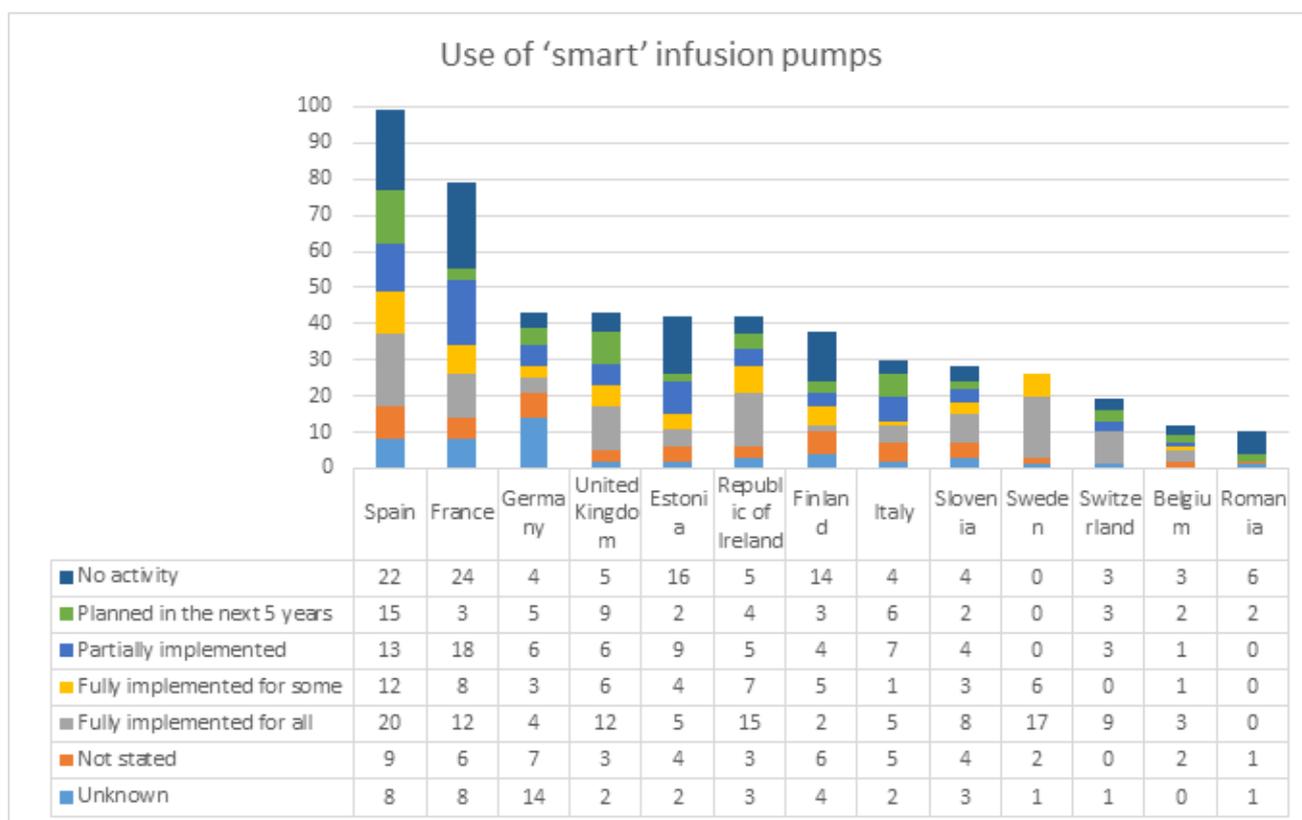
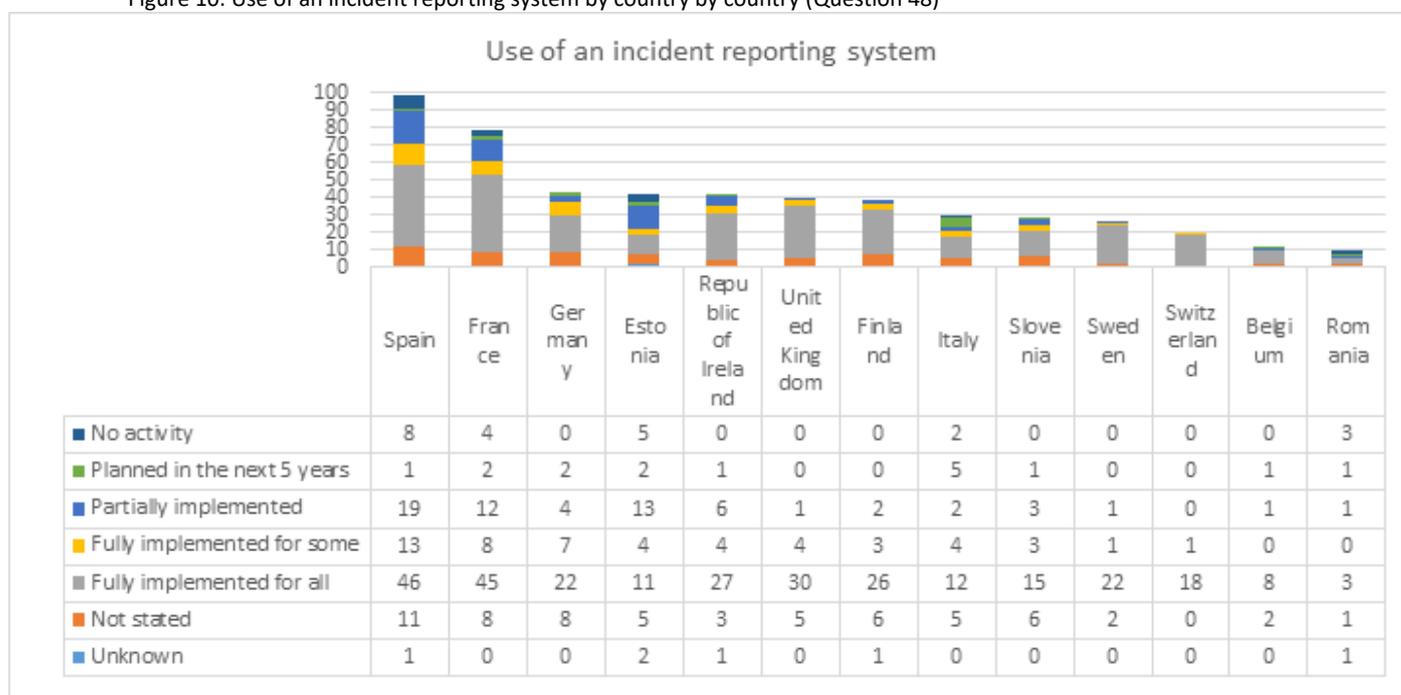


Figure 10: Use of an incident reporting system by country by country (Question 48)



Appendix V – Focus Group Cover Letter

EAHP's Special Interest Group for the Investigation of Medication Errors in Intensive Care Units (ICU) would like to invite you to take part in an online focus group interview.

The focus group interview is a part of extensive study composed of a literature review, a survey and focus group interviews on medication error prevention strategies and patient safety culture within the ICU environment across Europe. The language used in the focus group interview will be English.

The aim of the focus group is to explore the experiences of healthcare professionals of patient safety culture and medication error prevention strategies in intensive care settings across Europe. We hope that the information we get, along with other research we are conducting, can be used to develop policy recommendations for medication safety improvement in ICUs across Europe. This research has received ethical approval from the Ethical Review Board in the Humanities and Social and Behavioural Sciences, University of Helsinki (18/2022, 18.3.2022).

Healthcare professionals working in any intensive care setting involved with medicines or in any medication safety role can take part in this study.

Participation in this research is completely voluntary, and all the information you provide will be kept confidential. All data collected will be pseudonymised, meaning that any data identifying participants will be removed before the analyses. Please read the attached information sheet on the study which provides further detail on the research.

If you are interested in taking part in this research, please email the Principal Investigator, Adjunct Professor Raisa Laaksonen (raisa.laaksonen@helsinki.fi), University of Helsinki, Finland, co-chair of the EAHP Special Interest Group by the 10th of May 2022.

The focus group interview will be arranged using an online videoconferencing facility on

- Friday, 13th of May (12.00 to 14.00 CET)
- Tuesday, 17th of May (13.00 to 15.00 CET)
- Wednesday, 18th of May (12.00 to 14.00 CET)
- Monday, 23rd of May (12.00 to 14.00 CET)

Thank you for considering to take part in this research!

Appendix VI – Focus Group Participant Information Sheet

Patient Safety Culture and Medication Safety in Intensive Care across Europe: Focus Group Interviews

Participant Information Sheet

Principal Investigator: Dr Raisa Laaksonen

Co-Investigators: Special Interest Group for the Investigation of Medication Errors in Intensive Care Units, European Association of Hospital Pharmacists (EAHP)

Thank you for considering participating in this research project. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish, as well asking us if there is anything that is not clear or if you would like more information. You can find the relevant contact details below.

Should you decide to take part keep a copy of this information sheet and your signed consent form.

What is the purpose of the study?

The purpose of this study is to explore the patient safety culture that exists in intensive care units as experienced by the healthcare professionals working in that setting across Europe. We are interested in knowing more about the practices that exist to promote medication safety, and to determine barriers and enablers to the implementation of medication error prevention strategies in the intensive care setting. We are hoping that the findings from these focus groups will be used to inform the development of policy recommendations to support medication safety in intensive care units.

Who is this study for?

Healthcare professionals (e.g. doctors, nurses and pharmacists) working in intensive care units and patient safety experts from different European countries have expertise in, and experience of, the topics explored in this study.

Why have I been invited?

You have been invited to take part in this study as you have been identified as being in one of the above groups of individuals.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. After signing the consent form, please scan the signed consent form and email it to the Principal Investigator. If this option is not suitable for you, please inform the Principal Investigator of your intention to participate by email: you will be able to consent verbally at the start of a focus group interview, and we will audio record this. If you decide to take part you are still free to withdraw at any time, also during the focus group interview, without giving a reason, and without affecting any aspects of your employment.

Will I get paid for taking part?

There is no payment for taking part in the study.

Contents

1. What will happen to me if I take part?
2. What are the possible disadvantages and risks of taking part?
3. What are the possible benefits of taking part?
4. What if something goes wrong?
5. What will happen to the results of the research study?
6. Who is organising and funding the research?
7. Who has reviewed the research study?
8. Contact for further information

1. What will happen to me if I take part?

If you agree to take part, we will ask you to participate in an online focus group interview together with other healthcare professionals working in other intensive care settings. The language used in the focus group interview will be English. The focus group interview will take place in April-May 2022. It is expected that the focus group will last up to a maximum of 90 minutes, and will take place using the Zoom online videoconferencing facility. You will also have the option of joining by telephone. In the focus group, you will be invited to discuss your thoughts on, and experiences of, patient safety culture and medication safety initiatives in the intensive care unit and how medication safety can be improved to enhance patient safety.

We will audio record the focus group interview with a voice recorder. As a back-up, we will also use the videoconferencing facility to audio and video record the focus group; the video recording will be deleted immediately after the interview, only the audio recording will be kept for transcription. Additionally, you may turn your video camera off if you would prefer to be recorded using audio only. The audio recording will then be transcribed to provide an accurate record of the discussion. You will be identified by a participant code and not by name. This code will not be shared with anyone outside the research team.

Participation in this study is completely voluntary. There is no obligation to participate, and should you choose to do so, you can refuse to answer specific questions, or decide to withdraw from the focus group. Once the focus group has been concluded, your contribution cannot be withdrawn as the focus group will be an amalgam of voices generated from the focus group audio file, and it is not possible to delete your data.

All of the information you provide will be kept confidential. Please see the attached Data Protection Statement. Details such as the name of participants will be seen only by the Principal Investigator and will be stored in a locked filing cabinet at the Faculty of Pharmacy, University of Helsinki. All data from the focus group will immediately be transferred to an encrypted computer, stored in passcode secured

files on the cloud service of the University of Helsinki and wiped from the recording device. The data will then be transcribed by a transcriber. As a participant, you will be given the opportunity to verify the accuracy and completeness of the transcript of your focus group interview if you so wish. We will also ensure that all identifying information will be removed from the transcripts. Once the focus group interviews are transcribed and verified, all audio recordings will be deleted and only the pseudonymised, coded, transcript will remain. All data will be available only to the research team. Please be aware, however, that while we can guarantee that we will maintain confidentiality, and we will ask all participants to maintain confidentiality, we cannot guarantee that group members will do the same.

All materials recorded on paper and all data recorded electronically will be securely stored for 24 months after the publication of the research, after which they will be destroyed safely.

2. What are the possible disadvantages and risks of taking part?

You will need to take the time to participate in the online focus group. You will also need to provide us with your name and contact details. The online videoconferencing facility, Zoom, is a licensed product of Zoom Inc., but all audio and video data are transferred only between servers located in the Nordic countries. For licensing purposes only, the names, email addresses and IP addresses of the participants will be transmitted to servers of Zoom within the European Union (EU). To maintain your confidentiality, we will adhere to the General Data Protection Regulation (GDPR) 2016 (EU), Data Protection Act 2018 (Finland) and data protection policies of the University of Helsinki. Please see the attached Data Protection Statement.

3. What are the possible benefits of taking part?

While there may be no immediate benefit to you from participating, we hope that the final study report and policy recommendations from this research will be of value to intensive care units across Europe whose managers may choose to utilise the findings and the developed policy to benefit their intensive care unit and hospital. You will be given the option of receiving a summary of this final study report.

4. What if something goes wrong?

If you have a concern about any aspect of this study, you can contact the Principal Investigator, Adjunct Professor Raisa Laaksonen via email at raisa.laaksonen@helsinki.fi. If you are still not satisfied with the response, you may contact the University of Helsinki Data Protection Officer via email at tietosuoja@helsinki.fi.

5. What will happen to the results of the research study?

It is anticipated that the findings of the research study will be disseminated via a number of avenues, such as through a report to the EAHP, a peer reviewed research paper and presentations at academic conferences. Additionally, summaries of the findings will be produced, targeted at relevant groups

such as health care professionals working in the intensive care setting, professional bodies, and policy makers. It will not be possible to identify participants from any reports or outputs of the study.

6. Who is organising and funding the research?

This research is organised by the Special Interest Group (SIG) for the Investigation of Medication Errors in Intensive Care, European Association of Hospital Pharmacists (EAHP). The EAHP has received funding from BD (Becton, Dickinson and Company) for the running of the project. The research, its outcomes and decisions on recommendations delivered by this working group remain independent from this financial support. The SIG is comprised of professional clinical experts (doctors, nurses and pharmacists) and patient safety experts from different European countries.

7. Who has reviewed the study?

The Principal Investigator has obtained approval from the Ethical Review Board in the Humanities and Social and Behavioural Sciences, University of Helsinki (18/2022, 18.3.2022), stating that the study meets the ethical requirements set for research in the human sciences.

8. Contact for Further Information

If you would like further information on any aspect of the study, please do not hesitate to contact us.

Co-chairs of the SIG for the Investigation of Medication Errors in Intensive Care:

Principal Investigator, Adjunct Professor Raisa Laaksonen (raisa.laaksonen@helsinki.fi), University of Helsinki, Finland

Dr Virginia Silvari (virginia.silvari@hse.ie), Health Care Executive, Ireland

If you agree to take part in this study, please keep a copy of this information sheet and sign the attached informed consent form.

Please scan the signed informed consent form and email it to the Principal Investigator Raisa Laaksonen (raisa.laaksonen@helsinki.fi). She will contact you to arrange the focus group interview.

Thank you for your time!

Appendix VII – Focus Group Consent Form

Patient Safety Culture and Medication Safety in Intensive Care across Europe

Consent Form

Principle Investigator: Adjunct Professor Raisa Laaksonen

I confirm that I have read and understand the participant information sheet dated 18.3.2022 for the above study and have had the opportunity to ask questions which have been answered fully.

I understand that my participation is voluntary, and I am free to withdraw (without giving any reason and without my legal rights being affected) at any time before or during the focus group interview; however, for the reasons outlined in the participant information sheet, I understand that it may not be possible delete my data. I understand that data from fellow participants in the focus group will be retained.

I give permission for the interview to be recorded for transcription purposes only.

Participant

I agree to participate in this study

Signed	Place
PRINT NAME	Date

Principal Investigator

I confirm that the above mentioned participant has received information on the research (nature, purpose, duration, and expected outcomes) and the participant has given informed consent to participate.

Signed	Place
PRINT NAME	Date

Please scan and email to the Principal Investigator Raisa Laaksonen (raisa.laaksonen@helsinki.fi).

Appendix VIII – Focus Group Topic Guide

Topic Guide

Objectives:

- To explore patient safety culture and advancement of medication safety in ICUs across Europe through focus group discussions;
- To explore factors influencing implementation of medication error prevention strategies in ICUs across Europe through focus group discussions;

Introductions (10 min)

Topics to be discussed (80 min)

Patient safety culture and medication safety (30 min)

Patient safety culture may be described as “**the extent to which an organisation's culture supports and promotes patient safety**. It refers to the values, beliefs, and norms that are shared by healthcare practitioners and other staff throughout the organisation that influence their actions and behaviors.”

How would you describe the patient safety culture in the ICU(s) in your hospital?

How is patient safety / medication safety promoted / advanced in your ICU? How are healthcare professionals engaged in developing medication safety?

How healthcare professionals are engaged in reporting medication errors?

Medication error prevention strategies and their implementation (50 min)

Many hospitals in Europe have implemented different medication error prevention strategies, for example, using smart infusion pumps, double checking, electronic prescribing, or clinical pharmacy services.

Which medication error prevention strategies are in use in your ICU? Why these strategies?

Which strategies are planned to be implemented in your ICU in the next five years? Why?

Are there any strategies that have been discussed but have been rejected in your ICU? Why?

Are there any strategies in use but might be perceived ineffective in your ICU? Why?

In your opinion, what enablers might support the implementation of medication error prevention strategies in your ICU?

In your opinion, what barriers might prevent the implementation of medication error prevention strategies in your ICU?

Appendix IX – Delphi Participation Cover Letter

Dear Madam/Sir,

The European Association of Hospital Pharmacists (EAHP) Special Interest Group for the Investigation of Medication Errors in Intensive Care Units (ICU) would like to invite you to become part of an expert consensus panel to inform the development of recommendations for medication safety development within the ICU environment. As a member of this expert panel, you will be asked to assist in reaching consensus on the inclusion and subsequent prioritisation of individual recommendations to inform the final EAHP recommendations. The consensus process that will be used is referred to as a 'Delphi' process. The Delphi process uses a panel of experts and predefined consensus criteria to reach consensus on a series of defined statements. It is commonly used in health research where inconsistent or inadequate evidence is available on particular subject matter.

The Delphi panel is a part of extensive study composed of a literature review, a survey and a focus group interviews on medication error prevention strategies and patient safety culture within the ICU environment across Europe. The language used in the Delphi panel will be English.

The aim of the Delphi panel is to identify and prioritise the policy recommendations that have emerged from the earlier parts of the study. The results of this study will enable the development of recommendations for medication safety development within the ICU environment ranked according to their priority for implementation.

We hope that the information we get, along with other research we are conducting, can be used to develop policy recommendations for medication safety improvement in ICUs across Europe.

This research has received ethical approval from the Ethical Review Board in the Humanities and Social and Behavioural Sciences, University of Helsinki (18/2022, 18.3.2022).

All members of the SIG can take part in this study. Participation in this research is completely voluntary, anonymous and all the information you provide will be kept confidential. Please read the attached information sheet on the study which provides further detail on the research.

The Delphi process will include up to three rounds. During each round, you will be asked to individually score a series of recommendations. You will then be asked to record this score and any comment you may wish to make about that recommendation using a web-based online survey tool, called 'easy feedback.com'. Participation is anonymous and the survey tool (easy-feedback.com) is fully GDPR-compliant and does not register IP-addresses of the participants. The Delphi panel survey data will be recorded on a server in Germany; no data leaves the EU.

If you have any questions on this research, please email the Principal Investigator, Adjunct Professor Raisa Laaksonen (raisa.laaksonen@helsinki.fi), University of Helsinki, Finland, co-chair of the EAHP Special Interest Group.

If you decide to take part in this research, you will be provided with a link to the online survey during the SIG meeting on October 13th2022. Please note that the submission of your responses via the online survey tool will be considered as proof of your informed consent to participate.

The list of recommendations which will be presented to you is also attached. This is being provided to you in advance of the SIG meeting to allow you to consider your responses and to assist in smooth and timely running of the meeting. Supporting reference material for each response is also provided.

Thank you for considering to take part in this research!

Best wishes,

Raisa Laaksonen

Appendix X – Delphi Participant Information Sheet

Medication Safety in Intensive Care across Europe: Delphi Panel

Participant Information Sheet

Principal Investigator: Dr Raisa Laaksonen

Co-Investigators: Special Interest Group for the Investigation of Medication Errors in Intensive Care Units, European Association of Hospital Pharmacists (EAHP)

Thank you for considering participating in this research project. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish, as well asking us if there is anything that is not clear or if you would like more information. You can find the relevant contact details below.

Should you decide to take part keep a copy of this information sheet.

What is the purpose of the study?

This phase of the study involves the use of an expert consensus panel to identify and prioritise the policy recommendations for medication safety development within the ICU environment that have emerged from earlier phases of the study (a literature review, a survey and focus group interviews). As a member of this expert panel, you will be asked to assist in reaching consensus on the inclusion and subsequent prioritisation of individual recommendations to inform the final EAHP recommendations. The consensus process that will be used is referred to as a 'Delphi' process. The Delphi process uses a panel of experts and predefined consensus criteria to reach consensus on a series of defined statements. It is commonly used in health research where inconsistent or inadequate evidence is available on particular subject matter. The results of this study will enable the development of recommendations for medication safety development within the intensive care environment ranked according to their priority for implementation.

Who is this study for?

All members of the SIG will be invited to participate as member of the Delphi panel. This will provide a panel comprised of a diverse representation of healthcare professionals with suitable expertise based on their selection for SIG membership. The SIG is comprised of professional clinical experts (doctors, nurses and pharmacists) and patient safety experts from different European countries.

Why have I been invited?

You have been invited to take part in this study as you have been identified as being in one of the above groups of individuals.

Do I have to take part?

It is up to you to decide whether or not to take part. Participation is voluntary. If you decide to take part, you will be given this information sheet to keep. If you decide to take part you are still free to withdraw at any time, also during the Delphi panel, without giving a reason, and without affecting any aspects of your contribution to the SIG.

Will I get paid for taking part?

There is no payment for taking part in the study.

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1. What are medication error prevention strategies?
2. How have these strategies been selected?
3. What will happen to me if I take part?
4. What are the possible disadvantages and risks of taking part?
5. What are the possible benefits of taking part?
6. What if something goes wrong?
7. What will happen to the results of the research study?
8. Who is organising and funding the research?
9. Who has reviewed the research study?
10. Contact for further information

1. What are medication error prevention strategies?

Preventing medication errors is possible by the implementation of risk-prevention strategies that reduce or eliminate the possibility of errors, make errors visible, and minimise their consequences. Selecting the best error-prevention strategy is not easy. Risk-prevention strategies tend to focus on system design, which are often most effective or human factors principles, which are less effective than system design strategies.¹

2. How have these strategies been selected?

¹ IMSN Global Targeted Medication Safety Best Practices. <https://www.intmedsafe.net/imsn-global-targeted-medication-safety-best-practices/>

A list of the policy recommendations has been devised by the Principal Investigator in conjunction with a sub-group of SIG members. The following sources of information, as provided by earlier phases of this study, have been used to support this process.

- Medication error prevention strategies used to improving medication safety in the ICU environment as identified through a literature review
- Medication error prevention strategies both currently in use and being planned in ICUs across Europe as identified through a f
- Medication error prevention strategies that have emerged from focus group interviews

3. What will happen to me if I take part?

If you agree to take part, we will ask you to participate in a up to three rounds of Delphi panel surveys online together with other healthcare professionals working in other intensive care settings. The Delphi panel rounds will take place in the autumn of 2022. Suitable dates for each round of the Delphi process will be agreed as per usual SIG administration processes. Members will be asked to confirm their availability by e-mail. The language used in the Delphi panel will be English. You can stop being part of the study at any time, without giving a reason. As participation in the Delphi panel is anonymous, we cannot identify your contribution to the panel and will keep information about you that we already have.

The Delphi panel will be arranged using a web-based online survey tool, easy-feedback.com. If you decide to take part, you will be able to access the online survey via a link that will be e-mailed to the SIG group prior to the scheduled date of each round. By providing your responses to the survey, you give your informed consent to participate. Participation is anonymous: the GDPR-compliant survey tool (easy-feedback.com) does not register IP-addresses of the participants. The Delphi panel survey data will be recorded on a server in Germany; no data leaves the EU. Once the anonymously submitted responses have been exported from the online data collection tool for further analysis, they will be deleted from the online survey tool. This collected data will be shared with other researchers working on the project as necessary; data will not be shared with any other source. All data recorded electronically will be handled on the personal computers of the researchers and on a secure limited-access shared folder available to SIG members via EAHP. All data will be securely stored for 24 months after the publication of the research, after which they will be destroyed safely.

Identification of Recommendations

Prior to the start of the Delphi panel rounds, the Principal Investigator in collaboration with a sub-group of SIG members has devised a list of the policy recommendations to be presented to the Delphi panel.

Delphi panels: Iterative Consensus Rounds

A number of iterative rounds of consensus will be conducted as outlined below. The complete list of recommendations will be presented to the expert panel at round 1. At subsequent rounds, only those recommendations where consensus has yet to be reached will be included. During each round, participants will be asked to independently score each recommendation using an online survey tool (easy-feedback.com). Participants will be instructed that they need not conform to the group view. They will be instructed to use a 9-point Likert scale where a score of 1 indicates “definitely not a priority” and a score of 9 indicates “a key priority”. Participants will also be invited to record any comments on individual recommendations within a dedicated section on the online survey. These

comments provide a better understanding of the rationale behind the responses provided at each round.

Round 1:

A virtual presentation will be delivered to the expert panel by the Principal Investigator during an SIG meeting. Participants will be presented with a brief description of each recommendation. Each participant will independently score each recommendation using the 9-point Likert scale and record any comments on individual recommendations using the online data collection tool as described above.

Round 2:

Those recommendations for which consensus is not reached during Round 1 will be included in Round 2. This will be conducted by e-mail in consideration of geographical diversity and time constraints of individual panel members. Each participant will be sent a data sheet containing: the Round 2 recommendations; the median and inter-quartile range (IQR) of the group's scores; and any comments provided by individual panel members from Round 1 whose identity will not be known.

On completion of each round, participants will be asked to record their submitted responses via the options made available on the online tool i.e. exporting a PDF record or requesting a link to their responses by e-mail. This maintains anonymity of all entered responses. Once the survey closes and the researchers have completed data analysis, all participants will receive feedback by e-mail on the group responses comprising of the distribution of the panel's responses for all recommendations and the complete list of anonymously recorded comments. This allows panel members to compare their own self-recorded responses with those of the rest of the panel without knowing the identity of the individuals providing the scores or comments.

Participants will be asked to resubmit their scores via link provided in the e-mail to the same online data collection tool (easy-feedback.com) used in Round 1. You will have the option to amend or retain your Round 1 score after having considered the group results. A maximum of two separate reminder emails at two weekly intervals will be sent to all members of the panel as participation is anonymous.

Round 3:

A third round will be conducted in the same manner as Round 2 for any recommendation where consensus has not been reached as deemed necessary by the research team. Again, a maximum of two separate reminder emails at two weekly intervals will be sent to all. Consensus will be determined after Round 3; a fourth round will not be conducted.

4. What are the possible disadvantages and risks of taking part?

We do not expect there to be any major risks. If you do feel uncomfortable or distressed you can stop taking part at any time and you can provide feedback on any areas of concern.

You will need to take the time to participate in the Delphi panel. You have given your name and contact details to the SIG and they will be used to conduct the study. However, the participation is anonymous: the GDPR-compliant survey tool (easy-feedback.com) does not register IP-addresses of the participants. The Delphi panel survey data will be recorded on a server in Germany; no data leaves the EU. To maintain your confidentiality, we will adhere to the General Data Protection Regulation (GDPR) 2016 (EU), Data Protection Act 2018 (Finland) and data protection policies of the University of Helsinki. Please see the attached Data Protection Statement.

5. What are the possible benefits of taking part?

While there may be no immediate benefit to you from participating, we hope that the final study report and policy recommendations from this research will be of value to intensive care units across Europe whose managers may choose to utilise the findings and the developed policy to benefit their intensive care unit and hospital. You will be given the option of receiving a summary of this final study report.

6. What if something goes wrong?

If you have a concern about any aspect of this study, you can contact the Principal Investigator, Adjunct Professor Raisa Laaksonen via email at raisa.laaksonen@helsinki.fi. If you are still not satisfied with the response, you may contact the University of Helsinki Data Protection Officer via email at tietosuoja@helsinki.fi.

7. What will happen to the results of the research study?

It is anticipated that the findings of the research study will be disseminated via a number of avenues, such as through a report to the EAHP, a peer reviewed research paper in an international journal and presentations at academic conferences. Additionally, summaries of the findings will be produced, targeted at relevant groups such as healthcare professionals working in the intensive care setting, professional bodies, and policy makers.

It will not be possible to identify participants from any reports or outputs of the study. However, if you tell us that you want to be acknowledged for your contribution, your name will be included in a specific acknowledgements section of the publication. We will not present your individual thoughts in the publication; rather all results will be presented according to the different groups that took part.

8. Who is organising and funding the research?

This research is organised by the Special Interest Group (SIG) for the Investigation of Medication Errors in Intensive Care, European Association of Hospital Pharmacists (EAHP). The EAHP has received funding from BD (Becton, Dickinson and Company) for the running of the project. The research, its outcomes and decisions on recommendations delivered by this working group remain independent from this financial support. The SIG is comprised of professional clinical experts (doctors, nurses and pharmacists) and patient safety experts from different European countries.

9. Who has reviewed the research study?

The Principal Investigator has obtained approval from the Ethical Review Board in the Humanities and Social and Behavioural Sciences, University of Helsinki (18/2022, 18.3.2022), stating that the study meets the ethical requirements set for research in the human sciences.

10. Contact for Further Information

If you would like further information on any aspect of the study, please do not hesitate to contact us.

Co-chairs of the SIG for the Investigation of Medication Errors in Intensive Care:

Principal Investigator, Adjunct Professor Raisa Laaksonen (raisa.laaksonen@helsinki.fi), University of Helsinki, Finland

Dr Virginia Silvani (virginia.silvani@hse.ie), Health Care Executive, Ireland

If you agree to take part in this study, please keep a copy of this information sheet. Please note that by providing your responses to the survey, you have given your informed consent to participate.

Thank you for your time!

SIG - FINAL REPORT

Special Interest Group for The Investigation of Medication Errors in Intensive Care Units



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