



ECAMET

European Collaborative Action on
Medication Errors and Traceability



WHITE PAPER

Call to Action developed by the ECAMET Alliance on

The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm



March 2022

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Glossary

ADCs	Automated Dispensing Cabinets	EMR	Electronic Medical Record
AEs	Adverse Events	eMAR	Electronic Medical Administration Record
BCMA	Barcode Medication Administration	EPS	Electronic Prescribing System
CPOE	Computerised Physician Order Entry	MEs	Medication Errors
DERS	Dose-error Reduction Software	NHS	National Health Service
EBN	European Biosafety Network		

FOREWORDS



MEP Tomislav Sokol
EPP – Croatia



In this day of technology, we have the tools to lift the burden from healthcare professionals and eliminate human errors, especially in the area of medication errors. Indeed, it is interesting to note that the introduction of IT to digitalise the complex medication process can reduce medication errors by around 60%. IT systems have a very significant impact, but of course other actions, such as training, patient education, medicine branding and package design, continual improvement processes must also be applied.

The term digitalisation, could perhaps be accused of being an overused term, and perhaps the panacea to everything that requires systemisation. In the case of preventing patient harm by having a clear end to end picture of the medication process via digitalisation, provides the backbone within any hospital system. However, this comes with an economic price. But how can you put a value on even a single life lost, as just one significant error is one too many, which can on occasions result in significant compensation claims.

The WHO is committed to the eradication of medication errors and launched a global initiative called “The Third Global Patient Safety Challenge: Medication Without Harm” in 2017. The aim of this initiative is to reduce medication errors and the associated harm in all countries around the world by 50% within 5 years. In this third challenge, the WHO has asked health ministers to establish national plans covering four aspects of the safe use of medication: the involvement of patients and the general public, medicines as products, the education, training and monitoring of health professionals, and medication management systems and practices.

This is because the WHO has identified a real need in the are of medication errors and I quote “Every person around the world will, at some point in their life, take medications to prevent or treat illness. However, medications sometimes cause serious harm if incorrectly stored, prescribed, dispensed, administered or if monitored insufficiently.

Unsafe medication practices and medication errors are a leading cause of avoidable harm in health care across the world. Medication errors occur when weak medication systems and human factors such as fatigue, poor environmental conditions or staff shortages affect the safety of the medication use process. This can result in severe patient harm, disability and even death. The ongoing COVID-19 pandemic has significantly exacerbated the risk of medication errors and associated medication-related harm. It is in this context that **‘Medication Safety’** has been selected as the theme for World Patient Safety Day 2022, with the slogan **‘Medication Without Harm’**.

Hospitals have shown that they are good at adhering and adapting to systems that require them to act. We can certainly make the same happen with medication errors by using digital means to take out the human error whilst at the same time introducing efficiencies that free up time for quality care to be enhanced.

I for one will support recognition of this patient safety issue. I am aware that there are voices calling for this to be part of future actions in the EU Pharma Strategy. This is to be welcomed and I commend this work to DG SANTE who can play a vital role in ensuring health agencies across the Member States galvanise resource and support the implementation of traceability systems accompanied by an open and honest approach by all concerned to effect positive cultural change within the hospital environment.



Mike Isles
Executive Director,
European Alliance for
Access to Safe Medicines



As MEP Tomislav Sokol has stated in his foreword, this year the WHO theme for World Patient Safety Day on 17th September is 'Medication Safety' with the slogan 'Medication Without Harm'.

The timing of this White Paper entitled "The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm" is therefore very aptly timed. This has only been made possible by the creation of the ECAMET Alliance, made up of twenty-one organisations which are listed on page 14. Within the Alliance, the Scientific Committee has also given strong support. The expert advice afforded to ensure that the pan-European survey of 37 primary questions were entirely relevant to extract the maximum amount of information, was vital.

In total there are 25 reports comprising 13 country reports in English, 8 languages translations, a private hospitals report, specialised oncology and ICU reports and one consolidated report.

In addition, to enable a comparison between the countries and their reports an interactive dashboard has been created. This allows the use to search by question against criteria such as hospital size or discipline.

Medication errors are the most common adverse event in hospitals, not only in terms of number, but as well in morbidity and mortality, and have significant economic and health consequences. The reports reveal many positive aspects within hospitals across Europe whilst at the same pointing to areas that would benefit greatly from development in terms of funding, training and implementation of traceability systems.

This White Paper recommends requirements to reduce medication errors in hospitals and highlights the need to:

1. Establishing a culture of safety
2. Create strategies to improve communication
3. Raise awareness and organising regular multi-disciplinary training meetings
4. Systematically use accreditation/certification systems
5. Introduce technological tools

The above topics are backed up with scientific proof of effectiveness of such measures with the survey results adding a contemporary view. The 317 completed surveys can be regarded as statistically valid and so adds to the credibility of this White Paper's Call to Action - [click here](#).

The reports can be found on the official website www.ecamet.eu alongside the interactive dashboard.

If you would like more information on the Alliance or if you would like to join it, please contact mike.isles@eaasm.eu.

The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm


EXECUTIVE SUMMARY

Medication errors are the most common adverse event in hospitals, not only in terms of number, but as well in morbidity and mortality¹ and have significant economic and health consequences.² Adverse events related to an erroneous use of medication cause greater mortality than traffic accidents, breast cancer or the human immunodeficiency virus (HIV).³ In addition, healthcare staff directly or indirectly involved in an adverse event, the 'second victims', may also suffer from emotional harm.⁴

In Europe, the European Medicines Agency (EMA) highlighted that the rate of medication errors in hospitals varies from 0.3% to 9.1% in prescription and from 1.6% to 2.1% at the dispensing stage.⁵ A UK study estimated that there are 237 million medication errors happening at some point in the medication process in England annually, with 66 million being potentially clinically significant. Errors occur at all stages of the medicines use process: prescribing (21.3%), transition (1.4%), dispensing (15.9%), administration (54.4%) and monitoring (7.0%); and in all settings: primary care (38.4%), care homes (41.7%), and secondary care (19.9%). Definitely avoidable ADEs are estimated to cost the NHS £98 million per year, consuming 181 626 bed-days, and causing/contributing to 1708 deaths. Furthermore, 28% of the errors had a moderate to serious nature of harm.⁶ In Spain, the Estudio Nacional sobre los Efectos Adversos Ligados a la Hospitalización, the ENEAS study (National Study on Hospitalisation-Related Adverse Events) concluded that the incidence of adverse events in hospitalised patients was 8.4%, with the most frequent adverse event being medication errors, which accounted for 37.4% of the total.⁷

The WHO estimates the annual cost from medication errors in the world comes to USD42bn.⁸ In the United Kingdom, the estimated costs for the NHS of definitively avoidable adverse reactions to medication come to £98.5m a year (2.9% of UK NHS). This is close to estimates from other publications such as the UK's National Patient Safety Agency (NPSA) and the United States' Institute of Medicine.⁹ In Spain, the cost of medication errors is estimated at €2bn (accounting for 3% of total national spending on health).

Clinical evidence shows that the introduction of medication traceability systems in hospitals is the most effective way to minimise medication errors,¹⁰ as well as improving the efficiency and quality of care of nursing staff. An overall medication error reduction of 58% was recorded in the Boston metanalysis.¹¹ Medication traceability systems include electronic prescription, electronic preparation, barcode medication administration and smart pumps, all connected to health records and hospital management systems.



This alarming patient safety issue led to the creation of an alliance called the European Collaborative Action on Medication Errors and Traceability (ECAMET), a patient safety initiative developed by a group of healthcare professionals and stakeholders.

The ECAMET Alliance includes 21 organisations committed to the formation and promotion of regulations and/or guidelines on medication traceability to prevent medication errors in Europe amongst policy makers within the EU.

To establish the current practices within hospitals around Europe, the ECAMET Alliance commissioned a major Pan-European survey among hospital pharmacists. The objective was to identify areas of improvement and thus stimulate innovation in the hospital setting via proven digital processes and internal dynamic behavioural changes.

The survey in fact revealed many important observations, with a lack of consistency and harmonisation being a major theme which is illustrated as follows. It shows the low implementation of medication traceability systems as well in European hospitals.

Pharmacists clearly identified the most important areas to reduce medication errors:

- Traceability systems such as electronic prescription, medication error surveillance and barcode medication administration systems
- Funding, human resources and lack of trained staff are listed as main barriers for implementing these improvements

Given the magnitude of medication errors occurring and the lack of consistency and harmonisation of processes and the low implementation of medication traceability systems across European hospitals, the ECAMET Alliance calls on all relevant stakeholders to:

1. Include medication safety in the Pharmaceutical Strategy for Europe, in the EU general pharmaceutical legislation and in Europe's Beating Cancer Plan through medication traceability systems in a healthcare setting to minimise medication errors.
2. Prioritise strategic investments in medication traceability systems in the EU4Health program to minimise medication errors.
3. Foster the development and implementation of ECDC guidelines and key indicators on medication errors in EU healthcare settings.
4. Facilitate the systematic exchange of best practices between healthcare providers both at European and national levels to reduce medication errors in healthcare settings.

MEDICATION ERRORS: THE MOST COMMON ADVERSE EVENT IN HOSPITALS

Facts on medication errors

The United States National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as: “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”¹²

Medication errors are the most common adverse event in hospitals and have significant economic and health consequences.¹³ Adverse events related to an erroneous use of medication cause greater mortality than traffic accidents, breast cancer or the human immunodeficiency virus (HIV).¹⁴ In addition, healthcare staff directly or indirectly involved in an adverse event, the ‘second victims’, may also suffer from emotional harm.¹⁵

As stated by the WHO, medication errors occur when unreliable medication systems and/or human factors such as fatigue and lack of health care workers affect the practice of prescribing, dispensing, administering, and monitoring medication. The most frequent errors occur during the medication administration phase in hospitals. High workloads and lack of health care personnel contribute to 23% of medication errors.¹⁶

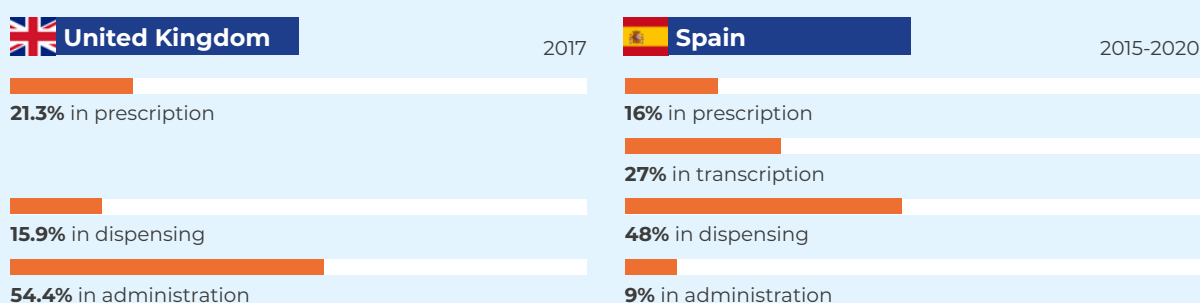
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The Spanish NHS Patient Safety Strategy document covering the period 2015-2020, indicates that there are up to 17 medication incidents per day for every 100 patients hospitalised, 16% in prescription, 27% in transcription, 48% in dispensing and 9% in administration²⁰ (see table 1).

Table 1: Percentage of medication errors in hospitals



The Institute for Safe Medication Practices (ISMP) has published a report on the most common medication errors in 2020 with serious consequences for patients. According to this report, the ten most common errors are shown in table 2 below:²¹

Table 2: Ten types of medication errors with the most serious consequences detected in 2020.

- | |
|---|
| 1. Errors due to omission or delay in medication |
| 2. Administration of medication to the wrong patient |
| 3. Errors associated with allergies or adverse events known for the medication |
| 4. Errors in calculating the dosage for paediatric patients |
| 5. Errors due to likeness in labelling or the packaging of medication sold |
| 6. Errors associated with lack of use of smart infusion pumps |
| 7. Errors due to accidental administration of neuromuscular blockers |
| 8. Mistaken intravenous administration of oral liquid medications |
| 9. Errors in medication reconciliation on hospital admission and discharge |
| 10. Errors due to comprehension problems among patients about how to use the medication |

Table modified from the original. Institute for safe medication practices, ISMP-España. Available at: <http://www.ismp-espana.org/>. Last seen: January 2022.

Second victims

The most significant victims of medication errors are the patients and their relatives. However, they are not the only people affected. The healthcare staff directly or indirectly involved in an adverse event, the 'second victims', may also suffer from emotional harm.²²

The term second victim was coined by Wu²³ in 2000 referring to professionals involved in an adverse event who were traumatised as a result or incapable of coping with the situation. Some years later, Scott et al. (2009)²⁴ broadened this definition to all healthcare staff involved in an adverse event who were traumatised as a result.

Nurses, pharmacists, and other members of the healthcare team are also susceptible to error and vulnerable to unanticipated patient harm. Trainees and interns may be particularly defenceless to continuing damage to their clinical confidence and self-esteem.²⁵

Surveys show that up to 50% of all hospital workers become a second victim at least once in their career. Being involved in an incident can affect the quality of subsequent patient care to some extent. Second victims experience both a professional and personal impact. They suffer, for example, from loss of self-confidence, fear of litigation or reputational damage, guilt, anger, and fear.²⁶

In Spain, studies concluded that every year 15% of clinical professionals are involved in an adverse event with serious consequences for the patients, with medication errors being the main adverse event.²⁷

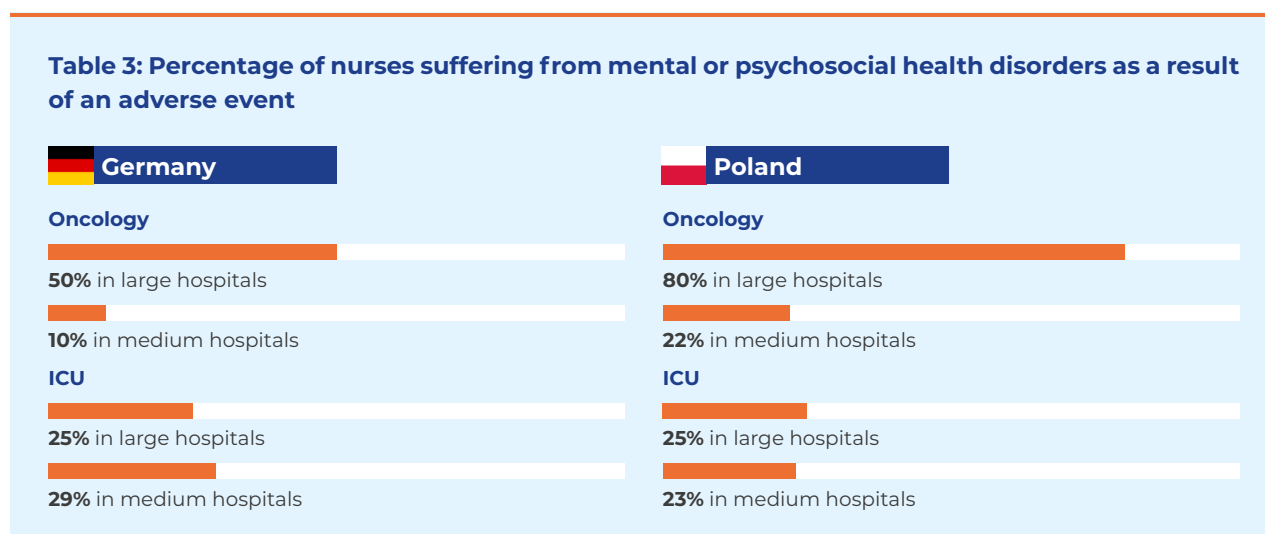
A survey from the European Biosafety Network (EBN) entitled “Research into the mental and psychosocial health of nurses in Europe”²⁸ highlights alarming results. The EBN commissioned research from Ipsos MORI to receive robust data on the type and rate of mental and psychosocial disorders amongst hospital nurses, their causes and effects and whether they are linked to a medication error causing a serious adverse event.

13% of nurses suffering from mental and psychosocial health disorders have been involved in an adverse event with serious consequences for the patient, mainly during the COVID pandemic. This percentage is higher in critical areas such as oncology (16%) and in big hospitals with more than 900 beds (22%) and the same percentage in Intensive Care Units (ICU) and medium-sized hospitals with 500-900 beds (13%) where critical patients are admitted.

The most prevalent cause of an adverse event are medication errors being one third of all adverse events, increasing to 38% of total adverse events in ICU. These adverse events have mainly caused anxiety, leading to chronic workplace stress at work.

By country, the percentage of nurses suffering from mental or psychosocial health disorders as a result of an adverse event amounts to 25% in Germany and Poland and 14% in Spain.

When combining the figures from both big hospitals and the critical areas of oncology and ICU, results for the percentage of nurses suffering from mental or psychosocial health disorders as a result of an adverse event are concerning and can be reviewed in table 3 below.



The main consequence for nurses involved in one adverse event is chronic workplace stress which leads to 31% of them taking time off work for an average length of 2-3 months.

Associated costs

The WHO estimates the annual cost from medication errors in the world comes to USD42bn.²⁹

In the United Kingdom, the estimated costs for the NHS of definitively avoidable adverse reactions to medication come to £98.5m a year (2.9% of UK NHS). This is close to estimates from other publications such as the UK's National Patient Safety Agency (NPSA) and the United States' Institute of Medicine.³⁰ In Spain, the cost of medication errors is estimated at €2bn (accounting for 3% of total national spending on health).

Medication errors prevention initiatives

WHO

The global initiative launched by the WHO in 2017, called “Third Global Patient Safety Challenge: Medication Without Harm” aims to reduce medication errors and the harm associated with them by 50% over the next five years. In this initiative, health ministers are invited to set up national plans to cover the four aspects of safety in usage of medications: participation from the patients and the public; medicines as products; training, skills-learning and monitoring of health care professionals; and the systems and practices for managing medications. The WHO must use its rallying and coordinating power to foster a series of worldwide measures related to safety in the use of medications.³¹

The WHO recommends launching electronic systems in the areas of prescription, preparation, dispensing, administration and monitoring (figure 1 below).³²

Figure 1: Medication without harm. Global patient safety challenge.



Figure modified from World Health Organization.

Due to the predominance of the problem, ‘**medication safety**’ has been selected as the theme for World Patient Safety Day 2022, with the slogan ‘**medication without harm**’.

EAHP

In its document “Position Paper on Patient Safety. Hospital pharmacists – making the difference by improving medication safety”, the European Association of Hospital Pharmacists (EAHP) recommends:³³

- Launching different risk management tools including single-dose barcodes, quality control and risk management committees and electronic prescriptions systems.
- Adoption of a system of a closed-loop complete medication traceability management enabling safer and more efficient administration of medication in hospitals.

ISMP

The Institute for Safe Medication Practices has set out the following chart showing the most efficient technology to prevent medication errors³⁴ (table 4 below).

Table 4: ISMP. Use of technology
A fully integrated CPOE system that includes the possibility of creating medication safety alerts and clinical decision rules. It must intervene directly with the laboratory and pharmacy, list the drug-drug and drug-illness interactions, and provide support for clinical decision-making.
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Point-of-care systems with barcodes which are designed to detect medication errors upon distribution and/or administration of the medication. Using a barcode scanner to scan barcodes on a medication and the patient's bracelet, users can record all of the medications administered to the patient.
Smart infusion pump systems enable users to enter medication infusion protocols into a medication library with predefined dosage limits. If a dosage is programmed outside the established limits or the clinical parameters, the pump stops or an alarm sounds. Some pumps can include monitoring of the patient and their other parameters.
ADCs (automated dispensing cabinets) are robust dispensing systems that must be integrated with the health centre's information system and interact directly with the pharmacy system. Furthermore, the ADCs must be able to use barcode technology for the re-supply process.
A “robust” system for placing pharmacy orders that is completely interconnected with a CPOE system that can create safety alerts for medication, interact directly with a healthcare facility's IT systems and generate an eMAR (electronic medical administration record) to be used by nurses when they administer medication.
IV workflow technology combines software with automated pharmaceutical workflow technology to prepare sterilised products. It receives information about the dosages from healthcare IT systems and uses robotics, gravimetric analysis and barcode scanning together with video or digital image technology. Some systems can generate specific notes and labels to administer medication for nurses to scan them at the point of care.

ADC: automatic dispensing cabinet system; AE: adverse event; CPOE: computerised physician/provider order entry; eMAR: electronic medication administration registry; GAT: gap analysis tool; GEDSA: Global Enteral Device Supplier Association; HER: electronic health record; IV: intravenous; OR: operating room; PN: parenteral nutrition. Table modified from Reckmann MH, et al. 2009.

In its report “Targeted Medication Safety Best Practices for Hospitals”, the ISMP also includes the following good practices:³⁵

- Administer medication with a programmable infusion pump using dose error reduction systems (library of drugs and speed limits incorporated).
- Keep up a percentage above 95% of the programme for infusions using the dose error reduction system.
- Monitor compliance with use of the dose error reduction systems for smart pumps monthly.
- Use a smart pump that enables the bolus to be programmed (or the dose loaded) and the speed of continual infusion with separate limits for each of them.
- Assign resources for maintenance, software updates and the medication library for all the smart pumps.
 - Ensure that the medication library's content is coherent with the information and nomenclature of the medication (for example, name of medication, dosage units, speed of dosage) in the electronic clinical record.
 - Plan the implementation of the interoperability of the bi-directional smart infusion pump (i.e. automatic programming and electronic registration of the administration with the electronic health record).
- Make an independent double-check when preparing sterile mixtures to ensure the adequate components are included (medications and dilutants), including confirmation of the suitable amount (volume) of each component before adding it to the final recipient.
- Eliminate the use of indirect methods of verification for compound sterile medication preparations (for example, the “syringe extraction method”, verifying a label of the real components instead). Except in the event of an emergency, carry out this verification everywhere that compound sterile preparations are made, including patient care units.
- Use technology to help in the verification process (for example, verification of components by barcode scanning, gravimetric verification, robotics, etc.). When using technology, it is important for there to be procedures to ensure it is maintained, for the software to be up to date, and for the technology to always be used in a way that makes the utmost use of such systems' medication safety features.

EUROPEAN COLLABORATIVE ACTION ON MEDICATION ERRORS AND TRACEABILITY PATIENT SAFETY PROJECT (ECAMET)



Introduction

Based on this wealth of scientific evidence and as a result of the burden of medication errors in acute care settings across European countries, a major European patient safety project is under way to promote the prevention of medication errors in acute care settings.

This project aims to prevent patient as well as 'second victim' harm at European and national levels through the implementation of medication traceability systems, combined with internal dynamic behavioural changes. Key initiatives are focused on ensuring medication errors are prevented through awareness, education, and promotion of traceability systems.

To achieve this, a European Alliance* made up of Scientific and Patients' organisations, under the project name "The European Collaborative Action on Medication Errors and Traceability" (ECAMET) has been created (see figure 2 below). With patient safety at its heart, the Alliance's composition and focus includes experts from acute care settings that are more susceptible to medication errors, namely: pharmacy, oncology and intensive care, nurses as well as patient organisations. In addition, the ECAMET Alliance has appointed a Scientific Committee,† comprising experts from different specialties, to provide expert advice as well as supporting the development of a pan-European survey on medication errors.

Figure 2: ECAMET Alliance



* Associação Portuguesa de Farmacêuticos Hospitalares (APFH), Action against Medical Accidents (AvMA), European Alliance for Access to Safe Medicines (EAASM), European Biosafety Network (EBN), European Network for Safer Healthcare (ENSH), European Cancer Patient Coalition (ECPC), European Patient Safety Foundation (EUPSF), European Sepsis Alliance (ESA), European Society of Intensive Care Medicine (ESICM), European Society of Paediatric and Neonatal Intensive Care (ESPNIC), European Specialist Nurses Organisation (ESNO), European Union of Private Hospitals (UEHP), Spanish Patients' Forum (FEP), Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA), Health First Europe (HFE), Institute for Safe Medication Practices (ISMP), International Alliance of Patients' Organizations (IAPO), Melanoma Patient Network Europe (MPNE), Spanish Society of Hospital Pharmacists (SEFH), Società di Italiana di Farmacia Ospedaliera e dei Servizi Farmaceutici delle Aziende Sanitarie, Société Française de Pharmacie Clinique (SFPC)

† A clinical oncologist, a hospital pharmacist, an oncology pharmacist, a clinical intensive care specialist for adults, a clinical intensive care specialist for paediatrics, patient and healthcare workers safety representatives, a specialist nurse, a private hospital representative, EAASM Executive Director, a medication safety representative.

Key activities of the ECAMET patient safety project

Recommendations and a Call for Action to raise awareness amongst EU institutions and Member States

Provide clear clinical evidence from international scientific associations to develop a set of regulations and a call for action to allocate funding to minimise medication errors across hospitals in Europe.

Pan-European survey to understand current hospitals' practices and plans to reduce medication errors

In close liaison with the Scientific Committee, the ECAMET Alliance developed a comprehensive-based survey, to be answered by Hospital Pharmacy Managers, which covered the following areas:

- Hospital background information
- Medication errors and preventable adverse events' detection and monitoring
- Information systems (electronic medical record, electronic prescribing system, electronic drug dispensing system, electronic drug compounding system, electronic medication administration system)
- Unit dose medication systems
- Pharmacy inventory systems
- Future plans

The Pan-European survey among hospital pharmacists has been managed by a European market research company, Ipsos MORI. It includes questions about the size of the problem of medication errors, the level of awareness and education and the existing traceability systems in place in acute care settings.

The survey has been delivered to 13 countries (see figure 3 overleaf) and the European Union of Private Hospitals (UEHP) conducted the survey among its members. Where necessary the survey was distributed in the native language.

The ECAMET Alliance is grateful that hospital Pharmacists' Associations distributed the survey to all their members on a pro bono basis:

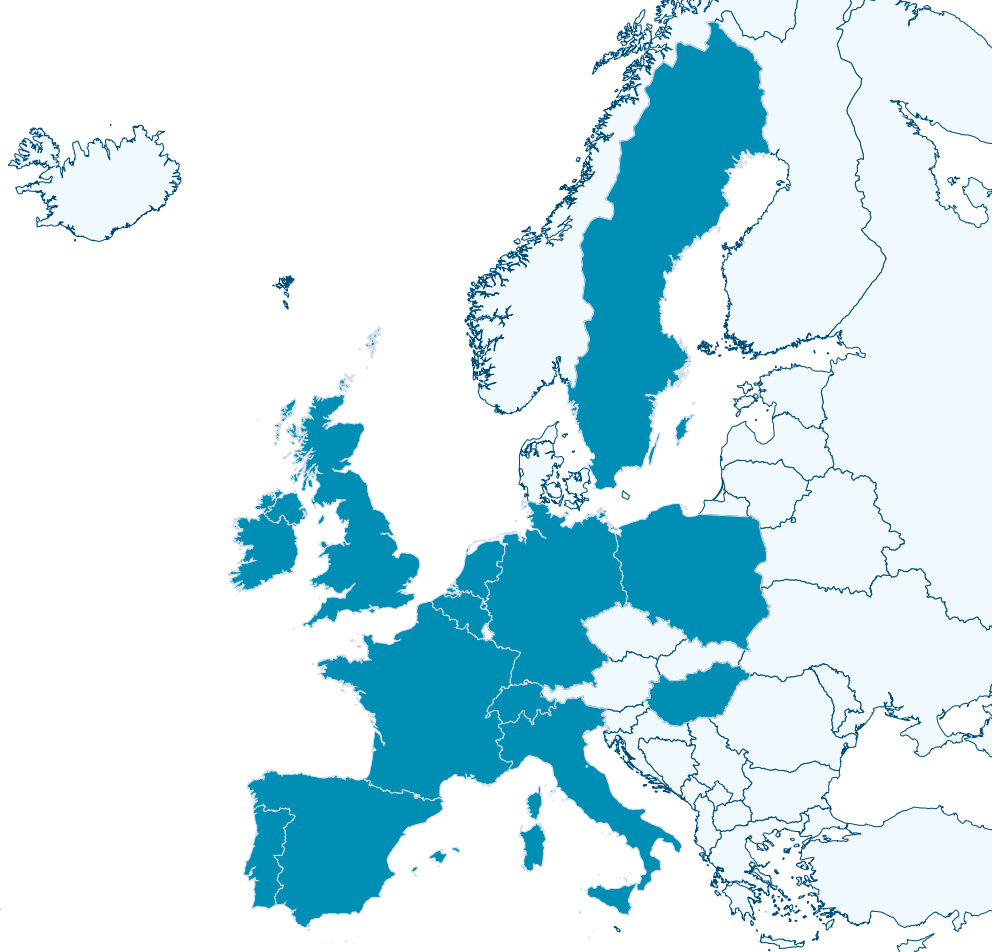
- France: Société Française de Pharmacie Clinique (SFPC)
- Italy: Società Italiana di Farmacia Ospedaliera e dei Servizi Farmaceutici (SIFO)
- Portugal: Associação Portuguesa de Farmacêuticos Hospitalares (APFH)
- Spain: Sociedad Española de Farmacia Hospitalaria (SEFH)
- Switzerland: Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA)

For the rest of the countries, Ipsos MORI distributed the surveys. The number of surveys completed amounted to 317.

Figure 3: Country Distribution

Belgium	10
France	42
Germany	40
Hungary	6
Ireland	4
Italy	42
Netherlands	10
Poland	20
Portugal	36
Spain	41
Sweden	5
Switzerland	12
UK	40
*Private Hospitals (UEHP)	9
Total	317

*European Union of Private Hospitals (UEHP)



Main observations around medication errors

To access all of the reports and to use an interactive dashboard to compare results across Europe, click [here](#)

The main observations around the numbers of errors and drivers of errors are:

- Most hospitals record between 100-250 MEs per year. But 25% of hospitals do not know this data.
- Not all MEs are analysed, mainly in those hospitals that record every year between 100-250
- Distribution of errors by process is as follows: 29% administration, 21% electronical prescriptions, 17% manual prescriptions, 17% dispensing and 16% preparation.
- Main drivers of medication are as follows (see table 5 below).

Table 5: Main cause of medication errors (ranking)

Environmental staffing or workflow problem	24%	74%	Drug storage or delivery problem	6%	38%
Lack of staff education	17%	69%	Patient education problem	4%	33%
Miscommunication of drug order	16%	54%	Drug delivery device problem	4%	23%
Drugname, label, package problem	10%	60%	Drug information missing	3%	34%
Clinical information missing	8%	51%	Not supplied from warehouses	2%	23%
Lack of quality control or independent check system	7%	42%			

Key: ■ 1st place ■ Mentioned

RECOMMENDATIONS TO PREVENT MEDICATION ERRORS AND SURVEY RESULTS

Based on the survey results, the ECAMET Alliance has identified 5 general recommendations to avoid medication errors and enhance patient safety. Please consult our report for a complete analysis. (see Annex A for an overview table of the consolidated results).

Establishing a culture of safety

It is advisable to foster a culture of safety in healthcare organisations in an aim to improve the safe use of medication. Healthcare professionals should not be afraid of reporting errors in order to thus create a safe system in which mistakes serve to improve the quality and safety, so they do not happen again.³⁶ Systems to record and report medication errors are critical to learn from errors and avoid repeating them. Nevertheless, notification and recording systems are not intended to estimate the frequency of adverse events in the hospitals, but a way of obtaining valuable information about the cascade of events that lead to their occurrence.^{37, 38}

Survey results:

- In Europe an average of 8% of hospitals do not record medication errors in a database, and only 13% of hospitals make medication errors data available to the public.
- However, 33% of hospitals do not have medication errors' databases for sharing continual improvements.
- 14% of hospitals do not routinely track medication errors
- 71% of hospitals track medication errors centrally and are mainly used as a root cause analysis to resolve incidents and investigated at regular quality meetings. Nevertheless, 23% of hospitals do not use that system regularly.

Creating strategies to improve communication

Strategies to improve communication among the professionals involved in prescribing, validating, preparing, administrating and dispensing medication are key to reduce medication errors.³⁹ **In its report "Targeted Medication Safety Best Practices for Hospitals",⁴⁰ the ISMP also includes the following good practices:**

- Search for and use information about safety errors and risks in medication that have occurred in other organisations outside one's own facilities and take steps to avoid similar errors.
- Designate one single healthcare professional (preferably a head of safety) to be responsible for supervising all of this activity in the hospital.
- Identify resources with a good reputation (for example, ISMP, the Joint Commission, Emergency Care Research Institute (ECRI), patient safety organisations, state agencies, etc.) to learn of the risks and errors that have occurred externally.
- Set up a formal process for a monthly review of the medication risks and errors reported on by external organisations, with a new or existing interdisciplinary team or committee responsible for safety with medication.
- Review the hospital's current systems for using medication (whether manual or automated) and other data such as internal medication safety reports in order to identify any potential area of risk that may allow a similar risk or error to occur in the hospital.
- Identify the appropriate action to be taken to minimise the risk of those types of error occurring in the hospital.
- Document the decisions taken and get approval for the required resources if necessary.
- Share external stories about risks and errors with all of the staff, together with the changes that will be made in the hospital to minimise their occurrence.
- Periodically monitor the selected activities to ensure they are still being implemented and are effective in achieving the desired reduction in risks.

Survey results:

- 56% of hospitals have trained healthcare professionals dedicated to detecting medication errors and enhance patient safety, being mainly hospitals and quality managers.
- 74% of hospitals discussed medication errors and near misses in an open/transparent way to help to ensure continual improvement.

Raising awareness and organising regular multi-disciplinary training meetings

Awareness campaigns by scientific associations, including recommendations and best practice, are very important to create one safety culture in the organizations and to set best practice and recommendations to prevent medication errors.^{41, 42}

Training of healthcare professionals is another key enabler of a safety culture in hospitals. Specific curricula on medication errors' processes and best practice have been developed with the aim of being introduced into degree-level education for such professions across several disciplines. In 2011, the WHO presented a multi-professional version of the Curricular Guide to patient safety in order to train future healthcare professionals in this matter.

It is also advisable to prepare training and awareness programmes for patients and families.

Survey results:

- 94% of hospitals believe that staff training is one of the most important areas to be improved.
- 53% of hospitals believe that lack of staff training is an obstacle to implementing technologies to enhance its medication management.

Systematically using accreditation/certification systems

Accreditation/certification systems enable strong systems and processes and are a commitment to guaranteeing quality and ongoing improvement. They provide harmonised resources and techniques with optimal use of them, helping to ensure the best and safest care for patients. Accreditation/certification systems should include prevention of adverse events, including medication errors, as a significant element. They should be regularly updated to incorporate the role of new technologies to prevent adverse events.⁴³

Survey results:

- 82% of hospitals are accredited, but 13% of those accreditations do not include medication errors.
- There is a wide variation of medication errors registered and analysed per year.
- Medication error reports are largely not accessible to the public.

Introducing technological tools⁴⁴

Medication traceability systems

The introduction of medication traceability systems is highly recommended based on existing clinical evidence.⁴⁵ It is advisable to use technology that fosters the standardisation of medication use to reduce variability, especially in the stage when the medication is prepared in these units.⁴⁶

Medication traceability systems include:

- Electronic prescriptions with systems to support clinical decisions
- Automated dispensing cabinets
- Electronic preparation system with volumetric and gravimetric solutions that ensure the medication and prepared dosage are correct
- Barcode medication administration (BCMA) to administer medication, ensuring that the medication prepared, the patient, the moment and the means of administration are correct
- Smart pumps with safety systems to prevent programming errors. Some new infusion pumps allow for a connection with the hospital's prescription system so they can be programmed automatically
- Complete connectivity for all systems

Electronic prescription systems

Evidence shows the importance of computerized provider order entry systems (CPOE)⁴⁷ in minimising medication prescription errors.⁴⁸

It is estimated that at least a quarter of all harm related to medication can be prevented by using CPOEs by eliminating errors from incorrect manual transcriptions.⁴⁹

It is recommended that CPOE include functions such as alerts about allergies, interactions, duplications, maximum dosages, proposal of dosage according to weight, etc., that may reduce errors even further.

It is very important to integrate CPOE with electronic medical records, pharmacy dispensing and manufacturing systems, medication cabinets and infusion pumps.⁵⁰

Survey results:

- 94% of hospitals have electronic prescription systems, nevertheless:
 - Only 20% of them are integrated with a clinical decision support system.
 - Only approximately 50% of the electronic prescription systems are available for all patients in critical areas of Intensive Care Units (ICUs) and Oncology-Ambulatory and Wards.
 - 14% of prescriptions are not validated by a pharmacist and 44% are not always validated by a pharmacist.
 - Integration with hospital systems is limited: over 50% for electronic medical records, but below 33% for medication cabinets and below 20% for infusion pumps.

Automated drug cabinets

Medication safety cabinets, including the connection with computerised physician order entry (CPOE), reduce the rate of medication errors and costs and improves efficiency of healthcare staff.⁵¹ Clinical studies suggest the importance of optimally introducing automated dispensing systems to ensure the utmost clinical success and economic benefits.⁵²

The additional auditable security, traceability and electronic registered chain of custody records of controlled substances provided by ADCs (with their 2 factor authentication for example) and the software, drives down the opportunities and risks of diversion and medication error in comparison to today's common practice using "dumb safes," paper orders, records and registers.

Survey results:

- Availability of automated drug cabinets is very limited. This is especially true in critical care areas such as ICUs, only 25%, and Oncology wards 16% and 12% in Oncology-Ambulatory or One day hospitals.
- In those hospitals where they are available the average number varies between 2.2 - 2.5.
- Only 16% have a barcode system to verify drug selection prior to dispensing or refilling automated cabinets.

Electronic preparation/compounding systems & digitalised medication inventory management

Central Pharmacies in hospitals are the best equipped in terms of skilled resources and technology to prepare medication.⁵³ Nevertheless, there is a significant volume of medication that is prepared outside of central pharmacies, in critical care units and general wards and so similar resourcing and skills should be made available in any given setting.

Survey results:

- Only 19% of medication in hospitals is prepared by central pharmacies. 22% is prepared in ICUs, 26% in ambulatory areas and 33% in general wards.
- 66% of hospitals have pharmacists involved with implementing nursing standards operating procedures for aseptic or injectable preparation on the wards.

As a result, it is critical to implement electronic systems in preparation areas to support preparation and ensure safety. **There are 2 types of electronic preparation systems:**

- **Volumetric systems:**⁵⁴ These are connected to the prescription system. By reading the barcode of the medication to be used in the preparation, they enable verification of whether it is correct. However, they do not enable verification that the prepared dosage is correct.
- **Gravimetric systems:**⁵⁵ The gravimetric method is a quantitative one to determine the amount of substance required by measuring its weight with a scale. These systems, which are also connected to the prescription system, also enable verification that the medication to be used in the preparation is correct, the one prescribed, and they also ensure that the dosage prepared is correct. The system does not allow the preparation process to be followed if the exact dosage has not been processed in any of the stages of preparation. Preparation systems using gravimetric workflow have great potential to reduce errors in identifying the medication used, but even more importantly, in reducing dosage errors. They are also highly efficient, avoiding the need for a double visual inspection in the preparation process that many ICUs have established for high-risk medication. Gravimetric preparation systems are considered critical in neonatal and paediatric intensive care services for all preparations with a higher risk of dosage, considering that dosage error is the main cause of medication error in such units.

Electronic preparation/compounding systems prevent omission errors since the systems keep healthcare staff informed about medication prescribed and non-prepared.

Survey results:

- The availability of electronic preparation/compounding systems is low with only 14% of ICU units and 31% and 11% respectively for Oncology Wards and Oncology-Ambulatory or One day hospital areas. Central Pharmacy is the area with highest penetration of these systems at 48%.

Barcode medication administration (BCMA) and identification systems

BCMA reads the barcode of the patient's bracelet, the healthcare worker's identification and the medication. The system verifies: the right medication, the right patient, the right moment. It verifies as well that medication is administered only by authorised staff.

Clinical evidence suggests that BCMA is a very effective technology to prevent medication errors in administration.⁵⁶

BCMA prevents omission errors, since the systems keep healthcare staff informed about medication non-administrated and the right time.

Double nurse checking is advisable for high-risk medication in critical units when there is not availability of BCMA.

Administration of medication by means of an identification and barcode reading system was shown to be an effective solution in preventing medication errors by identifying the correct patient, correct medication, correct moment, and correct means, as well as efficiently controlling information about the patients and improving the documentation process.

Survey results:

- Availability of electronic systems for monitoring medication administration for all patients is below 30%.
- Availability of BCMAs for checking patient and medication is overall below 45%. Specifically, Oncology – Ambulatory or One day hospital at 44% and ICU at 26%.
- In ICUs only 37% of medication is checked by two nurses. In Oncology Wards and Ambulatory or One day hospital it is 45%.

Dose Error-Reduction Software (DERs) Smart pumps

New smart pumps include the support for clinical decision-making provided by dose error reduction software (DERS) connected to infusion pumps. It includes alerts about minimum and maximum levels for the dose and concentration. This support can avoid incorrect programming of the pumps or errors in pressing keys (for example, programming 55mg instead of 5 mg).⁵⁷

Clinical evidence shows the benefits of smart pumps to prevent programming errors.⁵⁸

The increase in individual wards for patients' privacy in ICUs makes it difficult for nursing staff to control and monitor medication infusions. There are now infusion centres (installed for nursing staff to control, for example) that connect all of the infusion pumps for a unit or floor to a personal computer or tablet. These systems enable the record of infusion activities to be reviewed, such as events, alerts and alarms, including problems like blockages, air in the line, alarms for pressure, bolus and infusion nearing its end. They enable the patient's fluid balance to be calculated, as well as the infusion volumes from the pumps continuously, and to control the pressure in the lines.⁵⁹

In addition, technological progress in smart pumps now allows for the possibility of:

- Self-programming: when the patient, medication and pump are identified by a BCMA system by reading their barcodes, the infusion instructions from the prescription system are automatically sent to the chosen infusion pump. The nursing staff only have to confirm the infusion order on the pump. These new pumps will enable medication errors related to infusion pumps to be reduced even further, since human error will be eliminated on handling the pump.
- Automatic documentation: the pumps automatically send all of the information about their activity to the unit's clinical system, meaning a substantial improvement in productivity for nursing staff, especially in critical patient units. Manually documenting the many infusions administered to critical patients requires a considerable amount of work and implies a high risk of error.

Survey results:

- Very limited availability of near-miss infusions errors tracked via DERs systems, below 17%.
- Most hospitals do not monitor infusions from a central location, below 16%.

CONCLUSIONS

Medication errors are the most important adverse event that patients suffer when entering a hospital, with significant consequences for patients in terms of morbidity and mortality. In addition, healthcare staff directly or indirectly involved in a medication error may also suffer from emotional harm. Medication errors also give rise to significant incremental costs that have financial as well as cultural consequences within a Member State healthcare system.

Medication errors take place across the medication management process in hospitals: prescription, validation, preparation, dispensing and administration. The survey revealed that electronic prescription, ME surveillance and barcode medication administration systems are the most important areas to reduce MEs. These recommendations can be broadly termed as traceability systems. The survey also revealed that most pharmacists believe there are important areas to improve in order to reduce MEs (e.g. digitalisation, improvements in specific hospital areas, medication management, training and increased staffing and quality).

Funding, human resources and lack of trained staff are the main barriers to implementing these improvements.

Traceability systems prevent human errors often caused by an over-worked healthcare professional due to lack of resources. They serve to digitalise and connect processes that lead to standardisation. Such systems free up the time of the healthcare professional by introducing efficiencies and reducing unnecessary medication manual work.

Nevertheless, the ECAMET pan-European survey shows a low level of implementation of traceability systems. This is true in the whole medication management process, but especially true in the preparation and the administration of medication.

CALL TO ACTION



The ECAMET Alliance calls on European and national and regional authorities and all relevant stakeholders to:

1

Include medication safety in the Pharmaceutical Strategy for Europe, in the EU general pharmaceutical legislation and in Europe's Beating Cancer Plan through medication traceability systems in a healthcare setting to minimise medication errors.

2

Prioritise strategic investments in medication traceability systems in the EU4Health program to minimise medication errors.

3

Foster the development and implementation of ECDC guidelines and key indicators on medication errors in EU healthcare settings.

4

Facilitate the systematic exchange of best practices between healthcare providers both at European and national levels to reduce medication errors in healthcare settings.

ANNEX A – OVERVIEW OF CONSOLIDATED SURVEY RESULTS

Medication Errors

Whilst 82% of hospitals are accredited, 13% do not include MEs. Most hospitals do routinely record MEs for sharing continual improvement initiatives but very few are available to the public. ME databases are not present in all countries but respondents believe there should one for sharing continual improvement. There is a wide variation of MEs registered per year with 40% of hospitals <100 but 11% >500. 25% were unable to estimate the number of MEs. Most MEs are centrally tracked (but 14% do not routinely track MEs) and most centres use MEs & AEs data monitoring as a root cause analysis to resolve incidents as well as being investigated at regular quality meetings. MEs mainly occur at administration (29%) and electronically prescription stages (21%). Environmental, staffing or workflow problems are the main cause of MEs. Open discussions are the best solution for continual improvement. 56% of hospitals have trained HCP to detect MEs and enhance patient safety.

Information systems

Nearly all hospitals have an electronic medical record (EMR) system although not available for all patients, and only 51% of them have it integrated with primary care. Nearly all hospitals have an electronic prescribing system (EPS) but electronic prescriptions are not available for all patients. EPSs are variably integrated with other systems and would benefit from more integration with clinical decision support systems. Electronic prescriptions are not always validated by a pharmacist. EPSs are mainly integrated with electronic medical records and pharmacy dispensing systems. Automated drug cabinets are not widely available with central pharmacy and ICU having the highest availability. Not all hospitals (66%) implement nursing standard operating procedures for aseptic or injectable preparation on the wards.

Technology

Most do not have an electronic system for monitoring administration. Barcoding to verify drug selection prior to dispensing or refilling automated cabinets is low. Electronic barcode / electronic system for checking patient and medication and IV dose are not widely available. Only 19% of infusion medication is prepared in central pharmacy. Double nurse check when electronic checking systems are not available is not fully implemented but is highest in central pharmacy. There is very limited availability of near-miss infusion medication errors tracked via DERS and infusions are not monitored from a central location. 42% of hospitals do not have unit dose medication systems. Manual shelves and counts and information systems are mostly used to manage pharmacy inventory. Only 25% have central pharmacy robots.

Future

Electronic prescription, ME surveillance and barcode medication administration systems are the most important areas to reduce MEs. Most pharmacists believe there are important areas to improve in order to reduce MEs (e.g. digitalisation, improvements, in specific hospital areas, medication management, training and increased staffing and quality). Funding, human resources and lack of trained staff are the main barriers to implementing these improvements.

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