



WHITE PAPER Call to Action developed by the ECAMET Alliance on

Staff Shortages and Burn Out in Cancer Medication Administration in Europe

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FOREWORD



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ECAMET European Collaborative Action on Medication Errors and Traceability



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This report is a timely reminder that the EU is at a crossroad in its goal to enhance healthcare of its citizens. We are increasingly aware of the benefits due to AI and this is helping to catalyse an acceleration of digital solutions within the field of health and healthcare. However, there are fundamentals that our health institutions still need to address. Ensuring the correct human resource levels are in place is vitalfor safe and secure improved health outcomes.

It is a startling fact, that based on scientifically peer reviewed meta-analysis studies, no less than 163,000 patients across Europe will die from a medication error in any one year. This is compounded by all the unnecessary added harm from medication errors that is being caused to patients with the inevitable trauma to families as well as those health professionals involved in the incident. We should recall that medication 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%). However. it is especially acute in the complex areas of cancer care.

This area is especially important as many different chemotherapy regimens are used to treat cancer and at different centres throughout the care pathway. Discrepancies in regimens can lead to confusion and risk patient safety. This highlights the complexity of cancer treatment pathways. And it therefore follows that a drive for efficiency is essential. However, such efficiencies cannot be realised if there is not the staff to deliver these.

This report highlights the fact that there is a shortage of staff to administer complex medication regimens. A lack of human resources can only lead to a spiralling down of standards and efficiency of care.

There are however solutions that can be implemented quickly and efficiently. The comprehensive study carried out by the ECAMET Alliance established from 317 senior hospital pharmacists that the main barriers to implement such digital solutions were funding and human resources.

If we take human resources first, emphasis must be placed on training and remuneration commensurate with responsibilities. The medication pathways within cancer care are complex and involve a number of responsibilities that, at present, are not automated. Digital automation should therefore be part of any future solution to enable the drive towards greater efficiencies.

Whilst within the EU Member States there have been financial burdens placed upon them due to COVID and geopolitical issues, we should always remember that preventative measures actually reduce costs in the short, medium and the long term.

We believe strongly that this issue of increased efficiency through digital solutions combined with the right human resource levels is fundamental to patient safety and enhanced health outcomes. We therefore call upon the EU institutions to address this within relevant legislation to ensure that the Member State -wide staff shortage is acted upon with urgency.

Staff Shortages and Burn Out in Cancer Medication Administration in Europe

EXECUTIVE SUMMARY

The impact of staff shortages

Several studies and reports highlight workforce shortages, dealing with medication administration in Europe.

This is of overriding concern especially where staff shortages have a significant impact on both waiting times and patient safety in the administration of cancer medication.

When there are not enough healthcare professionals available to provide medication treatment, patients may experience longer wait times before receiving treatment. This can lead to delays in treatment and potentially reduce the effectiveness of the medication.

In addition, staff shortages can also increase the risk of medication errors and other adverse events. When healthcare professionals are overworked or stretched too thin, they may be more likely to make mistakes in the preparation or administration of cancer medication, such as chemotherapy drugs. This can result in serious complications for patients, including toxicity, organ damage, or even death.

Similarly, several studies highlight the importance of addressing medical and nursing staff shortages to improve waiting times.

Staff shortages in healthcare settings, particularly in oncology departments, have been linked to an increased risk of medication errors during cancer medication administration. The shortage of skilled staff, such as pharmacists, nurses, and physicians, can lead to increased workloads and stress, which can contribute to errors in medication prescribing, preparation and administration.

The size of the problem?

In cancer medication, errors occur at a rate of about one to four per 1,000 orders, affect at least 1–3% of adult and paediatric oncology patients, and occur at all stages of the medication use process.

Medication errors have serious health and economic consequences and are the most common adverse event in hospitals in number, mortality, and morbidity (Elliott, et al., 2018). Within OECD member countries hospital-acquired medication-related harm cause approximately 3 million avoidable hospital days annually costing a total of \$3.4 billion; the total annual cost of medication errors in OECD countries amounts to \$51 billion (OECD, 2022).

The great impact on "Second Victims"

Patients and their families are not the only ones affected or suffer when a medication error occurs. Health professionals involved directly or indirectly in one adverse event experience psychological and emotional harm becoming second victims; a phenomenon that is on the rise.

In Europe, a study conducted by European Biosafety Network (EBN) showed that 13% of nurses involved in an adverse event, with serious consequences for the patient, experience mental health or psychosocial disorders (European Biosafety Network, 2021) and in worst-case scenarios complete suicide (Grissinger, 2014). EBN's study further revealed that in critical areas like oncology, ICU, and in hospitals with more than 900 beds, the incidence of psychological disorders amongst nurses involved in an adverse event reached up to 22% and depending on the country and setting (e.g. ICU, Oncology departments) up to 80% of nurses experience a mental health episode because of an adverse event (European Biosafety Network, 2021).

Technology solutions will alleviate staff shortages in cancer medication

Numerous scientific bodies, alliances and societies back electronic traceability systems and automation, being introduced as the most efficient way to reduce medication errors in cancer medication and improve efficiency to mitigate staff shortages, minimising waiting lists (EHMA 2022). Nevertheless, the introduction of these systems in European hospitals and outpatient settings are very low, as the ECAMET survey, (ECAMET 2022) has shown.



There are number of effective options open to hospitals and in outpatient settings to alleviate staff shortage and significantly reduce medication errors, they include:

- 1. Electronic prescriptions with systems to support clinical decisions (CPOES).
- 2. Automated dispensing systems (ADS)
- 3. Electronic systems to control preparation (ESCPS)
- 4. Barcode medication administration (BCMA)
- 5. Smart pumps

Each of these digitally driven solutions can be implemented rapidly and have proven to be highly effective in reducing medication errors, alleviate staff shortages and reduce harm to patients whilst also protecting the Second victim.

The ECAMET Alliance therefore calls upon the EU Institutions with the following recommendations and calls to action

- 1. Prioritise the requirement for all Member States to put in place recruitment plans to ensure that the staff shortage crisis is addressed.
- 2. Prioritise strategic investments in Member States in digitalisation and automation of medication management in cancer to reduce waiting times by improving efficiency of healthcare workers and minimise medication errors which will alleviate immediately the burden placed on staff which are in short supply.
- 3. Incorporate digitalisation and automation of medication management in cancer in the European Beating Cancer Plan (EBCP) and prioritise strategic investments in digitalisation and automation of medication management systems in cancer in the EU4Health program.

MEDICATION ADMINISTRATION IN CANCER TREATMENT

Treatment overview

Medication administration in cancer is an important treatment option for cancer patients, particularly for those with advanced or metastatic disease. Medication works by targeting and killing rapidly dividing cancer cells in the body, which can help to shrink tumours and slow the progression of the disease. It is often used in combination with other treatments such as surgery or radiation therapy, and it can be administered before or after these procedures to improve outcomes. It is also used as a standalone treatment in some cases, particularly for cancers that are not amenable to surgery or radiation.

While cancer medication can be associated with significant side effects such as nausea, vomiting, hair loss, and fatigue, these can often be managed with supportive care measures such as anti-nausea medications or pain management.

Overall, cancer medication plays a critical role in the treatment of many types of cancer and has helped to improve survival rates and quality of life for countless patients. Ongoing research and development of new medication drugs and treatment strategies continue to expand the options available for cancer treatment.

The frequency of cancer medication administration can vary depending on the type of cancer, the stage of the disease, and the specific medication regimen being used.

Medication can be administered in different cycles, which may last anywhere from a few days to several weeks. The frequency of administration may also depend on the goals of treatment, such as whether the medication is being used as a primary treatment to shrink the tumour, or as a palliative treatment to manage symptoms and improve quality of life. For some types of cancer, medication may be administered on a continuous basis, while for others it may be given in cycles, with periods of rest in between to allow the body to recover.

In addition to the frequency of administration, the duration of medication treatment can also vary widely. Some medication regimens may be administered for a few weeks or months, while others may be administered for years, depending on the individual patient's response to treatment.

Ultimately, the frequency and duration of medication administration is determined by the healthcare provider in consultation with the patient, and takes into account a variety of factors including the patient's overall health, treatment goals, and potential side effects.

Prescription, preparation, and administration of cancer medication is a complex process that requires the coordination of multiple healthcare professionals to ensure patient safety and treatment efficacy. Here is a brief overview of each step:

- 1. Prescription: Medical oncologists or other specialists trained in the treatment of cancer prescribe cancer medication for their patients. They base their decisions on the type and stage of cancer, patient's health status, and potential side effects of the drugs.
- 2. Preparation: After the medication regimen is prescribed, the drugs are prepared in a pharmacy or compounding facility. The drugs may be pre-packaged or compounded into the appropriate dosage and formulation for the patient. This step is critical for ensuring the proper dosing, dilution, and compatibility of the drugs.
- 3. Administration: Medication is usually given in a hospital or clinic setting, and the administration varies based on the type of drug, the dose, and the patient's condition. Medication can be given intravenously, orally, or by injection. Patients typically receive multiple cycles of treatment, and their response to the treatment is closely monitored by their healthcare team.

Cancer patients may receive cancer medication in two different settings:

Hospital settings

The administration of cancer medication in hospitals for inpatients is one common approach to cancer treatment. Inpatient medication administration treatment is typically reserved for patients who require more intensive monitoring or who have more complex medical needs.

Inpatient medication treatment may be necessary if a patient has a weakened immune system, has significant medical comorbidities, or requires close monitoring due to the risk of complications. Patients undergoing inpatient medication administration may receive treatment in a specialised oncology unit or in a general medical-surgical unit depending on their specific needs.

Outpatient settings

The administration of cancer treatment in outpatient settings, such as clinics or infusion centres, has become increasingly common in recent years. This is due to a variety of factors, including improvements in cancer treatment regimens and the desire to reduce healthcare costs and hospital stays.

Outpatient cancer treatment allows patients to receive medication, radiation therapy, and other treatments in a comfortable and convenient setting, while also reducing the risk of hospital-acquired infections and other complications. In addition, outpatient treatment can often be administered on an ambulatory basis, allowing patients to return home the same day and resume their normal activities.

Overall, outpatient cancer treatment has become an important option for many patients and has helped to improve access to high-quality cancer care while reducing the burden on the healthcare system.

STAFF SHORTAGES IN EUROPE AND CANCER MEDICATION ADMINISTRATION

Several studies and reports highlights workforce shortages, dealing with medication administration in Europe.

A 2020 report by the European Society for Medical Oncology (ESMO) on the state of medical oncology in Europe found that there are significant workforce shortages in the field. The report notes that there are not enough medical oncologists to meet the increasing demand for cancer care, with some countries experiencing a shortage of up to 50%.¹

A 2019 study published in the European Journal of Cancer Care found that there is a shortage of oncology nurses in Europe. The study notes that the demand for oncology nursing services is increasing due to the aging population and advances in cancer treatment, but there is a limited supply of trained oncology nurses.²

A 2018 report by the European Commission identified shortages of healthcare professionals, including oncology doctors and nurses, as a major challenge for healthcare systems in Europe. The report notes that the shortage of healthcare professionals is expected to worsen in the coming years, due to factors such as an aging population and increasing demand for healthcare services.³

Staff shortages can have a significant impact on both waiting times and patient safety in the administration of cancer medication.

When there are not enough healthcare professionals available to provide medication treatment, patients may experience longer wait times before receiving treatment. This can lead to delays in treatment and potentially reduce the effectiveness of the medication. In addition, staff shortages can also increase the risk of medication errors and other adverse events. When healthcare professionals are overworked or stretched too thinly, they may be more likely to make mistakes in the preparation or administration of cancer medication, such as chemotherapy drugs. This can result in serious complications for patients, including toxicity, organ damage, or even death.

Longer wait times

Several studies highlight the importance of addressing medical and nursing staff shortages to improve waiting times.

A study published in the Journal of Oncology Practice in 2019 evaluated the relationship between staff shortages and waiting times in medication administration at an academic hospital in the United States. The study found that waiting times for medication administration increased significantly during periods of medical and nursing staff shortages.⁴

A report from the American Society of Clinical Oncology (ASCO) highlighted that medical and nursing staff shortages are one of the main barriers to cancer care worldwide. The report emphasised that the lack of medical and nursing staff can increase waiting times for medication and other treatments and negatively affect the quality of patient care.⁵

Another study, published in the European Journal of Cancer in 2016 evaluated the relationship between staff shortages and waiting times for cancer medication administration in breast cancer patients in Spain. The study found that waiting times for medication administration were significantly longer in hospitals with a greater shortage of medical and nursing staff.⁶

Timely access to cancer medication for optimal cancer treatment outcomes is critical. Medication administration delays have a significant impact on overall survival rates.

A study published in the Journal of Clinical Oncology in 2012 evaluated the impact of cancer medication delays on overall survival in breast cancer patients. The study found that delays of more than 60 days were associated with a significantly worse overall survival compared to those who started medication administration within 30 days.⁷

A systematic review and meta-analysis published in the European Journal of Cancer in 2020 evaluated the association between cancer medication delays and survival outcomes in patients with solid tumours. The review found that longer medication administration delays were associated with worse overall survival and progression-free survival.⁸

A study published in the journal Supportive Care in Cancer in 2018 evaluated the impact of cancer medication delays on quality of life in breast cancer patients. The study found that longer waiting times for medication were associated with worse quality of life, including increased anxiety and decreased physical and social functioning.⁹

Higher risk of adverse events

Staff shortages in healthcare settings, particularly in oncology departments, have been linked to an increased risk of medication errors during cancer medication administration. The shortage of skilled staff, such as pharmacists, nurses, and physicians, can lead to increased workloads and stress, which can contribute to errors in medication prescribing, preparation, and administration.

Some cancer medications, like chemotherapy, are potent and have a narrow therapeutic index, meaning that small errors in dosing or administration can have serious consequences for patients. Studies have shown that chemotherapy medication errors can result in adverse drug events such as toxicity, organ damage, or even death.

Research has also found that healthcare providers may be less likely to report errors when staffing levels are inadequate, leading to a potential under-reporting of medication errors in these settings.

Clinical oncologists

Clinical oncologists prescribe cancer medications and manage the side effects of medication, mainly chemotherapy. The prescription process involves selecting the appropriate medication agents and dosages based on the patient's medical history, current health status, and cancer type and stage. The clinical oncologist then writes the medication prescription.

One study conducted to estimate the frequency and type of prescription errors in patients receiving cancer medication showed that most of the errors intercepted are due to a high patient load and inattention of the prescriber to omissions in prescription.¹⁰

In a study among oncologists in the United States reported high levels of burnout were associated with higher rates of self-reported medical errors, including prescription errors.¹¹

Pharmacists

The compounding process is often considered a critical step, as many of the possible errors at this stage cannot be detected downward in the process. For example, the nurse who administers the treatment could not detect a dose error in a bag solution.

One systematic review from 2017 examines cancer medication preparation and administration errors in oncology. The review identifies several factors that contribute to errors, including staff shortages and heavy workloads. The authors suggest that strategies to reduce errors should focus on improving staffing levels and providing training and support for healthcare professionals involved in medication preparation and administration.¹²

Between October and November 2020, members of the Haematology/Oncology Pharmacy Association from USA were invited to complete a cross-sectional, anonymous, online survey. The survey included 58 questions composed of the Maslach Burnout Inventory, Well-Being Index, and sociodemographic and occupational factors linked with burnout. Pharmacists with burnout were four times as likely to report they had made a major medication error in the past three months and were more likely to report an intent to leave their current position within two years.¹³

Nurses

With more patients to care for, nurses are likely to miss their breaks, work overtime, and experience burnout. Nurses who feel burnout have more difficulty providing quality patient care and report work dissatisfaction. Improper patient care can lead to increased length of stay, infection, patient dissatisfaction, re-admission, and even more alarming – increased mortality rates.

The quality of care provided to a patient decreases as the number of patients assigned to a nurse increases. Each additional patient a nurse is given increases the likelihood of that patient dying within 30 days of admission by 7%.¹⁴

One retrospective longitudinal observational study using routinely collected data showed that the hazard of death was increased by 3% for every day a patient experienced registered nurse (RN) staffing below ward mean. Relative to ward mean, each additional hour of RN care available over the first five days of a patient's stay was associated with 3% reduction in the hazard of death. Days where admissions per RN exceeded 125% of the ward mean were associated with an increased hazard of death.¹⁵

A Nursing Outlook study showed that just one more patient per nurse was associated with an 8% increase in job dissatisfaction.¹⁶

In a survey conducted among oncology nurses in Turkey the most important underlying reasons for medication errors were heavy workload (49.7%) and insufficient number of staff (36.5%).¹⁷

With less staff support, nurses must spread their time across more patients, leading to:

- Less time to monitor patients increased patient falls and accidents.
- Rushed or incomplete nursing care bathing, mouth care, feeding, and toileting.
- Medication errors: delayed or missed doses of medication.

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MEDICATION ERRORS: THE SIZE OF THE PROBLEM (EHMA 2022)

In cancer, medication errors occur at a rate of about one to four per 1,000 orders, affect at least 1–3% of adult and paediatric oncology patients, and occur at all stages of the medication use process.

In the "ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy", the overall medication error rate was 8.1 errors per 100 clinic visits. For adults, errors were associated with 7.1% of clinic visits and 18.8% of paediatric clinic visits.

More than half of oncology medication errors reach the patient. The most commonly reported event types included dose omissions and wrong dose/overdosage. It is notable that most reported events were related to antineoplastic agents, which are high-alert medications.

Errors occurred across all phases of the medication use system, but administration (56%) and ordering (36%) errors were the most common. Another study found a substantially lower rate (3%) of errors in medication orders in the outpatient infusion centre at a major cancer centre. The error rate with oral medication agents is less well studied, but serious medication errors can occur with these therapies across all phases of the medication-use system. Taylor and colleagues documented a 9.9% error rate with oral chemotherapy given to pediatric patients with acute lymphoblastic leukaemia. In this study, the errors occurred at the prescribing and administration steps. Regardless of the exact rate of medication errors for chemotherapy agents, the safe use of these therapies presents unique challenges that demand additional safety systems. Chemotherapy agents can cause severe toxicities and often have a narrow therapeutic index, and are used in complex, multidrug regimens. Complex dose calculations and adjustments, such as dosing per body surface area and frequent adjustment according to renal function, toxicity, and other clinical parameters are required.

Medication errors have serious health and economic consequences and are the most common adverse event in hospitals in number, mortality, and morbidity (Elliott, et al., 2018). Within OECD member countries hospital-acquired medication-related harm cause approximately 3 million avoidable hospital days annually costing a total of \$3.4 billion; the total annual cost of medication errors in OECD countries amounts to \$51 billion (OECD, 2022).

The latest data on healthcare expenditure as % of GDP in the EU amounts to 9.92% (Eurostat, 2021). When considering that GDP in 2021 in the EU amounted to \leq 14.5 trillion (Statista, 2022), then the annual cost of medication errors in the EU amounts approximately to \leq 43 billion. According to the OECD (OECD, 2019), 15% of hospital activity and expenditure is associated with patient harm, and up to 70% of resources are wasted in any country due to poor drug management systems (Iqbal, et al., 2017). This clearly demonstrates that if medication errors could be reduced then the EU would greatly benefit in economic as well as healthcare gains.

Second victims: The continuous circle

Patients and their families are not the only ones affected or suffer when a medication error occurs. Health professionals involved directly or indirectly in one adverse event experience psychological and emotional harm becoming second victims; a phenomenon that is on the rise. A study carried out in the USA and Canada indicated that only 5% of doctors escape close, or direct, involvement with adverse events during their entire careers (Waterman, et al., 2007). In Europe, a study conducted by European Biosafety Network (EBN) showed that 13% of nurses involved in an adverse event, with serious consequences for the patient, experience mental health or psychosocial disorders (European Biosafety Network, 2021) and in worst-

case scenarios complete suicide (Grissinger, 2014). EBN's study further revealed that in critical areas like oncology, ICU, and in hospitals with more than 900 beds, the incidence of psychological disorders amongst nurses involved in an adverse event reached up to 22% and depending on the country and setting (e.g. ICU, Oncology departments) up to 80% of nurses experience a mental health episode because of an adverse event (European Biosafety Network, 2021).

One Dutch study showed that the duration of mental health episodes related to adverse events is directly linked to the harm (https://bmjopen.bmj.com/content/9/7/e029923). Furthermore, 31% of nurses involved in an adverse event reported that they required an average 2–3- month absence from work due to chronic workplace stress (European Biosafety Network, 2021).

One Dutch study showed that the duration of mental health episodes related to adverse events is directly linked to the harm (https://bmjopen.bmj.com/content/9/7/e029923). Furthermore, 31% of nurses involved in an adverse event reported that they required an average 2–3- month absence from work due to chronic workplace stress (European Biosafety Network, 2021).

Therefore:

- Shortages of healthcare professionals drive higher adverse events for patients.
- Higher adverse events drive psychological and emotional harm among healthcare workers involved.
- Psychological and emotional harm drive absence from work (average 2-3 months).
- Absence from work drive additional healthcare workers shortages.

TECHNOLOGY SOLUTIONS TO ALLEVIATE STAFF SHORTAGES IN CANCER MEDICATION: DIGITALISATION AND AUTOMATION OF **MEDICATION MANAGEMENT**

Numerous scientific bodies, alliances and societies back electronic traceability systems and automation, being introduced as the most efficient way to reduce medication errors in cancer medication and improve efficiency to mitigate staff shortages, minimise waiting lists (EHMA, 2022). Nevertheless, the introduction of these systems in European hospitals and outpatient settings are very low (ECAMET, 2022).

Digitalisation and automation of cancer medication includes the following technological solutions:

Electronic prescriptions with systems to support clinical decisions (CPOES)

Electronic prescription systems with clinical decision support (CDS) can be a valuable tool in improving the safety and effectiveness of cancer medication treatment. Here are some ways in which these systems can support clinical decision making in cancer medication:

- 1. Dose calculation and adjustment: Electronic prescription systems with CDS can calculate medication doses based on patient-specific factors such as age, weight, and renal function, and adjust doses based on factors such as laboratory results and toxicity.
- 2. Drug interaction checking: CDS systems can flag potential drug interactions between medication agents and other medications, reducing the risk of adverse drug events.
- 3. Allergy checking: CDS systems can check for allergies to medication agents or other medications, reducing the risk of allergic reactions.
- 4. Protocol adherence: CDS systems can provide alerts or reminders to ensure adherence to medication protocols, reducing the risk of errors or omissions.
- 5. Patient-specific information: Electronic prescription systems can provide access to patient-specific information such as laboratory results and medical history, allowing for more informed and individualised medication treatment decisions.
- 6. Monitoring and follow-up: Electronic prescription systems can provide alerts and reminders for monitoring and follow-up, ensuring that patients receive appropriate care and reducing the risk of treatment-related complications.

By providing support for clinical decision making, electronic prescription systems with CDS can help to improve the safety and effectiveness of cancer medication treatment. These systems can also help to reduce the burden on healthcare professionals, allowing them to focus on other aspects of patient care. However, it's important to note that these systems should not replace the need for clinical judgement and expertise and should be used in conjunction with other clinical decision-making tools and resources.

A systematic review published in the Journal of Medical Systems in 2018 found that electronic prescription systems can significantly reduce medication errors, including those related to cancer medication. The review also found that electronic prescription systems can improve efficiency in medication management, including the prescribing, dispensing, and administration of medications.¹⁸

A study published in the Journal of Oncology Pharmacy Practice in 2019 found that the implementation of an electronic cancer medication ordering system resulted in a significant reduction in prescribing errors and improved the efficiency of cancer medication ordering and dispensing processes.¹⁹

A study published in the Journal of Clinical Oncology in 2012 found that the use of electronic prescribing for cancer medication significantly reduced the incidence of prescribing errors, including those related to incorrect dosing and drug interactions.²⁰

A study published in the Journal of Oncology Practice in 2017 found that the implementation of an electronic medication prescribing system resulted in a significant reduction in prescribing errors and improved the efficiency of cancer medication ordering and dispensing processes.²¹

Overall, these studies suggest that electronic prescription systems can be an effective tool in reducing medication errors and improving efficiency in healthcare, including in the context of cancer medication. However, it's important to note that the effectiveness of electronic prescription systems may depend on various factors such as the specific system used and the implementation strategy. Therefore, careful planning and evaluation are necessary to ensure the optimal use of these systems.

Penetration of CPOES in Europe (ECAMET 2022):

- 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.
- 33% for medication cabinets and below 20% for infusion pumps.

Automated dispensing systems (ADS)

Automisation in dispensing medication improves efficiency and reduces the rate of medication errors. Direct connections for electronic prescription and automated dispensing systems also improve the quality of the dispensing process and increase its efficiency. Clinical studies show that automated dispensing systems, pharmacies and clinical units provide benefits over traditional methods of manual dispensing in clinical and economic terms. The main benefits of launching these systems include reductions in medication errors, in time and in medication administration costs.

A literature search in 2017 on publications investigated any ADS in the inpatient setting which included central pharmacy and ward-based systems. The studies demonstrate that both pharmacy and wardbased ADS offer benefits over traditional manual dispensing methods in terms of clinical and economic outcomes. The primary benefits following implementation of an ADS include reductions in medication errors, medication administration time and costs.²²

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• Integration with hospital systems is limited: over 50% for electronic medical records, but below

Penetration of ADS in Europe (ECAMET 2022):

- 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 in Oncology-Ambulatory or one-day hospitals (12%).
- 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 systems to control preparation (ESCPS)

ESCPS are classified in two different systems:

Volumetric systems

These are connected to the CPOES. 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

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 ICU's 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. A gravimetric system for preparing medication works as follows:

- The system is accessed to prepare the medication.
- The active or excipient ingredients or the vehicle are validated by reading a barcode. This validation completely eliminates the possibility of error on selecting the active or excipient ingredient or the vehicle to be added.
- The components of the preparation are weighed, including the primary packaging material that is going to be used. This system enables the densities of liquids to be included, as well as the weighed product's accepted range of tolerance, and informs the healthcare professional step-by step about the processes to be carried out, thinking about the preparation at each stage.
- When all of the components have been weighed and their packaging material added, an identifying label is printed with the barcode exclusive to the preparation. 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 oncology units have established for high-risk medication.²³

The scientific evidence shows that preparation systems using volumetric and 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, established for high-risk medication.

Efficiency

A study published, in the American Journal of Health-System Pharmacy conducted in one oncology ambulatory care pharmacy, using a volumetric-based process was used to reconstitute vials shows technician production time decreased by 34%, and pharmacist checking time decreased by 37%.

Safety

In the above study, over the study period, 15,843 doses were prepared utilising gravimetric system, with a total of 1,126 errors (7%) detected by the workflow software during dose preparation. All errors were detected during compounding, eliminating the need to correct errors after production.²⁴

In one European retrospective analysis related to studies on medication errors identified during preparation of antineoplastic drugs in 10 pharmacy services ("centres") in five European countries following the introduction of an intravenous workflow software gravimetric system. Errors were defined as errors in dose volumes outside tolerance levels, identified during weighing stages of preparation of medication solutions which would not otherwise have been detected by conventional visual inspection. The gravimetric system detected that 7.89% of the 759,060 doses of antineoplastic drugs prepared at participating centres between July 2011 and October 2015 had error levels outside the accepted tolerance range set by individual centres, and prevented these doses from reaching patients.²⁵

Penetration of ESCPS in Europe (ECAMET 2022):

• 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)

Barcode medication administration and identification systems enable the barcode to be read from the patient's bracelet and from the medication. The system thus verifies that the medication, the patients, the moment and the means of administration are all correct. Administration of medication by means of an identification and barcode reading system has 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 efficiency.

In one retrospective analysis twenty-one studies reporting the impact of 12 different health information technology (HIT) implementations on nurses' documentation time were identified. Weighted averages were calculated for studies that implemented BCMA and two weighted averages for those that implemented EHRs, as these studies used different sampling units; both showed an increase in the time spent in documentation (+22% and +46%). However, the time spent carrying out medication administration following BCMA implementation fell by 33%. HIT also caused a redistribution of nurses' time which, in some cases, was spent in more "value-adding" activities, such as delivering direct patient care as well as interprofessional communication.²⁶

In another study, the use of a handheld barcode scanning device for nurses reduced the time for medication administration from ≈6 minutes per item to 41 seconds, with a mean average saving of 5 minutes and 19 seconds per item, that gives a saving of three hours and 24 minutes of nursing time per day, equivalent to 0.425 full-time nurses per annum.27

Penetration of BCMA in Europe (ECAMET 2022):

- 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 Oncology Wards and Ambulatory or One day hospital it is 45%.

Smart pumps

Smart pumps with safety systems prevent programming errors. Numerous studies carried out show the benefits of smart pumps in preventing errors in programming them.^{28,29,30}

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).³¹

Clinical evidence shows the benefits of smart pumps when programming pumps.³²

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.33

Penetration of Smart Pumps and DERS in Europe (ECAMET 2022):

- 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%.

Robots

Pharmacy robots in chemotherapy preparation

Two large hospital pharmacies in the US, Allegheny General Hospital Pharmacy and Johns Hopkins Weinberg Pharmacy, have adopted robots systems to automate their compounding processes.³⁴ The intravenous (IV) compounding robots mix medications within a self-contained system to protect staff from potential exposure and improve the accuracy and efficiency of chemotherapy compounding.

The robots are programmed with a drug library that includes information on how to compound common chemotherapies. They also contain highly precise scales that weigh ingredients and automatically reject any end products that fall out of the correct weight range. Pharmacy staff have to prime the system with clinical information, such as the number of doses required and the patient's height and weight.

They also have to load the system with infusion bags, syringes and medication needed to produce the chemotherapy. The robot then prepares individualised doses, which are ready to be administered. IV compounding robots can keep an electronic record of all chemotherapies that have been prepared.

Implementing these automated systems in oncology pharmacies requires considerable planning and knowledgeable pharmacy staff to calibrate the robots. Some pharmacies have hired automation specialists to ease the transition to automated processes and train staff appropriately.

Pharmacy medication dispensing robots

There are many studies that support the clear benefits in robotic dispensing, integrated with the prescription system.^{35,36,37,38,39,40,41} It offers more storage space and flexibility. For items in the robot, there is no scope to make a dispensing error, improving patient safety; the process is much more efficient, and the skill mix of staff can be adjusted within the dispensary. As a consequence of all of the above, the speed of the prescription dispensing process increases dramatically.

The ability to have 'instantaneous dispensing' means there is more time for the pharmacists to devote to the clinical care of the patient, and thereby doing more 'value added' clinical roles.

Penetration of Robots for dispensing and compounding in Europe (ECAMET 2022):

- penetration of compounding robots).
- Only 25% of hospital pharmacies have medication dispensing robots.

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• Only 58% hospital pharmacies have a unit dose dispensing system available (with a very low

CONCLUSIONS AND RECOMMENDATIONS

Staff shortages and burn out in Europe have direct implications for patients: longer waiting times and medication errors in cancer medication administration.

Digitalisation and automation of medication management in European hospitals and oncology outpatient setting is the most efficient way to improve healthcare workers efficiency in cancer medication, driving shorter waiting times, minimising medication errors and improving healthcare workers satisfaction and retention.

CALL TO ACTION

The ECAMET Alliance therefore calls upon the EU Institutions with the following recommendations and calls to action:



Prioritise the requirement for all Member States to put in place recruitment plans to ensure that the staff shortage crisis is addressed.



Prioritise strategic investments in Member States in digitalisation and automation of medication management in cancer to reduce waiting times by improving efficiency of healthcare workers and minimise medication errors which will alleviate immediately the burden placed on staff which are in short supply.



Incorporate digitalisation and automation of medication management in cancer in the EBCP and prioritise strategic investments in digitalisation and automation of medication management systems in cancer in the EU4Health program.

ABOUT THE ECAMET ALLIANCE

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 was undertaken by the ECAMET Alliance to promote the prevention of medication errors in acute care settings. This White Paper and Call to Action is part of that patient safety project. It complements the comprehensive research project that can be found here entitled "The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm".42

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 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.

















APPENDIX A

Best practices

There are several cases of best practices around digitalisation and automation of medication management. Below two examples, one at Hospital level and another one at Country level.

Denia Hospital

The center validated the six level in the EMRAM international standards of HIMSS Analytics and thus becomes the first health center in Europe to achieve it.

It became the first center in Europe and first in the world outside the United States to achieve the HIMSS Davies Award. It is an international award from the independent rating firm HIMSS Analytics that classifies hospitals, according to the degree of integration of Electronic Medical Records.

Vicent Moncho Mas is the Chief Information Officer at Marina Salud Hospital, Spain said:

"The adoption of the Connected Medication Management strategy has truly revolutionised our approach to medication management at Marina Salud and contributes achieving HIMSS Electronic Medical Record Adoption Model stage 7 as one of the first centres in the world outside the United States. It has become our new way of working, streamlining, automating, and digitalising most steps of the medication management process, from prescription to administration. As a result, we have seen a significant reduction in medication errors and an increase in the quality of care provided to our patients. The integration of informatics, analytics, and automation has improved decision making processes in both clinical and financial domains, enabling us to optimise our resources and enhance patient safety. Overall, the Connected Medication Management strategy has brought about positive changes that have positively impacted our hospital operations and the well-being of our patients.

In our oncology ward, we implemented a compounding solution with chemotherapy prescribing software and a barcode scanning process to identify patients and their treatments. This new process greatly improved patient safety and reduced errors. Nurses quickly adapted to the new way of working, instilling confidence in the staff and patients alike.

With the implementation of the Connected Medication Management strategy, medications in our hospital network can now be managed through automated dispensing cabinets (ADCs), and our logistical processes are fully automated. This allows us to efficiently manage all operations with just seven staff members overseeing the hospital and 24 primary care facilities. The cabinets automatically send orders when safety stock levels are reached, reducing the need for large stockpiles and minimising dependence on staff for the re-ordering process. This has allowed us to implement a 'less than one week' stock policy in the wards without risking medication availability, reducing wastage, and improving cash flow".

National Cancer Information Systems Ireland

The Irish National Cancer Information System (NCIS) project is led by the Irish National Cancer Control Programme in response to requirements identified by healthcare professionals delivering cancer care services. Some of the key concerns noted included a lack of information sharing systems between hospitals, difficulties in obtaining patient records and the absence of a centralised IT system.

The NCIS is a computerised system that records information about a patient's cancer case, diagnosis, and treatment. NCIS aims at being introduced in all Irish public hospitals providing cancer care services. This project is making a significant difference for all patients receiving systemic anti-cancer therapy across Ireland enabling digital support for prescribing and administering chemotherapy.

The goal of the NCIS is to deliver a clinical information system to support care for oncology and haematooncology patients. Patient's cancer treatment record is accessible through the NCIS, as a result of thorough work to make health data more interoperable across Ireland and thanks to the establishment of dedicated platforms for patients, healthcare providers and researchers. This ensures that all relevant healthcare providers have access to the patient's data in an appropriate and timely manner. In addition, NCIS has several key functionalities, which can be used by various healthcare providers including electronic prescribing, preparation and administration of medication that minimises medication errors.⁴³

APPENDIX B DIGITALISATION AND AUTOMATION OF MEDICATION MANAGEMENT IN ONCOLOGY

Good practice, guidelines and organisational innovation

Cancer drugs are an important treatment option for cancer patients, particularly for those with advanced or metastatic disease. Prescription, preparation, and administration of cancer drugs is a complex process that requires the coordination of multiple healthcare professionals to ensure patient safety and treatment efficacy.

Digitalisation and automation of medication management in cancer plays a key role in alleviating the workforce crisis impact in healthcare professionals and patients, by improving healthcare professionals efficiency, reducing the bureaucratic process (eliminating manual documentation in Electronic Health Records) and minimising medication errors.

The European Cancer Organisation Manifesto 2024 highlights the benefits of digitising medication management processes and the need that it becomes a European goal in cancer.

Digitalisation and automation of medication management systems encompass electronic prescriptions with clinical decision support, automated dispensing cabinets, electronic preparation systems ensuring correct medication dosage, dispensing and compounding robots, barcode medication administration for accurate patient dosage, and smart pumps with safety features to prevent programming errors and inventory and compounding pharmacy robots.

Digitalisation of medication management is part of the CraNE Joint Action-JA (Network of Comprehensive Cancer Centres-Preparatory activities on creation of National Comprehensive Cancer Centres and EU Networking). The CraNe Joint Action-JA was funded under the Europe's Beating Cancer Plan (EBCP) with the aim of establishing by 2025 an EU Network of National Comprehensive Cancer Centres (CCCs) in every Member State, ensuring that 90% of eligible patients have access to high-quality early detection, screening, diagnosis, treatment, and support by 2030, as well as enhancing cancer research and training of health professionals. The CraNe joint action has already published the standard for CCCs. This standard sets out the requirements to be met by CCCs.⁴⁴

On page 33, under 6.2 Organ-specific systemic therapy, in point 6.2.10 the standard sets the following requirement: **"An electronic drug prescription and administration system which controls the entire drug pathway and interfaces with the patient record should be available".**

APPENDIX C ORGANISATIONS WITH AGENDAS TO REDUCE MEDICATION ERRORS AND INTRODUCE TRACEABILITY SYSTEMS

Several organisations recommend the implementation of digitalisation and automation of medication management, a number of which are recognised here.

WHO

The global initiative called "Third Global Patient Safety Challenge: Medication Without Harm"⁴⁵ launched by the WHO 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 general public; medicines as products; training, skills-learning and monitoring of health care professionals; and the systems and practices for managing medications.

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



OECD

OECD published in September 2022 the report "The economics of medication safety".⁴⁶ Poor medication practices and inadequate system infrastructure, resulting in poor adherence, medication-related harms, and medication errors too often results in patient harm. As many as one in 10 hospitalisations in OECD countries may be caused by a medication-related event and as many one in five inpatients experience medication-related harms during hospitalisation. Together, costs from avoidable admissions due to medication-related events and added length of stay due to preventable hospital-acquired medication-related harms total over USD 54 billion in OECD countries.

EAHP

In its document "Position Paper on Patient Safety. Hospital pharmacists - making the difference by improving medication safety",⁴⁷ the European Association of Hospital Pharmacists (EAHP) underscores the pivotal role hospital pharmacists play in ensuring patient safety and quality care across European hospitals. With a dedicated focus on medication safety, EAHP emphasises the need for robust risk management tools, including single unit dose barcoding and quality control committees, to mitigate medication errors and enhance patient outcomes.

The adoption of closed loop medication management is advocated to streamline the administration process, ensuring faster and more accurate medicine delivery. Additionally, EAHP highlights the critical role of hospital pharmacists in medication reconciliation during care transitions, calling for their expertise to guarantee accurate and complete medication information transfer.

Medication concordance, involving patient-centred care and effective communication, is identified as key, with a plea for adequate staffing of hospital pharmacists to support this initiative. Strengthened interprofessional collaboration among healthcare professionals is deemed essential to reduce medicationrelated problems and improve overall treatment safety.

Finally, EAHP recommends universal application of infection prevention and control measures to combat healthcare-associated infections, reinforcing the importance of hand hygiene in promoting patient safety. In essence, EAHP's comprehensive approach underscores the collective efforts required to enhance patient safety, emphasising the integral role of hospital pharmacists in medication management and collaborative inter-professional practices in European hospital.

Alliance for the Digitalisation of Medication Management in **European Hospitals (ADMMEH)**

The Alliance for the Digitalisation of Medication Management in European Hospitals is a group of more than 20 Brussels-based NGOs, founded in February 2022, advocating for the digitalisation of the medication management pathway in European Hospitals. The alliance published the document "DIGITAL MEDICATION MANAGEMENT IN HEALTHCARE SETTINGS: AN OPPORTUNITY FOR THE EUROPEAN UNION CALL FOR ACTION BY THE ALLIANCE FOR THE DIGITALISATION OF MEDICATION MANAGEMENT IN EUROPEAN HOSPITALS TO SUPPORT THE DIGITALISATION OF HOSPITALS' MEDICATION MANAGEMENT PATHWAYS"⁴⁸

The report stated: "Low digitalisation of the medication management pathway has significant implications for patient safety. Medication errors are more likely to occur amongst children and adults with comorbidities and in complex care settings such as Intensive Care and Oncology Units.

Medication errors are the highest cause of adverse events in hospitals, in terms of morbidity and mortality rates; Other potential implications arising from low levels of digitalisation in the medication management pathway include employee well-being, hospital resilience, the combat against antimicrobial resistance, environmental sustainability of medicines and data generation in interoperable systems to enable primary and secondary use of medication treatments and the implementation of artificial intelligence. Investments in hospitals' medication management pathways are key to building health system resilience. It is paramount to use the current momentum for the European digital decade to invest in digital medication management innovations, such as e-prescribing and electronic medication management systems, that offer value to patients, healthcare professionals, health managers and health systems to ensure the future readiness of European hospitals.

The digitalisation of hospitals' medication management pathways is imperative to cater to the European Medicines Agency's new role and prepare for the EU-wide implementation of the European Health Data Space. Innovations to hospitals' medication management pathways will act as an enabler for personalisation and precision medicine and provide critical data to improve prescribing practices in hospitals".

ECAMET Alliance

The European Collaborative Action on Medical Errors and Traceability (ECAMET) is a patient safety initiative developed by an alliance of scientific societies and European patient organisations. The aim of this alliance is to significantly reduce medication errors and to foster the setting up of comprehensive systems of electronic medication traceability in hospitals at the European and Member State level, thereby becoming a benchmark project aimed at protecting and fostering patient safety in the European Union.

The ECAMET Alliance has published the document "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."49

The report said: "Medication traceability systems include electronic prescription, electronic preparation, barcode medication administration and smart pumps, all connected to health records and hospital management systems. 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
- 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".

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Funding, human resources and lack of trained staff are listed as main barriers for implementing these

ISMP

The Institute for Safe Medication Practices (ISMP) has set out the following chart showing the most efficient technology to prevent medication errors:⁵⁰

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.

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.

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.

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ACKNOWLEDGEMENTS

The work involved in this white paper call to action has been made possible by funding from EAASM Members.

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EAASM EU Transparency register Identification number: 861368611058-84

