

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**



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Introduction

On the occasion of the revision of the basic pharmaceutical regulation, health managers, patients, healthcare professionals and the medical technology industry have joined forces under the **Alliance for the Digitalisation of Medication Management in European Hospitals** to issue recommendations to the European Commission, the European Parliament and the Member States on fostering the digitalisation of medication management.

The Alliance for the Digitalisation of Medication Management in European Hospitals is a group of Brussels-based NGOs, founded in February 2022, advocating for the digitalisation of the medication management pathway in European Hospitals.

Our Alliance members are:



Our Supporters are:



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Executive summary

Health system deficiencies have been obvious for many years, but the past two years have been a wake-up call on the strategic importance of access to high-quality, well-resourced hospital systems. As issues in the healthcare sector have become a priority for European citizens and the European Union, the creation of an European Health Union demonstrates the need for innovative, resilient, and comprehensively resourced health systems.

To create a strong European Health Union investment in the digital infrastructure of hospitals' core activities should be prioritised. Digital transformation in hospital settings, particularly investments in hospitals' medication management pathways, is a key opportunity for the European Union as medication management is a crucial core activity for hospitals throughout Europe.

Medication is a main part of the therapeutic process for hospital patients; at any time, up to 200 medications are held in hospital stock to treat patients (Iqbal, et al., 2017). Changes in patient need and hospital demand can affect the availability of medicines in hospitals, thus visibility of medication demand and stocks are crucial to ensuring medication availability. Moreover, hospital management and pharmacists need adequate stocks of medication and a detailed, accurate medication demand and inventory overview to make informed procurement and supply chain decisions.

However, the visibility of medicine demand and stock in European hospitals is low, as manual activities are a large part of medication management activities. A recent study by the ECAMET Alliance (European Collaborative Action on Medication Errors and Traceability) of hospitals in 13 European countries, revealed the missed opportunities in the implementation of digitalisation and automation of medication management pathways in Europe (ECAMET, 2022).

Low digitalisation of the medication management pathway also 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; one-

in-five patients in the OECD region experience medication-related harm during hospitalisation (OECD, 2022), 18% of European citizens claim to have experienced a serious medication error during hospital admission (OECD, 2017) and 1 person per million dies every day because of a medication error (WHO, 2017). In Sweden, it is suspected that 3% (almost 345,000 people) of the population die because of a medication error (Wester, et al., 2008). The OECD estimates that costs from preventable hospital-acquired medication-related harm total over \$54 billion (OECD, 2022).

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.

For this reason, the Alliance for the Digitalisation of Medication Management in European Hospitals, a group of Brussels-based NGOs, calls on the European Union to include the digitisation of medication management in the EU4Health Programme, the revised Pharmaceutical Legislation, the Digital Europe Programme, and the European Health Data Space.

Calls for action

1 | European Shortages Monitoring Platform

The European Medicines Agency (EMA) new mandate entails the setting up and maintenance of an IT platform known as the European Shortages Monitoring Platform (ESMP). The ESMP will be used to facilitate information gathering on medicines supply, demand, and shortages to monitor, prevent, and manage actual or potential shortages of medicines. The scope of the ESMP is currently limited to processing information on the supply of and demand for, critical medicinal products during public health emergencies or major events and outside of those situations, to allow for reporting on shortages of medicinal products that are likely to lead to public health emergencies or major events.

EU hospitals will be key stakeholders of the ESMP, along with the pharmaceutical industry, wholesalers, and retail pharmacists, in providing supply information and demand to ESMP. However, most European hospitals are poorly equipped to provide the supply and demand information required by the ESMP due to the lack of adequate IT systems.

Challenge: Most European hospitals are poorly equipped to provide the supply and demand information required by the ESMP due to the lack of IT adequate systems.

Therefore, we call upon the European Commission to support the implementation of electronic medication management systems in EU hospitals as a critical success factor and key digital enabler for the effective, and efficient, functioning of the future ESMP platform.

2 | The revised pharmaceutical legislation

The EU has launched a new strategy to improve and accelerate patients' access to safe and affordable medicines and to support innovation in the EU pharmaceutical industry. One element of the strategy will involve the revision of the EU pharmaceutical legislation. However, without the digitalisation of the medication management pathway and the use of global standards for identification and barcoding, such as GS1 standards [1], it will not be possible to ensure the three objectives of the strategy are met by EU hospitals, namely accelerating access (visibility of stocks and demand to improve shortages management), ensuring safe use of medicines (minimisation of medication errors) and providing affordable medicine (reduce inefficiencies in the medication pathway to make medicines more affordable).

Challenge: Without the digitalisation of the medication management pathway, it will not be possible to ensure the three objectives of the strategy are met by EU hospitals, namely accelerating access (visibility of stocks and demand to improve shortages management), ensuring safe use of medicines (minimisation of medication errors) and providing affordable medicine (reduce inefficiencies in the medication pathway to make medicines more affordable).

Therefore, we call on the European Commission to include a measure recommending the digitalisation of hospitals' medication management pathways to enhance patient safety and the resilience of hospitals' pharmaceutical systems within the new pharmaceutical legislative framework. This could include recommendations for a staged implementation of EU-wide primary package identification, by using barcodes according to international standards (GS1).

[1] This would further leverage the falsified medicines directive labelling requirements.

3 | The Digital Europe Programme

The Digital Europe Programme will provide strategic funding to answer digitalisation innovations and challenges, supporting projects in five key capacity areas: supercomputing, artificial intelligence (AI), cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society, including through Digital Innovation Hubs.

The Programme, however, will not address these challenges in isolation, but rather complement the funding available through other EU programmes, such as the Horizon Europe Programme, the Connecting Europe Facility, the Recovery and Resilience Facility, and the Structural Funds, to name a few. The programme forms part of the current long-term EU budget, the Multiannual Financial Framework 2021-2027.

The European Commission, in the document “Assessing the impact of digital transformation of health services Report of the Expert Panel on effective ways of investing in Health (EXPH)” (European Commission, 2019), includes, among other digital opportunities, European automated dispensing of medication and robots for manipulation. The success case of Ireland's National Cancer Information System for Oncology demonstrates the importance of digitalisation of medication management in generating harmonised data for treatment evaluation, research, and AI. Such digitalisation will play a key role in providing harmonised and interoperable data for research on treatments, medicines, implementation of AI and improving the efficiency of healthcare services and patient care. The existing low levels of digitalisation in European hospitals is a critical barrier impeding the digital transition of health services.

Challenge: The existing low levels of digitalisation in European hospitals is a critical barrier impeding the digital transition of health services.

Therefore, we call on the European Commission to include in the future Digital Europe work programmes specific objectives supporting hospitals to update their IT infrastructure for the digitalisation of the medication management pathway within the EU.

4 | The EU4Health Programme

The EU4Health Programme is the European Commission's landmark €5.3 billion response for investment in EU member state health systems following COVID-19. The objective of the programme is to strengthen Europe's health system and promote innovation. Three of the four programme focus areas are crisis preparedness, health systems and healthcare workforce, and digitalisation with a cross-cutting focus on cancer. The Programme builds synergies between other Union programmes, policies, instruments and actions including the Union Civil Protection Mechanism/rescEUsearch, Digital Europe and the Connecting Europe Facility and the Emergency Support Instrument.

EU health systems depend on the availability of high-quality digital health services and the availability of a high-quality workforce. Staff must be employed in environments that reduce the risk of adverse events. This in turn will reduce risks to their psychosocial, and emotional, well-being. A resilient healthcare workforce and modern hospital infrastructure are crucial to ensure that health systems can monitor and collect information on medicines and be prepared for the next crisis.

Challenge: A resilient healthcare workforce and modern hospital infrastructure are crucial to ensure that health systems can monitor and collect information on medicines and be prepared for the next crisis.

Therefore, we call on the European Commission to include in the 2023 EU4Health work programme a specific funding mechanism, incorporating support for change management and building cultures of safety in hospitals, to support member states to implement digitised medication management systems in hospitals.

Furthermore, we call for sustained investment by the EU4Health Programme to support the development of digital skills of the EU's health workforce and ensure that trained experts will support change management to implement the digital transition of European hospitals.

5 | European Health Data Space (EHDS)

The EHDS Proposal aims to reconcile the regulation of the primary use of health data by EU citizens and health professionals and health data's secondary use by researchers, innovators, and policymakers. The first pillar of data use in the draft EHDS regulation empowers European Union citizens to control and share their health data, granting healthcare professionals permission to access patients' health data for their treatment and care in hospitals in and across member states (otherwise known as primary data use). Healthcare professionals will be obliged to enter and update common, interoperable, primary data in the European Health Record System (EHR).

As levels of digitalisation in hospitals are low across the European Union, with gaps in interoperable infrastructure in individual healthcare settings, EHDS proposals requiring hospitals to make their data available place challenging obligations on hospitals; hospital management will be required to install and provide access to digital tools and interoperable systems to facilitate the exchange of electronic health data. Furthermore, Article 5 of the draft regulation precludes data on the availability, visibility and traceability of medications in hospitals with priority categories limited to (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports.

In widespread communication on the EHDS, electronic prescriptions and electronic dispensations refer only to general medication prescriptions obtained in community pharmacies located in other EU countries and appear to exclude electronic prescription, preparation, administration and dispensing of medication in EU hospitals in the priority categories of personal electronic health data for primary use. Information on medication from hospital settings is critical for the primary and secondary use of data by hospital-based healthcare professionals and for innovation, research and policy-making.

Challenge: Information on medication prescribed, prepared, dispensed and administered in hospital settings is critical for the primary and secondary use of health data.

Therefore, we call on the European Commission to include medication treatment data from ambulatory care and hospitals as key data to be generated and shared by Member States within the European Health Data Space, to support the primary and secondary use of medical treatment data. To achieve this goal, standardised medication treatment data generation in interoperable systems is required. This is only possible through the digitalisation of medication management systems in ambulatory care and hospital settings.

Background information on digital medication management

1. The medication management pathway in hospitals

Many hospital patients are prescribed anything from 5 to 9 medications during a hospital admission (Carroll & Richardson, 2019), thus medication management is a critical activity for the procurement, supply, and safe administration of medicines.

The medication management pathway in hospitals is a complex activity, covering ordering, reception, storing, prescription, compounding, distribution among wards and departments, dispensing/administration to patients, and monitoring of this complex process. Often referred to as the **medication management pathway**, activities within this pathway are multiple and require various clinical groups to manage the safe and effective use of medications for each episode of patient care.



To increase the availability, visibility, and traceability of medication in European hospitals' medication management pathways, it is crucial that medication stock management, prescribing, dispensing and administration are overseen by healthcare professionals, including hospital pharmacists, of relevant competency and that the **medication management process is fully digitalised and automated**. The digitalisation of medication management means full track-and-trace medication management solutions, also named as Closed-Loop Medication administration systems, from pharmacy to ward to the patient's bedside with a smart, automated, completely integrated digital approach.

Digital tools and solutions exist allowing hospitals to tackle weaknesses in medication management pathways. Yet, studies show that implementation of digital tools for medication management lags and the level of digitalisation of medication management in EU hospital settings is low. A recent OECD publication "*The Economics of Medication Safety, improving medication safety through collective, real-time learning*" highlights that 'digital technologies and automated systems—such as barcode medication administration, smart infusion pumps, and automated cabinets for high-risk medications—hold great potential for improving medication safety outcomes... but **systematic uptake of these interventions is lagging**' (p. 7). For example, only one EU country has implemented a national programme using barcodes for medication traceability, two countries systematically use barcode systems at a regional level and no country has nationally adopted automated dispensing cabinets for high-risk or other medications (OECD, 2022).

Furthermore, a study released by the ECAMET Alliance (ECAMET, 2022) involving 317 hospitals in 13 countries, revealed the missed opportunities in the implementation of digital tools and medication management systems with the following gaps identified:

Digital tool	Description	Level of use
Pharmacy information systems & central logistic pharmacy robots (vs shelves and manual control of inventory)	Pharmacy information systems integrated and connected with logistics robots and ward automated medication dispensing cabinets to break down supply chain silos in the hospitals. A pharmacy robot is an automated solution for reception, storing, and dispensing medication.	66% of hospitals have pharmacy information systems to manage pharmacy inventory, but only 18% of hospital pharmacies have robots for inventory management , and most pharmacies manage medicine inventory through manual shelves and counting.
Electronic medication prescription (CPOE) (vs manual prescription)	The process of a medical professional entering and sending medication orders and treatment instructions electronically via a computer application instead of on paper charts.	94% of hospitals surveyed have CPOEs but only one-fifth are integrated with a clinical decision support system and just half of CPOEs are available for all patients in Intensive Care Units (ICUs), oncology wards. CPOE's integration with wider hospital systems is limited : only 50% with electronic medical records, 33% with medication cabinets and less than 20% with infusion pumps.
Automated dispensing cabinets (ADCs) (vs shelves and manual control of inventory in the wards)	ADCs are computerised drug storage devices that allow drugs to be stored and dispensed near the point of care while controlling and tracking drug distribution. Hospital pharmacies have traditionally provided drugs to the wards through the ward-stock system. The ADCs are designed to replace non-automated ward stock storage and have facilitated the transition to alternative delivery models and more decentralised medication distribution systems.	Availability of ADCs is poor – only 25% of ICUs and 16% of Oncology wards and 14% of oncology ambulatory settings have access to ADCs.
Electronic compounding systems	To support medication preparation including unit dose systems to ensure medication doses prepared/compounded are the right ones and ensure traceability through global standards for identification and barcoding, such as employing GS1 standards.	Availability of Electronic compounding systems is low. 80% of medication is prepared outside of central hospital pharmacies and most frequently manually. Only 14% of ICUs, 31% and 11% of oncology wards, oncology-ambulatory or one-day hospital areas respectively have access to electronic compounding systems.
Barcode medication administration (BCMA)	Using global standards, e.g. GS1 barcoding standards, connected to electronic prescriptions systems and electronic health records in wards to check the right patient, the right medication, and the right time.	Barcode Medication Administration (BCMA) using global barcoding standards to ensure the right medication is administered to the right patient is available in less than 30% of hospitals surveyed . ICU BCMA is available in one-quarter of hospitals and in less than half of oncology settings.
Smart pumps with Dose Error Reduction Systems (DERS)	To prevent programming errors. New smart pumps include full connectivity and interoperability with electronic systems, including auto-pump programming and auto-documentation functionalities to prevent errors and increase efficiency.	Access to smart pumps with dose error reduction software (DERS) connected to infusion pumps is insufficient as less than 20% of hospitals have this equipment . Furthermore, less than 15% of hospitals monitor infusions from a central location.

Table 1 - Existing tools to support and advance the digitalisation of the medication process and their level of use

As **medication in hospitals is the highest spending chapter, after human resources, for health budgets**, according to OECD data, the lack of digitalisation of medication management in EU hospitals becomes a significant weakness for EU healthcare systems (OECD & European Union, 2020)

This is especially alarming considering that data from several European countries suggests that pharmaceutical spending growth in hospital settings is outpacing that of retail pharmaceuticals, although in some countries this may reflect deliberate policy decisions to transfer high-cost medicines to hospital dispensing (OECD/European Union, 2020).

2. Benefits of digitalisation of medication management for Europe

Innovations in digitisation (robots, e-prescription, e-preparation, medication safety cabinets, barcode medication administration and smart infusion pumps) have significant potential to improve European hospitals' medication management processes. Implementing and scaling up digitalisation and digital tools for medication management in European hospitals can ramp up efforts EU-wide to improve patient safety, and increase the resilience of hospitals, healthcare professionals, and health systems. The widespread availability of interoperable digital tools in European hospitals can support healthcare professionals, pharmacists, and health managers deliver on national and European policy priorities for the availability of medicines, data sharing of patient information, actions to combat antimicrobial resistance, and European goals for a green and digital transition. However, given the low levels of digitalisation of EU hospitals' medication management pathways, the main potential implications arising from these levels are:

2.1. Medication errors

The WHO considers medication errors as one of the top 10 patient harm issues; a concern marked by the 2022 World Patient Safety Day as medication errors account for 1% of the global burden of adverse effects from medical treatment (Nauman, et al., 2020). In OECD countries, more than one million patients experience preventable medication-related harm in hospitals (OECD, 2022).

Medication errors can occur when a medicine has been inappropriately prescribed, prepared, dispensed, or administered to a patient and include monitoring errors. 18,800 deaths are caused by preventable medical errors in Germany (Healthcare-in-Europe, 2014), in England, 1,700 deaths occur annually from medication errors in hospitals (Barrett, 2020), in Sweden, it is suspected that 3% (almost 345,000 people) of the population die due to a medication error (Wester, et al., 2008) and in Spain, the most frequent adverse event for hospitalised patients is medication errors accounting for 37.4% of total adverse incidents (Ministerio De Sanidad Y Consumo, 2005). Estimations suggest that in Europe one person per million dies every day from a medication error (Mullen, 2015) overshadowing deaths from road traffic accidents, breast cancer or Human Immunodeficiency Virus (Kohn, et al., 2000). Studies show that transcribing, dosage, and omission errors are amongst the most common errors impacting patient safety (Batista, et al., 2021), (Mulac, et al., 2020).



**In Europe, 1 person per
1,000,000 dies every day
from a medication error**

In Europe rates of medication errors in hospitals reach up to 9.1% in the prescription stage, 2.1% during the dispensing stage (European Medicines Agency, 2013) and up to 49% of medication errors occur during IV medicine dose preparation in hospital wards (European Medicines Agency, 2014). In Norway, a study showed that 68% of errors originated in the administration stage, one-quarter in the prescribing stage and 73% of dosing errors occurred during administration (Mulac, et al., 2020).

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 **annual cost** of medication errors **amounts to \$51 billion** in OECD countries

In Europe, figures from Spain and the UK respectively show that errors cost up to 3% of their respective national healthcare budgets (Elliott, et al., 2021), (Spanish Ministry of Health, 2016). In Germany, each non-fatal medication error results in an average of about € 3,000 in avoidable costs from extended hospital stays (von Eiff, 2021). And in England 237 million medication errors occur at some point during the medication process consuming over 180,000 bed days and extending patients' length of stay by 4 days (Elliott, et al., 2018).

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 €14.5 trillion (Statista, 2022), then the annual cost of medication errors in the EU amounts approximately to €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.

Medication Errors: Ane and Yara's Story

Ane and Yara were born prematurely in the Basque Region in late 2019 and respectively weighed 600 and 800 grams. Both Ane and Yara were in incubators since birth and began to experience a worsening in their condition in early January. It was discovered that both new-borns were administered a powerful anaesthetic drug instead of the feeding serum they should have been given.

On the 8th of January one of the new-borns died. The surviving infant was left physically disabled and requires permanent oxygen support.

In a report delivered by the Basque Health Service-Osakidetza to the families of the two new-borns, it admits a "pharmacological incident could have caused one to die and the other to survive with physical consequences" [2].

Medication is the main part of the therapeutic process for hospital patients and errors are more likely to occur in complex care settings such as Intensive Care and Oncology Units (Otero, et al., 2021) with children and older adults most likely to be affected (WHO, 2016). In a Spanish study (ISMP España, 2021) for the prevention of medication errors in Intensive Care Units, it was observed that dosage in dilutions (e.g., antibiotics) prepared to be administered did not usually coincide with the prescribed dosage. Medication dosages were either lower (in the case of antibiotics) or higher (in the use of Phenobarbitals) than the medication prescribed.

Risk is even higher for new-born infants as up to 8 times more medication errors occur in neonatal ICUs than in ICUs for hospitalised adults (Reece, et al., 2016), (Cayot-Constantin, et al., 2010); premature babies have a proportionally higher risk of suffering a medication error than full-term new-borns (Manrique-Rodríguez, et al., 2016). In children, it is therefore essential to pay even more attention to the medication process than in adults as the characteristics of the paediatric population make

[2] 'Piden a la Fiscalía que investigue la muerte de una bebé en San Sebastián por un error en el suministro de medicamentos' available via https://www.abc.es/espana/pais-vasco/abci-piden-fiscalia-investigue-muerte-bebe-san-sebastian-error-suministro-medicamentos-202009281208_noticia.html?ref=https%3A%2F%2Fwww.google.com%2F

children, and new-borns, particularly sensitive to the medication process, as the individual calculation of the correct dose based on body weight, for example, is very decisive (Healthcare Safety Investigation Branch I2020/26, 2022). Throughout children's growth and development factors of absorption, distribution, metabolism, and elimination that determine the pharmacokinetics of the drug constantly change. Therefore, a child's risk of suffering medication errors is higher for reasons including the use of drugs in conditions different from those described in the technical specifications not backed by clinical trials, a lack of commercial presentations of drugs adapted to new-born and children's needs and the requirement to measure small volumes, divide up units and carry out complex dilutions (Fernández Oliveira, et al., 2020,).



For critical patients with serious, complex conditions high-risk medications including those used intravenously and requiring close multi-disciplinary communication between care team members the risk of a preventable medication-to-medication interaction and/or adverse event occurring increases (Zheng, et al., 2018), (ISMP España, 2021), (Larrubia , et al., n.d.). Calculation errors can be minimised using electronic medication management tools that support hospital implementation of standardised medication management protocols. Data captured at the point of care from global standards for identification and barcoding, such as GS1 standards, for example, on medication packaging is key to ensuring accurate data to develop standardised medication management protocols and for the elimination of bedside medication errors.

2.2. Potential consequences of medication errors on the healthcare professionals and the health system

A recent paper by the European Cancer Organisation (ECO) highlighted that ‘inadequate preparation or administration of medicines, or inaccurate delivery of treatments such as surgery or radiation therapy, by stressed and over-loaded personnel, not only pose a significant patient safety risk but contributes to work-related stress affecting cancer care providers’ well-being, leading to psychological distress, compassion fatigue, exhaustion, and burnout’ (European Cancer Organisation, 2022). Thus, 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 [3]; 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). 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).

Medication error: Kimberley’s story

Unfortunately, mental ill health episodes resulting from medication errors sometimes end in fatal consequences for the healthcare professionals involved. That is the case of then nurse, Kimberly, 50, from the United States of America. Kimberly committed suicide on 3 April 2011, just 7 months after making a medication error that ended in the fatal death of an infant in her care.

Kimberly’s error was mathematical which led to an overdose of calcium chloride and the subsequent death of a critically ill infant. Kimberly’s 27 years of employment was terminated following an investigation of the event.

To satisfy state licensing disciplinary actions, Kimberly agreed to pay a fine and accepted a 4-year probation that included medication administration supervision at any future nursing job.

Prior to Kimberly’s death, she had aced an advanced cardiac life support certification exam to qualify for a flight nurse position. Sadly, according to media reports, this and countless other efforts produced no job offers, increasing her isolation, despair, and depression about the fatal event [4].



[3] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117748/>

[4] <https://www.ismp.org/resources/too-many-abandon-second-victims-medical-errors>

To prevent healthcare professionals from becoming “second victims” and to reduce pressure on hospital systems, hospitals should strive to build a culture where medication errors can be prevented, and healthcare professionals are protected. Research has shown that employees working at psychologically unsafe hospitals [5] are less likely to report an error than employees working in psychologically safe environments (Derickson, et al., 2015). Error reporting is negatively affected in organisations with poor patient safety cultures. In comparison organisations with robust safety cultures significantly reduce the incidence of medical errors (Jang, et al., 2021). Judicious balances between a no-shame and a no-blame policy and accountability are indispensable components of a safety culture in hospitals (WHO, 2021). Reporting and the implementation and use of digital tools, such as barcode scanning, are crucial steps.

The European Association of Hospital Pharmacists (EAHP) in its position paper on Patient Safety recommends a wider application of different risk management tools, including but not limited to computerised order entry systems, barcoding, risk management, and quality control committees in hospitals to lower medication errors for the benefit of patients. This would not only benefit patients, but also second victims. Furthermore, the European Cancer Organisation's workforce network has identified ‘abundant opportunities’ to achieve more progress in implementing e-tools for medication management systems (European Cancer Organisation, 2022).

Further enhancements for patient safety, can be achieved by using closed-loop medication administration systems (also known as a track and trace system) which are defined as a process integrating automated and intelligent systems to completely close the inpatient medication management and administration loop. As shown by a study conducted in the UK closed-loop medication management reduced medication administration and prescription error rates and freed up time for pharmacists who could concentrate on other aspects of care (Franklin, et al., 2007). The German Association of Hospital Pharmacists declared the adoption of closed-loop medication management as one of its goals that should go hand in hand with the regular use of ward pharmacists for better medication management (Dörje, et al., 2018). Moreover, in a study of closed-loop medication management systems over 80% of nurses considered the system helpful in preventing medication errors and ensuring patient safety (Shi, et al., 2018). Finally, where hospitals introduced barcode scanning during medication dispensing a 76% reduction in error rates was observed (Courtney, 2020). Research on the implementation of the EU False Medicines Directive (FMD) shows that the implementation of standardised barcodes on medication packs has delivered value for patient safety and enhanced clinical effectiveness (Courtney, 2020).

Digital tools can also deliver tailored information to healthcare professionals and patients promoting collaboration between both parties. In this context, electronic product information [6] (ePI), has been identified as part of the solution (European Commission, 2020): while healthcare professionals already use electronic versions of the leaflets, many patients in hospital settings receiving healthcare professional administered products do not have access to patient leaflets. In a survey conducted by the EAHP (European Association of Hospital Pharmacists, 2021) respondents recognised the future potential of ePI to facilitate easier and faster access to product information for healthcare professionals and patients. Digital tools, such as ePI, would also allow faster dissemination of updated information to healthcare professionals and patients. For example, time-lags on access to updated medication information in paper leaflet form may impact prescribers' awareness and unnecessarily endanger patients. With digital access to medication information, patients can choose to actively participate in treatment decisions which may, in turn, reduce the number of medication errors occurring and positively contribute to the development of person-centred care in hospital settings.

[5] Psychologically safe workplaces are those where employees feel comfortable taking interpersonal risks, such as pointing out an error (Derickson, et al., 2015)

[6] Electronic Product Information (ePI) is authorised, statutory product information for medicines which provides a summary of product characteristics, package leaflet and labelling adapted for electronic handling to allow for dissemination via the internet and other platforms.

2.3. More resilient hospital systems with increased capabilities

COVID-19 has exacerbated the problem of healthcare professional staff shortages in Europe. A recent report by the Lancet estimates that worldwide 43 million extra doctors, nurses and other health care workers are needed to meet staffing shortages (GBD 2019 Human Resources for Health Collaborators, 2022). Furthermore, **40% of doctors are close to retiring age** in one-third of European countries and **9 out of 10 nurses intend to quit their jobs** (WHO, 2022) at a time when the gap between the supply of nurses and midwives is at its most acute with deficits in the profession amounting to 30.6 million worldwide (GBD 2019 Human Resources for Health Collaborators, 2022).

Meanwhile, to manage medication some hospitals have created new posts and processes (e.g., excess stockholding, new administrative tasks) (Miljković, et al., 2019) to handle increased workloads. For example, an EAHP research paper identified that managing medication shortages in the hospital medication chain is 'time-consuming' for hospital pharmacists, creates additional work in procuring and informing hospital staff and adds up to 5 hours per week to pharmacists' workloads.

Now, more than ever, it is necessary to find ways to reduce staff workloads and drive productivity within healthcare systems. High-quality care depends on a high-quality workforce which professionals need support to deliver. However, with shortages of healthcare professional staff numbers rising fast and up to 40% of nurses' time being spent on administrative and non-healthcare activities (Herranz, 2017) patients care quality will inevitably be impacted.

An EU Expert Panel on effective ways of investing in health identified that digitalisation reduces administrative burden and increases staff satisfaction (European Commission, 2019). Indeed, by introducing handheld barcode scanning devices nurses can save up to 3 hours 24 minutes of nursing time per day on medication administration tasks, the equivalent of 0.425 full-time nurses annually (Meren & Waterson, 2021). In one hospital, following the implementation of a robotic dispenser linking prescribing and dispensing functions a team of 36 (who managed medication manually) is now managed by 7-10 people (Courtney, 2020). Moreover, the introduction of closed-loop medication administration systems has been shown to reduce nurse time spent on the administration of oral medication by up to 12 minutes (Shi, et al., 2018). Furthermore, **60% of nurses found the system helpful for their work**, and **50% believed closed-loop medication administration can reduce their workload and enhance working efficiency** as medication without barcodes require visual checks, data verification with colleagues and paper files needs to be archived and stored (Shi, et al., 2018). Finally, in locations where False Medicine Directive systems and processes have been integrated with normal operations to leverage the use of conveyor systems and robotics workload impact has been reduced by up to an expected 80% (Courtney, 2020).



The Pharmaceutical Strategy identifies reducing waste as critical to achieving efficiency in health systems (European Commission, 2020). Optimising medication prescribing, administration, and the processes within the hospital medication management pathway could reduce waste by preventing excess stock from being generated. Digital tools that support professionals with stock management can optimise prescribing and dispensing processes and redispense unused medication contributing to medicine sustainability within hospitals (D'Accolti, et al., 2019). However, these management processes require accurate quantification of stock supply, advanced logistic systems in pharmacies, and information on consumption data and prescription patterns (Iqbal, et al., 2017). Currently, these processes are mostly manual and thus a complicated, resource-intensive exercise that is highly prone to errors (Iqbal, et al., 2017) (IG Solutions, n.d.). Implementing automated inventory management systems can result in significant cost savings such as that achieved in one hospital where **£4 million was saved from reductions in medication over-ordering** (Courtney, 2020).



Additionally, lack of visibility and data on medicine stocks and demand results in unnecessary environmental waste arising from unused and expired medicines. The medication compounding process in hospital areas is not supported by digital systems, driving a source of waste. As a result, leftovers from vials of medication are usually discarded after preparation (Smale, et al., 2021). Medical waste negatively influences health outcomes both within and outside hospital walls as waste from medicines, as well as medication waste metabolised by patients, considerably impacts economies and the environment.

A report by a Spanish Health Technology Agency showed that after the introduction of logistics robots of medication dispensing in hospitals, with one investment of between €400,000 and €500,000, **there was a 26.4% reduction in medication stocks**, and associated costs, **and 80% reduction in waste of drugs with expired dates** (Giménez, et al., 2019). The report estimates an annual cost of 22.22€ per hospital bed from expired medication, because of manual medication management. Extrapolating this cost per bed to the total number of hospital beds in the EU, 1.7 million beds (Eurostat, 2020) the potential annual savings for the EU could amount to €37 million.

As the above examples demonstrate, digitalisation of the medication pathway would optimise spending, drive productivity, and reduce waste throughout the entire medication pathway in EU hospitals by the:

- Automation of manual activities (storing, reception, inventory counting, medication preparation).
- Reduction of non-reliable manual processes (ordering).
- Reduction of manual documentation (reception, dispensing, and administration to patients).
- Reduction of time-consuming archiving on manual written documentation.
- Reduction of the number of steps in daily work (preparation, dispensing and administration to patients).
- Providing hospital managers and pharmacists with data on stock levels and information on expiring drugs supporting the 'greenification' of supply chains.

EU policies and actions in public health aim to support the modernisation and digitalisation of health systems and infrastructure and improve the resilience of Europe's health systems. Digital solutions for medication management can revolutionise health and care services potentially helping millions of patients receive, and health care professionals deliver, quality care regardless of location. Medication management is critical operation for hospitals. As the Spanish case shows, improved medication management and digitalisation of care settings is a critical part of strengthening health systems resilience and resource efficiency. However, while clear benefits are promised by the digitalisation of hospital processes, evaluating, and investing in the preparedness and digital literacy of the health workforce is equally essential. Studies from information science, sociology, and cognitive science show that system-based errors in digital technologies cannot be disregarded (Healthcare Safety Investigation Branch, 2022). Implementation, use, and training of new digital systems and tools must be considered in conjunction with the system and the human factors of respective working environments. Investment and focus on improvement of overall digital literacy will enable better use of digital technology in practice (including digital prescribing and management of medicines). The educated use of digital technology will accelerate their adoption and allow healthcare professionals to fully familiarise themselves with the benefits and limitations of digital tools to best impact their daily routines and practices.

2.4. More reliable information about the availability of medicines

Medicines shortages require urgent attention; studies have found that shortages are at crisis level in the EU, specifically in availabilities of oncology drugs, ICU medicines and blood-derived products (European Commission, 2021). COVID-19 has exacerbated some of the common causes of medicines shortages. Medicines shortages are not only a pharmacy problem; addressing shortages requires action on multiple supply chain fronts. With hospitals requiring up to 200 drugs (Iqbal, et al., 2017) to treat patients' continuous availability of medicines is required and EU hospitals must therefore have the right protocols and technology systems in place to manage medicine shortages. In their position paper on medicine shortages, the European Social Insurance Platform advocated that real-time information is needed by healthcare professionals, hospitals, and suppliers to better manage shortages and provide greater transparency along the supply chain (ESIP, 2020).



The 'Regulation for a reinforced role for the European Medicines Agency', provides a new, additional, mandate for the European Medicines Agency (EMA), states that to prepare for and support the monitoring of medication shortages and for capacity building EU Funding mechanisms should be considered to explore the coordination of the development of IT solutions to monitor and manage medication shortages in Member states (European Parliament and Council, 2022). The new EMA mandate states that the **EMA shall set up, maintain, and manage an IT platform to be known as the European Shortages Monitoring Platform (ESMP)**. The ESMP will be used to facilitate information gathering on medicines supply, demand, and shortages to monitor, prevent, and manage actual or potential shortages of medicines.

However, current hospital medication inventory management, mainly manual counting by pharmacists, to assess inventory supply is time consuming and inefficient, can significantly contribute to a general lack of full supply chain visibility and may potentially impede the EMA's ability to maintain an effective monitoring platform. While hospital pharmacies, have the best view of medication inventory as medication is stored in the pharmacy, stock visibility decreases significantly when medicines are transferred to dispensing locations. Some of the main potential implications from low visibility of inventory in the hospital supply chain are:

Before shortages

- Inability to predict potential shortages due to manufacturers/wholesaler supply chain issues.
- Low reliability of medication ordering, driving potential medicinal product stock-outs.
- In case of a product recall, time-consuming tasks to investigate and find impacted drugs batches on hospital wards.

During shortages

- Inability to allocate production among hospitals in a region, a country, or within the EU during shortages crises.
- Incremental time and resources for the best management of alternative medicines.

Digital tools, such as ePI, inventory robots, automated dispensing cabinets and connected IT systems can provide full visibility of medicine stocks, demand projections, and ordering process for hospitals. They can prevent and improve medicine shortages management and provide accurate and real-time data for the future ESMP, to support reallocation of medicines across Member States while still allowing healthcare professionals and patients to access product information in their language. Digitalisation, through integrated technologies along with the employment of global standards, are key to breaking down supply chain silos throughout the hospital supply chain and to providing real-time and accurate demand and inventory data in hospitals.

2.5. Interoperable systems

The European Commission's recently launched draft regulation for the European Health Data Space (EHDS), one of the central building blocks for a strong European Health Union, will provide a quantum leap forward in the way healthcare is provided to people across Europe. The EHDS recognises the improved efficiency of healthcare services and patient care relies on integrated and interoperable data that can be utilised by the growing number of digital healthcare tools. Digital tools are reliant on standardised integrative, interoperable solutions to minimise data silos, improve the efficiency of healthcare services and patient care. Medication data generation, collection, standardisation, and interoperability of patient-generated health data are critical for the delivery of personalised healthcare, provided by digital tools, and estimates show that hospitals can save up to 15% on their budgets with better use of health information (Olesch, 2022). Data on medication prescribed and dispensed/administrated to patients in hospitals is key to monitoring and evaluating treatments performance and for the delivery of trustworthy, efficient, personalised healthcare. Moreover, good quality standardised data generation is a vital key driver for the implementation of artificial intelligence (AI). However, **it is not possible to generate continuous data** on the medication pathway considering the low levels of digitalisation of hospitals medication management pathways and the lack of basic timely data for decision making.



Hospitals therefore require integrated digital infrastructure (both hardware and software) that is versatile, easy to install and use, and is interoperable across hospital systems. While interoperability is a key component and ingredient for better adoption of digital technologies and data sharing within and between institutions, design and user experience are also significant factors. It is known that poorly designed health information systems are one of the leading contributors to increasing burnout rates within the healthcare profession (National Academies of Sciences, Engineering, and Medicine, 2019), (Edward, et al., 2020). Hence, when designing such systems, co-design is key. While implementing new digital systems cultures of safety, that promote constructive feedback from staff, should be created ensuring that benefits from new digital systems are maximised and systems provide safe working environments for healthcare professionals. Including and consultation with healthcare professionals is essential to ensure the sustainable, effective, adoption and positive impact of digital medicine management platforms. Co-designed, digital systems and tools, and bed-side scanning, can provide full traceability of medication in hospitals and would ensure the generation, collection, and standardisation of information on medical treatments dispensed, and administrated, to patients which can enhance evidence-based clinical decision making.

2.6. Antimicrobial stewardship

Antibiotic misuse and over-use are the main drivers of antimicrobial resistance (AMR) compromising the effectiveness of intensive care treatment, treatment for cancer and for other common healthcare-associated infections. AMR is a serious challenge for the EU as according to the European Centre for Disease Control (ECDC), 37,000 patients die annually as a direct consequence of Healthcare Associated Infections (HAI) (D'Accolti, et al., 2019) with trends for eastern and southern European countries particularly concerning. While overall antibiotic use has declined in the EU, greater decreases have occurred in the community compared to the hospital sector where broad-spectrum antibiotic consumption has seen an overall increase between 2011 and 2020 (ECDC, 2022). According to the OECD, in some healthcare services inappropriate antimicrobial consumption may reach 90% and the rate of inappropriate antibiotic prescriptions in long term care facilities (LTCFs) reaches up to 75% and up to 96% of antibiotics prescriptions are given to residents without testing (ECDC, 2022).

A position paper by European Hospital and Healthcare Federation Association (HOPE) maintained that 'a significant driver for the selection of multidrug-resistant bacteria responsible for healthcare-associated infections in hospitalised patients is the extensive use of antibiotics' (HOPE, 2020) while, inappropriate use of antibiotics in LTCFs is associated with high rates of multidrug-resistant organisms that exacerbate the threat of AMR, both in LTCFs and in the community (ECDC, 2022).

To better manage and monitor antibiotic consumption in healthcare facilities and thus reduce antimicrobial resistance, a declaration by HOPE, the joint report by the ECDC, EFSA, EMA, and the OECD and a position paper by Healthcare Without Harm (Healthcare Without Harm, 2019) respectively made the following recommendations for antibiotic stewardship programmes:

- 1 | Make the best use of technology**
- 2 | Scale up electronic prescribing**
- 3 | Strengthen surveillance systems of antibiotic consumption**

Furthermore, during the recent 'Hearing of the Expert Panel on Effective Ways of Investing in Health in the opinion on managing antimicrobial resistance across the health system' electronic clinical decision support systems including e-prescribing and electronic medication management were amongst the innovative and emerging technologies identified as tools that can improve the fight against AMR (European Commission, 2022). The introduction of digitalisation of medication management linked to antimicrobial stewardship programs, can improve the prudent use of antibiotic prescriptions, reduce consumption of antibiotics and support healthcare professionals to ensure that the correct dose of the most appropriate antibiotic is administered to patients which will in return reduce the risk of increasing AMR. **Europe's AMR challenge cannot be achieved without the implementation of digital tools and electronic medication management systems.**



Making it happen - Case studies from Europe

Case study 1: Italy - Piano operativo regionale, Regione Lombardia, digitisation of 40 hospital facilities [7]

The Information Systems Organisational Unit of the General Directorate of Welfare coordinated the activities of identifying and classifying technical interventions aimed at the complete digitisation of 40 hospital facilities belonging to 28 Aziende Socio-Sanitarie Territoriali (ASST) in the Lombardy Region.

Technical activities proposed by each ASST as part of their digitisation plan included the implementation of an evolved Electronic Medical Record which included new features including the refinement of the pharmacotherapy process from prescription to administration at the patient's bedside, and the introduction of clinical decision support systems. Automated drug logistics systems were also introduced to hospital pharmacies with automated cabinets for the computerised management of drug handling and integration with application modules for the management of pharmacotherapies implemented as part of Electronic Medical Records.

The area of greatest impact was highlighted to be the Electronic Medical Record applied to the management of inpatient episodes for acute, sub-acute and high-intensity care (ICU, Subintensive Care, Coronary Care Unit) and to the management of outpatient specialty care pathways. In their report the Region of Lombardy states that the digitisation of the entire hospital process offers the opportunity to manage in a transparent, effective, and simple way all diagnostic and treatment activities that are carried out in inpatient settings, improving collaboration between professionals, simplifying internal processes, increasing the level of safety for patients, enhancing the clinical scope information assets, and implementing hospital-territory integration scenarios.



[7] Piano operativo regionale, Regione Lombardia, Investimenti Missione 6 Salute (2022)

Case study 2: Ireland - The Irish National Cancer Information System – NCIS: Case of Success on digitalisation of medication management [8]

The Irish National Cancer Information System (NCIS) project is led by the Irish Health Service Executive's National Cancer Control Programme. The NCIS is a computerised system that can record information about a patient's cancer case, diagnosis and systemic therapy treatment. Digitalisation of medication management is a key enabler of the NCIS. It was created in response to requirements identified by health professionals delivering cancer care services and went live in 2019; the aim is to ultimately introduce NCIS to all 26 public hospitals in Ireland providing cancer services.

The goal of the NCIS is to deliver a clinical information system to support the care of oncology and haemato-oncology patients. Access to the patient's longitudinal cancer systemic therapy treatment record is available through the NCIS. Key concerns such as the lack of information-sharing systems between hospitals, difficulties in obtaining patient records and the absence of a centralised IT system have been addressed by the NCIS.

The platform ensures that all relevant healthcare providers have access to a patient's data in an appropriate and timely manner. In addition, NCIS has several key functionalities which can be used by various health care professionals including prescribing, electronic medication administration records, support for aseptic compounding, multidisciplinary team meetings and medication management. A single deployment makes access to cancer data possible in a standardised way and overcomes many of the barriers associated with a shared record. This standardisation and collection may also support a broader research application.

This project is making a significant difference for patients receiving systemic anti-cancer therapy in Irish hospitals enabling digital support for prescribing and administering of medicinal cancer treatments.



Image 1 - 'About the National Cancer Information System (NCIS)' from National Cancer Control Programme

[8] <https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/projects/frequently%20asked%20questions%20-%20ncis.html>

Case study 3: Germany – The Hospital Future Act (Krankenhauszukunftsgesetz, KHZG) [9, 10, 11]

Passed in September 2020, the KHZG follows a series of policy and legislative decisions to support German's healthcare system transition to digitalised healthcare systems. The aim of the 'Krankenhauszukunftsgesetz' or 'Hospital Future Act' is to boost investment in IT infrastructure and digital health solutions. The act is a unique opportunity for German hospitals to modernise their medication management systems and create a resilient hospital pharmaceutical supply chain that can absorb shocks from unexpected events supporting Germany's pathway to digital transition.

With access to a 'hospital future fund' amounting to €4.3 billion hospitals can make investments in emergency capacities, digital infrastructure, developing and strengthening regional care structures, and IT security. Of eleven eligible projects under the legislation digital medication management systems, digital care & treatment documentation, and establishing partially or fully automated clinical decision support systems are included. The establishment of digital medication management systems in German hospitals is anticipated to provide information on all drug-related treatment throughout the entire care process and increase patient safety from drug therapy. Emphasis is also placed on the interoperability of systems including technical, structural, process and multidisciplinary communications. Funding can also cover investments in qualified staff who are needed to implement and run the projected measures.

The act described as 'the biggest digital health investment opportunity in Europe' will also impose penalties on hospitals that obtain funding but fail to introduce eligible digital services by 2025.



[9] <https://www.karlstorz.com/de/en/krankenhauszukunftsgesetz.htm>

[10] <https://avelios.com/khzg/>

[11] <https://www.healthcareitnews.com/news/emea/german-hospitals-receive-digital-health-boost>

Conclusions

Investments in digital tools for hospitals medication management pathways present opportunities to improve patient safety from medication harm, reduce costs to health systems from medication errors, improve health care professional satisfaction and productivity levels, build resilient hospital pharmaceutical supply chains, and provide real-world data and evidence for patient care, decision making and research. Experience from COVID-19 demonstrated the need for a European Health Union capable of delivering an enhanced and resilient response to patient and healthcare professionals' needs while providing continuity in the availability of medicines.

The WHO, an EU Expert Panel on an effective way of investing in health, the European Cancer Organisation, The European Association of Hospital Pharmacists, the OECD, and an Expert Panel on Effective Ways of Investing in Health in the opinion on managing antimicrobial resistance, amongst others, have called for the greater use and implementation of digital tools and systems, including medication management systems, to ensure the provision of high-quality healthcare services.

Evidence shows that where digital tools and systems have been partially implemented, medication use has improved, and patient safety enhanced. Secondary benefits from these systems include increased visibility of medication demand and stocks, optimised pharmaceutical spending, reduced waste from expired medication and improvements in healthcare professionals' wellbeing. However, existing levels of digitalisation of hospitals' medication management pathways prevent the full potential of electronic management systems for health systems from being realised. Moreover, when digital systems, and tools, have been poorly implemented health professionals' workload and feelings of burnout have increased and data exchange and collection has been impeded.

The digitalisation of medication management pathways offers opportunities to manage treatment activities in inpatient settings in a transparent, effective, and simple way, provides opportunities to break down supply chain silos and shorten medication supply chains in Europe. Moreover, the digitalisation of medication management pathways is key to providing real-time, accurate demand and inventory data in hospitals which is required both for the EMA's Medication Shortages Platform while patient treatment data is required for the successful implementation of the European Health Data Space. Comprehensive implementation of digital medication management systems will play a key role in providing harmonised and interoperable data for research on treatment, medicines, and implementation of AI within Europe's Health Union Strategy. Therefore, the Alliance for the Digitalisation of Medication Management in European Hospitals calls for the inclusion of digitisation of the medication management pathway in key EU Health Policies and Programmes, as well as increased investments in supporting transformations for the digitalisation of hospitals medication management pathways.

References

- Barrett, A., 2020. More than 1,700 deaths due to 'avoidable' medication errors in England each year. [Online] Available at: <https://www.sciencefocus.com/news/more-than-1700-deaths-due-to-avoidable-medication-errors-in-england-each-year/> [Accessed 25 May 2022].
- Batista, A., Polidori, P. & Kohl, S., 2021. Position Paper on Patient Safety. *European Journal of Hospital Pharmacy*, Volume 28, pp. 129-132.
- Carroll, N. & Richardson, I., 2019. Enablers and barriers for hospital pharmacy information systems. *Health Informatics Journal*, pp. 406-419.
- Cayot-Constantin, S. et al., 2010. Description de la prévention et estimation de la fréquence des erreurs de programmation de vitesse d'administration en continu des médicaments en réanimation par une application informatique [Assessment of the usefulness to use a software supervising cont. *Ann Fr Anesth Reanim*, 29(3), pp. 204-8.
- Courtney, G., 2020. Benefits beyond the EU Falsified Medicines Directive, London: Be4ward.
- D'Accolti, M., Soffritti, I., Mazzacane, S. & Caselli, E., 2019. Fighting AMR in the Healthcare Environment: Microbiome-Based Sanitation Approaches and Monitoring Tools. *International Journal of Molecular Sciences*, 20(7).
- Derickson, R. et al., 2015. Psychological safety and error reporting within Veterans Health Administration hospitals. *J Patient Saf*, 11(1), pp. 60-66.
- ECAMET, 2022. Medication Errors White Paper. [Online] Available at: www.ecamet.eu
- ECDC, E. E. & O., 2022. Antimicrobial Resistance in the EU/EEA: A One Health Response, s.l.: European Centre for Disease Prevention and Control.
- Edward, M. R. et al., 2020. The Association Between Perceived Electronic Health Record Usability and Professional Burnout Among US Physicians. *Mayo Clin Proc*, 95(3), pp. 476-487.
- Elliott, R. A. et al., 2021. Economic analysis of the prevalence and clinical and economic burden of medication error in England. *BMJ Qual Saf*, p. 96-105.
- Elliott, R. et al., 2018. Prevalence and Economic Burden of Medication Errors in the NHS in England, Universities of Sheffield and York: Policy Research Unit in Economic Evaluation of Health and Care Interventions.
- ESIP, 2020. Position Paper on Preventing and Managing Medicine Shortages, Brussels: European Social Insurance Platform.
- European Association of Hospital Pharmacists, 2021. EAHP Survey: The future potential of electronic product information (ePI), s.l.: European Association of Hospital Pharmacists.
- European Biosafety Network, 2021. Mental and Psychosocial Health in Healthcare; Preventing Medication Errors and Adverse Events and Disorders in Healthcare Workers. [Online] Available at: <https://www.europeanbiosafetynetwork.eu/mental-and-psychosocial-health-in-healthcare-preventing-medication-errors-and-adverse-events-and-disorders-in-healthcare-workers/>
- European Cancer Organisation, 2022. Working Against Cancer, Brussels: European Cancer Organisation.
- European Commission, 2019. Task Shifting and Health System Design: Report of the Expert Panel on effective ways of investing in health, s.l.: European Commission.
- European Commission, 2020. Pharmaceutical Strategy for Europe, Brussels: European Commission.
- European Commission, 2021. Future-proofing pharmaceutical legislation study on medicine shortages (revised), Brussels: European Commission.
- European Commission, 2022. Expert Panel on Effective Ways of Investing in Health: Opinion on managing antimicrobial resistance (AMR) across the health system. Public hearing 20 June 2022. Brussels: European Commission.
- European Medicines Agency, 2013. Medication-errors workshop; Final Programme, London: European Medicines Agency
- European Medicines Agency, 2014. Medication Errors - Follow-up Actions from Workshop, s.l.: European Medicines Agency.
- European Parliament and Council, 2022. Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. [Online] Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2022:020:TOC>
- Eurostat, 2020. Healthcare resource statistics - beds. [Online] Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_resource_statistics_-_beds#Hospital_beds
- Eurostat, 2021. Healthcare Expenditure Statistics. [Online] Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics [Accessed 07 July 2022].
- Fernández Oliveira, C. et al., 2020,. Impacto de la implantación de la prescripción electrónica asistida en la seguridad del paciente pediátrico. *Anales de Pediatría*, 93(2), pp. 103-110.

GBD 2019 Human Resources for Health Collaborators, 2022. GBD 2019 Human Resources for Health Collaborators. Measuring the availability of human resources for health and its relationship to universal health coverage for 204 countries and territories from 1990 to 2019: a systematic analysis for the Global Burden. *Lancet*, S0140-6736(22).

Giménez, E., Reynolds, J. & Espallargues, M., 2019. Evaluación del impacto económico, organizativo económico, y de la seguridad de la dispensación robotizada de fármacos en hospitales en España, s.l.: Informes de Evaluación de Tecnologías Sanitarias.

Grissinger, M., 2014. Too many abandon the “second victims” of medical errors. *P & T* : a peer-reviewed.

Healthcare Safety Investigation Branch I2020/26, 2022. Summary: Weight-based medication errors in children, s.l.: Healthcare Safety Investigation Branch I2020/26.

Healthcare Safety Investigation Branch, (, 2022. Weight-based medication errors in children. Independent report by the Healthcare Safety Investigation Branch I2020/026., s.l.: Healthcare Safety Investigation Branch.

Healthcare Without Harm, 2019. Tackling AMR in Europe's healthcare facilities: Best practice to prevent the development and spread of drug-resistant bacteria, Brussels: HCWH.

Healthcare-in-Europe, 2014. <https://healthcare-in-europe.com/en/news/statistics-where-is-there-safety-in-numbers.html>. [Online] Available at: <https://healthcare-in-europe.com/en/news/statistics-where-is-there-safety-in-numbers.html> [Accessed 25 5 2022].

Herranz, A., 2017. ALIANZA MULTIDISCIPLINAR FRENTE A LOS ERRORES EN LA MEDICACIÓN DEL PACIENTE HOSPITALIZADO EN ESPAÑA [Multi-disciplinary alliance against errors in hospitalised patients in Spain as good scientific practice], s.l.: Carlos III Health Institute.

HOPE, 2020. HOPE Position on Antimicrobial Resistance (AMR), Brussels: European Hospital and Healthcare Federation.

IG Solutions, n.d. Hospital procurement tips for optimizing pharmacy inventory. [Online] Available at: https://ig.solutions/news_items/hospital-procurement-tips-for-optimizing-pharmacy-inventory/

Iqbal, M. J., Geer, M. I. & Dar, A. P., 2017. Medicines Management in Hospitals: A Supply Chain Perspectiv. *Systematic Reviews in Pharmacy*, pp. 80-85.

ISMP España, 2021. Resultados del Estudio 2020: De la Seguridad del Uso de Los Medicamentos en Los Servicios de Medicina Intensiva, s.l.: s.n.

ISMP España, n.d. Instituto para el uso seguro de los medicamentos.. [Online] Available at: <http://www.ismp-espana.org/> [Accessed 2 June 2022].

Jang, S. J., Lee, H. & Son, Y. J., 2021. Perceptions of Patient Safety Culture and Medication Error Reporting among Early- and Mid-Career Female Nurses in South Korea. *Int J Environ Res Public Health*, 18(9).

Kohn, L., Corrigan, J. & Donaldson, M. eds., 2000. Errors in Health Care: A Leading Cause of Death and Injury. In: *To Err is Human: Building a Safer Health System*. Washington D.C.: National Academies Press.

Larrubia, M. M., Taravilla, C. B., Cruz, M. E. & Esteban, C. C., n.d. Errores de medicación en pediatría en la comunidad de Madrid., Madrid: Consejería de Sanidad. Comunidad de Madrid.

Manrique-Rodríguez, S. et al., 2016. Safe intravenous administration in pediatrics: A 5-year Pediatric Intensive Care Unit experience with smart pumps.. *Med Intensiva*, 40(7), pp. 411-21.

Meren, Ü. & Waterson, J., 2021. Evaluating An Automated Compounding Workflow Software for Safety and Efficiency: Implementation Study. *JMIR Hum Factors*, 8(4).

Miljković, N. et al., 2019. Results of EAHP's 2018 Survey on Medicines Shortages. *European Journal of Hospital Pharmacy*, pp. 60-65.

Ministerio De Sanidad Y Consumo, 2005. Estudio Nacional sobre los Efectos Adversos ligados a la Hospitalización, s.l.: s.n.

Mulac, A., Taxis, K., Hagesaether, E. & Gerd Granas, A., 2020. Severe and fatal medication errors in hospitals: findings from the Norwegian Incident Reporting System. *Eur J Hosp Pharm*, pp. 56-61.

Mullen, N., 2015. Deaths by medication errors dwarf RTAs. [Online] Available at: <https://www.imt.ie/news/deaths-by-medication-errors-dwarf-rtas-30-09-2015/> [Accessed 25 05 2022].

National Academies of Sciences, Engineering, and Medicine, 2019. Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being.. Washington, DC: The National Academies Press.

Nauman, J. et al., 2020. Global Incidence and Mortality Trends due to Adverse Effects of Medical Treatment, 1990-2017. *Cureus*, 12(3).

OECD & European Union, 2020. Health at a Glance: Europe 2020: State of Health in the EU Cycle, Paris: OECD Publishing.

OECD/European Union, 2020. Health at a Glance: Europe 2020: State of Health in the EU Cycle.

OECD, 2017. The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level, Paris: Organisation for Economic Co-operation and Development.

- OECD, 2022. OECD Health Working Papers No.147: The economics of medication safety: Improving medication safety through collective, real-time learning, s.l.: OECD.
- Olesch, A., 2022. THE EUROPEAN HEALTH DATA SPACE PROPOSAL (EHDS) EXPLAINED. [Online] Available at: <https://ictandhealth.com/the-european-health-data-space-proposal-ehds-explained/news/> [Accessed 2 June 2022].
- Otero, M. et al., 2021. Evaluación de la implantación de prácticas seguras con los medicamentos en los Servicios de Medicina Intensiva. *Medicina Intensiva*.
- Poon, E. G. et al., 2010. Effect of Bar-Code Technology on the Safety. *The New England Journal of Medicine*, 362(18), pp. 1698-1707.
- Reece, K., Lozano, M., Roux, R. & Spivey, S., 2016. Implementation and evaluation of a gravimetric i.v. workflow software system in an oncology ambulatory care pharmacy. *Am J Health Syst Pharm*, 173((3)), pp. 165-73.
- Sakiris, M. A. et al., 2020. Prevalence of adverse drug events and adverse drug reactions in hospital among older patients with dementia: A systematic review. *British journal of clinical pharmacology*, Volume 87/2, pp. 375-385.
- Shi, L-P., Liu, C.-H., Cai, J.-F. & Ku, Y., 2018. Development and application of a closed-loop medication administration system in University of Hongkong-Shenzhen Hospital. *Frontiers of Nursing*, 5(2), pp. 105-109.
- Spanish Ministry of Health, S. S. a. E., 2016. Patient Safety Strategy in the National Health System 2015-2020, s.l.: Spanish Ministry of Health, Social Services and Equality.
- Statista, 2022. Gross domestic product of the European Union (EU27) from 1995 to 2021(in million euros). [Online] Available at: <https://www.statista.com/statistics/279447/gross-domestic-product-gdp-in-the-european-union-eu/#:~:text=In%202021%20the%20gross%20domestic,economic%20strength%20of%20a%20country.> [Accessed 07 July 2022].
- von Eiff, W., 2021. Closed Loop Medication Administration: Mit „Unit Dose“ und „Smart Cabinets“ zum fehlersicheren Medikationsmanagement, s.l.: das Krankenhaus.
- Waterman, A. et al., 2007. The emotional impact of medical errors on practicing physicians in the United States and Canada. *Jt Comm J Qual Patient Saf*, 33(8), pp. 467-76.
- Wester, K. et al., 2008. Incidence of fatal adverse drug reactions: a population based study. *Br J Clin Pharmacol*, Volume 65(4), pp. 573-9.
- WHO, 2016. Medication Errors: Technical Series on Safer Primary Care, s.l.: WHO.
- WHO, 2017. WHO launches global effort to halve medication-related errors in 5 years. [Online] Available at: <https://www.who.int/news/item/29-03-2017-who-launches-global-effort-to-halve-medication-related-errors-in-5-years> [Accessed 21 June 2022].
- WHO, 2017. World Health Organisation. Patient safety The third WHO Global Patient Safety Challenge: Medication Without Harm, s.l.: WHO.
- WHO, 2021. WHO Global Patient Safety Action Plan 2021-2030: Towards eliminating avoidable harm in health care, Geneva: World Health Organisation.
- WHO, 2022. Ticking timebomb: Without immediate action, health and care workforce gaps in the European Region could spell disaster. [Online] Available at: <https://www.who.int/europe/news/item/14-09-2022-ticking-timebomb--without-immediate-action--health-and-care-workforce-gaps-in-the-european-region-could-spell-disaster> [Accessed 26 Sept 2022].
- Zheng, W. Y. et al., 2018. Drug-drug interactions and their harmful effects in hospitalised patients: a systematic review and meta-analysis. *European journal of clinical pharmacology*, Volume 74/1, pp. 15-27.



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