



**WHITE PAPER**

# **STRENGTHENING HEALTHCARE SYSTEMS THROUGH BETTER PATIENT SAFETY IN THE FIGHT AGAINST CANCER: A CALL FOR STRONGER EU ACTION**

# ACKNOWLEDGEMENTS

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# FOREWORD

First of all, I would like to thank the European Network for Safer Healthcare (ENSH) and Health First Europe (HFE) for launching this White Paper on patient safety in oncology – a cornerstone of healthcare provision within any sector but absolutely essential within oncology.

As a nurse, patient care has always been one of my main priorities, and as a member of the European Parliament, I try to transfer my experience and patient needs to policies that put patient wellbeing at the centre.

Despite the undeniable importance of this concept, it was not included as such in the Europe's Beating Cancer Plan. This may be due to its cross-cutting nature and the direct association we usually make between healthcare centres and treatment, recovery, and wellbeing. However, healthcare systems and processes are becoming more complex, and there is an increasing need for collaboration and synergies between the health sciences and health workforce and IT systems to improve clinical benefits and health outcomes by enhancing patient safety. Now more than ever, it is time to call for a stronger EU action on patient safety, especially in the area of oncology.

Patient safety should be reflected in all current and upcoming health policies, such as the pharmaceutical strategy for Europe- including medication safety requirements-, in the EU4Health program- implementing patient safety within EU4Health- or in the European Health Data Space- through increased digitalisation of medication management and traceability systems in healthcare settings- among others. Besides, I embrace the initiative to include the high-level policy recommendations to the Europe's Beating Cancer Plan and updating of the 2014 Council conclusion on patient safety and care.

Finally, I would like to thank the multiple contributors for carrying this crucial initiative and wishing for this White Paper to leave a long-lasting impact within national and European policymakers that will eventually lead to establishing patient safety as key indicator of healthcare provision in Europe.

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# EXECUTIVE SUMMARY

Europe's Beating Cancer Plan (EBCP) is a major political commitment and places the interests and well-being of patients, their families and the wider population at its heart, every step of the way. It aims to maximise the potential of new technologies and developments; lower the risks of neglect; strengthen cooperation and opportunities for EU added value; eradicate inequalities in access to cancer knowledge, prevention, diagnosis, and care; and deliver improved health outcomes to patients.

However, Europe's Beating Cancer Plan fails to include the critical concept of patient safety, which remains a serious challenge for healthcare systems across the globe. This includes developed countries such as those in the European Union. This paper illustrates and draws attention to the most common types of preventable patient harm, the prevalence and severity of the identified harm, and aims to encourage the inclusion of patient safety in the implementation of the Beating Cancer Plan. Also, to ensure patient safety is firmly respected and acknowledged within EU policy.

Irrespective of the origin of harm, whether it comes from medication errors or healthcare-associated infections, patients can be severely affected both physically and emotionally. It should also be remembered that the healthcare workforce can also suffer severe consequences.

Due to the complexity of healthcare systems and processes, there is an increasing need for collaboration and synergies between the health sciences and health workforce and IT systems to improve clinical benefits and health outcomes by enhancing patient safety. This re-enforces the need for an improvement of knowledge and skills across a range of disciplines. In short there is an ever-increasing requirement for a multi-disciplinary approach which can only be optimised by increased digitalisation of IT infrastructure within the hospital and community environments.



# ENVISIONING PATIENT SAFETY IN THE YEARS AHEAD: 10 POLICY RECOMMENDATIONS

Patient safety in oncology should remain a standard indicator of quality of care and a critical objective on the EU health policy agenda as all European citizens deserve the same level of safeguarding and protection at all stages of their healthcare. Patient safety is also a critical indicator of life overall, as any irreversible or reversible patient safety issue potentially affects the quality of life. This report calls on European policy makers and national health authorities to:

1

Implement patient safety within the framework of Europe's Beating Cancer Plan and related flagship initiatives, such as the European Cancer Inequalities Registry, the European Health Data Space as well as in the EU4Health annual work programmes;

2

Update the 2014 Council conclusions on patient safety and quality of care, including the infection prevention and control of healthcare-associated infection (HAI) and antimicrobial resistance;

3

Place medication safety requirements in the Pharmaceutical Strategy for Europe, in the EU revision of the general pharmaceuticals legislation and in the recent Commission's proposal of the European Health Data Space through digitalisation of medication management and traceability systems in healthcare settings to minimise medication errors, improve affordability and accessibility of medicines, efficiency of healthcare professionals and standardise and collect data to evaluate the impact of cancer medication on patient outcomes;

4

Create a European framework on healthcare-associated infection (HAI) prevention and control (including surgical site infections, catheter-related bloodstream infections and sepsis) and increase adherence to ECDC evidence-based guidelines and protocols;



5

Develop harmonised protocols for the right selection algorithms of vascular access management in cancer settings and training healthcare professionals to prevent vascular complications (such as extravasations and phlebitis);

6

Facilitate the systematic exchange of best practices between healthcare stakeholders both at national and European level to address the issue of variability in the standards of care;

7

Incorporate to the European Cancer Centre's (ECC) Certification Programme a one cross-tumour Catalogue Requirement for patient safety based on existing clinical evidence;

8

Improve occupational conditions to protect the safety and well-being of healthcare professionals working in cancer care, by promoting education and development opportunities for health personnel, addressing oncology workforce shortages, and reducing unnecessary barriers to professional mobility;

9

Invest in medical technologies and adopt process-improvement techniques to enhance patient safety, enable improvement of oncology treatment and improve communication between healthcare professions and the community;

10

Work systematically on the improvement and development of a safety culture in all healthcare settings whereby active leadership, open communication, transparency and accountability are indispensable components.

# CHAPTER 1

## WHAT IS PATIENT SAFETY?

Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered and weighed against the risk of non-treatment or alternative treatment.<sup>2</sup>

Patient harm is any unintended and unnecessary harm resulting from, or contributed to, health care. This includes the absence of indicated medical treatment. Patient harm is often caused by adverse events during care, which includes incidents of medication errors, incorrect or delayed diagnosis as well as healthcare-associated infections.<sup>3</sup>

A patient safety culture is a pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the process of care delivery.<sup>4</sup>

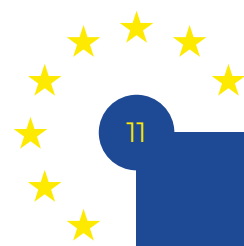
A patient safety culture is fundamental to delivering quality essential health services which are effective, safe and people centred. However, it remains a challenge for healthcare systems across the globe, including in wealthy countries such as those in the European Union.

## DID YOU KNOW?

- ★ Patient harm is the 14th leading cause of the global burden of disease, alongside diseases such as malaria and tuberculosis;<sup>5</sup>
- ★ 15% of hospital expenditure and activity in Organisation for Economic Co-operation and Development (OECD) countries can be attributed to treating safety failures;<sup>6</sup>
- ★ It is estimated that 8-12%<sup>7</sup> of patients admitted to a hospital in the EU suffer from adverse effects whilst receiving healthcare;
- ★ Only **one-in-two healthcare workers** believe that their hospital management provides a work climate that promotes patient safety and shows that **patient safety is a top priority** (50%) or that staff can **freely speak** to colleagues and authorities about patient safety issues in their work setting (52%).<sup>8</sup>
- ★ In addition to patient harm, health professionals (often referred to as the second victim) involved directly or indirectly in an adverse event and who suffer emotionally as a consequence, though less visible, are also victims.
- ★ In healthcare, a culture of safety is a key part of healthy work environments that enable staff to consistently deliver high-quality and safe healthcare services.<sup>9</sup>

With such figures in mind, a patient safety culture should be given a higher priority focus across all stages of the patient care and experience pathway. Countries and organisations should identify their own optimal ways of achieving a culture of safety, though certain elements remain indispensable. **Leadership commitment, transparency, open and respectful communication, learning from errors and best practices and a judicious balance between a no blame policy and accountability are indispensable components of safety culture.** A strong safety culture is not only core to reducing patient harm but also critical for providing a safe working environment for health workers. This includes creating a psychologically safe work environment, whereby health workers can speak up regarding patient safety and other concerns without fear of negative consequences.<sup>10</sup>

In line with this, there is a need for a new generation of patient safety leaders who are skilled and passionate to create the conditions and organisational and team cultures for safer care, to ensure that all systems and procedures comply with the highest standards, and to guide and motivate healthcare personnel.



## THE BURDEN OF HARM

Every year, millions of European patients suffer from reversible/irreversible harm or die because of unsafe and poor-quality healthcare. Many medical practices and risks associated with healthcare are emerging as major challenges for patient safety and contribute to the burden of harm due to unsafe care.

### **Over 1 in 10 patients continue to be harmed from safety lapses during their care.**

Globally, unsafe care results in well over 3 million deaths each year. Furthermore, the Organisation for Economic Co-operation and Development (OECD) estimates that direct costs of treating safety failures resulting in unnecessary harm to patients can amount to as much as 15% of total health expenditure and healthcare activity, mostly due to need for additional care. Patient harm can be caused by a range of adverse events and approximately 50% of lapses are considered preventable.<sup>11</sup> Such patient safety lapses can result from issues including medication errors due to the low implementation of medication traceability systems, healthcare-associated infections (HAIs) due to poor infection prevention, control measures and the rising antimicrobial resistance (AMR), and surgical procedures, radiation doses, blood safety, and so forth.<sup>12</sup>

Some serious health challenges, which are thoroughly analysed in the second chapter, are causing most concern:

1

**Medication errors** are a common cause of harm to patients in oncology and acute care settings and can lead to no harm, minor harm, or range to major errors which can result in morbidity, mortality, poor quality of life for the patient, lack of efficacy of medication, suboptimal patient adherence, and poor patient experience. In turn, these may have significant health and economic consequences, including the increased use of health services, preventable medication-related hospital admissions and death. High workloads and lack of healthcare personnel contribute to 23% of medication errors.<sup>13</sup> Among patients admitted to hospitals, about 2-14% experience a medication error, with estimations of around 1-2% of patients being harmed as a result.<sup>14</sup>



2

**Healthcare-associated infections:** 1 in 15 patients get at least one healthcare-associated infection on any given day in acute care settings.<sup>15</sup> The European Centre for Disease Prevention and Control (ECDC) estimated that about 9 million HAIs occur each year in European acute care hospitals and long-term care facilities.<sup>16</sup> HAI can also result in sepsis (around 20% of sepsis cases occur in healthcare settings) that can cause long-term consequences such as physical and neuro-cognitive disabilities. Lapses in safety not only result in significant suffering for patients and their families but impose a considerable and avoidable financial burden on healthcare budgets in Europe and beyond.

3

**Adverse events related to infusion therapy** are a common cause of harm to patients in healthcare settings.<sup>17</sup> High toxicity, low therapeutic indices and intravenous administration drive a significant number of adverse events in cancer patients including acute infusion-related allergic and allergic-like reactions. These reactions range from mild cutaneous appearances (e.g., pruritus and hives) to life threatening anaphylaxis with hypotension, oxygen desaturation and cardiovascular collapse, and death.<sup>18</sup> Infusion therapy adverse events include infections, extravasations, and phlebitis.<sup>19</sup>

4

**Surgical safety:** Surgery is essential for cancer care. The World Health Organisation reported<sup>20</sup> that in industrialised countries, nearly half of all adverse events in hospitalised patients are related to surgical care and at least half of those are preventable. To this end, in 2009 the WHO introduced, in association with the Harvard School of Public Health, the Surgical Safety Checklist<sup>21</sup> (SSC), a simple tool including nineteen items to prevent “never-events” (mistakes that should never happen in surgery), to promote safe administration of anaesthesia and skin antisepsis, reduce surgical site infections, and improve teamwork and communication in the operating room. Despite substantial evidence supporting its use, several barriers have been identified impairing its adoption including hierarchy in the operating rooms, a perceived delay (especially in emergency setting), impact on the workload and misalignment of staff.

## A MISSED OPPORTUNITY FOR PATIENT SAFETY IN CANCER CARE

As highlighted<sup>22</sup> by the President of the European Commission Ms. Ursula **von der Leyen** *“in 2020, while we were all fighting against the COVID-19 pandemic, many of us were fighting a silent battle. The battle against cancer. In 2020, we lost 1.3 million Europeans to this disease. And sadly, the number of cases is on the rise.”*

It is in this context that on 3rd February 2021, in the eve of the World Cancer Day, the European Commission presented Europe's Beating Cancer Plan.<sup>23</sup> This is regarded as the main priority in the area of health and a key pillar of a strong European Health Union.<sup>24</sup>

**Europe's Beating Cancer Plan (EBCP) is a key policy initiative placing the interests and well-being of patients, their families and the wider population at its heart, every step of the way.** It is designed to maximise the potential of new technologies and insights; strengthen cooperation and opportunities for EU added value; eradicate inequalities in access to cancer knowledge, prevention, diagnosis, and care and deliver improved health outcomes to patients. It thus reflects a political commitment to leave no stone unturned to act against cancer.<sup>25</sup>

With new technologies, research and innovation as the starting point, the Cancer Plan tackles the entire disease and experience pathway, from prevention to quality of life or even dignity of end-of-life cancer patients and survivors, focusing on actions where the EU can add the most value. While talking about prevention, early diagnosis, treatment and care, and the quality of life of patients and former patients, **patient safety should be a top priority of the EU Health policy agenda as many concerns still persist in oncology.**

Due to the complexity of cancer diseases and treatments, oncology patients have among the highest hospitalisation rates.<sup>26</sup> Adverse events associated with cancer care, whether in outpatient or inpatient settings, are among the main challenges for patient safety. The combination of high-risk patients (cancer patients are frequently immunocompromised and at risk of a wide range of healthcare-associated infections and sepsis) and high-risk treatments (high toxicity, low therapeutic indices, and intravenous administration) means that cancer patients are an especially vulnerable group.

Unexpected and unwanted events can and do happen at any stage of care provision and in any setting where healthcare or related care is delivered (primary, secondary, and tertiary care, community care, social and home care, acute chronic, rehabilitative, and palliative care). **Despite this, there is not a single reference to patient safety within Europe's Beating Cancer Plan.**



# CHAPTER 2 STRENGTHENING PATIENT SAFETY IN THE FIGHT AGAINST CANCER

Currently, regulatory responses and protocols vary considerably across Member States as well as across individual regions and even individual hospitals. This represents a major concern.

To ensure the successful implementation of patient safety strategies, there is a need for:

- ★ clear policies
- ★ information management systems
- ★ leadership capacity
- ★ data to drive safety improvements
- ★ skilled healthcare professionals (HCPs) and effective involvement of patients in their care

**While patient safety remains primarily the responsibility of Member States, the EU Commission has a vital supporting role to play, by encouraging and facilitating cooperation as well as the exchange of best practices and lessons learned. This is essential to ensure high-quality and standardised healthcare for all EU citizens.**

Due to the complexity of cancer diseases and treatments, oncology patients have among the highest hospitalisation rates, with a high risk of suffering adverse events across all stages of care and in any healthcare setting (primary, secondary, tertiary care, community care, social and home care, acute, chronic, rehabilitative and palliative care).

Counteracting these main adverse events plays an important role in improving patient safety. Technological means are one key component for addressing medication errors, healthcare-associated infections and adverse events related to infusion therapy. The other central element is frontline healthcare workers such as nurses, pharmacists and physicians that through their individual contributions increase patient safety.



As stewards of patients' medication safety, hospital and clinical pharmacists are for instance the safeguards ensuring the safe, effective and rational use of medicines.<sup>27</sup> In the clinical setting, they interact with patients and are thus a valuable source of information on adverse effects, contraindications and interactions of combinations of different medications. Their involvement in medication reviews in the hospital setting can be very effective in preventing adverse drug reactions which are oftentimes feared by patients and may result in non-adherence.<sup>28</sup> Like all other patients, cancer patients benefit immensely from interactions with HCPs, in particular, if these are also carried out in accordance with patient-centred care through a therapeutic alliance between the involved HCPs and the patient in which both interact as equals.<sup>29</sup>

Below is an overview of the main adverse events in cancer care.

## MAIN ADVERSE EVENTS IN CANCER CARE

### Medication errors: the most prevalent adverse event

Medication errors constitute the highest adverse events in hospitals, not only in terms of numbers but as well in morbidity and mortality.<sup>30</sup> Medication errors and consequent adverse drug events (ADEs) continue to be frequent and costly.

According to the European Medicines Agency, the medication error rate in hospital settings varies from between 0.3% and 9.1% at prescription initiation and between 1.6% and 2.1% at the dispensing stage.<sup>31</sup>

A 2020 study estimates that over 237 million medication errors occur in England each year, with 66 million (27.8%) resulting in moderate or severe harm.<sup>32</sup>

In the UK, a 2017 study in the English NHS quantified 47 million medication errors in one year in secondary care, of which 8% in prescription, 3.6% in dispensing and 28.8% in administration.<sup>33</sup>

In Spain, the "Patient Safety Strategy in the National Health System 2015-2020"<sup>34</sup> indicates that there are up to 17 medication incidents per day for every 100 hospitalised patients, 16% in prescription, 27% in transcription, 48% in dispensing and 9% in administration.

**In terms of economic burden, the WHO estimates<sup>35</sup> the annual cost of medication errors worldwide at USD 42 billion.**



The estimated cost to the UK NHS arising from avoidable adverse events related to medication in hospitalised patients, combined with those that led to hospital admissions and emergency consultations, would be approximately £98.5 million<sup>36</sup> (representing 2.9% of NHS healthcare expenditures).

In Spain, the “Patient Safety Strategy in the National Health System 2015-2020” estimates the cost of medication errors at around 2 billion euros (representing 3% of the total National Healthcare expenditure).

### **Medication errors in cancer patients: First Victims**

In the “ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy”, the overall chemotherapy 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.<sup>37</sup>

In chemotherapy, errors occur at a rate of about one to four per 1000 orders, affect at least 1–3% of adult and paediatric oncology patients, and occur at all stages of the medication use process.<sup>38</sup>

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.<sup>39</sup>

Errors occurred across all phases of the medication use system, but administration (56%) and ordering (36%) errors were the most common. Another study<sup>40</sup> found a substantially lower rate (3%) of errors in chemotherapy orders in the outpatient infusion centre at a major cancer centre. The error rate with oral chemotherapy 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<sup>41</sup> documented a 9.9% error rate with oral chemotherapy given to paediatric 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<sup>42</sup> 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 in cancer patients: Second victims

The main victims of medication errors are the patients who are harmed and their families. However, they are not the only ones affected or who suffer consequences. The health professionals involved directly or indirectly in one adverse event and who consequently suffer emotionally, though less visible, are also victims.

According to the available research,<sup>43</sup> the most common emotional reactions of second victims include: anxiety, obnubilation, confusion, difficulty concentrating on tasks, depersonalisation, frustration, guilt, sadness, mood changes, insomnia, constant replaying of the incident, lack of professional confidence, and fear of legal action and loss of reputation. Only 5% of clinicians are not closely or directly involved with adverse events during their entire professional careers.<sup>44</sup> 62.5% of clinicians working in primary care and 72.5% of those working in hospitals reported having gone through the second victim experience in the previous 5 years, either directly or indirectly through a colleague.

Recent research on the mental and psychosocial health of nurses in Europe<sup>45</sup> showed that two thirds of respondents had suffered from mental and psychosocial health issues, with anxiety the main disorder nurses are suffering, mainly causing them chronic workplace stress and 13% of nurses with disorders have been involved in medication errors or Adverse Events (AE). Medication errors are the most prevalent cause of an AE, 31% of nurses involved in an AE have chronic workplace stress and take time off for an average of 2-3 months. **Increased pressure of work, stress and shortages of staff and resources** were stated to be the main reasons for these disorders. Worryingly, over half of nurses had not received any professional and adequate psychological therapy.

Last year saw unprecedented damage inflicted on health systems and on the nursing workforce.

2022 marks no change in the continuing relentless pressure of the pandemic on individual nurses, and on the nursing workforce. Recent evidence<sup>46</sup> of the International Centre on Nurse Migration, accounts for the fact that **nurse burnout is linked to reduced patient safety and adverse events**, including medication errors, infections and falls. **When healthcare professionals experienced burnout, patient dissatisfaction and family complaints increased.**<sup>47</sup>

Patient safety incidents can have a significant impact on the professional involved, many of whom may experience “intense feelings of incompetence, inadequacy or guilt after a medical error”.<sup>48</sup>



Good patient safety practice is associated with good psychological and social behaviour in healthcare workers, but these functions are jeopardised by stress caused by prolonged high workload, excessive cognitive work tasks and lack of social support and teamwork. Given the symbioses of patient and healthcare worker safety, **improving support and efficiency for healthcare professionals also improves patient safety.**



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### Technology to prevent medication errors

Manual processes and paper-based systems often used to transfer patient data and administer treatments (i.e., hand-written prescriptions, manual drug dose calculation), as well as disconnected departments along the pathway (i.e., prescription, pharmacy, and administration), can contribute to generating errors.<sup>49</sup>



These errors are preventable through comprehensive and systematic approaches to patient safety throughout the medication use process.

Evidence shows the importance of computerised provider order entry systems (CPOE)<sup>50</sup> in minimising medication prescription errors.<sup>51</sup> It is estimated that at least a quarter of all harm related to medication can be prevented by using CPOEs by eliminating errors from incorrect manual transcriptions.<sup>52</sup>

Medication safety cabinets, including the connection with computerised physician order entry (CPOE), reduce the rate of medication errors and costs and improves efficiency of healthcare staff.<sup>53</sup> Clinical studies suggest the importance of optimally introducing automated dispensing systems to ensure the utmost clinical success and economic benefits.<sup>54</sup>

Bar code medication administration (BCMA) is another highly effective technology to prevent medication errors in administration.<sup>55</sup> It reads the barcode of the patient's bracelet, the healthcare worker's identification, and the medication. The system verifies: the right medication, the right patient, the right moment, ascertaining as well that medication is administered only by authorised staff.

There is also no doubt that the **education of healthcare professionals combined with digital innovation of medication traceability systems and reporting processes are critical success factors in addressing this patient safety issue.**

The Institute for Safe Medication Practices (ISMP), in its report<sup>56</sup> dated 2019, recommends the following systems to minimise medication errors in healthcare settings:

## TECHNOLOGY (TECH) KEY

1

A fully integrated computerised prescriber order entry system includes the capability to build medication safety alerts and clinical decision rules. It should directly interface with laboratory system and pharmacy, list drug-drug and drug-disease interactions, and offer clinical decision support.

2

**Barcode-enabled point-of-care systems** are designed to detect medication errors during medication distribution and/or administration. Using a barcode scanner to scan barcodes on a medication and a patient's wristband, users can verify and record all drugs administered to the patient.

3

**“Smart” infusion pump systems** allow users to enter drug infusion protocols into a drug library with predefined dose limits. If a dose is programmed outside established limits or clinical parameters, the pump halts or sounds an alarm. Some pumps can integrate patient monitoring and other patient parameters.

4

**Automated dispensing cabinets** are robust, point-of-use dispensing systems. Automated dispensing cabinets should be integrated with the healthcare facility’s information system and directly interface with the pharmacy system. In addition, automated dispensing cabinets must be able to use barcoding technology for the restocking process to prevent medication errors.

5

A **“robust” pharmacy order entry system** is fully interfaced with a computerised prescriber order entry system and must be able to produce medication safety alerts, directly interface with a healthcare facility’s information systems, and generate a computerised medication administration record to be used by nurses while they administer medications.

6

Intravenous workflow technology combines software and automated pharmacy workflow technology for compounding sterile products. It receives dose information from health IT systems and uses robotics, gravimetric analysis, and barcode scanning with video technology or digital images. Some systems can generate drug-specific administration notes and labels for point-of-care scanning by nurses.

Automation and digitalisation of medication management, including traceability systems, can substantially reduce opportunities for human errors in medication delivery from prescription to administration.

While none of those solutions can eliminate the problem of medication error on its own, they can substantially reduce patient suffering and unnecessary health care costs when implemented as part of a comprehensive risk reduction strategy. **Digital innovations also lead to greater efficiency of healthcare professionals, increasing pharmacy and medical staff time and reducing their workload.**<sup>57,58</sup>

### Case study: The Irish National Cancer Information System (NCIS)

The Irish National Cancer Information System (NCIS) project is led by the Irish National Cancer Control Programme<sup>59</sup> 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 haemato-oncology 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.

Preventing medication errors is an essential component of caring for patients and must be a core mission of all healthcare professionals. Automation and digitalisation of medication management, including traceability systems, can substantially reduce opportunities for human errors in medication delivery from prescription to administration, as well as improve efficiency of healthcare workers.

## The European Collaborative Action on Medication Errors and Traceability

In 2020, the European Collaborative Action on Medication Errors and Traceability (ECAMET) Alliance<sup>60</sup> was formed with a view to reduce medication errors at European and national levels, to protect and enhance patient safety and the quality of healthcare. Coordinated by the European Alliance for Access to Safe Medicines (EAASM), the ECAMET Alliance now includes 22 healthcare organisations, such as patient and scientific groups as well as healthcare professionals who can have a direct impact on supporting solutions, such as hospital pharmacists and IT managers.

A comprehensive White Paper<sup>61</sup> on 'The Urgent Need to Reduce Medication Errors in Hospitals to Prevent Patient and Second Victim Harm' was released in March 2022, collecting the results of a pan-European survey on medication errors. In total there are 25 reports<sup>62</sup> comprising 13 country reports in English, 8 languages translations, a private hospitals report, specialised oncology and ICU reports and one consolidated report. In addition, to enable a comparison between the countries and their reports an interactive dashboard has been created. This allows the use to search by question against criteria such as hospital size, type or area.

The reports reveal many positive aspects within hospitals across Europe whilst at the same pointing to areas that would benefit greatly from development in terms of funding, training and implementation of traceability systems. For example:

- ★ Approximately only 50% of hospitals have electronic medication prescription systems for ALL patients;
- ★ Despite 81% of medication being prepared outside of the hospital's central pharmacy, the availability of electronic preparation systems is below 31%;
- ★ Technological tools used to verify in advance if the right patient receives the right medication at the right time, are only available in 39% of oncology wards and 26% of intensive care units.

The ECAMET White Paper recommends prerequisites to reduce medication errors in hospitals and highlights the need to:

- ★ Establish a culture of safety
- ★ Create strategies to improve communication
- ★ Raise awareness and organise regular multi-disciplinary training meetings
- ★ Systematically use accreditation/certification systems
- ★ Introduce technological tools to stimulate innovation and prevent medication errors in healthcare settings

In line with the ECAMET Alliance organisations, it calls on European and national health authorities to commit to:

- ★ Include medication safety in the Pharmaceutical Strategy for Europe, in the EU general pharmaceutical legislation and in Europe's Beating Cancer Plan through different solutions, including medication traceability systems at the healthcare setting level to minimise medication errors.
- ★ Prioritise strategic investments in medication traceability systems in the EU4Health program to minimise medication errors.
- ★ Foster the development and implementation of ECDC guidelines and key indicators on medication errors in EU healthcare settings.
- ★ Facilitate systematic exchange of best practices between healthcare providers both at European and national levels to reduce medication errors at healthcare setting level.<sup>63</sup> The reports can be found on the official website [www.ecamet.eu](http://www.ecamet.eu) alongside the interactive dashboard.

## HEALTHCARE-ASSOCIATED INFECTIONS

### The burden of healthcare-associated infections

One in 15 patients get at least one healthcare-associated infection on any given day in acute care settings.<sup>64</sup> 37,000 patients die as a direct consequence of HAIs in the European Union each year<sup>65</sup> and HAIs cost the EU healthcare system an estimated €7 billion per year.<sup>66</sup> Yet, **these incidents are preventable**. The most common healthcare-associated infections are surgical site infections, catheter-related urinary tract infections and catheter-related bloodstream infections.<sup>67</sup>

Interprofessional collaboration is an important mean for facilitating communication between healthcare professionals in clinical practice and fostering prevention of healthcare-associated infections. Involving different professions in multidisciplinary team discussions is not only beneficial for the exchange among professionals but also contributes immensely to patient safety.

### Healthcare-associated infections in cancer patients

Some types of cancer can damage the immune and blood systems or change the way they work, leading to severe healthcare-associated infections. In addition, treatments can also cause short- or long-term immunosuppression making patients more exposed to the risk of infection and sepsis.



## A. SURGICAL SITE INFECTIONS (SSIS)

Despite the increasing number of therapeutic options available to cancer patients, surgery represents a mainstay of treatment. In fact, surgical site infections (SSIs) are among the most common healthcare-associated infections (HAIs).

An SSI is an infection that occurs after surgery in the part of the body where the surgery took place. According to the ECDC,<sup>68</sup> the burden of SSIs in the EU/EEA is estimated at 543,149 cases annually.

SSIs are associated with longer postoperative hospital stays, may require additional surgical procedures, and intensive care and result in higher attributable morbidity and mortality.<sup>69</sup> SSIs are also an important target for the surveillance of HAIs and a priority for surveillance in several EU/EEA countries.

SSIs account for frequent patient morbidity and the true incidence of these infections is probably underestimated. Little data exist that identify SSI rates among patients with cancer. Due to their disease, intensive treatment regimens, or both, profound immunosuppression is an all too frequent occurrence among cancer patients. Thus, these patients may have a higher intrinsic risk for acquiring an SSI<sup>70</sup> and subsequent sepsis.

Similar to any other HAIs, SSIs are largely avoidable and up to one-half can generally be prevented through successful implementation of clinical practice guidelines.

The first-ever global guidelines for the prevention of SSIs<sup>71</sup> were published in November 2016 by WHO, which were updated in some parts and published in a new edition in December 2018. The 2016 WHO Global guidelines for the prevention of SSIs are evidence-based guidelines which include systematic reviews of current practices and present additional information in support of actions to improve infection prevention. The guidelines include 13 recommendations for the preoperative period and 16 for preventing infections during and after surgery. At the same time, national and international guidelines such as those from The National Institute for Health and Care Excellence (NICE NG125 2019),<sup>72</sup> The Clinical Practice Guide for Surgical Patient Safety of the National Health System in Spain (2010),<sup>73</sup> the ECDC Systematic review and evidence-based guidance on perioperative antibiotic prophylaxis (2013),<sup>74</sup> the Canadian Patient Safety Institute Guideline (2014)<sup>75</sup> and the CDC guidelines are already in place.

All these guidelines are supported by different levels of evidence generation.

**Yet common and harmonised guidelines have not been developed in Europe.**

Hospital policy or protocol for prevention of SSIs are clearly in place in European hospitals, but there is **no consensus on the measures to be implemented** (not even in the same hospital, surgical speciality within the hospital, region, and country). At the same time, it is worth highlighting that the lack of European guidelines and the existence of national guidelines do not facilitate the use of harmonised and evidence-based practices to prevent SSIs.

As highlighted by many experts<sup>76</sup> in the Insight Report of Health First Europe<sup>77</sup> entitled “Identifying the gaps between evidence and practice in the prevention of surgical site infections”, it is **possible to prevent SSIs but the striking gaps between evidence-based measures suggested by official guidelines and actual medical practice in European hospitals represent a serious concern for the safety of European patients**. The overall cost of SSIs in Europe is estimated to be around €19 billion per year.

A study<sup>78</sup> from 2017 analysed the data related to the burden of SSIs in the ‘big five’ European countries (France, Germany, Italy, Spain, the UK) and showed the following:



#### France

**Additional Cost: €17,434**

French patients who developed an SSI constitute a total per-patient medical cost €17,434 higher than those patients who did not develop an SSI.



#### Germany

**Additional Cost: €22,900**

The development of an SSI was associated with additional total medical costs of €22,900, relative to uninfected patients.



#### Italy

**Additional Cost: €32,000**

The development of an SSI was associated with additional total medical costs of €32,000, relative to uninfected patients.



#### Spain

**Additional Cost: €10,232**

The development of an SSI was associated with additional total medical costs of: \$10,232 relative to uninfected patients.



#### UK

**Additional Cost: €11,766**

Patients who contracted an SSI constituted an additional healthcare financial burden of £10,523 per patient.








Such figures could be drastically reduced if there was consensus on the measures to be implemented across European hospitals for cancer treatment in line with the official guidelines.






The examples below show serious discrepancies among EU countries:

### Preoperative bathing






Preoperative whole-body bathing or showering is considered good clinical practice to make the skin as clean as possible prior to surgery in order to reduce the bacterial load, especially at the site of incision. When considering the available evidence, the most relevant question is whether preoperative bathing or showering with an antimicrobial soap is more effective than plain soap to reduce SSI.

Do you recommend a preoperative bath or shower to your patients?					
Yes	100%	51%	85%	94.5%	81%
No	0%	49%	15%	5.5%	19%






  

Where do you recommend a preoperative bath or shower for your patients?					
A bath at home	4.8%	4.1%	17.5%	0.3%	14.5%
A bath at the hospital	1.2%	6.1%	6.2%	0.9%	0%
A shower at home	49.2%	16.3%	34%	30.9%	57%
A shower at the hospital	44.8%	24.5%	27%	62.5%	9.5%
Nowhere	0%	49%	15.3%	5.4%	19%

Is there a hospital policy on skin preparation?					
Yes	95.5%	90.4%	76%	87.1%	78%
No	5%	9.6%	24%	12.9%	22%

What type of product is used for the patient skin antiseptics?					
Chlorhexidine gluconate	4.8%	16.3%	40.7%	57.2%	56%
Povidone iodine	49.5%	26.5%	50.3%	23.3%	13%
An alcoholic solution	32.5%	47%	6.8%	7.8%	5.3%
An aqueous solution	0%	0%	1.1%	10.6%	0%
Other (please specify)	13.2%	10.2%	1.1%	1.1%	26%

The figures in this paper intend to draw attention to the need to change practices to save lives, especially the ones of oncology patients. Echoing the HFE policy recommendations,<sup>79</sup> this report calls upon European policy makers to reduce the incidence of SSIs in Europe by:

1

### **Creating a European Framework on HAI prevention and control**

Within a broader European legislative framework on infection prevention and control, it is necessary to build consensus around evidence-based guidelines such as the one from WHO and define clear protocols to prevent SSIs.

2

### **Harmonising evidence-based guidelines and protocols**

The European Commission should facilitate the creation of an Expert Forum with ECDC to develop and adopt evidence-based guidelines (such as the WHO Guidelines) and to support their implementation across Europe. It is necessary to foster scientific associations' involvement into intersectoral training of HAI prevention and control. At the same time, it is necessary to include recommendations on HAI reduction in the European Semester as a policy tool to motivate national progress on HAI prevention and control; to design future EU funding opportunities and conditionalities to boost national policy and implementation capacity.

A European framework on HAI prevention and control, and harmonised clinical guidelines at EU level would minimise HAI rates in cancer patients.

## Case Study: Safe Surgery Saves Lives

The Lancet Oncology Commission on global surgery in 2015,<sup>80</sup> estimated that of the 15 million new cases of cancer, more than 80% will need surgery. However annually, by 2030, 45 million surgical procedures will be needed worldwide and less than 25% of cancer patients globally will get safe, affordable, or timely surgery.

The reasons behind this data are multidimensional, affecting primary low-income countries, however, and more generally, the issue of safety in surgical care has been largely investigated worldwide. Indeed, in 2015, the Global Surgery 2030 Report<sup>81</sup> identified **ten needs for the provision of safe surgical and anaesthesia care**, including:

- ★ Trained surgical provider;
- ★ Trained anaesthesia provider;
- ★ Infrastructure, equipment and supplies necessary to perform safe general anaesthesia, loco-regional anaesthesia etc;
- ★ Decontamination and sterilisation capacity;
- ★ Safe (screened and cross-matched blood) and affordable blood supplies;
- ★ Drugs, including antibiotics, pain medicines, and anaesthetics;
- ★ Nursing care;
- ★ On-call services for surgical cover;
- ★ Quality-improvement processes, including audit of perioperative mortality and;
- ★ Risk assessment and operation planning for planned procedures and these principles apply also to cancer care.

Also, the World Health Organisation reported<sup>82</sup> that in industrialised countries, nearly half of all adverse events in hospitalised patients are related to surgical care and at least half of those are preventable.

To address this issue, the WHO launched a global campaign entitled “Safe Surgery Saves Lives”, aimed to improve the safety of surgical care around the world by defining a core set of safety standards that could be applied in all WHO Member States. To this end, in 2009 the WHO introduced, in association with the Harvard School of Public Health, the **Surgical Safety Checklist** (SSC),<sup>83</sup> a simple tool including 19 items to prevent “never-events” (mistakes that should never happen in surgery), to promote safe administration of anaesthesia and skin antiseptic, reduce surgical site infections, and improve teamwork and communication in the operating room. Although SSC was conceived for a widespread use, and not limited to surgical oncology practice, its application is essential, given that surgery is the gold standard for most solid tumours.



A pilot study<sup>84</sup> conducted at eight pilot hospitals in low-, middle-, and high-income countries and published in 2009, documented that **SSC use was associated with a reduction of nearly 50% in mortality and of 36% in postoperative complications.**

Since then, the Checklist has been implemented in nearly 70% of countries worldwide,<sup>85</sup> although the vast majority of those were high-income. A recent meta-analysis<sup>86</sup> of twenty systematic reviews confirmed that WHO SSC had a positive impact on mortality, morbidity, surgical site infection, pneumonia, unplanned return to the operating room, urinary tract infection, blood loss requiring transfusion, unplanned intubation<sup>87</sup> and sepsis. However, and despite substantial evidence supporting its use, several barriers have been identified impairing its adoption including hierarchy in the operating rooms, a perceived delay (especially in emergency setting), impact on the workload and misalignment of staff.

*Safety is a priority issue in all disciplines of surgical care. The application of WHO principles have a reliable positive impact to prevent morbidity and mortality”, Laura Lorenzon MD PhD, Surgeon, Fondazione Policlinico Universitario Agostino Gemelli, Roma.*

## **B. CATHETER-RELATED BLOODSTREAM INFECTIONS**

Infections are one of the most serious complications to consider among cancer patients, owing to both the treatment and malignancy conditions of the disease and the conditions related to the venous access itself.<sup>88</sup> The incidence of catheter-related bloodstream infections ranges from 0.05 to 6.8 infections per 1000 catheter days.<sup>89,90</sup>

Some studies<sup>91</sup> performed in cancer patients showed significantly lower rates with peripherally inserted central catheters (PICCs) versus centrally inserted central catheters (CICCs) (1.23 vs. 5.3/100 days of catheter use) or a lower incidence with PICCs in outpatients, while other data suggest that in the short term the incidence of infection is similar.

According to the information<sup>92</sup> provided by the Spanish Foundation for Excellence and Quality in Oncology (ECO), the Spanish Society of Medical Oncology (SEOM) and the Spanish Society of Oncology Nursing (SEEO), there are approximately 150 centres in Spain that administer oncology therapy intravenously. Considering the incidence revealed by the survey for each of the main related complications, and extrapolating the costs involved in the management of these events reported in US hospitals, the approximate annual costs amount to €17,221,000 for the management of bacteraemia resulting from a catheter use.



To reduce the negative impact of venous punctures, it is beneficial to have a stable venous access that can be reused, facilitating both the administration of drugs and appropriate monitoring of the patient's condition, and reducing the anxiety associated with this procedure.<sup>93</sup> To achieve this, there are many devices, for both central and peripheral venous access,<sup>94,95</sup> a prerequisite for all of them being that they should be reliable and safe to use, since there are intrinsic complications of both the medication and the procedure that must be adequately addressed to achieve the best clinical results. It is essential to analyse the different vascular access options available and to establish appropriate criteria for selecting the most suitable device in each case, considering key aspects such as the physicochemical characteristics of the therapy and its duration, the physical condition and history of the patient, the resources, and devices available or the integrity of the patient's vascular system and their personal preferences.<sup>96</sup> It is also important to consider the experience and level of training of the professionals in charge of their insertion and care, as it has been established that the greater the specific professional preparation, the fewer associated problems.<sup>97</sup>

Harmonised protocols for infusion device selection linked to electronic prescription systems and training programmes for healthcare staff in charge of intravenous therapy are extremely important to reduce the risk of catheter-associated infections for cancer patients.

## C. CATHETER-ASSOCIATED URINARY TRACT INFECTIONS (CAUTI)

The indwelling urethral catheter is an essential tool for many hospitalised patients. It is placed for several reasons, including output monitoring of unstable patients, voiding management for patients with urethral obstruction, and perioperative use for selected surgical procedures. However, it may carry predictable and unavoidable risk of urinary tract infection (UTI), perturbing host defence mechanisms and providing easier access of uropathogens to the bladder.<sup>98</sup>

**Studies estimate that 41-58% of catheters in place are probably unnecessary.**<sup>99</sup>

The risk for catheter-associated urinary tract infections (CAUTIs) increases by 5% for each day with a catheter.<sup>100</sup>

**CAUTIs are common and preventable HAIs,** and cancer patients are at higher risk for developing them.

To minimise patient safety incidents and drive improvements in safety and quality, evidence-based strategies are urgently needed to reduce CAUTI-associated morbidity and mortality.<sup>101</sup>

**Official guidelines to prevent CAUTIs have been adopted** by the European Association of Urology (EAU) and the European Association of Urology Nurses (EAUN) including:<sup>102</sup>

- ★ The European and Asian guidelines on management and prevention of catheter-associated urinary tract infections (2016).
- ★ Evidence-based guidelines for best practice in urological healthcare. Catheterisation indwelling catheters in adults urethral and suprapubic (2012).<sup>103</sup>

Unfortunately, **evidence shows that these guidelines are not sufficiently respected within the European Union**; and this has led to high costs and serious consequences in terms of patient health due to CAUTIs.<sup>104</sup>

The WHO has published a CAUTI training module and student handbook in the context of a broader infection prevention and control training package.<sup>105</sup>

The Spanish Association of Urology (AEU) and the Foundation for the Investigation of Urology (FIU) developed recommendations on the prevention of urinary tract infections related to the use of urinary catheters.<sup>106</sup> They recommend regular training to hospital staff, ongoing surveillance, and the use of urinary catheterisation kits, which lead to an average reduction of 80% of CAUTIs.<sup>107</sup> They also highly recommend maintaining awareness of the catheter's existence, put reminder interventions in place and when not necessary, stop interventions.

Improving adherence to the official guidelines has been further highlighted in a recent report "Increasing adherence to CAUTI guidelines: Recommendations from existing evidence"<sup>108</sup> co-written by Health First Europe (HFE) and the European Association of Urology Nurses<sup>109</sup> (EAUN).

The document identifies common barriers to adherence to existing best-practice guidelines and proposes solutions for healthcare professionals to improve adherence and reduce the huge negative impact of CAUTI-related patient suffering and cost within the EU.



Centralised surveillance of catheter-associated urinary tract infections, awareness-raising on the existing guidelines and the correct implementation of their recommendations on how to improve adherence have the potential to significantly reduce catheter-related urinary tract infections in cancer care:

- ★ Regular education / training / awareness of healthcare professionals
- ★ Ongoing surveillance and analytics
- ★ Bundles' check lists
- ★ Regular internal audit programmes with patients
- ★ Protocols to restrict catheter placement
- ★ Urinary catheterisation kits/sets
- ★ Reminder interventions, including a daily checklist, verbal/written reminder, a sticker reminder on the patient's chart or catheter bag, an electronic reminder that a catheter is still in place
- ★ Stop order interventions

## ADVERSE EVENTS RELATED TO INFUSION THERAPY

With over 100,000 doses of chemotherapy and over 1,000,000 intravenous (IV) infusions given every day around the world, keeping adverse events and complications of these procedures to a minimum is another essential aspect for both the patients receiving them and the healthcare systems in which they take place.

Infusion reactions present as allergic reactions and may involve a wide range of symptoms, affecting body systems such as: cardiovascular, central nervous CNS, dermatologic, endocrine, gastrointestinal, genitourinary and respiratory; they vary in severity from mild to life-threatening. Such reactions need to be managed by a multidisciplinary team containing nurses, pharmacists, physicians and various other health providers. Healthcare facilities should provide the staff with adequate training to ensure rapid recognition and proper therapy of infusion reactions. Special **emergency kits** for infusion therapy reactions should be kept at hand, proper **premedication** should also receive special attention- that can be tailored to specific patients' conditions and following the manufacturer's recommendations- and comprehensive **protocols** for the medical team to consult in infusion reaction management.

In the cancer patient population, the risk of catheter-related complications is potentially higher, owing to the presence of immunosuppression, thrombocytopenia, and coagulopathy from both the disease and its treatment, increasing the incidence of infections and thrombosis. On the other hand, most of the time the treatments used are potentially harmful to the tissues, with the consequent risk of extravasation and complications.

**Extravasation is a potential accidental complication associated with the administration of chemotherapy with serious consequences for the patient.**

It may result in tissue necrosis associated with various factors, such as the characteristics of the chemotherapy agent (e.g., vesicant potential, volume and concentration administered, rate and duration of infusion) or the patient (e.g., access to small or fragile veins, presence of lymphoedema or obesity or history of multiple venous punctures). Its prevalence varies between around 0.1–6% when administered through a peripheral catheter and between 0.26–4.7%<sup>110</sup> if a central catheter is used.

A survey conducted in Spain among ambulatory oncology services showed an average of 7 extravasations per year, with an average of 3% driving severe consequences for the patients. Extrapolating the costs involved in the management of these events reported in US hospitals, the approximate annual costs amount to €1,257,400 for the resolution of phlebitis, €15,635,000 for the management of moderate extravasations, multiplying almost tenfold in the case of severe extravasations, which undoubtedly impose a huge burden on the healthcare system.<sup>111</sup>

Considering the incidence revealed by the survey for each of the main related complications, and extrapolating costs involved in the management of these events reported in US hospitals, the approximate annual costs amount to €17,221,000 for the management of bacteraemia resulting from catheter use.

Harmonised protocols or the right selection algorithms of vascular access management in cancer settings and awareness-raising and training for healthcare professionals have the potential to reduce vascular access adverse events in cancer care.



# CHAPTER 3

## STRENGTHENING HEALTHCARE SYSTEMS

The COVID-19 pandemic and the experience gathered over the decades on vaccine development have clearly shown us that when we come together, when we pool our efforts and resources, it is possible to make unprecedented progress.

Providing safe and high-quality health services when treating cancer patients is a prerequisite for strengthening healthcare systems and making progress towards effective universal health coverage (UHC) under Sustainable Development Goal 3 (Ensure healthy lives and promote health and well-being for all at all ages).

We need more awareness and solidarity on health, not only to combat epidemics, but also to strengthen public health systems in Europe and elsewhere. And, echoing the words of Ms. Stella Kyriakides, EU Commissioner for Health and Food Safety, “a strong European Health Union is a Union where citizens are protected from avoidable cancers, where they have access to early screening and diagnosis, and where everyone is empowered with access to high-quality care, at every step of the way”.<sup>112</sup>

### **Certification programmes: One opportunity for patient safety in Europe’s Beating Cancer Plan**

There is wide-ranging evidence of multiple tangible benefits for cancer patients being treated in certified cancer centres that meet specific quality standards in terms of structures and procedures of medical care.

In Europe, there are several initiatives in terms of cancer centres certification:

- ★ The Organisation of European Cancer Institutes’ (OECI) Standards for Accreditation and Designation<sup>113</sup>
- ★ The German Cancer Society (Deutsche Krebsgesellschaft) Standards for recognition as “European Cancer Centres”<sup>114</sup>
- ★ Other European societies produce similar standards for cancer centres including European Society of Breast Cancer Specialists (EUSOMA)<sup>115</sup>

At the EU level, the European Cancer Centre' (ECC) Certification Program is the most important one and aims to contribute to European initiatives such as the Joint Action innovative Partnership for Action Against Cancer (iPAAC), European Commission's Joint Action on Cancer (CanCon) and the European Commission Initiative on Breast Cancer (ECBIC) by implementing Comprehensive Cancer Care Networks (CCCN) in European member states and thereby improving the quality of cancer care.<sup>116</sup>

The objectives of such EU certification programmes are to:

- ★ Define the Europe-wide quality of oncological healthcare services.
- ★ Reduce differences in the quality of cancer healthcare services and provide standardised/uniform oncological healthcare services in all member states; and
- ★ Establish a pan-European database to lay the foundations for comprehensive Europe-wide cancer health service research.

Currently Catalogues of Requirement and data sheets are available for the following tumour entities: breast cancer, colorectal cancer, gynaecological cancer, lung cancer, neuro-oncology cancer, prostate cancer and skin cancer. Catalogues of Requirements exist for several other tumour entities and can be made available upon request.

Furthermore, Catalogues of Requirements are available for two main cooperation partners: pathology and radio-oncology.

Nevertheless, **a common cross-tumour Catalogue Requirement for patient safety that covers patient safety is missing**. This is especially important in the area of medication treatments prescription, infusion systems selection, preparation, labelling, administration, and monitoring.

The Association for Clinical Oncology (ASCO) in United States has developed Quality Oncology Practice Initiative (QOPI®) Certified Practices that routinely evaluate practice performance against quality measures and standards established by experts in the oncology field.<sup>117</sup>

The QOPI® Certification Program (QCP™) Standards have four defined domains of responsibility:

1

### **Creating a Safe Environment-Staffing and General Policy**

Defines staff qualifications, minimum chart documentation requirements, defines relevant patient resources, and policies for patient documentation and follow-up.

2

### **Treatment Planning, Patient Consent and Education**

Defines requirements for consent and education processes prior to treatment.

3

### **Ordering, preparing, dispensing, and administering chemotherapy**

Defines requirements for chemotherapy order set, order verification, labelling and safe handling and extravasation management procedures.

4

### **Monitoring after chemotherapy is given, including adherence, toxicity, and complications**

Defines requirements for emergency management, monitoring and care of toxicities, and oral chemotherapy adherence.

The QOPI® Certification Program (QCP™) incorporates the benefit of digital technology, like computerised provider order entry (CPOE), gravimetric verification, robotics, IV workflow software and bar-code scanning, to assist verification process in preparation and administration of cancer treatments.

## MEDICATION SAFETY IN CANCER PATIENTS

Medication safety in cancer patients receiving complex medication regimens is an important problem for healthcare settings.

Accreditation from external bodies has the potential to be powerful, with accredited centers excelling in publicly reported outcomes. This may have positive outcome in terms of patient safety provided that the accreditation systems include prevention of adverse events in the accreditation process.

Medication errors are the first adverse event for cancer patients when being treated in healthcare systems. Prescription, preparation, administration, and monitoring of cancer medication is a high-risk area, and mistake may compromise seriously the patient safety.

Therefore, cancer centers accreditation systems should include, at least, specific criteria on safety prescription, preparation, administration, and monitoring of oncology medication.

Digital technology, it means medication traceability systems are a significant ally of healthcare settings and healthcare professionals in preventing medication errors. From medication cabinets to e-prescription, e-preparation, and e-administration/dispensing systems. Therefore, accreditation systems should consider the role of digital technology in the accreditation process, as a subrogate of human/manual controls.

As mentioned above, an excellent example is ASCO QOPI® certification program. The QOPI® Certified Practices routinely evaluate practice performance against quality measures and standards established by experts in the oncology field - ordering, preparing, dispensing, and administering chemotherapy.

Safety standards included in this certification program are: 1) Double Check in chemotherapy preparation; 2) Double Check in chemotherapy administration; 3) Patient Safety Measures.

The QOPI® Certification Program is a public recognition of a practice commitment to safety and quality of care. Nowadays in Europe, 15 practices have been certified, 13 of them in Spain. The certification process of these centres has been done together with ECO Foundation (Excellence and Quality in Oncology) who has an outstanding collaboration with ASCO.



The incorporation to the ECC Certification Program of one cross-tumour Catalogue Requirement for patient safety, similar to the ASCO QOPI® Certification Program (QCP™), would significantly improve the safety of cancer patients in Europe.

## **STRENGTHENING HEALTHCARE SYSTEMS**

The COVID-19 pandemic and the experience gathered over the decades on vaccine development have clearly shown us that when we come together, when we pool our efforts and resources, it is possible to make unprecedented progress.

Providing safe and high-quality health services when treating cancer patients is a prerequisite for strengthening healthcare systems and making progress towards effective universal health coverage (UHC) under Sustainable Development Goal 3 (Ensure healthy lives and promote health and well-being for all at all ages).

We need more awareness and solidarity on health, not only to combat epidemics, but also to strengthen public health systems in Europe and elsewhere. And, echoing the words of Ms. Stella Kyriakides, EU Commissioner for Health and Food Safety, “a strong European Health Union is a Union where citizens are protected from avoidable cancers, where they have access to early screening and diagnosis, and where everyone is empowered with access to high-quality care, at every step of the way”.<sup>118</sup>

### **Strengthening healthcare systems through better patient safety in the fight against cancer: A call for stronger EU action**

The safety of cancer patients receiving care in healthcare settings is of serious concern.

**Patient safety in oncology should remain a standard indicator of the quality of care and a core element of the EU health policy agenda, especially in Europe’s Beating Cancer Plan and the EU4Health program, by creating a special taskforce on patient safety.**



The European Network for Safer Healthcare and its partner organisations call on European, national and regional authorities and all relevant stakeholders to:

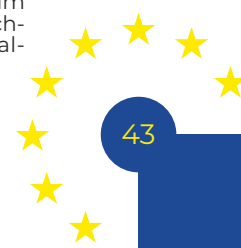
- ★ Implement patient safety within the framework of Europe's Beating Cancer Plan and related flagship initiatives, such as the European Cancer Inequalities Registry, the European Health Data Space as well as in the EU4Health annual work programmes;
- ★ Update the 2014 Council conclusions on patient safety and quality of care, including the infection prevention and control of healthcare-associated infection (HAI) and antimicrobial resistance;
- ★ Place medication safety requirements in the Pharmaceutical Strategy for Europe, in the EU revision of the general pharmaceuticals legislation and in the recent Commission's proposal of the European Health Data Space through digitalisation of medication management and traceability systems in healthcare settings to minimise medication errors, improve affordability and accessibility of medicines, efficiency of healthcare professionals and standardise and collect data to evaluate the impact of cancer medication on patient outcomes;
- ★ Create a European framework on healthcare-associated infection (HAI) prevention and control (including surgical site infections, catheter-related bloodstream infections and sepsis) and increase adherence to ECDC evidence-based guidelines and protocols;
- ★ Develop harmonised protocols for the right selection algorithms of vascular access management in cancer settings and training healthcare professionals to prevent vascular complications (such as extravasations and phlebitis);
- ★ Facilitate the systematic exchange of best practices between healthcare stakeholders both at national and European level to address the issue of variability in the standards of care;
- ★ Incorporate to the European Cancer Centre's (ECC) Certification Programme a one cross-tumour Catalogue Requirement for patient safety based on existing clinical evidence;
- ★ Improve occupational conditions to protect the safety and well-being of healthcare professionals working in cancer care, by promoting education and development opportunities for health personnel, addressing oncology workforce shortages and reducing unnecessary barriers to professional mobility;
- ★ Invest in medical technologies and adopt process-improvement techniques to enhance patient safety, enable improvement of oncology treatment and improve communication between healthcare professions and the community;
- ★ Work systematically on the improvement and development of a safety culture in all healthcare settings whereby active leadership, open communication, transparency and accountability are indispensable components.





# REFERENCES

- 1 The European Network for Safer Healthcare official website <https://www.eusaferhealthcare.eu/>
- 2 WHO Patient Safety, WHO 2018
- 3 Slawomirski, et al. "The Economics of Patient Safety in Primary and Ambulatory Care." OECD, 2018, <https://www.oecd.org/health/health-systems/The-Economics-of-Patient-Safety-in-Primary-and-Ambulatory-Care-April2018.pdf>
- 4 Kristensen, S. and P. Bartels (2010), Use of Patient Safety Culture Instruments and Recommendations Use of Patient Safety Culture Instruments and Recommendations 2 Content, <http://www.esqh.net>
- 5 Slawomirski L., Auraaen A. and Klazinga N., 2017, "The Economics of Patient Safety: Strengthening a Value-based Approach to Reducing Patient Harm at National Level", OECD, [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\\_Downloads/P/Patientensicherheit/The\\_Economics\\_of\\_patient\\_safety\\_Web.pdf](https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/P/Patientensicherheit/The_Economics_of_patient_safety_Web.pdf)
- 6 Please refer to ref 5.
- 7 European Commission, DG SANTE Public Health, 7 April 2017, Patient safety: Policy, [https://ec.europa.eu/info/sites/default/files/research\\_and\\_innovation/research\\_by\\_area/documents/ec\\_rtd\\_patient-safety\\_factsheet.pdf](https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_patient-safety_factsheet.pdf)
- 8 de Bienassis, K. and N. Klazinga (2022), "Developing international benchmarks of patient safety culture in hospital care: Findings of the OECD patient safety culture pilot data collection and considerations for future work", OECD Health Working Papers, No. 134, OECD Publishing, Paris, <https://doi.org/10.1787/95ae65a3-en>.
- 9 de Bienassis, K., et al. (2020), "Culture as a cure: Assessments of patient safety culture in OECD countries", OECD Health Working Papers, No. 119, OECD Publishing, Paris, <https://doi.org/10.1787/6ee1aeae-en>.
- 10 WHO Global Patient Safety Action Plan 2021-2030; <https://www.who.int/publications/i/item/9789240032705>
- 11 "The Economics of Patient Safety - OECD." OECD, 2020, <https://www.oecd.org/health/health-systems/Economics-of-Patient-Safety-October-2020.pdf>.
- 12 "Reduction of Medication Errors - Ecamet.eu." Ecamet.eu, IPSOS, Feb. 2022, [https://ecamet.eu/wp-content/uploads/2022/03/21016698-IN0104-EAASM-Medication-errors\\_Consolidated.pdf](https://ecamet.eu/wp-content/uploads/2022/03/21016698-IN0104-EAASM-Medication-errors_Consolidated.pdf)
- 13 ECAMET Alliance official website <https://ecamet.eu/>
- 14 European Medicines Agency, EMA/787897/2015, 27 November 2015, Streamlining EMA public communication on medication errors, [https://www.ema.europa.eu/en/documents/other/streamlining-ema-public-communication-medication-errors\\_en.pdf](https://www.ema.europa.eu/en/documents/other/streamlining-ema-public-communication-medication-errors_en.pdf)
- 15 Suetens C, et al. Eurosurveillance 15 November 2018. [https://ec.europa.eu/chafea/health/newsroom/events/28112018/documents/eupha-28112018-08\\_en.pdf](https://ec.europa.eu/chafea/health/newsroom/events/28112018/documents/eupha-28112018-08_en.pdf)
- 16 Suetens C, et al. Prevalence of healthcare-associated infections, estimated incidence and composite antimicrobial resistance index in acute care hospitals and long-term care facilities: results from two European point prevalence surveys, 2016 to 2017 Accessible at <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2018.23.46.1800516>
- 17 Vogel W.H., April 2010, Infusion reactions: diagnosis, assessment, and management, Clin J Oncol Nurs;14(2): E10-21, <https://pubmed.ncbi.nlm.nih.gov/20350882/>
- 18 Cancer Care Alberta (2020) Acute Infusion-Related Adverse Events to Chemotherapy and Monoclonal Antibodies, <https://www.albertahealthservices.ca/assets/info/hp/cancer/if-hp-cancer-guide-supp019-infusionreactions.pdf>
- 19 Extravasation: Inadvertent infiltration of vesicant solution or medication into surrounding tissue; rated by a standard tool or definition. Phlebitis: Inflammation of a vein; may be accompanied by pain/tenderness, erythema, edema, purulence, and/or palpable venous cord; rated by a standard scale or definition. Health Line International Corp. website, [https://hlic.net/infiltration-and-extravasation/#:~:text=Phlebitis%3A%20Inflammation%20of%20a%20vein,a%20blood%20clot%20\(thrombus\).](https://hlic.net/infiltration-and-extravasation/#:~:text=Phlebitis%3A%20Inflammation%20of%20a%20vein,a%20blood%20clot%20(thrombus).)
- 20 <https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery>
- 21 WHO Surgical Safety Checklist <https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery/tool-and-resources>
- 22 European Commission, Press Release IP/21/342, 3 February 2021, Europe's Beating Cancer Plan: A new EU approach to prevention, treatment and care, [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_342](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342)
- 23 European Commission, COM(2021) 44, 3 February 2021, Europe's Beating Cancer Plan, [https://ec.europa.eu/health/sites/default/files/non\\_communicable\\_diseases/docs/eu\\_cancer-plan\\_en.pdf](https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf)
- 24 European Commission, Press Release IP/20/2041, 11 November 2020, Building a European Health Union: Stronger crisis preparedness and response for Europe, [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_2041](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041)
- 25 Smith, Jonathan, et al. "Europe's Beating Cancer Plan and EU Mission on Cancer Add Real Momentum to Tackle the Entire Disease Pathway." Horizon Magazine, 15 Feb. 2022, <https://ec.europa.eu/research-and-innovation/en/horizon-magazine/europes-beating-cancer-plan-and-eu-mission-cancer-add-real-momentum-tackle-entire-disease-pathway>.





- 26 Silva, Flávia Feliciano, et al. "Hospitalizations and Length of Stay of Cancer Patients: A Cohort Study in the Brazilian Public Health System." PLOS ONE, Public Library of Science, May 2020, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0233293>
- 27 Batista A, Polidori P, Kohl S, Position paper on patient safety, European Journal of Hospital Pharmacy, 2021;28:129-132.
- 28 Hughes, C.M. Medication Non-Adherence in the Elderly. *Drugs Aging* 21, 793–811 (2004).
- 29 Bell JS, Airaksinen MS, Lyles A, Chen TF, Aslani P. Concordance is not synonymous with compliance or adherence. *Br J Clin Pharmacol.* 2007;64(5):710-713.
- 30 The European Collaborative Action on Medication Errors and Traceability (ECAMET) <https://ecamet.eu/>
- 31 European Medicines Agency, 2013, EMA/35980/2013, Medication-errors workshop, [https://www.ema.europa.eu/en/documents/agenda/agenda-medication-errors-workshop-final-programme\\_en.pdf](https://www.ema.europa.eu/en/documents/agenda/agenda-medication-errors-workshop-final-programme_en.pdf)
- 32 Elliott R. A. et al., Policy Research Unit in Economic Evaluation of Health & Care Interventions (EEPRU), 2018, Prevalence and Economic Burden of Medication Errors in the NHS in England, <http://www.eepru.org.uk/wp-content/uploads/2020/03/medication-error-report-edited-27032020.pdf>
- 33 Elliott RA, Camacho E, Jankovic D, et al, 2021, Economic analysis of the prevalence and clinical and economic burden of medication error in England *BMJ Quality & Safety*; 30:96-105.
- 34 Ministerio de Sanidad, Servicios Sociales e Igualdad, 2015, Patient Safety Strategy for the National Health System, <https://seguridaddelpaciente.es/resources/documentos/2015/Spanish-Patient-Safety-Strategy-2015-2020.pdf>
- 35 WHO, March 2017, WHO launches global effort to halve medication-related errors in 5 years, <https://www.who.int/news/item/29-03-2017-who-launches-global-effort-to-halve-medication-related-errors-in-5-years>
- 36 Hodkinson A, Tyler N, Ashcroft DM, et al. 2020. Preventable medication harm across healthcare settings: a systematic review and meta-analysis. *BMC Med.*; 18(1):313. doi:10.1186/s12916-020-01774-9
- 37 American Society of Hospital Pharmacists, Medication Safety – Guidelines, ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-chemotherapy-biotherapy.pdf>
- 38 Saul N Weingart, MD, et. al., 2018, Chemotherapy medication errors, [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(18\)30094-9/fulltext#:~:text=Chemotherapy%20errors%20occur%20at%20a,particular%20area%20of%20growing%20risk](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30094-9/fulltext#:~:text=Chemotherapy%20errors%20occur%20at%20a,particular%20area%20of%20growing%20risk).
- 39 Banasser G., Karpow C., et. Al., 2017, Medication Errors in Outpatient Hematology and Oncology Clinics, [http://patientsafety.pa.gov/ADVISORIES/documents/201712\\_oncology.pdf](http://patientsafety.pa.gov/ADVISORIES/documents/201712_oncology.pdf)
- 40 "Preventing Medication Errors with Chemotherapy and Biotherapy." American Society of Health-System Pharmacists, 2015, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-chemotherapy-biotherapy.pdf>
- 41 Please refer to reference 36.
- 42 American Society of Hospital Pharmacists, Medication Safety – Guidelines, ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-chemotherapy-biotherapy.pdf>
- 43 Second and Third Victim Research Group, 2015, Recommendations for providing an appropriate response when patients experience an adverse event with support for healthcare's second and third victims, [http://www.segundasvictimas.es/data/documentos/segundas\\_victimas\\_maquetacion\\_ingles\\_impresion\\_v06.pdf](http://www.segundasvictimas.es/data/documentos/segundas_victimas_maquetacion_ingles_impresion_v06.pdf)
- 44 Please refer to reference 32.
- 45 Research by Ipsos MORI on behalf of the European Biosafety Network, 2022 – Mental and psychosocial health of nurses in Europe <https://www.europeanbiosafetynetwork.eu/mental-and-psychosocial-health-in-healthcare-preventing-medication-errors-and-adverse-events-and-disorders-in-healthcare-workers/>
- 46 Buchan, J., Catton, H., Shaffer, F. A., (January 2022) - Sustain and Retain in 2022 and Beyond: The global nursing workforce and the COVID-19 pandemic <https://www.icn.ch/system/files/2022-01/Sustain%20and%20Retain%20in%202022%20and%20Beyond-%20The%20global%20nursing%20workforce%20and%20the%20COVID-19%20pandemic.pdf>
- 47 Dall'Ora C, Saville C (2021) Burnout in nursing: what have we learnt and what is still unknown? *Nursing Times* [online]; 117: 2, 43-44.
- 48 S D Scott et al, The natural history of recovery for the healthcare provider "second victim" after adverse patient events, *BMJ Quality & Safety*: Volume 18 Issue 5, 2009. <https://qualitysafety.bmj.com/content/18/5/325>
- 49 Institute for Safe Medication Practices, 2020, Medication Errors: the year in review 2019 [https://www.pharmacypracticenews.com/download/MedErrors\\_PPNSE1220\\_WM.pdf](https://www.pharmacypracticenews.com/download/MedErrors_PPNSE1220_WM.pdf)
- 50 Radley DC, et al. Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. *J Am Med Inform Assoc.* 2013 May 1;20(3):470-6.
- 51 Romero M, et al. Human error, patient safety and medical training. *Educación Médica.* 2019;20(1):169-174.
- 52 Jessurun JG, Hunfeld MGM, de Roo M, et. al., Prevalence and determinants of medication administration errors in clinical wards: A two-centre prospective observational study. *Journal of Clinical Nursing*, 00, 1–13, 2022.
- 53 Cruz Martín Delgado M, Trenado Álvarez J, Sanz López E, et. al., op. cit.
- 54 Batson S, et al. Automated compounding technology and workflow solutions for the preparation of chemotherapy: a systematic review. *Eur J Hosp Pharm.* 2020 Nov;27(6):330-336.
- 55 Truitt E, Thompson R, Blazey-Martin D, NiSai D, Salem D. Effect of the Implementation of Barcode Technology and an Electronic Medication Administration Record on Adverse Drug Events. *Hosp Pharm.* 2016;51(6):474-483. doi:10.1310/hpj5106-474
- 56 Please refer to reference 31.
- 57 Bryony Dean Franklin et al. - The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study; *Qual Saf Healthcare* 2007;16:279–284. doi: 10.1136/qshc.2006.019497

- 58 Shi, Lan-Pin et al - Development and application of a closed-loop medication administration system in University of Hongkong-Shenzhen Hospital; 10.2478/fo-n-2018-0014, *Frontiers of Nursing*. [https://www.researchgate.net/publication/327036363\\_Development\\_and\\_application\\_of\\_a\\_closed-loop\\_medication\\_administration\\_system\\_in\\_University\\_of\\_Hongkong-Shenzhen\\_Hospital](https://www.researchgate.net/publication/327036363_Development_and_application_of_a_closed-loop_medication_administration_system_in_University_of_Hongkong-Shenzhen_Hospital)
- 59 NCIS - HSE.ie official website <https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/projects/>
- 60 The European Collaborative Action on Medication Errors and Traceability (ECAMET) is a patient safety initiative developed by a group of health professionals and stakeholders. They work together to tackle the issue of medication errors through the implementation of a Pan-European survey which will act as a catalyst to identify best practices and thus stimulate innovation in the hospital setting via proven digital processes and internal dynamic behavioural change.
- 61 WHITE PAPER March 2022 – A 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, available at <https://ecamet.eu/wp-content/uploads/2022/03/ECAMET-White-Paper-Call-to-Action-March-2022-v1.pdf>
- 62 <https://ecamet.eu/ecamet-white-paper/>
- 63 If you would like to learn more, please do not hesitate to contact Mr. Mike Isles, Director of the EAASM at [mike.isles@eaasm.eu](mailto:mike.isles@eaasm.eu)
- 64 Please refer to reference 14.
- 65 European Centre for Disease Prevention and Control. Point Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in European Acute Care Hospitals 2011-2012; 2013.
- 66 European Centre for Disease Prevention and Control. Annual Epidemiological Report on Communicable Diseases in Europe 2008: Report on the State of Communicable Diseases in the EU and EEA/EFTA Countries; 2008.
- 67 European Centre for Disease Prevention and Control. 2013, Point Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in European Acute Care Hospitals 2011-2012.
- 68 ECDC Facts about surgical site infections [https://www.ecdc.europa.eu/en/surgical-site-infections/facts#:~:text=The%20burden%20of%20SSIs%20in,%2D2012%20\(ECDC%20PPS%20\)](https://www.ecdc.europa.eu/en/surgical-site-infections/facts#:~:text=The%20burden%20of%20SSIs%20in,%2D2012%20(ECDC%20PPS%20)).
- 69 Alessandro Cassini et al., 2016, "Burden of Six Healthcare-Associated Infections on European Population Health: Estimating Incidence-Based Disability-Adjusted Life Years through a Population Prevalence-Based Modelling Study", <https://doi.org/10.1371/journal.pmed.1002150>
- 70 Barber G R, Brown A E (1993) Surveillance of surgical wound infections in cancer patients. *Cancer Pract*;1(1):72-6. PMID: 8324533. <https://pubmed.ncbi.nlm.nih.gov/8324533/>
- 71 WHO (2018) Global guidelines for the prevention of surgical site infection, <https://apps.who.int/iris/handle/10665/277399>
- 72 Surgical site infections: prevention and treatment. <https://www.nice.org.uk/guidance/ng125/resources/surgical-site-infections-prevention-and-treatment-pdf-66141660564421>
- 73 Clinical Practice Guideline for the Patient Safety at Surgery Setting <https://www.nice.org.uk/guidance/ng125/resources/surgical-site-infections-prevention-and-treatment-pdf-66141660564421>
- 74 Systematic review and evidence based guidance on perioperative antibiotic prophylaxis. <https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/Perioperative%20antibiotic%20prophylaxis%20-%20June%202013.pdf>
- 75 Patient Safety Forward with Four. <https://www.patientsafetyinstitute.ca/en/About/Documents/CPSI%20Annual%20Review%202015.pdf>
- 76 Health First Europe (2020) Insight Report. Identifying the gaps between evidence and practice in the prevention of surgical site infections. <https://healthfirsteurope.eu/wp-content/uploads/2020/11/A3A4-48pp-Booklet-Spreads-1.pdf>
- 77 Health First Europe is a non-profit, non-commercial alliance of patients, healthcare workers, academics, healthcare experts and the medical technology industry. We are joining forces to transform health care through innovative solutions. Since we believe that every European citizen should benefit from the best medical treatments available, we aim to ensure that equitable access to modern, innovative and reliable healthcare solutions is seen as a vital investment in the future of Europe.
- 78 Badia, J. et al. (2017), "Impact of surgical site infection on health care costs and patient outcomes: a systematic review in six European countries", *J Hosp Infect* 2017; 96: 1-15, <http://dx.doi.org/10.1016/j.jhin.2017.03.004>
- 79 Please refer to reference 43.
- 80 Sullivan R, Alatisse OI, Anderson BO, Audisio R, Autier P, Aggarwal A, Balch C, Brennan MF, Dare A, D'Cruz A, Eggermont AM, Fleming K, Gueye SM, Hagander L, Herrera CA, Holmer H, Ilbawi AM, Jarnheimer A, Ji JF, Kingham TP, Liberman J, Leather AJ, Meara JG, Mukhopadhyay S, Murthy SS, Omar S, Parham GP, Pramesh CS, Riviello R, Rodin D, Santini L, Shrikhande SV, Shrimel M, Thomas R, Tsunoda AT, van de Velde C, Veronesi U, Vijaykumar DK, Watters D, Wang S, Wu YL, Zeiton M, Purushotham A. Global cancer surgery: delivering safe, affordable, and timely cancer surgery. *Lancet Oncol*. 2015 Sep;16(11):1193-224. doi: 10.1016/S1470-2045(15)00223-5. PMID: 26427363
- 81 Sullivan R, Alatisse OI, Anderson BO, Audisio R, Autier P, Aggarwal A, Balch C, Brennan MF, Dare A, D'Cruz A, Eggermont AM, Fleming K, Gueye SM, Hagander L, Herrera CA, Holmer H, Ilbawi AM, Jarnheimer A, Ji JF, Kingham TP, Liberman J, Leather AJ, Meara JG, Mukhopadhyay S, Murthy SS, Omar S, Parham GP, Pramesh CS, Riviello R, Rodin D, Santini L, Shrikhande SV, Shrimel M, Thomas R, Tsunoda AT, van de Velde C, Veronesi U, Vijaykumar DK, Watters D, Wang S, Wu YL, Zeiton M, Purushotham A. Global cancer surgery: delivering safe, affordable, and timely cancer surgery. *Lancet Oncol*. 2015 Sep;16(11):1193-224. doi: 10.1016/S1470-2045(15)00223-5. PMID: 26427363
- 82 <https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery>
- 83 2009 WHO Surgical Safety Checklist [http://apps.who.int/iris/bitstream/handle/10665/44186/9789241598590\\_eng\\_Checklist.pdf?sequence=2](http://apps.who.int/iris/bitstream/handle/10665/44186/9789241598590_eng_Checklist.pdf?sequence=2)
- 84 Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009 Jan 29;360(5):491-9. doi: 10.1056/NEJMs0810119. Epub 2009 Jan 14. PMID: 19144931
- 85 M. Buissonniere. Checking in on the checklist: uptake, impact, and opportunities for the next decade; Available at: <https://www.lifebox.org/wp-content/uploads/2020/01/Checking-In-On-the-Checklist-web.pdf>

- 86 Sotto KT, Burian BK, Brindle ME. Impact of the WHO Surgical Safety Checklist Relative to Its Design and Intended Use: A Systematic Review and Meta-Analysis. *J Am Coll Surg*. 2021 Dec;233(6):794-809.e8. doi: 10.1016/j.jamcollsurg.2021.08.692. Epub 2021 Sep 27. PMID: 34592406.)
- 87 <https://www.sciencedirect.com/topics/medicine-and-dentistry/intubation>
- 88 Chopra V, et al. 2013. Risk of venous thromboembolism associated with peripherally inserted central catheters: a systematic review and meta-analysis. *Lancet*; 382:311–25.
- 89 Dreesen M, Foulon V, Spriet J, Goossens GA, Hiele M, De PL, et al. (2013) Epidemiology of catheter-related infections in adult patients receiving home parenteral nutrition: a systematic review. *Clin Nutr*; 32:16–26.
- 90 Cotogni P, Barbero C, Garrino C, Degiorgis C, Mussa B, De FA, et al. 2015, Peripherally inserted central catheters in non-hospitalized cancer patients: 5-year results of a prospective study. *Support Care Cancer*; 23:403–9.
- 91 A role for peripherally inserted central venous catheters in the prevention of catheter-related blood stream infections in patients with hematological malignancies; 2014 10.1007/s12185-014-1677-9
- 92 Magallón-Pedraza, I., Pérez-Altozano, J., Virizueta Echaburu, J.A. et al., ECO-SEOM-SEEO (2020) Safety recommendations guideline for cancer patients receiving intravenous therapy. *Clin Transl Oncol* 22, 2049–2060. <https://doi.org/10.1007/s12094-020-02347-1>
- 93 Durán-Briones G. 2014. Accesos vasculares en el paciente oncológico. *Rev Mex Anest*; 37 (Suppl 1): S28–S32.
- 94 American Cancer Society. Catéteres venosos centrales. Available at <https://www.cancer.org/treatment.ht>
- 95 Carrero Caballero MC, et al. 2014, Medial venous catheter or midline (MVC). *Rev Enferm*;37 (1): 36–41.
- 96 Bertoglio S, et al. 2017, Improving outcomes of short peripheral vascular access in oncology and chemotherapy administration. *J Vasc Access*;18(2):89–96.
- 97 Pan M, et al., 2019, Nursing interventions to reduce peripherally inserted central catheter occlusion for cancer patients: a systematic review of literature. *Cancer Nurs.*, 42(6): E49–E58.
- 98 Increasing adherence to CAUTI guidelines: Recommendations from existing evidence, op. cit.
- 99 ECDC, 2016, Field Epidemiology Manual Wiki, <https://wiki.ecdc.europa.eu/fem/Pages/CAUTI.aspx>.
- 100 Please refer to the above reference.
- 101 Srisatidnarakul S., Tarver C., 2021, Reducing Catheter-associated Urinary-tract Infections in Cancer Patients: A Nurse and Infection Preventionist-led Interprofessional Program, *AJIC*, vol. 49(6), [https://www.ajicjournal.org/article/S0196-6553\(21\)00245-5/fulltext](https://www.ajicjournal.org/article/S0196-6553(21)00245-5/fulltext)
- 102 Increasing adherence to CAUTI guidelines: recommendations from existing evidence, 2021, <https://www.eusaferhealthcare.eu/wp-content/uploads/Increasing-adherence-to-CAUTI-guidelines-recommendations-from-existing-evidence.pdf>
- 103 Catheterisation Indwelling catheters in adults – Urethral and Suprapubic, <https://nurses.uroweb.org/guideline/catheterisation-indwelling-catheters-in-adults-urethral-and-suprapubic/>
- 104 Increasing adherence to CAUTI guidelines: Recommendations from existing evidence, op. cit.
- 105 World Health Organisation, May 2018, Advanced Infection Prevention and Control Training – Student Handbook on Prevention of catheter-associated urinary tract infection (CAUTI)
- 106 Spanish Association of Urology (AEU) and Foundation for the Investigation of Urology (FIU), 2020, Evidence-Based Recommendation on the Prevention of Urinary Tract Infections Related to the Use of Urinary Catheters.
- 107 Study at Sherwood Forest Hospital, *British Journal of Nursing*, 2019, Vol 28, No 1
- 108 European Network for Safer Healthcare (ENSH), 2021, Report “Increasing adherence to CAUTI guidelines recommendations from existing evidence” <https://www.eusaferhealthcare.eu/2021/06/30/increasing-adherence-to-cauti-guidelines-recommendations-from-existing-evidence-2/>
- 109 The European Association of Urology Nurses official website <https://nurses.uroweb.org/>
- 110 Please refer to reference 31.
- 111 Fundación para la Excelencia y Calidad en Oncología (ECO), la Sociedad Española de Oncología Médica (SEOM) y la Sociedad Española de Enfermería Oncológica (SEEO), 2020, IniciatIvas. Seguridad del paciente oncológico en la terapia intravenosa: situación y recomendaciones [https://drive.google.com/file/d/1U1zDsb5B3PDA2f5\\_dP90LhuQIoCGCYhT/view](https://drive.google.com/file/d/1U1zDsb5B3PDA2f5_dP90LhuQIoCGCYhT/view)
- 112 Please refer to the above reference.
- 113 [https://www.oeci.eu/accreditation/Page.aspx?name=OECL\\_STANDARDS#:~:text=The%20OECL%20accreditation%20programme%20is,tool\)%20for%20self%20assessment](https://www.oeci.eu/accreditation/Page.aspx?name=OECL_STANDARDS#:~:text=The%20OECL%20accreditation%20programme%20is,tool)%20for%20self%20assessment)
- 114 <http://www.ecc-cert.org/certification-system/document-collection/>
- 115 <https://www.eusoma.org/en/recommendations/breast-centre-requirements/1-148-1->
- 116 <http://ecc-cert.org/european-cancer-centre/>
- 117 <https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative>
- 118 Please refer to the above reference.







# ABOUT THE EUROPEAN NETWORK FOR SAFER HEALTHCARE

The European Network for Safer Healthcare is an informal group of health stakeholders working together to ensure patient and healthcare workforce safety is in the EU policy limelight.

Its members include Health First Europe, the European Federation of Clinical Chemistry and Laboratory Medicine, the European Health Management Association, the European Specialist Nurses Organisation, the European Society for Emergency Medicine, the Global Alliance for Infections in Surgery, the Global Sepsis Alliance, the International Alliance of Patients' Organisations, the World Alliance Against Antibiotic Resistance, the European Union of Private Hospitals and the European Network to Promote Infection Prevention for Patient Safety.

The network's mission is to represent a constructive, vigilant, and responsive third-party voice to support European and national initiatives aimed at enshrining best practices in patient safety in the EU.

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