PATHWAYS FOR FOSTERING PATIENT SAFETY ACROSS EUROPE

LEARNING FROM REGIONAL SUCCESS STORIES

A follow up report from the collaborative discussion between policy-makers, patients, healthcare professionals and other stakeholders on the future of patient safety in Europe.

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GLOSSARY OF TERMS

HFE – Health First Europe

OECD – Organisation for Economic Co-operation and Development

ECDC – European Centre for Disease Prevention and Control

WHO – World Health Organization

HAI – Healthcare-Associated Infection

AMR – Antimicrobial Resistance

IAPO - International Alliance of Patients' Organisations

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FOREWORDS

MEP ISTVÁN UJHELYI

Member of the European Parliament (S&D, Hungary)

The issues of patient safety and healthcare more generally have often struggled to attract sufficient attention at the European level and previously have been left largely to the discretion of national and regional authorities. The COVID-19 pandemic challenged the viability of such compartmentalisation. The crisis once again demonstrates the central role of public health for economic and human development as well as the need to address this challenge with a common European approach.

The currently existing imbalances and disparities in the European healthcare systems are untenable and have been further exasperated by the crisis. It is unacceptable that patients in Hungary face three times higher risk of acquiring hospital-associated infections in the course of their treatment than their counterparts in Germany. The healthcare outcomes of Europeans cannot be dependent on their country or place of residence. The major disparities in the funding, operation and standard of healthcare across the Member States of the European Union and even across different regions needs to be addressed. We need a European Health Union with minimum quality standards for public healthcare systems across Europe. The EU4Health programme provides an important first step towards fostering patient safety and advancing the healthcare agenda in a truly European fashion.

Given the complexity and importance of this topic it is crucial that we adopt a collaborative approach and we learn from each other's successes and failures. This debate and others like it are essential in this process.

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FOREWORDS

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As patients we always expect our interactions with the healthcare system to be safe but unfortunately this is not always the case even in advanced healthcare systems such as those in the European Union. In fact, patient safety incidents remain concerningly common even in the most highly developed European countries. The human cost of such lapses is profound and largely avoidable. This is why we at the International Alliance of Patients' Organisations (IAPO) have put the issues of patient safety and quality of care at the heart of our work.

European policy-makers, national governments and regional authorities have a duty to recognise patient safety as a priority in health policy and work together in order to make healthcare in Europe safe and reliable for all Europeans. The need for swift action has never been clearer than in the midst of the global COVID-19 pandemic. The crisis has overwhelmed many healthcare systems across the world, including in Europe, threatening to reverse important progress made over the past decades. To tackle this, more than ever we need a truly unified effort to ensure that best practices are upscaled and adopted rapidly across European hospitals and that patients benefit from the highest and safest standard of care available regardless of their location.

To this end, we call on the European Council to develop a new set of recommendations on patient safety in order to build on the work done since the publication of the last recommendations in 2009. A new set of recommendations taking into account the knowledge accumulated over the past decade is necessary to give the issue of patient safety a new impetus and boost efforts for reducing and mitigating preventable healthcare-related harm.

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INTRODUCTION

This report summarises the main takeaways from a virtual roundtable discussion on patient safety best practices which took place digitally on 8 September 2020. The event brought together healthcare authorities, academics, patients, healthcare providers and workers as well as EU policy-makers and focused on patient safety success stories from across Europe's regions and local governments. The discussion during the webinar focused primarily on best practices for mitigating medication error and preventing healthcare-associated infections (HAIs) and antimicrobial resistance (AMR) as well as on reporting systems for adverse events although it was recognised that those address only some of the most common sources of patient harm. The purpose of the discussion and this resulting paper is to highlight the value and potential of innovation for the advancement of patient safety and quality of care in European healthcare settings. European regions have many success stories to share and implement across borders. The examples below are just a few of the many best practices worth sharing.

WHAT IS PATIENT SAFETY AND WHY DOES IT MATTER?

Patient safety refers broadly to "the reduction of the 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." [1] Patient harm can be caused by a range of adverse events both preventable and non-preventable. Such patient safety lapses can result from issues including HAIs due to growing anti-microbial resistance or poor sanitation protocols, medication errors, diagnostic errors, patient falls, venous thromboembolism or death during interventions with otherwise low mortality rates.

Patient safety remains a challenge for healthcare systems across the globe, including in wealthy countries such as those in the European Union.

[1] World Health Organization (WHO), Technical report on Conceptual Framework for the International Classification for Patient Safety, January 2010, pp. 15-16.
Accessible from: https://www.who.int/patientsafety/implementation/taxonomy/ICPS-report/en/

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According to the World Health Organization (WHO), patient harm is the 14th leading cause of disease burden globally, alongside diseases such as malaria and tuberculosis. In some European countries, patient harm imposes as big a burden as chronic diseases such as multiple sclerosis or some types of cancers [1]. Currently, medical errors and other healthcare-related adverse events occur in 8% to 12% of the hospitalisations in Europe [2]. 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[3]. Lapses in safety not only result in significant suffering for patients and their families but impose a considerable and avoidable financial burden on European healthcare budgets and beyond. 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.

> *ECDC now includes structure and process indicators of infection prevention and control and antimicrobial stewardship in its protocols for surveillance of healthcare-associated infections (HAIs). Monitoring and benchmarking of countries, hospitals and long-term care facilities on these indicators should contribute to improving practices, and subsequently reducing HAIs and antimicrobial resistance (AMR) in Europe.*

Dominique Monnet, ECDC

[1] OECD, The Economics of Patient Safety: Strengthening a value-based approach to reducing patient harm at national level, March 2017, p. 47.
Accessible from: http://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety_5a9858cd-en;jsessionid=6gui8p7gjfrmp.x-oecd-live-02

[2] OECD, The Economics of Patient Safety: From analysis to action, October 2020, p.15. Accessible from: https://www.oecd.org/health/health-systems/Economics-of-Patient-Safety-October-2020.pdf

[3] 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 from: https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2018.23.46.1800516#abstract_content

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Estimates suggest that each euro spent on measures to tackle AMR alone can be converted into 2.5 euros of savings for the healthcare system[1]. Beyond the direct costs, however, patient safety lapses reduce patients' capacity and contribute to considerable loss of productivity.

Such data highlights the crucial importance of promoting patient safety in European hospitals. To this end, various initiatives have been launched including the 2017 WHO Resolution on Sepsis [2] and the 2020 WHO campaign "SAVE LIVES: Clean Your Hands", raising awareness of the role of appropriate hygiene practices in improving patient safety. At the European level, the Council published its Recommendations on Patient Safety in 2009 [3] and last year issued additional Conclusions on the next steps in combatting AMR [4], an issue strongly associated with patient safety.

OBSTACLES TO PATIENT SAFETY IN EUROPE

One of the most considerable obstacles to patient safety in Europe remains the fact that regulatory responses and protocols vary considerably across Member States as well as across individual regions and even individual hospitals. While patient safety remains primarily the responsibility of Member States, with the Commission having only a supporting role, the European Union has a vital role in encouraging and facilitating cooperation as well as the exchange of best practices and lessons learned as part of the effort to ensure high-quality and standardised healthcare for all citizens of the Union.

Lawmakers and healthcare professionals need to broaden their understanding of patient safety and the many issues associated with it as well as of the potential of innovation and digital solutions in preventing harm in order to advance the quality of care in Europe's hospitals.

[1] OECD and ECDC, Antimicrobial Resistance Tackling the Burden in the European Union- Briefing note, 2019, p.16. Accessed from: http://www.oecd.org/health/health-systems/AMR-Tackling-the-Burden-in-the-EU-OECD-ECDC-Briefing-Note-2019.pdf

[2] WHO, Improving the prevention, diagnosis and clinical management of sepsis, May 2017. Accessible from: https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R7-en.pdf?ua=1

[3] Council of the EU, Council recommendations on patient safety, including the prevention and control of healthcare associated infections, June 2009.
Accessed from: https://ec.europa.eu/jrc/sites/jrcsh/files/2_June_2009%20patient%20safety.pdf

[4] Council of the EU, Council conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance, June 2019. Accessed from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019XG0625(01)&from=EN

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This need has never been more pressing than in the face of one of the biggest challenges for European and global healthcare systems to date, namely the COVID-19 pandemic. The crisis has once again demonstrated the paramount importance of patient safety protocols for infection prevention and control and the need for timely and efficient implementation of best practices for preventing harm and saving lives.

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PATIENT SAFETY BEST PRACTICES: CASE STUDIES FROM ACROSS THE EU

The September 2020 roundtable discussion featured three key case studies on patient safety best practices tackling the issues of medication errors, HAIs and AMR, respectively, as well as the utility of adverse events reporting systems for reducing patient safety lapses. Those case studies represent just a snapshot of the possible causes of patient harm and some strategies for addressing them.

The aim of this report is not to present a comprehensive catalogue of all possible improvements in the European healthcare system but rather to illustrate the huge potential of innovation and the promotion of best practices for improving the quality of care to the benefit of both patients and society as a whole. A truly comprehensive approach towards improving patient safety would need to encompass a wider range of issues.

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CASE STUDY 1

HYGIENE IN HEALTHCARE SETTINGS

The first case study was introduced by **Professor Elisabetta Caselli** from the University of Ferrara in Italy and focused on innovative hospital hygiene technologies. Built environments are recognised to have their own microbiome, and more confined environments, such as hospitals, have more "anthropic" and drug-resistant microbiomes compared with unrestricted environments[1].

This becomes crucial for hospitalised patients, since the hospital microbiome can transmit HAIs, which currently affect up to 4 million patients per year in the EU alone, leading to 33,000 deaths and 1.1 billion EUR of associated sanitary costs. Additionally, the antimicrobial resistance (AMR) of HAI-associated pathogens contributes to HAI morbidity and mortality, as most such pathogens are multi-drug or even pan-drug resistant due to the selective pressure exerted by disinfectants and antibiotics. Notably, since conventional chemical-based sanitation could in some cases favour AMR selection, the WHO recently warned of the potential risk of further worsening the growth of AMR due to the significant increase in the use of disinfectants and antibiotics during the COVID-19 pandemic[2].

In addition, the inability of traditional sanitation protocols to prevent recontamination as well as their negative environmental impact makes them a suboptimal tool for preventing HAIs in the hospital setting. The use of innovative sanitation approaches could, however, offer a viable alternative to traditional chemical sanitation tools. Such innovative approaches are based on the use of ecologically sustainable detergents containing spores of probiotic Bacilli (PCHS, Probiotic Cleaning Hygiene System).

[1] The National Academies of Sciences, Engineering and Medicine, Microbiomes of the Built Environment, 2017; Mahnert, A., Moissl-Eichinger, C., Zojer, M. et al. Man-made microbial resistances in built environments. Nature Communications 10, 968 (2019).

[2] The Guardian, WHO warns overuse of antibiotics for Covid-19 will cause more deaths, June 2020.

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Early results suggest that such solutions provide for a stable and reliable remodulation of the hospital microbiome. Inspired by the microbiome balance principles and competitive exclusion mechanism used in probiotic therapy, this approach is shown to decrease pathogens on treated surfaces up to 80% more successfully than conventional disinfectants. This results in an up to 99% drop in the AMR originally present upon treatment. Importantly, such remodulation of the hospital microbiome is shown to halve the risk of acquiring a HAI for hospitalised patients (-52%). It also contributes to a substantial reduction of HAI-associated drug consumption (-60%) as well as of overall costs (-75%)[1].

The data is promising and could open new perspectives in the fight against HAIs, introducing the possibility of preventing them by controlling the colonisation and spread of AMR pathogens in the hospital environment. The relevance of such innovative solutions is especially significant in order to mitigate the impacts of the current pandemic but also to avoid eventual future pandemics due to resistant bacteria.

LESSON LEARNED

High hygiene standards are essential for preventing the colonisation and spread of bacteria in the healthcare setting but traditional disinfectants are not necessarily the most effective means of achieving the highest hygiene standards. The use of innovative sanitation approaches could offer a viable alternative to traditional chemical sanitation tools. Together with traditional hygiene measures such as hand washing, innovative hospital hygiene solutions have the potential to substantially reduce the chance of acquiring HAIs and thus dramatically improve patient safety.

[1] Caselli E, Arnoldo L, Rognoni C, D'Accolti M, Soffritti I, Lanzoni L, Bisi M, Volta A, Tarricone R, Brusaferro S, Mazzacane S, Impact of a probiotic-based hospital sanitation on antimicrobial resistance and HAI-associated antimicrobial consumption and costs: a multicenter study, DovePress - Infection and Drug Resistance 2019:12 501–510.

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CASE STUDY 2

INFORMATION TECHNOLOGIES & MEDICATION SAFETY

Professor Pascal Bonnabry, Head of Pharmacy at Geneva University Hospital in Switzerland, discussed the problem of medication errors and the potential of information technology (IT) solutions to mitigate this issue.

Medication errors refer to any errors that occur in the medication delivery process, from prescription to administration. Alongside HAIs and AMR, the issue of medication errors represents one of the most common sources of patient harm, accounting for up to 25% of preventable adverse events recorded in the healthcare setting. According to a recent meta-analysis, one avoidable adverse event linked to medication occurs once per every 66 hospitalised patients. One of every 550 hospitalised patients experiences a severe medication error event[1]. Harm resulting from such medication errors is associated with significant costs both in terms of patient suffering and healthcare spending.

Tackling the problem of medication error requires a multi-dimensional approach integrating three main aspects of healthcare provision, namely Processes, Persons (i.e. interprofessional collaboration, patient empowerment) and Products (i.e. ready-to-use injectables, Good Manufacturing Practices (GMP) facilities in hospitals). Already existing IT solutions based on digitalisation, automation and robotisation have the potential to improve safety through significantly limiting human errors. They can also make processes more reliable while boosting traceability and efficiency, allowing hospitals to do more with less staff while freeing up valuable time for patient care.

[1] Panagioti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, Bower P, Campbell S, Haneef R, Avery AJ, Ashcroft DM. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. BMJ. July 2019.

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Studies at the Geneva University Hospital show that robotised drug distribution at the central pharmacy can reduce distribution errors from 0.93% to 0.13% (-86%). Similarly, the implementation of automated dispensing cabinets in wards has been shown to decrease dispensing errors from 5.0% to 1.1% (-78%) in comparison with the traditional manual method of picking drugs in stocks. Overall, such solutions can reduce error incidents by as much as 60% from today's levels, thus significantly reducing patient suffering as well as healthcare spending.

Given the high return on investment of the deployment of automation and robotisation technologies, hospitals must be encouraged to invest in innovative systems despite potentially high up-front costs. It should, however, also be remembered that the deployment of such technologies alone is insufficient to completely eradicate patient harm resulting from medication errors and should thus be accompanied by robust strategies for risk reduction and management. The need for addressing medication error and developing safe and efficient process organisation strategies in the healthcare setting is particularly crucial in a period of crisis and system overload as demonstrated by the current COVID-19 pandemic.

LESSON LEARNED

Automation, robotisation and other innovative solutions implemented in the process of medication distribution in the hospital environment can substantially reduce opportunities for human errors in medication delivery from prescription to administration. While none of those solutions can eradicate the problem of medication error alone, they can substantially reduce patient suffering and unnecessary healthcare costs when implemented as part of a comprehensive risk reduction strategy.

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CASE STUDY 3

REPORTING SYSTEMS
IN EU PRIVATE HOSPITALS

The third case study, submitted by **Dr. Paul Garassus,** President of the European Union of Private Hospitals (UEHP), covers the importance of appropriate systems for risk and information management and "adverse event" reporting for preventing patient safety lapses. The governance systems for incident reporting put in place by the German private hospital groups Sana Kliniken AG and Asklepios Kliniken represent a best practice which, if implemented more broadly across other healthcare institutions, could considerably boost the quality of care and reduce the costs of patient harm.

In addition, as an umbrella organisation, UEHP advocates for a European collaboration to reduce adverse events or prevent cybersecurity risks in "Smart Hospitals". UEHP organises Clinical Risk Management Workshops for Patient Safety initiatives in order to facilitate discussions between medical teams and managers, promoting a positive attitude shared by the entire workforce. Without quality, no patient will trust healthcare settings, and financial incentives based on quality indicators by national governments must be developed to uptake related solutions for caregiver support. Reducing patient harm requires a multi-dimensional approach integrating three main aspects of healthcare provision, namely Processes, Persons (i.e. interprofessional collaboration, patient empowerment) and Products (i.e. ready-to-use injectables, Good Manufacturing Practices (GMP) facilities in hospitals). Already existing IT solutions based on digitalisation, automation and robotisation have the potential to improve safety through significantly limiting human errors. They can also make processes more reliable while boosting traceability and efficiency, allowing hospitals to do more with fewer staff while freeing up valuable time for patient care.

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On cybersecurity and "Smart Hospitals", the organisation has called for a European patient data storage across EU Member States. To reach this goal, strategic investment and quality-based financing using information systems and patient registers are required. Quality and patient safety demand new solutions. A European collaborative process is the right solution is to learn using relevant experience and to broadly share practical recommendations.

LESSON LEARNED

Overall, strategic investments in IT solutions are required to develop 'smart' hospitals and to improve efficiency in data and patient records exchange between health providers as well as between private and public hospitals. Such exchanges are essential for the provision of informed treatment and the establishment of a stronger safety culture in the healthcare setting. The deployment of such surveillance and reporting systems, however, should happen in parallel with the implementation of high standards for cybersecurity and data protection. In this context, addressing the issues of data management and storage is a central aspect of ensuring patient safety.

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CONCLUSIONS - THE WAY FOWARD

Unnecessary and preventable patient harm can occur from a broad spectrum of safety lapses ranging from inadequate hygiene standards to improper medication dispensation to human errors. This makes patient safety a complex problem and one that requires a comprehensive and multi-dimensional approach in order for it to be addressed effectively.

The identification, exchange and upscaling of existing knowledge and local best practices for addressing patient safety challenges in the healthcare setting are of crucial importance. Bolstering political and public awareness of the problem as well as of the significant cost-savings potential of improving patient safety is just the first step.

> " The European authorities should support the implementation of patient safety best practices by the competent local regulators. EU common standards and surveillance systems can ensure safe healthcare for all. "
>
> **Jean-Luc Vanraes**
>
> **Interregional Group on Health and Wellbeing**
> **European Committee of the Regions**

The current status quo, characterised by significant inconsistency of healthcare quality and patient safety protocols across individual hospitals and Member States, needs to be addressed through the development of an EU-wide public accreditation system with clear benchmarks and quality standards.

Institutions such as the Committee of the Regions have a central role to play in facilitating the exchange of best practices and advancing standardisation efforts but currently remain underutilised. Concerted EU support is necessary to equip Member States and regional authorities with the tools to ensure the highest quality of patient care in their local hospitals.

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CALL TO ACTION

The roundtable debate and the case studies presented outlined a number of effective strategies for ensuring high quality of care and patient safety standards across the European Union. In order to reap the full potential of existing best practices, we call on European, national and regional authorities and on all relevant stakeholders to:

① Facilitate the systematic exchange of best practices between healthcare providers both at national and European level in order to address the issue of fragmentation in the standards of care and to promote an improved safety culture in all healthcare settings.

② Strengthen the role of the ECDC and foster the implementation of ECDC guidelines and programmes on HAIs and AMR, while supporting the development of a truly European Surveillance System for AMR and HAIs, under the lead of the ECDC.

③ Value sanitation process as an essential resource in the fight against HAIs and AMR, especially those solutions with high standards to protect environment.

④ Prioritise strategic investments in automation, innovative solutions and IT systems while taking into account the long-term return on investment of such solutions as well as the up-front costs.

⑤ Ensure that each healthcare facility has in place a comprehensive strategy for a long-term reduction of medication errors and other sources of unnecessary patient harm.

⑥ Develop a European framework for consolidating and sharing science-based data regarding adverse events in order to ensure greater comparability and standardisation.

⑦ Ensure the implementation of robust cybersecurity and data protection standards as an essential aspect of the patient-centred deployment of technology-assisted patient safety solutions.

⑧ Developing European digitalization guidelines and programme for medication management in European hospitals to prevent medication errors, to use medicines more efficiently and address shortages.

⑨ Include patient safety in the Europe's Beating Cancer Plan and any relevant upcoming EU initiatives on healthcare.

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ABOUT HEALTH FIRST EUROPE

Since its inception in 2004, Health First Europe (HFE) has worked continuously to advocate for safety and quality of care in healthcare settings, particularly through our publication of recommendations and the collaborative partnership in the joint action on patient safety. In December 2017, under the Patronage of the Estonian Presidency of the Council of the EU, HFE launched the Declaration for Patient Safety, which called for a joint effort to prevent unnecessary harm to patients across Europe. We called upon health authorities, policy-makers, healthcare professionals, providers and patients to join hands to prevent unnecessary harm in healthcare by promoting safer health systems and higher quality standards for patient safety across Europe.

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