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A framework for integrated safety in safety-management systems in healthcare

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Abstract

Purpose – Notwithstanding increased patient safety initiatives, adverse events and their impact on those involved continue. The strategic approaches adopted to manage safety by other high-intensity, high-risk and complex industries, such as aviation, have led to an increase in the systems approach for safety management in healthcare organisations. Professional expertise from members of the European Researchers' Network for Second Victims (ERNST) highlighted that safety and the second victim phenomenon are interconnected across the healthcare ecosystem, extending beyond individual healthcare organisations.

Design/methodology/approach – Evidence from different sources, mainly the literature and practitioner professional expertise, was iteratively aggregated and analysed using theoretical systems-based approaches to conceptualise a framework for integrated safety in safety management systems in health.

Findings – A cross-sectional view of the healthcare organisation affected by adverse events was presented as a baseline. The whole system (system levels) approach, representing the healthcare system at the micro-, meso- and macro-level, adapting the model for integrated care, was then adopted. A safety-generating culture was considered to integrate and network across the levels of the healthcare system. The "system" (processes) approach, also considering external factors, was incorporated. This iterative conceptualisation led to a proposed framework for integrated safety. This framework was applied to systematically make recommendations for actions to support safety across the healthcare ecosystem.

Originality/value – Aggregation of evidence from the literature, together with expertise from professionals and iterative conceptualisation across models adopting the systems approach, led to a comprehensive framework for integrated safety in safety-management systems.

Keywords Evidence-based practice, Organizational development for effective clinical governance, Safety culture, Patient safety, Governance structures, Process mapping, Health law or regulation, Public health regulations, Adverse events or outcomes

Paper type Research article

Patient safety and the impact of adverse events

Despite increased efforts to prioritise patient safety within the healthcare agenda, the last 25 years demonstrate that current policies and practices for patient safety have not been sufficient to secure patient, professional and organisational safety, and the incidence of adverse

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events and preventable harm remains high. Recently, in their Global Patient Safety Action Plan 2021–2030, the World Health Organisation (WHO) confirmed that unsafe care is still a significant and expanding problem, leading to death and disability globally (World Health Organisation, 2021).

Patients are the first victims of adverse events. Recent data shows that in high-income countries, ten per cent of patients experience harm in healthcare, half of which is preventable (World Health Organisation, 2024). The impact of adverse events on healthcare professionals has also been recognised. In 2000, Wu (2000) published an editorial in the British Medical Journal titled "*Medical error: The Second Victim, The doctor who makes the mistake needs help too*". He coined the term "second victim" in recognition of healthcare professionals who are also adversely affected by safety incidents (Wu, 2000). The literature supports Wu's concerns about the traumatic effect that adverse events can have on healthcare professionals (Vanhaecht *et al.*, 2019; Rinaldi *et al.*, 2022; Seys *et al.*, 2012; Mira *et al.*, 2015; Strametz *et al.*, 2021a, b). Studies estimated that about 45–91% of healthcare professionals working in hospitals will experience some form of trauma during their careers as a result of adverse events (Simms-Ellis *et al.*, 2025; Rinaldi *et al.*, 2022). Healthcare professionals, who normally consider themselves "enablers of patient health", may experience guilt after an adverse event. This may lead them to a process of analysing their role in the event through root cause analysis, assessing their level of responsibility, exploring positive and negative contributions to the incident and considering factors like the social environment, the organisation, supervisors and peers. This evaluation can either alleviate or exacerbate feelings of guilt and ultimately influence the healthcare professional's sense of identity and subsequent practice (Rafter *et al.*, 2014). Even serious near-misses can trigger symptoms of distress among healthcare professionals (Watermann *et al.*, 2007). Recognition of the phenomenon has grown, and the concept has since been expanded, with some authors now referring to the healthcare organisation as the "third victim" (Russ, 2017; Liukka *et al.*, 2020; Mira *et al.*, 2015). Though it is acknowledged that institutions can experience loss in this context, for example, reputational damage, financial costs and cultural setbacks, it is important to note that so-called organisational harm differs fundamentally from the acute impact on individuals. The appropriateness or otherwise of the term "victim" in this context notwithstanding, Wu's conceptualisation of the second victim phenomenon has served to highlight the significant impact adverse events have on those involved, demonstrating the importance of enhancing patient safety.

Initiatives for increasing safety

WHO's Patients' Rights Charter states that patient safety refers to the processes, procedures, and cultures established in health systems which promote safety and minimise the risk of harm to patients (World Health Organisation, 2024).

The literature mapped various initiatives employed to support patients and healthcare workers and organisations. These interventions both directly and indirectly improve patient safety, healthcare quality, person-centred care and human resources management (World Health Organisation, 2021). Healthcare organisations need to first have a support framework for patients and their families, including open disclosure, apologising for incidents, steps to prevent recurrence and appropriate supports in place (Liukka *et al.*, 2020; Mira, 2023). Legal and regulatory frameworks should support this. Inclusion of patients and their families should be at the centre of the framework, with an emphasis on open and honest communication. One proposed measure is that healthcare organisations should consider, where appropriate, the inclusion of patients in the analysis of incidents and solutions, contributing to a more comprehensive understanding of the root causes of safety events (Liukka *et al.*, 2020; Van Gerven *et al.*, 2016; Mira *et al.*, 2017). At times, healthcare systems focus mainly on the needs of healthcare professionals and institutions but lack communication and collaboration with patients, their families and advocacy groups (Clarkson *et al.*, 2019).

Organisations should also support the healthcare professionals within them and consider the role of institutional culture (Mira *et al.*, 2015, 2017). Although less studied, the culture of

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blame, which is still present in many healthcare institutions, hinders progress towards a safety-generating culture. This persistent blame culture discourages open communication, learning from errors and the implementation of systemic improvements, ultimately making it more difficult to enhance patient safety (Mira *et al*., 2024a, b, c).

Governance, medicolegal and other factors

A lack of proper reporting and accountability can hinder efforts to implement corrective and preventive actions to minimise harm and avoid the occurrence of future adverse events (Mira, 2023). Governance, legal schemes, culture and attitudes differ widely within and across countries (Mira, 2023; Mira *et al*., 2017). In certain countries, such as the United States, disclosure of adverse events to patients and the organisation and learning from mistakes are requirements of accrediting and licensing bodies, professional organisations and governmental entities (Wadhwa and Boehning, 2024). Similarly, the Canadian Disclosure Guidelines oblige physicians to communicate with patients and disclose what has occurred. Beyond a legal or regulatory requirement, honest, open and timely communication is the ethical thing to do. Research also suggests that where open disclosure takes place, litigation is less likely (Disclosure Working Group, 2011).

Litigation culture can significantly impact healthcare culture. There is no harmonised approach to medical negligence litigation internationally, and significant differences exist between civil and common law jurisdictions. Whilst a detailed discussion of litigation frameworks and alternative compensatory systems in individual jurisdictions is outside the scope of the current discussion, it is useful to note that whilst litigation can offer "therapeutic benefits" for some stakeholders, it can also cause emotional and psychological distress for both patients and healthcare professionals (Wu and Steckelberg, 2012). Alternative actions to resolve disputes, such as mediation, were considered a more holistic and less disruptive approach to resolving such disputes (Tumelty, 2021a, b; Baungaard *et al*., 2022). While accountability is crucial, and patients who suffer harm are entitled to access compensation, litigation can be counterproductive. It can ultimately harm patient safety. For example, litigation can have a significant emotional impact on healthcare professionals, possibly leading to "clinical judicial syndrome", "medical malpractice stress syndrome" and "law-caused harm" (Wu and Steckelberg, 2012; PSU-Akut, 2024).

Lack of legislation which adequately protects physicians from tort actions, coupled with expensive individual malpractice insurance, can lead to defensive practice, which is narrowly defined as "healthcare professionals" deviation from sound medical practice motivated by a wish to reduce exposure to malpractice litigation or other self-protective motives' (Baungaard *et al*., 2022). Regulatory and legal frameworks that protect healthcare professionals who disclose mistakes from legal and disciplinary action are needed. Such a framework must also do justice to the patient through communication about why the event occurred, what will be done to prevent recurrence and provide fair compensation (Mira, 2023).

Safety culture in healthcare

Between 1970 and 1990, there were a series of severe accidents, including aviation, nuclear and travel accidents, which led to the study of causation and understanding of accidents, particularly through the systems approach (Waterson, 2014). The systems approach led to the concept of safety culture. The Advisory Committee on the Safety of Nuclear Installations (ACSNI) defined the safety culture of an organisation as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation's health and safety management. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and confidence in the efficacy of the preventive measures" (Advisory Committee on the Safety of Nuclear Installations, 1993).

Mira *et al*. (2017) identified variances in safety culture and attitudes in different healthcare practices and countries. It has been explained how patient safety culture determines how

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healthcare professionals, teams and healthcare organisations function on a daily basis, manage risks when providing healthcare and cope with the impact of adverse events (Mira, 2023). Safety culture creates an environment which supports or hinders the recurrence of adverse events (Mira, 2023). A safety-generating culture is dependent on the psychological safety of healthcare professionals, the transparency and trust within the environment and the application of a just culture which enables the support of professionals after incidents (Mira, 2023; Mira *et al*., 2024a, b, c). The risk of safety incidents is increased in organisations where there is a fear of communication about safety incidents and where affected healthcare professionals are not supported. The change to developing a safety-generating culture requires a broad social commitment, the need to establish the system's and the individual's responsibilities, ensuring accountability and the empowerment of professionals and organisations to learn from their mistakes. There is a need for an open and honest environment where professionals are valued and treated fairly and justly (Mira, 2023). Mira (2023) stressed the principles of just culture and the importance of an open and honest environment where stakeholders are valued and treated fairly and justly. In case of honest mistakes, second victims should be treated as a problem of the workplace and not as an individual failing of the healthcare worker (Mira, 2023).

The systems approach for safety in healthcare

The Institute of Medicine's report "To Err is Human" (2000) was pivotal in shifting the focus of the root cause of medical errors from individual healthcare providers to systemic issues (Institute of Medicine US Committee on Quality of Health Care in America, 2000). James Reason also considered that problems of human error have been used in two ways: the person approach, which focuses on the errors of individuals and blaming them for their shortcomings, and the system approach, which focuses on the conditions and the systems where the individuals work and build interventions to avert errors or mitigate their effects (Reason, 2000).

Healthcare has implemented the systems approach for quality management for a long time, but safety processes and safety management systems only started to be considered more recently (Health Services Safety Investigations Body, 2023, 2025; Chatzi and Kourousis, 2024; Zhelev *et al*., 2025). A recent systematic review on the implementation of safety management systems in healthcare showed that the Netherlands has a safety programme based on a safety management systems approach. This approach was also being introduced in other countries, but in a less systematic manner (Zhelev *et al*., 2025).

The European Researchers' Network Working on Second Victims (ERNST)

In 2020, the European Researchers' Network Working on Second Victims (ERNST), funded by European Cooperation in Science and Technology, was established with the aim "to facilitate discussion and share scientific knowledge, perspectives and best practices concerning adverse events in healthcare institutions to implement joint efforts to support second victims and to introduce an open dialogue among stakeholders about the consequences of this phenomenon based on a cross-national collaboration that integrates different disciplines and approaches". The network consisted of professionals from various disciplines (healthcare, legal, academic and policy), with different backgrounds, organisations and countries, which joined together to create new knowledge from a wide range of perspectives (ERNST, 2024).

The experience of working and interacting within ERNST, particularly the iterative and open discussion between the different professionals within the network, has shown that patient safety and the second victim phenomenon are integrated and complex and cannot be considered in isolation. The authors, all professionals from different fields related to patient safety and members of the ERNST Consortium, applied their knowledge, perspectives and experiences to discuss and evaluate different aspects, approaches and concepts. The discussions between the professionals from the ERNST consortium demonstrated that the concepts of patient safety and the victim phenomena are interdependent and cannot be considered in isolation from each other. Safety is relevant and integrated across the whole

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healthcare system and cannot be considered only at the level of patient care or within individual healthcare organisations. Healthcare professionals giving clinical services tend to consider that patient safety is mainly relevant for clinical practice at the level of care of individual patients. They find it quite difficult to consider partnership and collaboration with other professionals, such as regulators and policymakers at the macro level, when it comes to patient safety and governance.

This paper describes how evidence from the literature and from professional experts was iteratively contextualised using systems approaches to formulate a framework for integrated safety in safety-management systems.

Method

The model for evidence-based management by Barends and Rousseau (2018) was used to design this research. This model recommends the gathering of evidence from different sources: scientific literature, practitioner professional expertise, stakeholder values and concerns and organisation internal data. The evidence is consolidated using a process with 6 steps, the 6 As: ask a specific question, acquire evidence from the different sources, appraise the evidence, aggregate the evidence, apply the evidence for decision-making or setting of strategy and assess by evaluating the outcome of the intervention. In this research, evidence was acquired from the scientific literature and from practitioners' professional expertise through professionals from the European Researchers' Network Working on Second Victims (ERNST) network. As described in Figure 1, data from the two sources were aggregated using theoretical and conceptual models to iteratively conceptualise a framework for integrated safety across healthcare systems. This framework was subsequently applied to propose actions for safety within healthcare systems.

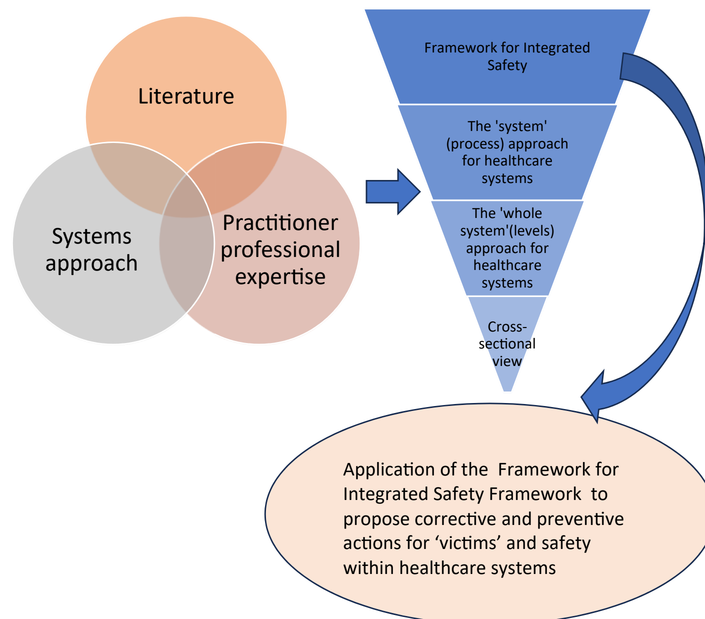

Figure 1. Description of the steps in the method for this paper: for the setting of the framework for integrated safety and for its application to propose corrective and preventive actions for safety within healthcare systems.
Source: Authors' own work

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Discussion

A snapshot of healthcare organisations

Figure 2 presents a snapshot of healthcare organisations. Adverse events and other stressful clinical events, such as physical assaults (collectively marked as AE triangles), happen in the healthcare system and affect patients and their families, healthcare workers (the arrows) and healthcare organisations, leading the whole system to suffer. Adverse events lead to victims: first, second and third victims. The patient and the healthcare professionals involved in the adverse event are usually within a healthcare organisation. Organisations need to be prepared to minimise the harmful consequences of adverse events (the circle) and to prevent stressful clinical events, which can increase the risk of further patient safety incidents. Organisations are within a wider context of the healthcare system, which includes healthcare providers and the regulatory environment at the national and international levels. The environment of the healthcare system, including social, cultural and legal frameworks, can affect healthcare processes and outcomes.

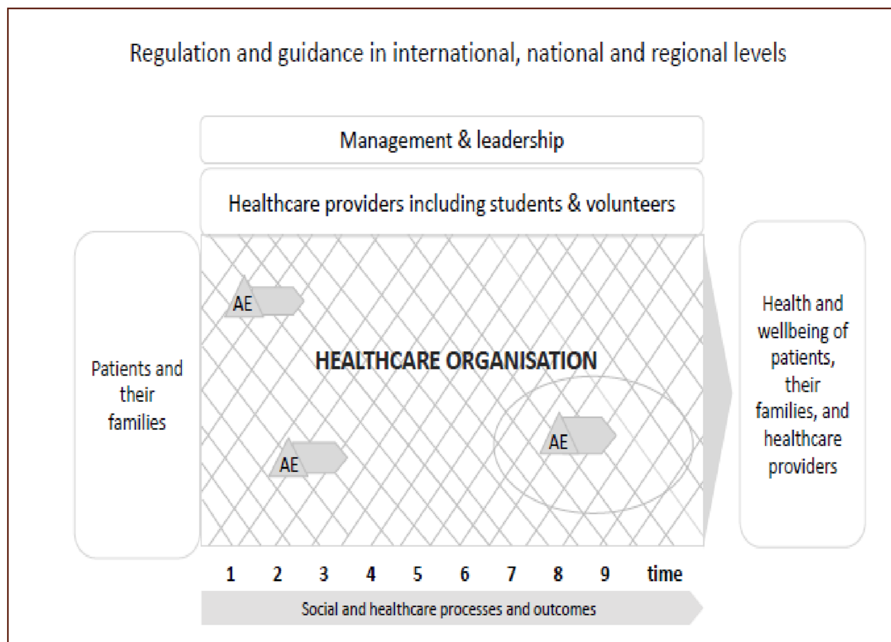

Figure 2. A snapshot of healthcare organisations. Adverse events and other stressful clinical events in healthcare organisations (represented by the triangles marked AE) happen within healthcare organisations. They affect (harm) patients and their families (first victims), healthcare workers and professionals (second victims marked with arrows) and the organisation and providers (third victims). Organisations need to be prepared and have the resources and programmes available to minimise the harmful consequences of adverse events (the circle) and to prevent stressful clinical events, which can increase risk. Source: Authors' own work

Conceptualisation of integrated safety using the multi-level whole systems approach

Chandler and Vargo (2011) presented the context of a healthcare system at different levels (micro, meso and macro). They showed the different contextual framings of exchange and how context affects the value of the service provided. The three levels were conceptualised to fit the

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healthcare system as presented in Figure 3. The micro level includes individual stakeholders such as healthcare professionals, patients and their families. At the micro level, there is direct and reciprocal interaction, communication and provision of service and care. The meso level comprises care service provider organisations at a private and public level, including hospitals, primary care services and rehabilitation services. At the meso level, the stakeholders connect directly or indirectly to serve and create value. The stakeholders at the macro level include the government, organisations that define national health policies and professional regulatory bodies (Chandler and Vargo, 2011). The interactions and communications between the different levels and within the levels form and define the system in an iterative and continuous process of creation of value (Beirao *et al.*, 2017). Chandler and Vargo (2011) describe how context influences the co-creation of value and markets by impacting resources and services. The authors show that every actor in the system integrates resources through exchanges between actors and services. The model joins stakeholders directly or indirectly (Chandler and Vargo, 2011).

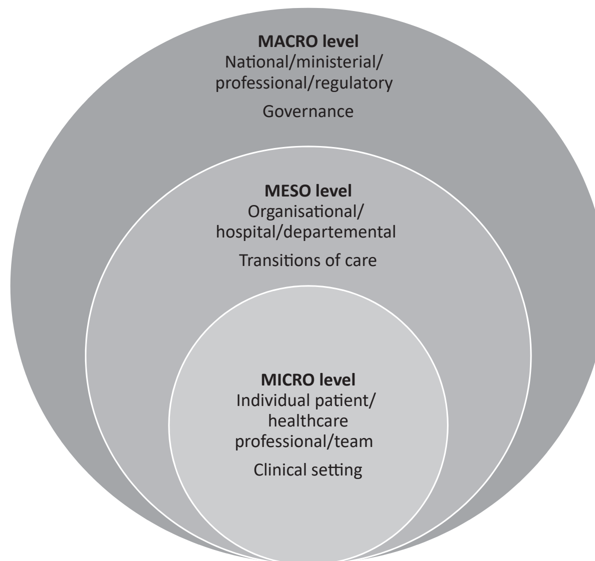

Figure 3. The levels of healthcare systems. Adapted from Slawomirski and Klazinga (2022) and Chandler and Vargo (2011)

The conceptualisation of the health system in multi-levels was also used to explain different contexts, including in the description of the multi-level approach to integrated care (Hughes *et al.*, 2020), in the development of the Rainbow Model of Integrated Care (RMIC) (Valentijn, 2016), to study the implementation of policy (Caldwell and Mays, 2012) and to show the implications of response shift for patient-reported outcome measures for health decision-making at the different levels (Sawartzky *et al.*, 2021). Beirao *et al.* (2017) presented the benefit of collaboration for multilevel co-creation of value in service ecosystems (Beirao *et al.*, 2017). Valentijn (2016) stressed that trust-based and control-based collaboration is needed to achieve a culture of integration (Valentijn, 2016). Hughes *et al.* (2020) identified a gap between the hope for unity in models of integrated care and what happened in practice. The theoretical assumptions of integrated care and its representation by the rainbow model consolidate the levels of the healthcare system, with normative and functional integration being conceptualised as enablers for putting the different levels together (Hughes *et al.*, 2020; Valentijn, 2016).

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As depicted in Figure 4, the elements related to safety and the victim phenomena fit well into the system levels model. Mira (2023) explains that the integration of the different levels depends on a culture that seeks the good of the stakeholders in a just manner, with the main outcome being the generation of safety across the whole system. Culture is represented across the levels to the right of the model in Figure 4.

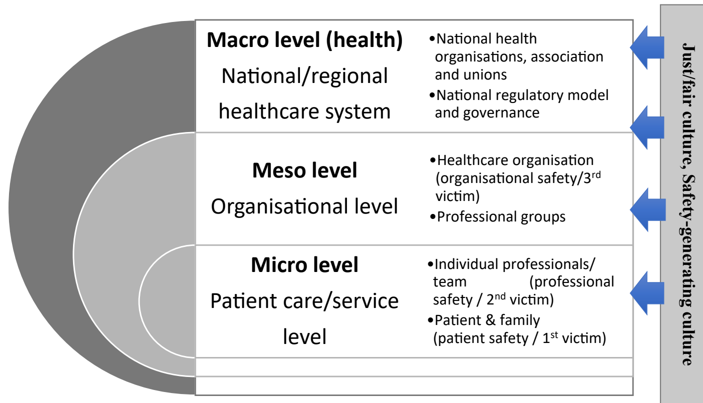

Figure 4. Application of the systems-level approach and the concept of culture to represent the safety and victim phenomena. Source: Authors' own work

Compounded conceptualisation through the "system" (processes) approach

The programme logic model (McLaughlin and Jordan, 1999) is well established to conceptualise healthcare systems as a programme. This model adopts a process-based approach and gives four main elements for planning a programme: structure/input, processes, outputs and outcomes. It also includes external factors affecting the programme (McLaughlin and Jordan, 1999). The programme logic model was adapted to represent safety in healthcare systems, as represented in Figure 5, and factors relevant to healthcare system safety were

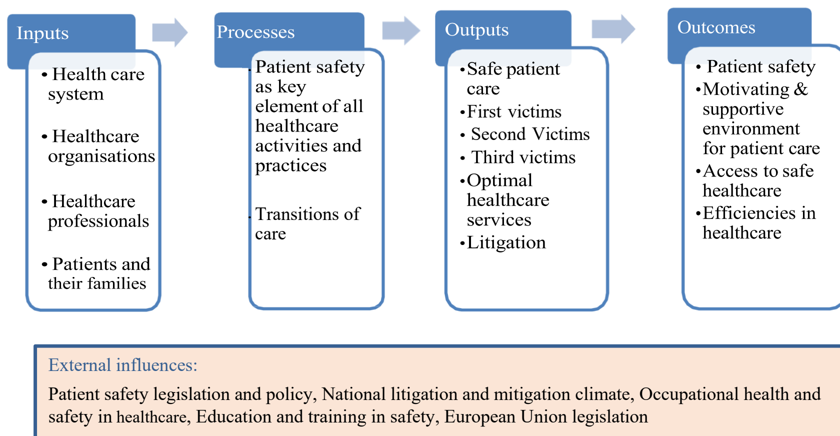

Figure 5. Elements of the programme logic model as applicable to the safety and victim phenomena in healthcare systems. Adapted from McLaughlin and Jordan (1999)

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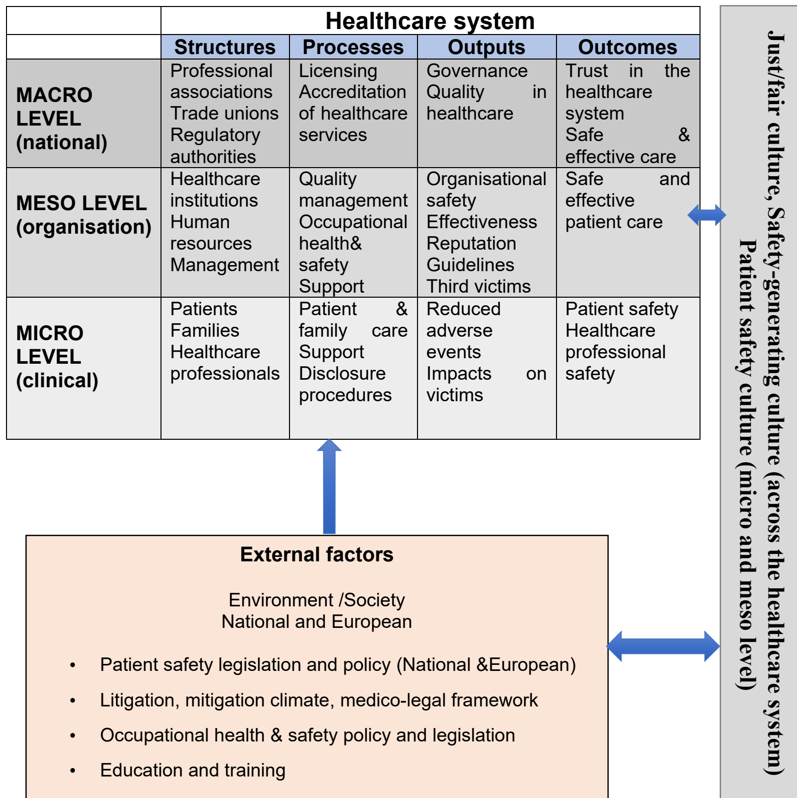
incorporated to support understanding of this model. The resources include human and financial resources. The inputs required to support the programme include patients and their families, healthcare professionals, healthcare organisations and the healthcare system. The activities are all the actions needed to produce programme outputs. The outputs include the products, goods and services provided to the programme's direct customers, in particular services for patient care. The outcomes are those changes, benefits and negative impacts that are associated with or caused by the programme outputs, mainly patient safety and the impact of adverse events on healthcare professionals and organisations. The external influences are factors external to the programme and not under its control that could influence its success either positively or negatively, such as national mitigation and litigation culture and legal framework and education and training (Mc Laughlin and Jordan, 1999).

Aggregation of systems approaches and evidence into a framework for integrated safety

As explained in Figure 1, the whole system (levels) and the systems (processes) approaches and the evidence from the literature and the professional expertise were aggregated to formulate a framework for integrated safety, presented in Figure 6. The safety concepts were integrated using the systems approach across all three levels of the healthcare ecosystem. Integrated safety depends on a safety-generating culture, justice/fairness and interaction across the levels of the healthcare system. Integrated safety is dependent on the interaction across all levels of the healthcare system.



	Healthcare system			
	Structures	Processes	Outputs	Outcomes
MACRO LEVEL (national)	Professional associations Trade unions Regulatory authorities	Licensing Accreditation of healthcare services	Governance Quality in healthcare	Trust in the healthcare system Safe & effective care
MESO LEVEL (organisation)	Healthcare institutions Human resources Management	Quality management Occupational health& safety Support	Organisational safety Effectiveness Reputation Guidelines Third victims	Safe and effective patient care
MICRO LEVEL (clinical)	Patients Families Healthcare professionals	Patient & family care Support Disclosure procedures	Reduced adverse events Impacts on victims	Patient safety Healthcare professional safety

Figure 6. Framework for integrated safety across healthcare systems. Source: Authors' own work

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Application of the framework for integrated safety for the implementation of action for safety

Both the Organisation for Economic Co-operation and Development (OECD) and the Global Patient Safety Action Plan (2021–2030) adopted a systems approach at different levels of the healthcare ecosystem for implementation to conceptualise patient safety and make recommendations for action (Slawomirski and Klazinga, 2022; WHO, 2021). This approach was in line with the Framework for Integrated Safety conceptualised through this study. The OECD stressed that improving safety and generating value and return on investment across a system requires a whole-system approach with interventions encompassing all "strata" of the health system (clinical, organisation and system) (Slawomirski and Klazinga, 2022). The Global Patient Safety Action Plan 2021–2030 also adopted the systems-levels approach and recommended various actions for stakeholders at different levels: governments, healthcare facilities and services, stakeholders and the WHO Secretariat (World Health Organisation, 2021).

In accordance with the "Apply" stage of the 6 As of the model by Barends and Rousseau (2018), the Framework for Integrated Safety was used to conceptualise and present preventative and corrective actions for integrated safety across the whole healthcare system. These were presented in Figure 7. The template for Figure 7 was structured using the framework for integrated safety in Figure 6, considering the different levels of the healthcare system and actions relevant to each level. Culture was considered across the levels. External factors considered included the medico-legal framework, social environment, education and training and European legislation. The information included within the different sections was collated from workshops of a Working Group from ERNST.

Healthcare systems realised the importance of a holistic, collaborative and integrated approach during the COVID-19 pandemic and should prioritise actions towards integrated safety. The lessons learnt during the COVID-19 pandemic, including the need to decrease the stigma towards asking for help among healthcare workers (Mira *et al*., 2021; Lopez-Pineda *et al*., 2022) and the importance of coordinating across the levels, can be useful in addressing integrated safety.

Conclusions and recommendations

The framework for integrated safety in healthcare systems gives a comprehensive model. The fact that the evidence was obtained from different sources supports the robustness of the framework. This framework allows healthcare systems to adopt a collaborative approach to safety akin to other industries like aviation and nuclear sectors. Drawing from the systems-based approaches of high-risk industries, healthcare can cultivate a safety-oriented culture across its entire system at all levels. However, the examples and information applied to the framework for integrated safety to date are limited. This can limit the generalisability and applicability of the framework to different contexts and cultures. There are different types of healthcare systems, funding and types of organisations. Organisational culture within the same country can vary depending on factors like public or private funding, political involvement, etc. Although the framework is generic and allows for flexibility and customisation within the different sections, the overall template is rigid.

It is important to validate the framework and its applicability across different contexts, different healthcare models and systems as well as different countries. This can be done by implementing the framework for integrated safety in different practices as case studies in order to validate this framework and to support its continuous improvement. As a first step, this framework should be validated through its use by members of the ERNST Consortium in their various practices. The publication of the framework in this paper and of possible subsequent case studies will support the validation of the framework.

The focus of patient safety in practice to date has been mainly at the micro and meso levels, and this bias is also reflected by the literature. Aggregation of evidence from different sources helped to widen the perspective. In particular, the professional expertise showed that patient safety and victimisation of stakeholders go beyond the clinical services, and there is a great

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Level		Actions/considerations
Macro level	National regulatory model & governance	Professional regulatory bodies Principles of good ethical practice Professional guidelines by European and national associations Regulation and accreditation of healthcare professionals Regulation and licensing of healthcare organisations
Meso level	Organisation (3rd victim)	Organisational reputation Systems approach to minimising risk Implementation of occupational health and safety policy Setting and maintenance of standards Clinical guidelines and other interventions for patient safety, clinical risk management and quality management Infrastructure and resources for patient safety and quality management/improvement Programs for employee support, first aid responses HR policies Availability of resources Organisational-level insurance and indemnity Patient safety culture to support patient safety Organisational strategies, SV support programs, rapid response teams, first aid response, teams of peers Professional external support Employee support training, training manual
	Professional Groups, teams, systems	Professional practice and ethics Occupational health and safety Incident reporting culture The medico-legal situation, tort, and liability Training as part of graduate / post-graduate HCP education Ongoing skills development Continuous Professional Development (CPD)
Micro level	Individual healthcare professional (2nd victim)	HCW safety and well-being, psychological safety Occupational health and safety HCW insurance and professional indemnity Incident reporting culture HCP personal strategies for SV, peer support, learning from adverse events, online support tools Ongoing skills development Continuous Professional Development (CPD)
	Patient & family (1st victim)	Patient safety Patient and family support in case of adverse event Disclosure to patients

External factors	
National medico-legal framework	National legislation and law practice Medico-legal, liability and tort culture
Social environment	Social context Victim-offender mediation
Education and training	Education at the graduate and post-graduate level Healthcare professional and healthcare system safety
European legislation	Introduction of legislation for occupational health and safety at the European level to support the free movement of persons (HCPs) National occupational health and safety legislation/ standards (general and specific to healthcare establishments)

Safety-generating culture; just culture; patient safety culture

Figure 7. Considerations for preventive and corrective actions for integrated safety within the healthcare system

impact from the macro level and environmental factors. A strategic approach across the different levels mediates safety-management systems.

In particular, the macro level would benefit from more concrete recommendations to support progress in patient safety across countries, for example, by strengthening regulations, allocating adequate budgets and reinforcing the structures responsible for managing patient

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safety systems. Priority should be given to legislation, policy and initiatives which support a safety-generating culture. Governance structures that protect healthcare professionals who report honest mistakes from legal and disciplinary action, and stronger occupational health and safety laws are needed. Legislation and policy at the European level, such as the European Charter of Patients' Rights and European Occupational Health and Safety Legislation, can help to ensure that there is at least a minimal and standardised level of governance for the safety of all stakeholders in all countries of the European Union. Integrated and coordinated preventive and corrective actions should be implemented in a way that justly supports safety and minimises victimisation for all the stakeholders concerned.

The last step from the 6 As, "Assessment", entails an evaluation of outcomes from the use of the Framework. This would require the implementation of the Framework in practice, continuously over time. Hopefully, there is increased patient, professional and organisational safety and a decrease in the incidence of adverse events and preventable harm. The outcomes from this approach can mainly be monitored through the use of indicators for safety activities at the different levels of the healthcare system (refer to Figure 7). Monitoring may include measurement of patient safety culture at the organisational level and monitoring of indicators for national outcomes of the healthcare system, such as the OECD indicators for healthcare, which are collated regularly by many countries.

Safety is a right of all stakeholders, and all stakeholders should collaborate to optimise the safety of each other for the benefit of all. To date, initiatives for patient safety and to support victims have been highly disjointed and mostly at the individual healthcare provider or service provider levels. A paradigm shift for safety-management systems within healthcare systems is needed. The framework for integrated safety, which was drawn up in this study, serves as a comprehensive development to support increased safety and fewer victims.

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