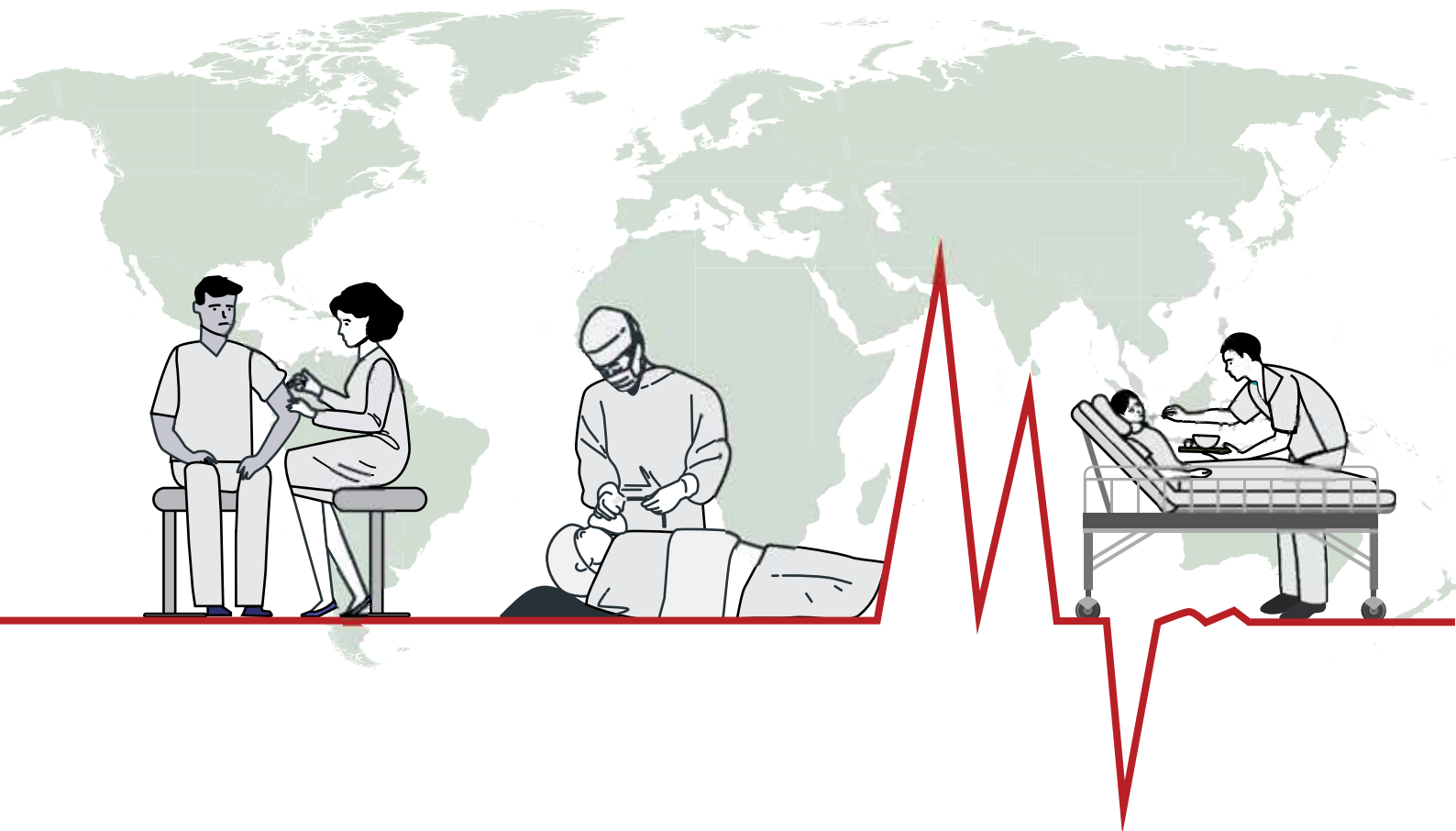Patient
Safety

World Health
Organization

# Global
# patient safety
# report 2024

# Executive summary

The pursuit of universal health coverage is aimed at ensuring every person and community has access to safe and quality health care without facing financial strain. The key to realizing this vital goal lies in ensuring the safety of health services. Without this, the full potential of expanded coverage will be lost, leading to a decline in trust and a reluctance to seek care, even when it is most needed.

Recognizing this crucial need, the Seventy-second World Health Assembly (2019) adopted the resolution WHA72.6 entitled *Global action on patient safety*. This resolution emphasizes the critical role of patient safety in the establishment, functioning and evaluation of all health care systems. It reasserts the foundational principle of 'First, do no harm', underscoring the imperative to enhance patient safety in health systems across all dimensions, sectors and environments, encompassing both physical and mental health. The resolution called upon the Director-General of the World Health Organization (WHO) to develop a comprehensive global patient safety action plan, in collaboration with Member States and all relevant stakeholders.

In 2021, the Seventy-fourth World Health Assembly also made a pivotal decision to adopt the *Global patient safety action plan 2021–2030*. This decision also included a request for the Director-General to regularly report to the Assembly on progress in the implementation of the action plan, starting in 2023 and continuing every two years until 2031.

In response to this directive, the WHO secretariat initiated a global patient safety survey for Member States in 2022. An interim report, based on an initial analysis of the data received in response to the survey, was presented to the World Health Assembly in May 2023. This first *Global patient safety report* presents a comprehensive global overview, highlighting a wide range of patient safety initiatives and progress made around the world alongside the challenges encountered.

The *Global patient safety report* provides a foundational understanding of the current state of patient safety globally. It contains insights and information beneficial to health care professionals, policy-makers, patients and patient safety advocates, researchers – essentially anyone involved or interested in the improvement of health care and patient safety globally. It offers insights into specific areas that need attention and investment, recognizing that progress in patient safety measures has been uneven across different regions.

The methodology of the report is grounded in the first ever global patient safety survey conducted by the WHO. This survey was a pivotal effort in assessing the implementation of the action plan across Member States.

Unsafe care is a major public health problem that affects millions of patients worldwide, with estimates suggesting that more than one in ten patients suffer from adverse events. The severity of nearly half of patient harm extends beyond mild injuries and temporary harm. As much as 12% of harm causes permanent disability or patient death. Latest estimates indicate that unsafe care causes more than 3 million deaths every year globally, and that around half of all harm due to unsafe care is preventable.

Patient harm due to unsafe care also causes irreversible reputational damage to health care systems, detrimentally affecting patient experience, trust and engagement with health care services, the morale and well-being of health care workers and public opinion about the value of investing precious societal resources in health care systems.

Around two thirds of all patient harm due to unsafe care – and the resulting years lost to disability and death – occur in low- and middle-income countries (LMICs). Each year, 134 million adverse events occur in hospitals in LMICs, contributing to approximately 2.6 million deaths.

Unsafe care in health care systems incurs significant financial and economic costs. It leads to additional medical interventions, consuming resources that could be allocated elsewhere. In high-income countries (HICs), unsafe care can account for a substantial portion of total health expenditure, with recent analysis indicating about 15% of health spending goes to managing the consequences of patient harm. The direct financial impact is considerable, affecting both acute and long-term care sectors. Studies in LMICs, though limited, suggest similar cost implications.

In health care, acute care settings (e.g. hospitals) bear high costs due to safety lapses such as infections, medication errors and surgical complications. Costs include increased hospital stays and treatment expenses, significantly impacting health care budgets. Primary and ambulatory care also face substantial costs from medication and diagnostic errors. Long-term care settings incur costs due to adverse events such as pressure ulcers and falls. Overall, the direct costs of patient harm are substantial and likely underestimated, while indirect costs like lost productivity can exceed direct costs.

Patient harm significantly impacts productivity and labour supply, with indirect costs often exceeding direct health care costs. Studies using the human capital approach highlight substantial productivity loss and income reduction due to patient harm. This impact is more pronounced in socially and economically disadvantaged groups. The overall economic burden of patient harm is considerable, comparable to major chronic diseases such as diabetes, reducing global economic output significantly. These costs, while variable in different studies, underscore the extensive economic consequences of unsafe health care practices.

Investing in patient safety interventions offers a high return on investment and is cost-effective compared to other medical services. Strategies targeting common and harmful events such as infections, medication errors and pressure ulcers are particularly valuable. Technological solutions such as barcode systems are effective in reducing medication errors. Additionally, engaging patients and improving health literacy can substantially decrease harm and associated economic burdens, benefiting both patients and health care systems.

# Summary of findings

This global report explores the global patient safety situation, offering a comprehensive and detailed analysis of Member State survey data as well as other published sources. It presents a global overview, highlighting a wide range of patient safety initiatives and progress made around the world, in line with the strategic framework and suggested actions and its 7x5 matrix outlined in the Global patient safety action plan 2021–2030. The structure of the report directly aligns with the strategic objectives of the action plan, focusing on the implementation of strategies across nations to enhance patient safety.

## Policies to eliminate avoidable harm in health care (strategic objective 1)

- Although most countries recognize patient safety as a national health priority, only one third of countries have fully incorporated patient safety into their national strategies for achieving UHC.
- The development of policies, strategies, action plans, and programmes for patient safety is still in its early stages, and an even smaller fraction of countries report having adequate financial and human resources for implementation.

- Regulatory mechanisms such as mandatory licensing of health care facilities are widely used to enforce safety, with a significant number of countries enacting laws on the use of medical products and implemented the safety standards in health care facilities.

- World Patient Safety Day, established in 2019, has created unprecedented international momentum with 80% of Member States actively participating in annual campaigns and events to enhance awareness of patient safety.

- The WHO Global Patient Safety Challenges address critical risks to patient health and safety. Countries have taken actions on these initiatives, with almost 90% of countries addressing at least one of the challenges and one third of the countries implementing all the three challenges.

## High-reliability systems (strategic objective 2)

- A safety culture in health care is recognized as crucial by most countries, yet only a quarter of countries reported to have made efforts towards developing a culture of safety in health care facilities and services.

- The WHO Global patient safety action plan 2021–2030 advocates for good governance in patient safety, with around half of the countries having designated national patient safety officers and establishing national coordination bodies.

- Although the significance of human factors in health care is increasingly being acknowledged globally, only around a quarter of countries have started to implement human factors principles in patient safety measures in clinical practice, use of medical devices, information technology solutions, and service delivery processes.

- A proactive and systematic approach to managing patient safety risks involves meticulous identification, examination and mitigation of potential hazards and risks in health care settings. Only a quarter of countries report implementation of risk management strategies and conduct regular mock drills.

- Most countries have established physical safety norms for health care infrastructure, but only about half report enforcing these norms, highlighting a gap between policy and practice in infrastructure safety.

## Safety of clinical processes (strategic objective 3)

- Around 41% of countries have launched patient safety improvement programmes tailored to their specific contexts, addressing different sources of harm. Health care-associated infections and medication errors are prioritized in the majority of countries implementing such initiatives.

- Two thirds of countries have endorsed and are implementing the third WHO Global Patient Safety Challenge: *Medication Without Harm*. However, only a quarter of countries are actively addressing all three priority areas of the Challenge: high-risk situations, transitions of care, and polypharmacy.

- Around 60% of the countries report having a national programme for infection prevention and control, and half of the countries report implementing active surveillance systems for health care-associated infections.

- Countries have made significant investments in ensuring the safety of medical products. Almost all countries have functional pharmacovigilance programmes, nearly 80% have implemented blood safety programmes, and about half of the countries have initiatives for the safety of medical devices.

- Patient safety in primary and ambulatory care is less prioritized compared to safety in hospitals, with only 17% of countries systematically including safety in primary care programmes.

## Patient and family engagement (strategic objective 4)

- Patients and their families are key partners in creating and executing policies and action plans for patient safety. However, only 13% of countries have appointed a patient representative to the governing board of the majority of their hospitals.

- Countries have recognized patient rights charters as a means of empowering patients, and around 70% of countries have either developed or are in the process of developing such charters at the national level.

- Collecting feedback from users on safety and service quality is a common practice for improving services. 80% of countries have mechanisms in place to gather such feedback, with nearly 20% also measuring patient-reported care outcomes.

- Access to medical records is recognized as a key patient right. Around 80% of countries report having procedures in place for patients and families to access their medical records, although only 50% have taken proactive actions to inform patients about the procedures for accessing patients' medical records.

- Health care organizations should have policies to promote transparency, including full disclosure if patients are harmed in health care. However, only a quarter of countries have established procedures for disclosing adverse events to patients and families.

- Increasing public awareness and education about patient safety is of paramount importance for making health care safer. While two thirds of countries have developed information and educational materials only 14 of countries have launched a focused campaign to provide information and education to patients and families for their involvement in self-care and empower them for shared decision-making.

## Health worker education, skills and safety (strategic objective 5)

- Understanding of patient safety is essential for all health workers, yet comprehensive integration of patient safety in health professional education and training remains limited globally. Only around one fifth of countries have incorporated patient safety in their undergraduate and postgraduate professional education.

- While a quarter of countries provide specialized in-service training courses on patient safety, there is a significant global shortage of trainers on patient safety, with 14% of countries reporting sufficient training capacity.

- A quarter of countries have established patient safety competencies for all categories of health workers, and only in 14% of the countries core competencies for patient safety are incorporated in licensing and re-licensing requirements.

- There is a strong interdependence between patient safety and health worker safety that was highlighted during the COVID-19 pandemic, leading to increased national efforts in ensuring health workers' health and safety. Around 70% of countries have established or are working towards establishing a national programme for occupational health and safety of health workers.

- While WHO recommends vaccination for all at-risk health workers, coverage of health workers against vaccine-preventable diseases, as per the national immunization policy, is reported by nearly 55% of the countries.

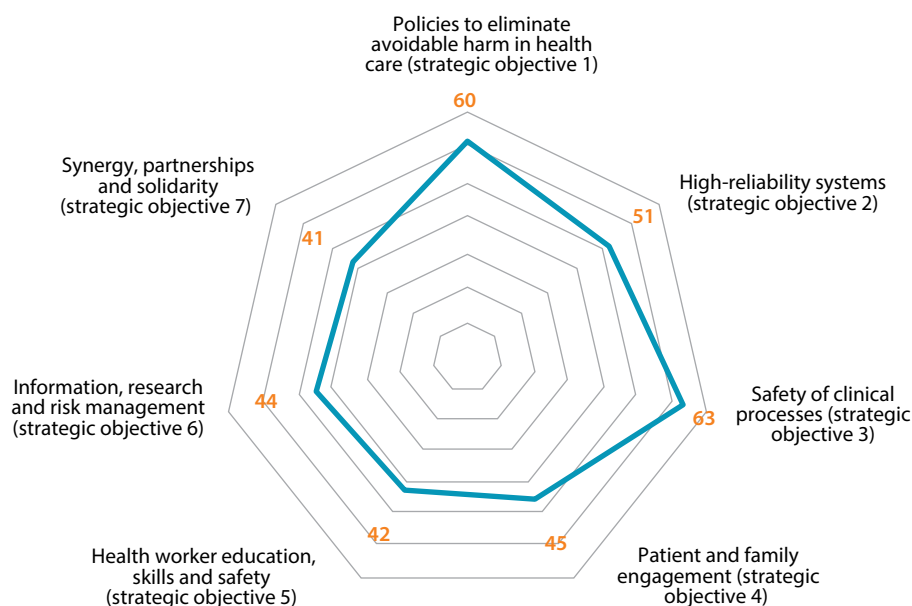## Information, research and risk management (strategic objective 6)

- Although patient safety incident reporting and learning systems have been introduced in 70% of countries, their effectiveness remains limited, and only in one third of countries do the majority of health care facilities actively report safety incidents to these systems.

- Interoperability and international collaboration for sharing data between patient safety incidents reporting systems are limited, with only around one third of countries aligning their reporting formats with the WHO minimum information model.

- The implementation of electronic health records (EHR) in health care systems is increasingly recognized, with nearly 90% of countries reporting their adoption. However, full integration of EHR with health care processes is reported by only one quarter of countries.

- Three quarters of countries have identified patient safety indicators, yet only a minority integrate these into health information systems or publish annual safety reports, indicating a gap in data utilization for safety improvement.

- Research on patient safety remains a low priority, with only 11% of countries considering it a priority, although some integrate safety risk assessments in health technology evaluations.

## Synergy, partnerships and solidarity (strategic objective 7)

- Enhancing patient safety and care quality through stakeholder engagement remains an evolving endeavour. Though around one-third of countries have identified key stakeholders, only 17% have implemented effective coordination mechanisms to fully engage these stakeholders.

- Professional associations and academic institutions are widely involved in patient safety efforts in most countries, indicating strong multisectoral collaboration.

- Countries are increasingly involved in global and multilateral discussions on patient safety, with around three quarters of countries participating in global ministerial summits on patient safety.

- Nearly 20% of countries report having established patient safety networks that facilitate programme coordination and sharing of best practices.

- Despite the growing recognition of the private sector as a key stakeholder in patient safety, there remains significant room for improvement in their involvement. While 65% of countries acknowledge private sector and industry as key stakeholders, only 12% actively engage them in their national patient safety initiatives.

▶ **Fig. Global status on progress on strategic objectives of Global patient safety action plan 2021–2030 (performance scores out of 100)**

# Progress in achieving the core indicators[1]

**29%**
Proportion of countries that have developed a national patient safety action plan or equivalent

**20%**
Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals

**38%**
Proportion of countries that have established their national targets on reducing health care-associated infection rate

**18%**
Proportion of countries that publish an annual report on patient safety

**38%**
Proportion of countries that have implemented a system for reporting of never events (or sentinel events)

**18%**
Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter

**13%**
Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals

**21%**
Proportion of countries that have established a national patient safety network

**21%**
Proportion of countries that have established their national targets on reducing medication related harm

**32%**
Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system

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[1]  *These percentages refer only to the 108 countries that completed the survey.*

*Portrait of an elderly woman at her home in Viet Nam after her annual eye check-up. @ WHO / Sebastian Meyer*

# Background

The pursuit of universal health coverage (UHC) is a vital and noble endeavour, aimed at ensuring every person and community has access to safe and quality health care without facing financial hardship. The key to realizing this sustainable development goal (SDG) target lies in ensuring the safety of health services. Without this, the full potential of expanded coverage will be lost, leading to a decline in trust and a reluctance to seek care, even when it is most needed.

Recognizing this crucial need, the Seventy-second World Health Assembly (2019) adopted the landmark resolution (WHA72.6), entitled *Global action on patient safety (1)*. This resolution emphasizes the critical role of patient safety in the establishment, functioning and evaluation of all health care systems. It reasserts the foundational principle of 'First, do no harm', underscoring the imperative to enhance patient safety in health systems across all levels, settings and sectors, encompassing both physical and mental health. The resolution called upon the Director-General of the World Health Organization (WHO) to develop a comprehensive global patient safety action plan, in collaboration with Member States and all relevant stakeholders.

In 2021, the Seventy-fourth World Health Assembly made a pivotal decision of adopting the *Global patient safety action plan 2021–2030 (2)*. This decision also included a request for the Director-General to regularly report to the World Health Assembly on progress in the implementation of the action plan, starting in 2023 and continuing biennially until 2031.

In response to this directive, the WHO secretariat initiated a global patient safety survey for Member States in 2022. An interim report, based on an initial analysis of the data received in response to the survey, was presented to the 76th World Health Assembly in May 2023 *(3)*. The current global report explores the global patient safety situation more extensively, offering a comprehensive and detailed analysis of the Member State survey data as well as other published sources.

*WHA resolution 'Global Action on Patient Safety' emphasizes prioritizing patient safety globally. Subsequent adoption of the Global Patient Safety Action Plan 2021–2030 reaffirms this commitment and mandates biennial reporting on its implementation.*

# What this report is about

This report presents a comprehensive global overview of the status of patient safety implementation across the world, specific regions and individual countries. The report is closely aligned with the strategic framework of the Global patient safety action plan 2021–2030. It provides an in-depth look at how countries are addressing challenges and implementing actions to strengthen patient safety through multiple dimensions such as policies, strategies, plans, legislation, regulations, programmes, practices, initiatives, coordination mechanisms, investments, international collaborations, clinical programmes, education, and more. The aim is to present a broad perspective on the state of patient safety on a global scale, highlighting both the progress made and persistent challenges and opportunities for improvement.

*The report provides a global perspective on patient safety implementation, in line with the Global Patient safety action plan 2021–2030.*

*The report covers a comprehensive analysis of global patient safety efforts, including actions taken by countries, the burden of unsafe health care practices, case studies and comparative analyses.*

The contents of this report encompass:

- An analysis that compiles and describes actions taken by countries, including the summary of these actions across different WHO regions and income levels based on Member State survey.

- An in-depth summary presenting evidence on the overall burden of unsafe health care practices, viewed broadly as well as within specific population groups, clinical domains, and according to major sources of harm.

- Case studies showcasing how different countries are learning and developing patient safety solutions within their unique contexts, along with feature stories highlighting key global initiatives and interventions in patient safety.

- Comparative analyses offering deeper insights into crucial areas such as patient safety policies, legal frameworks, patient involvement, educational initiatives, reporting and learning systems, and the involvement of various stakeholders.

## Who this report is for

Considering patient safety is a universal concern, this report is relevant and valuable for a wide range of audiences. It contains insights and information beneficial to health and care workers, policy-makers, patients and their advocates, researchers – essentially anyone involved or interested in the improvement of health care and patient safety globally.

*It offers insights into global patient safety strategies, helping leaders prioritize and shape approaches. It also guides developmental partners in identifying areas needing furthermore attention.*

*Policy-makers and health care leaders:* The report provides a global perspective on patient safety strategies, identifying where efforts are thriving and where gaps exist. It comprises an overarching view of global trends in patient safety strategies, highlighting the gaps and strengths in different regions. Such insights are vital for policy-makers, health care and political leaders to effectively prioritize and formulate their strategic and operational approaches. For political leaders in particular, the report offers understanding in shaping public policy and legislation, aligning health policies with the latest global trends in patient safety. Furthermore, the report facilitates international collaboration, helping leaders to engage in global health initiatives and share best practices across borders.

*International organizations and developmental partners:* For bilateral and multilateral organizations, non-governmental entities, as well as national and international developmental partners, donors and funding agencies, the report serves as an important tool. It guides them in identifying specific areas of patient safety that require more attention, resources and funding, thereby ensuring that their investments yield substantial impacts on health care safety and quality.

*Research and academic institutions:* The report is a useful reference for institutions engaged in patient safety education and research and related fields. It helps in identifying emerging areas where evidence is lacking, pointing out the need for further research to enhance the implementation of patient safety strategies and interventions.

*Health care organizations and managers:* Even though the report primarily focuses on national aggregated data, it offers valuable insights for health care organizations and facility managers. They can use this data to understand the broader context of patient safety and initiate targeted actions in their areas of work.

*Health care industry:* The report serves as a useful resource for health care corporations, pharmaceutical companies, medical device manufacturers and digital industry, offering deeper understanding for strategic foresight and planning. It guides these industries in aligning their product development, innovation strategies and market expansion plans with current patient safety needs and challenges, facilitating global compliance and the adoption of best practices.

*Patients, communities and advocacy groups:* Ultimately, the report is profoundly relevant to patients, families and communities as the end-users of health care. It empowers patient organizations, consumer groups, patient advocates and champions to advocate for safer health care. By understanding the complexities involved in ensuring safe care, they can become more effectively engaged in the pursuit of safer health care, from policy dialogues to practice at the point of care.

## How this report was developed

The approach for assessing patient safety progress was intricately developed alongside the strategic framework of the Global patient safety action plan 2021–2030. The action plan outlines 10 core indicators (see Annex 1) and a set of advanced indicators, all aligned with each of the plan's seven strategic objectives.

Following the directive from the World Health Assembly in 2021, the WHO secretariat promptly began crafting a comprehensive framework and tools to assess progress against the global action plan. This involved consulting with leading global experts to devise a practical and scientifically robust method for tracking progress. It was decided that the WHO secretariat would conduct a structured patient safety survey with Member States to evaluate implementation of the suggested actions in the action plan. This initial survey was designed to establish a set of baseline data, with subsequent surveys every two years coinciding with the reporting cycle to the World Health Assembly.

The WHO secretariat then developed the initial version of the global patient safety assessment tool, which underwent several rounds of refinement with input from global experts and technical teams within WHO headquarters and regional offices. The survey, designed for self-assessment, aims to catalyse action for enhancing patient safety and foster a policy environment conducive to establishing a safety culture and sustainable patient safety programmes.

Initiated in October 2022 and available in all six UN official languages, the survey on the WHO 'Dataform' platform required each Member State to designate an officer within their health ministry to oversee and respond to the assessment tool. The Patient Safety Flagship unit at WHO headquarters took global

*This report is a vital resource for various stakeholders, including research institutions, health care organizations, industry players and advocacy groups. By providing insights into global patient safety strategies and identifying areas for improvement, it empowers stakeholders to drive positive change in health care safety and quality.*

*The WHO conducted a patient safety survey with Member States to assess progress on the Global patient safety action plan 2021–2030. This survey, will be repeated every two years for reporting to the World Health Assembly.*

leadership in centrally coordinating the survey, in close collaboration with WHO regional and country offices. It also facilitated various information sessions and capacity-building initiatives for Member States, aimed at enhancing the quality and thoroughness of their responses.

Recognizing the integral role of patient safety in all aspects of clinical and health programmes, the survey emphasized the need for collaboration and information exchange with a range of organizations and institutions. To facilitate effective data collection, small working groups were established within countries to consolidate information from multiple sources. The process of nominating officers and managing survey responses was coordinated by the health ministries of each country, in collaboration with the relevant WHO regional and country offices, as applicable.

The development of this report, including data analysis and writing, was a collaborative effort coordinated by the WHO Patient Safety Flagship unit at WHO headquarters. It involved contributions from several technical units within the organization, as well as a network of global experts and academic partners, ensuring a comprehensive and expert-driven approach. Patient safety is fundamentally focused on enhancing the safety of patients and accordingly patients' representatives played an active role in the development of the survey tool, participated in consultations, and contributed to both writing and reviewing of this report, ensuring that their perspectives and experiences were integral throughout the process.

All external experts submitted to WHO a declaration of interest disclosing potential conflicts of interest that might affect, or might reasonably be perceived to affect, their objectivity and independence in relation to the subject matter of the meeting / guidance. WHO reviewed each of those and had concluded that none could give rise to a potential or reasonably perceived conflict of interest related to development of this report.

## Survey tool

The global patient safety assessment tool was meticulously developed to objectively evaluate the progress in implementing the strategic framework of the Global patient safety action plan 2021–2030. The design of the tool aligns with the '7 x 5' strategic matrix of the action plan (see Annex 2), encompassing seven strategic objectives and 35 corresponding strategies. Five assessment criteria were assigned to each strategy, culminating in a comprehensive set of 175 criteria focused on specific suggested actions. For every criterion, respondents were tasked with evaluating their country's current status and responding with one of three options: 'fully met'; 'partially met'; or 'not met'. Clear guidelines were provided for each criterion to determine the performance level defined for meeting each benchmark. Additionally, in cases where a criterion may not be relevant or applicable to a country's specific context, respondents had the option to mark it as 'not applicable'.

*The survey highlighted collaboration among organizations for the purposes of effective data collection. Small working groups within countries consolidated information, coordinated by health ministries and WHO offices.*

*The survey tool aligns with the strategic framework of the Global patient safety action plan 2021-2030, featuring seven objectives, 35 strategies, and 175 specific assessment criteria. It enables respondents to evaluate their country's progress for each criterion.*

## Measuring performance

The global patient safety assessment tool was primarily designed to support the survey and to provide an overview of the progress made in the implementation of the Global patient safety action plan 2021–2030, and importantly to stimulate action at the country level. The tool is completed through self-assessment, enabling countries to identify their areas of relative strength and where further action is needed. The report also leverages the aggregated survey data set to facilitate insightful analysis across various WHO regions and World Bank income groups, aiming to highlight overarching trends, priorities and gaps on a global and regional basis. However, it is important to note that the survey and its measurement approach are not intended for making country comparisons, as each country faces unique challenges in maintaining safety within its health care system. This makes a universal comparison index less practical given the inherent reduction of national complexities and validity problems. The report provides global, regional and income group scores at the start of each strategic objective section, and how these scores have been calculated is outlined below.

### a. Scores for strategic objectives

Each strategic objective includes five strategies, with a total of 25 criteria. For every criterion, a score is assigned as follows: 2 for 'fully met', 1 for 'partially met', and 0 for 'not met'. Responses marked as 'not applicable' are excluded from the scoring. Thus, the maximum possible score for each strategic objective is 50. To enhance clarity, these scores are calculated out of 100.

### b. Scores for strategies

Each strategy encompasses five criteria, meaning the maximum score for a given strategy is 10. The scores for strategies are presented as actual scores obtained (i.e. out of 10).

It is important to note that overall scores are derived by averaging the responses that were either 'partially met' or 'fully met'. However, for individual criteria, the performance is based solely on the number of countries that reported 'fully met' for each criterion.

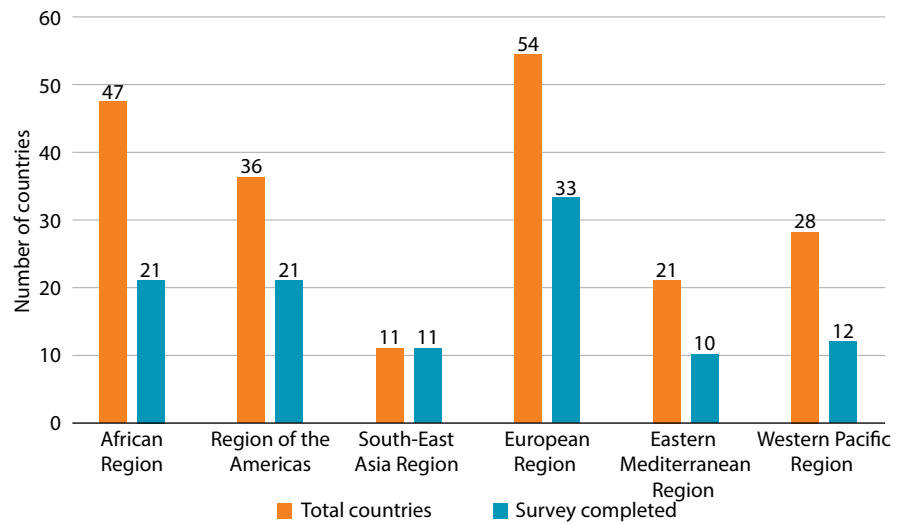## Response characteristics of the survey

The survey invited participation by all 194 WHO Member States and three associate members. Of these, 141 Member States initiated the survey process, and 108 of these ultimately submitted their responses. For the purposes of analysis, only the surveys that were completed and submitted were taken into consideration. The data presented in the report reflect responses provided by countries between November 2022 and May 2023. Countries from across

*The survey tool facilitates analysis across WHO regions and income groups but is not intended for country comparisons due to the unique challenges faced by every nation.*

*The survey invited all 194 WHO Member States and three associate members to participate. Ultimately, 108 responses were completed and submitted.*
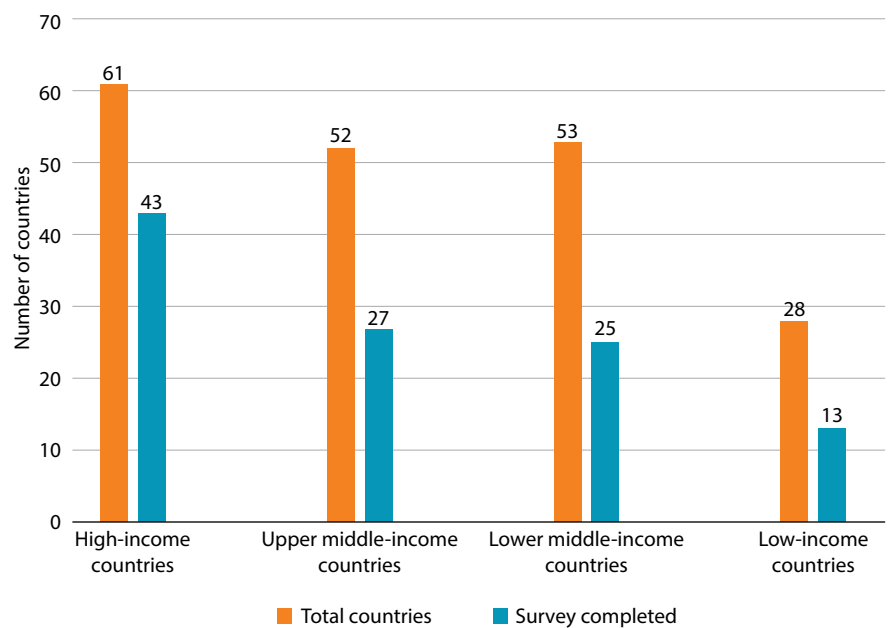
all six WHO regions took part in the survey, although response rates varied by region (Fig. 1). This variance in participation levels, offers valuable insights into the global engagement and commitment to the principles and practice of patient safety.

Number of countries

| | African Region | Region of the Americas | South-East Asia Region | European Region | Eastern Mediterranean Region | Western Pacific Region |
|---|---|---|---|---|---|---|
| Total countries | 47 | 36 | 11 | 54 | 21 | 28 |
| Survey completed | 21 | 21 | 11 | 33 | 10 | 12 |

■ Total countries   ■ Survey completed

The countries that responded to the survey were representative of all World Bank income groups, although the response rates were marginally higher among high-income countries (HICs) (Fig. 2) *(4)*.

Number of countries

| | High-income countries | Upper middle-income countries | Lower middle-income countries | Low-income countries |
|---|---|---|---|---|
| Total countries | 61 | 52 | 53 | 28 |
| Survey completed | 43 | 27 | 25 | 13 |

■ Total countries   ■ Survey completed

*The findings of this report, based on responses from 108 countries, cover about 84% of the global population.*

Patient safety represents a vital concern in public health, with policies, programmes and initiatives at the country level having a direct impact on patients, their families and the broader population. Based on responses from 108 countries, the findings of this report encompass approximately 84% of the global population.

## Limitations

As the first WHO Global report on patient safety, this report primarily offers a cross-sectional snapshot of the current status of patient safety across the world, based on the data provided by WHO Member States. This initial limitation means that the report does not provide data showing trends or progressions in patient safety metrics. Subsequent reports will be able to track and analyse the trajectory and pace of improvements and progress made over time, offering a more dynamic and longitudinal perspective. This will enable stakeholders to not only understand the current state of patient safety but also to observe trends, monitor the effectiveness of interventions over time, and adjust strategies based on these evolving insights.

The current report focuses primarily on process and structural domains, with reference to only a limited range of macro-level outcome indicators. The section on the burden of harm offers some estimates of the extent of harm in various clinical areas and sources, based on existing studies and meta-analyses. However, these studies often have limitations, such as small sample sizes and limited geographic representation, and frequently exclusion of data from low- and middle-income countries (LMICs), resulting in a notable lack of comprehensive, credible data on global outcomes regarding the reduction of patient harm and improvement in patient safety.

As countries and health care organizations begin to implement the suggested actions outlined in the global action plan – especially for patient safety measurement and surveillance – it is expected that future reports will provide a clearer picture of real-world changes in patient harm, with desired improvements in patient safety. This evolving robustness of available data will also be instrumental in understanding the effectiveness of investments in process and structural interventions for yielding safer care outcomes, such as patient safety policies, programmes, institutional frameworks and capacity building. Establishing a clear link between these investments and tangible improvements in patient safety will be crucial for designing more effective and cost-efficient strategies and interventions in the future.

In all countries and settings, the intricacies of patient safety are deeply intertwined with the organization and delivery of health services. The national level data in the report are helpful for increasing understanding of the overall status of patient safety, but this may mask variations within countries, especially those with specific patient safety challenges. In nations with decentralized, federal structures, the diversity in health care delivery across regions can lead to varied patient safety scenarios that are not fully reflected in broad national level status summaries. Similarly, in countries where private health care providers play a significant role, government-led patient safety programmes may have limited reach and impact, resulting in a discrepancy between national level performance and the actual on-the-ground situation involving a public–private mix of health care facilities.

The current report relies on the data provided in response to the Member State survey. The surveys were completed by respondents officially nominated by the

*This first WHO Global report on patient safety provides a snapshot of patient safety worldwide, but it is a static view without trends. Future reports will track progress over time, offering a more dynamic perspective.*

*Patient safety is inextricably linked to health care delivery worldwide. While national-level data provide valuable insights, they may overlook variations within countries.*

*The reliance on self-reported data may introduce biases and variations in reporting accuracy.*

health ministries of their respective countries. Since the responses were not anonymous, this may have led to a bias towards answers perceived as more favourable. Additionally, the survey was self-reported, requiring countries to assess themselves against set criteria and categorize their compliance as fully, partially or not met. To enhance the accuracy of these reports, countries were asked to provide justifications and, where possible, verifiable evidence for their assessments. However, the thoroughness and depth of the evidence provided inevitably varied among respondents. While significant over-reporting was not observed for most countries, these factors could still impact the overall accuracy of the aggregated global and regional data.

Patient safety is integral to all clinical and health programmes, and responding accurately to the survey often required meticulous coordination and information gathering from various sources within the health sector, sometimes extending beyond the health ministry's purview. Consequently, the appointed respondents may not have had complete and accurate information available to them, potentially affecting the reporting accuracy for certain criteria that may or may not be directly connected to the patient safety programme.

*Emergency nurse assisting a doctor with an unconscious patient in the ER at a hospital in Jamaica. © WHO / Jayme Gershen*

# Burden of harm in health care

# Organization of section

## Burden of harm to the patients

- Geographic distribution of harm in health care
- Burden of harm by demographic distribution
- Burden of harm by medical setting and clinical domain
- Burden of harm by source
- Measurement considerations and conclusions

## Financial and economic burden of unsafe care

- The direct costs unsafe care imposes on health care systems and budgets
- Direct costs by setting and source of harm
- Indirect costs of unsafe care

# Key messages

Unsafe care is a significant global public health issue, with more than one in ten patients experiencing harm in medical care settings – half of which could be preventable – leading to millions of deaths and substantial economic costs annually.

The burden of unsafe care disproportionately affects low- and middle-income countries, where the majority of patient harm and associated deaths occur.

Vulnerable populations, including older adults, children and ethnic minorities, face higher risks of patient harm, highlighting the importance of tailored interventions for safety of these groups within health care systems.

Globally, 1 in 20 patients suffer from preventable medication harm, highlighting a significant challenge across health care systems. Specifically, over half (53%) of this harm arises at the prescribing stage, pointing to a crucial need for improving medication safety practices.

Highly specialized care settings, such as intensive care, emergency and surgical units, are associated with the highest rates of patient harm, including both overall harm and preventable harm. In primary care, an estimated 7% of patients experience harm.

# Burden of harm to the patients

*Improving patient safety can prevent half of the harm in health care settings, potentially saving over 3 million lives annually.*

Unsafe care is a major public health problem that affects millions of patients worldwide. According to a recent systematic review *(5)*, 12% of patients experience harm across different medical care settings, which means that more than one in every ten patients is harmed from adverse events due to unsafe care. The severity of around half of patient harm extends beyond mild injuries and temporary harm. As much as 12% of adverse events cause permanent disability or patient death. Around half of all harm due to unsafe care were considered preventable *(5)*. Recent estimates indicate that unsafe care causes more than 3 million deaths every year. Patient harm also exerts a great economic cost on health systems and society, consuming valuable resources that could be put to productive uses elsewhere *(6)*.

Moreover, patient harm due to unsafe care causes reputational damage to health care systems, detrimentally affecting trust in health care services *(7)*, the morale and well-being of health and care workers *(8)* and public opinion about the value of investing precious societal resources in health care systems *(9)*.

## Geographic distribution of harm in health care

*Strengthening health care safety in LMICs is vital, as it accounts for around two thirds of global patient harm.*

Around two-thirds of all patient harm due to unsafe care – and the resulting years lost to disability and death – occur in LMICs *(10)*. It is estimated that each year, 134 million adverse events occur in hospitals in LMICs, contributing to approximately 2.6 million deaths *(11)*. An analysis used data from the 2016 Global burden of disease study *(12)* to estimate the number of deaths due to poor quality health care related to 61 conditions targeted by the Sustainable Development Goals (SDGs) *(13)*. The study compared case fatality rates between 137 LMICs with corresponding data from 23 reference HICs with relatively strong health systems. It concluded that around 5 million people died in 2016 across LMICs due to poor quality care for these SDG-related conditions. The highest per capita death rates were seen in central and west Africa and in South Asia *(13)*.

# Burden of harm by demographic distribution

## Age

Most evidence on patient harm to date has been derived from studies involving adults aged from 18 to 65 years, and so most of the key estimates of patient harm refer to this population group. Less research has examined patient harm in older adults, adolescents and children, despite these groups being increasingly viewed as vulnerable to unsafe or low-quality care *(5)*.

One study reported that the prevalence of in-hospital adverse drug reactions (ADRs) is 16% among older adults aged ≥65 years *(14)*. Several factors – such as clinical complexity, co-morbidities, illness severity and reduced functional ability – may result in unnecessary interventions during hospitalization. This in turn can lead to complications and an extended length of stay. When combined with lower quality of care, these factors contribute to the high levels of patient harm in older adults. However, the incidence of adverse events in older adults can be as low as 6% in re-analyses of large adverse event studies and as high as 60% in studies in which the definition of adverse events is broader including falls, delirium and incontinence *(15)*.

Similarly, the incidence of adverse events among hospitalized children varies significantly. A systematic review and meta-analysis demonstrated that the 95% prediction intervals for adverse events range from 3.8%–53.8% for general care patients and 6.9%–91.6% for intensive care patients using the 'Trigger tool' methodology,[2] and from 0.3% to 33.7% among general populations using the Harvard medical practice study methodology *(16)*.[3] Researchers in the United States of America found that the national rate of hospital-reported medical errors in children ranged from 1.81 to 2.96 per 100 discharges. Children with special medical needs or dependence on a medical technology had higher rates of medical errors *(17)*.

In summary, the evidence base of patient harm is smaller in older adults, as well as adolescents and children, compared to adults aged 18–65 years. Differences in the methodologies and definitions used have a major impact on the size and accuracy of the estimates of patient harm.

## Sex

The 2019 Global burden of disease study (GBD 2019) assessed the adverse effects of medical treatments on men and women *(18)*. It estimated that

*Addressing patient safety issues for vulnerable populations, particularly older adults, is crucial due to the heightened risk of harm.*

*Enhancing patient safety for children is essential, as adverse event rates are particularly worrying among those with special medical needs or reliant on medical technology.*

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2   *The Institute for Healthcare Improvement (IHI) Global trigger tool for measuring adverse events (AE) provides instructions for training reviewers in this methodology and conducting a retrospective review of patient records using triggers to identify possible AEs. See:* https://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx *(accessed 16 April 2024).*

3   *The Harvard medical practice study methodology estimates the incidence and causes of adverse events in health care settings. It involves reviewing a random sample of medical records to identify potential adverse events, and then determining the preventability and severity of each event. See:* https://www.nejm.org/doi/full/10.1056/NEJM198908173210725 *(accessed 16 April 2024).*

medical treatments harmed more than 1.3 million people in 2019, with women slightly more affected than men (prevalence rate of 18.1 per 100000 in females compared with 17.6 per 100000 in males). These adverse effects were fatal for 55 400 women and 50 300 men. Women lost slightly more years of healthy life than men, with 1.97 million disability-adjusted life years (DALYs) compared to 1.87 million DALYs for men. The report also noted that the situation improved over time, as the death rates for adverse effects of medical treatments dropped by over 10% for both men and women since 2010 *(18)*.

Women may experience more ADRs than men. According to a study that analysed VigiBase,[4] the WHO global database of individual case safety reports, from 1967 to 2017, there were more ADRs reported for female than male patients across all regions *(19)*. The study included 15 million ADR reports, and also found that male patients had a higher proportion of serious and fatal ADRs than female patients.

Overall, current evidence indicates that females experience greater levels of patient harm compared to males. However, gender differences in relation to patient harm are under-investigated, largely because case record review studies rarely report data on gender and it is hard to establish differences in patient-level factors from secondary analyses such as systematic reviews.

## Race and ethnicity

Stark health inequities affect people of African descent, Roma and other ethnic minorities as well as indigenous peoples *(20)*. A recent research study in United States of America revealed that black adult patients experienced significantly worse patient safety relative to white patients in comparable age and gender groups, and who were treated in the same hospital *(21)*. It has also been shown that people from ethnic minority backgrounds have higher rates of health care-associated infections (HCAIs), complications, adverse drug events (ADEs) and dosing errors when compared to the wider population *(22)*.

There are also ethnic differences in patient harm reported, in both voluntarily reporting systems and those organized within the health system. For example, one study found that more white patients reported care-related harms than expected (47% voluntary reporting and 40% health system reported), whereas fewer black patients (46% and 52% respectively) and less patients of other ethnicities (6% and 8% respectively) reported harms *(23)*. Studies have also revealed racial or ethnic disparities in ADEs, with Asians at higher risk of anticoagulant-related ADEs, black patients at higher risk for diabetes agents-related ADEs and white patients at increased risk for opioid-related ADEs *(24)*.

Key factors contributing to the increased risk of patient harm among ethnic minorities include language proficiency, beliefs about illness and treatment, formal and informal interpreter use, patient engagement, and interactions with health professionals *(22)*.

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4   *VigiBase is maintained for WHO by the Uppsala Monitoring Centre (Uppsala, Sweden). See:* https://who-umc.org/vigibase/ *(accessed 16 April2024).*

In general, ethnic minority patients experience inequity in the safety of care and are at higher risk of patient harm. However, robust estimates of the comparative risk of patient harm in ethnic minorities and the wider population across countries are lacking. This is mainly because existing studies have not been specifically designed to evaluate racial or ethnic disparities, and they lack a standardized approach to racial/ethnic categorization as well as controlling for potential confounders. The limited evidence available prompts further monitoring of ethnic inequalities in experiencing adverse events.

## Patient complexity

Patient complexity is a key risk factor for lapses in health care safety. Complexity can be clinical as well as biological, psychological and/or social in nature. In a study from Spain, the majority of primary care patients who experienced harm had clinical risk factors such as hypertension (32%), diabetes (18%), obesity (14%), dyslipidaemia (13%) and depression (11%). Generally, these patients require continuity of care to avoid deterioration of their health status and well-being *(25)*. In an Organisation for Economic Co-operation and Development (OECD) survey from 26 countries, experts considered multi-morbidities, psychiatric conditions, diabetes, polypharmacy and being immunocompromized to be some of the most important clinical risk factors for patient harm in ambulatory and primary care *(9)*.

*Patients with complex health conditions, including multimorbidities and chronic issues such as hypertension, diabetes, and obesity, face higher risks of patient harm in health care settings.*

# Burden of harm by medical setting and clinical domain

A large meta-analysis reports that approximately three in 25 patients experience preventable harms in highly specialized care settings, compared to one in 25 patients and three in 100 patients in general hospital and primary care settings, respectively *(5)*. The study showed that highly specialized care settings had higher estimates of all harm and preventable patient harm. This includes intensive care units (ICU) (all harm ~34%; preventable harm ~18%), emergency departments (all ~5%; preventable ~3%) and surgical units (all ~20%; preventable ~10%).

Reducing the burden of harm in **intensive care settings** remains a persistent challenge despite evidence-based practices known to reduce the prevalence of harm *(26)*. Up to one in five ICU patients experience patient harm, corresponding to up to 80.5 events per 1000 patient-days, of which 13% are lethal or life-threatening *(27)*. Patient harm increases the length of ICU stays by an average of 6.8 days, and the length of hospital stays by 8.9 days *(28)*. Medical errors and deaths due to preventable harms are more common in ICUs due to the severity of illness, complexity of care, and number of therapies provided to patients treated in this environment *(27)*.

*Specialized care settings, especially ICUs, have higher rates of patient harm, with preventable incidents significantly extending hospital stays and increasing complications.*

**Surgery** is also a high-risk setting for patient harm, mainly because surgery units deal with relatively high-risk patients in whom complex clinical procedures are implemented. Surgical procedures are intended to improve and save

*Surgical procedures pose a high risk for patient harm, with complications affecting up to 25% of patients, leading to significant global health impacts.*

lives; however, unsafe surgical care can cause substantial patient harm. An investigation of 14 surgical patient review studies estimated that 14.4% of surgical patients had experienced harms, and 5.2% of these were found to be potentially preventable *(29)*. Interventions in surgery account for approximately 13% of the world's total patient DALYs that are lost to care-related harms. Complications in in-patient operations occur in up to 25% of patients, which accounts for nearly half of all adverse events in hospitalized patients *(30)*. Estimates suggest that up to 7 million surgical patients globally suffer significant harm annually, 1 million of whom die during or immediately following surgery (due to perioperative adverse events). At the same time, it is estimated that at least half of surgical harm is preventable *(31)*. The most frequent causes of surgical adverse events include non-operative management errors. These include monitoring errors, incorrect or delayed treatment, and diagnostic errors or delays. The most frequent potentially preventable surgical harm consequences are wound problems, followed by bleeding, infections and/or sepsis, and cardiovascular complications *(32)*. WHO has implemented essential global and regional initiatives, including a checklist *(33)*, to address surgical safety as part of the second global patient safety challenge 'Safe surgery saves lives' launched in 2007. Nevertheless, the level of surgical harm remains high.

In **general hospitals** the prevalence of all patient harm is approximately 10% of all patient interactions and preventable harm is around 5% *(5)*. The number of deaths due to preventable harm in hospitalized patients may be as high as 400 000 per year globally, and an estimated 2 to 4 million non-lethal preventable harms occur each year *(34)*. Researchers in France have estimated the incidence of harms in medical and surgical wards in public and private hospitals. Together, 8754 patients were observed in 292 wards within 71 hospitals. The incidence of harms was 6.6 per 1000 days of hospitalization. Invasive procedures were the source of around half of all harms *(35)*.

*Patient harm in primary care is significant, with up to 40% of patients potentially affected, and the majority of incidents – including diagnostic and medication errors-s – being preventable.*

In **primary care,** the reported prevalence of all harm is 7% and preventable harm is 3%, but estimates are reliant upon a small number of studies *(5)*. A recent case note review involving 13 general practices in the United Kingdom found that the incidence of significant preventable harm was 35.6 per 100 000 patient-years *(36)*. Three types of incidents accounted for more than 90% of harm: problems with diagnosis (60.8%), medication-related (25.7%) and delayed referrals (10.8%). A survey of 48 primary care centres across Spain found that the prevalence of harm was 0.8% and that about two thirds of harms were preventable (64%) and 6% were severe *(25)*. Other global estimates suggest that as many as 4 in 10 patients may be harmed in primary and outpatient care, and that up to 85% of this harm is preventable, indicating that the burden of harm in primary and community care settings are likely to be much higher *(9)*. Globally, the evidence of harm in primary care settings is incomplete and there is a need for a wider range of methods to measure harm in these settings given the large and heterogenous pool of people treated in primary care. Problems in communication and administration appear to be at the root of many incidents of patient harm in primary care *(37)*.

In **long-term care**, patients remain in the setting for long periods and have an increased risk of harm. Research shows that over half of the harm that occurs is

preventable, and over 40% of admissions to hospitals from long-term care are avoidable. The root causes of these events can be addressed through improved prevention and safety practices, and workforce development, including skill-mix and education *(38)*.

In **mental health settings**, estimates of the scale and nature of patient harm are lacking. In one evaluation of 4536 patients in primary health care and emergency departments, the risk of a reported case of preventable harm in patients with all psychiatric diagnoses was nearly double that seen in other patients *(39)*. Another study found that the incidence of ADEs was 2.6 per 1000 patient days and that 20% of these ADEs were preventable. The majority of ADEs were of at least moderate clinical severity (62%), and antipsychotics and antidepressants were implicated in almost all cases of harm *(40)*.

Patients receiving **palliative care** are vulnerable to inadvertent harm during their medical and nursing care, with some risks specific to this patient population. An investigation involving 475 reports of serious incidents in patients receiving palliative care in the United Kingdom found that 266 reports were related to pressure ulcers, 91 to medication errors, 46 to falls and 21 to HCAIs *(41)*. Resulting harms included worsened symptoms, disrupted end of life, serious injury and hastened death. Better coordination of the delivery of palliative care and wider availability of specialist palliative care advice and support may make care safer.

**Radiotherapy** is one of the major treatment options in cancer management and is widely known to be one of the highly standardized and reliable areas of modern medicine *(42)*. It is estimated that the overall incidence of radiotherapy errors is around 1500 per million treatment courses 43). Toxicities and harms of radiotherapy often relate to overexposure to radiation and wrong-patient or wrong-site identification, and therefore dose calculation and regulation are of particular concern *(44)*. In fact, data shows that in oncological radiotherapy, 30% of errors occur in the planning phase of therapy and 29% are encountered in the treatment step *(45)*. This may suggest that the planning phase needs a more robust universally standardized control system and many studies have attempted to elucidate areas of improvement regarding geometric discrepancies resulting in errors *(46)*.

In **paediatric care** settings, such as high-risk paediatric ICUs, harm occurs with an incidence as high as 74 per 100 admissions *(47)*. Similarly, one in six patients in paediatric ICUs experience one or more ADEs, with an incidence of 16.7 per 1000 patient-days and more than half of the ADEs thought to be preventable *(48)*.

**Telemedicine and digital health** have significantly expanded, particularly during and since the coronavirus disease (COVID-19) pandemic. Telemedicine, while enhancing access to care, presents unique patient safety concerns including diagnostic errors due to inadequate history taking, limited physical examinations, and reliance on patients for vital sign measurements *(49)*. When compared with in-person encounters, the use of telemedicine for acute health concerns may lead to increased in-person follow-ups, raising safety concerns *(50)*. Additionally, the effectiveness of telemedicine can be compromised by gaps in medication safety, with poor communication affecting medication reconciliation and leading to potential ADEs *(49)*. A report from the WHO

Regional Office for Europe reveals that while most European countries (44 out of 53) have adopted national digital health strategies, only a third (19) have specified how they will evaluate the safety and effectiveness of these initiatives *(51)*. Additionally, the report points out that only 13 Member States in the region have policies to regulate private companies' use of 'big data' in health care research. Similarly, only 16 countries have evaluated their telemedicine services, despite 30 countries introducing legislation to support telemedicine. Moreover, digital health literacy policies aimed at promoting equitable access to digital services are only in place in 27 countries, potentially leaving vulnerable populations behind. The report emphasizes the need for universal access to affordable broadband services, data security, and interoperability of digital health tools to ensure more equitable benefits for all. There is currently a lack of consistent data on the potential harms of telemedicine and digital health, as highlighted in a recent scoping review that called for more comprehensive data collection and transparent reporting of near-miss and adverse events during telemedicine-based mental health assessments and related care *(52)*.

Patient harm and safety in **dentistry** remain strikingly unexplored. Using the trigger tool methodology, a study in Canada found that the prevalence of patient harm in dentistry was 1.8% (158 out of 8931 patient records contained an adverse event), 6% of which (i.e. 9 harm cases) were severe *(53)*. One recent mixed-methods study of severe incident reports from primary care dentistry submitted to England and Wales' National Reporting and Learning System found that the main sources of unsafe care in primary care dentistry were delays in treatment (23.6%), procedural errors (15.6%), ADEs (11.1%), equipment failure (6.2%) and x-ray-related errors (6.0%). The prevalence of patient harm was 5.3%, around half of which was due to wrong tooth extractions (48.1%) mainly resulting from distraction of the dentist *(54)*. Studies have also underscored the importance of guaranteeing the safe and effective administration of anaesthesia in dental settings, especially when employing sedation and general anaesthesia *(55)*, but a systematic review found that the only type of interventions that have been tested in dentistry to reduce or minimize harm have been surgical safety checklists *(56)*.

Only a limited number of studies have investigated the prevalence of patient harm in **obstetrics** services, which has been estimated at between 2% and 4%, with approximately half of these cases considered preventable *(5)*. A more recent retrospective study from Germany, which specifically focused on preventable harm, identified harms in 23% of the 2865 births that took place in one hospital in 2018. Among these cases, 13% exhibited at least one preventable harm. The main categories of preventable harms included peripartum therapy delay (44%), diagnostic errors (36%), inadequate maternal birth positions (34%), and organizational errors (33%). The study also identified key risk factors for preventable harms, which included primiparous women (56%), multiparous women (44%), on-call duty during birth (44%), labour induction (43%), missed birth date (35%), and obesity (24%) *(57)*.

**The emergency unit** is acknowledged as high-risk settings for patient harm, attributed to factors such as high patient volume, complex cases, time

constraints, and varying physician training. A systematic review revealed significant disparities in the incidence of patient harm in emergency care, spanning from 0.2% to 6%, with the preventability of harm ranging from 36% to 71%. The most frequent types of harm were related to management, diagnosis and medication. The variations in research findings and the scarcity of high-quality studies on the prevalence and nature of harm in emergency care underscore the necessity for studies featuring robust, standardized outcome assessment and reporting *(58)*. Another systematic review also found that boarding in the emergency unit may be a risk factor for increased patient harms *(59)*. In a recent study conducted in the United States, which reviewed 5582 selected records using a standard two-tiered trigger tool approach, it was determined that the prevalence of patient harm was approximately 8% over a 13-month period, with 12% of cases being classified as severe or resulting in death. The primary types of harm were predominantly related to medication (65%), followed by other forms of care (15%), medical devices (14%), and surgical or procedural issues (6%) *(60)*.

**Trauma**, as seen for example in the field of orthopaedics, is a potential risk factor for patient harm. A study utilizing data from the US National Surgical Quality Improvement Program (NSQIP) from 2005 to 2011 and involving 146 773 orthopaedic patients (including 22 361 trauma cases) revealed that the incidence of patient harm within the trauma group was 11.4%, in contrast to 4.1% in the general orthopaedic group. Further analyses indicated that the presence of trauma was associated with a doubling of the probability of patient harm *(61)*. Another study in the Netherlands (Kingdom of the) found that patient harm occurred in over half of orthopaedic trauma surgical procedures (54%). The primary causes of patient harm were predominantly linked to technical equipment and logistics, which could have been prevented. In 36% of the procedures, patient harm led to prolonged operation times *(62)*. Furthermore, a 5-year analysis of trauma patients requiring CT scans at a major trauma centre in South Africa revealed that approximately 12% experienced patient harm, with 85% of these incidents being preventable and attributed to human error. Of the cases, 25% resulted in moderate harm, while 10% were classified as severe or life-threatening *(63)*.

## Burden of harm by source

Seven types of harm acquired in hospitals have been estimated to account for an annual loss of 23 million DALYs at the global level These include ADEs, catheter-related urinary tract infections, catheter-related bloodstream infections, hospital-acquired pneumonia, venous thromboembolisms (VTEs), falls and pressure ulcers. The prevalence and impact of these harms vary significantly between HICs and LMICs. Notably, VTEs are the leading cause of harm in LMICs with 5.4 million DALYs, whereas hospital-acquired pneumonia is the predominant source of harm in HICs with 2.5 million DALYs. *(10)*.

A recent study from the US estimated that the most common sources of patient harm in hospitals were ADEs (39%); events related to surgeries or other clinical procedures (30%); patient care events such as falls or pressure ulcers (15%); and HCAIs (12%) *(64)*.

*Emergency units are high-risk settings for patient harm, with incidences ranging from 0.2% to 6%, primarily due to issues relating to management, diagnosis, and medication.*

*Trauma patients, particularly in orthopaedics, face higher risks, with harm rates significantly exceeding those of non-trauma patients.*

**Medication errors** are the single most important source of patient harm in health care systems. A recent WHO report *(65)* found that at least 1 in 20 patients (5%) experience preventable medication-related harm globally. Preventable medication-related harm was 7% in 30 studies conducted in LMICs and 4% in 70 studies in HICs. The highest prevalence rates of preventable medication-related harm were reported in the African region (9%) and South-East Asia region (9%). Almost one quarter of preventable medication-related harm is severe or life-threatening. Preventable harms are worryingly high in geriatric care settings and in highly specialized care settings (e.g. surgical care, intensive care and emergency medicine). Antibiotics, antipsychotics, medicines for cardiovascular disease and gastrointestinal conditions, and non-steroidal anti-inflammatory drugs each accounted for at least 10% of medication-related harm.

Globally about half (53%) of all preventable medication-related harm occurs at the ordering/prescribing stage and around a third (36%) at the monitoring/ reporting stage. In LMICs, almost 80% of preventable medication-related harm occurs during the ordering/prescribing stage. Investments are needed to further investigate the error-prone medication administration and the prescribing stages, and also explore the dynamics of severe incidents, which can then inform targeted prevention strategies *(65)*.

An analysis of 526 186 medication incident reports to the national reporting and learning system in England and Wales showed that 75% of medication incidents were from acute general hospitals and 8.5% of reports were from primary care *(66)*. 16% of medication incidents reported actual patient harm with 822 (0.9%) instances resulting in death or severe harm. Omitted and delayed medicine (16%) and wrong dose (15%) represented the largest error categories.

A systematic review of medication errors conducted in 2011 in Middle Eastern countries reveals a significant variation in rates, spanning from 7.1% to as high as 90.5% for prescribing errors, and from 9.4% to 80% for administration errors *(67)*. Among the prescribing errors, the most prevalent were incorrect dosages, occurring at rates ranging from 0.15% to 34.8% of prescriptions, alongside wrong frequency and/or strength.

A systematic review of African hospital data in nine African countries uncovers alarming rates of ADEs and medication errors *(68)*. Approximately 8.4% of patients experience ADEs upon admission, with 43.5% of these considered preventable. The review highlights prescribing errors in 57.4% of prescriptions and dosing problems in 15.5%, indicating substantial challenges. Factors such as practitioner fatigue and high workload contribute to these errors, underscoring the critical need for enhanced safety protocols in African hospitals.

**Diagnostic errors** are increasingly recognized as a key source of patient harm, with estimates indicating that 5% of adults are affected by diagnostic errors in outpatient environments in the United States *(69)*. A systematic review and meta-analysis of harmful diagnostic errors in hospitalized adults revealed that at least 0.7% of admissions involve such errors, with common diseases such as malignancy and pulmonary embolism being frequently missed. In the United States alone, this accounts for an estimated 249 900 errors yearly *(70)*.

Similar meta-analysis found that globally, 16% of preventable patient harm across the health system may be due to diagnostic errors *(5)*. Diagnostic harm stemming from errors in primary health care services requires more research to identify successful strategies *(46, 71–73)*. The 2018 OECD patient safety survey *(9)* reported that delayed diagnosis/intervention was among the most common causes of patient harm in ambulatory/primary care settings, particularly in LMICs. One recent retrospective patient record review in 21 United Kingdom general practices identified possible diagnostic errors in 4.3% of the reviewed consultations, 37% of which resulted in moderate to severe avoidable patient harm *(74)*.

Problems in patient–practitioner encounters – such as history taking, examination or ordering tests, performance and interpretation of diagnostic tests and follow-up, and tracking of diagnostic information – were the most common contributing processes in diagnostic errors. In most diagnostic errors, however, more than one contributing process was involved, and the development and evaluation of multi-pronged interventions, along with policy changes to support them, are needed *(74)*.

**Health care-associated infections** are one of the most common complications in hospital care and cause very significant consequences in terms of disability and premature mortality *(75)*. Global estimates from WHO suggest that 7% of hospital patients in HICs and 15% of hospital patients in LMICs will acquire HCAIs, according to the best quality studies conducted in 2011. *(76,77)*. A recent global study estimated that some 136 million hospital-associated infections that are resistant to antibiotics occur every year *(78)*. On the basis of data from 2016–2017, the European Centre for Disease Prevention and Control (ECDC) calculated that 8.9 million episodes of HCAIs occurred every year in patients admitted to acute care hospitals and long-term care facilities in the European Union (EU) and European Economic Area (EEA) countries. In these countries, the burden of the six most frequent HCAIs in terms of disability and premature mortality was twice the burden of 32 other infectious diseases combined *(79)*. The United States Centers for Disease Control and Prevention (CDC) estimates that, on any given day, one in 31 hospital patients and one in 43 nursing home residents has a HCAI *(80)*.

HCAIs may affect up to one in five hospital patients in LMICs but estimates are inconsistent due to inadequate infrastructure such as data collection and record-keeping *(81)*.

Up to 30% of patients in intensive care can be affected by HCAIs, with an incidence that is two to 20 times higher in LMICs than in HICs, in particular among neonates *(77)*. The most frequently reported types of HCAIs are those of the respiratory tract, surgical sites, urinary tract, bloodstream and gastrointestinal tract. There are numerous factors that heighten the risk for developing HCAIs, such as increased age, immunosuppression, multiple underlying co-morbidities, increased length of hospital stay, admission to intensive care and mechanical ventilatory support. Several preventive measures exist with demonstrated effectiveness to prevent transmission of HCAIs, with hand hygiene and other standard precautions and transmission-based precautions being among the most important ones. *(82,83)*.

*Diagnostic errors contribute to 16% of preventable patient harm globally, often due to issues in patient-practitioner encounters such as history taking, examination, and test interpretation.*

*HCAIs affect 7% of hospital patients in high-income countries and 15% in LMICs, causing significant disability and premature mortality globally.*

Hospitalization, surgery and other health care procedures involving prolonged immobility increase the risk for **venous thromboembolism** (VTE, or more simply blood clots). VTE is one of the most common and preventable causes of patient harm and has an annual incidence of 5 to 12 people per 10 000 (84). As many as 3.9 million people in HICs and 6 million people in LMICs are affected by VTE in 2009 (10). VTE is a leading cause of adverse events in LMICs and globally there are almost 10 million hospital-associated VTE in 2009. Amongst all sources of patient harm, the biggest source of lost DALYs appears to be VTE (5.4 million DALYs in LMICs, 95% CI 1.1 million to 11.7 million) and 2.3 million in HICs (95% CI 1.1 million to 3.9 million). Using a combination of surveillance data and modelling methods, the US CDC estimated the annual VTE-related death incidence ranges from 60 000 to 100 000 in United States. *(85)*. The global VTE burden is primarily associated with recent hospitalization for surgery or acute illness (up to 60%) and cancer (around 20%) *(86)*. The harmful consequences for patients who develop VTE are exacerbated by the risk of recurrent VTE, post-thrombotic syndrome and chronic pulmonary hypertension *(87)*.

**Sepsis** is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Because sepsis-related infections are often resistant to antibiotics, they can rapidly lead to deteriorating clinical conditions that must be diagnosed rapidly to prevent death. Sepsis affects an estimated 31 million people worldwide and causes over 5 million deaths per year *(88)*. Analysis of data for adults admitted to hospitals in seven HICs reported 19.4 severe million sepsis incident cases annually and 5.3 million sepsis-related deaths. A recent global analysis that used 2017 Global burden of disease study data from 195 countries, estimated 48.9 million incident cases of sepsis worldwide in 2017 and 11.0 million sepsis-related deaths, representing about one fifth of all global deaths *(89)*. Age-standardized sepsis incidence fell by 37% and mortality decreased by 53% from 1990 to 2017. The highest burden of sepsis incidence and mortality is found in areas with a lower socio-demographic index (SDI) including sub-Saharan Africa, Oceania, south Asia, east Asia and southeast Asia. This striking increase is largely attributable to the far higher burden among people living in areas with a lower SDI, for whom data had previously been lacking. These updated estimates highlight the need for greater prevention, diagnosis and treatment of sepsis, particularly in poor areas of the world.

**Patient falls** are one of the most common adverse events in hospital settings *(90)*. According to some studies, patient falls occur at a rate of 3 to 5 per 1000 bed-days, and more than one third of them cause injury *(91)*. This negatively affects the safety and quality of care and the cost-effectiveness of health systems *(92)*. Therefore, preventing and managing patient falls is a crucial aspect of hospital safety and quality improvement.

**Pressure ulcers**, also known as bedsores, are damage to the skin or underlying tissue caused by prolonged pressure on certain areas of the body. They can occur in patients who are bedridden, wheelchair-bound, or have limited mobility. Pressure ulcers can lead to serious infections and even death if left untreated. They are a common and preventable problem in health care settings, affecting more than 10% of adult hospital patients *(93)*. Pressure ulcers have a negative impact on the physical and mental well-being of patients, as well as their quality of life *(94)*.

**Patient identification errors** can have serious consequences for health care delivery and lead to severe adverse events, such as operating on a wrong patient or the incorrect site. A 2018 report indicated that, from 2014 to 2017, 409 out of 3326 sentinel events (12.3%) were associated with patient identification errors in the United States. Similarly, the National Patient Safety Agency in the United Kingdom reported that, between 2006 and 2008, there were 1309 incidents related to patient identification errors, with the vast majority (97%) occurring in hospitals. In a Brazilian hospital, out of 385 analysed patients, 11.9% had errors in their identification wristbands, and 4.2% were without any form of identification *(95)*.

**Unsafe transfusion practices** expose patients to the risk of adverse transfusion reactions and transmission of infections. Data on adverse transfusion reactions from a group of 62 countries show an average incidence of 12.2 serious reactions per 100 000 distributed blood components *(96)*.

Each year, 16 billion injections are administered worldwide, and **unsafe injection practices** place patients and health workers at risk of infectious and non-infectious adverse events *(97)*. Using mathematical modelling, a study estimated that in a period of a decade (2000–2010), 1.67 million hepatitis B virus infections, between 157 592 and 315 120 hepatitis C virus infections, and between 16 939 and 33 877 HIV infections were associated with unsafe injections globally *(98)*.

## Measurement considerations and conclusions

Patient harm has tragic effects on both patients and health workers including physical and/or psychological harm, a loss of trust in the health care system, and reduced staff morale. Even though the numbers and proportions of patient harm presented in some research reports may vary or appear relatively small, it is important to keep sight of what they really mean. Even seemingly small proportions of harm equate to several hundreds of thousands of people potentially harmed through health care each year. It is important to be mindful that behind each statistic there is a person.

The impact of patient harm on health workers is one of the major hidden burdens of patient harm *(8)*. Staff are often described as the 'second victims' of adverse events, experiencing detrimental impacts on their physical and mental health, retention problems and increased risks for more unsafe care incidents *(99)*. A systems-based approach can maximize the potential to avoid future adverse events, but it requires shifting from a 'blame culture' to a 'just culture', which achieves a balance between no blame and accountability, as well as successfully implemented safety improvement strategies *(100,101)*.

At present, the higher absolute burden of patient harm in LMICs compared to HICs partly reflects differences in the population sizes of countries. Analyses fail to show marked differences in the actual percentages of patient harm across geographic and social economic regions. However, there is a substantial evidence gap between HICs and LMICs given that most of related studies have been conducted in HICs and very few – often low-quality studies – are

*Unsafe blood transfusion and injection practices pose significant health risks, with an average of 12.2 serious transfusion reactions per 100 000 blood components as well as millions of infections, including hepatitis B, hepatitis C, and HIV, linked to unsafe injections each year.*

*Small proportions of patient harm affect hundreds of thousands of people annually. Adopting a systems-based approach and shifting from a 'blame culture' to a 'just culture' can help prevent future adverse events.*

*The burden of patient harm in LMICs is likely to be underestimated due to a lack of high-quality studies, highlighting the need for better medical records and improved research methodologies to produce accurate estimates.*

conducted in LMICs. Thus, the burden of patient harm due to unsafe care in LMICs is very likely underestimated. Investments in establishing high-quality medical records and designing studies with better standards of reporting quality are essential for producing accurate estimates of the burden of patient harm due to unsafe care in LMICs.

The burden of patient harm has been calculated using many different methods and a variety of data sources including patient charts, safety incident reporting, electronic databases, interviews with clinical staff and direct examination of patients. Currently, there is no internationally agreed measurement strategy to reliably identify and analyse the burden of patient harm and monitor the impact of safety improvement programmes *(100)*.

A minimum set of appropriate and feasible standards for measuring patient harm should be established and adhered to globally. These standards should include screening criteria that are applied, assessment of reviewers, timeframes for harm detection and for determining harm causality, preventability and severity. Specific reporting guidelines for patient harm are also necessary to strengthen the current evidence base and to help shed light on variations reported across studies and countries. Finally, there is a need to move from non-systematic methods such as voluntary reporting to coordinated systematic measurement. This could involve a combination of methods including national audits, screening programmes and annual reviews of patient charts to reliably map the landscape of patient safety *(9)*.

# Financial and economic burden of unsafe care

# Key messages

Unsafe care significantly burdens health care budgets, consuming up to 12.6% of total health expenditure in high-income countries, translating into approximately $878 billion annually.

Patient harm's financial impact varies by setting: in acute care, complications inflate costs; in primary care, adverse drug events and misdiagnoses lead to unnecessary hospital use; and in long-term care, conditions such as pressure ulcers add significant expenses, showing the broad economic effects of unsafe care.

Patient harm significantly reduces productivity and increases income loss, imposing indirect costs on economies that can surpass direct health care costs. Improving patient safety could have profound economic benefits, potentially increasing global economic output by 15% over two decades.

The global willingness to invest in preventing patient harm, potentially averting US$1.17 trillion annually in costs, underscores the strong rationale for health care systems to prioritize patient safety.

Effective patient safety interventions, such as the WHO Surgical Safety Checklist and strategies to prevent healthcare-associated infections (HCAIs), offer high returns on investment, demonstrating that targeted efforts to improve care safety are not only medically beneficial but also economically wise.

*Unsafe care incurs significant costs and diverts resources away from patient care, impacting health services and outcomes. Reducing safety-related harm can free up capacity and reduce opportunity costs.*

In addition to the resulting human toll and disease burden, patient harm due to unsafe care also incurs considerable financial and economic costs. These include the direct financial cost of treating morbidity caused by safety lapses: additional investigations, therapies and interventions that consume scarce resources that could be deployed towards other priority care needs. It also comprises the economic and societal costs of unsafe care beyond the health system, such as through lost productivity, foregone income as well as what societies would be willing to pay to prevent such harms.

## The direct costs unsafe care imposes on health care systems and budgets

Unsafe care requires resources to ameliorate the resulting patient harm. This includes additional diagnostic testing, acute, non-acute and other health system activity (including administrative actions) that would not otherwise have been needed had the safety lapse not occurred. There is an opportunity cost of using these resources because every time a harmed patient requires additional care, someone else either misses out or must wait for their care or other services. Reducing safety-related harm decreases this opportunity cost, freeing up capacity that can be used more effectively to achieve other important health outcomes.

Use of additional resources because of unsafe care can be valued in monetary terms. Because managing the consequences of harm diverts resources from other activities (such as medical care, prevention and research), other direct costs can also be quantified as forgone benefits as a consequence of what is *not* done.

Most analyses on the costs of unsafe care have been conducted in HICs. Of such studies, most examine specific types of harm (e.g. HCAI, ADEs), with the majority focusing on acute care and related settings such as ICUs. More recently, other settings – especially primary and ambulatory care, community-based and aged/long-term care – are receiving increased attention. Available evidence typically comprises estimated costs of additional care brought about by a safety lapse. The sum of these additional costs can be expressed as a total cost, or as a proportion of what a country or health system spends overall on health services, allowing for inter-country comparisons.

*In selected HICs 12.6% of health expenditure, amounting to $878 billion annually, is spent on managing the consequences of patient harm.*

The most recent analysis of the total direct financial cost of unsafe care across the main health care settings (i.e. acute/hospital care, primary/ambulatory/community care, and aged/long-term care) in selected HICs was conducted by the OECD in 2022.[5] The headline figure was that 12.6% of total health expenditure devoted to in-patient/acute, primary/ambulatory and long-term care is allocated to managing the consequences of patient harm (Fig. 3). This proportion of total health spending is approximately US$ 878 billion (2018 purchasing power parity (PPP)) across OECD countries each year, or equivalent

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5   *Countries were selected on having reliable data on the costs of unsafe care.*

to about 1.4% of their combined gross domestic product (GDP) *(6)*.[6,7] As a result, only 87.4% of the resources made available for health services in the countries examined is used for treating illness and disease of spontaneous (or *idiopathic*) origin. The rest is consumed on *iatrogenic* conditions, resulting from unsafe care. In taking into account the proportion of preventable patient harms, the direct financial cost of avoidable harm is estimated to be 8.7% of total health expenditure**,** or US$ 606 billion across OECD countries *(6)*.
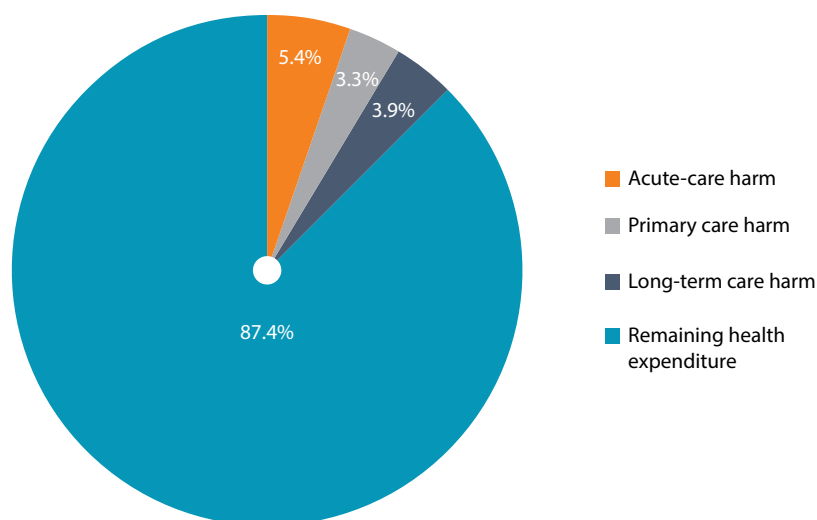


Source: Slawomirski L and Klazinga NS, 2022 (6).

**Fig. 3.**
**Direct costs of unsafe care in selected high-income countries as a proportion of expenditure on health care services**

As mentioned, studies of the costs of unsafe care in LMICs are limited. Based on available evidence, however, direct costs are likely to be similar to HICs estimates. A recent study in Thailand examined the direct cost of adverse events in acute care using five years of administrative data, and focusing on excess length of hospital stays as the main cost driver. Results suggest that 7% of admissions included one or more harmful incidents. The annual number of excess bed days was 3.5 million, which was costed at Thai Baht (THB) 9.6 billion (US$ 278 million). According to the study authors, this equates to 5.5% of the national health budget *(102)*.

## Direct costs by setting and source of harm

In acute care, some of the most common safety lapses include HCAIs, VTEs, medication-related adverse events, falls and pressure ulcers *(7,103)*. Safety lapses in sub-settings such as surgery and ICU incur higher direct costs relative to other settings *(104)*.

A study conducted in a hospital in Ethiopia found that HCAIs almost doubled patients' length of stay, and increased the cost of hospital treatment approximately 2.7-fold, as well as doubling the risk of death during the hospital stay *(105)*. A study involving 10 hospitals in Henan Province in China found that

*Studies of the costs of unsafe care in LMICs are limited, but the available evidence suggests that the direct costs are likely to be similar to those in high-income countries.*

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6   This figure includes all health care harm.

7   Based on 2020 gross domestic product and health expenditure data in OECD countries (https://data.oecd.org/).

HCAIs were associated with a 1.8-fold increase in length of stay and a 2.5-fold increase in admission costs *(106)*. In Australia, the annual costs of managing surgical site infections in public hospitals amounts to AUD 323,5 million (approximately US$210 million) per year, or 0.4% of public hospital spending *(107)*. A systematic review found that 2.7% of health care budgets globally is spent on managing sepsis cases *(108)*.

In the United States, the annual direct cost of hospital-acquired VTE is estimated to be US$ 7–10 billion *(109)*. Surgical harm has been associated with a 2-fold increase in length of stay and a 1.5-fold increase in direct hospital costs *(110)*. About 70% of US patients undergoing colorectal surgery have at least one complication, which are associated with an estimated 40% increase in treatment costs *(111)*. The direct costs of post-operative delirium in United States are estimated at US$ 33 billion annually *(112)*.

The direct costs of harm in acute care typically include additional care required during the admission when the safety lapse occurred. For the most part, however, they exclude additional care required in the non-acute setting and consequent hospital re-admissions. These can be considerable. For example, after adjusting for complexity, patients who suffered hospital harm are re-admitted at 1.2 times the frequency of those who do not. The rate is 1.56 for some types of harm such as surgical wound opening (or dehiscence) *(113)*.

In the primary/ambulatory setting, a lot of patient harm stems from ADEs, as well as wrong or delayed diagnosis and treatment *(6)*. The direct costs of unsafe community care include the costs of additional non-acute care, emergency department visits and hospital admissions. About 4% of in-patient expenditure could be attributed to unnecessary admissions for five conditions that can be managed in the community setting,[8] while medication-related harms may account for as much as 4% of in-patient capacity and 3.6% of hospital admissions *(6)*. Other estimates suggest that as much as 15% of hospital admissions were associated with medication-related problems sustained in the ambulatory setting *(103)*. A Netherlands (Kingdom of the) study reported that 29% of presentations to the emergency department of a hospital during a 5-month period were a direct result of adverse events. The most common were ADEs *(114)*. The combined cost of ADEs across all health care settings across OECD countries has been estimated at US$ 54 billion annually, or 1% of total health expenditures *(103)*.

In long-term care, the most common adverse events include pressure ulcers, falls, ADEs, malnutrition and infections. These can result in premature death (as witnessed throughout the COVID-19 pandemic), but typically cause additional morbidity requiring additional care or hospital admission(s). The latter has been found to account for about 6.25% of in-patient expenditures in OECD countries, with the cost of pressure ulcers acquired in this setting estimated at around 2% of expenditure *(6)*. The aggregate direct costs of pressure injuries in Australia were recently estimated to be AUD 3.6 billion (US$ 2.3 billion) or 1.6% of national health expenditure *(115)*.[9]

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8   *Asthma, chronic obstructive pulmonary disease, heart failure, diabetes and hypertension.*

9   *Hospital expenditure data were obtained from* https://www.aihw.gov.au/.

Finally, it should be noted that estimates of the direct costs of harm vary considerably. For example, some studies place the costs of harm in acute care at around 2% of total health expenditure *(116–119)*. Other studies – using different methods, data and assumptions – place the aggregate burden of hospital harm from 6% to 12% of total health expenditure *(120,121)*.

In general, the cost estimates presented are most likely to be conservative.

## Indirect costs of unsafe care

Indirect costs comprise the burden of patient harms on people's productivity, labour participation and associated income loss. As with idiopathic conditions such as diabetes or cardiovascular disease, for example, patient harm hinders economic activity and societal welfare. These costs can exceed direct costs by orders of magnitude *(115)*. They are often calculated using approaches such as the human capital (or cost-of-illness) and willingness-to-pay approaches *(122)*.

### Patient harm hinders productivity and labour supply

The human capital approach is one way to value productivity. Using the human capital approach, studies have sought to establish the indirect cost of patient harm in terms of productivity and associated income loss. However, only the effects on patients are typically included in such analyses *(6)*.

Other studies have applied variations of the human capital approach to specific types of harm *(123)*. Linking data from several national registries, a study from Sweden estimated the total costs of ADEs in Sweden. The indirect costs (based only on productivity loss from sick leave and from income support/disability pension) were US$ 3405 per patient experiencing at least one instance of patient harm. This was more than double that of patients not experiencing unsafe care. The difference in total direct and indirect costs per patient between the patient samples amounted to US$ 3794 *(123)*.

More recently, a cost-of-illness study of surgical site infections in Australian public hospitals found the indirect costs – driven principally by lost productivity – were estimated at AUD 3 billion (US$1.9 billion), which represents approximately 1.5% of total Australian health expenditure (or 0.3% of its GDP). This is nine times the direct costs of AUD 323 million (US$209 million). *(107)*. A similar study examined pressure ulcers found the indirect costs to be AUD 5.5 billion (US$3.6 billion), compared to AUD 3.6 billion (US$2.3 billion) in direct costs *(115)*. The varying ratios between direct and indirect costs of these two Australian studies can be attributed to differing methods and assumptions, and because pressure ulcers are suffered predominantly by people who are no longer of working age.

Disadvantaged people are more likely to be disproportionately impacted by the indirect costs of harm. As previously highlighted, socially and economically disadvantaged populations experience higher rates of harm in health care and the resulting disease burden. This is illustrated by consistently greater funding adjustments for minority populations in various pay-for-performance schemes targeting patient safety *(124–126)*. Thus, it can be argued that unsafe care indirectly contributes to inequalities in incomes and poverty.

*Estimates of the direct costs of harm in acute care vary widely, ranging from 2% to 12% of total health expenditure.*

*Indirect costs of patient harm, such as lost productivity and income, can far exceed direct medical costs.*

*Disadvantaged populations are disproportionately affected by the indirect costs of patient harm, exacerbating income inequalities and poverty.*

The indirect cost of unsafe care can also be estimated by combining what is known about the disease burden of patient harm with cost-of-illness studies for other diseases. For example, a study modelled the indirect costs of chronic disease among Australians aged 45–64 years at 1.6% GDP, comprising lost productive life years, welfare payments and lost tax revenue due to chronic diseases *(127)*.

An indicative estimate of the economic burden of patient harm can also be derived from the cost-of-illness of other diseases. For example, the world-wide economic cost of adult diabetes has been estimated at US$ 1.31 trillion. About 35% (US$ 458 billion) of these costs were indirect *(128)*. Diabetes accounts for approximately 57 million lost DALYs each year *(129)*. Estimates of the global burden of patient harm range from 23 million to 64 million DALYs lost *(6, 10)*. Assuming a similar impact profile of health care harm and adult diabetes, patient harm may reduce global economic output up to 0.7% each year *(6)*. This may not seem like much but, over time, even a fraction of a percentage point can compound to a sizable total amount. If all unsafe care had been eliminated in 2000, gross world product (GWP) would have been 15% higher two decades later (US$ 111 trillion versus US$ 96 trillion) (Fig. 4). The cumulative GWP gain would have been about US$ 120 trillion over this timespan *(6)*.

**Fig. 4.**
**Actual gross world product, with and without health care harm, 2000–2021**
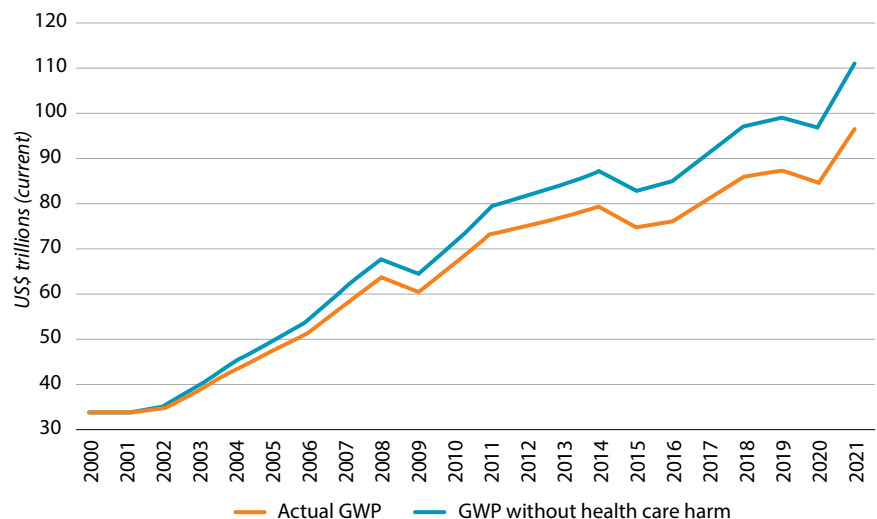


Note: GWP: gross world product.

Sources: Updated previous calculation by Slawomirski and Klazinga (2022) *(6)*. GWP data taken from: http://data.worldbank.org/ *(accessed 27 April 2024)*.

*The economic burden of patient harm is substantial, potentially reducing global economic output by up to 0.7% annually. If unsafe care had been eliminated in 2000, the gross world product could have been 15% higher two decades later.*

While these figures are illustrative and must be interpreted with caution, they nevertheless highlight substantial downstream costs of unsafe care. Even if the impact is half or even a quarter of what is projected here, the effect would still compound to trillions of US dollars over a decade.

## Estimating the cost of unsafe care based on willingness to pay

A willingness-to-pay approach seeks to empirically establish how much societies would be willing to pay for additional health or, in the case of patient harm, for preventing illness and disability. Specifically, a supply-side willingness-to-pay method examines the cost of a health condition based on

what health care budget holders would be willing to pay to ameliorate or avoid it given that health care budgets are fixed (effectively, the opportunity cost of foregone health and/or health services) *(6)*. Typically, countries evaluate the health benefits either in terms of adding a unit of health (e.g. a quality-adjusted life year (QALY)) or avoiding a unit of illness (e.g. a DALY), when they consider the cost-utility ratio of health interventions *(130)*. If the extent to which unsafe care increases patients' disability is known, a monetary value can be calculated based on what society – or rather decision-makers overseeing health budgets– would likely be willing to pay to prevent it or an equivalent health impact *(6)*. This method has been applied to estimate that the indirect cost of patient harm in the United States approaches US$ 1 trillion per annum *(6,7)*.

Naturally, this amount varies considerably between countries, and even within countries depending on factors such as the target disease, patient type and ability to pay and other contextual factors. For example, authorities in the United Kingdom use a supply-side threshold of approximately GBP 25 000 per QALY (just over half of the GDP per capita of the United Kingdom)[10] when deciding whether a medical intervention should be funded by the government. However, this threshold has been found to vary in some cases depending on the disease, with more recent guidelines permitting up to GBP 100 000 *(131)*. The United States, meanwhile, does not explicitly refer to such a threshold. But the figure can be inferred from how much payers such as Medicare, for example, are willing to pay for equivalent interventions. This can range from US$ 50 000 to US$ 150 000 per QALY (0.7 to 2 times GDP per capita) depending on location, payer and patient type *(132)*.

Other countries such as the Republic of Korea and the Slovak Republic apply a 'floating' cost-utility threshold set at their respective GDP per capita, while Hungary and the Republic of Poland set theirs at three times GDP per capita *(130)*. In LMICs, this figure has been estimated to be up to 50% of GDP per capita *(133)*. Combining the figure of 64 million DALYs lost per year *(6)* with a conservative willingness-to-pay value of 1.5 times GDP per capita would place the annual global societal cost of unsafe care at US$ 1.17 Trillion.[11] These figures must be interpreted with caution, however, as they do not consider preventability of harm and are based on willingness to pay for medical interventions to treat morbidity and mortality, not prevent them.[12]

Societies and populations may place a lower or higher value on avoiding patient harm from unsafe care. Indeed, some evidence suggests that avoiding certain types of iatrogenic patient harm attracts significantly more resources per unit of health than that typically spent on medical interventions. For example, in some HICs the marginal cost of screening donated blood (to reduce the risk of HIV and hepatitis B and C transmission during a blood transfusion) exceeds US$ 50 million per QALY *(135–137)*, suggesting a very high societal cost of safety lapses in blood transfusions safety.

*The indirect cost of patient harm is estimated to be substantial, highlighting the significant economic value societies place on preventing illness and disability.*

*The annual global societal cost of unsafe care is estimated to be US$ 1.17 trillion, based on a conservative willingness-to-pay value of 1.5 times GDP per capita, highlighting the substantial economic impact of patient harm.*

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[10]  *According to:* www.worldbank.org/en/home.

[11]  *Using 2021 World Bank estimates of gross world product.*

[12]  *This approach also interchanges DALYs and QALYs, which depends on factors such as age, duration of disease, mortality rate and disability weights used (134).*

## Investing in strategies to reduce harm can pay high dividends

*Investing in patient safety interventions, particularly those targeting high-cost and harmful events – such as HCAIs, VTEs, and medication errors – offers significant returns, with some interventions delivering a saving-to-cost ratio of 7:1.*

Countries invest a considerable amount of their national income in health care. The return on this investment in terms of improving people's health and preventing or ameliorating disease varies considerably *(138)*. Many existing strategies and interventions to improve the safety of care are very cost-effective when compared to medical services and interventions, and focusing on reducing the most common and harmful safety lapses often represents good value for money. According to the OECD report, The economics of patient safety: from analysis to action *(6)*, some patient safety interventions have a very high return on investment (ROI) in many settings, particularly those targeting the most costly and harmful events, such as HCAI, VTE, medication errors, pressure injuries and falls. These events account for a large share of the adverse outcomes and costs of unsafe care. They can also be improved feasibly. They offer a great opportunity for health systems to increase value by improving safety and reducing costs. For example, interventions targeting HCAIs can deliver a saving-to-cost ratio of 7:1 (i.e. a 7-fold ROI) *(139,140)*. Targeting infections can deliver a good return irrespective of baseline performance or income per capita *(141,142)*.

The WHO Surgical safety checklist, when implemented in a structured and evidence-based manner, has been an effective and highly efficient tool to reduce surgical harms and improve outcomes in both HICs and LMICs *(143–147)*. Preventing pressure ulcers and patient falls in acute and long-term care settings is also an excellent value proposition in terms of financial savings as well as health outcomes *(6,38,148)*. Technological interventions such as barcodes or computerized provider order entry systems have been found to be a cost-effective way to reduce medication errors over the medium term *(6,149,150)*.

*Implementing the WHO Surgical safety checklist and other interventions, such as preventing pressure ulcers and patient falls, significantly improves outcomes and reduces costs. Technological solutions such as barcodes and computerized order entry systems are also cost-effective, with safety programmes showing a high return on investment.*

A crew resource management programme was implemented in a large academic medical centre in the United States to improve patient safety. The programme cost about US$ 3.6 million, mainly for training and staff time. The programme reduced the incidence of various types of harm acquired during hospital care. The researchers calculated that this saved between US$ 12.6 million and US$ 28 million, equivalent to an ROI of US$ 3.5 to US$ 6.8 per dollar over a period of four years.

This study demonstrates that comprehensive, systemic patient safety strategies are worthwhile, including those that target organizational culture *(6, 151)*.

Patient engagement and health literacy are key factors for improving health outcomes and reducing harms. By applying these strategies and programmes in a consistent and effective way, harm could be decreased by up to 15%. This is a significant benefit for both patients and health systems *(9)*.

# Policies to eliminate avoidable harm in health care

*Doctor at Philippine General Hospital in Manila, Philippines. © WHO / Blink Media - Hannah Reyes Morales*

"

Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere

# Organization of section

### Strategy 1.1. Patient safety policy, strategy and implementation framework

- Patient safety as a priority in national health policy
- Integration of patient safety in UHC service delivery packages
- Patient safety policy and strategy
- National patient safety action plan
- National patient safety programme

### Strategy 1.2. Resource mobilization and allocation

- Budget category and allocation of financial resources
- Human resource plan and gap closure
- Recognition and reward mechanisms

### Strategy 1.3. Protective legislative measures

- Mandatory licensing for health care facilities and services
- Laws for authorization of medical products
- Legal protection against reporting of patient safety incidents
- Data protection and confidentiality

### Strategy 1.4. Safety standards, regulation and accreditation

- Minimum safety standards
- Safety standards in health care licensing
- Safety standards for all specified clinical services
- Safety standards in health services assessment tools
- Voluntary accreditation programmes and safety standards

### Strategy 1.5. World Patient Safety Day and Global Patient Safety Challenges

- World Patient Safety Day
- Global Patient Safety Challenges

# Key messages

Although most countries recognize patient safety as a national health priority, only one third of countries have fully incorporated patient safety into their national strategies for achieving UHC.

The development of policies, strategies, action plans, and programmes for patient safety is still in its early stages, and only 11% of countries report having adequate financial and human resources for implementation.

Regulatory mechanisms such as mandatory licensing of health care facilities are widely used to enforce safety, with around 80% of countries enacting laws on the use of medical products and implemented the safety standards in health care facilities.

World Patient Safety Day, established in 2019, has created unprecedented international momentum with 80% of Member States actively participating in annual campaigns and events to enhance awareness of patient safety.
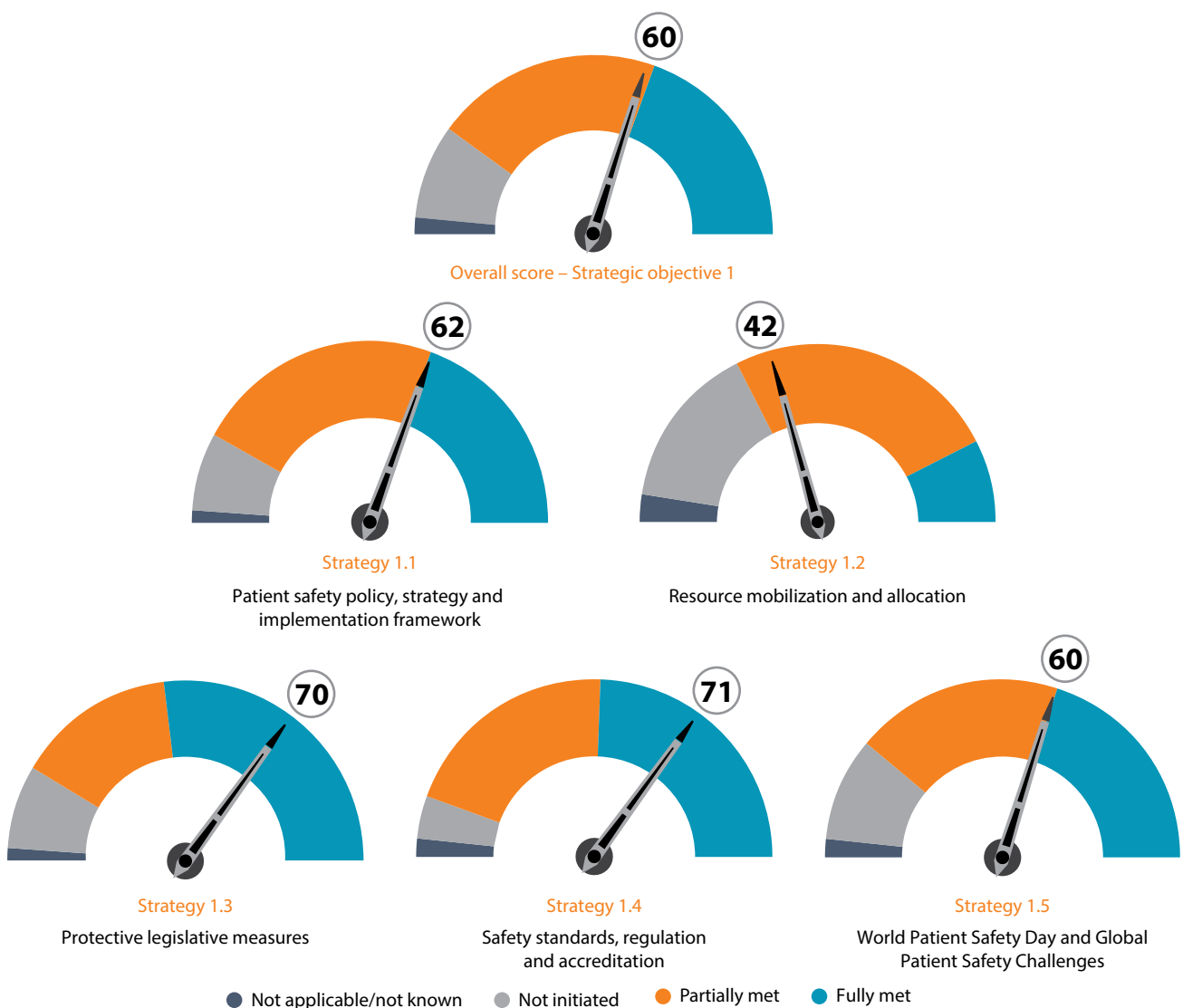
The WHO Global Patient Safety Challenges address critical risks to patient health and safety. Countries have taken actions on these initiatives, with almost 90% of countries addressing at least one of the challenges and one third of the countries implementing all the three challenges.

The *Global patient safety action plan 2021–2030 (2)* advocates for zero harm in health care settings globally. The action plan does not set specific goals for reducing harm; it drives a philosophy and a mindset of zero harm, which can be adjusted to different contexts, so that preventing patient harm is a priority and a guiding principle for all health workers and stakeholders. To achieve this, patient safety should be established as a strategic priority and a core value in the design and delivery of health care services, policies and programmes. This involves developing a national patient safety action plan and implementing a well-funded patient safety programme in the country. Moreover, using protective legislative measures to enable safe delivery of care, setting safety standards, regulation and accreditation, and raising awareness and maintaining a public profile for patient safety, are all essential elements for success of patient safety programmes.

Overall, reported country performance in areas covered by strategic objective 1 of the plan appears to be moderate, indicating a balanced blend of strengths and areas needing improvement across the 108 Member States that responded to the survey. The overall score for this strategic objective is 60 (out of 100) with an average of 39% of criteria being fully met and another 41% criteria partially met (Fig. 1.1). For 17% of the criteria, countries reported no action taken.
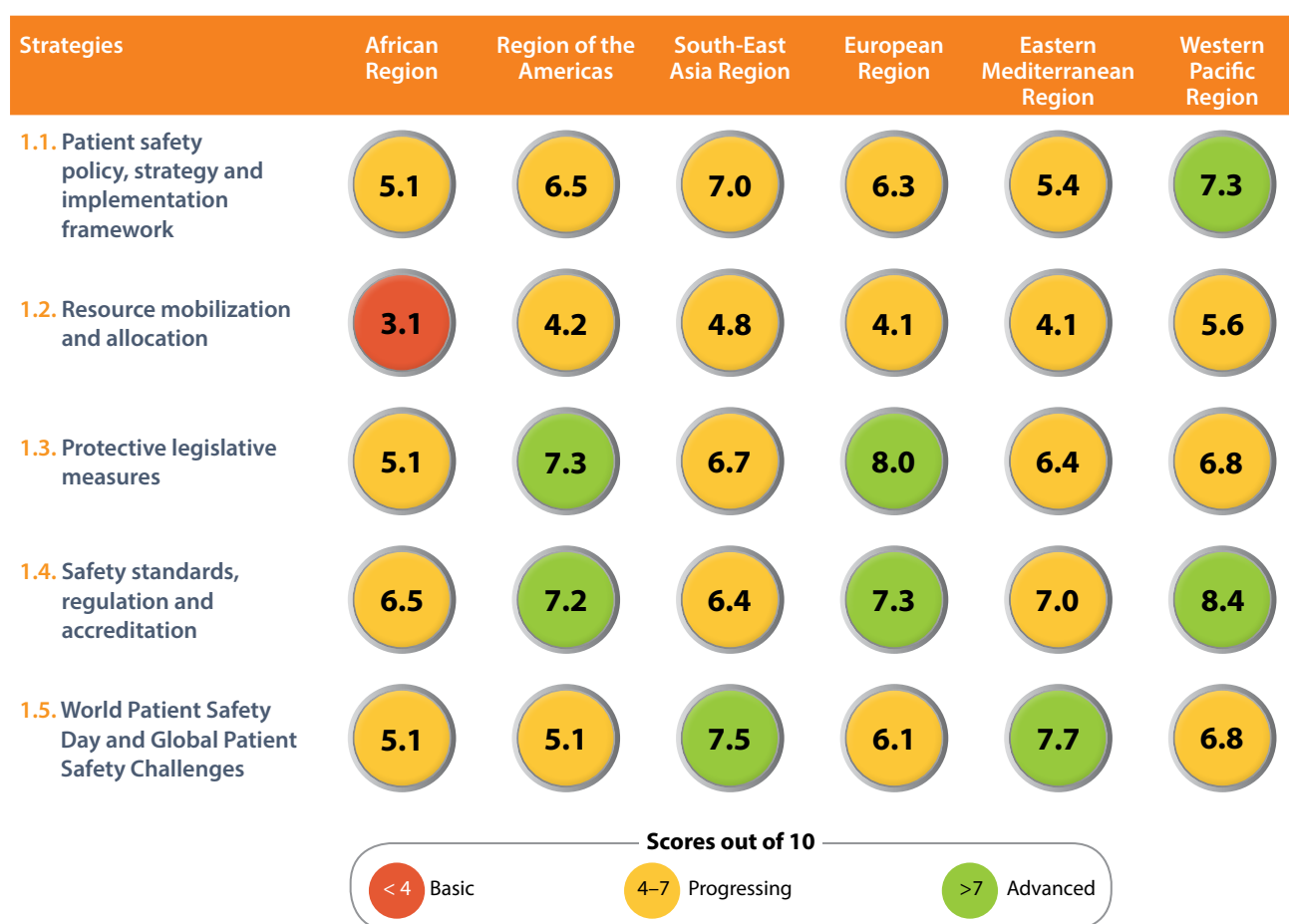
While there is a clear acknowledgement of the importance of patient safety within national health policies, actual implementation and strategic action are lacking. Over half of the respondents have recognized patient safety in their health policies, yet fewer have worked on operational aspects such as a patient safety action plan or programme. Financial and human resources dedicated to patient safety are notably insufficient, with only a small fraction fully addressing these aspects.

▶ **Fig. 1.1. Global performance scores for strategic objective 1**



**60**

Overall score – Strategic objective 1

**62**

Strategy 1.1

Patient safety policy, strategy and implementation framework

**42**

Strategy 1.2

Resource mobilization and allocation

**70**

Strategy 1.3

Protective legislative measures

**71**

Strategy 1.4

Safety standards, regulation and accreditation

**60**

Strategy 1.5

World Patient Safety Day and Global Patient Safety Challenges

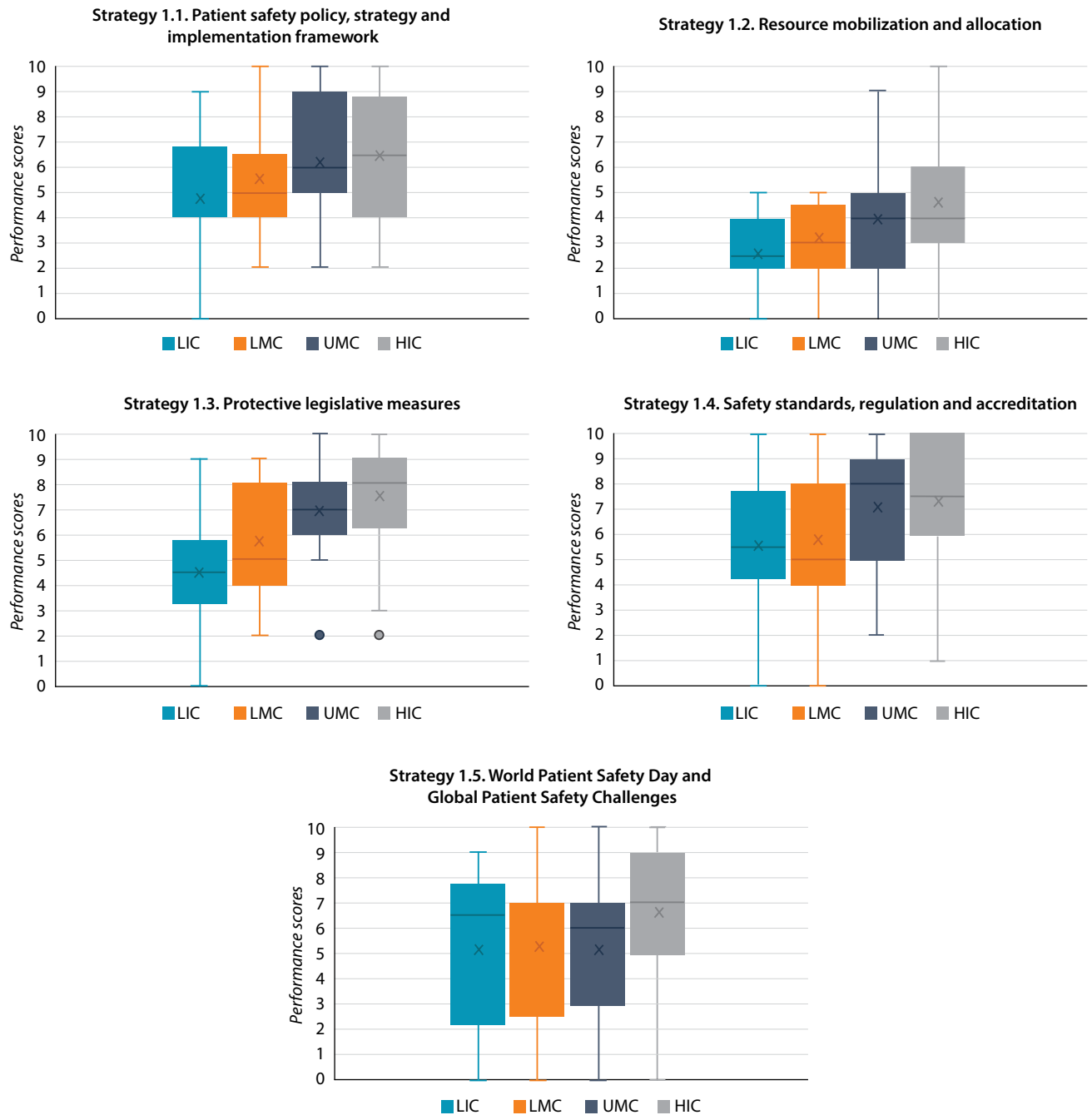● Not applicable/not known　● Not initiated　● Partially met　● Fully met

Closer analysis reveals significant regional disparities in average national performance scores (Fig. 1.2). Countries of the South-East Asia Region stand out for their robust policy frameworks, and exceptional observance of World Patient Safety Day, suggesting a strong regional focus on patient safety awareness and engagement. The Region of the Americas and the European Region exhibit strong regulatory environments, particularly in the licensing of health care facilities and the authorization of medical products, highlighting a commitment to legal and regulatory mechanisms for patient safety. However, all regions show deficiencies in human resources planning and allocation, which are critical for sustaining patient safety efforts. The African Region, while showing some progress in legal frameworks, faces significant challenges in policy development and resource allocation, indicating a need for more comprehensive strategies to elevate patient safety standards. The Western Pacific Region's commitment is evident in its prioritization of patient safety in health policy and the establishment of safety standards, although much remains to be done in relation to monitoring and implementation.

▶ **Fig. 1.2. Distribution of strategic objective 1 performance scores across the five strategies, by WHO region**

| Strategies | African Region | Region of the Americas | South-East Asia Region | European Region | Eastern Mediterranean Region | Western Pacific Region |
|---|---|---|---|---|---|---|
| **1.1. Patient safety policy, strategy and implementation framework** | 5.1 | 6.5 | 7.0 | 6.3 | 5.4 | 7.3 |
| **1.2. Resource mobilization and allocation** | 3.1 | 4.2 | 4.8 | 4.1 | 4.1 | 5.6 |
| **1.3. Protective legislative measures** | 5.1 | 7.3 | 6.7 | 8.0 | 6.4 | 6.8 |
| **1.4. Safety standards, regulation and accreditation** | 6.5 | 7.2 | 6.4 | 7.3 | 7.0 | 8.4 |
| **1.5. World Patient Safety Day and Global Patient Safety Challenges** | 5.1 | 5.1 | 7.5 | 6.1 | 7.7 | 6.8 |

Scores out of 10

| < 4 Basic | 4–7 Progressing | >7 Advanced |

The country survey scores indicate clear gradients across income groups, with HICs typically reporting stronger patient safety strategies, from policy and strategic frameworks to the allocation of resources (Fig. 1.3). HICs also tend to lead in establishing and enforcing rigorous safety standards, regulations and accreditation, as evidenced by their higher median scores. Financial and human resource allocations for patient safety show relatively lower differences across income groups, suggesting a universal underfunding in patient safety, regardless of a country's resources. Global initiatives such as World Patient Safety Day and Global Patient Safety Challenges see participation from countries across all income levels. Exceptional performers were seen within all income categories, underscoring that economic capability, while influential, is not the sole determinant of the success in patient safety endeavours.

**Fig. 1.3. Distribution of strategic objective 1 performance scores across the five strategies, by income group**

**Strategy 1.1. Patient safety policy, strategy and implementation framework**



**Strategy 1.2. Resource mobilization and allocation**



**Strategy 1.3. Protective legislative measures**



**Strategy 1.4. Safety standards, regulation and accreditation**



**Strategy 1.5. World Patient Safety Day and Global Patient Safety Challenges**



*Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.*

**Strategic objective 1**

## Strategy 1.1.

# Patient safety policy, strategy and implementation framework

> **Develop a comprehensive patient safety policy, strategy, institutional framework and action plan for the country's health system and all its components, as a key priority in working towards universal health coverage**
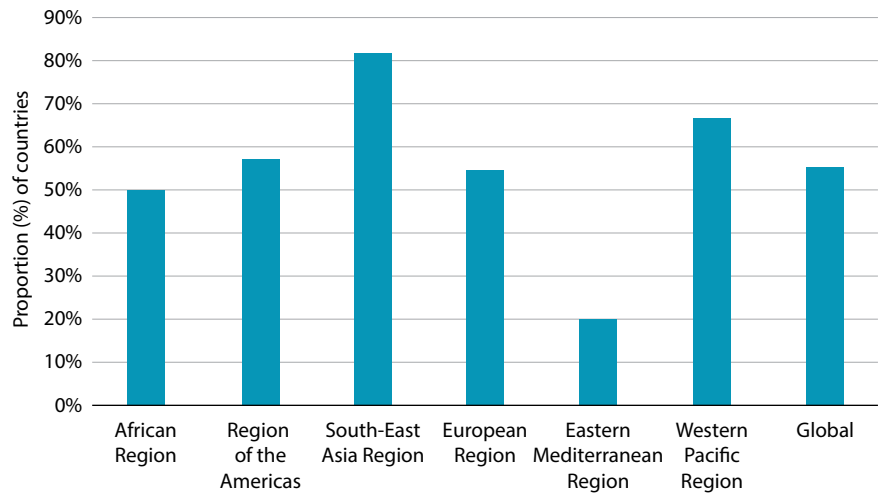
To deliver safe care, countries and regions have to deal with unique challenges that demand tailored national policies and strategies for reducing patient harms. Patient safety should be a core component of national health policies, programmes and health system strengthening initiatives. The extent to which countries integrate patient safety into their national health policies and actions, and the existence of institutional frameworks to regulate and provide safe care in health settings, are each an indication of national commitment to patient safety.

## Patient safety as a priority in national health policy

Of the 108 countries responding to the patient safety survey, most stated that patient safety is priority for them. While 55% of countries reported that patient safety has been recognized as a key priority in their national health policies, the majority (42%) of the remaining countries reported that this process is still ongoing in their national settings, with only some elements of patient safety having been included in their national health policy. Countries in the South-East Asia and Western Pacific regions reported the highest level of patient safety prioritization in national health policies (82% and 67% respectively) (Fig. 1.4 ).

*Most countries globally have recognized the importance of patient safety, incorporating its principles into their health policies. This indicates that there is a universal commitment to prioritizing patient safety, not just as a health care intervention, but as a key policy issue.*

Proportion (%) of countries

| Region | Value |
|---|---|
| African Region | 50% |
| Region of the Americas | 57% |
| South-East Asia Region | 82% |
| European Region | 55% |
| Eastern Mediterranean Region | 20% |
| Western Pacific Region | 67% |
| Global | 55% |

## Examples of how patient safety is prioritized in national health policies

Patient safety has been identified as a priority in the **Sri Lanka** National health strategic master plan, which guides the development of the health system until 2025. The plan also includes a separate policy on health care quality and safety, which outlines the standards, indicators and mechanisms for ensuring safe and effective care. The policy also emphasizes the importance of patient rights, feedback and participation *(152)*.

The Ministry of Health of **Brunei Darussalam** has published its strategic plan for 2019–2023, entitled "Investing for our future". One of the strategic goals of this plan is to enhance patient safety and quality of care across the health system. The plan outlines the key initiatives and performance indicators that will guide the ministry and its partners in achieving this goal *(153)*.

The Government of **Ireland** has made patient safety a key priority in its Programme, which sets out its vision and goals for the health system. The programme states that the government is committed to ensuring high-quality, safe and effective care in all health settings, and to learning from adverse events. The government has established the National Patient Safety Office, developed a national patient safety strategy, and introduced legislation to protect whistle-blowers and regulate health professionals *(154)*.

In **New Zealand**, the Healthy futures act is a bill that aims to improve patient safety and quality of care in the health sector. It proposes to establish a new independent agency, the Health Quality and Safety Commission, to monitor and report on health outcomes, standards and adverse events. The bill also seeks to strengthen the accountability and transparency of health care providers, regulators and funders, and to promote a culture of learning and improvement in the health system *(155)*.

**Myanmar** has been prioritizing patient safety for years and in 2018 the country did a patient safety baseline assessment.

*Countries worldwide are embedding patient safety into their national health policies in various ways such as through strategic planning, defining vision and goals, establishing dedicated agencies, enacting protective legislation and accountability measures.*

# Integration of patient safety in UHC service delivery packages

Universal health coverage (UHC) means that all people have access to the full range of safe and quality health services they need, when and where they need them, and without incurring financial hardship. It covers the continuum of essential health services, from health promotion to prevention, treatment, rehabilitation, and palliative care, across the life course.

While countries are striving to achieve UHC, the benefits of increased access to health care are often undermined by service structures, cultures and/or behaviours that inadvertently harm patients and may lead to fatal consequences. Recent estimates suggest that 12.6% of total health care expenditure is spent on managing the adverse effects of patient harm in OECD countries. This implies that reducing patient harm could free up significant resources that could be invested in expanding and improving UHC packages *(6)*. In addition, patient safety builds trust and confidence among the public that their health and well-being are protected by their health care providers. In this way, safe care enhances access to and quality of UHC by influencing health-seeking behaviours and making more resources available for delivery of essential service packages (Fig. 1.5).
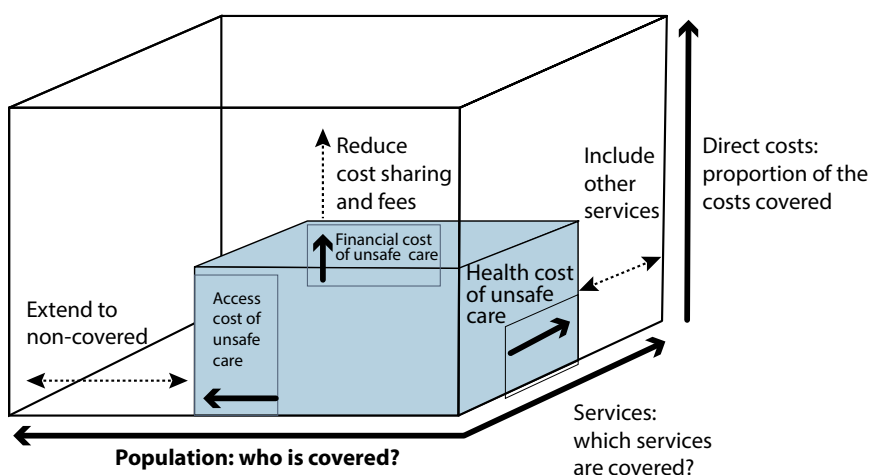
*Reducing patient harm in health care settings can save significant resources and enhance public trust, thereby improving both access to and the quality of universal health coverage.*



**Fig. 1.5.**
**Model of the contribution of patient safety to universal health coverage**

According to survey responses, just over one third of countries have fully incorporated patient safety into their national efforts for achieving UHC, and the majority have taken some measures to do so. The Western Pacific and European regions have the highest proportion of countries (around 50%) reporting patient safety as integrated into their national UHC plans (Fig. 1.6).

Among the various income groups, HICs have the highest percentage (52%) of countries that have taken actions to integrate patient safety into their UHC efforts, followed by low-income countries (LICs) (33%) and upper middle-income countries (UMCs) (29%).

*Over one third of countries have reported full integration of patient safety into their UHC efforts, with high-income countries leading and low-income countries reporting higher integration than upper-middle-income countries.*

Fig. 1.6.
Status of patient safety
integration into national UHC
plans, by WHO region ◀

## Examples of where patient safety has been integrated into national UHC efforts
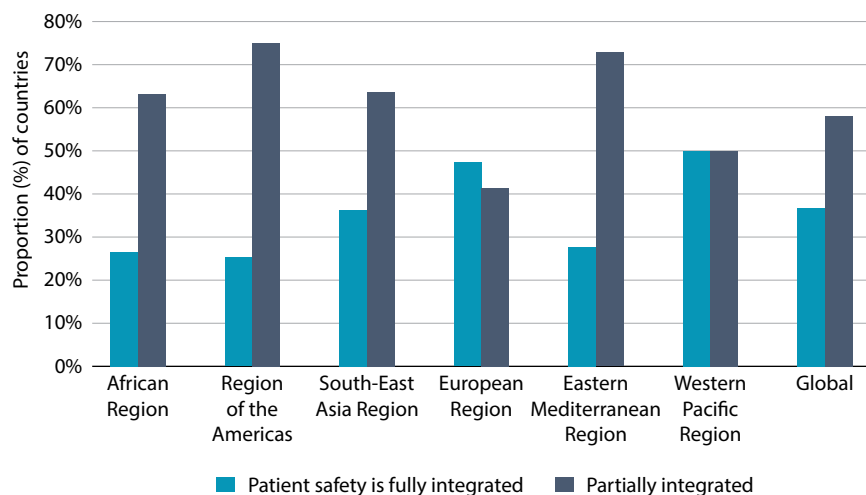
*Countries moving towards UHC are addressing patient safety across various essential areas, including maternal health, surgical services, and medication management, in order to provide safe and effective health care.*

In **India,** packages of essential services and delivery of UHC incorporate patient safety measures in various domains (e.g. maternal health and safe childbirth practices, surgical safety protocols and medication safety guidelines).

The universal public health insurance programme in **Australia** (Medicare) covers various safety aspects of health care, such as safe childbirth, surgical safety (national surgical audit), medication safety and access (through the Pharmaceutical Benefits Scheme).

The National Health Service (NHS) in **England** (United Kingdom of Great Britain and Northern Ireland) operates on the principle of universal access, free at the point of need. Patient safety is an integral component of all NHS-funded care, both in terms of operational safety at the point of delivery, through clinical governance and risk management, and through national regulatory mechanisms.

## Patient safety policy and strategy

*Nearly 80% of countries are working towards establishing national patient safety policies and strategies.*

A national patient safety policy is a formal government statement that defines priorities and parameters for action, as well as available resources and political considerations. It is developed in close consultation with stakeholders, including patients, families and communities, to ensure that patient safety is a shared responsibility and a core value of health care delivery. A national patient safety strategy operationalizes the policy, and guides the implementation of patient safety activities, monitoring and evaluation of progress, future planning and resources.

Over three quarters (79%) of country respondents indicated that their government has taken steps towards creating a patient safety policy and strategy. Around a half of these countries reported they have already completed and published their strategy.

# National patient safety action plan

A national patient safety action plan is a key step in ensuring that patient safety policy is translated into improvements in delivery of safe care. An action plan guides the efforts of various stakeholders to prevent harm and improve the safety of health care services and may also align with existing or emerging policies and programmes in specific domains. A national patient safety action plan typically includes a vision, goals, objectives, indicators, actions, timelines and responsibilities for different actors, such as governments, health care organizations, professionals, patients, families, and civil society.

Around one third of responding countries reported that they have a national patient safety action plan that is available in the public domain (Fig. 1.7). Another 38% of countries are in process of developing a national plan.
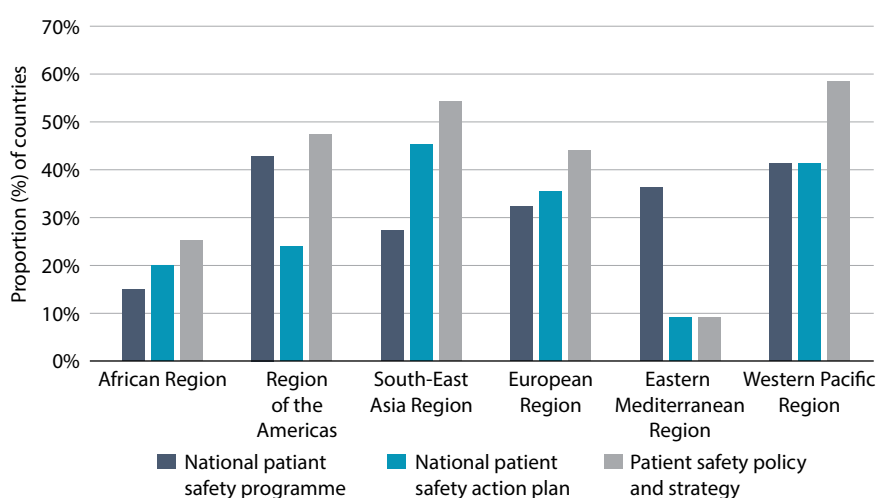
*The establishment of a national patient safety action plan is imperative for enhancing health care safety, with regional strategies potentially serving as a catalyst for progress, irrespective of a country's income level.*



**Fig. 1.7.**
**Proportion of countries with national patient safety action policies and strategies, action plans and programmes in various stages of development, by WHO region**

Establishment of national patient safety action plans does not appear to be influenced by country income group. However, a larger proportion of countries appear to have made related progress in the South-East Asia Region, which may be attributed to a regional strategy for patient safety that stimulated national actions *(156)*.

# National patient safety programme

A national patient safety programme is a systematic effort to promote and enhance the safety of health care delivery in a country. It involves the collaboration and coordination of multiple stakeholders, such as government authorities, health care providers, professional bodies, patient groups, regulators, insurers, technical experts and development partners. The main goals are to implement, monitor, evaluate and improve the national patient safety policies and action plans in both the public and private sectors.

Only a third of the survey participants indicated that their countries had implemented a specific and functional national programme for patient safety, while another half of respondents said that patient safety issues were partially

*The survey reveals a significant gap in the implementation of dedicated national patient safety programmes, emphasizing the urgent need for more comprehensive efforts.*

addressed within the existing health service improvement programmes. The Americas and Western Pacific regions had the highest proportion (>40%) of respondents who reported having operational national programmes for patient safety.

## Examples of national patient safety initiatives

*The widespread adoption of national patient safety policies and programmes reflects a global consensus on the necessity of prioritizing health care safety and quality, showcasing a commitment to tailored strategies for addressing specific challenges within each country's health care landscape.*

**Thailand** has recently introduced an extensive policy known as the Patient Safety Policy, also referred to as the 3P Safety policy, which encompasses Public Health Personnel and the General Public. The aim of this initiative is to steer the nation towards a health service system of superior quality that ensures safety for all involved *(157)*.

The national policy of health care quality and safety in **Sri Lanka** outlines the vision, mission, goals, objectives, strategies and action plan for improving the quality and safety of health services in the country. It aims to ensure that all people have access to safe, effective, efficient, equitable and people-centred health care that meets their needs and expectations *(158)*.

Actions for patient safety in the field of health care in **Argentina** seek to prevent, detect and mitigate adverse events that may occur during the provision of health services. Actions include correct identification of patients, hand hygiene, HCAIs, safety in surgery, safety in medication, effective communication between professionals and patients, and the management of incidents and complaints *(159)*.

The National patient safety framework of **Maldives** aims to create a culture of patient safety, enhance the capacity of health workers, strengthen governance and accountability mechanisms, and promote evidence-based practices and innovations *(160)*.

The National quality and patient safety framework developed in **Canada** outlines the vision, principles and goals for improving quality and safety of health services. It also provides guidance on how to implement, measure and evaluate quality and patient safety initiatives across different levels of the health system *(161)*.

*The increasing adoption of national patient safety initiatives signifies a growing acknowledgment of the vital role comprehensive policies and programmes play can in promoting a culture of safety and continual improvement in health care delivery.*

**Sweden** has developed the National action plan for increased patient safety in Swedish health care 2020–2024 with the vision of good and safe care, and the overall goal of no patient suffering avoidable injury *(162)*.

The Patient safety strategy 2.0 outlines the goals and measures to improve the quality and safety of health care in **Austria**. The updated strategy aims to raise awareness of the issue and support decision-makers, financiers and health care professionals in ensuring a high level of safe care for all *(163)*.

**Portugal's** National plan for patient safety 2021–2026 consolidates and promotes safety in the delivery of health care, particularly in the National Health Services, including the specific contexts of modern health systems, and increasingly complex care environments *(164)*.

**Philippines** has established a national policy on patient safety in health facilities with the objective of driving effective implementation and institutionalization of the patient safety programme in health facilities. Key elements of the programme include leadership and governance, risk management, teamwork and communication, human resource development, health worker safety, and patient-centred care and empowerment *(165)*.

**Greece's** national patient safety programme includes several hospitals.

**Ireland** has established the patient safety programme as a key initiative of the National Quality and Patient Safety Directorate. Its aim is to implement the Patient safety strategy 2019–2024 *(166)*, which outlines the vision, goals and actions for improving patient safety across the health system.

**Cabo Verde** is in the process of creating a programme for patient safety and health worker safety to support the ongoing patient safety efforts.



*Mother caressing her son in his hospital bed at a hospital in Kabul, Afghanistan. © WHO / Kiana Hayeri*

## Pioneering national patient safety frameworks: Kenya and India's policy transformations

Kenya and India, both active members of the Global Patient Safety Collaborative, are taking important steps to improve patient safety and health care quality. Kenya has developed the comprehensive National policy and action plan on patient safety, health worker safety, and quality of care. Similarly, India has established the National patient safety implementation framework, aiming to unify and enhance safety measures across its diverse health care settings. These efforts are critical in addressing ongoing issues within each country's health care system and ensuring safer care for all patients. Both countries' proactive approaches serve as valuable models for others seeking to enhance patient safety and health care outcomes globally.

### Kenya: Development of the National policy and action plan on patient safety, health worker safety, and quality of care

The need for comprehensive reforms in patient safety and quality of care in Kenya became evident following a series of challenges, including medical errors, HCAIs, insufficient health worker protection measures and broader implications on health system resilience related to the COVID-19 pandemic. Recognizing these challenges, the Government of Kenya initiated a strategic process to address these critical areas through a health systems approach. The main objective of the development of the national policy was to create a unified framework that would ensure patient safety, protect health workers, and improve the quality of care at all levels of health care provision and in all settings. The development of the policy and action plan was conducted through a consultative process involving multiple stakeholders including the Ministry of Health departments and agencies at the national and county governments, health care providers from both public and private sectors, academic institutions, professional associations, regulatory bodies, non-governmental organizations, international partners and donors, as well as patient advocacy groups.

The initial phase involved extensive data collection to explore the current state of patient safety and health worker safety as well as to assess health care quality in Kenya. This included a desk review, hospital surveys, interviews with health and care workers, and consultations with international health experts. A series of workshops were held to gather insights and feedback from various stakeholders, that helped in identifying core areas of concern and potential strategies for addressing them. With the information gathered, a draft policy document was developed, outlining key policy objectives, including the strengthening of governance and coordination mechanisms, protecting patients from avoidable harm, maintaining health and promoting the overall well-being of health workers, and ensuring the provision of quality health services. The draft was made available for public consultation, allowing for wider community input and ensuring the policy was aligned with the needs and expectations of the Kenyan public. Incorporating the feedback from public and stakeholder consultations, the policy was finalized and the corresponding action plan was developed, subsequently approved by the Kenyan government in 2022 and launched within the frame of commemoration of World Patient Safety Day (WPSD) 2022.

The development of the National policy and action plan on patient safety, health worker safety, and quality of care[a] represents a significant step forward in tackling the systemic issues plaguing health care in the region. The policy embodies the spirit of the Constitution of Kenya 2010,[b] Vision 2030,[c] the Kenya health policy (2014–2030),[d] and the global commitments as envisioned in the Global patient safety action plan 2021–2030.[e]

## India: Development of the National patient safety implementation framework (NPSIF)

India's health care system is vast and varied, encompassing an array of services across the public and private sectors, from large tertiary care hospitals in urban areas to small rural clinics. It continues to evolve, addressing the various challenges, including access to health care and affordability, patient safety and quality of care, that are common in South-East Asia Region in general. The systemic issues leading to a high burden of preventable harm in health care under the overarching mandate of UHC underscored the need to bring patient safety to the centre at all levels of health care and across all modalities of health care provision in the region, and the Regional strategy for patient safety in the WHO South-East Asia Region (2016–2025)[f] was developed. That prompted the Indian government to prioritize patient safety as one of the key policy objectives within the national health agenda and to establish a comprehensive framework that aimed to standardize patient safety policies and practices across all levels of care throughout the country.

The development process of the National patient safety implementation framework (NPSIF) began with the approval of the Ministry of Health and Family Welfare, and the constitution of an expert group comprising government officials and state health departments, health care professionals and policy experts, public and private health care providers, academic and research institutions, non-governmental organizations, patient rights groups, and international patient safety experts. Subsequently, a nationwide assessment was undertaken to document existing patient safety interventions and identify gaps in health care practices across different states and types of health care facilities. The draft framework was developed based on the assessment findings and was informed by successful models from other countries, tailored to fit India's unique health care landscape and challenges. Drafts of the framework were circulated among wider groups of stakeholders, including frontline health workers, hospital administrators and patient groups, for feedback and suggestions, and were discussed in several technical consultations and roundtable discussions.

The NPSIF 2018–2025[g] was approved by the Government in 2017 and incorporates the six strategic objectives. The development of the NPSIF was imperative for India because even though a range of initiatives for patient safety were previously implemented in the country, they were implemented in a fragmented manner by multiple stakeholders. It was vital to bring everything together under one umbrella to address operationalization issues. The framework guides the implementation of patient safety activities in a coordinated manner and contributes to the broader health system strengthening efforts within the UHC agenda in India.

*Sources:*

[a] *National policy and action plan on patient safety, health worker safety, and quality of care. Nairobi: Ministry of Health; 2022 (https://repository. kippra.or.ke/bitstream/handle/123456789/4102/Policy-January-2023-1.pdf?sequence=1&isAllowed=y, accessed 29 April 2024).*

[b] *Constitution of Kenya, 2010. Nairobi: National Council for Law Reporting, 2010 (https://kdc.go.ke/wp-content/uploads/2021/12/Constitution-of-Kenya-2010-min.pdf, accessed 29 April 2024).*

[c] *About Vision 2030 [website]. Nairobi: Vision 2030 Delivery Secretariat, 2024 (https://vision2030.go.ke/about-vision-2030/, accessed 29 April 2024).*

[d] *Kenya Health policy 2013–2030: Towards attaining the highest standard of health. Nairobi: Ministry of Health; 2014 (https://repository.kippra.or.ke/ bitstream/handle/123456789/4681/kenya_health_policy_2014_to_2030.pdf?sequence=1&isAllowed=y, accessed 29 April 2024).*

[e] *Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/343477, accessed 29 April 2024). https://iris.who.int/bitstream/handle/10665/343477/9789240032705-eng. pdf?sequence=1*

[f] *World Health Organization, Regional Office for South-East Asia. Regional strategy for patient safety in the WHO South-East Asia Region (2016–2025). New Delhi: Regional Office for South-East Asia, 2015 (https://iris.who.int/handle/10665/205839, accessed 29 April 2024).*

[g] *National patient safety implementation framework (2018–2025). New Delhi: Ministry of Health and Family Welfare Government; 2018 (https://main. mohfw.gov.in/sites/default/files/national%20patient%20safety%20implimentation_for%20web.pdf, accessed 29 April 2024). https://nhsrcindia. org/sites/default/files/2021-08/National%20Patient%20Safety%20Implementation%20Framework_0.pdf*

| 1.1 | 1.2 | 1.3 | 1.4 | 1.5 |
|-----|-----|-----|-----|-----|
| Patient safety policy, strategy and implementation framework | Resource mobilization and allocation | Protective legislative measures | Safety standards, regulation and accreditation | World Patient Safety Day and Global Patient Safety Challenges |

**Strategic objective 1**

## Strategy 1.2.

# Resource mobilization and allocation

> Mobilize and allocate adequate resources for patient safety implementation throughout every level of the health care system

Patient safety is a vital component of health care systems and requires dedicated and sustained investment from all stakeholders. The allocation of sufficient human and financial resources is a key indicator of national commitment to patient safety. Furthermore, integration of such resources into the larger financial structures of the health system, and the budgeting and human resource planning that are in place at every level of the health care system, are also major determinants of quality and safety of health care.

## Budget category and allocation of financial resources

*Insufficient allocation of financial resources and a lack of specific budget categories for patient safety underscore the urgent need for increased investment in patient safety initiatives within health care systems.*

Despite reported commitment by most countries to prioritize patient safety and develop supportive national policies, strategies and action plans, the allocation of patient safety resources remains a challenge. According to the Member State survey, only a fifth of responding countries reported a specific budget category for patient safety, while less than half reported that patient safety was at least mentioned in the health budgets. Over 25% of respondents reported no budgetary provision for patient safety at all. Only 11% of respondents reported sufficient financial resources to implement all planned patient safety interventions most of them from UMC and HIC categories (Fig. 1.8).
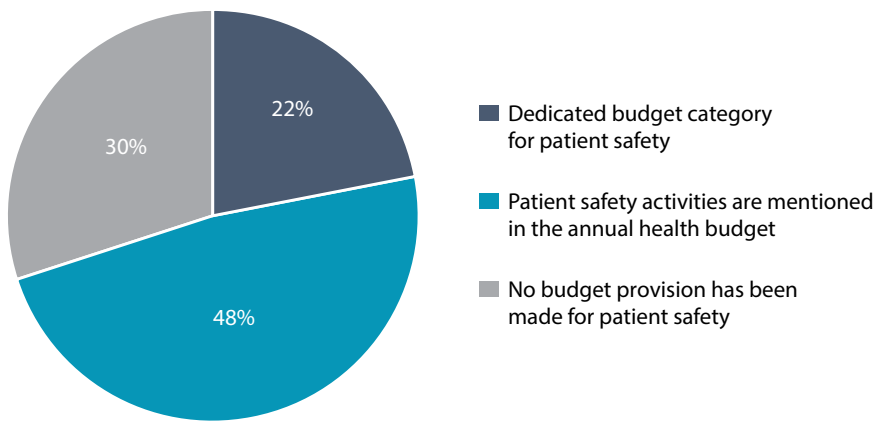
22%

30%

48%

■ Dedicated budget category
  for patient safety

■ Patient safety activities are mentioned
  in the annual health budget

■ No budget provision has been
  made for patient safety

**Fig. 1.8.**
**Patient safety in national health budgets**

## Examples of dedicated national patient safety budgets

In **Ethiopia,** the Annual Directorate Plan allocates a dedicated budget for the following areas linked with patient safety: infection prevention and control (IPC), antimicrobial resistance (AMR), safe surgery, and medication safety. These areas are aligned with the Global Patient Safety Action Plan 2021–2030 and the national health sector transformation plan.

In **Spain**, an annual budget is dedicated to implement the actions included in the national strategy on patient safety. The regions also have a budget to implement their specific patient safety strategies or programmes.

In **Australia**, the 2022/23 federal budget outlines a dedicated category for 'Safety and quality in health care'. The category includes funding for entities such as the Australian Commission on Safety and Quality in Health Care.
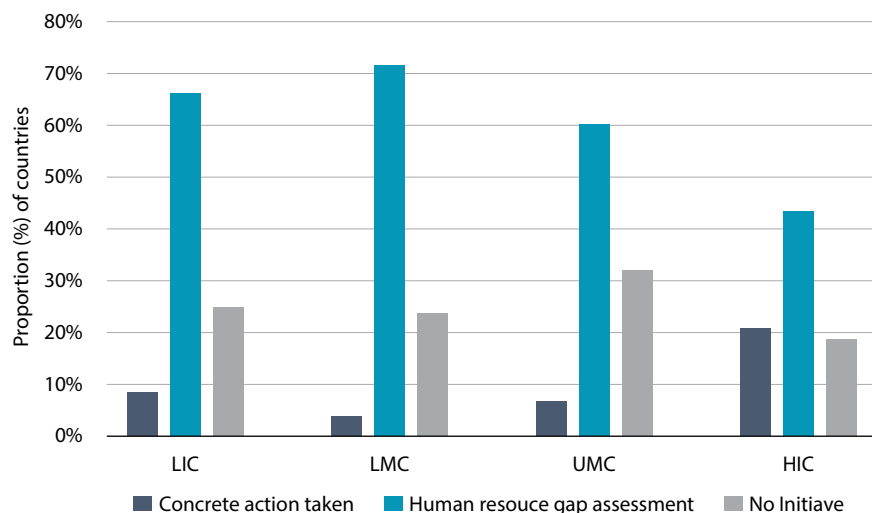
## Human resource plan and gap closure

To achieve their intended outcomes, patient safety interventions require sufficient human resources and technical personnel to be implemented effectively. Moreover, a lack of human resources or understaffing can increase the risk of all types of patient safety incidents at the point of care.

Globally, only 10% of responding Member States reported having a patient safety human resources plan in place. Only 12% indicated that concrete measures have been undertaken to fill existing human resource gaps and maintain adequate staff-to-patient ratios at health care facilities. Irrespective of income groups, the majority of respondents reported that these processes are currently ongoing – and that their governments are currently conducting assessments of the human resource requirements and gaps in their national contexts (Fig. 1.9).

*The scarcity of patient safety human resource plans and ongoing efforts to address staffing gaps emphasizes the urgent need for comprehensive strategies to ensure there are sufficient health workers.*

Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

# Recognition and reward mechanisms

*The global trend towards developing recognition and reward programmes for patient safety underscores a proactive approach to incentivizing health care facilities to prioritize and improve patient safety*

Incentives and rewards can play a crucial role in improving patient safety. Financial incentives, for instance, can be used to reward health workers for delivering safe and high-quality services and penalize them for poor performance. However, it is important to note that financial incentives are not a panacea and can have unintended consequences. Therefore, it is essential to design incentive programmes carefully and to monitor their impact on patient safety.

61% of responding countries reported that they are in the process of developing a scheme or programme to recognize and reward health care facilities according to their performance in patient safety and quality of care. Of these, 19% stated that these reward programmes have already been initiated, and health facilities have already been rewarded. Most of these efforts are concentrated in UMCs and HICs.

## Examples of patient safety recognition and reward mechanism

In **Thailand**, '2P' safety hospitals receive awards every year on World Patient Safety Day based on their performance in patient safety and quality of care.

In **Bangladesh**, Health Minister's Awards are given to recognize achievements in health care.

In **Oman**, the annual Patient Safety Prize was initiated in 2020 to acknowledge the best practices and achievements in patient safety.

In **Argentina**, the Initiative for Recognition of Health Establishments uses a good practices instrument to improve the quality of health services and to certify the health establishments that meet the standards *(167)*.

In **Peru**, the Comprehensive Policy of Compensation and Financial Contributions of Health Personnel in the Service of the State includes safe practices of adherence to hand hygiene, safety checklist in surgery, and risk management and continuous quality improvement through the application of patient safety rounds as commitments to improvement *(168)*.

In **Singapore**, patient safety is one of the components under the Pay for Performance Scheme, which is an incentive-based tool to encourage desired cluster/hospital behaviours.



*Young boy undergoing physical therapy at a children's hospital in Kyiv, Ukraine. © WHO / Christopher Black*

| | 1.1 | 1.2 | 1.3 | 1.4 | 1.5 |
|---|---|---|---|---|---|
| **Strategic objective 1** | Patient safety policy, strategy and implementation framework | Resource mobilization and allocation | Protective legislative measures | Safety standards, regulation and accreditation | World Patient Safety Day and Global Patient Safety Challenges |

## Strategy 1.3.

# Protective legislative measures

> " Use selective legislation to facilitate the delivery of safe patient care and the protection of patients and health workers from avoidable harm

*Robust legal and regulatory requirements, including mandatory licensing for health care facilities, are essential to ensure the safe delivery of health services and products and to maintain public trust in health care systems.*

To guarantee the safe delivery of health services and products, it is imperative for every country to establish and enforce optimal legal and regulatory requirements. This is crucial not just for the providers of these services and products, but also for maintaining public trust in the health care system. The absence of effective regulation can lead to grave consequences, such as the infiltration of substandard and falsified medicines into the consumer market. To mitigate these risks, it is essential to implement mandatory licensing for health facilities and to require pre-market authorization for all medical products.

To uphold safety standards, comprehensive regulatory and statutory requirements are essential for health care facilities and service providers. Robust mechanisms to measure and ensure compliance with these practices are equally vital.

### Mandatory licensing for health care facilities and services

Mandatory licensing of health care facilities is the process by which a government agency grants permission to an individual or organization to operate a health care facility or provide related services. This ensures that all facilities meet minimum standards of care to protect the health, safety and welfare of patients.

72% of all responding countries stated that laws have been enacted for mandatory licensing of health care facilities and services, while 22% stated that such laws and regulations are currently being developed. This data suggests varying levels of regulation and emphasis on health care licensing across different regions. The European Region has the highest proportion of health care facilities and services that require mandatory licensing (82%), followed closely by the Region of the Americas (80%). The South-East Asia Region reported the lowest proportion at 55% (Fig. 1.10).
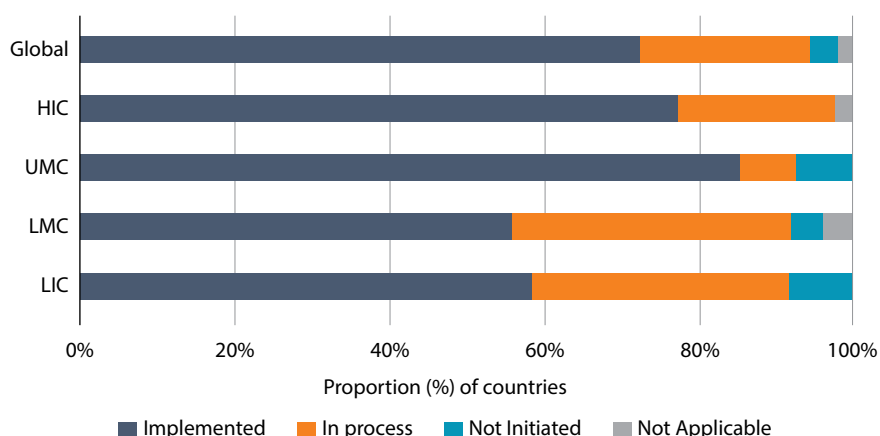


**Fig. 1.10.**
**Status of implementation of mandatory licencing, by income group**

Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

The survey data also suggest a possible association between a country's income classification and the emphasis on mandatory licensing for health care facilities and services. The highest proportions were seen among UMCs, suggesting that as countries progress economically, there might be a stronger drive towards formalizing and regulating health care practices. This could reflect increased availability of resources, better governance, or a higher demand from the population for standardized care. While HICs also prioritize licensing, their reported proportion of mandatory licensing is slightly lower than that in UMCs. This could imply that HICs have other complementary mechanisms or criteria in place for health care regulation, beyond a sole reliance on licensing. In contrast, about half of LICs and lower middle-income countries (LMCs) reported they had mandatory licensing systems and laws in place, highlighting potential challenges in implementing or enforcing such mandates, possibly due to limited resources or other socio-economic factors.

*The survey suggests that higher-income countries prioritize mandatory licensing for health care facilities more than lower-income ones, reflecting a possible association between economic development and regulatory emphasis, albeit with implementation challenges in lower-income settings.*

## Laws for authorization of medical products

79% responding countries reported that laws authorizing use of medical products had been enacted, such as for medicines, medical devices, diagnostics, blood products, assistive technologies and digital health products. The Region of the Americas stands out with a distinctive 90% adherence, indicating stringent regulations or mature health infrastructures in these areas (Fig. 1.11). Higher adherence was reported in HICs (84%), although proportions of licensing in LICs and LMCs were not substantially lower.

Fig. 1.11.
Proportion of countries
have established laws for
authorization of medical
products, by
WHO region ◀
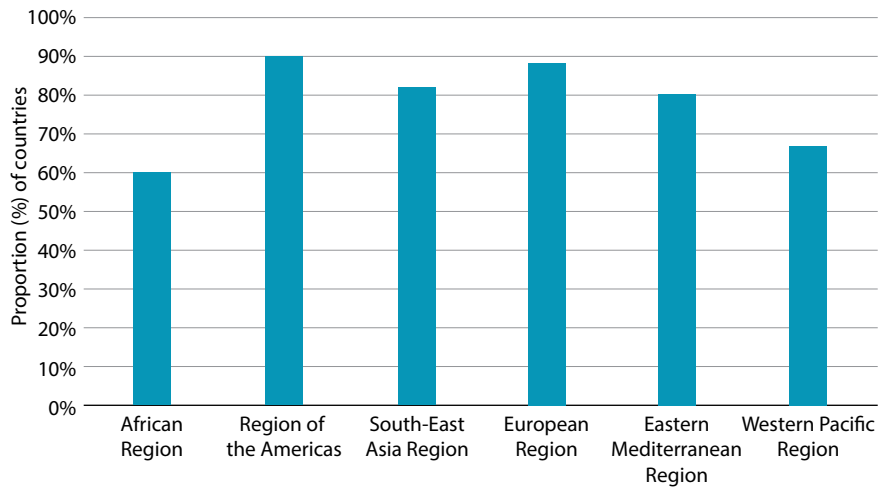
## Legal protection against reporting of patient safety incidents

*Legal protection for health workers reporting patient safety incidents is crucial for fostering a culture of transparency and learning, yet its global adoption remains limited, with only a minority of countries, primarily high-income, enacting such laws.*

One of the barriers to improving patient safety is the fear of legal consequences for reporting adverse events or errors. To encourage a culture of learning from errors and prevent similar incidents from recurring, one option is to provide legal protection to health workers on reporting patient safety incidents. This means that the information reported cannot be used as evidence in civil, criminal or disciplinary proceedings against the health care providers involved, unless there is evidence of gross negligence or malicious intent. Legal protection can help foster trust and transparency among health care professionals and patients, and facilitate the collection and analysis of data on patient safety incidents.

While critical for establishing a culture of openness and learning, the global acceptability of such legal measures is limited (Fig. 1.12). In the Member State survey, only 19% countries confirmed a law protecting health workers from punitive action for reporting safety incidents has been enacted and is in force. 14 of these countries are HICs. Half of these countries are in the European

**Fig. 1.12.**
**Proportion of countries with established laws for protecting health workers on reporting of patient safety incidents** ◀



- Laws established
- Under process of development
- Not initiated
- Not applicable
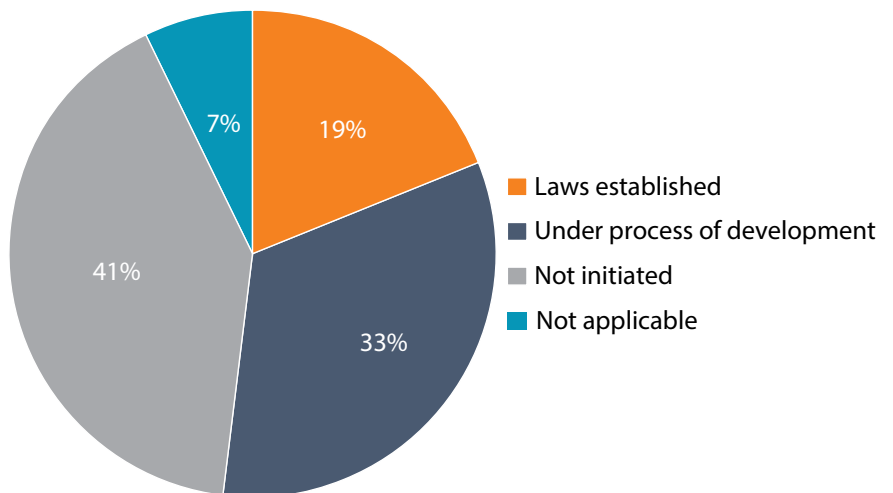
Region. Many countries reported lack of legal protection as a major barrier to establish a sustainable patient safety incident reporting and learning system (PSRLS).

## Examples of legal protection to health workers on reporting of patient safety incidents

In **New Zealand**, the Protected Disclosures (Protection of Whistleblowers) Act 2022 allows health workers to raise serious risks about public health, or the health or safety of any individual, and to be protected against retaliation.

In **Denmark**, there is a non-sanctioning reporting and learning system for patient safety incidents and a national authority for supervision of health care facilities and licensed health care workers.

In **Romania**, the Law on Patient Rights and Obligations (Law no. 46/2003) and the Law on the Quality and Safety of Medical Assistance (Law no. 95/2006) both include provisions that protect health care professionals who report patient safety incidents in good faith and in accordance with professional standards. They also encourage a culture of safety and learning from mistakes to improve patient care.

In the **United Kingdom**, the law promotes reporting of patient safety incidents (e.g. Care Quality Commission regulations require certain incidents to be reported and organizations and professionals are required to disclose incidents to patients under professional and organizational duty of candour). Furthermore, disclosures of concerns, including incidents, in the public interest are protected under the Public Interest Disclosure Act.

## Data protection and confidentiality

The protection and confidentiality of health data are fundamental to the overall safety and well-being of patients. Proper data regulations ensure that individuals' medical information remains secure, limiting unauthorized access and potential misuse. Likewise, to encourage reporting and learning from adverse events, safety incident data should be safeguarded by appropriate mechanisms such as law.

These regulations serve as a backbone to prevent data breaches and ensure that health information is not only stored safely but also accessed and shared in a manner that respects individual privacy.

Globally, 64% of countries reported having established laws focused on health data protection and confidentiality. This demonstrates a considerable global commitment to ensuring the safety and privacy of patient information. Notably, the Region of the Americas and the European Region lead the way in this domain, with over 80% of their countries having such regulations in place.

*The widespread establishment of laws focused on health data protection and confidentiality globally underscores a significant commitment to safeguarding patient information, promoting trust in health care systems.*

## Examples of dedicated legislation to protect patient information and privacy in different countries

*Holistic patient safety legislation, characterized by comprehensive laws that emphasize systemic approaches and proactive measures, embodies a systemic shift towards prioritizing patient safety and preventing health care harm.*

**Thailand**. Implemented the Personal Data Protection Act (B.E. 2019) focusing on health data privacy and protection and including safety incidents.

**Switzerland**. Adopted the Federal Act on Data Protection to ensure lawful and transparent personal data processing.

**Peru**. Upholds a general personal data protection law complemented by a Ministerial Resolution on personal health-related data.

**South Africa**. Enforces the National Health Act no 61 (2003), emphasizing confidentiality of user's health information.

**Canada**. Safeguards health data safeguarded under various laws, including federal and provincial/territorial privacy laws.

**Belize.** Mandated Oath of Confidentiality for all Ministry of Health and Wellness personnel.

**Qatar**. Practices health data protection under Data Privacy Law 13, with a specific health data policy in development.

**Kazakhstan**. Adheres to a health code that regulates digital health care entities' handling of personal medical data.

**Australia**. Multiple legislations, such as the Privacy Act 1988 and My Health Records Act 2012, guide health data protection.

**Türkiye**. Relies on the Personal Data Protection Law and an additional Regulation on Personal Health Data.

**New Zealand**. Ensures data protection in line with the Health Information Privacy Code 2020.

**Romania**. Bases its data protection framework on Law no. 506/2004 and has additional health data regulations overseen by the National Supervisory Authority for Personal Data Processing.

**United Kingdom**. Safeguards personal and health data under the Data Protection Act 2018.

**Ghana**. Data Protection Act 843 (2012) sets out the rules governing the protection of the privacy of individuals and personal data by regulating the processing of personal information.

**Burkina Faso**. Protects the privacy and patient information by enforcing code of ethics and code of public health.

Some countries have taken holistic approaches towards patient safety legislation and have enacted dedicated legislation for addressing patient safety issues. For example, in Sweden The Patient Safety Act (2010:659)*(169)* is a comprehensive law that emphasizes the importance of patient safety in health care. It marks

a shift from focusing on individual accountability to a systemic approach for enhancing patient safety. Health care providers, including state authorities, regions, municipalities, and private entities, are mandated to ensure systematic patient safety efforts. This involves planning, leading and controlling health care activities to prevent patient injuries, investigating incidents that could lead to harm, and reporting serious incidents to the Inspectorate for Care (IVO). Health care staff are responsible for reporting any potential risks to patient safety, highlighting the act's comprehensive approach to preventing health care injuries and promoting a culture of safety within the Swedish health care system.
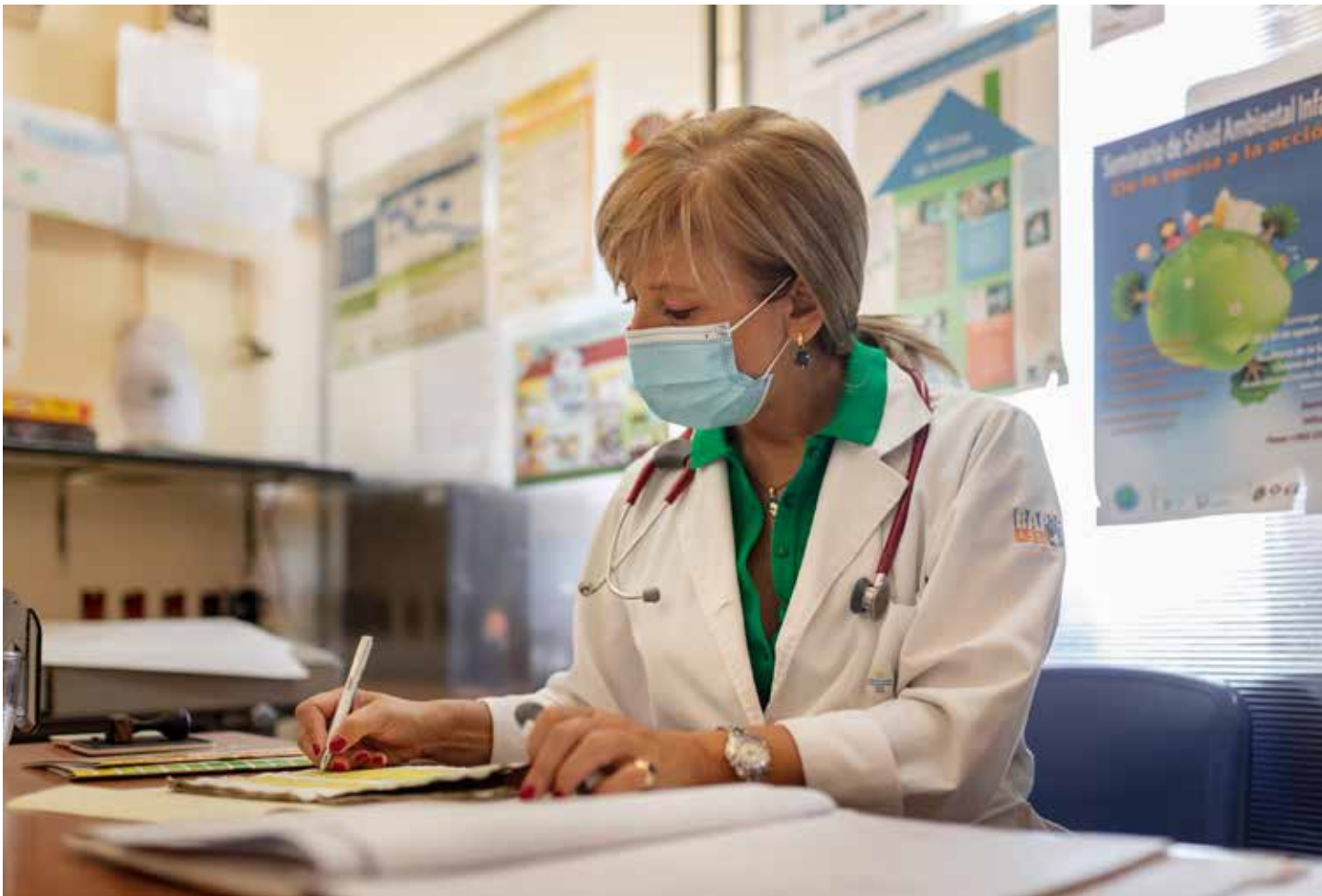


*A pediatrician stamps a patient form at Unidad Pediátrica Ambiental in Montevideo, Uruguay. © WHO / Blink Media - Tali Kimelman*

## Feature story 2

## Danish National Patient Safety Advisory Board

The Danish National Patient Safety Advisory Board, established by the Danish Patient Safety Authority[a] in 2015, has a central coordinating role in patient safety activities in Denmark. The crucial role of the board was strengthened when it became a legal requirement in 2021. The board's work relies heavily on long-term relationships established with colleagues in Danish regions, municipalities, clinical organizations and the Danish Patient Safety Authority, and this collaborative, action-oriented approach has driven sustainable change in patient safety.

*"The requirement by law is a strengthening and legitimisation of a collaborative effort."*

*(Representative of the Danish Patient Safety Authority)*

The advisory board provides professional feedback on publications, engages in activities at the national level, suggests topics that should be addressed at the national level and exchanges information about current issues at all levels. Overarching issues that cannot be resolved by individual health care facilities or at the municipal/regional level can be referred to the board by the Danish Patient Safety Authority.

*"You need to involve all relevant stakeholders in a balanced way; involve the right people relative to the context, and at different levels, not just the top level. There needs to be trust between stakeholders; they need to all feel represented."*

*(Representative of the Danish Patient Safety Authority)*

Alongside the legal reinforcement of the advisory board, building trust with municipalities and clinical organizations has aided essential collaborations. Relationships between the advisory board and regional and institutional patient safety teams are crucial as the board does not have the mandate to influence regional policies and programmes. This enables open dialogue about challenges and solutions across the system.

*"They [members of the advisory board] trust us and they come to us to seek help in solving their problems…we have built this relationship over many years. They give us very good feedback about what is working and what are their expectations."*

*(Representative of the Danish Patient Safety Authority)*

Systemic improvement projects require the involvement and engagement of many stakeholders. While patient safety is the core driver for the advisory board, there are many competing priorities to be considered. Making the Danish National Patient Safety Advisory Board a legal requirement has enabled the prioritization of patient safety, and helped Denmark ensure a strong mandate for prioritizing patient safety at the national level.

*Source:*

[a]  *Targets and tasks. In: About us [website]. Copenhagen: Danish Patient Safety Authority; 2024 (https://en.stps.dk/about-us/targets-and-tasks, accessed 29 April 2024).*

| 1.1 | 1.2 | 1.3 | **1.4** | 1.5 |
|-----|-----|-----|---------|-----|
| Patient safety policy, strategy and implementation framework | Resource mobilization and allocation | Protective legislative measures | Safety standards, regulation and accreditation | World Patient Safety Day and Global Patient Safety Challenges |

**Strategic objective 1**

## Strategy 1.4.

# Safety standards, regulation and accreditation

> Align health care regulatory, inspectorial and accreditation activities with the goal of improving performance on patient safety

Incorporating minimum safety standards for health care facilities, health system performance assessments, and voluntary accreditation standards are essential steps in aligning patient safety policy with desired actions within health systems. Such steps not only ensure basic standardization but also promote a culture of continuous improvement in the context of patient safety.

## Minimum safety standards

Safety standards in health care encompass a set of established guidelines, rules and norms aimed at ensuring the optimal well-being and protection of patients as well as health workers. Patient safety is central to these standards, which may encompass but is not limited to: hand hygiene and sterilization; medication safety with safe prescription and monitoring; infrastructure safety to prevent hazards (e.g. falls or fires); radiation safety for equipment such as X-rays; and waste management protocols for secure disposal of medical waste.

Responses to the Member State survey suggest a significant global trend towards defining safety standards in health care facilities. However, it also indicates areas or regions where more work is needed to ensure comprehensive safety standards across all types of settings.

*The global trend towards defining safety standards in health care facilities highlights a commitment to patient safety, though efforts are needed to ensure comprehensive standards across all settings.*

The majority of survey respondents (57%) indicate that minimum safety standards are in place for all health care facilities and health system levels. Of the remainder, 42% of countries report that standards have been defined for some categories of health care facilities, but not all.

Member States from the Western Pacific Region, the Region of the Americas and the European Region are leading the way in this area (Fig. 1.13).

Fig. 1.13. Proportion of countries that have defined minimum safety standards

Legend:
- Not initiated
- Minimum safety standards developed for some health care facilities
- Minimum safety standards developed for all health care facilities
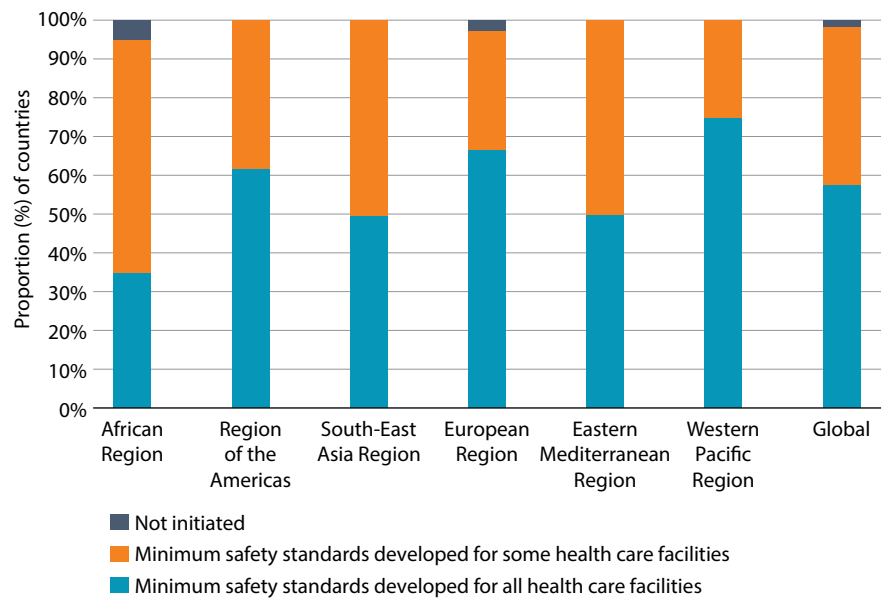
*Global integration of safety standards into health care licensing emphasizes a commitment to universal safety norms, yet implementation and enforcement require strengthening in lower-income settings*

## Safety standards in health care licensing

Integrating safety standards into health care facility and service licensing is a pivotal strategy to ensure universal adherence to essential safety norms across the health system. This approach establishes clear and measurable expectations for health care providers. Regular updates to these standards ensure alignment with new evidence, evolving best practices and address emerging safety concerns. By holding facilities accountable through regular audits and potential legal implications, this integration ensures that patient care is consistently and safely delivered.

The Member State survey indicated that about half of responding countries have integrated safety standards into the licensing criteria across all levels of the health system. Among them, the Western Pacific region countries have an impressive 75% adherence rate.

However, deeper analysis reveals that HICs and UMCs are more consistent in enforcing these standards through specific legislative acts or national accreditation criteria (Fig. 1.14). Some LICs and LMCs also follow safety standards, but the implementation may be partial or in need of strengthening and comprehensive enforcement.
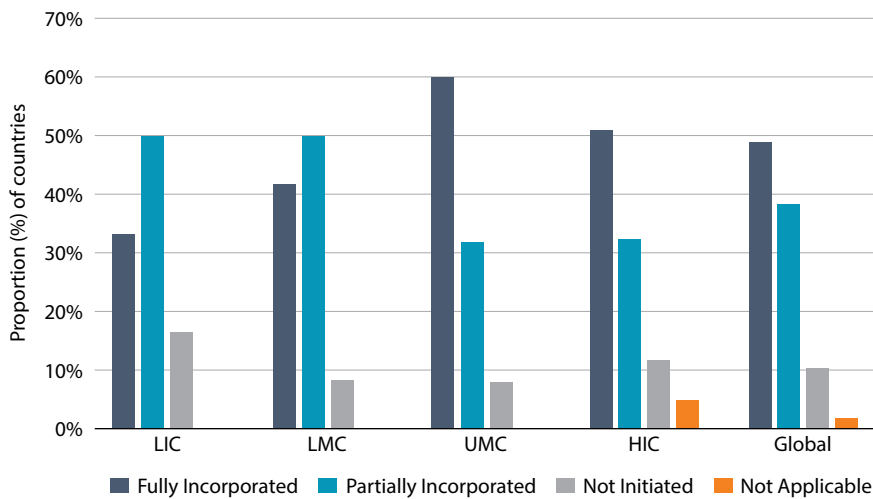
Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

## Safety standards for all specified clinical services

Safety standards in clinical services are vital to ensure high-quality patient care and health worker protection. These standards span a variety of sectors. For example: in radiotherapy, the focus is on precision and radiation dose management; in dialysis, equipment sterilization and water purity are crucial; blood transfusion emphasizes screening and storage; emergency services prioritize triage and resuscitation; surgical services highlight sterilization and anaesthesia safety; diagnostic services require equipment calibration and quality control; maternity services emphasize antenatal, delivery and postnatal care; dental services mandate infection control and radiation safety; and hospice services focus on pain management and psychological support. These broad guidelines should be adapted to local regulations and organizational policies, emphasizing regular updates from authoritative health bodies.

Around 43% of countries reported that they have defined safety standards for specific clinical services. The data indicate that safety standards are being developed for various clinical services around the world, but the focus is not the same in every region and country, as they face different health care issues and goals. Many countries have defined safety standards for blood transfusion services and surgical services, implying that they have higher risks that require standardized procedures. Several countries have prioritized maternity centres, neonatology and obstetric services, indicating a global concern for maternal and child health. Nuclear medicine, intensive care, radiotherapy and dialysis services are less common, suggesting that emerging fields or specialities are still developing safety standards in many countries.

*Global variation in development of safety standards for specific clinical services emphasizes the need for comprehensive standards across all health care specialties.*

# Safety standards in health services assessment tools

Incorporating safety standards into health service assessment tools and related programmes is an effective way to embed the goals of improved patient safety into day-to-day service delivery.

52% of responding countries reported including safety standards in their regular health services assessment tools for inspectorial and evaluation purposes. Several countries have developed assessment tools that incorporate patient safety standards.

## Examples of health service assessment from different countries that include safety standards

**India**. The Safety and quality, self-assessment tool for health facilities (SaQushal) has been introduced. Health facilities are encouraged to self-report to ensure they meet safety standards *(170)*.

**Seychelles**. Safety standards are available for various programmes, namely reproductive, maternal, newborn and child health), IPC and the expanded programme on immunization.

**Liberia**. The country has routine assessment tools available for health facilities to check adherence to safety standards.

**Uganda**. A health facility quality of care assessment programme is in place to evaluate the quality and safety of health care services.

**Côte d'Ivoire**. To maintain and enhance safety standards, the country conducts evaluations of health establishments through various health programmes.

**Uruguay**. The existing regulatory framework primarily focuses on specialized health care units such as institutes of highly specialized medicine, ICUs and haemodialysis units. These units are inspected by the Fondo Nacional de Recursos.

**Nepal**. An assessment using minimum service standard tools, that have a standard on safety and security, is performed twice a year.

**South Africa**. Health service assessment tools for health care facilities in South Africa have incorporated safety standards.

**Belgium**. Authorities use assessment tools for routine inspections, quality assurance programmes and accreditation. However, not all of these processes operate on a national level.
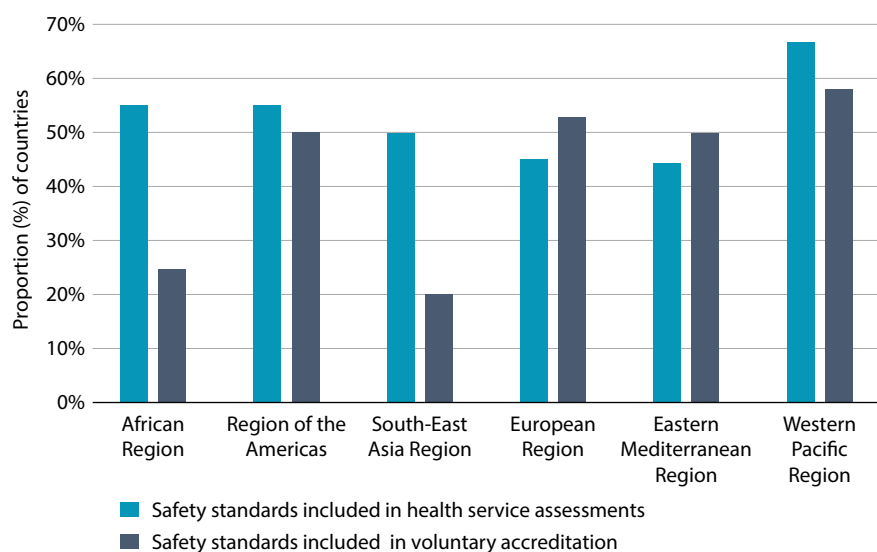
**Qatar**. WHO Patient Safety Friendly Hospital Initiative (PSFHI) is being use for patient safety assessment.

*Diverse approaches to assessing safety standards in health care facilities are evident across different regions, ranging from self-assessment tools to routine assessment programmes, reflecting a concerted effort to uphold safety and quality standards in health care provision.*

# Voluntary accreditation programmes and safety standards

Voluntary accreditation refers to the process by which health care facilities, such as hospitals and clinics, voluntarily undergo evaluation by recognized accrediting bodies to ensure they meet established standards of care and safety. While some forms of accreditation may be mandated, most are elective, chosen by institutions as a commitment to excellence and to distinguish themselves in the health sector. While the process can be demanding in terms of time and resources, the benefits are significant, including quality assurance, a competitive edge in the health care sector, improved risk management, and enhanced staff and patient confidence.

*While voluntary accreditation programmes provide a valuable framework for ensuring safety standards in health care facilities, their acceptance is not universal, with some regions relying more on internal assessments.*

Through the Member State survey, 44% of countries reported to have incorporated safety standards in their voluntary accreditation programmes. Around 58% of countries in the Western Pacific Region indicate a higher emphasis on integrating safety protocols in their health care accreditation, possibly due to more developed health care systems or stronger regulatory frameworks (Fig. 1.15). Whereas only 20% of countries in the South-East Asia Region reported having voluntary accreditation programmes in place, suggesting either nascent stages of their accreditation processes, different regional priorities, or related resource constraints. Overall, internal health service assessment is the preferred method for ensuring safety standards in resource-constrained settings, while external evaluation and accreditation is more prevalent in HICs.



**Fig. 1.15. Proportion of countries implemented safety standards in health service standards and accreditation mechanisms, by WHO region**

- Safety standards included in health service assessments
- Safety standards included in voluntary accreditation

# Characteristics of national accreditation processes identified by the Member State survey

**Variability in implementation**. The degree to which safety standards have been incorporated into voluntary accreditation programmes varies greatly by country. Many HICs, such as Canada, Chile and Oman, have established robust

*There is significant variability in the implementation of safety standards within national accreditation processes across countries, highlighting the importance of tailored approaches to ensure health care safety standards.*

standards and guidelines within their accreditation systems. While some lower income countries are still in the process of developing or initiating programmes, LICs such as Mozambique and Uganda have actively implemented voluntary accreditation.

**Specificity of implementation**. Certain nations have focused on specific aspects of health care for accreditation, such as laboratory services in Ethiopia and Uganda, or blood transfusion in Malta.

**Mandatory vs voluntary**. A significant trend is the distinction between mandatory and voluntary accreditation. Countries such as North Macedonia and Australia have made accreditation mandatory, while others have kept it voluntary (e.g. India and Türkiye). Some countries, such as Nepal, have not yet initiated voluntary accreditation programmes.

**Reference to external standards**. A few countries, including Ireland and Singapore, refer to international standards or bodies, indicating an inclination to adopt or benchmark against globally recognized best practices.

**Legislation and regulation**. In the **Dominican Republic** safety standards are guided by various existing laws. Moreover, some countries, such as **Czechia** and **Georgia**, are in the process of implementing safety standards as legislation or regulation of health services, suggesting a formalized and potentially more enforceable approach to maintaining health care safety standards.

**Strategic objective 1**

| 1.1 | 1.2 | 1.3 | 1.4 | 1.5 |
|-----|-----|-----|-----|-----|
| Patient safety policy, strategy and implementation framework | Resource mobilization and allocation | Protective legislative measures | Safety standards, regulation and accreditation | World Patient Safety Day and Global Patient Safety Challenges |

## Strategy 1.5.

# World Patient Safety Day and Global Patient Safety Challenges

" Create maximum awareness of World Patient Safety Day and Global Patient Safety Challenges as a way of maintaining a high public and political profile for patient safety

Patient safety is an integral component of health systems and affects several aspects of health services. WHO organizes global campaigns and initiatives to highlight specific issues or practices that can enhance the safety of health care. These include World Patient Safety Day and the Global Patient Safety Challenges, which aim to address particular sources of harm or areas for improvement in health care delivery.
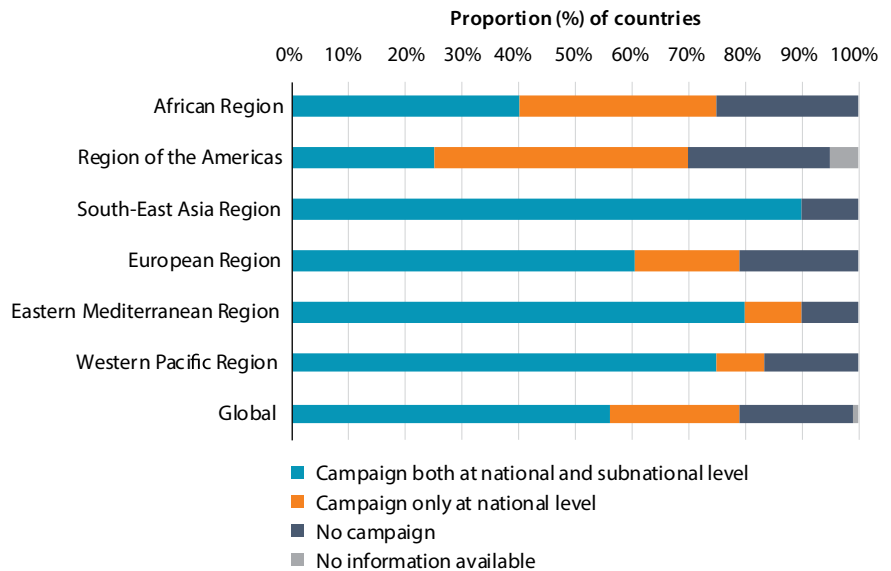
## World Patient Safety Day

World Patient Safety Day is a global campaign observed every year on 17 September *(171)*. It raises awareness and prompts action for improving patient safety in health care. Since 2019, countries have joined hands to highlight the importance of ensuring the safety of patients, and governments have reaffirmed their commitment to patient safety, showcasing country achievements and progress. Each year, WHO launches a global campaign focused on a selected theme where patient safety needs to be prioritized, with a call to action for all stakeholders to promote and take concerted actions related to the theme.

According to Member State survey responses, around 80% of countries have designed a national campaign in alignment with the theme of World Patient

*World Patient Safety Day sees extensive global engagement, with 80% of countries designing national campaigns and over half implementing initiatives at both national and subnational levels.*

Safety Day. Moreover, more than half of countries report they have launched campaigns at both national and subnational levels. Overall, the data suggest a varying approach to annual campaigns. Some countries adopt a comprehensive strategy with a strong subnational focus, while others lean more towards centralized, national approaches. 90% of countries in the South-East Asia Region have reported the launch of campaigns at both levels (Fig. 1.16). Overall responses indicate the campaign is popular across all countries, regardless of their income levels.
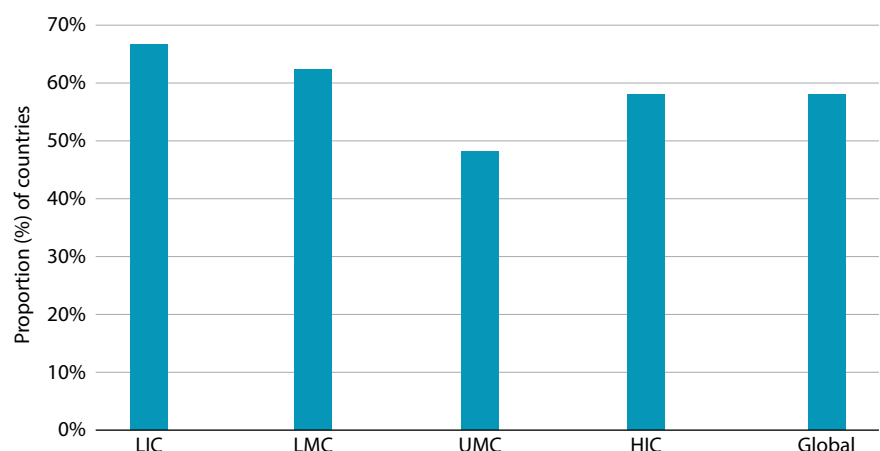
**Fig. 1.16.**
**Proportion of countries launching a national and/ or subnational campaign for observing World Patient Safety Day, by WHO region** ◀

Proportion (%) of countries



- ■ Campaign both at national and subnational level
- ■ Campaign only at national level
- ■ No campaign
- ■ No information available

*The involvement of senior leaders in national World Patient Safety Day events, particularly prominent in lower middle-income and low-income countries, underscores a strong commitment to addressing patient safety issues.*

The involvement of senior leadership in such initiatives is crucial for driving change and ensuring that patient safety is prioritized at all levels of the health care system. Over half of the countries (58%) report holding a national World Patient Safety Day event with the involvement of senior leaders (Fig. 1.17). Survey data suggest that LICs and LMCs have higher levels of senior leadership involvement compared to UMCs and HICs. This demonstrates high levels of commitment to address patient safety issues among senior leaders in LICs and LMCs.. This could be due to a recognition of the importance of patient safety in improving overall health care outcomes and a commitment to making necessary changes to enhance safety.

**Fig. 1.17.**
**Proportion of countries where national World Patient Safety Day event was attended by senior leadership of the government** ◀



*Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.*

Varying levels of engagement are reported, with all countries of the South-East Asia Region organizing an event. Countries in the Western Pacific, Eastern Mediterranean and African regions are also significantly engaged, reporting 75%, 64% and 60% respectively. In the European Region and the Region of the Americas, countries reported lower levels of engagement at 44% and 43%, respectively.

## How countries celebrate World Patient Safety Day

**Social media campaigns** (67%). Given the widespread use of social media platforms and their potential for virality, this is a strategic choice for quickly raising awareness and reaching a global audience.

*Countries utilize diverse strategies for enhancing patient safety during World Patient Safety Day, emphasizing the importance of tailored approaches to address health care challenges at local levels.*

**Engaging with stakeholders** (62%). Direct engagement with stakeholders indicates a focused approach to ensuring that key players in the health care sector are involved and informed. It provides a platform for discussions, feedback and collaborative strategies.

**National campaign launch** (55%). National campaigns, possibly involving multimedia platforms such as TV, radio and print, have significant traction. They can unify messages and actions across regions, as well as serving the local audiences.

**Press conference and media activities** (53%). Engaging the press is crucial for widespread dissemination of information. Media activities can lead to detailed coverage and can help in garnering public attention.

**Awareness-raising events with patients and patient organizations** (48%). Engaging directly with patients and patient organizations emphasizes a patient-centred approach, fostering trust and collaboration.

**Scientific workshop or training** (45%). Such activities suggest an emphasis on updating and training health care professionals on the latest best practices, research and protocols.

**Symposium/Forum** (44%). Providing platforms for open dialogue, knowledge exchange and networking among experts can lead to innovative solutions and broader consensus.

**Lighting up of national monuments** (36%). Symbolic gestures such as this can be visually powerful, creating landmarks of global solidarity and raising public curiosity.

**Release of publications or memorabilia** (26%). Publications offer detailed insights, guidelines and findings, while memorabilia can serve as lasting reminders.

**Awards** (18%). Recognizing and honouring outstanding contributions can motivate professionals and institutions to adopt best practices.

**Films** (15%). Documentaries or fictional films can emotionally resonate with audiences, offering narratives that highlight the importance of patient safety.

**Event engaging the general public** (17%). Engaging the public directly can lead to increased awareness among communities, fostering a collective spirit.

**Pledge-taking** (13%). While it had a lower percentage, pledge-taking is nevertheless a symbolic commitment to the patient safety cause.

**Survey** (12%). Surveys can be a tool to gauge current awareness levels, attitudes and beliefs, guiding future actions.

**Event based on arts and performance** (10%). Artistic events can be powerful mediums to convey messages emotionally and memorably.

While digital campaigns and stakeholder meetings were the most reported events, countries have reported a wide range of activities around World Patient Safety Day, each serving its unique purpose in promoting patient safety.

# WHO Global Patient Safety Challenges

*WHO's Global Patient Safety Challenges, initiated to address significant risks to patient safety worldwide, have garnered substantial commitment and support from countries and regions, with increasing engagement over time.*

Initiated by WHO, the Global Patient Safety Challenges are designed as initiatives to promote substantial improvements in patient safety worldwide. To achieve this, they urge governments to prioritize and dedicate adequate resources towards focused areas of concern for patient safety. Each challenge focuses on a topic that poses a major and significant risk to patient health and safety. Since their inception, WHO has launched three Global Patient Safety Challenges.

The first WHO Global Patient Safety Challenge: *Clean care is safer care*, was launched in 2005 *(172)*, and aimed to combat the spread of HCAIs, which significantly impact human lives and affect millions of patients worldwide each year.

The second WHO Global Patient Safety Challenge: *Safe surgery saves lives*, was launched in 2008 and aimed to improve the safety of surgical care around the world *(173)*. The challenge aimed to reduce the number of preventable deaths and complications from surgery by implementing a set of evidence-based practices and standards. One of the main tools of the challenge is the WHO Surgical safety checklist, a simple tool that covers the essential steps of safe surgery.

The third WHO Global Patient Safety Challenge: *Medication Without Harm (174)* was launched in 2017 and aimed to reduce severe avoidable medication-related harm by 50% over a period of five years.

The strategic framework of the third challenge focuses on four domains: patients and the public; health care professionals; medicines as products, and systems and practices of medication.

The Member State survey highlights the commitment of countries and regions to the WHO Global Patient Safety Challenges. Globally, 31% of countries have implemented all three challenges, and over half (56%) have acted on at least one.

Regionally, countries of the South-East Asia Region lead in fully implementing all three challenges (at 40% of countries), closely followed by the Region of the Americas and the European Region. To date, the African Region has the lowest rate for country implementation (15%) but demonstrates a significant commitment with 75% having implemented at least one challenge. Countries

of the Eastern Mediterranean Region also have a high engagement, with 72.7% focusing on at least one challenge.

Support for the Global Patient Safety Challenges has steadily increased with each new Challenge (68%, 69% and 74% respectively) (Fig. 1.18).
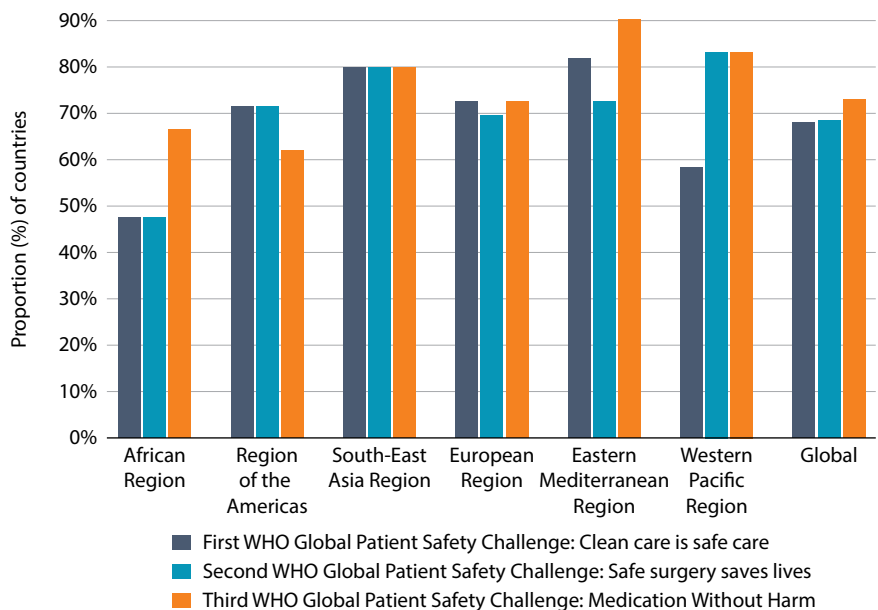
Legend:
- First WHO Global Patient Safety Challenge: Clean care is safe care
- Second WHO Global Patient Safety Challenge: Safe surgery saves lives
- Third WHO Global Patient Safety Challenge: Medication Without Harm

## Factors influencing country engagement in the WHO Global Patient Safety Challenges initiative

**Human and financial resources**. Several LICs and LMCs acknowledge the need to address the Global Patient Safety Challenges, however implementation may be limited due to human and financial resource constraints.

**Long-term commitment**. Several countries, including some HICs and UMCs, demonstrated a long-term commitment to implementing actions on the WHO Global Patient Safety Challenges.

**National coordination**. Numerous countries mention the presence of national coordination groups or working committees dedicated to patient safety.

**Endorsement vs full implementation**. In some cases, countries may have endorsed the specific WHO Global Patient Safety Challenges but not fully implemented them. It is essential to distinguish between endorsement and effective implementation, as the latter requires practical actions and interventions.

**Adaptation to local context**. Countries often adapt the WHO Global Patient Safety Challenges to their local health care contexts and needs. This adaptability allows countries to tailor their patient safety efforts to address specific issues effectively.

**Incentivizing health care personnel**. In some countries, the practice of patient safety has been included in mechanisms that financially reward health care personnel for their commitment to implementation of the WHO Global Patient Safety Challenges.

*The level of country engagement in the WHO Global Patient Safety Challenges initiative is influenced by various factors such as resource constraints, long-term commitment, national coordination efforts, adaptation to local contexts, and incentivization of health care personnel.*

# The evolution of World Patient Safety Day

The establishment of World Patient Safety Day (WPSD) was the result of a visionary initiative that emerged from the Global Ministerial Summits on Patient Safety, a global initiative that brought together political leaders and subject matter experts from around the world to address the issue of patient safety. The proposal to mark a day dedicated to patient safety was championed or spearheaded by the former Minister of Health of Oman, the United Kingdom's Secretary of State for Health and Social Care, and the German Minister of Health at the first and second summits, held in London in 2016 and Bonn in 2017, respectively. This unprecedented global momentum and high-level advocacy for patient safety... resulted in the historic 2019 World Health Assembly Resolution 'Global Action on Patient Safety'[a] officially establishing as one of the 11 'official' WHO global public health days, to be observed annually on 17 September. WPSD has since become a key platform to raise awareness, understanding and for action on patient safety worldwide.

## World Patient Safety Days from 2019 to 2023

Since 2019, World Patient Safety Day has become an annual milestone in the global health calendar. Each year, a new theme is selected to bring together countries, partners and the general public to accelerate efforts towards eliminating avoidable harm in health care.

The theme **Patient Safety: a global health priority** marked the first WPSD in 2019 with the slogan "Speak up for patient safety!" setting the day's legacy and urging stakeholders to place patient safety high on the global health agenda.

In 2020, the COVID-19 pandemic had devastating impacts on health systems globally, revealing weaknesses in the safety of the health workforce. As a result, the WPSD 2020 theme was **Health worker safety: A priority for patient safety**. The slogan of the campaign – "Safe health workers, Safe patients" and call to action "Speak up for health worker safety!" – emphasized how the safety of health workers and patients are like two sides of the same coin, highlighting the need for institutionalizing measures to safeguard the health and safety of health workers alongside that of patients. Such measures were seen as critical in preserving not only the well-being of health workers but also in ensuring safe and quality care for patients. To commemorate the day, WHO launched a landmark charter: Health worker safety: A priority for patient safety[b] that proposes key measures for Member States and relevant stakeholders to enhance the health and safety of health workers worldwide.

The theme of WPSD 2021 was **Safe maternal and newborn care** and the accompanying slogan – "Act now for safe and respectful childbirth!" – served as a call to action for stakeholders to ensure the safe and respectful delivery of care to women and newborns with particular focus around childbirth when most related harm occurs.

**Medication Safety** was chosen as the theme for WPSD 2023, helping to raise awareness on the huge global burden of medication-related harm. The day harnessed the ongoing efforts of the third WHO Global Patient Safety Challenge: *Medication Without Harm*[c] that was launched in 2017 and aimed to reduce severe medication-related harm by 50% over a five-year period. The slogan "*Medication Without Harm*" emphasized the need to strengthen medication use systems and safety of medication practices. The campaign drew attention to three areas identified for priority action, namely: high-risk situations, transitions of care, and polypharmacy.

Recognizing the central role that patients, their families and caregivers play in advancing safe care, the theme selected for WPSD 2023 was **Engaging patients for patient safety** with the slogan "Elevate the voice of patients!". The day supported the existing Patients for Patient Safety (PFPS) programme[d] and the implementation of Strategic Objective 4 of the Global patient safety action plan 2021–2030[e] focused on patient and family engagement. On this occasion, WHO unveiled the Patient safety rights charter[f] during a global conference, marking a significant step in integrating patient safety within the framework of human rights.
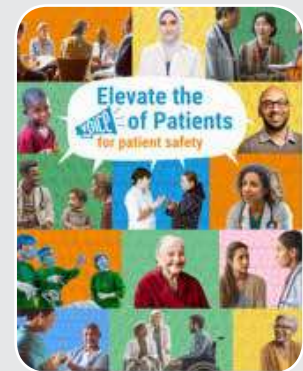
Improving diagnosis for patient safety" has been selected as the theme for WPSD 2024, recognizing the critical importance of correct and timely diagnoses in ensuring patient safety. Through the slogan "Get it right, make it safe!", WHO calls for concerted efforts to significantly reduce diagnostic errors through multifaceted interventions rooted in systems thinking, human factors and active engagement of patients, their families, health workers and health care leaders. In an effort to utilize WPSD as a catalyst for positive change within health care systems, WHO introduced a technical component to the campaign in 2020. Since then, numerous technical resources have been released each year aligned with the designated WPSD themes.

## The world in orange: A signature mark of global solidarity and commitment

The colour orange has been selected as the signature colour of WPSD, conveying warmth, hope and positivity, and given its existing association with UHC. Iconic landmarks are lit up in orange around the world on 17 September, serving as a powerful visual display emphasizing the importance of patient safety, while also elegantly linking it to UHC. All regions of the world have been part of this powerful gesture, from the Twin Towers in Malaysia, and the Colombo Lotus Tower in Sri Lanka, to the Nelson Mandela Statue in South Africa; and from the Pyramids of Giza in Egypt, the National Palace of Culture in Bulgaria, to Christ the Redeemer in Brazil, among many others. The number of monuments annually illuminated in this way has increased each year, highlighting the growing global commitment to patient safety. The number of participating monuments increased from 78 in 2019 to over 400 in 2022.

The gesture extends beyond landmarks to encompass a variety of 'orange' themed ideas. People around the world wear orange in various forms to mark WPSD. Many organizations decorate their buildings with orange flags, bake orange-coloured cakes, and prepare orange floral, balloon and lantern displays.

## Celebrating the day across borders

World Patient Safety Day receives wide recognition and participation from all stakeholders and has been observed in more than 165 countries since its inception. Ministers of health, policy-makers, health care leaders and facility managers, health workers, patients, and the general public all get actively engaged in related activities. The festivities are organized by both public and private sectors, and typically last from a single day to an entire week. Some stakeholders even plan year-long events signifying the need for continuous promotion of patient safety.

Leadership at various levels of care showcase their commitment by adopting patient safety laws, establishing national patient safety bodies, formulating committees, and launching national policies, strategies, action plans or standards close to the day. Policy-makers also make public statements and proclamations in support of patient safety. Capacity-building activities are often organized both for the health workforce and students. Activities aimed at promoting awareness and empowering patients are also organized. Knowledge on patient safety is shared through publications by academic and research institutions and social media campaigns. WPSD also attracts significant media coverage including through press conferences, news releases, talk shows, TV interviews, radio shows, blogs, op-eds and podcasts. Recognition ceremonies honour patient champions and health workers alike, while creativity and art are on full display with candle-lighting ceremonies, music concerts, skits, games, and blood donation drives. World Patient Safety Day is a testament to the power of collective action, urging the world to prioritize patient safety and setting the stage for safer health care.

*Sources:*

[a]  *Resolution WHA72.6. Global action on patient safety. In: Seventy-second World Health Assembly, Geneva, 20–24 May 2019. Geneva: World Health Organization; 2019 (https://iris.who.int/handle/10665/329284, accessed 29 April 2024).*

[b]  *Charter: health worker safety: a priority for patient safety. World Health Organization; 2020 (https://iris.who.int/handle/10665/339287, accessed 29 April 2024).*

[c]  *The third WHO Global Patient Safety Challenge: Medication Without Harm. Geneva: World Health Organization; 2017 (https://iris.who.int/handle/10665/255263, accessed 29 April 2024).*

[d]  *Patients for patient safety [website]. Geneva: World Health Organization; 2024 (https://www.who.int/initiatives/patients-for-patient-safety, accessed 29 April 2024).*

[e]  *Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/343477, accessed 29 April 202).*

[f]  *Patient safety rights charter. Geneva: World Health Organization; 2024. (https://iris.who.int/handle/10665/376539, accessed 29 April 2024).*


*The Jet d'Eau in Geneva, illuminated in orange, supporting the cause to 'Elevate the voice of patients' on the occasion of World Patient Safety Day.*
*© WHO / Chris Black*

**Strategic objective 2**

# High-reliability systems

*Pediatrician at a clinic in Yerevan, Armenia. © WHO / Nazik Armenakyan*

"

Build high-reliability health systems and health organizations that protect patients daily from harm

# Organization of section

## Strategy 2.1. Transparency, openness and no blame culture

- Safety culture implementation
- Never and/or sentinel events reporting
- No blame policy and just culture

## Strategy 2.2. Good governance for the health care system

- Institutional framework for patient safety
- National focal point for patient safety

## Strategy 2.3. Leadership capacity for clinical and managerial functions

## Strategy 2.4. Human factors/ergonomics for health systems resilience

- Applying human factors for improving patient safety
- Structural and non-structural safety of health care infrastructure

## Strategy 2.5. Patient safety in emergencies and settings of extreme adversity

- Patient safety integration in health emergency preparedness, response and recovery plans
- Risk management for patient safety

# Key messages

A safety culture in health care is recognized as crucial by most countries, yet only a quarter of countries reported to have made efforts towards developing a culture of safety in health care facilities and services.

The WHO Global patient safety action plan 2021–2030 advocates for good governance for patient safety, with around half of the countries having designated national patient safety officers and establishing national coordination bodies.

Although the significance of human factors in health care is being increasingly recognized at the global level, only around a quarter of countries have started to apply human factors principles in patient safety interventions in clinical practice, use of medical devices, information technology (IT) solutions, and service delivery processes.

A proactive and systematic approach to managing patient safety risks involves meticulous identification, examination and mitigation of potential hazards and risks in health care settings. Only a quarter of countries report implementation of risk management strategies and conduct regular mock drills.

Most countries have established physical safety norms for health care infrastructure, but only about half of them report enforcing these norms, highlighting a gap between policy and practice in infrastructure safety.

Creating health systems and organizations with high reliability is about consistently safeguarding patients from harm. Such systems are judged not only by their ability to operate safely under normal conditions but also by their resilience in the face of errors, with an emphasis on rapid recovery and reinstatement of safety protocols. This demands investments in capabilities that enable anticipation of challenges, diligent operational monitoring through data analysis, and embracing lessons from both successes and failures. Transformative changes in patient safety hinge on strategic learning from these outcomes, along with a deep understanding of the complex interplay between social elements and technology within health care systems.

It is also essential to foster an organizational culture and leadership that contribute to reflective practices on patient safety. It is crucial to move from a blame culture to one that is just and promotes openness about both systemic weaknesses as well as personal mistakes leading to patient safety incidents. This shift requires embedding robust practices such as use of data, continuous process monitoring, and fostering an environment where respect and open communication among staff are the norm.

Leaders play a pivotal role in this context: they must champion a vision for patient safety, inspire their teams to meet high standards of care, and proactively address systemic issues that contribute to risks. Investing in building capacity of such leaders is indispensable for a high-reliability health system.

Understanding the human aspect – how individuals interact with and affect health care systems and components – is also crucial. This interdisciplinary 'human factors' (or ergonomics) approach aims to enhance human well-being and system efficiency. The exploration of how human factors impact system performance, such as the interactions of health workers in their work environment, or patients within their care trajectory, typically focuses on stakeholder experiences and inputs. The human factors approach is participatory and design-focused in nature, applies a systemic lens to incident analysis, and upholds the principle of ongoing learning for continuous improvement.

Responses to the Member State survey highlight the diverse progress in establishing high-reliability health systems across countries, with many still in the implementation phase. Out of 108 countries assessed against 25 criteria related to this strategic objective, only 27% of countries fully achieved the criteria, while 42% partially fulfilled them. On average, about a quarter of the recommendations suggested actions outlined in the Global patient safety action plan 2021–2030 remain untouched by countries striving to promote high-reliability systems, resulting in an overall aggregated performance score of 51 out of 100 for the strategic objective (Fig. 2.1).
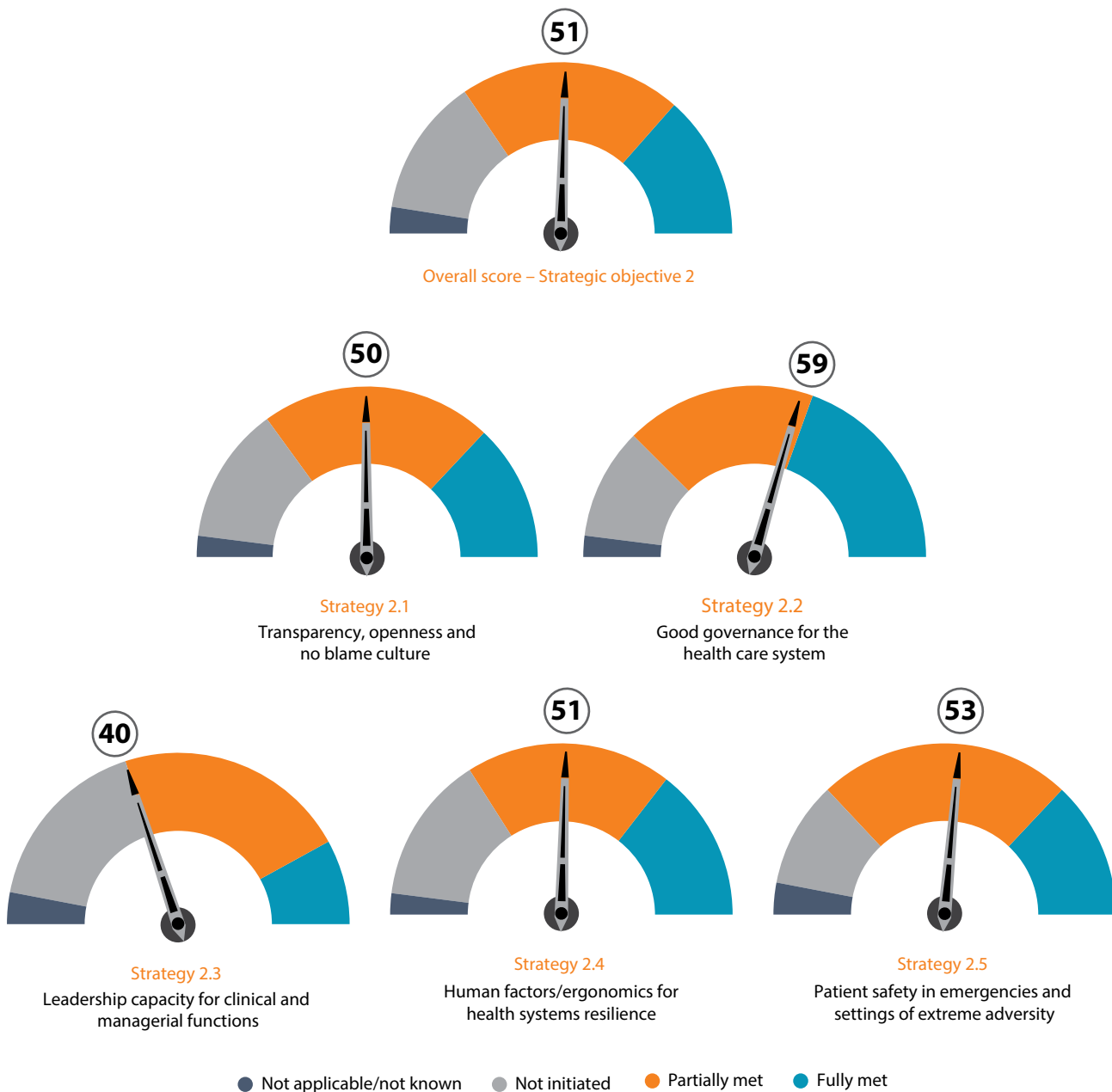
The survey offers a comprehensive snapshot of the state of high-reliability systems in health care. Transparency, openness and cultivating a safety culture, which scored at 50, reveals an important gap, with only 26% of countries fully meeting these criteria and 44% partially achieving them. The institutional framework for patient safety, which scored at 59, indicates significant progress, with 39% of countries meeting the criteria, although 21% have yet to commence related efforts.

Leadership capacity for clinical and managerial functions, which scored at 40, presents a considerable hurdle, with merely 16% of countries fully meeting the criteria. Meanwhile, the application of human factors/ergonomics for ensuring physical safety, which scored at 51, demonstrates room for improvement, with 27% of countries yet to implement related measures. Lastly, patient safety in emergencies and extreme adversity, which scored at 53, raises a pressing concern, with only 26% of countries meeting expectations and nearly half (48%) only partially addressing this critical aspect.

Overall, country responses suggest a prioritization of structural elements over process initiatives to build high-reliability systems. For instance, many countries have efficiently appointed national patient safety officers and established national bodies for coordinating safety efforts. Additionally, 42% of countries adhere to structural safety norms, emphasizing their commitment to infrastructure and standards compliance. In contrast, process-oriented initiatives lag behind. Only 9% of countries focus on developing the leadership capacity of early-career professionals in patient safety. Furthermore, 25% of countries conduct regular rehearsals/mock drills to improve responses to risks, and 23% assess organizational
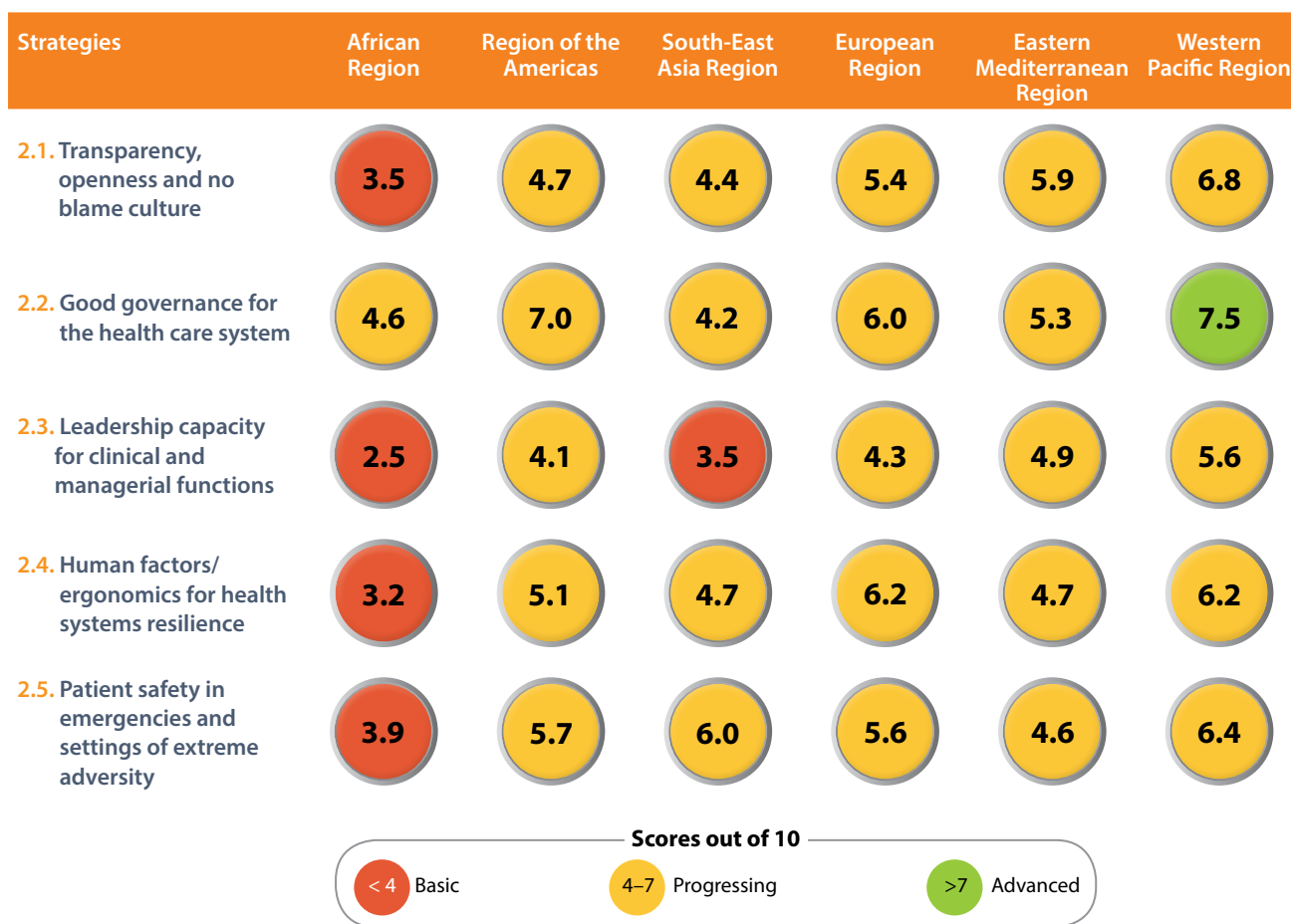
safety culture through periodic surveys. These discrepancies highlight a significant gap between process-oriented initiatives and structural components, emphasizing the urgent need for targeted interventions and resource allocation to bridge these disparities. Efforts to strengthen process criteria, such as leadership capacity building, human factors integration, regular rehearsals of emergency responses, safety culture assessments through surveys, and improved sentinel event reporting mechanisms, are crucial for building high-reliability and safe health systems globally.

**▶ Fig. 2.1. Global performance scores for strategic objective 2**



**51**

Overall score – Strategic objective 2

**50**

Strategy 2.1
Transparency, openness and
no blame culture

**59**

Strategy 2.2
Good governance for the
health care system

**40**

Strategy 2.3
Leadership capacity for clinical and
managerial functions

**51**

Strategy 2.4
Human factors/ergonomics for
health systems resilience

**53**

Strategy 2.5
Patient safety in emergencies and
settings of extreme adversity

● Not applicable/not known ● Not initiated ● Partially met ● Fully met

Analysis across different WHO regions offers valuable insights into the strengths and potential areas for improvement in strategies to build high-reliability systems (Fig. 2.2). The Region of the Americas and the European Region exhibit robust governance structures and strong leadership capacities. The Western Pacific Region stands out for its emphasis on transparency and a focus on human factors for system resilience. However, while the Eastern Mediterranean Region demonstrates strengths in transparency, openness, and leadership capacity, it does not score as high in areas such as human factors for system resilience and patient safety in emergencies compared to other regions.
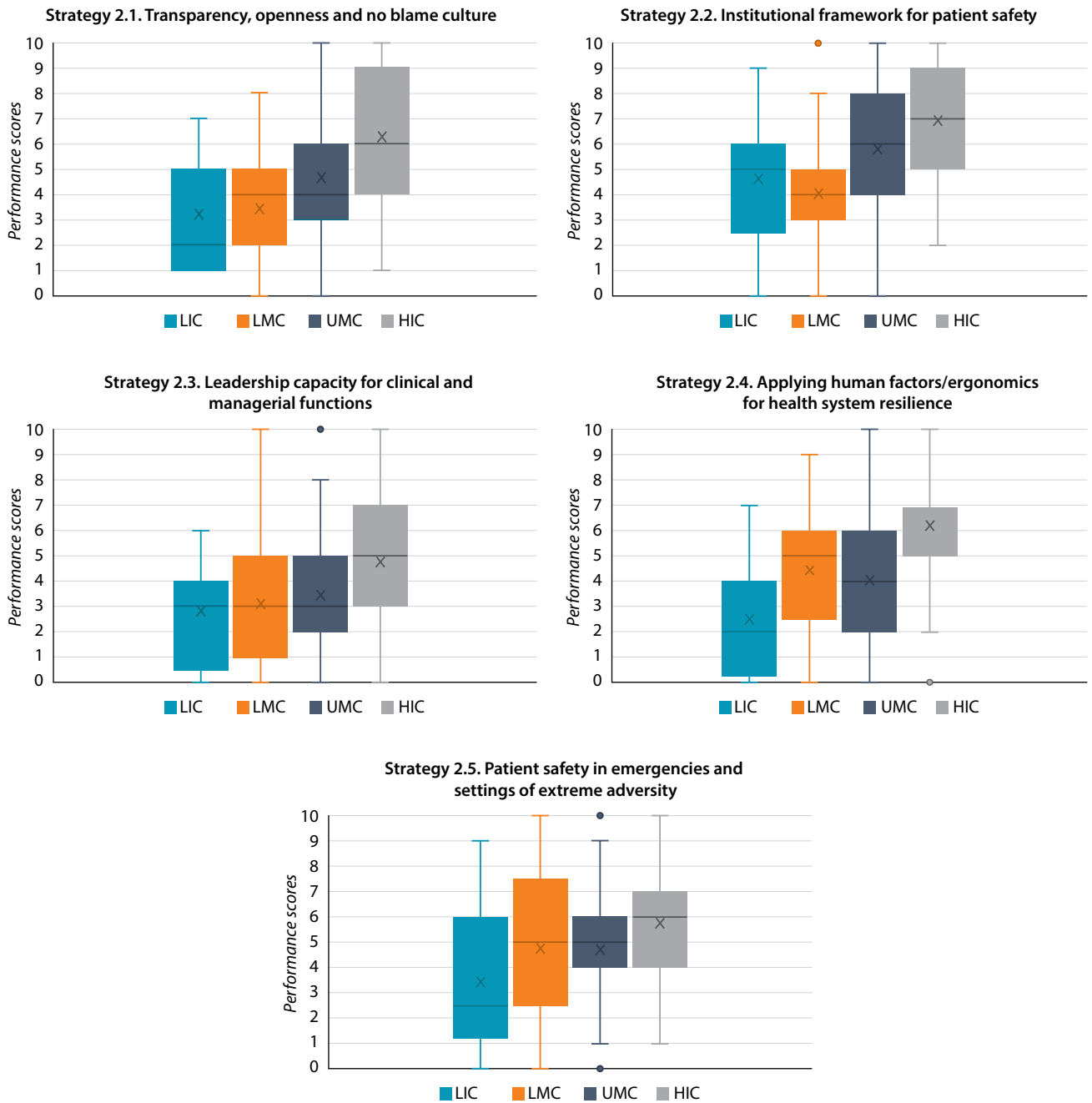
**Fig. 2.2. Distribution of strategic objective 2 performance scores across the five strategies, by WHO region**

| Strategies | African Region | Region of the Americas | South-East Asia Region | European Region | Eastern Mediterranean Region | Western Pacific Region |
|---|---|---|---|---|---|---|
| 2.1. Transparency, openness and no blame culture | 3.5 | 4.7 | 4.4 | 5.4 | 5.9 | 6.8 |
| 2.2. Good governance for the health care system | 4.6 | 7.0 | 4.2 | 6.0 | 5.3 | 7.5 |
| 2.3. Leadership capacity for clinical and managerial functions | 2.5 | 4.1 | 3.5 | 4.3 | 4.9 | 5.6 |
| 2.4. Human factors/ ergonomics for health systems resilience | 3.2 | 5.1 | 4.7 | 6.2 | 4.7 | 6.2 |
| 2.5. Patient safety in emergencies and settings of extreme adversity | 3.9 | 5.7 | 6.0 | 5.6 | 4.6 | 6.4 |

Scores out of 10

< 4 Basic    4–7 Progressing    >7 Advanced

Similarly, the South-East Asia Region shows opportunities for improvement in governance, leadership and the promotion of a culture of transparency and patient safety. Scores on strategy 2.4 regarding human factors comprise two indicators focusing on physical safety, which exhibited better performance across all regions compared to specific indicators concerning the application of human factors, which showed relatively lower performance in most countries.

Descriptive analysis of scores across income groups indicates that higher economic status tends to be associated with better scores in high-reliability systems related to patient safety (Fig. 2.3). High-income countries typically display higher median scores across several dimensions, suggesting more effective implementation of systems that promote high reliability in health care practices. The overlap between the scores of LMCs, UMCs and HICs highlights that higher economic resources are not the exclusive factor influencing these patient safety measures. There are exceptional instances where less affluent countries match or surpass the patient safety performance of their richer counterparts, particularly in areas concerning leadership capacity and patient safety in emergency preparedness. Overall while financial prosperity may be seen as a reliable indicator of the reliability of patient safety systems, the data reflect a complex landscape with notable disparities and individual successes within each income group.

**Fig. 2.3. Distribution of strategic objective 2 performance scores across the five strategies, by income group**

Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

| 2.1 | 2.2 | 2.3 | 2.4 | 2.5 |
|-----|-----|-----|-----|-----|
| Transparency, openness and no blame culture | Good governance for the health care system | Leadership capacity for clinical and managerial functions | Human factors/ ergonomics for health systems resilience | Patient safety in emergencies and settings of extreme adversity |

**Strategic objective 2**

## Strategy 2.1.

# Transparency, openness and no blame culture

**"**

*Develop and sustain a culture of respect, openness and transparency that promotes learning, not blame and retribution, within each organization providing patient care*

---

*A positive safety culture, emphasizing trust, shared safety perceptions, and learning from errors, is crucial for patient safety management.*

Safety culture is the product of individual and group values, attitudes, perceptions, competence and patterns of behaviour that determine the characteristics of an organization's health and safety management *(175)*. Organizations with a positive safety culture are characterized by communications based on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures. One of the key aspects of patient safety culture is the notion of a 'no blame' culture. This means that instead of pointing fingers and punishing individuals for errors, the organization focuses on learning from errors and improving systems and processes. Blame cultures tend to create fear and distrust and discourage reporting and transparency. However, some may argue that a no blame culture is unrealistic or inappropriate in some cases. Therefore, some prefer the term 'just culture', that recognizes the complexity of situations and events and acknowledges that whilst most patient safety failures are the result of weak systems, there is a minority of situations where an individual should be held to account, for example, where there has been reckless behaviour or wilful misconduct. A strong safety culture is essential for implementing and sustaining patient safety interventions.

# Safety culture implementation

Through the Member State survey, 26% of countries reported that their governments have made efforts towards achieving a culture of safety in health care facilities and services.

Many countries are integrating safety culture promotion into their national quality improvement and management training curriculum. Mandatory criteria, staff training and patient education on safety are emphasized in some countries. Additionally, efforts in countries involve implementing safety culture through safety hospital programmes, accreditation programmes, and comprehensive patient safety strategies.

Nevertheless, there are significant variations in the adoption of a safety culture across different regions. The Western Pacific Region has the highest inclusion rate at 50%, suggesting a strong emphasis on safety culture in this region. In contrast, the African Region has reported the lowest rate at 14%, indicating potential challenges in implementing safety culture initiatives. There is a clear correlation between income groups and the inclusion of a safety culture, with HICs having the highest inclusion rate at 42%.

Implementing, enhancing and maintaining patient safety within health care organizations often begins with fostering a robust safety culture framework. Regular administration of surveys to gauge the establishment and progression of organizational safety culture is essential to this endeavour. Globally, approximately 23% of countries engage in periodic safety culture surveys, reflecting a commitment to evaluating processes and advancing towards the goal of achieving zero harm. Notably, there is a fairly consistent pattern across WHO regions, with percentages ranging from 20% to 30%, except in the African Region, where only 5% of countries report conducting safety culture surveys (Fig. 2.4).
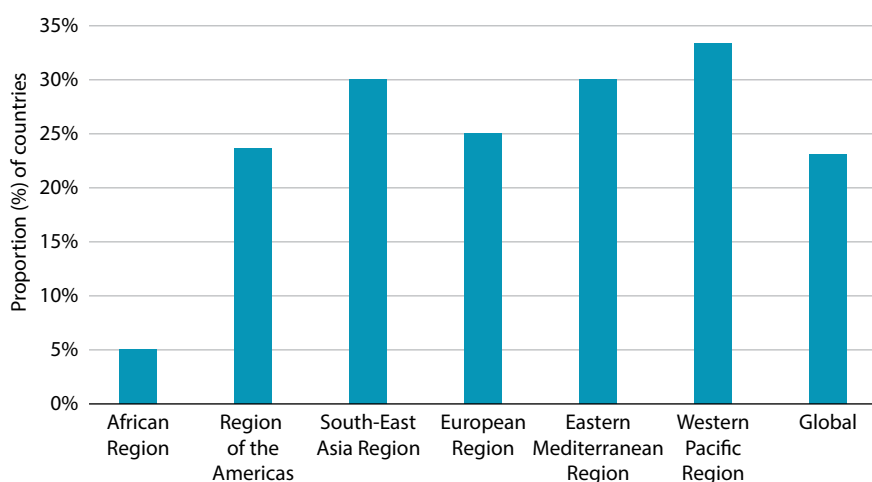
*Global efforts to promote safety culture in health care vary widely, with some regions showing stronger initiatives than others.*

*About one in four countries globally conduct regular safety culture surveys to improve patient safety.*



**Fig. 2.4.**
**Proportion of countries conducting organizational safety culture surveys, by WHO region**

## Examples of countries using varying approaches to monitor and improve their health-related safety culture

**Thailand** conducts a yearly survey as part of the 2P Safety Hospital Programme, which covers more than half of its hospitals. **Liberia** and **Uganda** have adopted tools for assessing organizational safety culture to facilitate its development and conducted a patient safety practice survey. **Sri Lanka** utilizes a supervision tool for assessing the quality of patient management and conducts performance reviews for hospitals above the 'base' hospital level. **Singapore** uses various tools (e.g. Agency for Healthcare Research and Quality Patient safety and culture survey and Employee engagement survey). **Malaysia** has had tools in place since 2010 to assess clinical governance and patient safety culture, with plans underway to incorporate periodic surveys into its national action plan for patient safety. **Türkiye** has recently started implementing a patient safety and culture survey and plans to expand its use. The **United Kingdom** relies on the NHS staff surveys to assess the safety culture among its health workers. **Argentina** is conducting initial organizational climate surveys incorporating safety culture concepts. **Poland's** National Centre for Quality Assessment in Health Care conducts safety culture surveys at the hospital level, and **Belgium** has been conducting safety culture measurements in hospitals for 15 years.

These examples illustrate the diverse approaches taken by countries worldwide to assess and improve organizational safety culture within their health care systems.

## Never and/or Sentinel events reporting

Patient safety incidents characterized as 'never' (or 'sentinel') events can have devastating consequences for patients, families and health care providers. Never events are particularly shocking medical errors – such as performing surgery on the wrong body part or wrong patient – that should never occur. Sentinel events are unexpected occurrences that result in death or serious physical or psychological injury, or the risk of such outcomes *(176)*. For example, a patient falling from a hospital bed and suffering a brain injury, or a medication error that causes a cardiac arrest. Both types of incidents require immediate investigation and response to prevent recurrence and improve patient safety.

One of the stepping stones for building a safety culture is to have well-defined procedures and reporting systems for never and sentinel events.

Of the 108 global survey respondents, 38% stated that such a reporting system was in place and operational. Another 44% stated that they have defined reportable never/sentinel events, but the system has not yet been operationalized.

There are noticeable differences across regions and income groups in the implementation of related reporting systems (Fig. 2.5). The Western Pacific Region leads with 58% of countries reporting they have such systems in place – well above the global average of 38%. The African Region reported at 19%. Other

regions range from 33% in the South-East Asia Region to 42% in the Region of the Americas. As might be expected, countries with higher income levels appear to have more systems in place: 60% of HICs have operational systems, in contrast to 30% of UMCs, 21% of LMCs and 15% of LICs.
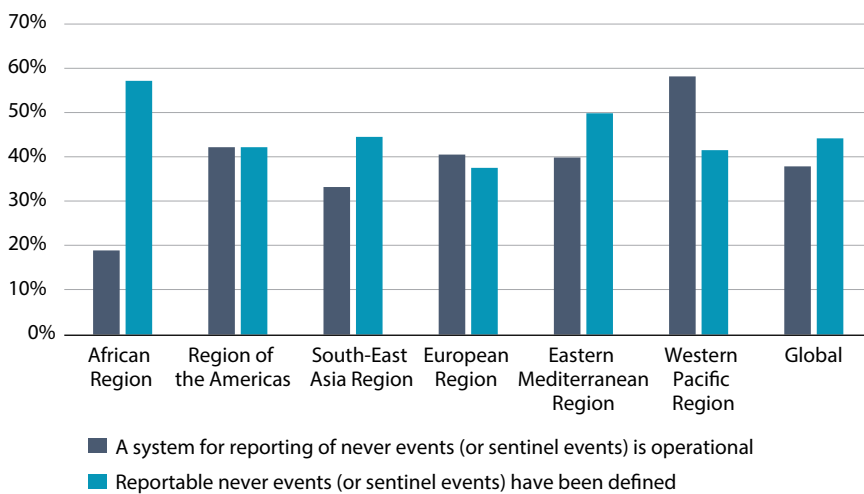


**Fig. 2.5.**
**Global status of never/sentinel event reporting systems, by WHO region**

Legend:
- A system for reporting of never events (or sentinel events) is operational
- Reportable never events (or sentinel events) have been defined

## Examples of national reporting mechanisms

Some countries – such as **Australia** (with its Australian Sentinel Events List) and **Canada** (Vanessa's Law) – incorporate the reporting of never events into the broader health and safety legislative framework.

While many countries employ electronic and online platforms for reporting, some countries, such as **Benin**, offer toll-free lines, highlighting the diversity of mechanisms tailored to country resources and infrastructure.

In countries with federal systems, such as **Canada** and **Spain**, both national and regional (or provincial) systems coexist. This layered approach caters to the diverse and specific needs of different regions while ensuring overall standardization.

Many countries, such as **Chile**, **Czechia**, **Netherlands (Kingdom of the)**, **New Zealand, South Africa** and **Thailand**, have specific national reporting and learning systems in place. This centralized approach ensures standardized reporting and learning across the entire country.

While the modalities and specific implementations vary, there is a global trend towards recognizing the significance of never events, reporting them, investigating their root causes, learning from them, and taking corrective actions to enhance patient safety.

## No blame policy and just culture

To promote a culture of safety and accountability, it is essential to establish and enforce administrative and legal protection mechanisms for those who report adverse events, or those who voice concerns about the safety of services.

*Countries are adopting diverse mechanisms for reporting 'never' and sentinel events, including national legislative frameworks, electronic platforms, toll-free lines, and regional systems.*

*Around one quarter of countries have implemented no blame policies, and 17% have made efforts to establish a just culture, focusing on confidentiality and protection for reporters.*

These mechanisms should aim to prevent retaliation, discrimination, or other negative consequences for the reporters, and to encourage learning from errors and improving the work system, rather than blaming or punishing individuals. Protection mechanisms should be based on evidence and best practices from previous patient safety failures and should be widely communicated and accessible to all stakeholders involved in the delivery of services.

According to survey responses, around one quarter of countries have made sustained efforts to implement no blame policies. Various systems prioritize confidentiality, protection for reporters, and clear differentiation between human errors and negligent actions. In addition 17% have made sustained efforts to implement a just culture in health care facilities and services. Most of these efforts are concentrated in UMCs and HICs (Fig. 2.6).

**Fig. 2.6.**
**Status of no blame policy and accountability mechanism, by income group** ◀
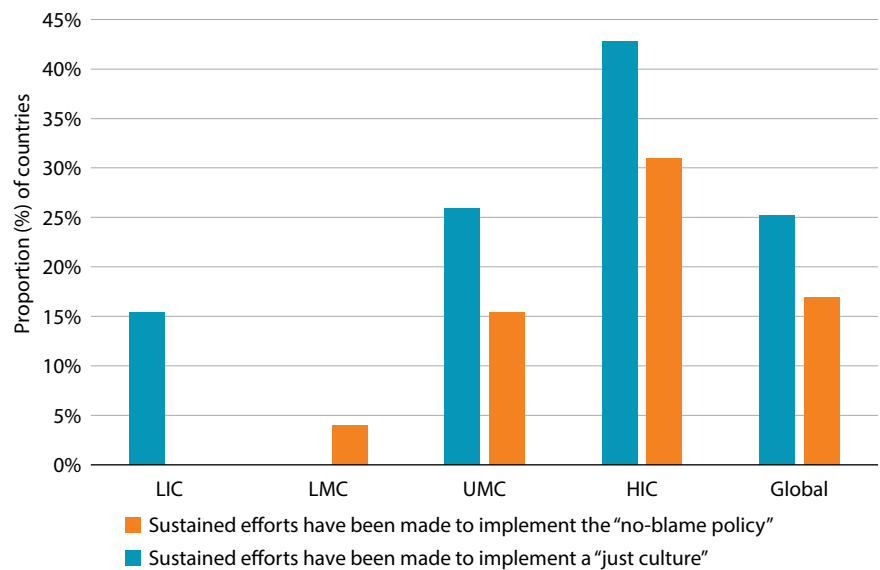


Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

## Examples of country experiences in implementing just culture

**United Kingdom**. The NHS Just culture guide *(177)* provides a consistent framework for addressing incidents, focusing on understanding the underlying factors influencing human behaviour. While inadvertent errors, when admitted, are not typically penalized – to promote safety reporting – a just culture does not shy away from holding individuals accountable in cases of gross negligence.

**Spain**. The approach to reporting is voluntary, emphasizing that there is no obligation for professionals to do so. Importantly, the system is entirely separate from any punitive or sanctioning mechanisms, both inside and outside of health care facilities. Confidentiality is of utmost importance, ensuring that information is shielded and only accessible by authorized individuals. Additionally, reporters have the flexibility to remain anonymous or provide their identity. However, for those choosing to be identified, their personal data is diligently removed after a period of fifteen days. It is important to note that

serious incidents, such as patient abuse with evident legal implications, are not part of the notification system.

**Malaysia**. The incident reporting and learning system focuses on the spirit of no blame and just culture. Staff are encouraged to report errors and near misses without fear of punishment or blame, and the information is used to learn from mistakes and improve patient safety.

**Uruguay**. In recent years, training sessions have been conducted in various cities across the country to ensure that reporting adverse events does not result in sanctions for the individuals involved. Institutions are encouraged to have their patient safety commission analyse reports with a focus on identifying systemic errors, rather than assigning blame. The Department of Quality of Care and Patient Safety at the Ministry of Public Health, has established concepts related to just culture, including a taxonomy that clearly defines human errors, risky behaviours, and negligent or reckless actions.

**South Africa**. A national guideline for patient safety incident reporting and learning outlines the principles of incident management, including a just culture approach. This helps managers and senior clinicians assess the actions of staff involved in adverse events and to decide on appropriate management actions.

**Denmark**. A reporting and learning system for patient safety incidents is widely used and complied with by authorized health professionals to report errors or adverse events without fearing punishment or disciplinary actions.

**Romania**. Whistle-blower protection, particularly for those reporting medical errors, is embedded within the legal framework. The Law on Patient Rights (Law no. 46/2003) ensures that individuals who highlight medical mishaps are shielded from retaliation or any form of disciplinary action. Furthermore, the National Authority of Quality Management in Health has established comprehensive guidelines and procedures to fortify this protection.

**Uganda**. A maternal perinatal death surveillance response system is being implemented that identifies the causes and contributing factors of maternal and perinatal deaths, and recommends actions to prevent similar deaths. This involves the participation of health workers at different levels, especially the immediate supervisors who play a key role in supporting and protecting their direct reports.

*Various countries have adopted just culture frameworks to promote the reporting of errors and adverse events without fear of punishment. These approaches emphasize understanding systemic issues, protecting reporters, and clearly differentiating between human errors and negligent actions.*

## Feature story 4

## The SingHealth Duke–National University of Singapore Institute for Patient Safety and Quality

### Summary

The Singapore Health Services (SingHealth) Duke- National University of Singapore (NUS) Institute for Patient Safety and Quality (IPSQ) was established in response to a serious infectious disease outbreak at a flagship hospital in Singapore. From its early work in developing systems to improve patient safety, IPSQ has continually evolved its focus of improving the culture of safety, staff well-being and patient involvement. IPSQ programmes have led to improvements in the culture of speaking up for patient safety and have staff well-being at their core.

### What was done and why?

An example of IPSQ work is TeamSPEAK™, an initiative that promotes psychological safety, enhances a 'speaking up' culture and provides the staff with the tools and opportunity to practice speaking up to highlight patient safety concerns. A training-of-trainers format has enabled the programme to be rolled out widely to SingHealth staff.

The initiative on patient safety culture, developed further after the COVID-19 pandemic, highlighted the importance of staff well-being in contributing to a healthy culture of safety. Staff burnout has increasingly been recognized as a key issue, and staff well-being is of critical importance for patient safety. SingHealth has formed a 'Joy at work' taskforce committee to identify areas where they can reduce staff burnout and make efforts to enhance joy at work. Holistic staff well-being frameworks are under development in their institutions. Some examples of projects currently being piloted are TeamTHRIVE™, a programme in team resilience; and TeamJOY™, a programme aimed at helping team leaders to build healthy and joyful physical and psychological workspaces.

### Improvements in speaking up for safety

TeamSPEAK™ workshops have so far trained over 20 000 staff. The SingHealth employee engagement survey demonstrates significant improvements in the culture of speaking up for patient safety over a five-year period, alongside a significant increase in the number of reported near miss events.

### Sustaining a focus on staff well-being

IPSQ has embraced the concept of a patient safety ecosystem, which recognizes the synergistic relationship between improving patient safety culture, promoting staff well-being, and the role of patient partners.

*'When we started, we wanted to improve culture; Joy at work was going to come later. We were focusing on psychological safety, but we didn't realize that everything is interrelated, and health worker well-being is just as important. Joy at work is central – we need to take care of health workers.'*

*(Representative of IPSQ)*

*Source: For more information, see:*

*SingHealth - Duke-NUS [website]. Singapore: SingHealth; 2024 (https://www.singhealthdukenus.com.sg/ipsq, accessed 30 April 2024).*

| 2.1 | 2.2 | 2.3 | 2.4 | 2.5 |
|-----|-----|-----|-----|-----|
| Transparency, openness and no blame culture | Good governance for the health care system | Leadership capacity for clinical and managerial functions | Human factors/ ergonomics for health systems resilience | Patient safety in emergencies and settings of extreme adversity |

**Strategic objective 2**

# Strategy 2.2.

# Good governance for the health care system

**"**

Develop and operate effectively a good governance framework within each component of the health care system

To ensure a robust and effective patient safety system, it is essential to have dedicated teams of patient safety experts at different levels of governance, from national to local. These teams should have diverse skills and backgrounds, so that they can address the various challenges and complexities that may arise.

Their main tasks are to coordinate and implement patient safety activities across all levels by establishing standards and indicators for patient safety, monitoring and evaluating patient safety performance, identifying and disseminating best practices, and supporting capacity building and training.
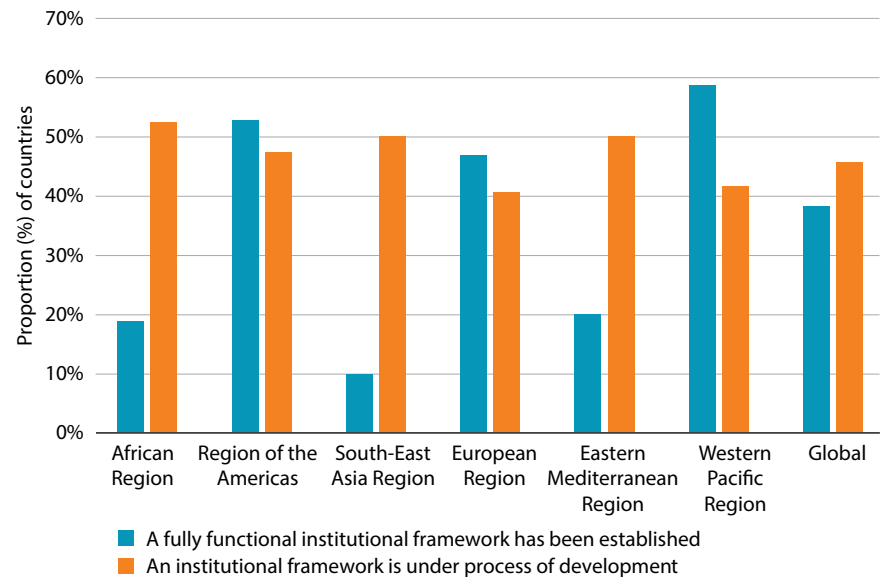
## Institutional framework for patient safety

The Member State survey reveals that countries are at varied stages of implementing patient safety institutional frameworks. 38% of all respondents reported that a fully functional patient safety institutional framework has been established through policies or legislation, while another 46% of countries stated that such a framework is currently under development. About one third of countries reported that they have established and put into practice operational guidance that outlines the roles, responsibilities and procedures for the effective functioning of a patient safety institutional framework.

*The Member State survey shows that around one third of countries have a fully functional patient safety framework.*

Around 58% of countries of the Western Pacific Region report having a fully functional framework, whereas only 10% of countries in the South-East Asia Region (Fig. 2.7). Notably, 50% of countries in both the South-East Asia Region and the Eastern Mediterranean Region are actively developing such frameworks.

Established institutional frameworks were reported most frequently in HICs and UMCs. LICs and LMCs also are demonstrating a significant drive towards developing institutional frameworks for patient safety.

**Fig. 2.7.
Status of patient safety institutional frameworks, by WHO region**



■ A fully functional institutional framework has been established
■ An institutional framework is under process of development

## National focal point for patient safety

*Low-income countries have initiated the designation of national patient safety officers, while high-income countries establish dedicated centres or institutes.*

The Global patient safety action plan 2021–2030 recommends the designation of a national patient safety officer, team, agency, institute or centre. This national focal point is tasked with the oversight and execution of national patient safety initiatives and policies. Their pivotal role includes creating and promoting evidence-based guidelines and best practices suitable for diverse health care settings. They also establish and track national patient safety metrics to evaluate and enhance both performance and outcomes. They act as catalysts for the reporting and in-depth analysis of adverse events and near misses, ensuring that these incidents are leveraged as learning opportunities to prevent similar future occurrences.

Analysis of Member State survey responses reveals the diverse strategies countries adopt based on their economic status (Fig. 2.8). LMCs and LICs may face challenges or resource constraints when establishing larger institutional entities dedicated to patient safety institutional entities dedicated to patient safety and have initiated the process institutionalizing patient safety by appointing a national patient safety officer. On the other hand, robust health care infrastructures within HICs allow them to focus on creating sustainable institutional frameworks, translating their resources into structural advancements. UMCs strike a balance, indicating a transitory phase from individual-led initiatives to systemic, organizational endeavours.

Globally, there is almost an equal emphasis on both individual roles and institutional mechanisms for patient safety, with 52% of countries designating an officer and 51% establishing a national body. 22% of countries also reported having functional patient safety teams at subnational level.
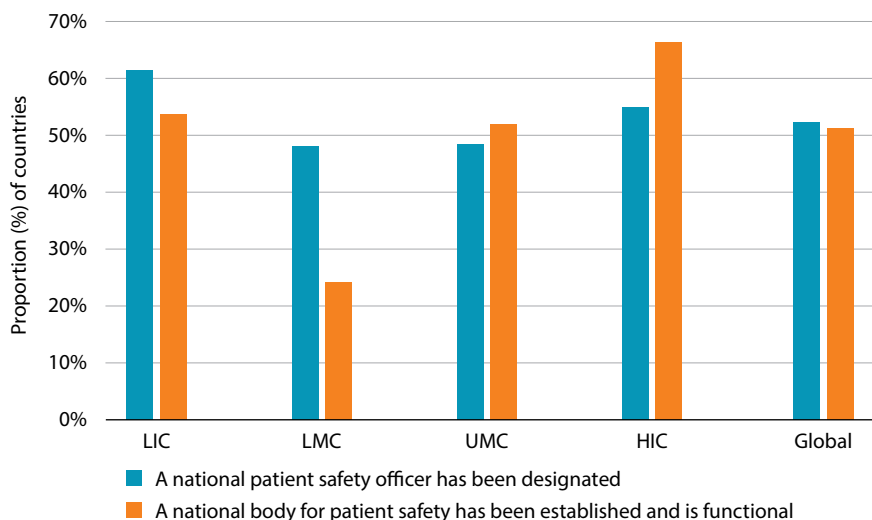
Fig. 2.8.
**Status of patient safety officers and national patient safety institutes, by income group**

Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

Patient safety is sometimes integrated with other related domains such as clinical governance, primary health care, health workforce, quality of care, and accreditation programmes, emphasizing a holistic approach. Integration with other programmes' or policies is also a recurring theme, as seen with countries integrating with IPC guidelines or health facilities licensing regulations.

While many countries, for example **Luxembourg**, **Japan**, **Republic of Korea** and **the United Arab Emirates**, have established a patient safety framework, operational guidelines are still in development or under review in many countries.

Several regions have established patient safety frameworks through legislation and policy directives, demonstrating government commitment to prioritizing patient safety. In countries with federal systems, patient safety frameworks can often be decentralized with regions or provinces establishing their own strategies.

Despite the progress made in many regions, there are gaps and areas for improvement, particularly in defining implementation mechanisms, updating policies, and clarifying roles and responsibilities.

The designation of patient safety focal points and responsible leadership is highlighted as an essential component of patient safety frameworks by several countries in their responses. These individuals or entities play a critical role in coordinating and driving patient safety initiatives. In some countries with resource constraints, assigning a patient safety focal point could be the entry point to establishing a broader institutional framework and patient safety programme.

Although most countries have reported the establishment or ongoing progress of national institutional frameworks dedicated to patient safety, there remains a significant gap at the subnational level.

*Countries are integrating patient safety with related domains (e.g. clinical governance and quality of care). Despite progress, significant gaps remain in implementing patient safety frameworks at the subnational level.*

## Hospital surveys on patient safety culture in Saudi Arabia

The Saudi Patient Safety Center (SPSC) is a governmental organization committed to ensuring safer health care at the national level in Saudi Arabia, and the first of its kind in the Eastern Mediterranean Region.

### What was done and why?

One of the key initiatives of SPSC is a hospital patient safety culture survey. The centre has used the results of the survey to support hospitals across the country in identifying areas of strength and weakness to facilitate targeted improvements in their safety culture. It has also enabled SPSC to identify recurring issues or themes to connect hospitals facing similar challenges.

### What were the outcomes and impact?

Through a series of workshops across the country, SPSC has been supporting hospitals to learn and derive ideas for improvement based on the results of the safety culture survey. The workshops focus on guiding hospitals to understand their own reports and to generate an action plan based on the findings. SPSC also offers ongoing review and coaching to hospitals in implementing their action plans, and hospitals are encouraged to contact SPSC with questions and feedback as they progress.

*'Prior to the workshops, the feedback was that hospitals did not know how to interpret the results. So, we taught them how to read their facility report, to understand their areas of weakness; and how to drill down and focus on their improvement efforts.'*

*(Representative from the Saudi Patient Safety Center)*

Building on this, SPSC is developing an online platform that links patient safety mentors with mentees to encourage further collaboration.

*'We're trying to create a collaborative learning community. It's helpful when hospitals talk to each other – they realize that problems exist across the system.'*

*(Representative from the Saudi Patient Safety Centre)*

In the survey responses, many leaders expressed the ambitions of fostering a fair and just culture among health workers. In response, SPSC has created a campaign aiming to support frontline personnel to feel comfortable in sharing and reporting safety concerns, while maintaining professional accountability.

### What's next?

Further work involves establishing and leading a committee that will be working with the Ministry of Justice and legal experts in identifying and amending laws and policies that hinder the realization of a fair and just culture.

The Saudi Patient Safety Center is developing initiatives for patients and families to give feedback on their perception of patient safety during their care, with the aim for hospitals to receive valuable patient feedback alongside their staff safety culture data.

*Source: For more information, see: Just culture [website]. Riyadh: Saudi Patient Safety Center; 2024 (https://www.spsc.gov.sa/English/HSPSC/JustCulture/Pages/default.aspx, accessed 30 April 2024).*