



# Global patient safety report 2024





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# Foreword



A handwritten signature in blue ink, which appears to read 'Tedros Adhanom Ghebreyesus'.

**Dr Tedros Adhanom Ghebreyesus**

WHO Director-General

Patient safety is one of the most ancient and fundamental principles of medicine, and an essential part of every country's journey towards universal health coverage, and the other health targets in the Sustainable Development Goals.

And yet, nearly one in ten patients is harmed in health care, translating into over three million deaths globally each year. More than half of this harm is preventable. This shocking statistic must serve as a call to action for systemic change.

The Global patient safety action plan 2021–2030, adopted by the World Health Assembly in 2021, is a testament to the collective resolve of WHO Member States to confront this challenge. The action plan aims to eliminate avoidable harm in health care and empower patients and their families to demand and receive safer care. Developed with the insight and dedication of safety experts, patient advocates and millions of health workers worldwide, the action plan is a blueprint for building more resilient health systems that are safe and adaptable in the face of emergencies.

In 2023, World Patient Safety Day emphasized the critical role of patients and families in shaping health care. From informed consent and shared decision-making at the point of care to their involvement in policy-making and governance, their voices are indispensable. However, this report shows nearly half of the countries surveyed have yet to take meaningful steps to involve patient representatives in health care governance.

This inaugural Global patient safety report sheds light on the commendable progress made by many countries, but also underscores the vast scope for further improvement. While patient safety has gained recognition in national health policies, translation into strategic action and tangible implementation solutions lags, due to resource constraints and inadequate execution of patient safety policies and programmes.

This report captures progress made and charts the course forward, offering a comprehensive strategy to promote patient safety through the systemic changes outlined in the global action plan. This kind of change doesn't just happen; it requires strong political commitment and concerted effort at national and local levels. I hope this report serves as a call to action to political leaders and policy-makers, health service providers, advocates and especially patients and their families to unite for safer care. Because if it's not safe, it's not care.

# Foreword



*Liam Donaldson*

**Sir Liam Donaldson**

WHO Director-General Special Envoy for Patient Safety

Almost 25 years have passed since two seminal reports captured public and professional attention on the little-recognised subject of unsafe care. In 1999, the Institute of Medicine in the United States published *To err is human* and, in parallel, in the United Kingdom in 2000, *An organisation with a memory* set out a way forward for the country's National Health Service.

Until then, the adverse effects of medical care were largely seen through the lens of medical negligence. When something went wrong, the first call would be to a lawyer. Instead, both reports implied that, in future, viewing the harmful outcome and the events that led to it through the lens of accident causation was more likely to save lives. In turn, although it would have seemed fanciful at the time, perhaps the first call should be to human factors experts, rather than lawyers.

Although this turn-of-the 21<sup>st</sup> century-thinking was recognising a new paradigm for avoidable harm in health care – a focus on systems and their vulnerabilities rather than individual error – it took time to unfold in health systems around the world.

An initiative, led and funded by the United Kingdom, formed the World Alliance for Patient Safety, a group of experts and leaders that forged a partnership with WHO to drive forward action on patient safety at global level. Crucially, the World Alliance reached out to, and fully engaged with, safety experts from other high-risk industries. An initial programme of work included: the first Global Patient Safety Challenge (*Clean care is safer care*), a patient safety research programme, and a programme led by patients and families who had suffered harm (the Patients for Patient Safety Programme).

After laying the foundations for an organised approach to preventing harm in health care, and providing a crucial initial period of innovative global leadership, the work of the World Alliance for Patient Safety was absorbed within WHO's management structure in the late 2000s. The World Alliance's work has stood the test of time with much of it being carried forward in the patient safety programmes that followed.

Certain key advances have marked the patient safety journey during the 21st century, including:

1. Greater awareness that the scale of avoidable harm from unsafe care ranks highly in global burden of disease terms.

2. Regular and widespread commitments by policy-makers, health leaders and professional bodies that patient safety should be a priority of health systems and in all places where health care is delivered.
3. A clear understanding of why and how care becomes unsafe, including the importance of systems thinking and the human factors perspective.
4. The establishment of patient safety incident reporting and learning systems in many places.
5. A recognition that patient and family engagement and involvement is essential to the planning, design and delivery of safe health care.
6. The growth, and greater funding, of research studies of patient safety.

While there has been advancement in each of these areas, it has been slow and very uneven. For example, while many health systems and health facilities have accorded a high priority to patient safety in their strategic and business plans, a smaller proportion have been able to integrate necessary actions to reduce risk and prevent harm within their day-to-day operations. Similarly, not all professional staff have made patient safety foundational to their practice. Moving patient safety from the territory of enthusiasts and academics to the mainstream has been a slow and faltering process. It is not there yet. It must remain a fundamental and transformational aim of patient safety programmes everywhere.

Moreover, whilst the experience of patients and families have been shaping actions to improve the safety of care at global, national and health facility levels, this is also patchy. There are still too many examples around the world of patients and their families not being listened to when they have valid concerns about the safety of care being provided. Victims of harm often have to fight to uncover the truth of what happened.

In some jurisdictions, the opportunity to learn from patient safety incident reports is being lost because of organisational cultures characterised by fear, blame and retribution for those who make errors.

The ground-breaking, first *Global patient safety action plan 2021–2030* was adopted by the 74<sup>th</sup> World Health Assembly in 2021. It took stock of the progress that has been made but noted the low impact on avoidable harm relative to the effort and money put into trying to reduce such harm, and keep patients safer. It set out seven core objectives with truly transformative potential and commended them to all WHO Member States, to every health system and to each and every health care facility and health service around the world.

Across all the dimensions of patient safety in the last quarter century, the greatest difficulty has been in achieving successful implementation of action to reduce harm to patients.

There is great diversity in the structure, funding and governance of health care around the world. There are also many different designs of health care systems and great variation in the way that health care facilities are led and managed. Settings where care is delivered are very diverse too.

The implementation of the *Global patient safety action plan 2021–2030* leaves room for flexibility of approach, taking account of existing organisational context and resource deployment options. It is essential, though, to ensure that there is absolutely no departure from the determination to deliver the core objectives and supporting actions of the plan.

This *Global patient safety report* aims to assess the early phase of delivery of the action called for in the *Global patient safety action plan 2021–2030*. It will serve as a baseline for judging future progress, and as a source of learning and improvement. It will be a stimulus and inspiration for the ultimate commitment that must be made to patients and families: showing them that health services around the world can protect them from harm on every step of their care journey, every time they make one.

# Foreword



A handwritten signature in blue ink, appearing to be 'B Aylward', with a horizontal line underneath.

**Dr Bruce Aylward**

Assistant Director-General  
Universal Health Coverage, Life Course  
World Health Organization

The importance of patient safety as a key component of all health care has been globally and increasingly recognised over the past decade with strong national and international commitments to advance the provision of safe care. Every year millions of people are harmed and suffer disability or death as a result of unsafe health care. People in low- and middle- income countries (LMICs) are disproportionately affected, with an estimated 134 million adverse events contributing to 2.6 million deaths each year in LMICs.

In the last five years, there have been significant developments in patient safety. Advocacy by diverse stakeholders and groups has culminated in the adoption of Resolution 72.6, 'Global action on patient safety', at the seventy-second World Health Assembly (2019). The decision of the seventy-fourth World Health Assembly to adopt the Global Patient Safety Action Plan 2021-2030 marked a new phase in implementing patient safety. As a result, Member States are increasingly recognising patient safety as a policy priority, and committing to work towards zero harm in health care.

However, there is still much work to be done, to ensure safe and high-quality care is a key component of building better systems to provide universal health coverage and ensure better health outcomes.

This landmark global patient safety report highlights both the work already done to implement the recommendations of the Plan and reduce harm, and the considerable distance that remains to ensure safe care for all. It serves as a starting point to track and report progress to 2030 against the seven strategic objectives of the Plan, as adopted by the World Health Assembly. WHO's new global patient safety reporting and monitoring system, to which 108 countries responded, forms the basis of this report and is essential to enable regular tracking of progress over time, to celebrate achievements and identify gaps, while providing a common foundation for national reports on patient safety.

Sustainable political commitment and investment is essential to advance the patient safety agenda. This report finds that while 55% of countries recognise patient safety as a key priority in their national health policy, safety incidents still cost health systems billions of dollars each year. Investments in safety are cost-effective and crucial in an era of significant demands on resources.

As part of investing in patient safety, ensuring the safety of health workers is crucial. The COVID-19 pandemic demonstrated how the health and well-being of health workers is inextricably connected to the safety of patients. We must do more to protect health workers. Importantly, this report finds that almost 70% of countries have established or are working towards establishing a national programme for occupational health and safety of health workers.

This report provides a benchmark for future improvements and aims to accelerate action on patient safety in all Member States. As implementation of the Global Patient Safety Action Plan advances, we must continue our endeavour to learn more, working with health workers, patients and families, and our partners, expanding research capacities, increasing improvement efforts, and embedding a safety culture in health systems. WHO remains fully committed to delivering the health-related Sustainable Development Goals and collaborating with all stakeholders to ensure that patients around the world receive safe and high-quality care.



# Preface



A handwritten signature in blue ink, reading 'Neelam Dhingra'.

**Dr Neelam Dhingra**

Unit Head

Patient Safety Flagship Unit  
World Health Organization

The paramount goal of modern medicine is to ensure that treatments benefit patients without causing harm. However, as we delve into the intricacies of health care systems worldwide, it is clear that achieving this ideal consistently is a significant challenge. The issue of patient harm casts a long shadow, presenting not merely as sporadic errors but also as pervasive problems requiring urgent and substantial change. As the field of medicine progresses, emphasizing patient safety and reducing preventable risks becomes essential to protect the health and well-being of those we serve.

Whenever we ask ‘How big is the problem?’, we find estimates based on studies mainly from high-income countries. The data from low- and middle-income countries are still scarce. It is reasonable to say that the actual burden of patient harm in health care is grossly underestimated or actually unquantifiable, because it cannot take into account the human suffering and devastation it causes in people’s lives. And the impacts of such harm – which is both unnecessary and easily preventable – are disproportionately severe compared to the original error or unsafe practice. As a medical student, I can recall incidents of harm that were regarded as normal consequences of treatment, such as a patient having jaundice after blood transfusion. Back then, harm in health care was normalized.

In the interim, there have been years of extensive efforts to improve patient safety globally, spearheaded by the strategic and visionary leadership of global patient safety champions, influencers and political leaders. The global momentum created by the annual ministerial summits on patient safety since 2016 led to a landmark World Health Assembly resolution in 2019: ‘Global action on patient safety’ identified patient safety as a global health priority and established World Patient Safety Day. In response to this global call, WHO established a flagship initiative entitled A Decade of Patient Safety 2020–2030 to support strategic actions in patient safety at the global, regional and national levels. The WHO flagship initiative cuts across different areas of work within the organization, focusing on linkages between patient safety and health care safety components in the various health systems elements, and linkages with disease-specific and clinical programmes, which have direct impact on patient safety and health outcomes at the point of care.

Given the complex challenges that health care systems face globally, two key questions arise: “Can we eliminate avoidable harm in health care?” and, if so, “How do we achieve it?” We need to put in place systems, protocols and procedures to reduce the risks of harm and, if harm occurs, reduce its impact.

Effective action for improved patient safety relies on enhanced trust in health services, better patient experience and improved health outcomes. Only strong leadership, commitment for sustained efforts, and concerted actions at global, national, subnational, institutional and community levels can bring the global vision of patient safety to reality.

As we move ahead, it is imperative that we keep patient safety at the forefront of health care policies and practices. This isn't just a professional obligation, it is a moral imperative to uphold the trust placed in us by those who seek our care. The discourse surrounding patient safety is not merely a technical area – it is a narrative of human lives, of real suffering, and the indomitable spirit of survival. It is incumbent upon each one of us, from practitioners to policy-makers, to ensure that this narrative bends towards safety, healing and hope.

This *Global patient safety report 2024* is an important first step to demonstrate incremental improvements in patient safety over a decade. I truly believe that the key messages emerging from this report will provide a huge impetus for countries and stakeholders to prioritize action and pave a way for transformative changes in the safety of health care.

# Preface



**Dr Rudi Eggers**

Director

Integrated Health Services Department  
World Health Organization

The World Health Organization presents this inaugural Global patient safety report as a key output of the Integrated Health Services Department. Since its inception, catalysed by the World Alliance for Patient Safety in the early 2000s, our department has been dedicated to enhancing the safety and quality of health care worldwide. This report encapsulates our journey and accomplishments and charts a path forward for integrating quality of care and patient safety into the broader context of health system strengthening.

Patient safety is an integral and key part of delivering quality health services at the point of care. It cuts across technical areas and various health system themes to assure integration, with touch points in service delivery, health workforce, governance, and health informatics.

This report reflects collective and continuous efforts to weave patient safety and quality of care into the fabric of health care delivery. It touches on the safety of traditional and complementary medicines, hospital physical safety, and the pivotal role of health service assessment and information systems in enhancing patient safety.

Collaboration has been a cornerstone of our shared success to date. Mirroring this joint commitment, the report has been enriched by contributions from various technical departments and units across WHO, illustrating the power of collective expertise and shared goals. However, there remains an urgent need to accelerate efforts to prioritize patient safety at the national level. Currently, only a fraction of countries has fully integrated patient safety into their health systems, indicating that, for many, it remains a work in progress.

As we present this report, we hope it will serve as a crucial reference point and inspire all stakeholders involved in health care to champion the cause of making health care safer and more resilient. The challenges are significant, yet the opportunities for improvement and innovation are vast.

Together, we continue to strive for a world where patient safety is not optional, but a guarantee of quality health services.

# Acknowledgements

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### **Burden of harm in health care**

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# Abbreviations

ADE	adverse drug event
ADR	adverse drug reaction
AEFI	adverse events following immunization
AI	artificial intelligence
AMR	antimicrobial resistance
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease-19
DALY	disability-adjusted life year
ECDC	European Centre for Disease Prevention and Control
ED	emergency department
EEA	European Economic Area
EHR	electronic health record
EU	European Union
FIP	International Pharmaceutical Federation
GDP	gross domestic product
GPSC	Global Patient Safety Collaborative
GPSN	Global Patient Safety Network
GWP	gross world product
HCAI	health care-associated infection
HIC	high-income country
HIS	health information system
HIV	human immunodeficiency virus
HSSIB	Health Services Safety Investigations Body
HTA	health technology assessment
IAPO	International Alliance of Patients' Organizations
ICM	International Council of Midwives
ICN	International Council of Nurses
ICPS	International Classification for Patient Safety
ICU	intensive care unit
IEA	International Ergonomics Association
IHF	International Hospital Federation
ILO	International Labour Organization
IPC	infection prevention and control



IPSQ	Institute for Patient Safety and Quality
ISQua	International Society for Quality in Health Care
ISTH	International Society on Thrombosis and Haemostasis
IT	information technology
IUPHAR	International Union of Basic and Clinical Pharmacology
IVD	in vitro diagnostics
JHH	Johns Hopkins Hospital
LIC	low-income country
LMC	lower middle-income country
LMIC	low- and middle-income country
MoU	memorandum of understanding
NHS	National Health Service
NPSIF	national patient safety implementation framework
NQPS	national quality policy and strategy
NSA	non-state actor
NUS	National University of Singapore
OECD	Organisation for Economic Co-operation and Development
PIDM	Programme for International Drug Monitoring
PFPS	Patients for Patient Safety
PREM	patient-reported experience measure
PROM	patient-reported outcome measure
PSIRLS	patient safety incident reporting and learning system
PV	pharmacovigilance
QALY	quality-adjusted life year
ROI	return on investment
SARS	severe acute respiratory syndrome
SDGs	Sustainable Development Goals
SDI	socio-demographic index
SOP	standard operating procedure
TCM	traditional and complementary medicine
THB	Thai Baht
TB	tuberculosis
UHC	universal health coverage
UMC	upper middle-income country
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VTE	venous thromboembolism
WFME	World Federation for Medical Education
WHO	World Health Organization
WMA	World Medical Association
WONCA	World Organization of Family Doctors
WPSD	World Patient Safety Day
WSFA	World Federation of Societies of Anaesthesiologists
WTP	willingness to pay

# Glossary of terms

Term	Definition
accreditation	A formal process by which a recognized body, usually a non-governmental organization, assesses and recognizes that a health care organization meets applicable pre- and published standards. Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. An accreditation decision about a specific health care organization is made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years. Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation (1).
adverse drug event (ADE)	Any injury resulting from medical interventions related to a drug. This includes both adverse drug reactions in which no error occurred and complications resulting from medication errors (2).
adverse drug reaction (ADR)	An adverse drug reaction is a response to a medicinal product that is noxious and unintended and which occurs at doses normally used in adults/children for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function (3).
adverse event	An incident that resulted in harm to a patient (4).
adverse events following immunization (AEFI)	Any untoward medical occurrence that follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease (5).
competencies	The minimum set of competencies that constitute a common baseline for all health promotion roles (i.e. what all health promotion practitioners are expected to be capable of doing to work efficiently, effectively and appropriately in the field (6).
digital health	The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data and robotics (7).

Term	Definition
disability-adjusted life years (DALYs)	One DALY represents the loss of the equivalent of one year of full health. DALYs for a disease or health condition are the sum of the years of life lost due to premature mortality (YLLs) and the years lived with a disability (YLDs) due to prevalent cases of the disease or health condition in a population (8).
electronic health records	Real-time, patient-centred records that provide immediate and secure information to authorized users. These typically contain a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results. A national electronic health records system is most-often implemented under the responsibility of the national health authority and will typically make a patient's medical history available to health professionals in health care institutions and provide linkages to related services such as pharmacies, laboratories, specialists, and emergency and medical imaging facilities (9).
haemovigilance	Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence (10).
health care-associated infections (HCAIs)	An infection occurring in a patient during the process of care in a hospital or other health care facility, which was not present or incubating at the time of admission. Health care-associated infections can also appear after discharge (11).
health literacy	This represents the personal knowledge and competencies that accumulate through daily activities and social interactions and across generations. Personal knowledge and competencies are mediated by the organizational structures and availability of resources that enable people to access, understand, appraise and use information and services in ways that promote and maintain good health and well-being for themselves and those around them (12).
health worker	Health workers are all people engaged in work actions whose primary intent is to improve health, including doctors, nurses, pharmacists, midwives, public health professionals, laboratory, health and medical and non-medical technicians, community health workers, and healers and practitioners of traditional medicine. It also includes health management and support workers, such as hospital administrators, district health managers and social workers, cleaners, drivers, and other occupational groups in health-related activities (13).
human factors	Study of the interrelationships between humans, the tools, equipment and methods they use, and the environments in which they live and work (4).
in-service training	Training received while one is fully employed in the health sector. The aim is to equip health workers or the trainers of health workers with the skills to deliver specific interventions (6).
interprofessional education	Faculty and students from two or more health professions engaged in learning with, from, and about each other in all components of curricula including the practical ones, to enable effective collaboration and improve health outcomes (6).
just culture	An environment that seeks to balance the need to learn from mistakes and the need to take disciplinary action (4).

Term	Definition
licencing	A government-endorsed regulatory process to grant permission and specify scope for the health care practice of an individual or organization, usually preceding accreditation (14).
medical device	An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means (15).
medication error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use (16).
medication-related harm	The harm caused by medication if taken incorrectly, monitored insufficiently or as the result of an error, accident or communication problem (17).
'never' event	A patient safety incident that results in serious patient harm or death (this refers to particularly shocking medical errors - such as wrong-site surgery, that should never occur) (18).
palliative care	Palliative care is an approach that improves the quality of life of patients (adults and children) and their families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through the early identification, correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual (19).
patient engagement	The facilitation and strengthening of the role of those using services as co-producers of health, and health care policy and practice (20).
patient safety	Patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur (18).
pharmacovigilance	Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems (21).
polypharmacy	Polypharmacy is the concurrent use of multiple medications. Although there is no standard definition, polypharmacy is often defined as the routine use of five or more medications. This includes over-the-counter, prescription and/or traditional and complementary medicines used by a patient (3).
preventable harm	Accepted by the community as avoidable in the particular set of circumstances (4).
primary care	A key process in the health system that supports first-contact, accessible, continued, comprehensive and coordinated patient-focused care (15).
resilience	Ability of all actors and functions related to health, to collectively mitigate, prepare, respond and recover from disruptive events with public health implications, while maintaining the provision of essential functions and services, and using experiences to adapt and transform the system for improvement (22).

Term	Definition
sentinel event	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome (18).
sepsis	Life-threatening organ dysfunction caused by a dysregulated host response to infection (23).
severe harm	Patient outcome is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function. Severe harm results in permanent disability (4).
transitions of care	The various points where a patient moves to, or returns from, a particular physical location or makes contact with a health care professional for the purposes of receiving health care (24).
universal health coverage (UHC)	Ensured access for all people to needed promotive, preventive, resuscitative, curative, rehabilitative, and palliative health services, of sufficient quality to be effective, while also ensuring that the use of these services does not expose any users to financial hardship (15).



Therapist assisting patient with balance exercises in a hospital in Russia. © WHO / Noor / Sebastian Liste

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# 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)

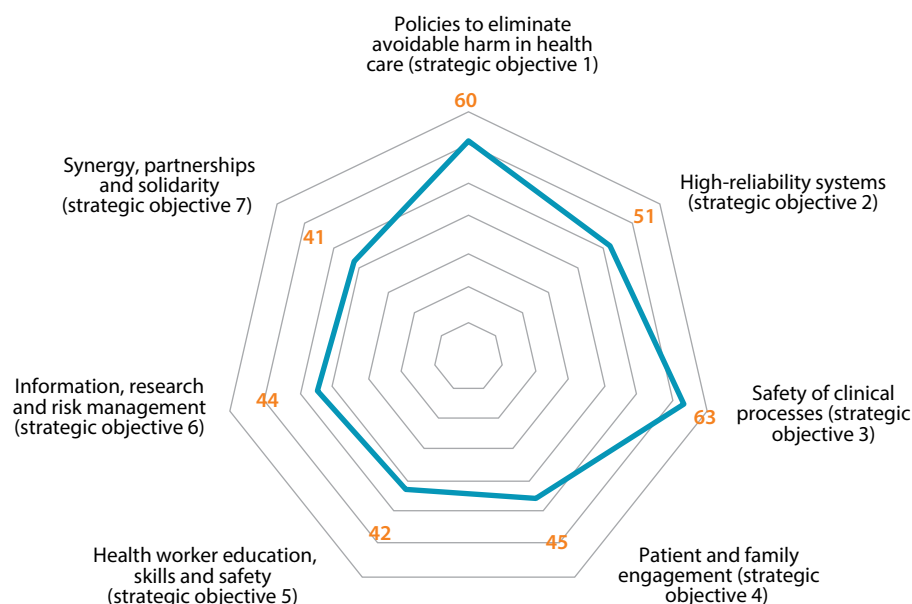
- Although patient safety incident reporting and learning systems have been introduced in 70% of countries, their effectiveness remains limited, and only in one third of countries do the majority of health care facilities actively report safety incidents to these systems.
- Interoperability and international 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<sup>1</sup>



<sup>1</sup> These percentages refer only to the 108 countries that completed the survey.

**Pedds Ward**



*Portrait of a nutritionist at a hospital in Kenya. @ WHO / Billy Miaron*

# Introduction





*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 76<sup>th</sup> 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.

## 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.

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*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.*

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



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*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.

*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.

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*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.*

*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

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*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.*

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*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.*

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*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.*

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

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*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.*

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'.

## 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

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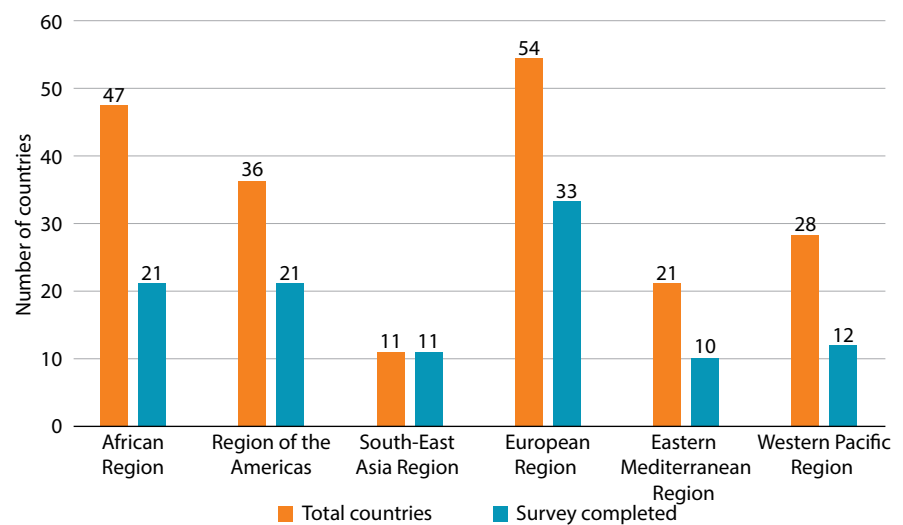
*The survey tool facilitates analysis across WHO regions and income groups but is not intended for country comparisons due to the unique challenges faced by every nation.*

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*The survey invited all 194 WHO Member States and three associate members to participate. Ultimately, 108 responses were completed and submitted.*

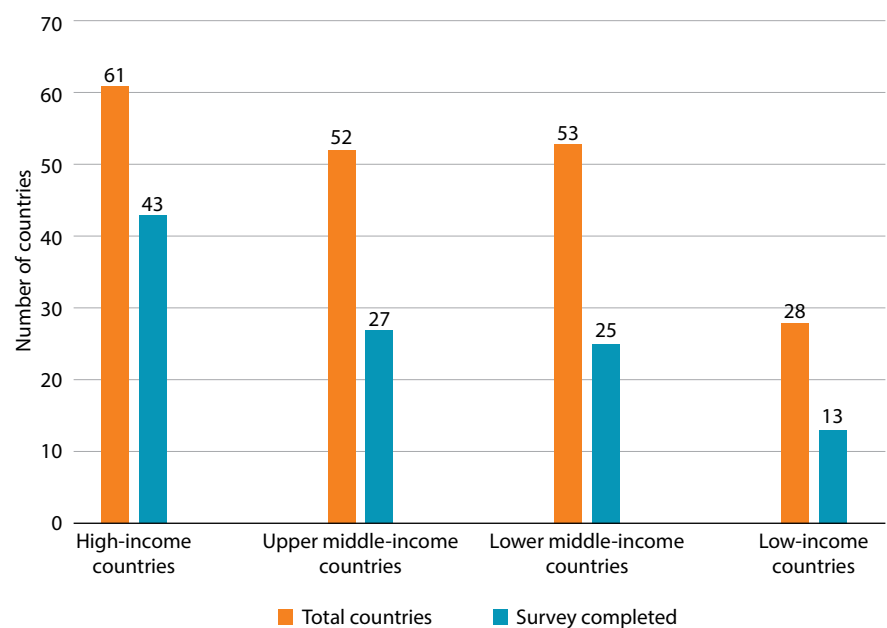
all six WHO regions took part in the survey, although response rates varied by region (Fig. 1). This variance in participation levels, offers valuable insights into the global engagement and commitment to the principles and practice of patient safety.

**Fig. 1.**  
Number of countries that responded the Member State survey, by WHO region



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).

**Fig. 2.**  
Number of countries that responded to the Member State survey, by World Bank income country classification 2022–2023



*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

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*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.*

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

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*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

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*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

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*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  $\geq 65$  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,<sup>2</sup> and from 0.3% to 33.7% among general populations using the Harvard medical practice study methodology (16).<sup>3</sup> 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

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

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*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.*

<sup>2</sup> 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.ihl.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx> (accessed 16 April 2024).

<sup>3</sup> 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).

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*Addressing gender disparities in health care is necessary, as women consistently experience higher levels of patient harm compared to men.*

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,<sup>4</sup> 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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*Addressing racial and ethnic disparities in health care is critical, as minority groups face increased risks of patient harm, including higher rates of infections, complications and adverse events.*

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<sup>4</sup> VigiBase is maintained for WHO by the Uppsala Monitoring Centre (Uppsala, Sweden).  
See: <https://who-umc.org/vigibase/> (accessed 16 April 2024).

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 multimorbidities, 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).

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*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).

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*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

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*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).

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*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 – 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 heterogeneous 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 HCAs (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

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*Patients with psychiatric diagnoses face nearly double the risk of preventable harm compared to others.*

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*Radiotherapy errors, affecting 1500 per million treatment courses, often occur in the planning and treatment phases, with concerns about dose calculation and regulation.*



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*Telemedicine, while expanding access to care, presents unique patient safety concerns including diagnostic errors, medication safety gaps, and increased in-person follow-ups, with inconsistent data on its potential harms.*

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).

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*Patient harm in obstetrics services affects 2% to 4% of cases, with about half being preventable.*

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).

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*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.*

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

## 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 HCAs (12%) (64).

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*Medication errors are the leading source of patient harm, with 5% of patients globally affected.*

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*Most preventable medication-related harm occurs during the prescribing stage especially in LMICs.*

**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 HCAs, 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 HCAs 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 HCAs 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).

HCAs 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 HCAs, 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 HCAs are those of the respiratory tract, surgical sites, urinary tract, bloodstream and gastrointestinal tract. There are numerous factors that heighten the risk for developing HCAs, 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 HCAs, with hand hygiene and other standard precautions and transmission-based precautions being among the most important ones. (82,83).

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*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.*

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

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*VTE is a common and preventable cause of patient harm, with an annual incidence of up to 12 people per 10 000. It is the leading source of lost DALYs.*

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.

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*Patient falls and pressure ulcers are common and preventable adverse events in hospitals, with falls occurring at a rate of 3 to 5 per 1000 bed-days and pressure ulcers affecting over 10% of adult hospital patients.*

**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

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*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.*

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*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.*

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*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.

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*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.

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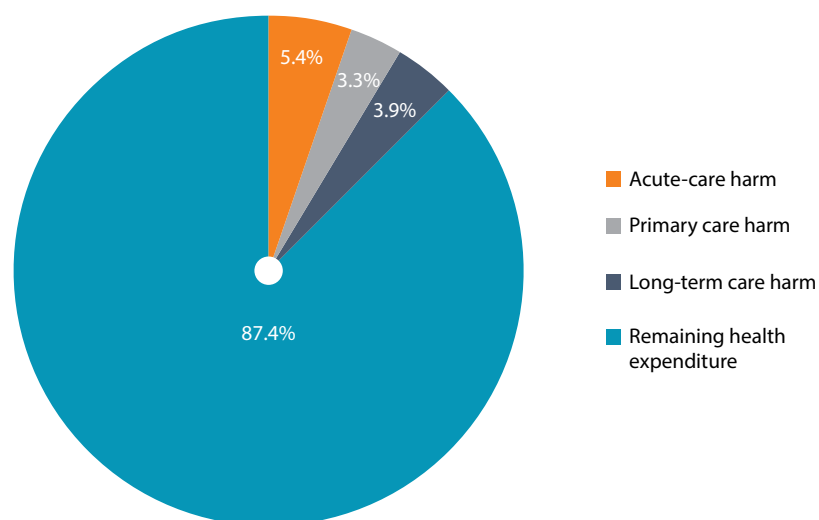
*In selected HICs 12.6% of health expenditure, amounting to \$878 billion annually, is spent on managing the consequences of patient harm.*

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.<sup>5</sup> 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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<sup>5</sup> 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).<sup>6,7</sup> 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).



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

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

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 HCAs, 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 HCAs 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.*

<sup>6</sup> This figure includes all health care harm.

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

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*HCAIs significantly increase patient length of stay and treatment costs globally. Managing sepsis consumes 2.7% of health care budgets worldwide, while hospital-acquired VTEs and surgical complications contribute substantially to health care expenses.*

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*In primary and ambulatory care settings, patient harm from adverse drug events, misdiagnoses, and delayed treatments results in significant costs, including emergency visits and hospital admissions.*

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,<sup>8</sup> 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).<sup>9</sup>

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<sup>8</sup> Asthma, chronic obstructive pulmonary disease, heart failure, diabetes and hypertension.

<sup>9</sup> 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.

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

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

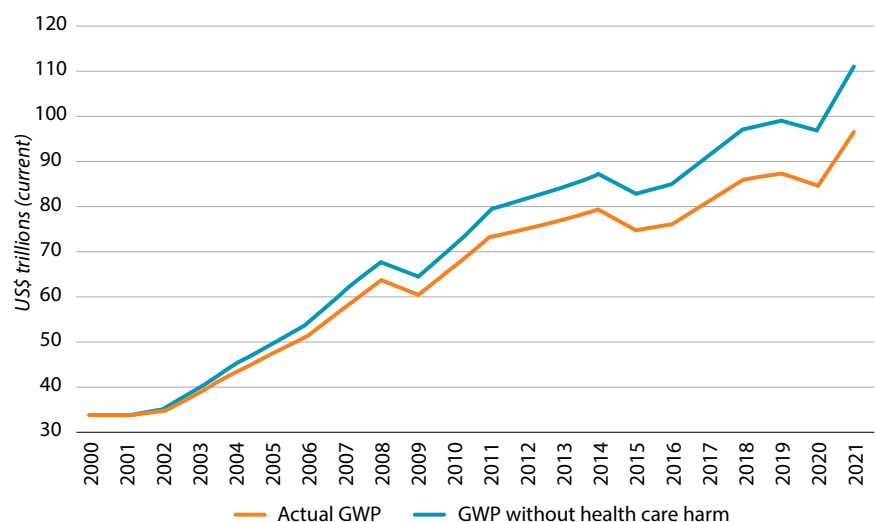
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*Disadvantaged populations are disproportionately affected by the indirect costs of patient harm, exacerbating income inequalities and poverty.*

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)<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup>

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.

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

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*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.*

<sup>10</sup> According to: [www.worldbank.org/en/home](http://www.worldbank.org/en/home).

<sup>11</sup> Using 2021 World Bank estimates of gross world product.

<sup>12</sup> 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

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*Investing in patient safety interventions, particularly those targeting high-cost and harmful events – such as HCAs, 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 HCAs 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).

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*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).



Strategic  
objective

1

# 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.



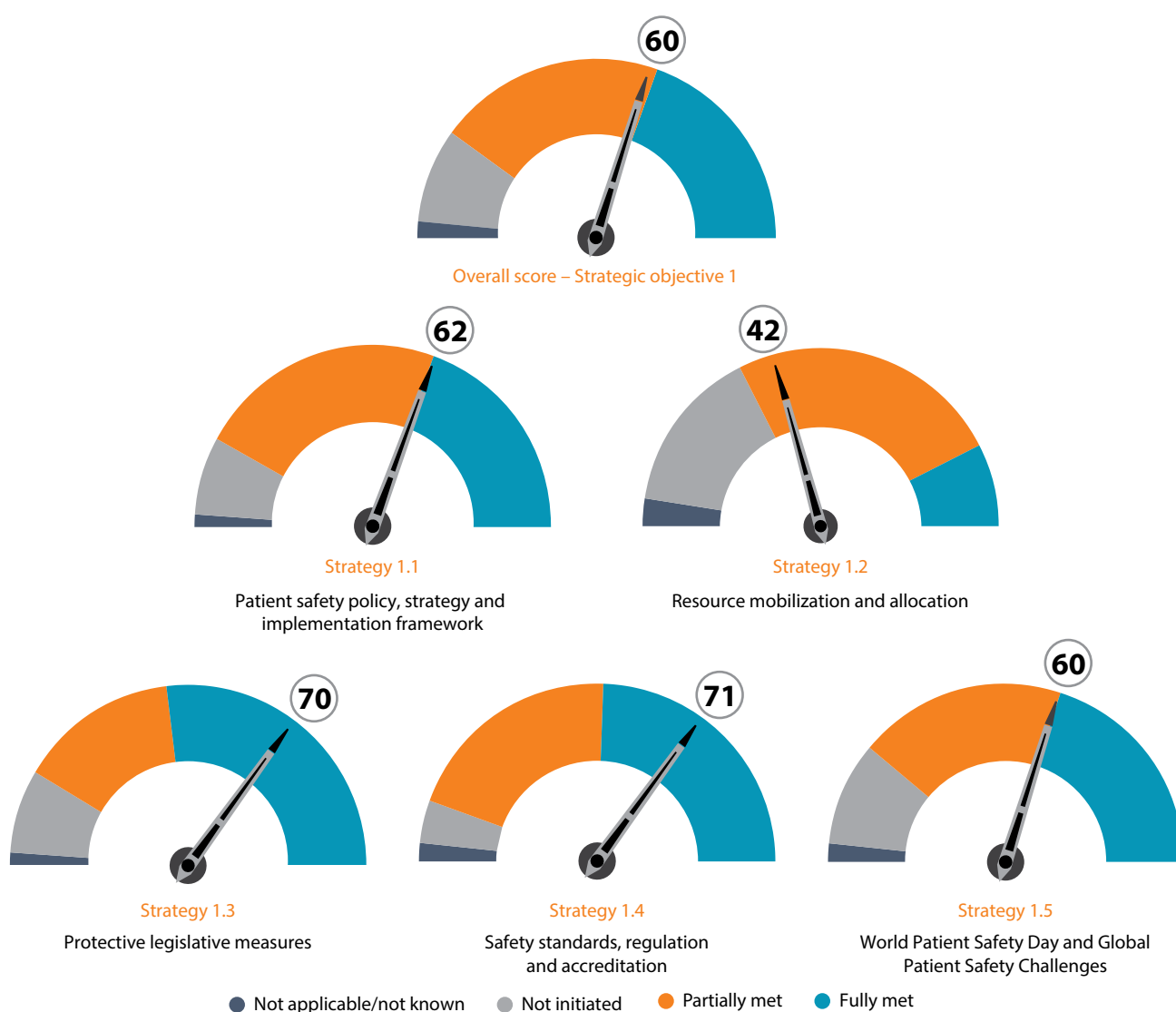
The WHO Global Patient Safety Challenges address critical risks to patient health and safety. Countries have taken actions on these initiatives, with almost 90% of countries addressing at least one of the challenges and one third of the countries implementing all the three challenges.

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.

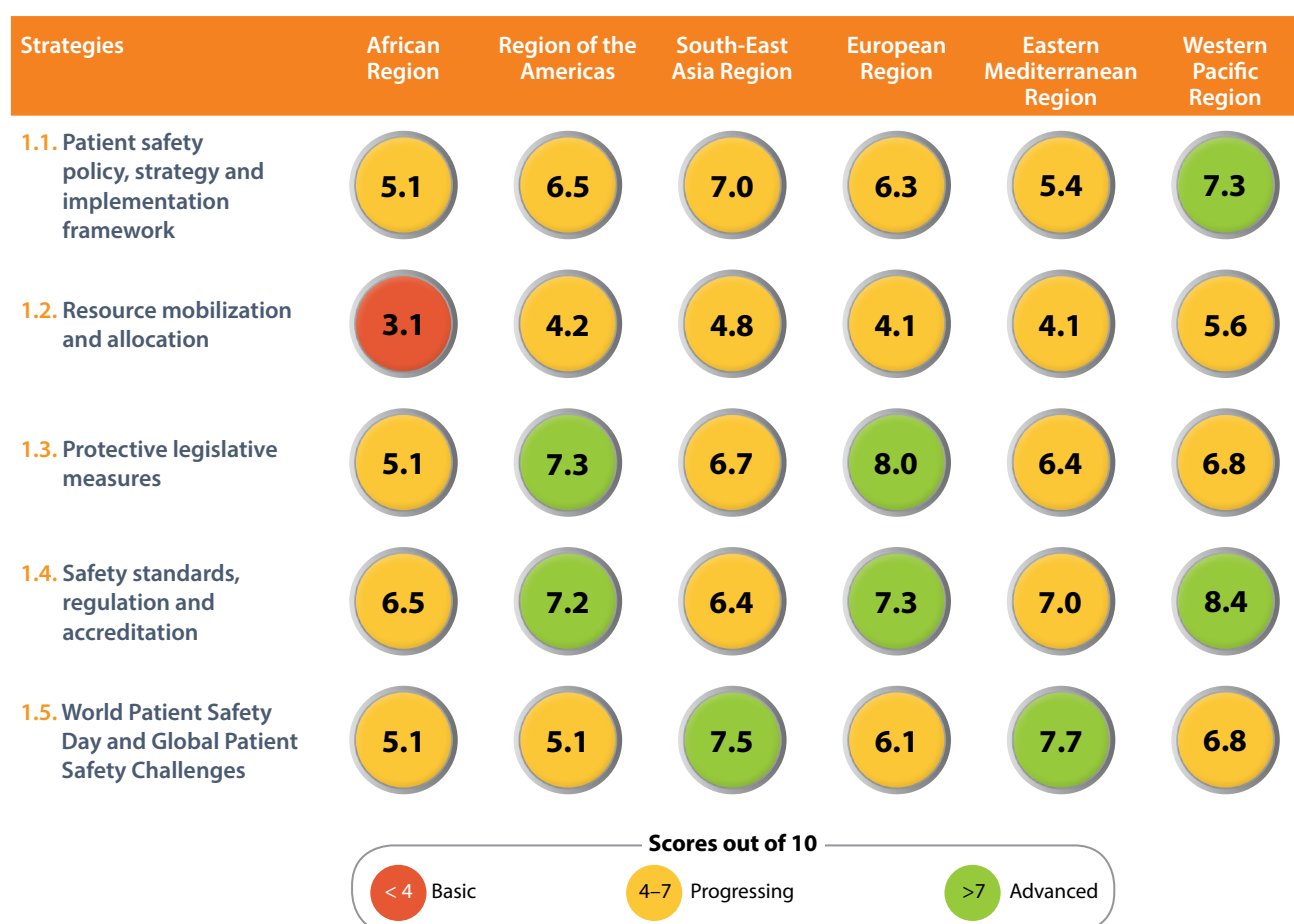
While there is a clear acknowledgement of the importance of patient safety within national health policies, actual implementation and strategic action are lacking. Over half of the respondents have recognized patient safety in their health policies, yet fewer have worked on operational aspects such as 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



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.

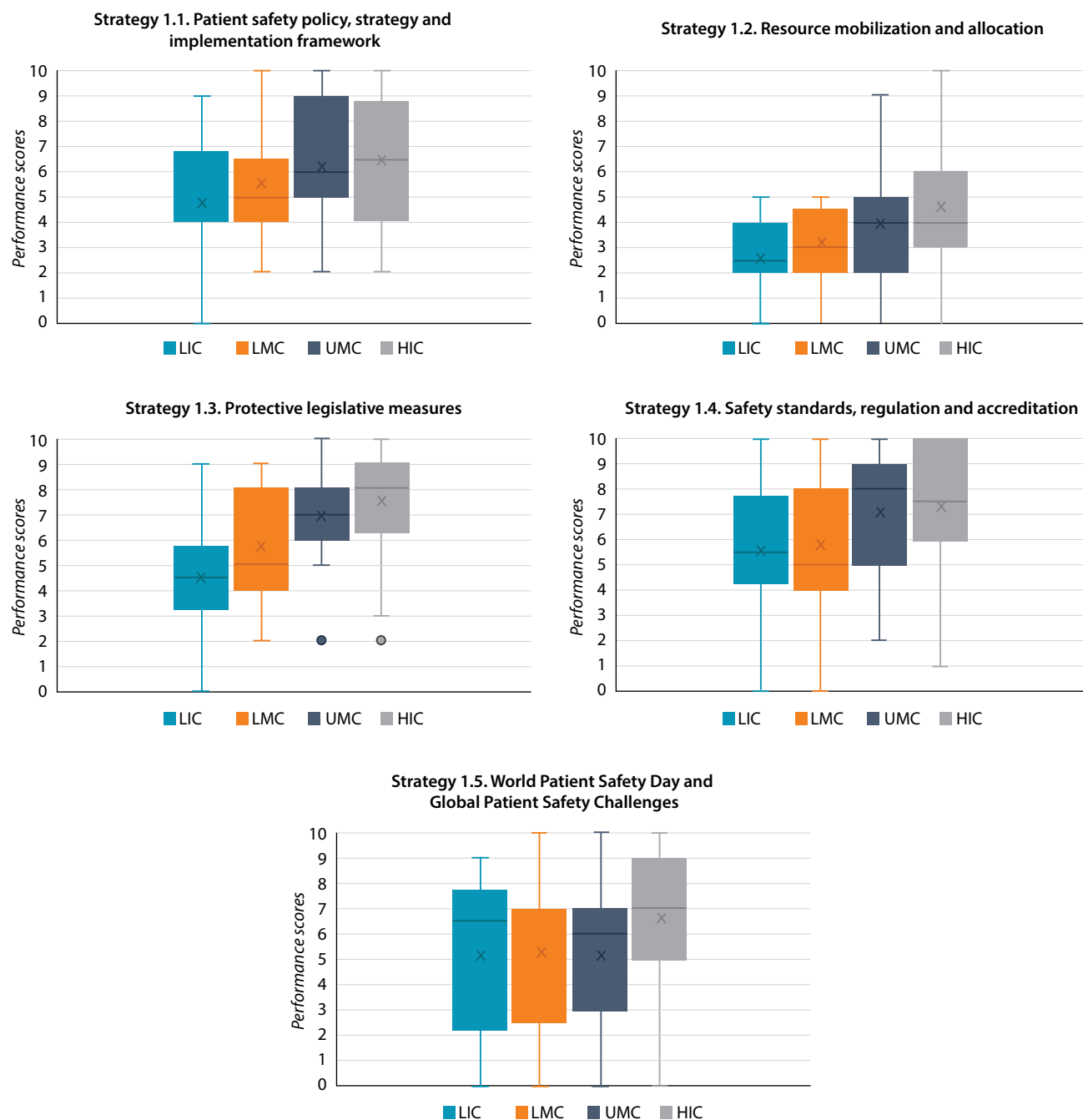
► Fig. 1.2. Distribution of strategic objective 1 performance scores across the five strategies, by WHO region



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**



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

	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 1.1.

# 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

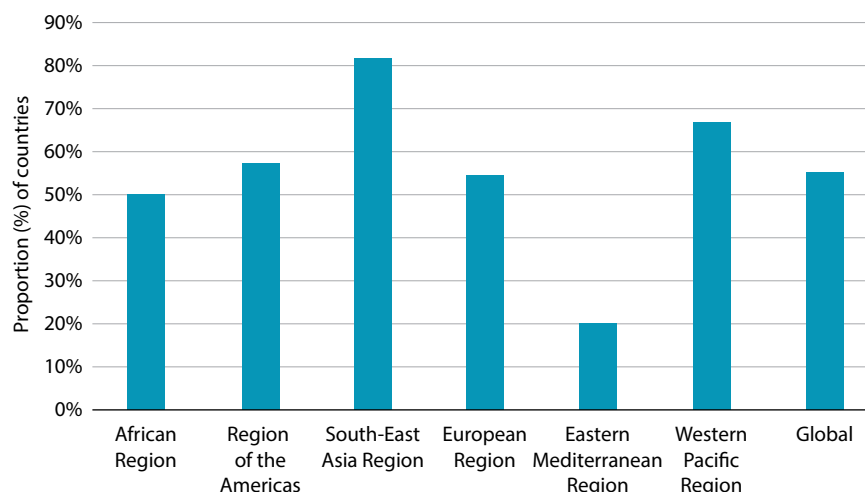
To deliver safe care, countries and regions have to deal with unique challenges that demand tailored national policies and strategies for reducing patient harms. Patient safety should be a core component of national health policies, programmes and health system strengthening initiatives. The extent to 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.*

**Fig. 1.4.**  
**Proportion of countries**  
**reporting patient safety as a key**  
**priority in the national health**  
**policy, by WHO region**



## 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 whistleblowers 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).

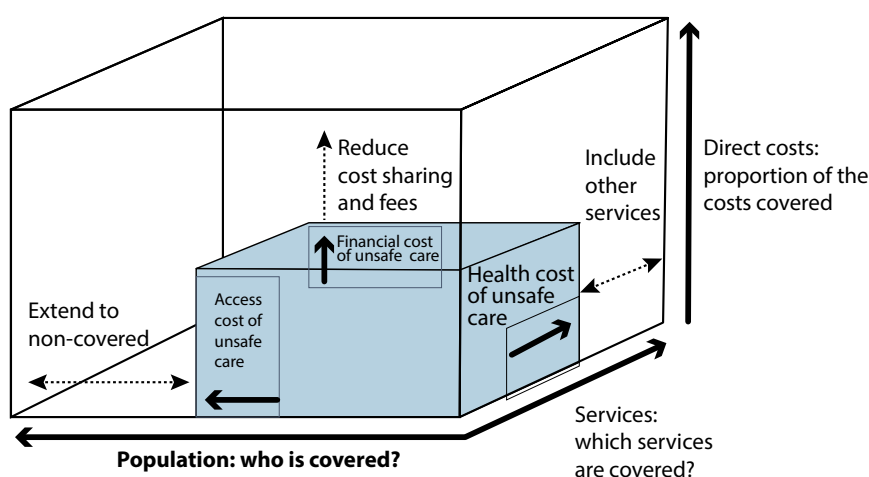
**Myanmar** has been prioritizing patient safety for years and in 2018 the country did a patient safety baseline assessment.

*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.*

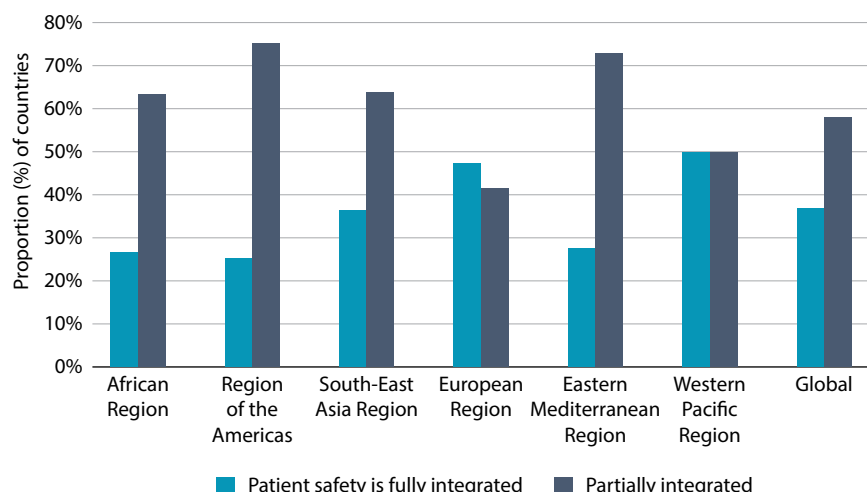
**Fig. 1.5.**  
**Model of the contribution of patient safety to universal health coverage**

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.*

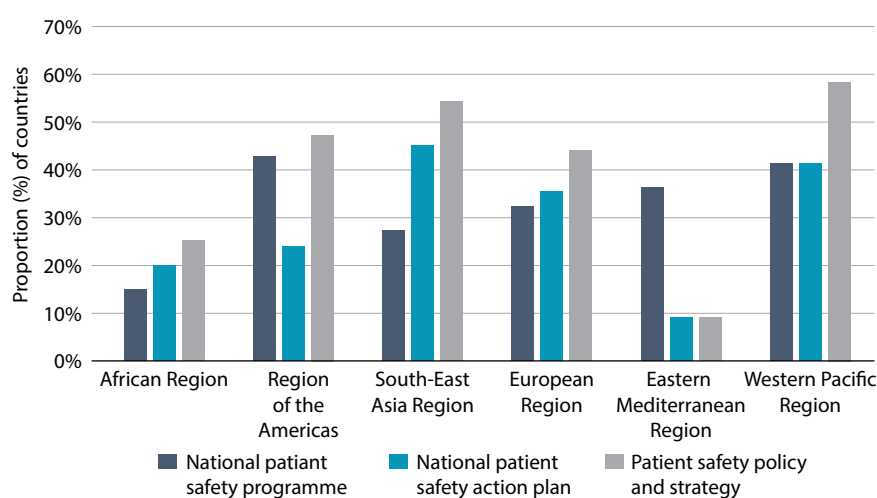
A national patient safety policy is a formal government statement that defines priorities and parameters for action, as well as available resources and political considerations. It is developed in close consultation with stakeholders, including patients, families and communities, to ensure that patient 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

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*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, HCAs, 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).

**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).

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

**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*

## Feature story 1

### 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, HCAs, 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<sup>a</sup> 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,<sup>b</sup> Vision 2030,<sup>c</sup> the Kenya health policy (2014–2030),<sup>d</sup> and the global commitments as envisioned in the Global patient safety action plan 2021–2030.<sup>e</sup>

## 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)<sup>f</sup> 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<sup>g</sup> 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:

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- <sup>d</sup> 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](https://repository.kippra.or.ke/bitstream/handle/123456789/4681/kenya_health_policy_2014_to_2030.pdf?sequence=1&isAllowed=y), accessed 29 April 2024).
- <sup>e</sup> 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>
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- <sup>g</sup> 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](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](https://nhsrcindia.org/sites/default/files/2021-08/National%20Patient%20Safety%20Implementation%20Framework_0.pdf)

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 1.2.

Resource mobilization and allocation



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

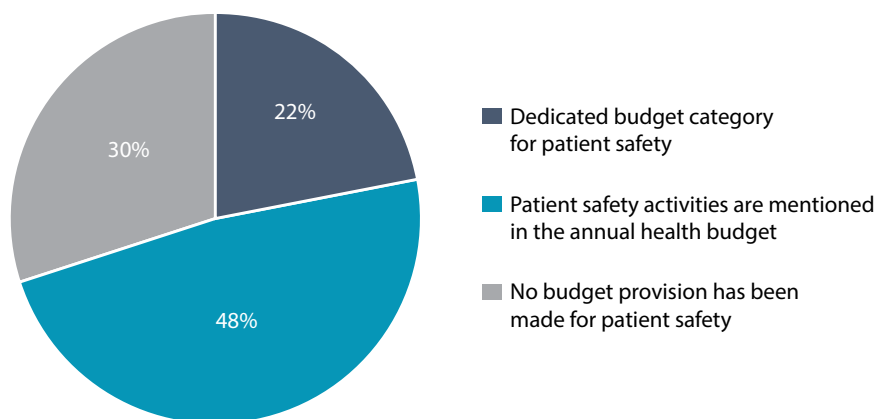
Patient safety is a vital component of health care systems and requires dedicated and sustained investment from all stakeholders. The allocation of sufficient human and financial resources is a key indicator of national commitment to patient safety. Furthermore, integration of such resources into the 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).





**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

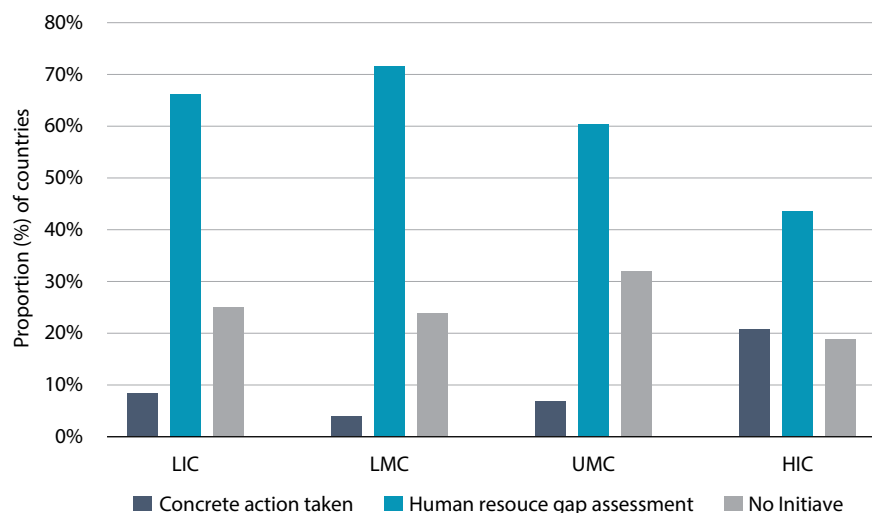
To achieve their intended outcomes, patient safety interventions require sufficient human resources and technical personnel to be implemented effectively. Moreover, a lack of human resources or understaffing can increase the risk of all types of patient safety incidents at the point of care.

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.*



**Fig. 1.9.**  
Proportion of countries taking  
initiatives to close the human  
resource gap for patient safety,  
by income group



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

*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*

## Recognition and reward mechanisms

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*

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 1.3. 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.*

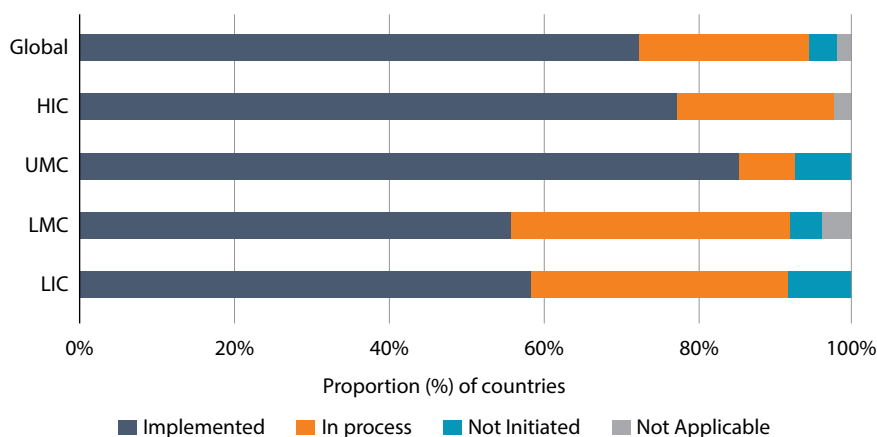
To guarantee the safe delivery of health services and products, it is imperative for every country to establish and enforce optimal legal and regulatory requirements. This is crucial not just for the providers of these services and products, but also for maintaining public trust in the health care system. 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 licensing, by income group

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

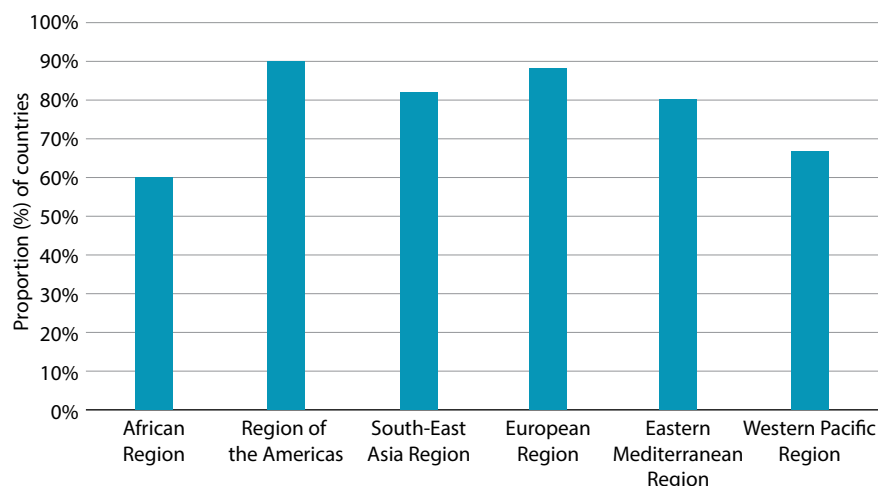
The survey data also suggest a possible association between a country's income classification and the emphasis on mandatory licensing for health care facilities and services. The highest proportions were seen among UMCs, suggesting that as countries progress economically, there might be a stronger drive 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



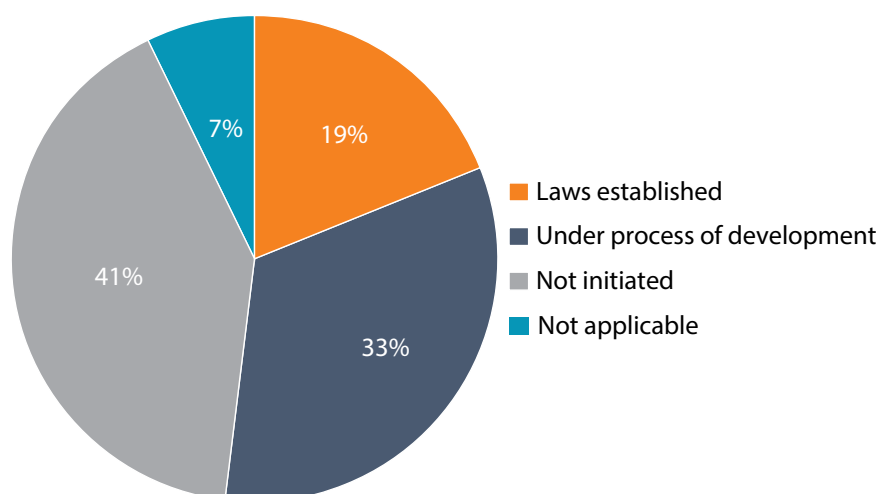
## Legal protection against reporting of patient safety incidents

*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



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.

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*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

**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.

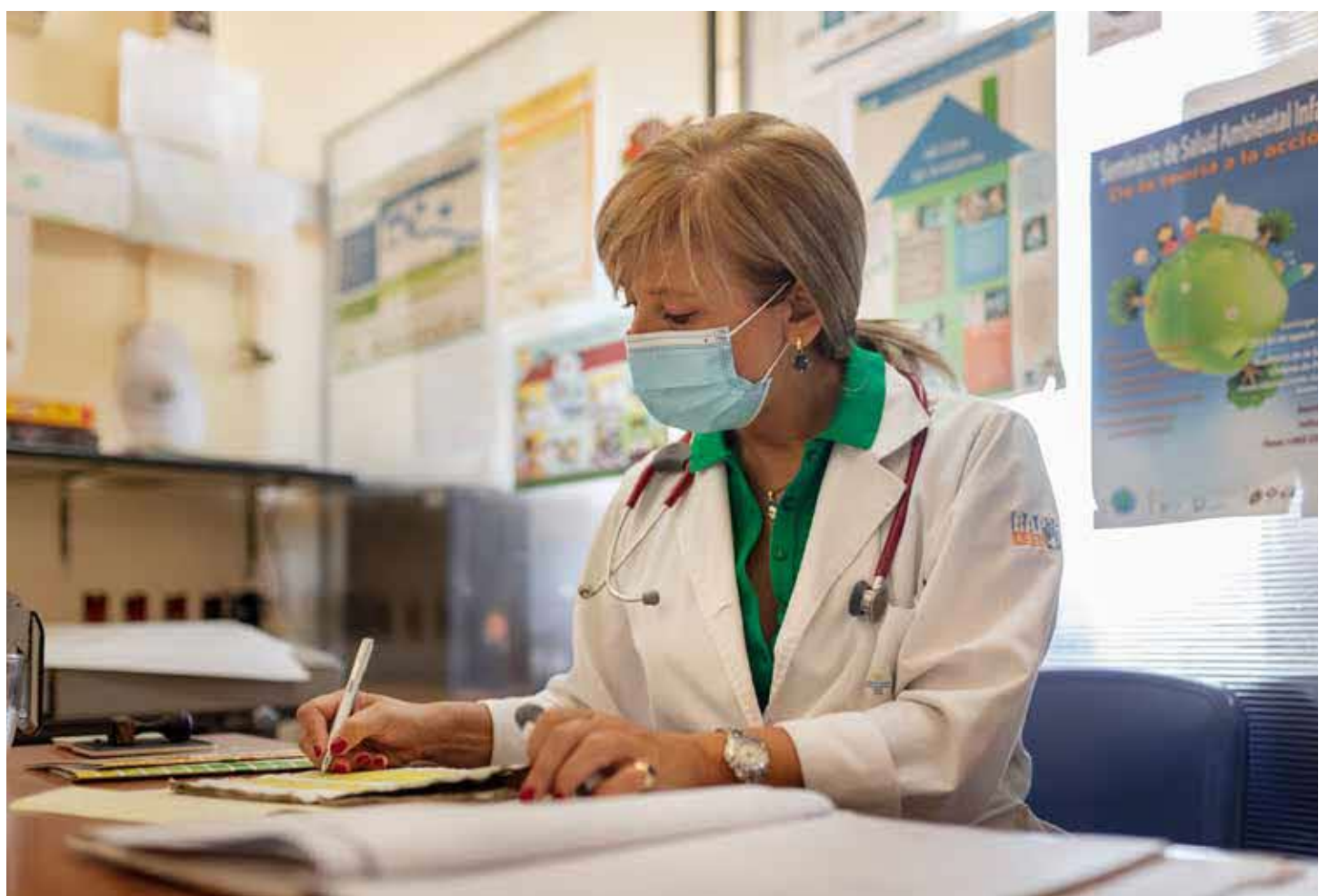
**Burkina Faso.** Protects the privacy and patient information by enforcing code of ethics and code of public health.

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

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*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.*

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<sup>a</sup> 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:

<sup>a</sup> 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).

## 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 1.4.

## 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.

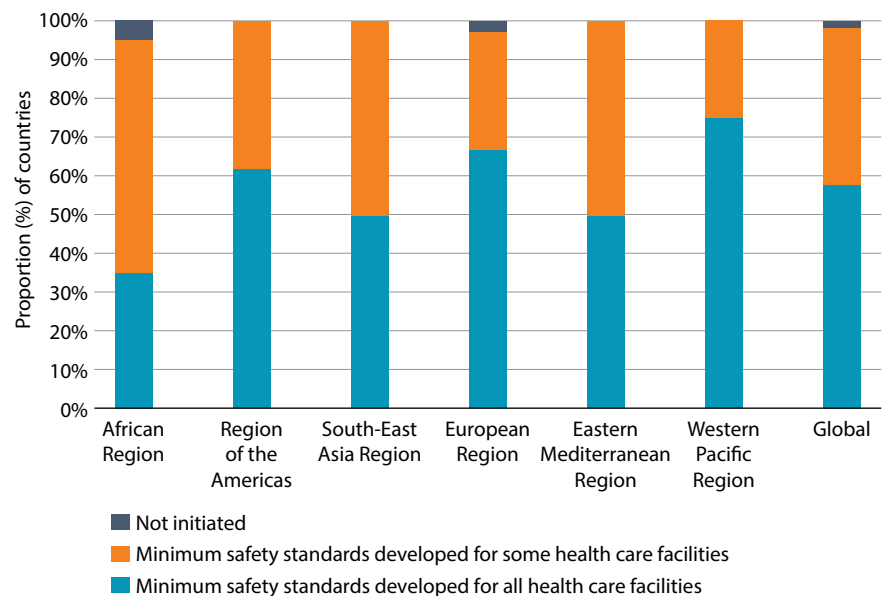
Responses to the Member State survey suggest a significant global trend towards defining safety standards in health care facilities. However, it also indicates areas or regions where more work is needed to ensure comprehensive safety standards across all types of settings.

*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



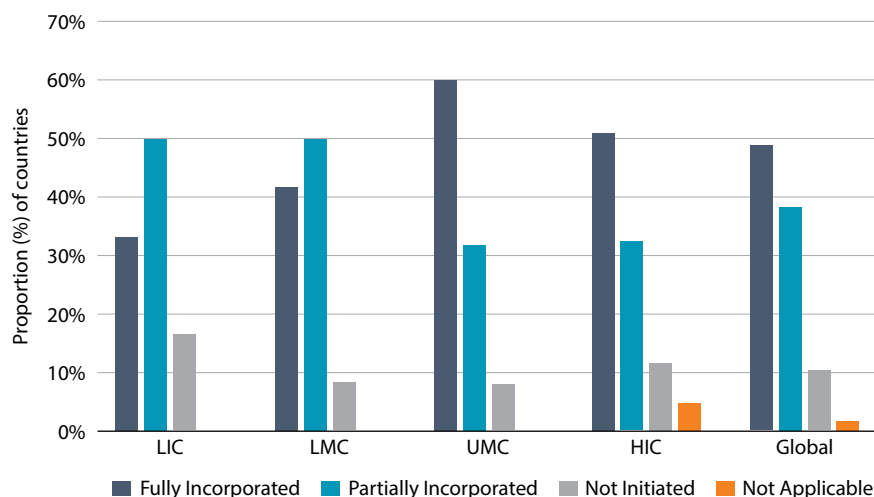
## Safety standards in health care licensing

*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*

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.



**Fig. 1.14.**  
Proportion of countries that have incorporated safety standards in licencing criteria for health care facilities

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 specialties 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 used for patient safety assessment.

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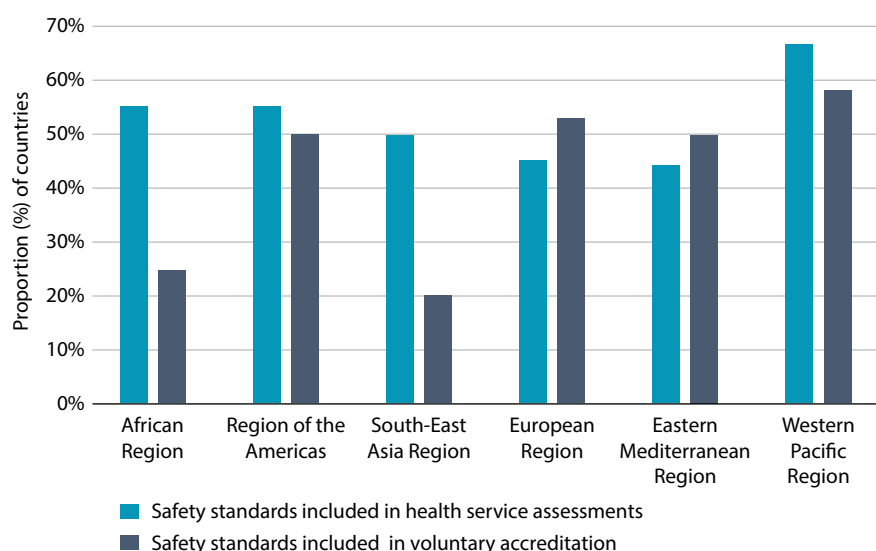
*Diverse approaches to assessing safety standards in health care facilities are evident across different regions, ranging from self-assessment tools to routine assessment programmes, reflecting a concerted effort to uphold safety and quality standards in health care provision.*



## 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.

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.



*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.*

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

## 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

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*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

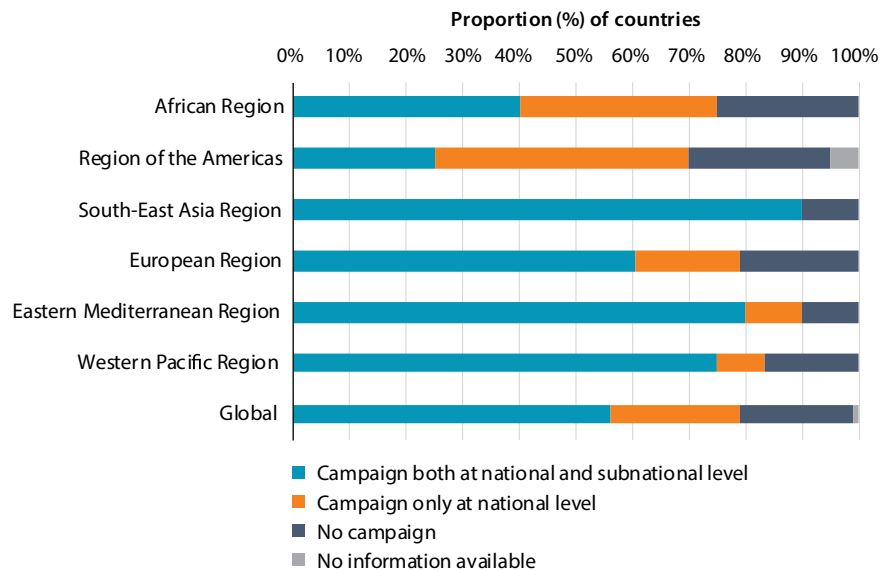
World Patient Safety Day is a global campaign observed every year on 17 September (171). It raises awareness and prompts action for improving patient safety in health care. Since 2019, countries have joined hands to highlight the importance of ensuring the safety of patients, and governments have reaffirmed 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.

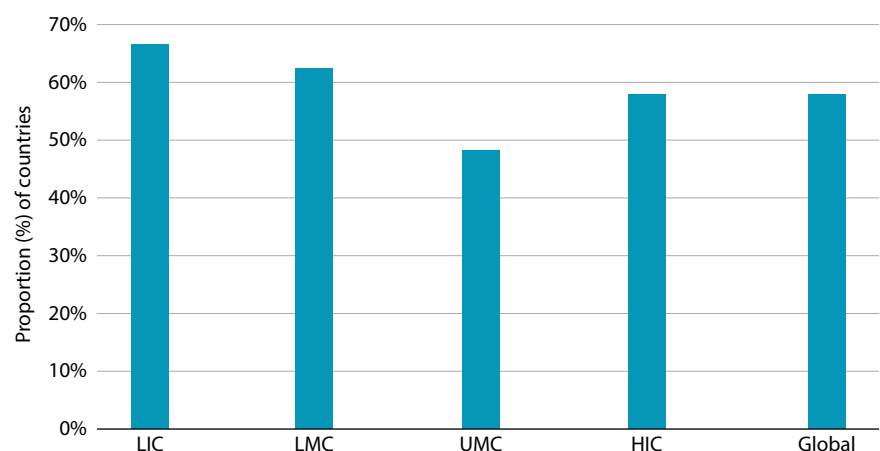
**Fig. 1.16.**  
Proportion of countries  
launching a national and/  
or subnational campaign for  
observing World Patient Safety  
Day, by WHO region



*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.*

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

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.



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.

**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.

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*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.*

**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

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*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 HCAs, 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.

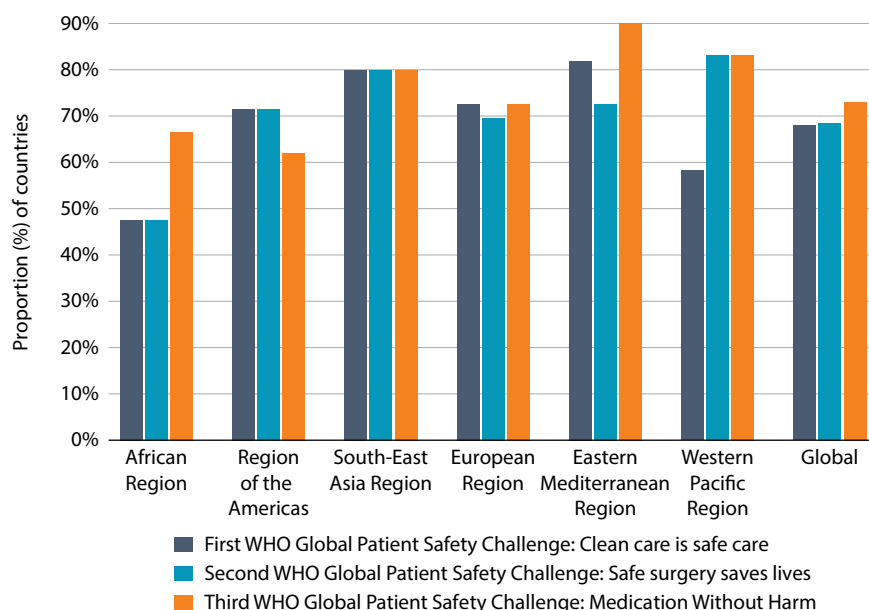
The Member State survey highlights the commitment of countries and regions to the WHO Global Patient Safety Challenges. Globally, 31% of countries have implemented all three challenges, and over half (56%) have acted on at least one.

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).



**Fig. 1.18.**  
Country engagement in successive WHO Global Patient Safety Challenges, by WHO region

## 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.*

## Feature story 3

### 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'<sup>a</sup> 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<sup>b</sup> 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*<sup>c</sup>

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 (PPFS) programme<sup>d</sup> and the implementation of Strategic Objective 4 of the Global patient safety action plan 2021–2030<sup>e</sup> focused on patient and family engagement. On this occasion, WHO unveiled the Patient safety rights charter<sup>f</sup> 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:

- <sup>a</sup> 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).
- <sup>b</sup> Charter: health worker safety: a priority for patient safety. World Health Organization; 2020 (<https://iris.who.int/handle/10665/339287>, accessed 29 April 2024).
- <sup>c</sup> 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).
- <sup>d</sup> Patients for patient safety [website]. Geneva: World Health Organization; 2024 (<https://www.who.int/initiatives/patients-for-patient-safety>, accessed 29 April 2024).
- <sup>e</sup> 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).
- <sup>f</sup> 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



Strategic  
objective

2

## 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



Strategic  
objective

2

## 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).

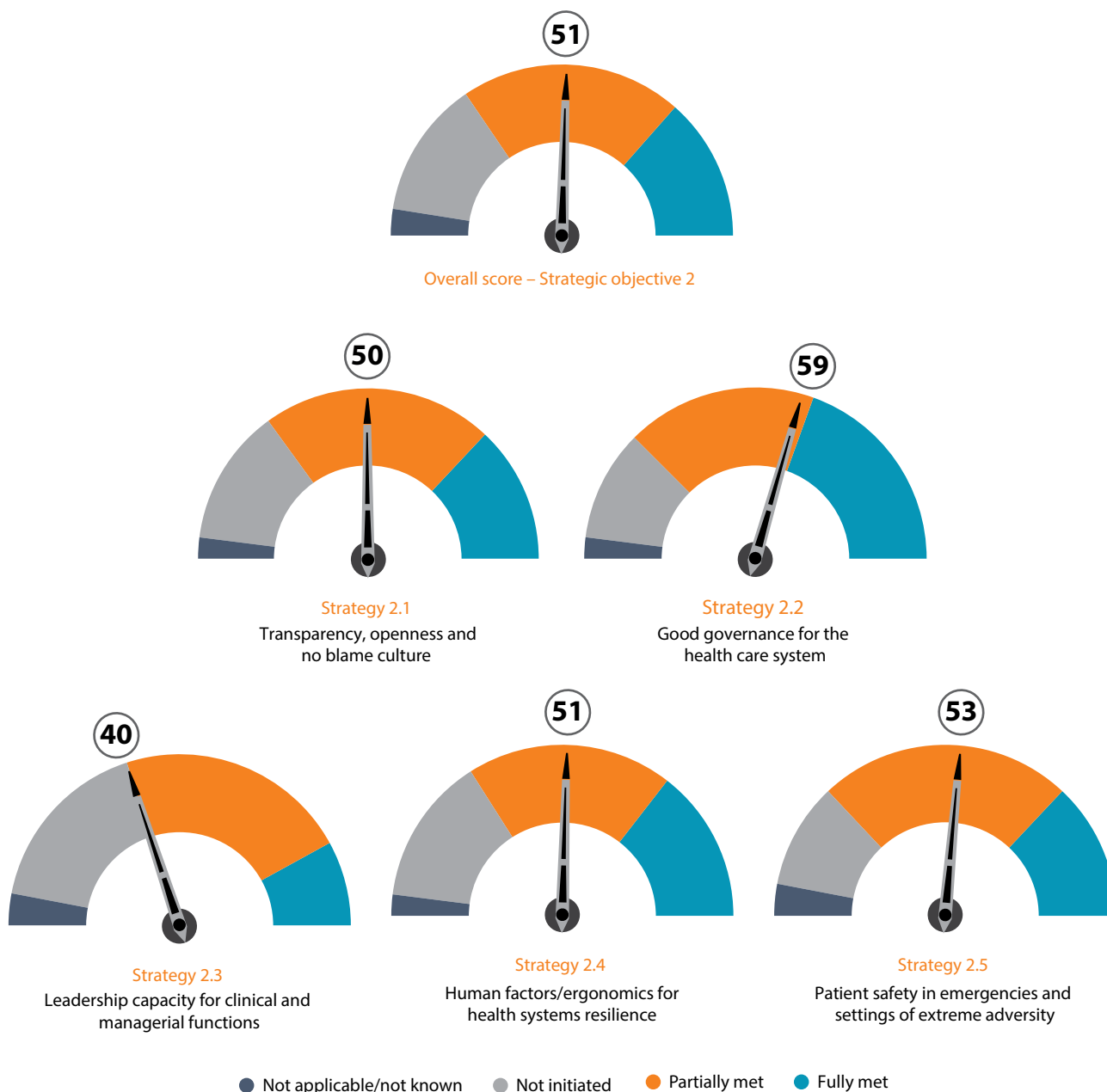
The survey offers a comprehensive snapshot of the state of high-reliability systems in health care. Transparency, openness and cultivating a safety culture, which scored at 50, reveals an important gap, with only 26% of countries fully meeting these criteria and 44% partially achieving them. The institutional 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

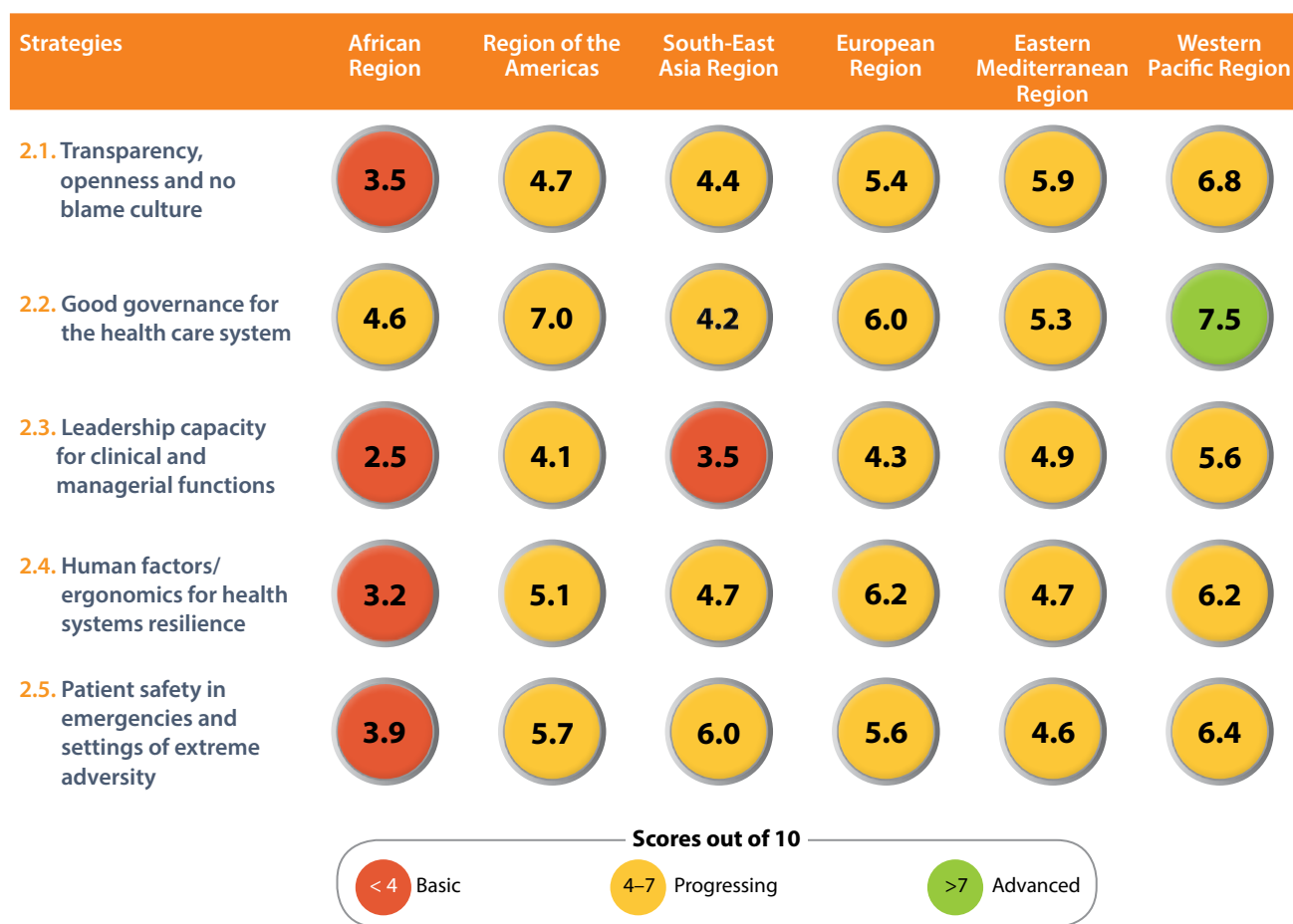
safety culture through periodic surveys. These discrepancies highlight a significant gap between process-oriented initiatives and structural components, emphasizing the urgent need for targeted interventions and resource allocation to bridge these disparities. Efforts to strengthen process criteria, 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**



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.

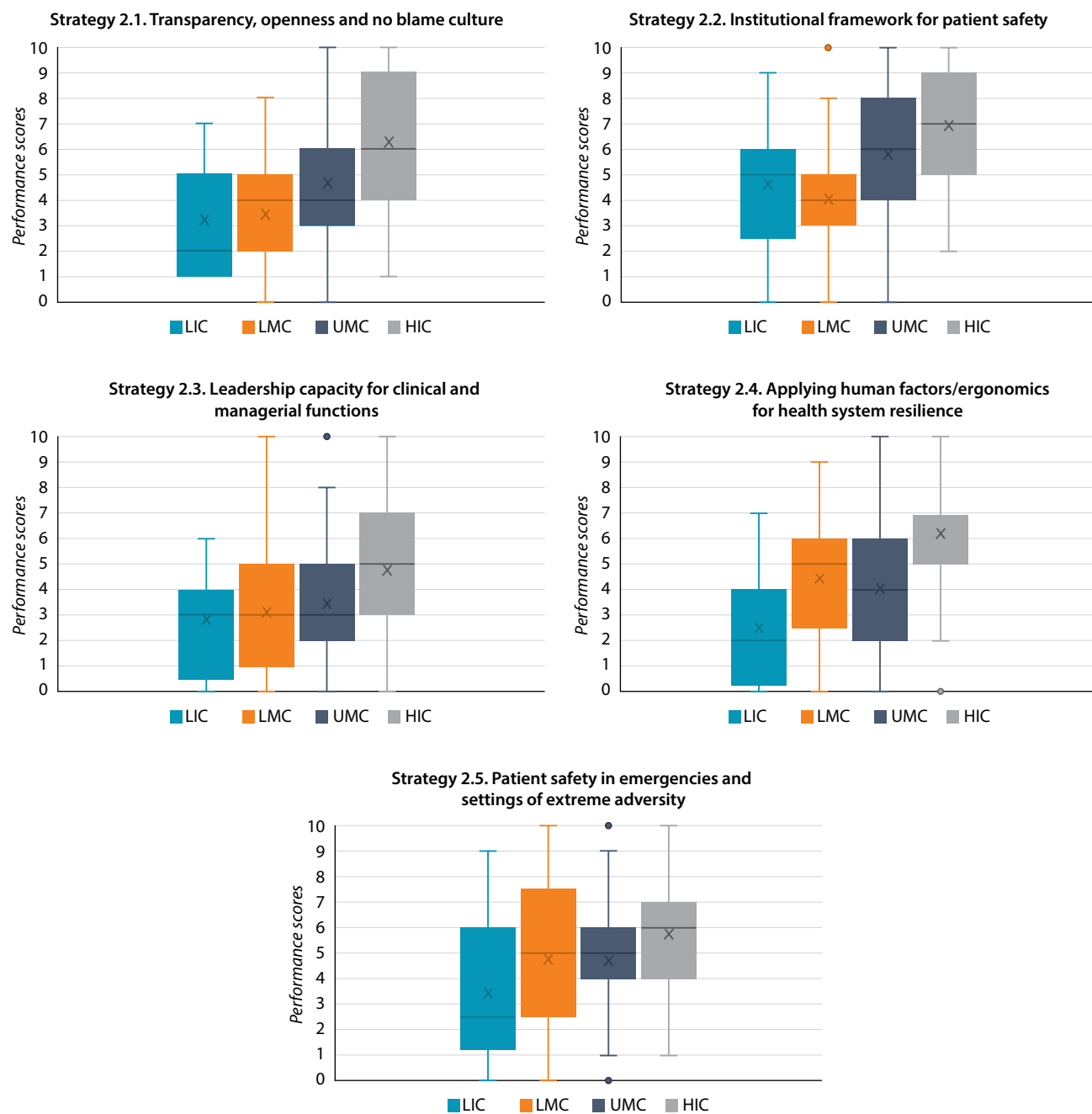
► Fig. 2.2. Distribution of strategic objective 2 performance scores across the five strategies, by WHO region



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.

Strategic objective 2		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

## 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.



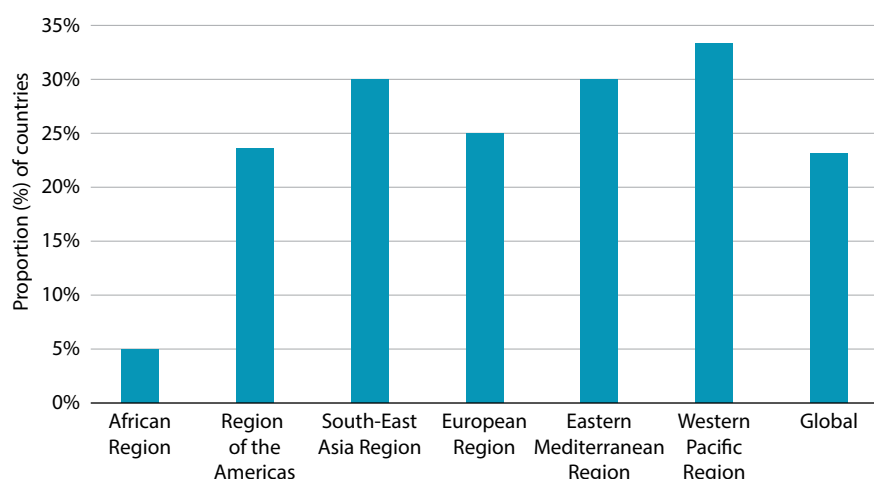
## Safety culture implementation

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

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*Countries use diverse approaches to monitor and improve their safety culture, such as annual surveys, organizational assessments, and performance reviews*

**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.

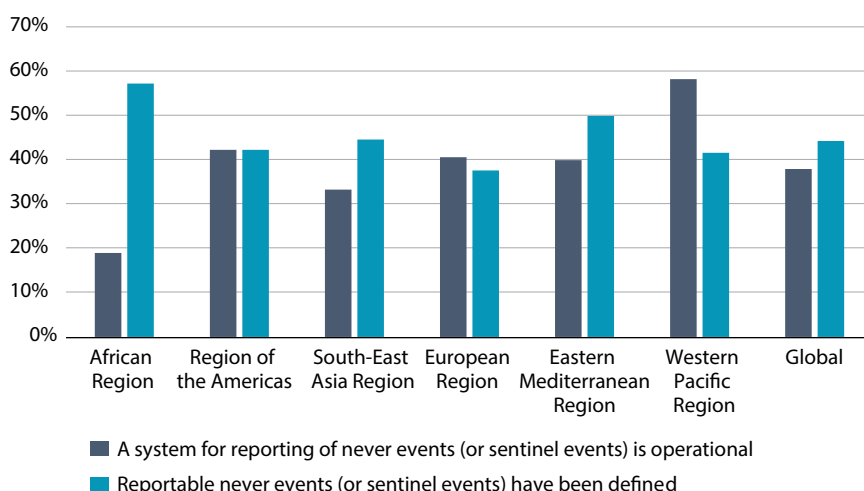
Of the 108 global survey respondents, 38% stated that such a reporting system was in place and operational. Another 44% stated that they have defined reportable never/sentinel events, but the system has not yet been operationalized.

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

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*Among Member State survey respondents, around one third of countries state that they have an operational reporting system for 'never' and sentinel events.*

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

## 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.

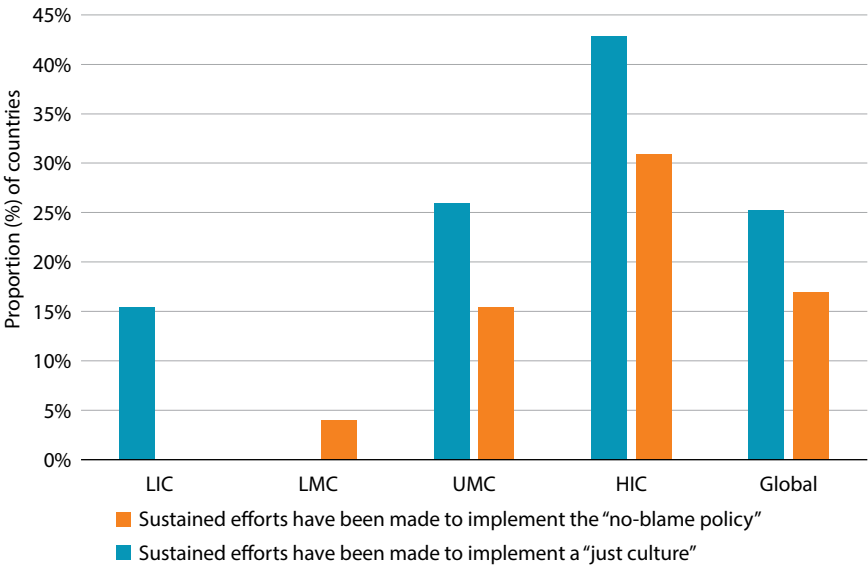
*Countries are adopting diverse mechanisms for reporting ‘never’ and sentinel events, including national legislative frameworks, electronic platforms, toll-free lines, and regional systems.*

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.

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*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
Strategic objective 2	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

## 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

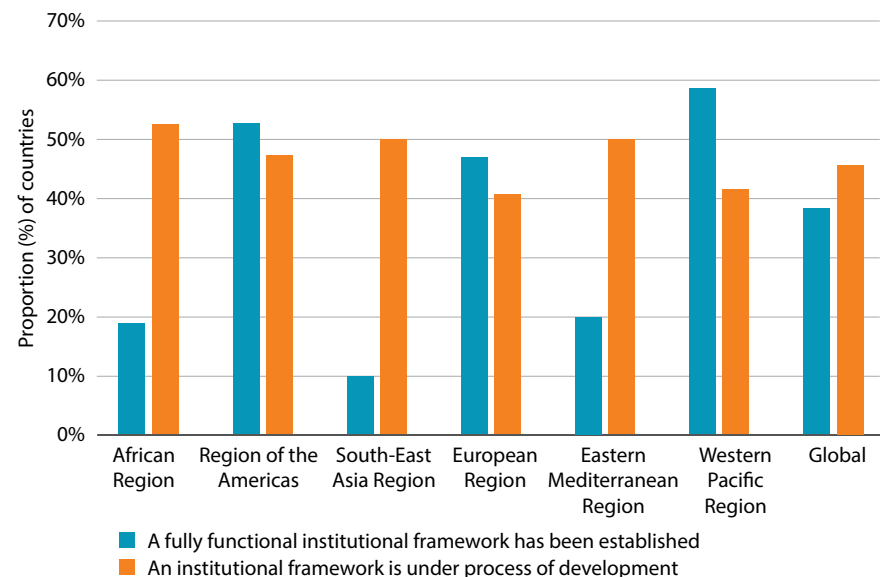
The Member State survey reveals that countries are at varied stages of implementing patient safety institutional frameworks. 38% of all respondents reported that a fully functional patient safety institutional framework has been established through policies or legislation, while another 46% of countries 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**



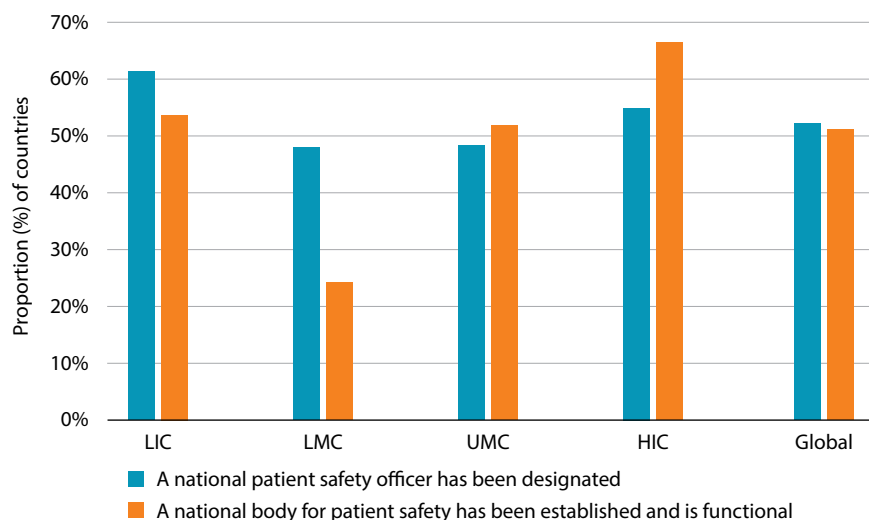
*Low-income countries have initiated the designation of national patient safety officers, while high-income countries establish dedicated centres or institutes.*

## National focal point for patient safety

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 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 transitional 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.*

## Feature story 5

### 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).

	2.1	2.2	2.3	2.4	2.5
Strategic objective 2	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

## Strategy 2.3.

# Leadership capacity for clinical and managerial functions



Develop clinical and managerial leadership capacity and capability at all levels to ensure a strong and visible focus on eliminating avoidable harm in health care

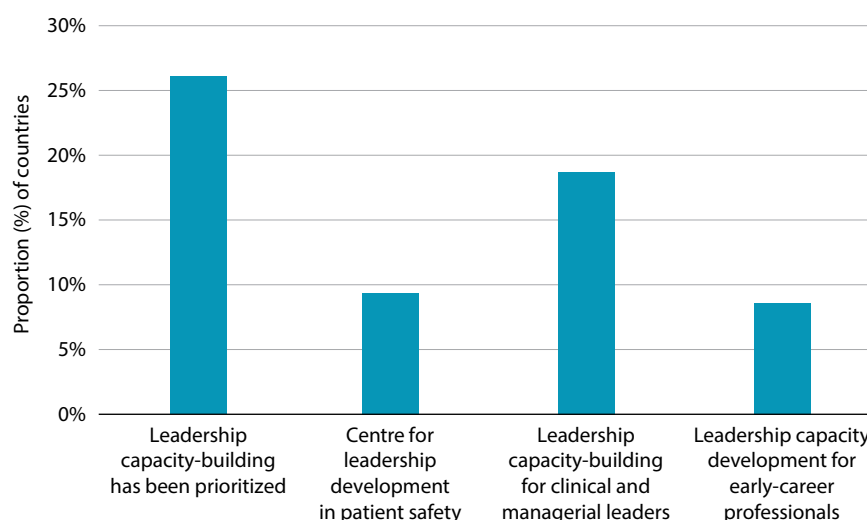
Enhancing patient safety hinges on cultivating robust leadership that promotes a 'safety first' mindset, champions continuous learning and innovation, and streamlines strategies across the health care system. A pivotal step is to designate a dedicated centre to nurture leadership skills specifically for patient safety. Such a centre should be at the forefront of patient safety research and innovation, ensuring the dissemination and implementation of evidence-informed practices.

Around 26% of survey participants indicated that leadership capacity-building related to patient safety has been emphasized across safety improvement programmes (Fig. 2.9). Only 9% confirmed the designation of a specific centre for fostering such leadership skills. Interestingly, only 19% of respondents mentioned the presence of an active programme dedicated to leadership capacity building in the realm of patient safety. A similar trend was observed when focusing on initiatives geared towards early-career professionals, with just 9% noting the existence and operation of such specialized programmes.

This suggests a recognition of the significance of leadership capacity building for patient safety, and a clear gap in establishment of programmes for building leadership capacity. This might point to challenges in resource allocation, decision-making or even the complexity of setting up such specialized

*Improving patient safety requires strong leadership, continuous learning, and innovation. However, there is a notable lack of emphasis on leadership capacity-building, with few countries having dedicated centres or active programmes for developing leadership skills in patient safety.*

**Fig. 2.9.**  
**Status of leadership capacity-**  
**building efforts for patient**  
**safety globally**



## Country examples of advancing patient safety leadership capacity

*Countries are enhancing patient safety leadership through WHO-supported programmes, non-governmental organizations, national health strategies, and specialized training institutes, focusing on skills in safety, quality improvement, and fostering a culture of excellence.*

In **Afghanistan**, with the technical and financial support of the WHO country office, the Quality and Safety Department has become the centre for patient safety capacity-building programmes.

**Canada** has a strong network of non-governmental organizations that support the development of health care leaders. These organizations offer various programmes and initiatives to enhance the skills and competencies of health care professionals, managers and executives. Healthcare Excellence Canada, a federally-funded independent organization, has included leadership capacity building in several programmes and initiatives.

In the **United Kingdom**, the NHS Patient safety strategy places significant emphasis on leadership capacity building. Patient safety specialists are designated leaders within health care institutions and are responsible for spearheading senior-level patient safety initiatives. They are instrumental in fostering a culture centred on patient safety and are actively involved in shaping safety systems and driving improvement activities (178).

In **Qatar**, the Hamad Healthcare Quality Institute provides training, coaching and mentoring programmes for health care leaders and professionals to develop their skills and competencies in patient safety, quality improvement and innovation. The institute is committed to fostering a culture of excellence and learning in the health care sector, and to contributing to the national vision of transforming Qatar into a leading regional and global centre for health care quality.

One of the objectives of the National School of Public Health in **Cuba** is the training and enhancement of leadership, reserves and talent pools of the



national health system. Its mission is the education and development of human capital in public health, encompassing doctorates, specializations, master's degrees, and other organized forms of teaching, both nationally and internationally.

In **Lebanon**, the national accreditation programme addresses leadership capacity as part of patient safety improvement.

All state and territory health systems in **Australia** offer health leadership training, especially in patient safety. The New South Wales Health Education and Training Institute, for example, delivers various courses, programmes and education opportunities to meet the training needs of health leaders.

**Ireland** is making strides in patient safety leadership training. University College Dublin provides a 5-year programme called Collective Leadership and Safety Cultures. By fostering quality and safety cultures, it introduces a leadership model linked with effective team outcomes. A toolkit for multidisciplinary teams has been developed for the training (179).

Strategic objective 2		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

## Strategy 2.4.

# Human factors/ergonomics for health systems resilience



Bring a strong human factors/ergonomics perspective and input to strengthening the resilience of health organizations and clinical practices

*Applying human factors principles to health care can significantly improve patient safety and treatment outcomes by optimizing the interaction between humans and technology.*

Human factors apply wherever humans work. This discipline focuses on improving the interface between humans and technology, using insights from related human behaviours, capabilities and constraints. By understanding these elements, we can design equipment, processes, and environments that better cater to human needs, ensuring efficiency, safety and comfort. Many adverse events in health care are tied to human factors, and by leveraging principles from this discipline, we can greatly enhance patient safety and improve treatment outcomes.

### Applying human factors for improving patient safety

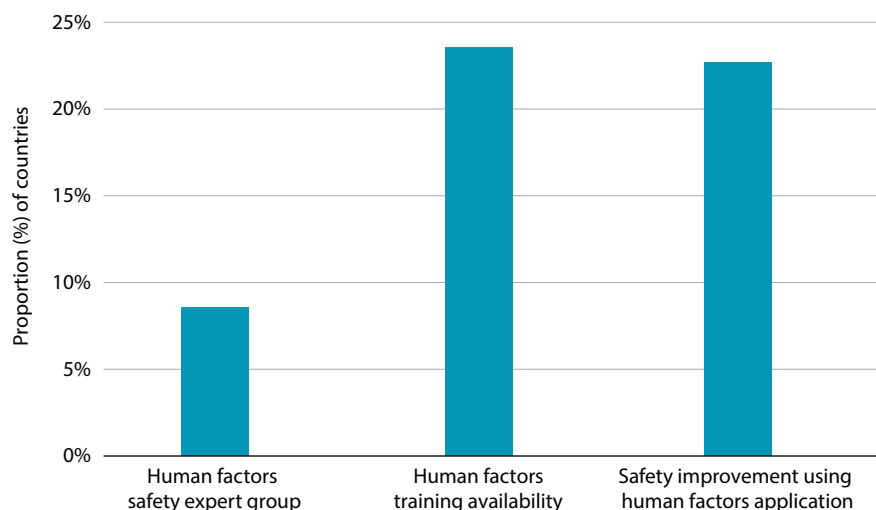
*Globally, only one out of four countries have started implementing human factors strategies and training programmes to enhance safety of health care.*

Specialized expert groups focused on human factors in relation to patient safety are essential to enhance the efficacy and safety of health systems for both patients and health workers. This expert knowledge can guide the selection, application and evaluation of medical equipment and technology, as well as the design of related tasks and procedures.

However, on a global scale, only about 9% of countries indicate consulting with experts in human factors when applying these principles to bolster patient safety (Fig. 2.10). Meanwhile, roughly a quarter of countries have taken

steps 2 and 3 bar should be swapped - graph order is different and does not match the description, which is first about application and then about training

Globally, the significance of human factors and ergonomics in health care is increasingly acknowledged. Many countries have recognized the intersection of medical technology, health care delivery and human factors as critical for enhancing patient safety.



**Fig. 2.10.**

**Global status of human factors implementation for improving patient safety**

## Country examples for applying and integrating human factors perspectives to improve patient safety

In **Canada**, the Canadian Human Factors in Healthcare Network, established by the former Canadian Patient Safety Institute, was designed to offer expert insights on human factor principles to enhance patient safety. Canadian health care providers collaborate with non-governmental entities to obtain specialized expertise within their institutions.

The Ministry of Health of **Singapore** employs a team of part-time professionals to provide a range of human factors services under the Ensure Safer Systems initiative. They have developed a root cause analysis guide that integrates a human factor analysis and classification systems framework. This guide is instrumental in pinpointing and addressing the root causes of safety incidents in health care environments.

In **Sweden**, a national council is dedicated to patient safety, and its advisory role on the application of human factors involves ten agencies and five national organizations. The perspective on human factors has been seamlessly incorporated. There are also regional expert groups focusing on human factors, consisting of chief medical officers, chief nursing officers, and leaders in patient safety.

In **Denmark, Georgia** and **Poland**, human factors methodologies are integrated to enhance the safety and efficiency of medical devices and IT systems. These nations recognize the importance of human-centric approaches in not only the design and use of medical technology, but also in the procedures of service delivery.

*Countries are integrating human factors principles into their health care systems, emphasizing expert insights, root cause analysis, and the intersection of medical technology and human factors to advance patient safety*

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*Academic programmes and SOPs can significantly contribute to the application of human factors, enhancing patient safety globally.*

The patient safety surveillance system in the **Netherlands (Kingdom of the)** places a significant emphasis on the intersection of medical technology and human factors. The principles of human factors are not only incorporated into the design and use of medical technology, but are also integral when scrutinizing and drawing insights from incident reports.

**Ireland** has introduced advanced academic programmes – including a postgraduate diploma and a master’s degree – focusing on human factors (180, 181). The academic programmes are designed for various types of health care professionals at the hospital level in addition to safety and quality managers. Additionally, safety and quality managers can also benefit from these courses.

**Indonesia** has rolled out comprehensive guidance has established standard operating procedures (SOPs), and provides detailed work instructions specifically focused on the application of human factor approaches to improve safety of medical products and procedures.

The application of human factors and ergonomics is deeply integrated into health care systems in the **United Kingdom**. The NHS Patient safety syllabus has embedded human factors as one of its fundamental components. Various academic institutions offer courses on human factors. The Medicines and Healthcare products Regulatory Agency (MHRA) has highlighted the necessity of applying human factors to the design and optimization of medical devices, ensuring they are crafted with minimal risks to patients and users (182). Beyond this, the NHS has set forth clinical risk management standards specifically for the manufacturers of health IT systems.

## Structural and non-structural safety of health care infrastructure

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*Ensuring structural and non-structural safety in hospitals is essential for maintaining functionality and patient care during routine operations and emergencies, especially in hazard-prone areas.*

Structural safety in hospitals is crucial, ensuring they remain functional during routine operations as well during disasters and other emergencies. From meeting modern safety standards shaped by previous incidents to considering the complexities of design, materials and the proximity surrounding buildings, each factor contributes to the durability of a hospital’s infrastructure. Factors such as structural redundancy, foundation integrity and addressing irregularities in building layouts further improve physical safety. Especially for hospitals in hazard-prone areas (e.g. due to geological, hydro-meteorological, biological, societal or technological phenomena), ensuring resilience against varied threats such as earthquakes, floods or tsunamis is essential to safeguard lives and maintain uninterrupted medical services (183).

Non-structural safety in hospitals pertains to elements that, while not bearing loads or contributing to the building’s structural integrity, are vital for its functioning and patient care. These encompass architectural features, essential access and exit pathways, and critical systems such as electricity, water, waste management and fire protection. The safety and security of medical and laboratory equipment, both stationary and mobile, along with essential supplies for diagnosis and treatment, fall under this category. Ensuring the safety and operability of these non-structural elements is paramount, as compromising

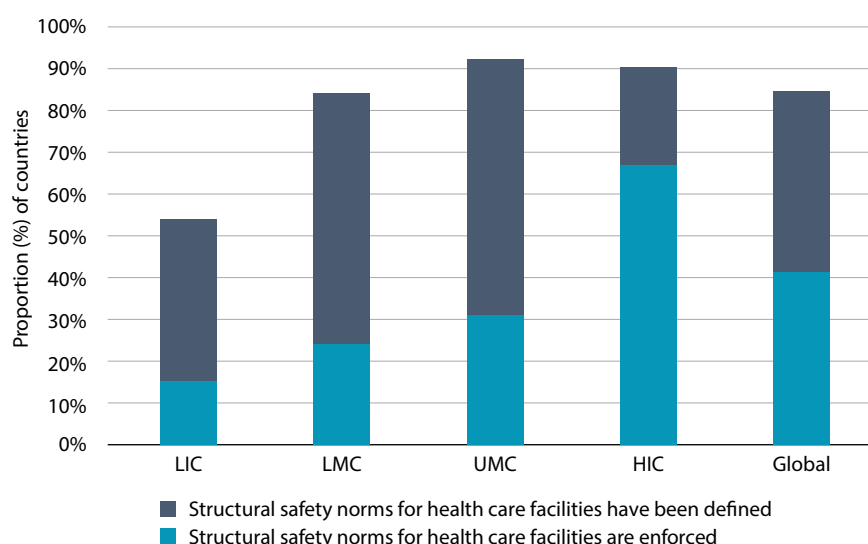
them could severely disrupt hospital operations, jeopardize patient care, and increase vulnerability during emergencies (183).

To guarantee comprehensive safety in health care facilities, it is essential to enforce both structural and non-structural safety norms through stringent mechanisms such as licensing, accreditation, authorization and regular inspections.

According to the data collected from Member States, 85% of countries have established structural safety standards for health facilities (Fig. 2.11). However, only half of these countries (42%) have reported that they can effectively enforce these standards.

While defining structural safety norms has been undertaken to some extent across all income groups, the enforcement of these norms varies significantly. There is a clear trend of increased enforcement from LICs to HICs.

However, a striking observation is that roughly half of LICs report that they lack any form of structural safety norms for their health care facilities. Furthermore, on a global scale, approximately 43% of countries are unable to ensure the structural safety of their health care infrastructure. This inability to guarantee structural safety is concerning, as it is a fundamental prerequisite for providing safe health care services.



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

The implementation of non-structural safety elements exhibits a similar pattern, where approximately half of the countries globally report successful enforcement of the defined safety norms. Notably, compliance with these norms tends to improve as a country's income level rises.

These findings underscore the need for enhanced efforts to ensure safety standards in health care facilities, especially in countries with lower enforcement rates, to safeguard both structural and non-structural safety elements.

*While 85% of countries have established structural safety standards for health care facilities, only half of them enforce them effectively.*

**Fig. 2.11.**  
Status of implementation of structural safety norms for health care facilities, by income group

Strategic objective 2	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

## Strategy 2.5.

# Patient safety in emergencies and settings of extreme adversity



Incorporate patient safety elements within the context of emergencies, disease outbreaks and settings of extreme adversity

*The COVID-19 pandemic highlighted the fragility of health systems, with an increased level of HCAIs, medication errors, and diagnostic mistakes.*

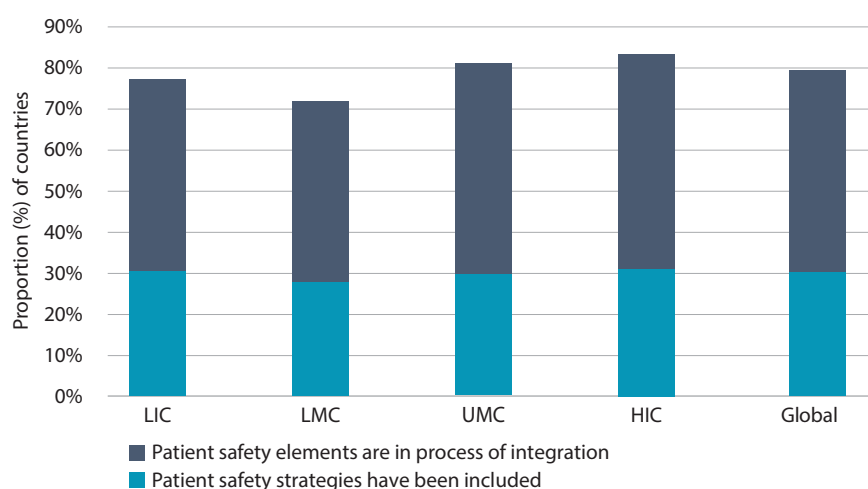
The COVID-19 pandemic underscored the fragility of health systems worldwide when faced with surges in demand and while striving to maintain the safety and quality of care provided. Infection control practices were rapidly strained by limited supplies and staffing, resulting in increased HCAIs. Medication safety was compromised, with errors in initiation, discontinuation and inadequate reviews, exacerbated by the absence of family caregivers. Diagnostic errors occurred due to false-negative tests, evolving COVID-19 knowledge, symptom similarities, exhaustion of health workers, and communication challenges. Surgical care faced restructuring and delays, contributing to patient safety issues. Patient falls and pressure injuries increased, while the COVID-19 vaccine roll-out raised concerns about immunization errors such as incorrect diluent, administration to wrong age group or contraindications not taken into consideration (184).

Estimates from other types of fragile contexts also reveal alarming statistics: In 2015, 60% of preventable maternal deaths, 53% of deaths among children under five years of age, and 45% of infant fatalities occur in 50 fragile states characterized by conflicts, displacement or natural disasters. Providing access to health care in these contexts can worsen health outcomes and heighten vulnerability to future public health crises. Prioritizing safe and high-quality care is arguably more crucial in fragile, conflict-affected and vulnerable settings due to the substantial health care needs of such populations (185).

## Patient safety integration in health emergency preparedness, response and recovery plans

It is crucial to ensure that various stakeholders within the health care system who work on patient safety are included in all coordination mechanisms, including those related to leadership, service delivery, finance, supply chain management, health workforce and health information systems (HISs). Additionally, it is essential to integrate elements of patient safety policy into national emergency policies, strategies and plans, covering preparedness, response, recovery and routine health care operations.

Member State survey responses showed that 30% of respondent countries have successfully incorporated patient safety elements into their strategies for health emergency preparedness, response and recovery (Fig. 2.12). An additional 50% of countries reported that they are actively working towards achieving this integration. The survey data further show relatively small variations among income groups in terms of the proportion of countries that have incorporated patient safety elements into their strategies for health emergencies. The lack of significant income-related variations suggests that factors beyond income – such as health care policies, governance and legislation may have a significant influence on a country's ability to incorporate patient safety elements effectively.



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

*Around one third of countries have integrated patient safety into health emergency plans.*

**Fig. 2.12.**  
Status of patient safety elements been included in strategies and/or a plan for health emergency preparedness, response and recovery, by income group

## Risk management for patient safety

A proactive and systematic approach to managing patient safety risks involves meticulous identification, examination and mitigation of potential hazards and harmful incidents in health care settings. Improving patient safety requires the formulation of strategies to address and reduce recognized risks, ensuring the meticulous documentation of possible challenges, and the consistent



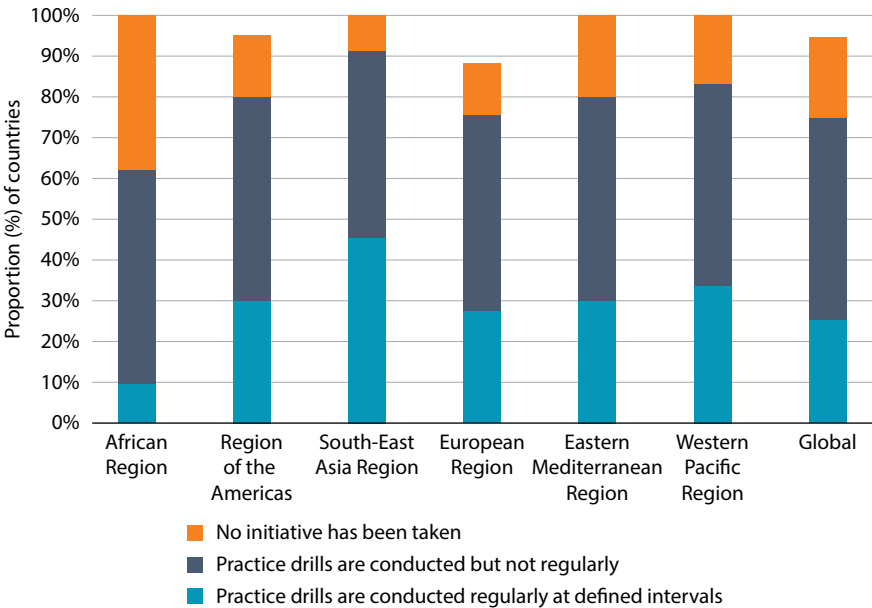
Around one quarter of countries have established risk registers and risk mitigation strategies for patient safety and conduct regular rehearsals to strengthen system resilience.

execution of practice drills to assess and strengthen the resilience of the system in both emergency and standard health care scenarios.

One quarter of the countries surveyed disclosed that they have established a risk register, a comprehensive log of all discernible and potential risks that could threaten the secure and efficient operation of health care systems. They have also drafted risk mitigation strategies to confront and alleviate these risks and threats.

A similar percentage (25%) of respondent countries confirmed that they systematically conduct practice drills and response rehearsals at predetermined intervals (Fig. 2.13). There is considerable regional variation in these practices, and countries from the South-East Asia Region have the highest reported adherence to periodic practice drills.

Fig. 2.13.  
Status of regular rehearsals (mock drills) to test and improve responses to identified risks, by WHO region



### Examples of how countries have addressed threats to their health care systems

In **Bhutan**, risk mitigation measures are applied to high-risk clinical procedures, complemented by a comprehensive hospital contingency plan.

**India** has systematically identified health care threats, listing them in the E-SPAR document, and strategized risk mitigation through the National Disaster Management Authority.

**Namibia** upholds risk mitigation as a crucial component within its health care facility quality standards.

**Liberia** has developed a risk assessment tool and is diligently working towards establishing a corresponding risk mitigation strategy.

**Azerbaijan** organizes mock drills annually through collaborative efforts among the Ministry of Emergency Services, the Ministry of Health and the United Nations Population Fund (UNFPA).

**Cameroon** has employed various surveys and situational analysis to identify potential threats to its health system and has developed a multi-risk plan for public health events.

**Malaysia** safeguards its health care facilities with well-defined risk and disaster management tools and follows a national action plan.

Countries such as **Chile, Costa Rica, El Salvador** and **Poland** validate their risk mitigation efforts through citations of specific documents or adherence to national standards.

In **Uruguay**, the National Emergency System, situated under the Presidential Office, diligently identifies and mitigates health care threats.

**Iceland** has a real-time alert system but it does not cover the entire country.

**Trinidad and Tobago's** regional health authorities have embedded patient safety protocols within various hazard-specific response plans.

**North Macedonia** adheres to its health and safety legislation, mandating risk assessments at health care facilities, the development of risk management strategies and plans, and considering human factors in all these processes.

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*Countries address health care system threats through risk mitigation measures, comprehensive contingency plans, systematic threat identification, and regular practice drills, ensuring resilience through national standards and collaborative efforts.*



*Doctor consulting with a mother about her infant's health at a clinic in Port-au-Prince, Haiti. © WHO / TDR / Andy Craggs*

A photograph of surgeons in an operating room, wearing blue scrubs and masks, performing surgery under large overhead lights. A green circular graphic with the number 3 is overlaid on the right side of the image.

Strategic  
objective

3

# Safety of clinical processes

*Surgeon performing cancer surgery at Centre Léon Bérard, a specialized cancer hospital in Lyon, France. © WHO / Gilles Reboux*



Assure the safety of every clinical process



## Organization of section

### Strategy 3.1. Safety of risk-prone clinical procedures

- Identifying sources of significant patient harm
- Patient safety improvement initiatives to address major sources of harm
- Patient safety improvement initiatives in clinical disciplines

### Strategy 3.2. Global Patient Safety Challenge: *Medication Without Harm*

- Implementation of the third Global Patient Safety Challenge: *Medication Without Harm* at the national level
- Key action areas for medication safety
- Patient education about medicines
- Safety initiatives for traditional and complementary medicines
- Mechanisms of reporting and measuring adverse drug events and medication-related harm

### Strategy 3.3. Infection prevention and control and antimicrobial resistance

- National infection prevention and control programmes
- Infection prevention and control guideline implementation and monitoring
- Infection prevention and control education and training
- Health care-associated infection surveillance

### Strategy 3.4. Safety of medical devices, medicines, blood and vaccines

- Safety regulations for medicines and medical products
- Programmes for safety of medicines
- Programmes for safety of blood and blood products
- Programmes for safety in immunization services
- Programmes for safety of medical devices

### Strategy 3.5. Patient safety in primary care and transitions of care

- Transitions of care and clinical pathways for primary care
- Certification and accreditation programmes for primary care services
- Implementing patient safety systems interventions in primary care
- Patient safety in mental health services

## Key messages



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.



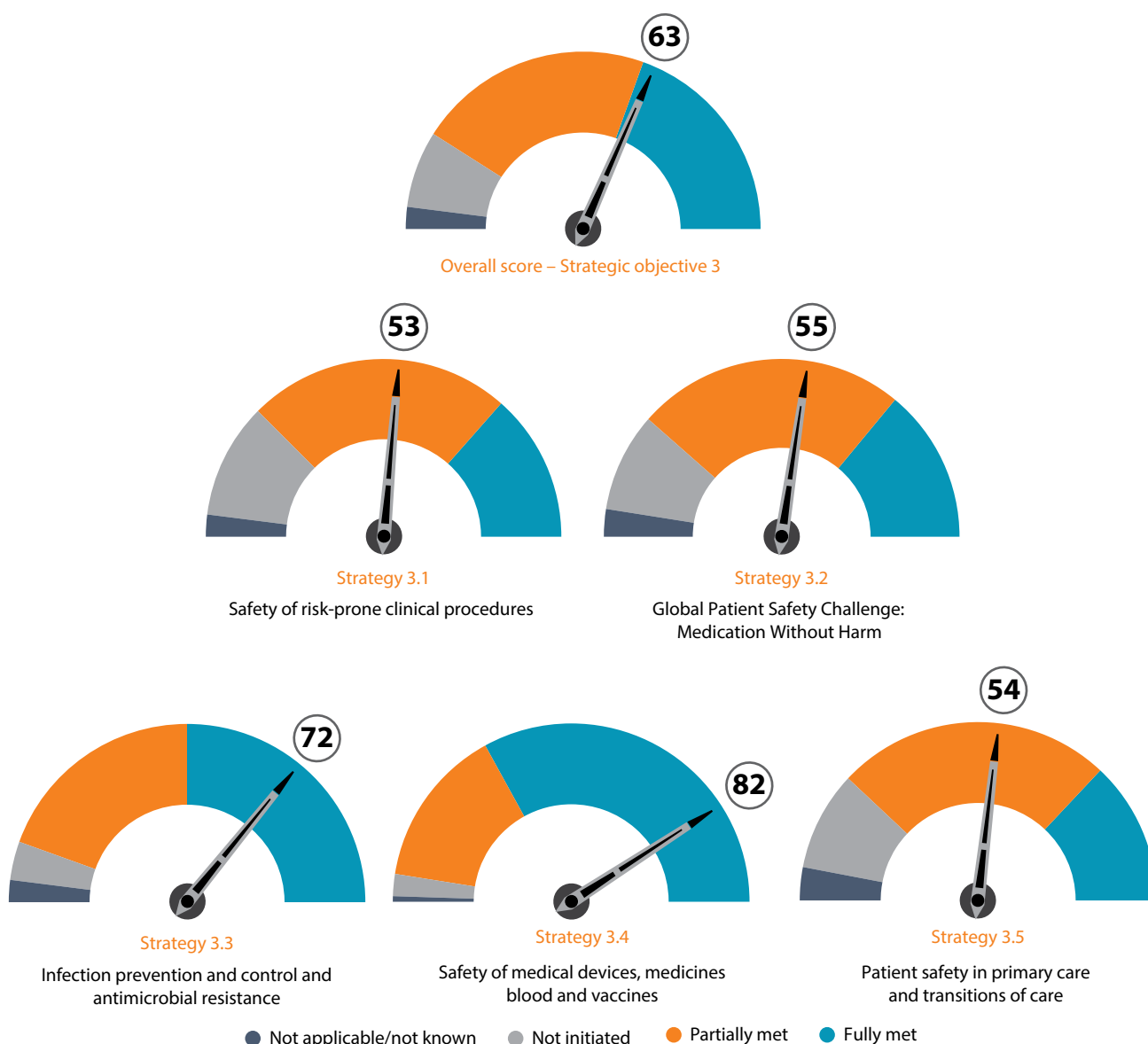
Patient safety in primary and ambulatory care is less prioritized compared to safety in hospitals, with only 17% of countries systematically including safety in primary care programmes.

When patients attend a health care facility for medical advice, investigation, diagnosis, treatment or rehabilitation, they enter a series of care pathways that are often closely interconnected. It is critical to identify patient care processes that are potential sources of significant risk and harm, and to develop initiatives to address safety failures in those processes.

While patient safety is typically considered primarily an issue within hospital settings, considerable harm also takes place at the primary care level.

Across 108 Member States surveyed, aggregated data reveals that 39% of the criteria related to clinical care safety were fully met, while an additional 43% were partially met (Fig. 3.1). Notably, approximately 14% of the criteria have yet to see any action by countries. With an overall score of 63 out of 100 for strategic objective 3, based on the weighted scores of fully and partially met responses, moderate performance appears to have been achieved. These aggregated scores are a slight improvement over other strategic objectives, suggesting that countries have established safety improvement programmes for key clinical service areas and medical products. Across different strategies aimed at ensuring patient safety, distinct patterns emerge regarding the level of implementation and adherence to safety protocols. Notably, while some areas exhibit commendable implementation progress, others reveal significant gaps. For instance, the safety of medical devices, medicines, blood and vaccines stands out with an impressive 66% of criteria fully met, indicating robust safety measures in place. Conversely, patient safety in primary care and transitions of care lags behind, with only 26% of criteria fully met, signalling areas in need of urgent improvement.

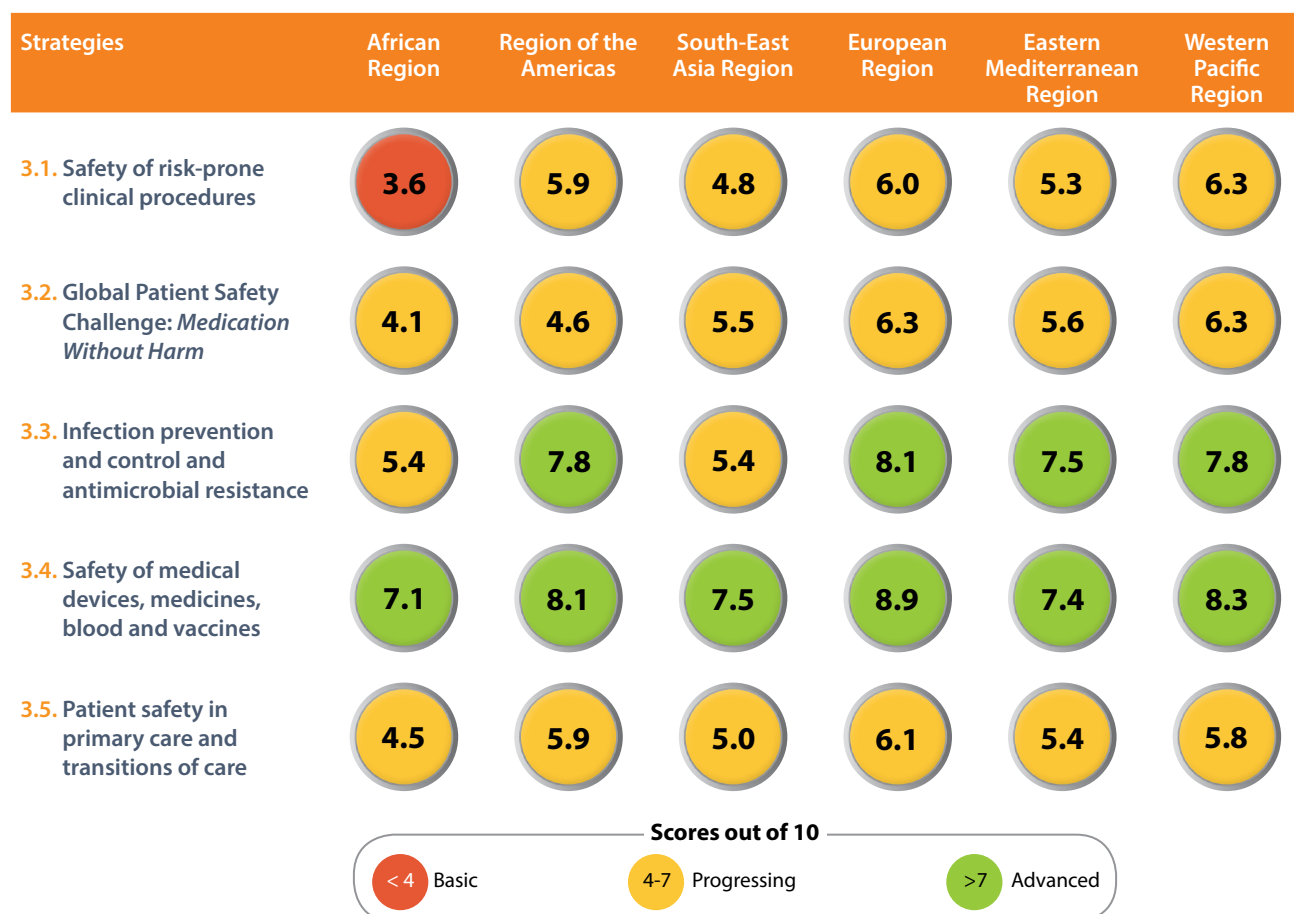
► Fig. 3.1. Global performance scores for strategic objective 3





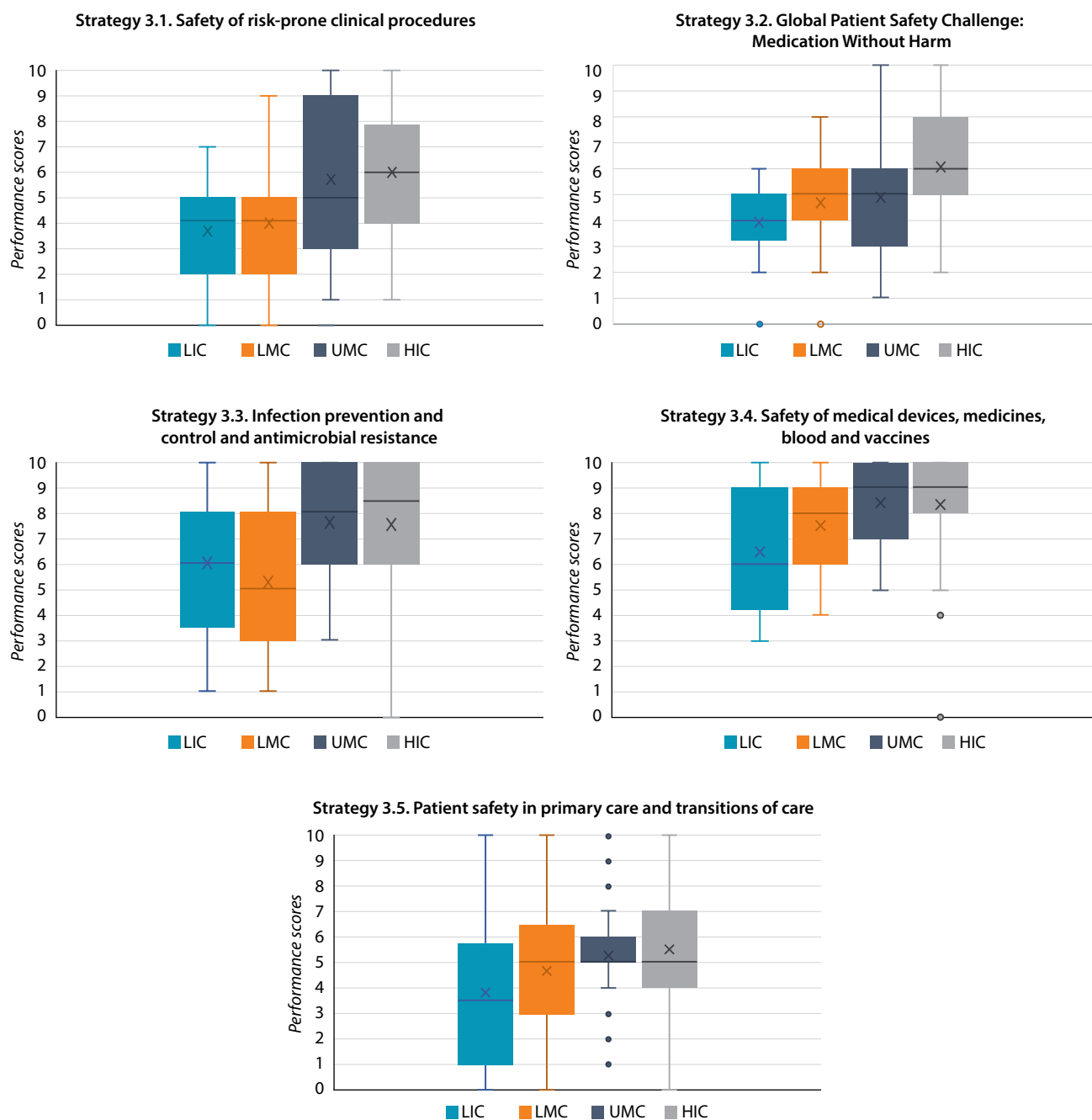
The analysis of performance scores across WHO regions reveals varied performances in strategies for ensuring clinical service safety (Fig. 3.2). Countries in the European Region consistently demonstrate robust scores in most of the strategies. Those in the Region of the Americas also perform well. Relatively strong scores are also observed in the Eastern Mediterranean Region, South-East Asia Region, and the Western Pacific Region, particularly in medical products safety. However, countries in the African Region generally score lower, particularly in risk-prone clinical procedures. These differences underscore the diverse challenges and strengths across regions, highlighting the importance of tailored approaches to improving patient safety universally.

► **Fig. 3.2. Distribution of strategic objective 3 performance scores across five strategies, by WHO region**



High-income countries generally report better performance, particularly in implementing clinical safety programmes in risk-prone clinical procedures and medication safety, as indicated by their higher median values (Fig. 3.3). The performance between income groups is less differentiated in IPC and the safety of medical products, with some lower-income countries showing comparable performance levels. The overlap seen in patient safety in primary care and care transitions across all income groups indicates this is a challenging area globally, with widespread variation in processes within each income group.

► **Fig. 3.3. Distribution of strategic objective 3 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.

	3.1	3.2	3.3	3.4	3.5
Strategic objective 3	Safety of risk-prone clinical procedures	Global Patient Safety Challenge: <i>Medication Without Harm</i>	Infection prevention and control and antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines	Patient safety in primary care and transitions of care

## Strategy 3.1.

# Safety of risk-prone clinical procedures



Identify risk-prone clinical procedures and mitigate their risks, taking account of national and local priorities

Patient safety is of critical concern across all health care settings, though the sources and extent of harm can vary widely depending on factors such as the burden of disease, available resources, and specific clinical contexts. While interventions aimed at improving patient safety systems can be broadly applicable across different health care settings, it is essential to tailor these interventions to address major sources of significant harm in each unique context.

For example, in regions with a high prevalence of noncommunicable diseases, ensuring the accuracy and reliability of diagnoses in primary care settings should be a high priority. This could involve investing in training and education for health workers, implementing robust quality assurance systems, and utilizing technology to aid in the diagnostic process.

In hospitals that consistently experience overcrowding, efforts should be directed towards reducing the incidence of HCAs and improving patient identification processes. This could involve enhancing IPC protocols, optimizing patient flow and bed management systems, and implementing wrist bands, barcodes or other patient identification interventions and technologies to ensure that the right patient receives the right treatment at the right time.

*Improving patient safety necessitates tailored interventions that address the unique challenges and needs of different health care settings to effectively mitigate risks and improve outcomes.*

Governments overseeing populations with a significant proportion of older people may choose to focus on reducing the risks associated with polypharmacy. This could involve developing guidelines for medication management in older adults, as well as providing education and support for health workers and caregivers.

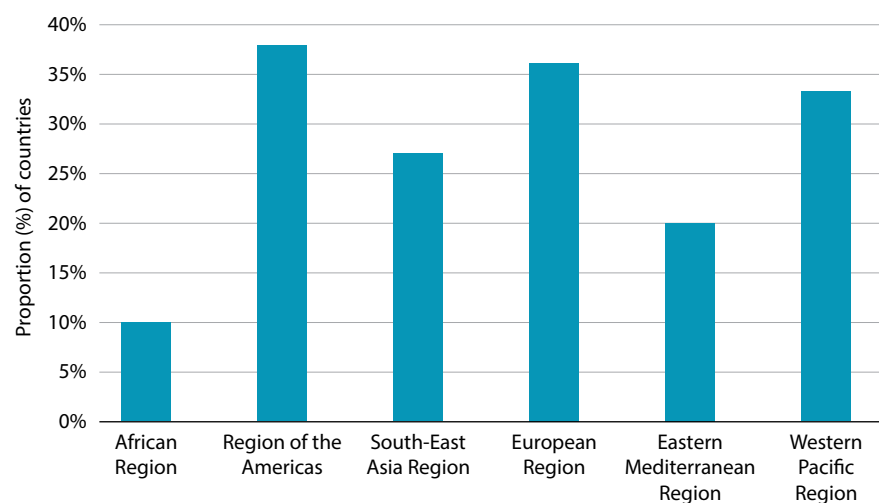
By proactively identifying and addressing the major sources of significant patient harm in each unique health care setting, it is possible to enhance the safety of health services and reduce the burden of harm on patients and their families.

## Identifying sources of significant patient harm

*Significant disparities exist in identifying patient harm across income levels and regions.*

According to Member State survey responses, 27% of countries report they have identified major sources of significant patient harm in local contexts. Survey data also reveal striking gaps in the identification and documentation of significant sources of harm across income groups and WHO regions. For example, HICs and UMCs report around one third of countries have identified sources of significant harm, whereas LICs and LMCs only around 10% of countries have reported positively on this criterion. There is also considerable variation among WHO regions (Fig. 3.4).

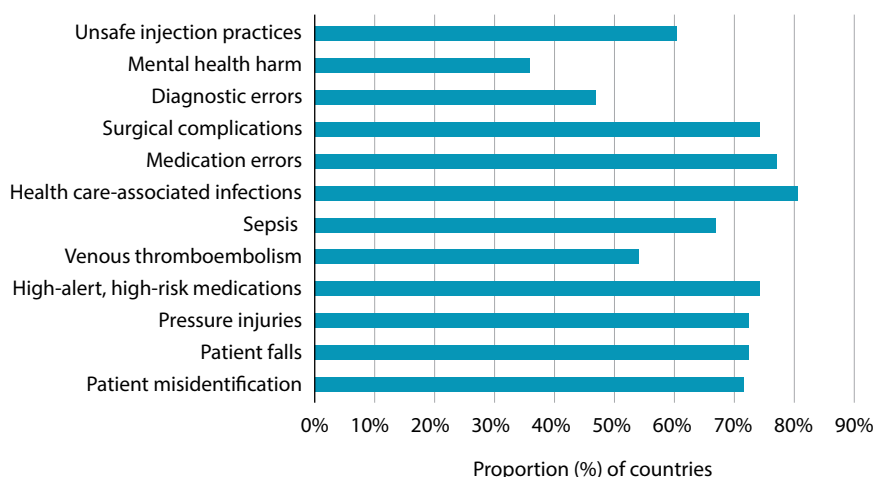
**Fig.3.4.**  
Performance on identification of sources of significant patient harm and their causes, by WHO region



## Patient safety improvement initiatives to address major sources of harm

To address major sources of harm due to unsafe care, countries need to establish a range of clinically-led patient safety improvement initiatives. These can be focused on: systemic issues (e.g. patient identification and diagnostic safety); specific patient populations (e.g. those with dementia or paediatric patients); various health care settings (e.g. primary care and nursing homes); potential harm sources (e.g. sepsis, VTEs and patient falls); specific clinical areas (e.g. surgery, obstetrics, critical care, emergency services or radiotherapy); and, public health initiatives (e.g. immunization, maternal health or reproductive health).

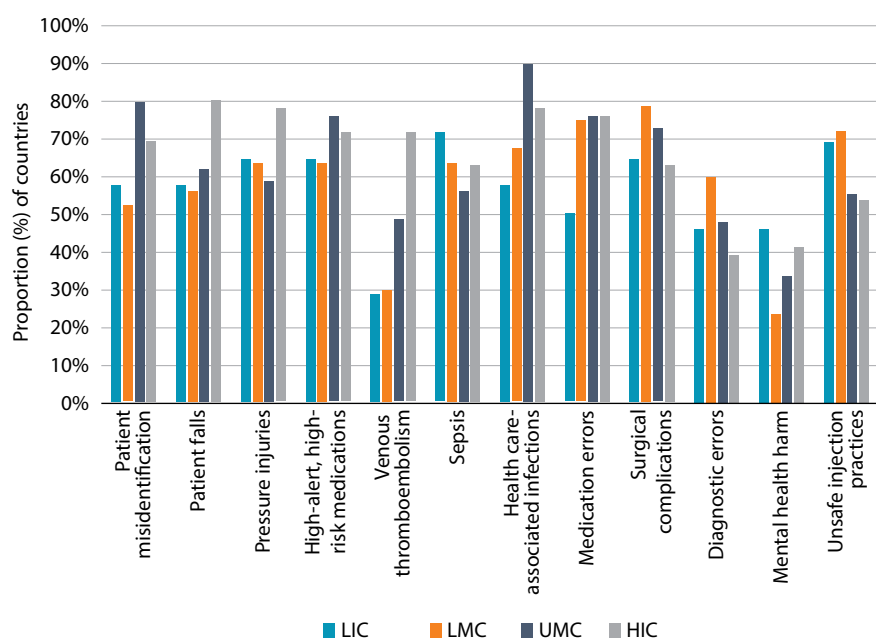
Many countries have taken initiatives to identify and address sources of patient harm, though the intensity and scope of these initiatives are variable. In the survey, 41% of countries indicated that they have implemented multiple initiatives to tackle key areas of concern within their local contexts. Additionally, almost half of countries (48%) mentioned that they have addressed at least one relevant major source of harm. The majority of country interventions are directed at tangible and immediate threats (Fig. 3.5), with HCAIs (82%) and medication errors (78%) identified as focus areas for patient safety interventions. Safety in mental health settings is not widely considered to be a priority and is only addressed by 36% of countries. Diagnostic errors – a critical area of risk that significantly affects care outcomes – is being tackled by only 47% of countries.



*Many countries have implemented patient safety measures, but these efforts vary significantly, focusing primarily on immediate threats such as HCAIs and medication errors.*

**Fig. 3.5.**  
Major sources of harm reportedly identified and addressed by countries

Beyond these global trends, examining patient safety improvement initiatives across different income groups highlights distinct priorities (Fig. 3.6). In LICs, there is a marked emphasis on addressing sepsis (77%) and unsafe injection practices (69%). LMCs are notably focused on mitigating surgical complications (84%). In UMCs there is a pronounced emphasis for HCAIs (96%), while most HICs countries have reported to focused interventions on patient falls (86%).



**Fig. 3.6.**  
Prioritization of patient safety programmes to address specific sources of harm, by income group

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

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*Countries worldwide are actively improving patient safety through targeted initiatives, expert committees, and systematic assessments to identify and address critical health care issues.*

## Country mechanisms for identifying major sources of harm and prioritizing improvement initiatives

As a proactive response, many countries have rolled out specific initiatives aimed at assessing current practices and identifying areas for improvement. National committees are often formed, drawing together expertise from various medical domains, to standardize and recommend best practices.

**India** is actively involving expert groups to evaluate clinical practices and creating training modules to spread these best practices across the medical fraternity.

**Bhutan** has embraced clinical audits to explore and identify current practices that need refining.

**The Plurinational State of Bolivia** has utilized assessment of essential conditions to identify and address major sources of patient harm.

**The Islamic Republic of Iran** has an active risk manager and patient safety expert in each hospital.

**Thailand** is championing both patient and staff safety, with expert teams setting objectives and protocols.

**Denmark** has institutionalized its efforts, with the Danish Patient Safety Authority advisory board consistently overseeing and providing guidance on safety measures.

**Uruguay**, through its institutional committees, pinpoints harm sources and errors.

## Patient safety improvement initiatives in clinical disciplines

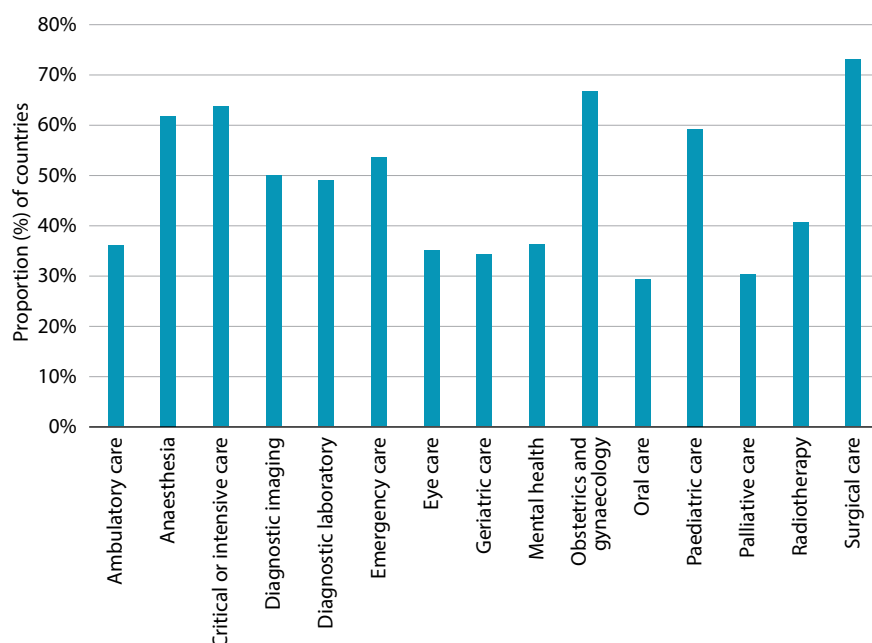
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*Global efforts to improve patient safety vary significantly across clinical disciplines, with high-risk areas such as surgical care receiving greater attention than others such as oral and palliative care.*

Around one fifth (19%) of countries have reported introduction of comprehensive safety initiatives related to most clinical specialties, while 63% have introduced safety programmes in at least one broad clinical discipline.

Safety of surgical care stands out with a significant 73% of countries globally adopting such initiatives, likely due to the inherent complexities and potential risks associated with unsafe surgical procedures. Initiatives on the safety of oral care and palliative care are implemented in only 30% of countries, suggesting a perception of less immediate consequences in these areas. Clinical disciplines such as obstetrics and gynaecology (67%), critical or intensive care (64%), and paediatric care (59%) indicate a widespread acknowledgment of patient safety concerns in these areas (Fig 3.7).

Additionally, survey data underscore that while the health care systems across the world recognize the importance of patient safety, implementation of patient safety strategies and interventions varies considerably across regions (Table 3.1).



**Fig. 3.7.**  
Patient safety initiatives related to specific clinical disciplines

**Table 3.1. Patient safety initiatives related to specific clinical disciplines, by WHO region**

	African Region	Region of the Americas	South-East Asia Region	European Region	Eastern Mediterranean Region	Western Pacific Region
<b>Ambulatory care</b>	14%	52%	40%	36%	45%	33%
<b>Anaesthesia</b>	67%	48%	70%	55%	73%	83%
<b>Critical or intensive care</b>	52%	67%	80%	52%	82%	83%
<b>Diagnostic imaging</b>	38%	43%	60%	45%	73%	67%
<b>Diagnostic laboratory</b>	57%	38%	60%	36%	73%	58%
<b>Emergency and trauma care</b>	48%	52%	50%	45%	73%	75%
<b>Eye care</b>	48%	24%	30%	21%	55%	58%
<b>Geriatric care</b>	14%	33%	40%	42%	45%	33%
<b>Mental health</b>	33%	29%	30%	39%	36%	50%
<b>Obstetrics and gynaecology</b>	81%	62%	60%	52%	91%	75%
<b>Oral care</b>	29%	29%	40%	24%	36%	33%
<b>Paediatric care</b>	67%	62%	40%	48%	73%	75%
<b>Palliative care</b>	33%	29%	30%	30%	27%	33%
<b>Radiotherapy</b>	19%	43%	40%	42%	55%	58%
<b>Surgical care</b>	71%	67%	90%	64%	91%	83%

For instance, certain regions display an acute focus on safety of clinical services such as surgical care, hinting at their response to region-specific challenges, or the outcomes of focused advocacy and policy-making. The lower emphasis on ambulatory and geriatric care in certain regions, could be indicative of limited resources, other pressing health care priorities, or gaps in awareness about these specific areas.

The variability in some disciplines – such as diagnostic imaging – could reflect differing technological advancements, infrastructure capabilities, and training opportunities available in each region.

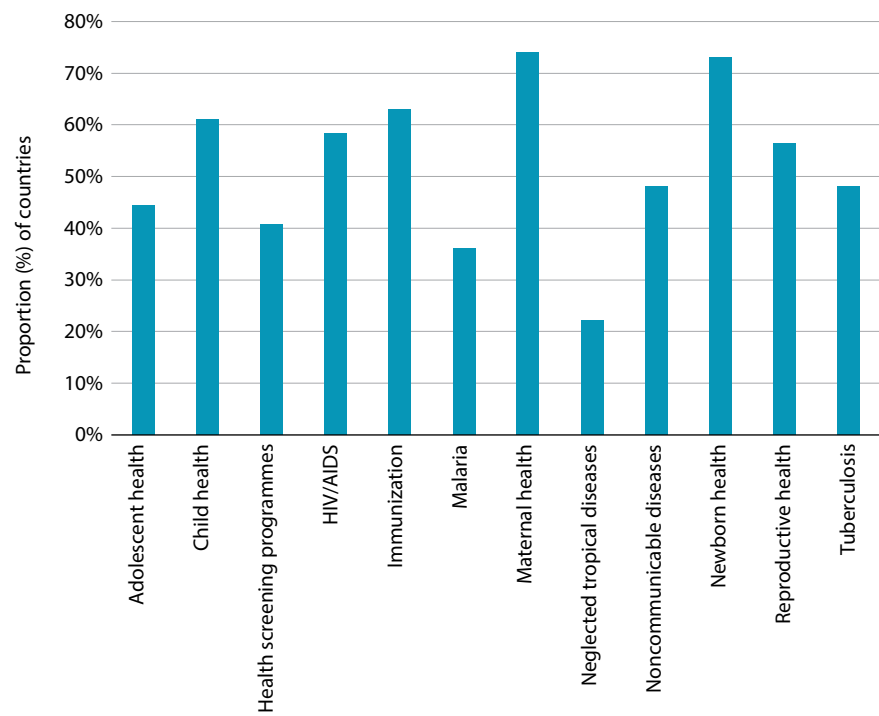


While many countries prioritize patient safety strategies for maternal and newborn health and immunization, there is a need to broaden these efforts to include areas such as malaria and neglected tropical diseases.

**Fig. 3.8.**  
**Patient safety initiatives implemented within public health programmes**

The discrepancies in focus areas across regions signals the necessity for more integrated global collaboration, knowledge exchange and tailored resource allocation to ensure holistic patient safety advancements worldwide.

Several countries have initiated incorporation of patient safety strategies in public health programmes (Fig. 3.8). Globally, initiatives have been most often introduced in maternal health, newborn health, and immunization. Malaria and neglected tropical diseases are among the least addressed areas from a patient safety perspective.



Several countries have taken initiatives to consolidate and disseminate the learning from focused patient safety programmes. 21 countries have reportedly developed a repository of knowledge and tools for patient safety. A further 35 countries reported they have documented and disseminated the lessons learned from patient safety and quality improvement programmes.

Country actions for documenting and sharing lessons learned from patient safety programmes

**Argentina** initiated ‘Patient safety measures in health care’, addressing concerns such as medication and surgical safety, patient falls and HCAs.

In the **United Kingdom**, the National Patient Safety Improvement Programmes (NPSIPs) were launched in 2019. These programmes, aimed at facilitating the NHS Patient safety strategy, focused on reducing harm and improving patient outcomes in priority areas, including maternity and neonatal care, mental health, medication safety, and IPC.

**Spain** rolled out targeted efforts to enhance patient safety during surgical and critical care, and circulates insights gained from their annual patient safety conferences.

**Uganda** has emphasized injection safety and maternal–perinatal care safety.

**Qatar** has prioritized safety measures for VTE and sepsis.

**Kazakhstan** focuses on preventing patient falls and ensuring correct patient identification.

**Ireland** aims to mitigate prevalent sources of harm, with safety enhancement programmes spanning 13 domains, including safety enhancements for those with disabilities and mental health needs, and minimizing preventable birth injuries.

**Indonesia** has developed specialized patient safety programmes tailored to various clinical specialties and disease control.

**Benin, Cameroon, Côte d'Ivoire, Liberia** and **Malawi** all focus on obstetric care safety.

**Peru** has rolled out guidelines for a safe surgery checklist.

**Viet Nam** emphasizes safety in surgical care and laboratory procedures.

**South Africa** introduced an online knowledge hub for national guidelines and resources.

**Sweden** has set up a comprehensive patient safety resource centre under its National Health Board.

**Brazil**, highlighting global best practices in patient safety, has featured them on their World Patient Safety Day website.

**Singapore** shares insights from patient safety and quality improvement initiatives through detailed reports on significant safety events and bulletins.

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*Countries are implementing diverse patient safety programmes addressing specific local challenges, sharing lessons learned, and adopting best practices across various clinical domains to enhance health care quality and patient outcomes.*



Child accompanying her mother at a health facility in a refugee camp in eastern Sudan. © WHO / Ala Kheir

## Feature story 6

### WHO Surgical safety checklist

#### Background

The WHO *Surgical safety checklist*<sup>a</sup> was developed after extensive consultation aiming to decrease errors and adverse events, and increase teamwork and communication in surgery. This simple, low-cost, low-tech solution has been used for over a decade, with demonstrated benefits and acceptability. The 19-item single sheet technical product was an output of the Safe Surgery Saves Lives initiative, launched in 2009, during the second Global Patient Safety Challenge.<sup>b</sup> It was designed to be a non-binding guidance, modifiable to fit local practice, and was not intended to be comprehensive. Its success inspired the creation of the *Trauma care checklist* and the *Safe childbirth checklist*, which are based on the same principles.

#### Development journey

The early pilots of the checklist demonstrated significant reductions in mortality (1.5% to 0.8%) and morbidity (17% to 11%), with greater benefits in LMICs.<sup>c</sup> Subsequent studies failed to replicate this checklist effect. A Canadian study involving over 100 hospitals had equivocal results before and after implementation.<sup>d</sup> There is demonstrable variance in mortality and complication rates across studies.

Despite the variability in results, the checklist is still used in a wide range of settings and this remains testimony to its benefits in surgical outcomes. While use of the complete checklist was encouraged, even partial implementation demonstrated results, mainly related to non-technical skills of improved communication and teamwork.<sup>e</sup> The Surgery safety checklist was a strong advocacy tool for the use of pulse oximeters.<sup>f,g</sup> The learnings from the past decade of implementation were that the checklist alone cannot transform the culture of patient safety.<sup>f</sup> The barriers of senior clinician resistance,<sup>h</sup> poor understanding of the use, single-centre implementation and failure to adapt to the context, are well understood.<sup>i</sup> To drive change in the patient safety culture, the checklist has to be accompanied by standardized care pathways, multidisciplinary training, leadership support and equipment infrastructure. It cannot be sustained simply by policy or by champions.<sup>f</sup>

At the national policy level, some countries have mandated the use of the checklist within their health systems. The National Patient Safety Agency in the United Kingdom implemented the checklist in hospitals within the NHS, for example. A similar mandate is in place in Brazil, France and many other countries, as part of their national patient safety programmes.<sup>f</sup>

#### Way forward

For the coming decade, there is a need for an updated, evidence informed version 2.0 of the checklist. Robust guidance and support on implementation in LMICs is also vital. Implementation science tools, qualitative studies and the policy-to-routine practice gap have been repeatedly emphasized in the successive ministerial patient safety summits, and will be key technical content required to maximize impact.

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Migrant worker using a tele-kiosk to speak with a doctor in a dormitory in Singapore. © WHO / Blink Media - Juliana Tan

Strategic objective 3	3.1	3.2	3.3	3.4	3.5
	Safety of risk-prone clinical procedures	Global Patient Safety Challenge: Medication Without Harm	Infection prevention and control and antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines	Patient safety in primary care and transitions of care

## Strategy 3.2.

# Global Patient Safety Challenge: Medication Without Harm

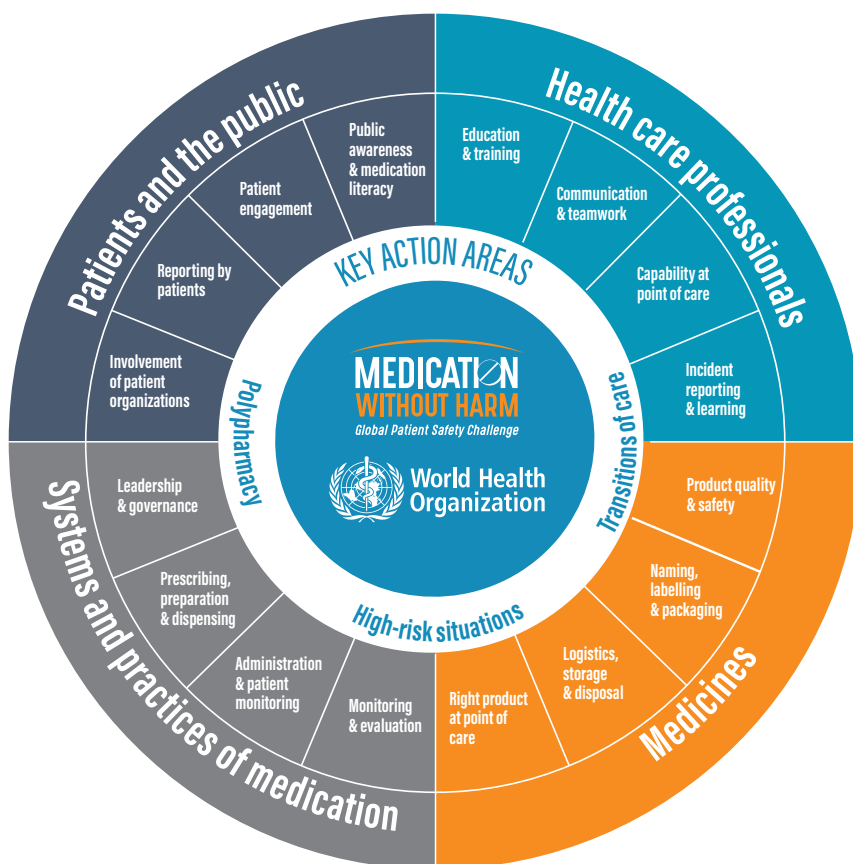


Implement a programme to transform the safety of medication management and use based on the third WHO Global Patient Safe Challenge: *Medication Without Harm*

WHO’s third Global Patient Safety Challenge: Medication Without Harm aims to reduce severe, avoidable medication-related harm by 50% globally through coordinated efforts across all health care stakeholders

Medication is a vital part of health care, but medications can also cause serious harm if not used safely. According to a recent study, medication-related harm accounts for up to half of the overall harm in health care systems worldwide (186). Medication errors can happen at any stage of the medication use process, from prescribing to monitoring. Various factors – including weaknesses in the medication use process, human factors such as fatigue, poor work environment conditions and staff shortages – increase the risk of errors. To address this major risk to patient safety, WHO launched the third Global Patient Safety Challenge with the theme ‘Medication without harm’ (Fig. 3.9).

The initiative aims to reduce severe, avoidable medication-related harm by 50% globally. This requires a coordinated effort from all stakeholders involved in medication safety, from policy-makers to health care leaders, and from health workers to patients and their families.



**Fig. 3.9. Schematic showing the strategic framework of the third WHO Global Patient Safety Challenge: Medication Without Harm**

## Domains and sub-domains of the WHO Global Patient Safety Challenge: Medication Without Harm

### Domain 1: Patients and the public

The general public are not always well informed about medications, and it can be difficult to understand health information. Moreover, patients are too often regarded as passive recipients and are not empowered to play their part in making the medication process safer. The Challenge seeks to educate, engage and empower patients, as well as their family members and caregivers, to take an active role, provide feedback, and report on medication safety incidents. The Challenge aims to raise public awareness and health literacy.

### Domain 2: Health care professionals

To reduce medication-related harm, it is essential to enhance the competence and performance of health care professionals who are involved in the medication use process (i.e. through prescribing, ordering, storage, dispensing, preparation, administration and monitoring). This requires stakeholders responsible for standards and curriculum setting, and health care organizations,

*Patient empowerment and health worker professional competence is crucial to reducing medication-related harm, by actively involving patients in their care and improving the education and practices of health care professionals involved in medication management.*



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*Reducing medication errors requires both regulatory actions to improve medication naming, labelling, and packaging, and the implementation of resilient health care systems and practices that promote safety.*

to invest in appropriate education, training and skill development of health care professionals, using patient-centred care and competency-based learning approaches. Patient-centred multidisciplinary teams lead to improved teamwork and increased focus on communication at transitions of care and clinical handovers, reducing the risk of medication-related harm.

### **Domain 3: Medicines as products**

Many medication errors are caused by misleading medication names, labels or packages. Sometimes, medicines have similar names that can be easily confused, they may look very similar to one another, do not have clear warnings about interactions or other important considerations, or may have insufficient information on how to use them safely. Appropriate logistics, storage and disposal systems can reduce medication-related harm: to health care professionals in the context of the Challenge, patients, the public and the environment. The Challenge urges countries to take regulatory action on the naming, labelling and packaging of medications to reduce the risk of medication errors.

### **Domain 4: Systems and practices of medication**

To ensure the safety of medication use, health care systems and practices need to be well designed and resilient to risk and harm. This requires effective and efficient leadership and governance at the national, facility and community levels, such as blame-free reporting, learning from medication errors and near misses, promotion of medication safety research, supportive legislation and evidence-based decision-making. At the point of care, unsafe practices can be prevented by using standard operating procedures (SOPs) and best practices, such as prescribing guidelines, dispensing protocols, and user-applied labelling of injectable medicines and other medications prepared or compounded by health care professionals.

## **Implementation of the third Global Patient Safety Challenge: Medication Without Harm at the national level**

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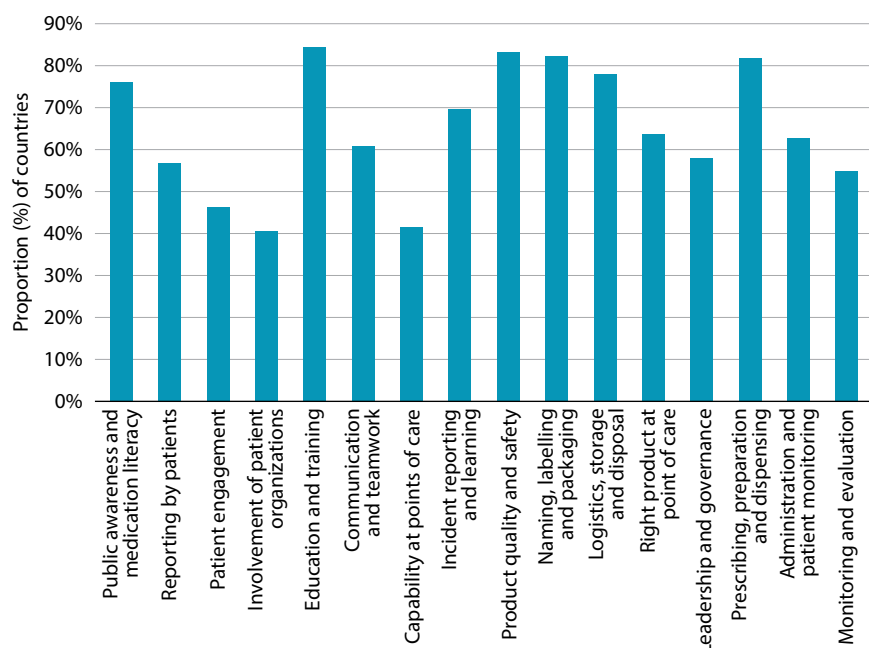
*While 74% of countries have endorsed the Medication Without Harm challenge and are implementing related activities, there is significant variation in their priorities, with most focusing on regulatory aspects and education and training.*

The Member State survey reveals that 74% of countries have endorsed the third Global Patient Safety Challenge: *Medication Without Harm*, and are implementing the activities aligned with the four domains of the Challenge. Nevertheless, there is considerable variation in how and what countries have prioritized for implementing the Challenge.

Most countries reported working on regulatory aspects and safety of medicines as products, such as product quality and safety (83%), naming, labelling and packaging (82%), and logistics, storage and disposal (78%) (Fig. 3.10). Countries have also prioritized working on public awareness and medication literacy (76%), education and training (84%) and safety of medication use process (90%)



while prescribing, preparation and dispensing. The most neglected areas are the involvement of patient organizations and building the capability of health care professionals at the point of care.



**Fig. 3.10.**  
Country implementation of the third Global Patient Safety Challenge

## Key action areas for medication safety

The Challenge identified three key action areas for countries and institutions to prioritize to reduce medication errors:

### ● High risk situations

Some clinical situations have a higher risk of harm, these can be related to medications that are used, patient and provider factors, or systems (work environment). Interruptions in the workflow, use of high-risk/high-alert medications that have a narrow therapeutic window or medicines that are otherwise prone to errors lead to high-risk situations. Medication errors can affect some groups of people more than others, such as very young children, older adults, and those with kidney or liver problems.

### ● Polypharmacy

Another factor that can contribute to medication errors is polypharmacy, which means taking four or more medications at the same time. Sometimes patients use or are prescribed unnecessary medications, but for some patients, it is clinically necessary to have multiple medications, thus it is important to assess the appropriateness of polypharmacy. Polypharmacy is especially common among older adults with multimorbidity. Polypharmacy can reduce the quality of life, increase the risk of side-effects and falls, cause interactions, and lead to medication non-adherence, which can all affect the safety and effectiveness of the medications.

*To reduce medication errors, countries and institutions should prioritize addressing high-risk situations, managing polypharmacy, and ensuring safe transitions of care, as these are critical areas where errors are most likely to occur and cause harm.*

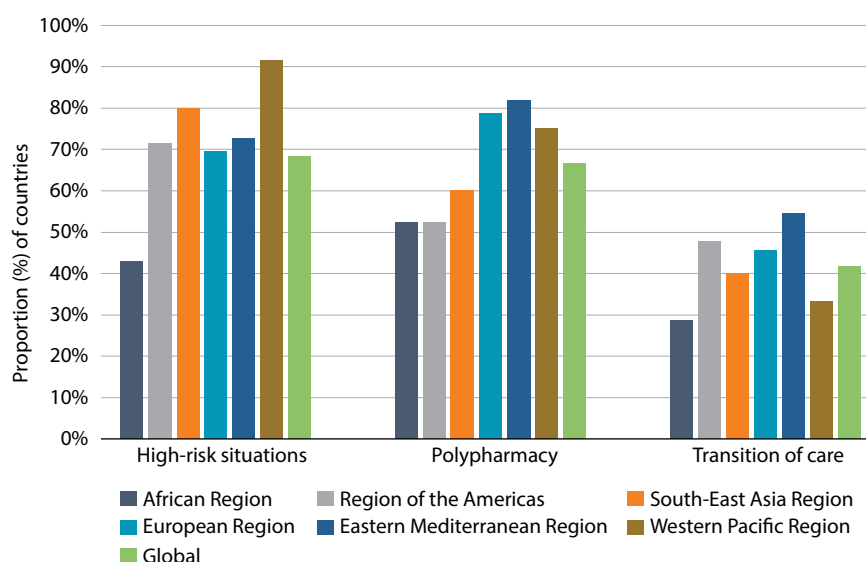
## ● Transitions of care

Only 27% of countries have addressed all three key action areas for medication safety, with most prioritizing high-risk situations.

Medication errors can also happen when patients move from one setting to another, such as from a hospital to a home, from a nursing home to a hospital, or from a primary care provider to a specialist. These transitions of care can create communication gaps, that can lead to missing, incorrect or duplicated information about medications. This can result in serious errors that can harm patients. Therefore, transitions of care are critical moments for preventing and detecting medication errors.

The results of the Member State survey show how many countries in individual WHO regions have taken early action to protect patients from harm arising in these three key areas (Fig. 3.11). Only 27% of countries have reported taking action on all three key action areas, while most other countries (65%) have focused on at least one of them. High-risk situations are the most common priority among countries (69%), followed by polypharmacy and transitions of care. The highest level of early action is found in the European Region and Western Pacific Region.

**Fig. 3.11.**  
Actions taken by countries to reduce medication errors in the three key action areas, by WHO region

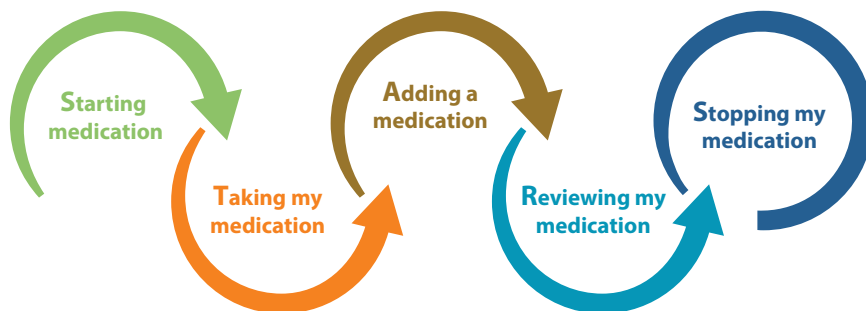


Convening of a national expert group has been proposed to support systematic implementation across all four domains of the Challenge. The recommended group composition includes representatives from various stakeholders, such as medication safety experts, health professionals, regulators, policy-makers, patients and civil society. Member State survey responses reveal that only 18% of countries have a functional national expert group formed.

## Patient education about medicines

An effective strategy to improve medication safety is to educate patients about their medicines and how to use them correctly. Patients can play an important role in preventing medication errors and harm by being aware and informed about the important moments within the medication use process. WHO has developed a patient engagement tool called 5 Moments for Medication Safety

to help patients do this. The tool describes five key moments when patients or caregivers can ask critical questions to reduce the risk of medication-related harm (Fig. 3.12). Some questions are for the patients to think about themselves, and some need the help of a health professional (187).



**Fig. 3.12.**  
**Schematic summary of the**  
**WHO 5 Moments for medication**  
**safety tool**

According to the Member State survey, the majority of the countries have taken some steps to educate the public about the safe use of medicines. Furthermore, a quarter of them have launched specific platforms and campaigns in both mass and social media to increase awareness of this issue.

### Country initiatives to improve the safety of medication use

**Switzerland** is testing new ways to reduce overmedication and inappropriate prescribing in nursing homes.

**Portugal** has issued guidelines on how to prevent errors and adverse events with high-risk medicines, how to reconcile medication lists during transitions of care, and how to optimize the medication management process.

**Ghana** is promoting the rational use of medication for chronic diseases in partnership with civil society organizations.

The **United States** has developed a national action plan to prevent adverse drug events caused by anticoagulants, diabetes drugs and opioids.

**Poland** is using digital technologies to address the problem of polypharmacy among older adults.

**Mozambique** has taken action to address the priority areas of the challenge, and the future steps include exploring more digital solutions.

**Bhutan** is using key performance indicators, including targets, to address medication-related harm.

Among many other countries, **Niger** has systems in place for reporting medication-related harm in facilities.

Some countries have also taken steps to improve medication safety at the national level:

**Sri Lanka** has launched a national action plan on medication safety.

*Countries are implementing various strategies to enhance medication safety, including reducing overmedication, issuing guidelines for high-risk medicines, promoting rational use for chronic diseases, developing plans to prevent adverse drug events, and using digital technologies to address polypharmacy.*

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*Countries are enhancing medication safety through national action plans, expert committees, and public awareness initiatives, focusing on improving safe medication practices and educating the public about the risks and proper use of medicines.*

**Sudan** has established a national medication safety committee.

**Cuba** has established a three-tier system for medication safety with a national pharmacology group at the national level, a pharmacy society at the subnational level and drug and therapeutic committees at the health care institution level.

**Spain** has established expert groups in collaboration with the Institute for Safe Medication Practices (ISMP).

A national multidisciplinary expert group has been established in **Indonesia** (Komite Nasional Keselamatan Pasien).

As part of the national patient safety strategy, **Finland** is committed to improve safe medication practices and is in the process of setting a national indicator for medication safety.

Some countries are also raising public awareness of safe medication practices:

**Malaysia's** pharmaceutical services division has launched a website that provides information and guidance on how to use medicines safely and effectively.

**Brazil** celebrates May 5th as the day for rational use of medicines and has created a dedicated website that informs the public about the benefits and risks of medicines.

The **United States** Food and Drug Administration (FDA) regularly communicates with the public about drug safety issues and updates. The US CDC also runs campaigns to educate the public about appropriate antibiotic use and safe storage of medicines away from children.

**Czechia** has developed a web portal that informs the public about common safety issues with widely used medicines.

**Kazakhstan's** national centre for rational use of medicines operates a website that offers drug information and education for both health professionals and the general public. The website also has a section where people can ask questions and get answers about safe use of medicines.

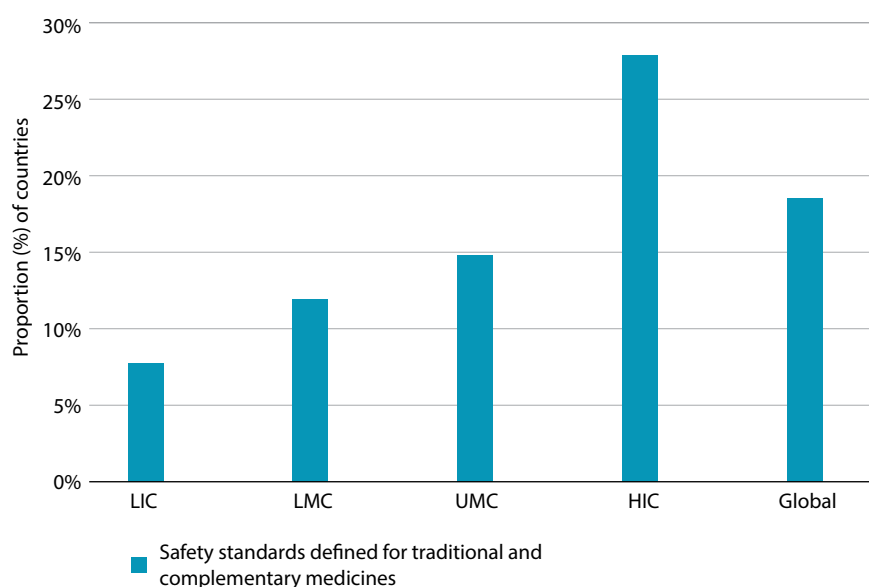
## Safety initiatives for traditional and complementary medicines

Traditional and complementary medicine (TCM) is a health practice with strong historical and cultural roots across the world. WHO acknowledges the contribution of TCM to health, wellness, people-centred health care and UHC and seeks to bring evidence-based traditional medicine into the mainstream of health care, appropriately, effectively and, above all, safely.

According to the WHO Global report on traditional and complementary medicine 2019 (188), 170 Member States have reported on the use of traditional medicine by their populations. Because many are considered natural, they are perceived to be safer than pharmaceutical products. However, contrary

to popular belief, traditional medicine products are not always safe and can have negative health consequences, including allergic reactions, overdose or interactions, particularly when used in combination with other medicines or when taken in inappropriate combination of different medicinal plants in one formula/prescription. Moreover, there is a risk that a TCM product is contaminated (e.g. with pesticides, heavy metals or other substances), or practices may lead to trauma due to inexperienced or poorly trained practitioners (189).

WHO has issued several guidelines for benchmarking the training and practice of TCM, including: good clinical practice, good manufacturing practice, pharmacovigilance (PV) and quality control of herbal medicines (190–193). The ever-growing use of TCM interventions and cross-border trade of herbs calls for a robust research methodology and appropriate regulations to augment the standardization, safety, quality, efficacy and post-marketing surveillance of TCM products.



*TCMs can significantly contribute to health, wellness and people-centred care, however, despite their natural origins, they are not always safe and can pose health risks, necessitating careful and effective integration into mainstream health care.*

**Fig. 3.13.**

**Safety standards for traditional and complementary medicines, by income group**

The safety of TCMs can be monitored through a national PV system. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-/vaccine-related problem.

According to the Member State survey, more than half of the countries have included TCM-related adverse events in their pharmacovigilance system (Fig. 3.13). Moreover, only 19% of countries have set safety standards for TCM products and practices. These gaps pose challenges for ensuring the quality and safety of TCM services and products.

Many countries have established safety standards for TCMs, either by regulating them as pharmaceutical products or by creating specific related programmes and committees:

**Chile** has defined safety standards for traditional and herbal medicines by its Ministry of Health.

*To ensure the quality and safety of TCMs, it's crucial to include TCM-related adverse events in national pharmacovigilance systems and establish safety standards*

Many countries are establishing safety standards and monitoring systems for traditional and complementary medicines to ensure their quality and safety, addressing significant gaps in pharmacovigilance and regulation.

**El Salvador** monitors TCMs through its national pharmacovigilance system.

**Sri Lanka** has an Ayurveda Formulary Committee and an ADR reporting mechanism for traditional medicines.

**Côte d’Ivoire** has a national programme for the promotion of traditional medicine.

**Ghana** has formed Traditional Medicine Practice Council as a statutory institution under the Ministry of Health.

**Panama’s** Law 17 (2016) regulates the protection of traditional indigenous medicine and has an article focusing on safety and quality.

**South Africa** requires the registration of complementary medicines with the regulatory authority, which ensures their quality, safety and efficacy.

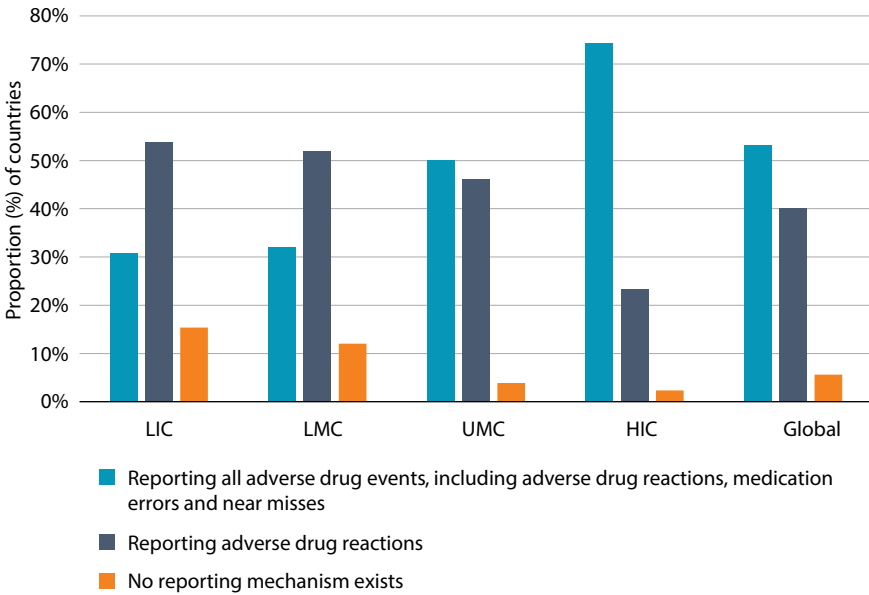
**Poland** integrates reporting of adverse reactions from TCM products into its pharmacovigilance system.

### Mechanisms of reporting and measuring adverse drug events and medication-related harm

Comprehensive ADE reporting is vital for medication safety, yet significant gaps remain, especially in low- and middle-income countries where reporting often only includes adverse drug reactions.

To achieve and monitor the objectives of the third Global Patient Safety Challenge, nations need to evaluate the prevalence of harm caused by medications in their specific contexts. The process of reporting ADEs provides valuable insights that can enhance medication safety. While the vast majority of countries (94%) have some form of ADE reporting system in place, the content of what is reported varies based on the maturity and scope of their pharmacovigilance, and PSIRLs (Fig. 3.14). In HICs, about three quarters of the countries have reported that all ADEs, including ADRs, medication

**Fig. 3.14.**  
Variation in reporting of adverse drug events, by income group



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



errors and near misses, are reported from health care facilities. However, this comprehensive reporting drops to 31% in LICs. The majority of LICs and LMCs currently report only ADRs, revealing a significant gap in learning from medication errors and improving the medication use process.

In addition, nearly one third of countries have established indicators for medication-related harm, and 21% of countries have set a national target for reducing medication-related harm. However, only 17% of countries have recently (within the past five years) reported estimates of the burden of medication harm in their nation.



*Mother and child at a hospital in Rzeszow, Poland, for medical tests. © WHO / Christopher Black*



## Feature story 7

### A national action plan for medication safety in Sri Lanka

#### Summary

The Sri Lanka Directorate of Healthcare Quality and Safety (DHQS) is the designated office for patient safety and quality of care in the Ministry of Health, Sri Lanka. The National action plan on medication safety for Sri Lanka,<sup>a</sup> developed in response to the third WHO Global Patient Safety Challenge, provides a roadmap for improvement of medication safety across the country. The priority of the DHQS leadership has been to focus on small scale, achievable change to improve medication safety, and on transferrable learning for scaling up improvement across a range of care settings.

#### What was done and why?

Guided by early stakeholder engagement and analysis of data from multiple sources, the Directorate developed a range of projects based on the four domains of the WHO Global Patient Safety Challenge:

**Patients and the public** – by consulting with patient advocacy groups on ways that patients can play a role in medication safety, they have:

- translated medication labels from English to Sinhala and Tamil to make information more understandable;
- used the WHO 5 moments for medication safety tool<sup>b</sup> to guide the design of educational videos for patients; and
- developed patient information leaflets on the most frequently prescribed medicines.

*“We wanted to improve patient knowledge about the medicines they are taking. We found that patients often don’t know the names of their medicines or the indication: they describe it by its appearance. One of the reasons of poor medication literacy is that medicines labels are often written in English. When labelling is done in a language that patients’ understand, this would improve patients’ knowledge of medicines they use and would encourage them to actively participate in discussions about their medications.”*

*(National action plan team member)*

**Health care professionals** – considering how education for future and practicing professionals can improve outcomes, they have:

- supported universities to identify areas that should be included in the health care curricula;
- tackled the issue of illegible handwritten prescriptions by introducing electronic prescribing and assigning identifiers of prescribers to aid traceability; and
- held a national competition for hospitals, on medication safety activities implemented for World Patient Safety Day 2022.

*“Many of the most successful projects focussed on simple and easily reproducible ideas... legible and accurate documentation, clear labelling of shelves and racks, standardization of medication trolleys, customized drug charts, and labelling and safe packaging of drugs.”*

*(National action plan team member)*

## Medicines

Identified a list of ‘look-alike, sound-alike’ medicines and ‘high-alert’ medicines for distribution to health facilities with recommendations such as labelling, segregating storage and using ‘tallman’ lettering (the practice of writing part of a medicine’s name in upper case letters to help distinguish from other medicines).

Systems and practices

Introduced a new medication safety incident reporting and learning form and a mechanism to implement preventive actions.

### What’s next?

The focus on simple interventions that can be scaled up across different settings is a perceived strength of the work. Emphasis on early stakeholder engagement and collaboration between institutions has led to greater standardization of practices and buy-in from professionals for their adoption. The Directorate team is hopeful that the approach sets a strong foundation for sustainable improvement.

Sources:

<sup>a</sup> Dharmaratne GSK, Ranaweera D, Galappatthy P, Liyanage P, Prabha DGAS. National action plan on medication safety for Sri Lanka. Colombo: Directorate of Healthcare Quality and Safety, Ministry of Health Sri Lanka; 2021 ([https://quality.health.gov.lk/images/2021/Medication\\_safety\\_book\\_13-09-2021\\_complete.pdf](https://quality.health.gov.lk/images/2021/Medication_safety_book_13-09-2021_complete.pdf), accessed 24 April 2024).

<sup>b</sup> 5 moments for medication safety. Geneva: World Health Organization; 2019 (<https://iris.who.int/handle/10665/311153>, accessed 24 April 2024)

Strategic objective 3	3.1	3.2	3.3	3.4	3.5
	Safety of risk-prone clinical procedures	Global Patient Safety Challenge: Medication Without Harm	Infection prevention and control and antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines	Patient safety in primary care and transitions of care

## Strategy 3.3.

# Infection prevention and control & antimicrobial resistance



Put in place rigorous and evidence-based measures for infection prevention and control to minimize the occurrence of health care-associated infections and antimicrobial resistance

Health care-associated infections (HCAIs) are a major challenge for patient safety and quality of care in health facilities. They affect both patients and health workers, especially in LMICs, where the risk of acquiring an infection is around twice as high as in HICs (75). Various microorganisms can cause HCAIs, and many may be resistant to antimicrobial medicines, making them difficult to treat and control. The costs of health care are increased by HCAIs as they prolong hospital stays, require additional tests and treatments, and may result in disability or death.

*HCAIs significantly impact patient safety and health care costs, especially in LMICs, highlighting the critical need for comprehensive, multidisciplinary infection prevention and control measures to protect patients and health workers.*

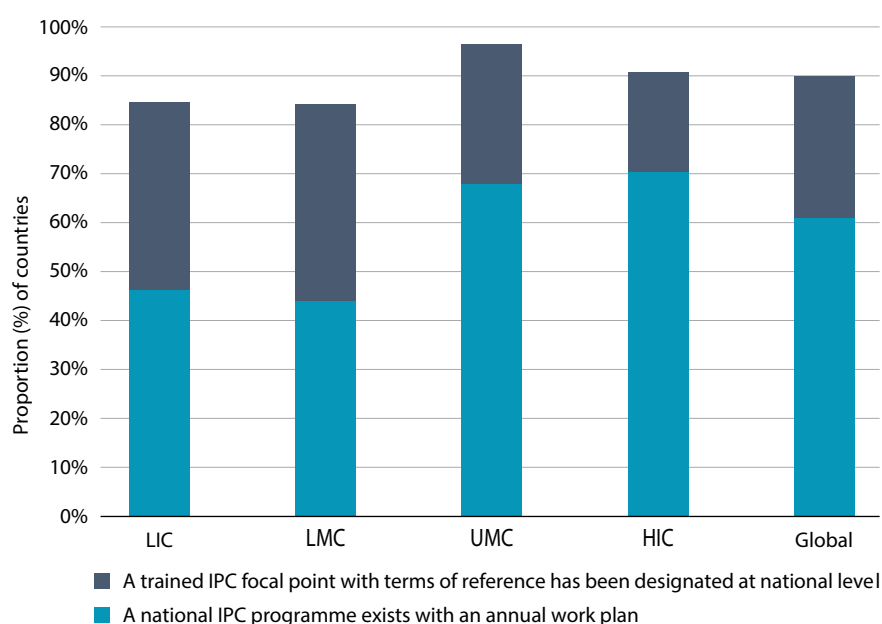
Infection prevention and control (IPC) approaches protect patients, health workers and visitors from avoidable infections. IPC encompasses various aspects of health care delivery, such as integration with care practices pathways, design and renovation of health care facilities, process flow and management of patient beds, among others. IPC requires a multidisciplinary approach that involves collaboration among health workers, IPC professionals, hospital planners, administrators, engineers and patients.

The WHO Global Patient Safety Action Plan urges governments to take action to ensure patient safety by implementing effective IPC programmes in health care facilities. This includes adapting WHO technical guidance and strategies to the national context, building capacity for IPC core components, and reporting HCAIs, AMR, and other adverse events to local and national authorities.

## National infection prevention and control programmes

According to Member State survey responses, the majority of countries (60%) have national IPC programmes. Another 30% are in the process of developing a national programme and have appointed an IPC focal point with a clear role at the national level. However, there are significant differences among the WHO regions. Countries of the European Region and Eastern Mediterranean Region have the highest proportion of IPC programmes (82% and 80% respectively), while those of the South-East Asia Region have the lowest (36%). Responses from the African Region, the Western Pacific Region and the Region of the Americas were 43%, 67% and 62% respectively.

The presence of national IPC programmes increases with higher income levels (Fig. 3.15).



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

*While 60% of countries have national IPC programmes and 30% are developing them, significant regional disparities exist.*

**Fig. 3.15**  
Status of national IPC programmes, by income group

## Infection prevention and control guideline implementation and monitoring

One way to improve IPC programme implementation is to use a multi-modal strategy, which involves several integrated elements (usually five) that guide and focus implementer actions. These elements are: 1) system change – providing the necessary infrastructure, equipment, supplies and resources for IPC; 2) training and education – improving the knowledge of health and care workers on IPC; 3) monitoring and feedback – monitoring and using IPC data, driving change and documenting improvements; 4) reminders and communications – using posters, visuals, etc. as part of campaigns; and 5) a safety culture – creating an organizational environment that values the intervention, with the support of senior managers, champions or role models (194).

Around half of countries are implementing IPC guidelines using WHO multi-modal strategies.

The Member States survey revealed that most countries have developed national IPC guidelines (91%). More than half of the countries (51%) reported they implement their IPC guidelines using WHO multi-modal strategies. The IPC guidelines are widely available across all the WHO regions and income groups. However, the implementation of a multi-modal strategy is more prevalent in UMCs and HICs. Furthermore, only 40% of countries reported that they have a system for monitoring and evaluating compliance with IPC guidelines and an integrated system for regular collection, analysis and feedback of data.

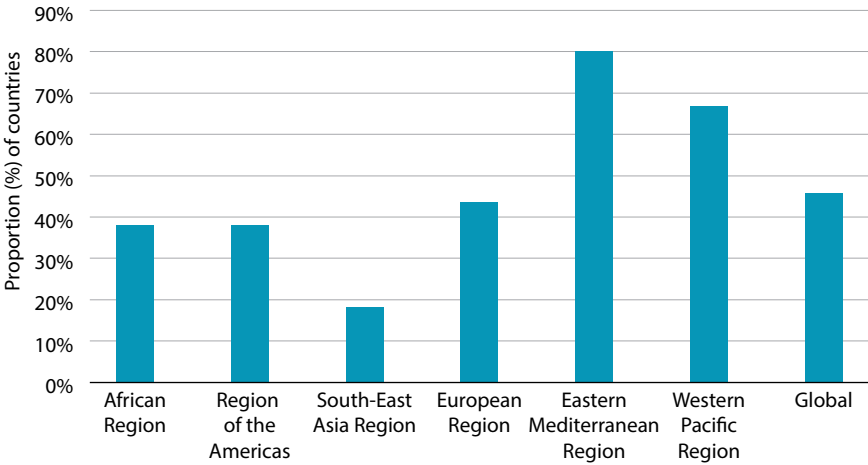
## Infection prevention and control education and training

It is essential that health and care workers receive education on how to prevent and control infections. This should involve team- and task-based approaches that require active involvement and hands-on learning. This can involve training at the bedside and using simulation scenarios to practice skills and knowledge. For this to happen, countries should have a national policy that mandates in-service IPC training for all health workers and have an approved IPC national curriculum that aligns with national guidelines and is endorsed by the appropriate body. A standardized and comprehensive IPC training can help improve the safety of health care services and prevent the spread of infections and AMR.

Despite widespread in-service training policies for IPC, less than half of the countries have standardized IPC training in their national curricula.

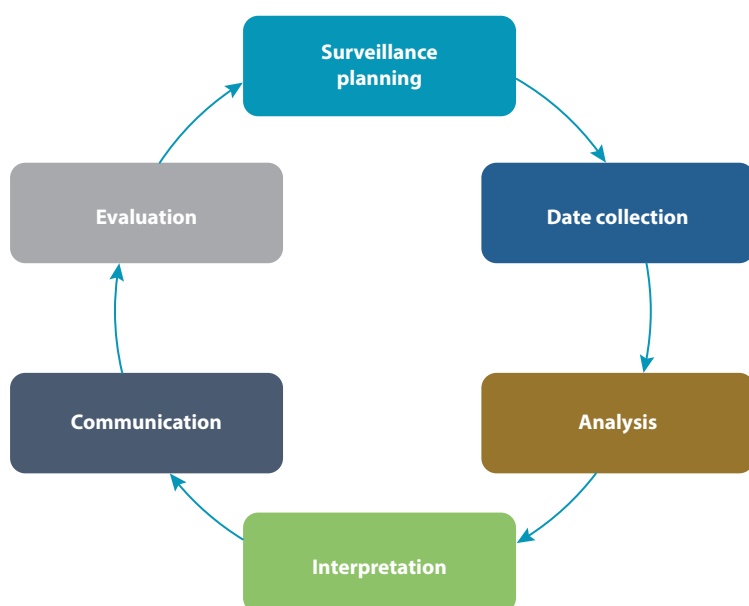
According to the Member State survey, almost all countries (91%) have a policy to train health workers on IPC through in-service training. However, less than half of the countries (46%) have a national curriculum for IPC training that is consistent with the national IPC guidelines for both in-service and pre-service trainings. The survey also shows significant variations among WHO regions (Fig. 3.16). National curricula for IPC were most frequently reported in the Eastern Mediterranean Region (80%) and least common in the South-East Asia Region (18%).

**Fig. 3.16.**  
Status of national infection prevention and control curricula for in-service and pre-service training and education, by WHO region



## Health care-associated infection surveillance

Surveillance for HCAs is a key strategy to prevent and control infections that occur in health care settings (Fig. 3.17) (75, 76, 195–200).



**Fig. 3.17.**  
▶ **Cycle of health care-associated infection surveillance**

Surveillance helps track the frequency, causes and impact of HCAs, identify gaps and priorities, assess the effectiveness of interventions, and provides feedback and guidance to health workers and managers. A multidisciplinary technical group for HCAI surveillance and IPC monitoring should be established by countries to develop a national strategic plan for HCAI surveillance, with a focus on priority infections based on the local context and IPC monitoring. At the facility level, active HCAI surveillance should be performed, including information on AMR. The surveillance system should have adequate structures and resources (e.g. reliable laboratories, medical records and trained staff), guided by an appropriate method of surveillance. Feedback should be given to key stakeholders, especially hospital administration, in a timely and regular manner to prompt appropriate actions.

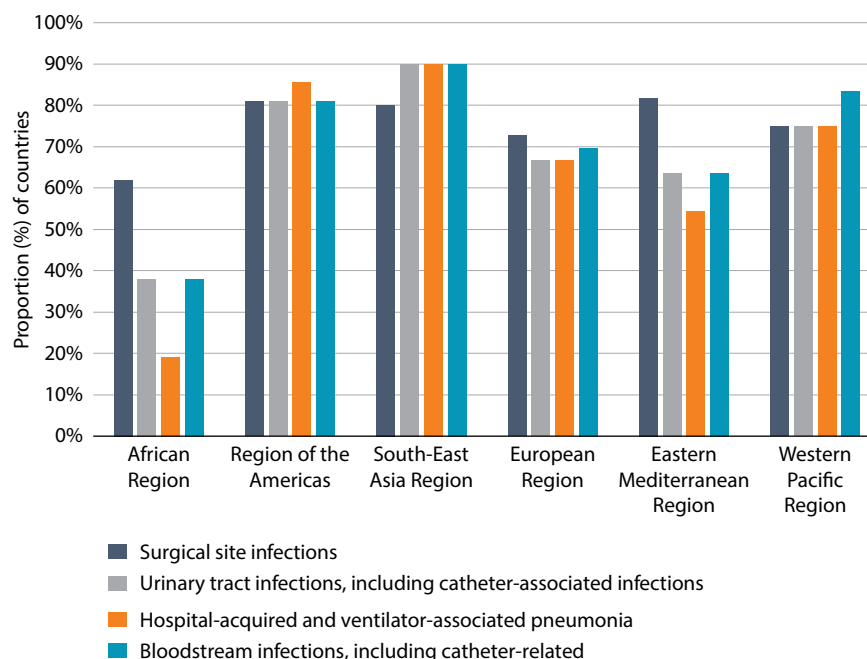
According to the Member State survey results, more than half of the respondents (51%) indicated that their country has an active and reliable system of surveillance for HCAs that regularly produces quality-controlled data. Another 35% of the participants stated that their country is in the process of developing such a system and has already formed a technical group to plan and implement it. 11% of the participants reported that their country does not have any HCAs surveillance system in place. Most HICs and UMCs have established systems for monitoring HCAs. However, the types of HCAs that are measured and adopted definitions vary widely.

Surgical site infections are the most frequently reported HCAI category in most regions (Fig. 3.18).

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*Over half of the surveyed countries have established a functional surveillance system for HCAs.*

**Fig. 3.18.**  
Most frequently reported  
health care-associated infection  
categories, by WHO region



Only 38% of the 108 surveyed countries have established national targets to reduce the rate of health care-associated infections.

According to survey responses, 45% of countries have implemented some measures to assess the impact of HCAs. However, there is a lot of variation in the indicators and methods used for measuring HCAs. Countries have variously used prevalence, incidence or a combination of both, to estimate the extent of HCAs. Several countries have conducted regular point prevalence surveys to monitor the HCAs situation. Out of 108 countries, only 38% have set national targets for lowering the rate of HCAs.

### Country experience and good practices with infection prevention and control programmes

The IPC programmes in **Belize, Brazil, Indonesia, Liberia** and **Romania** are national initiatives that aim to prevent and control HCAs. They involve assigning IPC nurses, developing guidelines, conducting trainings and collaborating with various stakeholders.

Countries are improving IPC through national programmes that establish rigorous guidelines, ensure regular training, and implement monitoring systems to protect patients in health care settings.

**Botswana, Burkina Faso, Islamic Republic of Iran, Malawi, Maldives, Norway, Seychelles** and **Sudan** are some of the countries that have developed and implemented national IPC guidelines in their health care settings. These guidelines are based on the best available evidence and international standards, and cover various aspects of IPC including waste management, sterilization, isolation, operation theatre procedures, blood collection and surveillance. The guidelines are also aligned with the accreditation and quality assurance systems of each country, and are monitored and evaluated regularly by the relevant authorities. The aim of these guidelines is to protect the health and safety of patients, health workers and visitors from the risk of infections.

Each hospital has an IPC committee in **Jamaica**. In **Trinidad and Tobago** in addition to individual hospitals, each regional health authority also has an IPC department. **China** and **Guinea-Bissau** have made IPC training and education available for all health workers.



Many countries have implemented surveillance systems for HCAs. For example: **Argentina** has the VIHDA National Program of Epidemiology and Hospital Infection Control; **Bhutan** has quality monitoring indicators for HCAs; **Finland** performs prevalence and incidence studies for HCAs; **France** has national prevalence surveys of HCAs and anti-infectious treatments; **Israel** has a system for monitoring and evaluation of IPC guidelines and indicators; **Kazakhstan** has official reporting of HCAs and pilot studies using point prevalence survey methodology; **Qatar** has the National Healthcare Associated Infection Surveillance Policy and System; **Türkiye** has the National Nosocomial Infections Surveillance Network; and **Uruguay** has the National Epidemiological Surveillance System for Hospital Infections.

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*Countries have implemented diverse surveillance mechanisms for HCAs, ranging from national prevalence surveys and quality monitoring to official reporting and pilot studies.*

Strategic objective 3	3.1	3.2	3.3	3.4	3.5
	Safety of risk-prone clinical procedures	Global Patient Safety Challenge: Medication Without Harm	Infection prevention and control and antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines	Patient safety in primary care and transitions of care

# Strategy 3.4. Safety of medical devices, medicines, blood and vaccines



Assure the safety of medical devices, medicines, blood and blood products, vaccines and other medical products

Ensuring the safety, quality, and efficacy of medical products is vital, as substandard and falsified medicines pose significant health risks and are linked to many preventable deaths.

Quality-assured, safe and effective medicines, vaccines, blood and blood products, other biologicals and medical devices are fundamental to a functioning health system. Such products can prevent, diagnose, treat or cure various diseases and conditions, but they can also pose risks as a consequence of adverse effects, infections, injuries or malfunctions.

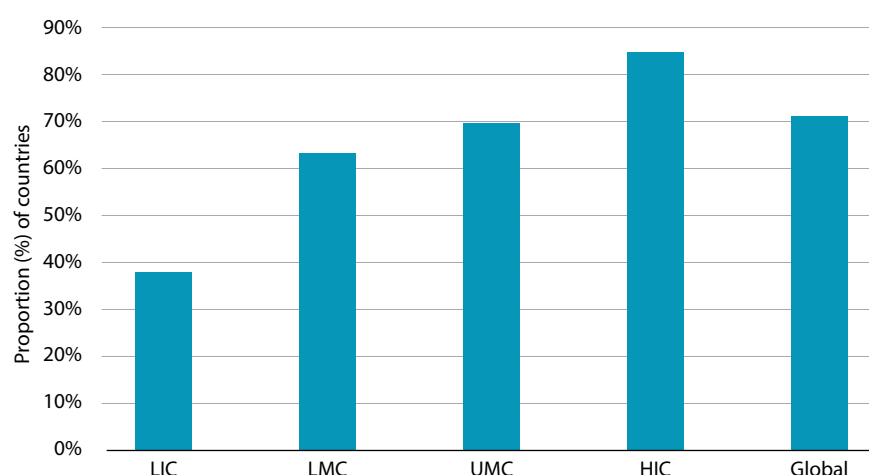
Substandard and falsified medicines are a serious threat to the health and safety of patients. According to a WHO study (201), about 10% of the medicines in LMICs are estimated to be substandard or falsified. Such products are also a problem in HICs, particularly when patients purchase medical products through informal markets including unregulated online marketplaces (202).

Each year, substandard and falsified medicines cause around 250 000 deaths from tuberculosis (TB) alone (11). Similarly substandard and falsified antimalaria medicines contributed to an estimated 72 000–267 000 deaths in sub-Saharan countries (201). As a result, it is important to ensure that medical products meet the highest standards of safety, quality and efficacy before they are authorized to be prescribed by health workers, and for use by patients. The Global patient safety action plan 2021–2030 recommends ongoing improvement in the safety of medical products through appropriate policies, laws and regulations and through linkages with patient safety programmes.

## Safety regulations for medicines and medical products

Regulatory authorities are responsible for overseeing the development, evaluation, approval and monitoring of these products, as well as for enforcing the relevant laws and regulations. They also collaborate with pharmaceutical developers and manufacturers, researchers, health workers and patients to promote the safe use of medicines and medical products and to address any emerging issues or concerns. However, many countries around the world lack the capacity to provide adequate regulatory oversight, which poses a risk to public health and may also hinder access to essential medical products. It is crucial to help regulatory authorities perform their role in competent, efficient, consistent and transparent ways.

Member State survey responses show that most countries have established policy and regulatory frameworks to ensure the safety of medical products. A large proportion of countries (72%) have comprehensive policy and regulatory frameworks that cover key medical products such as medicines, vaccines, blood and blood products, as well as medical devices. The remaining countries have a limited regulatory framework that may not encompass all medical products (Fig. 3.19).



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

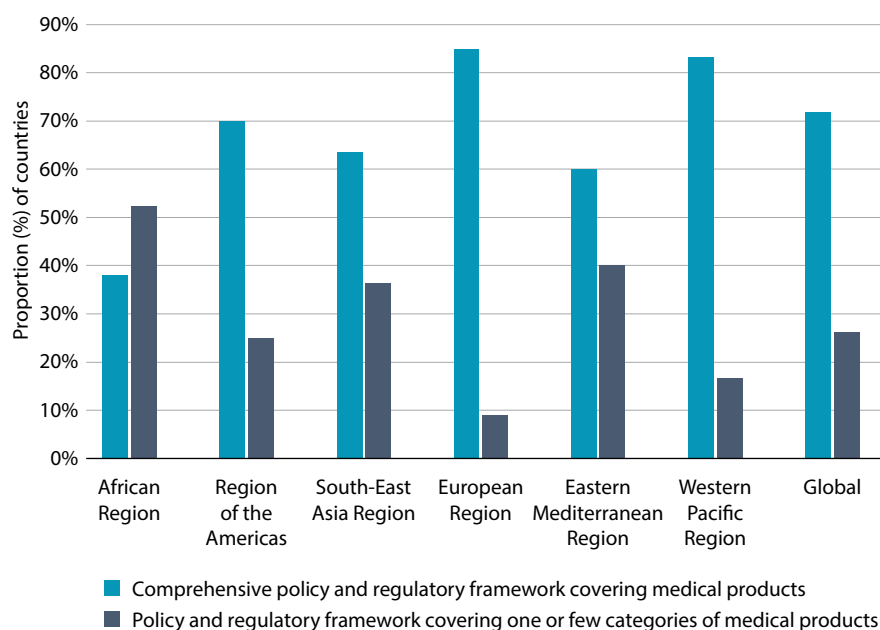
While these data show a positive trend, the comprehensiveness of the regulatory frameworks varies across income groups, with higher income groups having more inclusive frameworks for all categories of medical products. There is also considerable regional variation in policy and regulatory frameworks (Fig. 3.20) with countries of the European Region and Western Pacific Region having more comprehensive frameworks than others.

Regulatory frameworks are essential for ensuring the safety of medical products, but they may not be sufficient. As part of these regulatory approaches, product safety surveillance programmes are also implemented, such as pharmacovigilance for medicines and haemovigilance for blood and blood products.

*According to the Member State survey, around three quarters of countries have established comprehensive regulatory frameworks to ensure the safety of essential medical products.*

**Fig. 3.19.**  
**Status of policy and regulatory frameworks for medicines and medical products, by income group**

**Fig. 3.20**  
**Policy and regulatory frameworks, by WHO region**



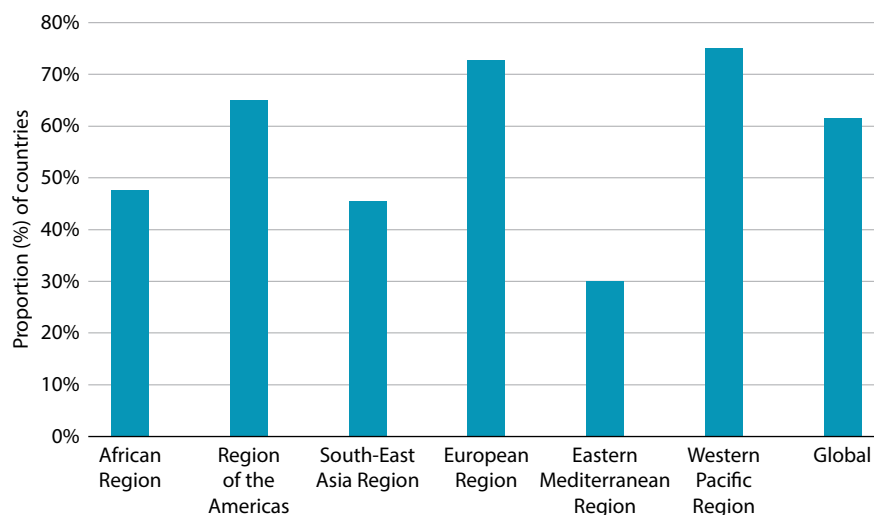
While the majority of countries have pharmacovigilance systems in place, only about two thirds actively share safety information with manufacturers and health service providers, indicating a need for enhanced communication to improve system usability and effectiveness.

## Programmes for safety of medicines

Pharmacovigilance provides evidence-based information to support the assessment of benefits, harms, effectiveness and risks of medicines, and to promote their safe, rational and cost-effective use. The WHO Programme for International Drug Monitoring (PIDM) (203) connects national pharmacovigilance centres (PVCs) and national regulatory authorities from more than 170 countries. PIDM members collate adverse event reports from health workers, patients and marketing authorization holders and submit suspected adverse reactions to the WHO Vigibase database.

As of July 2023, over 35 million reports of adverse reactions were held in VigiBase, each recorded in a structured and comprehensive way to allow the detection of potential medicinal safety hazards (203). One of the main purposes of this database is to enable the identification of rare and serious problems associated with medicines that were not detected during the pre-marketing phase. Signal detection is identifying a possible causal relationship between the medicine and the adverse reaction, including allergic reactions, that is repeated usually throughout several reports. Once the signal is detected, it is analysed to verify the causality. If a causal relationship is confirmed, further action includes looking into whether the reaction is well-documented, the safety profile of the product is considered and taking further action such as contacting relevant stakeholders. The focus is on identifying signals of harm that are serious, rare and/or not detected during clinical trials.

According to the patient safety survey, most countries (94%) have a PV system in place, with a designated national entity for monitoring. However, only about two thirds of respondents (62%) reported periodically sharing the safety information from the PV system with manufacturers and health service providers (Fig. 3.21). This indicates room for improvement in the usability of these systems for end-users.



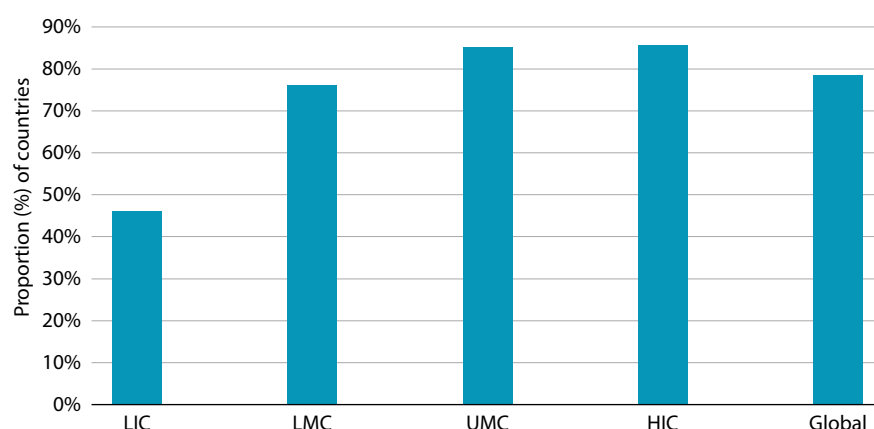
**Fig. 3.21.**  
Provision of pharmacovigilance safety information to manufacturers and health service providers, by WHO region

## Programmes for safety of blood and blood products

Every country should make sure that they have enough safe blood for their people and that they follow the national health policy and rules. All steps involved in collecting the blood from donors, testing it, storing it and giving it to patients should be well organized and connected at the national level. The national blood policy and laws should help keep the quality and safety of blood and blood products high and consistent. However, many people who need blood transfusion for their health and survival do not have timely access to safe blood and blood products. Lack of access to safe blood transfusion and unsafe blood supplies is still a big patient safety challenge, in particular in middle- and low-income countries.

Patients who receive transfusions with unsafe practices may face serious complications, such as adverse transfusion reactions and potential bloodborne infections. These transfusions also waste blood products that could be used for patients who really benefit from them. To ensure the safety of transfusion processes, WHO recommends the establishment of hospital transfusion

*Although most countries have haemovigilance systems in place, the functionality of these systems remains a challenge, particularly in lower income countries.*



**Fig. 3.22.**  
Establishment of functional haemovigilance systems, by income group

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

committees and haemovigilance systems to monitor and improve the safety of transfusion practices. By monitoring and reporting adverse events and reactions related to blood transfusion, haemovigilance systems provide valuable information on how to enhance patient safety (204). According to survey responses, 79% of countries have a functional haemovigilance system established as part of the national blood transfusion programme (Fig. 3.22). The availability of functional haemovigilance systems is greater in higher income countries.

## Programmes for safety in immunization services

Modern vaccines are safe and effective and are stringently tested for safety and efficacy. However, like other medical products, vaccines are not free from adverse reactions (205–207).

Vaccines rarely cause serious adverse reactions, which are usually minor and self-limited. Vaccine safety is assessed by monitoring adverse events following immunizations (AEFI). An AEFI may be caused by a vaccine reaction but more often coincidental to vaccination or, very rarely, are caused by an error in administration or handling of a vaccine (205). Regardless of the specific cause, an AEFI may lead to public hesitancy for a given vaccine. Vaccine pharmacovigilance, which includes the surveillance of AEFI (i.e. systematic collection of data on medically important events following immunization), should be part of all immunization programmes as this helps sustain public confidence in the programme (205).

WHO recommends that serious AEFIs should be fully investigated, and an independent national expert committee should be established to examine any serious cases, as well as AEFIs that may have raised public concerns. The independent committee should perform causality assessment with the assistance of the immunization programme at all levels, the relevant national regulatory authority (NRA), and the government (208).

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*Nearly all countries have established immunization safety systems, but variability in reporting rates of AEFI to the global database, VigiBase.*

The Member State survey showed that almost all the countries have a functional immunization safety system with a national committee to review AEFIs. Moreover, 70% of respondents submit individual serious AEFI cases to VigiBase, the global vaccine safety database.

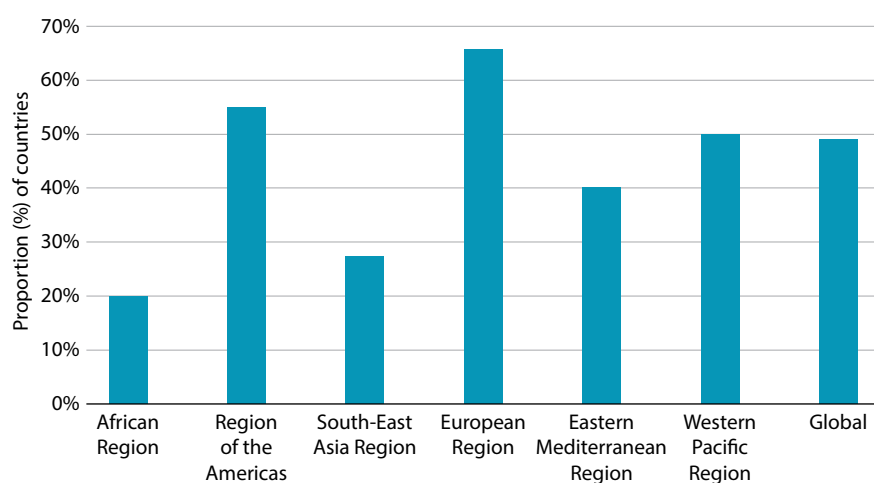
The WHO Programme for International Drug Monitoring also found that 181 out of 184 countries where data was available, had a national system to monitor AEFI (203).

WHO tracks vaccine safety worldwide by analysing the data shared by countries into VigiBase. Countries that report at least one serious AEFI case per million total population indicate that they have a functional AEFI surveillance system. Based on 2022 data from 215 member states and territories, 43% reported at least one serious AEFI per million total population, 13% reported less than one serious AEFI event per million (209).

## Programmes for safety of medical devices

Health technologies are essential for a functioning health system. Medical devices are particularly crucial for safe and effective care. Medical devices should be safe, of good quality and appropriate to the settings in which they are used. The WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (210) aims to develop, implement and strengthen regulatory frameworks to ensure the safety and quality of medical devices used in respective countries. The framework provides a comprehensive and transparent approach to ensure the safety, quality and performance of medical devices and in vitro diagnostics (IVDs), as well as their appropriate use and access. WHO has also issued guidance that aims to support post-market surveillance activities of medical device manufacturers and market surveillance activities of regulations (211). The guidance describes the measures taken to ensure the ongoing compliance of medical devices with the requirements for safety, quality and performance after they are placed on the market.

Responses to the survey of Member States revealed that 49% of the countries have implemented a post-market surveillance system for medical devices. These systems are mostly prevalent in UMCs and HICs. Another 36% of countries have indicated that they are developing such a system and have set safety standards for medical devices. Countries of the European Region are ahead, with 66% of its countries having a post-market surveillance system for medical devices in place (Fig. 3.23).



*While nearly half of countries have implemented post-market surveillance systems for medical devices to ensure ongoing safety and quality, many are still in the process of developing these systems.*

**Fig. 3.23.**  
**Post-market surveillance system established for medical devices, by WHO region**



Strategic objective 3	3.1	3.2	3.3	3.4	3.5
	Safety of risk-prone clinical procedures	Global Patient Safety Challenge: Medication Without Harm	Infection prevention and control and antimicrobial resistance	Safety of medical devices, medicines, blood and vaccines	Patient safety in primary care and transitions of care

## Strategy 3.5.

# Patient safety in primary care and transitions of care



Assure the safety of patients in all settings, including in mental health settings and care homes, with a focus on primary care and transitions of care

Given that up to 40% of primary care patients may experience harm, improving safety in these settings is critical to enhancing overall health outcomes.

Primary care is central to many health systems worldwide. It is typically the first point of contact for individuals seeking health services. The safety and quality of primary care can greatly influence overall health outcomes and the efficiency of the entire health system. When primary care is not safe or effective, it can lead to the exacerbation of a condition, unnecessary hospital admissions, and even death.

While there is a global effort to make health care safer, much of the research and focus has been centred around hospital care, leaving a gap in our understanding of safety in primary care settings. Since the majority of health care interactions occur in primary care, ensuring its safety is crucial (212).

The estimates of patient harm in primary and ambulatory care are alarming. Up to four of every ten primary care patients may experience harm, representing up to half of all patient harm globally. In industrialized countries, the impact of such harm is comparable in scale to certain cancers, such as malignant melanoma or thyroid cancer. In resource-constrained settings, it has a similar scale of impact as typhoid fever (9).

Improving safety in primary care can lead to better overall health outcomes and a more efficient health care system.

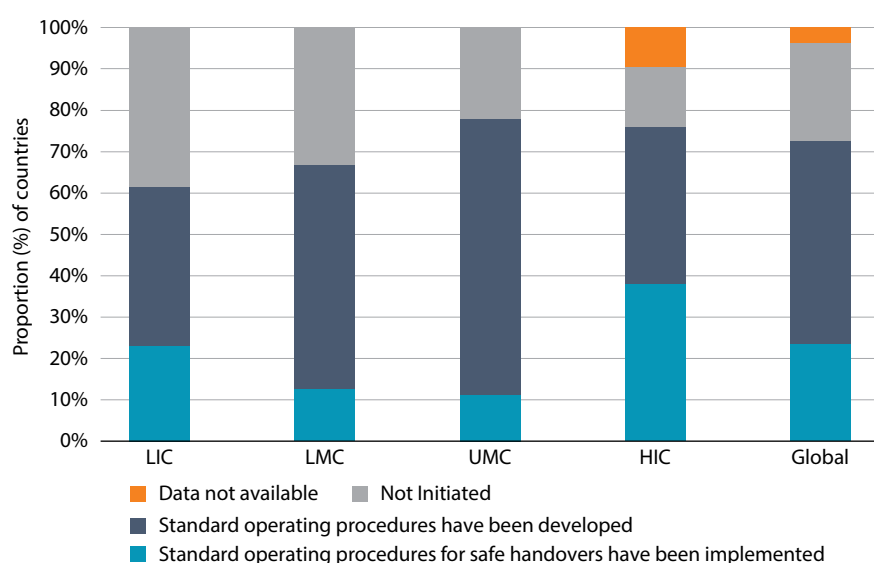
## Transitions of care and clinical pathways for primary care

Transitions of care, encompass the various points where a patient moves to, or returns from, a particular physical location or makes contact with a health care service/professional for the purposes of receiving health care (212). These transitions can range from moving between home, hospital, residential care settings, or engaging with various health care providers in a given care facility.

Effectively managing these transitions – especially between primary care and hospital settings – is crucial, as these shifts are acknowledged as high-risk situations for patient safety. One effective approach to ensuring the continuity of care during these transitions is by standardizing clinical handovers and establishing two-way communication, within health care facilities and/or between them and community-/home-based care (212).

The Member State survey reveals that around three quarters of countries have developed standard operating procedures (SOPs) for safe handovers during care transitions, though only a quarter could confirm that these SOPs have been implemented in the majority of their health facilities. Around a quarter of respondent countries report that they have yet to initiate any work towards standardizing handover processes.

Analysing the implementation of SOPs for safe handovers across income groups reveals marked differences (Fig. 3.24).



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

The development and implementation of diagnosis, treatment and referral pathways for primary care provide evidence-based guidance and support for health workers to deliver safe care, reduce errors and avoid unnecessary harm. They also facilitate timely and appropriate referrals to specialist services when needed, ensuring optimal outcomes for patients. By following these pathways, primary care providers can enhance their clinical decision-making,

*Although around three quarters of countries have developed SOPs for safe handovers during care transitions, only a quarter have widely implemented these SOPs across their health facilities.*

**Fig. 3.24.**  
Availability and implementation of clinical handovers in health care facilities, by income group

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*Only about 40% of countries have implemented evidence-based pathways for diagnosis, treatment, and referrals in primary care.*

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*Countries are implementing comprehensive patient transfer plans, structured clinical handovers, and organized referral systems to enhance primary care effectiveness and safety.*

communication and coordination of care, and contribute to the overall improvement of the health system.

Globally around 40% of countries reported that they have implemented pathways in diagnosis, treatment and referral pathways in primary care.

Further analysis of survey data reveals that all income groups recognize the importance of primary care pathways. LICs are doing relatively better despite constrained resources, probably as they see primary care as a cost-effective approach to address a broad spectrum of prevalent health issues, reducing the need for more expensive hospital-based care. LICs often become the focus of international support from major organizations, such as WHO and the United Nations Children's Fund (UNICEF), which prioritize the implementation of primary care pathways. This external support may help in amplifying the efforts of LICs in establishing robust primary care systems and highlighting a shared commitment to improving global health outcomes.

### Country progress in patient safety within primary care

Numerous countries around the world have made significant progress in implementing SOPs and treatment pathways for primary care.

**Colombia** has a comprehensive plan for patient transfers, ensuring safety in urgent cases and situations. **El Salvador's** technical guidelines facilitate structured clinical handovers, while **Cuba's** well-organized primary care system includes clear norms for patient referrals. **Indonesia** has successfully implemented SOPs in many health care facilities. **Ghana** and **Namibia** have established national guidelines to support primary care providers in diagnosing and treating various conditions and facilitating patient referrals. Similarly, **Belize** has implemented primary care pathways, and **Poland** has efficiently coordinated care through diagnosis, treatment and referral pathways. In **Türkiye**, primary health care services are well-structured, with clear definitions for the referral process. **Kazakhstan, Liberia, Malaysia, Maldives** and **Peru** have also made progress in establishing SOPs and pathways, albeit with varying scales of implementation. These countries' efforts reflect their commitment to enhancing patient care transitions and the overall effectiveness of their health care systems.

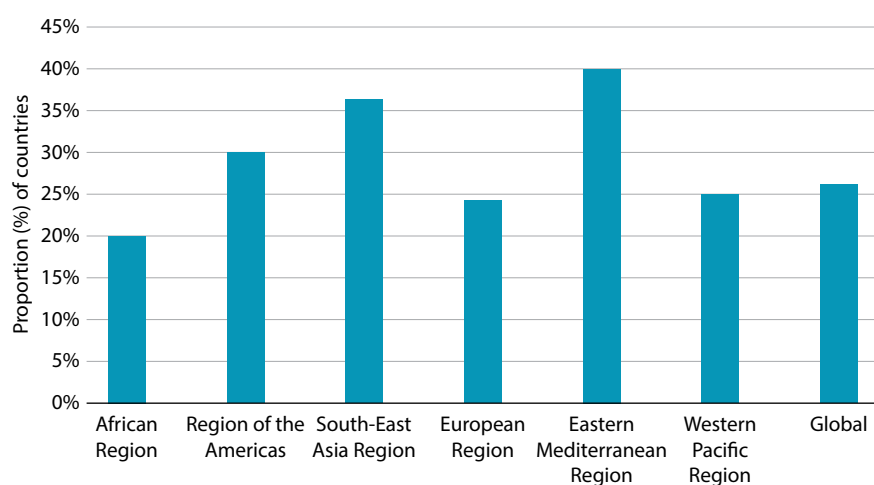
### Certification and accreditation programmes for primary care services

Enhancing patient safety within primary care requires a comprehensive approach that addresses various sources of errors and harm. This approach involves implementing system-wide interventions designed to improve safety at every stage of care. These interventions encompass several key components, including robust reporting and learning systems that facilitate the identification and analysis of safety incidents. Additionally, the integration of digital technologies plays a vital role in enhancing communication and coordination among health care providers and patients, reducing the risk of errors.

Fostering a safety culture within health care organizations is essential, as it promotes a proactive and positive attitude towards safety issues. Moreover, engaging patients in their own care is crucial, empowering them to actively participate and provide valuable feedback. By extending these interventions across the entire care continuum, including primary care, hospice, and home-based care services, patient safety can be elevated to new levels.

It is also imperative to incorporate patient safety elements into service delivery standards, licensing requirements and accreditation criteria for primary care and related services. This ensures that these health care providers meet and maintain the minimum standards for safety and quality, ultimately benefiting patient well-being.

According to the Member State survey, 26% of countries reportedly have certification and accreditation programmes implemented in primary care settings, with considerable variation across different WHO regions (Fig. 3.25).



*Only 26% of countries have implemented certification and accreditation programmes in primary care settings.*

**Fig. 3.25.**  
Inclusion of primary care facilities in certification or accreditation programmes, by WHO region

## Country licensing and accreditation mechanisms for primary health care facilities

In **India**, the National Quality Assurance Standards oversee public health facilities, community health centres, and wellness centres. **Chile** mandates private primary care establishments to obtain accreditation from the National Accreditation System by 2025, while public entities have their own specific regulations. **Malaysia** uses a dual approach: while private primary care services need licensing, public counterparts undergo quality improvement measures and audits.

**Colombia's** primary health care services are an integral part of national improvement programmes, with some integration into the accreditation process. **Argentina** offers national evaluation and accreditation for primary care through its National Accreditation Agency for Health Services Quality. The Health Facilities Regulatory Agency (HeFRA) in **Ghana** inspects, licenses and monitors health facilities. Both **Peru** and **Singapore** emphasize patient safety and minimum care standards in their licensing prerequisites for primary care services. In **South Africa**, the regulation of certification and complaint handling

Countries adopt varied approaches to primary care quality, with some mandating accreditation and others offering voluntary accreditation.

for all health establishments, including primary care, rests with the Office of Health Standards Compliance and the Health Ombud.

In **Costa Rica** accreditation is voluntary while **North Macedonia** stands out with its mandatory accreditation for health institutions at every level, including primary health. **Czechia**, currently reliant on a private entity for primary care certification, plans to introduce state regulation by 2023. **Belize** maintains its primary health care standards by accrediting and conducting regular evaluations. While **Qatar's** Primary Healthcare Corporation supports international accreditation, **Kazakhstan** upholds outpatient care standards. **Cuba's** primary health care system operates under specific regulations and is currently developing an accreditation manual for its polyclinics. **Liberia**, on the other hand, is modifying its accreditation standards across all levels of care to be in line with the national health policy and strategy. **Malawi** has piloted accreditation services, and **Cyprus** is currently establishing them. **Australia** is launching a new sector-wide accreditation programme, while **Georgia** relies on a resolution passed in 2010 regarding medical activity licensing. In **Romania**, primary care providers such as general practitioners and dental offices have the option, not obligation, to pursue certification and accreditation.

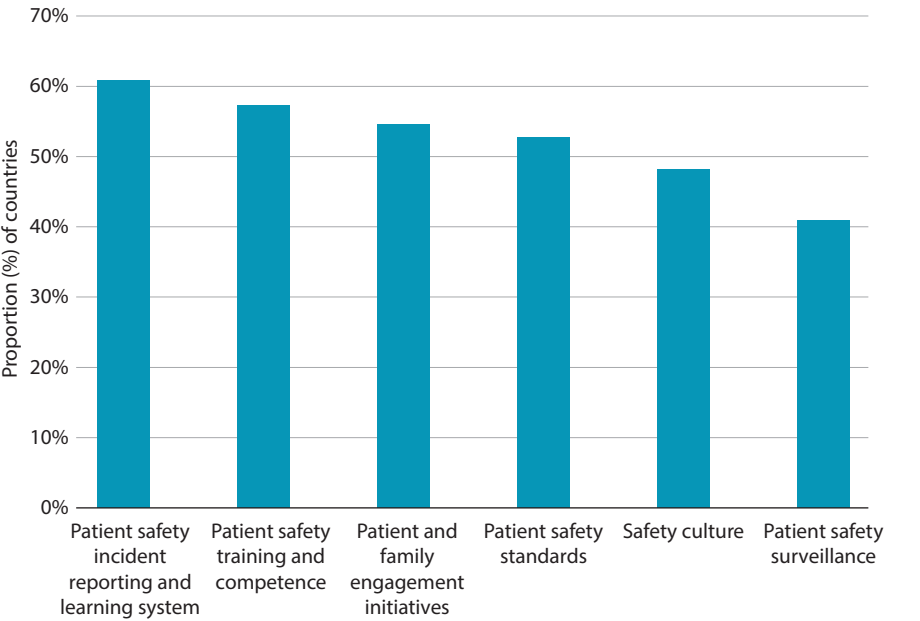
### Implementing patient safety systems interventions in primary care

While more than two thirds of countries have started implementing patient safety interventions in primary care, only about 17% adopted a comprehensive approach.

Among the responding countries, 67% have begun implementing at least one of the following interventions within primary care services: incident reporting and learning, patient safety training, family engagement, patient safety standards, safety culture, and patient safety surveillance.

However, a more comprehensive approach is less common, with only 17% of countries reporting the implementation of all the elements within their primary care systems. Overall, this suggests that while progress has been made in

Fig. 3.26. Global prioritization of specific patient safety interventions in primary care services



certain areas, there is room for further development and integration of patient safety measures across the entire health care continuum.

Further analysis of data reveals countries are actively prioritizing patient safety in primary care, but their focus areas vary (Fig.3.26).

The mechanisms of ensuring safety and quality vary considerably based on each nation's unique health challenges, priorities and resources. However, the universal emphasis on primary care underscores its significance as a cornerstone for robust health systems.

## Patient safety system interventions in primary care services

**Chile** has taken a holistic approach, focusing on patient and family participation, person-centred care, and rigorous safety training. **Singapore's** Ensure Safer Systems framework, a major initiative, has been incorporated into their primary care services. Meanwhile, **Spain** and the **United Kingdom** emphasize the importance of learning from patient safety events, with the latter releasing pivotal resources on the matter. **Namibia's** commitment is evident in its development of primary health care quality standards. **Argentina** is publishing guidelines on best practices for quality and safety in primary health care.

**Timor-Leste**, through its Servisu Integrado du Saude Comunidade, is championing patient and family engagement, and **Poland** has incorporated the PSIRL into its primary care accreditation standards. Other notable mentions include specialized approaches by **Guinea** and **Ghana**, focusing on blood exposure accidents and adverse drug reporting, respectively. The **United Kingdom** (in Scotland) and **New Zealand** are ensuring that safety interventions are foundational in general practices, with the latter seeking expansion in other primary care settings.

## Patient safety in mental health services

Mental health treatment settings are susceptible to various errors and adverse events that can result in detrimental outcomes for patients. Medication errors may arise from provider mistakes or systemic issues such as understaffing. Other types of medical errors—such as inadequate monitoring of the patient—can also pose threats to patients.

Risk of self-harm in psychiatric units is significant, with several challenges in prediction and prevention, emphasizing the importance of assessing and monitoring high-risk individuals. The use of restraint and seclusion, controversial methods to prevent self-harm and violence, can sometimes lead to patient harm if misused or if applied inappropriately.

Allowing contraband items—such as sharp objects or other potentially dangerous items that can be used to injure self or others—into the psychiatric unit due to incomplete searches is a prevalent error (213).

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*Countries are enhancing primary care safety through diverse interventions, including patient and family engagement, rigorous safety training, and systematic learning from safety events.*

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*Mental health treatment settings are prone to errors and adverse events, highlighting the need for robust patient monitoring and risk management to ensure safety.*

The design of in-patient mental health treatment facilities has an impact on patient safety and the involvement of peers and caregivers in delivering care can improve safety.

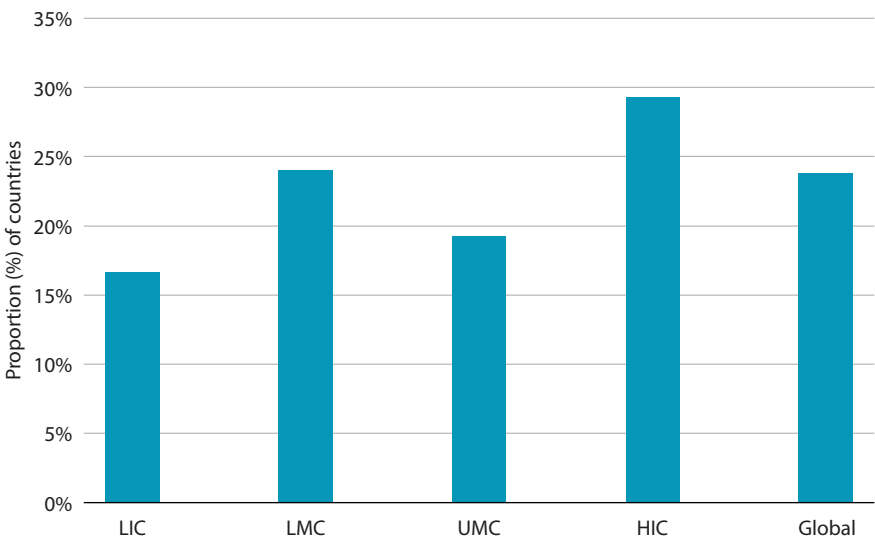
Patient safety in mental health services also encompasses the promotion of a culture of safety, learning and accountability among staff, patients and families.

Globally, around one quarter of countries responding to the Member State survey stated that they are implementing patient safety interventions in primary mental health care facilities, and this varies significantly across WHO regions. The Western Pacific Region demonstrates the highest commitment with patient safety interventions being implemented in a reported 42% of countries. Whereas in the African Region, patient safety interventions are implemented in only 15% of the mental health facilities. Other regions, such as the Region of the Americas and the European Region, exhibit intermediate progress at 26% and 22% respectively. Meanwhile, the South-East Asia Region and the Eastern Mediterranean Region have lower implementation rates of 18% and 20%. This distribution suggests varying levels of prioritization and resource allocation to patient safety in mental health settings around the world.

The data also highlights disparities in the implementation of patient safety interventions in mental health settings based on a country's economic status (Fig. 3.27). High-income countries lead in prioritizing patient safety in these settings. Whereas LICs may face challenges of limited resources and lack effective implementation. Intriguingly, LMCs surpass their UMC counterparts, suggesting factors other than just income – such as health care policies or international collaborations – might also play an important role.

Globally, only about one quarter of countries are implementing patient safety interventions in mental health primary care facilities, indicating a need for greater prioritization and resource allocation.

**Fig. 3.27.**  
**Implementation of patient safety interventions in mental health settings, 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 progress with integrating patient safety in mental health services

National standards for the conduct of reviews of patient safety incidents were developed in **Ireland** to ensure that services conduct reviews of patient safety incidents in a consistent and person-centred way. The standards aim to promote learning and improvement from such incidents and to foster a culture of openness and accountability in the health and social care sector.

The National Safety and Quality Digital Mental Health Standards, and the National Safety and Quality Mental Health Standards for Community Managed Organizations are two new initiatives launched by **Australia** to improve the safety and safety of mental health services delivered online and by community-based organizations. These standards aim to provide a consistent framework for assessing and enhancing the performance of digital and community mental health providers, and to ensure that consumers and carers receive safe, evidence-based, and person-centred care.

In **Germany**, there are various initiatives that aim to enhance patient safety in mental health care. These include guidelines for diagnostics and treatment, standards for structural safety, risk management for suicide prevention, medication safety, and work with relatives and other stakeholders. These initiatives address the challenges of dealing with aggressive behaviour and other issues that may arise in mental health settings and provide guidance for improving the safety of care.

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*Countries are implementing national standards, digital health initiatives, and comprehensive safety guidelines to integrate patient safety into mental health services, ensuring consistent, person-centred, and evidence-based care.*

## Feature story 8

### Diagnostic safety: Implications for policy and practice

#### Summary

The *Global patient safety action plan 2021–2030* highlights the need to assure the safety of clinical processes, including diagnostic procedures. Countries should consider interventions aimed at reducing diagnostic errors as one of the key strategies for improving patient safety.

#### Scope of the problem

A diagnostic safety event is defined as the occurrence of one or both of the following:<sup>a</sup>

- *Delayed, wrong or missed diagnosis:* One or more missed opportunities to pursue or identify an accurate and timely diagnosis of the patient's health problems based on the information that existed at the time.
- *Diagnosis not communicated to the patient:* An accurate diagnosis of the patient's health problem was available, but it was not communicated to the patient.

Diagnostic errors represent missed opportunities for making correct and timely diagnoses. They often relate to various aspects of the diagnostic process, including recognition of key signs and symptoms, as well as follow up and interpretation of test results. Most adults will experience at least one diagnostic error in their lifetime.<sup>b–e</sup>

#### Underlying factors

Contributory factors that lead to diagnostic errors often include a combination of cognitive- and systems-based factors. Cognitive factors involve clinician training and experience as well as predisposition to biases, fatigue, stress and other influences. Systemic factors refer to organizational vulnerabilities that predispose to diagnostic errors and include communication, workload, teamwork issues, and a lack of decision support.<sup>f,i</sup>

#### What's next?

Several types of interventions can be implemented to reduce diagnostic errors, such as: 1) technique improvements (e.g. changes in diagnostic procedures or equipment); 2) technology-based system interventions; 3) educational interventions; 4) personnel changes; 5) structured process changes; and 6) additional review methods (such as the introduction of a second reviewer in interpreting test results).<sup>j</sup> Technology-based systems, such as alerting abnormal laboratory results and computer-aided diagnostic tools, and structured process changes, such as triage protocols or examination checklists, are potentially promising interventions.<sup>k,l</sup>

Recently, several tools and resources have been developed to address the complexity of measuring diagnostic errors and for improving patient safety by the Agency for Healthcare Research and Quality.<sup>m</sup> Such resources can help generate learning and improvement opportunities in diagnosis in many types of care settings. Policy-makers and safety professionals might find some of these tools useful as they develop solutions. By engaging in multi-

faceted approaches, health care organizations, quality and safety professionals, and clinicians can begin activities needed to reduce preventable harm from diagnostic errors.

- <sup>a</sup> *Measure DX: A Resource to identify, analyze, and learn from diagnostic safety events*. Rockville (MD): Agency for Healthcare Research and Quality; 2022 (<https://www.ahrq.gov/sites/default/files/publications2/files/MeasureDx-guide.pdf>, accessed 24 April 2024).
- <sup>b</sup> Balogh E, Miller B, Ball J. *Improving Diagnosis in Health Care*. Washinton DC: National Academies of Sciences, Engineering and Medicine. National Academies Press; 2015 (<https://www.ncbi.nlm.nih.gov/books/NBK338596/>, accessed 24 April 2024).
- <sup>c</sup> Gunderson CG, Bilan VP, Holleck JL, Nickerson P, Cherry BM, Chui P, Bastian LA, Grimshaw AA, Rodwin BA. Prevalence of harmful diagnostic errors in hospitalised adults: a systematic review and meta-analysis. *BMJ Qual Saf*. 2020;29:1008–18. doi: 10.1136/bmjqs-2019-010822.
- <sup>d</sup> Singh H, Schiff GD, Graber ML, Onakpoya I, Thompson MJ. The global burden of diagnostic errors in primary care. *BMJ Qual Saf*. 2017;26:484–94. doi: 10.1136/bmjqs-2016-005401.
- <sup>e</sup> Cheraghi-Sohi S, Holland F, Singh H, Danczak A, Esmail A, Morris RL et al. Incidence, origins and avoidable harm of missed opportunities in diagnosis: longitudinal patient record review in 21 English general practices. *BMJ Qual Saf*. 2021;30:977–985. doi:10.1136/bmjqs-2020-012594.
- <sup>f</sup> Graber ML, Kissam S, Payne VL, Meyer AN, Sorensen A, Lenfestey N et al. Cognitive interventions to reduce diagnostic error: a narrative review. *BMJ Qual Saf*. 2012;2:535–57. doi:10.1136/bmjqs-2011-000149.
- <sup>g</sup> Kostopoulou O, Delaney BC, Munro CW. Diagnostic difficulty and error in primary care—a systematic review. *Fam Pract*. 2008;25:400–13. doi:10.1093/fampra/cmn071.
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- <sup>i</sup> Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. *Arch Intern Med*. 2005;165:1493–9. doi:10.1001/archinte.165.13.1493.
- <sup>j</sup> McDonald KM, Matesic B, Contopoulos-Ioannidis DG, Lonhart J, Schmidt E, Pineda N et al. Patient safety strategies targeted at diagnostic errors: a systematic review. *Ann Intern Med*. 2013;158:381–9. doi:10.7326/0003-4819-158-5-201303051-00004.
- <sup>k</sup> Dave N, Bui S, Morgan C, Hickey S, Paul C. Interventions targeted at reducing diagnostic error: systematic review. *BMJ Qual Saf*. 2022;31:297–307. doi: 10.1136/bmjqs-2020-012704.
- <sup>l</sup> Abimanyi-Ochom J, Bohingamu Mudiyansele S, Catchpool M, Firipis M, Wanni Arachchige Dona S, Watts JJ. Strategies to reduce diagnostic errors: a systematic review. *BMC Med Inform Decis Mak*. 2019;19(1):174. doi:10.1186/s12911-019-0901-1.
- <sup>m</sup> *Tools To Improve Diagnostic Safety* [website]. Rockville (MD): Agency for Healthcare Research and Quality; 2024 (<https://www.ahrq.gov/diagnostic-safety/tools/index.html>, accessed 24 April 2024).



*Nurse working at a COVID isolation center in Hargeisa, Somalia, providing essential care during the pandemic. © WHO / Blink Media - Mustafa Saeed*



A photograph of a physiotherapist in a blue polo shirt assisting an elderly male patient in a grey sweater. The patient is lying on a table, secured with a black strap. The physiotherapist is leaning over the patient, holding a black strap. The background shows large windows with a view of a building.

Strategic  
objective

4

# Patient and family engagement

*Patient and physiotherapist during a rehabilitation session at Sunnaas Rehabilitation Hospital in Norway. © WHO / Noor / Sebastian Liste*



Engage and empower patients and families  
to help and support the journey to safer  
health care

## Organization of section

### Strategy 4.1. Co-development of policies and programmes with patients

- Patient engagement in policies, programmes, and governance
- Identification of patient organizations
- Patient engagement as assessment criterion for health care facilities
- Patient safety rights charter

### Strategy 4.2. Learning from patient experience for safety improvement

- Patient feedback mechanisms
- Learning from patients' stories

### Strategy 4.3. Patient advocates and patient safety champions

- Recognition and capacity building of patient advocates and champions
- Patients for Patient Safety networks

### Strategy 4.4. Patient safety incident disclosure to victims

- Guidance for obtaining informed consent
- Patient access to medical records
- Disclosure of adverse events to patients and families
- Psychological support in case of adverse events

### Strategy 4.5. Information and education to patients and families

- Health literacy and patient engagement
- Information about safety and quality of health services
- Use of digital technologies

## Key messages



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 patient safety. 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.



Patient engagement refers to the process of building the capacity of patients, families, carers, as well as health care providers, to facilitate and support the active involvement of patients in their own care – in order to enhance safety, quality and people-centredness of health care service delivery (214). Patient and family engagement is a pivotal strategy to advance safety in health care. Their first-hand experience of the entire patient journey and care outcomes, offers a unique perspective that may otherwise be missed by health care professionals. Their contributions are vital for a comprehensive understanding of patient safety, harm prevention, existing safety culture and overall system needs. Studies have shown that meaningful patient engagement can potentially reduce the burden of harm by up to 15%.

Patient engagement can take many forms. This includes transparent access to their care information through informed consent, access to medical records, and full disclosure of risks and harms experienced. It is also important for patients to feel empowered to raise concerns, tell their stories, share their care experiences and submit incident reports.

The active involvement of patient representatives, advocates and champions in organizational and health system governance structures allows for ongoing dialogue about patient safety, making it a subject of community and national oversight. In this way, patients can be engaged in decision-making and participate in patient safety leadership, amplifying the voices and experiences of health system users to drive action.

Similarly, the active involvement of health workers and leaders who champion patient engagement is a critical component of this process, and can lead to the co-creation of safety-related interventions and the creation of a safety culture.

As a result, WHO included patient and family engagement as one of the seven strategic objectives of the Global patient safety action plan 2021–2030 and dedicated World Patient Safety Day 2023 to the theme: “Engaging patients for patient safety” (215). The theme calls on all stakeholders to take necessary actions to ensure that patients are involved in policy formulation, represented in governance structures, engaged in co-designing safety strategies, and are active partners in their own care. This can only be achieved by providing platforms and opportunities for diverse patients, families and communities to add their voice, concerns, expectations and preferences to advance safety, patient-centeredness, trust-building and equity.

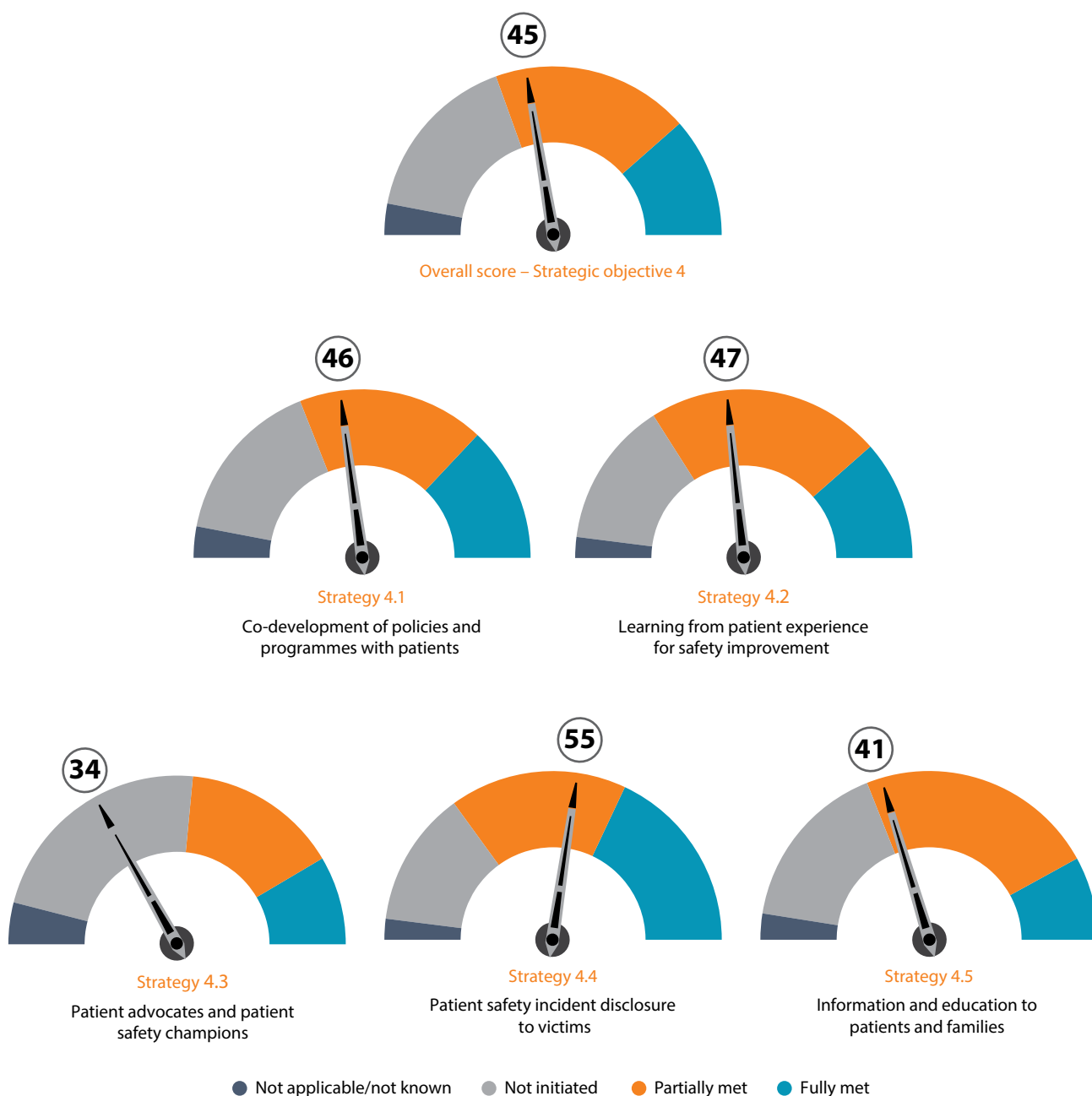


*Pediatrician at Wigmore Clinic in Yerevan, Armenia, involved in introducing new health guidelines. © WHO / Nazik Armenakyan*

Member State survey responses reveal that many countries have made progress in engaging patients in safety improvement initiatives, but also that significant challenges persist. Based on responses from 108 countries, 23% of patient engagement criteria were fully met, with another 38% partially met. For one third of the criteria, countries have reported they have not started any action. The overall weighted performance score based on all criteria is 45% (Fig. 4.1).

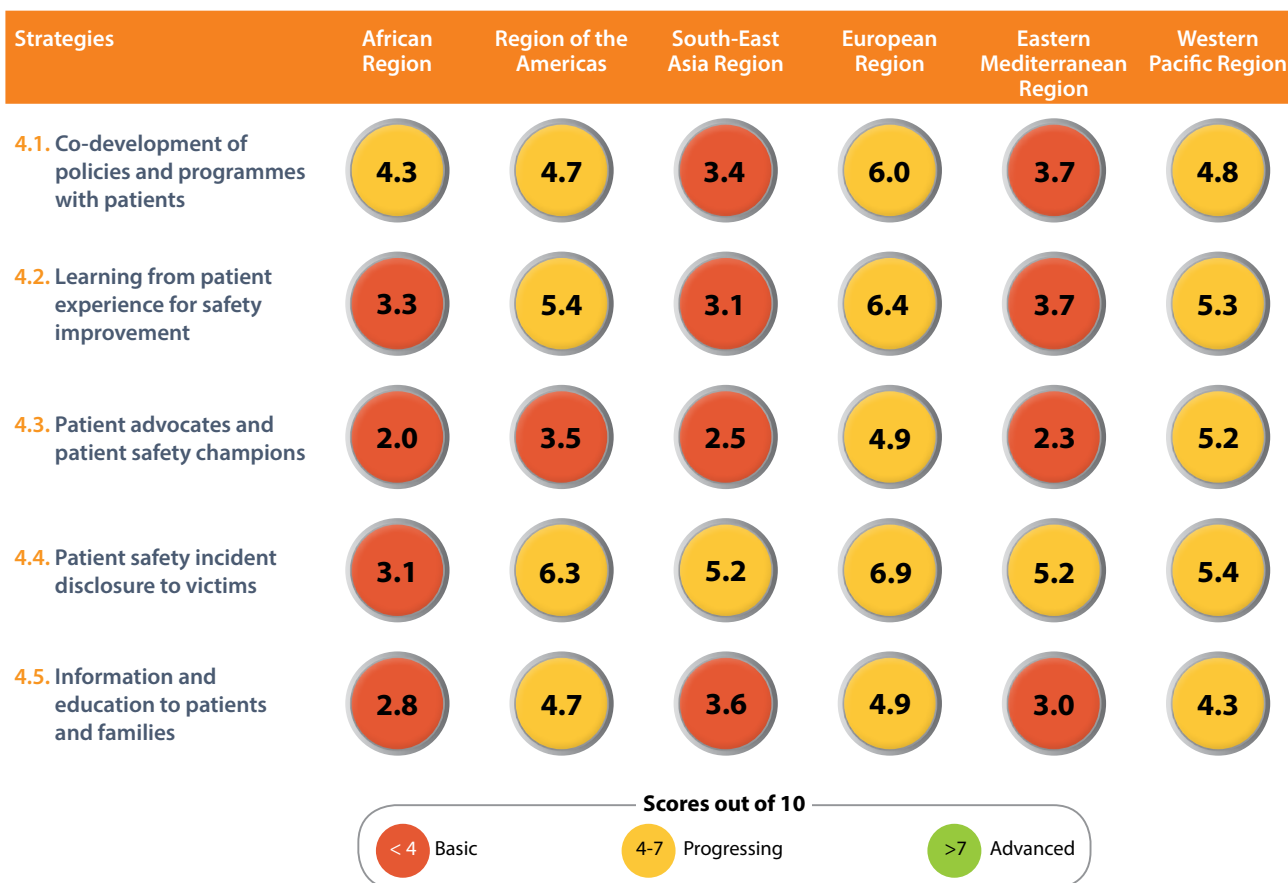
Most countries reported positive results on criteria related to informed consent and collecting patient feedback on safety and quality of services. However, criteria related to having patient involvement in health care governance, providing psychological support to patients and families after serious events, and building the capacity of patient advocates and champions typically scored very low.

► **Fig. 4.1. Aggregated and average global performance scores for strategic objective 4**



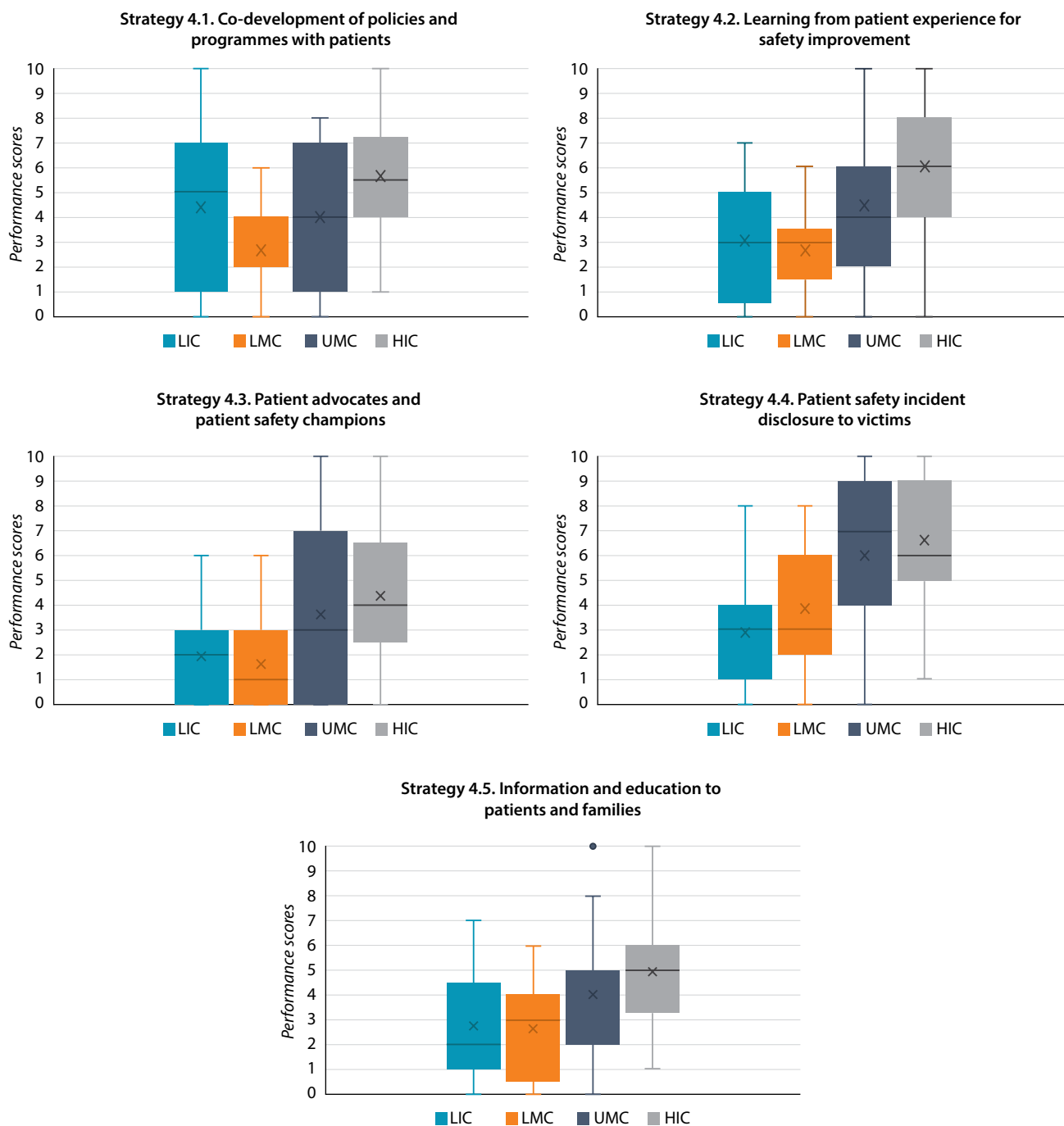
The data on patient engagement demonstrates distinct regional variations (Fig. 4.2). The European Region consistently records higher performance scores across all strategies, particularly excelling in patient safety incident disclosure to victims and learning from patient experience for safety improvement, with scores of 6.9 and 6.4 respectively. Countries in the Region of the Americas also show strong performance, especially in learning from patient experience and incident disclosure. Performance appears to vary across different categories, reflecting the unique challenges and focuses of each region. No region achieved an advanced performance level (greater than 7) in any of the patient engagement strategies. This regional diversity also highlights the importance of understanding and addressing the specific patient engagement needs and opportunities in each region. While one region's practices may serve as a model for others, the differing needs and contexts of individual regions must be considered if effective improvements are to be achieved in patient engagement and safety.

► **Fig. 4.2. Distribution of strategic objective 4 performance scores across the five strategies, by WHO region**



The survey results on patient engagement in safety practices (Fig. 4.3) demonstrate a consistent pattern where HICs tend to have higher median performance scores, implying better engagement. Lower income countries (i.e. LICs and LMCs) exhibit greater variability in their performance, particularly in areas such as co-development of policies and education of patients and families. All income levels demonstrated a range in performance, illustrated by the interquartile range with upper-middle-income countries (UMCs) generally largest. Despite the general trend that sees HICs leading in patient engagement, there are exceptions within lower income groups that rival or exceed the performance in higher income settings. This highlights not only a potential for improvement across all economic strata, but also points to successful strategies in patient engagement that transcend income levels.

► Fig. 4.3. Distribution of strategic objective 4 performance scores across the five strategies, by income group



Strategic objective 4					
4.1		4.2	4.3	4.4	4.5
Co-development of policies and programmes with patients		Learning from patient experience for safety improvement	Patient advocates and patient safety champions	Patient safety incident disclosure to victims	Information and education to patients and families

# Strategy 4.1. Co-development of policies and programmes with patients



Engage patients, families and civil society organizations in the co-development of policies, plans, strategies, programmes and guidelines to make health care safer

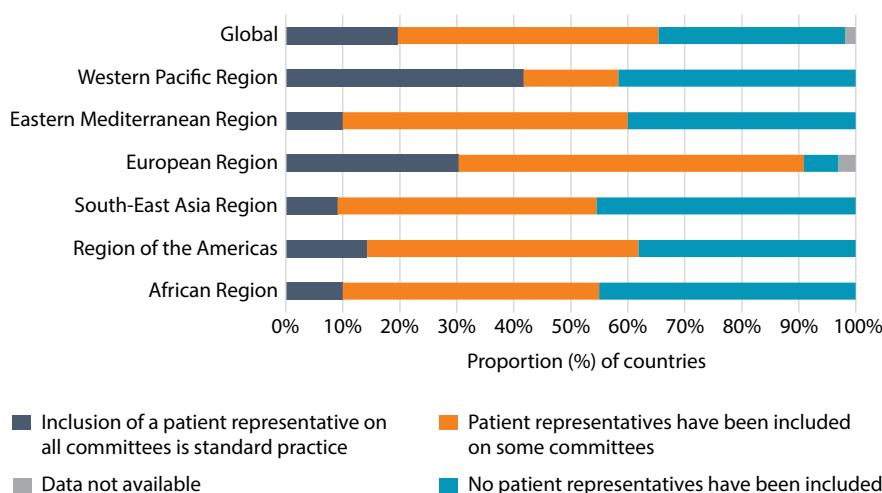
Despite recognition of its importance, only one in five countries consistently involves patients in health care policy-making.

Patients and their families – as well as civil society groups that represent them – are key partners in creating and executing policies and action plans for patient safety. They can share their perspectives and expectations as health system users and propose innovative actions to protect their rights and safety. A practical way to boost patient engagement is to invite patients and their representatives to join formal groups such as working groups, task forces, organizational governance structures, and to embed patient and family engagement into accreditation and evaluation programmes. These actions can help to re-shape care policies and processes and inform them considering the experiences and priorities of patients and families (216).

## Patient engagement in policies, programmes and governance

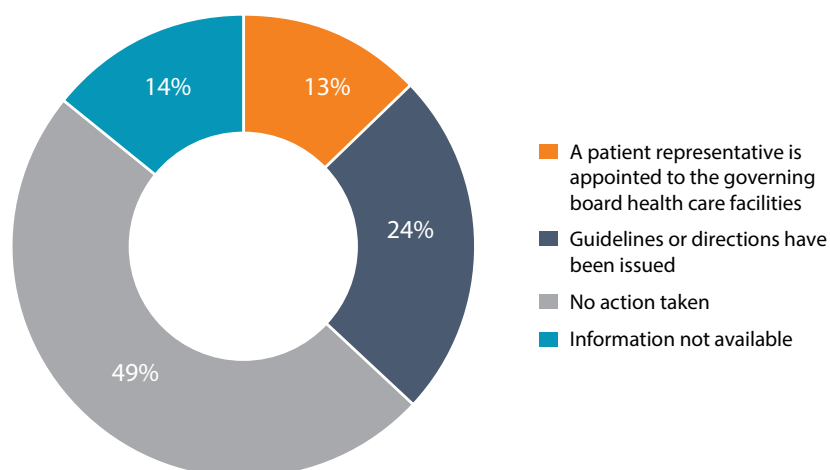
Only one in five countries around the world reported that they always involve patients in the decision-making processes related to improving the safety of health care. This demonstrates the extent to which patients are inadequately represented on national or subnational committees and similar bodies that develop policies, programmes and guidelines for making care safer.

Another 46% of countries responded that they recognize the importance of patients being involved in policy and guideline development work, although this practice is not universally implemented. There is considerable variation between WHO regions about this critical aspect of patient engagement (Fig. 4.4).



**Fig. 4.4.**  
Inclusion of patient representatives on committees for policy, programmes and guidelines development, by WHO region

Incorporating a patient representative into the hospital governing board could be a key approach to improving patient engagement in day-to-day delivery of health care services. This is one of the core indicators for measuring the implementation of the Global Patient Safety Action Plan 2021–2030. According to Member State survey responses, over a third of countries have already taken steps in this direction (Fig. 4.5). Only 13% of countries reportedly have patient representatives in governing boards of the majority (i.e. >60%) of hospitals, and another 24% have issued related guidelines or directives. However, almost half of respondents (49%) reported that they are yet to take action on involving patients in governance mechanisms.



*Only 13% of countries have patient representatives on the governing boards of the majority (>60%) of their hospitals.*

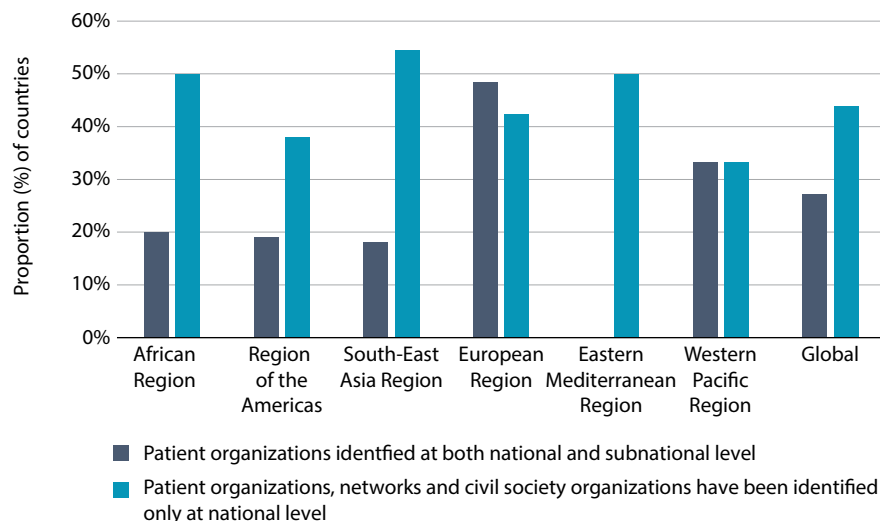
**Fig. 4.5.**  
Patient representation on hospital governing boards

## Identification of patient organizations

There is evidence of increasing recognition and involvement of patient groups and civil society actors in patient safety and engagement initiatives. 27% of survey respondents indicated that they have identified patient organizations,

Twenty-seven percent of survey respondents have identified organizations engaged in patient advocacy and involvement at both national and subnational levels.

**Fig. 4.6.**  
**Identification of patient organizations at national and subnational level, by WHO region**



## Patient engagement as an assessment criterion for health care facilities

The Member State survey reveals that globally more than a quarter of countries have incorporated patient engagement as one of the assessment criteria for health care facilities. This indicates that patient engagement is increasingly recognized as an important factor in improving the safety and quality of health care.

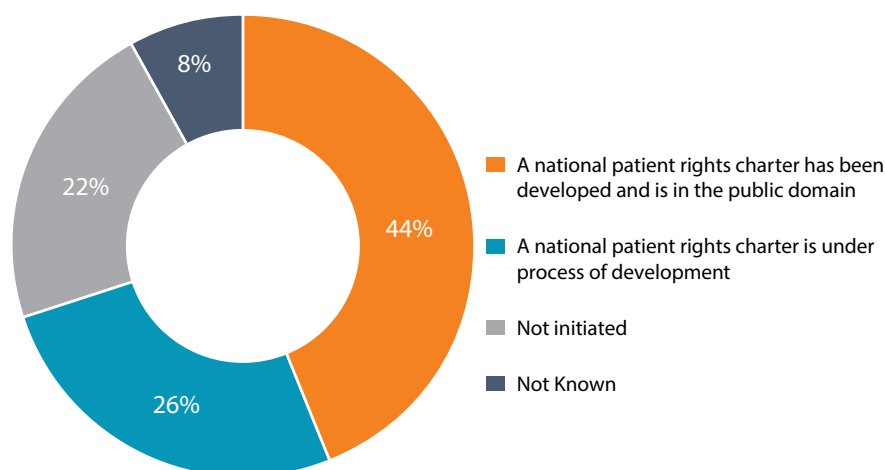
## Patient rights charter

To empower patients and protect their rights to receive safe, respectful, autonomous and reliable care, the Global Patient Safety Action Plan 2021–2030 calls for governments to develop a national patient rights charter or bill. Such charters help ensure that patients have access to information and transparency about their health status, treatment options and potential risks, and promote the concept of safe, respectful care as a human right. WHO has recently launched a patient safety rights charter. The charter covers 10 patient safety rights crucial to mitigate risks and prevent inadvertent harm, which includes the right to timely, effective and appropriate care, the right to safe health care processes and practices, the right to qualified and competent staff, and the right to patient and family engagement amongst others (217).

According to the survey, 44% of countries have already developed such a charter or bill and made it available publicly, while another 26% are in the process of developing a charter (Fig. 4.7).

Nearly half of the surveyed countries have developed and publicly shared a national patient rights charter or bill.





**Fig. 4.7.**  
**Status of national patient rights charters based on response from 108 countries**

## Country initiatives for patient engagement

**Thailand** has established a patient safety network in adherence with the WHO Patients for Patient Safety (PFPS) programme; and patient representatives have been included on its National Patient and Personnel Safety Committee.

**Czechia** has instituted a Patient Council in 2017, comprising representatives of patient organizations. This council acts as an intermediary for the voice of patients to the Ministry of Health, consults on legislative matters and proceedings as a representative of patients, and is a permanent advisory body of the Minister of Health.

**Australia** has a Consumers Health Forum, which has been established as a national body representing the interests of patients and their families and has identified patient networks for each of its states and territories.

**Kazakhstan's** Code of the Republic includes an article that asserts the right to patient safety throughout the health care system.

Health services in **Chile** have established the Councils of Civil Society as a way of involving civil society organizations in the health sector. The council comprise diverse and representative members of the public who can provide their views and feedback on the decision-making, implementation and evaluation of public policies, plans and programmes of the Ministry of Health.

**Cyprus** has a legal framework for ensuring the participation of patients in health policy decision-making (218). According to the law, patients have the right to be represented in all national committees that deal with health-related issues, such as quality and safety, health technology assessment (HTA), health promotion, and health education. This way, patients can voice their needs and preferences, and contribute to the improvement of the health system and the health outcomes of the population.

**Belgium** has a law specifically defining the rights as a patient. This law also lays the foundation of a good and enduring relationship between patients and health workers.

*Various countries have implemented strategies to enhance patient safety through the involvement of patient representatives and the establishment of patient councils or networks, as well as the enactment of laws and frameworks to protect patient rights and promote their participation in health care decision-making.*

**Uruguay** has an established law on the rights and obligations of patients and users of health services (219). It aims to protect the dignity, autonomy, privacy and confidentiality of people who access health care, as well as to promote their participation and information.

The Patients' Bill of Rights in **Nigeria** outlines the rights and responsibilities of patients, health care providers and the government in the health care sector. It was developed by the Consumer Protection Council, the Federal Ministry of Health and other stakeholders.

In the **United States**, the President's Council of Advisors of Science and Technology provided concrete recommendations in a report to the President entitled A transformational effort on patient safety, which states: "Patients, families and community members should be involved in the development of all phases of patient safety planning, programming, assessment and evaluation" (220).

	4.1	4.2	4.3	4.4	4.5
Strategic objective 4	Co-development of policies and programmes with patients	Learning from patient experience for safety improvement	Patient advocates and patient safety champions	Patient safety incident disclosure to victims	Information and education to patients and families

## Strategy 4.2.

# Learning from patient experience for safety improvement



Learn from the experience of patients and families exposed to unsafe care to improve understanding of the nature of harm and foster the development of more effective solutions

To design effective patient safety programmes and solutions, it is crucial to incorporate the insights from patients who have experienced harm from unsafe care, as well as the perspectives of their family members through approaches such as storytelling and patient-reported experience surveys. Opportunities for people with lived experience to connect with other patients and families who have experienced harm, and also with other advocates, champions and organizations who are working to improve the safety of health care, are also important.

Health care organizations should set up ways to collect and analyse feedback from patients and families. These pathways can include surveys, interviews, focus groups, complaints, compliments and suggestions. The feedback received is used to identify areas for potential improvement, monitor progress and recognize best practices. The organization should also communicate the results of its reporting systems back to the patients and families, as well as to staff and the public, to demonstrate its commitment to continuous improvement.

*Although most countries collect patient and family feedback on health service safety, only around a quarter report back on the improvements made based on this feedback.*

## Patient feedback mechanisms

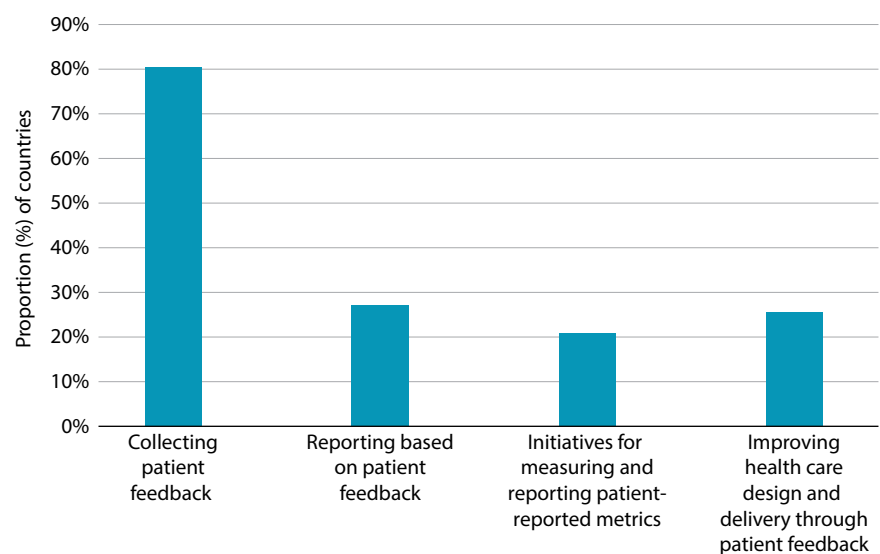
Most of the respondent' countries (80%) reported that a mechanism exists to collect feedback from patients and their families about the safety and quality

of their health services (Fig. 4.8). However, only 27% of respondent countries mentioned that systems were in place to report back to patients and their families what changes had been done to improve the services based on their feedback.

*One in five countries regularly use patient-reported experience measures and patient-reported outcome measures.*

Another approach to assess patient safety involves the use of patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs). PREMs evaluate patients' perceptions of the care quality and safety they receive, focusing on aspects like communication effectiveness, response timeliness and respectfulness of treatment. PROMs, on the other hand, gauge the impact of the health care received on patient health outcomes, including functional ability, pain levels and overall results of treatment. According to the survey data, one in five countries reported that they regularly measure and collate patient-reported outcomes and experiences.

**Fig. 4.8.**  
**Mechanisms for seeking feedback from patients and families on the safety and quality of services**



## Learning from patients' stories

*Twenty-one percent of countries have implemented initiatives to collect and document patients' stories of harm.*

Collecting and documenting patients' stories of harm and unsafe care is an important strategy for improving patient safety. It can help to identify the root causes of the problems, bring learning from the experiences and perspectives of patients, and shape the design and implementation of effective solutions. Moreover, it can also empower patients to voice their concerns and to participate in the improvement process. Survey data indicate that 21% of countries have implemented initiatives to collect and document patients' stories of harm as part of their wider initiatives towards patient engagement.

## Country initiatives for patient feedback mechanisms

**Colombia** reports that adverse events and complications of patients are monitored through a range of mechanisms, including quarterly follow ups and evaluations, feedback collection, and documentation within its quality information system.

In **Cuba**, each health institution has an Office of Attention to the Population, which responds to the concerns of patients and their relatives. There are mechanisms for strengthening user satisfaction embedded throughout the structures of the health system and larger governance bodies, and records of patient dissatisfaction cases are studied to inform better practices and outcomes.

**Türkiye** has developed a platform to document and learn from patients' stories of harm and unsafe care. It allows patients to evaluate the service they receive through patient experience surveys and conducts quality of care studies based on suggestions and complaints filed by patients.

In **New Zealand**, the Health Quality and Safety Commission administers a national adult inpatient experience survey (221), and is in the process of developing a set of national PROMs. The country also has a code of expectations for health entities' engagement with consumers.

**Qatar** has conducted national surveys to gain insights on patient experiences. A patient advocacy framework has been developed but it is yet to be implemented.

**United Kingdom** (Scotland) is in the process of developing a Patient Safety Commissioner role to act as a patient advocate in patient safety issues; the country also uses principles of co-design and co-production to engage patients and health system users in the design of public health care services.

**Trinidad and Tobago's** quality departments – under its regional health authorities – routinely conduct randomized surveys with patients and their families on the quality of services and keep records of all instances of unsafe care or practices.

In **Ireland** the National Care Experience Programme is a joint initiative from the Health Information and Quality Authority, the Health Service Executive and the Department of Health. Its surveys ask people about their experiences of care to improve the quality of health and social care services. The programme aims to provide a voice for patients and service users, and to use their feedback to inform improvements at local and national levels (222).

**Australia** has sophisticated national, state and territory health complaints systems, and information is drawn from these organizations to document harm and unsafe care. Each state and territory has an incident management system, which investigates and provides learnings about patients' stories of harm and unsafe care.

The national reporting and learning system in **Denmark** allows patients and families to share their experiences of patient safety incidents. The Danish Patient Safety Authority can also receive reports from patients and families about patient safety risks related to health care facilities or individual health care workers.

A patient ombudsman is a function that exists in **Czechia** to protect and promote the rights of patients. Many hospitals have a similar role to provide information and assistance to patients who have questions or concerns about their treatment.

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*Countries worldwide are advancing patient safety through diverse feedback mechanisms, including national surveys, patient advocacy roles, and documenting experiences of harm. These initiatives empower patients to voice their concerns and shape safer health care systems.*

## Feature story 9.

### Patient advocacy can improve patient safety: a case study from the United States

I was 34 years old when my son experienced preventable brain damage, known as kernicterus, when his newborn jaundice was not tested or treated in a timely matter. Four years later, my husband, Pat, also suffered a patient safety event when the malignant pathology of a tumour in his neck failed to get communicated to the neurosurgeon or to us. He died at age 45. I was devastated and alone.

As a single mom raising a disabled son and a four year-old daughter, I committed to making health care safer for others. I educated myself about the United States health care system, learned how to effectively tell my story, learned advocacy and diplomacy skills, and co-founded a non-profit organisation that successfully changed the standard of care for jaundice management in the country. I testified at government agency summits and before the US Congress about the importance of safer care. My family's story and my advocacy were featured in the Wall Street Journal and USA Today, and in international documentaries including one entitled To err is human.

During my advocacy journey I have had the honour of serving as external lead and advisor to the WHO Patient Safety Flagship. I also served in leadership positions in government and government-funded health care agencies in the US. More recently, I co-founded the Patients for Patient Safety US advocacy group and was appointed to a patient safety working group of the President's Executive Advisory Committee.

Through the past 28 years, I have learned that patients and family members can become effective leaders in patient safety advocacy, awareness raising and in co-developing policy initiatives. I have also witnessed the power of partnering with policy-makers, accreditors, researchers and other patients who have suffered harm in health care.

Finally, I have learned to never give up (Pat's words).



© Susan Sheridan

*Susan Sheridan, BA, MBA, DHL  
Founding Member  
Patients for Patient Safety (PFPS) United States*

	4.1	4.2	4.3	4.4	4.5
Strategic objective 4	Co-development of policies and programmes with patients	Learning from patient experience for safety improvement	Patient advocates and patient safety champions	Patient safety incident disclosure to victims	Information and education to patients and families

## Strategy 4.3.

# Patient advocates and patient safety champions



Build the capacity of patient advocates and champions in patient safety

A patient-centred patient safety programme requires the involvement and empowerment of patient advocates and champions, who can influence the design and delivery of health services.

**This can be achieved in various ways. For example, they can:**

- raise awareness, and educate patients and the public about patient safety issues and best practices;
- share their experiences and perspectives with health workers and policy-makers and provide feedback on the safety and quality of care;
- participate in decision-making processes and co-design solutions that address the needs and preferences of patients and their families;
- monitor and evaluate the implementation and impact of patient safety initiatives and policies, and hold health workers and authorities accountable.

To enable patient advocates and champions to perform these functions effectively, countries need to invest in building and strengthening their networks and capacities. This includes providing them with education, resources, technical support and leadership development opportunities, as well as facilitating collaboration among different patient advocacy groups.

*Patient-centered safety programmes require empowering patient advocates to influence health service design and delivery, necessitating national investment in their resources, education, and networks for effective advocacy.*



### Box 4.1. WHO Patients for Patient Safety programme

Historically, WHO has championed the engagement of patients, families and communities in health and health care. WHO commitment was demonstrated by the development of the WHO Patients for Patient Safety (PFPS) programme in 2005.<sup>a</sup>

PFPS engages and empowers patients and families and facilitates their partnerships with health professionals and policy-makers to make health care services safer worldwide.

PFPS is a unique international network of patients who have been victims of avoidable harm, those who have lost a loved one to unsafe care, as well as other dedicated advocates. PFPS was developed and is managed by a team of patient safety advocates. The programme aims to highlight the rights of patients and family members, establish the principles and practice of openness and transparency, demonstrate the power of partnership, and enhance patients' roles in achieving patient safety.

The London Declaration, created by the PFPS, outlines the following areas of action: programmes for patient safety and empowerment; constructive dialogue among all stakeholders; systems for reporting and addressing patient harm; and, promoting best practices in dealing with health care harm.<sup>b</sup>

Note:

<sup>a</sup> *Patients for patient safety* [website]. Geneva: World Health Organization; 2024. (<https://www.who.int/initiatives/patients-for-patient-safety>, accessed 25 April 2024).

<sup>b</sup> *London Declaration: Patients for Patient Safety*. Geneva: World Health Organization; 2016 ([https://cdn.who.int/media/docs/default-source/patient-safety/pfps/pfps\\_london\\_declaration\\_2010\\_en.pdf](https://cdn.who.int/media/docs/default-source/patient-safety/pfps/pfps_london_declaration_2010_en.pdf), accessed 25 April 2024).

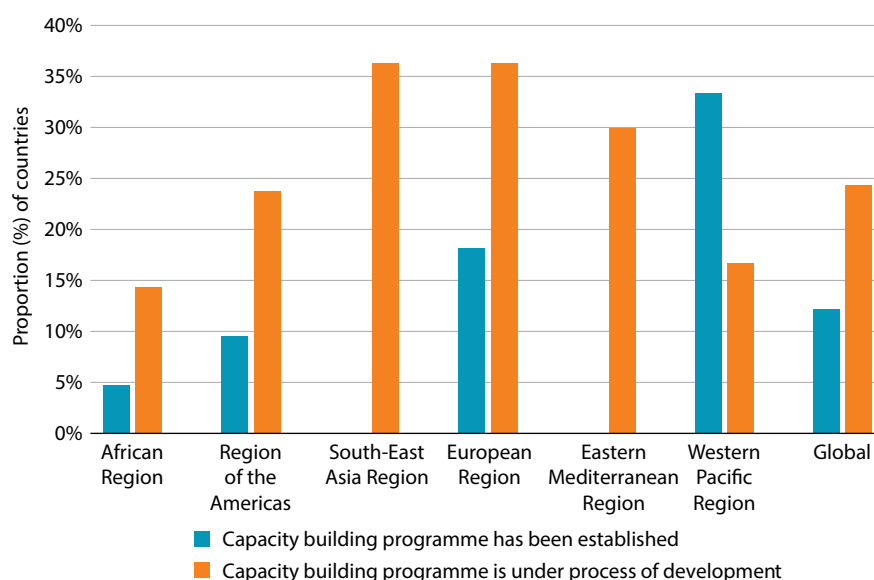


Ms. Melissa Sheldrick, Patient Safety Advocate, giving remarks at the start of the World Patient Safety Day conference at WHO headquarters in Geneva. © WHO / Christopher Black

## Recognition and capacity building of patient advocates and champions

In their responses to the Member State survey, more than half of countries reported that their governments recognize and support the role of patient advocates and champions in enhancing patient safety. However, only 12% of the countries said that they have created educational and technical resources to build the skills and abilities of patient advocates and champions and established capacity building programs targeted to them. Additionally, around one quarter of the countries said that patient advocates and champions were invited to join national and local events related to patient safety, such as seminars, conferences and consultations. Events can also work as an opportunity to stimulate discussion and advance sharing of best practices.

*While over half of countries recognize and support the role of patient advocates in enhancing patient safety, only 12% have established programmes to build their skills and capacities.*



**Fig. 4.9.**  
Status of capacity-building programmes for patient advocates and champions, by WHO region

## Patients for Patient Safety networks

Networks and other platforms enable patients and their families to make their voices heard and share their experiences of safe and unsafe care.

The WHO Patients for Patient Safety (PFPS) network (223) provides a significant opportunity for patient safety advocates to collaborate and share their experiences. However, there is still a gap in the development of such networks at the national and subnational levels. According to the Member State survey, only 28% of countries reported having PFPS networks. Most active networks are located in HICs and UMCs. Furthermore, 10% of countries reported that their national patient networks collaborate with the WHO PFPS programme.

*Twenty-eight percent of countries have established Patients for Patient Safety networks, with the most active ones primarily in high-income and upper middle-income countries.*

## Country initiatives to build the capacities of patient advocates and champions

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*Countries are actively developing initiatives to enhance the capabilities of patient advocates and champions, with efforts including the establishment of dedicated departments, training curricula, resource provision, and strategic alliances.*

The Ministry of Health of **Czechia** has established a Department for the Support of Patients' Rights. The objective of the department is to build the capacities of patient representatives to enable them to be active participants in the process of creating and implementing health policies.

In **Namibia**, the Ministry of Health and Social Services has piloted a Consumer Involvement Training Curriculum within HIV care services, with the aim of developing a clear set of stakeholder roles and responsibilities that can be used to inform implementation across other departments.

In **Pakistan**, training resources for building the capacity of patient advocates and champions are available from provincial health care commissions.

**Peru's** governmental agency for the promotion of health rights has developed platforms for users of health services; and its office of the Ombudsman for Health and Transparency monitors fulfilment of patient rights, conducts workshops to promote patient rights, and builds strategic alliances with relevant stakeholders (224).

**Philippines'** National Policy on Patient Safety in Health Facilities has demarcated roles and responsibilities for a range of stakeholders including patient advocacy groups and networks, government personnel, civil society agencies, academic bodies and multilateral organizations (165).

## Feature story 10.

### Patients for Patient Safety Canada

#### Summary

What started as a patient- and family-led movement in early 2000 became a pledge for partnership through the WHO Patients for Patient Safety (PFPS) Network (2005) and the London Declaration (2006).<sup>a</sup> Both continue to shape the pursuit of safer care in Canada<sup>b</sup> and more widely.

*“In honour of those who have died, those left disabled, our loved ones today and the world’s children yet to be born, we will strive for excellence, so that all involved in health care are as safe as possible as soon as possible. This is our pledge of partnership.”*

**(London Declaration)**

#### What was done and why?

Patients for Patient Safety Canada<sup>c</sup> was launched in 2007 as a patient-led community and the Canadian arm of the global network. Since then, their members have partnered with safety-focused organizations and patient groups, and have shaped many patient safety resources, guidelines, education initiatives, standards, strategies, policies, practices and programmes in Canada.

Patients for Patient Safety Canada collaborates with Health care Excellence Canada to work towards safer health care in the country. It facilitates the involvement of its members in bringing the patient voice to various patient safety initiatives; lending their credibility and contacts to expand the reach of the patient safety movement.

Currently, PFPS Canada has 62 members from across Canada. To complement membership numbers, a patient safety alliance group was established so PFPS Canada could connect with other diverse patient groups and patient partners that expressed an interest in advancing patient safety. As of 2023, the Patient Alliance for Patient Safety<sup>d</sup> comprises 20 organizations as well as independent patient partners. The common patient safety aim for all alliance members is public engagement focused on improving the safety of care journeys. This alliance provides a forum for sharing resources and supporting the patient work of alliance members.

*“I believe that if we hadn’t meaningfully involved patients we wouldn’t have generated and inspired so much innovation and improvement.”*

**(Representative of Healthcare Excellence Canada)**

#### What’s next?

Today, there are numerous and varied patient interest groups, including active patient voices at the local, provincial and national health care levels. There is still a need to ensure that all patient voices are heard with

flexible formats for inclusion. A key objective now is to enhance the collaboration and coordination with other patient groups and patient partners, including those whose voices are not typically heard – promoting equity, diversity and inclusion, especially with the First Nation, Inuit and Metis communities.

Sources:

<sup>a</sup> *London Declaration: Patients for Patient Safety*. Geneva: World Health Organization; 2016 ([https://cdn.who.int/media/docs/default-source/patient-safety/pfps/pfps\\_london\\_declaration\\_2010\\_en.pdf](https://cdn.who.int/media/docs/default-source/patient-safety/pfps/pfps_london_declaration_2010_en.pdf), accessed 25 April 2024).

<sup>b</sup> *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*. Ottawa: National Steering Committee on Patient Safety; 2002 (<https://era.library.ualberta.ca/items/eda9644a-1f91-4ec9-880a-7b69c651bf0c>, accessed 25 April 2024).

<sup>c</sup> *Patients for Patient Safety Canada [website]*. Ottawa: Patients for Patient Safety Canada; 2024 (<https://www.patients4safety.ca>, accessed 25 April 2024).

<sup>d</sup> *Patient Alliance for Patient Safety [website]*. Ottawa: Patients for Patient Safety Canada; 2024 (<https://www.patients4safety.ca/en/essential-care-partners/patient-alliance>, accessed 25 April 2024).

	4.1	4.2	4.3	4.4	4.5
Strategic objective 4	Co-development of policies and programmes with patients	Learning from patient experience for safety improvement	Patient advocates and patient safety champions	Patient safety incident disclosure to victims	Information and education to patients and families

## Strategy 4.4.

# Patient safety incident disclosure to victims



Establish the principle and practice of openness and transparency throughout health care, including through patient safety incident disclosure to patients and families

The fundamental principles for safe patient-centred care include transparency: being open and honest with patients and their families about all aspects of their care. Transparency involves ensuring that patients provide informed consent before any treatment or procedure, that all involved can access their own medical records, that they are informed of any safety incidents that affect them or could have affected them, and that they have ways to voice their concerns and seek help when needed. Transparency also requires that health workers are supported to disclose adverse events in a respectful and compassionate way, and that both patients and health workers receive psychological and other support after serious patient safety incidents. To promote transparency, governments and health systems should develop national guidance and standards for workers, as well as educate and empower patients and their families about their rights and responsibilities as partners in care. Patient advocacy organizations and champions can play a vital role in raising awareness and influencing policy and practice in this area.

*Transparency in patient care requires health workers to be supported in disclosing adverse events respectfully and compassionately.*

## Guidance for obtaining informed consent

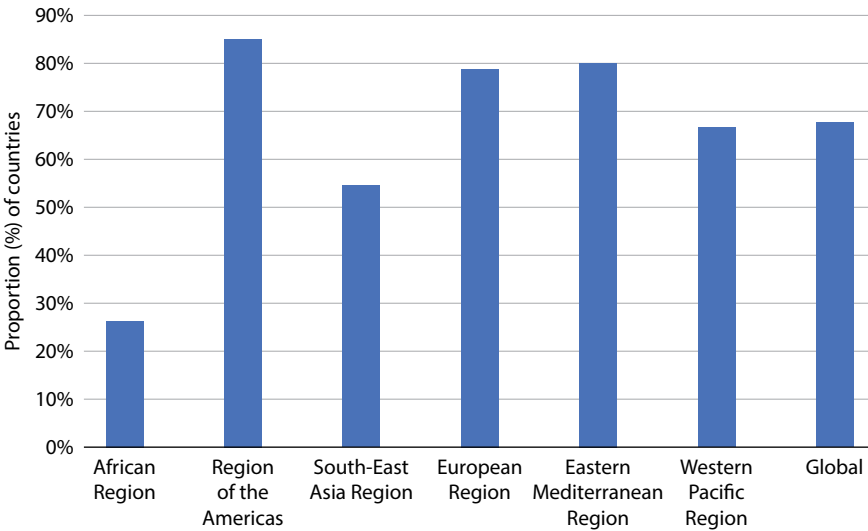
Informed consent is a vital process in health care that ensures the respect for patients’ autonomy and dignity. It involves providing clear and accurate

More than two thirds of countries have established and disseminated national guidelines on obtaining informed consent.

information about the benefits, risks, alternatives and potential consequences of a proposed treatment or procedure, and obtaining the voluntary agreement of the patient (or their legal representative) to proceed. Informed consent protects both the patient and the health worker from potential harm or legal disputes. Developing national guidance for obtaining informed consent from patients and families can help to standardize the practice, and promotes patient safety across different settings and situations.

More than two thirds of the participating countries reported they have established and disseminated national guidelines on how to obtain informed consent from patients and their families (Fig. 4.10). The regions with the highest rates of reporting such national guidelines were the Eastern Mediterranean Region, the European Region and the Region of the Americas, where more than 70% of the participating countries confirmed their availability in the public domain.

**Fig. 4.10.**  
Availability of guidance on obtaining informed consent from patients and families, by WHO region



### Patient access to medical records

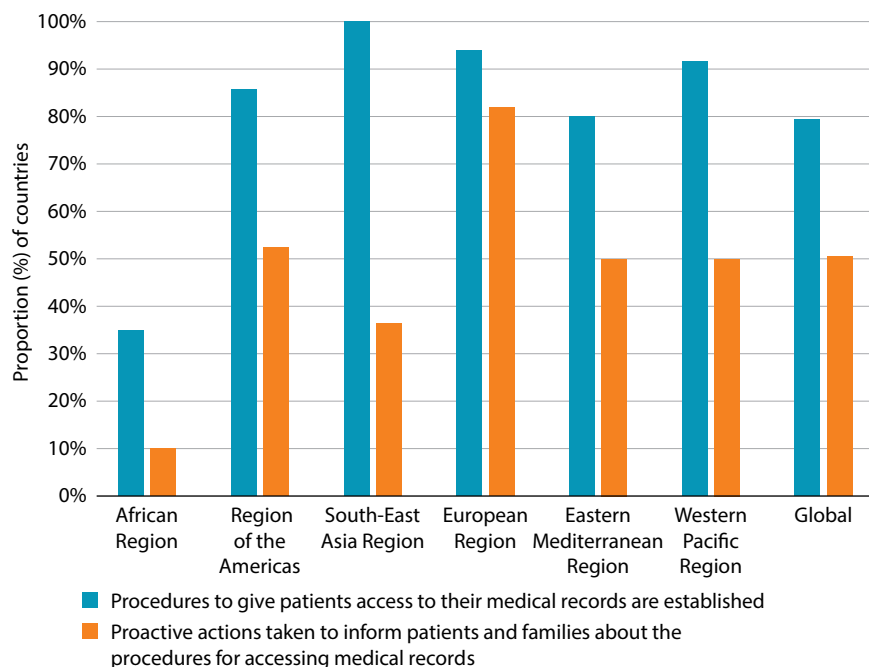
The majority of countries (80%) have established procedures that allow patients to access their medical records, enhancing patient safety and empowerment, though only half have actively informed patients of these procedures.

Access to patient’s records is a valuable tool for improving patient safety and patient rights, as well as empowering patients to take control of their health. A systematic review found that patient-accessible records can enhance patient–provider communication, patient adherence, patients’ knowledge about their own health, and patient satisfaction (225). Data from the Member State survey shows that most countries (80%) have set up procedures that allow patients to access their own medical records. Although only 50% of countries have taken proactive actions to inform patients about the procedures for accessing patients’ medical records. This is a positive step towards strengthening patient empowerment, health literacy, transparency and accountability in health care delivery.

Access to medical records varies significantly across different regions of the world, reflecting the diverse legal, ethical norms that influence the recognition and implementation of patient rights (Fig. 4.11). The South-East Asia Region



stands out, with all its countries providing procedures for patient access to records, as do almost all countries in the Region of the Americas and the European Region. Other regions also demonstrate a substantial level of access to medical records, with the exception of the African Region, which has a lower level of access. These variations are indicative of the different approaches and priorities in health care systems and patient rights across the globe.



**Fig. 4.11.**  
Procedures in place to give patients access to their medical records, by WHO region

## Disclosure of adverse events to patients and families

The disclosure of adverse events to patients and their families is also an important aspect of patient safety. When an adverse event occurs, patients and their families have the right to know what happened, why it happened, how it might affect them, and what will be done to reduce any impact on their health and to prevent the incident from happening again. They also deserve an apology and compassion from the health workers involved. Disclosing errors is not only ethical, but also promotes restoration of the doctor–patient relationship and facilitates learning (226). However, disclosure is often challenging and stressful for both patients and providers. Important barriers include fear of consequences, attitudes about disclosure, lack of skill and role models, and lack of peer and institutional support (227).

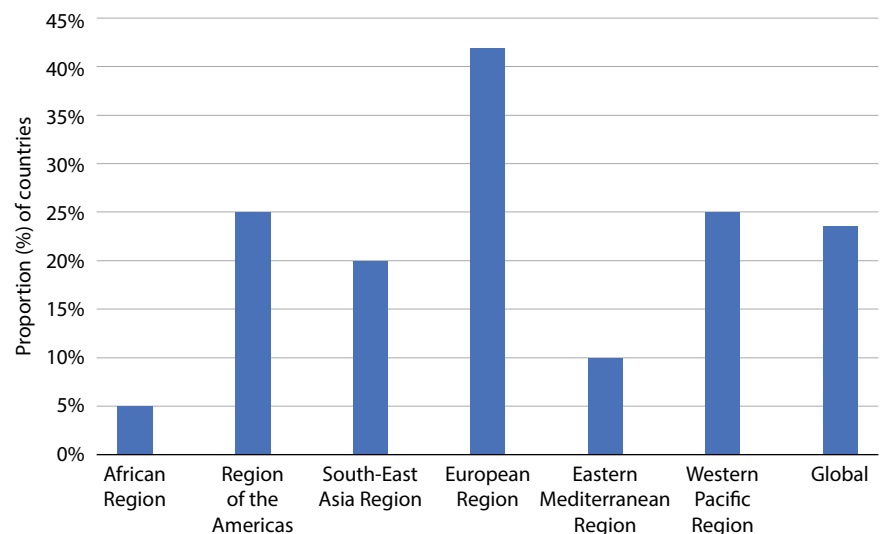
It is essential to have a system for overseeing disclosure that is part of a health care organization's patient safety programme. Such a system should include policies, procedures, training, support and evaluation of disclosure practices. Disclosure practices can be improved by strengthening policies and supporting health workers in disclosing adverse events (228).

Almost a quarter of the countries responding to the Member State survey reported that their health facilities have guidelines or SOPs for disclosing adverse events to patients and their families. However, the survey also showed

*A quarter of countries have implemented guidelines or SOPs in health facilities for disclosing adverse events to patients and their families.*

that this practice is not consistent across different regions (Fig. 4.12). In general, disclosure procedures are seen most often in HICs (39%), followed by UMCs (26%) and LMCs (8%). No LICs reported having such procedures in place.

**Fig. 4.12.**  
Procedures in place for  
disclosure of adverse events to  
patients and families, by WHO  
region



*Only 10% of countries have established guidelines for providing psychological support to patients, their families, and health workers affected by serious patient safety incidents.*

## Psychological support in case of adverse events

Psychological support to patients, their families and health workers after a serious patient safety incident is an essential component of patient safety culture. It aims to mitigate the emotional and psychological distress caused by an incident, promote healing and recovery, and prevent adverse outcomes such as post-traumatic stress disorder, depression, anxiety or litigation. Psychological support can take various forms, such as emotional first aid, peer support, counselling, or therapy, depending on the needs and preferences of the affected individuals.

Only 10% of countries have reported having guidelines for offering psychological support to patients, their relatives and health workers who were affected by a serious patient safety incident.

## Country initiatives to promote transparency and obtain informed consent

In **Pakistan**, Healthcare Commission standards include guidance for obtaining informed consent from patients and families. Informed consent forms are a vital component of the patient file at the hospital level and is strictly obtained prior to any procedure.

Health authorities in the **Islamic Republic of Iran** have issued guidelines for obtaining informed consent from patients who undergo invasive procedures. These guidelines specify the policy and procedures of informed consent, as well as the list of invasive procedures that require informed consent. The guidelines have been disseminated to hospitals and are being implemented. In **Sudan**, informed consent is required prior to all surgical procedures.

The 2013 Patient Rights Act in **Germany** (229) protects the rights of patients in the health care system. It states that patients must be informed by their health care provider about everything they need to know to give their consent for a treatment, in a way that they can understand. It also gives patients the right to access their documentation of treatment, and to be notified by their health care provider if there was a mistake in their treatment that could affect their health, or if they are entitled to claim compensation for harm they may have suffered.

The Freedom of Information Act in **Seychelles** is a law that ensures the right of citizens to access their medical records. Additionally, **Cambodia, Bulgaria, Iraq** and **Slovakia** have procedures in place to enable patients to access their medical records.

According to the Law on Medical Care in **Armenia** (Article 14.2/10), patients have the right to access their medical records and information related to their health condition and treatment(s).

**Chile** has regulations around delivery of information and expression of informed consent with patients, and has disseminated a charter to health system users outlining the rights and duties of patients.

In **South Africa**, assessment criteria for certification of health facilities include indicators on informed consent and medical record access. National guidelines for patient safety provide guidance on disclosing adverse events to patients and families, and providing psychological support to patients, families and health workers involved in adverse events.

**Spain** has laws around patient autonomy and rights in the context of clinical procedures that uphold patients' entitlements around informed consent, clinical documentation and access to medical records.

The Open Disclosure Framework (230) is a set of principles and guidelines that aim to promote transparency and accountability in the health care system in **Australia**. The framework outlines the best practices for communicating with patients and families if something goes wrong in their care. The framework also outlines the requirements for psychological support to patients, their families and health workers after a serious patient safety incident.

The duty of candour regulation is a legal requirement for health and social care providers in the **United Kingdom** to act in an open and transparent way with people who use their services. The regulation aims to ensure that providers inform people about any notifiable safety incidents that might occur during their care or treatment, provide them with reasonable support, truthful information and an apology, and record the incident and the actions taken (231). A newly launched Patient safety incident response framework also emphasizes the importance of engaging and involving patients, families, carers and staff in a compassionate and respectful way throughout the process (232).

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*Countries worldwide are enhancing transparency and informed consent in health care through specific legal and regulatory frameworks.*

Strategic objective 4	4.1	4.2	4.3	4.4	4.5
	Co-development of policies and programmes with patients	Learning from patient experience for safety improvement	Patient advocates and patient safety champions	Patient safety incident disclosure to victims	Information and education to patients and families

## Strategy 4.5.

# Information and education to patients and families



Provide information and education to patients and families for their involvement in self-care, and empower them for shared decision-making

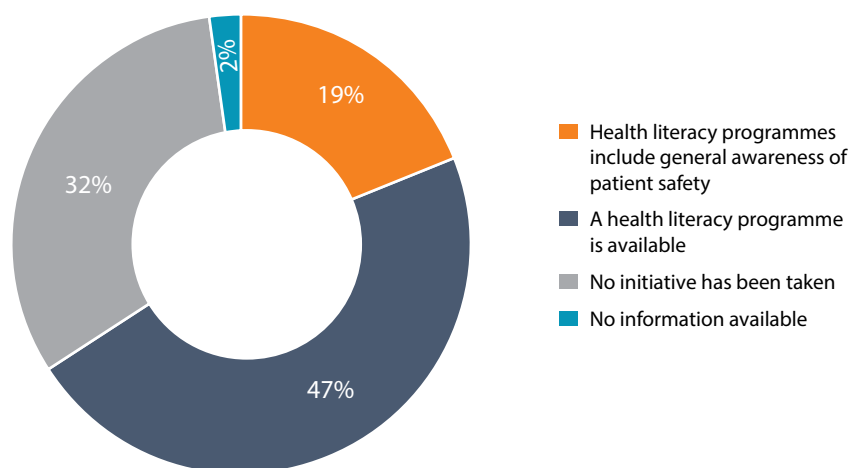
To empower patients and their families to participate in decision-making and express their care preferences, the first step is to raise public awareness about patient safety through broad outreach channels such as information, education and community awareness programmes. A national curriculum on patient safety education should be created to support the process, tailored to different age and audience groups. Enhancing patients’ and families’ skills in managing their health, understanding care delivery and self-care, and knowing the safety risks of clinical procedures enables them to communicate their needs and concerns more effectively in health care settings.

### Health literacy and patient engagement

*Enhancing patient safety involves improving health literacy, enabling informed decision-making, and fostering patient engagement through accessible education and clear communication.*

Enhancing patient safety can be achieved by boosting health literacy: the ability to find, understand and use health information to make informed decisions about one’s health (233). Enhancing health literacy allows people to become more aware of the risks and benefits of different treatments, prevent harm, and communicate better with health care providers. Initiatives to enhance health literacy include developing clear and easy-to-read materials, using plain language and visual aids, providing education and training programmes, and creating a culture of patient engagement and empowerment.

According to the survey data, 66% of countries have implemented health literacy programmes. Within this group, 19% of these programmes include components specifically dedicated to raising awareness about patient safety. (Fig 4.13). The survey data also revealed that public awareness of patient engagement is not widely integrated into the formal education system. Only a small fraction of the respondents (6%) reported that skills that support the active involvement of patients in their own care are taught at all levels of education, from school to university.



*The survey data shows that 66% of countries have implemented health literacy programmes, with 19% of these specifically raising awareness about patient safety.*

**Fig. 4.13.**  
**Inclusion of patient safety in public health literacy programmes**

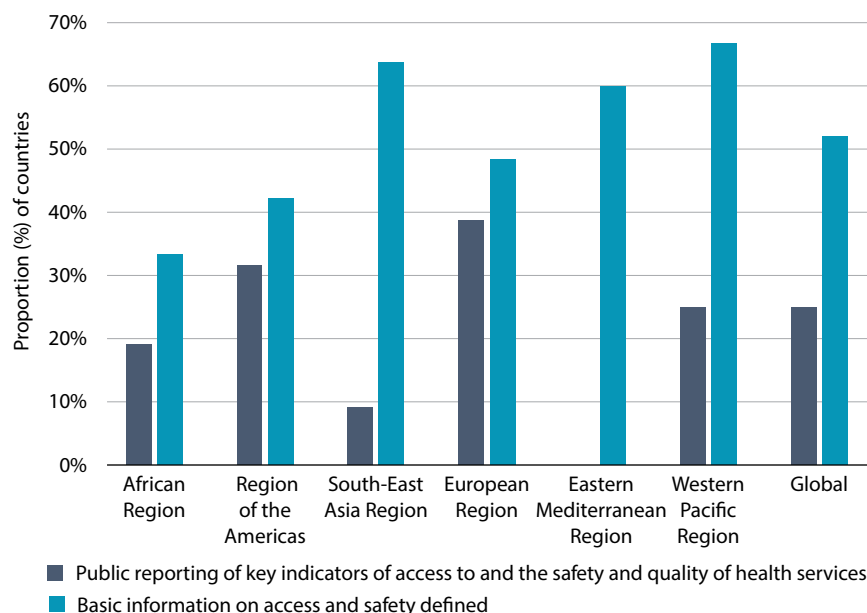
## Information about safety and quality of health services

One of the challenges that patients face when choosing a health care facility is the lack of reliable and transparent information about the safety and quality of the services provided. Information such as waiting times, mortality rates, complication rates, patient satisfaction, safety and quality scores, can help patients make informed decisions and compare different options. Therefore, there is a need to improve the availability and quality of information about health care facilities and their services.

According to the Member State survey, only 25% of countries make information about access, safety and quality of health services available to the public, such as waiting times, mortality rates, complication rates and patient satisfaction. Majority of countries (52%) report they have defined a minimum level of information on access and safety that health care facilities must provide to users. There is also wide variation in the standards and requirements across different regions and countries (Fig. 4.14). This includes established charters and quality standards in some regions. Various countries use online platforms, including dedicated websites and digital reports, to make health care access and safety data available. Some countries either have or are in the process of developing a legal framework that requires health care facilities to disclose safety and quality information. Inspection bodies in certain countries perform related oversight and publish their findings to ensure facilities meet quality norms. The survey responses underscore a range of transparency levels, from comprehensive public reporting to more limited data availability, reflecting a spectrum of health care information dissemination practices worldwide.

*Twenty-five percent of countries publicly provide information on health service access, safety, and quality, highlighting the need for greater transparency to help patients make informed health care decisions.*

**Fig. 4.14.**  
Availability of information  
about access, safety and quality  
of services, by WHO region



## Use of digital technologies

Digital technologies and smartphones have become ubiquitous tools for enhancing patient engagement and patient safety in health care settings. They can facilitate communication, education, self-management and shared decision-making between patients and providers, as well as improve the quality and efficiency of care delivery. Patients can use smartphone applications to monitor their health conditions, access their medical records, and communicate with their care teams. These applications can also help patients report adverse events, provide feedback, and seek support from other patients or caregivers. Providers can use digital platforms to share best practices, coordinate care, and provide feedback to patients.

The COVID-19 pandemic posed unprecedented challenges for health care systems and public health authorities around the world. One of the key strategies to prevent and control the spread of the virus has been to educate patients and the public about the symptoms, transmission, prevention and treatment of COVID-19. However, traditional methods of health education – such as face-to-face consultations, brochures and posters – were not always feasible or effective in the context of widespread social distancing measures. Therefore, digital technology and smartphone applications emerged as innovative and accessible tools to deliver health education to a large and diverse population.

*Only 16% of countries have implemented a comprehensive strategy for using digital technology to enhance patient and family involvement in patient safety.*

The Member States survey revealed that digital technology is playing an increasingly important role in engaging patients and their families in patient safety. The survey found that 45% of country respondents had implemented at least one new use of digital technology to enhance patient and family involvement in patient safety. However, only 16% reported implementing a comprehensive strategy for use of technology for patient engagement. The European Region and the Region of the Americas reported the highest rate of implementation of technologies, where more than 20% of countries had developed multiple novel uses of technology.

## Country examples of providing information and education to patients and families

One of the rights that users of the **Cuba** National Health System have is to receive clear and accurate information about the services they can access and the safety measures they must follow. The information covers topics such as prevention, diagnosis, treatment, rehabilitation and palliation of health problems, as well as the rights and duties of users and providers. It is provided by the health workers at each level of care, from the family doctor's office to the hospital, and is also disseminated through various media, such as radio, television, newspapers and social networks.

There are initiatives using digital technologies as part of reproductive health services in **Afghanistan** that engage patients and families in safe care.

In **Spain**, the Network of Health Schools for Citizens is an initiative of the Ministry of Health that aims to promote citizen participation in the field of health, as well as to encourage health education and self-care. The network offers training, information and support resources to people and entities involved in the development of community health actions, based on the principles of equity, solidarity and co-responsibility (234).

The **Azerbaijan** health authorities, including the Management Union of Medical Territorial Units (TABIB), the Health Insurance System and the Ministry of Health, are committed to ensuring transparency and accountability in their health services. They inform patients and the public about the quality, safety and effectiveness of the services they provide, as well as the rights and responsibilities of the service users.

In **Colombia**, experience with improving health provider and patient communication during the COVID-19 pandemic has informed the country's overall approach towards using digital technology to improve patient safety outcomes; they also publish all patient safety information through their National Observatory of Quality in Health, under the National Institute of Health.

In **Poland**, the minimum information on access and safety to be provided by health care facilities to users have been defined in the law on quality and patient safety, currently processed in the Polish parliament. The Ombudsman of Patient Rights organizes regular meetings with patient organizations and patient networks.

In **Namibia**, the private health sector has adopted various methods of communicating with patients and their relatives about adverse medication events, including through online messaging, websites and cell phones.

**Liberia** is one of the countries that has adopted the WHO Medsafe application, a tool that helps health workers and patients improve medication safety.

Liga Inan is a programme that uses mobile phones to enable communication between pregnant women and health professionals in **Timor-Leste**. The aim is to improve the quality of prenatal, delivery and postnatal care, reducing the risks of complications and maternal and child mortality.

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*Countries are enhancing patient and family education and involvement in health care through various initiatives, including digital technologies, health information dissemination, and patient safety education programmes, to improve transparency, safety, and patient outcomes.*

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*Only 10% of countries have enough specialized trainers in patient safety, posing a major challenge in expanding training programmes.*



Vigo Health is a smartphone application created for stroke rehabilitation in **Latvia**. The application offers personalized exercises based on scientific research and cognitive therapy principles. The application is available for both clinicians and patients and allows to track progress and receive support from specialists (235).

#### Box 4.2. Empowering patients through WHO MedSafe application

In a significant step towards improving medication safety and patient engagement in health care, WHO introduced the MedSafe smartphone application<sup>a</sup> at the 4th Global Ministerial Summit on Patient Safety, held in Jeddah, Saudi Arabia, in 2019. Developed by WHO in collaboration with the United Nations International Computing Centre (UNICC), the application represents a key initiative under the third WHO Global Patient Safety Challenge.

The MedSafe application is centred around the '5 moments for medication safety', a concept that highlights critical points in the medication use process where patient or caregiver actions can greatly reduce the risk of harm. The application encourages users to actively participate in discussions with health workers, promoting an environment of open communication and curiosity about use of medications.

Designed for patients, family members, caregivers, and health workers across various care settings, MedSafe empowers users to manage their medications effectively. By facilitating important questions about medications and helping organize the responses, the application seeks to improve medication management and overall health outcomes.

The 5 moments for medication safety cover essential health care interactions, including visits to a range of health workers, transitions such as admissions and discharges from health care facilities, and receiving care at home. For each moment, the application provides a set of important questions designed to encourage users to think about their medication use and seek the necessary information from health workers.

Health workers are also encouraged to use MedSafe as a tool to promote patient engagement and safety. By recommending this application to patients and their support networks, health workers can help empower them to take an active role in their own care, contributing to the broader goal of enhancing patient safety worldwide.



Source:

<sup>a</sup> Introducing mobile application on 5 moments for medication safety. Geneva: World Health Organization; 2019 ([https://cdn.who.int/media/docs/default-source/patient-safety/medsafe-flyer.pdf?sfvrsn=72c0b9ef\\_2](https://cdn.who.int/media/docs/default-source/patient-safety/medsafe-flyer.pdf?sfvrsn=72c0b9ef_2), accessed 25 April 2024).

A portrait of a middle-aged man with dark hair, wearing a light blue medical scrub top over a yellow collared shirt. He is smiling slightly and looking towards the camera. In the foreground, a medical monitor is visible, displaying various data and graphs. The background is a blurred hospital setting.

Strategic  
objective

5

# Health worker education, skills and safety

*Portrait of a health worker during ICU training at Setthathirath Hospital in Lao People's Democratic Republic. © WHO / Blink Media - Bart Verweij*

“

Inspire, educate, skill and protect health workers to contribute to the design and delivery of safe care systems

## Organization of section

### Strategy 5.1. Patient safety in professional education and training

- Adoption of WHO Patient Safety Curriculum Guide
- Patient safety in undergraduate and postgraduate curricula
- In-service training on patient safety and health worker safety

### Strategy 5.2. Centres of excellence for patient safety education and training

- Patient safety institutions and training centres
- Innovative teaching methods and simulation

### Strategy 5.3. Patient safety competencies as regulatory requirements

- Establishment of patient safety core competencies
- Patient safety core competencies as a regulatory requirement
- Authorization for working in high-risk clinical areas

### Strategy 5.4. Linking patient safety with appraisal system of health workers

- Performance appraisal systems for health workers
- Performance linked reward and recognition programmes

### Strategy 5.5. Safe working environment for health workers

- Endorsement of WHO Health worker safety charter
- National occupational health programmes for health workers
- Mental health services for health and care workers
- Vaccination programmes for health workers
- Protection for violence against health and care workers

## Key messages



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 only 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.

Health workers' education and curriculum design are typically based on a traditional approach that focuses on the acquisition of biomedical knowledge and clinical skills. However, this approach does not address the complex and dynamic factors within the broader health system context that affect the safety of health care delivery, including the interactions between people, processes, technology, culture and environment. To improve patient safety and health outcomes, health workers' education and curriculum design need to incorporate a systems thinking perspective that recognizes the interdependence and variability of these factors. Moreover, health workers' education and curriculum design need to foster a humanistic attitude that values empathy and compassion, and prioritizes development of soft skills, such as teamwork and communication.

A system's thinking approach enables health workers and health care leaders to identify, assess and manage risks in health care settings, and to address factors that may cause harm. However, it has not been widely adopted in existing curricula for several reasons, such as the limited space in the educational curriculum due to competing priorities, lack of leadership commitment and support, or inadequate coordination and planning of educational activities. These challenges might be even more severe in low-resource settings, where health workers face multiple clinical demands and heavy workloads, while having limited training opportunities.

One way to improve patient safety is to ensure it is integrated into the existing education and training of all health workers, regardless of their role or specialty. This will help instil a culture of safety that values teamwork and communication, enhances the ability to prevent and manage patient harm, and strengthens advocacy for patient safety. Teaching patient safety requires innovative methods and multidisciplinary approaches, based on learnings from health care as well as other high-risk sectors.



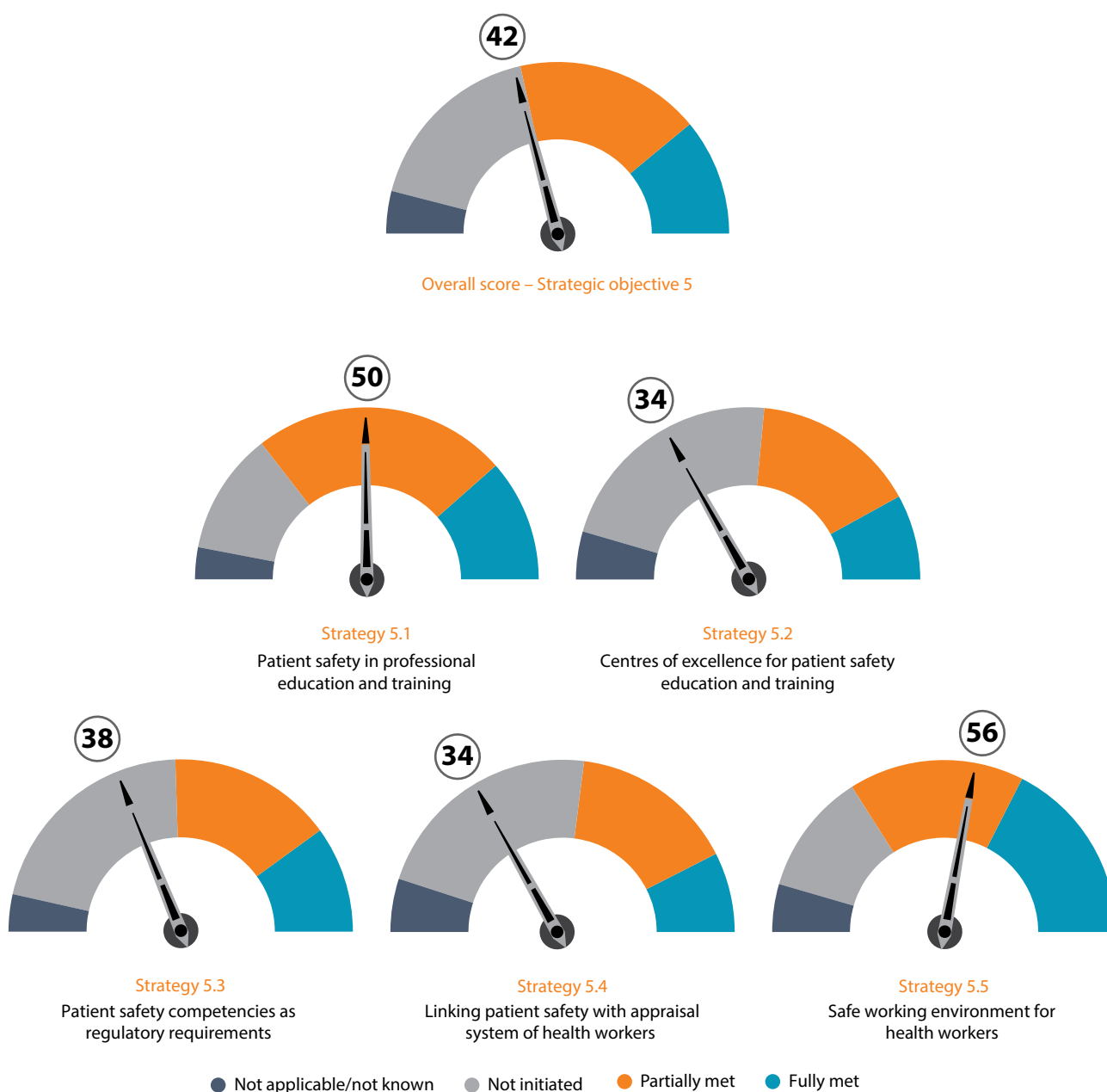
Health worker entering child vaccination data into a mobile app at a rural health unit in Hyderabad district, Pakistan. © WHO / Asad Zaidi



Health worker safety and patient safety are interlinked, and safety risks to health workers can pose a risk of harm to patients.

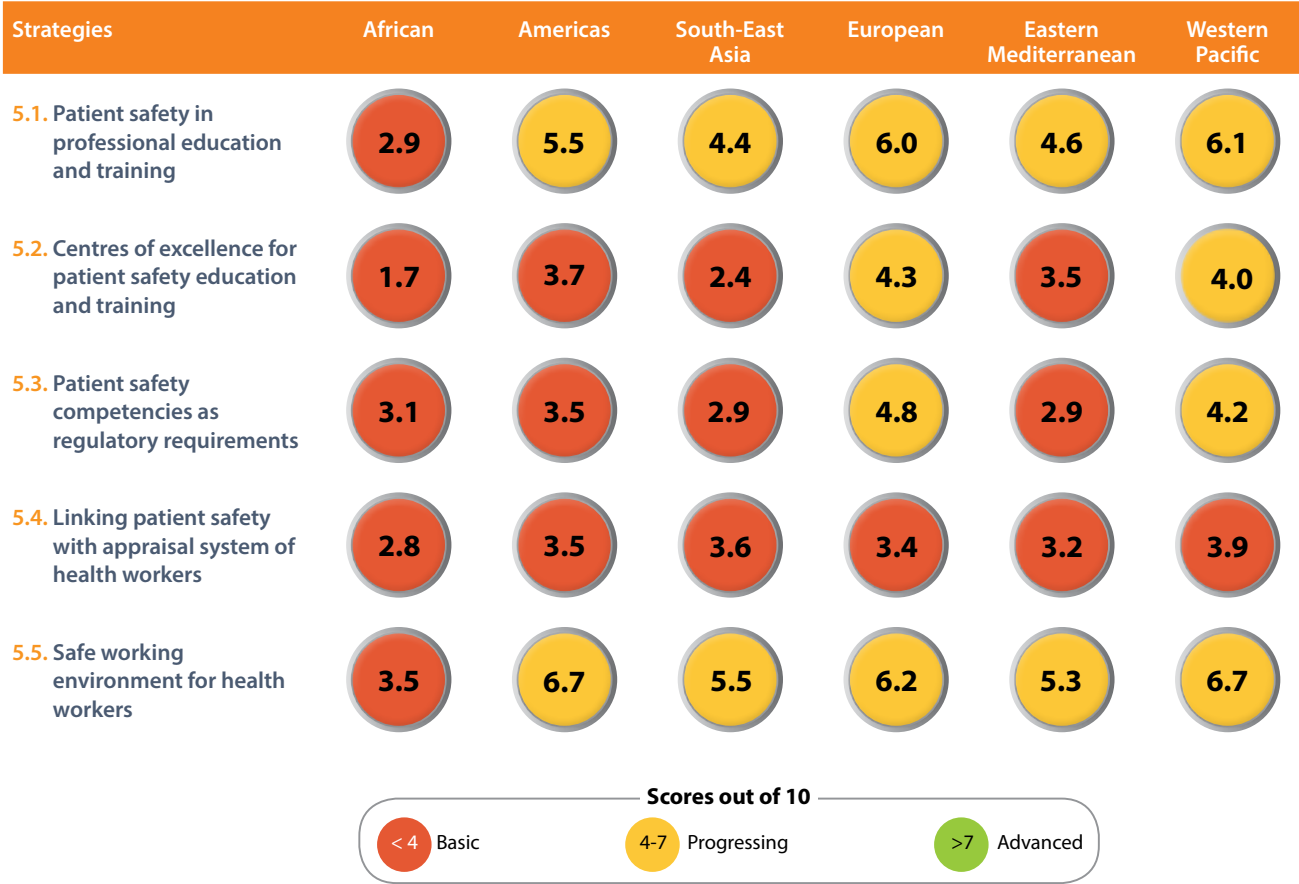
According to the survey data, the world is less than halfway to achieving the Global patient safety action plan 2021–2030 recommendations, as they relate to health worker education, skills and safety. The Member State survey found that the average global performance score against criteria for strategic objective 5 was 42 (out of 100) (Fig. 5.1). Overall, only 22% of criteria were fully met by responding countries, while 35% were partially met. However, there was a significant variation across individual criteria. Some of the criteria that received relatively positive responses from countries were those related to health worker safety, such as having a national programme for occupational health, vaccinating health workers, and implementing policies and laws to protect them. This may be attributed to the increased awareness and advocacy for health worker safety during the COVID-19 pandemic. Conversely, some of the areas with the most persistent challenges included those related to periodic assessment of patient safety core competencies, and linking them with licensing requirements for health care professionals.

► Fig. 5.1. Global performance scores for strategic objective 5



Analysing scores on health worker education, skills and training across WHO regions reveals diverse approaches and focuses. (Fig. 5.2). Countries of the Western Pacific Region show a strong commitment to patient safety in professional education and safe working environment. The European Region scores well in integrating patient safety competencies into regulatory frameworks. Respondents from the Region of the Americas prioritize safe working environment for health workers. There is a general performance gap in towards incorporating patient safety metrics into health worker appraisals, with all regions showing low scores. However, there is significant variation in performance of the various strategies and regions, indicating a general opportunity and need for improvement.

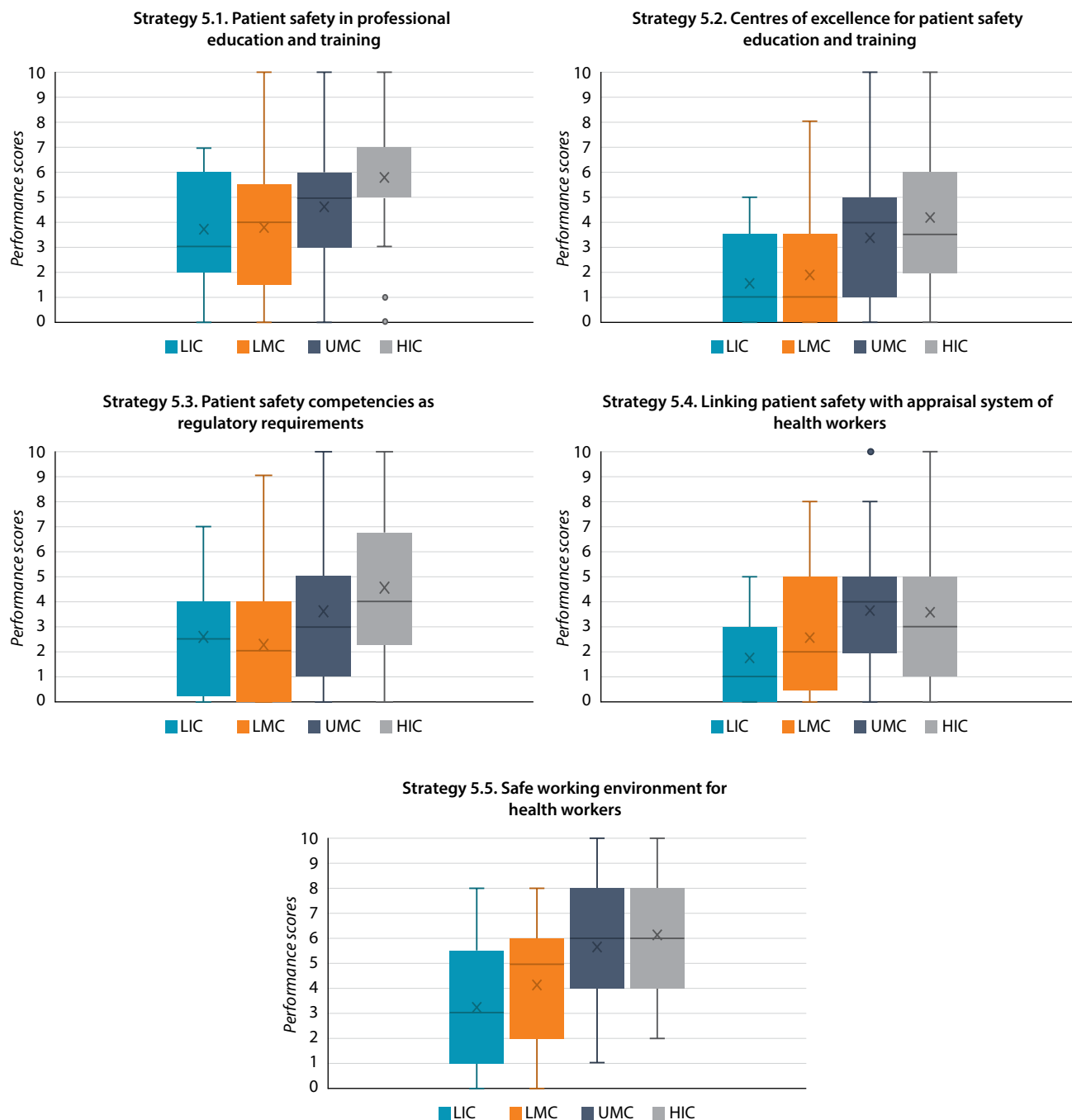
► Fig. 5.2. Distribution of strategic objective 5 performance scores across the five strategies, by WHO region



Further analysis of survey data demonstrates the varying integration of patient safety within the education, training, and workplace environment of health workers across income groups. HICs consistently show higher median scores, indicating a robust inclusion of patient safety in professional education and regulatory requirements. Despite HICs leading in most categories, the data reveal a substantial variance within all income groups, suggesting inconsistencies in how health worker education and safety is prioritized and managed. While the median scores tend to improve with increasing country income, the overlap in interquartile ranges indicates that income does not entirely determine the extent of patient safety practices (Fig. 5.3). The considerable range in performance for creating safe working environment and linking safety to worker appraisals points to these as key areas where improvement is necessary and possible, regardless of economic status.



► **Fig. 5.3. Distribution of strategic objective 5 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.

Strategic objective 5					
5.1		5.2	5.3	5.4	5.5
Patient safety in professional education and training		Centres of excellence for patient safety education and training	Patient safety competencies as regulatory requirements	Linking patient safety with appraisal system of health workers	Safe working environment for health workers

Strategy 5.1.

# Patient safety in professional education and training

Incorporate patient safety within health professional undergraduate and postgraduate education curricula and continuing professional development, with an emphasis on interprofessional learning

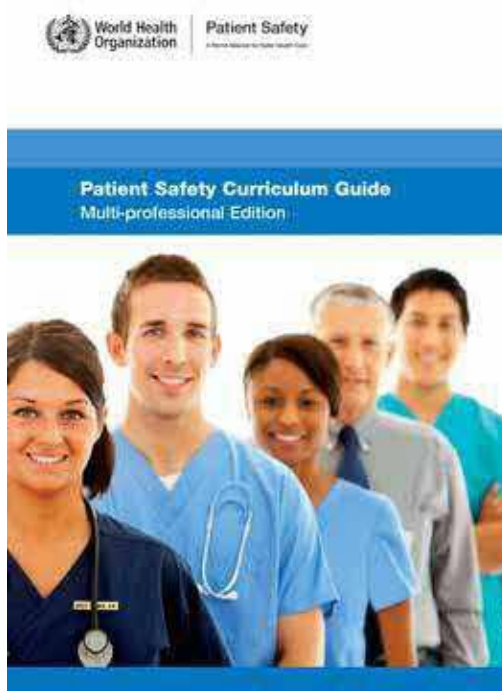
Integrating patient safety into standardized health education and training is essential for developing a safety-oriented health care workforce across all specializations and clinical settings.

Integrating patient safety into health education curricula and in-service training programmes requires the adoption of a standardized curriculum guide at the national level, and improved collaboration between the varied stakeholders that develop and set health worker education curricula. Appropriate education and training, delivered through inter-professional learning approaches imparts knowledge on health worker and patient safety, with a focus on managing safety risks and optimizing patient safety. It is important to ensure that patient safety is covered comprehensively in undergraduate and postgraduate curricula, across all specializations and medical domains. Training mechanisms – including forums and platforms, online and on-site patient safety courses – are critical elements of building a more patient safety-oriented health workforce. These trainings may cover various patient safety topics, such as development of team-based and task-based improvement strategies, as well as additional patient safety aspects in high-risk clinical settings (e.g. intensive care and emergency departments) or high-risk areas (e.g. medication safety, HCAs).

### Box 5.1. WHO Patient Safety Curriculum Guide

The WHO Patient Safety Curriculum Guide: Multi-professional Edition is a comprehensive guide to assist effective capacity building in patient safety education by academic institutions.<sup>a</sup> The guide is designed to be easily integrated into existing health care education curricula and is applicable to different cultures and contexts.

It aims to provide a comprehensive and evidence-based framework for learning about patient safety concepts, principles and practices. The guide covers topics such as human factors, teamwork, communication, adverse events, quality improvement, risk management and patient engagement. It also offers practical guidance on how to design, implement and evaluate patient safety education programmes in different settings and contexts. The guide is intended to foster a culture of safety and inter-professional collaboration.



Source:

<sup>a</sup> Patient Safety Curriculum Guide: Multi-professional Edition. Geneva: World Health Organization; 2011 (<https://iris.who.int/handle/10665/44641>, accessed 25 April 2024).

## Adoption of WHO Patient Safety Curriculum Guide

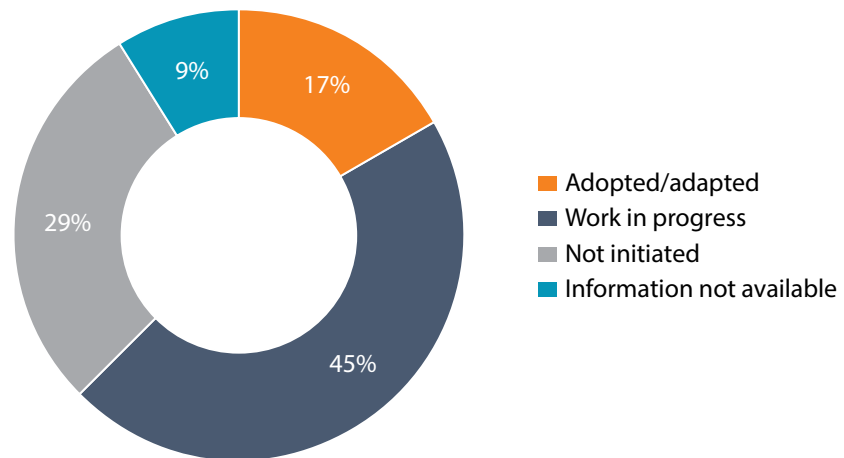
The Global patient safety action plan 2021–2030 provides concrete recommendations around health workers' education, skills development and safety, including adoption of a WHO Patient safety curriculum guide (236) at the national level, as well as incorporation of patient safety in professional education and in-service trainings programmes. The survey findings suggest that there are some early adopters of the curriculum guide, although in most countries it is a work in progress.

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*Globally, one sixth of countries have adopted or adapted the WHO Patient safety curriculum guide.*

Globally, only 17% of countries have adopted or adapted the WHO Patient safety curriculum guide nationally (Fig. 5.4). Most of the early adopter countries are HICs and UMCs. Another 45% of countries indicated that its adoption is underway. One quarter of countries reported having no initiative in this area.

**Fig. 5.4.**  
Countries reporting adoption or adaptation of the WHO Patient safety curriculum guide



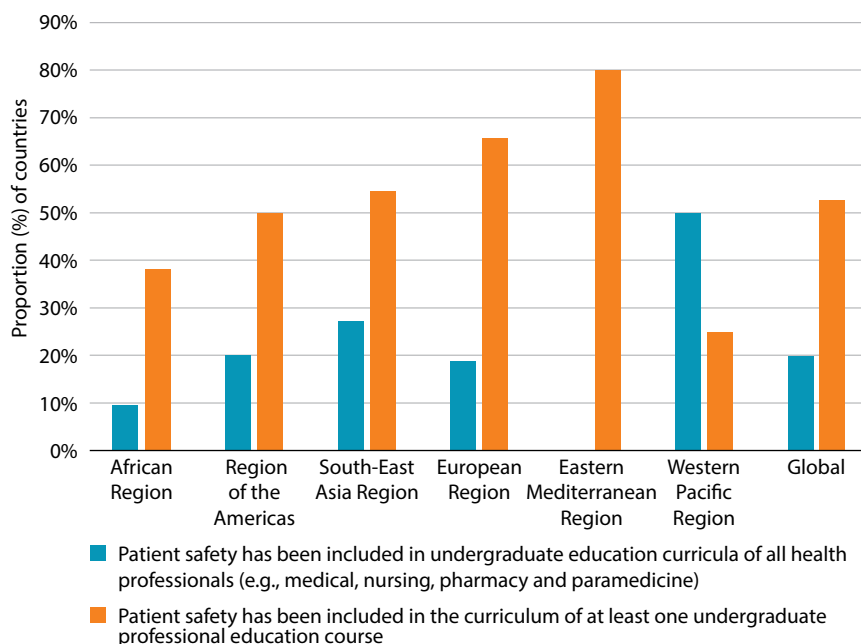
## Patient safety in undergraduate and postgraduate curricula

The WHO Patient safety curriculum guide recommends a multi-professional approach to patient safety education and training, which requires patient safety to be embedded in educational curricula of all health workers (e.g. medical doctors, nursing and midwifery personnel, pharmacists, dentists and others). In addition, the Global patient safety action plan 2021–2030 promotes an inter-professional approach that encourages joint learning among health workers and students from different professional disciplines, with the aim of fostering holistic understanding of patient safety collaborative practice.

*Patient safety education varies globally, with 20% of countries including it in all undergraduate curricula and 23% in all postgraduate curricula.*

One fifth of the countries reported that patient safety has been included in undergraduate educational curricula of all health professionals, and another half of the countries (53%) reported they have included patient safety in the curriculum of at least one undergraduate professional education course. Similarly, 23% of countries have incorporated patient safety into curricula of all relevant postgraduate professional education streams, while 43% reported that patient safety had been included in the curriculum of at least one postgraduate professional education stream. Patient safety integration into professional education varies significantly across WHO regions (Fig. 5.5). Although there is a broad consensus on the importance of including patient safety in professional education, the degree to which it is implemented can differ widely from one region to another.

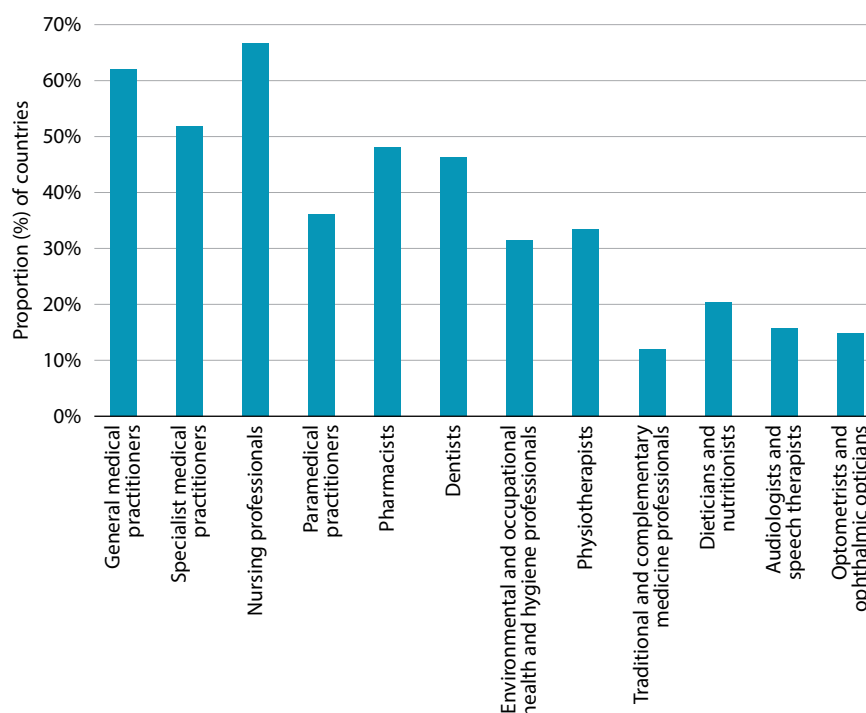
The WHO Patient safety curriculum guide is a useful tool for countries to integrate patient safety into their health professional education. Most of the countries (65%) that have fully implemented patient safety curricula at both the undergraduate and postgraduate levels have also adopted the WHO guide.



**Fig. 5.5.**  
Status of inclusion of patient safety in undergraduate education curricula, by WHO region

This suggests that using the WHO guide can facilitate the inclusion and roll out of patient safety in mainstream health professional education.

The integration of patient safety into the education curricula of different health professional categories shows significant variation across countries (Fig. 5.6). Notably, nursing education stands out as the most progressive field, with 67% of countries acknowledging the incorporation of patient safety principles into their nursing education programmes. This reflects a global recognition of the critical role that nurses play in ensuring patient safety. However, when it comes to traditional and complementary medicine practitioners, optometrists and audiologists, the situation is markedly different. These professional categories are identified as having the least developed patient safety education frameworks.



*Nursing education is the most progressive in incorporating patient safety principles, with 67% of countries including them in their curricula.*

**Fig. 5.6.**  
Incorporation of patient safety in professional education curricula for various health worker categories

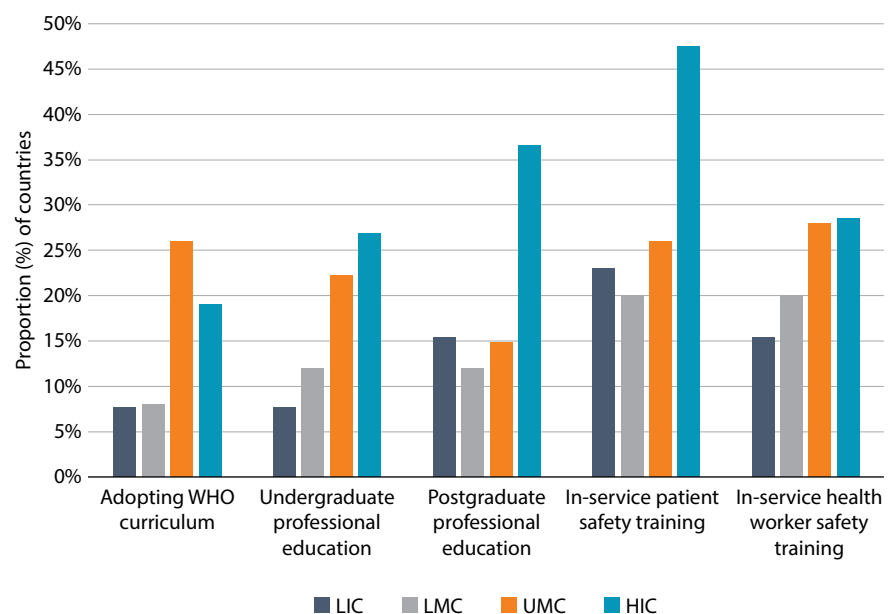
## In-service training on patient safety and health worker safety

*A quarter of countries report having well-established in-service training programmes focused on patient safety.*

Incorporating patient safety into educational curricula equips health care workers with the foundational knowledge needed to provide safe care. However, the sustainability of this education relies on consistent in-service training that refreshes and enhances their skills. Despite its importance, only a quarter of countries report having well-established in-service training programmes focused on patient safety. Similarly, 19% of countries reported that they have continuing professional development programmes in place for patient safety. A third of all respondents reported that health worker safety had been incorporated into in-service training of health professionals.

Overall, HICs are doing better in patient safety education and training, although the variation is more pronounced in education compared to training (Fig. 5.7), signifying ease of implementing training interventions as compared to education programmes, regardless of resource settings.

**Fig. 5.7.**  
Integration of patient safety into areas of health professional education and training, by income group



Note:

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

## Examples of WHO Patient safety curriculum guide in action

**Mongolia** reported that the WHO guide has been translated into Mongolian and the first six-month training on patient safety started in 2022.

Since 2017, **Malaysia** has taken the proactive step of enhancing patient safety by introducing a patient safety awareness course for junior health care professionals. The course is aligned with the WHO guide and aims to equip participants with the knowledge and skills to prevent and manage adverse events.

**The Islamic Republic of Iran** has translated the WHO curriculum guide, but it still needs to be integrated into the education curricula of various disciplines.

The WHO guide has influenced health professional education in **Australia**. All undergraduate and postgraduate health courses have patient safety as part of their curricula. The Work Health and Safety Act 2011 also requires all workers to receive training and supervision on work health and safety issues.

**Switzerland** stated that elements of the WHO guide were included in the overarching core competencies required for medical education programmes, and curricula vary by education institution.

In **Costa Rica**, legislation is in place to ensure that health establishments with ten or more employees must receive in-service training around worker safety.

The National Outcomes Framework for Medical Graduates in **Singapore** is based on the WHO guide; and induction/orientation programmes for health workers include components of health worker safety.

**Sweden** has adapted the WHO guide and assessed its applicability in their health system.

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*Countries are implementing the WHO Patient safety curriculum guide through translation, integrated training courses, and legislative measures to enhance patient safety education for health care professionals.*



Strategic objective 5					
5.1		5.2	5.3	5.4	5.5
Patient safety in professional education and training		Centres of excellence for patient safety education and training	Patient safety competencies as regulatory requirements	Linking patient safety with appraisal system of health workers	Safe working environment for health workers

## Strategy 5.2.

# Centres of excellence for patient safety education and training



Identify and establish collaborations with centres of excellence in patient safety education and training

Twenty-two percent of countries have a national institution offering patient safety education and training for health care workers.

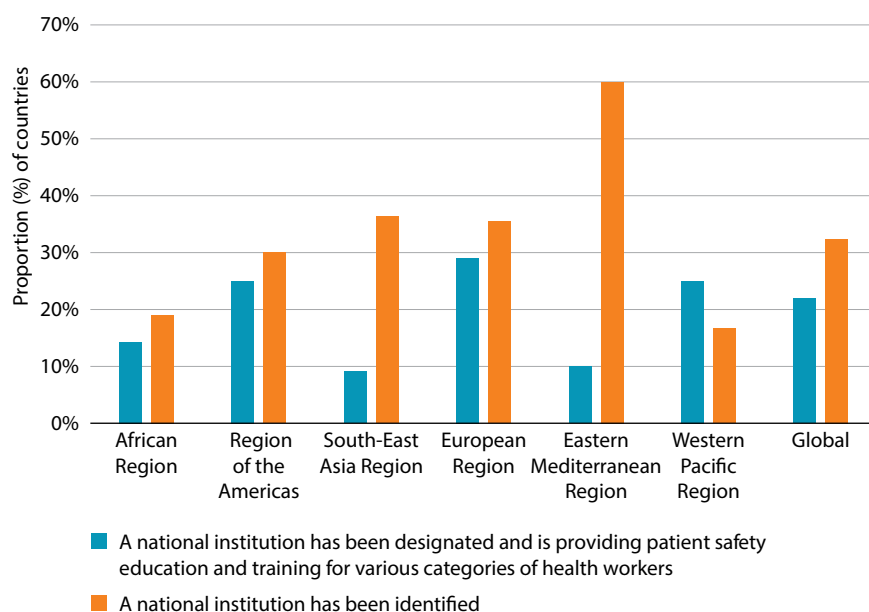
One way to promote patient safety education and training is to establish centres of excellence in patient safety that can equip health workers with the competencies, knowledge, skills and attitudes to provide safe and high quality heath care. Such centres can offer innovative teaching methods and simulation techniques, share best practices and collaborate towards establishment of national networks. Furthermore, centres of excellence can address the diverse needs and challenges of different regions and populations, and facilitate dialogue and advocacy around patient safety and importance of continuous competency development.

### Patient safety institutions and training centres

Patient safety training is a crucial aspect of improving the safety of health care. However, there are many challenges in providing such training at the national and subnational levels. The Member State survey revealed that only 22% of countries have an operational national institution that offers education and training in patient safety for different categories of health workers. Moreover, a third of countries have identified a specific national centre focused on patient

safety and are currently working towards making it operational. Countries of the European Region reported a higher concentration of these national centres that specialize in training and education for patient safety (Fig 5.8). At the subnational level, only 14% of countries reported having operational training centres delivering patient safety training.

To meet the training requirements of many health care professionals, it is important for countries to establish a pool of qualified trainers. These trainers would be responsible for designing and conducting training programmes in patient safety. However, as it stands, only 10% of countries have reported having enough of these specialized trainers who are capable of providing such training. This shortage indicates a significant challenge in scaling up patient safety initiatives.



*Only 10% of countries have enough specialized trainers in patient safety, posing a major challenge in expanding training programmes.*

**Fig. 5.8.**  
Proportion of countries in which a national institution has been designated for education and training for patient safety, by WHO region

## Innovative teaching methods and simulation

The Global patient safety action plan 2021–2030 recommends the use of innovative teaching methods and simulation techniques for patient safety education and training. These methods and techniques aim to enhance the competencies of health workers and students in preventing and managing adverse events. Innovative teaching methods can include interactive pedagogy, case-based discussions, interprofessional team-based learning and reflective learning practices. Further simulation training can contribute to improving patient safety by providing opportunities for learners to develop and enhance their clinical skills, knowledge and attitudes in a realistic but risk-free setting. Simulation training can also help in identifying and addressing system-level issues, such as communication, teamwork and human factors that may affect patient outcomes. According to the survey, 19% of all respondents report full incorporation of these methods into their curricula. Additionally, 33% of responding countries reported that they have conducted pilot trainings using these innovative techniques.

*Nineteen percent of countries fully incorporate innovative teaching methods and simulation into their patient safety curricula.*

## Examples of country activities on patient safety training and education

In **Seychelles**, the National Institute of Health and Social Studies covers patient safety as a core component in the training provided to different categories of health workers. **Brazil** offers online specialization courses in patient safety.

**Türkiye** reported that education and training curricula for patient safety are developed by the Ministry of Health and higher education institutions, and that there is a pool of expert trainers and certified quality evaluators trained by the ministry.

The Occupational Health and Environment Research Unit and the Faculty of Health Sciences at the University of **Benin** have been designated as key institutions for education and training on patient safety; the Regional Institute of Public Health (IRSP) is responsible for coordinating and providing subnational level trainings.

Simulation techniques are one of the innovative teaching methods that medical schools and health care training institutions in **Singapore** use to train their students in patient safety. Both SingHealth and the National Healthcare Group have their own institutes that focus on training and education in patient safety.

In **Belize**, infection prevention and control (IPC) nurses are trained to conduct training in patient safety.

In the **United Kingdom**, Health Education England, in collaboration with NHS England and NHS Improvement, the Academy of Medical Royal Colleges and e-Learning for Healthcare, have developed patient safety training materials for all NHS staff in England, including those who do not have direct contact with patients.

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*Countries are actively enhancing patient safety training through initiatives such as specialized courses, expert trainer programmes, and innovative simulation techniques, ensuring comprehensive education for health care workers across various regions.*

Strategic objective 5	5.1	5.2	5.3	5.4	5.5
	Patient safety in professional education and training	Centres of excellence for patient safety education and training	Patient safety competencies as regulatory requirements	Linking patient safety with appraisal system of health workers	Safe working environment for health workers

## Strategy 5.3.

# Patient safety competencies as regulatory requirements



Ensure that patient safety core competencies are part of regulatory requirements for health professionals

It is important that all health workers, regardless of their category or sector, develop patient safety core competencies. These competencies incorporate both technical skills and non-technical (soft) skills, such as teamwork and communication. To make sure that health workers develop these competencies, they should be part of the requirements for obtaining and retaining professional licenses, both in the public and private health sectors. Other ways to ensure patient safety competencies are developed are: including them as mandatory competencies in job descriptions; linking them to health institutions' service standards; and doing regular evaluations on patient safety.

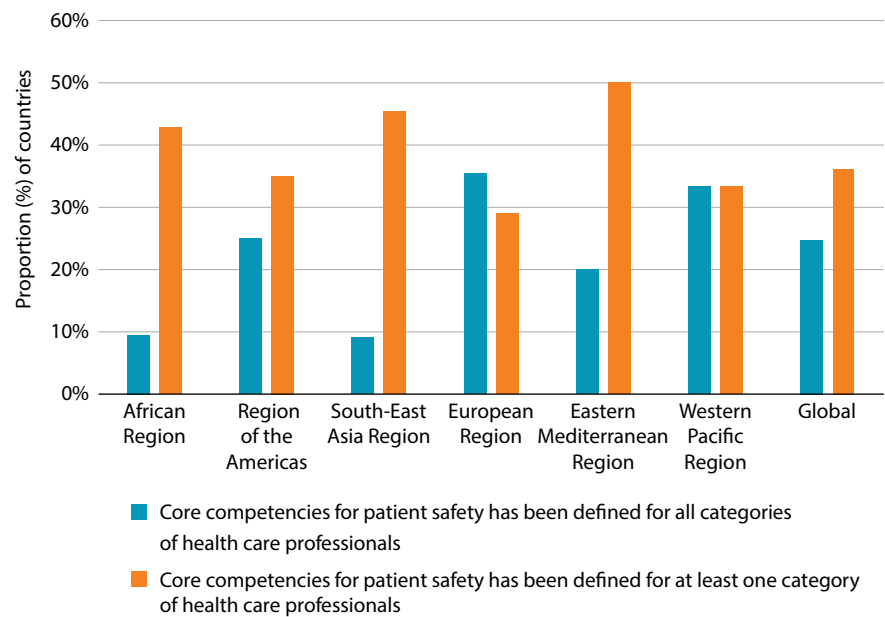
## Establishment of patient safety core competencies

A quarter of the countries surveyed have established patient safety competencies for all categories of health workers, while more than a third indicated that they have done so for at least one group of health workers. This was most common in the European Region and the Western Pacific Region (Fig. 5.9). Only one in ten countries reported having a mandatory policy to regularly assess the core competencies of health workers for patient

*A quarter of countries surveyed have established patient safety competencies for all health workers.*

safety. Another 26% of the respondents indicated that their authorities had recommended, but not required, such assessments. These practices were more common in HICs.

**Fig. 5.9.**  
**Establishment of patient safety**  
**core competencies,**  
**by WHO region**



## Box 5.2. The Safety competencies framework of Healthcare Excellence Canada

The Safety competencies framework is a tool that helps health care educators integrate patient safety principles into their curricula. It consists of enabling competencies that can be customized and applied to different health care disciplines and contexts. The framework can also serve as a reference for regulators and accreditors who want to promote system-wide improvements in patient safety.

**The Safety competencies framework comprises six domains:**

### Domain 1. Patient safety culture

Improving patient safety culture involves recognizing the importance of ongoing collaboration and the commitment to advocate for change.

### Domain 2. Teamwork

High-performing inter-professional teams demonstrate capabilities and competencies that are essential to efficient, effective and safe collaborative practice.

### Domain 3. Communication

Effective communication benefits both patients and health care providers, builds trust and is a precondition of obtaining patient consent.

### Domain 4. Safety, risk and quality improvement

Health care providers need to collect and monitor performance data to assess risk and improve outcomes.

### Domain 5. Optimize human and system factors

Optimizing the human and environmental factors that support the achievement of best human performance is an essential safety competency for all health care providers.

## Domain 6. Recognize, respond to and disclose patient safety incidents

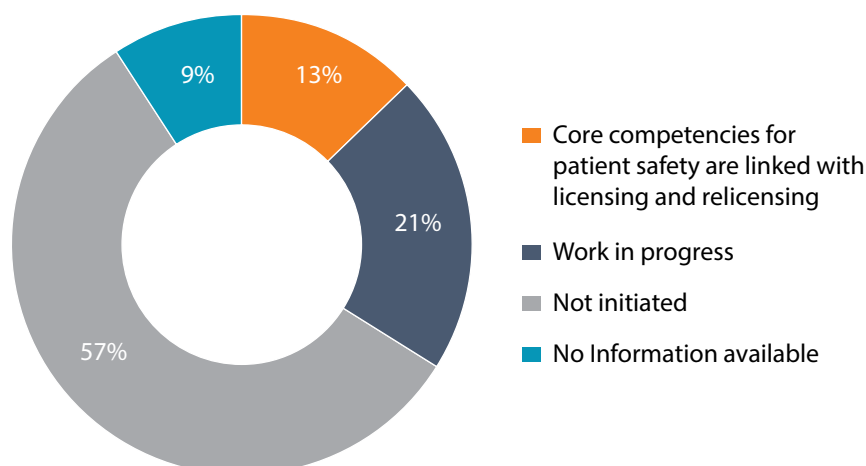
Open, honest and empathetic disclosure and appropriate apologies by health care providers benefit everyone: patients and families, health care providers and their organizations.



Source: *Safety competencies framework* [website]. Ottawa: Healthcare Excellence Canada; 2020 (<https://www.healthcareexcellence.ca/en/resources/safety-competencies-framework/>, accessed 25 April 2024).

## Patient safety core competencies as a regulatory requirement

The survey indicates that most of the countries are still in the early stages of linking patient safety competencies with regulatory requirements. Health workers in 13% of countries have core competencies for patient safety incorporated in their licensing and re-licensing requirements, and another 21% are in the process of incorporating these into their regulatory system (Fig. 5.10).



*Only 13% of countries have incorporated core patient safety competencies into licensing and re-licensing requirements for health workers.*

**Fig. 5.10.**  
Global status of patient safety core competencies as regulatory requirement

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*Thirty-one percent of respondent countries have established specific criteria for competencies required for health workers to practice in various clinical areas.*

## Authorization for working in high-risk clinical areas

Some clinical specialties, such as paediatric nursing, radiation therapy, intensive care and emergency medicine, pose higher risks for patient safety and require distinct skills and competencies among health workers. According to 31% of respondent countries, specific criteria for competencies have been established for authorizing health workers to practice in various clinical areas.

## Country examples of strengthening patient safety core competencies

In **Germany**, the national competency-based learning objectives catalogue specifies the core competencies for patient safety that medical doctors should acquire. These core competencies are essential for the licensing of doctors and the furthermore these core competences will also be taken into account in upcoming reforms for other professional categories.

The process of evaluating doctors in residency programmes in **Singapore** includes checking their ability to manage patients safely, which is also part of the evaluation system that measures the safety and quality of patient care. Doctors who want to renew or apply for a new practising certificate must fulfil the continuing medical education requirements. Other professions may also need to complete continuing professional education courses, but they are not always compulsory.

The code of conduct developed by the **Australian** Health Practitioner Regulation Agency (AHPRA) sets out the core competencies for patient safety for each category of health worker. The AHPRA and the National Safety and Quality Health Service (NSQHS) standards also require health workers to demonstrate specific clinical practice competencies. To ensure that clinicians are competent and up to date, the NSQHS standards mandate health care facilities to define, monitor and review the scope of clinical practice regularly and whenever there is a change or modification in the clinical service, procedure or technology.



## Feature story 11.

### Piloting a COVID-19 safety officer programme in Ethiopian hospitals

#### Summary

The COVID-19 pandemic highlighted a widespread need for foundational knowledge among health care professionals and non-clinical hospital staff to prevent health care-associated infections (HCAIs). The COVID-19 Safety Officer Programme was developed at the Johns Hopkins Hospital (JHH) in response to a need for staff training and support in IPC. It was later adapted for use in two Ethiopian hospitals with support from JHPIEGO (formerly the Johns Hopkins Program for International Education in Gynecology and Obstetrics), a global health affiliate of Johns Hopkins University, through the United States Agency for International Development (USAID) Reaching Impact, Saturation and Epidemic Control (RISE) Ethiopia project. Early feedback has been positive, and the programme provides a foundation that could be adapted to a broader context.

#### What was done and why?

Representatives from JHH Hospital Epidemiology and Infection Control, Johns Hopkins Armstrong Institute for Patient Safety and Quality, RISE Ethiopia and Hawassa and Gondar University Comprehensive Specialized Teaching Hospitals collaborated to adapt the JHH COVID-19 Safety Officer Programme and related training of trainers (TOT) workshop to the Ethiopian setting.

*“One of the important things that we always kept in the back of our minds was ensuring that we were developing the programme material with the appropriate cultural context.”*

**(Representative of JHH Hospital Epidemiology and Infection Control)**

This Safety Officer Programme is unique in its emphasis on health care workers developing skills to ‘be safe and feel safe’ while they cared for patients with COVID-19. Training topics include teaching techniques, the epidemiology of SARS-CoV-2, the chain of infection and behaviours that prevent the spread of the virus. Non-clinical workers such as porters and housekeeping staff are included in the training.

#### Outcomes and impact

The course provides a flexible training resource, which participants are encouraged to adapt to their own environments and settings. The presence of hospital leadership, in addition to identified champions of the programme, allowed for the development of robust action plans for implementing a COVID-19 Safety Officer Programme in the participating hospitals. Following the workshop, the RISE Ethiopia team visited participating hospitals to monitor progress of implementation, provide technical support in the development and finalization of their action plans, and also to develop a supportive supervision checklist.

#### What’s next?

Immediate feedback from participants was overwhelmingly positive, and the team at JHPIEGO are staying in touch with the hospitals in Ethiopia to monitor their progress. Following this success, the organizers of the programme felt strongly that it could be transferrable to different settings, and for other HCAs, giving it relevance beyond the COVID-19 pandemic.

Strategic objective 5					
	5.1	5.2	5.3	5.4	5.5
	Patient safety in professional education and training	Centres of excellence for patient safety education and training	Patient safety competencies as regulatory requirements	Linking patient safety with appraisal system of health workers	Safe working environment for health workers

## Strategy 5.4.

# Linking patient safety with appraisal system of health workers



Link commitment to patient safety with appraisal systems for health care professionals and managers

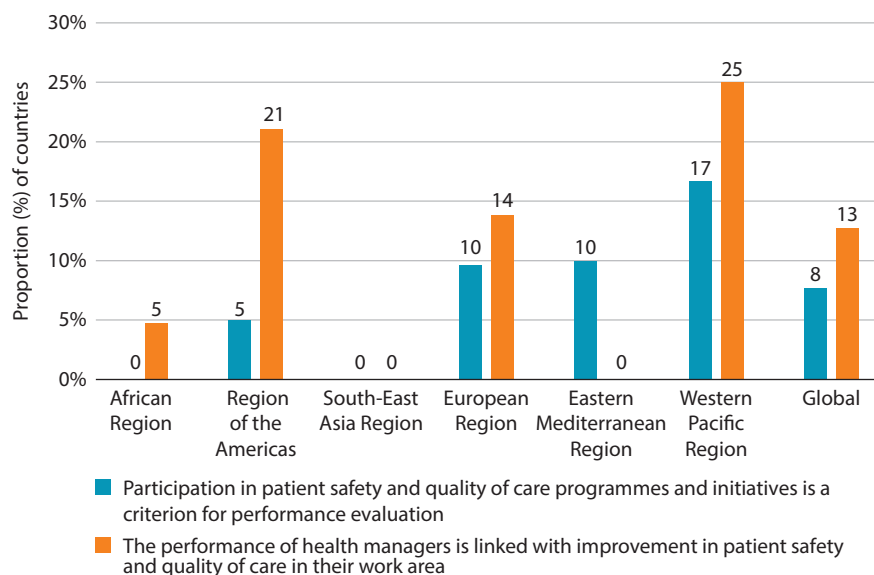
Linking health worker development to patient safety initiatives, with added incentives and recognition, can enhance engagement and improve patient safety.

To develop the competencies of health workers in identifying and addressing potential sources of harm, health systems should link the professional development and performance assessments of health workers to their involvement in patient safety programmes and initiatives. Furthermore, as outlined in the Global patient safety action plan 2021–2030, health systems could also explore incentives and recognition programmes for health workers who show strong commitment to patient safety and enhance the dialogue on how to define and measure excellence in patient safety. These measures may help to motivate and empower health workers to better engage in teamwork, communicate effectively and develop potential solutions for patient safety issues.

### Performance appraisal systems for health workers

A periodic performance appraisal system allows health workers to receive feedback on their work performance and identify areas for improvement. It also helps managers to monitor the safety of service delivery and recognize the achievements of their staff. This is applied to all categories of health workers, regardless of their role and responsibilities.

According to the survey responses, only 26% of countries have a regular system for evaluating the performance of all categories of health workers in their organizations. Only 8% of countries take health care workers' participation in patient safety programmes and initiatives into account when evaluating their performance. Furthermore, 13% of survey respondents reported that health care managers are appraised based on how they contributed to improving patient safety and quality of care in their work area. There is considerable variation in these practices across WHO regions (Fig. 5.11).



**Fig. 5.11.**  
Performance appraisal linked with patient safety and quality of care, by WHO region

## Performance linked reward and recognition programmes

Only 12% of the respondent countries reported that they have established a reward and/or recognition scheme for health workers who achieve exceptional results in patient safety. Additionally, around one quarter of countries are in the process of establishing such recognition incentives, which are reported across all income groups and geographic regions (Fig. 5.12).

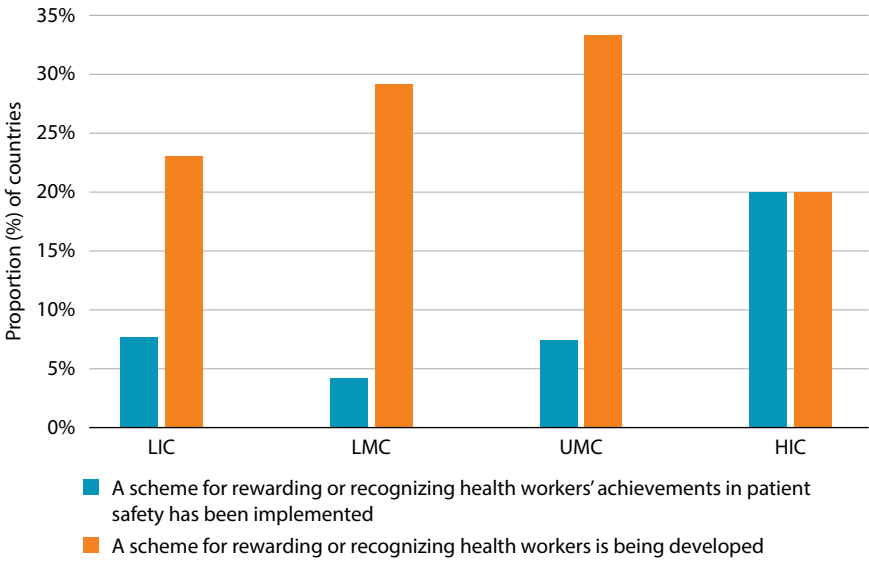
*Only 12% of countries have established reward or recognition schemes for health workers who achieve exceptional patient safety results.*



X-ray of a tuberculosis patient displayed on a computer screen at a TB center in Vose, Tajikistan.  
© WHO / Lindsay Mackenzie

18% of the global respondents reported that training in patient safety is linked to continuing professional development in their countries. Countries of the Eastern Mediterranean Region have the highest proportion of such schemes (40%), followed by the Western Pacific Region (17%).

**Fig. 5.12.**  
**Reward and recognition**  
**schemes for patient safety, by**  
**income group**



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

### Country examples where appraisal systems are linked with commitment to patient safety

In **Namibia**, the Ministry of Health and Social Services introduced performance appraisals for health workers including activities on quality and safety: related performance appraisals are conducted every three months.

**South Africa** reported the implementation of a performance management development system among all health workers, including core components of patient safety and quality of care. The system has provisions to incentivize good performance and support poor performance through corrective measures.

**Armenia** has implemented a performance appraisal system at the primary care level. **Belize** conducts mid-year and annual performance appraisals among all categories of health workers, and credits for training in patient safety are required for applying for medical license. In **Cuba**, awards are presented to academics, professionals, innovators and young professionals who conduct high-quality research on patient safety. National Patient Safety Awards are also an initiative of the **Saudi Arabia** Patient Safety Center (SPSC). The awards honour and celebrate the achievements of health workers and organizations that have implemented innovative and effective solutions to improve patient safety and reduce harm. The awards also seek to disseminate and share the best practices and lessons learned from these successful projects and initiatives across the Saudi health care sector.

Several countries have implemented performance appraisal systems and recognition programmes to incentivize health workers for their contributions to patient safety.

Strategic objective 5	5.1	5.2	5.3	5.4	5.5
	Patient safety in professional education and training	Centres of excellence for patient safety education and training	Patient safety competencies as regulatory requirements	Linking patient safety with appraisal system of health workers	Safe working environment for health workers

## Strategy 5.5.

# Safe working environment for health workers



Design care settings, environments and practices to provide safe working conditions for all staff

There is a close linkage between the safety and well-being of health workers and patients, as the problems that health workers encounter can lead to harm and poor outcomes for patients. Health workers often deal with occupational hazards, such as occupational infections, violence, burnout, musculoskeletal problems, mental and physical exhaustion, that can compromise their ability to provide safe care. In addition, unsafe work environments, shortage of health workers, high turnover and absenteeism can all impact the safety and well-being of patients, demonstrating that patient safety requires sufficient investment in the safety and well-being of health workers. Protecting health workers is key to ensuring a well-functioning health system.

To ensure safe and resilient health systems, the health and safety of health workers must be protected. This requires adopting and implementing national policies and programmes that address the occupational health and safety challenges of health workers and allocate sufficient resources for safe work environments. Unsafe working conditions, stress, or in some countries, the perceived or real lack of personal security, are among the main reasons for the attrition of health workers, exacerbating health workforce shortages (237). There should be zero tolerance for violence in the health sector, and mental well-being and social support services should be in place, work-life balance

*Ensuring health worker safety and well-being is vital for patient safety and a resilient health care system, requiring national policies, sufficient resources, and supportive work environments.*

should be promoted and burnout among health workers should be prevented. Other organizational measures, such as establishing reasonable work hours and workloads, reducing administrative burden on health workers, and providing preventative health services (e.g. vaccinations, ergonomic workstations, personal protective equipment) are also crucial in enhancing health worker safety and well-being.

WHO has published guidance on key elements of occupational health and safety programmes for health workers at national, subnational and facility levels, as well as advice for the development and implementation of such programmes (238).

*Eighteen percent of countries have signed the WHO Health worker safety charter, highlighting the need for broader commitment to protecting health worker safety.*

## Endorsement of WHO Health worker safety charter

WHO has issued a Health worker safety charter (239) that calls on governments and health care leaders to take five actions to: better protect health workers from violence; improve their mental health; protect them from physical and biological hazards; advance national programmes for health worker safety; and connect health worker safety policies to existing patient safety policies and strategies. WHO Member States and all relevant stakeholders are encouraged to support and endorse the charter by signing up to it (240).

**Fig. 5.13.**  
**Launch of the WHO Health worker safety charter in 2020**

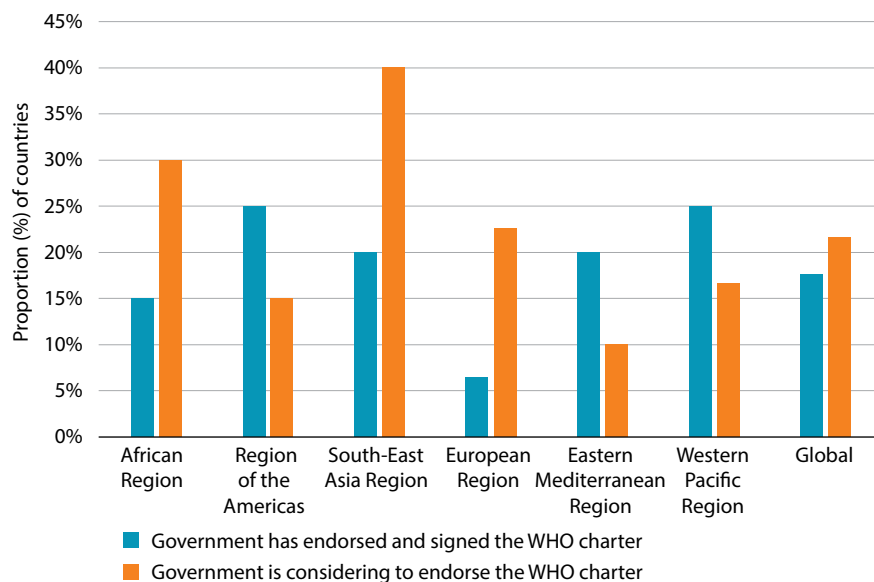


*WHO Director-General Dr. Tedros Adhanom Ghebreyesus and ILO Director General Guy Ryder at the launch of the WHO Health Worker Safety Charter in 2020. © WHO / Christopher Black*

In the Member States survey, it is reported that 18% of countries have formalized their commitment to the charter by signing it, while governments from an additional 22% are contemplating joining. The acceptance of the charter shows variation across income groups, with notably higher commitment rates in LMCs and UMCs. There is also considerable variation



in uptake of the charter among WHO regions (Fig. 5.14). Surprisingly, about one quarter of the respondents disclosed they lack information regarding the endorsement of the charter, pointing to a significant gap in awareness. This gap underlines the critical need for enhanced advocacy and promotion efforts at the international level to ensure widespread recognition and support for the charter.



**Fig. 5.14.**  
Country endorsement of WHO Health worker safety charter, by WHO region

## National occupational health programmes for health workers

The WHO–International Labour Organization (ILO) Global framework for national occupational health programmes for health workers (241) aims to enhance health systems and health care settings in line with the WHO Global plan of action on workers’ health (2008–2017) (242) and the ILO Convention concerning promotional framework for occupational safety and health (243). The main objectives are to protect and promote the health and safety of health workers, patients and the community.

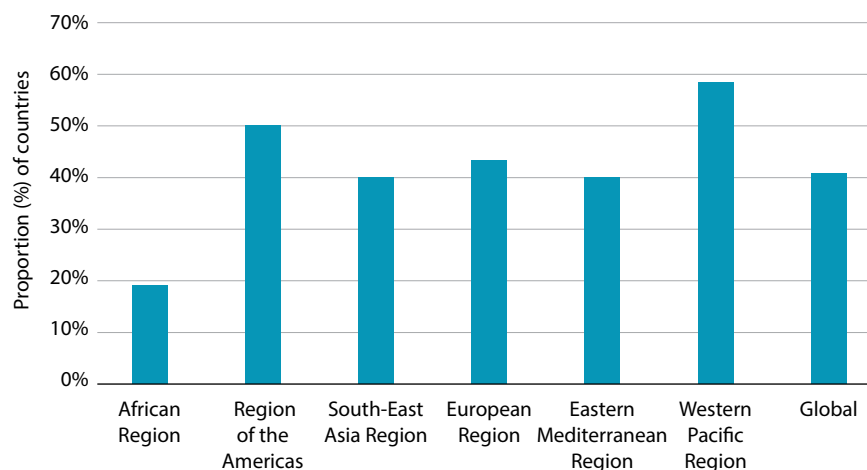
The framework recommends that ministries of health should collaborate with other relevant ministries, such as ministries of labour, social security, or other agencies in charge of health worker’s health and safety in both the public and private sectors, to develop a national occupational health programme for health workers. Such programmes aim to prevent diseases and injuries arising out of, linked with or occurring in the course of work, while improving the safety and quality of care, safeguarding the health workforce and promoting environmental sustainability in the health sector (238, 241).

According to the survey, 41% of participating countries have health worker safety programmes in place, while a further 30% indicated that they are in the process of developing them. The survey also revealed some regional and income group disparities in the implementation of these programmes (Fig. 5.15).

*Forty-one percent of countries have established health worker safety programmes, with an additional 30% developing them.*



**Fig. 5.15.**  
Country implementation of  
occupational health and safety  
programmes for health workers,  
by WHO region



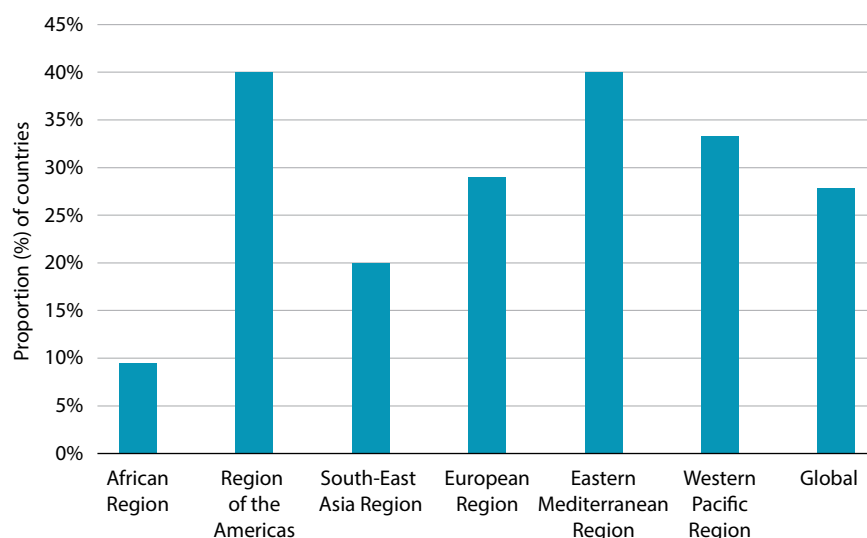
The highest proportion of countries implementing national programmes was found among HICs (56%), followed by UMCs and LMCs (44% and 25% respectively), with LICs reporting the lowest rate (15%). These findings suggest that more efforts are needed to ensure that all health workers have access to adequate occupational health and safety measures, regardless of the country income level they represent or their geographical location.

### Mental health services for health and care workers

*Twenty-eight percent of countries provide mental health support for health workers.*

The COVID-19 pandemic has put enormous pressure on health workers, who have faced increased risks of infection, exhaustion and burnout. To protect their mental health and well-being, many countries have launched programmes or initiatives to provide them with psychological and social support. However, the coverage and quality of these services vary widely within and across countries representing different income levels. According to the survey results, only 8% of LICs report having such programmes or initiatives, compared to 13% of LMCs, 30% of UMCs, and 43% of HICs. The global average is 28%, which shows a significant gap in the availability and accessibility of mental health and well-being support for health workers. There is a significant variation across WHO regions regarding availability of mental health services for health and care workers (Fig. 5.16). There is an urgent need to scale up and strengthen these services, as well as to monitor and evaluate their impact and effectiveness.

**Fig. 5.16.**  
Availability of mental health  
services for health and care  
workers, by WHO region

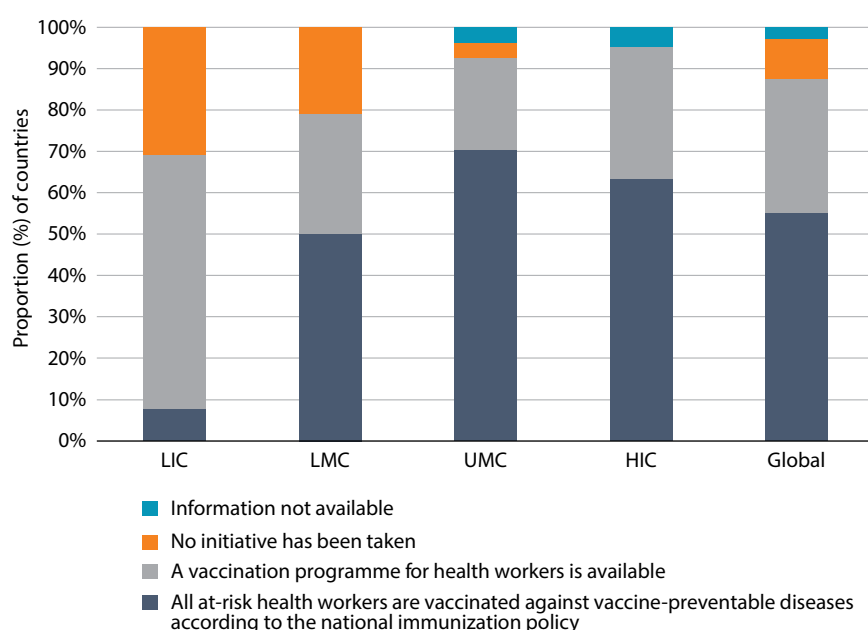


## Vaccination programmes for health workers

Vaccination of health workers is a crucial strategy to protect them from the risk of contracting and transmitting infectious diseases, such as TB, hepatitis B, polio, pertussis, diphtheria, measles, rubella, meningococcal meningitis, influenza, varicella, COVID-19 and cholera (238, 244). Vaccines are safe and effective tools that can prevent serious illness and death, as well as reduce the burden on the health system and society. WHO recommends health workers should be among the first groups to receive COVID-19 vaccines, as they are at high risk of exposure and play a vital role in responding to the pandemic. However, vaccination of health workers faces many challenges, such as vaccine hesitancy, supply shortages, inequitable distribution, and lack of awareness and trust (245). Therefore, it is important to promote vaccination of health workers as well as to address the barriers and concerns that may prevent them from getting vaccinated (244).

While vaccination of health workers is a crucial strategy to protect them from vaccine-preventable infections and to prevent the spread of diseases to vulnerable patients, the coverage of vaccination among health workers varies widely across countries and regions, depending on the availability of vaccines, the national immunization policy, and the awareness and acceptance by health workers. According to the survey responses, 88% of countries have a vaccination programme for health workers, but only 55% of countries ensure that all at-risk health workers are vaccinated according to the national policy. The survey also reveals significant disparities in vaccination coverage among all at-risk health workers by income group with only 8% of LICs reporting such programmes (Fig. 5.17). These findings highlight the need for more efforts to improve the access and uptake of vaccination among health workers in all settings, and especially in low-resource settings, and to monitor and evaluate the impact of vaccination programmes on health worker safety and patient outcomes.

*Fifty-five percent of countries ensure that all at-risk health workers are vaccinated according to national policy.*



**Fig. 5.17.**  
**Status of vaccination programmes for all at-risk health workers, by income group**

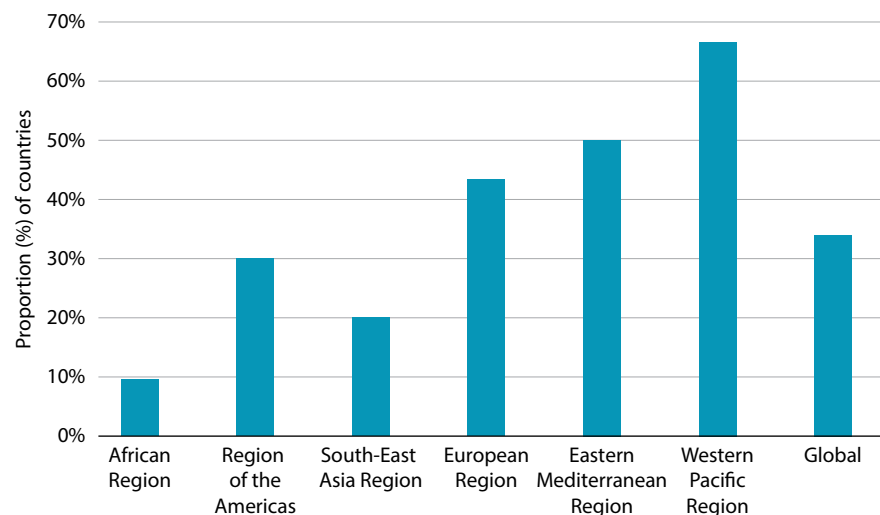
Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

## Protection for violence against health and care workers

*Thirty-four percent of countries have enacted specific laws and policies to prevent and eliminate violence against health workers.*

Violence against health workers is a serious threat to the security, safety and well-being of health workers, as well as to the safety and accessibility of health services in general. To address this issue, various policies, laws and administrative measures have been implemented at the global, regional and national levels. The survey reveals that 70% of responding countries reported they investigate serious incidents of violence at health care facilities and take priority action. However, only 34% of the countries reported that they have enacted specific laws, policies and administrative measures to prevent and eliminate violence against health workers in sustained ways. Survey responses also revealed significant disparities between WHO regions (Fig 5.18). Income groups with the highest proportion of countries with such measures were HICs (54%) and UMCs (33%), while the countries with the lowest percentage were among the LICs (8%) and LMCs (17%). These findings indicate that more efforts are needed to ensure that health workers are protected from violence in all settings and contexts.

**Fig. 5.18.**  
Availability of laws, policies and other administrative measures to prevent and eliminate violence against health workers, by WHO region



## Country programmes to protect the safety, health and well-being of health workers

The Environmental and Occupational Health Directorate in **Sri Lanka** is responsible for development of regulations around occupational safety and health of health workers. In the **Islamic Republic of Iran**, the health and well-being of health service staff is implemented by the Work and Environment Health Centre within hospitals and medical institutions; health records are created for employees and vaccination programmes are available for employees. In **Peru**, a law on Safety and health at work requires health organizations to assess areas of occupational health, and assess potential risk and hazards, including among health workers. During the COVID-19 pandemic, some health projects were initiated in **Haiti** to support the well-being of health

workers. Also, the **Democratic People's Republic of Korea** has implemented a programme on the occupational health and safety of health workers. The NHS people plan (2020) outlines the steps that need to be taken by organizations, employers, staff and systems in the **United Kingdom** to ensure the safety, health and well-being of NHS staff. The plan recognizes the physical and psychological challenges that staff face and provides quality health and well-being support for everyone. **Thailand** has been implementing the Thailand personnel safety goals since 2018, which are aligned with the WHO health worker safety charter. Occupational health is also part of the national accreditation standards. To protect health workers from biological hazards, **Germany** has enacted new regulations. Employers must follow technical and organizational measures to reduce infection or contamination risk. Health workers have duties such as wearing personal protective equipment, reporting incidents and getting medical check-ups. Employees in **Ireland** who need psychological support can access it through the employee assistance programmes set up by the Department of Health and the Health Service Executive. These programmes offer sessions with qualified therapists who can help employees cope with various issues and challenges. To protect themselves and their patients from infections, health workers in **Guyana** must comply with the national immunization policy. This policy mandates that all health workers are vaccinated for hepatitis B, tetanus, varicella and COVID-19. According to the Ministry of Health and Social Protection of **Colombia**, health workers who work in direct contact with patients must comply with a minimum vaccination schedule.

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*Countries are implementing various programmes to protect the safety, health, and well-being of health workers, including regulations on occupational safety, vaccination programmes, psychological support, and national safety goals.*

## Feature story 12.

### Health worker safety

Health worker safety is an essential prerequisite for patient safety. Without workers who are supported and protected, the health system cannot deliver high quality, safe care. Health workers face a range of daily challenges including the emotional burden of their work and its effects on their mental health, environmental hazards and the risk of physical violence. To provide a safe, efficient and effective service, health workers need to feel physically and psychologically safe, secure, and work in an environment in which organizational leadership invests in their well-being.

The COVID-19 pandemic has had an unprecedented impact on health worker safety and brought to the forefront the close link with the safety of care provided.<sup>a</sup> Despite learnings from the previous outbreaks of Ebola virus disease, Middle East respiratory syndrome (MERS), and severe acute respiratory syndrome (SARS), health workers were not provided with adequate protection as part of the emergency preparedness plans and therefore were disproportionately affected in terms of deaths and infections.<sup>a</sup> WHO estimates that between 80 000 and 160 000 health and care workers died from COVID-19 between January 2020 and May 2021, suggesting a mid-range number of 115 500 deaths – still likely to be a vast underestimate.<sup>b</sup>

Inequity is a major challenge for health workers. A study of NHS Health workers in United Kingdom found the workers of black and minority ethnicity were more likely to die from COVID-19.<sup>c</sup> As of October 2021, two in five health workers were fully vaccinated on average globally, with just one in ten fully vaccinated in the WHO African Region, while 22 mostly HICs reported that above 80% of their personnel were fully vaccinated.<sup>d</sup>

A 2005 WHO global study reported that sharp injuries resulted in approximately 66,000 hepatitis B, 16,000 hepatitis C, and 1,000 HIV infections annually, which lead to approximately 1000 deaths and significant disability per year.<sup>e</sup> More than 90% of these infections occur in LICs and many are preventable.<sup>f</sup>

Health workers face significant threats to their mental health, with the potential for this to lead to an inevitable impact on the safety of care provided. Compounded by a global shortage of health workers, long shifts and the emotional stress of caring work, burnout rates among health workers have increased, with recent pooled estimates of burnout among health workers ranging from 41% to 52%.<sup>g</sup> This was further exacerbated by the threat of infection and concerns about the safety of their families during the COVID-19 pandemic. A healthy, cohesive workforce is essential for the delivery of safe, high-quality and patient-centred care.

Violence against health workers, particularly in crisis settings, is growing and spans from individual verbal or physical attacks to the systematic targeting of health facilities and workers during conflict. Those working in fragile settings already face challenges of scarce resources, lack of supplies and high stress situations.<sup>h</sup> If health workers do not feel safe they cannot provide high-quality, patient-centred and safe care.

Sources:

<sup>a</sup> Shaw A, Flott K, Fontana G, Durkin M, Darzi A. No patient safety without health worker safety. *Lancet*. 2020; 396:10262:1541–2. doi:10.1016/S0140-6736(20)31949-8.

- <sup>b</sup> *The impact of COVID-19 on health and care workers: a closer look at deaths*. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/handle/10665/345300>, accessed 25 April 2024).
- <sup>c</sup> Bailey S and West M. *Ethnic minority deaths and Covid-19: what are we to do?* London: The Kings Fund. 2020 (<https://www.kingsfund.org.uk/blog/2020/04/ethnic-minority-deaths-covid-19>, accessed 25 April 2024).
- <sup>d</sup> *Health and care worker deaths during COVID-19* [website]. Geneva: World Health Organization; 2021 (<https://www.who.int/news/item/20-10-2021-health-and-care-worker-deaths-during-covid-19>, accessed 25 April 2024).
- <sup>e</sup> Pruss-Ustun A, Rapiti E, Hutin Y. Estimation of the Global Burden of Disease Attributable to Contaminated Sharps Injuries Among Health-Care Workers. *American J Industrial Med*. 2005; 48(6):482–90. doi:10.1002/ajm.20230.
- <sup>f</sup> Kermode M, Jolley D, Langkham B, Santhosh Thomas M, Crofts N. Occupational exposure to blood and risk of bloodborne virus infection among health care workers in rural north Indian health care settings. *Am J Infect Control*. 2005; 33(1):34–41. doi:10.1016/j.ajic.2004.07.015.
- <sup>g</sup> Abdul Rahim hF, Fendt-Newlin M, Al-Harabsheh ST, Campbell J. *Our duty of care: A global call to action to protect the mental health of health and care workers*. Doha: World Innovation Summit for Health; 2022 (<https://wish.org.qa/reports/a-global-call-to-action-to-protect-the-mental-health-of-health-and-care-workers/>, accessed 25 April 2024).
- <sup>h</sup> 2021 designated as the International Year of Health and Care Workers [website]. Geneva: World Health Organization; 2020 (<https://www.who.int/news/item/11-11-2020-2021-designated-as-the-international-year-of-health-and-care-workers>, accessed 25 April 2024).



*Nurse on duty in the dengue ward at Dhaka Medical Hospital during a severe outbreak in Bangladesh. © WHO / Fabeha Monir*





Strategic  
objective

6

# Information, research and risk management

*Data processing center for Ebola vaccine clinical trials in Conakry, Guinea, managed by WHO. © WHO / Sean Hawkey*

“

Ensure a constant flow of information and knowledge to drive the mitigation of risk, a reduction in levels of avoidable harm, and improvements in the safety of care

## Organization of section



### Strategy 6.1. Patient safety incident reporting and learning systems

- Patient safety incidents classification and reporting format
- Functional patient safety incident reporting and learning systems
- Paper versus electronic reporting
- Voluntary versus mandatory reporting
- Types of incidents reported
- Safety alerts based on learning from incidents

### Strategy 6.2. Patient safety information systems

- Identification and mainstreaming of patient safety indicators
- Monitoring of patient safety indicators
- Annual reporting on patient safety

### Strategy 6.3. Patient safety surveillance systems

- Sources of patient safety information
- Investigation mechanisms in cases of serious harm

### Strategy 6.4. Patient safety research programmes

- Identification of research priorities for patient safety
- Safety risk assessment integration with health technology assessment

### Strategy 6.5. Digital technology for patient safety

- Use of digital technologies for improving access and safety
- Electronic health records
- Patient safety in digital health

## Key messages



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.

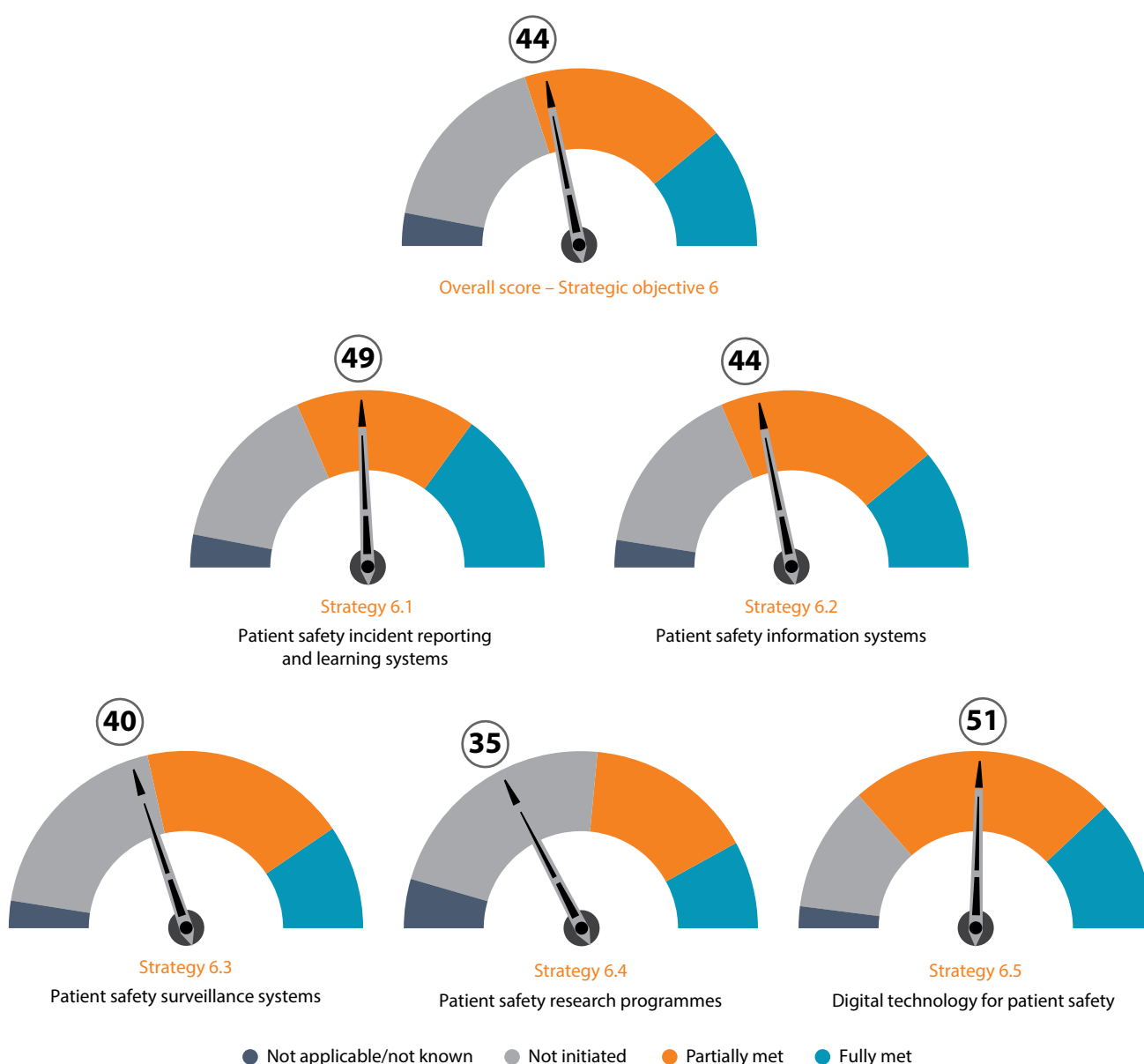


Research on patient safety remains a low priority, with only 11% of countries considering it a priority.

The importance of robust and reliable data in patient safety is crucial for identifying problems, setting benchmarks and monitoring performance. Despite global efforts to improve patient safety, there is a persistent lack of high-quality, comprehensive and integrated information systems for patient safety. Currently, various data sources such as incident reports, complaints and case notes provide only a fragmented view of patient safety issues. There is a pressing need for comprehensive and integrated information systems focused on patient safety, and incorporating patient and family experiences. Such systems should ideally document all incidents in health care services, inform care process re-design and measure risk reduction effectiveness. While achieving optimal reporting and learning may not be immediately feasible for all health systems, prioritizing incident types and themes can aid real time risk management. Moreover, integrating patient safety data with regular operational data and medical records can enhance understanding of harm causation and reduction strategies, closing the loop between learning and practical improvements.

The Member State survey responses provide an overview of the maturity of information systems in countries, and reveal country initiatives to promote research and optimal use of technology to improve patient safety. When aggregated at the global level, reported country performance against strategic objective 6 – information, research and risk management scores 44 (out of 100) (Fig. 6.1). Overall, 22% of related criteria were fully met and another 38% were partially met. Around one third of countries are yet to commence any related efforts.

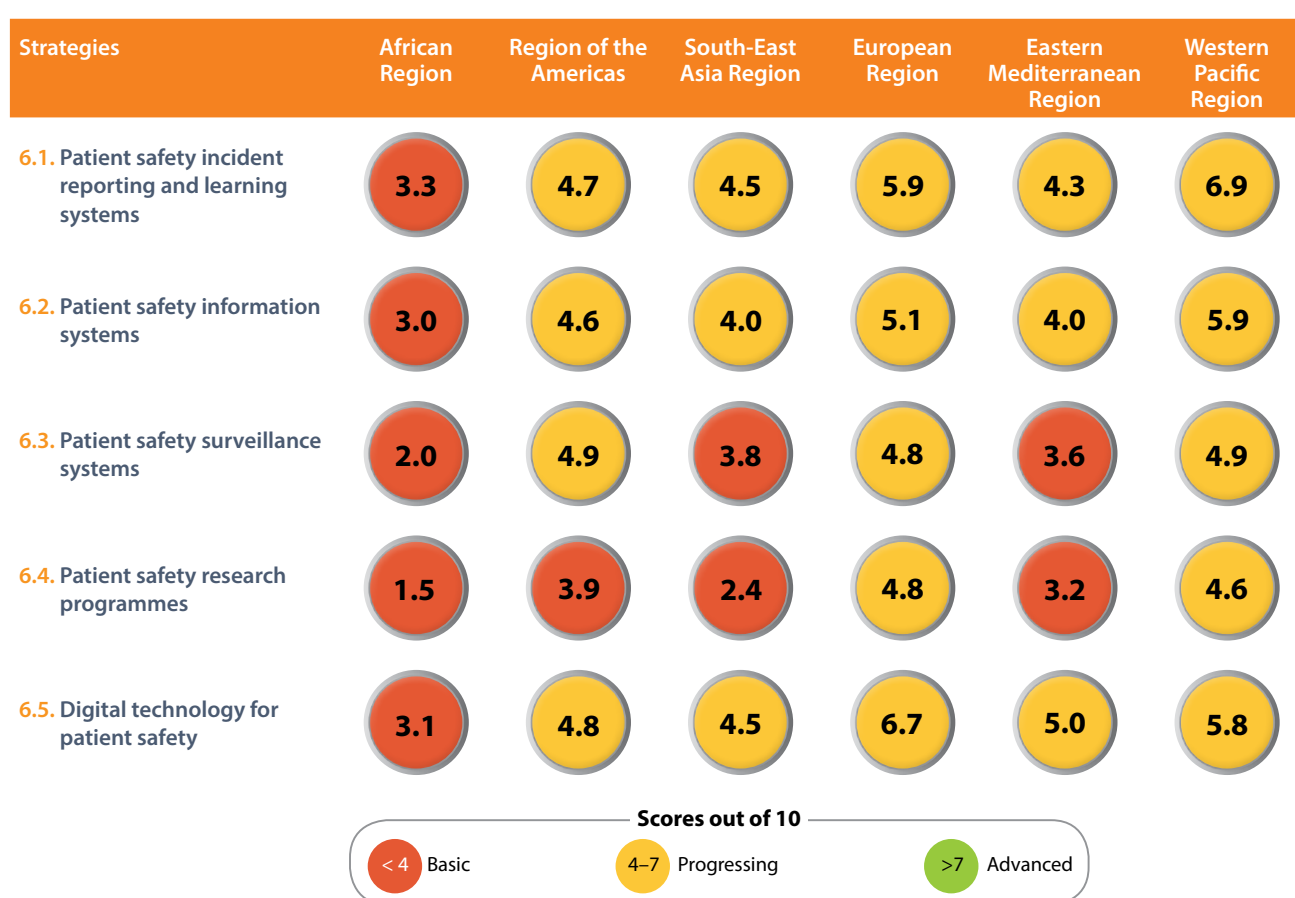
► Fig. 6.1. Global performance scores for strategic objective 6



Strategy-related performance scores reflect moderate strengths in patient safety incident reporting and use of digital technologies. However, they also reveal a significant need for improvement in the areas of patient safety research and information systems.

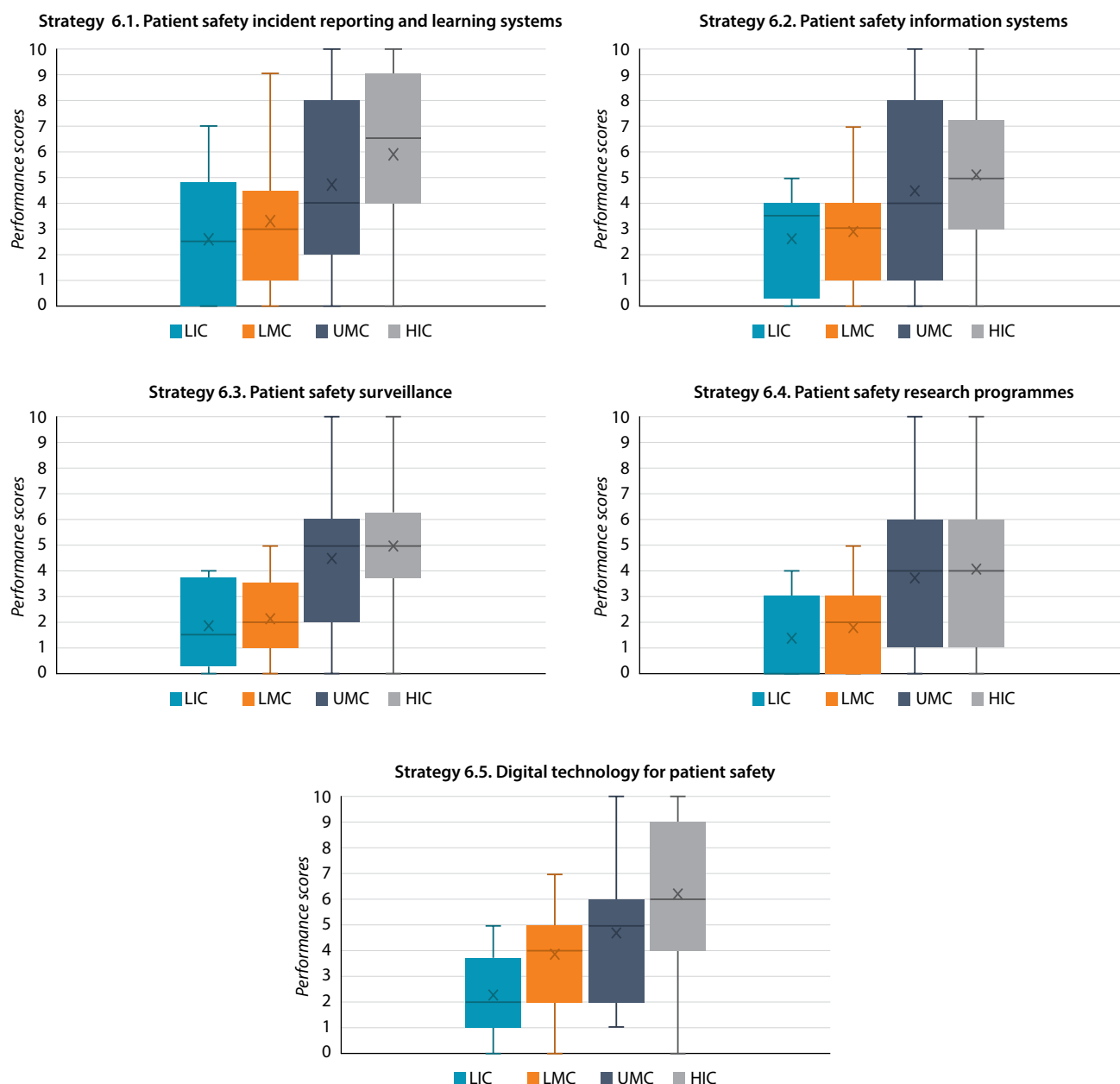
The overview of patient safety strategies across regions reveals a varied picture of efforts and outcomes (Fig. 6.2). The Western Pacific Region shows strong performance in incident reporting and learning systems, suggesting a focus on learning from patient safety incidents. Countries of the European Region lean towards using digital technology in patient safety, pointing to an interest in technological solutions. The Region of the Americas and the South-East Asia Region have moderate performances in various strategies, with the former showing some focus on patient safety surveillance systems. The Eastern Mediterranean Region demonstrates a commitment to leveraging digital technology for patient safety improvement. Importantly, countries of the African Region present a significant opportunity for improvement and development in all of the strategies.

► **Fig. 6.2. Distribution of strategic objective 6 performance scores across five component strategies, by WHO region**



Further analysis suggests that performance demonstrates a positive correlation between a country's income level and its median scores in patient safety incident reporting, information systems, surveillance, research, and the use of digital technology (Fig. 6.3). High-income countries generally report higher scores, indicative of more established and sophisticated patient safety information infrastructures. However, the spread within each income group, highlights diverse implementation levels. Notably, despite economic differences, there are lower-income countries with scores that approach or overlap with higher-income counterparts, pointing to successful initiatives that could serve as models for improvement across the spectrum. The data indicates the potential for enhancing patient safety measurement and improvement globally, with an emphasis on leveraging digital technologies and reinforcing research programmes, especially in lower-income settings.

► **Fig. 6.3. Distribution of strategic objective 6 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.

## Strategic objective 6

6.1

Patient safety incident reporting and learning systems

6.2

Patient safety information systems

6.3

Patient safety surveillance systems

6.4

Patient safety research programmes

6.5

Digital technology for patient safety

### Strategy 6.1.

## Patient safety incident reporting and learning systems



Establish or strengthen patient safety incident reporting and learning systems

Patient safety incident reporting and learning systems (PSIRLSs) are essential instruments for ongoing efforts to enhance patient safety and quality of care in health care settings. They are structured to collect detailed reports of safety incidents, which include accidents, near misses and any other events that could potentially compromise patient care. The analysis of these data is crucial for health care organizations as it allows them to understand the reasons behind safety events and to develop strategies to prevent future occurrences.

#### Box 6.1. Functions of patient safety incident reporting systems

**Public accountability:** They help ensure that health care providers are answerable to the public by maintaining transparency regarding safety incidents. Maintaining independence of these systems is critical for public accountability, ensuring that safety incidents are reported and processed impartially, free from any influence.

**Response to patients and families:** These systems provide a means for addressing the concerns of patients and families affected by safety incidents.

**Communication alert route:** They act as an alert system to communicate potential risks across the health care facility.

*Patient safety incident reporting and learning systems are crucial for improving health care safety by promoting transparency, enhancing communication, and enabling continuous learning and prevention of incidents.*



*Barometer of risk:* The systems serve as an indicator, providing insights into the levels of risk prevalent within health care settings.

*Foundation for learning and improvement:* Perhaps most importantly, PSIRLs create a database of incidents through which health care providers can learn and improve their practices without assigning blame or any fear of retribution.

*Source:*

*Patient safety incident reporting and learning systems: technical report and guidance.* Geneva: World Health Organization; 2020 (<https://iris.who.int/handle/10665/334323>, accessed 30 April 2024).

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*Learning from failures is essential for advancing patient safety, while health care benefits from the adoption of rigorous, transparent, and blame-free incident reporting systems, inspired by strategies in other high-risk industries.*

The importance of such systems is informed and reinforced by successful parallel strategies in other high-risk industries, such as aviation, where rigorous reporting and investigation of incidents have significantly reduced risks. In health care, the maxim ‘we must learn from the things that go wrong’ has propelled the establishment of incident reporting systems worldwide, with variations in their implementation regarding their voluntary or mandatory nature, the types of data collected, the extent of public involvement, and the depth of related investigation.

While reporting and learning are pivotal in improving patient safety, their success hinges on a delicate balance of functions, comprehensive structural support, and a culture that promotes transparent, blame-free reporting. As the health sector continues to evolve, so too must these systems, adapting and improving to ensure they fulfil their primary purpose of making patient care safer.

The WHO Patient safety incident reporting and learning systems: Technical report and guidance (176) provides an invaluable framework for countries aiming to develop and expand their reporting and learning systems. This comprehensive guide offers practical advice and strategic insights for the implementation of effective systems that can track, analyse and learn from patient safety incidents.

## Patient safety incidents classification and reporting format

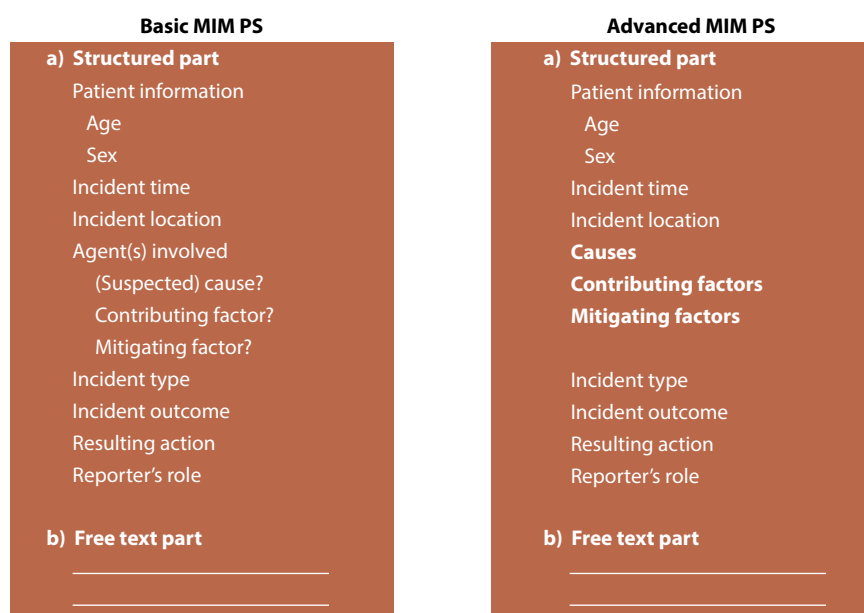
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*Defining and classifying patient safety incidents are important initial steps for building reliable reporting and learning systems.*

One of the foundational steps towards building a reliable reporting and learning system is to define and classify patient safety incidents. WHO has developed a Conceptual framework for the international classification for patient safety (ICPS) (246). The framework provides a comprehensive understanding of the patient safety domain and outlines a continuous learning and improvement cycle that emphasizes identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience.

In addition, a user guide on Minimal information model for patient safety incident reporting and learning systems (247) provides a structure for PSIRLs. It

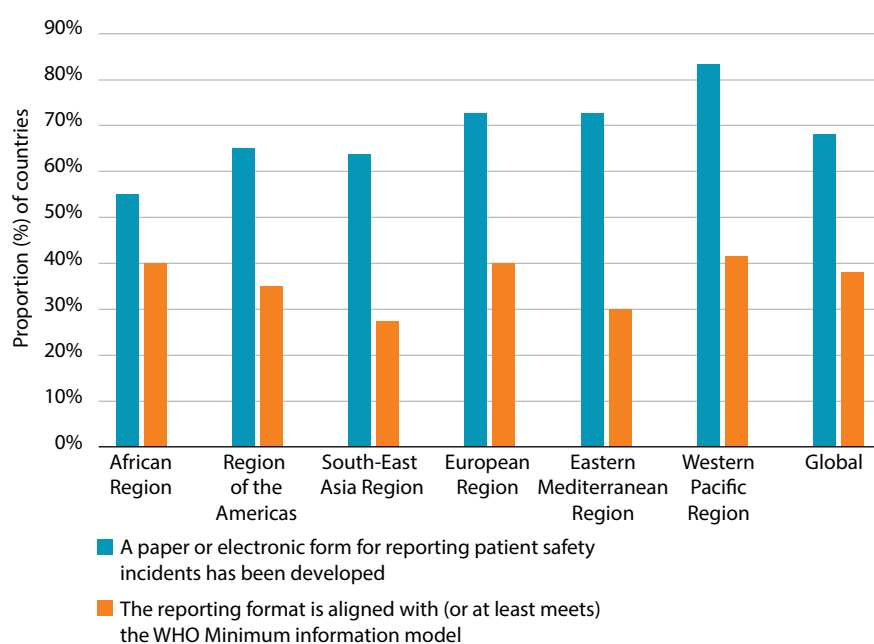
is divided segmented into two tiers: the basic model comprising eight critical data categories, and the advanced model encompassing ten data categories (Fig. 6.4).



**Fig. 6.4.**  
Basic and advanced minimal information model for patient safety incident reporting and learning systems

The Member State survey reveals that 29% of country respondents reported that definitions and classification of patient safety incidents had been developed, in alignment with the WHO international classification.

Around 68% of countries said that a standard format is established for reporting patient safety incidents. Around half of these countries have their incident reporting format aligned with the WHO minimum information model. There are regional variations in these practices (Fig. 6.5).



*A third of countries have developed definitions and classifications for patient safety incidents aligned with WHO standards.*

**Fig. 6.5.**  
Availability of a standard format for reporting patient safety incidents, by WHO region

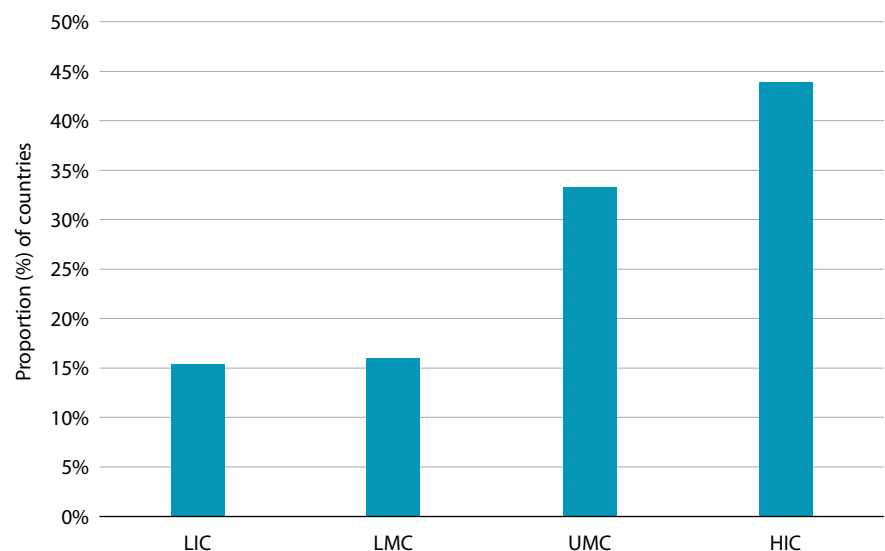
## Functional patient safety incident reporting and learning systems (PSIRLS)

*Approximately one third of countries, primarily in high-income settings, have dedicated institutions overseeing patient safety incident reporting and learning systems.*

Setting up an effective PSIRLS requires substantial resources and infrastructure. Sufficient financial backing is essential, as is a robust information technology system to handle sensitive data. Skilled professionals must be employed to analyse this data, and strict confidentiality and data security policies must be in place to protect both patient information and the anonymity of individuals who report. The system should also include clear protocols for clinical governance, established rules for reporting, accessible reporting channels, and a mechanism for providing feedback to reporters to encourage ongoing participation and trust in the system.

Managing intricate processes related to PSIRLSs requires a designated institution with sufficient resources and technical capacity. Approximately one third of the countries surveyed indicated that their PSIRLSs are overseen by a specific institution or agency. The majority of these institutions are located in UMCs and HICs (Fig. 6.6).

**Fig. 6.6.**  
**Availability of a designated institution for managing patient safety incident reporting and learning systems, by income group**



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

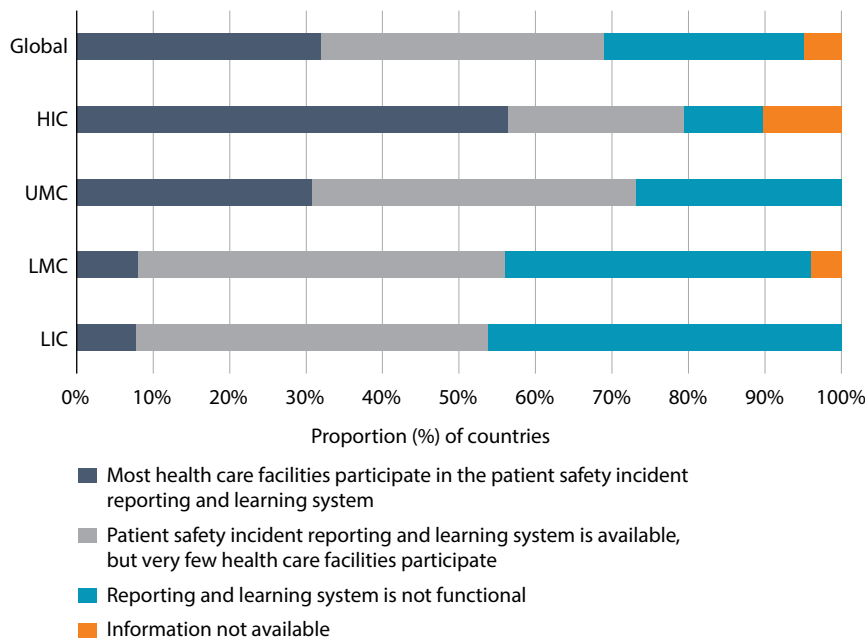
*In 32% of countries surveyed, a majority (over 60%) of health care facilities, including both public and private, actively participate in their patient safety incident reporting and learning systems.*

While the availability of a well-functioning reporting and learning system is fundamental, the effectiveness of these systems is determined by whether health care facilities have trust in such systems and use them regularly to report safety incidents. Survey data reveals that in 32% of countries, a significant majority (over 60%) of both public and private health care facilities are actively engaged with these reporting and learning systems. This reflects a widespread implementation and utilization of the reporting and learning systems in these countries.

The Member State data also reveals a diversity in availability of PSIRLSs across various income levels, and the considerable gap that exists between accessibility and active participation, with many countries reporting available systems that remain underutilized (Fig. 6.7). The most substantial participation

is seen among HICs, with over half of countries actively involved in using PSIRLSs. Conversely, LICs and LMCs typically struggle, with a notable proportion of non-functional systems, which may be indicative of the challenges faced in the implementation and operational effectiveness of these systems.

Globally, there is a need for targeted interventions to enhance the adoption and functionality of PSIRLSs and to address the challenges that prevent health care facilities from participating to improve patient safety and care standards, especially in lower-income regions.



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

The majority of existing PSIRLSs are coordinated centrally at the national level (62%). While central coordination remains the most common approach, a considerable proportion of countries reported having localized handling of patient safety incidents at subnational, organizational and health care facility level, potentially allowing for quicker, more tailored responses to specific local contexts.

## Governance of patient safety incident reporting and learning systems

Patient safety incident reporting and learning systems vary significantly by country, and depend on factors such as the various health care settings and ownership of health care facilities.

**Estonia** is in the process of developing a standard format for reporting that is aligned with the minimum information model.

The **United Kingdom** NHS trusts are all participants in centralized PSIRLSs, with efforts to include smaller providers.

*Patient safety incident reporting and learning systems show substantial disparities in use and functionality.*

**Fig. 6.7.**  
Adoption and functionality of patient safety incident reporting and learning systems, by income group

*Most patient safety systems are centrally managed, yet significant localized handling allows for quicker, context-specific responses.*

In **Sri Lanka**, government facilities mostly participate, and some private hospitals have their own systems.

**Chile** requires such systems in inpatient care for both public and private establishments, but not in outpatient care.

**Ireland** extends its National Incident Management System to public health services and some private hospitals.

In **South Africa**, the National Department of Health manages the PSIRLs for public (i.e. government-run) health facilities. Private health groups have developed their own systems.

**New Zealand** has a well-established hospital reporting system, yet outside of the hospital setting usage is less consistent and not mandatory.

## Paper versus electronic reporting

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*Patient safety incident reporting is shifting towards technology, with over half of countries adopting digital systems for enhanced data management.*

Survey responses indicate that globally, 52% of countries are now utilizing dedicated software applications or Internet-based systems to report patient safety incidents, signifying a shift towards leveraging technology for more efficient data capture and analysis. Additionally, e-mail is employed as a reporting mechanism by 32% of countries, serving as a supplementary channel that bridges the immediacy of digital communication with the ease of traditional formats. Concurrently, some countries continue to use paper-based reporting methods, which might point to traditional approaches still being predominant or limitations in digital infrastructure. The varied use of reporting mediums reflects a transitional phase in health care reporting systems as they evolve to incorporate more advanced technologies.

## Voluntary versus mandatory reporting

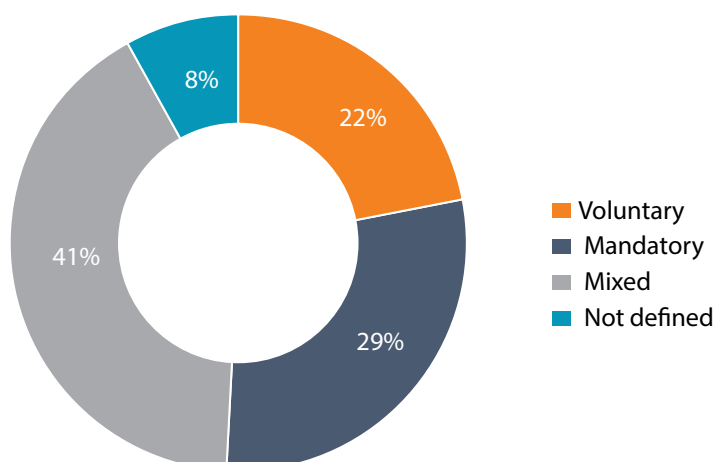
The dual purpose of accountability and learning from PSIRLSs often leads to conflicting roles. Predominantly utilizing systems for accountability can foster an atmosphere of fear among health workers, making them reluctant to report errors due to concerns about resulting repercussions. The central challenge for reporting systems is to strike a delicate balance where the system serves as a tool for both organizational learning and appropriate accountability, without discouraging incident reporting.

Policies within reporting systems are defined to determine the nature of reporting (i.e. whether it is to be done on a voluntary basis or is mandated by policy). In certain systems, there is a hybrid approach that typically mandates the reporting of critical safety events such as patient deaths, severe harm, or 'never' events, while less serious events are reported on a voluntary basis. This approach aims to ensure that while serious incidents are rigorously documented, a supportive environment is maintained for reporting lesser issues that also drive systemic improvement.

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*Patient safety incident reporting systems vary globally, with 22% of countries employing voluntary methods, 29% mandating reporting, and 41% using a hybrid approach to balance learning with accountability.*

Of the respondent countries, 22% reported their systems are voluntary (Fig. 6.8). In contrast, 29% have instituted mandatory reporting requirements. A significant proportion (41%) has implemented a hybrid approach, where reporting obligations are determined by the severity of the incident or ownership of health care facility (i.e. private or public).



**Fig. 6.8.**

**Obligation to report patient safety incidents, globally**

Patient safety incident reporting varies across WHO regions, reflecting different health care system approaches. The South-East Asia Region seems to favour voluntary reporting. The Region of the Americas and the African Region show a tendency towards mandatory reporting, possibly to ensure consistent and standardized patient safety measures. The Western Pacific Region employs a balanced strategy, where the decision to mandate reporting depends on the severity of the incident, suggesting a flexible yet structured approach. The European and Eastern Mediterranean Regions also present a mixed system, hinting at an adaptable patient safety environment. These regional differences highlight tailored responses to the unique needs and circumstances within each health care framework. HICs generally lead in adopting mixed reporting strategies (54%), significantly higher than other income groups, possibly reflecting a more developed, nuanced approach to patient safety, and one that integrates both mandatory and voluntary elements depending on the severity of the incident.

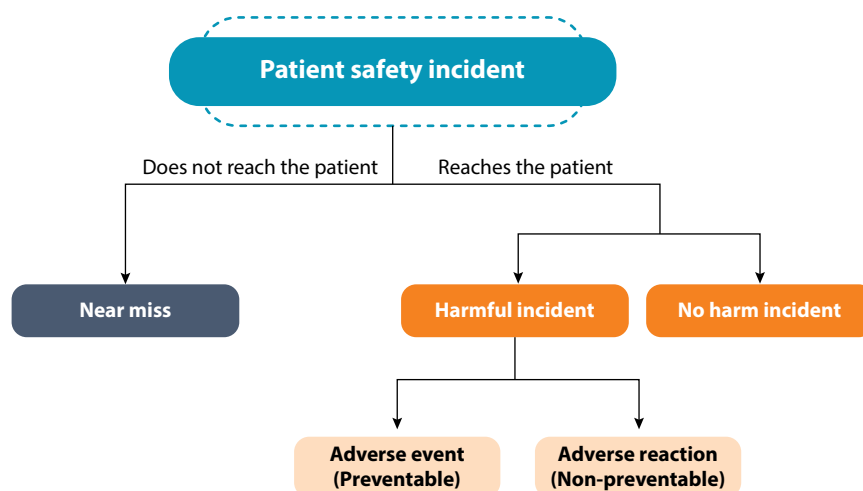
*Patient safety incident reporting varies by WHO region, with some areas favouring voluntary methods and others mandating reporting for consistency.*

## Types of incidents reported

Patient safety incident reporting and learning systems classify incidents into three distinct categories for more detailed analysis and learning (Fig. 6.9). A 'near miss' is an event that could have harmed a patient, but was averted before causing any impact –such as the interception of a misallocated blood transfusion. 'No harm incidents' reach a patient but do not result in observable damage –such as the administration of a wrong but compatible blood type. Lastly, 'harmful incidents' directly result in patient harm, for example, a transfusion with an incompatible blood type leading to a severe adverse reaction (176). This classification helps health care providers focus on prevention, learn from mistakes and improve overall patient safety.

*To facilitate detailed analysis, patient safety incident reporting systems categorize events into near misses, no harm incidents, and harmful incidents.*

**Fig. 6.9.**  
Classification of patient  
safety incidents



Global patient safety reporting systems widely acknowledge the importance of learning from all incident types, with about half of countries reporting near misses and non-harmful incidents, and a majority documenting both preventable and non-preventable adverse events.

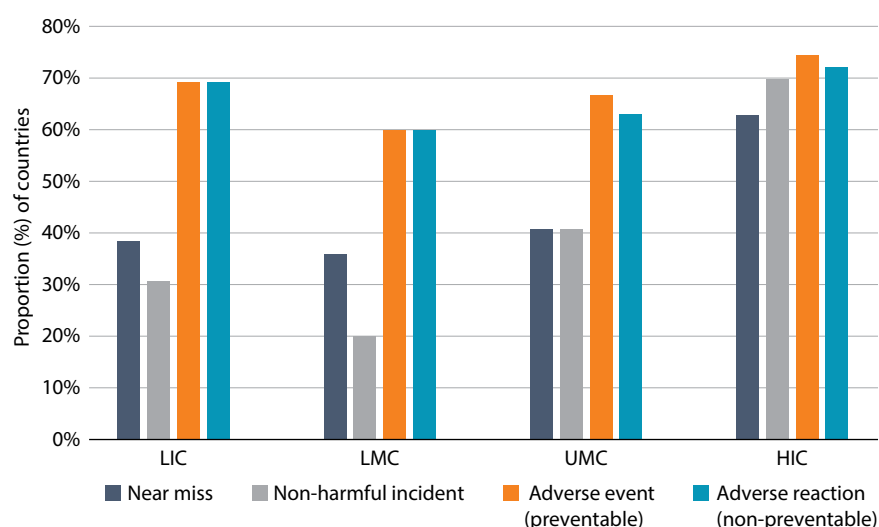
The data collected from Member States provides insights into the types of incidents that are most commonly included in PSIRLS globally (Fig. 6.10).

**1. Near miss and non-harmful incidents.** Both near misses and non-harmful incidents are included in reporting and learning systems by roughly half of the countries (48% and 46% respectively). This indicates a widespread recognition of the value in reporting incidents that do not result in harm, as they represent opportunities to learn and implement preventative measures before patients are harmed.

**2. Adverse events and reactions.** The majority of countries (69%) for preventable adverse events and 67% for non-preventable adverse reactions) include both adverse events and adverse reactions in their reporting systems. This reflects an understanding of the importance of learning from both preventable incidents and those that were not preventable, given the circumstances and knowledge at the time.

**3. Serious, never or sentinel events.** Around one third of countries exclusively report only serious, never or sentinel events in their reporting systems. This

**Fig. 6.10.**  
Types of patient safety incidents  
reported, by  
income group



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



could indicate that some countries prioritize their resources for the most severe cases due to limited resources or policy decisions focusing on the most critical issues first.

Further data reveal that HICs have higher reporting rates of near misses and non-harmful incidents compared to other income groups, suggesting a more mature patient safety culture.

## Safety alerts based on learning from incidents

The central objective of reporting and learning systems within health care systems is to mitigate the risk of future patient harm. It is important to communicate the details of an incident to facility staff and share lessons across the health system. Patient safety alerts are critical tools for communicating potential risks and necessary actions to prevent harm in health care settings. To be most effective, these alerts should be concise and straightforward, enabling quick understanding and response from health care providers. It is essential that they are disseminated through a well-planned distribution strategy that ensures they reach the appropriate audience in every necessary location. Alert content must be carefully considered and actionable, with complex instructions simplified to facilitate ease of implementation.

Furthermore, patient safety alerts need to be adaptable, allowing for customization according to the specific needs and constraints of various health care environments. Given the high volume of communications that health care providers may receive, it is also vital to prioritize and coordinate safety alerts to prevent information overload, and to ensure that each message is given the appropriate level of attention.

Around 27% of countries reported that they regularly distribute alerts about critical sources of patient risk and harm, and that these are derived from the analysis of incident reports to prompt necessary actions. Many countries reported that such alerts are limited to medical products or specific programmes, such as maternal and neonatal health.

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*More than a quarter of countries regularly distribute patient safety alerts based on incident reports.*

### **Box 6.2. National patient safety alert system in the National Health Service (England, United Kingdom)**

The National Health Service (NHS) England patient safety alert system is a vital mechanism for identifying and addressing new or not well acknowledged safety concerns within the health care system in England.<sup>a</sup> It utilizes a national reporting system and additional sources to conduct clinical reviews of incidents. Upon identifying an issue that which necessitates national intervention, the system mobilizes a collaborative approach involving frontline staff, patients, professional entities and partnering organizations to determine the best course of action.

In situations where it is necessary for the NHS to directly influence outcomes, it issues national patient safety alerts. These alerts command actions that health care organizations must take to mitigate risks of injury or death. Established in November 2019, the NHS Patient Safety Team holds the distinction of being the first national entity accredited to disseminate these alerts by the National Patient Safety Alerting Committee (NaPSAC). To conform to stringent thresholds and standards set by the committee, alerts are formulated with the contributions of patients, frontline workers, experts and advice from a National Patient Safety Response Advisory Panel. This panel comprises health care workers, patient advocates, safety specialists and representatives from royal colleges and other professional and national bodies, ensuring that the actions recommended in the alerts are clear, actionable and effective in enhancing patient safety.

Source:

<sup>a</sup> See: *Our National Patient Safety Alerts* [website. Leeds: National Health Service England; 2024 (<https://www.england.nhs.uk/patient-safety/patient-safety-alerts/>, accessed 1 May 2024)].

## Feature story 13.

### Reporting and learning systems: Innovations and lessons from Thailand, South Africa and the United Kingdom (England and Wales)

#### Thailand's experience

Building on pre-existing hospital risk management structures, Thailand has set up a national reporting and learning system (NRLS) that allows for better understanding of incident types at a national level.

#### What was done and why?

Since 1997, the Healthcare Accreditation Institute<sup>a</sup> in Thailand has worked to integrate risk management into hospital accreditation, promoting patient safety incident reporting at a hospital level. However, the lack of a centralized system for national-level reporting and guidance for hospitals on incident reporting systems posed challenges. In 2016, inspired by a WHO consultation and Japan's reporting system experience, the institute initiated a platform with 80 hospitals to prototype a reporting and learning system and conducted a self-assessment identifying the need for a national system as a priority. Consequently, in collaboration with government ministers and fifteen national stakeholder organizations, Thailand developed a national patient and personnel safety policy in 2017, prioritizing a national incident reporting and learning system, guided by WHO recommendations. This policy aims to enhance patient safety through national guidelines, engagement of patients and families, and stakeholder support.

*"Talking with others at the inter-regional consultation inspired us to develop the system in Thailand. Having that platform for sharing and learning was so important. The WHO technical tools were very useful in providing direction at the start of the project, and WHO's involvement also motivated government support."*

*Representative of the Healthcare Accreditation Institute*

#### Outcomes and impact

The Healthcare Accreditation Institute launched a national reporting and learning system (NRLS) for voluntary participation by Thailand hospitals, with 950 (67% of the country's hospitals) joining to date. This free system allows hospitals to submit patient safety incident reports either via new software or existing systems, providing real-time updates on incidents both locally and nationally. The focus is on encouraging reporting, with incidents analysed by type, location, and severity to aid hospitals in identifying improvement areas. A practitioner and expert community has been formed for sharing learnings

*"It has been very important to motivate and empower every hospital to report. We have focused on developing a good reporting culture and continuing to build up trust between the Healthcare Accreditation Institute and the hospitals."*

*Representative of the Healthcare Accreditation Institute*

#### What's next?

The institute plans to build their capacity to analyse incidents in more depth, including supporting hospitals to conduct investigations to help understand safety incidents in more detail. An additional arm of the project that is

under development aims to involve patients and families in incident reporting, working on this together with the Patients for Patient Safety group that already exists in Thailand. The team envisages a system built on collaboration between health care providers, government, patients and others, that can provide insights into health care-associated harms and informing practical action for change.

*"We have tried to empower people by saying: Everybody owns this system; Everybody can report into it; and, Everybody can use the data."*

*Representative of the Healthcare Accreditation Institute*

Source:

<sup>a</sup> The Healthcare accreditation institute (public organization) [website]. Bangkok: Healthcare Accreditation Institute; 2024 (<https://www.ha.or.th/EN/Home>, accessed 1 May 2024).

## South Africa's Experience

### What was done and why?

Prior to 2018, the patient safety reporting landscape was variable across South Africa. The National Department of Health Directorate of Quality Assurance had minimal oversight of what was happening at a provincial level. The directorate developed a plan for a standardized system for reporting adverse events to enable the collection of aggregated data on the burden of harm nationally. The first step was to conduct a survey of local hospitals about their current practices, which revealed a considerable lack of consistency in reporting systems and practices.

*"We did a quick survey in the provinces, asking them: Do you have a system? If you have a system, are you using any classifications? Which ones are you using? What we found was that there were more differences than there were similarities!"*

*Representative of the Directorate of Quality Assurance*

Given the discrepancies in systems between hospitals, the directorate decided to adopt the WHO International classification for patient safety to structure the development of their own national system.<sup>a</sup> The first National guideline for patient safety incident reporting and learning with the accompanying web-based PSIRLS was rolled out to all provinces in 2018.<sup>b</sup> The guideline was developed working closely with WHO, in-line with its minimum information model.<sup>c</sup>

### Outcomes and impact

Compliance with the web-based PSIRLS serves as a progress indicator for the national guideline's implementation. A health facility is deemed compliant if it reports a patient safety incident or a 'null' report monthly. Five years post-guideline launch, compliance rose from 37% to 69%, but data quality issues persist due to a challenging safety reporting culture and staff's limited reporting knowledge, hindering the system's potential.

*"When we look at the incidents being reported, very few of them are in the high severity or 'never' event category. These are the types of events that we would like to see [being reported], but we know that staff are still very scared of being disciplined if they report something."*

*Representative of the Directorate of Quality Assurance*

In 2021, the UK-funded Better Health Programme assisted South Africa's Health Ministry in analysing two years of incident reports, leading to a revised classification system to better identify trends and enable learning. Following this, the national guideline was updated in 2022. An online training course, offering three continuous professional

development points, was introduced in July 2022 to educate staff on the updated guideline. The team now releases quarterly and annual incident reports by category and promotes a competitive improvement culture among hospitals. Focus areas include educating staff on accurate reporting, especially when incidents are frequently categorized as 'other'. Quality assurance officers often handle reporting, but there is a push for all front line clinical staff to report. Provinces with low reporting rates receive targeted educational visits to boost reporting.

*"We want hospitals to feel that having a high number of incidents is not indicative of poor care. We want to see many incidents being reported, because it is probably an indicator of a good culture of reporting."*

*Representative of the Directorate of Quality Assurance*

## What's next?

Work is ongoing to continue improving the quality of reporting and to strengthen the safety culture, while encouraging and supporting hospitals to use their data to inform local improvement initiatives and inform change at a national level too.

*"It is so important that facilities can use the data they capture to guide improvement of their systems and processes. Otherwise, there is no point in capturing all this information. We hope that staff will see the point in this exercise when they start to see that what they are reporting is informing change."*

*Representative of the Directorate of Quality Assurance*

### Sources:

- <sup>a</sup> World Alliance for Safer Health Care, World Health Organization. Conceptual framework for the international classification for patient safety version 1.1. Geneva: World Health Organization; 2009 (<https://iris.who.int/handle/10665/70882>, accessed 1 May 2024).
- <sup>b</sup> National guideline for patient safety incident reporting and learning in the health sector of South Africa. Version 2-2022. Pretoria: National Department of Health; 2022 (<https://knowledgehub.health.gov.za/elibrary/national-guideline-patient-safety-incident-reporting-and-learning-health-sector-south>, accessed 1 May 2024).
- <sup>c</sup> Minimal information model for patient safety incident reporting and learning systems: user guide. Geneva: World Health Organization; 2016 (<https://iris.who.int/handle/10665/255642>, accessed 1 May 2024).

## England and Wales experience

### What was done and why?

The National Reporting and Learning System (NRLS) in England and Wales, launched in November 2003, established a national database for patient safety incidents, marking the first time such incidents could be monitored and shared across the country.<sup>a</sup> From its inception, annual reporting surged from under 85 000 to approximately 2.4 million by March 2005. A clinical review team analyses the data to identify new and lesser-known risks, leading to actions including 5–10 National Patient Safety Alerts annually, requiring specific mitigations by providers, and collaboration with specialist networks and regulatory bodies for other issues. The NRLS has been integral to promoting a fair-blame reporting culture and educating clinicians on the value of reporting, despite challenges in data analysis for actionable insights. It is transitioning to a new cloud-based system, the Learn from patient safety events (LFPSE) service, to continue these efforts.<sup>b</sup>

### Outcomes and impact

A new learning-focused taxonomy will update the current list of incident types with a greater emphasis on understanding the ways in which things went wrong, and what tangible components were involved, guiding recorders to provide information with a greater emphasis on the mechanisms by which incidents occur.

*“A fall is a poor outcome for a patient, but the incident itself could have been due to poor hydration, wrong footwear, building design or medication; so unless this data is also captured, recording a fall does not necessarily help target interventions for improvement. There is still space to capture free text, which is where the ‘gold dust’ is in terms of learning; and the best categories and taxonomy cannot replace this.”*

*Representative of the LFPSE service*

Given the number of reports each year, another area of focus for the new system is refining the process of deciding which incident reports are reviewed by the clinical team. Review of incident reports is labour intensive, and the clinical team only have capacity to review 30 000 of the 2.2 million reports received annually. In the current system, all incidents graded as severe or fatal are reviewed, but other important incident reports may be being missed.

The team is refining incident reporting by incorporating questions about the strength of the perceived link between the incident and its outcome, the reporter’s concern level, and whether the problem is known or unknown. Concurrently, the PFPSE is leveraging artificial intelligence (AI) and machine learning to extract significant insights from report narratives, particularly focusing on identifying novel incident types, with promising initial outcomes from these advanced data analysis techniques.

*“We are hoping that all this may help us pick up some lower harm incidents before they cause a more severe harm. Artificial intelligence will never be able to do the whole process for us, but it may be able to help us pick out the important reports that contain new or unknown problems, and suggest which records should be prioritized for clinical review when resources only exist to examine a small percentage.”*

*Representative of the LFPSE service*

## **What’s next?**

The team is enhancing incident reporting in primary care and broadening learning from patient experiences, aiming to increase report numbers and incorporate patient insights more effectively. A new, more user-friendly online platform has been developed for primary care to boost reporting. Efforts are ongoing to integrate patient feedback from various sources, including social media and complaints departments, into the NRLS without burdening patients with multiple reporting channels.

The LFPSE service is focused on making data accessible and transparent for widespread benefit, reflecting national data back to providers to inform improvements. By making anonymized data widely available, the LFPSE encourages a diverse group of users – including clinical specialists, safety scientists, and academics – to engage with the data, fostering a collaborative approach to enhancing patient safety insights.

*“The initial temptation can be to collect lots of data, but there needs to be a plan about how you learn from the data; and how you turn an incident report into an intervention. Overall, we have shifted our thinking to recognize that we can never collect data on everything that goes wrong, but instead should focus on collecting enough of the right information, encouraging more analysis and use of the data by providers, and enabling a good safety culture.”*

*Representative of the LFPSE service*

### **Sources:**

<sup>a</sup> Welcome to NRLS Reporting [website] (<https://report.nrls.nhs.uk/nrlsreporting/>, accessed 1 May 2024).

<sup>b</sup> Learn from patient safety events (LFPSE) service. London: National (<https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/learn-from-patient-safety-events-service/>, accessed 1 May 2024).

## Strategic objective 6

6.1

Patient safety incident reporting and learning systems

6.2

Patient safety information systems

6.3

Patient safety surveillance systems

6.4

Patient safety research programmes

6.5

Digital technology for patient safety

### Strategy 6.2.

## Patient safety information systems



Create a patient safety information system based on all sources of data related to risks and harm inherent in the delivery of health integrated with existing health management information systems

Measuring patient safety performance is a critical step in understanding the various challenges related to patient safety, as well as in evaluating the effectiveness of implemented safety interventions. This process is not only vital in identifying existing issues but also in determining the impact and efficacy of current patient safety measures. By systematically tracking and analysing patient safety indicators, health care organizations can gain insights into areas where safety interventions are successful and where they need improvement. Furthermore, regular measurement and analysis enable health care facilities to adapt and evolve their patient safety strategies in response to emerging challenges, technological advancements and changes in health care delivery models.

Measuring patient safety indicators faces numerous challenges, including issues with data quality and availability, as health care facilities often have incomplete or inconsistent records. The lack of standardized metrics across different providers complicates this further. A significant concern is the underreporting of incidents, driven by fear of retribution or cultural barriers. Interpreting the collected data correctly requires specialized expertise, and any misinterpretation can lead to ineffective strategies.

*Measuring patient safety performance is crucial for identifying challenges and improving interventions. Despite data quality and underreporting issues, systematic analysis helps improve safety strategies.*



The safety of health care organizations is a complex and multifaceted issue that cannot be reduced to a single measure or standard. Different aspects of safety require different types of evidence and inquiry (248).

## Identification and mainstreaming of patient safety indicators

While three quarters of countries have begun identifying patient safety indicators, only 25% have defined and shared specific indicators with health care facilities for monitoring and reporting.

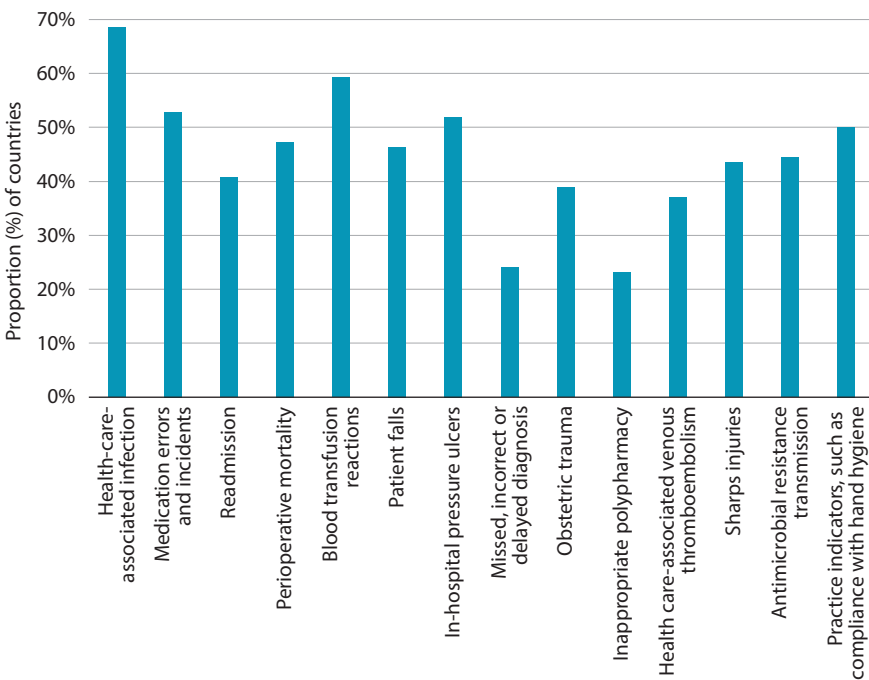
The Global patient safety action plan 2021–2030 outlines a set of indicators to monitor and evaluate the safety of health care services from the policy to point-of-care levels. Additionally, the WHO primary health care measurement framework and indicators provide a specific set of measures for assessing patient safety in primary care settings (249).

The Organisation for Economic Co-operation and Development (OECD) has a programme that uses a set of six indicators to measure and compare the quality and outcomes of health care across different countries, including a focus on patient safety. They are also developing new indicators that which move beyond traditional data to capture the experiences and perceptions of patients regarding their safety (250).

The Member State survey reveals that around three quarters of participating countries reported they have initiated identification of patient safety indicators. However, only 25% of countries report that specific indicators have been identified and disseminated to health care facilities for monitoring and reporting.

Further data analysis reveals that some patient safety indicators are prioritized for measurement globally. The most commonly measured indicators and are highlighted in Fig. 6.11.

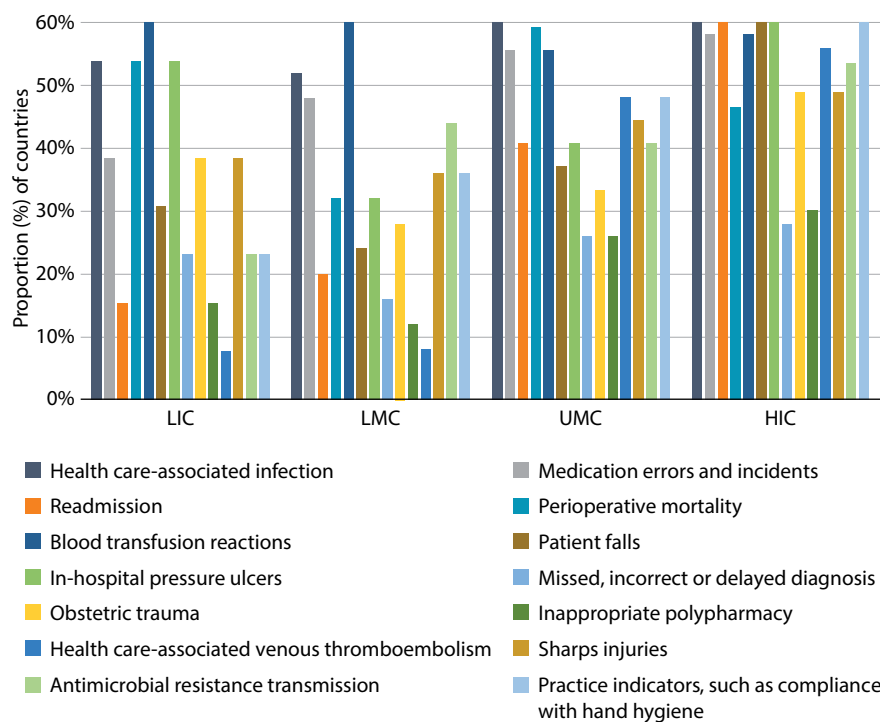
Fig. 6.11.  
Global measurement of patient safety indicators



The data show considerable variation across WHO regions, with the Region of the Americas and the Eastern Mediterranean Region prioritizing infection control, evident in their high rates of monitoring health care-associated infections. Countries in the Western Pacific include monitoring of medication errors, blood transfusions and patient falls, suggesting a broader approach to patient safety. Medication safety is also commonly tracked by countries of the South-East Asia Region. Countries in the African Region show significant variation in patient safety indicator monitoring, with notably low reporting across most indicators, hinting at potential resource constraints or differing health care focuses.

Further analysis underscores a probable association between economic status and approaches to measure various patient safety indicators, with HICs generally leading in the extent of indicators monitored (Fig. 6.12). Higher income countries report particularly strong engagement in complex patient safety issues such as polypharmacy, readmission rates and VTEs. A mixed picture is typically seen with LMCs and LICs, with notable efforts in monitoring critical patient safety measures such as health care-associated infections and blood transfusion reactions but generally lower engagement elsewhere, pointing to evolving health care systems with selective focus areas. This landscape points to an overarching need for enhanced support and resource allocation for patient safety systems in lower-income countries, to ensure global health equity in patient safety and care quality.

*Economic status influences patient safety monitoring, with high-income countries having comprehensive indicator tracking, while lower income countries concentrate on critical areas.*



**Fig. 6.12.**  
Proportion of Member States monitoring patient safety indicators in various domains, by income group

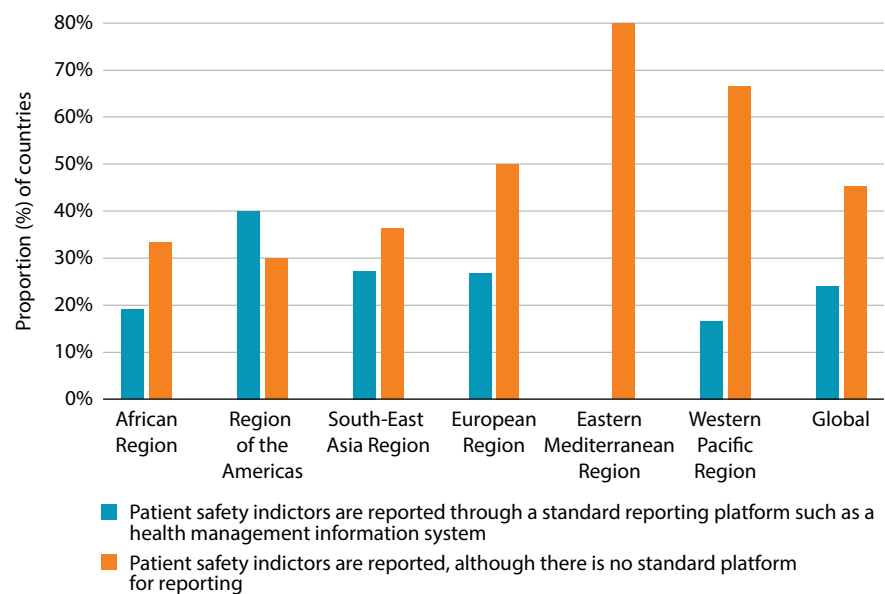
Note: LIC: low-income countries; LMC: lower middle-income countries; UMC: upper middle-income countries; HIC: high-income countries.

## Monitoring of patient safety indicators

*Incorporating patient safety indicators into mainstream health information systems ensures regular reporting and analysis, though only a quarter of countries have done so.*

Including patient safety indicators in mainstream HISs ensures that these indicators are regularly reported to a designated agency and analysed alongside other health service delivery indicators. A quarter of respondent countries stated that patient safety indicators have been incorporated into national or subnational level standard reporting formats and HISs, while 45% stated that although patient safety indicators are reported, there is no standard platform for such reporting. Countries in the Region of the Americas (Fig 6.13) have the highest levels of incorporation of such indicators in their HISs.

**Fig. 6.13.**  
**Mechanisms for reporting of patient safety indicators, by WHO region**



## Trends in monitoring of patient safety indicators

Analysis of Member State survey responses shows that monitoring of patient safety indicators through health information systems is complex and varied.

*Lack of standardization:* There is a lack of standardization across countries regarding which patient safety indicators are monitored and how they are reported. This makes international comparisons challenging and may hinder global efforts to improve patient safety. There is significant diversity in how countries implement and integrate patient safety indicators into their HISs.

*Use of existing digital platforms:* Several countries are using digital platforms to collect and report patient safety data. For example, **Thailand** uses the National Reporting and Learning System, while **Spain** uses the SINAPS platform. These systems potentially allow for more efficient data management and accessibility for stakeholders. Many countries – including **Côte d'Ivoire**, **Guinea**, **Liberia** and **Sudan** – reported that district health information systems (DHIS) are being used for integrating patient safety indicators.

*Barriers to activation:* Some countries, such as **Sudan**, have identified patient safety indicators but face challenges in disseminating and activating them due

to issues such as coordination. This indicates that beyond the technical aspects of integrating patient safety indicators into HIS, there are also organizational and systemic barriers to implementation.

*Variability in data reporting:* Reporting practices vary widely– from sophisticated, comprehensive web-based information systems to PDF-based report form submissions – indicating different levels of technology adoption.

*Regional differences:* While some countries within a given region may share similar health care challenges, their approaches to monitoring patient safety indicators can be vastly different.

*Focus on specific indicators:* Some countries focus on particular aspects of patient safety, such as HCAs, which may reflect local priorities or the state of health care system challenges.

*Integration with payment systems:* **Singapore** integrates patient safety indicators into their 'Pay-for-Performance' framework, suggesting a trend where patient safety measures are tied to financial incentives – a potentially powerful driver for improvement.

*Public reporting:* Countries such as the **United Kingdom** and **Germany** have systems in place for public reporting of patient safety incidents, which can enhance transparency and accountability.

*Global gaps in response:* A significant number of countries did not provide information or had incomplete data, pointing to potential global information gaps in patient safety monitoring practices.

## Annual reporting on patient safety

An annual report on patient safety is a document that summarizes the performance of health care organization/s in preventing and reducing medical errors, adverse events and harm to patients. Such reports typically include data on the types, causes and outcomes of patient safety incidents, as well as the actions taken to improve safety culture, processes and practices. The report also highlights the achievements, challenges and lessons learned from patient safety initiatives and related programmes. The purpose of an annual report on patient safety is to inform stakeholders – such as patients, staff, regulators and the public – about the safety and quality of care provided by the organization, and to demonstrate accountability and transparency in addressing patient safety issues.

Around 18% of countries issue an annual public report detailing patient safety performance. Notably, most of these countries that consistently publish such reports are concentrated in UMCs or HICs.

Nearly one fifth of countries have put in place accountability frameworks aimed at enhancing patient safety indicators and ensuring health care facilities receive feedback on their performance.

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*Monitoring patient safety indicators through health information systems is complex and varies globally, with challenges in standardization, diverse implementation practices, and both technical and organizational barriers, highlighting the need for consistent global efforts to improve patient safety.*

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*Annual patient safety reports are issued by 18% of countries, primarily in higher income brackets.*

## Country examples of annual reports on patient safety

**Malaysia** publishes an annual report on national patient safety goals. The report covers performance in implementing clinical governance, WHO global patient safety challenges, safety of blood transfusion and blood products, medication safety, clinical communication, patient falls, and others (251).

In **Chile**, safety indicators reported by public inpatient health care facilities include adherence to the WHO Surgical safety checklist, monitoring of unscheduled re-operations, prevention of VTEs in transfused surgical patients, strategies to prevent pressure ulcers, falls reports in hospitalized patients, and maintenance of critical medical equipment (252).

In **Sweden** the national report on patient safety is a key document that evaluates the effectiveness of the national plan for improving patient safety, as outlined by the Act on safe care. This foundational report marks the beginning of a continuous, nationwide evaluation of patient safety indicators. It is prepared in collaboration with regional and municipal bodies to monitor health care safety and reduce patient harm. The report presents current findings, assesses the current state of patient safety, and pinpoints areas needing further development, especially where data and metrics are insufficient. Primarily aimed at health care administrators, it provides crucial guidance for decision-making in the governance of patient safety (253).

## Feature story 14.

### Standardizing patient safety measurement

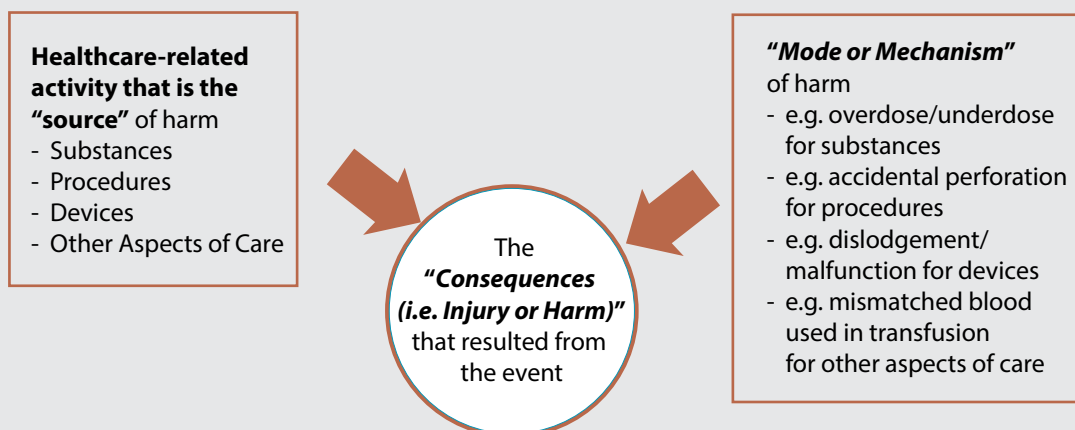
Through digitization, the health sector has increasing access to timely and reliable data. This enables organizations and governments to use information about health care activities, safety, quality and costs to inform service delivery and planning, and for researchers to identify areas of unmet need or improvement, and to test innovative models of care. However, data systems that are not standardized can limit sharing and use of data for direct patient care and for understanding research, as well as trends over time and between organizations.

One of the roles of WHO is to standardize concepts and classifications, including diseases and interventions, through its set of international classifications and terminologies. These allow health workers and patients to communicate using one language and for health systems across the world to be measured and compared at all levels – patient, clinician, department, institution, system and country – helping to inform and drive improvement.<sup>a</sup>

Patient safety data and measurement is one area benefiting from such standardization. In 2009, the inconsistent use of language and conceptual definitions in the field of patient safety was addressed through the *WHO International classification for patient safety (ICPS)*.<sup>b</sup> The ICPS defined, harmonized and grouped a standardized set of patient safety concepts, into an internationally acceptable classification. The ICPS was organized around a conceptual framework of 10 high-level classes and about 600 concepts that group incidents into clinically meaningful categories, to inform learning and analytical processes. One feature of patient safety is the need to view it from multiple lenses. The ICPS is comprehensive but also adaptable, enabling classifications in primary care to be developed.

The WHO International Classification of Diseases (ICD)<sup>c</sup> is the international standard for systematic recording, reporting, analysis, interpretation and comparison of mortality and morbidity data. Its organized codes allow health information to be used in disease surveillance activities, analyses that inform health system financing, epidemiological and health services research, and measurement of safety and quality of care including provider and hospital performance.<sup>d</sup> The implementation of the 11th ICD revision (ICD-11) in the 2020s offers further opportunities for standardization and efficient collection and analysis of patient safety information. The approach of the ICD-11 to capture health care quality and safety information has been guided by the ICPS framework and the US Agency for Healthcare Research and Quality (AHRQ) Common Formats.<sup>e</sup> Although ICD-10 has codes to capture patient safety incidents, ICD-11 provides flexible and in-depth capture of data at the source.

ICD-11 has an explicit three element model to capture information in relation to health care associated harm (see Figure).



## ICD-11 information model for health care-associated harm

The new three element information model, and other features of ICD-11 – such as enhanced coding specificity combined with linked codes – provide comprehensive structured information to be collected on health care-associated harm. An example of the enhanced ICD-11 coding specificity is in relation to the mechanism of medication incidents is that there are codes for wrong timing of a drug, wrong rate, wrong dose and wrong drug. This level of specificity of medication incidents is essential to understanding the type of errors that are taking place and to design interventions to prevent their recurrence.

Diagnostic safety incidents can result in serious harm to patients and medico-legal claims, and are arguably the most under-reported incident type in reporting systems. Diagnostic safety incidents have not been addressed across most health care settings, despite current estimates suggesting one in ten diagnoses are likely to be incorrect. Their incorporation into ICD-11 is an important step to learn more about which patients and clinical conditions are at risk of diagnostic incidents at health service level and across systems, and to inform interventions to reduce harm.

ICD-11 could enable reduction in the fragmentation of patient safety data sources and facilitate linkage of data sources, and also enable insights from emerging technologies such as AI. Interrogation of ICD-11 data could become the default approach to studies investigating the epidemiology and disease burden from patient safety incidents and for efficiently capturing key quality and safety indicators that are aligned with national and global patient safety targets. This access to data and analytics will assist in filling extensive gaps in our knowledge on the scale and nature of harm in mental health services, and among vulnerable groups of patients such as older adults and people with disabilities. ICD-11 is another step in international standardization and harmonization of patient safety data to enhance operational and research insights to reduce harm for patients.

Sources:

- <sup>a</sup> *Classifications and terminologies*. Geneva: World Health Organization; 2022 (<https://www.who.int/standards/classifications>, accessed 1 May 2024).
- <sup>b</sup> Sherman H, Castro G, Fletcher M et al. For World Alliance for Patient Safety Drafting Group. Towards an international classification for patient safety: the conceptual framework. *Int J Qual Health Care*. 2009;21(1):2–8. doi: 10.1093/intqhc/mzn054.
- <sup>c</sup> *International Statistical Classification of Diseases and Related Health Problems (ICD)*. Geneva: World Health Organization; 2022 (<https://www.who.int/standards/classifications/classification-of-diseases>, accessed 1 May 2024).
- <sup>d</sup> Southern DA, Pincus HA, Romano PS, Burnand B, Harrison J, Forster AJ et al. Enhanced capture of healthcare-related harms and injuries in the 11th revision of the International Classification of Diseases (ICD-11). *Int J Qual Health Care*. 2016;28(1):136–42. doi: 10.1093/intqhc/mzv099.
- <sup>e</sup> Drösler SE, Weber S, Chute CG. ICD-11 extension codes support detailed clinical abstraction and comprehensive classification. *BMC Med Inform Decis Mak*. 2021;21(Suppl 6):278. doi: 10.1186/s12911-021-01635-2.



Strategic objective 6	6.1	6.2	6.3	6.4	6.5
	Patient safety incident reporting and learning systems	Patient safety information systems	Patient safety surveillance systems	Patient safety research programmes	Digital technology for patient safety

## Strategy 6.3.

# Patient safety surveillance systems



Establish, synergize and scale up patient safety surveillance systems to ascertain the magnitude and causes of harm in health care

Patient safety surveillance is a developing field that focuses on aggregating and analysing information from various sources to identify and mitigate safety risks. This approach is crucial for rapidly identifying and addressing concurrent and new safety hazards, initiating independent inquiries in cases of significant harm or sentinel events, and conducting regular data collection to determine the extent of harm caused by unsafe care. Involving a diverse group of stakeholders, including experts in improvement science, can enhance the effectiveness of these safety surveillance systems.

## Sources of patient safety information

Analysing a broad spectrum of data related to patient safety incidents, including incident reports, patient feedback, legal claims, audit findings and medical product surveillance data, enables a comprehensive understanding of the causes and nature of preventable medical errors. Further enhanced by new data aligned with international safety standards, this approach deepens insights into the dynamics of medical harm, facilitating the development of effective accountability frameworks to reduce errors and improve patient safety. Additionally, fostering synergies and better data sharing between various patient safety information sources, both internal and external to the health care system, can overcome the limitations of traditional incident reporting systems, leading to more efficient and timely interventions to reduce harm from unsafe care (254).

*Comprehensive analysis of diverse patient safety data sources enhances understanding of preventable errors, supports effective accountability frameworks, and fosters timely interventions to improve patient safety.*

## Box 6.5. Sources of patient safety information

### Internal sources

*Safety walk rounds:* Senior leaders engage with front-line staff to identify potential safety issues directly. This approach fosters a culture of openness and immediate solution implementation.

*Focus groups:* These discussions with staff or patients/families can reveal insights into daily hazards and potential safety improvements in a more informal and engaging environment.

*Medical record review:* In-depth examination of patient records can uncover adverse events and quality issues, though it can be labour-intensive and subject to the limitations of the record-keeping quality.

*Focused review:* Targeted reviews can expose vulnerabilities in specific processes and lead to systemic improvements.

*Failure modes and effects analysis (FMEA):* This proactive approach identifies potential failures and their consequences in health care processes, aiming to pre-emptively correct or mitigate risks.

*Screening:* Using routine data to flag potential adverse events, such as unplanned re-operation, readmission rates, average length of stay or abnormal laboratory results, for further investigation.

*Observation:* Direct observation of health care processes by knowledgeable professionals can uncover errors not typically reported, offering rich data for system improvement.

### External sources

*Malpractice claims analysis:* Reviewing claims can offer detailed insights into serious adverse events that have led to litigation, although it may not reflect the broader scope of less severe or unreported issues.

*Surveillance:* Monitoring specific patient categories and health products on safety issues including safety surveillance programmes such as pharmacovigilance, haemovigilance and medical device surveillance data.

*Routine data collection:* Large-scale data gathering allows for risk-adjusted assessments of care quality and outcomes, fostering continuous improvement.

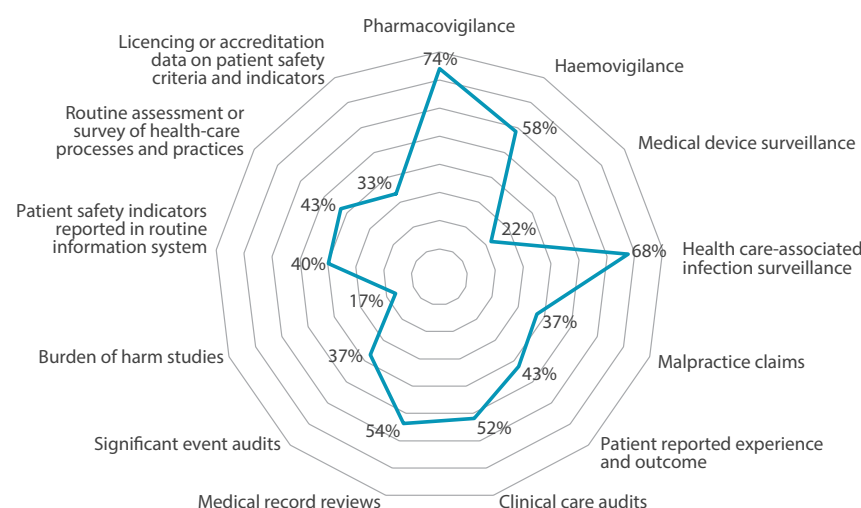
*The survey reveals that 41% of countries are integrating safety surveillance systems, though only 11% have comprehensive information-sharing with patient safety reporting systems.*

The Member State survey responses reveal that countries are moving towards establishing safety surveillance systems. The integration of existing safety surveillance programmes – pharmacovigilance, haemovigilance, medical devices surveillance and monitoring of health care-associated infections – represents a preliminary step before exploring or setting up additional information sources. According to the Member State Survey, 41% of countries have already started linking one or more such systems to evolve a patient

safety surveillance system. Only a small proportion (11%) reported having established comprehensive channels for sharing information between safety surveillance programmes and PSIRLS on a regular basis.

A further 23% of global respondents reported that multiple external and internal sources of information on patient safety (i.e. incident reporting, malpractice claims and clinical audits) are being used for patient safety surveillance.

The range of patient safety surveillance sources indicates a strategic prioritization of pharmacovigilance, haemovigilance and infection surveillance, reflecting an emphasis on medication safety, blood safety and IPC due to their high impact on patient health outcomes. The substantial use of medical record reviews and clinical care audits was also reported (Fig. 6.14). While patient-reported experiences and routine health care process assessments are used to a moderate extent – suggesting patient perspective and care quality are considered – there is less focus on medical device surveillance data.



*Patient safety surveillance prioritizes pharmacovigilance, haemovigilance, and infection control, with moderate use of patient-reported experiences and clinical audits.*

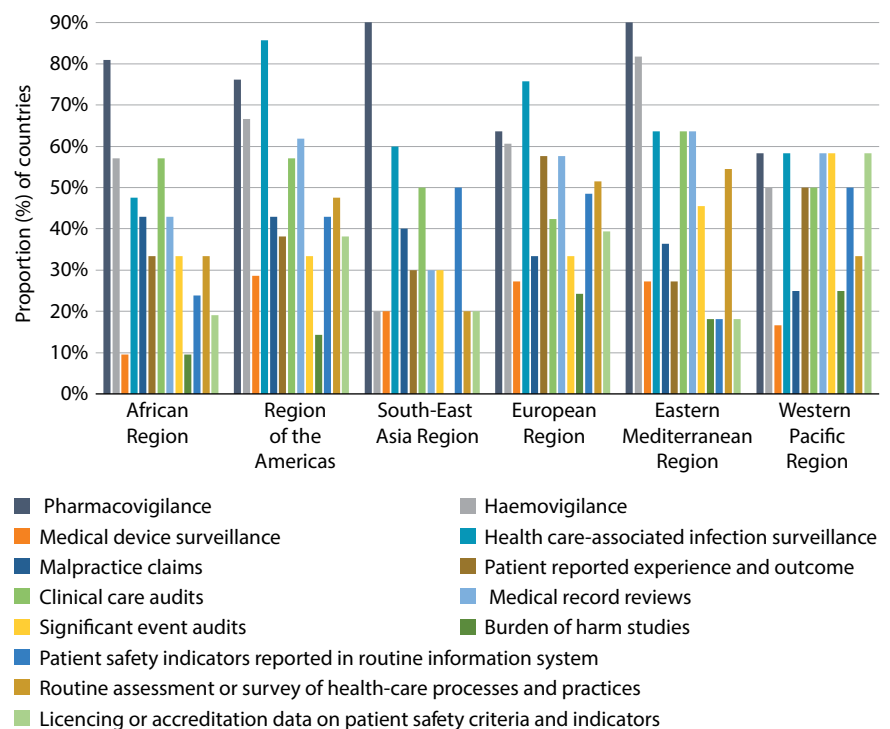
**Fig. 6.14.**  
Global distribution of data sources utilized for surveillance of patient safety

Further data reflect the varied adoption of patient safety surveillance measures across countries with differing income levels, revealing several trends. Pharmacovigilance is consistently utilized across all income brackets, but most extensively in LICs. Haemovigilance and HCAI surveillance are used more often in UMCs and HICs, suggesting a focus on specific patient safety areas aligned with available resources and health care system development. Notably, HICs place substantial emphasis on patient-reported experiences and routine information systems for patient safety indicators, indicating a prioritization of patient-centred metrics and systematic data collection. Conversely, the use of malpractice claims and clinical care audits does not show a clear correlation with economic status. The less frequent use of medical device surveillance and burden of harm studies in LICs may point to resource limitations or variable strategic focus in patient safety practices.

*Patient safety surveillance matures with income status, from widespread pharmacovigilance to a focus on patient-reported outcomes and systematic data collection in HICs.*

Country responses reveal varied implementation of patient safety surveillance strategies across different WHO regions (Fig. 6.15). Overall, the disparities in utilization rates across regions may be influenced by a combination of varying resource allocations, health care infrastructure maturity, and differences in policy-making decisions in the area of patient safety.

**Fig. 6.15.**  
Variation in sources of data  
used for surveillance of patient  
safety, by WHO region



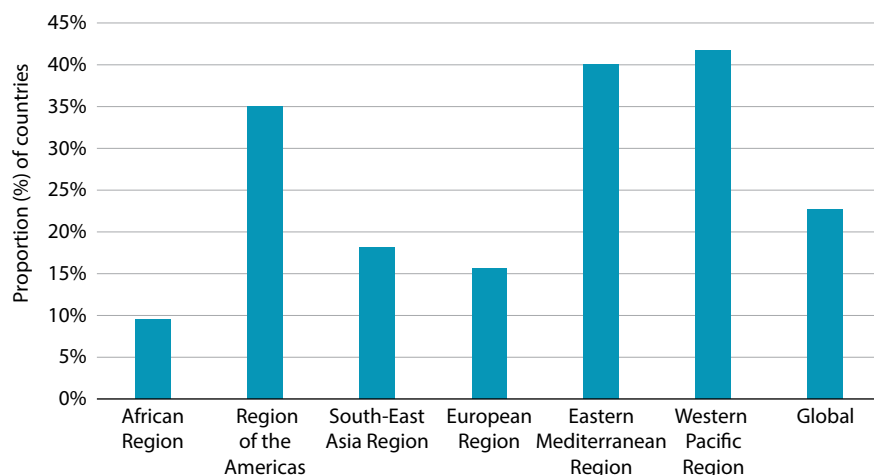
## Investigation mechanisms in cases of serious harm

*Twenty-three percent of countries have robust, independent systems to investigate severe harm incidents, with no such mechanisms in LMCs and LICs.*

Establishing a system for independent non-punitive investigation in instances of severe harm/never events/sentinel events is a critical step towards improving patient safety. This method entails the formation of a framework in which neutral experts are involved to perform comprehensive and impartial analyses of incidents resulting in significant patient harm or those with the potential for substantial adverse effects. Such a system should be endowed with the necessary authority to obtain all pertinent information and the capability to implement its recommendations effectively. The autonomy of such entities is essential to ensure credibility and adherence to its conclusions and suggestions. The primary aim is to identify and comprehend the underlying causes of such events. Insights gained from such investigations can drive improvements across the health care system and may lead to the development of national or local preventive measures. Additionally, the transparency generated by independent evaluations can improve public confidence in the health care system and demonstrate a commitment to patient safety.

Member State survey data indicate that only 23% of global respondents report the existence of a robust and independent system designed to probe severe harm and sentinel events within health care settings. However, no LMCs or LICs report the presence of an operational investigative mechanism. However,

approximately one-third of countries in the Western Pacific Region, the Eastern Mediterranean Region and the Region of the Americas have established and are maintaining a well-functioning system for investigating severe harm incidents (Fig. 6.16).



**Fig. 6.16.**  
Presence of independent mechanisms to investigate cases of severe harm and sentinel events, by WHO region

## Patient safety investigation in action

**Ecuador** uses care audits as an independent mechanism to investigate patient harm. The Health and Social Care Inspectorate (Inspektionen för vård och omsorg) (255) in **Sweden** supervises health and medical care, and social services. Patients and the public can contact the entity if they have a complaint or suspect malpractice.

In the **United Kingdom**, the Health Services Safety Investigations Body (HSSIB) (256) acts as an independent arm of the Department of Health and Social Care, which focuses on investigating patient safety concerns across NHS England and independent health care settings. The HSSIB approach is non-punitive, emphasizing understanding and learning from incidents without attributing blame. Its investigations, conducted by a team with diverse expertise from health care to aviation, aim to enhance safety by involving patients, families and health care staff, and sharing findings widely. Additionally, HSSIB's educational initiatives, based on human factors and investigation principles, extend beyond the UK, advising and potentially training health care sectors globally, highlighting its role as an influential body in improving global health care safety standards.

The National Professional Council of **Namibia** has a Professional Conduct Committee that is mandated to investigate cases of severe harm and sentinel events involving health professionals. The committee ensures that health professionals adhere to the ethical standards and codes of conduct of their respective professions and that they are accountable for their actions.

In **South Africa**, the Ombud (257) is a body that was created by the Health Amendment Act of 2013 as part of the Office of Health Standards Compliance. The Ombud has the authority to investigate certain sentinel events, which are serious adverse events that affect patient safety and quality of care. The Procedural Regulations specify which sentinel events fall under the Ombud's

*Independent mechanisms for investigating patient harm, such as care audits, supervisory bodies, non-punitive investigations, and professional conduct committees, emphasize accountability, transparency and learning to enhance patient safety.*

jurisdiction. The National guideline for patient safety incident reporting and learning outlines the different levels of patient safety committees that must be formed, and their role in overseeing the management/investigation of severe harm and sentinel events.

## Burden of harm studies

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*Regular burden of harm studies are essential for understanding and reducing patient harm, though only 13% of countries conduct them regularly.*

To gauge the scale of preventable harm and monitor ongoing improvement efforts, numerous countries undertake research at various levels of their health care systems, ranging from national to more localized, subnational studies. These studies are pivotal in establishing a foundational understanding of the extent of harm caused by unsafe health care practices and in tracking progress towards reducing such incidents.

The Member State survey highlights that only 13% of responding countries conduct these crucial studies on a regular basis. However, it is noteworthy that in specific regions – particularly among LMCs and countries of the African Region – there is a complete absence of such systematic studies.

Moreover, 22% of the countries participating in the survey reported that they have, at least once, undertaken a baseline study to understand the scale of patient harm resulting from unsafe care practices. These baseline studies are crucial as they provide an initial assessment of the problem, laying the groundwork for targeted interventions and policy changes aimed at improving patient safety.

## Feature story 15.

### Developing a national quality and patient safety surveillance system in Ireland

The Irish Health Service Executive has commenced development of a quality and patient safety surveillance system called the Quality and Safety Signals<sup>a</sup> programme. The purpose of the programme is to provide an online system that optimizes the use of available data for patient safety surveillance and quality improvement. The vision is to enable health and social care services in Ireland to monitor and reduce avoidable harm, and to identify and share learning from areas of excellence.

#### What was done and why?

Like its international counterparts, the Irish health system has invested in the collection, management and reporting on various datasets relating to the quality and safety of services such as: incident reports; audit of aspects of care delivery; regulator inspections; performance metrics; patient experience surveys etc. These datasets are not routinely combined to provide a composite profile of quality and safety, and to maximize the intelligence generated from available data.

*“People in the health system spend a huge amount of time collecting and submitting data, and usually they don’t see anything come back from it. As different types of reports and data are collected and managed separately, it takes a lot of time and effort to bring them together in a meaningful way, and key insights can be missed.”*

*National Clinical Director of Quality and Patient Safety*

Ireland’s *Patient safety strategy 2019–2024<sup>b</sup>* includes key actions concerned with the integration, analysis, display and dissemination of patient safety data and information to support patient safety surveillance at every level of health and social care services. These policy commitments were the catalyst for the Quality and Safety Signals programme.

#### What’s next?

A proof-of-concept implementation of the Quality and Safety Signals programme will take place in maternity and neonatal services from 2023 to 2024, with a view to scaling up the programme should it prove successful.

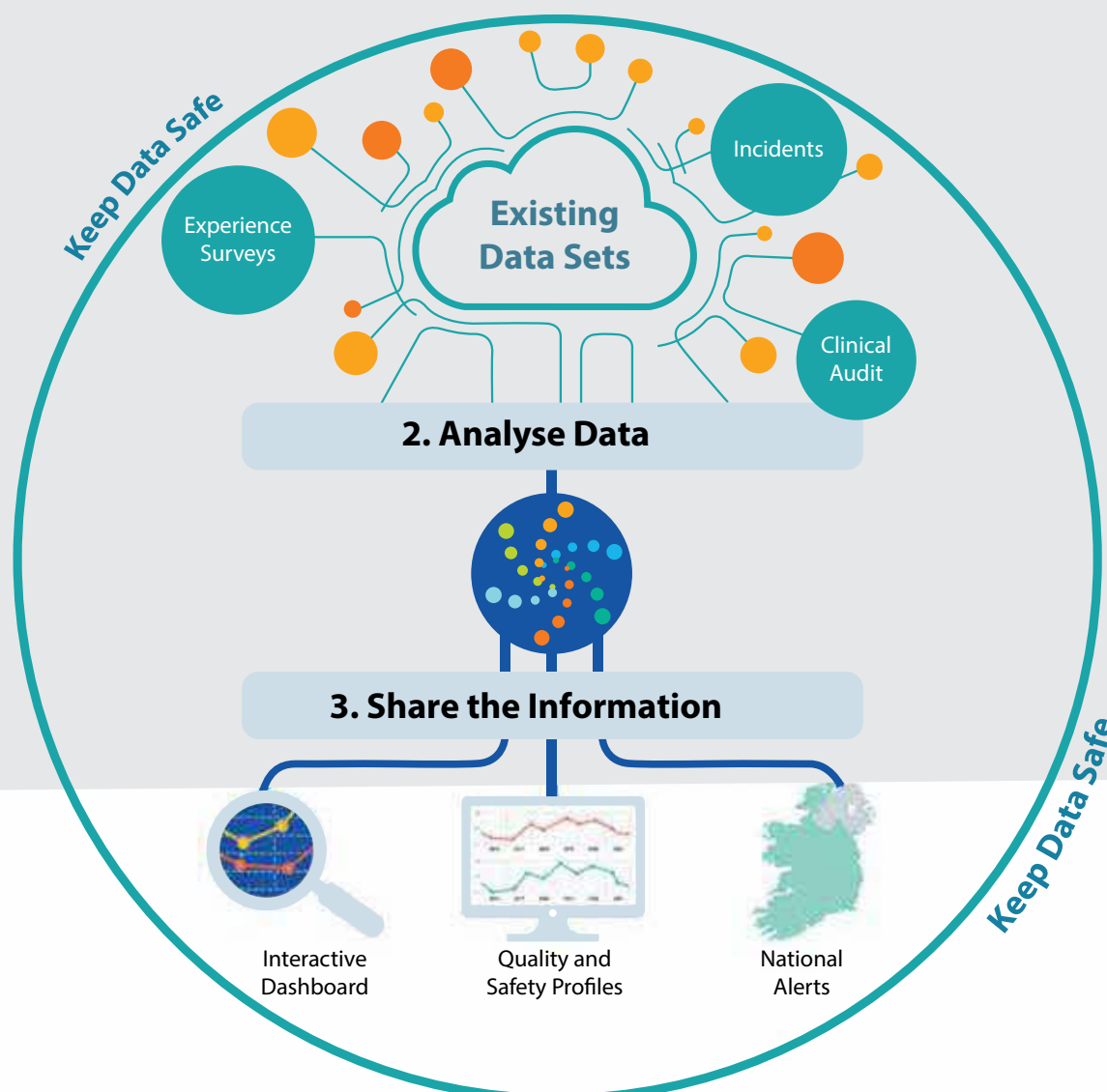
The project team and partners are also currently working on the following activities.

1. Aggregating data from multiple sources and storing these data securely and embedding a positive culture of data governance.
2. Analysing data to identify signals of excellence in quality and safety as well as signals of concern.
3. Making information available in online dashboards for interactive analysis and interrogation at the local level; providing quality and safety profiles at the click of a button for oversight and assurance; and identifying and disseminating alerts where a patient safety issue is identified at the national level.
4. Supporting implementation and evaluation of how a quality and patient safety surveillance system provides insights for action at different levels of the health care system, from quality improvement at the front line to evidence-based policy-making and planning at the national level.



# Quality and Safety Signals Model

## 1. Bring Data Together



Sources:

<sup>a</sup> Quality and Safety Signals. Dublin: Health Service Executive; 2023 ([https://assets.hse.ie/media/documents/Quality\\_and\\_Safety\\_Signals\\_Info\\_Sheet.pdf](https://assets.hse.ie/media/documents/Quality_and_Safety_Signals_Info_Sheet.pdf), accessed 1 May 2024).

<sup>b</sup> Patient safety strategy 2019–2024. Dublin: Health Service Executive; 2019 (<https://www.hse.ie/eng/about/who/nqpsd/patient-safety-strategy-2019-2024.pdf>, accessed 1 May 2024).

Strategic objective 6	6.1	6.2	6.3	6.4	6.5
	Patient safety incident reporting and learning systems	Patient safety information systems	Patient safety surveillance systems	Patient safety research programmes	Digital technology for patient safety

## Strategy 6.4.

# Patient safety research programmes



Develop active and funded patient safety research programmes, especially translational research

Mapping and identifying key areas for in-depth research is essential for developing a comprehensive understanding of patient safety and preventable harm. It is important to allocate adequate resources, develop capabilities and expertise to address research needs effectively. Translating research findings into practical, point-of-care applications is also crucial. Integrating safety risk evaluations into the existing assessment processes for procedures, medical technologies and medications is an important aspect of this. Collaboration among diverse stakeholders and public health organizations is vital for the ongoing progress in patient safety research. Additionally, designing patient safety improvement programmes tailored to each clinical service ensures that research on patient safety is integrally incorporated into all health care activities.

## Identification of research priorities for patient safety

In the Member State survey, only 11% of responding countries indicated that areas of patient safety relevant to their context are regularly identified as research priorities. Meanwhile, 36% of respondents confirmed the establishment of an expert group or task force to identify these priorities within a national

*Identifying research priorities is crucial for advancing patient safety, though only 11% of countries regularly prioritize context-specific patient safety research.*

Only 6% of countries allocate sufficient resources for patient safety research.

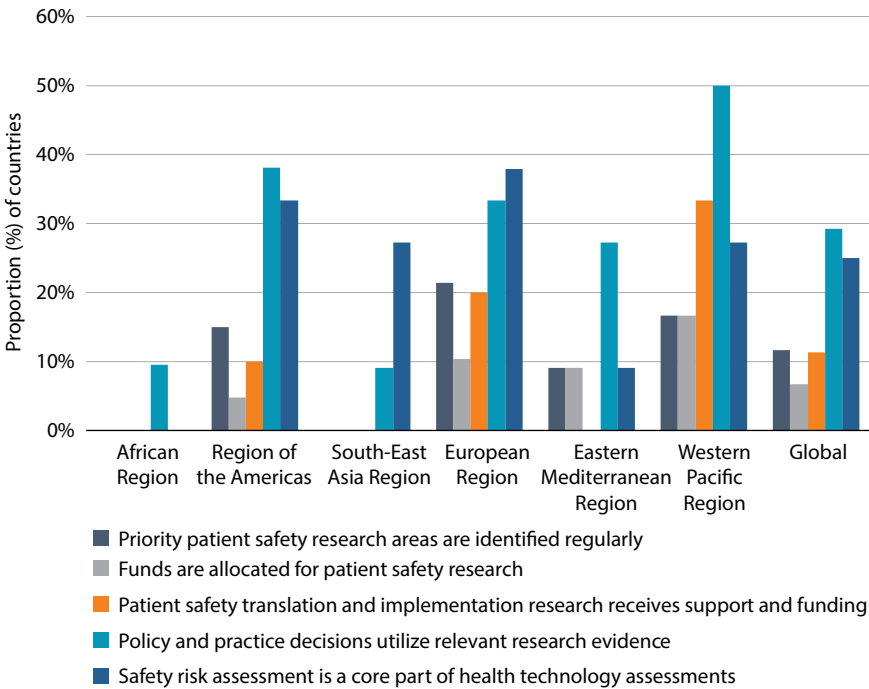
framework. However, countries in the South-East Asia and African Regions, as well as LMICs more broadly, reported no implementation in this area (Fig. 6.17).

A small minority of countries (6%) reported that they allocated sufficient resources for patient safety research. However, 31% acknowledged that some level of funding had been provided for research in this area. A significant 84% of LICs and LMICs reported that the process of allocating necessary resources for patient safety research had not commenced.

In addition, only 11% of countries reported to support translational and implementation research in patient safety.

Almost one third of respondents (29%) stated that evidence from international and national research is considered in making crucial policy and practice decisions. In countries in the African and South-East Asia Regions, and in LMICs more broadly, progress is even lower with less than 10% of countries reporting positive response on this indicator. These data underscore significant disparities in the integration of patient safety research into practice, particularly in lower-income countries and certain regional areas.

Fig. 6.17.  
Country performance on criteria  
for patient safety research, by  
WHO region



### Patient safety research activities in countries

**Germany** has recognized patient safety as an essential part of its annual health care funding, noting that the EU4Health Programme for 2021–2027 includes patient safety as a key area eligible for funding. Moreover, it offers specific funding for practical patient safety research through a competitive process known as the Innovation Fund (258).

In **Denmark**, the Danish Patient Safety Authority actively collaborates with researchers, providing valuable data from the national patient safety database to support research endeavours.

**Philippines** has integrated patient safety themes into its comprehensive health research strategy.

In **Cuba**, the translation of patient safety research into practice is facilitated through the Coordinating Centre for Clinical Trials and the Centre for State Control of Medicines, Equipment and Medical Devices. There, research findings are incorporated into policy and practice guidelines, with a synergistic relationship between the health care industry and policy-makers, guided by expert panels and multidisciplinary working groups that inform ongoing discussions on patient safety research.

## Safety risk assessment integration with health technology assessment

In the Member State survey, a quarter of countries indicated that safety risk assessments are an integral component of their health technology assessment (HTA) programmes. Additionally, 34% of the countries reported that while not all, some of their HTAs do incorporate the outcomes of safety risk assessments.

### Safety risk assessments in health technology assessment programmes

Further analysis of responses provides insights into the extent to which safety risk assessment is incorporated into HTAs.

*Varying degrees of integration:* There is a range of the extent to which countries integrate safety risk assessments into HTAs. Countries such as **Malaysia**, **Poland** and **Türkiye** indicate full integration, while others have not initiated the practice (or it is not widely used). This suggests a diverse global landscape in the adoption of comprehensive safety evaluation practices within HTAs.

*Resource and methodology availability:* Nations such as **Colombia** and **Cuba** highlighted the use of multidisciplinary approaches and specific methodologies, suggesting that having structured resources and frameworks can enhance the integration of safety assessments.

*Impact of regulatory bodies:* The existence of dedicated agencies or departments, as mentioned by **Australia** and **Singapore**, play a critical role in ensuring that safety risk assessments are a standard part of HTAs. These bodies can provide focused oversight and governance, leading to more systematic and regulated HTA practices.

*Digital and information technology as an enabler:* **Ireland's** emphasis on using IT to support patient safety highlights the growing trend of digital transformation in health care, where data and technology are leveraged to enhance HTA processes and outcomes.

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*A quarter of countries integrate safety risk assessments into their health technology assessment programmes.*

Strategic objective 6	6.1	6.2	6.3	6.4	6.5
	Patient safety incident reporting and learning systems	Patient safety information systems	Patient safety surveillance systems	Patient safety research programmes	Digital technology for patient safety

## Strategy 6.5.

# Digital technology for patient safety



Develop and implement digital solutions to improve the safety of health care

Twenty-seven percent of countries have identified key technologies to enhance access to and the safety of health services.

Governments and health care systems can harness the advantages of digital transformation to enhance patient safety. This includes leveraging cutting-edge tools, AI and big data. Developing a national digital health strategy, perhaps guided by resources such as the WHO Global strategy on digital health 2020–2025, is crucial (259). Such a strategy should outline the optimal approaches for digitizing medical records, implementing clinical decision support systems, improving patient engagement and managing electronic prescriptions. It should focus on integrating these technological advances into direct patient care and public health services. Equally important is the establishment of national guidelines that ensure the safety and reliability of health informatics and technological solutions before their introduction into the health sector. These guidelines should also regulate the use of health care data for real-time monitoring and analysis, ensuring that patient privacy and confidentiality are not compromised.

### Use of digital technologies for improving access and safety

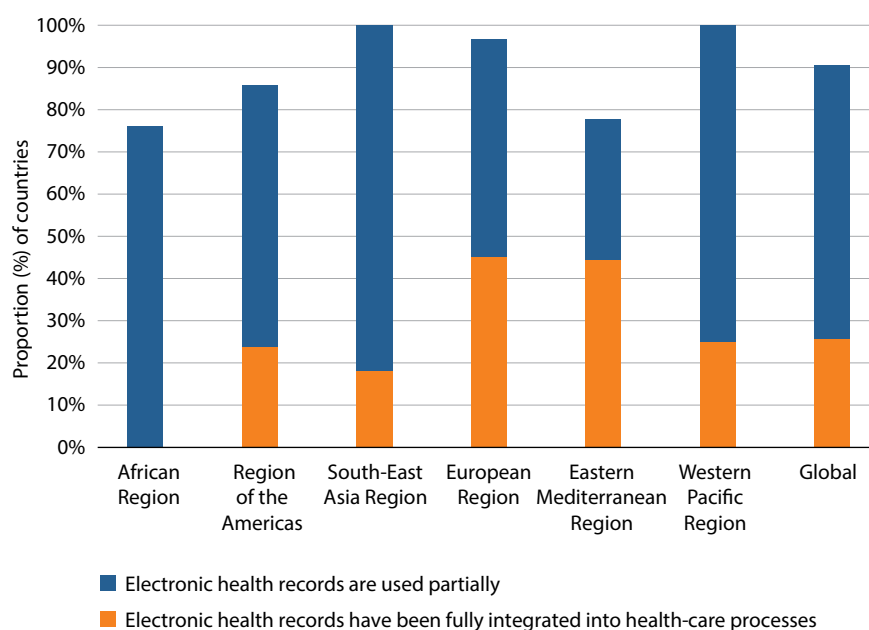
27% of Members State survey respondents said that key emerging and established technologies have been identified to improve access to and the safety of health services. Most of these countries are among the UMCs and HICs.

The survey data also provide a global snapshot of telemedicine implementation, illustrating varied stages of adoption across countries. Some nations are at the inception of integrating telemedicine, while others have more advanced systems and comprehensive digital health strategies. Challenges were also noted, such as a lack of infrastructure, supportive legislative frameworks and appropriate federal structures. The COVID-19 pandemic emerged as a significant driver for the rapid deployment and legislation of telemedicine in several regions. Despite diverse approaches –from telemedicine platforms to artificial intelligence (AI) –there is a unified intent to enhance patient safety and access to health care. Education for health care workers and public transparency are also emphasized as emerging areas for use of digital technologies by some countries.

## Electronic health records

Electronic health records (EHRs) can significantly enhance patient safety by streamlining medication management to reduce errors, providing health care professionals with swift access to comprehensive patient data, and facilitating seamless communication across different care providers. These systems standardize treatments through clinical guidelines, aid in the accurate and timely diagnosis of conditions, and offer decision-making support via clinical alerts and reminders. EHRs are instrumental in efficiently tracking of laboratory and other diagnostic test results and ensuring prompt follow up, while their capacity for data analysis aids in continuous quality improvement in patient care. Additionally, patient portals within EHRs can empower patients by giving them access to their own health information, further contributing to better outcomes.

26% of the surveyed countries indicated that EHRs are fully integrated into their health care processes, including ambulatory care, inpatient care and diagnostic services. Meanwhile, another 65% of the countries reported partial usage of EHRs in their health care systems. Countries of the European and Eastern Mediterranean Regions reported the highest use of EHRs across all health care processes (Fig. 6.18).



*Electronic health records (EHRs) enhance patient safety and care quality. Twenty-six percent of countries have fully integrated EHRs across health care processes, with another 65% reporting partial usage.*

**Fig. 6.18.**  
Country implementation of electronic health records, by WHO region

## Global landscape for implementation of electronic health records

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*The global landscape for EHR implementation varies widely, with countries at various stages of adoption and using differing approaches, from national initiatives to voluntary or mandatory use, emphasizing specific health programmes, and addressing interoperability challenges.*

*Progress at different stages:* There is a clear variation in the stages of EHR implementation across countries. While some are in the early phases of development or piloting (e.g. **Bhutan, India, Namibia, Seychelles**), others have more advanced, widespread implementation (e.g. **Switzerland, Türkiye**).

*Public and private sector usage:* In some countries, there is a variation in the use of EHRs between the public and private sectors. For example, in **Pakistan** most private hospitals use EHRs, whereas public sector hospitals are still in the process of adoption. In **Paraguay**, there is a process of implementing electronic ambulatory records in the public health service system. However, many services in the private sector already have EHRs in areas such as ambulatory care, hospitalization and diagnostics.

*National initiatives and policies:* Certain countries, such as **Australia, Germany, Spain** and **Singapore**, have national level EHR systems or initiatives, indicating a more centralized approach to health care data management.

*Voluntary versus mandatory use:* There is a range of voluntary and mandatory adoption of EHR systems. For instance, **Switzerland** has a voluntary system, while **Philippines** is transitioning to mandatory EHRs under the Universal Health Care Act. **Germany** is taking statutory measures to shift from a consent-based EHR system to an objection-based solution. This indicates a move towards making the use of EHRs mandatory for health service providers, particularly in ambulatory, inpatient care, and diagnostic processes.

*Emphasis on specific health programmes:* In **Namibia**, EHRs are specifically used for HIV and TB programmes and for vaccination records in **South Africa** suggesting a targeted approach towards certain health challenges.

*Interoperability:* In the context of EHRs, **Colombia** and **Uruguay** have adopted distinct approaches to interoperability. Colombia's method hinges on regulatory directives that mandate the standardization and sharing of patient data across its health care system. Whereas, Uruguay has implemented a National Electronic Health Record system designed to integrate with the EHRs of individual health service providers.

## Patient safety in digital health

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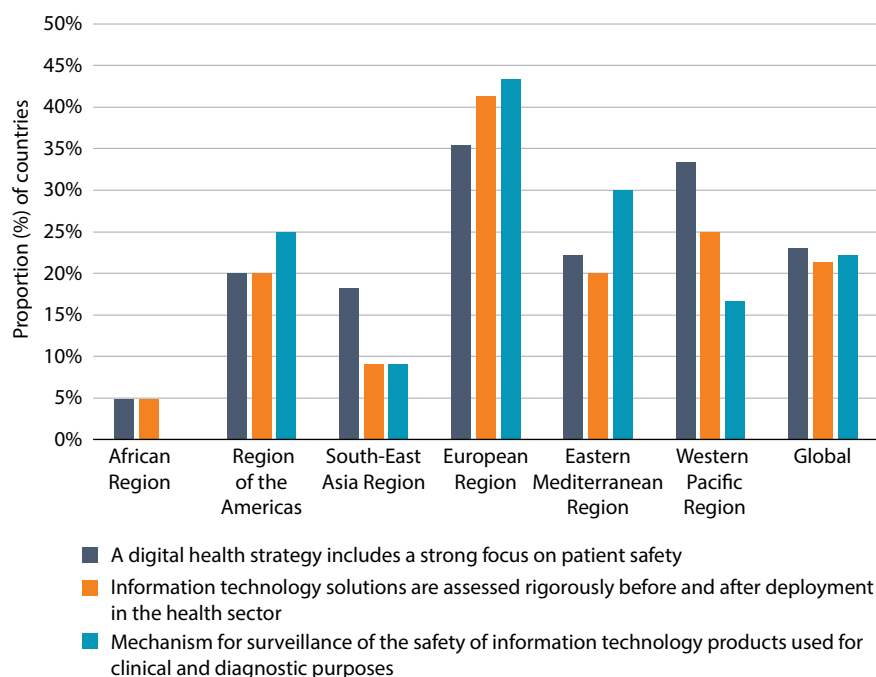
*One fifth of countries conduct comprehensive safety evaluations both before and after deploying new technologies in the health sector.*

Within digital health, the integration of patient safety measures varies considerably among countries. According to the Member State survey, only 23% of the countries have a functional digital health strategy with strong focus on patient safety considerations. Almost half (46%) are in the process of developing such strategies, while 28% have not yet initiated any such measures.

Just over one fifth (21%) of countries conduct thorough evaluations for safety both before and after these technologies are deployed in the health sector.



Furthermore, the establishment of surveillance mechanisms for monitoring the safety of digital health products used in clinical and diagnostic settings is present in only 22% of the responding countries. Notably, Countries of the European Region (45%), the Eastern Mediterranean Region and the Region of the Americas (each over 25%) have already set up these surveillance systems. This disparity underscores the varying levels of resources and focus allocated to patient safety in digital health across different regions and income groups (Fig. 6.19).



*Twenty-two percent of countries have surveillance systems for monitoring the safety of digital health products.*

**Fig. 6.19.**  
Status of mechanisms for integration of patient safety and digital health technologies, by WHO region

## Country examples mechanism for ensuring safety of digital health technologies

In **Singapore**, stringent guidelines are established for IT security as well as governance in deploying IT solutions. The approval process involves a thorough evaluation of both technical aspects, and clinical and operational considerations, with a detailed assessment of key risks. Additionally, Singapore is initiating a medical device forum to address the roles and responsibilities of various stakeholders in the deployment and operation of medical devices. Incidents related to EHRs are reported and closely monitored, particularly if they have an impact on operations or patient safety.

In **Türkiye**, the oversight of IT product security is conducted in accordance with the regulations set forth by the General Directorate of Health Information Systems, which operates under the jurisdiction of the relevant ministry. This structure ensures that IT products used in the health care sector meet the necessary security standards designed to protect sensitive data and maintain system integrity.

The **Australia** Digital Health Agency plays a central role in the management of digital health technology. It collaborates with other relevant agencies to

evaluate IT solutions both before and after they are implemented. Additionally, it is tasked with ongoing surveillance of these IT products to ensure they meet the required standards and are effective and safe for use within health care settings.



*Health worker at a hospital in India. © WHO / Hayley Goldbach*



Strategic  
objective

7



# Synergy, partnership and solidarity

*Group photo of conference attendees at WHO headquarters in Geneva, Switzerland, on World Patient Safety Day. © WHO / Ploy Phutpheng*



Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care

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Strategic  
objective

7

## Key messages



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.

Patient safety is most effectively enhanced through a holistic approach that focuses on ongoing improvement. It is essential to involve stakeholders from a variety of backgrounds and areas of expertise, who represent different roles and responsibilities across diverse settings and contexts. This inclusive and varied involvement is crucial for achieving effective outcomes and maintaining long-term progress in patient safety.

Broad engagement brings unique insights and experiences related to patient safety and help to promote understanding of different perspectives on how the risks in health care are perceived, assessed and ultimately managed. Leveraging collective expertise, influence and resources ensures systematic improvements in patient safety. Partnerships also help to facilitate identification and adoption of best practices, collaboration across borders, and advocacy for policies and investments that prioritize safety as a fundamental component of health systems globally.

Involving stakeholders in policy development and design of interventions from the outset fosters ownership, commitment and accountability as well as contributing to efficient use of resources – both human and financial. Partnerships are formed through different mechanisms at global, regional and country levels, but conceptually, the overall principles of engagement in addressing patient safety comprehensively are similar at all levels.

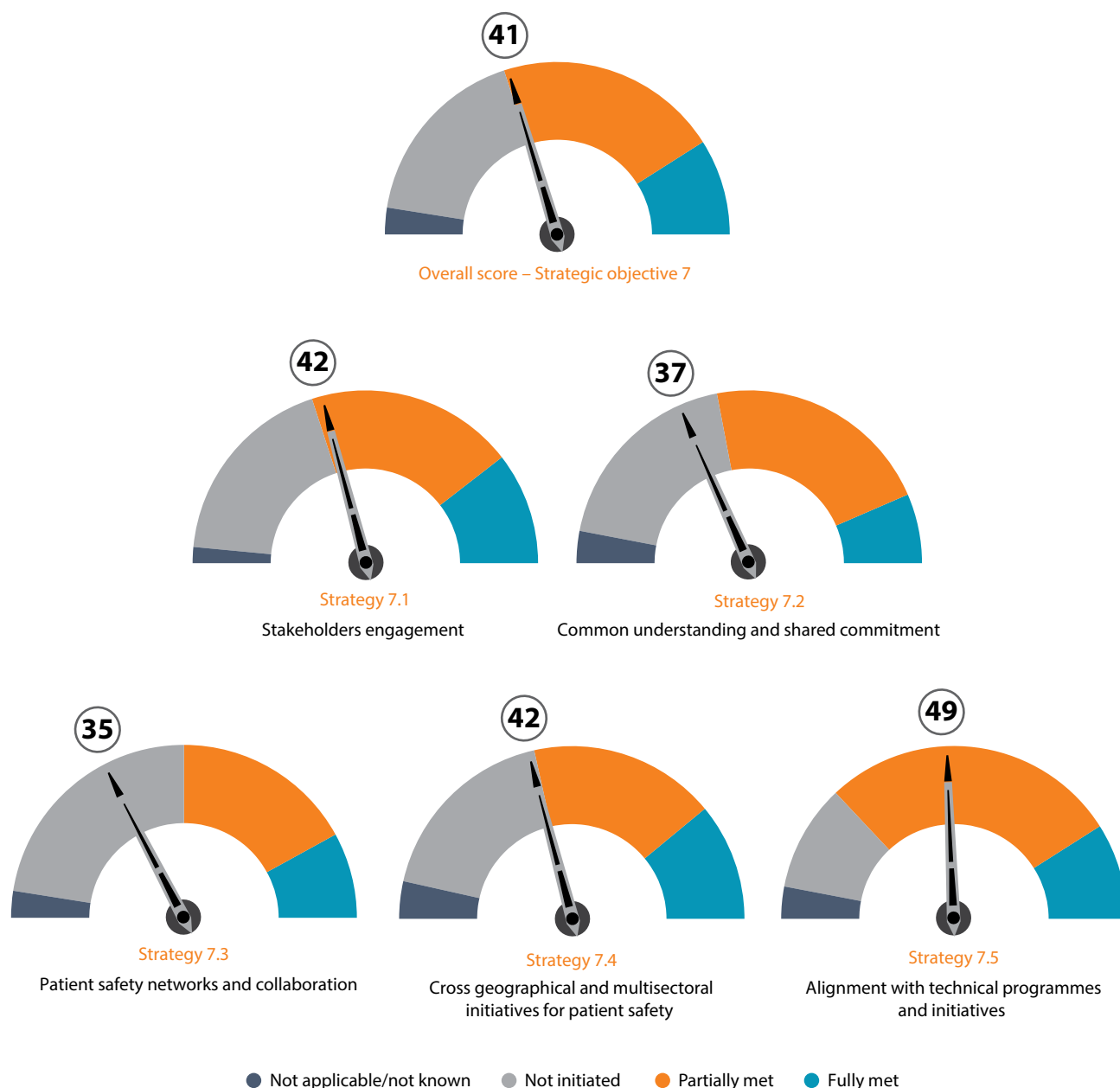
Partnerships enable strategic collaboration between various international entities, governments and advocacy groups, facilitating the exchange of knowledge and resources. These partnerships are instrumental in shaping policy directions and advocacy for safety measures in international frameworks. They also create platforms for knowledge sharing and capacity building, contributing to the training and skills enhancement of health workers worldwide. Furthermore, they strengthen data collection and analysis, providing vital insights into global patient safety trends. These collaborations are key to mobilizing resources for safety initiatives and in developing and disseminating guidance and standards. Additionally, they drive research and innovation, fostering global research networks to address emerging challenges in patient safety.

The Member State survey offers valuable insights into the global dynamics of collaboration and partnership in patient safety, both between and within countries. The survey evaluated responses on 25 criteria linked to synergy, partnership and collaboration under strategic objective 7, revealing a global performance score of 41 out of 100 (Fig. 7.1). Data from 108 countries indicated that 18% of the criteria were fully met, while 42% were partially met. However, it also showed that for about one third of the criteria, the countries reported not taking any action at all.



Family physician examining two young patients with the flu at a health center in Comrat, Moldova. © WHO / SRH / Maria Gutu

► Fig. 7.1. Global performance scores for strategic objective 7



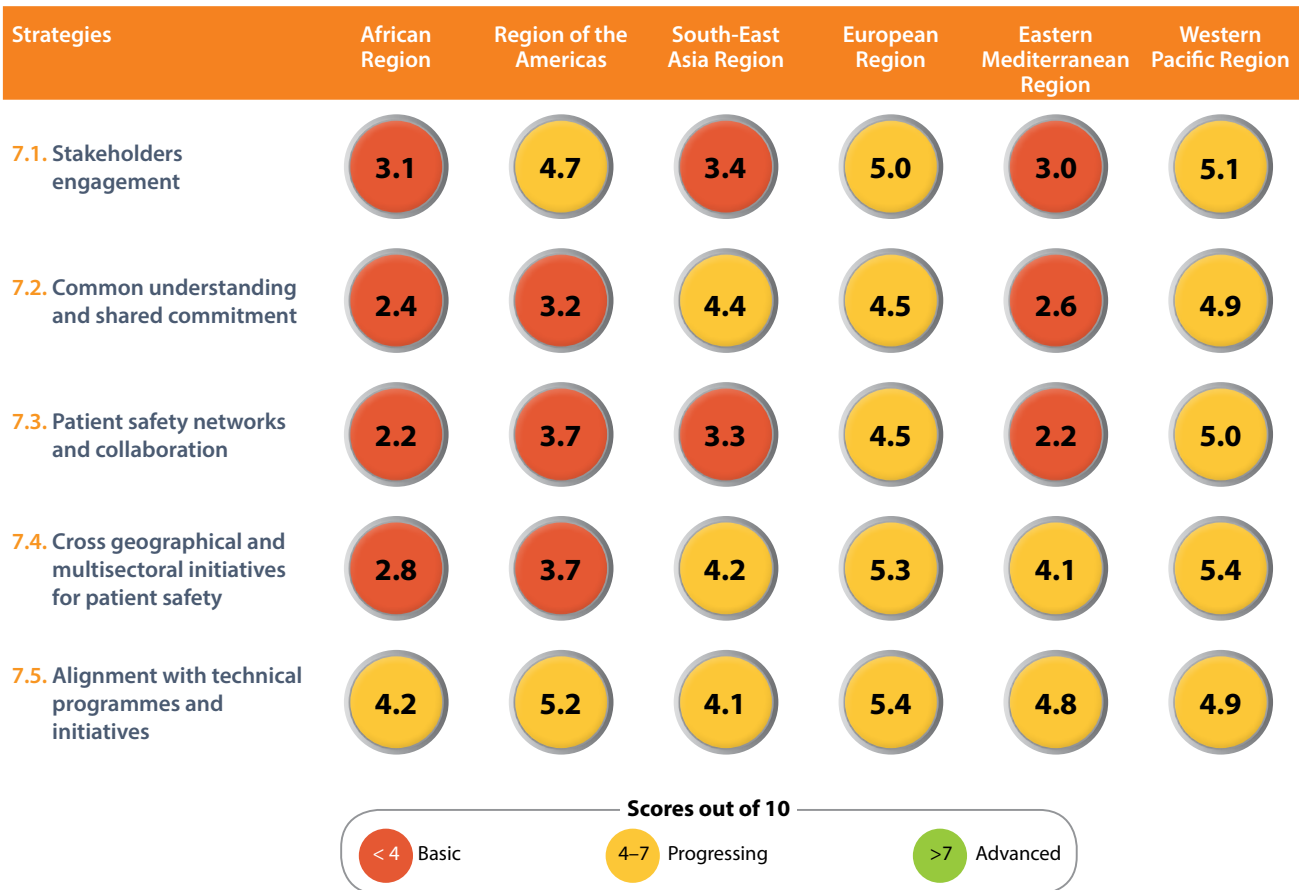
The data on five strategies of strategic objective 7 present a range of implementation levels. Stakeholder engagement has garnered a relatively positive response, yet it remains to be initiated in many entities. Similarly, cross-geographical and multisectoral initiatives have been adopted by some countries in line with the recommendations from the Global patient safety action plan 2021–2030, indicating partial but proactive response. The strategies of common understanding and shared commitment, as well as networks and collaboration, show a lower implementation. Variability is also evident in the alignment with technical programmes and initiatives, where responses range from significant advancement to a lack of initiation, though most of the countries reported that integration with patient safety programmes is very much work in progress.

The survey results reveal the variable landscapes of synergy, partnerships and solidarity across different regions. There is relatively strong engagement and effective strategy execution in the European Region and Western Pacific Region (Fig. 7.2). Countries in the Region of the Americas demonstrate a commendable alignment with technical programmes,



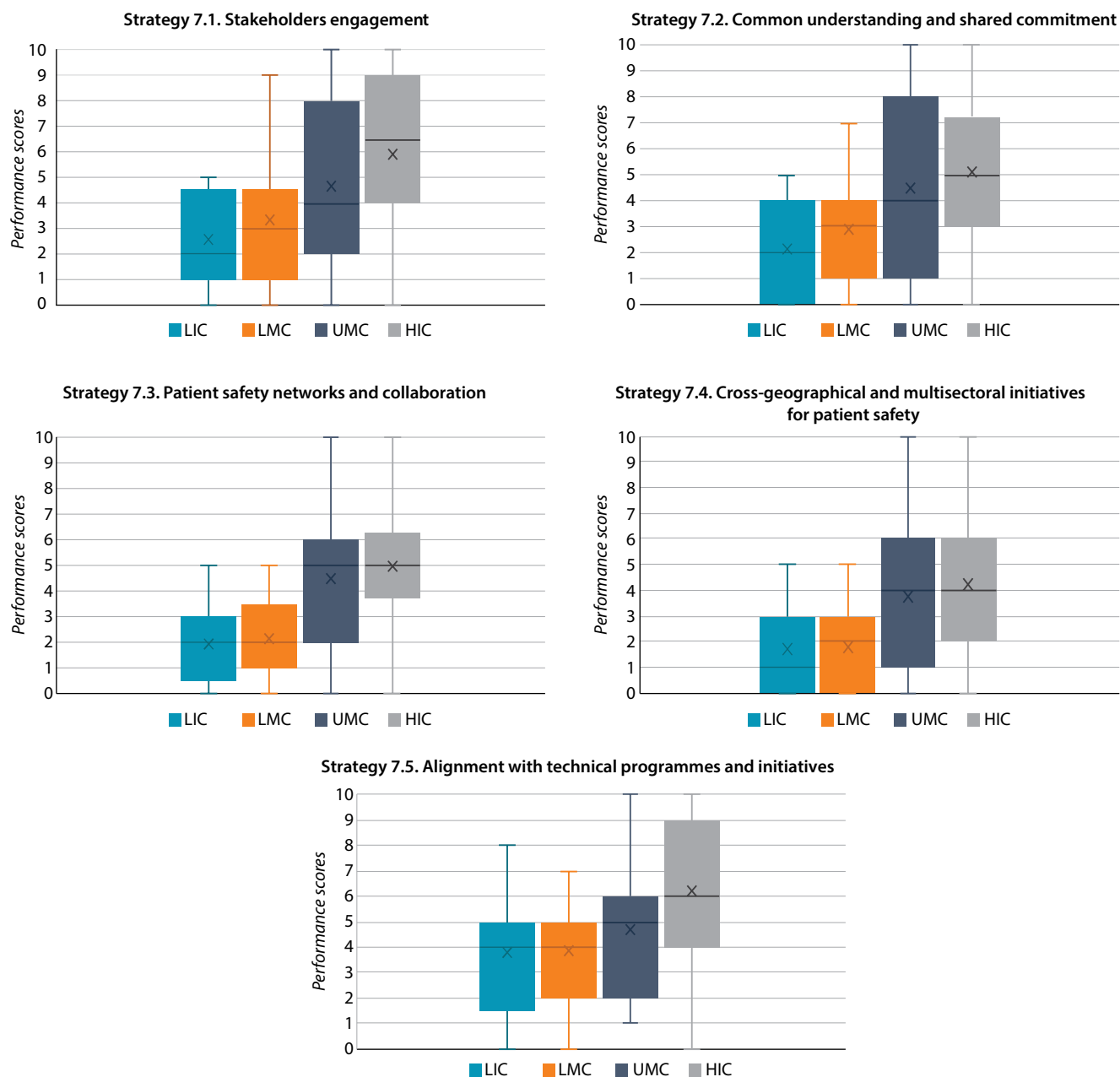
indicating an integrated approach to patient safety initiatives. There is noticeable scope for improvement in relation to many strategies in countries of the African Region and the Eastern Mediterranean Region. By leveraging the strengths of higher performing regions and addressing specific challenges, there is a tremendous opportunity to elevate partnerships and synergies for patient safety globally.

► **Fig. 7.2. Distribution of strategic objective 7 performance scores across five strategies, by WHO region**



Further descriptive analysis of survey data highlights varying levels of synergy, partnership and solidarity for patient safety across different income groups (Fig. 7.3). High-income countries consistently achieve higher median scores, indicating more established stakeholder engagement, shared commitment, and alignment with technical programmes. However, there is notable variability within each income category, especially among LMCs and UMCs, indicating significant variation in the implementation of these patient safety strategies. While income levels appear to correlate with the success of these initiatives, the data also suggest that effective collaboration and alignment with patient safety goals are possible across the economic spectrum, evidenced by the presence of higher-scoring outliers in lower-income groups.

► **Fig. 7.3. Distribution of strategic objective 7 performance scores, by income group**



Strategic objective 7					
7.1		7.2	7.3	7.4	7.5
Stakeholders engagement		Common understanding and shared commitment	Patient safety networks and collaboration	Cross geographical and multisectoral initiatives for patient safety	Alignment with technical programmes and initiatives

# Strategy 7.1. Stakeholders engagement

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Fully engage all stakeholders that have the potential to have a positive impact on patient safety

Effective engagement of stakeholders in patient safety initiatives begins with identifying and analysing key groups, ranging from policy-makers to patients and health and care workers, to ensure comprehensive involvement and collaboration for improvement efforts.

Engagement of stakeholders starts from identification and mapping of key groups who are already engaged in patient safety activities or have the potential to contribute to improvement efforts. This is followed by a detailed stakeholder analysis to gauge their roles, impact and interests in patient safety initiatives. Broadly, the range of stakeholders that may be involved in patient safety initiatives include, but are not limited to:

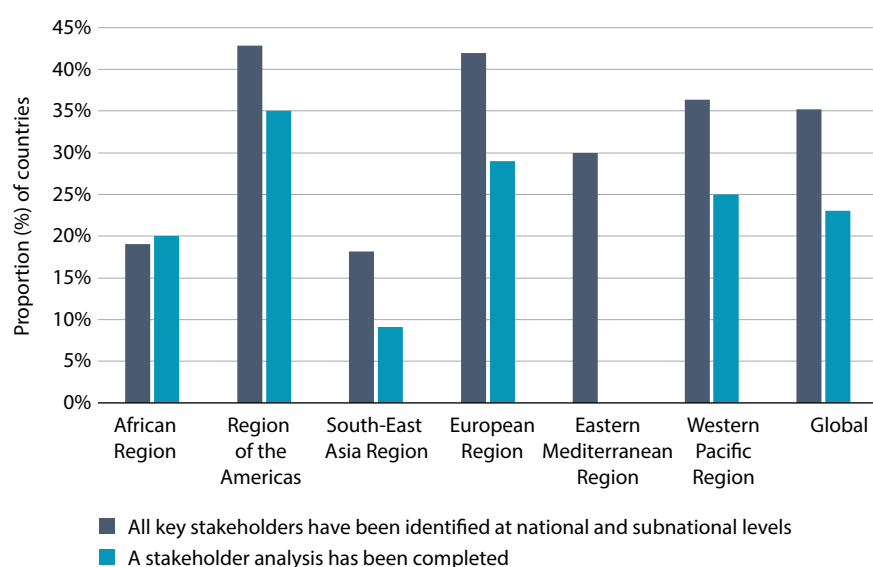
- policy-makers and political leaders;
- health care organization leaders;
- patients and their families, including patient advocates, champions and leaders;
- health and care workers working at different levels of heath care provision;
- private health service delivery sector;
- non-governmental organizations;
- patients’ groups and organizations;
- professional associations and educational councils;
- academic and research institutions;

- regulatory agencies and insurers;
- accreditation agencies;
- health care industry, including pharmaceutical and medical device industry; and,
- humanitarian and international development partners.

## Stakeholder mapping and analysis

Stakeholders operate at different levels (i.e. global, regional, national and subnational), and may represent both the public and private sectors. Considering that public–private partnerships can further facilitate sharing of knowledge, expertise and resources, drive innovation and lead to more effective and comprehensive patient safety initiatives, it is important to engage both sectors.

Countries adopt different approaches for engaging stakeholders and are at different stages of doing so. According to the Member State survey, 35% of countries reported that all key stakeholders have been identified at national and subnational levels. Around 23% of countries have conducted a stakeholder analysis to strengthen the engagement of all potential contributors and to learn from each other. However, there is considerable regional variation in these practices, with the European Region and Region of Americas showing relatively greater stakeholder identification and analysis initiatives for patient safety (Fig 7.4).



*Effective patient safety initiatives require stakeholder engagement across sectors, though only 35% of countries have identified key stakeholders, with 23% conducting analysis in order to strengthen engagement.*

**Fig. 7.4.**  
Status of stakeholder identification and analysis, by WHO region

## Stakeholder coordination mechanism

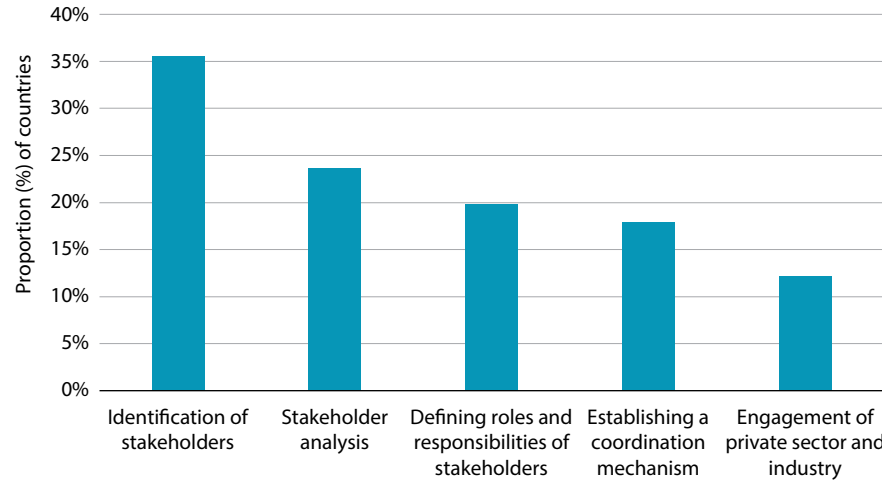
A critical aspect of meaningful participation is the clear definition of roles and responsibilities for stakeholders, ensuring clarity and accountability. Establishing robust coordination mechanisms is also essential for effective stakeholder engagement. About one fifth of respondent countries confirmed that the

Effective stakeholder engagement in patient safety requires clear role definitions and coordination mechanisms, though only about one fifth of countries have well-defined stakeholder roles and functional coordination mechanisms.

Fig. 7.5.  
Global status of stakeholder engagement initiatives

roles and responsibilities of stakeholders are well defined and communicated. Additionally, 17% reported establishing a functional coordination mechanism for stakeholder engagement. Engagement with the private sector remains limited, with 12% of respondents mentioning of full engagement of private sector and industry in patient safety and quality of care programmes. Around half of the respondents suggested the engagement of private sector and industry is initial stages and limited to specific projects.

The overall trend is towards a lower level of implementation as the process progresses from stakeholder mapping to their full integration (Fig. 7.5). While the initial steps of identification and mapping are reported more frequently, the deeper and more intricate aspects of engagement – such as comprehensive analysis, role definition and establishment of coordination mechanisms – are less developed across countries.



A more granular analysis highlights variations in engagement across different stakeholder groups (Table 7.1).

*Strong engagement of professional associations:* Globally, professional associations have the highest engagement rate at 71%. This suggests that professionals within the health sector are highly involved in initiatives aimed at ensuring patient safety. This engagement is universal across all regions, with countries of the Western Pacific Region reporting full engagement (100%).

*Variability across regions and sectors:* There is significant variability in the engagement levels of different stakeholder groups across different regions. For example, civil society organizations are highly active in the African Region (62%). Health insurance organizations are more likely to be involved in the European Region (55%) but show low engagement in the South-East Asia Region (9%). Engagement among development partners varies, with no engagement reported in the Eastern Mediterranean Region, limited engagement in the Region of the Americas (5%), and significantly active partnership in the South-East Asia (64%) and African Regions (57%).

*Robust academic involvement globally:* Engagement with academic and research institutions is strong across the board, with a notable global involvement rate of 62%. Countries of all regions, including the South-East Asia Region (82%)

Professional associations demonstrate high engagement in patient safety initiatives globally, while academic and research institutions are actively involved across all areas.

**Table 7.1. Reported engagement of various stakeholder groups in patient safety globally, by WHO region**

	African Region	Region of the Americas	South-East Asia Region	European Region	Eastern Mediterranean Region	Western Pacific Region	Global
<b>Civil society organizations</b>	62%	52%	64%	30%	10%	42%	44%
<b>Nongovernmental organizations</b>	71%	48%	55%	52%	60%	50%	56%
<b>Patients' organizations</b>	43%	29%	45%	79%	20%	58%	51%
<b>Professional associations</b>	62%	52%	73%	79%	70%	100%	71%
<b>Academic and research institutions</b>	57%	43%	82%	64%	70%	75%	62%
<b>Health care providers sector</b>	57%	67%	55%	52%	30%	58%	55%
<b>Development partners</b>	57%	5%	64%	18%	0%	42%	29%
<b>Accreditation agencies</b>	33%	48%	27%	48%	50%	67%	45%
<b>Pharmaceutical and medical devices industry</b>	24%	19%	45%	45%	30%	50%	35%
<b>Health insurance organizations</b>	29%	19%	9%	55%	40%	50%	36%

and Western Pacific Region (75%), report substantial academic engagement, highlighting educational and research institutions as one of the key partners in patient safety efforts.

*Moderate health care provider engagement:* The health care provider sector demonstrates a moderate global engagement level (55%) with a notable difference between regions such as the Region of the Americas (67%) and the Eastern Mediterranean Region (30%).

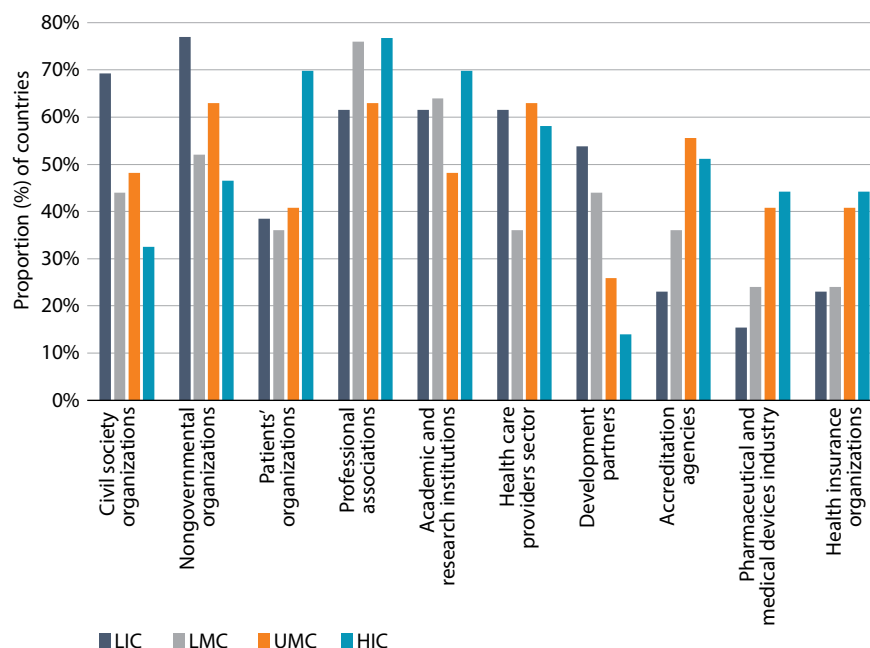
*Low engagement of pharmaceutical and medical devices industry:* Pharmaceutical and medical device companies have one of the lowest engagement rates (35% globally). This could be an area for potential growth, as the industry plays a critical role in patient safety, especially in areas such as medication safety.

Analysis of engagement of stakeholders across the countries representing different income groups reveals some emerging trends (Fig. 7.6). Civil society organizations and nongovernmental organizations are most active in LICs. Patient organizations increase their engagement significantly in HICs, pointing to the stronger advocacy efforts and emphasis on networks. Academic and research institutions maintain steady involvement across all income groups – with the highest activity in HICs – signifying their importance in advancing patient safety through education, training and research. The involvement of development partners declines with rising national income, suggesting a trend towards self-reliance in countries with higher income levels. There is a modest increase in engagement of the pharmaceutical industry in these countries as well. Health insurance organizations also show a slightly higher engagement in HICs, reflecting their greater role in such nations' health care systems.

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*Health care providers demonstrate moderate engagement in patient safety efforts, while the pharmaceutical and medical device industries show lower engagement levels.*

**Fig. 7.6.**  
Reported engagement of  
various stakeholder groups in  
patient safety, 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 actions for stakeholder engagement on patient safety

The Australian Commission on Safety and Quality in Health Care (ACSQHC) has developed a number of resources supporting patient-centered approaches, including defining how to identify stakeholders required to be consulted on patient safety initiatives throughout **Australia** (260). The Australian Government (and each state and territory) has developed a robust governance structure to outline the coordination and engagement of stakeholders.

*Robust strategies for stakeholder engagement in patient safety initiatives have been developed in various countries, highlighting the importance of clear governance structures and continuous monitoring of stakeholder positions.*

The **Danish** Patient Safety Authority is continuously monitoring the positions of stakeholders around patient safety efforts to promote and ensure engagement. They have established two advisory boards with representatives from a wide range of public and private stakeholder organizations: one for patient safety in general, and one for medication safety specifically.

In **Germany**, the composition of stakeholder groups engaged in patient safety processes and quality of care initiatives changes continuously, given the related improvements and actions are dynamic and have constantly developing goals. The responsibilities of stakeholders are clearly defined in the German health care system.

The Ministry of Health of **Guyana** has identified and works with public and private stakeholders. The private health sector in **Argentina** is engaged through the National Programme for the Strengthening of Health Teams for Quality and Safety (261).

Key stakeholders for patient safety at the national and state level have been identified in **Malaysia**; their roles and responsibilities are specified in the terms of reference assigned to members of Malaysian Patient Safety Council.



In **Malawi**, stakeholders working in quality improvement – especially in areas such as maternal and newborn health, as well as IPC – have been identified, and private facilities and Christian health facilities have been engaged to begin piloting patient safety.

In **Nigeria**, relevant partners such as the State Ministries of Health, the National Primary Health Care Development Agency, regulatory and professional bodies, private hospitals and WHO, have been identified as important partners to enhance patient safety.

In **Singapore**, the roles and responsibilities of stakeholders are defined under the Healthcare Services Act. Identification of relevant stakeholders takes place via the Ensure Safer Systems framework and the National Diabetes Collaborative, although patient engagement is limited. Private sector entities are engaged in some initiatives for patient safety and quality of care.

In **Thailand**, a total of 21 agencies, including the Ministry of Public Health, pledged their support and signed a Declaration on the intention to implement 3P safety, which was developed in collaboration with National Science and Technology Development Agency (157).

In **Türkiye**, all key stakeholders – including public institutions, universities and associations – are determined at national and subnational levels for making decisions and performing the patient safety studies carried out within the Ministry of Health, and their roles and responsibilities were determined through workshops.

In **Namibia** and **Sudan**, all stakeholders engaged in improving patient safety and quality of care have been identified and documented in their respective National quality policy and strategy. Furthermore, Sudan performed the same exercise while drafting the National medication safety action plan.

In **Liberia**, mapping of stakeholders is ongoing, while a stakeholder analysis was part of the national health care quality and strategy development.

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*Efforts are underway in several countries to identify and engage key stakeholders, including public and private entities, in improving patient safety and quality of care, displaying diverse approaches to stakeholder engagement on a national level.*

Strategic objective 7					
7.1		7.2	7.3	7.4	7.5
Stakeholders engagement		Common understanding and shared commitment	Patient safety networks and collaboration	Cross geographical and multisectoral initiatives for patient safety	Alignment with technical programmes and initiatives

## Strategy 7.2.

# Common understanding and shared commitment



Promote a common understanding and shared commitment among all stakeholders to successfully deliver the Global patient safety action plan

Only 15% of Member States have incorporated the strategic elements of the Global patient safety action plan 2021–2030 into their national policies, strategies, and planning for patient safety.

When stakeholders have a common understanding around what constitutes improvement in patient safety in policy and practice, they work towards the same goals, which streamlines efforts and maximizes the impact of patient safety strategies. Shared commitment facilitates open communication that, in turn, leads to better coordination. Shared vision builds trust among stakeholders – and if they share a commitment, they are more likely to take active roles and responsibilities for patient safety, ensuring that strategies are implemented effectively.

### Aligning national patient safety initiatives with global action plan

Around 15% of Member States reported that the strategic elements of the Global patient safety action plan have been included in their national policies, strategies and planning for patient safety. 20% of all respondents stated that national goals and targets on patient safety had been defined in line with the targets of the plan. However, only 10% of countries reportedly have a mechanism in place for periodic review of national implementation of the action plan at national and subnational levels.

## How Member States are adopting the global action plan in varied, yet cohesive ways

*National policies and frameworks:* Countries such as **India, Kenya, Malaysia, Thailand, Timor-Leste, Pakistan** and the **United Kingdom** have developed (or are developing) specific policies or frameworks aligned with the principles and objectives of the global action plan. This includes India's National patient safety implementation framework, Kenya's integrated approach with its national policy and Action plan on patient safety, health worker safety and quality of care. A similar trajectory is seen with Timor-Leste's Quality strategic plan 2020–2024.

*Integration into existing strategic programs and initiatives:* **Australia, Poland, Namibia, Singapore, South Africa** and **Uruguay** are incorporating action plan elements into their current health systems. For instance, Australia is using the Australian hospital patient experience question set for monitoring patient safety, while Singapore's Ensure Safer Systems programme focuses on zero harm across participating institutions.

*Stages of development:* Some countries, such as **Malawi, Nepal, Nigeria** and **Uruguay**, are in varying stages of developing their patient safety strategies. This includes the drafting, finalizing and alignment of national objectives with the action plan goals.

## Shared commitment for patient safety: Global collaborative landscape

Stakeholders collaborate and form partnerships at the global level through different mechanisms:

*Professional groups:* The International Council of Nurses (ICN), International Council of Midwives (ICM), World Federation for Medical Education (WFME), World Medical Association (WMA), World Federation of Societies of Anaesthesiologists (WFSA), World Dental Federation (FDI), International Pharmaceutical Federation (FIP), World Organization of Family Doctors (WONCA) and the International Union of Basic and Clinical Pharmacology (IUPHAR).

*Specific groups of people:* The International Alliance of Patients' Organizations (IAPO) and the Patients for Patient Safety (PFPS).

*Inter-disciplinary groups of experts working around specific thematic and/or clinical areas:* The International Ergonomics Association (IEA), International Federation of Gynecology and Obstetrics (FIGO), International Hospital Federation (IHF), International Society for Quality in Health Care (ISQua) and International Society on Thrombosis and Haemostasis (ISTH), and

*Specific countries or group of countries/regions:* Such as the OECD.

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*Global collaboration for patient safety is facilitated through partnerships among diverse stakeholders, including professional organizations, patient advocacy groups, interdisciplinary experts, and international alliances, all working towards common goals.*

### Box 7.1. Examples of collaboration of non-state actors with WHO on patient safety

The **International Pharmaceutical Federation (FIP)**<sup>a</sup> is one of the longstanding organizations in official relations with WHO. It represents around four million pharmacists, pharmaceutical scientists and pharmaceutical educators through the network of 156 national organizations, academic institutional members and individual members around the world. FIP contributes to policy development, practice improvement, standards development, innovation, knowledge sharing, professional development as well as establishment of strategic partnerships.

The **International Ergonomics Association (IEA)**<sup>b</sup> and WHO are co-developing the guidance document for application of human factors/ergonomics to patient safety, that will be followed by further translation of the application to the special contexts and populations.

The **International Society on Thrombosis and Haemostasis (ISTH)**<sup>c</sup> advances the understanding, prevention, diagnosis and treatment of conditions related to thrombosis and haemostasis and is a leading global professional organization with more than 7700 members in more than 110 countries. WHO and ISTH are in the process of co-development of a venous thromboembolism assessment tool.

The **International Council of Nurses (ICN)**<sup>d</sup> represents the nursing workforce worldwide (including more than 130 member organizations, representing around 28 million nurses across all geographical regions) to advance the nursing profession, promote the well-being of nurses, and advocate for health in all policies. The long-standing collaboration between ICN and WHO in the area of patient safety aims at leveraging the strengths of both organizations to reduce avoidable harm in health care and improve health outcomes, and focuses on policy development and advocacy, knowledge sharing, technical resource development and capacity building.

The **World Organization of Family Doctors (WONCA)**<sup>e</sup> connects 133 member organizations in 111 countries and territories with membership of about 500 000 family doctors. WONCA collaborates with WHO in the areas of quality of care and patient safety through the WONCA Working Party on Quality and Safety.

The **International Society for Quality in Health Care (ISQua)**<sup>f</sup> works to improve the quality and safety of health care worldwide and incorporates a network of health care professionals that spans over 70 countries and six continents. ISQua promotes incident reporting as a central requirement, addresses human factor/ergonomics and facilitates online educational programmes.

The **World Medical Association (WMA)**<sup>g</sup> is an international organization representing physicians and including 116 national medical associations. It provides a forum for its member associations to communicate freely, to co-operate actively, to achieve consensus on high standards of medical ethics and professional competence. WMA supports WHO in its efforts to build and strengthen health care systems, including in the area of patient safety.

The long-standing relationship between WHO and the **Organisation for Economic Co-operation and Development (OECD)**<sup>h</sup> focuses on issues related to improving collection, harmonization and dissemination of health-related data and indicators, issues in health systems and environment and health as well as noncommunicable diseases. The OECD is instrumental in the development of the series on the economics of patient safety.

WHO established and continues to facilitate the work of the **Patients for Patients Safety (PFPS)**<sup>i</sup> programme that engages and empowers patients and families, and facilitates their partnership with health and care workers and policy-makers to make health care services safer worldwide. Engaging patients and families who have experienced harm can provide insights and learning concerning system failure, thus it is essential to ensure that their voices are heard in health care, always and at all levels.

The **International Alliance of Patients' Organizations (IAPO)**<sup>j</sup> is a global alliance representing patients of all nations across all disease areas, and currently connects 300 member organizations from 71 countries representing 50 disease

areas. Patient safety is addressed in the work of IAPO through policy development, advocacy, capacity building, cross-sectoral alliances, research and collaborative work.

The **International Union of Basic and Clinical Pharmacology** (IUPHAR)<sup>k</sup>, representing the interests of clinicians and scientists in pharmacology and related fields globally, facilitates better use of medicines through education and research around the world. The Clinical Pharmacology Division oversees the interactions between IUPHAR and the WHO and between IUPHAR and the Council for International Organizations of Medical Sciences (CIOMS). The Sub-committee on Clinical Pharmacology in Developing Countries focuses on supporting the development of research, teaching and clinical services such as drug information, rational use of medicines, medication safety, and support to drug and therapeutics committees in developing and emerging countries. IUPHAR particularly engages in promoting the WHO Global Patient Safety Challenge: Medication Without Harm to improve safety of medication use processes globally.

Sources:

- <sup>a</sup> International Pharmaceutical Federation [website]. The Hague: International Pharmaceutical Federation (<https://www.fip.org/>, accessed 1 May 2024).
- <sup>b</sup> International Ergonomics Association [website]. Geneva: International Ergonomics Association (<https://iea.cc/>, accessed 1 May 2024).
- <sup>c</sup> International Society on Thrombosis and Haemostasis [website]. Carrboro: International Society on Thrombosis and Haemostasis (<https://www.isth.org/>, accessed 1 May 2024).
- <sup>d</sup> International Council of Nurses [website]. Geneva: International Council of Nurses (<https://www.icn.ch/>, accessed 1 May 2024).
- <sup>e</sup> World Organization of Family Doctors [website]. Brussels: World Organization of Family Doctors (<https://www.globalfamilydoctor.com/>, accessed 1 May 2024).
- <sup>f</sup> International Society for Quality in Health Care [website]. Dublin: International Society for Quality in Health Care (<https://isqua.org/>, accessed 1 May 2024).
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- <sup>h</sup> Organisation for Economic Co-operation and Development [website]. Paris: Organisation for Economic Co-operation and Development (<https://www.oecd.org/>, accessed 1 May 2024).
- <sup>i</sup> Patients for patient safety [website]. Geneva: World Health Organization (<https://www.who.int/initiatives/patients-for-patient-safety>, accessed 1 May 2024).
- <sup>j</sup> International Alliance of Patient Organizations [website]. London: International Association of Patient Organizations (<https://www.iapo.org.uk/>, accessed 1 May 2024).
- <sup>k</sup> International Union of Basic and Clinical Pharmacology [website]. Edinburgh: International Union of Basic and Clinical Pharmacology (<https://iuphar.org/>, accessed 1 May 2024).

## WHO engagement with stakeholders

One of the formal mechanisms for WHO to engage with stakeholders is through granting the status of non-state actors (NSA) in official relations with WHO (262) to nongovernmental organizations, international associations and philanthropic foundations that systematically engage in the work of WHO. The aims and activities of all these entities shall be in conformity with the spirit, purposes and principles of the WHO constitution, and they shall contribute significantly to the advancement of public health.

Another mechanism of engagement is related to the establishment of WHO Collaborating Centres – institutions that support activities of WHO programmes at all levels (263). The fundamental principle of establishing a WHO Collaborating Centre is to harness the expertise of an institution for the benefit of all countries.

One of the examples of a memorandum of understanding (MoU)-based partnership is the collaboration between WHO and SingHealth. It is aimed at

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*WHO collaborates with various stakeholders through formal mechanisms such as granting non-state actor status and establishing WHO Collaborating Centres, fostering partnerships aimed at advancing patient safety globally*

facilitating knowledge sharing and promoting collaborative activities in patient safety, including developing and facilitating the Global Knowledge Sharing Platform for Patient Safety (GKPS) (264). SingHealth has also established the Global Action for Leaders and Learning Organizations on Patient Safety (GALLOPS) programme in 2021, to promote and facilitate the Global patient safety action plan 2021–2030 implementation in the Asia-Pacific region. The programme promotes an integrated approach towards patient safety and quality of care for UHC, and contributes to building competencies of leaders in the region and beyond.

Many of the institutions are also engaged in Patient Safety Education and Training Network (PSET).

To support African francophone countries in the implementation of the global patient safety action plan, WHO has developed a collaborative partnership with Haute Autorité de Santé (“HAS”), France through a MoU.

There are also innovative collaborative models that allow engagement of multiple stakeholders, with strong focus on country-specific interventions, such as the Global Patient Safety Collaborative (265) (see also strategy 7.4).

Each stakeholder has unique expertise, either in relation to different systemic aspects of patient safety or clinical practice areas, and it is crucial to build on existing expertise and leverage the comparative advantage of all stakeholders. For example, several organizations are involved in the implementation of the third WHO Global Patient Safety Challenge: *Medication Without Harm* (266). They contribute to the development of technical tools and resources, patient engagement tools, medication safety assessment tools, a series of medication solutions, as well as taking part in capacity building for safe medication use at country level, and awareness-raising and advocacy efforts in this area.

Strategic objective 7	7.1	7.2	7.3	7.4	7.5
	Stakeholders engagement	Common understanding and shared commitment	Patient safety networks and collaboration	Cross geographical and multisectoral initiatives for patient safety	Alignment with technical programmes and initiatives

## Strategy 7.3.

# Patient safety networks and collaboration



Establish networks and convene consultative meetings to foster collaboration and partnership in patient safety

Patient safety requires a collaborative approach to problem solving and decision-making, knowledge sharing, and community and trust building. Bringing together key stakeholders helps in breaking down the silos between different sectors and stakeholders, facilitates the development of more effective policies and regulations, as well as resources optimization, thus creating an integrated approach to patient safety.

*Effective patient safety initiatives require collaborative stakeholder engagement, though data from the Member State survey indicate that only 17% of respondents have organized consultations on the implementation of action plans.*

## Stakeholder consultations for implementing patient safety action plans

Holding consultative meetings that include all key stakeholders, from both public and private sectors, is a critical approach to creating lasting frameworks for executing the Global patient safety action plan 2021–2030 and national patient safety strategies. Through the Member State survey, 17% of respondents reported that consultations had been organized on the implementation of the action plan, and 42% mentioned that such consultations are planned.



At the global level, a Policy-makers' Forum: Patient safety implementation – convened by WHO in collaboration with WHO regional offices in 2022 – initiated national action by policy-makers and health care leaders for implementation of the action plan. The forum culminated in adoption of a consensus statement that reaffirmed commitment of the global leaders to the implementation of the action plan (267).

### National level consultations on implementing the Global patient safety action plan 2021–2030

In **Brazil**, the discussions around the approaches to take forward implementation of the action plan were organized by the National Council of Health Secretaries, highlighting the importance of integration and building technical consensus.

In **Germany**, the German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit) dedicated its 2022 annual meeting to the adoption and adaptation of the action plan.

The SingHealth Patient Advocacy Network (SPAN) in **Singapore** organized the Singapore Patient Advocate Connection (SPACE) in 2022. It brought together patients, caregivers and health care professionals to share insightful stories and best practices, raising awareness on the importance of partnership between patients and health care teams in improving patient safety and quality of care.

As part of the development of the quality strategy that integrates the recommendations of the action plan, a national consultation was held in **Switzerland**.

### National patient safety networks

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*National patient safety networks are instrumental in sharing best practices and fostering mutual learning, though only 21% of countries have operational networks.*

Effective patient safety networks are crucial at both national and regional levels for sharing and distributing best practices in patient safety. These networks serve as key facilitators for mutual learning and play a significant role in reducing patient harm. The concept of a national patient safety network involves establishing a formal framework that coordinates the implementation of safety practices, fosters the exchange of ideas, and encourages collective learning about patient safety. The network can be effectively managed on a virtual platform, making it accessible to all relevant stakeholders.

According to the Member State survey, 21% of countries reported having an established and operational national patient safety network. Among these, countries in the Western Pacific Region showed the highest level of implementation at 58%. Establishment and functioning of national networks varies considerably across regions (Fig. 7.7)

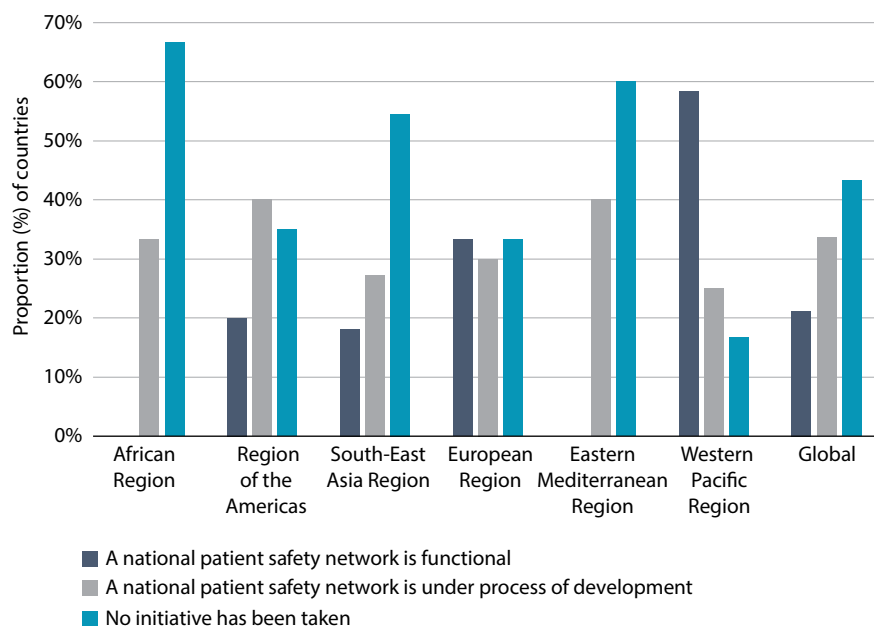


Fig. 7.7.

▶ Status of national patient safety networks, by WHO region

## Global Patient Safety Network

The Global Patient Safety Network (GPSN) is an innovative online platform that unites key stakeholders in health care to share ideas, approaches, tools and best practices for enhancing patient safety (268). It features a comprehensive repository of resources, including adaptable, cost-effective strategies, best practices and insights from past experiences. This network emphasizes the importance of dialogue and continuous learning, aiming to improve patient safety standards globally.

The network's mission is to foster a collaborative environment where health care professionals and organizations can exchange knowledge and expertise. This collaboration is crucial for advancing patient care and safety across various health care systems and cultural contexts, especially in regions with limited resources. By pooling collective wisdom and experiences, the network aims to be a catalyst for a safer health care in the future, worldwide.

Currently, over 3000 professionals from around 160 countries are members of this global network.

*The Global Patient Safety Network (GPSN) facilitates collaboration among health care stakeholders worldwide, fostering continuous learning and improvement in patient safety, with over three thousand members from 160 countries actively engaged.*

## Country examples of patient safety networks

In **Thailand**, a community of practice platform was created to learn and share best practices on safety with other high-risk industries.

In **Malaysia**, the network and governance for patient safety has been fully established: The Malaysian Patient Safety Council and Patient Safety Committees are functional at both the state and local level. A workshop with key stakeholders and experts was held in 2022 for the development of the

National action plan for patient safety, and collaborative partnerships have been established to promote patient safety programmes, including partnership between the Government and the International Medical University of Malaysia for the development of the online patient safety training modules.

In **Sri Lanka**, collaborative alliances have been formed between government agencies and partners to implement patient safety programmes, such as collaborative medication safety initiatives between the National Medicines Regulatory Authority, Medical Supplies Division, professional colleges, academia and patient groups.

**Sudan** has established a patient safety network to support implementation of patient safety and medication safety improvement programmes in a number of health facilities.

In **Switzerland**, as part of the development of the quality strategy, a national consultation was held on the action areas and four-year objectives. The Patient Safety Foundation was established as a national network by the Federal Government and currently functions independently.

## Collaborative alliance for promoting patient safety

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*Collaborative alliances in patient safety harness the collective expertise and resources of diverse stakeholders to address complex challenges and drive continuous improvement in health care services.*

Collaborative alliances play a pivotal role in the implementation of patient safety programmes and related initiatives. These alliances, which can be either formal or informal in nature, often take the form of agreements or an MoU. They are tailored to address specific areas of patient safety, including but not limited to training, research and public awareness campaigns. Additionally, these collaborations may focus on specific domains within patient safety, such as medication safety, ensuring safe surgical procedures, or enhancing the safety of maternal and child care.

The essence of these collaborative alliances is to pool expertise, resources and efforts from different stakeholders to create a more comprehensive and effective approach to patient safety. By working together, the strengths and knowledge of each member can be leveraged to tackle complex challenges in patient safety. This collaborative approach not only enhances the quality and reach of patient safety programmes but also fosters innovation and best practice sharing, which are essential for the continuous improvement of health care services.

## Examples of global initiatives on collaboration and advocacy for patient safety

*The Global Patient Safety Collaborative (GPSC)* is a strategic initiative established by the joint efforts of WHO and the Government of the United Kingdom to secure and scale up global action on patient safety, as well as to reduce the risk of avoidable harm and improve the safety of health systems at the country level

(265). The work of the collaborative is organized around three strategic areas: leadership, education and training, and research. The GPSC model incorporates two types of cooperation with countries: indirect/generic and direct/bespoke, and in the phase 1 of the GPSC (2019–2023), four countries benefited from the direct cooperation: India, Kenya, Mongolia and Pakistan. During the course of the GPSC implementation, WHO cooperates with the academic partner – Imperial College London – which provides all-inclusive support in the implementation of activities across the collaborative's three strategic areas.

*The Africa Patient Safety Initiative* was designed to be a strategic opportunity to build on the World Health Assembly resolution entitled Global action on patient safety, capitalize on synergies and provide a common platform to plan, implement and/or share experiences and initiatives in patient safety for countries in the African Region (269).

*African Partnerships for Patient Safety (APPS)* is an initiative of the WHO Flagship on Patient Safety that is aimed at strengthening sustainable hospital-to-hospital patient safety partnerships (270). While the programme is primarily focused on countries of the WHO African Region, it is open to hospitals in all regions. APPS advocates for patient safety as a precondition of health care and catalyses a range of actions to strengthen health systems. It also assists in building local capacity and reduce medical errors and patient harm. The partnership acted as a channel for patient safety improvements that could spread across countries, uniting patient safety efforts.

*The G20/Global Patient Safety Leaders Group (GPSLG)* was established following the Saudi Arabia G20 Presidency in 2020, and represents a significant international effort to enhance patient safety. With members primarily from G20 countries, the group reflects a broad international commitment. It was established to address patient safety as a key component of health systems strengthening, and is co-chaired by Saudi Arabia and WHO. The GPSLG fosters global collaboration, sharing best practices and innovative solutions to safety challenges. Its diverse membership includes health sector representatives, patient safety experts, and G20 state delegates, ensuring varied perspectives for tackling patient safety issues. GPSLG's objective align with the WHO Global patient safety action plan 2021–2030, focusing on empowering patients and health workers, and promoting awareness through events such as World Patient Safety Day. Initiatives also include the Twinning Partnership for Patient Safety, highlighting its commitment to practical, impactful strategies. The group's flexible, inclusive approach is adapted to evolving health challenges, promising a safer health care future. Its structure, objectives and achievements represent a comprehensive, collaborative effort in the global patient safety endeavour.

## National and regional examples of collaborative patient safety approaches

**Thailand** and **Malaysia** have taken steps to learn and share best practices on safety with other high-risk industries. Also in **Sri Lanka**, there are established collaborations with high-risk industries, including a partnership with the Special

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*Global initiatives such as the Global Patient Safety Collaborative, Africa Patient Safety Initiative, African Partnerships for Patient Safety, and the G20 Global Patient Safety Leaders Group demonstrate a concerted effort to enhance patient safety through collaborative action, sharing best practices, and fostering international partnerships across regions and sectors.*

Task Force of the Sri Lanka Police focusing on radiation safety. **Spain's** Ministry of Health has an agreement with the Spanish Nuclear Safety Council and has engaged in knowledge-sharing meetings with other industries. **Czechia's** Ministry of Health has formed a Working Group for Medical Imaging, addressing conceptual issues and setting national standards for medical imaging methods involving radiation.

In **South Africa**, the Presidential Health Summit (2018) brought together a wide range of constituencies, including government, health professionals, civil society, labour, business, academia, scientists and health service users to deliberate and propose solutions to address the challenges facing the South African health system, including health service provision, quality of care and patient safety, community engagement, leadership and governance.

## Strategic objective 7

7.1	7.2	7.3	7.4	7.5
Stakeholders engagement	Common understanding and shared commitment	Patient safety networks and collaboration	Cross geographical and multisectoral initiatives for patient safety	Alignment with technical programmes and initiatives

### Strategy 7.4.

## Cross geographical and multisectoral initiatives for patient safety



Promote cross-geographical and multisectoral initiatives to advance action on patient safety

*Global collaboration in patient safety enhances perspectives, innovation transfer, standardization, resource sharing, research, policy influence, crisis response, and equity in care.*

Cross-geographical and multisectoral initiatives can significantly advance patient safety action in a variety of ways:

- *Broadening perspectives:* They bring together diverse perspectives from different regions and sectors, leading to a more comprehensive understanding of patient safety issues.
- *Innovation transfer:* Collaborative initiatives enable transfer of innovative practices across borders, allowing regions and countries to learn from each other's successes and challenges.
- *Standardizing practices:* They help in developing and promoting standardized safety practices that can be implemented internationally.
- *Resource sharing:* Cross-geographical initiatives often lead to better sharing of resources, including knowledge, technology and funding, which can be particularly beneficial in resource-limited settings.
- *Research and development:* Multisectoral collaboration boosts research by combining different expertise and data sets, leading to more robust findings and evidence-based practices.
- *Policy influence:* A collective voice across regions and sectors can have a powerful influence on policy and legislation, leading to stronger patient safety regulations.

- *Crisis response:* In times of crisis, such as during pandemics, these initiatives can facilitate a rapid, coordinated response that is crucial for maintaining patient safety.
- *Equity in care:* By addressing patient safety on a global scale, these initiatives can help reduce disparities in health care safety and quality between different regions and sectors.

## Global Ministerial Summits on Patient Safety

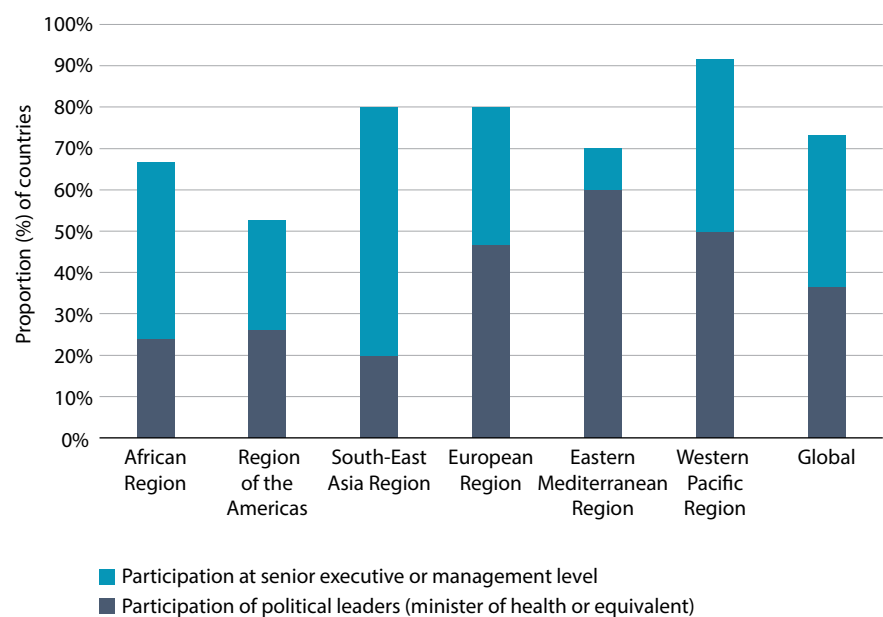
*Annual Global Ministerial Summits on Patient Safety unite policy-makers and health care experts to prioritize evidence-based solutions, with 73% of countries ensuring high-level participation, reflecting a global commitment to advancing patient safety*

Exploring innovative models for intergovernmental and interregional collaboration is critical in driving an international culture and priority around patient safety. One such sustainable mechanism to bridge patient safety policy and practice is the series of Global ministerial summits on patient safety (271).

The summits are an opportunity for policy-makers, technical expertise groups, professional societies and educational networks to converge on policy decisions with practical, evidence-based solutions, to jointly prioritize patient safety and express solidarity and commitment towards the goals of the Global patient safety action plan 2021–2030. The goal is to allow varied stakeholders from different care contexts and health systems to highlight critical challenges, present potential solutions and ideas for improvement, and strategize around how to incorporate patient safety learnings into policy agenda and service improvement.

Through the Member State survey 73% of countries reported that they have ensured high level participation in the recent Global Ministerial Summits on Patient Safety with presence of health ministers or senior executives from ministry of health (Fig. 7.8).

**Fig. 7.8.**  
**Reported high-level participation in Global Ministerial Summits on Patient Safety, by WHO region**





## Dissemination of innovative ideas and best practices

Best practices and innovations in patient safety are shared by 28% of countries through regional or global platforms, and 30% report they have compiled best practices but have not yet shared them. Notably, member countries of the Western Pacific Region reported the highest engagement in sharing best practices and innovative solutions, with 42% participation.

### Country initiatives to promote cross-geographical and multisectoral patient safety initiatives

In 2021, **Uruguay** ratified the Common Market of the South (MERCOSUR) Resolution, which focuses on good practice requirements for the operation of health services. The resolution states that all health services must establish strategies and actions aimed at patient safety, such as: Mechanisms for unequivocal identification of the patient, correct hand hygiene, actions to prevent and control adverse effects related to health care, mechanisms to ensure surgical safety, guidelines for the safe administration of medications, blood, blood products and blood components, mechanisms for the prevention of patient fall and pressure ulcers and guidelines to encourage patient participation in health care provision. The Common Market of the South (MERCOSUR) is a regional integration process initially instituted by **Argentina, Brazil, Paraguay** and **Uruguay**, to which **Venezuela** and **Bolivia (Plurinational State of)** have joined in later phases.

In **South Africa**, patient safety is embedded in the quality of care agenda, which serves as one of the indicators of the country's Medium Term Strategic Framework. Under the framework, a National Quality Improvement Programme for the health sector will be finalized and implemented before 2024/25 (272).

**Germany** has called for and actively engages in the development of European and global platforms to improve international collaboration.

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*Global dissemination of best practices and innovative ideas in patient safety is essential for advancing health care quality, with nearly one-third of countries actively sharing these insights.*

## Feature story 16.

### Global Ministerial Summits on Patient Safety

Recognizing the huge burden of avoidable harm in health care, political leadership from the Governments of the United Kingdom and Germany initiated annual Global Ministerial Summits on Patient Safety in 2016 and 2017. The summits enable direct dialogue on patient safety between government ministers and health care experts (i.e. renowned academics, policy-makers and other international stakeholders). The two-day summits are designed based on an expert-driven programme on the first day (Expert Summit), from which key recommendations from thematic sessions on the major challenges to patient safety are drawn by experts and presented to ministers on the second day (Ministerial Summit). Despite the diversity of languages, cultures, political systems and economic development status, delegates agree on significant priorities to advance patient safety at the global, regional and national levels.

Five successful annual summits have so far been delivered by the governments of the United Kingdom, Germany, Japan, Saudi Arabia, Switzerland and Chile.<sup>a</sup> These summits have inspired governmental policy and commitment to improving patient safety worldwide. Each summit has been instrumental in engaging political leaders, policy-makers, international experts and patients to initiate global action on patient safety. WHO leadership has been fully engaged, committed and supportive of this successful initiative.

The first summit, held in London, United Kingdom in 2016, aspired to galvanise international policy and governmental actors to prioritize patient safety. The second summit, held in Bonn, Germany in 2017, identified that safety must be central for health care systems, united ministers behind the idea of an annual World Patient Safety Day, and also provided the platform where WHO launched its third Global Patient Safety Challenge: *Medication Without Harm*.<sup>b</sup> The UK Government capitalized on this momentum to lead on developing and, with the Government of Kenya, negotiating a World Health Assembly resolution on patient safety. The third summit in Tokyo, Japan (2018)<sup>c</sup> and fourth summit in Jeddah, Saudi Arabia, (2019)<sup>d</sup> were instrumental in facilitating adoption of the resolution Global action on patient safety<sup>e</sup> (WHA72.6) at the 72nd World Health Assembly in May 2019. The resolution recognized patient safety as a global health priority for the first time, established an official annual World Patient Safety Day (17 September) and requested the WHO secretariat to formulate a global patient safety action plan. The WHO Global patient safety action plan 2021–2030<sup>f</sup> was subsequently adopted by the 74th World Health Assembly in May 2021, providing strategic direction and concrete actions to be taken by all countries and stakeholders in order to advance patient safety.

Following a hiatus due to the COVID-19 pandemic, the fifth summit was hosted in Montreux, Switzerland in 2023. It focused on sustainable patient safety implementation, building on the outcomes of the previous summits, and also led to the adoption of Montreux Charter for Patient Safety.<sup>g</sup> The summit saw a record participation of ministerial delegations from almost 80 countries (including 40 participating health ministers) and over 600 experts. It outlined the crucial importance of patient safety for the resilience of health care systems and the trust of the people in them, as demonstrated by the pandemic, and pushed for a seismic shift for all countries to move from plans to tangible action. The aligned perspectives of all participating ministers raised the hope that countries would be able to regain progress lost during the pandemic and continue to advance safer care.

The sixth summit was held in Santiago, Chile in April 2024 and emphasized the need for to ensure that patient safety implementation to become an integral component of health systems worldwide. The Summit addressed the challenges and opportunities in implementing patient safety policies, highlighting the importance of international cooperation to enhance patient safety globally, and culminated in the release of the ‘Santiago Commitment Charter on Patient Safety: Bringing and sustaining changes in patient safety policies and practices’. The Summit also provided the platform for launching the WHO Patient safety right charter.<sup>i</sup>

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	7.1	7.2	7.3	7.4	7.5	
Strategic objective 7	Stakeholders engagement	Common understanding and shared commitment	Patient safety networks and collaboration	Cross geographical and multisectoral initiatives for patient safety	Alignment with technical programmes and initiatives	

## Strategy 7.5.

# Alignment with technical programmes and initiatives

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Work closely with technical programmes to ensure alignment in patient safety action

Patient safety intersects with different aspects of the health care delivery system, including disease prevention and clinical care, health care policy and regulations, education and training, technology and the working environment. Patient safety issues are relevant to all health care disciplines and apply to all levels of health care provision – from direct patient care to organizational processes and health care policies. Therefore, aligning patient safety with other areas of work and ensuring a synergistic approach to planning and implementation is integral to delivering safe, efficient and high-quality health care.

WHO demonstrates synergies between patient safety and other clinical practice areas through various mechanisms. One is the launch and implementation of the Global Patient Safety Challenges and the selection of themes for the three challenges announced so far:

- Clean care is safer care (2005) (172)
- Safe surgery saves lives (2008) (173)
- Medication Without Harm (2017) (174)

World Patient Safety Day is also commemorated annually on 17<sup>th</sup> September with different themes chosen to highlight critical aspects that require global

*Initiatives, such as World Patient Safety Day and WHO Global Patient Safety Challenges, exemplify the importance of integrating patient safety into broader health care agendas.*

attention. The themes of the six previous World Patient Safety Days covered the following areas:

- Speak up for patient safety (2019) (273)
- Health worker safety: A priority for patient safety (2020) (274)
- Safe maternal and newborn care (2021) (275)
- Medication safety (2022) (276)
- Engaging patients for patient safety (2023) (277)
- Improving diagnosis for patient safety (2024) (278)

In many countries, patient safety activities and initiatives are organized as part of broader quality of care improvement initiatives. For example, through the development of a national quality policy and strategy (NQPS), or through clinical programmes such as IPC, blood and transfusion safety, vaccination safety, maternal and child health, safe surgery, medication safety etc.

## Integration of patient safety programmes

The integration of patient safety programmes with various associated themes and technical areas shows significant variation across the globe. About 30% of countries have reported implementing integration of safety-related programmes. However, the complete incorporation of patient safety strategies with programmes aimed at strengthening health systems and disease control has been reported by only approximately one sixth of countries worldwide. This indicates the nascent stage of the integration process for many countries, with most reporting that such integration efforts are still underway.

The extent of integration of patient safety strategies into different programmes varies across countries (Table 7.2).

**Table 7.2. Reported extent of patient safety integration into various health programme types**

Types of programmes	Extent of patient safety integration			
	All programmes	Some programmes	Not initiated	Not known
<b>Safety-related programmes</b> (e.g. surgical safety, injection safety, radiation safety, IPC, blood safety, vaccination safety)	<b>30%</b>	<b>56%</b>	<b>10%</b>	4%
<b>Health system strengthening programmes</b> (e.g. water, sanitation and hygiene, health workforce, occupational health, health governance, health financing, health information and quality of care)	<b>14 %</b>	<b>67%</b>	<b>17%</b>	3%
<b>Life-course health programmes</b> (e.g. reproductive health, childbirth, child health, adolescent health and aging population)	<b>16%</b>	<b>55%</b>	<b>21%</b>	8%
<b>Disease control programmes</b> (e.g. HIV, TB, noncommunicable diseases, emerging and re-emerging infectious diseases and mental health)	<b>16%</b>	<b>62%</b>	<b>13%</b>	10%

*Integration of patient safety programmes varies globally, with about 30% of countries implementing such initiatives.*

## Integration of patient safety with other clinical programmes at country level

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*Global efforts to integrate patient safety into clinical programmes span various health domains, such as maternal and child health, blood transfusion, and surgical procedures, demonstrating a commitment to aligning safety initiatives with broader health system objectives.*

In **Cuba**, strategies for patient safety are integrated into different programmes, such as the blood transfusion, immunization, maternal and child health, elderly care, primary health care, and communicable diseases.

**Guyana** mapped patient safety actions with the programmes related to maternal and child health (e.g. delivery in health facilities by skilled birth attendants, maternity waiting homes etc.) and transfusion services in hospitals across the country.

In **Brazil**, patient safety elements are incorporated into cardiovascular surgery service and interventional cardiology procedures.

In **Liberia**, patient safety actions are mapped for potential alignment with some programmes, such as maternal and child health, HIV, IPC, AMR, and water and sanitation, while integration into other programmes is ongoing.

Patient safety strategies have been integrated as part of the **Malaysia** Patient Safety Goals programme and others, including life-course health and occupational health, and are led by the respective departments in the Ministry of Health.

In **Mongolia**, patient safety strategies have been incorporated into safe surgery, blood safety and vaccination programmes.

In **Nepal**, patient safety has been incorporated into surgical safety and IPC.

In **Nigeria**, there are policies and strategies regulating safe injection practices, blood transfusion and IPC, and a policy on water sanitation and hygiene has been developed.

In **Sudan**, patient safety is mapped for alignment with safe childbirth, safe surgery and medication safety programmes, and patient safety is an integral part of the national strategy for hepatitis prevention.

In **El Salvador**, patient safety measures have been included in the manuals for hospitalization processes, surgical procedures, and emergency care.

In **South Africa**, patient safety strategies have been integrated into health system strengthening programmes including health workforce (during COVID-19), quality of care, and a survey on patients' experience of care, as well as occupational health and water and sanitation programmes.

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A mother with her 12-month-old daughter in front of the Eltomale Site Mobile Health and Nutrition Team in Chifra, Afar, Ethiopia.  
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# Annexes

*Seating for delegates at the 75th World Health Assembly at the Palais des Nations in Geneva, Switzerland. © WHO / Pierre Albouy*

**Annex 1:** Core Indicators – Global patient safety action plan 2021–2030

**Annex 2:** Framework for Action: The 7x5 matrix

**Annex 3:** Patient safety regional profiles



*Laboratory technician working on Ebola vaccine trials at Donka Hospital in Guinea. © WHO / Sean Hawkey*



## Annex 1.

# Core indicators – Global patient safety action plan 2021–2030

1.	Proportion of countries that have developed a national action plan (or equivalent) for implementing patient safety policy and strategies
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)
3.	Proportion of countries that have established their national targets on reducing medication related harm
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system
9.	Proportion of countries that publish an annual report on patient safety
10.	Proportion of countries that have established a national patient safety network

## Annex 2.

# Framework for action: The 7x5 matrix

1		<b>Policies to eliminate avoidable harm in health care</b>	<b>1.1</b> Patient safety policy, strategy and implementation framework	<b>1.2</b> Resource mobilization and allocation	<b>1.3</b> Protective legislative measures	<b>1.4</b> Safety standards, regulation and accreditation	<b>1.5</b> World Patient Safety Day and Global Patient Safety Challenges
2		<b>High-reliability systems</b>	<b>2.1</b> Transparency, openness and No blame culture	<b>2.2</b> Good governance for the health care system	<b>2.3</b> Leadership capacity for clinical and managerial functions	<b>2.4</b> Human factors/ergonomics	<b>2.5</b> Patient safety in emergencies and settings of extreme adversity
3		<b>Safety of clinical processes</b>	<b>3.1</b> Safety of risk-prone clinical procedures	<b>3.2</b> Global Patient Safety Challenge: Medication Without Harm	<b>3.3</b> Infection prevention and control & antimicrobial resistance	<b>3.4</b> Safety of medical devices, medicines, blood and vaccines	<b>3.5</b> Patient safety in primary care and transitions of care
4		<b>Patient and family engagement</b>	<b>4.1</b> Co-development of policies and programmes with patients	<b>4.2</b> Learning from patient experience for safety improvement	<b>4.3</b> Patient advocates and patient safety champions	<b>4.4</b> Patient safety incident disclosure to victims	<b>4.5</b> Information and education to patients and families
5		<b>Health worker education, skills and safety</b>	<b>5.1</b> Patient safety in professional education and training	<b>5.2</b> Centres of excellence for patient safety education and training	<b>5.3</b> Patient safety competencies as regulatory requirements	<b>5.4</b> Linking patient safety with appraisal system of health workers	<b>5.5</b> Safe working environment for health workers
6		<b>Information, research and risk management</b>	<b>6.1</b> Patient safety incident reporting and learning systems	<b>6.2</b> Patient safety information systems	<b>6.3</b> Patient safety surveillance systems	<b>6.4</b> Patient safety research programmes	<b>6.5</b> Digital technology for patient safety
7		<b>Synergy, partnership and solidarity</b>	<b>7.1</b> Stakeholder engagement	<b>7.2</b> Common understanding and shared commitment	<b>7.3</b> Patient safety networks and collaboration	<b>7.4</b> Cross-geographical and multisectoral initiatives for patient safety	<b>7.5</b> Alignment with technical programmes and initiatives



## Annex 3.

# Patient safety regional profile

## African Region

Number of Member States	: 47
Respondent Member States	: 21
Proportion of regional population covered	: 63%



### Respondent Member States

Benin; Botswana; Burkina Faso; Cabo Verde; Cameroon; Côte d'Ivoire; Ethiopia; Ghana; Guinea; Guinea-Bissau; Kenya; Liberia; Malawi; Mozambique; Namibia; Niger; Nigeria; Seychelles; South Africa; South Sudan; Uganda.

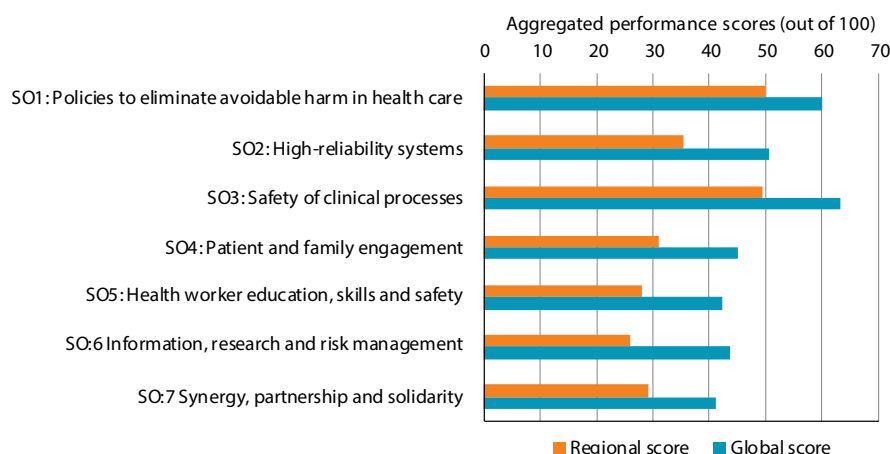
**Table A1a. Income group distribution**

	Respondent Member States	Regional total
High-income countries	1	1
Upper middle-income countries	3	6
Lower middle-income countries	7	18
Low-income countries	10	22

**Table A2a. Patient safety action plan core indicator status**

S. No.	Core indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	20%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	19%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	19%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	19%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	16%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	14%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	15%	18%
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	5%	32%
9.	Proportion of countries that publish an annual report on patient safety	0%	18%
10.	Proportion of countries that have established a national patient safety network	0%	21%

► Fig. A1a. Regional aggregated score card against strategic objectives (SOs)



The WHO African Region shows varying levels of achievement across the global patient safety action plan strategic objectives (Fig. A1a). The region's strongest performances are in establishing policies to eliminate avoidable harm in health care (SO1) with an aggregated score of 50 (out of 100). However, there is notable need for improvement in areas such as health worker education, skills and safety (SO5), and information, research and risk management (SO6), with scores of 28 and 26 respectively.

## Situational analysis



### Progress

Patient safety is increasingly recognized as important, with half of the countries identifying it as a priority within their national health policies. A significant number have enacted laws for mandatory licensing of health care facilities and for the authorization of medical products. Safety standards have been defined and included in the criteria for licensing health care facilities in 35% of countries, and 55% assess health service safety standards. Additionally, most countries commemorate World Patient Safety Day, and 57% have appointed a national patient safety officer, indicating a structured approach towards improving patient safety.



### Challenges

Despite the progress, patient safety challenges are substantial. Only a quarter of countries have developed a comprehensive patient safety policy and strategy, and even fewer have a dedicated action plan. Specific financial and human resource allocations for patient safety are notably lacking, with only 10% of countries having a designated budget line. Legal protections for health workers reporting safety incidents are scarce, potentially inhibiting a culture of transparency and improvement. Furthermore, there is a clear need for enhanced mechanisms for reporting 'never' or sentinel events, with only a small percentage of countries having functional systems in place.



### Opportunities

The current landscape presents several opportunities for advancement in patient safety in the African Region. There is considerable scope for increasing budget allocations and developing long-term resources to support patient safety programmes. Strengthening support for health workers through improved legal protections and establishing more robust reporting and alert systems could significantly enhance patient safety. Building upon the existing infrastructure for infection prevention and control could serve as a foundation for broader patient safety initiatives. Finally, by

engaging patient networks and civil society, and enhancing health worker education, countries can create more resilient health systems that are better equipped to handle patient safety challenges.

## Strategic objective 1.

### Policies to eliminate avoidable harm in health care

- **50%** of countries in the region have recognized patient safety as a priority in their national health policy.
- **25%** have developed a patient safety policy and strategy, while **20%** have developed a national patient safety action plan. Only **15%** have established a national patient safety programme.
- **10%** have a budget line in the national health budget for patient safety, however, no countries report having mobilized adequate financial and human resources to support a patient safety programme in the long term.
- **60%** have established laws for mandatory licensing of health care facilities and authorization of medical products; **15%** of countries have dedicated legislation addressing patient safety as part of health service delivery.
- **30%** have regulations for health data protection and confidentiality, although only **5%** provide legal protection to health workers who report patient safety incidents.
- **35%** have defined minimum safety standards and included them in criteria for licensing of health care facilities; **55%** have included safety standards as criteria for health service assessments; **45%** have defined safety standards for specific clinical services (e.g. radiotherapy, dialysis, transfusion services, surgical services, emergency service).
- **60%** of countries celebrate World Patient Safety Day, and **40%** launched an aligned national campaign. **15%** report prioritizing and implementing WHO Global Patient Safety Challenges nationally.

## Strategic objective 2.

### High-reliability systems

- **14%** of participating countries have included a culture of safety as a key intervention in their health programmes; **19%** of countries have legislation that establishes a patient safety institutional framework.
- **19%** report having a functional system to report never or sentinel events, and **9%** have an administrative mechanism in place to protect people who report adverse events; only **5%** report having periodic surveys and assessments on organizational safety culture.
- **57%** report having a national patient safety officer, and **33%** have a national body to coordinate patient safety activities.
- **19%** recognize leadership capacity building as a key strategy in patient safety programmes; with less than **10%** report having leadership capacity-building initiatives among clinical and managerial leaders, and/or development of resources for capacity development.
- Low reporting (**5%**) on expertise and training opportunities around the application of human factor principles to improve patient safety. Structural safety norms and codes were reported as being enforced in all health care facilities of **14%** of countries, and non-structural safety norms in **24%**.
- **19%** report that all known and potential threats to a safe and functional health system have been identified, and a risk mitigation strategy has been developed for these.
- **29%** report that patient safety has been incorporated into health emergency preparedness and response, and **19%** countries have a real time alert system for imminent patient safety risks.

### Strategic objective 3.

#### Safety of clinical processes

- **10%** of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and have patient safety improvement initiatives to address major sources of harm during care.
- **15%** have a programme to improve patient safety across each discipline and health programme, as well as mechanisms in place to disseminate lessons learned from safety and risk management programmes.
- **14%** have taken actions to improve medication safety in selected situations (i.e. transitions in care, high-risk situations and polypharmacy), and **19%** have a reporting mechanism in place to report adverse drug events and medication errors.
- **10%** or less have a national expert group to implement the third WHO Global Patient Safety Challenge: Medication Without Harm and/or initiatives to enhance patient awareness around safe medication.
- **23%** have a mechanism for measuring medication-related harm, and **19%** have set a national target for reduction of medication-related harm.
- **43%** have a national programme for infection prevention and control (IPC); **38%** have guidelines in place to prevent and control health care-associated infections, and provide IPC training to all health workers. **19%** of countries have a system in place to monitor compliance with IPC guidelines.
- **48%** have a programme to assure the safety of medicines; **62%** have a national blood programme.
- Standard operating procedures around safe transitions in care and continuity of care exist in **15%** of countries; **20%** have included patient safety interventions in primary care services.

### Strategic objective 4.

#### Patient and family engagement

- **20%** of participating countries have identified patient networks and civil society organizations who work on patient safety and patient engagement, and **10%** have formally included patient representatives to national/subnational committees.
- **45%** have developed a national patient rights charter, with safe care as a core component; **16%** have patient representatives appointed to the boards of at least **60%** health care facilities.
- **14%** have mechanisms to gather feedback from patients and their families on safety and quality of care.
- **5%** have initiatives to document patients' stories of harm and unsafe care that aim to incorporate feedback to health system design; **5%** recognize the role of patients in improved patient safety and have developed technical and educational resources to improve patient advocates' capacities.
- **26%** have national guidance around informed consent; **10%** or less have procedures in place to give patients access to their medical records, to disclose adverse events to patients and families, and to provide psychological support to patients and health workers following an adverse event.
- Less than **10%** of the region's countries have made investments in enhancing public knowledge on the subject of patient safety, and exploring digital technologies to better engage patients and families in safe care.

## Strategic objective 5.

### Health worker education, skills and safety

- 5% of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- 10% have incorporated patient safety in medical undergraduate curricula, and 14% have included it in postgraduate medical curricula.
- 19% have incorporated health worker safety into in-service training for health professionals.
- 14% have a national institution designated for the provision of education and training in patient safety; and 10% report having subnational training centres.
- 10% of countries have defined patient safety core competencies for health care professionals, linked with licensing procedures for health workers, and this competence is strengthened through in-service refresher trainings.
- 38% have a periodic performance appraisal system for all categories of health professionals; 5% have a linked system where credits for participating in patient safety count training towards in-service professional development programmes.
- 15% of countries have endorsed and signed the WHO health worker safety charter; 19% have a national programme on occupation health and safety of health workers and vaccinate all at-risk health workers against preventable infections as per national policy.

## Strategic objective 6.

### Information, research and risk management

- 10% of participating countries have a system to define and classify patient safety incidents, and 15% use a standardized format for reporting incidents, aligned with WHO model around classification and incident reporting.
- Less than 10% report consistent use of patient safety incident reporting across health facilities, or the dissemination of regular alerts on major sources of patient risk and harm based on analysis incident reports.
- 19% have incorporated patient safety indicators into their health information systems; 5% report the presence of an accountability mechanism to improve indicators on patient safety.
- 10% have an independent mechanism in place to investigate sentinel events or cases of severe harm; 5% have periodic assessments of patient safety processes and practices at health care facilities.
- 10% report using evidence from international and national research to inform policy and practice decisions; no countries reported investments in routinely identifying priority research areas at the local/national level, adequate resource allocation for patient safety research, translational or implementation research on patient safety.
- 5% of countries have identified emerging technologies that can improve safety of health services, and have created a digital health strategy that has a strong focus on patient safety.

## Strategic objective 7.

### Synergy, partnership and solidarity

- 19% of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety, and 20% have conducted a stakeholder analysis to understand how engagement, contributions and knowledge exchange can be strengthened.

- **10%** have developed a mechanism for coordinating the engagement of different categories of stakeholders and improving synergy through the engagement of private sectors.
- **10%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety, and have defined national goals and targets aligned with the global patient safety targets.
- **5%** report that patient safety is a priority agenda topic in high-level strategic and policy discussions, and **24%** report that the participation of high-level political leaders (ministers or equivalent) is ensured during high-level discussions and summits on patient safety.
- **19%** share best practices and innovative solutions on global and regional platforms; **5%** participate in global patient safety incident reporting systems.
- **29%** of countries have integrated patient safety strategies into all relevant programmes and disciplines (e.g. surgical safety, IPC, blood safety etc.), and **5%** have incorporated these into health system strengthening programmes (e.g. water, sanitation, occupation health etc.)

## Suggestions for improvement

- **Increased budgeting:** Allocate more national and local funds for patient safety programmes, ensuring the availability of financial and human resources for long-term sustainability.
- **Support for health workers:** Enhance legal protections for health workers, prevent punitive actions when reporting adverse incidents, and provide well-being and psychological support.
- **Awareness of WHO Global Patient Safety Challenges:** Raise awareness about the WHO Global Patient Safety challenges and implement these standards nationally.
- **Investment in incident reporting:** Consistently invest in systems for reporting patient safety incidents and adverse events. This includes developing functional systems for reporting critical incidents, conducting periodic surveys, and assessing organizational safety culture in real time.
- **Training and skills building:** Increase investment in training to develop expert groups. These groups should assess clinical practices that may contribute to harm and develop initiatives to improve patient safety.
- **Feedback from patients and families:** Implement more mechanisms to gather feedback from patients and their families on safety and quality of care. Use this feedback in health care design and delivery, and educate patients and families about patient safety.
- **Standard operating procedures:** Develop standard operating procedures for high-risk situations, such as during care transitions, to ensure continuity and safety.
- **Education and training:** Integrate patient safety components into medical and health care education curricula. Recognize patient safety as a core competence for health care professionals, incorporating it into licensing and in-service training.
- **Integration of patient safety and quality of care Programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

# Region of the Americas

Number of Member States	:	36
Respondent Member States	:	21
Proportion of regional population covered	:	81%



## Respondent Member States

Argentina; Belize; Bolivia (Plurinational State of); Brazil; Canada; Chile; Colombia; Costa Rica; Cuba; Dominican Republic; Ecuador; El Salvador; Guyana; Haiti; Jamaica; Panama; Paraguay; Peru; Trinidad and Tobago; United States of America; Uruguay.

**Table A1b. Income group distribution**

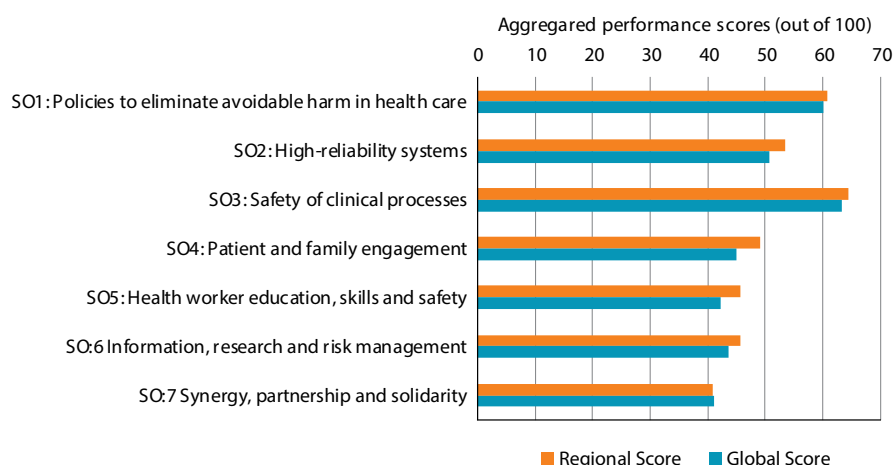
	Respondent Member States	Regional total
High-income countries	6	11
Upper middle-income countries	12	19
Lower middle-income countries	3	5
Low-income countries	0	0
Not classified	0	1

**Table A2b. Patient safety action plan core indicator status**

S. No.	Core indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	24%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	42%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	5%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	43%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	10%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	25%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	25%	18%
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	32%	32%
9.	Proportion of countries that publish an annual report on patient safety	25%	18%
10.	Proportion of countries that have established a national patient safety network	20%	21%



► Fig. A1b. Regional aggregated score card against strategic objectives (SOs)



In the WHO Region of the Americas, reported achievement of the global patient safety action plan strategic objectives was varied. The safety of clinical processes (SO3) scores highest at **65** (out of 100). Policies to eliminate avoidable harm in health care also scores relatively well at **61** (SO1), indicating that the foundational policy framework is in place. However, high-reliability systems (SO2) need improvement, with an aggregate score of **53**, pointing towards the need for more robust, resilient health systems. Patient and family engagement, health worker education, and information management all score below **50**. The lowest aggregate score is for synergy, partnership, and solidarity (**41**) (SO7), which suggests a critical need for better collaboration and integration among stakeholders to bolster patient safety efforts.

## Situational analysis



### Progress

Patient safety has been acknowledged as important in the national health policies by **57%** of countries, and a substantial number report taking legislative steps to enforce health care facility licensing and medical product authorization. There is also a commendable compliance with regulations for health data protection and confidentiality. The celebration of World Patient Safety Day by **60%** of countries in the region, and the implementation of WHO Global Patient Safety Challenges nationally by **33%** reflect growing awareness and commitment to patient safety. Furthermore, over half of the countries have established minimum safety standards for health care facilities, and there is a solid foundation in infection control programmes and medication safety.



### Challenges

However, the region faces significant challenges. Only a small fraction of countries have allocated specific budget lines or human resource plans for patient safety, indicating a gap in long-term sustainability. Legal protection for health workers reporting safety incidents is notably low, potentially affecting incident reporting and systemic improvements. Leadership capacity building and the application of human factor principles in patient safety are also areas needing more attention, alongside improvement in patient safety across disciplines and health programmes, which remains limited.



### Opportunities

Opportunities for enhancing patient safety are evident in the Region of the Americas. There is potential for increasing patient and family engagement in safety initiatives and incorporating their feedback into health care design, as current involvement is low. Education and training can be improved, with opportunities to further integrate the WHO Patient

safety curriculum into medical education and to expand specialized in-service training. Information management can be improved through more consistent incident reporting and research investment. Lastly, synergy and partnerships can be strengthened, with stakeholder engagement and alignment of patient safety actions across technical health programmes offering a pathway to more cohesive patient safety strategies.

## Strategic objective 1.

### Policies to eliminate avoidable harm in health care

- **57%** of participating countries have recognized patient safety as a priority in their national health policies and strategies.
- **48%** have developed a patient safety policy and strategy, and **43%** have a functional national patient safety programme; **24%** have developed a national patient safety action plan.
- **14%** have a budget line in the national health budget for patient safety, and **15%** have mobilized adequate financial support to sustain a patient safety programme in the long term. Less than **10%** of countries report having a human resources plan in place for patient safety, or having taken adequate measures to fill human resource gaps for patient safety.
- **80%** have established laws for mandatory licensing of health care facilities and authorization of medical products; **37%** of countries have dedicated legislation addressing patient safety as part of health service delivery.
- **84%** have regulations for health data protection and confidentiality; although only **11%** provide legal protection to health workers who report patient safety incidents.
- **62%** have defined minimum safety standards; **47%** have included them in criteria for licensing of health care facilities; **55%** have included safety standards as criteria for health service assessments; **45%** have defined safety standards for specific clinical services (e.g. radiotherapy, dialysis, transfusion services, surgical services, emergency service).
- **43%** of countries celebrate World Patient Safety Day, and **25%** launched an aligned national campaign aligned with the theme. **33%** report prioritizing and implementing WHO Global Patient Safety Challenges nationally, and **14%** conduct regular monitoring on progress on challenge implementation.

## Strategic Objective 2.

### High-reliability systems

- **26%** of participating countries in the region have included a culture of safety as a key intervention in their health programmes; **24%** have periodic surveys and assessments on organizational safety culture, and **17%** have accountability mechanisms to promote a 'just culture'.
- **42%** report having a functional system to report never or sentinel events; **16%** have an administrative mechanism in place to protect people who report adverse events.
- **63%** report having a national patient safety officer, and a national body to coordinate patient safety activities; **32%** have functional subnational patient safety committees.
- **47%** recognize leadership capacity building as a key strategy in patient safety programmes; **32%** report having developed resource materials to build leadership capacity, while about **21%** report having focused initiatives among clinical and managerial leaders, and **11%** have a centre dedicated to building leadership capacity in patient safety.
- **33%** provide training opportunities around the application of human factor principles in the patient safety context to their health care professionals and managers; **6%** have an expert group on the subject.

- Structural safety norms and codes were reported as being enforced in all health care facilities of **42%** of countries, and non-structural safety norms in **50%**.
- **35%** report that all known and potential threats to a safe and functional health system have been identified, and **25%** have developed a risk mitigation strategy for these threats.
- **30%** of countries report that patient safety has been incorporated into health emergency preparedness and response, and have a real time alert system for imminent patient safety risks.

### Strategic objective 3.

#### Safety of clinical processes

- **38%** of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and **45%** have patient safety improvement initiatives to address major sources of harm during care.
- **19%** have a programme to improve patient safety across every discipline and health programme.
- **10%** have taken actions to improve medication safety in selected situations (i.e. transitions in care, high-risk situations and polypharmacy), and established a national level expert group on the third WHO Global Patient Safety Challenge: *Medication Without Harm*.
- **55%** have a reporting mechanism in place to report adverse drug events and medication errors; **25%** have initiatives to enhance patient awareness around safe use of medicines.
- **33%** have a mechanism for measuring medication-related harm, and **5%** have set a national target for reduction of medication-related harm
- **62%** have a national programme for infection prevention and control (IPC); **52%** have guidelines in place to prevent and control health care-associated infections. **43%** countries have a system in place to monitor compliance with IPC guidelines.
- **70%** have policies and regulatory frameworks in place for assuring the safety of medicines, vaccines, blood and blood products and medical devices; **65%** countries have a programme to assure the safety of medicines.
- Standard operating procedures around safe transitions in care and continuity of care exist in **30%** of countries; **26%** have included patient safety interventions in mental health care.

### Strategic objective 4.

#### Patient and family engagement

- **19%** of participating countries have identified patient networks and civil society organizations who work on patient safety and patient engagement, and **14%** have formally included patient representatives to national/subnational committees.
- **24%** include patient and family engagement in assessment criteria for health care facilities; **48%** have developed a national patient rights charter, with safe care as a core component.
- **71%** have mechanisms to gather feedback from patients and their families on safety and quality of care; and **35%** incorporate patient feedback into health care design and delivery.
- **33%** recognize the role of patients in improved patient safety; **19%** have established a 'patients for patient safety' network, including patient advocates and civil society organizations.
- **85%** have national guidance around informed consent; **25%** have procedures in place to disclose adverse events to patients and families.
- **30%** of countries have invested in enhancing health literacy on the subject of patient safety.

## Strategic objective 5.

### Health worker education, skills and safety

- 24% of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- 20% have incorporated patient safety in medical undergraduate curricula, and 25% have included it in postgraduate medical curricula; specialized courses for in-service training of health workers on patient safety have been developed and offered in 30% of countries.
- 25% have a national institution designated for the provision of education and training in patient safety, and 20% have a pool of master trainers to conduct training on patient safety.
- 25% countries have defined patient safety core competencies for health care professionals; and 5% have patient safety as a core competence for licensing and re-licensing of health care professionals.
- 40% have a periodic performance appraisal system for all categories of health professionals; 21% have a linked system where credits for participating in patient safety training count towards in-service professional development programmes.
- 25% of countries have endorsed and signed the WHO health worker safety charter; 40% provide mental and social support to health workers, and 50% have a national programme on occupational health of health workers.

## Strategic objective 6.

### Information, research and risk management

- 35% of participating countries have a system to define and classify patient safety incidents, and 30% use a standardized format for reporting aligned with WHO protocol around classification and incident reporting.
- 30% have designated an institution to coordinate patient safety incident reporting and learning, aligned with WHO protocols; 32% report, majority of their health-care facilities participate in a patient safety incident reporting and learning
- 25% publish an annual report on patient safety performance; 25% have an accountability mechanism in place to improve indicators on patient safety.
- 35% have an independent mechanism in place to investigate sentinel events or cases of severe harm, and have periodic assessments of patient safety processes and practices at health care facilities.
- 15% report routinely identifying priority areas for research around patient safety; and 10% invest in translational or implementation research on patient safety.
- 20% of countries have a digital health strategy that includes a strong focus on patient safety, and 25% have a surveillance system to assess the safety of information technology products that are used for clinical and diagnostic purposes.

## Strategic objective 7.

### Synergy, partnership and solidarity

- 43% of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety; 35% have conducted a stakeholder analysis to understand how engagement, contributions and knowledge exchange can be strengthened.
- 26% have developed a mechanism for coordinating the engagement of different categories of stakeholders.

- **10%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety; **14%** have defined national goals and targets aligned with the global patient safety targets.
- **20%** report that consultations have been organized on the implementation of the Global patient safety action plan, and that a national patient safety network has been established.
- **30%** share best practices and innovate solutions on global and regional platforms; **15%** participate in global patient safety incident reporting systems.
- **25%** of countries have mapped patient safety actions for potential alignment with technical health programmes and clinical risk areas; and **20%** have integrated patient safety strategies into safety-related programmes (e.g. surgical safety, injection safety, radiation safety, IPC, blood safety, vaccination safety).

## Suggestions for improvement

- **Resource allocation:** Boosting national and local budgeting for patient safety is crucial to ensure the long-term availability of both financial and human resources.
- **Health worker support:** Implementing greater support mechanisms for health workers, including legal protections and well-being initiatives, is essential to encourage the reporting of adverse incidents without fear of punitive action.
- **Safety culture:** There is a need to invest in fostering a 'culture of safety' and 'just culture' within health systems. This involves raising awareness, implementing measures to safeguard health workers and conducting regular safety culture surveys.
- **Leadership capacity:** Initiatives should be developed to enhance leadership capacity in patient safety among clinical and managerial staff, and to instil patient safety through leadership among young professionals.
- **Risk management:** Systems should be put in place to assess all potential threats to health systems and to develop comprehensive risk mitigation strategies.
- **Medication safety:** A sharper focus is needed on medication safety, including measures to assess harm, especially in high-risk situations and care transitions.
- **Patient engagement:** Mechanisms for gathering patient and family feedback on the patient safety and quality of care should be expanded, with efforts to integrate this feedback into health care design and delivery, alongside enhancing patient and family awareness about patient safety.
- **Education and training:** Patient safety should be incorporated more thoroughly into medical and health care education curricula, with patient safety recognized as a core competence for health care professionals in licensing and ongoing training.
- **Integration of patient safety and quality of care Programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

# South-East Asia Region

Number of Member States	: 11
Respondent Member States	: 11
Proportion of regional population covered	: 100%



## Respondent Member States

Bangladesh; Bhutan; Democratic People's Republic of Korea; India; Indonesia; Maldives; Myanmar; Nepal; Sri Lanka; Thailand; Timor-Leste.

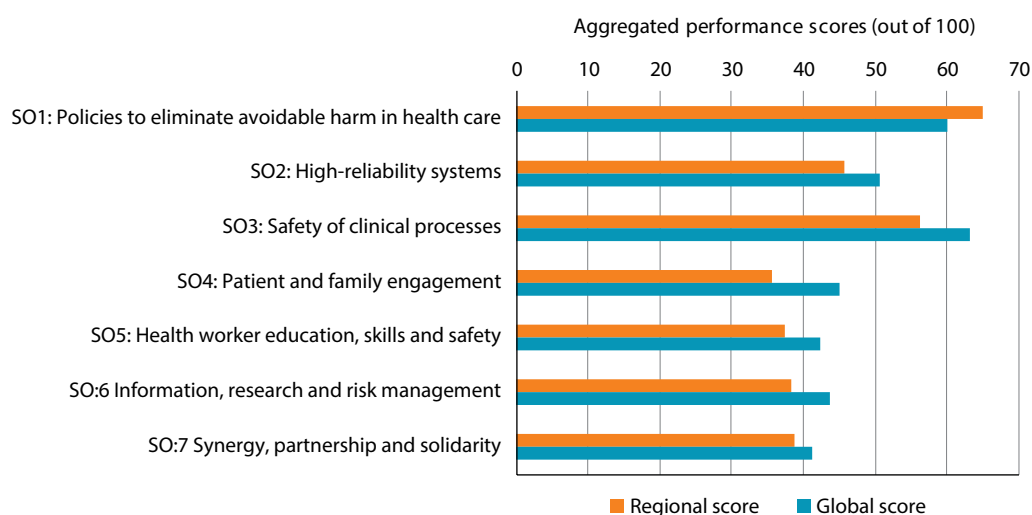
**Table A1c. Income group distribution**

	Respondent Member States	Total
High-income countries	0	0
Upper middle-income countries	2	2
Lower middle-income countries	8	8
Low-income countries	1	1

**Table A2c. Patient safety action plan core indicator status**

S. No.	Core Indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	46%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	33%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	46%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	9%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	0%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	18%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	20%	18%
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	18%	32%
9.	Proportion of countries that publish an annual report on patient safety	9%	18%
10.	Proportion of countries that have established a national patient safety network	18%	21%

► Fig. A1c. Regional aggregated score card against strategic objectives (SOs)



The regional scores for patient safety objectives reveal a mixed landscape, with the highest score in policies to eliminate avoidable harm in health care (SO1) at **65** (out of 100) and the lowest in patient and family engagement (SO4) at **36**. While clinical processes (SO3) show a moderate performance at **56**, there is a clear need for improvements in high-reliability systems (SO2), health worker education (SO5), information management (SO6), and collaborative partnerships (SO7), all scoring from **36** to **46**.

## Situational analysis



### Progress

There is notable progress in strategic patient safety initiatives across Member States in the region. A significant **82%** of countries have elevated patient safety as a key concern in their health policies. About half of the countries have developed action plans, reflecting a concerted effort towards patient safety. Notably, every country observed World Patient Safety Day, underscoring the universal recognition of the day across the region. There is also a substantial commitment to the regulation of health care facilities and medical products, with more than half of the countries implementing mandatory licensing laws.



### Challenges

However, several challenges impede the optimization of patient safety measures. Financial and human resource mobilization is a critical concern, with only **9%** reporting adequate support for patient safety programmes. In terms of legal protection for health workers less than half of the countries have appropriate regulations in place, which can discourage the reporting of safety incidents. A lack of expertise in applying human factor principles and a limited presence of safety norms and codes are also significant hurdles. Moreover, patient and family engagement, as well as health worker education and training on patient safety, remain notably low, suggesting a gap in incorporating comprehensive stakeholder perspectives and expertise.



### Opportunities

Opportunities for enhancement are evident. There is room for growth in developing real-time alert systems for patient safety risks, which currently exist in only **27%** of countries. Improving support mechanisms for health workers, such as psychological support and occupational health programmes, also presents an area for development. Increasing



the adoption of the WHO Patient safety curriculum and building a culture of safety within health programmes are critical steps forward. Furthermore, investing in research, especially at the local/national levels, and leveraging emerging technologies can provide significant advancements in patient safety. Establishing stronger partnerships and better-defined roles among stakeholders, including private sector involvement, could further augment patient safety initiatives.

## Strategic objective 1.

### Policies to eliminate avoidable harm in health care

- **82%** of participating countries have prioritized patient safety as a priority in the national health policy.
- **46%** have developed a patient safety action plan, while **27%** have an established patient safety programme.
- **36%** have a budget line in the national health budget for patient safety, although only **9%** report having mobilized adequate financial and human resources plan to support a patient safety programme.
- **27%** have a recognition and reward mechanism in place to promote improvement of patient safety.
- **55%** have established laws for mandatory licensing of health care facilities, and **82%** authorization of medical products.
- Regulations for health data protection and confidentiality have been implemented in **46%** of countries; **18%** provide legal protection to health workers who report patient safety incidents.
- **50%** have defined minimum safety standards and included them in criteria for licensing of health care facilities and health service assessments; **30%** have defined safety standards for specific clinical services.
- **100%** of countries celebrated World Patient Safety Day, and **90%** launched an aligned national campaign. Meetings with stakeholders and social media campaigns were the most reported activities to observe the day.

## Strategic objective 2.

### High-reliability systems

- **30%** of participating countries have included a culture of safety as a key intervention in health programmes.
- **20%** have an administrative mechanism in place to protect people who report adverse events; **33%** report having a functional system to report never or sentinel events.
- **10%** have taken steps to establish a patient safety institutional framework.
- **40%** have a national body to coordinate patient safety activities, however there are no functional subnational patient safety committees.
- **10%** report that a centre for development of leadership capacity has been established.
- No country in the region has established an expert group to advise on application of human factor principles to improve patient safety, although **20%** of countries provide training to health professionals on human factors.
- **27%** enforce structural safety norms and codes in all health care facilities, and **36%** enforce non-structural safety norms.
- **27%** reported that all known and potential threats to a safe and functional health system have been identified.
- **40%** reported that a risk mitigation strategy has been developed for known and potential threats, and **46%** reported that patient safety has been incorporated into health emergency preparedness and response.
- **27%** of countries have a real time alert system for imminent patient safety risks.

### Strategic objective 3.

#### Safety of clinical processes

- 27% of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and have patient safety improvement initiatives to address major sources of harm during care.
- 18% have a programme to improve patient safety across every discipline and health programme; 18% have a repository of lessons learned and mechanisms for safety and risk management through knowledge and tool dissemination.
- The most reported patient safety improvement initiatives have been around medical errors and surgical complications; the health specialties that have received the highest training around patient safety are obstetrics and gynaecology, and surgical care.
- 36% have taken actions to improve medication safety in the three priority areas of the third WHO Global Patient Safety Challenge, and 27% have a national expert group to implement the Challenge.
- 46% have a reporting mechanism in place to report adverse drug events and medication errors; 55% have a mechanism for measuring medication-related harm, and 46% have set a national target for its reduction and defined related indicators.
- 36% have a national programme for infection prevention and control (IPC); 27% have a system to monitor compliance with IPC guidelines; 18% have a system for surveillance of health care-associated infections.
- 36% have estimated the burden of health care-associated infection, and surgical site infections are reported as the highest contributors.
- 46% have a programme to assure the safety of medicines; 70% have a national blood programme; 27% have a programme for the safety of medical devices and technologies.
- Standard operating procedures around safe transitions in care and continuity of care exist in 18% of countries.
- 18% of countries have included patient safety interventions in primary care services, and in mental health care.

### Strategic objective 4.

#### Patient and family engagement

- 18% of participating countries have identified patient networks and civil society organizations who engage on patient safety, and 9% have formally included patient representatives to national/subnational committees.
- 27% have developed a national patient rights charter, with safe care as a core component.
- 91% have mechanisms to gather feedback from patients and their families on safety and quality of care; 9% have initiatives to document patients' experience of harm and unsafe care that aim to incorporate feedback to health system design; however, no initiatives are in place to regularly measure and report on patient-reported incidents of unsafe care.
- 9% recognized the role of patients in improved patient safety, have a 'patients for patient safety' network, and have developed technical and education resources to improve patient advocates' capacities.
- 55% have national guidance around informed consent; 36% have procedures in place to give patients access to their medical records; 20% have procedures to disclose adverse events to patients and families.
- None of the region's countries have made investments in enhancing public knowledge on the subject of patient safety, or in incorporating patient safety elements into school curricula.

## Strategic objective 5.

### Health worker education, skills and safety

- 9% of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- 27% have incorporated patient safety in medical undergraduate curricula, and 18% have included it in postgraduate medical curricula.
- 9% have a national institution designated for the provision of education and training in patient safety; however, no subnational level institutions for this purpose exist, and no centres of excellence or expert group of trainers has yet been invested in.
- 9% have patient safety as a core competence linked to licensing requirements for health workers; 36% of countries have identified overall competences for health care professionals to be authorized to work in clinical specialties.
- 18% have a periodic performance appraisal system for all categories of health professionals, and 10% have a linked system where credits for participating in patient safety training count towards in-service professional development programmes.
- 20% have endorsed and signed the WHO health worker safety charter, and have established programmes or initiatives to provide social and mental well-being support to health workers.
- 40% of countries have a national programme on the occupational health and safety of health workers; 60% provide vaccinations to all at-risk health workers against vaccine-preventable infections and 20% have measures to prevent violence against health workers.

## Strategic objective 6.

### Information, research and risk management

- 36% of participating countries have a system to define and classify patient safety incidents, and use a standardized format for reporting aligned with WHO protocol around classification and incident reporting.
- 18% report that over 60% of their health care facilities participate in patient safety incident reporting; 27% have a system for regular alerts on major sources of patient risk and harm based on analysis of incident reports
- In terms of measurement around patient safety, 27% of countries have identified indicators to monitor patient safety, and incorporated these indicators into their health information systems.
- 18% reporting having an accountability mechanism in place to improve performance on patient safety indicators, and that an independent mechanism has been established to investigate cases of severe harm and sentinel events.
- Periodic assessment of patient safety processes and practices are conducted in 27% countries.
- Baseline studies on the burden of harm of unsafe care have been conducted in 18% countries, and benchmarking programmes have been established to measure indicators of patient safety and quality of care.
- No country has reported to invest in routinely identifying priority research areas at the local/national level, adequate resource allocation for patient safety research, translational or implementation research on patient safety.
- 18% of countries have identified emerging technologies that can improve safety of health services, and have created a digital health strategy that has a strong focus on patient safety.
- 9% of countries have a rigorous assessment protocol for information technology solutions prior to deployment in the health sector, and have a surveillance system in place to assess their safety during clinical and diagnostic processes.

## Strategic objective 7.

### Synergy, partnership and solidarity

- **18%** of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety, and have developed a mechanism for coordinating the engagement of different categories of stakeholders; **9%** have clearly defined roles and responsibilities for each stakeholder.
- **46%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety; **36%** have defined national goals and targets to address patient safety.
- **9%** have encouraged non-governmental and private sector entities to incorporate the patient safety action plan's elements into their own strategic plans.
- **18%** have established a national patient safety network and conducted consultations on how the patient safety action plan can be implemented; and in **9%** of countries patient safety is a priority agenda topic in high-level strategic and policy discussions.
- **18%** have created a mechanism to learn and share best practices with other high-risk industries, and **27%** share best practices and innovate solutions on global and regional platforms.
- **20%** of countries have integrated patient safety strategies into all relevant programmes and disciplines (e.g. surgical safety, IPC, blood safety etc.), and **9%** have incorporated these into health system strengthening programmes (e.g. water, sanitation, occupation health etc.)

### Suggestions for improvement

- **Resource investment:** There is a pressing need for investment in patient safety programmes, requiring support not just from national governments but also international partners and aid organizations. Countries must ensure effective and sustainable patient safety programmes through adequate funding and human resource allocation.
- **Advocacy campaigns:** Regional advocacy efforts should be intensified, leveraging occasions like World Patient Safety Day and the Global Patient Safety Challenges to garner support for expansive patient safety initiatives.
- **Support for health workers:** Enhanced support mechanisms, including legal protections and psychological support for health workers reporting adverse incidents, are essential.
- **Expertise development:** There is a need to address the scarcity of experts and trainers in areas such as human factor principles and medication safety, by identifying opportunities for resource development.
- **Patient involvement:** The formal inclusion of patient safety advocates should be reinforced, and patient experiences with unsafe care should be systematically incorporated into health care system design.
- **Public knowledge and capacity building:** Investment should be directed towards improving public understanding of patient safety, safe care practices, and the process of reporting adverse events.
- **Patient safety education integration:** The WHO Patient safety curriculum guide needs broader integration into medical education and training programmes, alongside amplified investment in patient safety research.
- **Strategic integration and partnerships:** It is crucial to embed patient safety strategies more uniformly into health programmes and system strengthening efforts, fostering partnerships and collaborations among all stakeholders, including government, civil society and the private sector.
- **Integration of patient safety and quality of care programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

# European Region

Number of Member States	:	54
Respondent Member States	:	33
Proportion of regional population covered	:	62%



## Respondent Member States

Armenia; Austria; Azerbaijan; Belgium; Bulgaria; Cyprus; Czechia; Denmark; Estonia; Finland; France; Georgia; Germany; Greece; Iceland; Ireland; Israel; Kazakhstan; Latvia; Luxembourg; Malta; Netherlands (Kingdom of the); North Macedonia; Norway; Poland; Portugal; Romania; Slovakia; Spain; Sweden; Switzerland; Türkiye; United Kingdom of Great Britain and Northern Ireland.

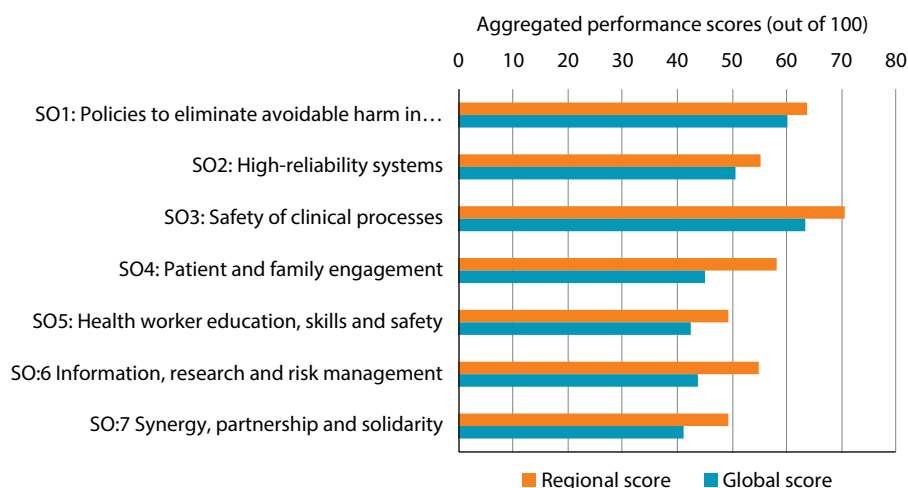
**Table A1d. Income group distribution**

	Respondent Member States	Regional total
High-income countries	26	35
Upper middle-income countries	7	15
Lower middle-income countries	0	4
Low-income countries	0	0

**Table A2d. Patient safety action plan core indicator status**

S. No.	Core indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	33%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	41%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	15%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	27%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	21%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	25%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	7%	18%
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	47%	32%
9.	Proportion of countries that publish an annual report on patient safety	23%	18%
10.	Proportion of countries that have established a national patient safety network	33%	21%

► Fig. A1d. Regional aggregated score card against strategic objectives (SOs)



The regional scores for respective strategic objectives reveal a mixed patient safety landscape. The highest achievement is seen in safety of clinical processes (SO3) with a score of **71** (out of 100), indicating robust systems for managing clinical risks. The score for policies to eliminate avoidable harm (SO1) is also relatively high at **64**, suggesting that policy frameworks are increasingly prioritizing patient safety. However, there is room for improvement in the areas of health worker education (SO5) and synergy, partnership and solidarity (SO7), which both scored **50**. These lower scores highlight the need for enhanced focus on health care education and collaborative efforts to strengthen patient safety. High-reliability systems (SO2), patient and family engagement (SO4), and information, research and risk management (SO6) present moderate scores, indicating some progress combined with the need for continued development in these areas.

## Situational analysis



### Progress

The current state of patient safety in the European Region shows notable progress in several key areas. A significant number of countries have successfully integrated patient safety into their national health policies and strategies, reflecting a growing recognition of its importance. Efforts are evident in the establishment of systems for reporting adverse events, enhancing infection control, and improving medication safety. Additionally, there has been a commendable focus on patient rights, with many countries developing national patient rights charters and mechanisms to gather feedback from patients and their families. The incorporation of patient safety into medical education further underscores the commitment to long-term improvement in this field.



### Challenges

A primary concern is the inadequate allocation of budget and human resources specifically dedicated to patient safety initiatives. This limitation hinders the effective implementation and sustainability of safety programmes. Furthermore, there is a lack of sufficient legal protection for health workers who report safety incidents, which can deter the reporting of such incidents and impede improvement efforts. The variability in the implementation of patient safety frameworks and reporting systems across countries also presents a significant challenge, which may lead to inconsistencies in patient care standards.



### Opportunities

There are several opportunities for enhancing patient safety in the region. Increasing investment in patient safety, both in terms of financial resources and human capital, is crucial for strengthening existing programmes and initiating new

ones. Improving legal protections for health workers who report patient safety incidents can encourage a more open and transparent safety culture. Additionally, there is a significant opportunity to broaden the scope of patient and family engagement in health care. By involving patients and their families more directly in health care decision-making and patient advocacy, health care systems can become more responsive and effective in ensuring safe care.

## Strategic objective 1.

### Policies to eliminate avoidable harm in health care

- **55%** of participating countries have prioritized patient safety in their national health policy.
- **46%** have developed a patient safety policy and strategy and **30%** countries have a functional national patient safety programme in place.
- **18%** have a budget line in the national health budget for patient safety; **15%** have a human resources plan in place to implement the patient safety action plan; and **12%** have taken action to fill human resource gaps at all levels of care.
- **30%** provide legal protection to health workers who report patient safety incidents, to prevent punitive action against them; **42%** have dedicated legislation addressing patient safety issues in health services delivery; **88%** countries have implemented regulations(s) for health data protection and confidentiality.
- **82%** have enacted law(s) for mandatory licensing of health care facilities.
- **67%** have defined minimum safety standards for health care facilities and services, and nearly **49%** have included them in criteria for licensing of health care facilities and health service assessments.
- **61%** of countries have launched a national campaign aligned with World Patient Safety Day; **37%** countries report that Global Patient Safety Challenges are being prioritized and implemented nationally.

## Strategic objective 2.

### High-reliability systems

- **25%** of participating countries have included a culture of safety as a key intervention in health programmes.
- **41%** report having a functional system to report never or sentinel events; **28%** have an administrative mechanism in place to protect people who report adverse events.
- **47%** have legislation that establishes a patient safety institutional framework, with clearly defined roles and processes.
- **50%** have a national body to coordinate patient safety activities, and **19%** have functional subnational patient safety committees.
- **16%** recognized leadership capacity building as a key strategy in improving patient safety and have established leadership capacity-building programmes for clinical and managerial leaders on this subject.
- **31%** provide training to health professionals on human factors, and **6%** report having established an expert group to advise on the application of human factor principles to improve patient safety.
- Structural safety norms and codes were reported as being enforced in all health care facilities of **58%** of countries, and non-structural safety norms in **70%** of countries.
- **18%** reported that all known and potential threats to a safe and functional health system have been identified; **21%** countries reported that a risk mitigation strategy has been developed for identified known and potential threats.
- **21%** of countries have a real-time alert system for imminent patient safety risks.



### Strategic objective 3.

#### Safety of clinical processes

- 36% of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and 55% have patient safety improvement initiatives to address major sources of harm during care.
- 18% have a programme to improve patient safety across every discipline and health programme; 39% countries have taken actions to improve medication safety in selected situations (i.e. transitions in care, high-risk situations and polypharmacy); 24% have a national level expert group on the third WHO Global Patient Safety Challenge: *Medication Without Harm*.
- 70% have a reporting mechanism in place to report adverse drug events and medication errors.
- 70% have a national programme for infection prevention and control; 55% have guidelines in place to prevent and control health care-associated infections.
- 85% have policies and regulatory frameworks in place for assuring the safety of medicines, vaccines, blood and blood products and medical devices.
- Standard operating procedures around safe transitions in care and continuity of care exist in 30% of countries; 12% indicate that patient safety system interventions have been extended to include primary care services.

### Strategic objective 4.

#### Patient and family engagement

- 49% of participating countries have identified patient networks and civil society organizations that engage on patient safety, and 30% have formally included patient representatives to national/subnational committees.
- 52% have developed a national patient rights charter, with safe care as a core component.
- 85% have mechanisms to gather feedback from patients and their families on safety and quality of care; 33% have initiatives to document patients' experience of harm and unsafe care; 30% have taken initiatives to measure and report regularly on patient reported outcomes.
- 36% provide support and acknowledge the role of patient advocates in improved patient safety; 15% have established a 'patients for patient safety' network, including patient advocates and civil society organizations.
- 79% have national guidance around informed consent; 42% have procedures in place to disclose adverse events to patients and families.
- 28% of countries have invested in enhancing public knowledge on the subject of patient safety.

### Strategic objective 5.

#### Health worker education, skills and safety

- 19% of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- 19% have incorporated patient safety in medical undergraduate curricula, and 25% have included it in postgraduate medical curricula.
- 29% have a national institution designated for the provision of education and training in patient safety, and 7% have a pool of master trainers to conduct training on patient safety.
- 36% recognize countries have defined patient safety core competencies for health care professionals; 23% have patient safety as a core competence for licensing and re-licensing of health care professionals.

- **23%** provide refresher trainings and continuing professional development programmes to build competence in patient safety; **10%** have a periodic performance appraisal system covering the subject for all categories of health professionals.
- **14%** have health care managers' performance linked with patient safety and quality of care.
- **7%** of countries have endorsed and signed the WHO health worker safety charter; **29%** provide mental and social support to health workers; and **43%** have a national programme on occupational health.

## Strategic objective 6.

### Information, research and risk management

- **34%** of participating countries have a system to define and classify patient safety incidents and **31%** use a standardized format for reporting aligned with WHO protocol around classification and incident reporting.
- **47%** report that the majority (over **60%**) of their health care facilities participate in a patient safety incident reporting and learning system.
- **34%** have designated an institution to coordinate patient safety incident reporting and learning.
- **26%** have identified indicators to monitor patient safety nationally/subnationally; **14%** have an accountability mechanism in place to measure indicators on patient safety.
- **16%** have an independent mechanism to investigate cases of severe harm and sentinel events.
- **21%** report routinely identifying priority areas for research around patient safety, and **20%** invest in translational and implementation research on patient safety.
- **36%** of countries have a digital health strategy that includes a strong focus on patient safety, and **43%** have a surveillance system to assess the safety of information technology products that are used for clinical and diagnostic purposes.

## Strategic objective 7.

### Synergy, partnership and solidarity

- **42%** of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety; **29%** have conducted a stakeholder analysis to understand how engagement, contributions and knowledge exchange can be strengthened.
- **23%** have developed a mechanism for coordinating the engagement of different categories of stakeholders, and improving synergy through engagement of private sectors.
- **13%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety, and **23%** have defined national goals and targets aligned with the global patient safety targets.
- **26%** report that consultations have been organized on implementation of the patient safety action plan, and **33%** report that a national patient safety network has been established.
- **17%** periodically review progress against the Global patient safety action plan; **33%** countries share best practices and innovative solutions on global and regional platforms.
- **10%** of countries have mapped patient safety actions for potential alignment with technical health programmes and clinical risk areas; **33%** have integrated patient safety strategies into all safety-related programmes (e.g. surgical safety, injection safety, radiation safety, infection prevention and control, blood safety and vaccination safety).

## Suggestions for improvement

- **Financial and human resources:** There is a need for increased national and local budgeting dedicated to patient safety. This includes ensuring long-term availability of financial and human resources to sustain patient safety programmes.
- **Support for health workers:** Enhanced support mechanisms for health workers are crucial. This involves improved legal protection, measures to prevent punitive actions when reporting adverse incidents, and ensuring their occupational health and safety. Additionally, providing well-being and psychological support is essential.
- **Incident reporting and safety culture:** Consistent investments are required in patient safety incident reporting systems and administrative mechanisms to protect those who are reporting adverse events, including functional systems for never or sentinel events. Periodic surveys and assessments should be conducted to evaluate the establishment of an organizational safety culture within the health system. Countries should prioritize the development of interoperable mechanisms to seamlessly integrate existing reporting systems.
- **Leadership and education initiatives:** Building initiatives among clinical and managerial leaders to enhance leadership capacity in patient safety is vital. Creating interventions at early stages of education to instil patient safety thought leadership among young professionals is also important.
- **Risk mitigation and safety focus:** Assessing potential threats to a safe and functional health system and developing risk mitigation strategies, along with real-time alert systems, are paramount. There should be an intensified focus on medication safety, and implementing procedures to minimize harm during high-risk situations and transitions of care. There is a recognized necessity to address the safety implications of medical devices and emerging digital technologies that are rapidly integrating into the health care sector.
- **Patient networks and advocacy:** Leveraging patient networks and civil society organizations to strengthen dialogue and action planning around patient safety is essential. This includes building leadership capacities among patient advocates, recognizing their critical role in patient safety, and establishing a 'patients for patient safety' network.
- **Education and research:** Ensuring that medical and health care education curricula incorporate patient safety training and information is important. Increasing the recognition of patient safety as a core competence for health care professionals, including as part of licensing and in-service training requirements, is necessary. Additionally, greater research around patient safety at the national and local levels should be prioritized.
- **Integration of patient safety and quality of care programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

# Eastern Mediterranean Region

Number of Member States	: 21
Respondent Member States	: 10
Proportion of regional population covered	: 66%



## Respondent Member States

Afghanistan; Iran (Islamic Republic of); Iraq; Lebanon; Oman; Pakistan; Qatar; Saudi Arabia; Sudan; United Arab Emirates.

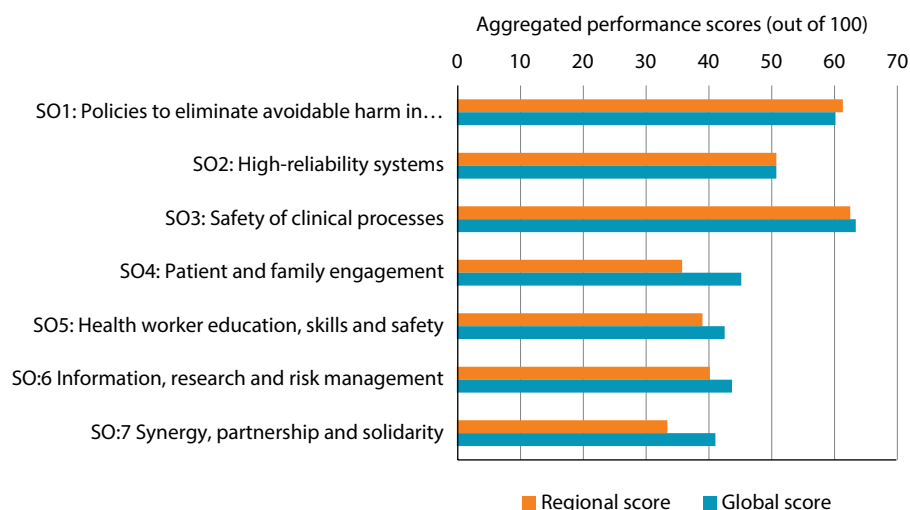
**Table A1e. Income group distribution**

	Respondent Member States	Regional total
High-income countries	4	6
Upper middle-income countries	1	3
Lower middle-income countries	3	7
Low-income countries	2	5

**Table A2e. Patient safety action plan core indicator status**

S. No.	Core indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	10%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	40%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	10%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	40%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	0%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	0%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	20%	18%
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	30%	32%
9.	Proportion of countries that publish an annual report on patient safety	10%	18%
10.	Proportion of countries that have established a national patient safety network	0%	21%

► Fig. A1e. Regional aggregated score card against strategic objectives (SOs)



The highest score is achieved in the domain of safety of clinical processes (SO3) with **62** (out of 100), suggesting that substantial efforts made to make clinical processes safe. Policies to eliminate avoidable harm in health care (SO1) also scores fairly highly at **61**, indicating proactive policy-making. High-reliability systems (SO2) have a moderate score of **51**. However, there is considerable room for improvement in areas such as patient and family engagement (SO4), health worker education, skills and safety (SO5), and information, research and risk management (SO6), with scores between **30** and **40**. The lowest score is in synergy, partnership and solidarity (SO7) at **33**, highlighting a significant need for better collaboration and partnership for patient safety initiatives. These scores can guide targeted improvements where they are most needed.

## Situational analysis

### Progress

The Eastern Mediterranean Region shows commitment to patient safety with a substantial number of countries actively participating in World Patient Safety Day, indicating an effort to raise public awareness. The region also actively addressing the three early priority areas of the Medication Without Harm challenge. There is a notable establishment of functional national patient safety programmes, with **36%** of countries implementing them effectively. The presence of infection control programmes in the region is substantially higher than the global average. Defining safety standards for health care facilities shows progress in creating safer health care environments.

### Challenges

Despite these efforts, the region grapples with considerable challenges. Patient safety has not been widely prioritized in national health policies, and the development of dedicated patient safety strategies is lacking, with only a minority of countries having comprehensive policies in place. Resource allocation for patient safety is insufficient, evidenced by the low number of countries with specific budget lines or human resources plans. Additionally, legal protections for health workers who report safety incidents potentially inhibiting the reporting culture necessary for systemic improvements. The incorporation of patient safety into medical education is also notably deficient, indicating a gap in the foundational training of health care professionals.



## Opportunities

Opportunities for enhancing patient safety in the region are evident. There is potential for improvement in establishing clear legal frameworks and enhancing financial commitment to support robust patient safety programmes. Strengthening training and education on patient safety for health workers and improving the reporting and learning from safety incidents can also lead to substantial improvements. Moreover, increasing patient and family engagement in patient safety, developing performance appraisal systems focused on safety, and building synergies and partnerships can further bolster patient safety initiatives. The integration of patient safety strategies into all safety-related programmes represents a significant opportunity for a more comprehensive approach to patient safety across the region.

### Strategic objective 1.

#### Policies to eliminate avoidable harm in health care

- **20%** of participating countries have prioritized patient safety as a priority in the national health policy.
- **10%** have developed a patient safety policy and strategy and **40%** have a functional national patient safety programme in place.
- **30%** have a budget line in the national health budget for patient safety; **10%** have a human resources plan in place to implement the Global patient safety action plan.
- **10%** provide legal protection to health workers who report patient safety incidents, **20%** countries have dedicated legislation addressing patient safety issues in health services delivery.
- **50%** have defined minimum safety standards for health care facilities and services, and have included them in criteria for licensing of health care facilities.
- **80%** of countries have launched a national campaign aligned with Global World Patient Safety Day; **30%** countries report that Global Patient Safety Challenges are being prioritized and implemented nationally.

### Strategic objective 2.

#### High-reliability systems

- **30%** of participating countries have included a culture of safety as a key intervention in health programmes.
- **40%** report having a functional system to report never or sentinel events, and have an administrative mechanism in place to protect people who report adverse events.
- **20%** have established a patient safety institutional framework.
- **50%** have a national body to coordinate patient safety activities, and **20%** have functional subnational patient safety committees.
- **30%** recognized leadership capacity building as a key strategy in improving patient safety; **20%** have established leadership capacity-building programmes for clinical and managerial leaders on this subject.
- Structural safety norms and codes were reported as being enforced in all health care facilities of **40%** of countries, and non-structural safety norms in **50%**.
- **10%** reported that all known and potential threats to a safe and functional health system have been identified and reported that a risk mitigation strategy has been developed for identified known and potential threats.
- **20%** of countries have a real time alert system for imminent patient safety risks.

### Strategic objective 3.

#### Safety of clinical processes

- **20%** of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and **50%** have patient safety improvement initiatives to address major sources of harm during care.
- **10%** have a programme to improve patient safety across every discipline and public health programme.
- **40%** have taken actions to improve medication safety in selected situations (i.e. transitions in care, high-risk situations and polypharmacy), and **18%** have a national level expert group on the third WHO Global Patient Safety Challenge: Medication Without Harm.
- **50%** have a reporting mechanism in place to report adverse drug events and medication errors in facilities.
- **80%** have a national programme for infection prevention and control; **56%** have guidelines in place to prevent and control health care-associated infections.
- **60%** have policies and regulatory frameworks in place for assuring the safety of medicines, vaccines, blood and blood products, and medical devices.
- Standard operating procedures around safe transitions in care and continuity of care exist in **20%** countries, and same number indicate that patient safety system interventions have been extended to include primary care services.

### Strategic objective 4.

#### Patient and family engagement

- No participating countries have identified patient networks and civil society organizations who engage on patient safety, although **10%** reporting having formally included patient representatives to national/subnational committees.
- **40%** of countries have developed a national patient rights charter, with safe care as a core component.
- **90%** have mechanisms to gather feedback from patients and their families on safety and quality of care; **10%** have taken initiatives to measure and report regularly on patient reported outcomes.
- **10%** provide support and acknowledge the role of patient advocates in improved patient safety, and have developed educational and technical resources to build capacities of patient advocates.
- **80%** have national guidance around informed consent; over **50%** give patients access to their medical records, however only **10%** have procedures in place to disclose adverse events to patients and families.
- **20%** of countries have invested in enhancing public knowledge on the subject of patient safety.

### Strategic objective 5.

#### Health worker education, skills and safety

- **20%** of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- No countries report having incorporated patient safety in undergraduate or postgraduate professional curricula.
- **10%** of countries have a national institution designated for the provision of education and training in patient safety, and have a pool of master trainers to conduct training on patient safety.



- **20%** of countries have defined patient safety core competencies for health care professionals; **20%** of countries provide refresher trainings and continuing professional development programmes to build competence in patient safety.
- **30%** have a periodic performance appraisal system covering the subject for all categories of health professionals; **10%** countries report that participation in patient safety programmes and initiatives is included in health care professionals' performance evaluations.
- **20%** of countries have endorsed and signed the WHO health worker safety charter; **40%** provide mental and social support to health workers, and same proportion have a national programme on occupational health.

## Strategic objective 6.

### Information, research and risk management

- **30%** of participating countries have a system to define and classify patient safety incidents and **40%** use a standardized format for reporting aligned with WHO protocols around classification and incident reporting.
- **30%** report that the majority (over **60%**) of their health care facilities participate in a patient safety incident reporting and learning system.
- **30%** have identified indicators to monitor patient safety nationally/subnationally; **20%** have an accountability mechanism in place to measure indicators on patient safety.
- **40%** have an independent mechanism to investigate cases of severe harm and sentinel events.
- **10%** report routinely identifying priority areas for research around patient safety, and **30%** use evidence from existing international and national research to make critical policy and practice decisions.
- **22%** of countries have a digital health strategy that includes a strong focus on patient safety, and **30%** have a surveillance system to assess the safety of information technology products that are used for clinical and diagnostic purposes.

## Strategic objective 7.

### Synergy, partnership and solidarity

- **30%** of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety. No mechanisms have been developed for coordinating the engagement of different categories of stakeholders, and improving synergy through engagement of private sectors.
- **10%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety, and **20%** have defined national goals and targets aligned with the global patient safety targets.
- No country report that consultations have been organized on the implementation of the Global patient safety action plan, and **20%** say that collaborative alliances have been established with partners to promote patient safety.
- **10%** periodically review progress against the Global patient safety action plan; **30%** share best practices and innovative solutions on global and regional platforms.
- **10%** of countries have mapped patient safety actions for potential alignment with technical health programmes and clinical risk areas, and **40%** have integrated patient safety strategies into all safety-related programmes (including surgical safety, injection safety, radiation safety, infection prevention and control, blood safety and vaccination safety).

## Suggestions for improvement

- **Policy commitment:** Increase government commitment to patient safety by establishing a safety culture within health systems and developing local/national patient safety policies and programmes.
- **Support for health workers:** Provide better support mechanisms for health workers, including legal protection, safeguards against punitive actions for reporting incidents, as well as well-being and psychological support.
- **Risk assessment and mitigation:** Invest in identifying threats to the health system and develop strategies and alert systems to manage risks effectively. Emphasize medication safety and harm mitigation in high-risk situations and care transitions.
- **Incident reporting investment:** Make consistent investments in systems for reporting patient safety incidents and adverse events. Conduct periodic surveys to assess the safety culture organizationally.
- **Patient and civil society engagement:** Develop platforms for patient networks and civil society organizations to engage in dialogue and action planning on patient safety. Engage patient representatives in committees and acknowledge the role of patient advocates.
- **Feedback mechanisms:** Create more avenues for patient and family feedback on care quality and incorporate this feedback into health care design and delivery. Raise awareness among patients and families about patient safety and medication safety.
- **Education and research:** Ensure that patient safety training is part of medical and health care education curricula. Recognize patient safety as a core competence for health care professionals and bolster patient safety research at national and local levels.
- **Integration of patient safety and quality of care programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

# Western Pacific Region

Number of Member States	: 28
Respondent Member States	: 12
Proportion of regional population covered	: 97%



## Respondent Member States

Australia; Brunei Darussalam; Cambodia; China; Japan; Malaysia; Mongolia; New Zealand; Philippines; Republic of Korea; Singapore; Viet Nam.

**Table A1f. Income group distribution**

	Respondent Member States	Regional total
High-income countries	6	8
Upper middle-income countries	2	7
Lower middle-income countries	4	11
Not classified	0	2

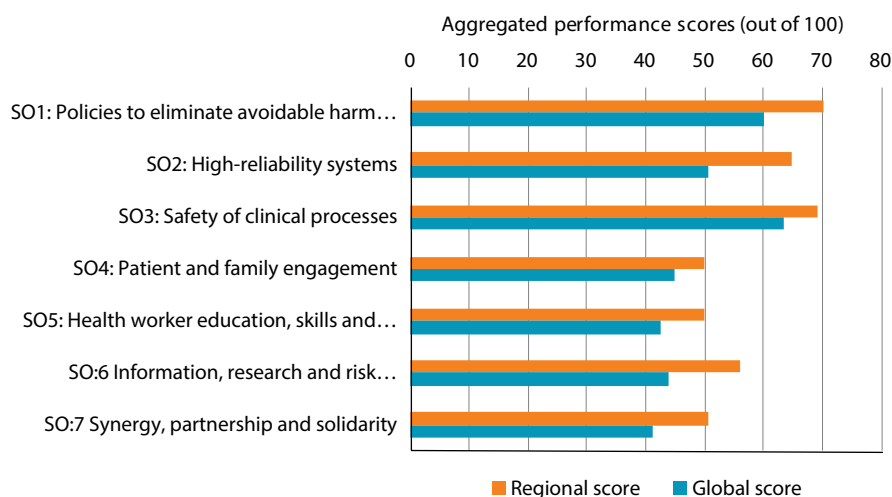
*Note: This section of the report contains findings based on responses from 12 Member States within the Western Pacific Region. We acknowledge that the representation of high-income countries (HICs) is significantly more pronounced than that of low- and middle-income countries. Given this skew towards HICs, conclusions drawn regarding the integration of patient safety into national health policies, the establishment of robust policy frameworks and the implementation of clinical safety measures across the region should be interpreted with caution. Efforts will be made in future surveys to address these disparities and better represent the diverse health policy landscapes across all income levels within the region.*

**Table A2f. Patient safety action plan core indicator status**

S. No.	Core indicator	Regional status	Global status (108)
1.	Proportion of countries that have developed a national patient safety action plan or equivalent	42%	29%
2.	Proportion of countries that have implemented a system for reporting of never events (or sentinel events)	58%	38%
3.	Proportion of countries that have established their national targets on reducing medication related harm	25%	21%
4.	Proportion of countries that have established their national targets on reducing health care-associated infection rate	50%	38%
5.	Proportion of countries that have a patient representative on the governing board (or an equivalent mechanism) in 60% or more hospitals	18%	13%
6.	Proportion of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals	50%	20%
7.	Proportion of countries that have signed up for implementation of the WHO Health Worker Safety Charter	25%	18%

S. No.	Core indicator	Regional status	Global status (108)
8.	Proportion of countries that have 60% or more health care facilities participating in a patient safety incident reporting and learning system	58%	32%
9.	Proportion of countries that publish an annual report on patient safety	50%	18%
10.	Proportion of countries that have established a national patient safety network	58%	21%

**Fig. A1f. Regional aggregated score card against strategic objectives (SOs)**



The regional scores for strategic objectives in patient safety highlight a disparity in implementation: While there is commendable advancement in policies to eliminate avoidable harm in health care **70** (out of 100) and safety of clinical processes **69**, there is a notable need for improvement in patient and family engagement **52**, health worker education **51**, and especially in synergy, partnership and solidarity **50**. These figures suggest robust policy frameworks and clinical safety measures are in place, yet engaging key stakeholders, educating health workers, and fostering collaborative partnerships require more focused efforts to enhance patient safety regionally.

## Situational analysis



### Progress

Significant progress has been made in several key areas of patient safety. Notably, a majority of countries have integrated patient safety into their national health policies, demonstrating a global commitment to this critical issue. In terms of creating high-reliability systems, around **67%** of countries now have a national body dedicated to coordinating patient safety activities. This move towards centralized oversight is a crucial step in standardizing safety practices. Furthermore, in the realm of health care facilities, **75%** of countries have established minimum safety standards, which are essential for maintaining consistent and high-quality care. These developments represent a substantial shift towards a more systematic and standardized approach to patient safety.



### Challenges

Despite these advancements, several challenges persist. Resource constraints are a significant hurdle, with only a limited number of countries allocating specific budget lines or human resources for patient safety initiatives. The lack of legal protection for health workers reporting safety incidents in a third of the countries hampers efforts to create a transparent and accountable health care environment. Additionally, continuity of care remains a critical challenge, as evidenced by the limited implementation of standard operating procedures for safe transitions in care. Patient engagement also needs more attention, with few countries actively involving patients and their families in safety initiatives or documenting their experiences of harm and unsafe care.

## Opportunities

These challenges, however, present opportunities for further improvements. There is considerable scope for expanding patient safety programmes, particularly in areas such as incident reporting systems, which currently see functional implementation in less than **60%** of countries. The integration of patient safety into medical education offers another avenue for enhancement, providing a foundation for future health care professionals to prioritize safety in their practice. Strengthening partnerships and collaborations, especially with the private sector, can also augment patient safety efforts. These opportunities, if seized, can lead to a more robust, comprehensive, and globally integrated patient safety framework, significantly improving the overall quality of health care services worldwide.

### Strategic objective 1.

#### Policies to eliminate avoidable harm in health care

- **67%** of participating countries have prioritized patient safety as a priority in the national health policy.
- **58%** have developed a patient safety policy and strategy and **42%** have a functional national patient safety programme in place.
- **33%** have a budget line in the national health budget for patient safety; **17%** have a human resources plan in place to implement the patient safety action plan; and **33%** have taken action to fill human resource gaps at all levels of care.
- **33%** provide legal protection to health workers who report patient safety incidents, to prevent punitive action against them; **42%** have dedicated legislation addressing patient safety issues in health services delivery.
- **75%** have defined minimum safety standards for health care facilities and services, and have included them in criteria for licensing of health care facilities and health service assessments.
- **75%** of countries have launched a national campaign aligned with the Global World Patient Safety Day; **33%** countries report that Global Patient Safety Challenges are being prioritized and implemented nationally.

### Strategic objective 2.

#### High-reliability systems

- **50%** of participating countries have included a culture of safety as a key intervention in health programmes.
- **58%** report having a functional system to report never or sentinel events, and have an administrative mechanism in place to protect people who report adverse events.
- **58%** have established a patient safety institutional framework, with clearly defined roles and processes; **67%** countries have a national body to coordinate patient safety activities.
- **33%** recognized leadership capacity building as a key strategy in improving patient safety, and have established leadership capacity building programmes for clinical and managerial leaders on this subject.
- **33%** have an expert group that can advise on applying human factor principles to improve patient safety; and **50%** provide training to health professionals on human factors.
- **50%** reported that structural and non-structural safety norms and codes are enforced across all health facilities.
- **42%** reported that all known and potential threats to a safe and functional health system have been identified; **50%** countries reported that a risk mitigation strategy has been developed for identified known and potential threats.
- **33%** of countries have a real-time alert system for imminent patient safety risks.

### Strategic objective 3.

#### Safety of clinical processes

- **33%** of participating countries have expert groups to assess key clinical practice domains that contribute to significant harm, and **42%** have patient safety improvement initiatives to address major sources of harm during care.
- **33%** have initiatives to improve patient safety across every discipline and health programme.
- **25%** have taken actions to improve medication safety in situations (i.e. transitions in care, high-risk situations and polypharmacy), and have a national level expert group on the third WHO Global Patient Safety Challenge: *Medication Without Harm*.
- **75%** have a reporting mechanism in place to report adverse drug events and medication errors in facilities.
- **67%** have a national programme for infection prevention and control and have guidelines in place to prevent and control health care-associated infections.
- **83%** have policies and regulatory frameworks in place for assuring the safety of medicines, vaccines, blood and blood products, and medical devices.
- Standard operating procedures around safe transitions in care and continuity of care exist in **25%** countries, and **8%** countries indicate that patient safety system interventions have been extended to include primary care services.

### Strategic objective 4.

#### Patient and family engagement

- **33%** of participating countries have identified patient networks and civil society organizations that engage on patient safety, and **42%** have formally included patient representatives to national/subnational patient safety committees.
- **42%** have developed a national patient rights charter, with safe care as a core component.
- **92%** have mechanisms to gather feedback from patients and their families on safety and quality of care; **8%** have initiatives to document patients' experience of harm and unsafe care; **25%** have taken initiatives to measure and report regularly on patient-reported outcomes.
- **42%** provide support and acknowledge the role of patient advocates in improved patient safety; **25%** have established a 'patients for patient safety' network, including patient advocates and civil society organizations.
- **67%** have national guidance around informed consent; **25%** have procedures in place to disclose adverse events to patients and families.
- **17%** of countries have invested in enhancing public knowledge on the subject of patient safety.

### Strategic objective 5.

#### Health worker education, skills and safety

- **25%** of participating countries reported that the WHO Patient safety curriculum guide has been adopted at the national level.
- **50%** have incorporated patient safety in medical undergraduate curricula, and have included it in postgraduate medical curricula.
- **25%** have a national institution designated for the provision of education and training in patient safety, and have a pool of master trainers to conduct training on patient safety.

- **33%** of countries have defined patient safety core competencies for health care professionals; **25%** countries have patient safety as a core competence for licensing and re-licensing of health care professionals.
- **17%** provide refresher trainings and continuing professional development programmes to build competence in patient safety, and have a periodic performance appraisal system covering the subject for all categories of health professionals.
- **25%** of countries have endorsed and signed the WHO health worker safety charter; **33%** provide mental and social support to health workers, and **58%** have a national programme on occupational health and safety of health workers.

## Strategic objective 6.

### Information, research and risk management

- **42%** of participating countries have a system to define and classify patient safety incidents and use a standardized format for reporting aligned with WHO protocol around classification and incident reporting.
- **58%** report that the majority (over **60%**) of their health care facilities participate in a patient safety incident reporting and learning system.
- **58%** have designated an institution to coordinate patient safety incident reporting and learning, and report consistent usage of patient safety incident reporting across health facilities.
- **42%** have identified indicators to monitor patient safety nationally/subnationally and have an accountability mechanism in place to measure indicators on patient safety.
- **42%** have an independent mechanism to investigate cases of severe harm and sentinel events; **33%** have established a benchmarking programme to measure indicators of patient safety and quality of care.
- **17%** report routinely identifying priority areas for research around patient safety, and **33%** invest in translational and implementation research on patient safety.
- **33%** of countries have a digital health strategy that includes a strong focus on patient safety, and **17%** have a surveillance system to assess the safety of information technology products that are used for clinical and diagnostic purposes.

## Strategic objective 7.

### Synergy, partnership and solidarity

- **36%** of participating countries have identified all relevant stakeholders who are to be engaged in improving patient safety; **25%** have conducted a stakeholder analysis to understand how engagement, contributions and knowledge exchange can be strengthened.
- **25%** have developed a mechanism for coordinating the engagement of different categories of stakeholders, and improving synergy through engagement of private sectors.
- **25%** have incorporated strategic elements of the global patient safety action plan into their national policies and plans for patient safety, and **33%** have defined national goals and targets aligned with the global patient safety targets.
- **42%** report that consultations have been organized on the implementation of the patient safety action plan, and **58%** report that a national patient safety network has been established.
- **25%** periodically review progress against the Global patient safety action plan; **42%** countries share best practices and innovative solutions on global and regional platforms.



- **25%** of countries have mapped patient safety actions for potential alignment with technical health programmes and clinical risk areas, and **42%** have integrated patient safety strategies into all safety-related programmes (including surgical safety, injection safety, radiation safety, infection prevention and control, blood safety and vaccination safety).

## Suggestions for improvement

- **Budgeting and resources:** There is a critical need for increased national and local budgeting specifically for patient safety. This includes ensuring long-term availability of both financial and human resources to sustain patient safety programmes effectively.
- **Support for health workers:** Improving support for health workers is essential. This involves enhanced legal protection to prevent punitive actions when reporting adverse incidents, ensuring their occupational health and safety, and providing well-being and psychological support.
- **Risk management:** Investing in assessing potential threats to a safe and functional health system is crucial. This includes developing risk mitigation strategies and real-time alert systems to effectively manage and address these threats. A focus on critical elements such as medication safety and procedures to mitigate harm in high-risk situations, including transitions of care, is also important.
- **Patient networks and advocacy:** Greater investment is needed in strengthening patient networks and civil society organizations. This should aim to build dialogue and action planning around patient safety and include mechanisms to engage these groups formally in patient safety committees at both national and subnational levels. Building leadership capacities among patient advocates and publicly acknowledging their role in advancing patient safety is also vital.
- **Patient safety awareness:** There is a need for improved awareness among patients and families about patient safety and safe medication practices. Advocacy at national and local levels to recognize the role of patients in enhancing patient safety is also crucial.
- **Education and training:** Ensuring that medical and health care education curricula across regions incorporate patient safety training and information is necessary. This includes increased investment in building capacities around patient safety among health care professionals, as part of licensing and in-service training requirements, and fostering greater research around patient safety at the national/local level.
- **Coordination and collaboration:** Improved coordination and collaboration among different stakeholder categories are key. This involves ensuring more efficient engagement and synergy between public and private sectors for patient safety outcomes and understanding how patient safety actions align across health programmes and clinical specializations.
- **Integration of patient safety and quality of care programme:** Integrate patient safety and health care quality improvement programmes as core elements of health systems strengthening. This alignment should extend to policymaking, strategic planning, and everyday operations, ensuring that safety and quality are essential components of health care delivery.

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