GLOBAL PATIENT SAFETY ACTION PLAN 2021–2030

Towards eliminating avoidable harm in health care

Patient Safety

World Health Organization

Patient Safety | World Health Organization

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Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care

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Executive summary

Why do we need a Global Patient Safety Action Plan?

Today, patient harm due to unsafe care is a large and growing global public health challenge and is one of the leading causes of death and disability worldwide. Most of this patient harm is avoidable. As countries strive to achieve universal health coverage and the Sustainable Development Goals, the beneficial effects of improved access to health services can be undermined by unsafe care. Patient safety incidents can cause death and disability, and suffering for victims and their families. The financial and economic costs of safety lapses are high. There is often reduced public confidence and trust in local health systems when such incidents are publicized. Health workers involved in serious incidents involving death or serious harm to a patient can also suffer lasting psychological harm and deep-seated feelings of guilt and self-criticism.

The benefits of having a strategic and coordinated approach to patient safety, addressing the common causes of harm and the approaches to preventing it, have been recognized by policy-makers and political and health leaders worldwide. Global advocacy in recent years has culminated in the adoption by the Seventy-second World Health Assembly (in 2019) of resolution WHA72.6 on "Global action on patient safety".

The resolution urges Member States – and, where applicable, regional economic integration organizations – to recognize patient safety as a health priority in health sector policies and programmes to achieve universal health coverage. The World Health Assembly also requested the World Health Organization (WHO) to formulate a global patient safety action plan in consultation with Member States and all relevant stakeholders.

The Seventy-fourth World Health Assembly (in 2021) approved the Decision WHA74(13) to adopt the Global Patient Safety Action Plan 2021–2030 and to request the Director-General to report back on progress in the implementation of the Global Patient Safety Action Plan 2021–2030 to the Seventy-sixth World Health Assembly in 2023 and thereafter every two years until 2031.

What is 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 errors less likely and reduce the impact of harm when it does occur."

How big is the problem of unsafe care?

Every year, large numbers of patients are harmed or die because of unsafe health care, creating a high burden of death and disability worldwide, especially in low- and middle-income countries. On average, an estimated one in 10 patients is subject to an adverse event while receiving hospital care in high-income countries. Available evidence suggests that 134 million adverse events due to unsafe care occur in hospitals in low- and middle-income countries, contributing to around 2.6 million deaths every year. According to recent estimates, the social cost of patient harm can be valued at US$ 1 trillion to 2 trillion a year.

What will success look like?

The Global Patient Safety Action Plan strives to eliminate avoidable harm in health care with the vision of "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere".

The ultimate goal is to achieve the maximum possible reduction in unavoidable harm due to unsafe health care globally.

The mission of the global action plan is to drive forward policies, strategies and actions, based on science, patient experience, system design and partnerships, to eliminate all sources of avoidable risk and harm to patients and health workers.

What principles will guide implementation?

Seven guiding principles establish underpinning values to shape the development and implementation of the action plan:

- engage patients and families as partners in safe care
- achieve results through collaborative working
- analyse and share data to generate learning
- translate evidence into actionable and measurable improvement
- base policies and action on the nature of the care setting
- use both scientific expertise and patient experience to improve safety
- instil a safety culture in the design and delivery of health care.

Who are the key delivery partners?

Patient safety is everybody's business and requires the active participation of many key partners ranging from patients and their families to governmental, nongovernmental and professional organizations. They include:

- **Governments.** Ministries of health and their executive agencies at both national and subnational levels, legislative institutions, other concerned ministries, and regulatory bodies.
- **Health care facilities and services.** All health care facilities ranging from primary health centres to large teaching hospitals, irrespective of ownership and scope of services.
- **Stakeholders.** Nongovernmental organizations, patients and patient organizations, professional bodies and scientific associations and societies, academic and research institutions and civil society organizations.
- **WHO Secretariat.** WHO at all levels – country offices, regional offices and headquarters.

What is the framework for action?

The global action plan provides a framework for action through seven strategic objectives and is further elucidated through 35 strategies, five under each of the strategic objectives, to create a seven by five matrix.

Each strategy has been further operationalized into suggested actions for four key groups or categories of partners: governments, health care facilities and services, stakeholders and the WHO Secretariat.

The seven strategic objectives (SOs) of the Global Patient Safety Action Plan 2021–2030 are as follows.

- SO1: Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere.
- SO2: Build high-reliability health systems and health organizations that protect patients daily from harm.
- SO3: Assure the safety of every clinical process.
- SO4: Engage and empower patients and families to help and support the journey to safer health care.
- SO5: Inspire, educate, skill and protect every health worker to contribute to the design and delivery of safe care systems.
- SO6: Ensure a constant flow of information and knowledge to drive mitigation of risk, a reduction in levels of avoidable harm and improvements in the safety of care.
- SO7: Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care.

How will implementation work at national and subnational levels?

The Global Patient Safety Action Plan 2021–2030 takes into account that countries are at different stages in creating the capacity and capability to reduce preventable patient harm in health care and to strengthen their national health systems to meet this aim. Their health care contexts also vary greatly. Member States are being asked to assess and analyse their current situations to identify areas where progress can be made.

The key implementation milestones at national and subnational levels are:

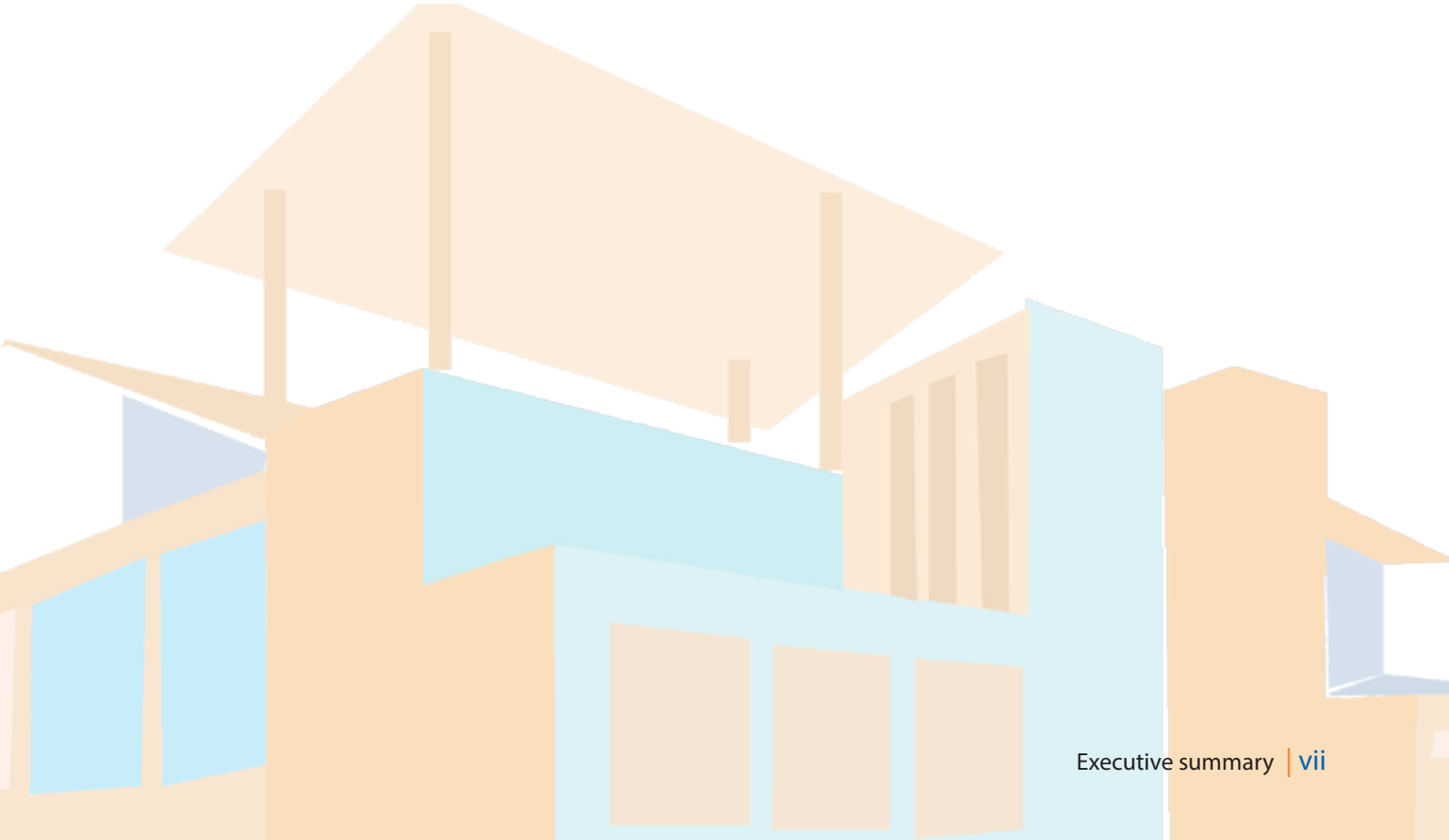
- a landscape assessment of major safety risks and barriers to improvement in patient safety has been carried out;
- strong commitment from political and organizational leadership has been secured;
- a sustainable mechanism to implement patient safety policies, strategies and plans is in place (within the context of existing national health plans and safety and quality policies);
- national context and priorities, are well aligned and consistent with the health care context of the country;
- a model of change for implementation has been agreed by all partners.

How will overall progress be measured?

A monitoring and reporting mechanism will assess progress in implementing the global action plan. This uses a set of 10 core indicators and global targets aligned with the strategic objectives. The WHO Secretariat will collect the necessary data in cooperation with Member States and partners and then analyse the progress made. An additional list of advanced indicators will assist countries in designing their own context-specific measurements for patient safety. Progress on implementation of the Global Patient Safety Action Plan 2021–2030 will be reported to the World Health Assembly every two years.

How will the plan support the Sustainable Development Goals (SDGs)?

Due to the interdisciplinary nature of patient safety, the global action plan contributes to achieving not only SDG 3 (good health and well-being) but also interlinks with other SDGs, including SDG 1 (no poverty), SDG 5 (gender equality), SDG 6 (cleaner water and sanitation), SDG 8 (decent work and economic growth), SDG 10 (reduced inequalities) and SDG 12 (responsible consumption and production).



Overview of the Global Patient Safety Action Plan 2021–2030

Vision

A world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere

Governments
Health care facilities and services

Stakeholders
World Health Organization

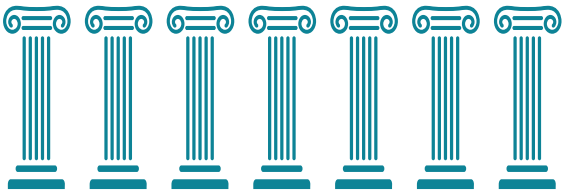
Mission

Drive forward policies, strategies and actions, based on science, patient experience, system design and partnerships, to eliminate all sources of avoidable risk and harm to patients and health workers

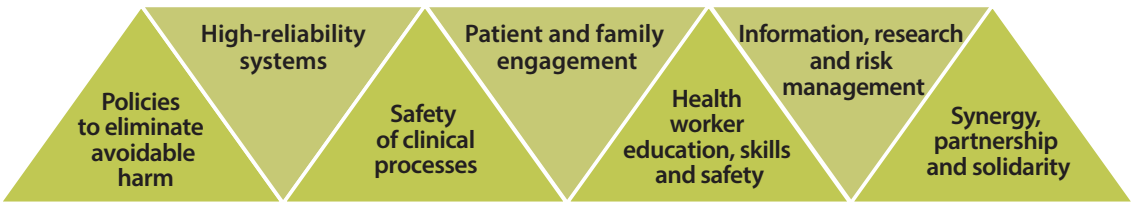
Goal

Achieve the maximum possible reduction in avoidable harm due to unsafe health care globally

Patients and families as partners
Results through collaboration
Data to generate learning
Safety culture



Evidence into improvement
Policies and action
Scientific expertise and patient experience



1. Introduction

Over the next 10 years, the World Health Organization (WHO), its global partners and its Member States will be working tirelessly to help all people of the world to have access to health services.

Universal health coverage is an inspiring goal whereby all individuals and communities receive safe and quality health services without suffering financial hardship. This is the target to be achieved if the world is to stay on track to achieve the United Nations Sustainable Development Goals (SDGs) and the "triple billion" goals in the WHO Thirteenth General Programme of Work. However, the sustainable development agenda will not be met without ensuring that health services are safe. In the absence of such assurance, the benefits of increased coverage cannot be fully realized, and people may experience reduced trust in health services and reduced willingness to seek health care – even when they most need it.

That is why the Seventy-second World Health Assembly in May 2019 adopted resolution WHA72.6 on "Global action on patient safety" to give priority to patient safety as an essential foundational step in building, designing, operating and evaluating the performance of all health care systems. The adoption of this resolution was a remarkable milestone in global efforts to take concerted action on patient safety and reduce the burden of patient harm due to unsafe health care.

The resolution requested the Director-General of WHO to formulate a global patient safety action plan in consultation with Member States and a wide range of partners and other organizations. To respond to resolution WHA72.6 and move forward from global commitment to tangible action, WHO launched a flagship initiative "A Decade of Patient Safety 2021–2030". This important step defines WHO's contribution to the global patient safety movement. Through its year-by-year milestones, this flagship initiative will be the driver for the successful implementation of the global action plan.

The global action plan, set out in this document, will provide a strategic direction for concrete actions to be taken by countries, partner organizations, health care facilities and WHO to implement World Health Assembly resolution WHA72.6. As a result, it will strengthen health systems globally to diagnose, treat, cure, and care, whilst striving to "first, do no harm" the celebrated maxim of the Greek physician, Hippocrates (460–375 BC).

1.1 Background

Every point in the process of care can contain an inherent risk. The nature and scale of risks vary greatly, based on the context of health care provision and its availability, infrastructure and resourcing within and across countries. The challenge for all health systems and all organizations providing health care is to maintain a heightened awareness to detect safety risks, as well as to address all sources of potential harm.

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 errors less likely and reduce impact of harm when it does occur.

The practice of patient safety involves coordinated action to prevent harm to patients, caused by the processes of health care themselves.

Patient safety is a strategic priority for modern health care and is central to countries' efforts in working towards universal health coverage.

As a theme of scholarship and research, patient safety draws on the concepts and methods of many disciplines, including health services research, applied psychology, behavioural science, ergonomics, communication science, accident theory and systems research.

1.1.1 Emergence of patient safety thinking

In the period immediately after the Second World War, when many countries were developing their health care systems, the idea of safety was limited to traditional hazards such as fire, equipment failure, patient falls and the risk of infection. There was also a belief that health workers, such as well-trained staff (that is, doctors and nurses), would always behave carefully and conscientiously and seek to avoid or minimize what were seen as inevitable "complications" of care. At that time, postoperative bleeding, fetal distress during childbirth and wound infections were – and still remain – consistent harms or complications associated with care. There are many more.

Similarly, there have long been events in health care considered as unexpected complications – for example, transfusion of the wrong blood group, administration of too high a dose of medication for a child, carrying out a surgical procedure on the wrong side of the body, and many more, sometimes resulting in the death of patients.

For most of the 20th century, whilst such occurrences would occasionally hit the headlines, cause momentary public concern, and be a preoccupation of medical litigation lawyers, they aroused little interest amongst doctors and health care leaders. Why? Essentially, they were seen as the inevitable cost of doing business in the pressurized, fast-moving environment of modern health care that was saving lives and successfully treating many more diseases. Mistakes happen, it was argued. They were also viewed mainly as local events best dealt with through internal investigation.

Studies in the 1990s began to view the safety of care through a different lens. They showed that the frequency of adverse outcomes amongst hospital patients was substantial and had hitherto been little recognized. They introduced the term "medical error" to describe this phenomenon, and it became widely adopted by policy-makers, researchers, clinicians, patient groups and the media. Other terms also came into common usage to describe safety failures in health care, such as incident, adverse event, serious untoward incident, never event, near miss and close call.

The paradigm shift in thinking about safety in health care came with the realization that it was not completely different from other high-risk industries, and when things went wrong it was seldom due to an error by a single individual. Rather, the true cause of an accident in aviation or an adverse event in health care was often human error embedded in a complex amalgam of actions and interactions, processes, team relationships, communications, human behaviour, technology, organizational culture, rules and policies, as well as the nature of the operating environment. With this realization came a deeper understanding that the poor design and operation of systems could provoke human error or worsen its impact when it occurred *(1)*.

In this systems thinking view of the risks of health care, the term "medical error" became something of a misnomer, since error in itself was not the primary problem. Indeed, harm to patients cannot be corrected solely by urging health workers to be more careful. The use of the term "patient safety", a more holistic concept, to describe the safety risks in health care and the measures to address these risks and patient harm came into being at the beginning of the 21st century *(2)*. It recognized the scale of the problem of inadvertent harm in the delivery of health care, the common causes that allowed similar kinds of adverse events to occur in all countries worldwide, the need to see human error as something to be mitigated and prevented rather than eliminated entirely, and the strong parallels with the experience of other high-risk industries, thus creating opportunities for transfer learning. An alternative emerging approach in patient safety (Patient Safety II) focuses on proactively making health care safer through an emphasis on the conditions under which people succeed rather than fail. This perspective views patient safety in terms of intended and acceptable outcomes to the extent possible.

1.1.2 Global burden of unsafe care

The magnitude of the problem of unsafe care attracted greater public attention with the release of the landmark report *To err is human: building a safer health system*, published by the United States Institute of Medicine in 1999 *(3)*. The report extrapolated a death rate from the incidence of adverse events in United States hospitals from two earlier studies and estimated that at least 44 000 and perhaps as many as 98 000 people died in hospitals each year as a result of medical errors. In 2000, the United Kingdom Department of Health published *An organisation with a memory (4)*. Both reports scoped the subject of safety and harm in health care, drew parallels with other high-risk industries, and provided the first

estimates of the burden of patient harm for what was to become a new health priority and a new field of research in health services.

In more recent years, the focus has also been on economic losses and access problems due to unsafe care that have the potential to become major barriers to achieving universal health coverage *(5)*. Research studies have shown that an average of one in 10 patients is subject to an adverse event while receiving hospital care in high-income countries *(6)*. The estimate for low- and middle-income countries suggests that up to one in four patients is harmed, with 134 million adverse events occurring annually due to unsafe care in hospitals, contributing to around 2.6 million deaths *(7)*. Overall, 60% of deaths in low- and middle-income countries from conditions amenable to health care are due to unsafe and poor-quality care *(8)*. People mostly link patient safety with hospital-based care; however, unsafe care is a systemwide problem. Half of the global disease burden arising from patient harm originates in primary and ambulatory care *(9)*.

The economic cost of unsafe care can be understood in two ways: the direct cost due to resource wastage and the indirect costs in loss of productivity in the population. In high-income countries, up to 15% of hospital expenditure can be attributed to wastage due to safety failures. For example, the National Health Service in England paid £1.63 billion in litigation costs because of safety lapses in 2017–2018 *(10)*.

Unsafe medication practices and errors – such as incorrect dosages or infusions, unclear instructions, use of abbreviations and inappropriate or illegible prescriptions – are a leading cause of avoidable harm in health care worldwide. Globally, the cost associated with medication errors has been estimated at US$ 42 billion annually *(11)*, not counting lost wages and productivity or increased health care costs. This represents almost 1% of global expenditure on health. Unsafe and poor-quality care leads to US$ 1.4 trillion to 1.6 trillion worth of lost productivity each year in low- and middle-income countries *(7)*.

Available evidence estimates the direct costs of harm, such as additional tests, treatments and health care, in the primary and ambulatory setting to be around 2.5% of total health expenditure, though this probably underestimates the true figure *(12)*. Harm in primary and ambulatory care often results in hospitalizations. Each year, these may account for over 6% of hospital bed-days and more than 7 million admissions among member countries of the Organisation for Economic Co-operation and Development (OECD). This is in addition to the 15% of acute care activity caused by harm occurring in hospitals alone *(6)*.

According to recent estimates, the social cost of patient harm can be valued at US$ 1 trillion to 2 trillion a year. A human capital approach suggests that eliminating harm could boost global economic growth by over 0.7% annually *(13)*.

1.1.3 Evolution of the global patient safety movement

In May 2002, the Fifty-fifth World Health Assembly adopted resolution WHA55.18. This urged Member States to pay the closest possible attention to the problem of patient safety and to establish and strengthen evidence-based systems necessary for improving patient safety and the quality of health care.

World Alliance for Patient Safety (2004–2014)

Subsequently, in May 2004, the Fifty-seventh World Health Assembly supported the creation of an international alliance to facilitate the development of patient safety policy and practice in all Member States and to act as a major force for improvement globally. In October 2004, the World Alliance for Patient Safety was launched as a working partnership between WHO and external experts, health care leaders and professional bodies. The creation of the World Alliance for Patient Safety was a hugely significant step in the struggle to improve the safety of health care in all Member States. Working in partnership with WHO, the World Alliance for Patient Safety took on this mantle and a programme of work was rapidly initiated, backed by a substantial allocation of foundation funding from the United Kingdom Government *(14)*.

The World Alliance for Patient Safety created a unique environment in which major new initiatives arose that individual partners were not able or willing to undertake alone. It became a vehicle for sharing knowledge and resources aimed at improving the safety of health care. It was envisaged that patient safety solutions, identified and evaluated by one or two health systems or major hospital groups, would be adapted for global or multi-country implementation. It was also foreseen that additional coordination and facilitation of international expertise and learning would reduce duplication of efforts and minimize the wastage of valuable resources.

A fundamental aim of the World Alliance for Patient Safety was to facilitate the development of patient safety policy and practices in Member States. It was planned that

this would be accomplished through the fulfilment of a number of core functions and other short-term initiatives as set out by the World Alliance for Patient Safety in an annual work programme.

Global Patient Safety Challenges

The first programme of work produced by the World Alliance for Patient Safety introduced the concept of the Global Patient Safety Challenge. This initiative identifies a patient safety burden that poses a significant risk to health, then develops front-line interventions and partnerships with countries to disseminate and implement the interventions. Each Challenge focuses on a topic that poses a major and significant risk for patient health and safety.

The topic chosen for the first Global Patient Safety Challenge in 2005 was health care-associated infections *Clean Care is Safer Care (15)*. This topic became a key element of WHO's early work was followed a few years later by *Safe Surgery Saves Lives*, the second Global Patient Safety Challenge *(16)*. Both Global Challenges aimed to gain worldwide commitment and spark action to reduce health care-associated infections and the risks associated with surgery, respectively.

The scale and speed of implementation of these Challenges were unprecedented. They secured strong and rapid commitment from ministers of health, professional bodies, regulators, health system leaders, civil society organizations and health care practitioners.

Other initiatives of the World Alliance for Patient Safety

In addition to designing and implementing the two Global Patient Safety Challenges, the World Alliance for Patient Safety established the following range of landmark initiatives in its initial work programme, which continued during the Alliance's lifetime:

- **Patients for Patient Safety** programme, led by individuals who had suffered harm from health care or by their family members;
- **Taxonomy for Patient Safety** initiative, ensuring consistency in the norms and terminology used in patient safety work, as well as a classification framework – the International Classification for Patient Safety;
- **Patient Safety Research** initiative to identify priorities for patient safety-related research in high-, middle- and low-income countries, as well as projects and capacity-building;
- **Patient Safety Solutions** programme to identify, develop and promote worldwide interventions to improve patient safety;
- **Reporting and Learning** best practice guidelines to aid in the design and development of existing and new incident reporting systems;
- **Patient Safety Curriculum** guides (in two editions: the first for medical schools, followed by a multi-professional edition) to assist in patient safety education in universities, schools and professional institutions in the fields of dentistry, medicine, midwifery, nursing and pharmacy;
- **African Partnerships for Patient Safety**, for building sustainable hospital-to-hospital patient safety partnerships.

WHO Patient Safety Initiatives (2015–2020)

In 2016, a WHO Global Consultation on Setting Priorities for Global Patient Safety provided a platform to recognize that the scale of avoidable harm in health care systems around the world was unacceptably high, with few signs of improvement *(17)*. Building on WHO's earlier work carried out jointly with the World Alliance for Patient Safety, this led to consolidation and further development of the second phase of WHO's global patient safety programme.

WHO established major global patient safety initiatives, engaged with a large number of stakeholders and partners, and held large-scale and high-level consultations, including:

- **The third WHO Global Patient Safety Challenge:** *Medication Without Harm,* launched as a multi-year initiative with the goal of reducing the severe, avoidable medication-related harm globally by 50% over a period of five years;
- **Global Patient Safety Network,** a highly interactive network established in collaboration with Member States, health care leaders, international experts and professional bodies;
- **Global Ministerial Summits on Patient Safety** initiated by the Governments of the United Kingdom of Great Britain and Northern Ireland Ireland and Germany in collaboration with WHO since 2016, as a series of annual summits;
- **World Health Assembly resolution** WHA72.6 on "Global action on patient safety", adopted in May 2019, and outlined a comprehensive and multifaceted patient safety strategy;

- **Global Patient Safety Collaborative**, launched in collaboration with the Government of the United Kingdom to collaborate with low- and middle-income countries to reduce the risk of avoidable patient harm;
- **World Patient Safety Day**, established by World Health Assembly resolution WHA72.6, the first of which was held on 17 September 2019; the 2020 event was dedicated to health worker safety and launched a landmark charter *Health worker safety: a priority for patient safety,* among other advocacy and technical products;
- **Publication of patient safety normative guidance and tools**, including the Technical Series on Safer Primary Care, the Safe Childbirth Checklist and accompanying implementation guide, the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (technical report and guidance), and technical reports on medication safety, among other WHO guidance and tools;
- **Africa Patient Safety Initiative**, a high-level forum jointly organized with key partners for working with countries in Africa to improve patient safety;
- **WHO Flagship Initiative "A Decade of Patient Safety 2021–2030"** launched to guide and support strategic action on patient safety at the global, regional and national levels. The flagship initiative's core work involves formulation of the Global Patient Safety Action Plan and supporting its implementation at all levels through advocacy, normative guidance and tools, strategic partnerships, campaigns, collaboration, patient and family engagement, knowledge sharing and technical work on building and strengthening patient safety systems and practices.

1.1.4 Coronavirus disease (COVID-19): a broader concept of avoidable harm

In 2020, the toll of the COVID-19 global pandemic brought increased recognition of risks to patients. The ongoing impact on health care delivery systems around the world will become clearer and fully quantified over time. However, important patient safety implications have emerged, giving heightened impetus to efforts that promote safer care at every level. Growing clinical familiarity with the SARS-CoV-2 virus and its manifestations began to reduce uncertainty, but with the new disease and its novel treatments came the greater risk of avoidable harm. The physical and psychological safety of health workers was widely compromised, together with the capacity and financial stability of health care delivery systems. Situational factors, such as staffing shortages, staff redeployment to unfamiliar roles, and "workarounds", all disrupted existing care processes in most health systems worldwide. In addition, the indirect effects of the virus on access to unrelated areas of care emerged as another form of serious harm. Delays arose from patients not seeking care due to fear, people unable to go to health facilities because of lockdowns, those with complex chronic conditions not receiving their routine ambulatory or preventive care due to health system overload, or COVID-19 admissions being given priority. In addition, patients experienced new types of diagnostic errors, some related to the virus and others not as much *(18)*.

Despite these negative effects and risks, the COVID-19 pandemic has provided some short-term benefits in key areas that could be a catalyst for subsequent improvement strategies. Shared commitment and responsibility have united health care stakeholders as never before. Many have spontaneously adopted key safety attributes such as transparency, active communication, collaboration and rapid adoption of patient safety practices. This may only be temporary and in selected settings and countries, but it illustrates how traditional silos and clinical territories can rapidly dissolve in the interest of fighting a common enemy.

It is sobering to realize that the chronic and widespread public health crisis of avoidable patient and workforce harm will remain as much of a challenge as before when the COVID-19 pandemic is over. The next five years will be a time for the global patient safety movement to learn from both the negative and positive effects of COVID-19. It will be a time to build safer health care systems that minimize harm to patients and to health workers. This global action plan is built from a deep understanding of the nature of avoidable harm in health care and the way in which it threatens patient safety in diverse and complex settings across the globe. Thinking through how COVID-19 adds to this context will help to harvest patient safety lessons from both pandemic failures and pandemic transformations. This is all part of the urgent need to "build back better" and "hardwire" positive changes, to promote the spread of safety strategies and innovations, and to make health care systems more resilient to the impact of harm than ever before.

1.2 Mandate

The Global Patient Safety Action Plan 2021–2030 draws its mandate from World Health Assembly resolution WHA72.6 on "Global action on patient safety". The

resolution requested the Director-General of WHO "to formulate a global patient safety action plan in consultation with Member States and all relevant stakeholders, including in the private sector". The plan must be submitted to the Seventy-fourth World Health Assembly in 2021 through the 148th session of the WHO Executive Board. The operating paragraphs of resolution WHA72.6 delineate the strategic and operational boundaries of this action plan *(19, 20)*.

1.3 Development process

This global action plan was co-developed through a participative process with the contribution of leading international experts on patient safety. The draft went through multiple rounds of stakeholder consultations including Member States, international organizations, academic institutions, patient groups, intergovernmental organizations, and WHO global, regional and country offices. The initial outline and development pathway of the action plan was developed by the Patient Safety Flagship secretariat at WHO headquarters in Geneva, with the guidance and support of WHO Patient Safety Envoy, and in consultation with relevant technical programmes, units and departments within the WHO system. A WHO global consultation was convened in February 2020 at WHO headquarters in Geneva to synthesize the first draft of the action plan. Leading patient safety experts and practitioners from 44 countries provided invaluable concrete recommendations on what should be the future course of global action on patient safety. Additional inputs were received from experts and stakeholders through the WHO Global Patient Safety Network.

A drafting and review task force was constituted with the mandate to take forward the recommendations from these consultations and prepare the draft action plan. The first draft was further discussed with Member States through regional committees and consultations. Additional technical briefings were organized with permanent country missions in Geneva. The draft action plan was made available online for public consultation on the WHO website for a period of one month. Feedback, comments and technical input from Member States and from the outcome of the public consultation were reviewed and appropriately addressed by the drafting and review task force. An advanced draft of the action plan was submitted to the 148th session of the Executive Board in January 2021 for review, discussion and approval. At its 148th session the Executive Board adapted a decision to recommend the global action plan for approval. The Seventy-fourth World Health Assembly in May 2021 deliberated and decided to adopt the Global Patient Safety Action Plan 2021-2030. The World Health Assembly also requested the Director-General to report back on progress in the implementation of the global action plan to the Seventy-sixth World Health Assembly in 2023 and thereafter every two years until 2031.

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2. Vision, Mission and Goal

Vision

A world in which no one is harmed in health care and every patient receives safe and respectful care, every time, everywhere

Mission

Drive forward policies, strategies and actions based on science, patient experience, system design and partnerships to eliminate all sources of avoidable risk and harm to patients and health workers

Goal

Achieve the maximum possible reduction in avoidable harm due to unsafe health care globally

3. Guiding principles

Creating a system for progressing towards universal health coverage in which patients are safer than they are today, especially at the point they receive care anywhere in the world, is a major challenge. It is this challenge that is addressed in the Global Patient Safety Action Plan 2021–2030. The following seven guiding principles establish an underpinning set of values to guide the development and implementation of the framework for action proposed in the global action plan. The framework includes seven strategic objectives and 35 strategies that are the foundation of the global action plan.

3.1 Engage patients and families as partners in safe care

Safe health care should be seen as a basic human right. As health care is predominantly a service, it is always co-produced with the users. Achieving safe care requires that patients be informed, involved and treated as full partners in their own care. In many parts of the world, this happens much less than it should. Patients, families and caregivers have a keen interest in their own health and that of their communities. Patient safety depends on their full involvement as the users of the health care system and the people who are most familiar with the entire patient journey. Patients and families should be involved at every level of health care, ranging from policy-making and planning, to performance oversight, to fully informed consent and shared decision-making at the point of care. Patients, families and communities have essential contributions to make in patient safety.

3.2 Achieve results through collaborative working

With A Decade of Patient Safety 2021–2030 initiative as a global mandate, WHO will provide policy guidance and implementation tools to countries to make health care safer at the point of delivery. There will inevitably be disruptive innovations and newer models of safer care evolving at local level. They should feed into global learning systems to redesign the policy architecture and promote global discourse on patient safety. Rather than a unidirectional flow of interventions, there is a need for a collaborative ecosystem whereby everybody (from global policy-makers to front-line service providers) contributes, shares and learns. All patient safety interventions will need to be carefully designed and tailored to meet countries' and communities' priorities, as well as their specific implementation needs. WHO will drive harm reduction impact in every country through policy dialogue, strategic support, technical assistance for safer service delivery. Global action can help, but the strength of the plan will lie in the passion and commitment for patient safety shown at the national, subnational and local levels.

3.3 Analyse and share data to generate learning

Reporting systems that gather data about adverse events and incidents from the point of care are widespread throughout the world. In 2020, WHO produced the document *Patient safety incident reporting and learning systems: technical report and guidance.* There are other sources of such data, including malpractice claims, patient-reported experience and outcome measures, clinical care audits, medical record reviews, surveys,

significant event audits, and safety surveillance data for blood products, medicines, vaccines and medical devices. Gathering data from these various sources provides a rich opportunity to gain greater understanding of why safety incidents occur and to devise solutions to prevent them. However, too often, great volumes of data are collected and most of the available time and resources are spent storing them. Less time is spent on analysing and sharing data in a way that is usable for learning and can reliably and consistently contribute to improving patient safety. There are also issues of data quality and reliability, which could best be addressed through building a culture of trust in reporting. Whilst it is always of interest to use such data to provide information on patterns and trends in the types of harm that occur, the emphasis must be firmly on their capability to make future care safer.

3.4 Translate evidence into actionable and measurable improvement

An area of weakness in many parts of health care, including patient safety, is the slow translation of evidence of effectiveness into routine practice: what is sometimes called the "knowing–doing" gap. There is also a wealth of provider and patient experience and tactical knowledge available for designing and testing solutions to improve patient safety. During the process of framing actions to improve patient safety, it is important to fully understand the process of change and utilize the established body of knowledge on improvement science to achieve the desired outcome. This also means working closely with leaders, managers, professional staff and patient representatives in health facilities and clinical services. It is also important to nurture centres of excellence, learn from them, and scale up proven best practices.

3.5 Base policies and action on the nature of the care setting

Most of the attention and research endeavour in patient safety has focused on the experience of high-resourced health care systems and large hospital groups. Yet, a great deal of good work has been taking place in low-resource settings. First, it has become clear that patient safety policies and solutions must be adapted to the local context. They do not simply translate from one setting to another, especially where the culture, traditions, health care system design and level of infrastructure can be very different. Second, learning is not just a one-way flow. The experience of finding patient safety solutions in resource-limited settings can be of value to those running programmes in well-resourced health care systems, as well as the usually favoured "North–South" route for advocating best practice.

3.6 Use both scientific expertise and patient experience to improve safety

Today, developing safe services for patients does not only involve the skills of planning, design and strategic investment, it also involves advocacy, awareness raising, political commitment, persuasion and localism. Traditionally, the scientific and technical expertise comes from the policy-makers, health system leaders, health care professionals, academics and managers, whilst the passion comes from the citizens, civil society organizations and patient advocates. Formulating and delivering a plan requires scientific and technical expertise, but it also must have the buy-in and positive emotional drive of those who remember that too many past patients and families have suffered loss and serious harm as a result of flawed health care. If these two elements – science and personal experience – are always brought together in improvement, it will be a winning combination.

3.7 Instil a safety culture in the design and delivery of health care

Developing a culture of safety is cardinal to any sustainable efforts towards patient safety improvement. Policy and legislative interventions can provide a conducive environment for a flourishing safety culture. Ultimately, though, a culture of safety has to percolate into the attitudes, beliefs, values, skills and practices of health workers, managers and leaders of health care organizations. The safety culture must intertwine with the overall organizational philosophy and culture. Countries and organizations can identify their own optimal ways of achieving a culture of safety, though certain elements remain indispensable. Leadership commitment, transparency, open and respectful communication, learning from errors and best practices, and a judicious balance between a no blame policy and accountability are indispensable components of safety culture. A strong safety culture is not only core to reducing patient harm, it is also critical for providing a safe working environment for health workers. This includes creating a psychologically safe work environment, whereby health workers can speak up regarding patient safety and other concerns without fear of negative consequences.

4. Partners in action

Comprehensive action on patient safety across all countries worldwide is a complex endeavour and requires the collective efforts of numerous stakeholders, ranging from policy-makers to health workers. To achieve the goal and strategic objectives of the Global Patient Safety Action Plan 2021–2030, it is important that partnerships develop at both the strategic and the operational levels. Collaboration in this way will add particular value to patient safety endeavours and strengthen the efforts of individual organizations.

By working together to achieve the vision of the action plan and improve the safety of care for all, partners can also accelerate progress to achieve their own respective goals. As shown below, four broad categories of partners have been identified to support implementation of the global action plan. The action plan also envisages patients, families and communities as key partners at all levels of action.

4.1 Governments

- National and subnational governments
- Parliament and subnational legislative bodies
- Ministries of health
- National and subnational specialized agencies and adjunct bodies, for example, national patient safety and quality institutes, centres or agencies, including planning agencies, scheme implementation bodies, public health institutions, and occupational health agencies
- Other ministries directly or indirectly involved in health, including ministries of education, finance, labour and social affairs, consumer affairs, justice and territorial administration
- National and subnational regulatory bodies, including standard setting, licensing and accreditation agencies, and health care safety investigative bodies

4.2 Health care facilities and services

- Tertiary and secondary care facilities and health care organizations
- Primary care facilities and service providers
- Long-term care facilities and service providers
- Palliative care service providers
- Mental health facilities and service providers
- Pre-hospital care service providers
- Specialized clinics and diagnostic service providers
- Substance use disorder facilities and dementia care facilities
- Outreach health care service providers
- Community-based and home-based health care service providers
- Subnational and district health service management teams

4.3 Stakeholders

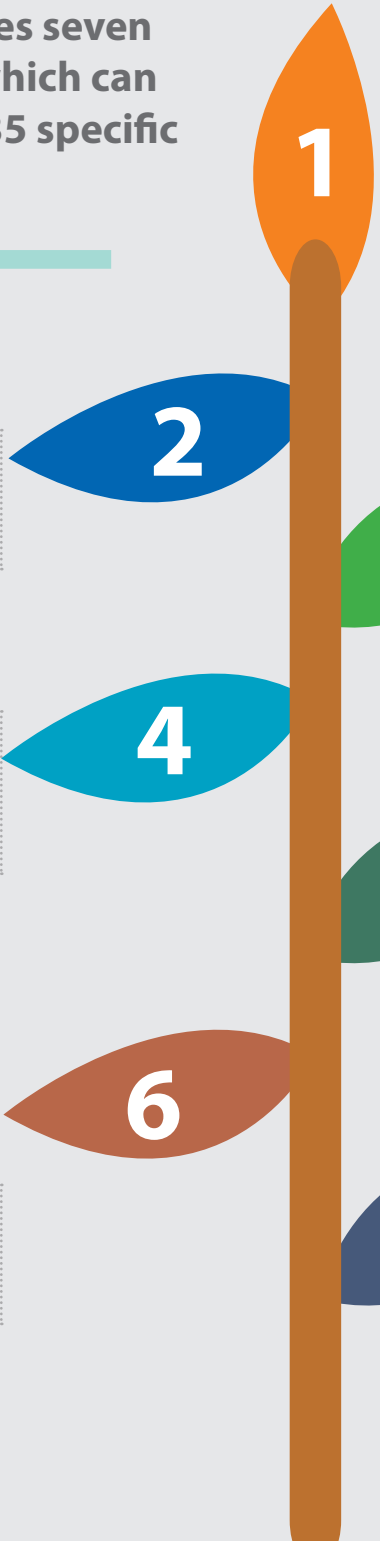
- Intergovernmental organizations, for example, European Commission, OECD
- International and national nongovernmental organizations
- International development organizations
- International and independent standard setting bodies and accreditation agencies
- International and national professional bodies and scientific associations and societies
- Universities, academic institutions, educational centres and other international and national training and capacity-building institutions
- Research institutions
- International and national consortiums and associations of health service providers
- Trade unions and other labour organizations representing health workers
- International and national civil society organizations, including patient organizations
- Community groups and organizations
- Media, including print, electronic and social media
- United Nations and other multilateral organizations
- Development partners, donors and funding agencies
- Pharmaceutical and medical devices industry
- Health care information technology industry
- Private sector entities, including commercial businesses (industry) and health service provider organizations
- Health insurance and maintenance organizations

4.4 The WHO Secretariat

- WHO at all levels – country offices, regional offices and headquarters
- WHO geographically dispersed offices

5. Framework for action

The framework includes seven strategic objectives, which can be achieved through 35 specific strategies:



1. Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere
2. Build high-reliability health systems and health organizations that protect patients daily from harm
3. Assure the safety of every clinical process
4. Engage and empower patients and families to help and support the journey to safer health care
5. Inspire, educate, skill and protect health workers to contribute to the design and delivery of safe care systems
6. 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
7. Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care

Framework for Action - The 7x5 Matrix

1	**Policies to eliminate avoidable harm in health care**	1.1 Patient safety policy, strategy and implementation framework	1.2 Resource mobilization and allocation	1.3 Protective legislative measures	1.4 Safety standards, regulation and accreditation	1.5 World Patient Safety Day and Global Patient Safety Challenges
2	**High-reliability systems**	2.1 Transparency, openness and No blame culture	2.2 Good governance for the health care system	2.3 Leadership capacity for clinical and managerial functions	2.4 Human factors/ ergonomics for health systems resilience	2.5 Patient safety in emergencies and settings of extreme adversity
3	**Safety of clinical processes**	3.1 Safety of risk-prone clinical procedures	3.2 Global Patient Safety Challenge: *Medication Without Harm*	3.3 Infection prevention and control & antimicrobial resistance	3.4 Safety of medical devices, medicines, blood and vaccines	3.5 Patient safety in primary care and transitions of care
4	**Patient and family engagement**	4.1 Co-development of policies and programmes with patients	4.2 Learning from patient experience for safety improvement	4.3 Patient advocates and patient safety champions	4.4 Patient safety incident disclosure to victims	4.5 Information and education to patients and families
5	**Health worker education, skills and safety**	5.1 Patient safety in professional education and training	5.2 Centres of excellence for patient safety education and training	5.3 Patient safety competencies as regulatory requirements	5.4 Linking patient safety with appraisal system of health workers	5.5 Safe working environment for health workers
6	**Information, research and risk management**	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
7	**Synergy, partnership and solidarity**	7.1 Stakeholders engagement	7.2 Common understanding and shared commitment	7.3 Patient safety networks and collaboration	7.4 Cross geographical and multisectoral initiatives for patient safety	7.5 Alignment with technical programmes and initiatives

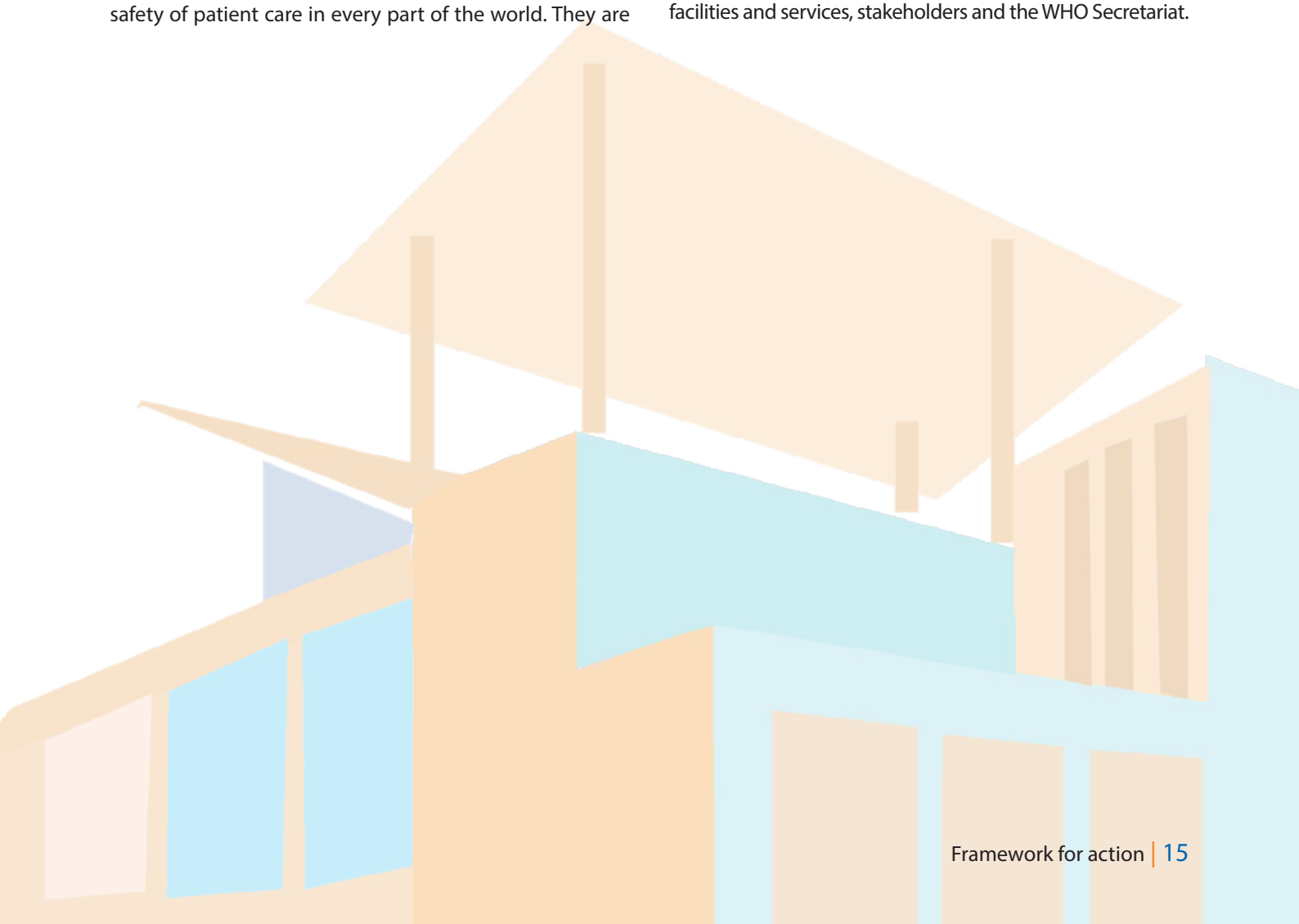
Strategic objectives and implementation strategies

Few large organizations in any sector across the world operate effectively without a clear, simple set of objectives that govern strategic and operational activities and are understood and owned by all staff. Establishing these at high-level for a system helps to focus all existing policies and activities of the health care system towards a common purpose. If few in number, and appropriately formulated, they can enable progress to be reviewed at strategic level and also at the level of the clinical team. The objectives should not create an extra burden, nor replace existing measures of performance within countries, nor in their systems and facilities. Instead, they should serve to unify the work of the leadership, the endeavours of managers and the care of doctors, nurses and other health workers. They should provide a test of everything from everyday clinical work to big strategic decisions about the design of health care systems. They should also provide a simple public accountability framework.

That is the purpose of the seven strategic objectives this framework provides for the global action plan. They are broad enough to make sense of the myriad of tasks required to reduce the risks and to improve the safety of patient care in every part of the world. They are articulated so that it is entirely permissible within their scope to formulate programmes of action that fit with local needs and priorities and that are shaped by the specific context. They do this precisely because they are intended to empower and not to constrain. So, for example, Objective 2 has meaning whether "high reliability" is being developed in a teaching hospital in Western Europe or in a rural health centre in a poor country in West Africa. Each will be aiming to do the very best they possibly can within their operating context and resource availability.

In turn, Objective 3, which deals with the important area of designing and operating safe care processes and pathways, is equally applicable to a high technology maternity service in a large Canadian city as it is to a service in a remote part of Sierra Leone trying to reduce maternal deaths from post-partum haemorrhage.

The strategic objectives are also intended to be easily understood and envisioned, readily communicated, and have an uplifting and inspiring tone as well as being few enough in number not to prove daunting and to cause implementation overload. The framework of action is further elucidated through 35 strategies, five under each of the strategic objectives, to create a seven by five matrix. Each strategy has been further elaborated into suggested actions for four sets of partners: governments, health care facilities and services, stakeholders and the WHO Secretariat.



Strategic Objective 1

Policies to eliminate avoidable harm in health care

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

This first objective, dealing with the idea of zero harm, has been very carefully judged. Arguments range in global health circles about the wisdom of setting a central or overarching goal. On the one hand, some people say that without a compelling vision, a programme will have no chance of adoption amongst the many global health programmes that set their direction on a highly desirable and beneficial outcome for humanity. Others claim that setting an unreachable goal is demoralizing and demotivating and will not attract people to its cause. The Global Patient Safety Action Plan 2021–2030 sets a vision and philosophy of zero harm, rather than a concrete target.

The need for a bold holistic objective to address the very existence of harm itself stems from the need to accept full accountability for solving definitively the problems that underlie safety, risk and harm in health care. The discourse on patient safety and its multifaceted nature over the last 20 years has not been enough to infuse leaders, clinicians and managers with the focus and commitment to drive major improvements in patient safety. Nor have the shocking numbers that paint the stark picture. To this day, health care systems and facilities deliver very variable levels of performance in patient safety. This can be seen across the world, within countries, between regions and localities, throughout fields of care. Errors provoked by flawed systems are common and continue to harm people. These problems are not unique to any one health system, but over the years they have proved mostly intractable.

Yet, the reduction of the currently unacceptable levels of avoidable harm is entirely within reach. Certainly, zero harm is unlikely to be achieved in any foreseeable timescale. But no one would argue that any harm caused to a recipient of health care should be tolerated. Getting the numbers down to zero will not be possible for now. However, a mindset of zero harm and a frame of reference for planning and delivering health care would be a seismic shift from the current status quo that lives with high levels of avoidable harm. Basing every thought in every plan, every step in the design of every programme, every decision in every clinical encounter, every opportunity to learn when something goes wrong, on this philosophy would create a new paradigm in health care. It will be truly transformative and, far from being purely idealistic and intangible, it has the potential to make huge reductions in death, disability, and physical and psychological injury from unsafe care.

Strategic objective 1:

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

STRATEGY 1.1:

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

Actions for governments

- Recognize patient safety as a health priority in health sector policies and programmes, making it an essential component for strengthening health care systems in order to achieve universal health coverage.
- Establish a national patient safety programme supported by a patient safety policy, strategy, institutional framework and action plan within the health care context in the country, including overall health priorities and goals; current levels and sources of avoidable risks and harm; resources available; and both public and private sector service providers.
- Work in collaboration with other countries, civil society organizations, patient organizations, professional bodies, academic and research institutions, industry and other relevant stakeholders to promote, prioritize and embed patient safety in all health policies and strategies.
- Map the existing national health policy and strategy landscape, including universal health coverage, primary health care, quality of care and health workforce, to create maximum opportunities for synergies with the patient safety policy framework.
- Integrate implementation with safety-critical technical programmes such as surgical safety, medication safety, blood safety, radiation safety, immunization safety, medical device safety, infection prevention and control and antimicrobial resistance, while establishing a national patient safety programme.
- Adapt WHO patient safety technical guidance, implementation strategies and tools to the national context and build capacity in patient safety.
- Create a national patient safety charter that includes institutional standards and patients' and health workers' rights and responsibilities.

Actions for health care facilities and services

- State a clear public commitment that the organization is working to orient culture and practices towards zero avoidable harm.
- Align and implement processes and practices at the facility level with patient safety guidelines, protocols and standard operating procedures.
- Review progress on patient safety performance at the organization's main management committee meetings and all other key governing body meetings.

Actions for stakeholders

- Advocate patient safety as a strategic priority for Member States and health care organizations.
- Engage with professional organizations and patient organizations to develop and implement the patient safety goals, objectives and values.
- Participate in, support and facilitate patient safety programmes at local, national and global levels.

Actions for the WHO Secretariat

- Provide high-level advocacy and guidance at global, regional and national levels to create a vision for eliminating avoidable harm in health care.
- Identify patient safety as a key strategic priority in WHO's work across the universal health coverage agenda, and in global strategies and interventions for achieving universal health coverage.

- Develop and disseminate guidance and tools for the formulation of national patient safety policy, strategy, framework and action plans.
- Collate and disseminate best practices in developing and implementing patient safety policies, strategies and plans.

STRATEGY 1.2:

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

Actions for governments

- Allocate adequate human resources and sustainable finances for a national patient safety plan within the financial structure of the health system through mechanisms such as a specific budget, health insurance or other mechanisms.
- Produce an annual budget and human resource plan for a national patient safety action plan.
- Take steps to limit overcrowding in hospitals through optimal resource planning, primary care gatekeeping, scientific layout and process design, and other evidence-based interventions.
- Ensure sufficient funding to deliver needs-based safe staffing and establish effective human resource planning to ensure an adequate supply of health workers to meet patient and population needs.
- Explore whether the system of funding of health care in the country can be adjusted to reward health organizations that achieve performance on patient safety.

Actions for health care facilities and services

- Incorporate activities for patient safety implementation in the organization's overall operational plan, including annual budget and human resource plan.
- Allocate adequate financial resources for patient safety implementation at the organizational level.
- Provide an adequate level of staffing with an appropriate skills mix; develop information systems based on reliable real-time data, agreed metrics, benchmarking and best practices to inform evidence-based planning.
- Ensure optimal staffing, infrastructure, layout and process flow to limit overcrowding in health care facilities.

Actions for stakeholders

- Advocate provision of adequate human and financial resources to tackle the most serious patient safety problems.
- Engage the private sector to help it define its role in improving patient safety.
- Publicize patient safety solutions to garner public support.
- Advocate measures to address overcrowding in health care facilities at the local, national and global levels.

Actions for the WHO Secretariat

- Provide advocacy to Member States and partners for sustainable financial mechanisms and allocation of adequate resources for patient safety implementation, and support resource mobilization.
- Create organizational structures with dedicated teams and provide adequate human and financial resources across WHO for patient safety activities.
- Mobilize, allocate and provide guidance on assessing and obtaining adequate resources for patient safety campaigns, initiatives, programmes and consultations, and for country cooperation and technical support.
- Provide guidance and recommendation for policies and tools to limit overcrowding in health care facilities.

STRATEGY 1.3:

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

Actions for governments

- Review and develop legislation governing the country's health system to facilitate the formulation and implementation of patient safety policies, practices and behavioural norms.
- Develop legislation to protect health workers from retaliation or punitive action in the case of reporting an adverse event; introduce mandatory licensing schemes for health care professional that incorporate patient safety aspects; recognize patient safety as a human right incorporating access to safe medicines, medical devices, blood products, and essential health services.

Actions for health care facilities and services

- Leverage opportunities through existing national legislation to strengthen measures to protect patients and health workers from avoidable harm and to systematically improve patient safety.
- Map regulatory and statutory requirements applicable to health care facilities and ensure full compliance, including obtaining and timely renewal of all licences.

Actions for stakeholders

- Coordinate professional organizations, civil society organizations, patient and community groups, and other bodies with an interest in patient safety to identify scope for new legislation, and then advocate to lawmakers and national government to enact such measures.
- Partner with patient-led organizations to raise public awareness of the impact that safe staffing has on patients, families and communities.

Actions for the WHO Secretariat

- Provide advocacy and technical support to Member States in developing and amending legislation for improving patient safety and health worker safety.
- Collate and disseminate best practices in legislation for the protection of patients and health workers from avoidable harm.

STRATEGY 1.4:

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

Actions for governments

- Define and incorporate minimum patient safety standards in regulatory requirements for health care facilities.
- Include or augment patient safety as a key component of voluntary accreditation standards and award criteria.
- Include patient safety requirements in health system performance assessment.
- Mandate patient safety requirements in licensing and relicensing schemes for health care professionals.

Actions for health care facilities and services

- Implement the licensing, regulatory and accreditation requirements for patient safety in all service areas.
- Communicate to all staff on a regular basis about patient safety licensing, regulatory and accreditation systems that the organization is signed up to.
- Incorporate a culture of continuous improvement of patient safety utilizing principles of quality improvement.
- Feed information back to national government on the ways in which licensing, regulatory and accreditation systems could be improved to better facilitate the achievement of higher standards of patient safety.

Actions for stakeholders

- Adequately address patient safety requirements in international accreditation standards and programmes.
- Convene researchers and research bodies to create an evidence base (including commissioning new research where necessary) on the effectiveness of licensing, regulatory and accreditation systems in improving patient safety.
- Bring together experts, health system leaders and civil society organizations to establish the ways to interpret and use patient safety performance information produced from the processes of licensing, regulation and accreditation of health care facilities and professionals.

Actions for the WHO Secretariat

- Provide technical support and expert guidance for Member States to build patient safety strengthening measures into their national health care licensing, regulatory and accreditation systems.
- Develop normative guidance on minimum standards for patient safety.

STRATEGY 1.5:

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

Actions for governments

- Participate in designing the World Patient Safety Day global campaign annually.
- Adapt, develop and launch national campaigns aligned with the theme of World Patient Safety Day each year.
- Observe World Patient Safety Day annually on 17 September through organizing activities and events (for example, lighting up iconic landmarks in orange) and educating the public on the importance of patient safety.
- Engage all related stakeholders and initiate sustained action on the theme of World Patient Safety Day.
- Restate the government's commitment to patient safety and showcase its achievements and progress towards reaching national milestones on World Patient Safety Day.
- Adopt and implement annual World Patient Safety Day goals and other theme-specific technical products.
- Monitor and evaluate the outcome and impact of World Patient Safety Day.
- Commit to prioritize and take action to achieve the goals of Global Patient Safety Challenges with required leadership, coordination, expert advisory structures, and monitoring and evaluation.

Actions for health care facilities and services

- Recognize and observe World Patient Safety Day every year.
- Adapt and develop local campaigns aligned with the national campaign and the theme of World Patient Safety Day each year.
- Showcase the patient safety work and achievements at the point of care over the previous year as part of the World Patient Safety Day communications.
- Implement annual World Patient Safety Day goals.
- Implement the actions required by the Global Patient Safety Challenges at health care service delivery level.

Actions for stakeholders

- Help to shape and amplify the messages of World Patient Safety Day every year through networks and partners.
- Support the implementation of annual World Patient Safety Day goals.
- Collaborate in implementation of existing WHO Global Patient Safety Challenges.
- Participate in the design of new Global Patient Safety Challenges.

Actions for the WHO Secretariat

- Develop a global campaign each year for World Patient Safety Day, including the selection of a theme, key messages, production of communication materials, and collation and dissemination of success stories.
- Launch a set of annual World Patient Safety Day goals linked with the annual theme for focused action.
- Organize events for World Patient Safety Day and coordinate action through WHO regions, Member States, professional organizations and civil society organizations.
- Evaluate the outcome and impact of World Patient Safety Day.
- Design WHO Global Patient Safety Challenges based on lessons learned from previous Challenges.
- Develop implementation tools and provide technical support to Member States for delivering the goals and activities of the Global Patient Safety Challenges.
- Develop monitoring and evaluation tools for assessing the progress of and possible improvements on the WHO Global Patient Safety Challenges and World Patient Safety Day.

Technical resources

Canadian Patient Safety Institute. 2019. Strengthening commitment for improvement together: a policy framework for patient safety. Edmonton, Alberta; CPSI/ICSP (https://www.patientsafetyinstitute.ca/en/toolsResources/PolicyFrameworkforPatientSafetyCanada/Documents/PolicyFramework%20Document%20ENG%20FINAL.pdf, accessed 16 July 2021).

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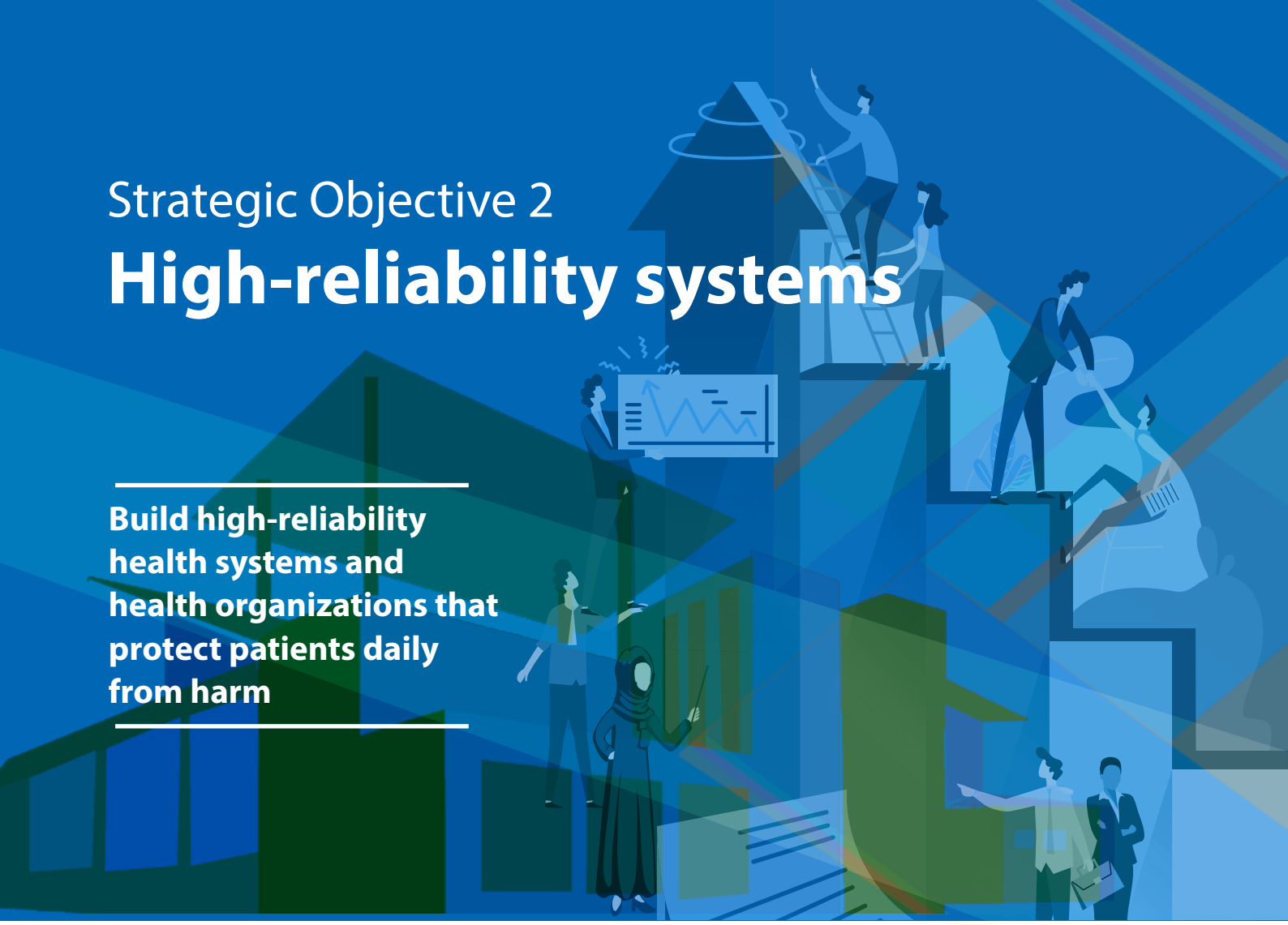

Strategic Objective 2

High-reliability systems

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

A key success factor in high-risk industries other than health care is the emphasis placed on preventing accidents, harm and mistakes that have serious consequences. The concept that has emerged from this approach is *resilience*, which is an organization's capacity and capability to constantly maintain a safe state of operating and to recover quickly and restore this safe state when something goes wrong. Such organizations have an ability to anticipate problems, use data to monitor processes and work conditions, respond to signals in anticipation of challenges, and consistently learn from successes and failures.

The promotion of resilience forms the basis of its practical application in the concept of *high-reliability organizations*. The academic work in this field is extensive and has sought to identify organizations whose safety performance is impeccable, especially in domains that are complex and where failure can be catastrophic. Most studies have been in industries and operating situations outside health care. However, the concept has prompted a debate in the patient safety about whether too much faith has been placed in learning from failure and not enough emphasis on understanding what creates success.

These two schools of thought have been called *Patient Safety I and Patient Safety II*. In reality, both are needed if transformational change is to be achieved in patient safety. It should be possible to learn from avoidable patient safety incidents and their causes as much as episodes of peer-reported excellence or positive deviance. The scientific discipline of patient safety and the tools and approaches developed to learn from incidents have an established ontology with standardized concepts and agreed definitions and preferred terms for reliable study. Sociotechnical systems are complex. The contributing factors thought to have played a part in the origin of an incident in one care setting that permit excellence to permeate in another. Those responsible for improving and sustaining safety in organizations must invest in learning mechanisms responsive to cues from both the good and the bad. However, it is fair to say that less strategic attention has been given to how to build high-reliability organizations in health care. That it is why it is important that it should be one of the seven strategic objectives in this global action plan.

Characteristics of high-reliability organizations

The work of Karl Weick and Kathleen Sutcliffe has attracted a great deal of interest from the patient safety community. Based on the study of many organizations and situations, these researchers have distilled five characteristics of a high-reliability organization.

- **Preoccupation with failure.** High-reliability organizations stand out because they treat every small lapse as a potential symptom of an important system weakness that could have major consequences down the track.
- **Reluctance to simplify.** Another feature of high-reliability organizations is the unwillingness to respond to the complexity of processes, technologies and delivery environments by adopting a simplified view of them in order to stay focused on a small number of key tasks. Some aspects of understanding a complex operation can be simplified, but a much more nuanced and holistic acceptance of the complex elements and how they are interconnected is essential to staying safe.
- **Sensitivity to operations.** In high-reliability organizations, there is a strong emphasis on paying attention to how small changes affect the rest of system. It involves a widened perspective so that focusing on one thing does not have negative repercussions on another. Sensitivity to operations is about the work itself, about seeing what we are actually doing, regardless of intentions, designs and plans.
- **Commitment to resilience.** The hallmark of a high-reliability organization is not that it is error free, but that errors do not disable it. Resilience is an amalgam of keeping errors small and allowing continued safe functioning.
- **Deference to expertise.** The fifth and final consistent feature of high-reliability organizations is their policy of cultivating diversity so that someone will understand each of the complex aspects of the system. Authority will migrate to the person with the greatest expertise, irrespective of their status within the organization. Hierarchies are generally bad for maintaining safe systems, as is deference to authority rather than to expertise.

Safety culture and leadership

When culture is mentioned in relation to patient safety, most people's thoughts will turn to the frequently discussed concept of the "no blame" culture. Since most mistakes are honest failures provoked by poorly designed systems, to blame and punish an individual is unfair and misguided. A culture that is based on blame and retribution will ultimately be unsafe because individuals will be afraid to admit their mistakes and will instead hide them. If a culture of blame and fear is dominant in a health organization, it is quite impossible to have a meaningful programme of patient safety.

Despite its success as a policy in other sectors, such as aviation, the idea of a no blame stance in response to serious avoidable events that harm patients has not made sense to the public and media. This is because it seems to dismiss any form of accountability for individuals. Attempts have been made to deal with the terminology aspect of this by adopting the term "a just culture". A just culture 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.

One informal definition of culture is: "the way we do things around here", to which is sometimes added: "… when no one is looking". Thus, a true patient safety culture would have other good habits such as using data, openness, respect, teamwork, transparency, willingness to learn and change, and being fully patient centred. To strengthen the leadership and patient safety culture, true transparency to both providers and patients at every level of the system is required – transparency to share information, but also transparency in reducing the hierarchical approach.

Developing and sustaining a strong patient safety-oriented culture requires strong leadership at all levels – in ministries of health, health care facilities and in every clinical team. There is a need for a new generation of patient safety leaders who are skilled and passionate to create the conditions and organizational and team cultures for safer care, to ensure that all systems and procedures comply with the highest standards, and to guide and motivate staff.

Human factors or ergonomics

Human factors or ergonomics is key to the creation of high-reliability, resilient health care systems and organizations. One of the biggest contrasts between health care and other high-risk industries is the emphasis given by the latter to human factors in understanding how safety problems develop and how this knowledge can be applied to building a system's defences to make it more resilient to accidents and adverse events.

The description "human factors" is today used interchangeably with the older term "ergonomics" and they are often used together – "human factors/ergonomics". In this report, the term "human factors" has been used.

This important discipline of science and practice is concerned with understanding interactions among humans and other elements of a system. The human factors approach applies theory, principles, data and methods from relevant fields to design for human well-being and overall system performance. Its practical application grew strongly after the Second World War and made major contributions to safety in aviation and other fields. In aviation, the standardized redesign of cockpits, strengthening of communication, introduction of strict protocols for handling in-flight emergencies, and investment in simulation training has greatly improved safety and has been driven by human factors perspectives.

Similarly, human factors are critical to the design of safe and resilient health care and patient safety systems. The human factors, multidisciplinary, integrative approach looks at the person embedded in a sociotechnical context, considering health workers in the work environment and the patient on the journey of care. Attention to human factors is evident in resilient and equitable health care systems. On the other hand, poor human factors are evident in inflexible or error-prone health care systems and is a consistent factor in adverse health care events. For some years, health care leaders and managers have been interested in the benefits to their health systems and organizations of the human factors approach and the potential gains in improved performance in patient safety, but implementation of the approach has so far been on a very limited scale. However, incorporating the following essential elements of human factors across all health care contexts is one of the keys to achieving the strategic objectives of this global action plan.

- **Person-centred approach** focusing on supporting human performance, effectiveness, and well-being in the health care context. This protects patients as well as caregivers.
- **Participatory approach** to health care system design, engaging all stakeholders (for example, caregivers, patients, managers) in the design and decision process to ensure appropriate and workable solutions.
- **Design-driven approach** focusing on the design of the system for all sizes and types of health care organizations at all stages of care and identifying the gaps in the system. A human factors approach draws on the relevant disciplines that are required and integrates the knowledge and findings to come up with a solution.
- **Systems approach** considers multiple levels: the micro level of the patient; the macro level of the organization; and the meso level, that is, the interaction between individuals, organizations and sociotechnical systems. The human factors approach takes into account not only the people in the system but also the environment, the surroundings and the physical context, as well as the procedures, artefacts, safety checks, teamwork, risks, organizational culture and structure, and national regulations and policies. Consideration and integration of all these factors is required to produce a system that is resilient and can enhance safety.
- **Continuous learning and refinement,** improving work systems iteratively through monitoring, reporting, evaluation, training, refining practices and redesigning.

Transformational leadership

The action required in this global action plan is transformational in nature. Transformational change must be led by high-quality leaders. The key areas of this leadership that will determine the effectiveness of the strategic objectives include:

- regular and consistent communication of a vision of patient-centred, harm-free, safe services as the central purpose of all health care;
- making the vision, guiding principles, strategic objectives and strategies set out here become the currency through which the business of patient safety worldwide is conducted;
- identifying, surfacing and addressing the issues in the design, organization and delivery of services that will have the biggest impact on the safety and resilience of services;
- creating a sense of "team" with clinical leaders (avoiding "us and them"), as well as listening and acting upon their concerns and ideas.

Emergency preparedness and response plans should not only clarify roles and responsibilities during an emergency to assure a coordinated response but should also contain basic projections of needed goods and services for the response to be carried out, patient safety to be assured, and health worker safety to be secured.

Strategic objective 2:

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

STRATEGY 2.1:

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

Actions for governments

- Introduce and implement administrative and legal protection mechanisms, as applicable, for those reporting adverse events or raising concerns about the safety of services.
- Ensure the protection mechanism is based on learnings from patient safety failures and refining the work system, rather than punishing individuals, and is widely available and known to all stakeholders.
- Appoint an independent organization for receiving, analysing, synthesizing and publicly reporting information on the safety of health care in the country and commenting upon progress, as applicable.
- Define clear-cut boundaries and distinctions between medical errors and medical negligence in order to establish a just culture and facilitate appropriate corrective actions.
- Adopt global approaches for establishment of a safety culture across the health system, including building competencies in methods for culture change.

Actions for health care facilities and services

- Establish and promote a non-punitive policy for responding to and learning from adverse events and errors as well as from what goes well, whilst clarifying the circumstances where individual accountability will apply.
- Develop a system for rapidly implementing recommendations from analyses of adverse events and through proactive risk management.
- Conduct a regular survey of the organization's safety culture, identify gaps and introduce innovative approaches to building safety culture, in line with international experience and best practice.
- Reduce hierarchical structures, attitudes and behaviour throughout the organization, promoting a speak-up culture.
- Promote transparency with patients; ensure that patients have access to their medical records and that fully informed consent is practised.
- Create open and respectful rights-based organizational cultures.

Actions for stakeholders

- Work with professional bodies to strengthen openness and learning in safety culture.
- Encourage members of the public to contribute to establishment of a safety culture in the health system by reporting to patient safety systems and learning from publicly reported safety data.
- Engage patients and families and seek their advice in building a safety culture and a just culture in health care.

Actions for the WHO Secretariat

- Advocate and promote the importance of just culture and safety culture concepts for patient safety improvements within health care systems.
- Develop and disseminate guidance on establishing a safety culture, including patient safety culture surveys, and other technical resources and tools.
- Provide technical support to Member States to establish a safety culture adapted to the local context, in all health care organizations and at all levels.

STRATEGY 2.2:

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

Actions for governments

- Designate a national patient safety officer, team, agency or centre, appropriate to the national context and responsible for the coordination of patient safety implementation within the country.
- Establish a national patient safety steering committee, including multidisciplinary representation from health workers, patients and the public, to advise on executing and monitoring the action plan, including resource allocation.
- Establish arrangements to strengthen organizational structures for patient safety at the national, subnational and local levels of health care planning and provision.
- Map the existing organizational structures related to patient safety, including all allied clinical areas, health programmes and quality improvement in the health system, and develop an optimal governance structure for patient safety following principles of quality management.
- Define roles and responsibilities within the institutional framework, with a clear demarcation of authority and responsibilities, channels of reporting and communication, and conflict resolution for operationalizing patient safety structures and processes at national and sub national level.
- Create a statutory requirement and accountability mechanism for all health care organizations to operate transparently, ensure minimum safety standards and publish an annual report on patient safety.

Actions for health care facilities and services

- Designate an officer or a team responsible for patient safety and clinical risk management in each health care facility to minimize patient harm, manage risks and improve patient safety.
- Establish a patient safety committee at the organizational level, including patient safety and clinical leadership, to adapt and implement national patient safety priorities aligned with local priorities.
- Establish a clear specification of roles and responsibilities to identify, mitigate and (where possible) eliminate risks to patients and staff.
- Design and implement an effective clinical governance structure to fully engage front-line health care professionals in the organization's patient safety policies and programmes.

Actions for stakeholders

- Bring together all key stakeholders (including national professional associations, academic experts, researchers, civil society organizations) to pool experience and knowledge, nominate patient representatives, and generate ideas about how to build institutional governance mechanisms for patient safety within health care systems.

Actions for the WHO Secretariat

- Establish a global patient safety advisory committee to guide and advise on the global implementation of World Health Assembly resolution WHA72.6.
- Establish a global governance mechanism for patient safety with participation of Member States, WHO Collaborating Centres, international professional associations, standard-setting agencies, patient organizations and research institutions, with elements of accountability and mandatory reporting on issues vital to patient safety internationally.
- Appoint or designate a focal person for patient safety within all functional levels of WHO.

STRATEGY 2.3:

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

Actions for governments

- Designate one or more centres in the country to develop capacity in patient safety leadership, research and innovation.
- Establish a leadership capacity development programme in patient safety for clinical and managerial leaders and multi-tiered levels of workforce education and training that could influence decisions and configuration at institutions.
- Establish a patient safety leader group for early career professionals in existing health care positions.

Actions for health care facilities and services

- Appoint or designate a senior officer in the organization to a patient safety leadership position.
- Designate patient safety leadership roles in every clinical service and train, develop and support existing staff to fill them.
- Make a leaders' succession plan to ensure continuity, sustainability and cultural consistency of the patient safety programmes in each clinical service.

Actions for stakeholders

- Convene wide-ranging discussions amongst stakeholders to identify priorities for leadership development in patient safety.
- Participate in the development of patient safety leadership training programmes by bringing in the perspective of different stakeholders.
- Promote implementation of the training programmes at national and subnational levels.

Actions for the WHO Secretariat

- Develop a leadership competency framework with implementation guidance and accompanying tools, and provide technical support to Member States for its implementation.
- Design training courses and programmes, including in e-learning format, for building leadership capacity in patient safety for different categories of health professionals.

STRATEGY 2.4:

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

Actions for governments

- Establish an expert group to report on the ways in which human factor-related principles and training could drive sustained improvements in patient safety.
- Incorporate expertise on human factors into the design, purchase, deployment, use and evaluation of equipment, devices and information technology, as well as in the design of tasks and procedures.
- Ensure that all licensing, regulatory and accreditation requirements for patient safety involve principles of and training on human factors.
- Develop or facilitate availability of training programmes on human factors for health care professionals and managers.
- Establish and enforce norms for fire safety, electrical safety and structural safety in health care facilities.

Actions for health care facilities and services

- Assess gaps in relation to human factors in service delivery processes, workplace design and care environments.
- Build the capacity of patient safety leaders in human factors.
- Provide all health care staff with training on human factors.
- Ensure compliance with physical safety norms such as fire safety, electrical safety and structural safety.

Actions for stakeholders

- Encourage researchers and research bodies to conduct and commission high-quality studies on the application of human factors in improving the safety of health care and reducing the level of avoidable harm.
- Promote and support educational specialist programmes on human factors.
- Mobilize the expertise and practical know-how of those in other high-risk industries to inform the design of action programmes to improve patient safety and build resilient health care organizations.

Actions for the WHO Secretariat

- Foster the development of a global network of individuals and organizations with expertise, academic knowledge and experience in human factors to focus their attention on improving patient safety and resilient health care.
- Incorporate human factor principles into global patient safety standards and other related guidance.

STRATEGY 2.5:

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

Actions for governments

- Ensure representation of patient safety focal points in coordination mechanisms, including all health system actors (leadership, service delivery, finance, supply chain management, health workforce, health information system) from related sectors (developmental or humanitarian).
- Ensure incorporation of patient safety elements in national policies, strategies and plans (preparedness, response, recovery, routine).
- Maintain a risk register of all known and potential threats to the safe and effective functioning of health care systems.
- Develop mitigation strategies for identified risks.
- Test the resilience of the plan by regular rehearsal exercises and strengthen them accordingly.

Actions for health care facilities and services

- Identify the risks associated within the context of emergencies, disease outbreaks and settings of extreme adversity that have the potential to cause patient and health worker harm.
- Prepare a risk mitigation plan in line with the government's guidance.
- Test the resilience of the plan by regular simulation exercises and strengthen it accordingly.

Actions for stakeholders

- Provide support and expertise for incorporation of patient safety elements in national policies, strategies, plans and normative guidance.
- Work with civil society organizations to mobilize the public, raise awareness and engage communities on the importance of patient and health worker safety and a safe working environment.
- Identify and facilitate opportunities for widening multisectoral collaboration, support and prioritization of safety in health care.

Actions for the WHO Secretariat

- Work with partners within WHO and externally to incorporate patient safety elements in guidance documents, policies, strategies and action plans (preparedness, response, recovery, routine).
- Provide normative guidance to ensure the safe and effective functioning of health care systems in terms of patient safety, health worker safety and safe working environment.
- Provide technical support to Member States on inclusion of patient safety elements into national policies, strategies and plans.

Technical resources

Auraaen A, Saar K, Klazinga N. 2020. System governance towards improved patient safety: key functions, approaches and pathways to implementation. OECD Health Working Papers No. 120. Paris: Organisation for Economic Co-operation and Development (https://doi.org/10.1787/2abdd834-en, accessed 16 July 2021).

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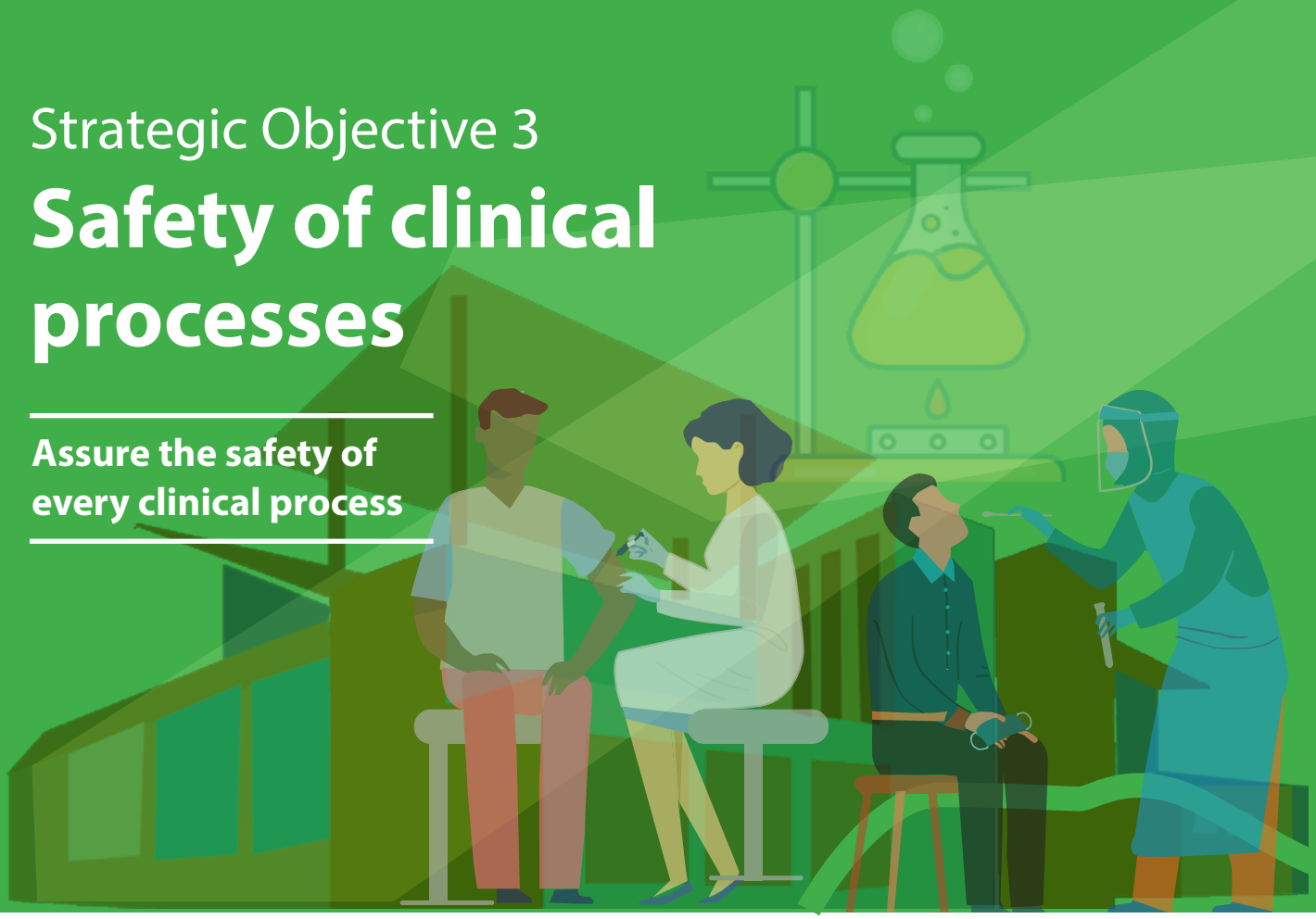
World Health Organization. 2018. Essential public health functions, health systems and health security: developing conceptual clarity and a WHO roadmap for action. Geneva: WHO (https://www.who.int/publications/i/item/9789241514088, 16 July 2021).

World Health Organization. 2020. Quality of care in fragile, conflict-affected and vulnerable settings: taking action. Geneva: WHO (https://apps.who.int/iris/bitstream/handle/10665/337842/9789240015203-eng.pdf?sequence=1&isAllowed=y, accessed 16 July 2021).

World Health Organization. 2020. Quality of care in fragile, conflict-affected and vulnerable settings: tools and resources compendium. Geneva: WHO (https://apps.who.int/iris/bitstream/handle/10665/338035/9789240018006-eng.pdf?sequence=1&isAllowed=y, accessed 16 July 2021).

Strategic Objective 3

Safety of clinical processes



Assure the safety of every clinical process

As patients seek help from a health care system for advice, investigation, diagnosis, treatment and rehabilitation, they enter a series of care processes that are often extensively interconnected. The number and range of clinical processes and procedures is huge and varies from the relatively simple, such as prescribing a medicine, to the much more complex, such as major heart surgery. In the latter case, every part of the preparation, the procedure itself, and the aftercare comprises many processes, each involving separate steps and stages, even routinely encompassing 60 people and sometimes more.

A high proportion of the patient safety incidents that occur in health care systems around the world is due to flaws in the design or operation of clinical processes. For example, research and patient safety incident reports show that patients' conditions are often misdiagnosed because of clinical misjudgements, or when the correct test is not carried out or test results are lost, or because of miscommunication between different parts of the same health care system, among other reasons. Prominent among these reasons is the failure to communicate well with the patient. In surgical services in different parts of the world, the wrong procedure is carried out, the wrong blood group or component is transfused, or the wrong prosthesis is inserted, or even the wrong patient is operated on. Patients die or are harmed because of failure to deliver care in a way that protects them from acquiring serious infection. Mothers and babies die during or after birth because of unsafe practices, failure to take the right action at the right time, or shortages of staff or equipment. Large numbers of patient safety incidents occur because of errors in the prescribing, ordering, storage, dispensing, preparation and administration of medicines, or failure to monitor processes related to and use of medicines.

In many low-income and some middle-income countries, the context of health care provision is very different. At times, facilities in those settings may be unable to provide the bare minimum to complete clinical work to a basic standard, let alone carry out tasks taking safety into account. For example, there may be no running water or soap; no sterilized instruments; no protective masks; no support to repair or maintain

the infrastructure, including electricity; ineffective clinical waste disposal systems; no robust supply chains and inadequate storage conditions for medicines; no technical support for the maintenance of devices; no fire safety measures; poor housekeeping and security; or no information technology or data sources. If this lack of basic infrastructure as a source of harm is not addressed, there is little virtue in enforcing checklists or complex patient safety interventions drawn from high-income settings.

A much broader approach to patient safety is required for countries with limited resources receiving visits from clinical experts from more affluent countries. This is an important form of support but, sometimes, rather than advice or training in surgical technique, what is needed from visitors to a hospital in a low-income country is someone who knows how to establish a safe clinical waste facility, or teach the maintenance of a neonatal incubator, or address the nutritional status of patients.

This broader thinking on what constitutes safe clinical care is also required in countries where there is conflict and political instability. There will already be a lack of resources, but the presence of weakened health systems will have greatly increased the need for health care. Large cross-border refugee or migrating populations and encampments, as well as frequent disease epidemics, create enormous challenges. The humanitarian agencies have much wisdom and experience to contribute here.

These examples highlight the need for a systems approach in the design of clinical processes. The requirements for safe design will vary depending on the circumstances and situation, so processes must be tailored accordingly. All factors that impact the clinical process must be considered in process design, that is, the environment, the surroundings and physical context, procedures, artefacts, safety checks, teamwork, risks, the organizational culture and structure, as well as national regulations and policies. Ultimately, the design and operation of safe clinical processes means overcoming the challenges of their diversity and complexity. There are more than 4000 medical and surgical procedures that can be carried out. For doctors and nurses managing clinical processes, the amount of information they need to guide them is increasing all the time. Every day, nearly 7000 papers are published and listed in the main clinical science database. Thus, it is incredibly difficult for the busy individual clinician to keep abreast of what is the latest and the best evidence.

There are a number of generic features of clinical processes that determine whether they are at risk of delivering an unsafe outcome. For example, incorrect patient identification is responsible for medication errors and wrong site, wrong patient surgery. Improving critical communication amongst health workers and with patients is crucial and would prevent millions of adverse events. The design of the packaging and labelling of medicines contributes to medication errors and deaths.

Then there are key clinical areas where adverse outcomes consistently occur because of failures in the safety of care. For example, reporting data and research studies show that patient falls account for a substantial proportion of avoidable harm. They occur in hospitals and health care facilities in all parts of the world, but 80% happen in low- and middle-income countries. Falls can have serious consequences, such as fractured hips, brain haemorrhage and sometimes death. Underlying process failures include poor supervision of elderly patients, neglecting to carry out assessment for ambulation, and hazardous environments. Successful solutions have involved more cohesive teamwork, good monitoring data, creating the right culture, a critical review of environmental hazards and strongly enforcing best-practice protocols for making prevention of falls a priority.

There is also a range of other clinical programmes that have organizational frameworks, leadership modalities and delivery mechanisms at global, regional, country, health facility and community levels. Most may not have a direct interaction or linkage with the patient safety programme. These programmes include immunization, blood transfusion, radiation therapy, injections, childbirth, surgery, mental health, ageing population, primary care, injury prevention, and noncommunicable and communicable diseases. Patient safety plays a central role in all these programmes, but the potential to identify sources of risk and harm and design ways to combat them has been underexplored.

Strategic objective 3:

Assure the safety of every clinical process

STRATEGY 3.1:

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

Actions for governments

- Create expert groups to identify, assess, map and widely communicate the information on key areas and sources of avoidable risk and harm in each domain of clinical practice.
- Create and regularly update a database of knowledge and tools to enable organizations and health care professionals to mitigate the risks and manage harm associated with clinical processes.
- Establish a range of clinically led patient safety improvement programmes each year consistent with the national patient safety plan and strategy (see strategy 1.1) that target systemic themes (patient identification, diagnostic safety); patient groups (dementia patients, paediatric patients); health care settings (primary care, nursing homes); sources of harm (venous thromboembolism, sepsis and patient falls); clinical practice domains (surgical care, obstetric services, critical care, emergency medical services, radiotherapy); and mental health and public health programmes (immunization, reproductive health, maternal health).
- Provide guidance and leadership support to annual patient safety improvement programmes, evaluate them, and disseminate lessons learned with overall safety and quality improvement programmes in the health sector.

Actions for health care facilities and services

- Designate or appoint patient safety officers or clinical risk managers in large health care facilities.
- Establish a clinical leadership group within the organization to adapt and drive forward the annual national patient safety improvement priorities together with local priorities for clinical services.
- Identify key clinical service areas requiring focused patient safety improvement based on national and local health priorities, criticality of delivered services, and safety incidents reported.
- Identify all risk-prone clinical procedures within the spectrum of care delivered to patients by the organization and develop a package of actions for risk mitigation.
- Apply basic principles for quality management and improvement science methods for improving clinical services and outcomes.
- Implement clinical risk management activities to improve patient care, for example to address venous thromboembolism, falls and pressure ulcers, patient identification and communication during transitions of care.
- Promote the wider use of validated standard operating procedures in all clinical areas in consultation with clinicians.

Actions for stakeholders

- Encourage and facilitate professional organizations to systematically identify the sources of risk and harm in each area of clinical care, and to formulate patient safety solutions for different health care settings and share their expertise.
- Set up mechanisms for patients and families to co-design safer health care processes.
- Support countries and health service providers in prioritizing clinical safety programmes based on context, burden and feasibility.
- Advocate inclusion of, incorporate and prioritize patient safety components in international public health programmes, such as maternal and newborn health, reproductive health, immunization and neglected tropical diseases.
- Form collaborative working arrangements with private sector partners to identify and mitigate risks inherent to their products and services.

Actions for the WHO Secretariat

- Review evidence to identify risk-prone clinical procedures in collaboration with professional bodies, experts, academia, and patient and family representatives, and other relevant stakeholders and partners.
- Develop assessment tools and guidance to identify and mitigate these risks, for example in the areas of diagnostic safety, patient falls, and hospital-associated venous thromboembolism.
- Develop patient safety improvement programmes in collaboration with related WHO departments that target different themes, patient groups, health care settings, sources of harm, clinical domains and public health programmes.
- Support the implementation, monitoring and evaluation of tools and resources, for example the WHO Surgical Safety Checklist and WHO Safe Childbirth Checklist.
- Collate and disseminate best practices and success stories.

STRATEGY 3.2:

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

Actions for governments

- Take early action to protect patients from harm arising from high-risk situations, polypharmacy and transitions of care.
- Convene national experts, health system leaders and practitioners in multidisciplinary task teams to produce guidance and action plans for each of the four domains (patients and the public, medicines, health care professionals, systems and practices of medication) of the third WHO Global Patient Safety Challenge: *Medication Without Harm*.
- Put mechanisms in place, including the use of tools and technologies, to enhance patient awareness and knowledge about the medicines and medication use process, including patients' roles in managing their own medications safely.
- Ensure that safety of traditional and complementary medication use is included in programmes to address medication safety.
- Designate a national coordinator to spearhead the third WHO Global Patient Safety Challenge: *Medication Without Harm.*
- Encourage reporting of adverse drug (medication) events (ADEs) and medication errors.

Actions for health care facilities and services

- Establish a leadership group within the organization to implement the third WHO Global Patient Safety Challenge: *Medication Without Harm,* to undertake assessment and to agree early actions, taking account of national guidance and priorities.
- Designate an officer or a team responsible for medication safety in each health care facility; raise awareness about medication risks and implement safety practices in every clinical service within the organization.
- Identify medication-related errors and harm through the organization's patient safety incident reporting and learning system, investigate their root causes, and take action to ensure that learning is prioritized.
- Monitor progress in reducing medication-related harm within the organization's services, using the existing pharmacovigilance system where appropriate. Alert national authorities to any apparently new source of medication-related harm.
- Co-design and implement measures to improve patient medication literacy. Ensure patients are aware of and have access to medication safety tools that allows the patient to focus on key points in the medication process to mitigate risks.
- Encourage all patients served by the organization to access the WHO mobile phone app MedSafe (*5 Moments for Medication Safety* tool), which allows the patient to focus on key points in the medication process to mitigate risk.

Actions for stakeholders

- Ensure that patients, families and civil society organizations are closely involved in all aspects of the Challenge and development of tools to help patients protect themselves from harm.
- Fully engage all stakeholders in implementing the Challenge, including educational and research institutions, regulatory authorities, health professional societies, pharmacy bodies, patient advocacy groups, donors and the pharmaceutical industry.

Actions for the WHO Secretariat

- Create and implement a communications and advocacy strategy and promote the global Know. Check. Ask. campaign and the 5 Moments for Medication Safety tool.
- Advocate and support assessment and identification of the burden of medication-related harm due to unsafe medication practices, and actively pursue efforts to improve medication safety.
- Lead the process of change and take global action to make progress in the four domains and three early action areas of the Challenge framework, providing countries with tools to support the change management process.
- Develop and disseminate technical materials, including patient safety solutions, technical reports, measurement tools and methodologies (such as medication safety assessment tools), and a monitoring and evaluation framework to monitor progress and evaluate the impact of the Challenge.
- Support countries to establish and strengthen mechanisms for medication error reporting, and strengthen the role of the multi-professional team in medication safety and promote learning from errors.
- Set out research priorities on the burden of medication-related harm and the effectiveness of interventions to address medication safety.

STRATEGY 3.3:

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

Actions for governments

- Build infection prevention and control (IPC) programmes to provide safety for patients, health workers and visitors.
- Aligned with the national patient safety policy and programme, establish a national IPC policy and programme with clearly defined objectives, functions and activities in accordance with national priorities for the purpose of preventing health care-associated infections and combating antimicrobial resistance through good IPC practices.
- Adapt WHO technical guidance and implementation strategies to the national context and build capacity for IPC core components.
- Encourage routine public reporting requirements for health care-associated infections, antimicrobial resistance and other adverse events from health care facilities (including hospitals and long-term care facilities) to local and national governments.
- Establish systems for the surveillance of health care-associated infections and antimicrobial resistance in order to monitor IPC practices and assess progress and improvement over time against established national targets and best practices.
- Establish and ensure appropriate health care laboratory testing capability and capacity at local, national and global levels to improve detection of and response to multidrug-resistant organisms in health care settings.
- Provide adequate regulatory provision, resources and guidance on handling and disposal of infectious waste.

Actions for health care facilities and services

- Implement minimum IPC requirements in health care facilities (refer to WHO Minimum requirements for infection prevention and control programmes, 2019).
- Designate an officer responsible in each health care facility to coordinate patient safety efforts and implement IPC practices to prevent health care-associated infections and to combat antimicrobial resistance.
- Implement IPC, antibiotic stewardship and comprehensive waste management education and training for all health workers by using team- and task-based strategies that include bedside and simulation training.
- Perform routine, regular surveillance of health care-associated infection (including antimicrobial resistance) to guide interventions and detect outbreaks, with rapid feedback of results (including reporting to national networks) to health workers, stakeholders and public health authorities.
- Encourage and implement use of diagnostic tests to strengthen early and accurate pathogen identification and antimicrobial resistance results to guide the most effective and safest patient treatment using the right drugs, doses and duration of treatment.
- Implement multimodal IPC strategies; audit the compliance with IPC standards and feedback results to the leadership of the organization and staff.
- Ensure a clean and hygienic environment that incorporates a water, sanitation and hygiene infrastructure, with availability of appropriate IPC materials and equipment.
- Implement evidence-based processes for the segregation, transportation and disposal of infectious waste.

Actions for stakeholders

- Maintain networks and groups with expertise and research involvement in the area of IPC to assist in producing guidelines and advising on their application in different health care settings and contexts.
- Link the work of all relevant programmes and professional organizations to national IPC programmes.
- Raise awareness on the importance of preventing health care-associated infections and combating antimicrobial resistance in health care at the local, national and global levels.
- Advocate allocation of dedicated resources to establish and sustain programmes related to IPC, health care-associated infections and antimicrobial resistance at local, national and global levels.
- Encourage accountability, public reporting of data and transparency to make progress towards preventing health care-associated infections and antimicrobial resistance in health care.

Actions for the WHO Secretariat

- Provide leadership, connectivity and coordination to support successful programmes of IPC and other related patient safety programmes across the diversity of health care settings worldwide.
- Ensure connectivity and coordinated efforts with water, sanitation and hygiene, antimicrobial resistance and health emergency departments within WHO.
- Provide guidance and recommendations on best practices and policies to prevent health care-associated infections and address antimicrobial resistance in health care.

- Design and run campaigns and advocacy initiatives to raise awareness of, generate enthusiasm for, and gain commitment to IPC programmes to reduce harm and prevent death.
- Facilitate and help to mobilize funding for IPC country capacity-building.
- Provide concrete goals and benchmarks and measure progress of IPC programmes around the world and extract key messages for global dissemination.
- Routinely reassess, evaluate and update IPC and other guidelines related to health care-associated infections and antimicrobial resistance, as needed, and ensure these guidelines align with other WHO guidance documents.

STRATEGY 3.4:

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

Actions for governments

- Strengthen safety programmes for medical devices, blood and blood products, vaccines and other medical products from their production, storage and supply through to their use in the hospital, clinic or community.
- Provide adequate policy, legal and regulatory provisions to ensure that these programmes can be implemented safely and effectively to fulfil their purpose.
- Establish bidirectional linkages of programmes for the safety of medical devices, medicines, blood and blood products, vaccines and other medical products with patient safety programmes.
- Establish a national blood programme supported by a blood policy and legislative framework.

Actions for health care facilities and services

- Use only authorized medical devices that meet the prescribed safety standards.
- Introduce mechanisms for the regular maintenance and calibration of all critical equipment.
- Ensure that the operating manual and safety instructions of equipment are always available at the point of use and that new staff receive induction training on appropriate use as well as training during device upgrade.
- Adopt standard operating procedures for transfusion services and participate in an external quality assessment programme and a haemovigilance programme.
- Adopt standard operating procedures and safety protocols for immunization services.

Actions for stakeholders

- Maintain mutually agreed international safety and quality standards for medical devices, blood and blood products, medicines and vaccines.
- Engage with industry leaders to improve products and devices in their respective fields.

Actions for the WHO Secretariat

- Develop normative guidance for ensuring the safety of medical products.
- Promote coordination amongst multisectoral stakeholders to prevent the proliferation of substandard and falsified medical products.
- Support Member States in developing, implementing and strengthening safety surveillance programmes for medical products.
- Promote and support the development of global campaigns, including observing and celebrating World Blood Donor Day on 14 June annually.

STRATEGY 3.5:

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

Actions for governments

- Implement integrated information infrastructures to enable free flow of information across all health care settings.
- Establish standardized and clear handover procedures and protocols within and between health care facilities and home-based care.
- Develop and implement diagnosis, treatment and referral pathways for primary care.
- Introduce and strengthen patient safety elements in service delivery, licensing and accreditation of primary care, and hospice and home-based care services.
- Extend patient safety system interventions such as reporting and learning systems, integration of digital technologies, safety culture and patient engagement across the care continuum, including primary care.

Actions for health care facilities and services

- Standardize formats for patient records in primary and ambulatory care, supported by electronic health records.
- Implement standard operating procedures and establish clear channels for communication with different health service providers across care transition, for example, from a primary care setting to a hospital setting for patient referral.
- Include primary and ambulatory care services in patient safety incident reporting and learning systems.
- Implement diagnostic and treatment pathways for primary care services, similar to the hospital services.
- Implement uniform handover procedures across health care facilities.

Actions for stakeholders

- Provide support in adapting and implementing patient safety strategies and interventions across the care continuum, including primary care and transitions of care.
- Build the capacity of primary care organizations to provide safer care.
- Promote patient safety research in areas and different settings across the care continuum, including primary care and transitions of care.
- Include and strengthen patient safety elements in international technical support programmes across the care continuum, including primary care and transitions of care.

Actions for the WHO Secretariat

- Integrate patient safety components in WHO work on continuity of care across all health care settings, with a focus on primary care.
- Develop tools and guidance for improving patient safety across the continuity of care, for example in primary care settings, including preventive and promotive care, and safe communication during transitions of care.
- Provide technical support to build country capacity in implementing patient safety strategies and interventions across the care continuum.
- Develop guidance and tools on patient safety in home-based care.

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Strategic Objective 4

Patient and family engagement

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

Patient engagement and empowerment is perhaps the most powerful tool to improve patient safety. Patients, families and other informal caregivers bring insights from their experiences of care that cannot be substituted or replicated by clinicians, managers or researchers. This is especially so for those who have suffered harm. Patients, families and caregivers can serve as vigilant observers of a patient's condition and can alert health care professionals when new needs arise. Given proper information, the patient and family can help to be the eyes and ears of the system.

Most countries, particularly low- and middle-income countries, do not have a strong participation in patient safety improvements. Patients' voices are not prominent in many health care systems, for several reasons: cultural specificities; failure to identify suitable patient advocates and champions or to encourage them to speak up; lack of leadership and understanding; absence of organizational infrastructure or space within governance structures; or lack of funding.

Since 2005, WHO has had a Patients for Patient Safety programme. This is a unique international network that has been co-developed and co-maintained with a team of patient safety advocates and champions comprising patients who are surviving victims of harm, or family members who have lost a loved one to unsafe care. It aims to emphasize patients' rights, transparency and partnership with health workers to enhance the patient's role in patient safety. In its years of existence, the group has established itself as a global voice to express the most important concern that patients have: the safety of their care. The group issued the London Declaration, which outlines four broad areas of action:

- devising and promoting programmes for patient safety and patient empowerment;
- developing and driving a constructive dialogue with all partners concerned with patient safety;
- establishing systems for reporting and dealing with patient harm on a worldwide basis; and

- defining best practices in dealing with health care harm of all kinds and promoting those practices throughout the world.

Collaboration with patients builds a strong foundation for health care system improvement. Patients travel through the entire health care system and so they are more likely than health workers to have a holistic view of it, rather than a focus on one small part of the system. Patients and families are the end users of the health care system. They are often the only ones to have full insight into the outcome of their care. Their perspective on how care can be made safer is invariably very valuable. The intense public and personal interest in health could be harnessed to make patients more frequent partners in improving patient safety.

The WHO Framework on Integrated People-centred Health Services is a call for a fundamental shift in the way health services are funded, managed and delivered. It supports countries' progress towards universal health coverage by shifting away from health systems designed around diseases and health institutions towards health systems designed for people.

WHO recommends five interwoven strategies that need to be implemented:

- engaging and empowering people and communities
- strengthening governance and accountability
- reorienting the model of care
- coordinating services within and across sectors
- creating an enabling environment.

Much is made of the current emotional distance and empathy gap between patients and health workers who provide their care. Sometimes complainants are taken to be the main voices of patients. The COVID-19 pandemic has shone a new light on this with the public expressions of gratitude for what is done by health workers around the world and concern at the conditions under which many are working. This speaks well for the opportunity for stronger partnerships based on compassion between patients and health care professionals in the future.

Patient and family engagement needs to be considered an integral part of patient safety as a pillar of health care practice. This can be achieved by building it into every health care organizational and governance structure, by having it as a subject of community and national oversight, and by giving them an equal seat at the table in global patient safety leadership and planning forums. This would enable the voice and experience of patients and families to have a powerful and beneficial influence, ranging from global and national policies through to bedside and clinical practices, and enable all strategies to be seen also through the lens of the patient.

While it is pivotal to identify patient advocates and champions to increase patient and family engagement, it is equally important to identify, grow and incentivize health care leaders with values aligned to this concept. Such leaders would champion patient participation in their governance structures, in their strategic priorities, and in their budgets. Their moral imperative would be to integrate patient and citizen roles into their organization's work and to create a culture of safety and respect that encourages active listening to the voices of patients within their organizations. This works both ways. A culture that is safer for patients will usually also be safer for health workers.

Most importantly, patients need to be given the information that they need to manage their own care and take charge of their safety to the greatest possible extent. Health care institutions, supported by national and international entities, should commit to policies to promote transparency to patients, including fully informed consent, patient access to medical records, and full disclosure if patients are harmed by their care. Patients should be able to escalate concerns within a health care organization and should be actively encouraged to submit reports to patient safety reporting systems. These reports should be given full standing as incident reports and not sidelined into a separate category as patient "complaints".

Countries are at different points on the journey to patient engagement. Even those that are farthest along have not tended to focus on patient safety. A shift in emphasis to view patient safety as a fundamental human right and one that should take priority in patient engagement is an important principle on which to base strategies. Activities that can help strengthen patient engagement include strengthening the WHO Patients for Patient Safety programme and establishing patient safety networks focused on patient safety in every country; embedding patient and family engagement in the principles and practice of patient safety through national patient safety charters; increasing public awareness and education about patient safety; and amplifying the patient voice as a force for the improvement of patient safety.

Strategic objective 4:

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

STRATEGY 4.1:

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

Actions for governments

- Develop a national patient safety rights charter or bill with legal standing, to include concepts such as patient rights to safety, respect, autonomy, reliable care, information and transparency; and promote the concept of safe, respectful care as a human right.
- Embed the WHO Framework on Integrated People-centred Health Services in the design and delivery of safe health services.
- Create formal mechanisms to include patients and families in national governance mechanisms, working groups, task forces and committees that plan and take action to improve patient safety in the country.
- Create alliances with existing patient and civil society organizations on patient safety.
- Embed patient and family engagement standards in accreditation and evaluation.
- Include goals related to patient and family engagement as key components of short- and long-term strategic plans.

Actions for health care facilities and services

- Involve patient or family representatives with experience of avoidable harm in health care in designing strategies and defining actions to reduce the likelihood of a recurrence.
- Appoint patient and family representatives to be part of the organization's boards and committees.
- Rearrange the care processes and wherever necessary reorient them to make services patient-centred and based on the cardinal principle of "what is important for patients and families".
- Create patient and family advisory councils that are focused on patient safety.
- Develop procedures around the provisions of the national charter or bill, including non-discrimination, patient autonomy, informed consent and shared decision-making, emergency response, access to medical records and full disclosure of adverse events.
- Develop institutional standards for patient and family engagement, and develop a practice of improvement based on patient experience.

Actions for stakeholders

- Conduct research to identify behaviours that constitute and support patient and family engagement – by patients, families, clinicians, administrators and other health professionals, within various health care settings.
- Disseminate a patient safety rights charter and promote the idea of patient safety as a human right.
- Advocate full participation of patients, families and communities in all patient safety planning and programmes at global, national and local levels.
- Share best practices and lessons learned on patient and family engagement from Member States and partners.
- Help create community oversight mechanisms for local health care facilities and local patient assistance programmes for people who encounter problems in their health care.

Actions for the WHO Secretariat

- Ensure involvement of patients, families, patient safety advocates and champions, Patients for Patient Safety network members, and patients' and civil society organizations in WHO activities for co-developing policy, strategies, guidance and tools related to patient safety.
- Develop action frameworks, principles for engagement and implementation tools for patient and family engagement for patient safety that countries and institutions can adopt at different levels.
- Provide advocacy to Member States for establishing policy and developing tools on patient and family engagement, including guidance on informed consent.
- Involve Patients for Patient Safety network members, patients and families with experience of avoidable harm, and patients' and civil society organizations in implementation of the Global Patient Safety Action Plan, and in its monitoring and accountability mechanisms.
- Create a model patient safety rights charter or showcase existing ones; offer a rationale for patient safety as a human right and guidance on developing and implementing charters.

STRATEGY 4.2:

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

Actions for governments

- Establish platforms, networks and events to bring together patient safety advocates, champions, patients and patient organizations to share their experience of avoidable harm or unsafe care and best practices in patient and family engagement.
- Create mechanism and strengthen platforms for sharing health care experiences of patients and families, including patient reporting on outcomes and experiences, that highlight patient safety problems and point to solutions for patient safety improvement.
- Ensure that the patient and family experience of harm informs the design of all patient safety programmatic areas (for example, policy, education and training, research and information).

Actions for health care facilities and services

- Create a culture and organizational framework whereby the encounters and experiences of patients and families with avoidable harm, told by themselves, are an integral part of all patient safety work within the organization's services.
- Include a patient and family experience, told by themselves, as a regular agenda item on the organization's main board meeting in order to give health care leaders a deep insight into the realities of the impact of unsafe care.
- Create patient safety reporting mechanisms that encourage patients and families to report and, by collecting, collating and analysing patient-reported experiences and outcomes of unsafe care, demonstrate actions for learning and improvement.

Actions for stakeholders

- Organize national and local workshops, symposia and events to share the experiences and expectations of patients and families, especially those who have suffered avoidable harm.
- Ensure that professional associations and specialist societies invite patients and family members with patient safety experiences to their annual conferences and scientific events.

Actions for the WHO Secretariat

- Provide advocacy to Member States to create mechanisms to learn from patient experience of safe and unsafe care, including patient reporting on experiences and outcomes .
- Develop tools and guidance to collect, collate and analyse patient-reported experiences and outcomes of unsafe care for patient safety improvement.
- Create and maintain a global collection of stories from patients and families with experiences of safe and unsafe care, avoidable harm and effective change, and disseminate those experiences to raise awareness of the importance of prioritizing patient safety within broader health system strengthening efforts.

STRATEGY 4.3:

Build the capacity of patient advocates and champions in patient safety

Actions for governments

- Support and empower the development of networks of patient advocates and champions, and collaborate with the WHO Patients for Patient Safety programme.
- Establish, train and support a panel of patient and family advocates for patient safety to act as speakers at national and local conferences.
- Share the findings of patient safety reporting and learning systems with patient advocates and champions.

Actions for health care facilities and services

- Conduct a wide-ranging review to assess the involvement of patients in the improvement of safety in health care within the organization.
- Institute measures to fully engage with patients and families to enhance their opportunities to contribute to processes to improve patient safety.
- Develop a strategy for involving patient safety advocates and champions as educators.

Actions for stakeholders

- Use networks and collaborations to identify, recruit and train patient advocates and champions for patient safety to serve as patient representatives in government and health care settings.
- Develop and disseminate patient information materials on different aspects of patient safety and participate in public awareness campaigns.
- Work with the government to support the development of the national Patients for Patient Safety programme.

Actions for the WHO Secretariat

- Strengthen the WHO Patients for Patient Safety programme and expand the Patients for Patient Safety global network.
- Provide advocacy and guidance to support the establishment of Patients for Patient Safety programmes and patient organizations at regional and national levels.
- Develop educational and technical resources, including e-learning programmes, guidance and tools, for patient safety advocates and champions.
- Support capacity-building of patient safety advocates and champions at regional, national and local levels.
- Facilitate relationships between civil society organizations, patient advocates and government agencies.

STRATEGY 4.4:

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

Actions for governments

- Develop national guidance for informed consent, for patient access to their medical records, and for a patient and family to escalate care concerns if they perceive a patient to be deteriorating.
- Develop a guidance framework and procedures for enabling health care professionals to disclose to patients and families the adverse events that have caused (or could have caused) inadvertent harm.
- Consider introducing legislation on disclosure policies to inform patients and families where guidance has not been effective.

Actions for health care facilities and services

- Develop institutional policies for robust informed consent, for patient access to their medical records, and for emergency escalation systems that can be triggered by patients and families.
- Develop and implement disclosure policies and procedures to inform patients and families of patient safety incidents that caused (or could have caused) inadvertent harm.
- Ensure that patients, families and health workers are given ongoing psychological and other support in the aftermath of a serious patient safety incident.

Actions for stakeholders

- Raise awareness about safety reporting systems, the right to access medical records, the right to informed consent and the right to an emergency response, including other patient safety avenues available to patients.
- Raise awareness of civil society organizations, patients and families and seek the full support of professional bodies and their members for a policy of open disclosure of patient safety incidents to patients and family members.
- Organize a flow of information from stakeholders about the practical experience of the open disclosure policy and other transparency initiatives and suggestions for improvement.
- Raise awareness of civil society organizations, patients and families about the positive purpose of the open disclosure policy and their entitlements under it.

Actions for the WHO Secretariat

- Collect, collate and disseminate model disclosure policies and procedures to inform patients and families of patient safety incidents that caused (or could have caused) inadvertent harm.
- Recommend policies on transparency, patient information and full disclosure, including references for sample policies and advice on implementation.
- Encourage Member States to introduce policies promoting transparency, including open disclosure policies, as part of the national patient safety policy, as a way of demonstrating their commitment to a positive patient safety culture in their health systems.
- Provide guidance on best practice in designing and operating open disclosure policies and legislation.

STRATEGY 4.5:

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

Actions for governments

- Incorporate activities to enhance public education, including in schools and communities, and increase awareness of patient safety in the national patient safety plan.
- Include patient and family engagement in the patient safety education curriculum, and develop a specific curriculum for school-aged children.
- Develop mechanisms for providing information and education to patients and families to enable them to partner with health care organizations and with other stakeholders.
- Develop and disseminate public service announcements with clear messages about what patient and family engagement is and why it is important.
- Promote use of digital technologies, including smartphones, in improving awareness about patient safety and enhancing patient and family engagement.

Actions for health care facilities and services

- Integrate patient and family engagement into the health care professionals curriculum, and develop standardized patient and family engagement competencies.
- Educate patients and families about their health and health care, support patients in managing their own health, and train families to deliver care, especially in responding to patients' needs in a home care environment.
- Develop patient information materials on clinical procedures, including safety risks, to empower patients when seeking information from health care professionals.
- Implement communication mechanisms that help clinicians understand patient perspectives and concerns.
- Structure care processes to support information sharing, care planning, self-management and shared decision-making, and implement patient-centred tools for patients and clinicians to support shared decision-making.

Actions for stakeholders

- Increase the use of peer education for patients and families, support patients in managing their own health and encourage them to take an active role.
- Include patient and family engagement and safety in educational curricula and training courses.
- Develop and disseminate patient information and education materials on patient safety.

Actions for the WHO Secretariat

- Develop, collate and disseminate information and educational materials and tools for enhancing the health literacy of patients and families and enabling their involvement in self-care and shared decision-making, including mobile applications, fact sheets and videos; make these resources readily available and encourage their use.
- Include patient and family engagement in WHO patient safety curriculum, and develop a specific curriculum for school-aged children.
- Advocate engagement of patients and families as educators in patient safety education and training activities.

Technical resources

Canadian Patient Safety Institute, Atlantic Health Quality and Patient Safety Collaborative, Health Quality Ontario, Patients for Patient Safety Canada. 2019. Engaging patients in patient safety: a Canadian guide. Edmonton: Canadian Patient Safety Institute (www.patientsafetyinstitute.ca/engagingpatients, accessed 16 July 2021).

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World Health Organization. 2016. Patient engagement: technical series on safer primary care. Geneva: WHO (https://www.who.int/publications/i/item/patient-engagement, accessed 16 July 2021).

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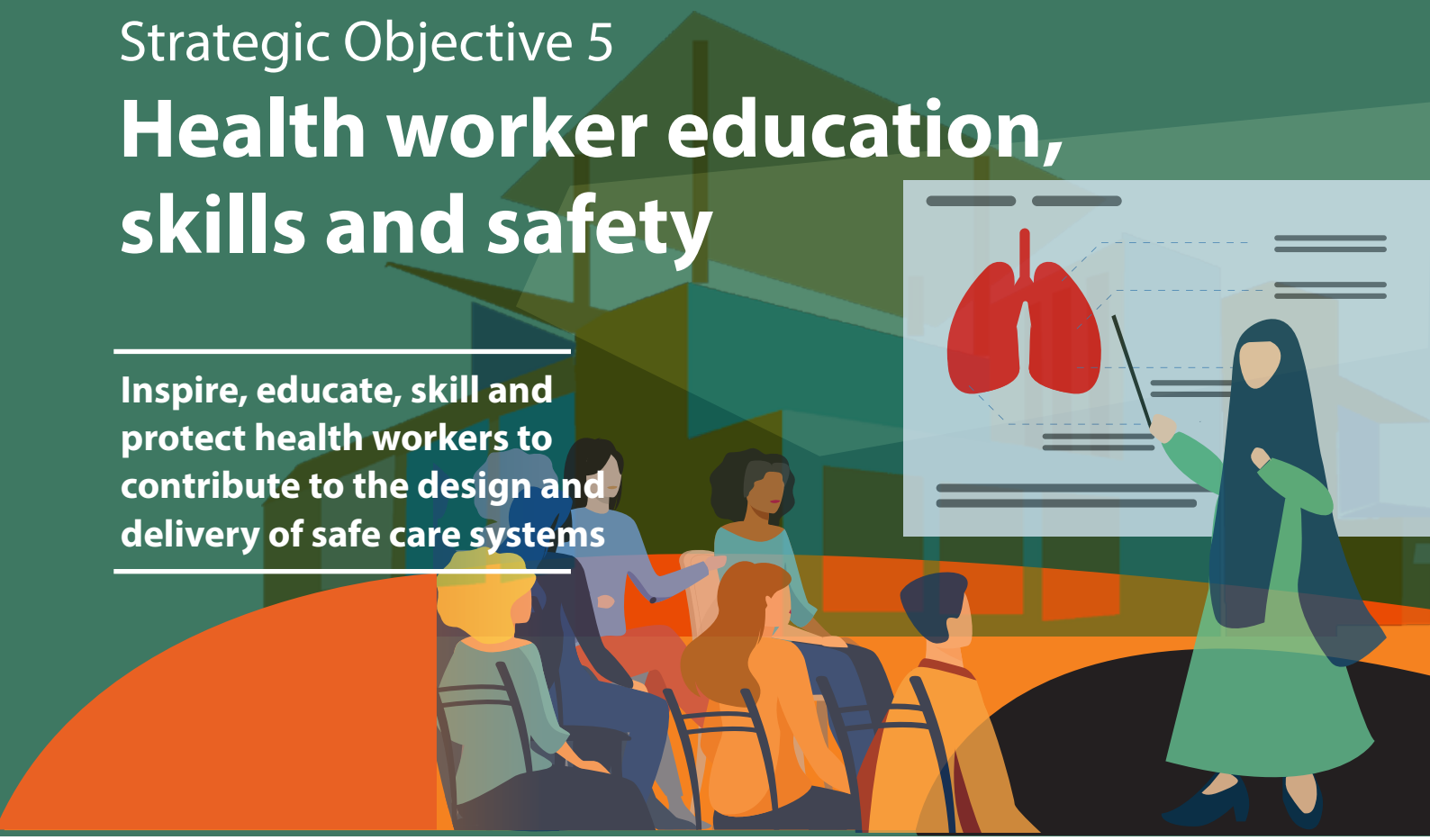
World Health Organization Regional Office for Europe. 2013. Exploring patient participation in reducing health-care-related safety risks. Copenhagen: WHO Regional Office for Europe (https://www.euro.who.int/__data/assets/pdf_file/0010/185779/e96814.pdf, accessed 16 July 2021).

Strategic Objective 5

Health worker education, skills and safety



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

Whilst all health workers are committed to keeping their patients safe, the majority will believe that they are discharging this commitment through practising within the ethical code of practice, which is synonymous with being a member of their profession. Fewer will think beyond this to fully appreciate the scope of the risks involved in the delivery of health care and the scale of avoidable harm, including preventable and treatable harm, that arise on a daily basis within every health care system in the world.

This lack of awareness and understanding of such an important problem amongst many health service providers at the point of care may seem puzzling. It is certainly not because of any lack of compassion on the part of health care professionals. It is because traditional undergraduate, postgraduate and continuing education programmes place emphasis on evidence-based practice and standards that are disease or clinical condition oriented. The systems aspects of safety issues are often missing, and programmes provide no training on human factors.

Moreover, training in the non-technical skills is largely focused on listening to and communicating with the patient. All this is important. Indeed, it is essential to delivering safe and quality care and achieving the best outcomes from diagnosis, treatment and other clinical processes of care. However, an approach based on a series of individual episodes of care is not enough. A full appreciation is necessary of the scale and nature of risks in the delivery of care, together with knowledge of how to gear practice towards minimizing or eliminating them. That requires a realization that every individual clinical encounter is embedded within a wider system of care delivery that can affect the safety of the patient at any particular moment.

It is essential that all health workers, managers and leaders understand patient safety. In particular, they must be clear about the nature and importance of risk and how harm is generated, the core concepts of patient safety science, the ways in which the causes of unsafe care are investigated and understood, and the actions necessary to ensure that care, and its constituent individual processes, is as safe as is possible.

WHO has published the *Patient safety curriculum guide for medical schools*, complemented by a multi-professional edition. Both have been widely disseminated and have been adopted in some countries. Major groups of health service providers around the world have developed patient safety educational curricula, as well as regulatory and professional education bodies in different countries.

Despite this, the influence of these initiatives on existing curricula has been very limited. The challenge is not in creating policies, it is in their implementation. There are multiple barriers to ensuring that patient safety is a major component of education and training programmes. These include lack of curriculum space, absence of buy-in from stakeholders, weaknesses in educational coordination and planning, limited leadership interest, and insufficient senior medical and nursing champions.

In addition, a number of factors have impeded patient safety education, including:

- unfamiliarity of educators or trainers with teaching patient safety as a new area of knowledge and learning;
- reluctance by academic institutions to teach knowledge outside clinical disciplines to health care students because of existing full curricula;
- failure of education to keep pace with technological and system advances for safe care.

In many low-income settings, there is not even sufficient training within a discipline. For example, radiation therapists might practise in their specialty without having been in any formal, accredited training programme. It then becomes even more challenging to train them in patient safety without basic training in their speciality.

In addition, many health care professionals provide a wide range of clinical services in such settings. They may perform general surgery, but also caesarean sections. They may investigate and care for children with high fevers and adults with malaria. They may treat a wide range of neglected tropical diseases and diagnose cancer without sophisticated technology. It is difficult for people heavily overloaded with such pressures of complex clinical multitasking to learn additional competencies in patient safety that they can integrate into their practice. The content of patient safety curricula in low-income countries must take account of the special and diverse circumstances faced by health care professionals working in these settings.

Decision-making for curriculum setting and implementation varies around the world. In many countries, the overall responsibility rests with ministries of education and not ministries of health. Accreditation bodies or professional regulators, where they exist, may have overall accountability for what gets taught, when and to whom. Professional bodies and membership associations such as medical and nursing colleges may set and monitor educational standards that then drive curriculum design. Obviously, the educational providers themselves, whether in universities or in free-standing schools and institutes, are also important policy-makers. Leverage from these disparate bodies to achieve change is absolutely essential and currently lacking.

In summary, the education and training of health care professionals has been underused and undervalued as a vital tool to address the challenges of achieving improved patient safety as it is understood today.

Traditionally, education of health care professionals gives little attention to the importance of patient safety, as a consequence of which:

- there is no professional ethos that a practitioner's responsibilities must extend beyond the care of individual patients to ensuring that their service as a whole is safe;
- there is little understanding of the nature of risk in health care and the importance of strengthening systems;
- there is minimal emphasis on the importance of teamwork and communication in protecting patients from harm.

Looking at best practice within health care and other high-risk industries, it is clear that new radical approaches, including interprofessional and multidisciplinary approaches, are needed if education and training are to play the full role that they should in improving patient safety.

Health worker safety and patient safety are inseparably interconnected practice domains. Health and safety risks to health workers can lead to risks for patients, patient harm and adverse patient outcomes. Violence against health workers, burnout and musculoskeletal disorders are all widespread occupational health problems in strained health care facilities, many of which also face acute shortages of competent health workers. Health worker absenteeism and attrition, resulting in suboptimal care outcomes, are aggravated by poor physical and mental health of health workers. Physically and psychologically sound health workers are less prone to make errors, contributing to safer care. The safety of health workers therefore directly impacts the safety of patients. The safety of health workers therefore directly impacts the safety of patients.

Strategic objective 5:

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

STRATEGY 5.1:

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

Actions for governments

- Reach an agreement with stakeholders responsible for standards and curriculum setting to incorporate patient safety in professional education and continuing professional development.
- Introduce the WHO Patient safety curriculum guide at national level and adopt key approaches and principles within the local context.
- Develop and offer specialized courses on patient safety for in-service training of health care professionals of different categories and at multiple levels.
- Include health and safety skills pertaining to personal safety in education curricula and training programmes with an interprofessional learning approach.

Actions for health care facilities and services

- Include patient safety in induction and orientation programmes as well as on-the-job trainings for staff.
- Introduce and implement specialized trainings on patient safety for all professional staff, with an emphasis on team- and task-based strategies that include bedside and simulation training, with certification of satisfactory completion.
- Provide advanced training on patient safety and quality improvement competencies for those with managerial and leadership roles.
- Encourage staff to take online and on-site courses on patient safety as part of continuing professional development.
- Design specialized training programmes for staff working in high-risk areas such as intensive care and emergency departments.

Actions for stakeholders

- Convene a forum for representatives of educational institutions, professional organizations and bodies, scientific societies and experts from industry to advise government on the design, content and delivery of patient safety education and training programmes and support their implementation.

Actions for the WHO Secretariat

- Review and expand the WHO *Patient safety curriculum guide* with a focus on a competency-based and interprofessional approach to education.
- Develop and promote patient safety courses and trainings, including in e-learning format, through open access platforms such as the WHO Academy.
- Establish a global repository of educational and training resources on patient safety and disseminate at different levels.
- Develop a training of trainers' programme for patient safety educational faculty and training specialists.
- Facilitate the design of patient safety education and training programmes at regional and national levels, for all categories of health workers.

STRATEGY 5.2:

Identify and establish collaborations with centres of excellence in patient safety education and training

Actions for governments

- Designate one or more patient safety centres in the country to provide leadership in patient safety education and training.
- Establish a national network of patient safety centres and allied agencies to support professional education and training in patient safety.
- Advance the use of simulation methods throughout the professional education and training in patient safety by identifying and designating centres to lead the development and implementation process.

Actions for health care facilities and services

- Work closely with national patient safety centres and the network, as applicable, to provide training opportunities in patient safety within the organization.
- Share feedback on best practices and innovations within the organization with the national patient safety centres and the network, as applicable, to ensure information sharing and wider application.
- Identify staff members for the training of trainers' programme for patient safety and facilitate their training and competency development.

Actions for stakeholders

- Bring together all relevant stakeholders at individual and organizational levels to advise on and support patient safety education and training at all levels.
- Agree upon the roles and responsibilities of stakeholders, covering different functions in education and training, such as the training of trainers' function, course and curriculum design, teaching and training methods, and development of simulation techniques.

Actions for the WHO Secretariat

- Identify centres of excellence in patient safety education and training, ensuring equal geographical representation, and establish strategic collaborations.
- Develop a global network of centres of excellence in patient safety education and training to share best practices and innovations, and support capacity development at national level.
- Promote establishment of regional and national networks of centres of excellence in patient safety education and training and advocate their representation in the global network.

STRATEGY 5.3:

Ensure that patient safety core competencies are part of regulatory requirements for health professionals

Actions for governments

- Work with licensing, regulatory and accreditation bodies to ensure linkages between individual and organizational performance and patient safety improvements in both the public and private sectors.
- Define patient safety core competencies for each category of health care professional and specialist clinical role for patient safety improvements. Competencies should include non-technical skills such as teamwork and communication.

Actions for health care facilities and services

- Conduct periodic assessment of patient safety competencies among health professionals.
- Incorporate patient safety competencies in scope of practice and job descriptions of health care professionals.
- Link patient safety competencies to service standards.

Actions for stakeholders

- Convene experts, researchers, educators and civil society organizations to discuss and agree upon initiatives to advance the routine use of patient safety competencies.

Actions for the WHO Secretariat

- Specify a set of patient safety competencies for different health professionals and align it with the WHO Global Competency Framework for Universal Health Coverage.
- Work with national professional licensing, accreditation and regulatory bodies to adopt a common global standard for patient safety competencies and their assessment.

STRATEGY 5.4:

Link commitment to patient safety with appraisal systems for health care professionals and managers

Actions for governments

- Ensure that performance assessments of health professionals are linked to participation in patient safety programmes and initiatives.
- Explore mechanisms, such as incentives and markers of esteem, that recognize exceptional achievement by individual staff members in improving patient safety.

Actions for health care facilities and services

- Establish an internal appraisal system to monitor competencies in understanding sources of harm and participation in development of solutions and identifying evidence of achieving gains in patient safety in clinical services.
- Incorporate team-based aspects of patient safety performance into assessments.
- Recognize particularly those who have identified sources of risk and implemented successful measures to combat them.

Actions for stakeholders

- Bring together the evidence and experience of all relevant stakeholders to provide advice on defining excellence in patient safety work by individual health professionals and teams and advise on the best assessment methods and tools.

Actions for the WHO Secretariat

- Develop global standards, tools and methods for performance assessment of individuals, health professionals and teams involved in patient safety work.

STRATEGY 5.5:

Design care settings, environments and practices to provide safe working conditions for all staff

Actions for governments

- Support and endorse the WHO charter *Health worker safety: a priority for patient safety* by signing up to it and supporting its implementation.
- Develop and implement national programmes for the occupational health and safety of health workers in line with national policies and provide adequate resources for sustainability of programmes.
- Adopt and implement relevant policies and mechanisms to prevent and eliminate violence in the health sector in accordance with national laws.
- Provide access to mental well-being and social support services for health workers, including advice on work–life balance and risk assessment and mitigation to tackle burnout, enhance well-being and promote resilience.
- Develop linkages of patient safety programmes with health, safety and environment and occupational health and human resource strengthening programmes at national and subnational levels.

Actions for health care facilities and services

- Ensure appropriate and fair duration of deployments, working hours and rest breaks, as well as minimizing the administrative burden on health workers to prevent burnout and enhance overall well-being.
- Ensure vaccination of all at-risk health workers against vaccine-preventable infections.
- Provide functioning and ergonomically designed equipment and workstations to minimize musculoskeletal injuries and falls.
- Maintain levels of personal protective equipment for health workers for the expected workload but store appropriate supplies to respond to emergencies.
- Implement measures to protect health workers from physical and mental violence, including incivility, bullying, harassment and discrimination.
- Proactively assess all care settings to identify and mitigate hazards and risks to safety of patients and health workers using the national framework as a guide.

Actions for stakeholders

- Engage professional bodies, the medical device industry and experts and researchers to provide advice to the government on actions to keep health workers safe in all respects.

Actions for the WHO Secretariat

- Advocate the development and implementation of adequate policy and regulatory frameworks for health worker safety and patient safety at international, national and subnational levels.
- Collate and disseminate best practices on patient safety and health worker safety for policy, legislative and regulatory frameworks.
- Develop norms, standards and guidance for design of care settings and environments to ensure health worker safety.
- Promote a global reporting, benchmarking and learning system for work-related adverse events concerning health workers and patients.
- Strengthen synergies and linkages between WHO work on occupational health, patient safety, IPC and the health workforce.
- Work with Member States and all relevant stakeholders to strengthen the occupational health and safety of health workers, with special focus on responders in emergency preparedness and response.

Technical resources

World Health Organization. 2009. WHO patient safety curriculum guide for medical schools. Geneva: WHO (https://www.who.int/publications/i/item/9789241598316, accessed 16 July 2021).

World Health Organization. 2011. WHO patient safety curriculum guide: multi-professional edition Geneva: WHO (https://apps.who.int/iris/bitstream/handle/10665/44641/9789241501958_eng.pdf?sequence=1, accessed 16 July 2021).

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World Health Organization. 2020. Health worker safety: a priority for patient safety. Geneva: WHO (https://apps.who.int/iris/handle/10665/339287, accessed 16 July 2021).

World Health Organization. 2020. Protection of health and safety of health workers: checklist for healthcare facilities. Geneva: WHO (https://www.who.int/publications/i/item/protection-of-health-and-safety-of-health-workers, accessed 16 July 2021).

World Health Organization. 2020. World Patient Safety Day goals 2020–21. Geneva: WHO (https://www.who.int/publications/i/item/who-uhl-ihs-2020.8, accessed 16 July 2021).

World Health Organization and International Labour Organization. 2020. Caring for those who care: national programmes for occupational health for health workers. Policy brief. Geneva: WHO and ILO (https://www.who.int/publications/i/item/9789240011588, accessed 16 July 2021).

Strategic Objective 6

Information, research and risk management

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

Every health programme requires a source of valid, reliable data to provide information and construct measures for its key activities, for example, identifying priorities and problems, comparative benchmarking, formulating action, and monitoring performance and impact. There has been a long tradition of developing such an information infrastructure in established fields of public health, notably communicable disease prevention and control. In some cases, this goes back to the late 19th century. Indeed, without good data and information systems, little progress would have been made in reducing the spread and overall burden of infection worldwide.

Throughout the 20th century, a similar approach was taken to noncommunicable diseases such as cancer, heart disease, diabetes, obesity and hypertension. Data were collected on risk, causal factors, mortality and other outcomes. These developments have continued into the 21st century and provide an essential resource to underpin national and global noncommunicable disease programmes. Similarly, the vitally important programmes to prevent premature deaths, reduce poverty-related illness and improve the health of adults and children in many parts of the world are dependent on good data and their focused analysis. The work to provide the breadth and depth of information required has been crucial to the gains that have been made.

The need for comprehensive information systems in programmes with clear goals and targeted improved health outcomes is beyond doubt.

Despite a decade or more of work in patient safety, the capacity and capability of global, national and local programmes to reduce risk, avoid harm and improve the safety of health care remains severely constrained by the absence of high-quality information systems. There are many different sources of data that can throw light on patient safety. These include incident reporting systems; complaints; malpractice claims; patient-reported outcomes; avoidable deaths; case note trigger tools; clinical care audits; burden of harm studies; organizational culture surveys; and sentinel event audits. Except for patient safety incidents, most data were developed for other purposes. They can only be seen as proxy indicators of patient safety, though some are very helpful in that function.

Current data sources are therefore fragmented and disparate and fall well short of the comprehensive, integrated information system needed within patient safety programmes. A few health care leaders can confidently describe which data their organizations use to monitor and learn from patient safety incidents. Even fewer understand their strengths and limitations for understanding patient safety. An appraisal of what each data source can add in relation to the key concepts described in the WHO International Classification for Patient Safety would pinpoint where further investment is needed.

Threading through all information flows should be the experiences and views of patients and their families. However, this is often missing or not prioritized in the design of health information systems.

The key role of reporting and learning systems

Investment of time and money in establishing and running patient safety incident reporting systems. Some have accumulated large databases. There is much to be learned from other high-risk industries where reporting, investigation and response takes place in a no blame culture with a strong emphasis on learning – so much so that a reduction in risk and improvement of safety are regularly demonstrated. This is not generally the case in health care, though there are some exemplars around the world, mainly at the health facility level.

Many patient safety programmes have raised very high expectations about the potential impact of incident reporting and learning systems. Ideally, all occurrences in a health service that have caused or could have caused harm would be quickly documented, fully reviewed and investigated. The resulting action would lead to a redesign of processes of care, products and procedures, and changes to the working practices and styles of individuals and teams. Such actions would usually lead to a measurable and sustained reduction of risk for future patients. Some types of harm would be eliminated entirely. Yet, very few health systems or health facilities in the world can approach this ideal level of performance in capturing and learning from incidents of avoidable harm.

A reporting system should aim to be resourced appropriately according to the quantity of incidents reported. If too many events are being reported to realistically handle or even look at, let alone review, this lets down those who are taking the time to conscientiously file these reports. In the absence of such a capacity, organizations could be selective about themes and topics and specify the types of incidents to be reported. This is moving reporting systems much more into real-time risk management and improvement systems (as they tend to be in other sectors). Local discussion and investigation will produce the deep insights into probable causation.

In order to address the difficulties in enabling patient safety incident reporting to reach its full potential, WHO published the document *Patient safety incident reporting and learning systems: technical report and guidance* in 2020.

Thinking more deeply about measurement

Whatever data are used to assess a health system's or health organization's level of patient safety, the process should be strongly linked to learning and improvement. If measurement does not have a "learning loop", it will be of very limited value.

This is easy to say, but operationalizing this principle is much more difficult. For example, how does the analysis of patient safety incident data:

- lead to the reduction of avoidable deaths in a hospital's intensive care unit?
- reduce serious medicine dispensing errors in every pharmacy in a country?
- stop all suicides in a mental health unit?
- reduce the health care-associated infection rates in a rural hospital with no fresh running water?
- eliminate the transmission of bloodborne viral diseases via contaminated needles in a refugee camp?

Measurement in patient safety should be grounded in the data that are collected regularly for operating and managing health care systems. It should also be supported by governance activities that are actually strengthening the information infrastructure in such a way that patient safety can be measured. Most of the discussion about patient safety data is about its reactive use. Much less attention is given to initiatives that use such data for anticipative, proactive learning.

There are also important opportunities to strengthen the capability of information systems, for example, linkage of patient safety incident reports to medical records and other data sources and the whole field of big data and artificial intelligence. Such innovations have the potential

to provide much deeper insights into the causation of harm, as well as ways to reduce it.

At the end of 2019, the Salzburg Global Seminar set out a series of principles for measuring patient safety, as follows:

- The purpose of measurement is to collect and disseminate knowledge that results in action and improvement.
- Effective measurement requires the full involvement of patients, families and communities within and across the health system.
- Safety measurement must advance equity.
- Selected measures must illuminate an integrated view of the health system across the continuum of care and the entire trajectory of the patient's health journey.
- Data should be collected and analysed in real time to proactively identify and prevent harm as often as possible.
- Measurement systems, evidence, and practices must continuously evolve and adapt.
- The burden of measures collected and analysed must be reduced.
- Stakeholders must intentionally foster a culture that is safe and just to fully optimize the value of measurement.

These principles will be more challenging to operationalize in some countries, health care organizations and care contexts than in others. Countries will have different levels of investment in information systems and, in turn, their capability for measurement will be hindered by the available technology, expertise and resources allocated. There is no doubt that commitment is needed to progress analytical capability to improve patient safety. In doing so, health care organizations should aspire to move from purely descriptive or diagnostic phases of working – from, what happened? and why did it happen? – to predictive (what is likely to happen?) and prescriptive (what can we make happen?) capabilities.

Once priority issues for intervention are identified, established methods of quality improvement can be used to design and redesign systems and processes to improve patient safety. From decades of successful application in health care, the models of change developed through improvement science can support teams to articulate the aim of the project and structure plans for developing and testing the changes, monitor the impact of the changes, and sustain success.

Research: generating knowledge through research offers solutions to unsafe care

One of the major strategic goals of patient safety research is to produce new knowledge that improves the capability of health care systems, as well as the health organizations and practitioners that comprise them, to reduce the harm associated with health care. Ideally, the outcomes of research studies should be generalizable to other health care systems around the world.

When the scale and nature of errors and harm in health care first became apparent in the late 1990s through studies of its incidence and prevalence in hospital patient populations, patient safety became a priority for health policy-makers in many parts of the world. An active field of research sprang up with considerable resources allocated to this discipline.

Research and development was one of the priority areas when the WHO Patient Safety Programme was first established. Patient safety research has taken a number of directions since then. This includes studies on the extent and causation of harm to patients in various clinical specialities (for example, anaesthetics), in treatment areas (for example, medication), in demographic groups (for example, neonates) and in settings (for example, operating theatres). In addition, problems with an established pattern of harm have been reconceptualized and studied in patient safety terms (for example, health care infection), technological and other solutions to reduce risk have been evaluated, and the safety concepts and interventions from other disciplines have been applied to medicine and health care.

Over the last decade, there have been attempts to translate this research to improve the safety of care and reduce the relatively high burden of harm. New methodological work is needed in some key areas, including (a) greater use of theory and logic models; (b) clearer understanding of the relationship between the surrogate end points employed in many studies and actual harm; (c) better descriptions of interventions and their proposed mechanisms of effect and pathways to implementation; (d) improved explanation of desired and unintended outcomes; and (e) more detailed description and measurement of context and how this influences intervention effectiveness.

Previous methodological advances should not be set aside lightly. Researchers should be alert to challenges, which can arise when unconventional concepts and definitions are used to improve the quality and value of this work. It will be particularly helpful to use agreed terminology, develop a core set of study patient safety outcome measures (and their hierarchical ordering), and produce more patient safety reporting checklists. Careful alignment with the WHO International Classification for Patient Safety will support the global sharing of data for priority setting and exchange of solutions for common challenges, thereby maximizing opportunities to learn from rare events.

The major research needed for the coming decade is for trials to formally evaluate the effectiveness of policy and public health actions or clinical interventions aimed at improving patient safety. In developing such trials, investigators must learn from progress in other clinical areas (such as cardiovascular and neurological diseases) where testing a range of intervention at scale has been possible through so-called "mega" trials. However, the parallel is not straightforward. Many such trials have involved therapeutic interventions, whereas in patient safety most interventions are likely to be complex, non-pharmacological interventions. The development of trials will require ambition and cooperation among investigators seldom seen previously in patient safety research.

There is a great paucity of research on the scale and nature of harm in primary care, in mental health services, and among vulnerable groups of patients (such as older adults and disabled people). In low- and middle-income countries, there is also an urgent need to identify, develop and test locally effective and affordable solutions and risk reduction strategies, and to evaluate the impact of patient safety interventions.

The global move from paper-based systems to digital infrastructures is an enabler for patient safety research and innovation to be carried out in timely, efficient and cost-effective ways. Interrogation of electronic health record data could become the default approach to studies investigating the epidemiology and disease burden from patient safety incidents. Such infrastructures can also be used to develop risk prediction models, augmented by artificial intelligence-based analytical approaches, to identify those at greatest risk of harm from patient safety incidents. Developments in health information technology also offer opportunities to support care delivery and self-management through professional or patient-facing computerized decision support. The move to digital infrastructures is not without risks – for example, from biased algorithms or data breaches that can involve entire populations. For the immediate future, these technologies will be limited to well-resourced health systems.

Human-centred technology can make an enormous contribution to patient safety. Digital strategies addressing foundational issues of standardization, interoperability, performance, needs assessment and growth should be developed and implemented at local, national and international levels. A human factors approach should be applied to the design and evaluation of standards, hardware and software applications. In medicine, well studied and effective therapies have side-effects. While health information systems have certainly advanced patient safety, we must be vigilant to identify and address the unintended safety consequences of new technologies. This consideration is especially important for the most advanced systems with a high level of automation and therefore a loss of human control. National digital strategies should include independent, formative evaluation programmes. Evaluations should also seek to understand the non-use of digital systems, as this is as essential for technology adoption and patient safety as it is to understand their use.

The translation of research into improvements in patient safety does not begin and end with the presentation of the research findings to policy-makers and practitioners. The implementation of new practices almost always involves a process of organizational development, including aspects of professional attitudes and culture. It must be a priority to focus research programmes on problems and apply definitive solutions if health care is to be made safer. Much closer relationships with policy-makers will be essential to move from the current "push" model of knowledge translation to a "pull" model in which researchers respond faster to the needs of decision-makers.

Strategic objective 6:

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

STRATEGY 6.1:

Establish or strengthen patient safety incident reporting and learning systems

Actions for governments

- Establish or strengthen existing mechanisms for patient safety incident reporting and learning in both the public and private health care sectors and make improvements where necessary to the system (refer to WHO *Patient safety incident reporting and learning systems: technical report and guidance,* 2020; and WHO *Minimal information model for patient safety incident reporting and learning systems: user guide,* 2016).
- Establish a system of safety alerts for the health care system to draw attention to and advise action on patient safety incidents that highlight risks with systemwide implications. Place emphasis on the need to investigate incidents, learn lessons and develop clear actions to mitigate the root cause of incidents that are reported.
- Support and facilitate timely access to data for research and development purposes.

Actions for health care facilities and services

- Appraise the functionality of the current patient safety incident reporting system aligned with WHO *Patient safety incident reporting and learning systems: technical report and guidance,* 2020, WHO *Minimal information model for patient safety incident reporting and learning systems: user guide,* 2016, and any national guidance.
- Create user-friendly, confidential and effective reporting mechanisms.
- Use the reporting and learning system to identify patient safety priorities to be addressed by improvement activities.
- Establish (if none present) or adjust the reporting and learning system to an appropriate scale according to the capacity of the organization to capture, analyse and investigate incidents; support increased capacity.
- Engage and enthuse all the organization's staff in the reporting and learning endeavour by feeding back what has been learned and what actions have been taken to improve safety.

Actions for stakeholders

- Raise awareness of the importance of reporting patient safety incidents and disseminating lessons learned, including the need to promote health organizational cultures and professional values to achieve this.

Actions for the WHO Secretariat

- Develop implementation tools and guidance to support countries in establishing reporting and learning systems.
- Disseminate WHO reporting and learning guidance and tools.
- Develop linkages with safety reporting and learning programmes across relevant WHO departments.
- Provide technical support to Member States in establishing and strengthening patient safety incident reporting and learning systems.
- Create a global network of national reporting and learning systems with the purpose of sharing knowledge about patient safety incidents and sources of avoidable harm that could affect multiple countries and health facilities, including the dissemination of lessons learned.

STRATEGY 6.2:

Create a patient safety information system based on all sources of data related to risks and harm inherent in the delivery of health care and integrated with existing health management information systems

Actions for governments

- Strengthen synergies and data-sharing channels between sources of patient safety information for timely action and intervention, such as incident reporting systems (including patient reports), malpractice claims, patient-reported experiences and outcome measures, clinical care audits, medical record reviews, surveys, significant event audits, burden of harm studies, and safety surveillance data for blood products, medicines, vaccines, medical devices and organ transplant procedures.
- Publish an annual report on patient safety performance of the health system of the country, including the frequency, nature and burden of avoidable harm in health care.
- Develop a set of indicators for patient safety aligned with global patient safety targets. These indicators should be comparable between health care facilities as well as at national level.
- Design accountability mechanisms, informed by rigorous evaluation, to ensure that progress is made in reducing harm and improving patient safety throughout the health care system.

Actions for health care facilities and services

- Identify and track the sources of avoidable harm across the organization and in each clinical service.
- Implement patient safety indicators and use these to track progress and monitor trends.
- Evaluate the impact of improvement programmes with an emphasis on sustaining the benefits over time.

Actions for stakeholders

- Convene groups of experts, researchers and civil society to develop better methodologies and data systems to measure the safety of health care and ways to evaluate progress.
- Share learning programmes within and between professional bodies and specialist societies to develop effective solutions to avoidable harm and death in health care.

Actions for the WHO Secretariat

- Monitor patient safety practices and assess progress against best practice and best performance benchmarks.
- Include global patient safety targets in the WHO *Thirteenth General Programme of Work* results framework.
- Create a repository of patient safety indicators.
- Develop and disseminate patient safety assessment tools for various health care settings.

STRATEGY 6.3:

Establish, synergize and scale up patient safety surveillance systems to ascertain the magnitude and causes of harm in health care

Actions for governments

- Establish systems for patient safety surveillance to monitor patient safety practices and assess progress against best practice and best performance benchmarks.
- Establish core laboratory capacity at national and subnational levels to quickly detect and respond to emerging infections and other patient safety risks.
- Institute an independent investigation mechanism in cases of severe harm and sentinel events warrant in-depth analysis.
- Conduct baseline and concurrent surveys to establish burden of harm due to unsafe care.

Actions for health care facilities and services

- Participate in the patient safety surveillance system at national and local levels.
- Produce benchmark analyses to compare the organization's performance in dealing with avoidable harm against best practices elsewhere in the country and in the world.

Actions for stakeholders

- Support governments and health care facilities in establishing and operationalizing safety surveillance systems.
- Bring together expertise and experience in improvement science both in other fields of health care and outside the health sector; make these resources available to advise on national and local programmes.
- Support establishing laboratory systems and networks at local, national and global levels to quickly detect and respond to emerging infections and patient safety risks.

Actions for the WHO Secretariat

- Conduct a baseline study on the global burden of avoidable harm in health care and assess progress and improvement over time.
- Support Member States in developing, implementing and strengthening patient safety surveillance systems, including laboratory networks, for identifying emerging patient safety risks.
- Develop normative guidance on learning and improvement methodology for patient safety.

STRATEGY 6.4:

Develop active and funded patient safety research programmes, especially translational research

Actions for governments

- Map, analyse and prioritize areas where research could yield substantial gains of knowledge about avoidable harm and its reduction in the country's health care system.
- Ensure that there is sufficient capacity, skills and resources to meet the country's need for patient safety research.
- Incorporate international research evidence, if applicable in the local context, in policy and implementation programmes for patient safety; facilitate its translation in point of care practices.
- Establish or incorporate safety risk assessment in existing health technology assessment programmes for medical procedures, medicines, devices and information technology products.

Actions for health care facilities and services

- Provide a conducive environment for research exploring the causes of avoidable harm and the development of effective interventions to improve patient safety.
- Base the design of patient safety improvement programmes in each clinical service on the priorities apparent from local data and use available research evidence on effective solutions and safest practices to improve the system.
- Partner with researchers on measurement and improvement research.

Actions for stakeholders

- Convene research funding bodies, researchers and research partners to advance the agenda of patient safety research.
- Ensure that patients and families play a substantive role in setting research priorities, study design, conduct of studies, advocacy for funding and research governance.

Actions for the WHO Secretariat

- Maintain an up-to-date research strategy identifying patient safety research priorities in high-, middle- and low-income countries.
- Mobilize resources to promote and support patient safety research.
- Promote and support patient safety research in specific areas such as patient safety in primary care, mental health, people with disabilities, and ageing populations.
- Promote and provide support to build research capacity in patient safety, particularly in low- and middle-income countries.

STRATEGY 6.5:

Develop and implement digital solutions to improve the safety of health care

Actions for governments

- Develop a national strategy and required tools or harmonize the existing relevant strategy to bring the benefits of digitization, including harnessing artificial intelligence and big data, to efforts to improve the safety of health care in the country, aligned with a national digital health strategy (refer to the WHO Global Strategy on Digital Health 2020–2025).
- Promote and support digitization of health care processes such as medical records, electronic prescribing and clinical decision support systems with due consideration to interoperability of digital solutions.
- Invest resources in digitalization of end user health services, such as telemedicine and telediagnosis, as well as public health services, such as health promotion, disease surveillance and prevention.
- Establish mechanisms for assessing and ensuring the safety of health informatics technology solutions before they are deployed for use in the health sector.
- Continuously monitor the safety aspects of health informatics technology products used in clinical and diagnostic processes.
- Provide regulatory or legal means to use health care data for timely analytical purposes without compromising the privacy, confidentiality and ethical standard of care of individual patients and citizens.

Actions for health care facilities and services

- Implement new and proven technologies to improve the safety of care at scale.
- Provide feedback on information and experience of using digital technology in the organization's patient safety programme to those responsible for the national strategy.

Actions for stakeholders

- Develop existing and new digital technologies to enhance the identification and analysis of risk, avoidable harm and patient safety incidents.
- Connect technology innovators to health system and clinical leaders to explore new, more effective ways to identify risk and potential harm and discover new routes to improve patient safety with active involvement of industry and the private sector.
- Promote and fund innovative use of digital technology for patient safety improvement.

Actions for the WHO Secretariat

- Explore digital approaches for identifying and communicating sources of avoidable harm and risk that are in health care systems globally.
- Identify and list areas where digital technology can help make health care safer.
- Evolve a policy framework, practice areas and ethical and regulatory considerations in the use of digital technologies to enhance patient safety.
- Develop a database and taxonomy of the patient harms potentially associated with digital technologies.
- Develop digital tools and applications for helping service providers to deliver safer care.

Technical resources

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Strategic Objective 7

Synergy, partnership and solidarity

Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care

Over the last two decades, the approach to improve patient safety has been primarily through a health system lens, with few defined mechanisms and structures to translate patient safety system elements to the point of care at the patient end.

Several allied, safety-related programmes and clinical programmes have had a tendency to operate in isolation with limited interaction, integration or any direct and mandated linkages with the health system elements of patient safety. The missing link has been the lack of institutionalization of patient safety in different programmes and practice areas. Patient safety is an important part of health care delivery at all levels, including community, primary and hospital settings.

It is vital to develop mechanisms to integrate and implement patient safety strategies in all technical health programmes, vertical disease programmes and risk areas. This will have a potential impact in reducing avoidable harm and mitigating the risk of such harm related to health care procedures, products and devices. Key areas within the scope for the action include medication safety, surgical safety, IPC, sepsis management, diagnostic safety, environmental hygiene and infrastructure, injection safety, blood safety, and radiation safety.

The commonalities and uniqueness of each area of safety needs to be recognized and identified. The Global Patient Safety Action Plan 2021–2030 seeks to do this through the integration and enhancement of capacity and resources for the greater good.

Due to the integrated role of patient safety in all health systems, it is essential to work in synergy with an extensive range of partnerships to improve patient safety globally, including Member States, intergovernmental bodies, specialized United Nations agencies (such as the United Nations Children's Fund and the International Labour Organization), developmental partners, professional organisations, civil society organization, patient organizations, universities, experts and patient safety advocates and champions.

Partnerships have helped to shape the design and delivery of WHO patient safety initiatives. For example, the first WHO Global Patient Safety Challenge: *Clean Care Is Safer Care* brought together almost all the world's experts in

health care-associated infection prevention and control. They helped to draw up the first ever set of evidence-based guidelines on hand hygiene issued by WHO to underpin implementation of the Challenge. A coalition of Member States, professional associations, academic centres, NGOs and patient representatives helped to drive forward a programme whose core objectives were adopted to cover 90% of the world's population.

WHO encourages stakeholders to build collaborative initiatives to improve and support the safety of health systems globally, particularly in low- and middle-income countries. Initiatives such as the Global Patient Safety Collaborative can help to reduce the risk of avoidable harm and improve the safety of national health care systems, including at facility level.

To amplify and disseminate good patient safety practices and learning at all levels, it is important to build partnerships and establish networks across the world. All collaborative initiatives and partnerships should be based on mutual respect and trust, clear communication and a shared vision of the desired outcome. All patient safety partnerships should be multidisciplinary and multisectoral in composition, with strong cohesive coordination, co-planning and co-production as the foundation for success.

It is of great value to have networks that stimulate dialogue, share adaptable strategies with low-cost interventions, and promote continuous learning and key lessons learned that can also work in low- and middle-income countries or fragile States. Patient safety multidisciplinary networks that include several types of stakeholders can be helpful in improving people-centred, integrated care and moving towards universal health coverage. Multiple stakeholders are active in the field of patient safety and a wealth of experience, best practices and lessons learned are available.

In the last few years, WHO has established a Global Patient Safety Network to connect actors and stakeholders from national and international patient safety and quality agencies and institutions; ministries of health; national, regional and zonal focal points from countries across all six WHO regions; WHO country, regional and global focal points for patient safety and quality of care, international professional bodies, and other key stakeholders. The key objectives of this network are to encourage leadership commitment; collect evidence from a variety of standpoints to inform future policies and practices; strengthen knowledge transfer and technical capacity across borders; institutionalize patient safety for sustainability; and encourage the sharing and application of best practices.

WHO's strategic objectives in the area of patient safety are to provide global leadership and to harness knowledge, expertise and innovation to improve patient safety in health care settings. The unique convening role of WHO at the all levels provides a vehicle for improving patient safety and managing risk in health care through international collaboration, engagement and coordinated action between Member States, institutions, technical experts, patients, civil society organizations, patient organizations, industry, development partners and other stakeholders.

Strategic Objective 7:

Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care

STRATEGY 7.1: **Fully engage all stakeholders that have the potential to have a positive impact on patient safety**	**Actions for governments** ◗ Conduct an analysis of stakeholders at national and subnational levels, including individuals and organizations, representing the public and private sectors, with the potential to be engaged in action on patient safety. ◗ Define the roles and responsibilities of all stakeholders in promoting and advancing patient safety within the country's health system. ◗ Establish clear and comprehensive coordination mechanisms for stakeholder engagement in action on patient safety. **Actions for health care facilities and services** ◗ Map stakeholders for the population served, including patients, families and local community leaders, local chapters of professional organizations, and training providers, and engage them in the organization's patient safety programmes and initiatives.

Actions for stakeholders

- Reduce working in silos and promote a unified movement on patient safety through the networks of professional organizations and industry representing different sectors of health care.

Actions for the WHO Secretariat

- Identify key stakeholders at global, regional and national levels that have roles and responsibilities in patient safety, as well as those with a potential to contribute and have a positive impact.
- Provide high-level advocacy, strategic leadership and guidance to all stakeholders to prioritize patient safety in their respective strategic plans.
- Establish networks of experts and representatives, such as civil society organizations, patient organizations, professional organizations, academic and research institutions, the private sector and industry.

STRATEGY 7.2:

Promote a common understanding and shared commitment among all stakeholders to successfully deliver the global patient safety action plan

Actions for governments

- Create a clear narrative that accurately reflects the goals, principles and objectives of the global action plan and is aligned with national patient safety policies, strategies and plans within the broader health care context of the country.

Actions for health care facilities and services

- Match the goals and objectives of the global action plan to the respective institutional plans, within the local context, and engage all staff, patients and families in implementation.

Actions for stakeholders

- Develop a clear and compelling narrative within the patient safety stakeholder community that explains the global action plan to all relevant audiences and advocates for its implementation.

Actions for the WHO Secretariat

- Monitor implementation of the global action plan, including identification of major barriers and proposing solutions.
- Expand and coordinate the expertise of the WHO Collaborating Centres and non-state actors in official relations with WHO to ensure inclusion of patient safety in their action plans and accelerate implementation of the global action plan.

STRATEGY 7.3:

Establish networks and convene consultative meetings to foster collaboration and partnership in patient safety

Actions for governments

- Establish national and subnational patient safety networks for sharing and disseminating patient safety best practices and ensuring mutual learning to reduce patient harm.
- Convene partners and stakeholders for consultative meetings to develop sustainable mechanisms for implementing the global action plan and the national patient safety policy and strategy.
- Engage partners and innovators from non-health sectors to promote creativity in finding new solutions to reduce avoidable harm and death in health care, including industry and the private sector.

Actions for health care facilities and services

- Set up an in-house academy to train individuals within the organization for proactive engagement in promotion and delivery of safe care within the organization.
- Participate in patient safety networks for exchanging experiences and resources and improving patient safety practices in day-to-day clinical care.

Actions for stakeholders

- Participate in global, regional and local initiatives, meetings and consultations related to patient safety.

Actions for the WHO Secretariat

- Strengthen the Global Patient Safety Network and expand subgroups on specific patient safety subject areas.
- Expand and strengthen thematic and regional networks on patient safety.
- Advocate creation of national and subnational patient safety networks to engage all partners in action on patient safety.
- Convene global, regional and national consultations for joint action on patient safety and collective ownership.

STRATEGY 7.4:

Promote cross-geographical and multisectoral initiatives to advance action on patient safety

Actions for governments

- Establish innovative intergovernmental collaborative models with strategically prioritized action on patient safety and participate in international collaborative patient safety initiatives.
- Consider participating in the annual Global Ministerial Summits on Patient Safety.
- Share and disseminate best practices and encourage mutual learning to reduce patient harm through regional and international collaboration.
- Encourage clinical and health care management leaders to seek out examples of best patient safety practices in other countries and adopt the approaches within the national health system.

Actions for health care facilities and services

- Participate in national and intercountry collaborative initiatives to seek out best patient safety practices and performance and incorporate them into the design of services and programmes within the organization.
- Identify opportunities for inter-organizational collaborative initiatives and set up schemes to allow the organization's staff exchange problem solving and improvement ideas across different systems and settings.

Actions for stakeholders

- Use established international networks and initiatives between professional organizations and medical societies, research groups and patient associations in different countries to strategically prioritize patient safety and express solidarity in support of the goals, principles and objectives of the global action plan.

Actions for the WHO Secretariat

- Mobilize the widest possible range of political commitment to and international solidarity for patient safety, including by continuing to foster the annual Global Ministerial Summits on Patient Safety.
- Establish formal collaborative mechanisms with common objectives around patient safety, such as the Africa Patient Safety Initiative and the Global Patient Safety Collaborative, and expand cooperation with countries within those mechanisms.
- Promote long-term strategic initiatives for alignment and synergy in action on patient safety among Member States and within special groups, such as the African Union, European Union, Group of 20 (G20), and OECD.
- Advocate prioritization of patient safety in the strategic agendas of collaborative mechanisms and initiatives, in line with the Global Patient Safety Action Plan 2021–2030, to ensure timely action and sustainability.
- Promote and support global patient safety initiatives, including observing World Patient Safety Day annually.

STRATEGY 7.5:

Work closely with technical programmes to ensure alignment in patient safety action

Actions for governments

- Review the range and scope of all technical health programmes within the country and identify the need for and potential benefit from alignment with patient safety action.
- Embed patient safety objectives and actions within technical programmes, in line with the local context.

Actions for health care facilities and services

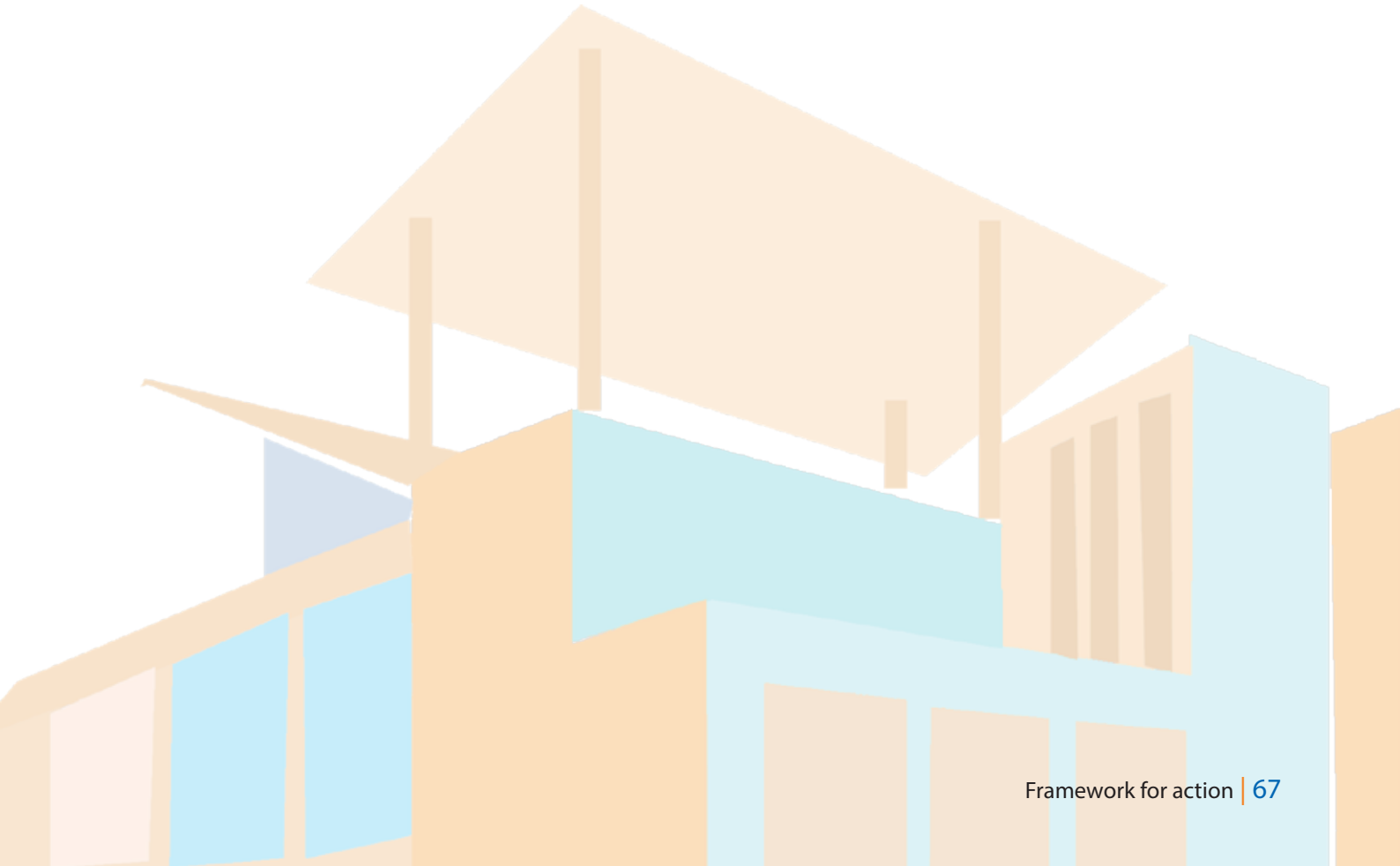
- Ensure that patient safety is incorporated within all health programmes that the organization is responsible for, especially those that have not traditionally explicitly recognized avoidable harm as a problem.

Actions for stakeholders

- Raise the profile of patient safety in global health technical programmes and international health cooperation programmes (including where it has not previously been recognized as an area of concern).
- Promote strategic prioritization of patient safety in discussion with donors and mobilize resources for joint action on patient safety.

Actions for the WHO Secretariat

- Develop clear insights into sources and levels of avoidable harm in services delivered through different health programmes and identify synergies and the scope for collaborative action, in line with the global action plan.
- Foster strategic cooperation and develop linkages with safety programmes, such as injection safety, radiation safety, IPC, blood safety, immunization safety, and water, sanitation and hygiene; clinical programmes, such as maternal health and newborn health, noncommunicable diseases, communicable diseases; and broader health system programmes, such as health workforce, occupational health, information and research, and quality of care, to ensure alignment and effectiveness of interventions.
- Ensure joint resource mobilization strategies at all levels for action on patient safety across all technical programmes.



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6. Implementation

6.1 Policy options for implementation of the global action plan

There is great diversity in the structure, funding and governance of health care systems worldwide and also a significant variation in the way that health care facilities are led and managed. Furthermore, policy objectives, strategic priorities and the effectiveness of interventions across different settings and by different subpopulation groups vary according to culture, context and resources. The Global Patient Safety Action Plan 2021–2030 has been developed with full recognition that countries are at different stages in their efforts to create safety capable environment and reduce preventable patient harm in health care and to strengthen their national health systems. There is therefore no single policy, strategic approach or intervention that can be universally applied to all types of health care settings. These need to be adapted before implementation. The approach to implementation needs also to be aligned with the national health agenda and harmonized in relation to the existing organizational structures, governance and management processes and expertise.

The Global Patient Safety Action Plan 2021–2030 provides seven strategic objectives achievable through 35 strategies and proposes actions to be taken by different partners and stakeholder groups. These suggested actions can be selected, prioritized, adapted and implemented, taking into consideration different factors.

Achieving full implementation at national level will be a long-term agenda for most Member States. Therefore, it is recommended that prior to implementation of the global action plan, Member States assess and analyse their situation to identify areas of progress that can be strengthened, as well as policy opportunities and practice gaps.

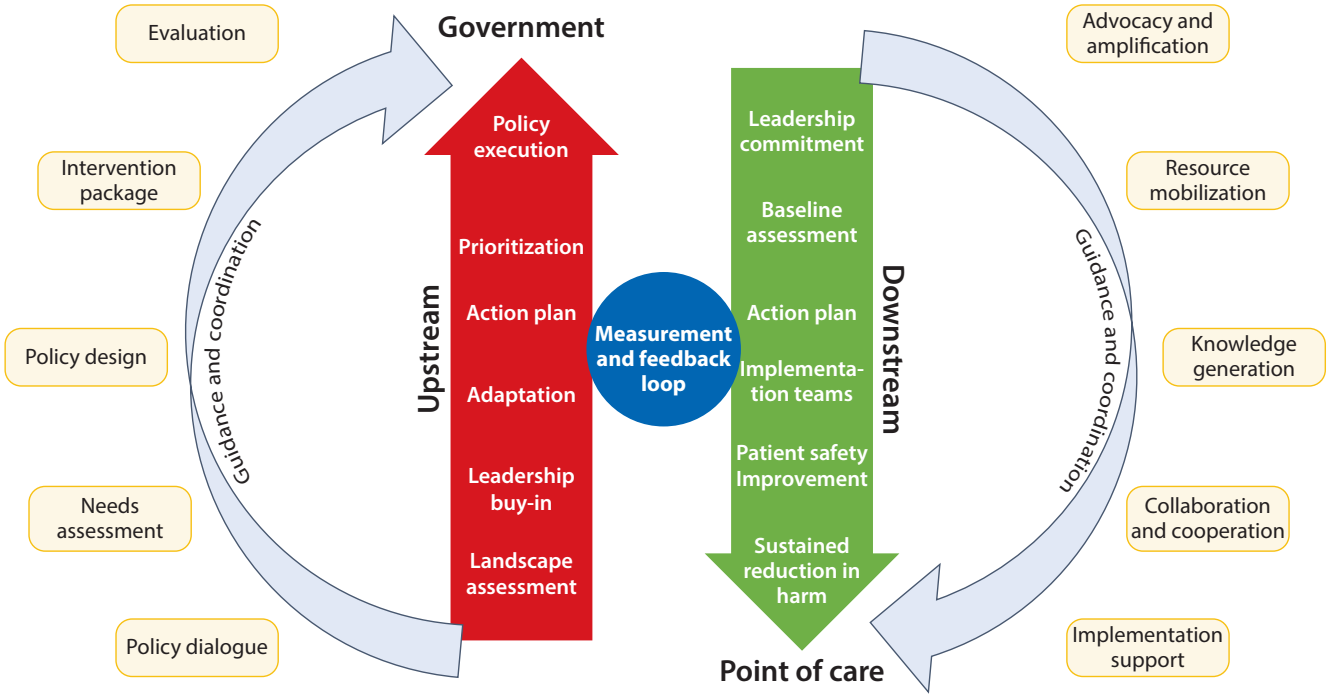
Policy interventions and strategic initiatives can start at subnational or institutional level to showcase exemplars of effectiveness and build momentum towards wider adoption at national level. Alternatively, implementation can start from the national level and follow an incremental approach, gradually involving subnational levels and more health care institutions. However, it is important to ensure that the global action plan is implemented in a holistic way, with a balanced range of upstream policy interventions and downstream improvement interventions.

Upstream policy interventions in areas such as regulation, accreditation, leadership, safety culture, competency building, and public reporting can be driving forces for patient safety improvement. Such interventions should show their value in contributing to significant reductions in harm at the point of care delivery. In addition, these interventions should be complemented by downstream patient safety improvement interventions in areas such as capacity-building, reporting and learning systems, teamwork and communication, and patient engagement, as well as solutions to high-risk clinical care processes. The patient safety improvement initiatives will trigger a demand for better-adapted policies and system-level interventions through the feedback loop (Figure 6.1).

6.2 Key milestones in implementing the global action plan

Patient safety is everybody's business. Implementation of the Global Patient Safety Action Plan 2021–2030 is beyond the scope of any single agency or stakeholder

Figure 6.1 The Ecosystem for Implementation of the Global Patient Safety Action Plan 2021–2030



group and will require effective partnerships. All partners in action must contribute to implementation of the plan at the global, regional, national and subnational levels, individually and through collaboration, taking into consideration the essence of cohesiveness and complementarity of actions. The implementation of the global action plan leaves room for flexibility of approach by taking account of the current policy environment, existing organizational context and resource deployment options, provided that the objectives can still be effectively progressed. Prioritization, feasibility and speed of implementation will also vary according to context. That is why it is suggested that all partners and stakeholders consider certain key milestones while implementing the global action plan.

Milestone 1: Landscape assessment

A landscape assessment should be conducted of the current situation in relation to patient safety developments at different levels, including identification of the policy environment and opportunities, safety risks, practice gaps, barriers to improvement and areas of progress that can be strengthened. Existing policies, strategies, programmes, regulations and institutional mechanisms should be mapped, and an analysis undertaken of the performance record. Credible assessment tools developed by WHO and other international organizations should assist in the process. The landscape assessment and mapping will illustrate the prerequisites for implementation of the global action plan and support selection and prioritization of respective actions.

Milestone 2: Secure strong commitment from political and organizational leadership

The landscape assessment will help make the case for prioritizing patient safety within the broader health agenda, as will information on the burden of patient harm and economic impact, especially if data are available in the national and local contexts. Media coverage of stories of patients experiencing avoidable harm can trigger a public discourse encouraging political leadership to take action for safer health care. Encouraging health leaders to participate in international platforms such as the Global Ministerial Summits on Patient Safety could help in gathering momentum and seeking commitment. Participating in WHO patient safety flagship initiatives such as the WHO Global Patient Safety Challenges and World Patient Safety Day can also provide visibility and facilitate early gains towards full commitment.

Milestone 3: Establish a sustainable mechanism for implementation

A sustainable mechanism for implementation of patient safety policy interventions and strategic initiatives

should be established within the broader context of national health plans and safety and quality policies. The preference of those accountable for implementing the global action plan at national or subnational level may be to harmonize and optimize the numbers of committees, task forces, advisory structures and other structures. Depending on the type of setting, availability of resources, and existing programme structures, a designated centre, institute, department, unit or a national patient safety coordinator is needed to coordinate and oversee implementation. Whichever mechanism is adopted, it needs to be translated to the subnational and institutional level with designation of a patient safety nodal person or a patient safety team for focused action on patient safety, infection prevention and control and medication safety. Similarly, where there are already well-developed arrangements for effective partnership, including those engaging with patients and families, the actions suggested in the action plan may be shaped by what is working well at national or local level. Policy interventions and strategic initiatives should be shaped by a rigorous consultative process involving all partners in action, including the nongovernmental and private sector.

Milestone 4: Align with national context and priorities

The Global Patient Safety Action Plan 2021–2030 provides a framework for action that will flow from national level to health facility and clinical team levels. Adaptation of the global framework to the country context needs to take account of the health care context within the country, the design and funding of the health care system, and existing priorities. Countries already having a national action plan with defined patient safety interventions, review and align it with the global action plan, updating and adjusting it accordingly.

Some of the criteria for prioritizing could be:

- core essential and critical action to reduce the highest risks for patients;
- interventions that are relatively easy to implement and make significant impacts on avoidable harm;
- patient safety interventions consistent with existing national or subnational health priorities;
- patient safety interventions that contribute to better health system performance and improved health outcomes;
- interventions that are systemic in nature, of benefit to large numbers of patients, and with the potential to ensure sustainable improvements in the long term.

Based on the prioritization and estimated implementation timelines, processes and outcomes should be identified that can be achieved in the short term (two to three years), medium term (three to six years), and longer term (seven to 10 years). Indicators should be defined to assess the performance at national and health care facility levels.

Milestone 5: Decide upon and design the model of change for implementation

A robust change management strategy should be in place to ensure a holistic approach to patient safety policy interventions and strategic initiatives, together with the engagement of key stakeholders with a clear vision and sustainable implementation. Some best practices are:

- adopt an incremental approach to improvement, starting with small-scale implementation with a quick turnaround;
- recognize and reward teams for their good work;
- use a project management approach to implement planned actions, assign roles and responsibilities to all stakeholders, define timelines and designate a key person for coordinating and monitoring implementation;
- develop a system of mentorship and coaching, identifying best practices and role models (individual and organizational) that could inspire improvements;
- break silos and be in constant touch and cooperation with other related programmes and stakeholders.

Success should be celebrated and promoted to raise political, stakeholder and public awareness and support. Mobilizing patients, families and communities to engage in the planning and implementation of solutions and actions is critical to success.

WHO and NGOs can shape and accelerate patient safety implementation in countries through advocacy, coordination, normative guidance and technical support. This whole systems approach that coordinates interventions at all levels will create an "ecosystem" of patient safety improvement globally over the next 10 years.

7. Monitoring and reporting

The Global Patient Safety Action Plan 2021–2030 aims to achieve the maximum possible reduction in avoidable harm globally due to unsafe health care. The action plan has not set a numerical reduction goal, acknowledging that there is no reliable estimation of the extent of burden of harm in most countries, especially in low- and middle-income countries. Thus, all countries are encouraged to establish their baseline estimates of safety-related performance and set targets to implement national efforts to improve patient safety. This section proposes a set of metrics to support Member States in monitoring and reporting progress on implementation of this action plan. Monitoring and reporting efforts could leverage existing health information management systems to obtain data to report and track progress on several of these proposed patient safety indicators.

Recognizing that countries are at different stages of health system maturity and have varied resources, capacity and priorities for improving patient safety, the adoption and application of monitoring and reporting mechanisms should be flexible to accommodate these variations. A global reporting mechanism on a minimum set of core indicators and targets could help evaluate implementation progress at global, regional and national levels.

The indicators presented here are aligned with the seven strategic objectives of the global action plan. These are suggested as representative "outcome" measures for action taken on the corresponding strategic objective. Indicators are categorized into "core" and "advanced" to limit the burden of collecting data and allow flexibility.

7.1 Core indicators

The 10 core indicators proposed are fundamental to measure the progress on implementation of this global action plan. The WHO Secretariat plans to monitor all the core indicators at the global, regional and national levels. Progress on achieving these indicators will be reported to the World Health Assembly through successive biennial progress reports as mandated by resolution WHA72.6. Most of the core indicators proposed are policy or programme related, and data on their progress will be collected through Member State surveys coordinated by the WHO Secretariat or partner organizations and institutions, as applicable.

The set of "advanced" indicators are proposed to enable measurement of additional aspects of patient safety actions. Countries are encouraged to select the most appropriate indicators based on their context, capacity and specific patient safety priorities. Progress measured based on both core and advanced indicators could be made publicly available at the national or local level and contribute to annual reporting on the status of patient safety improvements.

The WHO Secretariat will be developing detailed guidance on monitoring and reporting as part of an implementation toolkit for the action plan. This toolkit will provide information on definitions, sources of data, methods and the process of reporting and analysis.

The WHO Secretariat is also developing a patient safety assessment tool to support implementation of the global action plan. This tool will assist governments and health care facilities to assess the baseline and evaluate progress periodically. The assessment tool is aligned with the action plan's strategic objectives and strategies and could help generate numerical scoring to measure progress on actions and outcomes under each of the strategic objectives. The trends of these scores will provide an additional measure for monitoring progress of implementation of the global action plan.

Through its regional and country offices, WHO will provide technical support, training and mentoring for objective assessments and situational analyses of patient safety using indicators and assessment tools. WHO will also provide technical support to prioritize patient safety indicators and operationalize them for reporting, analysis and improvement.

STRATEGIC OBJECTIVE

1

Indicator

Number of countries that have developed a national action plan (or equivalent) for implementing patient safety policy and strategies

Global targets

Percentage of countries that have developed a national patient safety action plan or equivalent

2021	Establish a baseline
2023	30% of countries
2025	50% of countries
2027	80% of countries
2030	90% of countries

Source of data

Member State survey by WHO

Indicator

Number of countries that have implemented a system for reporting of never events (or sentinel events)

Global targets

Percentage of countries that have implemented a system for reporting of never events (or sentinel events)

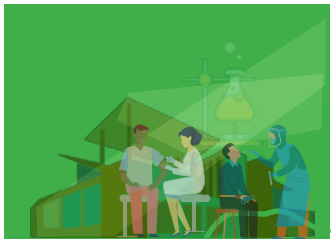
2021	Establish a baseline
2023	30% of countries
2025	50% of countries
2027	80% of countries
2030	90% of countries

Source of data

Member State survey by WHO or partner institution

STRATEGIC OBJECTIVE

2



STRATEGIC OBJECTIVE

3

Indicator

Significant reduction in health care-associated infections

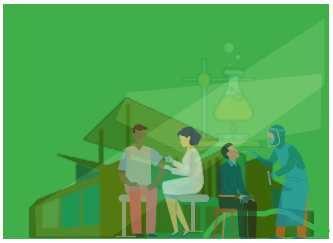
Global targets

Percentage of countries that have achieved their national targets on reducing the health care-associated infection rate

2022	Establish a baseline and national targets
2023	20% of countries
2025	40% of countries
2027	60% of countries
2030	80% of countries

Source of data

National health or patient safety information systems



STRATEGIC OBJECTIVE

3

Indicator

Significant reduction in medication-related harm (adverse drug events)

Global targets

Percentage of countries that have achieved their national targets on reducing medication-related harm

2022	Establish a baseline and national targets
2023	20% of countries
2025	50% of countries
2027	70% of countries
2030	80% of countries

Source of data

National health or patient safety information systems

Indicator

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

Global targets

Percentage of countries with more than 60% of hospitals having a patient representative on the governing board (or an equivalent mechanism)

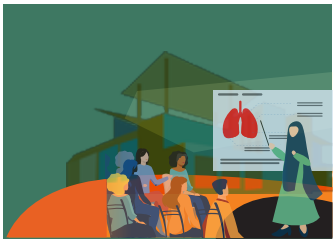
2022	Baseline established
2023	20% of countries
2025	30% of countries
2027	50% of countries
2030	70% of countries

Source of data

Survey by partner patient organization designated by WHO

STRATEGIC OBJECTIVE

4



STRATEGIC OBJECTIVE

5

Indicator

Number of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals

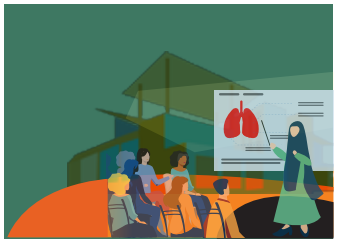
Global targets

Percentage of countries that have incorporated a patient safety curriculum in education programmes or courses for health care professionals

2021	Baseline established
2023	30% of countries
2025	50% of countries
2027	70% of countries
2030	80% of countries

Source of data

Member State survey by WHO or partner institution



STRATEGIC OBJECTIVE

5

Indicator

Number of countries that have signed up for implementation of the WHO Health Worker Safety Charter[1]

Global targets

Percentage of countries that have signed up for implementation of the WHO Health Worker Safety Charter

2021	Baseline established
2023	30% of countries
2025	50% of countries
2027	80% of countries
2030	90% of countries

Source of data

Member State survey by WHO or partner institution

STRATEGIC OBJECTIVE

6

Indicator

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

Global targets

Percentage of countries with 60% or more health care facilities participating in a patient safety incident reporting and learning system

2022	Baseline established
2023	20% of countries
2025	40% of countries
2027	60% of countries
2030	80% of countries

Source of data

Survey by WHO or partner institution

Reports from national patient safety incident reporting and learning system

Indicator

Number of countries that publish an annual report on patient safety

Global targets

Percentage of countries that publish an annual report on patient safety

2021	Baseline established
2023	20% of countries
2025	40% of countries
2027	60% of countries
2030	70% of countries

Source of data

Member State survey by WHO

1. Health worker safety: a priority for patient safety: https://apps.who.int/iris/handle/10665/339287.

Indicator

Number of countries that have established a national patient safety network

Global targets

Percentage of countries that have established a national patient safety network

2021	Baseline established
2023	30% of countries
2025	50% of countries
2027	60% of countries
2030	80% of countries

Source of data

Member State survey by WHO or partner institution

STRATEGIC OBJECTIVE

7

7.2 Advanced indicators

1. Strategic objective 1

1.1. Number of countries, provinces or health care facilities observing World Patient Safety Day

1.2. Number of health care facilities signed up for implementation of the annual World Patient Safety Day goals

1.3. Number of countries, provinces or health care facilities that have a system of rewarding health care facilities based on patient safety and quality of care performance

1.4. Percentage of countries or provinces that have incorporated minimum safety standards in regulatory requirements for health care facilities

1.5. Composite score for strategic objective 1 on the patient safety assessment tool

2. Strategic objective 2

2.1. Number of countries, provinces or health care facilities that have designated a patient safety officer, team or agency (or equivalent)

2.2. Number of countries or provinces that have established an institutional framework for patient safety implementation at all levels

2.3. Number of countries, provinces or health care facilities conducting regular patient safety culture surveys in health care facilities

2.4. Number of countries, provinces or health care facilities that have established a programme for building leadership capacity for patient safety

2.5. Number of countries, provinces or health care facilities that have established a non-punitive policy for reporting adverse events and raising safety concerns

2.6. Number of countries, provinces or health care facilities that have established a risk register for identifying and managing known and potential safety risks

2.7. Number of countries, provinces or health care facilities conducting regular rehearsals or simulation exercises to test the risk mitigation plan

2.8. Composite score for strategic objective 2 on the patient safety assessment tool

3. Strategic objective 3

Incidence rates and reduction related to specific patient safety outcome measures at national, subnational and health care facility level, related to:

3.1. Avoidable deaths due to health care-associated venous thromboembolism during or after hospitalization (up to 90 days post discharge)

3.2. Avoidable deaths due to health care-associated sepsis

3.3. Missed or delayed diagnosis

3.4. Inappropriate polypharmacy

3.5. Perioperative mortality

3.6. Avoidable deaths due to patient falls during hospitalization

3.7. Severe transfusion reactions

3.8. Obstetric trauma during normal and caesarean section deliveries

3.9. Neonatal trauma

3.10. In-hospital decubitus ulcer

3.11. Antimicrobial resistance transmission events

3.12. Ventilator-associated pneumonia incidents

3.13. Composite score for strategic objective 3 on the patient safety assessment tool

4. Strategic objective 4

4.1. Number of policies and guidelines on safer health care co-developed with patient and family representatives or patient organizations at national, subnational or health care facility level

4.2. Number of countries or provinces that have established networks of patient advocates and champions

4.3. Number of countries, provinces or health care facilities have established a patient and family advisory committee (or its equivalent)

4.4. Number of countries, provinces or health care facilities that have developed and implemented procedures for disclosure of adverse events to patients and families

4.5. Number of countries, provinces or health care facilities that measure patient-reported experiences or related safety outcomes

4.6. Composite score for strategic objective 4 on the patient safety assessment tool

5. Strategic objective 5

5.1. Number of countries or provinces that have incorporated minimum patient safety standards in licensing and relicensing programs and standards for health care professionals

5.2. Number of countries, provinces or health care facilities that are conducting periodic assessments for patient safety competencies of health care professionals

5.3. Number of countries, provinces or health care facilities that have established a programme for occupational safety of health workers

5.4. Number of countries, provinces or health care facilities where vaccination of health workers for prioritized vaccine-preventable diseases (including COVID-19) is offered

5.5. Composite score for strategic objective 5 on the patient safety assessment tool

6. Strategic objective 6

6.1. Number of countries, provinces or health care facilities that have implemented electronic health records

6.2. Number of countries, provinces or health care facilities that have established a system of safety alerts to rapidly communicate information on newly identified high-impact patient safety risks

6.3. Number of countries or provinces that have identified research priorities for patient safety

6.4. Number of countries or provinces conducting studies to measure the burden of harm in health care

6.5. Composite score for strategic objective 6 on patient safety assessment tool

7. Strategic objective 7

7.1. Number of countries, provinces or health care facilities that have established annual goals and targets for patient safety priorities

7.2. Number of countries or provinces that have established a patient safety steering committee involving all relevant stakeholders

7.3. Number of countries or provinces that that have integrated patient safety components in health programmes (such as mother and child health, communicable disease control, noncommunicable diseases, health emergencies, and blood and transfusion services, radiation safety)

7.4. Number of countries represented by a high-level policy-maker in the annual global ministerial summits on patient safety

7.5. Composite score for strategic objective 7 on the patient safety assessment tool

8. Alignment of patient safety with the United Nations Sustainable Development Goals

Patient safety is central to the realization of the United Nations Sustainable Development Goals (SDGs), in particular SDG3 ("Ensure healthy lives and promote well-being for all at all ages") and achievement of universal health coverage (target 3.8). Apart from this core target, patient safety has causality linkages with several other SDGs. Table 8.1 provides illustrations of how patient safety contributes to achievement of specific SDG targets, while Table 8.2 shows the central role of patient safety in achieving SDG 3 targets.

Table 8.1 SDG linkages with patient safety

SDG	Target	How patient safety contributes
SDG 1 NO POVERTY 	Target 1.2: By 2030, reduce at least by half the proportion of men, women and children of all ages in poverty in all its dimensions according to national definitions	Catastrophic health care expenditure pushes millions of families every year below the poverty line. Patient safety helps in reducing health care expenditure due to safety failures as well as in optimizing available resources to improve access to health services.
SDG 3 GOOD HEALTH AND WELL-BEING 	Target 3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100000 live births	Many maternal deaths are due to unsafe care in health care facilities and can be prevented with patient safety interventions.
	Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all	Improving patient safety could drastically reduce waste in health care and improve access by positively influencing health-seeking behaviour.

SDG	Target	How patient safety contributes
SDG 5 GENDER EQUALITY 	Target 5.2: Eliminate all forms of violence against all women and girls in the public and private spheres, including trafficking and sexual and other types of exploitation	The health sector and health workers have an important role to play in preventing and responding to violence against women. Through patient engagement and respectful care, patient safety promotes survivor-centred care, especially for survivors of gender-based violence. As approximately 70% of the health workforce are women, it is especially important to eliminate gender-based violence in the health care system. Health worker safety is an important dimension of patient safety.
SDG 6 CLEAN WATER AND SANITATION 	Target 6.1: By 2030, achieve universal and equitable access to safe and affordable drinking water for all	Water and sanitation in health care facilities is a key component of patient safety and could influence the sanitation behaviour of the community.
SDG 8 DECENT WORK AND ECONOMIC GROWTH 	Target 8.8: Protect labour rights and promote safe and secure working environments for all workers	Focusing on human factors and the safety culture could sustainably improve workplace safety in health care systems, which are a major employer in most economies.
SDG 10 REDUCED INEQUALITIES 	Target 10.2: By 2030, empower and promote the social, economic and political inclusion of all, irrespective of age, sex, disability, race, ethnicity, origin, religion or economic or other status	Engagement and empowerment of patients, families and communities is the cornerstone of patient safety and promotes equity and inclusiveness in health care.
SDG 12 RESPONSIBLE CONSUMPTION AND PRODUCTION 	Target 12.4: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks	Patient safety programmes promote proper management of infectious wastes and the goal of mercury-free hospitals, in accordance with the Minamata Convention on Mercury.

Table 8.2 Issues pertaining to patient safety in achieving SDG 3 targets

SDG 3 Targets	Examples of avoidable harm in health care
3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100 000 live births	◗ Missed diagnosis of high-risk pregnancy ◗ Obstetrical trauma ◗ Unsafe management of obstetrical complications, such as postpartum haemorrhage and obstructed labour ◗ Unnecessary and harmful practices, such as excessive fundal pressure and unnecessary induction, unnecessary episiotomy, and immediate cord clamping ◗ Venous thromboembolism in pre and post birthing
3.2 By 2030, end preventable deaths of newborns and children under 5 years of age	◗ Complications due to unsafe preterm and intrapartum care, for example, birth asphyxia ◗ Immunization safety issues ◗ Missed diagnosis of congenital anomalies ◗ Errors in paediatric dosages of medicines ◗ In-hospital falls of newborns and infants ◗ Failure to resuscitate ◗ Newborn sepsis ◗ Errors in oxygenation targets
3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases	◗ Sharps injuries in health care facilities ◗ Lack of personal protection products ◗ Unsafe blood transfusion practices ◗ Unsafe injection practices ◗ Occupational tuberculosis exposure ◗ Adverse drug (medication) events in the treatment of tuberculosis and malaria ◗ Misdiagnosis of multidrug-resistant tuberculosis ◗ Medication safety issues in mass drug administration for neglected tropical diseases ◗ Safety issues in snakebite envenoming
3.4 By 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being	◗ Missed early diagnosis and wrong diagnosis of noncommunicable diseases ◗ Polypharmacy ◗ Laboratory errors ◗ Prescription and administration errors in treatment with insulin ◗ Self-harm behaviour, adverse drug (medication) events, falls in mental health care ◗ Safety issues in chemotherapy and radiotherapy ◗ Failure to rescue ◗ Safety concerns with medical use of ionic radiation

SDG 3 Targets	Examples of avoidable harm in health care
3.5 Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol	◗ Failure to engage patients, leading to dropout and relapse ◗ Self-harm and violent behaviour ◗ Drug abuse and addiction ◗ Drug pilferage and misuse ◗ Complications with pharmacotherapy, for example overdose
3.7 By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education	◗ Complications from unsafe abortions ◗ Complications in sterilization surgeries, such as surgical site infections and adverse drug (medication) events ◗ Non-adherence to medical eligibility criteria for contraceptive use, leading to inappropriate prescription of contraceptives ◗ Contraceptive failure
3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all	◗ Extended hospital stays ◗ Readmissions ◗ Litigation costs due to safety incidents ◗ Repeat procedures ◗ Loss of trust leading to diminished health-seeking behaviour ◗ Substandard and falsified medical products
3.9 By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination	◗ Environmental contamination related to health care-associated hazardous and infectious waste ◗ Adverse effects from medical use of mercury ◗ Improper disposal of chemotherapeutic and radioactive agents ◗ Hospital effluent with hazardous and infectious material
3.c Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States	◗ Health worker burnout, compromised psychological safety ◗ Violence against health workers ◗ Lack of expertise in human factors to inform the design of safer care systems ◗ Physical and chemical hazards ◗ Staff skill and training deficits

9. Mapping World Health Assembly resolution WHA72.6 with the Global Patient Safety Action Plan 2021–2030

Table 9.1 shows how the operative paragraphs of World Health Assembly resolution WHA72.6, adopted by the Seventy-second World Health Assembly in May 2019, can be linked with the strategies of the Global Patient Safety Action Plan 2021–2030.

Table 9.1 Linkages between resolution WHA72.6 and strategies of Global Patient Safety Action Plan 2021–2030

Operating Paragraph	Statement	Linkage with strategies
	The Seventy-second World Health Assembly:	
1	Endorses the establishment of World Patient Safety Day, to be marked annually on 17 September in order to increase public awareness and engagement, enhance global understanding, and work towards global solidarity and action by Member States to promote patient safety	◗ Strategy 1.5: World Patient Safety Day and Global Patient Safety Challenges
2	Urges Member States:	
2.1	To recognize patient safety as a health priority in health sector policies and programmes, making it an essential component for strengthening health care systems in order to achieve universal health coverage	◗ Strategy 1.1: Patient safety policy, strategy and implementation framework ◗ Strategy 2.2: Good governance for the health care system
2.2	To assess and measure the nature and magnitude of the problem of patient safety including risks, errors, adverse events and patient harm at all levels of health service delivery including through reporting, learning and feedback systems that incorporate the perspectives of patients and their families, and to take preventive action and implement systematic measures to reduce risks to all individuals	◗ Strategy 6.1: Patient safety incident reporting and learning systems ◗ Strategy 6.2: Patient safety information systems ◗ Strategy 6.3: Patient safety surveillance systems

Operating Paragraph	Statement	Linkage with strategies
2.3	To develop and implement national policies, legislation, strategies, guidance and tools, and deploy adequate resources, in order to strengthen the safety of all health services, as appropriate	◗ Strategy 1.1: Patient safety policy, strategy and implementation framework ◗ Strategy 1.2: Resource mobilization and allocation ◗ Strategy 1.3: Protective legislative measures ◗ Strategy 5.3: Patient safety competencies as regulatory requirements
2.4	To work in collaboration with other Member States, civil society organizations, patients' organizations, professional bodies, academic and research institutions, industry and other relevant stakeholders to promote, prioritize and embed patient safety in all health policies and strategies	◗ Strategy 7.1: Stakeholder engagement ◗ Strategy 7.2: Common understanding and shared commitment ◗ Strategy 7.4: Cross-geographical and multisectoral initiatives for patient safety ◗ Strategy 7.5: Alignment with technical programmes and initiatives
2.5	To share and disseminate best practices and encourage mutual learning to reduce patient harm through regional and international collaboration	◗ Strategy 6.1: Patient safety incident reporting and learning systems ◗ Strategy 6.2: Patient safety information systems ◗ Strategy 7.3: Patient safety networks and collaboration ◗ Strategy 7.4: Cross-geographical and multisectoral initiatives for patient safety
2.6	To integrate and implement patient safety strategies in all clinical programmes and risk areas, as appropriate, to prevent avoidable harm to patients related to health care procedures, products and devices, for example, medication safety, surgical safety, infection control, sepsis management, diagnostic safety, environmental hygiene and infrastructure, injection safety, blood safety and radiation safety, as well as to minimize the risk of inaccurate or late diagnosis and treatment, and to pay special attention to at-risk groups	◗ Strategy 3.1: Safety of risk-prone clinical procedures ◗ Strategy 3.2: Global Patient Safety Challenge: *Medication Without Harm* ◗ Strategy 3.3: Infection prevention and control and antimicrobial resistance ◗ Strategy 3.4: Safety of medical devices, medicines, blood and vaccines ◗ Strategy 3.5: Patient safety in primary care and transitions of care ◗ Strategy 7.5: Linkages with technical programmes and initiatives
2.7	To promote a safety culture by providing basic training to all health professionals, developing a blame-free patient safety incident reporting culture through open and transparent systems that identify and learn from examining causative and contributing factors of harm, addressing human factors, and building leadership and management capacity and efficient multidisciplinary teams, in order to increase awareness and ownership, improve outcomes for patients and reduce the costs related to adverse events at all levels of health systems	◗ Strategy 2.1: Transparency, openness and no blame culture ◗ Strategy 2.3: Leadership capacity for clinical and managerial functions ◗ Strategy 2.4: Human factors/ergonomics for health systems resilience ◗ Strategy 6.1: Patient safety incident reporting and learning systems

Operating Paragraph	Statement	Linkage with strategies
2.8	To build sustainable human resource capacity, through multisectoral and interprofessional competency-based education and training, based on the WHO patient safety curricula and continuous professional development, to promote a multidisciplinary approach, and to build an appropriate working environment that optimizes the delivery of safe health services	◗ Strategy 5.1: Patient safety in professional education and training ◗ Strategy 5.2: Centres of excellence for patient safety education and training ◗ Strategy 5.4: Linking patient safety with appraisal system of health workers ◗ Strategy 5.5: Safe working environment for health workers
2.9	To promote research, including translational research, to support the provision of safer health services and long-term care	◗ Strategy 6.4: Patient safety research programmes
2.10	To promote the use of new technologies, including digital technologies, for health, including to build and scale up health information systems and to support data collection for surveillance and reporting of risks, adverse events and other indicators of harm at different levels of health services and health-related social care, while ensuring the protection of personal data, and to support the use of digital solutions to provide safer health care	◗ Strategy 6.2: Patient safety information systems ◗ Strategy 6.5: Digital technology for patient safety
2.11	To consider the use of traditional and complementary medicine, as appropriate, in the provision of safer health care	◗ Strategy 3.2: Global Patient Safety Challenge: *Medication Without Harm*
2.12	To put in place systems for the engagement and empowerment of patients' families and communities (especially those who have been affected by adverse events) in the delivery of safer health care, including capacity-building initiatives, networks and associations, and to work with them and civil society, to use their experience of safe and unsafe care positively in order to build safety and harm-minimization strategies, as well as compensation mechanisms and schemes, into all aspects of the provision of health care, as appropriate	◗ Strategy 4.1: Co-development of policies and programmes with patients ◗ Strategy 4.2: Learning from patient experience for safety improvement ◗ Strategy 4.3: Patient advocates and patient safety champions ◗ Strategy 4.4: Patient safety incident disclosure to victims ◗ Strategy 4.5: Information and education to patients and families
2.13	To mark World Patient Safety Day annually on 17 September to promote all aspects of patient safety including progress towards reaching national milestones, in collaboration with relevant stakeholders	◗ Strategy 1.5: World Patient Safety Day and Global Patient Safety Challenges
2.14	To consider participating in the annual Global Ministerial Summits on Patient Safety	◗ Strategy 7.4: Cross-geographical and multisectoral initiatives for patient safety

Operating Paragraph	Statement	Linkage with strategies
3	Invites international organizations and other relevant stakeholders to collaborate with Member States in promoting and supporting patient safety initiatives, including marking World Patient Safety Day annually	◗ Strategy 1.5: World Patient Safety Day and Global Patient Safety Challenges
4	Requests the Director-General:	
4.1	To emphasize patient safety as a key strategic priority in WHO's work across the universal health coverage agenda	◗ Strategy 1.1: Patient safety policy, strategy and implementation framework
4.2	To develop normative guidance on minimum standards, policies, best practice and tools for patient safety, including on safety culture, human factors, hygienic infrastructure, clinical governance and risk management	◗ Strategy 1.4: Safety standards, regulation and accreditation
4.3	To provide technical support to Member States, especially low- and middle-income countries, where appropriate and where requested, to help to build national capacities in their efforts to assess, measure and improve patient safety, in collaboration with professional associations, as appropriate, and to create a safety culture, as well as ensuring effective prevention of health care-associated harm, including infections, by building capacity in leadership and management, and open and transparent systems that identify and learn from the causes of harm	◗ Strategy 2.1: Transparency, openness and no blame culture ◗ Strategy 2.3: Leadership capacity for clinical and managerial functions ◗ Strategy 3.3: Infection prevention and control and antimicrobial resistance ◗ Strategy 6.2: Patient safety information systems ◗ Strategy 6.3: Patient safety surveillance systems
4.4	To provide support to Member States, on request, in establishing and/or strengthening patient safety surveillance systems	◗ Strategy 6.2: Patient safety information systems
4.5	To strengthen global patient safety networks to share best practice and learning and foster international collaboration including through a global network of patient safety trainers, and to work with Member States, civil society organizations, patients' organizations, professional associations, academic and research institutions, industry and other relevant stakeholders in building safer health care systems	◗ Strategy 7.1: Stakeholder engagement ◗ Strategy 7.2: Common understanding and shared commitment ◗ Strategy 7.3: Patient safety networks and collaboration ◗ Strategy 7.4: Cross-geographical and multisectoral initiatives for patient safety ◗ Strategy 7.5: Alignment with technical programmes and initiatives
4.6	To provide, on request, technical support and normative guidance on the development of human resource capacity in Member States through interprofessional competency-based education and training based on WHO patient safety curricula, and, in consultation with Member States, develop "training-of-trainers" programmes for patient safety education and training, and develop global and regional networks of professional educational councils to promote education on patient safety	◗ Strategy 5.1: Patient safety in professional education and training ◗ Strategy 5.2: Centres of excellence for patient safety education and training

Operating Paragraph	Statement	Linkage with strategies
4.7	To develop and manage, in consultation with Member States, systems for global sharing of learning from patient safety incidents, including through reliable and systematic reporting, data analysis and dissemination systems	◗ Strategy 6.1: Patient safety incident reporting and learning systems
4.8	To design, launch and support Global Patient Safety Challenges, and to develop and implement strategies, guidance and tools to support Member States in implementing each Challenge, using the best available evidence	◗ Strategy 1.5: World Patient Safety Day and Global Patient Safety Challenges
4.9	To promote and support the application of digital technologies and research, including translational research for improving the safety of patients	◗ Strategy 6.5: Digital technology for patient safety
4.10	To provide support to Member States, upon request, in putting into place systems to support the active engagement, participation and empowerment of patients, families and communities in the delivery of safer health care; and in establishing and strengthening networks for engagement of patients, communities, civil society and patient associations	◗ Strategy 4.1: Co-development of policies and programmes with patients ◗ Strategy 4.2: Learning from patient experience for safety improvement ◗ Strategy 4.3: Patient advocates and patient safety champions ◗ Strategy 4.4: Patient safety incident disclosure to victims ◗ Strategy 4.5: Information and education to patients and families
4.11	To work with Member States, international organizations and other relevant stakeholders to promote World Patient Safety Day	◗ Strategy 1.5: World Patient Safety Day and Global Patient Safety Challenges
4.12	To formulate a global patient safety action plan in consultation with Member States and all relevant stakeholders, including in the private sector, for submission to the Seventy-fourth World Health Assembly in 2021 through the 148th session of the Executive Board	
4.13	To submit a report on progress in the implementation of this resolution, for the consideration of the Seventy-fourth, Seventy-sixth and Seventy-eighth World Health Assemblies	

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Glossary

Term	Definition and source used in glossary (see separate glossary references below)
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-determined 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	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 event	An incident which resulted in harm to a patient *(3)*.
Caregivers	Individuals who provide care for a member or members of their family, friends or community. They may provide regular, occasional or routine care or be involved in organizing care delivered by others *(4)*.
Complication	A disease or injury that arises subsequent to another disease and/or health-care intervention *(3)*.
Equity	Fairness; people's needs guide the distribution of opportunities for well-being. All people have an equal opportunity to develop and maintain their health, through fair and just access to resources for health *(5)*.
Error	Failure to carry out a planned action as intended or application of an incorrect plan *(3)*.
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death *(3)*.
Hazard	A circumstance, agent or action with the potential to cause harm *(3)*.

Term	Definition and source used in glossary (see separate glossary references below)
Health care-associated infection (also referred to as "nosocomial" or "hospital infection")	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 *(6)*.
Health service	Any service (not limited to medical or clinical services) aimed at contributing to improved health or to the diagnosis, treatment and rehabilitation of individuals and populations *(4)*.
Health system	(i) All the activities whose primary purpose is to promote, restore and/or maintain health; (ii) the people, institutions and resources, arranged together in accordance with established policies, to improve the health of the population they serve, while responding to people's legitimate expectations and protecting them against the cost of ill-health through a variety of activities whose primary intent is to improve health *(7)*.
Health workers	Health workers are all people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, lab-, health- and medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities. Health workers include not only those who work in acute care facilities but also those employed in long-term care, public health, community-based care, social care and home care *(8)*.
Human factors	Study of the interrelationships between humans, the tools, equipment and methods they use, and the environments in which they live and work *(3)*.
Incident	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards *(3)*.
Just culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action *(3)*.
Licensing	A government-endorsed regulatory process to grant permission and specify scope for the health care practice of an individual or organization, usually preceding accreditation *(9)*.
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 *(4)*.
Medical error	An adverse event or near miss that is preventable with the current state of medical knowledge *(3)*.
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 *(2)*.

Term	Definition and source used in glossary (see separate glossary references below)
National patient safety policy	A formal government statement that defines priorities and parameters for action in response to a country's needs, available resources and political considerations, and that is developed in close consultation with stakeholders, including communities *(10)*.
Near miss	An incident that did not reach the patient *(3)*.
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) *(11)*.
Patient empowerment	A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation *(12)*.
Patient engagement	The facilitation and strengthening of the role of those using services as coproducers of health, and health care policy and practice *(13)*.
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 *(11)*.
Preventable	Accepted by the community as avoidable in the particular set of circumstances *(3)*.
Primary care	A key process in the health system that supports first-contact, accessible, continued, comprehensive and coordinated patient-focused care *(4)*.
Quality	The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge *(3)*.
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 *(14)*.
Risk	The probability of danger, loss or injury within the health-care system *(3)*.
Root cause	The most fundamental reason an event has occurred *(3)*.
Safe care	Safe care involves making evidence-based clinical decisions to maximize the health outcomes of an individual and to minimize the potential for harm *(3)*.
Safety culture	The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the characteristics of the organization's health and safety management. 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 *(15)*.

Term	Definition and source used in glossary (see separate glossary references below)
Sepsis	Life-threatening organ dysfunction caused by a dysregulated host response to infection *(16)*.
Systems approach	Using prompt, intensive investigation followed by multidisciplinary systems analysis... to [uncover] both proximal and systemic causes of errors... It is based on the concept that although individuals make errors, characteristics of the systems within which they work can make errors more likely and also more difficult to detect and correct. Further, it takes the position that while individuals must be responsible for the quality of their work, more errors will be eliminated by focusing on systems than on individuals. It substitutes inquiry for blame and focuses on circumstances rather than on character *(3)*.
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 *(17)*.
Universal health coverage	UHC means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course *(18)*.

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