ISQua | International Society for Quality in Health Care

Safe Care is the Right Care

ISQua White Paper
on Patient Safety for
Healthcare Organisations

Workgroup

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ISQua International Society for Quality in Health Care

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Table of Abbreviations

IPSG	International Patient Safety Goals
ISQua	International Society for Quality in Health Care
WHO	World Health Organization
AMR	Antimicrobial resistance
IHI	Institute of Healthcare Improvement
JCI	Joint Commission International
GPSAP	Global Patient Safety Action Plan
API	Associates in Process Improvement
FP	Foundation pillar
KPI	Key Performance Indicators
PPE	Personal protective equipment
VR	Virtual reality
AR	Augmented reality
LHS	Learning health systems
PFCAC	Patient- and family-centred advisory committees
PREM	Patient-reported experience measures
PROM	Patient-reported outcome measures
EHRs	Electronic health records
ICU	Intensive care unit
CPOE	Computerised physician order entry
CDSS	Clinical decision support systems
SOPs	Standard operating procedures
AI	Artificial intelligence
ML	Machine learning
BCMA	Bar-coded medication administration
BMJ	British Medical Journal
PFAC	Patient and Family Advisory Councils

Executive Summary

Patient safety is the core foundation of healthcare quality. Unsafe care is a significant challenge globally, due to unsafe practices, processes, or structural inefficiencies within healthcare organisations, which in turn lead to patient safety incidents.

The ISQua (International Society for Quality in Health Care) White Paper on Patient Safety in Healthcare Organisations, aims to address these challenging issues by providing a comprehensive framework to improve patient safety in hospitals and other healthcare settings.

The ISQua White Paper addresses the key challenges, starting from insufficient leadership commitment, inadequate staff training, inconsistent implementation of safe practices, and lack of patient and family engagement in key safety initiatives. These shortfalls undermine the efforts to reduce harm and deliver safe, high-quality patient care.

The ISQua White Paper on Patient Safety for Healthcare Organisations focuses on the critical aspects of patient safety within healthcare settings and gives recommendations on Advocacy, Leadership and Equity, Health Worker Education and Safety, Patient and Family Engagement and Empowerment, and Improvement in Clinical Processes.

- Leader advocacy efforts are critical to ensuring that patient safety is prioritised in all organisational policies and aligned with the organisation's vision.
- Strong governance is crucial to ensure leader accountability and foster a culture of safety by integrating safety into leadership and operational frameworks.
- Ensure environmental sustainability by adapting and integrating initiatives to mitigate climate-related health risks.
- Governance must adopt person-centred care principles to ensure that safety initiatives align with patients' needs, preferences, and values.
- Engaging patients, families, and carers in patient safety initiatives nurtures a culture of collaboration and shared engagement for safety.
- The physical and psychological safety of healthcare workers fosters well-being and belonging, reducing patient safety incidents, and promotes a culture of safety.

- Redesigning structures and processes of care enables healthcare workers to improve the quality of care delivery, contributing to patient safety and better outcomes.
- Improving clinical processes enhances safety and quality by reducing the variability through standardisation of processes, implementing evidence-based practices, and improving the culture of safety.

The focus on patient safety in this white paper aligns with ISQua's mission:
"To inspire and drive improvement in the quality and safety of healthcare worldwide through education and knowledge sharing, external evaluation, supporting health systems, and connecting people through global networks." (ISQua, 2025)

This white paper aims to create an implementation strategy that aligns with the World Health Organization (WHO) Global Patient Safety Action Plan (GPSAP) 2021–2030, prioritising patient well-being and reducing preventable harm at all levels of healthcare delivery.

SECTION I – Background and Rationale

Introduction

Patient safety is a fundamental component of quality healthcare, but it still remains a global challenge. Unsafe care is among the top 10 leading causes of death and disability worldwide, affecting vulnerable populations and is a significant burden on healthcare systems. Hospitals are complex high-risk environments that are prone to circumstances that can compromise patient outcomes and staff well-being.

Given this complexity, patient safety cannot be viewed as the responsibility of isolated individuals or departments but must be embraced as an organisational priority, deeply embedded within the entire healthcare system.

The WHO's definition of patient safety within the broader health system context is "a framework of organised 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" (WHO, 2023).

Despite increased awareness of the significance of patient safety, gaps in implementation persist, especially at the organisational level. The Global Patient Safety Report 2024 highlights progress in patient safety while emphasising the urgent need for stronger efforts in translating policies into practical implementation. Of note, the 2024 Report is based on the results of the first data collection on the implementation of the WHO GPSAP 2019–2021. The GPSAP provides a framework for action through seven strategic objectives, each with five strategies, thus creating the seven-by-five matrix. The pursuant 2024 Report of GPSAP global implementation serves as a crucial resource for all stakeholders, including healthcare organisations, empowering them to enhance safety and quality in healthcare systems worldwide.

The performance scores (out of 100) reveal the following key inferences:

- Areas of Strength are Safety of Clinical Processes (Score: 63) and Policies to Eliminate Avoidable Harm (Score: 60)
- Areas of Opportunity are Engagement with Patients and Families (Score: 45), Health Worker Education and Safety (Score: 42), Information, Research, and Risk Management (Score: 44), and Synergy, Partnerships, and Solidarity (Score: 41)

Implementing targeted strategies at the individual organisational level to improve system designs and functionality (which will enhance the scores) is essential. These strategies must be driven by strong leadership commitment, foster person-centred care, and invest in workforce development to aid the improvement of clinical processes. This calls for a comprehensive strategy aligned with the WHO GPSAP, emphasising the dual priorities of harm reduction and empowering healthcare workers to uphold safety standards.

To address these challenges, this white paper focuses on four foundation pillars (FPs) that are critical for embedding patient safety into healthcare systems:

Advocacy, Leadership, and Equity;
Health Worker Education and Safety;
Patient, Family and Carer Engagement and Empowerment;
Improvement in Clinical Processes.

By offering actionable implementation strategies, this white paper serves as a roadmap for healthcare organisations that aim to address gaps and accelerate progress across all dimensions of patient safety. It highlights the need for a collective effort to prioritise patient safety and health equity, encourage innovation, and improve health outcomes, ensuring that safety becomes integral to every aspect of healthcare delivery.

The Scope and Objectives

The main objective of the ISQua White Paper on Patient Safety:

To serve as a concise and actionable guide to healthcare leaders and healthcare providers and to improve patient safety policies and practices at the organisational level.

Specifically, this White Paper will:

Provide a comprehensive framework to improve patient safety at the organisational level. It addresses the critical gaps in current practices and policies. It offers actionable recommendations to enhance patient safety culture, empower healthcare workers, and improve clinical processes to ensure a person-centred approach to care.

The scope includes:

– Strategies to foster leadership commitment to patient safety, aligning organisational goals with safety initiatives to promote a culture of safety and person-centred care throughout healthcare organisations;
– Strategies to empower healthcare workers by investing in workforce capacity building through continuous education and providing a safe working environment to reduce patient safety incidents and address their well-being;
– Strategies to empower and engage patients and family members to include their needs and preferences;
– Strategies to streamline clinical processes and enhance efficiency, with patient engagement to ensure consistent, evidence-based, high-quality care delivery and minimise risk to create resilient systems.

To drive meaningful improvements, the functions of the system must be transformed. This requires:

- A clear vision and goal (that defines the desired state of patient safety);
- A set of actions designed to achieve this goal (i.e. the "What");
- A set of strategies to implement these actions (i.e. the "How") – this will, in most cases, require that the workforce change their habitual ways, sometimes even their beliefs;
- A way to measure progress towards the vision (i.e. track progress, ensure accountability, and drive continuous improvement).

Modified from the "Model for Improvement" [REF: How to Improve: Model for Improvement - https://www.ihi.org/resources/how-improve-model-improvement]

Successful improvement depends on the "What" and the "How".

The "How" can sometimes be the most challenging part. Improvement is as much a social as a technical intervention.

In Section II, you will find comprehensive strategies for implementing the "What."

In Section IV, you will find advice regarding the "How."

This white paper aligns these recommendations with global frameworks such as the WHO GPSAP 2021–2030. It focuses on creating practical, scalable solutions that can be implemented across diverse healthcare settings.

SECTION II – Foundation Pillars for Patient Safety in Healthcare Organisations

1. Advocacy and Leadership
2. Health Worker Education and Safety
3. Patient, Family and Carer Engagement and Empowerment
4. Improvement in Clinical Processes

5 x 4 Matrix: Patient Safety Matrix for Health Care Organisations

This white paper's foundational pillars for Patient Safety in Health Care Organisations have been designed to align with the WHO GPSAP Framework for Action (represented by the 7 x 5 matrix).

The four FPs are analysed using the five core elements outlined in the 5 x 4 matrix below.

The detail provided for each of the key drivers represents implementation solutions targeted at specific strategies within the GPSAP (e.g. 1.2: "Resource mobilisation and allocation"; 3.2: "Global patient safety challenge; medication without harm"; etc.).

Orange highlights indicate the highest-value opportunities to address the lowest-scoring elements from the 2024 GPSAP report of progress.

5 x 4 Matrix: Patient Safety Matrix for Health Care Organisations

Foundation Pillar (FP)	FP1. Advocacy and Leadership	FP2. Health Worker Education and Safety	FP3. Patient, Family, and Carer Engagement and Empowerment	FP4. Improvement in Clinical Processes
Core Elements	**Key Drivers**	**Key Drivers**	**Key Drivers**	**Key Drivers**
1. Policy and Strategy, Including Health Equity	Align organisational strategies and resources with global initiatives of GPSAP and ensure person-centred care to create a highly resilient organisation. (Gap: 1.2)	Prioritise physical and psychological safety of health workers with equitable accountability, safe work environments, reporting/learning culture, manageable workloads, and good practices. (5.5)	Develop a patient and family engagement strategy and policy that involves the patient/family/caregiver voice and input in operations and quality and safety initiatives while ensuring health equity by considering diverse cultural, linguistic, and socio-economic needs. (4.1)	Implement evidence-based clinical protocols, care pathways, and checklists to standardise care and reduce risks and disparities. (3.1) Prioritise medication without harm (Gap: 3.2)
2. System Strengthening for Risk Reduction	Prioritise fostering psychological safety, safety culture, reporting culture, and learning culture by implementing a just culture for all lapses of expectations, not limited only to patient safety incidents. (2.1)	Invest in ergonomic infrastructure, mental health support, and tools to ensure workers' physical and psychological safety. (2.4, 5.5)	Include patient/family/caregiver representatives in governing board(s), quality and safety committees, event learning teams, and patient grievance committees/ teams. (Gap 4.1)	Strengthen systems for care transitions, patient safety incident reporting, and process standardisation to prevent harm. (Gap: 3.5)
3. Capacity Building	Leadership teams to be hired for and trained to champion patient safety (Gap 2.3)	Where national centres of excellence do not exist, develop and implement comprehensive education and training for health workers on safety practices, self-care, and stress management. (Gap: 5.2)	Develop and engage patient advocates/activists and patient safety champions in the design and delivery of healthcare. (Gap: 4.3)	Regularly train clinical teams on updated protocols, patient safety incident prevention, and harm reduction techniques. (Gap: 3.1)

5 x 4 Matrix: Patient Safety Matrix for Health Care Organisations

Foundation Pillar (FP)	FP1. Advocacy and Leadership	FP2. Health Worker Education and Safety	FP3. Patient, Family, and Carer Engagement and Empowerment	FP4. Improvement in Clinical Processes
Core Elements	**Key Drivers**	**Key Drivers**	**Key Drivers**	**Key Drivers**
4. Measurement and Monitoring	Impact of leadership-driven advocacy on the organisation's safety culture and outcomes to be monitored and evaluated (4.2)	Monitor health worker satisfaction, work-related stress, including burnout, and safety commitments using periodic surveys and safety audits.(Gap: 5.4)	Adopt and monitor patient-reported outcome measures (PROMS, in addition to standardised patient experience measures) for periodic review by leadership and board(s). (4.2)	Implement clinical safety (e.g. infection control, medication error rates) KPIs (leading indicators) and monitor performance in real time. (Gap: 6.3)
5. Innovation and Research	Prioritise, resource, participate, and/or initiate one or more patient safety networks of hospitals locally, regionally, or nationally focused on collaborating for safe care. (Gap: 7.3)	Introduce technology, such as wearables or apps, to support health worker safety and provide real-time feedback on workplace risks. (6.5)	Innovate adoption and spread of Communication and Resolution Programmes that address transparency and subsequent patient/family needs following patient safety incidents. (6.1)	Pilot innovations like automated tools for diagnostics and infection control to enhance clinical safety practices. (6.5)

Foundational Pillar 1 – Advocacy and Leadership

Objective:

- Advocate for prioritisation of patient safety within hospital policies, practices, and culture.
- Ensure that patient safety is embedded as a core organisational value in every level of healthcare delivery.
- Establish a strong hospital governance structure that ensures leadership commitment to patient safety and accountability.

The following specific strategies are outlined within the framework of action. The 7 x 5 matrix of the GPSAP is aligned with FP 1 on Advocacy and Leadership.

- Strategy 1.1, 1.2, 1.3, 1.4, 1.5
- Strategy 2.1, 2.2, 2.3, 2.4, 2.5
- Strategy 6.1, 6.3, 6.4
- Strategy 7.2, 7.4, 7.5

Core Elements	Key Drivers	Implementation Strategies
1. Policy and Strategy, Including Health Equity	Align organisational strategies and resources with global initiatives of GPSAP and ensure person-centred care to create a highly resilient organisation. (Gap: 1.2)	1. Implement leadership commitment by positioning patient safety and health equity as core organisational values, integrating safety goals into the organisation's mission, vision, and annual performance goals with compliance to external evaluations and accreditations. 2. Develop a strategy for sustainability to mitigate the health impacts of climate change and to promote equitable outcomes for all patients: • Assess patient safety incidence and risk data for socio-economic disparities and implicit bias. • Address the identified gaps by targeted interventions with integration of health equity principles. • Promote access to sustainable, affordable, and eco-friendly healthcare solutions. 3. Allocate resources (human and financial) for sustainable patient safety implementation strategies. 4. Leadership endorsement and adoption of an equitable accountability policy will be communicated to staff in meetings to ensure transparency and learn from errors.

Core Elements	Key Drivers	Implementation Strategies
		5. Advocate for and model a safety climate to advance patient safety culture and practices towards zero avoidable harm. Recognise and reward individual staff or teams who contribute to proactively identifying risks and improving patient safety practices and outcomes.
2. System Strengthening for Risk Reduction	Prioritise fostering psychological safety and safety culture (reporting culture and learning culture) by implementing a just culture for all lapses of expectations, not limited to only patient safety incidents. (2.1)	1. Ensure compliance with statutory requirements and established international accreditation standards to contribute to a safe working environment. 2. Establish • Patient safety committee • Designate a qualified patient safety officer with the required training • Clear roles and responsibilities • Clear reporting channels 3. Develop • Risk mitigation plan and test regularly (emergencies, pandemics) • Risk register • Mitigation strategies – simulation exercise 4. Raise awareness of patient safety • Observe World Patient Safety Day every year • Implement the World Patient Safety Day themes to improve patient safety • Incorporate the implementation of the global patient safety challenges into action plans/programmes (for example, medication without harm) 5. Strengthen system safety through effective governance by integrating safety metrics into the organisational accountability framework.
3. Education and Training	Leadership teams to be hired for and trained to champion patient safety. (Gap 2.3)	1. Ensure availability of trained, skilled patient safety leaders with regular comprehensive training on core patient safety values. 2. Resource advanced-level training for patient safety leaders, for example: • Safety leadership/strategy; • Risk management/legal; • Change management/implementation; • System design; • Incident analysis; • Human-centred design. 3. Ensure training to empower leaders to identify patient safety gaps and implement corrective measures.

Core Elements	Key Drivers	Implementation Strategies
		4. Training should equip leaders with skills to: • Set a climate of safety; • Communicate to staff the importance of safety; • Embrace and lead system design for safety; • Drive policy changes; • Engage stakeholders at all levels; • Overcome system constraints imposing safety risks. 5. Invest in training on risk prevention and mitigation.
4. Measurement and Monitoring	Impact of leadership-driven advocacy on the organisation's safety culture and outcomes to be monitored and evaluated. (4.2)	1. Regularly identify and monitor patient safety indicators (including stratification to assess for disparities) with benchmark data analysis. 2. Monitor the implementation of the International Patient Safety Goals (IPSG) to ensure continuous quality improvement. 3. Establish patient safety incident reporting, detection, and learning systems to encourage learning from safety incidents. 4. Monitor compliance to safety standards on fire safety, electrical safety, and structural safety. 5. Perform regular surveys on organisational safety culture by capturing feedback from staff on risks; analyse the surveys for implementing leader-managed action plans to address opportunities for improvement.
5. Innovation and Research	Prioritise, resource, participate, and/or initiate one or more patient safety networks of hospitals locally, regionally, or nationally focused on collaborating for safe care. (Gap: 7.3)	1. Promote the use of technology that has been evaluated for usability and safety to improve patient safety. 2. Develop and implement innovative patient safety measures with evidence-based practices. 3. Support the adaptation of evidence-based practices to the local context to improve patient safety. 4. Support and build workforce capacity and capability in human factors. 5. Promote learning across healthcare and from other industries.

Foundational Pillar 2 – Health Worker Education and Safety

Objective:

- To empower health workers with the knowledge, skills, and tools to be proactive agents of patient safety within healthcare organisations through continuous education and training programmes.
- It prioritises the physical and psychological well-being of healthcare professionals to enhance workforce resilience to deliver safe and effective care.

The following specific strategies are outlined within the framework of action. The 7 x 5 matrix of the GPSAP is aligned with FP 2 on Health Worker Education and Safety.

- Strategy 2.4
- Strategy 5.1, 5.2, 5.3, 5.4, 5.5

Core Elements	Key Drivers	Implementation Strategies
1. Policy and Strategy, Including Health Equity	Prioritise physical and psychological safety of health workers with equitable accountability, safe work environments, reporting/learning culture, manageable workloads, and good practices. (5.5)	1. Implement an equitable workplace accountability model that • Ensures patient safety training programmes for all healthcare professionals; • Promotes psychological safety and reporting/learning culture; • Integrates performance metrics with adherence to safety protocols and participation in continuous professional development; • Uses these criteria as key components in employee appraisal and career progression. 2. Establish policies for health workers to access mental health resources within the organisation (workshops, counselling services, counselling and support for the second victim). 3. Establish and enforce zero-tolerance for workplace violence, including prevention of incivility and aggression, measures to protect staff from physical and mental violence, with well-defined reporting mechanisms and effective, timely response.

Core Elements	Key Drivers	Implementation Strategies
		4. Establish programmes for recognition and rewards for teams or individuals demonstrating excellent commitment to health worker and patient safety to encourage collective ownership of safety initiatives and pre-harm risk identification for system redesign. 5. Establish climate and practices for open communication about safety incidents, near-misses, and improvement strategies to improve organisational safety culture.
2. System Strengthening for Risk Reduction	Invest in ergonomic infrastructure, mental health support, and tools to ensure workers' physical and psychological safety. (2.4, 5.5)	1. Integrating safety into the workforce development plan with patient safety education as a core component of orientation, on-boarding, and professional development programmes (include clinical safety and non-clinical safety like fire safety, electrical safety, and structural safety). 2. Establish guidelines to promote ergonomic workplace designs to improve physical safety by preventing injuries among healthcare workers and ensure optimal working conditions with rest breaks. 3. Create mandates for personal protective equipment (PPE) availability and usage and staff vaccination, especially in high-risk settings. 4. Establish cross-functional committees involving frontline staff, administrators, and leaders to address health worker safety prevention and management issues. 5. Strengthen feedback mechanisms where staff learn from their experiences in a structured, non-punitive environment.
3. Education and Training	Where national centres of excellence do not exist, develop and implement comprehensive education and training for health workers on safety practices, self-care, and stress management. (Gap: 5.2)	1. Establish a comprehensive training infrastructure – internal and external – for continuous education on patient safety practices, adapting to the local context within the organisation. • Develop a key group of specialists as trainers who are qualified/competent in the modern safety sciences including human factors. • Create a role-specific safety curriculum tailored to the needs of the individual healthcare professionals, including clinical and non-clinical staff, and ensure updated content to reflect the latest evidence-based practices and international safety guidelines.

Core Elements	Key Drivers	Implementation Strategies
		2. Create specialised programmes for staff • Working in high-risk areas (infectious, personal injury, emotional stress, patient/visitor incivility, etc.; one or more types), including modules on self-care and stress management; • Including clinicians, staff, and stakeholders to promote sustainable healthcare practice and build climate resilience. 3. Establish mechanisms to identify gaps in staff competencies on patient safety: • Conduct regular retraining of all healthcare professionals. • Conduct simulation exercises and mock drills for crisis management and minimise risks of unintended harm. • Incorporate low-fidelity simulation (i.e. case studies scenarios) in huddles and routine meetings to reinforce safety behaviours and practices. 4. Promote interdisciplinary team training by continuing to learn about emerging risks and enhance collaboration and communication. 5. Equip healthcare workers with knowledge of implicit bias and skills to reduce its impact on patient care/safety and workforce interactions.
4. Measurement and Monitoring	Monitor health worker satisfaction, burnout levels, and safety commitments using periodic surveys and safety audits. (Gap: 5.4)	1. Establish Key Performance Indicators (KPIs) for health worker education and safety, such as participation in safety training, adherence to safety protocols, and patient safety incident reduction outcomes. These indicators must be regularly reviewed and updated to align with emerging patient safety priorities. 2. Conduct periodic audits with validated tools, safety culture audits, surveys, collaborative safety audits, and peer reviews of safety practices. • Promote proactive assessment of risk; • Evaluate compliance with training programmes; • Evaluate compliance with adherence to safety protocols; • Measure training effectiveness; • Assess the impact on patient and health worker outcomes. 3. Regularly survey health workers on work-related stress levels, burnout symptoms, and mental health needs to measure psychological well-being and use the feedback to refine strategies, ensuring that the policies and system design remain effective and relevant.

Core Elements	Key Drivers	Implementation Strategies
		4. To strengthen systems, regular assessments are needed to measure the effectiveness of ergonomic adjustments and alignment to workstations, equipment, and workflows. 5. Use analytics to identify trends and gaps, including socio-demographic and role-based disparities related to injury rates, incivility, and violence, to enable targeted interventions to strengthen safety systems and share information with frontline workers.
5. Innovation and Research	Introduce technology, such as wearables or apps, to support health worker safety and provide real-time feedback on workplace risks. (6.5)	1. Promote new innovations, including simulation technologies like virtual reality (VR) or augmented reality (AR) tools, to train health workers in high-risk procedures, creating patient safety scenarios with interactive safety training. 2. Promote the use of technology such as: • Wearables or apps to improve staff safety; • Enhance health worker safety monitoring systems; and • Implement digital tools for tracking workplace injuries, ergonomics drift/workarounds, and health worker well-being metrics. 3. Develop e-learning platforms to accommodate staff schedules and support asynchronous training. Mobile/cell applications can make it accessible to clinical and non-clinical staff. 4. Promote performance and/or adoption of research on health worker safety and ergonomics and based on analysis of staff feedback with real-time learning loops to adapt and improve safety. 5. Integrate learning health systems (LHS) principles to learn and prevent occurrence of avoidable harm.

Foundational Pillar 3 – Patient, Family, and Carer Engagement and Empowerment

Objective:

- To empower and engage patients, families, and carers in patient safety efforts.
- To ensure effective collaboration between healthcare providers and patients to improve safety and quality of care delivery.

The following specific strategies are outlined within the framework of action. The 7 x 5 matrix of the GPSAP is aligned with FP 3 on Patient and Family Engagement and Empowerment.

- Strategy 4.1, 4.2, 4.3, 4.4, 4.5
- Strategy 7.1

Core Elements	Key Drivers	Implementation Strategies
1. Policy and Strategy, Including Health Equity	Develop a patient and family engagement strategy and policy that involves the patient/family/caregiver voice and input in operations and quality and safety initiatives while ensuring health equity by considering diverse cultural, linguistic, and socio-economic needs. (4.1)	1. Leaders should focus on redesigning care to include the patient's voice and align with person-centred care principles; this creates enabling environments to improve healthcare outcomes. • Support an organisational culture to engage patients. • Ensure health equity by considering diverse cultural, linguistic, and socio-economic needs. • Promote open communication. • Ensure psychological support for patients, families, and carers after a serious patient safety event. • Encourage active patient participation in their care decisions. 2. Create patient- and family-centred advisory committees (PFCAC) in hospitals to serve as a voice for patients and families, advocating for their needs, enhancing the quality of care, and providing input on care system design.

Core Elements	Key Drivers	Implementation Strategies
		3. Involve patients and family members in care planning and shared decision-making roles at the institutional level, ensuring that their needs, values, and preferences are heard and incorporated into strategic planning. 4. Institutional policies should include provisions for a second opinion, access to their medical records, informed consent, and patient- or family-triggered emergency escalation systems to improve safety. 5. Leadership should promote the Patient Safety Rights Charter and ensure the creation and distribution of educational materials that empower patients and families with knowledge about their rights, care options, and safety practices and ensure accessibility.
2. System Strengthening for Risk Reduction	Include patient/family/caregiver representatives in governing board(s), quality and safety committees, event learning teams, and patient grievance committees/teams. (Gap 4.1)	1. Actively involve patients and families in the design and evaluation of care pathways, creating person-centred clinical process improvements: • Evaluate clinical processes such as discharge planning, medication management, and care coordination; • Provide ongoing feedback on clinical processes and safety protocols; • Help identify barriers to effective care and propose solutions to streamline processes while prioritising the patient's perspective; • Redesign clinical processes, to be person-centred "What matters to you"; • Drive co-creation of initiatives involving patients and staff to develop innovative safety solutions. Empowering patients on clinical processes helps to foster greater ownership of their health and improves safety. 2. Encourage patients to be members of the board to influence policy decisions related to patient safety; develop clear roles and responsibilities. 3. Support patients with knowledge and tools they need to actively engage in safety practices, such as infection prevention, medication management, and recognising warning signs. 4. Facilitate patients' and families' active participation in risk mitigation and event learning via risk assessments, root cause analysis, and safety event reviews and co-develop practical solutions using their insights and perspectives.

Core Elements	Key Drivers	Implementation Strategies
		5. Develop multilingual educational materials, signage, and consent forms that are culturally sensitive. The provision of access to interpreters would ensure the participation of patients and families from diverse backgrounds in their care and decision-making processes, creating a collaborative culture.
3. Capacity Building	Develop and engage patient advocates/ activists and patient safety champions in the design and delivery of health care. (Gap: 4.3)	1. Integrate patient and family engagement into healthcare professionals' curriculum and train healthcare workers to include family members in safety protocols, particularly in complex or high-risk scenarios. 2. Integrate patient and family experiences into healthcare worker education to enhance empathy, understanding, and communication among staff by including real-life stories and feedback from patients and families. 3. Train healthcare professionals to disclose unexpected and/patient safety incidents to patients and family members when harm occurs. Ensure that barriers to disclosure are removed or absent. 4. Train staff to analyse and respond constructively and timely to patients' and family members' feedback to enhance safety and care quality and foster a collaborative care environment. 5. Equip and empower patients and families with clear, accessible information about clinical procedures, including various treatment options, expected outcomes, and potential safety risks (informed consent processes) to foster greater ownership of their health and improve safety (videos, pamphlets, and various interactive group sessions tailored to various literacy levels could be considered).
4. Measurement and Monitoring	Adopt and monitor PROMs (in addition to standardised patient experience measures) for periodic review by leadership and board(s). (4.2)	1. Create systems that allow patients and families to provide real-time feedback on clinical processes (using digital surveys, suggestion boxes, and follow-up interviews.), including patient-reported experience measures (PREM) survey questionnaires. 2. Create a structured PROM framework for collecting, analysing, and reporting PROMs tailored to the hospital's clinical areas for different patient populations (e.g. chronic conditions, post-surgery) and standardise their use across departments; integrate PROMs into electronic health records (EHRs) and communicate results to patients.

Core Elements	Key Drivers	Implementation Strategies
		3. Establish a process to evaluate the effectiveness of patient/family involvement in committees and teams. Collect feedback from representatives, staff, and leadership and continuously improve the inclusion process to ensure sustained meaningful participation. Support patient- and family-led initiatives and projects that engage patients in monitoring safety and quality with tools. 4. Establish a multidisciplinary review team of clinicians, data analysts, and patient representatives to review PROM data and recommend actions for improvement. 5. Stratify patient- and family-derived experience and outcome data for disparities related to social demographics, from which action plans to eliminate the disparities will be enacted.
5. Innovation and Research	Innovate adoption and spread of Communication and Resolution Programmes that address transparency and subsequent patient/family needs following patient safety incidents. (6.1)	1. Establish a clear Communication and Resolution Programme outlining clear protocols for patient safety incident communication and resolution, with predesignated roles for staff. 2. Leverage technology to integrate Communication and Resolution Programme documentation into existing incident reporting systems with efficient, secure, and real-time updates. 3. Implement digital health tools (apps/online platforms) for patient empowerment for chronic disease management, ensuring their availability in multiple languages and making them accessible to all patient demographics. 4. Encourage and conduct research studies to test new patient engagement methods, such as virtual care models/interactive decision aids focused on enhancing the patient experience with tools like PREMs, improving communication, and developing new models of care. 5. Develop an internal and external knowledge-sharing platform (knowledge-sharing hub) for patient engagement innovations for best practices, case studies, and research findings. Maintain a digital library of resources for staff, patients, and families.

Foundational Pillar 4 – Improvement in Clinical Processes

Objective:

- Adopt evidence-based practices to manage patient safety risks in clinical care.
- Ensure standardising care, utilising technology, and measuring progress and effectiveness.

The following specific strategies are outlined within the framework of action. The 7 x 5 matrix of the GPSAP was aligned with FP 4 on Improvement in Clinical Processes.

- Strategy 3.1, 3.2, 3.3, 3.4, 3.5
- Strategy 6.2, 6.3, 6.5
- Strategy 7.3

Core Elements	Key Drivers	Implementation Strategies
1. Policy and Strategy, including Health Equity	Implement evidence-based clinical protocols, care pathways, and checklists to standardise care and reduce risks and disparities. (3.1) Prioritise medication without harm. (Gap: 3.2)	1. Establish an effective clinical governance structure to: • Engage frontline healthcare professionals to develop patient safety protocols in clinical departments; • Integrate clinical safety goals into the organisation's strategic plan, including measurable targets and timelines; • Incentivise health workers to report safety risks and patient safety incidents in a non-punitive environment that fosters accountability and promotes learning; • Redesign care delivery structures and processes based on identified disparities in patient safety outcomes. 2. Establish a hospital-wide policy requiring adherence to evidence-based clinical guidelines and safety protocols with directives for high-risk areas such as infection control (healthcare-associated infections, antimicrobial resistance), medication safety, and surgical processes.

Core Elements	Key Drivers	Implementation Strategies
		3. Adopt strategies to implement standardised clinical pathways for diagnosis and treatment/for common procedures – transitions of care, primary, ambulatory care, and high-risk tasks such as medication reconciliation, surgical safety, and infection prevention – to reduce variability. Periodically review and update pathways based on new evidence and best practices. 4. Create policies and strategies/checklists for emergency preparedness, recognising clinical deterioration early before a crisis occurs, establishing rapid response teams to handle clinical emergencies, and preventing the worsening of patient conditions. 5. Adapt staffing policies and procedures to ensure adequate healthcare professionals-to-patient ratio to reduce burnout and errors (including flexible staffing strategies) and to accommodate surges in patient volume to ensure safety.
2. System Strengthening for Risk Reduction	Strengthen systems for care transitions, error reporting, and process standardisation to prevent harm. (Gap: 3.5)	1. Achieve clinical workflow optimisation by redesigning clinical workflows using quality tools like Lean and Six Sigma methodologies. 2. Include community optimisation of input sources (ambulatory care, behavioural health, pre-hospital emergency services) and output/receiving sources/ standardise care transitions (skilled nursing facilities, rehabilitation facilities, inpatient behavioural health, etc.). 3. Enhance resilience by incorporating redundancy and fail-safe mechanisms into clinical systems and clinical risk management activities, such as: • Dual identity and product/medication verification and adoption of checklists for all risk-prone clinical procedures; • Promoting use of checklists to improve safety (WHO safe surgery checklist, WHO safe childbirth checklist); • Standardised handoff procedures utilising structured tools and technology to ensure seamless information flow and reduce communication gaps. 4. Strengthen the supply chain to ensure the consistent availability and maintenance of critical medical devices and safety-enhancing equipment (PPE, hand hygiene supplies, and advanced diagnostic equipment).

Core Elements	Key Drivers	Implementation Strategies
		5. Evaluate whether guidelines and standard operating procedures (SOPs) have been effectively designed for implementation with integration of human factors.
3. Education and Training	Regularly train clinical teams on updated protocols, error prevention, and harm reduction techniques. (Gap: 3.1)	1. Design and implement competency-based training for healthcare professionals tailored to their roles, focusing on patient safety best practices in clinical processes: • Establish smaller thematic teams specialised in patient safety, focusing on medication administration, infection control, antimicrobial resistance (AMR), blood transfusion and surgical procedures, and rapid response to prevent patient safety incidents. • Train staff on engaging patients and families in care processes, emphasising communication and shared decision-making. • Provide cultural and linguistic sensitivity and implicit bias training to staff to improve cultural competency and empathy in clinical interactions. 2. Design specialised training (including simulation to the maximum extent) for teams • In high-risk clinical settings, such as intensive care units (ICUs), emergency departments, and operating rooms; focus on managing high-risk patients and complex procedures, emphasising reducing preventable harm; • In conducting team-based learning sessions, including real case studies and role-play, to improve communication, collaboration, and coordinated care to minimise errors during transitions of care and complex procedures; • In conducting scenario-based drills regularly to evaluate system performance during emergency situations (incorporate "talk-through"/"walk-through" simulations into shift huddles, staff meetings, committee meetings, etc.); • In ensuring safety training on medical devices/procedures, like transfusion processes. 3. Establish leadership training for clinical team leads to • Foster a culture of safety and ensure continuous improvement; • Equip leaders with skills to mentor junior staff, manage team dynamics; • Advocate for patient safety within the organisation;

Core Elements	Key Drivers	Implementation Strategies
		• Support equitable accountability (just culture) responses to lapses of expectations, including but not limited to patient safety incidents. 4. Train healthcare workers to utilise technology: • Establish simulation labs for hands-on training in critical clinical scenarios, including emergency response, complex procedures, and patient safety incident management. • Focus on enhancing patient safety through proficient use of EHRs, computerised physician order entry (CPOE), and clinical decision support systems (CDSS). 5. Educate staff to report safety incidents and near-misses, integrate lessons learned from incidents, refine processes, and create preventive strategies and action plans.
4. Measurement and Monitoring	Implement clinical safety (e.g. infection control, medication error rates) KPIs (leading indicators) and monitor performance in real time. (Gap: 6.3)	1. Develop KPIs for clinical safety based on local context. • Define clear, measurable KPIs for clinical processes, such as infection rates (healthcare-associated infections, AMR), surgical complications, medication errors, and compliance with evidence-based protocols. Utilise change-sensitive leading indicators for timely action to eliminate hazards whenever possible. Analyse KPIs for disparities of care delivery and outcomes. • Continuously review and update these indicators to align with evolving safety priorities and standards. • Track patient/patient-reported outcomes, including mortality, morbidity, and readmission rates, to assess clinical safety performance. • Leverage benchmarking data to establish realistic and achievable safety goals. 2. Conduct regular audits of clinical practices. • Perform routine (automated, passive when possible) audits of clinical practices, including surgical safety protocols, hand hygiene compliance, and medication reconciliation. • Use audit reports to identify gaps and develop focused improvement strategies. • Implement real-time monitoring systems to track patient safety performance in each clinical service department. • Regularly assess and measure staff knowledge and identify gaps in competency in the application of best practices in clinical settings.

Core Elements	Key Drivers	Implementation Strategies
		• Evaluate the effectiveness of training for all staff and conduct periodic assessments to evaluate adherence to SOPs. 3. Regular analysis of reported data to identify the trends and areas for improvement. • Enhance the use of incident reporting systems to capture, analyse, and learn to improve safety. • Conduct event learning with appropriate tools/ methods to systematically analyse all safety incidents, including patient safety incidents and near-misses. • Perform thorough reviews of cases with unexpected outcomes to understand the opportunities for process improvement. • Use the findings to develop and implement actionable recommendations (applying the hierarchy of actions) and preventive strategies. 4. Strengthen systems by ensuring actionable and meaningful improvements through monitoring the implementation of safety measures, auditing practices, and promoting adherence to evidence-based protocols. 5. Establish safety monitoring committees to monitor adherence to clinical guidelines. • Create dedicated committees with multidisciplinary team members to oversee clinical safety monitoring, ensuring accountability and effective follow-through on safety improvement initiatives. • Measure compliance with clinical guidelines and protocols, such as antibiotic stewardship and sepsis management pathways, to improve clinical process safety.
5. Innovation and Research	Pilot innovations like automated tools for diagnostics and infection control to enhance clinical safety practices. (6.5)	1. Develop and test innovative safety technologies – such as artificial intelligence (AI) and machine learning (ML) to • Improve clinical decision-making; • Support early identification of issues, enabling timely interventions; • Streamline diagnostic processes, improving patient safety; • Ensure that chosen technologies have been usability tested and related implementation risks have been proactively assessed and mechanisms are in place to monitor these.

Core Elements	Key Drivers	Implementation Strategies
		2. Technology in staff training: • Adopt health technology solutions, including apps and devices, to enhance clinical safety and ensure staff training for effective use of technology. • Implement technology-enabled solutions, such as secure messaging systems, to bridge communication gaps. • Integrate simulation-based training to train healthcare professionals in managing complex clinical scenarios and preventing safety incidents, introducing VR and AR tools (when possible) to offer immersive learning experiences. 3. Strengthen the system with technology integration • To improve accuracy and reduce errors in the organisation such as CPOE, bar-coded medication administration (BCMA), and EHRs; • To encourage automation in the system (automated medication dispensing systems, AI-assisted diagnostic platforms, and robotic surgery systems) to reduce human error. 4. Implement real-time monitoring systems – leverage technology, such as dashboards and automated alerts, to monitor critical safety parameters in real time, including vital signs, lab results, medication administration, and high-risk procedures/surgeries. 5. Encourage research in improving clinical process safety. • In high-risk areas and clinical processes, collaborate with academic institutions and research organisations to develop evidence-based interventions tailored to hospitals' specific challenges. • Establish dedicated spaces within hospitals to create a safety innovation lab for multidisciplinary teams to design, test, and implement innovative safety solutions. Facilitate collaboration among clinicians, engineers, and technologists to co-develop impactful safety interventions. • Establish or join networks of hospitals engaged in collaborative research on patient safety innovations, sharing best practices to accelerate the implementation of successful interventions across healthcare institutions.

SECTION III – Implications for Policy and Practice

This white paper provides valuable insights with significant implications for policy and practice in healthcare settings, including the following:

Policy Implications:

- Integration of Patient Safety as a Core Priority: The recommendations advocate for the integration of patient safety into organisational policies and align with global standards such as the WHO GPSAP 2021–2030.
- Strengthening of Regulatory Frameworks: Policymakers are encouraged to adopt and enforce regulations and external evaluations that standardise patient safety practices and promote continuous improvement across healthcare institutions.
- Support Workforce Development: The white paper advocates for the development of policies that focus on continuous education, training, and well-being of healthcare workers, ensuring that they are empowered to address patient safety challenges effectively.

Practice Implications:

- Improvement of Safety Culture: The white paper calls for healthcare organisations to cultivate a safety-first culture by fostering leadership commitment, with regular safety assessments, and active involvement of patients and families in safety practices.
- Person-centred Care: The white paper emphasises the importance of creating care environments that prioritise the needs and perspectives of patients and their families, empowering them to ensure their active involvement in safety-related decisions and care processes.
- Evidence-Based Clinical Processes: The recommendations encourage healthcare providers to adopt and implement evidence-based practices and redesign clinical processes to reduce avoidable harm levels, enhance patient outcomes, and ensure efficient care delivery.

In summary, the white paper's implications for policy and practice provide a roadmap for fostering sustainable patient safety improvements, with an emphasis on collaboration, education, and innovation across all levels of the healthcare system.

EXPECTED BENEFITS/IMPACT

The ISQua White Paper for Patient Safety in Healthcare Organisations would create a significant impact on its target audience – healthcare organisations across the world. It would help healthcare organisations to implement evidence-based strategies to address patient safety challenges in the core areas, reduce preventable harm, and improve care quality, thereby enhancing both patient outcomes and staff satisfaction. Additionally, the white paper aligns with global priorities, like the WHO GPSAP, which would help organisations stay abreast with international standards and best practices.

The expected benefits of the white paper on healthcare organisations:

1. Strategic Guidance – Ensures a clear roadmap for implementing patient safety initiatives aligned with global frameworks.
2. Improved Patient Outcomes – Reduces harm and patient safety incidents; leads to higher quality of care and improved patient satisfaction.
3. Cost-Effectiveness – Decreases the financial burden associated with errors, patient safety incidents, and prolonged hospital stays with preventive measures.
4. Enhanced Trust and Reputation – Builds public confidence and trust by demonstrating a commitment to safety and quality care.
5. Increased Patient Retention – This creates a safer and more person-centred environment, encouraging more patients to choose the healthcare organisation.
6. Engaged and Resilient Workforce – Prioritises health workers' education, training, and well-being, which leads to greater job satisfaction, retention, and productivity.
7. Operational Efficiency – Promotes streamlined processes that reduce harm, optimise resources, and improve overall efficiency.
8. Leadership and Accountability – This programme equips leaders with tools to embed safety into governance structures, ensures accountability, and fosters a safety-first culture.
9. Innovation and Research – Encourages the adoption of innovative solutions and data-driven strategies to address safety challenges effectively.
10. Global Benchmarking and Collaboration – Creates organisations which are leaders in patient safety, align with international best practices, and enable knowledge sharing.

SECTION IV – Concluding Remarks and Way Forward

This White Paper can guide your journey towards the goal of eliminating preventable harm in your healthcare organisation. The number of actions listed in Section II may seem daunting; you will need to prioritise, distribute responsibility, engage staff and service users, and integrate continuous improvement into daily operations in order to succeed.

Your path forward should be guided by implementation science, human factors science, and insight into promoting a healthy culture in your organisation. As you will see, the three are closely linked.

Implementation science studies methods and strategies to promote the adoption, integration, and sustainability of evidence-based practices, interventions, and policies in real-world settings. It addresses the fact that implementing new practices may require people to change well-established ways of doing things, maybe even change their beliefs or disturb power balances. Applying a coherent and cohesive change management process to prepare the workforce for workflow, technology, and emotional/behavioural changes increases the likelihood of success. Implementation science seeks to bridge the gap between research and practice by understanding and addressing barriers to effective implementation and identifying and leveraging facilitators.

Human factors science draws on and applies knowledge from the human physical and cognitive, organisational and design sciences. In healthcare human factors applies systems and design-based thinking and methods to jointly improve organisational performance (patient safety, efficiency, effectiveness) and the well-being of people (patients, families, and staff). The objective is to design processes and systems that optimise system performance and enhance well-being. Key components are identifying and amending system vulnerabilities, including sub-optimal protocols. Technological interface and physical workplace design, to incentivise desired actions/behaviours and disincentivise the undesired. Human factors is not a behavioural science, it is a systems and design-based discipline. It is not about people per se but about designing for people. Prudent standardisation and protocolisation are employed to increase predictability by defining roles and responsibilities and establishing a set of action tools. Building system resilience is essential; resilience can be defined as the ability to perform as desired under varying and partly unpredictable circumstances. Resilience is achieved by building the capacity and capability to anticipate, monitor, respond, and learn. Teamwork is considered to be crucial.

One of the most important considerations for a healthcare facility leader is to promote a **patient safety culture**. Culture can be described informally as "The way we do things here and how we believe our system works." How is culture shaped? Staff will consider:

- What others do? – I'd better do as they do.
- What will my peers think of me? – I want their acceptance, trust, and recognition.
- How will my boss react? – I don't want to be punished or blamed.
- Guidelines and policies – How does the system imagine that work should be done?

Guidelines and policies are prone to be overruled and disregarded by the first three considerations if they are not aligned.

When it comes to patient safety, some of the beliefs needing change are as follows:

- Errors are caused mainly by people's carelessness and would not occur if everyone worked diligently all the time.
- If an error occurs, we will find the one or ones responsible and punish them.
- We should strive to eliminate errors – in a complex system, this is unrealistic and unneeded, errors are ubiquitous and largely inconsequential. Focus should be on harm.
- Don't challenge or embarrass your seniors. Keep your mouth shut, even if you think someone more senior is about to make a mistake.
- Errors should be covered up as much as possible to protect our reputation.
- Find someone to blame before you are blamed.
- Leaders don't want to hear bad news.

A leader is not able to control people's minds, but they are capable of influencing perceptions:

- People listen to what the leaders say.
- People observe what leaders do – if they "walk the talk" or act according to what they say. If they don't, their talk is ignored.
- People react to what is acknowledged and rewarded.

If a rule can be enforced, it will eventually change people's minds ("become a habit"). Banning smoking in public facilities has gradually made smoking in such places viewed as socially unacceptable.

Some specific ways to change the culture:

- Establish an equitable accountability patient safety incident reporting and learning system to support a just culture. Reports must be acknowledged, feedback given, and learning seen to occur.

- Introduce and participate in safety rounds and safety huddles.
- Celebrate pre-harm risk identification and success.
- Involve patients and families and address their safety concerns.
- Use simulation to enhance technical and team skills.

We would like to draw your attention to two papers showing the importance of culture and pointing out what you should strive for and avoid.

In the first paper [Reference: Dixon-Woods M., R. Baker, K. Charles, et al. *Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study.* BMJ Quality and Safety, 2014. **23**: p. 106–115; doi: 10.1136/bmjqs-2013-001947.], the authors collected data from multiple sources to identify factors associated with providing high-quality care.

A clearly articulated vision with explicit and specific goals at all levels of the organisation, linked to a strategy for achieving these goals, promotes quality. This is often lacking at both the board and the clinical levels.

An abundance of overlapping and contradictory externally imposed goals and priorities, lacking instructions on how to achieve them, is a significant problem. This can lead to a bureaucratised approach characterised by an excess of rules, procedures, and forms, mainly to ensure the organisation can demonstrate formal compliance with requirements.

When examining the healthcare system, bright spots and dark spots can be found. A characteristic of dark spots may be a tendency towards a task-oriented rather than a patient-centred approach to work.

Data collection is important for supporting quality development, but it should be noted that data must be transformed into "actionable knowledge" – knowledge that can be acted upon. Two approaches to this transformation can be identified: "problem-sensing" and "comfort-seeking."

Problem-sensing is an approach characterised by actively searching for weaknesses and supplementing mandatory hard data with soft data, including actively listening to patients and staff. This avoids complacency while being cautious not to merely assign blame but instead uses a more holistic approach to strengthen the organisation and its teams.

Conversely, comfort-seekers are primarily focused on maintaining their/the organisation's image and reassuring themselves that everything is fine. They often collect limited and only quantitative data, are preoccupied with demonstrating compliance with external requirements, do not listen to concerns and criticism, and are

unaware of frontline realities. In these cases, staff often perceive data collection as meaningless or, at worst, as a tool to assign blame if something goes wrong.

Common problem areas include:
- Poorly designed IT systems;
- Endless discussions about the patient's pathway (referral, transfer, involvement of auxiliary specialities, etc.);
- Poorly functioning transitions;
- Poorly functioning teams;
- Unclear responsibility, with perceptions of a "responsibility iron cordon" along organisational boundaries (within and between organisations).

The attitude of top management is crucial. Leadership that sees identifying and addressing systemic problems as a key role can significantly positively impact the culture – actively working to fix the system so staff can perform well within it.

Conversely, a lack of support, recognition, respect, and feeling of not being consulted or heard negatively impacts culture. In such organisations, it is often observed that management – especially if it is comfort-seeking – views staff behaviour and culture as the root cause of problems.

Key points can be summarised as follows:
- There must be clear and explicit goals throughout the organisation (from the national policy level to the ward).
- Organisations must actively work to review, strengthen, and improve their systems.
- Organisations must strive to develop a person-centred culture, not just task-centred.
- Organisations should be supported by sensible and coherent external control and support functions.

Conversely, one should avoid:
- Fragmentation;
- Multiple, competing, ambiguous, and/or contradictory demands;
- Diffusion of responsibility.

The second study [Reference: Liberati E.G., C. Tarrant, J. Willars, T. Draycott, C. Winter, S. Chew, M. Dixon-Woods. *How to be a very safe maternity unit: an ethnographic study.* Social Science & Medicine, 2019. **223**: p. 64–72.] examined a high-performing, very safe maternity unit and identified six mechanisms that appeared to be important for safety:
- Collective competence;
- Insistence on technical proficiency;

- Monitoring, coordination, and distributed cognition;
- Clearly articulated and constantly reinforced standards of practice, behaviour, and ethics;
- Monitoring multiple sources of intelligence about the unit's state of safety;
- A highly intentional approach to safety and improvement.

These mechanisms are well aligned with the notion that high-quality healthcare is not delivered by a collection of disconnected individuals, no matter how well-qualified they might be, but by a well-functioning team. The multidisciplinary team, not the individual, is the basic unit. The culture should emphasise and promote this view.

Additional Resources

1. World Health Organization, *Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health Care*. 2021, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/343477.
2. World Health Organization, *Global Patient Safety Report 2024*. Available from: https://www.who.int/publications/i/item/9789240095458.
3. Vincent, C. and R. Amalberti, Editors. *Safer Healthcare: Strategies for the Real World*. 2016, Springer, Cham (CH). Available from: https://www.ncbi.nlm.nih.gov/books/NBK481869/.
4. World Health Organization, *Global Burden of Preventable Medication-related Harm in Health Care: A Systematic Review*. 2023, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/376203.
5. WHO Patient Safety & World Health Organization, *Implementation Manual WHO Surgical Safety Checklist 2009: Safe Surgery Saves Lives*. 2009, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/44186.
6. WHO Integrated Health Services (IHS), *WHO Safe Childbirth Checklist Implementation Guide: Improving the Quality of Facility-based Delivery for Mothers and Newborns*. 2015, World Health Organization, Geneva. Available from: https://www.who.int/publications/i/item/9789241549455.
7. Molina, R.L., A. Pichumani, E. Tuyishime, L. Bobanski, and K.E.A. Semrau, *Promising practices for adapting and implementing the WHO Safe Childbirth Checklist: case studies from India and Rwanda*. Journal of Global Health Reports, 2022. **5**: p. e2021110. DOI: https://doi.org/10.29392/001c.30751.
8. Singh, H., A.N. Meyer, and E.J. Thomas. *The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations*. BMJ Quality & Safety, 2014. **23**: p. 727–731. DOI: https://doi.org/10.1136/bmjqs-2013-002627.
9. World Health Organization, *Global Report on Infection Prevention and Control*. 2022, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/354489.
10. World Health Organization, *World Patient Safety Day*. 2025, World Health Organization, Geneva. Available from: https://www.who.int/campaigns/world-patient-safety-day.
11. World Health Organization, *Launch of the Global Patient Safety Challenge: Clean Care is Safer Care*. 2005, World Health Organization, Geneva. Available from: https://www.who.int/news/item/13-10-2005-launch-of-the-global-patient-safety-challenge-clean-care-is-safer-care.

12. World Health Organization and WHO Patient Safety, *The Second Global Patient Safety Challenge: Safe Surgery Saves Lives*. 2008, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/70080.
13. World Health Organization, *Medication Without Harm*. 2017, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/255263.
14. World Health Organization, *Patient Safety Incident Reporting and Learning Systems: Technical Report and Guidance*. 2020, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/334323.
15. National Health Service England, *A just culture guide*, in *Patient Safety*. 2024, National Health Service England, Leeds. Available from: https://www.england.nhs.uk/patient-safety/a-just-culture-guide/.
16. World Health Organization, *Prevention of Hospital-acquired Infections: A Practical Guide,* G. Ducel, J. Fabry and L. Nicolle, Editors. 2nd. ed. 2002, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/67350.
17. World Health Organization, *World Patient Safety Day 2023: Engaging Patients for Patient Safety*. 2023, World Health Organization, Geneva. Available from: https://www.who.int/news-room/events/detail/2023/09/17/default-calendar/world-patient-safety-day-2023--engaging-patients-for-patient-safety.
18. World Health Organization, *Engaging Patients for Patient Safety: Advocacy Brief*. 2023, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/375011.
19. World Health Organization, *Patient Safety Rights Charter*. 2024, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/376539.
20. Australian Commission on Safety and Quality in Health Care, *Australian Open Disclosure Framework - Better Communication, a Better Way to Care*. 2014, Australian Commission on Safety and Quality in Health Care, Sydney. Available from: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-open-disclosure-framework-better-communication-better-way-care.
21. Care Quality Commission, *Regulation 20: Duty of Candour*. 2022, Care Quality Commission, London. Available from: https://www.cqc.org.uk/sites/default/files/2022-12/20220722-duty-of-candour-pdf-version-FINAL-2.pdf.
22. World Health Organization & WHO Patient Safety, *Patient Safety Curriculum Guide: Multi-Professional Edition*. 2011, World Health Organization, Geneva. Available from: https://iris.who.int/handle/10665/44641.
23. Vincent, C., S. Burnett, and J. Carthey, *Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety*. BMJ Quality & Safety, 2014. **23**: p. 670–677. DOI: https://doi.org/10.1136/bmjqs-2013-002757.

24. ISQua, *White Paper: Clarifying the Concept of External Evaluation*. Available from: https://www.isqua.org/resources-blog/blog/white-paper-clarifying-the-concept-of-external-evaluation.html.
25. ISQua, *White Paper - Person-Centred Care Systems: From Theory to Practice*. Available from: https://isqua.org/media/attachments/2022/10/03/person-centred-care-systems_-from-theory-to-practice.pdf.
26. Ossebaard, H.C. and A. Vyas, *ISQua GREEN PAPER: Green Care is High Quality Care*. 2024, ISQua. Available from: https://isqua.org/resources-blog/isqua-green-paper.html.
27. Braithwaite, J., A. Pichumani, and P. Crowley, *Tackling climate change: the pivotal role of clinicians*. BMJ, 2023. **382**, e076963 DOI: https://doi.org/10.1136/bmj-2023-076963.
28. Lachman, P., J. Brennan, J. Fitzsimons, A. Jayadev, and J. Runnacles, Editors. *Oxford Professional Practice: Handbook of Patient Safety*. 2022, Oxford University Press. Available from: https://global.oup.com/academic/product/oxford-professional-practice-handbook-of-patient-safety-9780192846877.
29. Murphy, P., P. Lachman, and B. Hillier, Editors. *Oxford Professional Practice. Handbook of Medical Leadership and Management*. 2023, Oxford University Press. Available from: https://academic.oup.com/book/44815.
30. Vincent, C., and R. Amalberti, *Safer Healthcare – Strategies for the Real World*. 2016, Springer Open. Available from: https://link.springer.com/book/10.1007/978-3-319-25559-0.
31. Patient Safety Movement, *Blog. Unleashing the Potential of Implementation Science to Prevent Harm in Healthcare*. 2023. Available from: https://psmf.org/psmf-blog/unleashing-the-potential-of-implementation-science-to-prevent-harm-in-healthcare/.
32. Carayon, P., A. Xie, and S. Kianfar, *Human factors and ergonomics as a patient safety practice*. BMJ Quality & Safety. 2014. **23**, 196–205. Available from: https://qualitysafety.bmj.com/content/23/3/196.
33. World Health Organization, *Patient Safety*. 2025. Available from: https://www.who.int/news-room/fact-sheets/detail/patient-safety. Accessed February 10, 2025.
34. International Society for Quality in Health Care, *ISQua's Mission Statement*. 2025. Available from: https://isqua.org/about.html. Accessed February 10, 2025.

Annexure

Critical implementation strategies for patient safety in hospitals

Critical implementation strategies for patient safety in hospitals refer to essential, evidence-based actionable approaches that ensure the systematic and sustained improvement of safety practices. These strategies would address the core aspects of error prevention and risk reduction and foster a culture of safety. These strategies should be tailored to the hospital's specific risks and operational context to reduce harm and improve clinical outcomes effectively.

Every hospital operates under unique conditions influenced by patient demographics, resource availability, cultural practices, and prevalent risks. Tailoring strategies based on the local context to fit these factors ensures maximum effectiveness. A leader must identify specific scenarios where implementing a particular patient safety strategy can have the most significant impact.

Examples of these critical moments could include the following:

- During patient handoffs and transitions of care: Structured communication protocols
- Before high-risk procedures: Surgical safety checklists
- After a patient safety incident: Communication and Resolution Programmes
- Increased workload, pandemic: Health worker education and support systems
- Introducing new technology: Training and usability testing

This approach would ensure that the implementation strategies are applied effectively at moments of highest risk to maximise their impact on patient safety.

FP1. Advocacy and Leadership

1. Executive safety rounds where leadership engages with frontline staff to identify safety and health worker concerns.

   Build trust and ensure psychological safety during periods of organisational change.

2. Designate safety champions in each department to drive safety initiatives and motivate and support health care staff.

Addresses both patient and staff safety in high-risk departments or high-turnover departments.

3. Public safety campaigns like World Patient Safety Day to promote safety and well-being initiatives targeting both patients and healthcare workers.

   Enhance awareness of shared safety goals, especially in diverse care settings.

4. Leadership workshops on equity and safety.

   Reduces disparities and fosters an inclusive safety culture in underserved areas.

FP2. Health Worker Education and Safety

1. Comprehensive training programmes on patient safety, mental health, and ergonomic practices.

   Would help strengthen workforce resilience in high-stress clinical environments.

2. Conduct regular evaluations of workplace ergonomics and staff well-being.

   Prevent injuries and ensure a safe working environment for health workers.

3. Establish mental health support systems and peer support programmes.

   Reduces burnout and fosters psychological safety in high-demand hospitals.

4. Link continuous professional development in safety practices to performance appraisals and career progression.

   Would encourage sustained engagement in safety initiatives among staff.

5. Health worker safety committees to address worker safety concerns and align them with patient safety goals.

   Ensures staff safety remains a priority alongside patient care improvements.

FP3. People Engagement and Empowerment

1. Patient and Family Advisory Councils (PFACs) where staff and patient feedback are included.

   During the design/revision of hospital policies, care pathways, and safety initiatives to reflect patient needs and expectations.

2. Co-design care plans with patients and families to develop personalised care plans that align with their goals, values, and preferences.

   At admission/discharge/managing chronic conditions to enhance care alignment and patient satisfaction.

3. Implement patient and family feedback mechanisms (through surveys, suggestion boxes, and digital platforms) to get real-time feedback on care.

   To identify and address areas of dissatisfaction and enhance service quality.

4. Provide education and resources for patients and families on hospital processes, patient rights, safety practices, and managing their health conditions.

   To empower patients to take an active role in their care and recovery during hospitalisation.

5. Create transparent communication channels through regular updates, bedside rounds, and post-discharge follow-ups.

   During critical decision-making moments (surgical consents/end-of-life discussions/ post-discharge).

FP4. Improvement in Clinical Processes

1. Develop and implement standardised protocols to address patient safety and ergonomic considerations for health workers.

   Prevents clinical errors and minimises worker fatigue during repetitive or high-risk tasks.

2. Checklists for critical tasks for high-risk clinical tasks.

Enhances compliance and reduces risks in both patient care and staff workflows.

3. Rapid response systems to be established for incident response.

   Provides immediate support to both patients and staff in critical situations.

4. Conduct regular audits to evaluate adherence to safety protocols and staff ergonomics.

   Identifies gaps in patient and worker safety practices.

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