A NATIONAL PATIENT SAFETY STRATEGY FOR MALTA

2026-2035

GOVERNMENT OF MALTA
MINISTRY FOR HEALTH
AND ACTIVE AGEING

A NATIONAL PATIENT SAFETY STRATEGY FOR MALTA

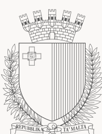
2026 - 2035

Zero Avoidable Harm

Superintendence of Public Health

Ministry for Health and Active Ageing

2026



GOVERNMENT OF MALTA
MINISTRY FOR HEALTH
AND ACTIVE AGEING

This strategy is dedicated to every patient who entrusts us with their care, to every relative and caregiver who stands by them with strength and compassion, and to every member of our healthcare team who strives each day to deliver safe, respectful, and dignified care.

Your voices, experiences, and unwavering commitment inspire the continuous pursuit of safety and excellence. This work belongs to all of us. Together, we build a culture where safety is not just a priority, but a shared promise.

Public Consultation

In line with the principles of Better Regulation, transparency, and participatory governance, this Strategy was developed following a public consultation process involving relevant stakeholders and the wider public. The feedback received was systematically reviewed and has informed the finalisation of this document. Where appropriate, the contributions made through the consultation process have been integrated into the final Strategy, with the aim of strengthening its evidence base, policy coherence, and practical applicability.

Foreword

Hon. Jo-Etienne Abela
Minister for Health and Active Ageing

The pursuit of universal health coverage (UHC) is a vital and noble endeavour, aiming to ensure that every person and every community can access quality health care without experiencing unnecessary financial hardship. The key to achieving this Sustainable Development Goal (SDG) target depends on the quality and safety of health services. Without these essential pillars, the benefits of expanded coverage risk being undermined, eroding public trust and discouraging people from seeking care, even when it is most needed.

International evidence shows that as many as 1 in 10 patients suffer harm while using healthcare services, and more than half of this harm is preventable. Unsafe care not only leads to avoidable patient suffering but also causes lasting reputational damage to health systems. Furthermore, it negatively impacts patient experience, trust and engagement with health care services, the morale and well-being of health care workers, and public opinion about the value of investing precious societal resources in the health system. For all these reasons, the development and implementation of Malta's first National Patient Safety Strategy 2026-2035 for the health service is both urgent and essential.

Our vision for patient safety is that every individual using health services in the public and private sectors will consistently receive the safest care possible. Achieving this goal requires nurturing a strong culture of safety that prioritises transparency, continuous organisational learning, and accountability. This culture must be supported by effective governance, visionary leadership, and a steadfast commitment to enhancing our safety capabilities. Embracing the principles of safety science will be essential to design and sustain safer systems of care.

This Strategy is based on six commitments:

- Strengthening governance and leadership for patient safety
- Reducing the common causes of harm
- Anticipating and responding to risks to patients during healthcare delivery
- Empowering staff for safer care provision
- Empowering patients through active engagement for a safer health system
- Measuring and learning to improve the safety of healthcare

Patient Safety is everyone's responsibility, and we all have a vital role to make our health services safer for everyone. This Strategy, which is the first national strategy for patient safety in Malta, belongs to all of us, and we are confident that, through collective commitment and full implementation, we will turn vision into action and achieve meaningful improvements in safety across the health system.

Introduction

Prof. Charmaine Gauci
Superintendent of Public Health

Patient safety is an essential component of high-quality health care. It is fundamental for safeguarding patient well-being, maintaining trust in the health system, reducing costs, and upholding ethical and regulatory standards. Patient safety is defined by the World Health Organisation (WHO) as "the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum". Within the broader health system context, it 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 errors less likely and reduce the impact of harm when it does occur."[1]

While healthcare has become more effective in many areas, its delivery has grown increasingly complex, with rapidly advancing technologies and treatment options more easily available. Several factors can cause harm during healthcare delivery, including external factors, organisational and internal systems, and technological, human, and patient-related factors.[2]

In response to this complexity, countries are making concerted investments to improve patient safety, as highlighted in the 2024 Global Patient Safety Report. [2] Despite improvement efforts, millions of patients continue to suffer harm or die every year because of unsafe and poor-quality health care. Current estimates indicate that unsafe care causes more than 3 million deaths globally every year with approximately half of this harm considered as preventable.[2] A staggering 12% of adverse events lead to permanent disability or death.[3] In high income countries specifically, one in every 10 patients experiences an adverse event while receiving hospital care.[4] These figures have significant implications, not only for patients and their families, but also for health care workers and the overall trust and credibility of the health system.

Unsafe care carries a substantial financial burden, accounting for up to 12.6% of the total annual health expenditure in high income countries.[5] In the OECD countries, extended hospital stays and avoidable admissions generate annual costs of over USD 54 billion, which is equivalent to 11% of total pharmaceutical spending within the same OECD countries.[6] Additional indirect costs include loss of productivity and psychological distress in patients and caregivers, lost taxation revenue, and increased welfare payments and compensation claims.[4]

Healthcare workers involved in adverse events (the second victims) may themselves also suffer significant psychological harm, including acute stress syndrome, post-traumatic stress

disorder, burnout or even suicide.[7] Beyond the individual impact, unsafe care can erode public trust and damage the health system's reputation (the third victim). In turn, this can impact health service utilisation, undermine progress towards universal health coverage, and diminish public support for healthcare financing through taxes or social insurance contributions.[5] Notably, improving patient safety has profound economic benefits, potentially increasing global economic output by 15% over the next two decades.[2]

There is clear evidence that targeted investments in patient safety can yield substantial economic returns. For example, interventions to reduce healthcare associated infections show a median saving-to-cost ratio of 7:1.[8] Other strategies, such as improved communication across healthcare settings and the use of digital technologies, can also be cost-effective if designed and implemented appropriately.[4]

The provision of safe patient care has been recognised as a strategic priority for Malta's health system. Malta's second National Health Systems Strategy (NHSS)[9] underscores the importance of coordinating efforts to improve patient safety, supported by documented plans and measurable actions. The NHSS also acknowledges ongoing efforts to improve healthcare standards, strengthen governance, and support initiatives undertaken by individual healthcare facilities and care providers. Furthermore, patient safety, together with quality of care, was identified as one of the WHO-Malta Country Cooperation Strategic Points for the 2022-2026 period.[10]

Building on WHO's Global Patient Safety Action Plan 2021-2030[1], Malta's first National Patient Safety Strategy seeks to map existing patient safety structures and initiatives, identify gaps, prioritise areas for improvement, secure the necessary resources, and ensure coordination across the entire healthcare system across the whole patient care pathway and including prevention services.

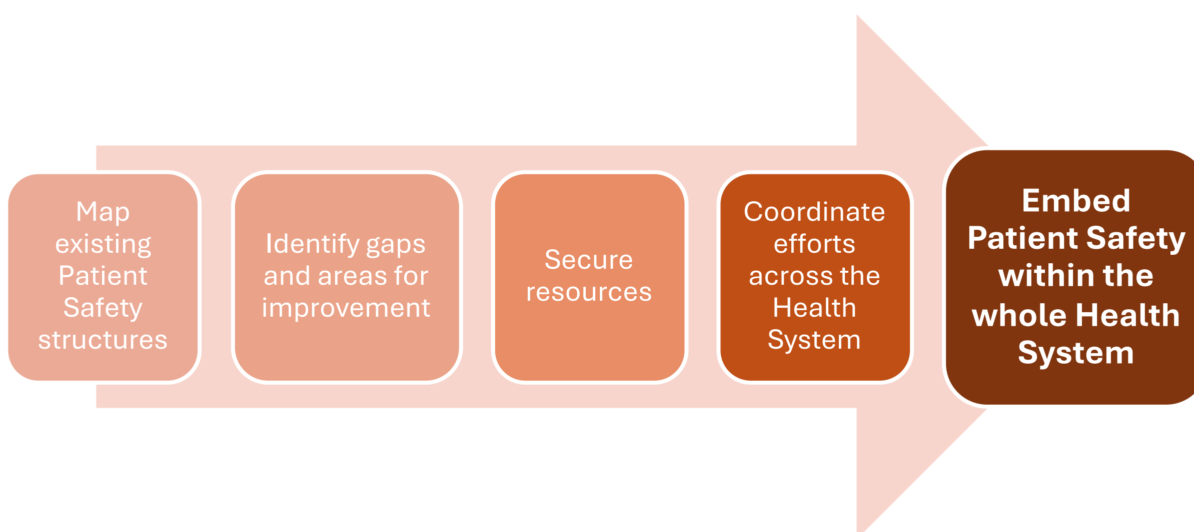


Figure 1: The aims of Malta's first National Patient Safety Strategy

This Strategy is the result of extensive consultation with a broad range of stakeholders across the health system, including a period of public consultation to ensure that it is truly owned by all actors involved. Its successful implementation now depends on the continued commitment and active participation of every stakeholder, so that together we can achieve meaningful and lasting improvements in patient safety. The goal is to embed patient safety within the fabric of the Maltese health system.

Executive Summary

Patient safety is an essential component of high-quality care and is a critical determinant of population health outcomes. Globally, unsafe care contributes to an estimated 3 million deaths every year, with one in every ten patients harmed while receiving care. According to the World Health Organisation, up to 50% of this harm is preventable, contributing to unnecessary human suffering and significant economic loss. In high-income countries, adverse events affect between 10-12% of hospitalised patients and account for over 12% of national health expenditure. Strengthening patient safety is essential to improve health outcomes, deliver people-centred and high-quality care, empower and safeguard the wellbeing of the workforce, and ensure sustainable health systems.

Malta's National Patient Safety Strategy (2026-2035) provides the first system-wide framework to enshrine patient safety as a foundational pillar of the health system. It builds upon the priority areas outlined in the National Health Systems Strategy 2023-2033 and aligns with international commitments, including the WHO Global Patient Safety Action Plan 2021-2030 and EU recommendations.

This document was shaped by extensive key internal stakeholder insights and collaborations with international partners, legal experts, and government bodies. Their contributions were instrumental in identifying key priorities and fine-tuning the proposed actions.

The proposed strategy is built around six strategic commitments that address persistent challenges to patient safety in the Maltese health system. The proposed strategic objectives and actions take into consideration the growing complexity of healthcare delivery, technological advancements, and emerging risks, and identify areas where more work is needed to strengthen patient safety during the delivery of care. The primary goal is to embed patient safety within the fabric of the Maltese health system and establish safety as a foundational principle of healthcare delivery.

The document's vision until 2035 focuses on strengthening legislative and regulatory provisions promulgating patient safety, promoting leadership and stakeholder engagement, capacity building, resource mobilisation, and continuous monitoring and evaluation. Recognizing the dynamic nature of healthcare, the strategy includes provisions for cyclical review to monitor and assess progress, adapt to emerging challenges, and ensure alignment with international commitments and best practices.

Through the successful implementation of this strategy, Malta aims to reduce avoidable harm, empower patients and the health workforce, strengthen the resilience of the health system, and align with global patient safety targets.

Table of Contents

Public Consultation 4
Foreword 5
Introduction 7
Executive Summary 9
Table of Contents 11
Glossary of Key Terms 12
List of Abbreviations 13
An Overview of Patient Safety Structures in the Maltese Health System 15
Vision 23
Mission 23
Strategic Aim 23
Guiding Principles 24

Strategic Objectives and Priority Actions 27

Strategic Objective 1:
Strengthening Governance Structures for Patient Safety 28

Strategic Objective 2:
Embracing a Patient Safety and Learning Culture at All Levels of the Health System 30

Strategic Objective 3:
Strengthening the Safety of Clinical and Care Processes 32

Strategic Objective 4:
Supporting the Health Workforce for the Delivery of High-Quality and Safe Care 34

Strategic Objective 5:
Engaging and Empowering Patients and Communities for Safer, More Effective, and People-Centred Services 36

Strategic Objective 6:
Harnessing Research and Innovation for Patient Safety 38

Stakeholder Involvement 40
Implementation Plan 41
Sustainability and Resource Mobilisation 41
Monitoring and Evaluation Framework 42
Conclusion and Way Forward 43
References 44
Contributors 48

Glossary of Key Terms

Adverse (or Harmful) Event: an incident that results in avoidable harm to a patient while receiving healthcare that may or may not be the result of error.[1]

Adverse Reaction: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.[1]

First Victim: patients suffering an adverse event and their families or caregivers.[7]

Hazard: a circumstance, agent, or action with the potential to cause harm.[1]

Human Factors Ergonomics: the scientific discipline that applies theory, principles, data, and methods to design in order to optimise human well-being and overall system performance. Human factors take in consideration the environmental, organisational, and work-related factors, and the human and individual characteristics that influence behaviour in a way that can affect health and safety. The terms human factors and ergonomics are often used interchangeably or as a unit.[11]

Just Culture: an environment supportive of open dialogue that considers wider systemic issues while maintaining individual accountability to enable learning from mistakes for continuous improvement.[12, 13]

Near Miss Event: an event with the potential for causing unintended harm to a patient while receiving healthcare, that was prevented following timely intervention.[1]

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.[1]

No-Harm Incident: a patient safety incident that reaches the patient but does not result in any discernible harm to the patient.[1]

Open Disclosure: the process of informing patients and their families of adverse outcomes of treatment, as distinguished from adverse outcomes that are expected from the disease or injury itself.[1]

Patient Safety: 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.[1]

Patient Safety Incident: any unplanned or unintended event or circumstance that could have resulted, or did result, in avoidable harm to a patient. This includes near miss events that could have resulted in harm, adverse events resulting in harm, and complaints from staff and patients that are associated with harm.[1]

Psychological Safety: a supportive work environment where members believe they can question existing practices, express concerns or dissent, and admit mistakes without suffering ridicule or punishment.[14]

Risk: the probability that an incident will occur.[1]

Root Cause Analysis: a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? until the underlying root causes have been elucidated.[1]

Second Victim: healthcare providers who have been involved in healthcare-related adverse event.[7]

Sentinel Event: an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase 'or risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.[1]

Third Victim: the healthcare organisation in which the adverse event occurs.[7]

List of Abbreviations

ADR	Adverse Drug Reaction
AMR	Anti-Microbial Resistance
CME	Continuous Medical Education
CMO	Chief Medical Officer
CPD	Continuous Professional Development
CPG	Clinical Practice Guidelines
CPSU	Central Procurement and Supplies Unit
DPA	Directorate for Pharmaceutical Affairs
EHDS	European Health Data Space
EPR	Electronic Patient Records
ESP	Employee Support Programme
HAI	Healthcare Associated Infections
HSPA	Health System Performance Assessment
HTA	Health Technology Assessment
IMU	Information Management Unit
IPC	Infection Prevention and Control
KPIs	Key Performance Indicators
MA	Medicines Authority
MHN	Malta Health Network
NCAP	National Clinical Audit Programme
NHSS	National Health Systems Strategy
NSCQPS	National Steering Committee for Quality and Patient Safety
OECD	Organisation for Economic Co-operation and Development
OHSA	Occupational Health and Safety Authority
OPSA	Older Persons Standards Authority
PHC	Primary Health Care
PREMs	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures
QAIAC	Quality Assurance Initiative Adjudicating Committee
SoHO	Substances of Human Origin
SOPs	Standard Operating Procedures
SPH	Superintendence of Public Health
UHC	Universal Health Coverage
WHO	World Health Organisation

An Overview of Patient Safety Structures in the Maltese Health System

Several initiatives to improve patient safety have been implemented in the Maltese health system over the years. The following section outlines key efforts undertaken to date in different areas of the health system.

Current Legislative and Regulatory Landscape

The governance of patient safety in Malta is embedded in national legislation via the 2013 Health Act,[15] which regulates healthcare provision with the aim of protecting patients from avoidable risks associated with healthcare delivery. Article 8(1) of this legislation established the Health Regulation Department, while Subsidiary Legislation 528.05 details the functions and responsibilities of the Department and its mission "to safeguard public health, license, monitor and inspect the provision of healthcare services in order to ensure their quality and safety, and to recommend the standards to be met by healthcare providers and advice the Minister on matters relating to public health".[16]

The Superintendence of Public Health (SPH), through the Healthcare Standards Directorate,[17] is responsible for licensing, monitoring, and assessment of healthcare facilities. It sets the standards and requirements for licensing of all hospitals, clinics, and other entities in the public and private sectors providing healthcare. There is an ongoing process to update the minimum licensing standards for all healthcare facilities, clinical services, and health service assessments.[18]

In line with the provisions of EU Directive 2005/36/EC on the Regulation of Professional Qualifications,[19] the Health Care Professions Act[20] specifies the need for healthcare professionals, which include medical practitioners, dental surgeons, nurses, midwives, pharmacists, pharmacy technicians, and professions complementary to medicine including the allied professions, to be registered with the relevant council before being able to practice. The Health Care Profession Councils include the Council for Nurses and Midwives, the Council for Professions Complementary to Medicine, the Medical Council and the Pharmacy Council. The Medical and Dental Specialist Accreditation Committees are tasked with accreditation of specialist training undertaken by medical doctors and dentists respectively and recommend specialist registration to the Medical Council. Regulations for other professionals working in the health and social care sector are included in separate laws specifying licensing and standards for social workers,[21] psychologists,[22] and psychotherapists.[23] On the other hand, counsellors are regulated by the Council for the Counselling Profession under the Counselling Profession Act,[24] while the Medicines Act regulates the authorisation, manufacture, distribution, sale and safe use of medicinal products and medical devices to protect the public and ensure medicines meet the required standards of quality, safety and efficacy with SPH as the licencing authority.[25]

Healthcare service providers across both the public and private sectors in Malta have established internal structures to support the delivery of high-quality and safe care. Individual organisational approaches vary as these were developed to address specific operational challenges. Examples of existing approaches include multidisciplinary teams, risk identification and mitigation processes, incident reporting and investigating mechanisms, development of clinical practice guidelines (CPG) and standard operating procedures (SOPs), and the collection and dissemination of safety-related data. Coordination of safety-related issues within healthcare organisations is often the role of patient safety committees or teams, whose role include actions related to monitoring and reporting of safety issues and developing safety protocols among others.

These internal structures play a significant role in driving the patient safety agenda at the organisational level; however, the fragmented approach limits effective implementation of system-wide efforts at the national level and highlights the urgent need for a central coordinating mechanism that promotes consistency, transparency, and accountability across the health system, while also enabling collaboration across healthcare entities.

Risk Mitigation Measures in Healthcare Service Delivery

Several patient safety measures have been integrated within both national and organisational initiatives with the aim of minimising patient harm and enhancing the safety of clinical and care processes. These measures span all levels of service delivery, from broad system-wide strategies to institution-specific practices. Targeted interventions have been prioritised in high-burden areas for patient safety, such as infection prevention and control and antibiotic stewardship, while innovative initiatives have been introduced to promote person-centred care and empower patients. The following selection of measures illustrate key focus areas and persistent challenges in the ongoing effort to improve patient safety.

National policies and programmes for high-burden patient safety issues

Malta has established comprehensive measures to tackle Antimicrobial Resistance (AMR) and Infection Prevention and Control (IPC) within the healthcare setting.

The National Antibiotics Committee was set up in 2008 with the objective of tackling AMR at a national level.[26] One of its key initiatives was the launch of the Strategy and Action Plan for the Prevention and Containment of Antimicrobial Resistance in Malta (2020-2028).[27] The Strategy adopted a One Health approach with the aim of minimising the development and spread of antimicrobial resistance, with one of the actions leading to the update of the terms of reference and the legislation pertaining to the National Antibiotics Committee in 2023 to form the National Antimicrobial Resistance Committee as an advisory body to the Superintendent of Public Health. This body brings together 17 representatives from the human, animal, and environmental health sectors, and a representative from the public to work together to implement and monitor the national AMR strategy. The Committee also launched initiatives to improve healthcare professionals' awareness and clinical practice by regularly distributing communication material and by spearheading the development of an app to support evidence-based antimicrobial prescribing in hospitals and the community.

A key Strategic Priority of the AMR strategy is to strengthen the national IPC programme in healthcare settings. Healthcare facilities are encouraged to develop an IPC policy and appoint trained IPC professionals responsible for monitoring the prevalence of healthcare associated infections (HAIs), preventing and managing outbreaks, and ensuring staff vaccination in line with the 2009 EU Council Recommendation on patient safety, including the prevention and control of HAIs.[28] Healthcare facilities are also responsible to develop and implement specific guidelines and SOPs to reduce the burden of HAIs, particularly in high-risk departments. They

provide staff with training and education opportunities and routinely collect data for surveillance purposes. This is reported to both national and international databases, documenting trends in HAIs and AMR. Compliance with IPC guidelines is routinely monitored and evaluated to ensure alignment with best practice and European Council Recommendations.

Risk Registers: Risk management, auditing, and evaluating care

Risk identification and management in healthcare settings is essential to reduce the opportunity for harm. This involves systematically identifying possible risks, assessing their potential impact and likelihood, and implementing mitigating actions. Constraints in human and financial resources allocated for clinical risk management can impact the effectiveness of these initiatives, often resulting in reactive rather than proactive approaches in harm prevention.

The Ministry responsible for Health established the Office of the Director General Compliance and Investigations and introduced Risk Registers across all departments starting in 2023, with the aim of strengthening governance and promoting a culture of risk assessment. This initiative stemmed from a broader effort by the Public Service to develop risk management competencies within key social and economic sectors. The project formed part of Malta's commitments under the Strategy Action Plan for Better Governance 2014-2020, arising from the *ex-ante* conditionality for the absorption of EU Funds.[29] Risk Registers were subsequently extended to administrative departments responsible for delivery of public healthcare services, embedding risk management within routine operations and decision-making. Apart from the identification of risks and their possible impact, each Risk Register identifies the person responsible, existing control structures, the residual risk, and any actions intended to mitigate the residual risk.

Cancer Care Pathways: Continuity of care in cancer care services

The establishment of the Cancer Care Pathways Directorate in 2014 marked a significant advancement in cancer care services within Malta's public health sector. This initiative introduced structured clinical pathways spanning the entire continuum of care, from initial referral or screening to diagnosis, treatment, survivorship, and palliative care. Each pathway is individualised for the specific needs of the patient and the type of cancer, ensuring a more tailored and responsive approach to care delivery.[30] In 2017, the service was enhanced with the introduction of nurse navigators with the aim of facilitating patient access to timely care, support patients during decision-making, and provide coordination across multidisciplinary teams. This personalised and integrated approach to cancer care has received international recognition. WHO commended this service for its patient-centred model, noting its potential to improve health outcomes for the individual patient and the broader health system.[31]

Digital health and innovation in healthcare services

The use of digital solutions in healthcare has contributed to patient safety and improvements in continuity of care across Malta's health system. Key innovations include the adoption of telemedicine and Electronic Patient Records (EPRs) in both the public and private health sectors. The transition from paper records to EPRs in Primary Health Care (PHC) has strengthened seamless care delivery and allowed service providers to securely access patient records from any Health Centre or Community Clinic of their choice.[32]

Patients' access to their own medical record was improved with the launch of the myHealth portal in 2012. This digital platform helps bridge the gap between the public and private health sectors by enabling patients to view their medical records, lab results, medical images and their reports, appointment details, and prescriptions. Over time, the portal has expanded its functionality and data sources, allowing access to a wider range of services and healthcare professionals that contribute to patient data.[33]

Patients can now take a more active role in managing their health. Features such as uploading medical documents, accessing doctors' notes, and monitoring health information empower individuals to actively engage in their care journey and participate in shared and more informed decision-making. Looking ahead, Malta's Digital Health and Health Data Strategy 2030 plans to further expand the use of digital technologies to enhance patient empowerment, patient safety, innovation, and integrated care delivery.[34]

The strategy's proposed actions include the implementation of a unified National Electronic Health Record (NEHR) platform with interoperable EPR systems, strengthened data governance structures, tools to reduce clinical errors such as a national e-prescription and e-dispensing platform and the use of AI for clinical practice, and the development of an Electronic Patient Master Index (EPMI) that uniquely identifies patients across multiple healthcare facilities among others. Moreover, the adoption of the European Health Data Space (EHDS) Regulation will strengthen patients' right to access their health data by enabling access in cross-border healthcare settings, while also establishing a common EU-wide framework to safeguard the use and exchange of electronic health data, including for research and innovation, across the EU.[34]

The EHDS Regulation for secondary use takes a practical stance on data interoperability, allowing necessary transformations of primary data and recognising the reality of diverse health information systems and enabling productive data utilisation for monitoring and surveillance. The EHDS creates a framework that unlocks the tremendous potential of health data in enhancing patient safety governance while respecting individual rights and ensuring ethical usage in an increasingly data-driven healthcare landscape.[35]

Adverse Event Reporting and Learning Systems

Adverse events and near misses occurring during the delivery of healthcare in the public and private sectors are captured through various incident reporting systems, which are tailored to the specific needs and characteristics of the respective setting. As a result, there is variability in reporting practices, including who reports incidents, the method of reporting, and the types of adverse events recorded.

For example, the system used in the Primary Health Care Department is mostly used by doctors and records both adverse events and near misses, whereas public and private hospital-based systems are largely used by nursing staff and focus on adverse events resulting in harm. The main acute hospital has different reporting systems for adverse events occurring in different departments and settings, including a platform for service user complaints and other platforms for incidents occurring in different clinical areas. There are also differences in the report submission process, which may be paper-based, electronic, or email-based. Additionally, reporting can be either anonymous or identifiable depending on the system and setting.

In most cases, adverse event reporting is voluntary, although mandatory reporting is required for adverse events occurring in Mental Health Services (MHS) and in relation to medicines and medical devices, and for substances of human origin (SoHO), including Tissues, Cells, and Blood. The Mental Health Act obliges the CEO of any licensed mental health facility to forward all patient incident reports on a monthly basis to the Commissioner for Mental Health for review, while the licensed mental health facility is responsible to review, analyse, and take necessary actions to avoid repeat incidents, as per own respective operational guideline. The Medicines Act defines the responsibilities and functions of the Medicines Authority, granting it the mandate and powers to monitor the safety of medicines and medical devices. This includes collecting and evaluating safety information obtained through submitted reports on medicinal products and medicinal devices. For other healthcare settings and SoHO incidents, the Office of the SPH holds regulatory responsibilities through the Health Care Standards Directorate,

whose responsibilities include oversight of safety and adverse event reports submitted within healthcare entities and in relation to the administration of tissue, cells, and blood.

In all cases, the organisation's management is responsible for identifying underlying and systemic failures that could have led to the adverse event and implementing corrective actions to prevent recurrence. Organisation-based patient safety committees are often responsible for the management of adverse events through the collection and review of incident reports, conducting internal investigations to ascertain the probable cause of the incident, and providing recommendations for action. In certain cases, internal investigations are supplemented by fact-finding investigations carried out by an ad-hoc board of inquiry, established by the office of the Permanent Secretary. The purpose of these investigations is to examine the circumstances around the event and recommend changes, including system-level changes, to prevent recurrence.

Despite these efforts, incident reporting remains low across the health system. A 2008 hospital safety evaluation using the Hospital Survey on Patient Safety Culture (HSoPSC) flagged significant underreporting at Malta's main acute hospital. This raised concern as underreporting undermines system–wide learning, prevents proactive risk management, and results in reactive measures only after harm occurs.[36] Local studies have identified several contributing factors to underreporting, reflecting a culture that is not yet fully supportive of open reporting. These include limited staff awareness of what constitutes a reportable event and of the reporting system itself, poor feedback loops that potentially impact the trust in the effectiveness of the system, a need for staff training on incident management, disclosure and communication, inconsistent managerial support, external pressures, and fears of blame or professional consequences.[37–41]

Adding to this, Grixti (2022)[42] and Bezzina (2019)[43] highlight weak leadership engagement and a disconnect between national policy and frontline implementation as critical gaps for establishment of an effective safety culture within the healthcare system. This observation calls for improved stakeholder engagement during policy development, mandatory leadership training, and regular safety culture audits across healthcare entities to reinforce accountability and commitment. Spagnol (2024)[41] further emphasised that a persistent punitive culture discourages reporting. Fear of blame, coupled with a lack of feedback, leaves staff feeling that reporting is futile. To address this, Malta must adopt a Just Culture approach, encourage anonymous, non-punitive reporting and close feedback loops to rebuild trust.

Supporting and Providing Resources for the Health Workforce

Healthcare workers encounter multiple challenges in the delivery of care that can compromise patient safety. These include, among other things, challenges related to working conditions, integration of new technologies and medical processes into usual practice and increasing cultural diversity amongst staff and patients. Local research indicates that long working hours, tedious tasks, and insufficient recognition negatively affect staff motivation, efficiency, well-being, and retention. Conversely, improved working conditions, higher degrees of job specialisation, and active participation in decision-making have been shown to improve both staff satisfaction and the safety culture in the workplace.[44]

An additional challenge arises from the increase in cultural diversity observed during the past few years amongst both healthcare staff and service users. A study carried out amongst nursing staff identified language barriers, cultural differences, discrimination, and human resource constraints management as pertinent factors that can impact patient safety.[45] Malta's first National Health Workforce Strategy published in 2022[46] acknowledged these challenges and outlined various measures to address them, such as a greater focus on training

and education, adaptation programmes for new staff, the use of cultural mediators during patient-staff interactions, and training in non-technical and soft skills.

All healthcare organisations are responsible for promoting the health and well-being of their workforce. Measures implemented include the development of guidelines and protocols to ensure a safe working environment, such as addressing workplace injuries, violence from patients, visitors, or colleagues, and providing access to support services, such as psychological support for personal or professional concerns. Challenges persist in providing effective psychological support and retraining opportunities for second victims. Barriers such as limited resources, stigma, confidentiality concerns, real or perceived lack of management support, and low awareness continue to hinder access to support services.

In the public sector, the Employee Support Programme (ESP),[47] offered centrally by the Office of the Prime Minister (OPM), provides individualised psycho-social support and organises training sessions, seminars, and conferences with the aim of promoting self-care, coping skills, and resilience among public service employees. This programme is not specific for healthcare staff but is offered to all workers within the civil service by a dedicated team of professionals. More resources are needed to reduce waiting times and enhance its effectiveness.

Education and training opportunities in patient safety have expanded significantly. The University of Malta introduced a post-graduate course at MQF level 7 in Patient Safety and Clinical Risk Management,[48] and entrenched patient safety topics in undergraduate and postgraduate courses at the Faculty of Health Sciences and the Faculty of Medicine and Surgery. Targeted courses have stimulated research in important areas, such as medication safety, patient engagement and patient voice, communication challenges, staff burnout, second victim concerns, audit, management and leadership, and safety culture.

In addition to formal academic training, healthcare entities also offer educational sessions and Continuous Professional Development (CPD) activities on several topics related to clinical care, often on a voluntary basis. Awareness campaigns and initiatives that are frequently organised by private entities in collaboration with international organisations have also contributed to a growing understanding of patient safety across the health workforce and student populations.

Patient, Family and Public Involvement

Recent years have seen patient and family empowerment placed higher on national and international agendas. The NHSS acknowledged the need for a strategic shift in healthcare delivery towards one that empowers patients to be more actively involved in their own care, during service-design, and in decision-making processes at both individual and health system levels.[9]

Legislative frameworks have played a significant role in supporting patient empowerment. Articles 27-29 of the Health Act (Cap 528)[15] make direct reference to patients' rights and safety of care. Additional legal protections are embedded within other key Acts, such as the Ombudsman Act (Cap 385),[49] the Public Health Act (Cap 465),[50] the Mental Health Act (Cap 525),[51] and the Data Protection Act (Cap 586).[52] Beyond health-specific legislation, broader provisions relating to patient and family rights are also found in the Civil Code (Cap 16)[53] and the Criminal Code (Cap 9).[54] Complementing these legal measures, Malta launched the first National Patient Charter in 2016,[55] which set out fundamental patient rights and responsibilities. At the same time, efforts to improve patient access to personal health information have been strengthened by digital tools such as the myHealth portal, which enables patients to contribute directly to their personal health records and control how their information is shared. Malta's Digital Health and Health Data Strategy 2030 outlines further actions to advance person-centred services and enhance the protection of health-related data.

Despite these advancements, challenges remain. Governance structures that actively support patient involvement in healthcare decision-making, particularly at the health system level, are still underdeveloped. Furthermore, the consistent delivery of person-centred services that respond to the diverse needs of different population groups is not yet fully embedded across the system. This is especially evident for marginalised and vulnerable groups such as persons with disabilities, people experiencing mental health challenges, children and young people, older persons, LGBTIQA+ individuals, migrants, and other culturally and linguistically diverse populations. In addition, further resources are required to provide effective support to patients and relatives impacted by adverse events. A national health literacy strategy is currently being developed by the Superintendence of Public Health with the aim of strengthening people's ability to access, understand, use and retain health information effectively. In the meantime, more robust efforts are needed to improve public and professional awareness of patient safety through frequent and regular awareness campaigns, educational activities, and stakeholder engagement activities that complement global initiatives, including the annual celebration of World Patient Safety Day on 17 September.

Evidence-Based Care and Research

Evidence-based care that is responsive to the needs of service users forms a critical pillar of patient-centred care.[56] A responsive health system requires a thorough knowledge of the current situation and a proactive approach to identify and address the evolving population health needs.

In recent years, initiatives aimed at promoting evidence-based care have led to a greater investment and uptake of research activities amongst healthcare professionals. Malta's NHSS highlighted the need to develop a robust research infrastructure to support knowledge-generation and facilitate the translation of evidence into clinical practice, ultimately improving health outcomes.[9] In addition, European funding mechanisms have supported this agenda, enabling the advancement of healthcare services towards a more evidence-based and patient-centred model, the promotion of research capacity across the health sector, and the provision of specialised training for healthcare professionals across different roles and grades. Further efforts to promote research and evidence-based care in the public sector included the establishment of the Merit Award Scheme in 2007 by the Quality Assurance Initiative Adjudicating Committee (QAIAC) within SPH to promote quality improvement in healthcare,[57] and the appointment of clinical leads focusing on audits and research in specific clinical areas. Additionally, the establishment of an online repository of Clinical Practice Guidelines (CPG) supports the use of evidence-based guidelines and best practices adapted to the local scenario, helping clinicians to align their care with the latest evidence.

Measurement, Monitoring and Evaluation of Patient Safety

Achieving visibility into the state of patient safety across the health system requires regular collection, measurement, and analysis of data. This enables the identification of gaps and the implementation of targeted actions to address areas of concern. Both public and private hospitals and healthcare organisations in Malta routinely collect patient safety data as part of their ongoing performance monitoring, with this data being used for internal quality improvement as well as for external reporting. In some cases, organisations use context-specific indicators with varying definitions and measurement methods that reflect local needs but that can impact their comparability potential and the possibility for oversight at the national level.

Comprehensive assessments of patient safety at the national level have not yet been integrated into system-wide performance evaluations, but an initial assessment of the status of some aspects of patient safety at national level was carried out in the development of Malta's first

Health System Performance Assessment (HSPA) in 2015,[58] with a second iteration repeated in 2018. While the HSPA did not specifically include patient safety as one of the dimensions, it did however measure aspects of safety through a small number of indicators within the Quality and Efficiency dimensions. A third HSPA iteration is currently ongoing.

A more comprehensive assessment of Malta's patient safety status was carried out by SPH in 2023. This assessment was conducted as part of Malta's reporting obligations under the WHO Global Patient Safety Action Plan 2021-2030, adopted by the 74th World Health Assembly (WHA) in 2021.[1] The action plan provides a structured framework for countries to implement strategic interventions that enhance patient safety and requires countries to report on the progress made every 2 years. The findings from the Malta 2023 assessment were included in the first WHO Global Patient Safety Report in 2024.[2] This exercise revealed significant gaps and highlighted priority areas that require system-level interventions. This assessment process is planned to be repeated every two years, creating an opportunity to regularly measure progress and refine actions accordingly. It also provided the foundational evidence on which this national patient safety strategy was built.

Vision

To develop and sustain a culture of safety and trust within the Maltese health system by enabling the consistent delivery of safe, effective, and compassionate quality care for every patient, every time.

Mission

Prevent unintended harm across all levels of care by cultivating and fostering a strong patient safety culture;

Establish, support, and strengthen governance structures that advance patient safety;

Empower patients, carers, the health workforce, and all stakeholders to actively engage in safety practices;

Leverage digital technology and innovative solutions for monitoring, surveillance, and learning; and

Promote continuous assessment and improvement of patient safety across the health system.

Strategic Aim

To embed patient safety at all levels of the Maltese health system and improve the overall safety and quality of care provided.

Guiding Principles

Malta's National Patient Safety Strategy 2026-2035 is grounded in the following guiding principles:

1. A culture of safety that places safety at the heart of the health system, through:

- Respect, open communication, and effective teamwork across professions and departments;
- Promoting and safeguarding the well-being of the health workforce;
- Accountability from all stakeholders involved in the delivery of healthcare services;
- A no-blame environment as an opportunity for learning and improvement of systems, where staff and patients can report errors and near-misses without fear of retribution;
- Strong governance structures supported by a committed, transparent and accountable leadership that champions patient safety.

2. Healthcare that responds to individual needs, preferences, and values, by:

- Placing the patient at the centre of all care delivery decisions;
- Patient and caregiver engagement in planning, decision-making, and implementation of services;
- Respecting and upholding patient autonomy by considering patients as partners and co-designers and respecting their right to make informed decisions regarding their care.

3. Investment in the health workforce capabilities and confidence through:

- Education and training in patient safety to all healthcare staff;
- Leadership competencies;
- Implementation of best practices, technology, and standardised protocols for delivering safe care;
- Access to resources, psychological safety, and timely support needed to build resilience and maintain well-being and preparedness.

4. Equity that benefits users and providers of healthcare through:

- A framework that enables the delivery of safe care to all persons across all settings;
- Equitable access to support structures for patients, relatives, second victims, and health service providers;
- Inclusive services to address diverse needs, particularly of vulnerable populations and those experiencing societal inequities;
- Risk identification strategies to prevent, control, and mitigate against existing risks.

5. Willingness to improve overall safety performance through:

- Robust monitoring, evaluation, and improvement processes;
- Regular reviews of patient safety outcomes and feedback to identify gaps;
- Targeted interventions to address areas of concern.

This strategy outlines a coherent framework of Actions grouped under six Strategic Objectives to address the existing gaps identified during the needs analysis.

Strategic Objective 1:
Strengthening Governance Structures for Patient Safety

Patient safety governance refers to the system-wide approaches implemented to minimize healthcare-related harm. Safety governance structures include legislative, ethical, regulatory, and oversight functions, and initiatives designed to promote accountability, continuous learning, and efficient resource allocation. To ensure effectiveness, safety governance structures should be context-specific, integrated and aligned with the broader health system governance, and encompass all levels of the health system, while coordination at the national level is essential to align the goals of individuals, institutions, the organisation, and society.[58]

Action 1: Review and strengthen Malta's legal framework to support a patient safety culture

Update Malta's legal framework to further support the development of a patient safety culture, including provisions for incident reporting and resolution. Proposed amendments aim to:

- Establish clear and accessible reporting pathways and procedures for the management of adverse events.
- Promote accountability.
- Safeguard the rights of all parties involved, including patients and staff.
- Ensure that systemic shortcomings contributing to adverse incidents are identified and addressed.

Responsible entity: Ministry for Health and Active Ageing, SPH

Action 2: Establish a National Steering Committee for Quality and Patient Safety

Establish a statutory National Steering Committee for Quality and Patient Safety (NSCQPS) to serve as the national coordinator for patient safety initiatives and overseeing implementation of this strategy across the health system. The NSCQPS will:

- Oversee implementation of actions from the patient safety strategy across the health system including specific dimensions of patient safety and drive progress.
- Collaborate with public and private healthcare providers, patient representatives, professional unions, and other stakeholders.
- Coordinate the implementation of a National Clinical Audit Programme (NCAP).

Responsible entity: Ministry for Health and Active Ageing, SPH

Action 3: Establish patient safety governance bodies at facility level

Establish a dedicated patient safety governance unit within each healthcare facility that is fully integrated with the facility's leadership and management structure. These units will:

- Implement national-level patient safety recommendations within their organisation;
- Organise training and capacity-building activities for staff.
- Monitor the activities of patient safety reporting and learning systems and act to address identified risks to patient care.
- Disseminate safety knowledge internally.
- Serve as communication nodes with the NSCQPS to facilitate system-wide feedback, knowledge-sharing for systems learning, and accountability.

Responsible entities: Healthcare Providers

Action 4: Launch a national clinical audit programme

Coordinate the establishment of a National Clinical Audit Programme (NCAP) that actively and dynamically supports continuous quality improvement through systematic, structured evaluation of clinical services. Under the direction of the NSCQPS, the NCAP will:

- Benchmark healthcare delivery against national standards and key performance indicators.
- Promote ongoing monitoring and improvement of clinical outcomes.
- Ensure a structured mechanism for quality assurance across healthcare providers.

Responsible entities: SPH, NSCQPS, Healthcare Providers

Action 5: Promote ethical practices as a foundation for safe, high-quality healthcare

Ethics guide healthcare professionals to prioritise the well-being, dignity, and rights of patients in every decision. The core ethical principles of autonomy, beneficence, non-maleficence, and justice promote the delivery of safe, transparent, and accountable care, while values such as honesty and respect towards patients and colleagues sustain the reporting of errors, promote informed consent, and support equitable treatment. Care delivery with this mindset is essential to prevent harm and to build trust within and towards the healthcare system. To strengthen and facilitate the application of ethical practices in healthcare delivery, actions include:

- Embedding ethical standards in clinical practice guidelines.
- Improving ethics education and training for all healthcare staff, including staff in leadership and management positions, as well as contracted staff.
- Strengthening the remit of ethics committees at national and organisational levels.

Responsible entities: SPH, NSCQPS, Health Ethics Committee, Bioethics Consultative Committee, Healthcare Providers

Strategic Objective 2: Embracing a Patient Safety and Learning Culture at All Levels of the Health System

Patient safety culture refers to the shared values, beliefs, and norms within an organisation that guide and influence the actions and behaviours of healthcare professionals, leaders, and other healthcare staff during the delivery of care. Establishing a safety culture is essential for resilient health systems that deliver high-quality and safe care. This requires a strong commitment to safety by all stakeholders, patient safety leadership, accountability, a mindset of continuous improvement, open communication, and a non-punitive response to mistakes.

Action 1: Build leadership competences for a patient safety culture

Strong leadership is essential to champion a culture of safety at every level of the health system. This action seeks to address current gaps in leadership skills and professional expertise in patient safety through the implementation of targeted capacity building initiatives, by:

- Developing and implementing programmes to build leadership capacity in patient safety across all healthcare levels.
- Promoting leadership that supports top-down and bottom-up engagement for patient safety initiatives.

Responsible entities: SPH, Healthcare Providers

Action 2: Establish a national set of patient safety indicators and introduce safety culture surveys

A national set of patient safety indicators and regular safety culture surveys are essential for tracking progress and informing system improvements. This action proposes the creation of national benchmarks and safety culture measurement tools to assess safety maturity and strategy effectiveness. Actions will include:

- Developing a core set of nationally consistent patient safety indicators for system-wide measurement and benchmarking.
- Conducting regular surveys to assess the safety culture within healthcare organisations.
- Using the findings to guide continuous improvement efforts and strategic decision-making.

Responsible entities: NSCQPS, Health Policy, DHIR, Healthcare Providers

Action 3: Develop an integrated information technology system for patient safety reporting and learning

Robust, integrated IT systems are crucial for capturing, analysing, and learning from patient safety incidents. This action proposes the development and deployment of an integrated IT system at national and organisation levels that supports organisational learning and facilitates cross-institutional data sharing, through the:

- Design and implementation of a national IT platform for incident reporting and learning.
- Ensuring system interoperability across public and private healthcare institutions.
- Support for organisations to develop internal systems aligned with national requirements, enabling timely reporting and knowledge transfer.

Responsible entities: IMU, Healthcare Standards Directorate, Healthcare Providers

Action 4: Advocate for inclusion of patient safety in all policies and strategic plans, including for strategic purchasing

Embedding patient safety into policy design ensures it remains a core component of health system development and resilience. This action promotes the mainstreaming of safety considerations across all strategies, policies, and action plans at the institutional and national levels by:

- Advocating for the integration of patient safety into all relevant policies, including service delivery, procurement, preparedness, and recovery plans.
- Ensuring that safety is considered from the initial stages of policy development through to implementation and review.

Responsible entities: SPH, Health Policy, Healthcare Providers, CPSU

Strategic Objective 3:
Strengthening the Safety of Clinical and Care Processes

Healthcare delivery is inherently complex. It involves high-stake decision-making and the input of several professionals and technologies. Several internal and external factors contribute to this complexity, resulting in inherent risks that can lead to patient harm. For this reason, health systems must implement mitigating measures that reduce the potential of harm and promote the delivery of safe clinical and care practices. Achieving this requires effective clinical risk management and implementation of evidence-based safety protocols across the continuum of care.

Action 1: Strengthen existing safety initiatives, including within existing infection prevention control, antimicrobial resistance, and medication safety policies and strategies

Many core aspects of patient safety are already integrated within existing policies, actions and strategies. This action aims to review and strengthen current efforts, particularly in existing protocols for Infection Prevention and Control (IPC), Antimicrobial Resistance (AMR), and medication safety. Actions include:

- Reviewing current IPC, AMR, and medication safety policies within healthcare entities.
- Identifying and addressing gaps in implementation.
- Supporting healthcare providers to align with the national recommendations and adopt updated protocols in these areas.

Responsible entities: SPH, National AMR Committee, NSCQPS, Healthcare Providers

Action 2: Develop and implement national protocols for high-burden patient safety issues

National protocols addressing system-wide common causes of harm are essential for consistent, evidence-based actions that make healthcare delivery safer. A national approach provides a framework to reduce preventable harm and improve outcomes at national level, while fostering accountability, promoting efficient and effective resource allocation, and strengthening health system resilience. This action will:

- Identify clinical areas and service settings with high-burden patient safety risks.
- Develop, implement, disseminate, and review national evidence-based protocols and guidelines for these areas.
- Ensure alignment with international and evidence-based best practices.
- Embed regular and continuous evaluation of effectiveness.

Responsible entities: NSCQPS, Healthcare Providers

Action 3: Strengthen further the integration of patient safety into medicines and medical device management

Procurement and lifecycle management of medicines and medical devices must prioritise safety together with cost and efficiency. This action promotes a safety-first approach throughout procurement, adjudication, and post-use monitoring and surveillance processes, by:

- Reviewing existing procurement management frameworks to embed patient safety principles.
- Strengthening post-market surveillance and feedback loops for medicines, devices, and technologies.
- Fostering cross-sector collaboration to ensure safe and effective product use across all healthcare settings.

Responsible entities: Directorate for Pharmaceutical Affairs, CPSU, Medicines Authority, SPH

Action 4: Enhance person-centred care through integration and safety of care transitions

Seamless transitions between levels of care and across healthcare providers are important for the delivery of safe, person-centred care. This action seeks to address fragmentation in care pathways and improve coordination between healthcare services. This action aims to:

- Improve integration of services to support continuity of care across the patient journey.
- Identify and focus on vulnerable transition points, including transitions from paediatric to adolescent or adult care, between different healthcare service settings, and between public and private sectors.
- Engage patients, families, NGOs, and community partners to co-design safer, accessible, and more responsive care pathways.

Responsible entities: DG Healthcare Services, Health Policy, Healthcare providers, Department responsible for Elderly Care, Ministry responsible for Children and the Family, Ministry responsible for Social Care, Ministry responsible for Disability

Action 5: Promote proactive risk assessment and risk mitigation strategies

Identifying risks before harm occurs is fundamental to improving patient safety. This action supports healthcare organisations in adopting proactive, structured, risk assessments and mitigation systems, by:

- Developing and implementing standardised tools for identifying and assessing clinical and operational risks.
- Supporting training and capacity-building for staff on proactive risk management.
- Integrating risk mitigation strategies into everyday clinical and organisational practices.

Responsible entities: NSCQPS, Healthcare Providers

Strategic Objective 4: Supporting the Health Workforce for the Delivery of High-Quality and Safe Care

The health workforce plays a central role in patient safety. Their expertise, skills, and dedication are invaluable for the delivery of high-quality and safe services. However, system-level issues such as inadequate training, staff shortages, excessive workloads, and burnout, undermine efforts to ensure a safety culture by exacerbating stressful working conditions that increase the risk of adverse events. Addressing these risks requires targeted actions that focus on improving the work environment, strengthen workforce competencies, and prioritise staff wellbeing. Investment in the health workforce will not only support healthcare professionals, but also contribute to safer care, better health outcomes for patients, and improved public trust in health organisations and the health system.

Action 1: Integrate patient safety modules into educational curricula

Embedding patient safety in education is essential to building a strong safety culture across the health system. This action proposes a comprehensive review and revision of healthcare-related undergraduate and postgraduate training curricula. Actions will focus on:

- Promoting early exposure to safety culture principles to normalise safety practices across all health disciplines.
- Integrating patient safety modules into all relevant undergraduate and postgraduate programmes, including clinical and healthcare management tracks to guarantee foundational knowledge in safety, quality improvement, and reporting practices.
- Ensuring that patient safety educational curricula are regularly updated to reflect emerging evidence and evolving societal needs.

Responsible entities: Academic Institutions

Action 2: Strengthen patient safety through evidence-based capacity building

To promote a safety-oriented workforce, this action focuses on enhancing in-service patient safety training and education for all staff working in the health sector. Actions will focus on:

- Developing and implementing structured patient safety training programmes for both clinical and non-clinical staff working in the health sector.
- Integrating patient safety topics into induction, in-service training, CPD, and CME initiatives.
- Strengthening leadership capacity in safety and quality improvement through targeted workforce development activities.

Responsible entities: Healthcare Providers

Action 3: Establish regulatory provisions and guidelines for patient safety competencies and link competency requirements to service standards

Professional regulatory councils have a decisive role in maintaining public trust and confidence in the ability of professionals to deliver services safely and effectively. To strengthen this commitment,

this action aims to align professional standards with institutional safety expectations. Actions will focus on:

- Developing regulatory provisions and professional guidelines for patient safety competencies.
- Updating patient safety competencies for healthcare professionals through ongoing education and training.
- Linking continuing professional development to the service quality standards expected of healthcare facilities.

Responsible entity: SPH, Healthcare Standards Directorate, Healthcare Providers, Healthcare Professionals

Action 4: Promote a healthy, safe, and supportive workplace for healthcare staff

Promoting a healthy, safe, and supportive workplace is essential to reduce occupational hazards, safeguard staff well-being, enhance resilience, and sustain high-quality care delivery. This action supports a comprehensive approach to workforce safety and well-being that integrates occupational health and safety, mental health support, and organisational safety culture, with implementation focusing on:

- Recognising staff well-being, resilience, and psychological safety as core enablers of health system performance and patient safety.
- Updating and implementing workplace health and safety policies and guidelines in line with the OHSA Act and relevant regulatory frameworks.
- Promoting and supporting the delivery of targeted mental health interventions to support healthcare staff experiencing psychological distress or work-related trauma in the course of their duties.
- Supporting the development of expertise among professionals providing mental health and psychosocial support services for healthcare staff.
- Developing educational resources and clear, structured pathways for timely, appropriate, and confidential access to support services.
- Fostering a supportive and stigma-free organisational culture that normalises help-seeking and encourages open discussion of mental health and well-being.
- Encouraging the adoption and implementation of the WHO Health Worker Safety Charter.

Responsible entities: Human Resources Departments; DG Healthcare Services; Healthcare Providers; Professional Unions; OHSA

Action 5: Provide comprehensive support for second victims

Healthcare staff involved in adverse events require timely and appropriate support. This action aims to strengthen support systems at both the national and organisational levels by:

- Supporting healthcare organisations in developing tailored second victim support services based on facility size and workforce needs.
- Advocating for expansion of the Employee Support Programme (ESP) to provide targeted psycho-social support for healthcare staff affected by adverse events and support service to be provided by the health care establishment in the private sector.
- Advocating for staff capacity-building within ESP to respond effectively to the psychological and professional needs of healthcare workers.

Responsible entities: Healthcare Providers, ESP

Strategic Objective 5:
Engaging and Empowering Patients and Communities for Safer, More Effective, and People-Centred Services

Meaningful engagement of patients and communities is essential for safe and people-centred health systems. Active participation in policy development, service planning, and healthcare evaluation empowers individuals and communities and is central for service responsiveness, improving health outcomes, and building trust in the health system. Due consideration needs to be given to service users experiencing adverse events or near misses while receiving care, including vulnerable groups who may be at higher risk of healthcare-related harm. Addressing their concerns, learning from their experiences and implementing preventive measures can help mitigate further harm, both for the affected individual and for others in similar circumstances. A health system that promotes collaboration, accountability, transparency, and shared decision-making ultimately delivers safer, more effective care.

Action 1: Advocate for patient representation in all governance bodies

Active patient and public engagement within healthcare governance is essential to ensure that decision-making reflects the needs and perspectives of service users. This action aims to embed patient voices in governance structures at all levels of the health system by:

- Promoting the inclusion of patient and public representatives in governance bodies at both national and facility levels where appropriate.
- Building the health literacy and capacity of patients and their representatives to promote meaningful engagement in decision-making.
- Supporting a system-wide shift towards co-production and collaborative leadership in health policy and service design.

Responsible entities: SPH, Health Policy, DG Healthcare Services, Healthcare Providers

Action 2: Provide comprehensive support to patients and families affected by patient safety incidents

Patients and families affected by patient safety incidents must be supported with compassion and transparency. This action focuses on developing structured support systems to assist those directly affected by adverse events. Actions will focus on:

- Developing services that provide psychological and practical support, tailored to the needs of affected individuals and families.
- Promoting transparent communication and compassionate care throughout the post-incident process.

Responsible entities: Healthcare Providers, NSCQPS

Action 3: Promote patient safety awareness through campaigns and education

Public awareness and understanding of patient safety are critical to fostering a culture of shared responsibility and informed participation. This action focuses on outreach and education to improve safety literacy among the public. Work will focus on:

- Carrying out regular, year-round educational activities to strengthen public awareness and involvement in patient safety across all communities.
- Supporting healthcare entities to design and implement safety awareness initiatives that are specific to their clinical area.
- Celebrating initiatives such as World Patient Safety Day through national activities that engage stakeholders, encourage dialogue, and prioritise safety on the public agenda.

Responsible entities: Ministry for Health and Active Ageing, SPH, Health Promotion and Disease Prevention Directorate, Healthcare Providers, Academic Institutions.

Action 4: Advocate for Health Impact Assessment to support person-centred and system level appropriate Patient Safety policies and actions

To uphold a person-centred approach to patient safety, it is essential that policies and actions are informed by a structured Health Impact Assessment (HIA). HIAs provide a systematic and evidence-based methodology for evaluating the potential effects of proposed initiatives on the health, safety, and well-being of individuals and communities. Embedding HIA within routine decision-making processes ensures that patient safety policies and actions are responsive to patients' needs, including those of vulnerable and marginalised groups, while promoting transparency, accountability and long-term sustainability. Actions will focus on:

- Advocating for the routine integration of HIA into the development and implementation of patient safety policies and action plans at national and healthcare entity levels.
- Providing leadership, guidance, and technical support to healthcare entities in the application of HIA principles to patient safety related initiatives.

Responsible entities: SPH, NSCQPS, Health Policy, DG Healthcare Services, Healthcare Providers

Action 5: Adopt and disseminate the WHO Patient Safety Charter

The WHO Patient Safety Charter provides a global framework for ensuring that safety is prioritised across all levels of the health system. This action promotes its adoption and dissemination throughout the Maltese health system. Actions will focus on:

- Advocating for the adoption of the Charter within all healthcare organisations as a guiding document for patient safety.
- Raising awareness of the Charter among patients, NGOs, healthcare professionals, and decision-makers to reinforce a system-wide commitment to safety.

Responsible entities: NSCQPS, DG Healthcare Services

Strategic Objective 6: Harnessing Research and Innovation for Patient Safety

Achieving lasting improvements in patient safety requires a system-wide commitment to research, innovation, and the translation of evidence into practice. Embedding a safety culture requires integrating the best available evidence, clinical expertise, and patient perspectives into both decision-making and policy development. As healthcare continues to evolve, health systems must remain responsive to emerging challenges and scientific advancements. Prioritisation of evidence-based practices not only improves patient outcomes and resource efficiency but also drives innovation and elevates the overall quality and safety of care.

Action 1: Engage with academic institutions to advance and translate research in patient safety

Academic and research institutions are key drivers of innovation and knowledge generation in patient safety. This action supports collaboration between stakeholders within the health and educational sectors to expand research and promote evidence-informed practice. Actions will focus on:

- Promoting collaboration with universities and research centres to identify priority research areas and secure funding for patient safety research.
- Encouraging undergraduate and postgraduate engagement in patient safety studies and projects.
- Promoting collaboration and cross-sector partnerships to advance the development of predictive models, decision-support tools, and digital solutions to strengthen the safety of clinical and care processes, while ensuring robust ethical standards and safeguarding measures to protect patients, data, and clinical integrity.

Responsible entities: NSCQPS, Academic Institutions, Research Institutions

Action 2: Promote and prioritise research in underserved areas of patient safety

To advance a safer and more equitable healthcare system, it is essential to prioritise research in underserved and historically overlooked areas of patient safety. These areas include but are not limited to: research involving marginalised and vulnerable populations such as persons with disabilities, persons suffering from mental health challenges, the young and elderly, LGBTIQA+ individuals, migrants, and other culturally diverse groups; research addressing patient safety issues related to social inequities such as gender biases, family responsibilities, and religious or cultural considerations; investigations of patient safety in low-resource settings; and patient safety considerations particular to emerging clinical and care areas among others. These areas frequently lack the evidence-base necessary to inform effective interventions. Focusing research on these gaps ensures that safety strategies are inclusive and responsive to the needs of all patients, not just those in well-studied environments.

While direct control over research activity is limited, highlighting these gaps and promoting their consideration within research, funding, and policy discussions can help strengthen the evidence base needed to inform inclusive and effective patient safety interventions.
Actions will focus on:

- Identifying current patient safety evidence gaps through meaningful engagement with marginalised and vulnerable groups, caregivers, and frontline staff.
- Promoting inclusive research practices by ensuring that diverse patient voices and experiences guide study design, priority-setting, and evaluation.

Responsible entities: NSCQPS, Academic Institutions, Research Institutions

Action 3: Establish a national centre of excellence for patient safety innovation

The NSCQPS, under the oversight of SPH, will coordinate the establishment of a national Centre of Excellence for patient safety innovation. The Centre will operate under the governance of the NSCQPS and within the remit of SPH, and is not envisaged as a standalone institution but as a coordinated national platform drawing on existing public health, healthcare, and academic capacity and expertise.

The aim is to promote collaboration, innovation, and system-wide learning in patient safety by coordinating research activities, disseminating findings and best practices, and supporting the translation of evidence into policy and practice. This action aims to institutionalise patient safety advancement through a structured and collaborative approach. Work will focus on:

- Creating a Centre of Excellence for Patient Safety innovation to serve as a national hub for research, education, and solution development.
- Promoting interdisciplinary collaboration and continuous learning among healthcare providers, professionals from other sectors, researchers, educators, and policymakers.
- Facilitating the development and implementation of technological and process innovations that improve safety and quality of care.

Responsible entities: SPH, NSCQPS, Academic Institutions

Stakeholder Involvement

Successful implementation of this strategy requires the input of several stakeholders, both within and outside the health sector.

The government, through the Ministry for Health and Active Ageing, holds oversight responsibility for the overall strategy and plays a key role in ensuring the successful implementation of proposed actions by providing the necessary resources and support.

The Office of the Superintendence of Public Health is responsible for the development, implementation, and monitoring of governance structures through regulations and guidelines that ensure that healthcare institutions in both public and private sectors provide safe care to patients. The Health Care Standards Directorate, the Older Persons Standards Authority, and the Social Care Standards Authority are responsible for ensuring that health and social care institutions adhere to the regulations and expected minimum standards for quality and safe services. The Medicines Authority is another important stakeholder overseeing the regulation of medicines, medical devices, and pharmaceutical activities for human use and carrying out pharmacovigilance.

Resource allocation and prioritisation of patient safety in service delivery is within the legal remits of the Office of the Chief Medical Officer (CMO) and the Director General Health Care Services, which together with CPSU and People Management are responsible for human resources and the procurement of healthcare services, medicines, medicinal devices, and other products used in the public health sector. Healthcare service providers at all levels of the health system, including ambulatory, secondary, tertiary, and quaternary care, associated support services with a role in safeguarding the safety of care processes, and organisations within both the public and private sector, are responsible for implementing the proposed actions to realise the vision and mission of this strategy. There is the need for close collaboration between healthcare entities and the Office of the SPH to ensure a common understanding of the measures that need to be implemented to create a safety culture that protects all parties, including service providers and users. Other key stakeholders include the Information Management Unit (IMU) which is responsible for implementation of safe and effective digital health solutions in healthcare, and the Directorate for Health Information and Research (DHIR) which is responsible for monitoring performance and health outcomes through indicators.

Ensuring patient safety extends beyond the health and care sectors. Stakeholders within the justice system, including legislators, the police and the judiciary, have a crucial role in spearheading, implementing, and promoting legislative changes that reinforce patient safety while simultaneously protecting the health workforce. Additionally, engagement with the academic community is vital to improve healthcare students' awareness about patient safety, and for driving innovation and translational research to improve the safety culture within health.

Patients and civil society are central stakeholders in the success of the strategy. The active involvement of patients ensure that healthcare policies and initiatives remain responsive to service users' needs. The buy-in from civil society is equally crucial in driving national-level implementation of patient safety measures successfully. Collaboration with organisations representing patients, vulnerable and marginalised groups, and healthcare workers, including worker unions and professional associations, is also important to safeguard the interests of all parties. This ensures that rights and responsibilities are clearly understood to help build a culture of transparency, accountability and continuous improvement in patient safety.

Implementation Plan

The successful implementation of the proposed actions requires the input and collaboration of several stakeholders from within the health sector and beyond. The NSCQPS will have a central role in coordinating the strategy implementation by providing guidance and support to healthcare organisations and other stakeholders outside the health sector. Implementation will be carried out through a phased approach to ensure stakeholder buy-in, allow for piloting of initiatives before rollout for continuous evaluation and refinement of actions, maximise effective resource management, and reduce disruption of essential health services.

The initial phase will focus on laying the groundwork for a stronger patient safety culture across the Maltese health system. Work will centre around instituting the essential legal provisions establishing the NSCQPS and amending existing legislation to improve safeguards for reporting adverse events. This phase will also introduce targeted training for the health workforce and identify patient safety issues that place the greatest burden on the health system. Building on this foundation, more targeted interventions will follow in priority areas. Regular audits and feedback mechanisms will ensure that the strategy remains responsive and effective, with progress tracked through defined key milestones and clear lines of accountability.

Sustainability and Resource Mobilisation

The long-term success of this strategy will be reflected by the integration of patient safety within the design and operational aspects of healthcare service provision. This requires integrating safety practices and ethical processes within routine clinical care, aligning the strategy with healthcare organisational goals, and embedding patient safety in existing quality improvement initiatives. Leadership commitment is needed to drive change at organisational level, secure resources, and ensure accountability. Investment in the health workforce is essential to build the patient safety capacity and capability required to implement change, while engagement of patients and the public through co-design and health literacy initiatives will support accountability for successful strategy implementation.

The comprehensive situation analysis and health-system wide evaluation exercise carried out prior to developing this strategy document will serve to steer the implementation of measures where gaps were identified. Moreover, actions will be aligned with existing organisational policies and stakeholder needs. Cost-effectiveness mechanisms will be implemented to maximise impact with the allocated budget. Dedicated funding will be secured through national budget allocations, and where possible, through EU funds and partnerships.

Monitoring and Evaluation Framework

Regular monitoring and evaluation of the strategy impact is needed for progress tracking, performance assessment, and accountability. The NSCQPS will implement a structured Monitoring and Evaluation Framework based on the strategic objectives and actions to support policymakers to identify successful initiatives and areas for improvement, recognise the need for adjustments of the strategic expectations, and enable informed decision-making based on real-world data. The aim is to facilitate data-driven and evidence-based decision-making for patient safety to improve the effectiveness and relevance of the strategy.

Conclusion and Way Forward

The development of Malta's first National Patient Safety Strategy (2026-2035) marks a pivotal moment in our journey towards embedding patient safety as a core pillar of the country's health system. Rooted in the guiding principles of transparency, accountability, equity, and continuous learning, this Strategy aligns with Malta's National Health Systems Strategy 2023–2033,[13] the World Health Organisation's Global Patient Safety Action Plan 2021–2030,[1] and the objectives of the European Union Council Recommendations on Patient Safety.[28]

The Strategy acknowledges the complex and evolving nature of healthcare delivery and the necessity of integrating patient safety into the fabric of the health system. It establishes a framework for coordinated action to ensure the highest standards of quality and safe healthcare, establish a safety culture across the whole health system, prevent avoidable harm, identify and mitigate risks proactively, and engage patients and communities to improve the safety of healthcare. Central to its successful implementation is the establishment of a National Steering Committee for Quality and Patient Safety, responsible for providing strategic oversight, fostering inter-sectoral collaboration, and ensuring accountability at all levels.

Key interventions outlined in this Strategy include strengthening governance and reporting structures through legislative review, establishing robust clinical audit systems, and embedding patient safety education within undergraduate and postgraduate curricula. Furthermore, it emphasises the importance of adopting digital innovations, such as interoperable patient record functionalities and incident reporting systems, to facilitate proactive risk management and system-wide learning. The Strategy also reinforces the necessity of empowering both the health workforce and patients. Investing in workforce development, including mechanisms to support second victims, is critical to maintaining resilience and morale. Simultaneously, enhancing patient engagement mechanisms will ensure that care delivery remains person-centred, responsive, and inclusive, consistent with the principles enshrined in Malta's Patient Charter[55] and international best practices.

Measurement and continuous evaluation will be integral to tracking progress and identifying areas for improvement. The adoption of national set of patient safety indicators and the alignment with international monitoring frameworks, such as the WHO biennial reporting obligations, will enable Malta to assess its performance objectively and transparently.

By implementing this Strategy, Malta is reaffirming its commitment to achieving zero avoidable harm in healthcare, contributing to the realisation of Universal Health Coverage, and safeguarding public trust in the health system. This collective endeavour calls upon policymakers, healthcare professionals, patients, and civil society to work together to embed a sustainable safety culture within the fabric of our healthcare service delivery.

Through shared responsibility and sustained action, this Strategy aspires to ensure that every patient receives care that is not only clinically effective but also safe, compassionate, and respectful of their rights. Patient safety is everyone's business, and together, we can build a safer, more resilient healthcare system for current and future generations.

References

1. World Health Organization. Global Patient Safety Action Plan 2021-2030. Towards eliminating avoidable harm in healthcare. World Health Organization; 2021 [cited 2024 Dec 30]. https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan
2. World Health Organization. Global patient safety report 2024. Geneva, Switzerland: World Health Organization; 2024 May. Report No.: ISBN 978-92-4-009545-8. https://www.who.int/publications/i/item/9789240095458
3. Panagioti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. BMJ. 2019 July 17;366:l4185.
4. Slawomirski L, Klazinga N. The economics of patient safety: From analysis to action. Paris; 2022 Aug [cited 2024 Dec 30]. (OECD Health Working Papers; vol. 145). Report No.: 145. https://www.oecd.org/en/publications/the-economics-of-patient-safety_761f2da8-en.html
5. Auraaen A, Slawomirski L, Klazinga N. The economics of patient safety in primary and ambulatory care. Paris: OECD Publishing; 2018 Nov [cited 2024 Dec 30]. Report No.: No 106. https://www.oecd.org/en/publications/the-economics-of-patient-safety-in-primary-and-ambulatory-care_baf425ad-en.html
6. De Bienassis K, Esmail L, Lopert R, Klazinga N. The economics of medication safety. Paris: OECD Publishing; 2022 Sept [cited 2024 Dec 30]. Report No.: No.147. https://doi.org/10.1787/9a933261-en
7. Holden J, Card AJ. Patient safety professionals as the third victims of adverse events. Journal of Patient Safety and Risk Management. 2019;24(4):166–75.
8. Arefian H, Vogel M, Kwetkat A, Hartmann M. Economic Evaluation of Interventions for Prevention of Hospital Acquired Infections: A Systematic Review. PLoS One. 2016;11(1):e0146381.
9. Ministry for Health. A National Health Systems Strategy for Malta 2023-2033. Valletta, Malta: Ministry for Health; 2024 Sept. https://health.gov.mt/wp-content/uploads/2023/04/A_National_Health_Systems_Strategy_for_Malta_2023_-_2030_Investing_Successfully_for_a_Healthy_Future_EN.pdf
10. WHO Regional Office for Europe. WHO Country Cooperation Strategy 2016-2021: Malta. Copenhagen, Denmark: World Health Organization; 2016 [cited 2022 Dec 28]. https://iris.who.int/handle/10665/249576
11. The International Ergonomics Association. What Is Ergonomics (HFE)? | International Ergonomics Association. IEA International Ergonomics & Human Factors Association. [cited 2025 June 19]. https://iea.cc/about/what-is-ergonomics/
12. Apold J, Daniels T, Sonneborn M. Promoting collaboration and transparency in patient safety. Jt Comm J Qual Patient Saf. 2006 Dec;32(12):672–5.
13. NHS England. A just culture guide. NHS England. [cited 2025 Feb 24]. https://www.england.nhs.uk/patient-safety/patient-safety-culture/a-just-culture-guide/
14. Tucker AL, Nembhard IM, Edmondson AC. Implementing new practices: An empirical study of organizational learning in hospital intensive care units. Management Science. 2007;53(6):894–907.
15. Health Act. Cap. 528 Oct 25, 2013. https://legislation.mt/eli/cap/528/eng
16. Functions and Responsibilities of the Department of Health Regulation Regulations. Subsidiary Legislation 528.05 Oct 25, 2013. https://legislation.mt/eli/sl/528.5/eng
17. Government of Malta. Home Page - The Department. HealthCareStandards.gov.mt. 2023 [cited 2024 Dec 30]. https://healthcarestandards.gov.mt/en/
18. Delnoij D, Farrugia J, Cachia J, Gauci C. Training Maltese inspectors in using hospital standards: a Maltese and Dutch public collaboration. European Journal of Public Health. 2023 Oct 24 [cited 2024 Feb 5];33(Supplement_2). https://dx.doi.org/10.1093/eurpub/ckad160.1471
19. European Parliament and Council. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance). 2005 Sept. https://eur-lex.europa.eu/eli/dir/2005/36/oj

20. Health Care Professions Act. Cap. 464 Nov 21, 2003. https://legislation.mt/eli/cap/464/eng/pdf
21. Social Work Professions Act. Cap. 468 June 1, 2004. https://legislation.mt/eli/cap/468/eng/pdf
22. Psychology Profession Act. Cap. 471 Feb 1, 2005. https://legislation.mt/eli/cap/471/eng/pdf
23. Psychotherapy Profession Act. Cap. 587 Sept 15, 2018. https://legislation.mt/eli/cap/587/eng/pdf
24. Counselling Profession Act. Cap. 538 May 1, 2015. https://legislation.mt/eli/cap/538/20191001/eng
25. Medicines Act. Cap. 458 Nov 21, 2003. https://legislation.mt/eli/cap/458/20200714/eng
26. Ministry for Health and Active Ageing. Our Mission. The Department. [cited 2025 Apr 4]. https://antibiotics.gov.mt/en/the-committee/our-mission/
27. Ministry for Health, Ministry for Agriculture, Fisheries, and Animal Rights. Malta: Strategy and action plan for antimicrobial resistance 2020-2028. Government of Malta; 2020 [cited 2025 Apr 4]. https://www.who.int/publications/m/item/malta-a-strategy-and-action-plan-for-amr-2020-2028
28. Council of the European Union. Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections. June 9, 2009. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2009_151_R_0001_01
29. Office of the Prime Minister. Development of Risk Management Competence. OPM Circular No 1/2016. Internal Audit and Investigations Department; 2016. https://iaid.gov.mt/wp-content/uploads/2024/04/OPM-Circular-No-1_2016.pdf
30. Ministry for Health. Cancer Care Pathways. Public Bodies - Departments. https://health.gov.mt/public-bodies/cancer-care-pathways/
31. WHO Regional Office for Europe. Malta 'nurse navigators' embody patient-centred care. News Release. 2022 [cited 2025 Mar 3]. https://www.who.int/europe/news/item/15-09-2022-malta--nurse-navigators--embody-patient-centred-care
32. Ministry for Health. Electronic Patient Records. Primary Health Care. 2024 [cited 2025 Mar 3]. https://primaryhealthcare.gov.mt/en/electronic-patient-records/
33. Agius Muscat H, Pace J, Buttigieg S. Digital Health in Malta. Public Health in Malta: 1999 - 2019 20th anniversary edition. 2019;25–8.
34. Information Management Unit. Digital Health and Health Data Strategy 2030. Ministry for Health and Active Ageing; [cited 2025 Dec 9]. https://www.gov.mt/en/publicconsultation/Pages/2025/NL-0041-2025.aspx
35. European Parliament and Council. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance). Feb 11, 2025. https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng
36. Zammit R. Mater Dei Hospital (MDH) Survey on Patient Safety Culture. Healthcare Standards Directorate; 2008. https://healthcarestandards.gov.mt/wp-content/uploads/2024/03/Patient_Safety_Culture_in_Mater_Dei_Hospital.pdf
37. Azzopardi L. PASQIT – SA (LEARN). [Unpublished and unofficial statistics.]; 2020.
38. Parnis T, van Hamel J, Ellul P. Patient safety incidents among foundation doctors. Ulster Med J. 2018 May;87(2):132–3.
39. Petrova E, Baldacchino DR, Camilleri M. Nurses' perceptions of medication errors in Malta. Nursing standard (Royal College of Nursing (Great Britain) : 1987). 2010;24(33):41–8.
40. Scicluna Ward C, Mangion D. Nurses' attitudes and barriers to incident reporting in Malta's acute general hospital. British Journal of Nursing. 2023 Feb 24;32(4):194–200.
41. Spagnol K (2024). Patient safety culture in oncology healthcare settings in Malta [Master's dissertation]. [Msida, Malta]: University of Malta; 2024 [cited 2025 Mar 10]. https://www.um.edu.mt/library/oar/handle/123456789/129876
42. Grixti V. Measuring Communication indices and the Patient Safety Culture in a Geriatric and Rehabilitation Hospital in Malta using the Hospital Survey on Patient Safety Culture (HSPSC). [Malta]: IDEA College; 2022.
43. Bezzina P. The Patient Safety Culture and Communication in a Radiotherapy Department in Malta using the Hospital Survey on Patient Safety Culture (HSOPSC). [Malta]: IDEA College; 2024.
44. Marketing Advisory Services Ltd. Comprehensive study on the positive integration, assimilation, and retention of foreign workers within the Ministry for Health in Malta. Valletta: People Management Division, Ministry for Health; 2022 Sept. Report No.: CFT017-0162/22 (CPSU 2343/21). https://peoplemanagement-health.gov.mt/wp-content/uploads/2024/04/Comprehensive_Study_on_the_Positive_Integration_Assimilation_and_Retention_of_Foreign_Workers_within_the_Ministry_for_Health.pdf
45. Buttigieg SC, Agius K, Pace A, Cassar M. The integration of immigrant nurses at the workplace in Malta: a case study. International Journal of Migration, Health and Social Care. 2018 Sept 11;14(3):269–89.
46. People Management Division. Health Workforce Strategy 2022-2030. Supporting and Empowering the

Health Care Workforce. Ministry for Health; 2022. https://peoplemanagement-health.gov.mt/wp-content/uploads/2024/04/Health_Workforce_Strategy_online.pdf
47. Government of Malta. ESP Service. [cited 2025 Mar 3]. https://publicservices.gov.mt:443/en/people/ESP/Pages/ESP-Service.aspx
48. L.-Università ta' Malta. Master of Science in Patient Safety and Clinical Risk Management [by Research]. L-Università ta' Malta. [cited 2025 Mar 3]. https://www.um.edu.mt/courses/overview/pmscpyrper1-2025-6-o/
49. Ombudsman Act. Cap. 385 July 25, 1995. https://legislation.mt/eli/cap/385/eng/pdf
50. Public Health Act. Cap. 465 Nov 21, 2003. https://legislation.mt/eli/cap/465/eng/pdf
51. Mental Health Act. Cap. 525 Oct 10, 2013. https://legislation.mt/eli/cap/525/eng/pdf
52. Data Protection Act. Cap. 586 May 28, 2018. https://legislation.mt/eli/cap/586/eng/pdf
53. Act XXIV of 2012 – Code of Organization and Civil Procedure and the Civil Code (Amendment) Act, 2012. Act XXIV of 2012 Dec 7, 2012. https://legislation.mt/eli/act/2012/24/eng
54. Criminal Code. Cap. 9 June 10, 1854. https://legislation.mt/eli/cap/9/eng
55. Ministry for Health. Patient's Charter. Healthcare Standards Directorate; 2016 [cited 2024 Nov 18]. https://healthcarestandards.gov.mt/wp-content/uploads/2024/03/Patients_Charter_EN.pdf
56. Engle RL, Mohr DC, Holmes SK, Seibert MN, Afable M, Leyson J, et al. Evidence-based practice and patient-centered care: Doing both well. Health Care Management Review. 2021 July 1;46(3):174.
57. Grech V, Borg Buontempo M, on behalf of QAIAC. Editorial. Malta Medical Journal. 2013;25(04):1.
58. Grech K, Podesta M, Calleja A, Calleja N. Report on the Performance of the Maltese Health System. Valletta, Malta: Ministry for Energy and Health; 2015. https://dhir.gov.mt/wp-content/uploads/2024/04/HSPA_Malta_Report_Final_050416.pdf
59. Auraaen A, Saar K, Klazinga N. System governance towards improved patient safety: Key functions, approaches and pathways to implementation. OECD Health Working Papers No. 120. OECD. 2020 [cited 2025 May 29]. https://www.oecd.org/en/publications/system-governance-towards-improved-patient-safety_2abdd834-en.html
60. World Health Organization. Charter: Health worker safety: a priority for patient safety. Geneva: World Health Organization; 2020 Sept [cited 2024 Jan 25]. Report No.: ISBN: 978 92 4 001159 5. https://www.who.int/publications/i/item/9789240011595

Contributors

Writing team

Tania Cardona
John Cachia
Nadine Delicata
Joanne Farrugia
Charmaine Gauci

Acknowledgments

WHO Regional Office for Europe Office on Quality of Care and Patient Safety (Athens, Greece)

João Joaquim Rodrigues da Silva Breda
Liesbeth Borgermans
Valter Bruno Ribeiro Fonseca

WHO Patient Safety Flagship (Geneva, Switzerland)

Irina Papieva

Technical legal advice

Office of the State Advocate