





Patient safety rights charter



Dedication

In memory of the patients who have lost their lives or suffered from avoidable harm in health care. May this Charter stand as a beacon of hope and commitment, ensuring that the right of every patient to safe care is protected, and their voices heard and valued.

Background

The World Health Organization (WHO) presents the Patient¹ Safety Rights Charter, a key resource intended to support the implementation of the *Global Patient Safety Action Plan 2021–2030: Towards eliminating avoidable harm in health care.* The Charter was developed within the framework of World Patient Safety Day 2023 under the theme "Engaging patients for patient safety" and slogan "Elevate the voice of patients!". It reflects a commitment to integrate essential concepts, such as patient and family engagement, equity, dignity, access to information, and risk management, into the core principles and practices of patient safety. The Charter plays a pivotal role in advancing Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages". It emphasizes the importance of delivering safe and quality health care as an essential component of universal health coverage. By advocating safe practices and the reduction of avoidable harm in health care, the Charter supports the improvement of patient health outcomes and well-being. It also promotes health workforce education and training. Its rights-based, risk management approach strengthens countries' abilities to manage major safety risks in health care.

Aim

With approximately one in every 10 patients being harmed in health care settings, and more than three million deaths occurring annually due to unsafe care globally (1), the Charter aims to outline patients' rights in the context of safety, especially given that over 50% of this harm is preventable (2). It promotes the upholding of patient safety rights, as established by international human rights standards, for everyone, everywhere, regardless of their age, gender, ethnicity or race, language, religion, disability, socioeconomic status or any other status. The Charter will support stakeholders in formulating policies and legislation, and in developing mechanisms to ensure that patients' rights to safe care are respected, protected and fulfilled.

Objectives

- 1. Affirm patient safety as a core patient right, for everyone, everywhere.
- 2. Identify the key patient safety rights that health and care workers² and health care leaders are to uphold when planning, designing and delivering safe health services.
- 3. Promote a culture of safety, equity, transparency and accountability within health systems.
- 4. Empower patients to actively participate in their own care as partners and to assert their right to safe care.
- 5. Support the development and implementation of policies, procedures and best practices that strengthen patient safety.
- 6. Recognize patient safety as an integral component of the right to health.

¹ Patient: a person who is a recipient of health care.

² Health workers are all people engaged in work actions whose primary intent is to improve health, including doctors, nurses, pharmacists, midwives, public health professionals, laboratory, health, and medical and non-medical technicians, community health workers, and healers and practitioners of traditional medicine. It also includes health management and support workers, such as hospital administrators, district health managers and social workers, cleaners, drivers, and other occupational groups in health-related activities.

Care workers provide direct personal care services, assisting with routine tasks of daily life and performing a variety of other tasks of a simple and routine nature. They include not only those who work in acute care facilities but also those employed in long-term care, public health, community-based care, social care and home care.

Target audience

The Patient safety rights charter is aimed at a wide range of stakeholders, each with a distinct role in affirming, claiming and upholding patient safety rights in health care. This includes:

- 1. patients, families, caregivers and the general public;
- 2. civil society organizations, patient organizations, patient groups and patient advocates;
- 3. health workers;
- 4. policy-makers, health care leaders and health care facility managers;
- 5. professional associations, patient safety experts, international organizations and intergovernmental organizations;
- 6. national and subnational regulatory authorities;
- 7. human rights experts, advocates, activists and organizations;
- 8. academia and research institutions.

Applicability

The Charter is universally applicable across all health care settings and is relevant at every level of health care provision. It provides direction on patient and health system interaction across the complete spectrum of health services, including promotive, protective, preventive, curative, rehabilitative and palliative care. In addition to patients, the Charter also recognizes the importance of engaging and empowering families and caregivers in health care processes and health systems at national, subnational and community levels.

Charter development process

The Charter has been developed through a consultative process with members of the World Patient Safety Day 2023 planning group, engaging a diverse range of stakeholders, including patient advocates, patient safety experts, hospital safety experts, human rights experts, health workers, policy-makers and health care leaders. It is based on a comprehensive review of existing patient rights charters and legal instruments from across the world. A draft of the Patient safety rights charter underwent critical review by the participants (in-person and virtual) of the WHO Global Conference "Engaging Patients for Patient Safety", organized within the framework of World Patient Safety Day 2023, which took place on 12 and 13 September 2023 at WHO headquarters in Geneva.

Patient safety and human rights

This section of the Charter explores the linkages between patient safety, the right to health and human rights more broadly. Human rights are enshrined in various international instruments, including the Universal Declaration of Human Rights (1948), the International Covenant on Economic, Social and Cultural Rights (1966), the Convention on the Elimination of All Forms of Discrimination against Women (1979), the Convention on the Rights of the Child (1989), the Convention on the Rights of Persons with Disabilities (2008), and other international and regional treaties. These instruments recognize and seek to uphold the fundamental principles of equality and non-discrimination that safeguard the dignity and worth of every individual, regardless of their background, and on which all human rights are grounded – the rights to health, life, liberty, security, equality, privacy, education, freedom of expression, and much more.

In health care settings, patient safety is an important application of human rights norms and standards.

Right to health. The right to health is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. All WHO Member States have ratified at least one international human rights treaty that

incorporates this right. As a result, countries have a legal obligation to develop and implement legislation and policies that ensure universal access to safe and quality health services and to give due attention to the conditions that enable individuals to live in the best health possible. Given that unsafe health care is a leading cause of morbidity and mortality worldwide, patient safety grounded in the ethical principle "First, do no harm" is an indispensable element of ensuring the safe engagement of patients with the health system and fulfilling the right to health.

Right to life, liberty and personal security. The right to life extends beyond the avoidance of intentional harm; it includes the right to health care that is free from unintentional harm, especially when it is preventable based on available evidence at the time. The right to liberty prohibits the arbitrary deprivation of liberty based on disability or impairment, including deprivation of liberty based on underlying mental health conditions. It requires the implementation of supported decision-making approaches to empower patients to provide free and informed consent for admission and treatment. Personal security in health care involves ensuring that patients are treated in a safe environment where they are shielded from any form of abuse, neglect, violence or exploitation.

Right to dignity. The right to dignity involves health care that is culturally appropriate and respects each patient's humanity, autonomy, will and preferences in relation to the acceptability of the health services provided.

Right to information. Every patient has the right to be provided with information about their health condition, treatment options, potential risks, benefits and prognosis in an accessible and understandable format. This empowers patients to actively participate in their health journey and make informed decisions about their care.

Right to privacy. The right to privacy is essential in health care settings and directly impacts patient safety. Patients are entitled to expect the safeguarding of their physical privacy, personal matters and medical information.

Right to non-discrimination. Safe health care must be accessible for every patient, everywhere, at all times, regardless of their age, gender, ethnicity or race, language, religion, disability, socioeconomic status or any other status, as established by human rights standards.

Right to freedom from cruel, inhuman or degrading treatment. The right to freedom from cruel, inhuman or degrading treatment safeguards individuals from actions that put their physical, mental, emotional and psychological well-being in jeopardy. It calls for a health care environment where patients are treated with compassion and respect.

Patient safety represents a tangible manifestation of realizing health-related human rights and is a litmus test of the global commitment towards respecting, protecting and fulfilling those rights.

10 patient safety rights

The following is a set of 10 patient rights that are crucial for mitigation of potential risks and prevention of patient harm in health care to ensure patient safety. These rights recognize that patient safety is impacted by multiple factors, such as health workforce management, availability of safe medical products, dignity, respect and non-discrimination, information sharing, and patient and family engagement. The rights also acknowledge that patient safety is influenced by the socioeconomic environment, the physical environment, and an individual's personal characteristics; therefore, they are formulated with an awareness of the broader context of the determinants of health.

 Right to timely, effective and appropriate care. Patients have the right to receive timely and effective care tailored to their health needs, particularly in situations where delays in receiving required health care in a timely manner could lead to disease progression, clinical deterioration, failure to rescue, and poor outcomes such as preventable patient harm. This right extends to receiving effective care during out-of-hours periods, ensuring its availability around the clock. Patients also have the right to be notified promptly of any critical test results, especially after discharge.

Effective care means that patients receive care that is evidence-based and aligns with established standards of care for specific conditions or health needs. The provision of appropriate care ensures that every aspect of patient care is tailored to the individual's cultural and specific needs and preferences and is provided in partnership with the patient, while preventing complications, risks and harm. Furthermore, patients have the

right to timely and effective post-discharge care to ensure the monitoring of recovery and to address any emerging complications at the earliest opportunity.

- 2. **Right to safe health care processes and practices.** Patients have the right to expect that health workers follow safe processes and practices and implement measures to identify, prevent, and manage risks and reduce preventable harm to patients. This includes among others, maintaining correct patient identification and accurate documentation; developing evidence-based clinical and diagnostic pathways; ensuring safe and comprehensive handovers, referrals and smooth transitions of care; adhering to safe practices for medications, surgery, blood transfusions, injections, and infection prevention and control; avoiding overdiagnosis and underdiagnosis; and ensuring effective treatment.
- 3. **Right to qualified and competent health workers.** Patients have the right to receive care from health workers who possess the necessary qualifications, skills, and competencies that are aligned with national and international standards and that enable them to provide safe care and prevent and mitigate safety risks and harm. Care should be delivered to patients with professional integrity, compassion, empathy, and respect for their rights, unique needs, personal preferences, and emotional well-being. Patients are entitled to be informed about the names of their health care team and to details about their health care facilities, including licensing, certification and safety ratings where available.
- 4. Right to safe medical products and their safe and rational use. Patients have the right of access to the medical products they need, including medicines, vaccines, medical devices, diagnostics, blood and blood products, traditional and complementary medicines, and assistive and medical technologies that meet recognized safety, quality, and efficacy standards and regulations. This right extends beyond accessibility and encompasses the safe and rational use of these products, including appropriate prescribing, ordering, storage, dispensing, preparation, administration, and monitoring of medicines and vaccines; safe use and maintenance of medical devices; and safe collection, testing, processing, storage, distribution, and transfusion of blood and blood products and their monitoring. Health workers and patients alike must be empowered on safe use and the identification and reporting to relevant authorities, as required, of suspected adverse drug reactions, transfusion reactions, adverse events following immunization, medication errors, substandard and falsified medicines and other medical products.
- 5. Right to safe and secure health care facilities. Patients have the right to receive care in health care facilities that are safe, resilient and easily accessible to everyone. Particular attention needs to be given to persons with disabilities, where the adoption of a universal design-based³ approach to the development, retrofitting, or refurbishment of health care facilities and services is of utmost importance. In instances where a universal design is not feasible, health care facilities are required to provide reasonable accommodation.⁴ This right also includes maintaining structural integrity and critical systems, ensuring climate resilience and smoke-free surroundings, implementing safe evacuation protocols and pathways, and adhering to safety standards for fire, electrical and radiation safety. In situations of emergencies and disasters, patients have the right to care in facilities that establish robust infrastructure designs to withstand natural and human-induced hazards to ensure the safety, quality and continuity of essential services such as power, illumination, water, sanitation, waste management, ventilation, and infusion systems, particularly in isolation units and operating theatres.

Patients have the right to be treated in settings that maintain high standards of cleanliness and enable infection prevention and control practices, including access to clean water, proper sanitation, adherence to good hygiene practices, and safe health care waste management. In addition, patients are entitled to receive safe and appropriate food tailored to their dietary and cultural needs and with consideration of any known allergies.

³ Universal design: the design of products, environments, programmes and services to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design. Universal design shall not exclude assistive devices for particular groups of persons with disabilities where this is needed.

⁴ Reasonable accommodation: necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms.

Patients have the right to protection from all forms of violence, abuse (mental, physical, sexual or verbal), neglect, exploitation, harassment, abduction and theft.

6. Right to dignity, respect, non-discrimination, privacy and confidentiality. All patients have the right to be treated with dignity and respect throughout their health care journey, irrespective of their background, beliefs, values, cultures or preferences. This right encompasses protection from any abuse, neglect, violence, degrading treatment, or deprivation of liberty, and is especially crucial in sensitive care scenarios such as palliative care and end-of-life situations, where dignity and comfort are crucial. The right extends to respecting patients' autonomy and honouring their choices.

Patients are entitled to care that is impartial and inclusive, ensuring that safety and quality are not compromised by any form of discrimination related to age, gender, race, language, religion, disability, socioeconomic status or any other status as established by international human rights standards. This entails putting measures in place to actively protect patients in situations of vulnerability and marginalization, including children, women, older persons, persons with disabilities, Indigenous Peoples, refugees, migrants, people living in humanitarian emergencies, and sexual, gender and ethnic minorities. It is essential that care is equitable, and that at-risk patients and communities are partners in shaping the care they receive, to ensure that their specific needs and concerns are addressed adequately.

Patients have the right to have their personal space and body and personal matters kept private. This includes having consultations in private environments, ensuring that their conversations are confidential, and carrying out medical procedures discreetly, away from public view. Going hand in hand with the right to privacy is the right to confidentiality. Every patient is entitled to the safeguarding of all personal and medical information. All identifiable information about a patient's medical condition, history or treatment must be kept confidential and should only be disclosed with the explicit consent of the patient or their chosen representative, or as required by law. Upholding privacy and confidentiality are essential for establishing and maintaining trust between patients and the health care team.

7. **Right to information, education and supported decision-making.** Patients have the right to receive timely, accurate and complete information about their health. This includes clear explanations about their medical condition, management plan, prescribed medicines or medical products – their names, purpose, benefits, possible adverse effects, interactions, contraindications and existing alternatives. Patients are entitled to receive information that empowers them to proactively stay healthy, contribute to their own safety and manage their conditions effectively, including self-care. They have the right to effective communication that is culturally appropriate and tailored to their age, literacy and individual needs, including the use of interpretation or alternative and accessible formats, if necessary, due for instance to language or sensory barriers.

Patients have the right to actively participate in discussions about their care and the decision-making process, and, when needed, to access adequate support before consenting to treatment, such as one-to-one consultations, decision aids, educational materials and videos. They possess the right to exercise their legal capacity by involving a legally authorized representative of their choice in the decision-making process. Additionally, patients are entitled to expect that in emergency situations, where obtaining formal consent is not feasible and a designated family member, caregiver or legal representative – who may know and communicate the will and preferences of the patient – are unavailable, health workers will expend their greatest effort to arrive at the best interpretation of the patient's will and preferences to guide their actions.

With the expanding use of artificial intelligence (AI) in health care, it is important that patients are informed about the strengths, limitations and risks of AI in patient education and decision-making.

8. **Right to access to medical records.** Patients have the right to access or obtain a copy of their records in a usable and an understandable format. This includes both physical and electronic records that are accurate and up to date. Patients are entitled to request corrections to factual inaccuracies and control the use of their information. A patient may designate a representative to access or obtain their records. Patients also have the right to easily transfer their medical records when seeking second opinions or changing health care facilities.

Patients are entitled to expect that their health information is kept secure and that access to this information is restricted to those directly involved in their care. Patients have the right to exercise their data protection rights, including understanding how their data are being used, shared and stored. They are entitled to be informed about any automated decision-making and associated risks involving their data, particularly in the context of telehealth, telecare, and the use of AI in health care. Robust security measures must be put in place to protect patient records from breaches or cyberattacks. Disclosure of patient information beyond legislated provisions should occur only with their explicit consent.

- 9. Right to be heard and fair resolution. Patients have the right to share their experiences, file complaints and report safety incidents occurring during their care. This includes adverse events leading to patient harm, near misses, and any other safety risks they perceive or safety concerns they have. Patients are to be provided with a supportive environment rooted in a culture of safety, whereby their voices are heard and their concerns expressed without the fear of retribution or negative repercussions. In the event of an incident, patients are entitled to clear explanations about what happened, the reasons behind it, and the actions taken for redressal, fair resolution and prevention of reoccurrence. Patients also have the right to be involved in a fair and just process for addressing any harm experienced. This involves a clear pathway for independent investigation, accountability, reconciliation and fair resolution, including compensation in line with the harm experienced, national legislation and best practices. Appropriate mechanisms for reporting safety incidents and systems to learn from these incidents should be in place and functional. In cases of serious incidents, patients are entitled to receive ongoing psychological and other forms of support as needed, and should be reassured that the health care facility is committed to implement the learnings from the incident analysis to improve the safety of care and prevent future occurrences.
- 10. **Right to patient and family engagement.** Patients have the right to be active partners in their care, with a particular focus on ensuring their safety at every step of care provision. This partnership involves the right to self-determination and informed participation in decision-making, understanding and managing potential risks, and contributing to the planning and monitoring of their treatment. In such a partnership, patients have the freedom to choose their preferred option of care, their health workers, or health care facility, and have the right to refuse care without coercion, pressure or undue influence from anyone. They also have the right to create advance directives, which allow patients to outline their health care preferences for future scenarios where they may be unable to make decisions. Patients retain the right to seek the opinion of another physician at any stage of their care, a practice that can further safeguard against medical errors and misdiagnoses. Furthermore, they are entitled to seek support from family members or caregivers throughout their health care journey. Family members, as designated by the patient, have the right to be actively involved in discussions and decisions regarding the patient's care, and play a vital role in identifying and flagging potential safety risks, particularly in situations where patients are unable to communicate or make decisions themselves.

In addition, patients, families, patient organizations and the public at large have the right to be involved in shaping their health system to promote patient safety, either as individuals or as members of a community or organization. This may take the form of public action, such as health awareness or educational campaigns; or participation in the policy development, service delivery, assessment, monitoring, evaluation and research that can be done through patient and family advisory committees or health care facility boards and committees.

Call for adoption by countries and stakeholders

WHO invites Member States and all stakeholders to adopt, disseminate and implement the Patient safety rights charter through the following multifaceted actions, while adapting it to the national and local context, as appropriate.

- Stakeholder engagement. Conduct a stakeholder analysis to identify relevant stakeholders, including patient organizations, the private sector and the non-health sector, to raise their awareness of, secure their commitment to, and ensure their active participation and engagement in adopting, adapting, implementing, reviewing and updating the Charter.
- Legislative framework and regulatory mechanisms. Conduct a comprehensive analysis of existing national and subnational legal instruments and regulatory mechanisms in relation to human rights, and their alignment with international and regional human rights instruments. Following this, adopt or adapt the Charter at national and institutional levels, and incorporate the rights articulated in the Charter in existing national instruments and regulatory frameworks, as applicable.
- Incorporation into policies and professional guidelines. Collaborate with stakeholders to incorporate the principles of the Charter into existing national and subnational policies, such as patient safety and quality improvement frameworks, as well as into professional guidelines and operational procedures.
- Accountability, remedial and incentive mechanisms. Create or use existing mechanisms for holding health care institutions and health workers accountable for informing patients, families and caregivers of the Patient safety rights charter and upholding these rights. Designate clear channels for reporting violations of patients' rights and establish remedial actions to address non-compliance. Consider introducing support measures to enhance adherence to the Charter, such as designating "Charter champions" in health care facilities, especially those in underserved areas.
- Communication and advocacy. Launch comprehensive awareness campaigns that promote the Charter, its purpose and its long-term impact on patient safety and health outcomes. Adapt communication messages as per the target audience and leverage various communication channels to ensure broad outreach. Evaluate the effectiveness of these communication and advocacy interventions in meeting their objectives. Concurrently, take steps to boost public health literacy to ensure individuals are equipped with the knowledge and skills to actively participate in their health journey and make informed decisions about their care. Additionally, collaborate with media outlets and utilize multiple media channels to disseminate information about safe medical practices, self-care interventions and other relevant health care topics.
- Capacity-building of health workers and patient advocates. Strengthen the capacity of health workers and patient advocates with the competencies necessary for advocating and implementing patient safety practices, including those outlined in the Charter. This can be achieved by incorporating patient safety into the education and training of health workers and patient advocates.
- Monitoring, evaluation and improvement. Establish mechanisms for ongoing monitoring, evaluation and improvement of the Charter and its implementation strategies by regularly assessing the effectiveness of various approaches and making adjustments as needed. Set up independent mechanisms or use existing mechanisms to assess compliance with patient safety rights, investigate complaints, and ensure transparency in the process.
- Research. Allocate resources to support research related to patient rights and safety, adoption of the Charter by various stakeholders, implementation strategies, and the Charter's impact on patient safety culture, burden of patient harm, patient experience and satisfaction, and health outcomes.
- International collaboration and sharing of best practices. Engage in international collaboration and sharing of best practices, challenges, and successes in implementing the Charter. This could include establishing a platform for information exchange or regular international forums focused on patient safety rights.

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