World Health Organization

SEVENTY-SECOND WORLD HEALTH ASSEMBLY **A72/26**
Provisional agenda item 12.5 **25 March 2019**

Patient safety

Global action on patient safety

Report by the Director-General

1. In January 2019, the Executive Board at its 144th session noted an earlier version of this report;[1] the Board then adopted resolution EB144.R12.

2. The global landscape of health care is changing and health systems operate in increasingly complex environments. While new treatments, technologies and care models can have therapeutic potential, they can also pose novel threats to safe care. Patient safety is now being recognized as a large and growing global public health challenge. Global efforts to reduce the burden of patient harm have not achieved substantial change over the past 15 years despite pioneering work in some health care settings. Safety measures – even those implemented in high-income settings – have had limited or varying impact, and most have not been adapted for successful application in low- and middle-income countries.

3. All Member States and partners are striving to achieve universal health coverage and the Sustainable Development Goals. However, the benefits of increased access to health care have been undermined by service structures, cultures and/or behaviours that inadvertently harm patients and may lead to fatal consequences. Global action on patient safety will enable universal health coverage to be delivered while reassuring communities that they can trust their health care systems to keep them and their families safe. Policy-makers will want to assure that, in planning and resourcing their vision of universal health coverage, they are not presiding over flawed and wasteful models of care.

GLOBAL BURDEN OF PATIENT HARM IN HEALTH CARE

4. It is estimated that 64 million disability-adjusted life years are lost every year because of unsafe care worldwide. This means that patient harm due to adverse events is probably one of the top 10 causes of death and disability in the world.[2] Available evidence suggests that annually 134 million adverse events due to unsafe care occur in hospitals in low- and middle-income countries, contributing to

[1] See document EB144/29 and the summary records of the Executive Board at its 144th session, sixteenth meeting, section 2 and seventeenth meeting, section 3.

[2] Presentation at the "Patient Safety – A Grand Challenge for Healthcare Professionals and Policymakers Alike" a Roundtable at the Grand Challenges Meeting of the Bill & Melinda Gates Foundation, 18 October 2018 (https://globalhealth.harvard.edu/qualitypowerpoint, accessed 5 November 2018). Forthcoming paper based on data from National Academies of Sciences, Engineering, and Medicine. Crossing the global quality chasm: Improving health care worldwide. Washington (DC): The National Academies Press; 2018 (https://www.nap.edu/catalog/25152/crossing-the-global-quality-chasm-improving-health-care-worldwide, accessed 13 February 2019).

2.6 million deaths.[1] Approximately two thirds of the global burden of adverse events resulting from unsafe care, including the disability-adjusted life years lost from them, occurs in low- and middle-income countries.[2] Estimates indicate that in high-income countries, about 1 in 10 patients is harmed while receiving hospital care.[3]

5. Many medical practices and risks associated with health care are emerging as major challenges for patient safety and contribute significantly to the burden of harm due to unsafe care. For example:

- **Medication errors** are a leading cause of injury and avoidable harm in health care systems: globally, the cost associated with medication errors has been estimated at US$ 42 billion annually;[4]

- **Health care-associated infections** prevalence in mixed patient populations of high-income countries is about 7.6% and about 10% in low- and middle-income countries, according to data from a number of countries.[5] In addition, people with methicillin-resistant staphylococcus aureus are estimated to be 64% more likely to die than people with a non-resistant form of the infection;[6]

- **Unsafe surgical care** procedures cause complications in up to 25% of patients; almost 7 million surgical patients annually suffer significant complications, 1 million of whom die during or immediately after surgery;[7]

- **Unsafe injections practices** given in health care settings can transmit infections, including HIV and hepatitis B and C, and pose direct danger to patients and health care workers; they account for an estimated 9.2 million disability-adjusted life years lost per year worldwide;[2]

[1] National Academies of Sciences, Engineering, and Medicine. Crossing the global quality chasm: Improving health care worldwide. Washington (DC): The National Academies Press; 2018 (https://www.nap.edu/catalog/25152/crossing-the-global-quality-chasm-improving-health-care-worldwide, accessed 13 February 2019).

[2] Jha AK, Larizgoitia I, Audera-Lopez C, et al. The global burden of unsafe medical care: analytic modelling of observational studies. BMJ Qual Saf Published Online First: 18 September 2013. doi: 10.1136/bmjqs-2012-001748 (https://www.ncbi.nlm.nih.gov/pubmed/24048616, accessed 13 February 2019).

[3] Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf, accessed 13 February 2019).

[4] Aitken M, Gorokhovich L. Advancing the Responsible Use of Medicines: Applying Levers for Change. Parsippany (NJ): IMS Institute for Healthcare Informatics; 2012 (https://ssrn.com/abstract=2222541, accessed 13 February 2019).

[5] Report on the burden of endemic health care-associated infection worldwide. Geneva: World Health Organization; 2011 (http://apps.who.int/iris/bitstream/handle/10665/80135/9789241501507_eng.pdf?sequence=1, accessed 13 February 2019).

[6] Antimicrobial Resistance: WHO Fact Sheet, 15 February 2018 (https://www.who.int/en/news-room/fact-sheets/detail/antimicrobial-resistance, accessed 13 February 2019).

[7] WHO guidelines for safe surgery 2009: safe surgery saves lives. Geneva: World Health Organization; 2009 (http://apps.who.int/iris/bitstream/handle/10665/44185/9789241598552_eng.pdf?sequence=1, accessed 13 February 2019).

- **Diagnostic errors** occur in about 5% of adults in ambulatory care settings, more than half of which have the potential to cause severe harm; most people will suffer a diagnostic error in their lifetime;[1]

- **Unsafe transfusion practices** expose patients to the risk of adverse transfusion reactions and transmission of infections;[2] data on adverse transfusion reactions from a group of 21 countries show an average incidence of 8.7 serious reactions per 100 000 distributed blood components;[3]

- **Radiation errors** involve overexposure to radiation and cases of wrong-patient and wrong-site identification;[4] a review of 30 years of published data on safety in radiotherapy estimates that the overall incidence of errors is 1500 per 1 million treatment courses;[5]

- **Sepsis** is frequently not diagnosed early enough to save a patient's life; as these infections are often resistant to antibiotics, they can rapidly lead to deteriorating clinical conditions, affecting an estimated 31 million people worldwide and causing over 5 million deaths per year;[6]

- **Venous thromboembolism** is one of the most common and preventable adverse events, contributing to one third of the complications attributed to hospitalization; annually, there are estimated to be 3.9 million cases in high-income countries and 6 million cases in low- and middle-income countries;[4]

- **Unsafe care in mental health settings** has special features, with concerns about avoidable harm principally linked to seclusion and use of restraint, self-harming behaviour and suicide, absconding and reduced capacity for self-advocacy.[7]

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[1] Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014 Sep;23(9):727-31. doi: 10.1136/bmjqs-2013-002627 (https://www.ncbi.nlm.nih.gov/pubmed/24742777, accessed 13 February 2019).

[2] Clinical transfusion process and patient safety: Aide-mémoire for national health authorities and hospital management. Geneva: World Health Organization; 2010 (http://www.who.int/bloodsafety/clinical_use/who_eht_10_05_en.pdf?ua=1, accessed 13 February 2019).

[3] Janssen MP, Rautmann G. The collection, testing and use of blood and blood components in Europe. Utrecht: European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe; 2014 (https://www.edqm.eu/sites/default/files/report-blood-and-blood-components-2014.pdf, accessed 13 February 2019).

[4] Boadu M, Rehani MM. Unintended exposure in radiotherapy: identification of prominent causes. Radiother Oncol. 2009; 93:609–617 (https://doi.org/10.1016/j.radonc.2009.08.044, https://www.ncbi.nlm.nih.gov/pubmed/19783058, accessed 13 February 2019).

[5] Shafiq J, Barton M, Noble D, Lemer C, Donaldson LJ. An international review of patient safety measures in radiotherapy practice. Radiother Oncol. 2009;92:15-21 (https://doi.org/10.1016/j.radonc.2009.03.007, accessed 13 February 2019).

[6] Fleischmann C, Scherag A, Adhikari NK, et al. Assessment of Global Incidence and Mortality of Hospital-treated Sepsis. Current Estimates and Limitations. Am J Respir Crit Care Med 2016; 193(3): 259-72 (https://www.ncbi.nlm.nih.gov/pubmed/26414292, accessed 13 February 2019).

[7] D'Lima D, Archer S, Thibaut BI, Ramtale SC, Dewa LH, Darzi A. A systematic review of patient safety in mental health: a protocol based on the inpatient setting. Syst Rev. 2016; 5:203 (https://doi.org/10.1186/s13643-016-0365-7, accessed 13 February 2019).

6. Failures in primary care contribute to the burden of unsafe care globally.[1] Half the global burden of patient harm originates in primary and ambulatory care, with as many as four out of 10 patients facing safety lapses. This may account for over 6% of hospital bed days and more than 7 million admissions in OECD countries. It is estimated that up to 80% of harm in primary care settings can be avoided.[2] Patient safety is of critical importance throughout the whole continuum of care, including home, primary and community care, and extending to acute and long-term care and palliative care.

7. Unsafe health care can have tragic consequences for individual patients, but its effects reach much further: a lack of focus on patient safety has major financial implications for both high-income countries and low- and middle-income countries. The available evidence suggests that 15% of hospital expenditure and activity can be attributed to treating safety failures in OECD countries.[3] Poor-quality care imposes costs of US$ 1.4 trillion to 1.6 trillion each year in lost productivity in low- and middle-income countries.[4] At the political level, the cost of safety failure includes loss of trust in health systems, in governments and in social institutions.[3] Overall, the sound and systematic implementation of patient engagement strategies and health literacy programmes could reduce aggregate harm by up to 15%, which would constitute a very good return on investment.[2]

8. Health care delivery systems are complex by design and prone to errors. Human factors are a core element in most cases of harm, operating in systems where procedures and practices are poorly designed. Punitive cultures of blaming individuals prevent reporting of safety-related incidents and impede learning. Certain patient groups are more vulnerable to safety incidents, including the elderly, children, migrant populations, patients with chronic conditions and those in palliative care.

WHO ACTION TO DATE

9. The global need for quality of care and patient safety was first put to the World Health Assembly in 2002. Resolution WHA55.18, entitled "Quality of care: patient safety", urged Member States to pay the closest possible attention to the problem of patient safety. Since 2002, improving patient safety has been mandated by successive regional committee resolutions and WHO has been instrumental in shaping the patient safety agenda worldwide, providing leadership, setting priorities, convening experts, fostering collaboration, creating networks, issuing guidance, facilitating change, building capacity and monitoring trends.

10. WHO's work on patient safety began with the launch of the World Alliance for Patient Safety in 2004; its nature has evolved over time, in step with the Organization's changing mandates and priorities. One of the concrete ways in which WHO has facilitated improvements in the safety of health

[1] Woods D, Thomas EJ, Holl JL, Weiss KB, Brennan TA. Ambulatory care adverse events and preventable adverse events leading to a hospital admission. Qual Saf Health Care. 2007;16:127–131 (https://doi.org/10.1136/qshc.2006.021147; https://www.ncbi.nlm.nih.gov/pubmed/17403759, accessed 13 February 2019).

[2] Slawomirski L, Auraaen A, Klazinga N. The Economics of Patient Safety in Primary and Ambulatory Care: Flying blind. Paris: OECD; 2018 (http://www.oecd.org/health/health-systems/The-Economics-of-Patient-Safety-in-Primary-and-Ambulatory-Care-April2018.pdf, accessed 13 February 2019).

[3] Slawomirski L, Auraaen A, Klazinga N. The Economics of Patient Safety: Strengthening a value-based approach to reducing patient harm at national level. Paris: OECD; 2017 (https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf, accessed 13 February 2019).

[4] National Academies of Sciences, Engineering, and Medicine. Crossing the global quality chasm: Improving health care worldwide. Washington, DC: The National Academies Press; 2018 (https://www.nap.edu/catalog/25152/crossing-the-global-quality-chasm-improving-health-care-worldwide, accessed 13 February 2019).

care within Member States is through the concept of a **Global Patient Safety Challenge**. The Challenges have identified a patient safety burden that poses a major and significant risk. The first WHO Global Patient Safety Challenge: Clean Care is Safer Care, launched in 2005, aimed to reduce health care-associated infection primarily through improved hand hygiene. The second WHO Global Patient Safety Challenge: Safe Surgery Saves Lives, launched in 2008, sparked action to reduce risks associated with surgery, supported by the WHO Surgical Safety Checklist. In 2017, the WHO Director-General launched the third WHO Global Patient Safety Challenge: Medication Without Harm, which aims to reduce the level of severe, avoidable harm related to medications by 50% over five years, globally.[1]

11. Since 2016, the Governments of Germany and the United Kingdom of Great Britain and Northern Ireland, in collaboration with WHO, have co-led annual **Global Ministerial Summits on Patient Safety,** seeking political commitment and leadership to prioritize patient safety at the global level. Health ministers, high-level delegates, experts and representatives from international organizations advance the patient safety agenda at the political leadership level. A different country hosts the Summit each year: the 2018 Summit was held in Japan and the 2019 Summit was held in Saudi Arabia.

12. Recognizing patient safety as one of the most important components of health care delivery, essential to achieving universal health coverage, and acknowledging the need for a strategic approach and collaborative action at all levels: global, regional and national, a new strategic collaborative initiative, the **Global Patient Safety Collaborative** was established in 2018 by the joint efforts of WHO and the Government of the United Kingdom of Great Britain and Northern Ireland. The main objective of the Collaborative is to secure and scale up global action on patient safety, and to collaborate closely with low- and middle-income countries in their efforts to reduce the risk of avoidable patient harm and improve the safety of their national health care systems. The Global Patient Safety Collaborative's broad scope covers three strategic areas: leadership to prioritize patient safety, promote patient safety culture and engage patients and families; education and training to build competent, skilled and compassionate health workforce through inter-professional education and training in patient safety; and research, including building research capacities, for evidence-based policy processes in patient safety.

13. WHO has been collaborating with key international partners and working in cooperation with several countries to advance improvements in patient safety. The Organization has created the **Global Patient Safety Network** to connect actors and stakeholders; currently, there are members from more than 125 countries and key international organizations participating in the Network. The Organization has been supporting the WHO-established **Patients for Patient Safety network** for the last 12 years in order to foster the engagement of patients and families.

14. **Technical guidance and resources.** WHO has published the Multi-professional Patient Safety Curriculum Guide to assist in patient safety education in universities, schools and professional institutions in the fields of dentistry, medicine, midwifery, nursing and pharmacy. The WHO Technical Series on Safer Primary Care is a series of nine monographs related to patients, the health workforce, care processes and tools and technology, which explore the magnitude and nature of harm and provide possible solutions and practical steps for improving safety in primary care. WHO has published the Safe Childbirth Checklist to reduce risks related to childbirth and the Surgical Safety Checklist to reduce risks associated with surgery. WHO has developed the Minimal Information Model for Patient Safety and a user guide to facilitate the collection, analysis and global learning derived from adverse events. WHO has published Patient Safety Solutions as standardized tools and the High 5s standard operating

[1] Medication Without Harm: WHO's Third Global Patient Safety Challenge (http://www.who.int/patientsafety/medication-safety/en/, accessed 13 February 2019).

procedures for safe clinical practices. In order to strengthen the science underlying patient safety, WHO has promoted research and established global priorities for research in patient safety,[1] generated estimates for the global burden of unsafe care and set up a research funding scheme

NEW IMPETUS FOR GLOBAL ACTION TO IMPROVE PATIENT SAFETY

15. Modern health care organizations serve as a good example of "complex adaptive systems".[2] As the levels of complexity and unpredictability continue to rise, more intangible determinants of patient safety are being given increasing prominence and recognition, as is the need for a more integrated, system-based view of safety. First, there is a "knowledge gap" in understanding the extent of the problem and the contributory and causal factors. There is hardly any systematic data or research on the burden and causality of harm in low- and middle-income countries. Second, there is a "policy gap" reflecting an inadequate policy environment. Most health systems have not formulated policies for patient safety, or if they have they are fragmented. There is a need to understand the policy options available and how to adapt them to the local context. Third, there is a "design gap" involving the inadequate application of science to design policies, strategies, plans and implementation tools for patient safety in the local context and in resource-limited settings. Fourth, teams of trainers in management science and practice need to be developed at the organizational and delivery-of-care levels to close the "delivery gap". Finally, there is the "communication gap", which can only be closed when isolated best practices, innovations and coping mechanisms are collated, generalized and disseminated globally.

16. The need to ensure patient safety spans almost all health systems attributes, fields of care, demographic groups and thematic areas. Thus, a system approach to designing and implementing patient safety policies, strategies and plans is essential in different settings and at different levels. A situation in which different interventions remain fragmented and disconnected poses a serious hazard to the lives and welfare of patients. Patient safety interventions must be aligned with overall health system goals and embedded in all programmes. They should form the foundation for the **strengthening of health systems**.

17. Primary care is the first point of contact between the population and health care. It is the setting in which overall public trust in health care systems is formed and sustained. Unsafe, poor-quality care is one of the critical reasons why patients often bypass primary care, opting instead to go directly to secondary care. Hence, addressing **patient safety at primary care level** is critical to ensuring trust and to having a functioning, high-performing health system. The approach for achieving universal health coverage is powerfully articulated in the Declaration of Astana on Primary Health Care.[3] Patient safety must be mainstreamed into that approach so that it becomes integral to systems and practices.

18. Evidence and knowledge generated from research are not always incorporated into policies and practices on patient safety. This disconnect needs to be tackled. **Translational research** in different contexts and settings will effectively address specific needs and respond to country-specific situations, while special attention to the needs of vulnerable population groups, including ageing populations and

[1] As set out in the publication, Global priorities for patient safety research. Geneva: World Health Organization; 2009 (http://apps.who.int/iris/bitstream/handle/10665/44205/9789241598620_eng.pdf?sequence=1, accessed 13 February 2019).

[2] Forrester JW. Counterintuitive behaviour of social systems. Cambridge, United States: Alumni Association of the Massachusetts Institute of Technology;1971 (https://ocw.mit.edu/courses/sloan-school-of-management/15-988-system-dynamics-self-study-fall-1998-spring-1999/readings/behavior.pdf, accessed 13 February 2019).

[3] Declaration of Astana on Primary Health Care (https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf, accessed 13 February 2019).

migrant populations, as well as children and patients with chronic conditions, will ensure prioritization of interventions.

19. **Patients, families and communities** are the co-producers of health. They have a central role in ensuring people-centred care. Engaging patients, families and caregivers is a key to the provision of safe care. Action must be taken to empower them and build their capacities as informed and knowledgeable health care partners. Health care organizations should provide a platform to ensure that the voice of patients is heard in shaping policy design and implementation processes, and to foster collaboration among patients, families, communities, health care providers and policy-makers. Public campaigns should be promoted as a way to increase people's awareness of their roles in ensuring safe care, as well as their rights to receive such care. Safe care and protection from harm should be the right of every individual treated in a health care system. Countries should consider developing and implementing patients' rights charters as a vehicle for pursuing this goal.

20. **Effective leadership and availability of a competent and compassionate workforce** is a prerequisite for the provision of safe care. Patient safety concepts and principles should become an indispensable part of clinical training, education and continuous professional development for all categories of health care professionals. Patient safety requires care processes to be redesigned and standardized procedures implemented at all levels of the health care system in order to make them less susceptible to human errors.

21. **Availability of information** on the extent, types and causes of errors, adverse events and near misses is central to the development and implementation of patient safety policies, strategies and plans. Hence, establishment of reporting and learning systems on adverse events should be given a special priority among other interventions to address patient safety. The reporting environment should be open, fair, blame-free and non-punitive to encourage health care professionals to report and learn from incidents and to provide an opportunity for patients, their families and caregivers to report on their experiences. There is also a need for more rigorous studies to estimate the overall burden of unsafe care.

22. **Application of digital technologies** is indispensable in the 21st century for implementing patient safety interventions, and monitoring and measuring their impact. In an era in which health care delivery systems are becoming increasingly complex, digital technology can help to support and enhance critical elements of patient safety, including incident reporting and the analysis of such reports to derive the lessons learned, monitoring of patient safety interventions, education and training of health care professionals, patient and family engagement and organizational learning.

23. Mainstreaming the multidimensional concept of **patient safety culture** into health care systems at all levels is a prerequisite for providing people-centred, safe care to populations. While safety culture is multifaceted, certain factors are critical, such as leadership and governance, organizational learning, human factors, teamwork and communication, and patient and family engagement. One important aspect of this effort is to appreciate the interconnection between people, systems and cultures, and how focusing on **system improvement and learning** is the best way to improve patient safety.

24. The grave burden of unsafe care can only be challenged by global coordinated efforts that are grounded in principles of accountability and cooperation. There is a need to establish a **global coordination mechanism** that has a mandate for enabling countries to implement minimum standards for patient safety, share information based on analysis of major patient safety incidents and subsequent learning and disseminate patient safety best practices, among other functions.

ROLE OF STAKEHOLDERS

25. National governments are in a position to identify patient safety as a policy priority within broader universal health coverage policies and plans, and to provide political support and resources for the assimilation of patient safety essential functions in health systems as well as in frontline care. Coordination and fostering inter- and intrasectoral collaborative action for patient safety is also an important role for health ministries and governments. Other governmental agencies, academic and research institutions, and the various bodies responsible for the education of health care professionals, civil society organizations, industry and other key stakeholders working at national and international levels will be important players in the transformation required.

26. WHO will work closely with WHO collaborating centres, international professional associations, patient organizations and international experts, which are active in the area of patient safety and national governments, to support the development and dissemination of technical resources and implementation of patient safety interventions at country level.

27. WHO will continue cooperating with countries and partners to enable the global action on patient safety through investing and mobilizing resources, sharing knowledge, coordinating efforts and fostering intersectoral action, providing technical expertise and establishing systems and practices for patient safety to ensure sustainable progress towards universal health coverage.

ACTION BY THE HEALTH ASSEMBLY

28. The Health Assembly is invited to adopt the draft resolution recommended by the Executive Board in resolution EB144.R12.

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