Regional strategy for patient safety in the WHO South-East Asia Region (2016–2025)

World Health Organization
Regional Office for South-East Asia

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Preface

The quality and safety of health care is a major concern of ministries of health in the South-East Asia Region. Governments are responsible for ensuring health services are safe and of good quality. Patient safety is an essential aspect of health-care quality. It includes preventing medical errors that may lead to adverse events and harm. The safety of the patient has to be kept in mind for all types of care and at all levels of care. As new health interventions have become more complex, the risk and potential for harm has increased.

Evidence shows that harm to patients is almost always a result not of failures of an individual health-care provider alone, but of a chain of failures in a health-care organization's operations as a whole. Therefore, it is of paramount importance that a systems approach to patient safety is adopted. Ensuring the quality and safety of health care is an enormous challenge for frontline health workers, health facility managers and ministries of health responsible for policy and regulatory frameworks. Towards this end, governments in Member States are adopting a range of policies, strategies and methods to improve patient safety, including strengthening related legislation and regulations.

Patient safety has been recognized as a growing international public health problem since 2002, when the World Alliance for Patient Safety was formed. In 2006, the Regional Committee of South-East Asia Region endorsed a resolution on patient safety.

The World Health Organization has developed guidelines, checklists and programmes to ensure quality and safety of health care and minimize health care-acquired infections, antimicrobial resistance and medical mismanagement as well as reduce hazards from clinical and biological waste. These can be used by Member States in their efforts to improve patient safety. The need for national patient safety strategies has also been emphasized.

To support the development of national patient safety strategies within the Region, an ad-hoc expert working group has developed this regional strategy. This has been endorsed by all Member States. It sets out six clear objectives that provide guidance for improving the quality and safety of health care in our Region.

Dr Poonam Khetrapal Singh
Regional Director

Acronyms

AIIMS	All India Institute of Medical Sciences, New Delhi, India
HAI	health care-associated infections
HCF	health-care facility/facilities
IndiaCLEN	India Clinical Epidemiology Network
IPC	infection prevention and control
MMR	maternal mortality ratio
OECD	Organization for Economic Co-operation and Development
UHC	universal health coverage

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Patient safety: a fundamental issue

Patient safety is a fundamental element of health care and can be defined as freedom for a patient from unnecessary harm or potential harm associated with health care. Medical errors can occur during various modalities of prevention, diagnosis, treatment and follow-up. Health care today is becoming increasingly complex and may include an array of complex procedures and processes, thereby increasing the probability of error.

Worldwide, adverse events occur in around 10% of hospital patients. Individual studies have reported adverse events from 4–17% of hospital admissions and 5–21% of these adverse events result in death. Evidence also suggests that half of these can be prevented. Adverse events in health care can occur due to a number of factors. These include:

- failures due to unsafe clinical practices such as unsafe surgery, poor hand hygiene practices, unsafe use of injections, blood products, medication, medical devices, and many others;
- unsafe processes such as communication failures and ineffective teamwork, not applying the principles of human factor ergonomics in pursuing patient safety, poor patient handovers, misdiagnosis, poor test follow-up; and
- poor systems and processes within an organizational culture that do not contribute to safety; a culture of blame, with production pressures, without effective regulation or accountability mechanisms, poor training and education of its health-care providers, and lack of organizational knowledge transfer and learning from adverse events.

Improving patient safety thus requires a system-wide effort involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and providing a safe environment of care.

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Burden of unsafe care

- In developed countries, as many as one in 10 patients is harmed while receiving hospital care. (WHO estimates)
- According to Institute of Medicine Report (1), in the United States of America, it is estimated that 44 000–98 000 medical error deaths occur annually (more deaths than from highway accidents, breast cancer, or AIDS).
- Health-care associated infections (HAI) complicate between 5% and 10% of admissions in acute care hospitals in industrialized countries.
- At any given time, 1.4 million people worldwide suffer from HAI (WHO estimates) and at least 50% of HAI are preventable.
- In the United States, there is one medication error/hospitalized patient /day (IOM data) and about 7000 deaths/year from medication errors in hospitals.
- Unsafe surgery leads to 7 million complications and 1 million deaths/year (WHO data).
- Unsafe injections account for 33% of viral hepatitis B (HBV), 42% of hepatitis C (HCV) and 2% HIV infections; over 70% of injections in primary care are unnecessary.
- In Australia, 15% of clinical handovers – when a patient is handled between units/health care team/ hospital-facilities/ community – lead to adverse events.
- In the USA, more than one million medical device error events occur annually, at a rate of 6.3 events per 1000 patient days. Between July 1999 and June 2000, there were 454 383 emergency department visits for an injury associated with a medical device and 58 000 died in the emergency department or were hospitalized.
- In the Republic of Korea, in 2005, 2006 and 2007, 1.8%, 2.7% and 12% respectively of persons interviewed reported that they suffered an adverse event with some form of traditional medicine (2).

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Magnitude in developing countries

Although not well documented, the scope of the patient safety problem in developing countries including in South-East Asia based on existing information is as follows.

- Evidence shows that the risk of acquiring HAI is 2–20 times higher in developing countries. Little information is available about national surveillance of HAI and data are mostly anecdotal. According to a recent review, surgical site infection is the most surveyed type of infection in low- and middle-income countries with incidence rates ranging from 1.2 to 23.6 per 100 surgical procedures and a pooled incidence of 11.8%. By contrast, surgical site infection rates vary between 1.2–5.2% in developed countries (3).
- A recent study on the burden of unsafe care estimates that there are 421 million hospitalizations in the world annually and approximately 42.7 million adverse events for the seven types: (i) adverse drug events, (ii) catheter-related urinary tract infections, (iii) catheter-related blood stream infections, (iv) nosocomial pneumonia, (v) venous thrombo-embolisms, (vi) falls and (vii) decubitus (pressure) ulcers, resulting in 23 million disability-adjusted life years lost per year. Approximately two thirds of all adverse events, and the disability-adjusted life years lost from them, occurred in low- and middle-income countries (4).
- Every year unsafe injections result in 1.3 million deaths mainly due to HBV, HCV and HIV(5). It is estimated that persons in the developing world receive on an average 1.5 injections per year and 50% of the injections are 'unsafe'. Unsafe practices include reuse of syringes and needles in the absence of (proper) sterilization, poor collection and disposal of dirty injection equipment which expose health-care workers and the community to the risk of needle stick injuries (6). According to an India Clinical Epidemiology Network (IndiaCLEN) study (7), on an average, in India, each person received 5.8 injections per year and nearly two thirds of the injections were administered in an unsafe manner (62.9%).
- Countries in South-East Asia produce over 1000 metric tons of health-care waste every day including injection-related waste which is not properly disposed of. In some countries, unsafe disposal can lead to re-sale of used equipment on the black market.

- At least 50% of medical equipment is unusable or only partly usable – resulting in substandard diagnosis and treatment (WHO). Although South-East Asia is a large producer of medical devices that are exported all over the world, the devices sold in the domestic market are often manufactured outside the regulatory framework and may not meet international standards.
- Developing countries account for 77% of all reported cases of counterfeit and substandard drugs and over 50% of all medicines prescribed, dispensed, or sold globally are not justified.

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WHO patient safety initiatives and programmes

- Resolution WHA 55.18 on Quality of care: patient safety (Annex 1) called upon Member States to pay the closest possible attention to the problem of patient safety and establish and strengthen science-based systems necessary for improving patient safety and quality of health care, including monitoring of drugs, medical equipment and technology. This was endorsed by the Regional Committee through resolution SEA/RC59/R3 on Promoting patient safety in health care (Annex 2). In October 2004, the WHO-hosted World Alliance for Patient Safety was launched with six major action areas. In 2009, the Alliance was renamed the Patient Safety Programme and became fully integrated into WHO as one of its regular programmes. The patient safety programme implements 12 programmes and special projects.
- One of the first initiatives of the Alliance was the global patient's safety challenge. The first challenge in 2005 focused on HAI with the theme "Clean care is safer care". The challenge promoted simple and practical measures such as handwashing in fighting the spread of HAI, which is a major issue in patient safety. Five countries in South-East Asia committed to the challenge. To gather momentum and commitment for the campaign, 5 May has been designated as the Global Hand Hygiene Day.
- The second challenge "Safe surgery saves lives" was about the application of standards of care for patients undergoing surgery and the implementation of the evidence-based WHO surgical safety checklist. By using the checklist, postoperative complication rates fall by one third, and death rates fall by a similar amount. The third challenge to be initiated in 2014 is on medication safety. This challenge aims to improve medication prescribing and develop awareness on medication safety.
- Patient safety research has been a major programme of WHO patient safety undertaking major global studies to understand and unveil the burden of unsafe care, primarily in developing and transitional countries, and strengthening the foundation for patient safety research, including building capacity in developing and transitional countries.

- Patients for patient safety is another major programme of WHO Patient Safety established in 2004. It aims to bring consumers, patients and their families at the centre of WHO efforts to improve patient safety worldwide.
- The patient safety education programme was established in 2009 to support the education and training of health-care professionals and students in quality improvements and patient safety. The multi-professional patient safety curriculum guide builds patient safety knowledge and capacity to practice safely.
- The African Partnership in Patient Safety is another major programme that aims to build sustainable patient safety partnerships between hospitals in countries of the WHO African Region and hospitals in other regions. The Partnership is concerned with advocating for patient safety as a precondition of health care and catalysing a range of actions that will strengthen health systems, assist in building local capacity and help reduce medical error and patient harm.
- Development of patient safety solutions through the High Fives Collaborative of WHO and seven developed countries, three standardized patient safety protocols have been developed. These are: 'Safe use of concentrated injectable solutions', 'Correct site surgery', and 'Medication reconciliation during transitions in care'.
- The WHO Safe Childbirth Checklist to support the delivery of essential maternal and perinatal care practices contains 29 items addressing the major causes of maternal and neonatal deaths and complications in low-income countries. It was developed following a rigorous methodology and tested for usability in 10 countries across Africa and Asia.
- Safe primary care is one of the WHO Patient Safety priority areas contributing to unveiling the burden of unsafe care in primary care settings and reviewing effective interventions to improve primary care safety.

WHO patient safety is implementing many supporting programmes such as 'Knowledge management for patient safety' and many projects such as the 'Minimal information model for patient safety' linked to reporting and learning systems, surgical unit-based safety programme, injection safety and others.

The patient safety programme has currently expanded its mandate for a greater integrated approach to service delivery, cutting across vertical programmes and inclusive of areas such as quality aspects of universal health coverage (UHC).

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Challenges and opportunities for patient safety in the South-East Asia Region

The South-East Asia Region of WHO includes 11 countries: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste. Most countries of the Region are developing countries, whereas some are in a state of transition. The general challenges for patient safety in health care in the Region are as follows.

- Limited resources, poor health-care infrastructure and equipment, particularly for infection control, the unreliable supply and quality of drugs and other supplies, and shortcomings in waste management, clean water and sanitation are major obstacles to patient safety.
- In some countries, hospital beds may be located in structures originally built for other purposes. This makes facilities for radiation protection and infection control extremely difficult to incorporate, with the result that such facilities are often either substandard or absent.
- Lack of safety culture and attitudes that overlook basic safety rules for both the patient as well as the health-care professional poses a serious problem.
- Patients do not question the doctor owing to lack of patient empowerment. Due to social and educational disparity, doctors feel there is no point in attempting to explain tests and test results to patients. Patients often sign consent forms without really understanding what they are consenting to.
- Health-care professionals are reluctant to register or talk about adverse events and medical errors for fear of embarrassment, punishment and litigation. Consequently, there is under-reporting of adverse events.
- Recently, the educated population has begun to challenge medical authority and the doctor–patient relationship is becoming more confrontational. For example, the number of litigation cases registered with the Thai Medical Council tripled between 1992 and 2002 from 32 to 105 per 10 000 medical doctors.

- Understaffing and lack of a skilled workforce ensures that an overburdened, frequently underskilled and inadequately supported health workforce is more prone to making medical errors.
- Regulation of the large and rapidly growing private health sector including the pharmaceutical and medical device manufacturing industries is a major challenge.

Many of the challenges for patient safety in the SEA Region can be attributed to health system weaknesses and are determined by broader public health policy and political and economic trends.

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Regional Committee resolutions

- Resolution SEA/RC59 on Promoting safety in health care adopted by the Regional Committee in Bangladesh in August 2006 calls for Member States and WHO to work together to ensure all actions to promote patient safety in the Region.
- Regional Committee resolutions pertaining to medication safety and rational and safe use of medicines are: SEA/RC62/R6 on Measures to ensure access to safe, efficacious, quality and affordable medicinal products, 2009 and SEA/RC63/R5 on Regional strategy on universal health coverage, 2010.
- In September 2013, the Regional Committee in its resolution SEA/RC66/R4 on Health intervention and technology assessment in support of universal health coverage, called for health technology assessment and research for information on their safety, effectiveness, quality and efficiency when they are integrated into health systems.

7

Progress in patient safety

Since the launch of the WHO patient safety programme eight years ago, reports from the countries of the Region have shown that there is a growing awareness of the problem, and countries with WHO assistance have shown the following progress in patient safety.

- In July 2006, prevention of HAI was identified as a priority area of work by participants at the first WHO regional workshop on patient safety, New Delhi, India.
- Regional workshop "Clean care is safer care" 2007 in Thailand promoted prevention of HAI and pledges were signed by ministries of health of the countries of the Region.
- Patients for patient safety workshop took place in Jakarta in 2007, and the Jakarta Declaration for patient-centred care was adopted (Annex 3).
- Patient safety / quality committees were established at the national level in India, Indonesia, Maldives, Sri Lanka, and Thailand. Patient safety became the driver of quality and accreditation.
- Policy-makers, head surgeons, anaesthesiologists and operating room nurses at the regional patient safety meeting discussed policies, standard processes and procedures and medical device planning and management to improve the safety of emergency and essential surgery at the first referral level in Bentota, Sri Lanka in January 2008.
- Bangladesh piloted WHO hand hygiene improvement guidelines and started the manufacture of alcohol-based hand rub according to WHO formulation in a Chittagong hospital.
- St Stephen's Hospital in Delhi was a pilot site to introduce the safe surgery checklist. This was also implemented at the All Institute of Medical Sciences, New Delhi, India (AIIMS).
- Maldives launched a national hand hygiene campaign.
- The Regional Office supported regional/national meetings, three each in 2008, 2009 and two in 2010, 2011.
- Thailand piloted a set of research tools for estimating adverse events.
- Patient safety champions collaborated with the College of General Practitioners in Sri Lanka to develop educational materials and patient and provider rights and responsibilities.

- The Jakarta Declaration was included in the Indonesian National Hospital Guidelines.
- Support was provided to national and subnational initiatives on the first and second challenges.
- Institutions encouraged and supported the celebration of Global Hand Hygiene Day on 5 May and implementation of hand hygiene tools.
- Health-care facilities (HCF) across Member States were encouraged and supported to implement the safe surgery checklist.
- Hospitals in the Region registered for "Save lives clean your hands" and "Safe surgery saves lives".
- In India, DGHS established patient safety programmes in all central government hospitals.
- Patient safety concepts were discussed in the network of medical councils to introduce the concepts in medical education and training.
- Maulana Azad Medical College, New Delhi, India and Patan Academy of Health Sciences in Nepal were the pilot sites for WHO Patient Safety Curriculum Guide. Medical schools across the Region are implementing the guide, mainly in India, Myanmar and Thailand.
- The Centre for Dental Education and Research of AIIMS was the pilot site for the Multi-professional Patient Safety Curriculum Guide.
- The WHO Safe Childbirth Checklist was piloted in a hospital in Karnataka, India.

Thus, with WHO support, countries of the South-East Asia Region are increasingly becoming aware of the need to pay attention and are making efforts to improve patient safety. Although isolated efforts have been shown to be effective, on the whole, the efforts are fragmentary and are facing resource and sustainability issues at many situations. In September 2013, through collaboration with the Organization for Economic Co-operation and Development (OECD), the WHO regional offices for South-East Asia and the Western Pacific have initiated a survey to review the status of quality of care and patient safety in the Asia–Pacific Region that includes all Member States of the Region.

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Need for a Regional strategy on patient safety

Resolution SEA/RC59/R3 requested WHO to "coordinate through an inclusive consultation the development of a strategic framework and package of interventions for strengthening patient safety which builds on successful interventions in the Region and worldwide".

In line with the RC resolution, there is urgent need to consolidate and build on the current efforts in the area of patient safety, analyse and learn from these efforts, and adapt and apply the best practices with due consideration to sustainability.

A strategic framework for patient safety for the Region is required to be developed to define future work in this area for Member States as well as WHO.

The regional strategy is being framed in response to the following needs:

- under the overarching mandate of UHC, the need to bring patient safety at the centre at all levels of health care – primary, secondary and tertiary – and all modalities of health care including prevention, diagnosis, treatment and follow-up;
- need to provide Member States of the Region with a strategic framework for patient safety as a basis for development of national plans and policies in patient safety;
- need to provide guidance for implementation of patient safety programmes at national and subnational and HCF levels; and
- need to integrate with vertical programmes in the cross-cutting areas to offer safe and quality service delivery.

It is also opportune that a detailed situation analysis be done in the Member States as a baseline to clearly define the status of patient safety in the Region to charter further progress. The survey initiated by WHO in collaboration with OECD in September 2013 will fulfil this need.

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Guiding principles

- **Focusing on health systems improvement**: Adverse events are primarily due to system failures rather than individuals. The numbers, distribution, skills of workforce and how the work is organized and service delivered should be improved. Human error does have a role, but it is only part of the problem of lapses in patient safety. Therefore, strategies for risk reduction must focus on strengthening and bringing about changes in systems along with targeting individual practices or products.
- **Strengthening capacity through education and training**: Building competencies and skills and making patient safety a necessary component of educational curricula and training of all levels of health-care workers is important.
- **Learning from mistakes and minimizing risks in future:** Building an enabling environment to support nonpunitive reporting and establishing systems of monitoring, measuring and learning is critical.
- **Adopting a patient-centred approach:** Empowering patients and involving them as partners in patient safety is imperative.
- **Targeting all levels of health care**: Being a fundamental cross-cutting issue, patient safety should be brought to the core of health care.
- **Introducing evidence-based interventions**: Interventions that have been shown to improve patient safety should be applied.
- **Establishing priorities:** Priorities should be established and implemented through a step-by-step incremental approach.
- **Identifying implementing agencies:** Governmental implementing agencies at all levels should be identified and progress monitored.
- **Ensuring sustainability:** Implementation of patient safety strategy should be guided by the cultural context in which the services are situated – efficient use of resources (human, physical and financial), the ability to scale up and be sustainable.

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Goal

Under the overarching goal of providing safe and quality UHC, the goal of the patient safety strategy is to improve patient safety at all levels of health care in both public and private sectors, from primary to referral level, and all modalities of health care, including prevention, diagnosis, treatment and follow-up.

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Objectives

The objectives of the patient safety strategy are to:

- improve the structural systems to support quality and efficiency of health care and place patient safety at the core of all levels of health care;
- assess the nature and scale of harm to patients and establish a system of reporting and learning at the national level;
- ensure a competent and capable workforce that is aware and sensitive to patient safety;
- prevent and control health care-associated infection;
- improve implementation of global patient safety campaigns and strengthen patient safety in all health programmes; and
- strengthen capacity for and promote patient safety research.

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Strategic objectives and key interventions

Strategic objective 1: To improve the structural systems to support quality and efficiency of health care and place patient safety at the core at national, subnational and health-care facility levels

Rationale

Patient safety is seen as a critical component of quality, which in turn is set in the broader context of provision of health services. Quality and safety are system issues and cut across many divisions, units and modalities of health care. An important patient safety issue is communication between health-care professionals and between health-care professionals and patients. This has wide ramifications, and miscommunication at various levels can result in unsafe care. The major areas where this can occur are: drug administration, phlebotomy, blood transfusions and surgical interventions. In health care today, each patient is cared for by an increasing number of team members, thereby adding to the likelihood of handover and other communication problems. To be effective and sustainable, efforts at establishing quality and a culture of safety need to be approached by an understanding of the existing culture and the wider cultural context in which the health services are situated.

1.1: Institutionalizing patient safety and strengthening the legal and regulatory framework and national policies for quality and patient safety

Interventions

- establishing patient safety as a priority in national health policies, plans and in all health programmes, specifying patient safety goals and targets and the corresponding timelines and affixing accountability and responsibility;
- establishing national multidisciplinary patient safety committees involving professional and nongovernmental organizations and consumer groups to formulate national priorities and actions;

- informing policy by operations research and evidence-based interventions;
- identifying key government departments and other bodies who will be responsible for execution of policies;
- developing a legal and regulatory framework as well as a system of enforcement for quality and patient safety, including legislation on the quality of health-care professionals, care of services (hospitals, nursing homes and clinics), quality and safety of drugs, technologies and laws on patient rights;
- establishing a dedicated quality and patient safety department in the ministries of health at the national, sub-national and institutional levels to coordinate patient safety;
- encouraging third party players to support and provide incentives for patient safety;
- educating and engaging the media and civil society as responsible partners; and
- promoting patient safety-friendly hospitals.

1.2: Establishing accreditation and other external quality assessment mechanisms

Interventions

- establishing independent and autonomous government-linked institutions for accreditation of HCF including laboratories and diagnostic facilities;
- involving health professional organizations;
- developing guidelines, national safety standards and indicators for health-care quality and safety for structure, process and outcomes with regular updates;
- liaising and collaborating with regional health-care accreditation institutions such as the Asian Safety and Quality Association, Thai and Indian accreditation bodies;
- establishing mechanisms for implementation of quality standards; and
- developing systems for monitoring and evaluation of quality and feedback.

1.3: Establishing a culture of safety and improving communication, patient identification, handing over and transfer protocols in health-care facilities (HCF)

Interventions

- identifying the individuals responsible for patient care quality and safety from the senior leaders in the organization and viewing patient safety as an organizational priority;
- ensuring that hospital managers, clinicians, and all levels of health-care staff are responsible for patient safety at their levels and held accountable;
- establishing a local mechanism to collaborate and set policies and procedures that support quality and patient safety and cooperation on a daily basis and ensure implementation;
- seeking to focus on human factors including interdisciplinary patient-centred care, team training, improving communication and handover and transfer protocols;
- establishing a system of patient identification and labelling to eliminate errors in transitions of care such as patient transfers and handovers;

- developing the infrastructure and capacity to introduce and strengthen information technology to minimize errors in patient care;
- promoting the use of checklists in patient care processes (e.g. surgery, childbirth, trauma care, discharge, admission);
- establishing and strengthening a clinical audit system for system improvement;
- including quality and safety elements in all outsourcing contracts for investigative facilities, housekeeping, waste management, food supply; and
- establishing a system for monitoring and feedback for all patient safety processes.

1.4 Establishing patient-centred care and involving patients as partners in their own care

Interventions

- involving patients and consumer advocates in patient safety committees and patient safety initiatives;
- identifying and protecting patients' rights in the context of patient safety and seeking to understand patient satisfaction/experience in the health-care process;
- ensuring that patients are informed and empowered to exercise their rights;
- obtaining informed consent for treatments and procedures carrying risk to patients;
- seeking the patient's participation in decisions regarding their care, communicating with patients in the cultural context in a language they can understand;
- involving patients and their families in their own care;
- creating an enabling environment in which individuals feel safe to report incidents and near-misses;
- encouraging and setting up mechanisms for reporting of incidents by patients and their families;
- establishing/strengthening the mechanism for handling grievances and complaints from patients and their families; and
- communicating and counselling patients and their families and also the staff involved when an adverse event occurs.

WHO has developed resources and a programme on Patients for Patient Safety (8).

(See Annex 3 for the Jakarta Declaration on Patients for Patient Safety, created as a result of the regional workshop held in Jakarta, Indonesia, in July 2007.)

Strategic objective 2: To assess the nature and scale of adverse events in health care and establish a system of reporting and learning

Rationale

Planning and prioritizing effective safety interventions require a thorough understanding of the nature of the problem. Countries must assess both the overall burden on the population and the health-care system of harm to patients in order to guide policy. At the clinical level, understanding the specific problems particular to each specialty is necessary for effective intervention. However, data collection is not an end in itself, but should be followed by effective action and need not delay action on immediate and obvious local problems. The importance of reporting near-misses cannot be emphasized enough, as they are the greatest sources of learning.

Interventions

- conducting a baseline assessment of the overall burden of unsafe care in the country by getting data from published reports, mortality and morbidity meetings, autopsy reports, analysis of patient complaints, medical litigation cases, media, clinical and technology audits and quality assurance programmes;
- developing patient safety incident surveillance and a system of reporting and learning from all adverse events and near-misses at national, subnational and HCF levels;
- establishing and implementing a proactive patient safety risk identification and management plan;
- establishing a nonpunitive culture (nonpunitive indemnity, medical liability) which encourages more open and transparent reporting of adverse events;
- developing patient safety taxonomy harmonizing with international patient safety taxonomy; and
- establishing a system of analysing all reported incidents (adverse events as well as near misses) to guide appropriate interventions at institutional, subnational, national and HCF levels to prevent their recurrence.

A WHO technical report detailing a conceptual framework for patient safety incorporating international patient safety taxonomy is available (9). A resource on reporting and learning from adverse events has also been developed by WHO (10).

Strategic objective 3: To ensure a competent and capable workforce that is aware and sensitive to patient safety

Rationale

Health-care workers at the frontline are critical in the delivery of patient care. Understaffing and poor performance of health-care workers are basic impediments to patient safety. Patients assume that the health-care professionals providing care and treatment are competent and capable. It is essential that there are adequate numbers of staff and all health-care professionals have valid credentials and the required competencies and skills and are aware of patient safety concepts and issues.

3.1: Strengthening education, training and professional performance inclusive of skills, competence and ethics of health-care personnel

Interventions

- developing policies related to licensing of health-care professionals, continuous professional education and development, professional certification and recertification;
- establishing accreditation of health-care professional education and training for improvement of standards of education and training;
- improving the way work is organized and services are delivered and appropriately skilled persons positioned for the task; and
- developing standard treatment guidelines and standard operating procedures for health-care practice and ensuring compliance.

3.2: Improving the understanding and application of patient safety and risk management in health care

Interventions

- identifying the roles of health professional councils, universities, professional associations for education and training in patient safety;
- integrating patient safety principles and practice in all health-care professional courses for doctors, nursing, dental and other paramedical professionals in undergraduate and postgraduate disciplines inclusive of patient safety concepts, development of core competencies, knowledge and skills;
- encouraging patient safety to be a part of bedside teaching, onsite learning and field work;
- reinforcing a culture of patient safety by advocacy, awareness, patient safety campaigns and behaviour modification methods for involvement and buy-in by all categories of health-care staff;
- addressing patient safety at the time of employment and induction and making it a component of performance reviews; and
- conducting periodic assessments of health-care staff on their understanding and awareness of patient safety principles and practice.

WHO has developed a curriculum guide for patient safety education that is responsive to the needs and requirements of the different professionals in the health-care workforce (11).

Strategic objective 4: To prevent and control health-care associated infections

Rationale

Health-care settings are environments with high prevalence of infectious disease agents and can be a source of infection to patients, their families, staff and the community at large. It is, therefore, imperative that infection control programmes are established. HAI cause major complications and adverse events that can occur in health care – particularly so in developing countries. HAI can

result in serious illness, prolonged hospital stay, draining of health-care resources and loss of life. Health-care workers' hands have been shown to be the single most important means of transmission of HAI. The first Global Patient Safety Challenge addresses control of HAI with the theme "Clean care is safer care". The term encompasses clean hands, clean products, clean equipment and clean environment, improvement of hand hygiene being the primary thrust area. WHO has developed guidelines on hand hygiene in health care (12) and tools to implement the recommendations (13). Pilot studies on hand hygiene improvement using the WHO multimodal strategy have shown that the implementation of the strategy is feasible and sustainable across a range of settings in different countries and leads to significant compliance and knowledge improvement in health-care workers (14). (See Annex 4 for details of pilot sites.)

Standards for cleaning and hygiene are lacking in many countries. A clean environment is important not only for aesthetic reasons, but because a contaminated environment can serve as an important source for transmission of infection and antimicrobial resistance. Infection and other hazards (injuries from sharps, chemicals and radiation) can also affect the community through improperly managed health-care waste. Appropriate and validated disinfection and sterilization processes for patient care items are critical to prevent infections, particularly in invasive procedures and forms an essential part of the infrastructure to ensure patient safety.

4.1: Strengthening infection prevention and control structure and programmes across all health-care services and all levels of care

Interventions

- establishing infection prevention and control (IPC) policies at national, subnational and HCF levels, from primary through referral care;
- focusing on improvement in hand hygiene practices as per WHO guidelines using the multimodal strategy for hand hygiene in line with resources and priorities, establishing and implementing the core components (15) of IPC programmes at national as well as HCF levels, inclusive of:
  - strengthening the structure for IPC, including infection control committee and team, allocating responsibility, appropriate design and ventilation of HCF, provision of sinks and running water, supplies for hand hygiene and other IPC practices, isolation precautions, provision of isolation facility and sterile supplies (4.2);
  - providing clean and safe environment (4.3);
  - building capacity and human resource for IPC, including training of infection control nurse, integrating infection control education and training in undergraduate, postgraduate courses and continuing medical education;
  - developing technical guidelines, standard operating procedures for IPC and practice (16);
  - establishing/strengthening surveillance of infection and compliance with infection control practices;
  - strengthening microbiology laboratory support; and
  - developing a system of monitoring, evaluation and continuous feedback for improvement.
- integrating infection control principles and practices across health services in all health programmes.

4.2: Providing appropriately cleaned, disinfected or sterilized equipment for patient care as required

Interventions

- strengthening sterile supply department in HCF for sterilization and disinfection of items for patient care, having trained workforce, appropriate equipment and validated processes and procedures.

4.3: Providing a safe and clean environment by improving the general hygiene sanitation and management of health-care waste in health-care facilities (HCF)

Interventions

- establishing policies at national, sub-national and HCF levels on environmental health and ensuring implementation;
- establishing and ensuring implementation of overall environmental standards for health care at national, subnational and HCF levels regarding supply of safe water, excreta disposal, drainage, waste management, cleaning and laundry, food storage and preparation, control of vector-borne diseases, building design including ventilation, construction and management, and hygiene promotion as recommended by WHO (17);
- establishing and ensuring systems for the sound management of health-care waste at all HCF levels and ensuring compliance;
- establishing a dedicated environmental services department in each HCF to look after cleaning and sanitation, waste management and disposal and putting in place infrastructure for safe, efficient, cost-effective cleaning and sanitation of the environment;
- building the awareness and capacity of health-care workers, sanitary and supervisory staff in cleaning and sanitation and occupational safety;
- building awareness of the principles of hygiene and sanitation for patients including visual reminders; and
- establishing systems to ensure standards of cleaning and sanitation are maintained including monitoring and process control.

Strategic objective 5: To improve implementation of global patient safety campaigns and strengthen patient safety in all health programmes – safe surgery, safe childbirth, safe injections, medication safety, blood safety, medical device safety, and safe (organ, tissue and cell) transplantation

5.1 Safe surgical care

After the first challenge "clean care is safer care", safe surgical care has been identified as the second global patient safety challenge or campaign. Globally, it is estimated that about 234 million major surgical operations are conducted a year (one operation for every 25 persons). Out of these, 7 million patients annually may have post-operative complications and 1 million patients may die

every year during or after an operation. In developing countries, the most vulnerable is the surgical care provided at the first referral level. In response to this, WHO has developed tools and guidelines (18) and an Aide memoire (19). Further, to prevent complications due to surgery and interventional procedures at all levels of care, a simple safe surgery checklist has been developed by WHO (20) along with guidance (21) on how to implement it in the HCF. Pilot studies of this checklist (one at New Delhi, India) have shown that the use of checklists significantly reduces surgical morbidity and mortality (22).

Interventions

- developing a national plan for surgical services at primary, secondary and tertiary levels of care;
- strengthening surgical and emergency obstetrical care at the first referral level through an integrated strategy including appointment of trained personnel, continuing education, provision of appropriate facilities and equipment and supplies, and improving systems for referral and transfer to specialized health facilities;
- ensuring the quality and provision of care at all levels of surgical care by:
  - implementing safe surgery checklist and guidelines for all surgical procedures;
  - establishing rational and appropriate antimicrobial prophylaxis in surgery;
  - promoting safe anaesthesia and surgery; and
  - establishing validated sterilization practices and protocols for regular monitoring of sterilization (as in 4.2).

5.2: Safe childbirth

Rationale

The South-East Asia Region of WHO has one of the highest maternal mortality and neonatal mortality rates in the world. Among the 11 countries in the Region, Bangladesh, India, Indonesia, Myanmar and Timor-Leste have an MMR of 200 or above per 100 000 live births; Bhutan and Nepal have over 150 maternal deaths per 100 000 live births. In India as a whole, 33 neonatal deaths occur per 1000 live births in the country. Universal access to high-quality health care is the cornerstone for designing and implementing programmes to improve maternal and child health. To improve the quality of care at childbirth and support the delivery of essential maternal and perinatal practices, WHO has developed a Safe Childbirth Checklist (23). Pilot studies have shown that the use of checklists is effective in ensuring that standard practices are followed at childbirth, leading to safer care.

Interventions

- applying interventions to strengthen the health system for delivery of quality maternal, newborn and child health services in alignment with the maternal, neonatal and child health programmes;
- ensuring basic standard of care at all levels from primary health care to all levels of referral care; and
- applying the WHO Safe Childbirth Checklist to support the delivery of essential maternal and perinatal practices.

5.3: Safe injections

Rationale

Each year, unsafe injections cause 1.3 million deaths, primarily due to transmission of blood-borne pathogens such as hepatitis B virus, hepatitis C virus and HIV. Unsafe practices include reuse of syringes and needles in the absence of (proper) sterilization, poor collection and disposal of dirty injection equipment that expose health-care workers and the community to the risk of needle stick injuries. In some countries, the proportion of injections given with syringes or needles reused without sterilization is as high as 70%. According to the IndiaCLEN Study, each person in India received on an average 5.8 injections per year and nearly two thirds of injections were administered in an unsafe manner (62.9%). Countries in South-East Asia produce over 1000 metric tons of health-care waste every day including injection-related waste that is not properly disposed of. In some countries, unsafe disposal can lead to resale of used equipment on the black market.

Interventions

- formulating national policies and plans for the safe and appropriate use of injections in alignment with list of essential medicines;
- ensuring the quality and safety of injection equipment and equitable access;
- developing and implementing national standards for safe injection practices;
- ensuring education to all health-care workers on safe and appropriate injection practices; and
- establishing regulations and guidelines on management of sharps waste.

To tackle the problem of unsafe and unnecessary injections, WHO has developed guidelines and tools on safe injection practices (24).

5.4: Medication safety

Rationale

The selection and use of medicines have a major impact on the quality of care and patient safety. Inappropriate selection of medicines and their use can cause considerable harm and is a frequent cause of medical error. Irrational use of antibiotics can lead to resistance in microbes and at times the organisms can develop resistance to all the available antibiotics. A regional strategy to control antimicrobial resistance was developed (25). Medication error can also occur due to miscommunication during handovers and the presence of sound-alike look-alike drugs causing inadvertent mistakes in drug administration. In many countries of the Region, traditional medicine is practised. These medicines may interact with medicines prescribed under the allopathic system. Further, traditional medicines may not be subject to regulation and quality control. Another issue that can compromise medication safety is that some medicines are counterfeit. Antibiotics and other essential medicines are often counterfeited and their use leads to treatment failure and sometimes death. Substandard products could result from poor manufacturing practices, unsuitable packaging, storage and distribution; or when generic drugs are produced by unregistered manufacturers. Donated medicines can also fail quality tests and potentially unsafe and irrational donation practices can compound the problem. Weaknesses in health-care systems and a shortage of resources lead to underdeveloped medicine control systems, unqualified health workers and poor medical services.

A weak regulatory system may also fail to prevent the availability of substandard or counterfeit medicines. Medication safety has been identified as the third global patient safety challenge to be launched in 2014.

Interventions

- establishing medicines policy including medication safety and a well-coordinated national system to implement and monitor the policy to ensure access to safe medicines at national, subnational and HCF levels;
- developing a national formulary of essential medicines (cost-effective and safe) focusing on priority conditions;
- developing/maintaining national standard treatment guidelines covering the common health conditions;
- establishing antimicrobial stewardship programme and system of monitoring antimicrobial resistance in alignment with the regional strategy on prevention and containment of antimicrobial resistance at national, subnational and HCF levels;
- strengthening regulatory mechanisms to ensure the quality of drugs and including pharmaco-vigilance as well as strengthening of drug-testing laboratories;
- strengthening procurement of medicines to ensure quality and avoidance of sound-alike look-alike drugs;
- bringing traditional medicines under mechanisms to ensure quality of products, practices and practitioners;
- making information regarding appropriate use, side effects and drug interactions of all medicines including traditional medicines easily available;
- ensuring that curricula of prescribers at undergraduate and postgraduate levels and in continuous medical education include the safe effective use of medicines through standard treatment guidelines and essential medicine lists and making the information readily available;
- improving the identification and labelling of medicines and communication of medication orders at HCF level; and
- engaging civil society, consumer groups and patient organizations to empower and educate patients about the risks and benefits of drugs.

WHO guidance is available on how to develop and implement a national drug/medicines policy (26). Guidance is also available on the rational use of medicines (27) and model essential drug lists (28).

5.5: Blood safety

Rationale

The supply of safe blood and blood products and their safe and rational use is one of the primary requirements for patient safety and plays a major role in preventing the transmission of HIV, hepatitis viruses and other blood-borne pathogens in the health-care setting. Voluntary, non-remunerated blood donations can reduce the risk of transmission of infections. In the Region, only around 75% of donated blood is obtained from voluntary donors. WHO recommends voluntary blood donation

and the safe and rational use of blood, reducing unnecessary transfusions, thus minimizing the risk of adverse events including errors, transfusion reactions and transmission of infections.

Interventions

- establishing well-organized nationally coordinated blood transfusion services supported by national blood policy and legal and regulatory framework that could ensure access to safe blood and blood products as part of UHC;
- establishing 100% blood collection from regular voluntary, non-remunerated blood donors from low-risk population;
- ensuring testing of all donated blood including screening for transfusion-transmitted infections, blood grouping, and compatibility testing;
- ensuring and strengthening quality system for blood transfusion and safety;
- reducing unnecessary transfusions through effective clinical use of blood, including use of simple alternatives, wherever possible; and
- establishing a haemo-vigilance programme.

WHO has defined the core components for developing a national blood system (29).Several tools and guidelines for blood safety including guidance for universal access to safe blood transfusion (30) and on clinical transfusion process and patient safety (31) are also available.

5.6: Medical device safety

Rationale

The use of appropriate, efficacious, quality and safe medical devices has a far-reaching effect on patient safety. It is, therefore, essential to strengthen the various stages in the lifespan of the medical device, including assessment, manufacture, acquisition, procurement and utilization. WHO estimates that at least 50% of medical equipment in developing countries is unusable or only partly usable, in some situations even upto 75–80%. Often the equipment cannot be utilized due to inappropriate selection and lack of supporting skills or commodities. As a result, diagnostic procedures or treatments cannot be performed.

Many countries procure medical devices that may be substandard. Some manufacturers of medical devices may also be unaware of minimum standards. Since most developing countries import medical devices, vendor and product registrations, user training and continued assessment of medical devices in use are required on priority basis.

Interventions

- developing a policy on health technology (medical devices) in collaboration with all stakeholders (manufacturers, importers, users and the public);
- dedicating a department for health technology at the national authority;
- developing capacity for health technology assessment, management and regulation;
- establishing/strengthening health technology assessment to inform the use of health technology;

- developing/strengthening national medical device regulatory or monitoring programme to include:
  - basic acceptance criteria: requirements on safety and performance, quality systems, packaging and labelling
  - import control
  - local production control
  - vendor and product registration
  - post-market surveillance
  - user education
  - donations
  - refurbished devices/equipments;
- adopting recommendations on global harmonization for regulatory requirements and procedures;
- ensuring that classified medical devices are manufactured in conformity with applicable quality system standards;
- applying human factor engineering approach;
- empowering the public to insist on safe, quality, affordable and sustainable products;
- establishing and implementing policies and protocols for the reuse of medical devices; and
- establishing link to international networks that monitor medical devices and participate in post-market surveillance and medical device alert issues.

Guidance on safe medical devices for national medical device administrators and technical report series on management of medical devices (32), medical device assessment (33) and medical device regulation (34) are available from the WHO.

5.7: Safe organ, tissue and cell transplantation and donation

Rationale

Human organ and tissue transplantation is end-stage therapy for diseases that cannot be treated by other means where successful outcomes require high levels of expertise, selection of correct donor and careful monitoring of recipient and recipient compliance. The transplantation of human organs, tissues and cells has led to concerns with respect to the direct transmission of communicable disease, control of processing and ensuring clinical safety and effectiveness. In addition, there are difficulties in overcoming religious and cultural bias and preventing the buying and selling of organs, the latter being fuelled by poverty.

Interventions

- establishing national organ transplantation programme and comprehensive legislation for all organs, tissues and cells for transplantation, using the WHO guiding principles (35);
- ensuring that regulations should include qualifications for transplant surgeons and physicians, ancillary and support services, standards for organ donor evaluation, screening and documentation, monitoring and surveillance;

- strengthening health system requirements including those of physical infrastructure and skilled human resource to meet the multidisciplinary requirements of transplantation with quality and safety as the fundamental principles;
- instituting an effective oversight mechanism to assure compliance with national regulations on organ transplantation;
- developing a deceased donor organ programme to enhance availability of organs;
- promoting community awareness to overcome religious, social and cultural myths associated with organ donation and stimulating altruistic feelings in the community;
- developing alliances between institutions within and outside the country for cooperation in legal, ethical and technical aspects; and
- instituting regulations of health tourism to inhibit illegal organ trafficking.

Strategic objective 6: To strengthen capacity for and promote patient safety research

Rationale

Evidence-based policy development in health systems including the decisions on resource allocation, service system designs and translation of policies into practice are weak in many developing countries. Capacities to research and document the health, economic, fiscal, social and ethical implications of health interventions, including those for patient safety need strengthening, as they are inadequate in most countries of the Region, resulting in incomplete information to guide rational policy and professional decisions.

Interventions

- promoting and facilitating research on patient safety by making patient safety a priority area;
- identifying research needs and priorities by surveys, consultations, expert group meetings;
- strengthening capacity in data quality and analysis, in research methodology, proposal writing and conducting operations research;
- facilitating access to scientific publications and articles;
- strengthening ethics committees to oversee patient safety research; and
- ensuring wide dissemination of research results and the translation of successful interventions into a form that can be replicated.

WHO has developed a series of documents on research in patient safety including a guide for training programmes for conducting research (36), developing core competencies for research (37) and ethical issues in patient safety research (38).

The Sixty-eighth session of the WHO SEA Regional Committee adopted the Regional Strategy for Patient Safety 2016–2025 by SEA/RC68/R4 Resolution (Annex 4). The Resolution urges Member States to translate the six strategic objectives of the Regional Strategy for Patient Safety in the WHO South-East Asia Region into actions, implementation, monitoring and evaluations in line with country context among others.

Annex 1

Resolution WHA55.18: Quality of care: patient safety

The Fifty-fifth World Health Assembly,

Having considered the report on quality of care: patient safety;

Concerned that the incidence of adverse events is a challenge to quality of care, a significant avoidable cause of human suffering, and a high toll in financial loss and opportunity cost to health services;

Noting that significant enhancement of health systems' performance can be achieved in Member;

States by preventing adverse events in particular, and improving patient safety and health-care quality in general;

Recognizing the need to promote patient safety as a fundamental principle of all health systems,

1. URGES Member States:

   (a) to pay the closest possible attention to the problem of patient safety;

   (b) to establish and strengthen science-based systems, necessary for improving patients 'safety and the quality of health care, including the monitoring of drugs, medical equipment and technology.

2. REQUESTS the Director-General in the context of a quality programme:

   (c) to develop global norms, standards and guidelines for quality of care and patient safety, the definition, measurement and reporting of adverse events and near misses in health care by reviewing experiences from existing programmes and seeking inputs from Member States, to provide support in developing reporting systems, taking preventive action, and implementing measures to reduce risks;

   (d) to promote framing of evidence-based policies, including global standards that will improve patient care, with particular emphasis on product safety, safe clinical practice in compliance with appropriate guidelines and safe use of medicinal products and medical devices taking into consideration the views of policy-makers, administrators, health-care providers and consumers;

   (e) to support the efforts of Member States to promote a culture of safety within health-care organizations and to develop mechanisms, for example through accreditation or other means, in accordance with national conditions and requirements, to recognize the characteristics of health-care providers that offer a benchmark for excellence in patient safety internationally;

   (f) to encourage research into patient safety, including epidemiological studies of risk factors, effective protective interventions, and assessment of associated costs of damage and protection; and

   (g) to report on progress to the Executive Board at its 113th session and to the Fifty-seventh World Health Assembly.

Annex 2

Resolution SEA/RC59/R3: Promoting patient safety in health care

The Regional Committee,

Recalling World Health Assembly resolution WHA55.18 relating to "Quality of care: Patient safety",

Noting with concern the high human and financial toll of adverse events in both developed and developing nations,

Conceding that the problem is likely to be even greater in developing nations,

Recognizing that most of the harm to patients is due to failures in the design, organization and operation of systems,

Acknowledging that a large proportion of adverse events are therefore preventable,

Noting with concern the potential problems in the Region because of the vicious cycle of adverse events and malpractices, law suits and medical liability insurance, the practice of defensive medicines and the rising costs of health care,

Aware that no single stakeholder has the expertise or delivery capabilities to adequately tackle the full range of patient safety issues, and

Having considered the report and recommendations of the Technical Discussions on Promoting patient safety at health-care institutions in South-East Asia during the Forty-third Meeting of the Consultative Committee for Programme Development and Management,

1. ENDORSES the recommendations contained in the report (SEA/RC59/11 (Rev.1) and SEA/RC59/Inf.4);

2. URGES Member States:

   (a) to assess the scope and nature of adverse events in health-care institutions as well as the contributing factors;

   (b) to establish or improve, with the involvement of all stakeholders, systems for the detection and reporting of adverse events with a primary focus on improving systems;

   (c) to develop national mechanisms to capture, share, respond, and learn from this information at all levels of the health system;

   (d) to promote interventions that have been shown to improve patient safety;

   (e) to support and enable health-care institutions, both public and private, from the primary health-care level through the referral level, to implement systems changes and practices conducive to patient safety;

   (f) to create, at all levels of the health-care system, through awareness raising and enabling policies and legislation, an open environment receptive to the operational changes needed to deliver safer care in health care institutions;

(g) to engage patients, consumer associations, health-care workers, and professional associations, hospital associations, health-care accreditation bodies and policy-makers, in building safer health-care systems, and creating a culture of safety within health-care institutions;

(h) to establish systems that respect the rights of both patients and providers, and

(i) to allocate adequate resources to implement the above activities, and

3. REQUESTS the Regional Director:

(a) to coordinate, through an inclusive consultative process, the development of a strategic framework and package of interventions for strengthening patient safety which builds on successful interventions and actions in the Region and worldwide;

(b) to provide strong technical leadership and support to Member States in designing and implementing patient safety interventions and monitoring systems;

(c) to ensure capacity building in different aspects of patient safety through training activities at the regional, sub-regional, and country levels;

(d) to facilitate collaboration and the exchange of information and best practices between Member States and the World Alliance on Patient Safety;

(e) to coordinate and facilitate research on patient safety in the Region, including baseline surveys on adverse events, and operational research to assess the cost effectiveness of interventions;

(f) to contribute to the development of a patient-safety taxonomy, systems for reporting and learning from adverse events, and best practices to improve patient safety, and

(g) to monitor and report on progress in this area in the Region.

Annex 3

Jakarta Declaration on Patients for Patient Safety in countries of the South-East Asia Region

We, the patients, consumer advocates, health care professionals, policy-makers and representatives of nongovernmental organizations, professional associations and regulatory councils having reflected on the issue of patient safety in the regional workshop on patients for patient safety', 17–19 July 2007, in Jakarta, Indonesia, referring to Resolution SEA/RC59/R3 on Promoting patient safety in health care, adopted at the Fifty-ninth Session of the Regional Committee for South-East Asia Region, which notes "with concern the high human and financial toll of adverse events" and "the vicious cycle of adverse events, law-suits, and the practice of defensive medicine and the rising cost of health care", and urges Member States to "engage patients, consumer associations, health-care workers, professional associations, hospital associations, health-care accreditation bodies and policy-makers, in building safer health-care systems and creating a culture of safety within the health-care institutions",

Considering the recommendations in the proceedings of the first regional workshop on patient safety, 12–14 July 2006, in New Delhi, India, inspired by the WHO World Alliance for Patient Safety, Patients for Patient Safety London Declaration (March 2006), we:

(1) declare that no patients should suffer preventable harm;

(2) agree that patients are at the centre of all patient safety efforts;

(3) acknowledge that fear of blame and punishment should not deter open and honest communication between patients and health-care providers;

(4) recognize that we must work in partnership in order to achieve the major behavioural and system changes that are required to address patient safety in our Region;

(5) believe that: transparency, accountability and the human touch are paramount to a safe health- care system; mutual trust and respect between health-care professionals and patients are fundamental; patients and their carers should know why a treatment is given and be informed of all risks, big or small, so that they can participate in decisions related to their care; patients should have access to their medical records;

(6) recognize that when harm does occur: there should be a system in place whereby the event can be reported and investigated with due respect to confidentiality; patients and their families should be fully informed and supported; providers involved in unintentional harm should also receive support; corrective actions should be taken to prevent future harm and widely share lessons learnt; there should be a mechanism to fairly compensate the patient and their family;

(7) commit to: consumer empowerment through frank and candid education; partnering with the media to encourage responsible reporting and seize opportunities to educate the public; active consumer participation in adverse event reporting; two-way communication among patients and health-care providers that encourages questioning; meaningful patient representation on patient safety committees and forums; and

(8) pledge to achieve through sustained efforts the following goals: functioning quality and patient safety systems in every health-care facility, both public and private, starting with the establishment of a patient safety committee and of an adverse event reporting and response system; adherence to guidelines that are evidence-based and ethical and avoidance of irrational treatments such as unnecessary medicines, investigations and surgical procedures; continuing medical education for health-care professionals; integration of patient safety concepts into pre- and in-service training of allied health-care professionals; rational load of patients in each health-care facility; adequate resources devoted to patient safety; motivated and competent health-care professionals; satisfied patients and providers.

Annex 4

Resolution SEA/RC68/R4: Patient safety contributing to sustainable universal health coverage

The Regional Committee,

Recalling Resolution RC59/R3 on promoting patient safety in healthcare,

Acknowledging that health services are still not as safe as they should be; that up to one in ten patients experience adverse events in health facilities, safety among health personnel is still a major concern, and that there are compelling health and economic arguments for improving patient safety,

Realizing that improved patient safety and quality of care are essential in gaining trust by the population, and an integral element in progressing towards universal health coverage, and further recognizing that improved quality and safety requires the engagement of stakeholders in particular patients and health professionals, and beyond health sector,

Recognizing barriers for improving patient safety, including reporting errors and adverse events, safety culture, effective communication and coordinated care among health professionals, and the need for a whole systems solution,

1. ENDORSES the Regional Strategy on Patient Safety (2016–2025)[1];

2. URGES Member States:

   (a) to translate the six strategic objectives of the Regional Strategy for Patient Safety in the WHO South-East Asia Region into actions, implementation, monitoring and evaluations in line with country context;

   (b) to engage all relevant stakeholders in building safer health-care facilities, creating and sustaining a culture of safety at all levels of health care;

   (c) to create awareness and engage patients and communities in the process of improved patient safety, in strengthening health systems and supporting UHC;

   (d) to consider allocating adequate resources to implement the country action plan; and

3. REQUESTS the Regional Director:

   (a) to provide technical support to Member States in implementing the Regional Strategy and country action plans;

   (b) to facilitate collaboration and the exchange of information and best practices between Member States, regional and global networks; and

   (c) to report progress, achievements and challenges in implementing this Resolution to the Regional Committee in 2017, 2019, and facilitate assessment of the patient safety in Member States in the Region, upon request, and report to the Regional Committee in 2021.

[1] *Regional strategy for patient safety in the WHO South-East Asia Region, SEA-HSD-378 http://apps.searo.who.int/PDS_DOCS/B5187.pdf?ua=1*

Annex 5

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The quality and safety aspect of health care is of utmost importance in health service delivery. Health services that are provided should be of very high quality and should be safe for the service providers as well as recipients.

Considering the importance of patient safety in the Region, a Regional strategy for patient safety was drafted to be adopted by Member States. The draft strategy was presented to a group comprising experts from the Region as well as from Headquarters and further improved. Based on the recommendations of the expert group, the draft was discussed at a regional consultation and finalized. This Regional Patient Safety Strategy was unanimously endorsed by representatives of all 11 SEAR Member States.

This document will be useful for service providers in the health-care sector, programme managers and those in charge of hospital administration.

Link for publication: http://www.searo.who.int/entity/patientsafety/documents/sea-hsd-378.pdf?ua=1

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