



# **Regional Strategy on Patient Safety**

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**Report of the regional consultation  
Colombo, Sri Lanka, 22-24 April 2014**

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## Acronyms

BMHC	Bhutan Medical and Health Council
CDC	Center for Disease Control, Atlanta, USA
CSMBS	Civil Service Medical Benefit Scheme
CME	continuing medical education
CPOE	computerized physician order entry
DALY	disability-adjusted life years
D/HQS	Director, healthcare quality and safety
DMS	Director, Medical Services
DOH	Department of Health
DRA	drug regulatory authority
FCHV	female community health volunteer
EHCS	essential health-care services
EMTD	essential medicines and technology division
HAI	health-care associated infection
HAMT	hospital administration and management transformation
HIV	human immunodeficiency virus
HCF	health-care facility
HSM	health systems management
HTA	health technology assessment
India CLEN	India Clinical Epidemiology Network
IPC	infection prevention and control

ISO	International Standards Organization
JCI	Joint Commission International
MMM	man money material
MMR	maternal mortality ratio
MOH	Ministry of Health
MOPH	Ministry of Public Health
NHSO	National Health Security Office
OECD	Organization for Economic Co-operation and Development
PG	postgraduate
PHCC	primary health-care services
PSM	preventive and social medicine
QA	quality assurance
QASD	quality assurance and standards division
RC	Regional Committee
SALA	sound alike, look alike
SEAR	South-East Asia Region
SSI	surgical site infection
SSO	social security office
TOT	training of trainers
TTI	transfusion-transmitted infection
UG	undergraduate
WHA	World Health Assembly
WHO	World Health Organization

# 1. Background

Patient safety is a fundamental issue of health-care. It can be defined as freedom for a patient from unnecessary harm or potential harm associated with health-care. Patient safety cuts across all modalities of health-care including prevention, diagnosis, treatment, follow-up and rehabilitation.

Health-care today is becoming increasingly complex and may include an array of complicated procedures and processes, thereby increasing the probability of error.

Worldwide, the occurrence of adverse events occurs in around 10% of hospital patients. Individual studies have reported adverse events from 4% to 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, and use of medical devices;
- unsafe processes such as communication failure and ineffective teamwork, not applying the principles of human factor ergonomics, 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.

### ***Burden of unsafe care in the developing world***

- The potential for unsafe care in developing countries is estimated to be much higher than in the developed world. Overall, the high potential for harm associated with health-care could be attributed to limited resources, poor health-care infrastructure and equipment - particularly for infection control, the unreliable supply and quality of drugs and other supplies, and deficiencies in waste management, clean water and sanitation. Evidence shows that the risk of acquiring a health-care-associated infection (HAI), one of the major problems for patient safety is 2–20 times higher in developing countries.
- 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 and exporter of medical devices, 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.
- 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, and poor collection and disposal of dirty injection equipment<sup>1</sup>.

A recent study on burden of unsafe care estimates that there are 421 million hospitalizations in the world annually and approximately 42.7 million adverse events, resulting in 23 million DALYs lost per year. Approximately two-thirds of all adverse events, and the DALYs lost from them, occurred in low- and middle-income countries<sup>2</sup>.

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<sup>1</sup> Simonsen L, Kane A, Llyod J et al Unsafe injections in the developing world and transmission of bloodborne pathogens: a review –*ibid*:-789-800

<sup>2</sup>Jha A; Larizgoitia I; Audera-Lopez C; Prasopa-Plaizier N; Waters H; Bates D. The Global Burden of Unsafe Medical Care: An Observational Study. *BMJ QualSaf*, 2013;22:809-815.]

Many of the challenges for patient safety in the South-East Asia Region can be attributed to health system weaknesses and are determined by broader public health policy as well as political and economic trends.

## **2. WHO initiatives for patient safety**

The potential of harm as a consequence of the process of health-care is increasingly being recognized and patient safety is seen as a major concern for health-care throughout the world.

World Health Assembly resolution WHA55.18 (May 2002) (**Annex 1**) called upon the Member States to pay the closest possible attention to the problem of patient safety and to establish and strengthen science-based systems necessary for improving patient safety and quality of health-care, including monitoring of drugs, medical equipment and technology.

In October 2004, the WHO-hosted World Alliance for Patient Safety was launched which was later named as the Patient Safety Programme and became fully integrated into WHO as one of its regular programmes.

## **3. Regional Committee resolutions on patient safety**

- Resolution SEA/RC59/R3 on Promoting safety in health care adopted by the Regional Committee for South-East Asia Region in Bangladesh in August 2006 called for Member States and WHO to work together to ensure all actions to promote patient safety in the Region (**Annex 2**)
- Regional Committee resolutions pertaining to medication safety and rational and safe use of medicines are: RC SEA/RC62/R6 (measures to ensure access to safe, efficacious, quality and affordable medicinal products, 2009) and SEA/RC63/R5 (Regional strategy on universal health coverage, 2010).
- In September 2013, the Regional Committee through 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 the

safety, effectiveness, quality and efficiency of health technologies when they are integrated into health systems.

## **4. Progress in patient safety in the South-East Asia Region**

Since the launch of the World Alliance for Patient Safety in 2004 followed by the WHO patient safety programme, reports from countries in the Region have shown that there is a growing awareness of the problem. The countries, with WHO support, have shown the following progress in patient safety.

- WHO regional workshop on patient safety was held in 2006, in New Delhi, India.
- Regional workshop on “Clean care is safer care” was held in 2007 in Bangkok, Thailand.
- Patients for patient safety workshop took place in Jakarta in 2007 and adoption of the Jakarta Declaration (**Annex 3**) for patient-centred care.
- Patient safety/quality committees were established at national level in India, Indonesia, Sri Lanka, Thailand and Maldives leading to patient safety becoming the driver of quality and accreditation.
- Workshop on emergency and essential surgery at the first referral level held in Bentota, Sri Lanka.
- In 2008, Bangladesh piloted WHO hand hygiene improvement guidelines and started to manufacture 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 check list. It was also implemented at the All India Institute of Medical Sciences, New Delhi.
- Maldives launched a national hand hygiene campaign.
- The WHO Regional Office for South-East Asia supported regional/national meetings, three each in 2008 and 2009 and two in 2010 and 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 in all Member States in the Region on the first and second challenges i.e. “Clean care is safer care”, “Safe surgery saves lives” of the five challenges identified by WHO patient safety programme.
- Institutions were encouraged and supported to celebrate 5 May as Global Hand Hygiene Day and to implement hand hygiene tools.
- Health-care facilities across the Member States were encouraged and supported to implement the safe surgery check list.
- 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 a meeting of the network of medical councils with the recommendation to introduce the concepts in medical education and training.
- Maulana Azad Medical College, New Delhi and Patan Academy of Health Sciences in Nepal were the pilot sites for WHO Patient Safety Curriculum Guide. Medical schools across the Region mainly in India, Thailand and Myanmar, are implementing the guide.
- The Centre for Dental Education & Research, at the All India Institute of Medical Sciences (AIIMS) is the pilot site for the multi-professional patient safety curriculum guide.
- The WHO safe child-birth check list 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 to patient safety and are making efforts to improve patient safety. Although isolated efforts have been shown to be effective, the efforts are generally fragmentary and are facing resource and sustainability constraints. In September 2013, in collaboration with OECD, the WHO regional offices for South-East Asia and the Western Pacific initiated surveys to review the status of quality of care and patient safety in the Asia-Pacific region which includes the 11 Member States of the South-East Asia Region.

## **5. Need for a regional strategy on patient safety**

The Regional Committee through resolution SEA/RC59/R3 requested WHO to “coordinate through an inclusive consultative process for 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 resolution there is an urgent need to consolidate and build on the current efforts in the area of patient safety, to 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 the Member States as well as WHO.

A regional strategy was framed in response to the following needs.

- Under the overarching mandate of universal health coverage, there is a 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 health-care facility (HCF) levels.
- 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 of patient safety be conducted in the Member States as a baseline to clearly define where we are in the Region in patient safety to charter further progress. The survey initiated by WHO in collaboration with OECD in September 2013 partly fulfilled the need.

## **6. Process for developing the regional strategy document**

### ***The first draft***

After reviewing available documentation on patient safety strategies globally and regionally, studying the challenges and the status of patient safety in the Region, identifying the existing gaps, examining World Health Assembly and Regional Committee resolutions in patient safety and related documents; a draft “Regional Strategy for Patient Safety” for South-East Asia Region was prepared. The list of documents reviewed and consulted is given in Annex 4.

### ***Expert group meeting***

The first draft prepared by Health System Management unit in the Regional Office was finalized in consultation with experts in patient safety at an expert group meeting held at the Regional Office in New Delhi from 10–11 October 2013. The experts were from different fields of health-care including health administration, accreditation and quality, clinical disciplines, education, infection control and health research. The various technical units in the Regional Office dealing with patient safety were also represented. The patient safety team from WHO/HQ participated through a video conference. The list of participants and the report of the expert group meeting is in Annex 5.

The experts deliberated on and reviewed the draft regional strategy for improvement of patient safety in the South-East Asia Region and made suggestions and recommendations.

The draft was revised based on these suggestions and recommendations. The revised draft was then circulated widely among patient safety experts and the concerned technical units in WHO/ HQ and the Regional Office for comments. The suggestions and comments were incorporated and a second draft was developed.

## 7. Draft regional strategy for patient safety

The draft regional strategy had the following components.

### *Guiding principles*

Adverse events are primarily due to system failures rather than due to individuals. The numbers, distribution, skills of the work force and how the work is organized and services delivered should be improved. Human error does have a role, but it is only part of the problem of lapses in patient safety.

- **Focus on health systems improvement:** focusing on strategies for risk reduction on strengthening and bringing about changes in systems along with targeting individual practices or products;
- **Strengthen 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;
- **Learning from mistakes and minimizing risks in future:** building an enabling environment to support non punitive reporting and establish systems of monitoring, measuring and learning;
- **Patient-centred approach:** empowering patients and involving the patient as a partner in patient safety;
- **Target all levels of health-care:** being a fundamental cross-cutting issue, bring patient safety at the core of health-care;

- **Evidence-based interventions:** applying interventions that have been shown to improve patient safety;
- **Establish priorities:** implementing through a step-by-step incremental approach;
- **Identify governmental implementing agencies:** monitoring the progress of implementation; and
- **Ensure sustainability:** implementing the patient safety strategy in the cultural context in which the services are situated, efficient use of resources (human, physical and financial), and the ability to scale up and be sustainable.

### **Goal**

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

### **Objectives**

The **strategic objectives** of the patient safety strategy are as follows:

- improving the structural systems to support quality and efficiency of health-care and place patient safety at the core at all levels of healthcare;
- assessing the nature and scale of harm to patients and establishing a system of reporting and learning at the national level;
- ensuring a competent and capable workforce which is aware and sensitive to patient safety;
- preventing and controlling health-care- associated infection;
- improving implementation of global patient safety campaigns and strengthening patient safety in all health programmes; and
- strengthening capacity for and promoting patient safety research.

### ***Interventions***

For each strategic objective, a set of interventions were framed to achieve the objective.

## **8. Tool for assessment of patient safety**

To define the baseline situation of patient safety and to assess the implementation of the strategy, an assessment tool was developed as a companion to the regional strategy document. The assessment tool was based on the strategic objectives of the regional strategy. Instructions were provided on the approach and how to fill the document.

## **9. Proceedings of the regional consultation for finalization of the documents**

A regional consultation to finalize the regional strategy on patient safety and its assessment tool was held in Colombo, Sri Lanka from 22–24 April 2014.

### **9.1 Objectives**

The objectives of the consultation were:

- to review the current status of patient safety programmes in Member States, assess gaps and draft action points;
- to review the draft regional strategy for patient safety and the assessment tool; and
- to discuss the way forward and agree on a roadmap for the next few years.

The participants included nominees and representatives from the ministries of health, and other patient safety stakeholders from the public as well as private health-care sector in countries of the Region.

The participants, resource persons, facilitators and the WHO secretariat for the consultation are listed in **Annex 6**. There was representation from all 11 Member States. However, three nominees from

the Government of India and one each from Bangladesh and Maldives could not attend the meeting. All participants had received the draft regional strategy as well as the assessment tool before the meeting and had been invited to make comments and suggestions and bring these to the meeting. An outline of the agenda and programme are listed in **Annexes 7 and 8**.

## **9.2 Inaugural session**

The Deputy Director Medical Services, Ministry of Health, Sri Lanka, Dr Lakshmi Somatunga, welcomed the participants and guests to the inaugural session. Dr Sunil Senanayake, WHO Regional Adviser for Health Systems Management and Patient Safety presented an overview of the consultation. He informed that patient safety is not a new concept but dates back to the fourth century BC to the time of Hippocrates and that the first medical audit was conducted by Florence Nightingale during the Crimean war.

Dr Arturo Pesigan, acting WHO Representative to Sri Lanka read the Regional Director's message (see text of message at **Annex 9**). In her message, Dr Poonam Khetrapal Singh stated that one out of 10 patients is harmed during hospital care all over the world and the burden of harm is much higher in developing countries as compared to the developed world. She informed that the South-East Asia Region is the first WHO Region to put together a regional strategy to improve patient safety and quality of care. The Sri Lankan Health Secretary's address was delivered by Dr Amal Harsha de Silva, Additional Secretary, Medical Services and the importance of patient safety in the health sector was reiterated. The Ministry of Health of Sri Lanka, recognizing the need for quality and safety in health-care, had established a separate Directorate for Health-care Quality and Safety and was working actively in promoting and establishing patient safety in the country.

## **9.3 Technical session**

Dr Ugen Dophu, Director-General, Medical Services, Royal Government of Bhutan and Dr Sathasivam Sridharan Director, Health-care Quality and Safety, Ministry of Health, Sri Lanka, were nominated as Chair and Rapporteur respectively.

Dr Senanayake presented the results of the WHO/OECD survey part I conducted in 2013, to identify the current status of patient safety in South-East Asia Region including policies, legislation and mechanisms in place for patient safety in the responding countries<sup>3</sup>. The points made are briefly summarized below:

- All countries have some documents or policies on quality of care developed over the past 10 years.
- A majority of countries have targets and goals, but only a limited number of countries have specific targets.
- All countries have institutions on quality of care and have some laws on quality of care.
- While some countries have specific laws on quality, others have more general laws including quality of care articles.
- The specific laws cover three categories: professionals, institutions, and safety of drugs and devices.

#### **9.4 Discussion on the draft regional strategy and assessment tool for patient safety**

The draft regional strategy document was presented in detail by Dr Geeta Mehta. Each strategic objective and the interventions to achieve the objective were deliberated upon by the participants. Suggestions and comments for improvement of the document were incorporated.

Similarly, the assessment tool was presented in detail. The various elements, including the recording and grading system were discussed thoroughly and changes and recommendations suggested and incorporated.

A final review of the regional strategy and assessment tool was done by the country participants. The 11 countries participating in the consultation were divided into three groups.

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<sup>3</sup> 8 out of 11 SEAR countries had responded to the OECD survey at the time, a further 3 countries (Bhutan, and ) have responded at the time of writing this report.(???)

After the final review of the strategy and its assessment tool, the individual country situations were discussed and a way forward defined for each country for the next 4–5 years.

## 9.5 Country presentations

### ***Bangladesh***

#### **Current status**

- MOH and WHO piloted the WHO guideline on multimodal strategy on hand hygiene in Chittagong Medical College Hospital in 2007.
- Prevalence survey of health-care-associated infection (HAI) was conducted.
- Training modules on hand hygiene for health-care providers—doctors, nurses, health workers were developed.
- Outcome of WHO project was disseminated.
- National hand hygiene guidelines were revised.
- Surgical checklist for introduction in HCF was prepared.

#### **Way forward**

- advocate on patient safety with policy-makers;
- create focal point for quality management and patient safety under the MOH;
- establish a separate unit under the Directorate of Health Services to implement patient safety initiatives;
- create a national accreditation programme to accredit health-care facilities at all levels;
- create a quality management unit at all tiers of HCF;
- develop guidelines and SOPs for quality of care;
- conduct training and adapt guidelines;

- conduct monitoring and evaluation of the activities related to patient care; and
- conduct periodical research to improve patient safety standards.

## ***Bhutan***

### **Current status and way forward**

In alignment with the Strategic objectives of the Regional patient safety strategy:

<b>Strategic Objective</b>	<b>In place</b>	<b>Way forward</b>
SO 1: Structure for patient safety	<ul style="list-style-type: none"> <li>• Bhutan Medical and Health Council (BMHC) – 2000</li> <li>• Drug regulator authority (DRA) – 2003</li> <li>• Quality assurance and standards division (QASD) – 2004</li> <li>• Essential medicines and technology division (EMTD)- 2010</li> <li>• Rollout of HAMT Activities in 2011</li> <li>• Patient safety guideline 2013</li> <li>• Patient safety policy (under development)</li> </ul>	Establish patient safety committees
SO 2: Assess nature and scale of adverse events	Incident reporting started in nursing division at national hospital	Introduce transparent reporting system of adverse events by all HCF in the country

Strategic Objective	In place	Way forward
SO 3: Develop competent and capable work force	<ul style="list-style-type: none"> <li>• SOPs developed at the national level</li> <li>• Guidelines on continuing medical education – 2009</li> </ul> <p>In the process of revising Medical and Health Council Act-2002</p>	Develop mechanism to assess compliance with Standards at different level of HCF
SO 4: Prevent and control HAI	<ul style="list-style-type: none"> <li>• HAI surveillance started in 2012</li> <li>• Revised - Infection Control and Waste Management guideline - 2014</li> </ul>	Develop guideline on recording and reporting of HAI
SO 5: Implementation of WHO patient safety campaigns and strengthening health programmes	<p>Guidelines and SOPs followed for implementation of:</p> <ul style="list-style-type: none"> <li>• Safe surgical care</li> <li>• Safe injections</li> <li>• Safe medicines</li> <li>• Blood safety</li> </ul>	Develop mechanism of assessing overall burden of unsafe care
SO 6: Promote patient safety research	Initiatives in patient safety research have not been taken	Include patient safety research in health research priority

***Democratic People’s Republic of Korea***

**Government commitment for patient safety:**

- universal free medical care since 1960s;
- robust health system covering central to peripheral levels;
- household doctor system;

- newly-built health facilities with advanced medical equipment and devices; and
- law on infection control in 2009, MOPH infection control board and hospital infection control board established in tertiary and county hospitals.

**Activities undertaken:**

- Guideline on “Prevention and control of hospital infection” was developed and distributed to all concerned.
- National training was conducted for over 300 doctors on patient safety on an annual basis.
- IEC poster, “Clean hand is top need for prevention of hospital infection” was developed and 10 000 copies distributed to all concerned which contributed to improving knowledge of six steps hand washing.
- A bacteriological monitoring system against hospital infection bacteria was established in Pyongyang Medical University in Kim Il Sung University since 2008.
- A system to monitor patients infected in hospital established.
- Delivery of culture medium supported by WHO to provincial hospitals was followed by local training on monitoring system for bacteriological examination experts.

**Way forward**

- update national strategic plan on patient safety in line with regional strategy;
- assess implementation status of patient safety programme and strengthen in depth research;
- develop local assessment tool in line with regional tool with WHO support;
- build health professionals on patient safety;



Strategic objective	In place	Gaps	Way forward (Action plan)
	system adapted JCI standards <ul style="list-style-type: none"> <li>• Accreditation programme is mandatory for all HCF</li> </ul>		stakeholders
SO 2: Assess nature and scale of adverse events	On-going web-based national reporting system for hospitals. Some hospitals implement incident reporting system	No integrated national reporting system, feedback, and learning  No policy on national reporting of adverse events	Develop integrated national reporting system, feedback, and learning  Formulate national policy on reporting of adverse events
SO 3: Develop competent and capable workforce	Implementation of curriculum on patient safety for 18 medical faculties since 2012 according to the WHO Standard	Curriculum on patient safety for other health-care professionals not developed  Lack of integration with the National strategy on Patient safety	Develop curriculum on patient safety for other health-care professionals education  Integrate with the National Strategy on Patient Safety
SO 5: Implementation of WHO patient safety campaigns and strengthening health programmes	National policy on safe surgical care, safe child birth, safe injection, safe medicine, safe blood safety.  Implementation of surgical checklist in some tertiary HCF at national level	Implementation of surgical checklist in all levels of HCF	Improve and disseminate surgical checklist

## Maldives

### Current status and the way forward

In alignment with the strategic objectives of the regional patient safety strategy:

Strategic Objective	In place	Gaps	Way forward (Action plan)
SO 1: Establish structure for patient safety	<ul style="list-style-type: none"> <li>National policy and planning division.</li> <li>National insurance policy (AASANDHA)</li> <li>QID (guidelines identification...)</li> <li>ISO-certified (Lab/Physiotherapy units)</li> </ul>	<ul style="list-style-type: none"> <li>Lack of accreditation</li> <li>No expansion of national policies and guidelines to regional and atoll hospitals</li> </ul>	Establish a mechanism for accreditation of tertiary hospital, regional hospitals, atoll hospitals and health posts
SO 2: Assess nature and scale of harm to patients and reporting	<ul style="list-style-type: none"> <li>Incident reporting (patient / staff) situation assessed/ investigated/ reported</li> </ul>	<ul style="list-style-type: none"> <li>Lack of national audit</li> <li>Lack of proper investigations at district level</li> </ul>	<ul style="list-style-type: none"> <li>Public reporting system.</li> <li>National audit.</li> </ul>
SO 3: Establish competent and capable work force	<ul style="list-style-type: none"> <li>Licensing policies (all professionals).</li> <li>Nursing procedure guidelines and SOPs (all departments).</li> </ul>	<ul style="list-style-type: none"> <li>Role of patient safety is not identified by regional and atoll councils as a priority</li> <li>No treatment guidelines</li> </ul>	<ul style="list-style-type: none"> <li>Initiate treatment guidelines</li> <li>Develop nationally nursing procedure guidelines</li> </ul>
SO 4: Prevent and control HAI	<ul style="list-style-type: none"> <li>ICP policy</li> <li>IC manuals/ guidelines</li> <li>Cleaning / disinfection guidelines</li> <li>Infection control committee</li> <li>IC nurse in every unit/</li> <li>Patient safety nurse</li> <li>Few HAI indicators (SSI/ incidents reports etc)</li> </ul>	<ul style="list-style-type: none"> <li>Lack of IC committees or PS nurse in district hospitals (regional / atoll/ health post)</li> <li>Lack of incineration facilities</li> </ul>	<ul style="list-style-type: none"> <li>Establish proper incineration facilities</li> <li>Conduct analysis of HAI nationally</li> <li>Strengthen the reporting system</li> </ul>

Strategic Objective	In place	Gaps	Way forward (Action plan)
SO 5: Implementation of global patient safety campaigns and patient safety in all health programmes	<ul style="list-style-type: none"> <li>Safe surgery check list (perioperative) maternal/ guidelines for medication/ injections and blood transfusion. Reuse of medical devices</li> </ul>	No organ, tissue and cell transplantation	<ul style="list-style-type: none"> <li>National implementation of the guidelines used in Indira Gandhi Memorial Hospital.</li> <li>Legal and a regulatory framework for quality and patient safety.</li> <li>Establish a register to follow up (transplant patients).</li> </ul>
SO. 6: Strengthen capacity and promote patient safety research	<ul style="list-style-type: none"> <li>People with ideas</li> </ul>	<ul style="list-style-type: none"> <li>Records not retained.</li> <li>Lack of access to information (national).</li> <li>No budget for research.</li> </ul>	<ul style="list-style-type: none"> <li>IT system.</li> <li>Begin patient safety research with information on quality indicators collected from HCF.</li> </ul>

## Myanmar

### Current status and the way forward

In alignment with the strategic objectives of the regional patient safety strategy

Strategic Objective	Way forward (proposed activities)
SO 1.1: Institutionalize patient safety and develop/strengthen legal/regulatory framework	<ul style="list-style-type: none"> <li>Patient safety as a priority in national health policy and plans</li> <li>Patient safety committee at national and other levels</li> <li>Policy and priorities</li> <li>Focal points DoH and medical division</li> <li>Legal and regulatory framework</li> </ul>
SO 1.2: Accreditation and external QA mechanism	<ul style="list-style-type: none"> <li>Develop accreditation mechanism for HCF with involvement of professional organizations</li> <li>Develop guidelines and national safety standards and indicators</li> <li>Establish system for monitoring and evaluation of quality</li> </ul>
SO 1.3: Local mechanisms for patient safety	<ul style="list-style-type: none"> <li>Patient safety committee</li> <li>Focal persons for quality management</li> <li>Mechanism for implementation of quality management including all outsourcing contracts</li> </ul>

Strategic Objective	Way forward (proposed activities)
SO 1.4 Patient-centred care and involvement as patients as partners in their own care	<ul style="list-style-type: none"> <li>• Involvement of patients and consumer advocates</li> <li>• Mechanism for reporting incidents</li> <li>• Mechanism for handling grievances and complaints</li> </ul>
SO 2: Assess the nature and scale of adverse events	Patient safety incident surveillance and a system of reporting
SO 3: Capable and competent workforce sensitive to patient safety	<ul style="list-style-type: none"> <li>• Integration of patient safety principles and practices in all courses for healthcare professionals in collaboration with director medical services (DMS)</li> <li>• Development of standard treatment guidelines and SOPs for healthcare practice (review and revise the existing ones)</li> </ul>
SO 4: Prevention and control of HAI	<ul style="list-style-type: none"> <li>• Clean and safe environment</li> <li>• Improvement in hand hygiene practices</li> <li>• Strengthen IPC</li> </ul>
SO 5: Improve implementation of patient safety campaigns and health programmes	<ul style="list-style-type: none"> <li>• Safe surgical care</li> <li>• Safe childbirth</li> <li>• Safe injections</li> <li>• Medication safety</li> <li>• Blood safety</li> </ul>
SO 6: Promote patient safety research	<ul style="list-style-type: none"> <li>• Promote research on patient safety in collaboration with Department of Medical Research and-identification of needs and priorities, as well as budget allocation and capacity building.</li> </ul>

## ***Nepal***

### **Current situation and the way forward**

- Nepal is adopting quality assurance (QA) in its national health policy and plan.
  - Nepal Health Sector Programme (NHSHP-II) focus on health promotion and prevention as well as quality of health service.
  - Endorsement of quality health care policy.
  - Quality-of-care-improvement-process-implementation-guidelines.

- NHSP Implementation Plan is largely focused on establishment of QA mechanism for the public and private sectors has been included in output # 8.
  - Nepal Health Sector Strategy: An agenda for Reform (2004), has recognized the importance of establishing service protocols and quality standard.
  - The Second Long-Term Health Plan has recognized the need for establishing QA systems in the public, NGO and private sectors.
  - It has also provided some strategic guidelines for developing QA system.
- **Initiatives towards patient safety:** Although patient safety has been grossly ignored, Nepal is presently taking the following initiatives:
- implementing national standards for basic maternal, neonatal and child health programmes;
  - following national healthcare waste management guidelines;
  - formulating IPC training guidelines to be implemented in all HCFs;
  - starting maternal and perinatal death review system;
  - implementing integrated health management system up to female community health volunteer level; and
  - starting QA in health-care services programme.
- The quality assurance programme will have the following elements:
- A QA steering committee will be formed at central and district levels to oversee, coordinate and monitor the policies and strategies related to quality of health-care services.
  - A QA section will be established at the management division under the Department of Health Services which will be developed as a focal point for quality improvement.
  - In the first phase, standards, guidelines and clinical protocols will be reviewed and/or developed for four major components of essential health-care services (EHCS) i.e rural

hospital, child health centres, centre for disease control (CDC) and Out Patient Departments.

- Managers and providers will be oriented on importance of quality of care, service provision and quality improvement approaches and user's rights to quality health services.
- A medical and death audit system such as maternal death audit or new-born death audit will be established up to the PHC level in a phased manner.
- Public/private/NGO sector health-care providers will follow and implement the national standards, guidelines and protocols of MoHP.
- Regular monitoring will be carried out by the quality assurance section at all levels of government, nongovernmental and private sector health institutions.
- Quality assurance committees will be formed at national and sub-national (district) levels. These committees will be multidisciplinary with representation from all stakeholders including consumer groups.
- The national health professional council, Nepal Medical Council, Nepal Nursing Council, Nepal Ayurveda Medical Council and Nepal Pharmacy Council will be involved in QA activities.

***Action plan for patient safety in the next 4–5 years***

- Appointment of focal person for QA and establishment of a patient safety unit at different levels of HCF under MoPH.
- Identification of available resources: man-money-materials and utilization.
- Implementation of the WHO regional strategy for QA and patient safety.
- Orientation, training, licensing and legalization of healthcare work force.
- Regular monitoring, supportive supervision and evaluation.

## **Sri Lanka**

### **Current status and the way forward**

In alignment with the strategic objectives of the regional patient safety strategy:

<b>Strategic Objective</b>	<b>In place</b>	<b>Way forward</b>
SO 1: Structure for patient safety	<ul style="list-style-type: none"> <li>• Policy on health-care quality and safety</li> <li>• Directorate of health-care quality and safety at national level</li> <li>• Health-care quality and safety established in 22 districts and 42 hospitals</li> <li>• Working group on healthcare quality and safety</li> </ul>	<ul style="list-style-type: none"> <li>• Further strengthen and establish health-care quality and safety at subnational and institutional levels</li> </ul> <p>Link basic health units and districts to D/HQS to monitor quality and safety</p>
SO 2: Adverse event reporting system	<ul style="list-style-type: none"> <li>• Draft adverse event report form and readmission form with process of reporting and guidelines are available</li> </ul>	<ul style="list-style-type: none"> <li>• Introduce national adverse event reporting form, readmission and death audit forms</li> </ul>
SO 3: Competent workforce sensitive to patient safety	<ul style="list-style-type: none"> <li>• Clinical guidelines and national guidelines developed on health-care quality and safety</li> <li>• TOT manual on health-care quality and safety</li> <li>• Patient safety included in a few medical schools</li> <li>• Quarterly performance review meetings initiated</li> </ul>	<ul style="list-style-type: none"> <li>• Complete the revision of clinical guidelines and guidelines on health-care quality and safety</li> <li>• Capacity building in patient safety</li> <li>• Introduce patient safety in UG medical, nursing and PSM curricula throughout the country</li> </ul> <p>Continue performance review meetings</p>

Strategic Objective	In place	Way forward
SO 4: Prevention and control of HAI	Every secondary and tertiary care hospital has infection control unit and a nurse in-charge of it Infection control meetings are encouraged to be held	<ul style="list-style-type: none"> <li>• Antibiotic policy for all institutions which will be taken into account when assessing performance</li> <li>• National review meetings on infection control</li> <li>• Three indicators – hand washing, microbial resistance staphylococcus aureus (MRSA) and post-surgical infection at national level</li> <li>• Training programmes for all infection control stakeholders will be conducted from July 2014 to reduce variability</li> <li>• Revision of national guidelines on infection control in collaboration with the College of Microbiologists</li> </ul>
SO 5: Strengthen global patient safety campaigns	Surgical safety checklist introduced	<ul style="list-style-type: none"> <li>• To be continued to cover all levels and all hospitals in the country</li> <li>• Introduction of adverse event reporting form with guidelines</li> <li>• Introduction of readmission form with guidelines</li> <li>• Introduction of guidelines for clinical audit</li> <li>• Monitoring of handwashing practice</li> </ul>
SO 6: Research on patient safety	<ul style="list-style-type: none"> <li>• Introduction of PG diploma in quality and safety</li> <li>• Research at MSc and MD level since 2011</li> <li>• Young medical officers being introduced to clinical audit</li> </ul>	<ul style="list-style-type: none"> <li>• To continue and extend to other universities</li> <li>• Share best practices at the end of every year</li> <li>• Strengthen research and publication in peer reviewed international journals</li> </ul>

## **Thailand**

### **Current status**

- Thailand has a well-developed patient safety programme which covers all levels of health-care.
- There is an integrated network of health-care services from primary to referral site.
- The programme covers the six strategic objectives of the patient safety strategy and all aspects of care from prevention and promotion to diagnostic, curative and rehabilitation.
- National policies on patient safety have been formulated by MOPH in collaboration with Health-care Accreditation Institute.
- Third party national health security office (NHSO), social security office (SSO) and Civil Service Medical Benefit Scheme (CSMBS) is established.
- Both private and public sectors are involved in patient safety activities in the respective health facilities

### **Way forward**

- **Action implementation**
  - Establishing committee from MOPH departments, HAI and partners
  - Mapping and aligning WHO's guidelines, tools to Thailand's patient safety goals 2008
  - Finding and filling the gaps
  - Integrated implementation at all levels of health-care services of the six strategic objectives and sub-objectives of the strategy.

- **Monitoring and evaluation**
  - Self-assessment
  - Inspection, evaluation and supervision
  - Surveillance and accreditation
- **Tools and references**
  - WHO guidelines and tool for assessment of regional patient safety strategy
  - Thailand hospital standard 2006
  - Thailand patient safety goals 2008

**Timor-Leste**

**Current status and the way forward:**

In alignment with the strategic objectives of the regional patient safety strategy:

Strategic Objective	In place	Way forward, beginning 2014
SO1: Establish infrastructure for patient safety	Dept. of quality control	Establish quality committee at national and HCF levels
	Legal regulatory framework	To finalize
	Accreditation mechanism for HCF	To strengthen
	Checklists for patient care process	To implement at national and district levels
	Patient satisfaction/experience in health-care process	Implement at national and district levels
SO 2: Assess nature and scale of adverse events	Dept. of quality control	To establish incident reporting mechanism
SO 3: Develop competent and capable work-force	Dept. of accreditation of professional affairs	To strengthen registration system, licensing of health-care professionals

<b>Strategic Objective</b>	<b>In place</b>	<b>Way forward, beginning 2014</b>
SO4: Prevent and control HAI	Cabinet of quality control in hospitals	Form ICC's and adopt/adapt WHO guidelines
SO 5: Implementation of WHO patient safety campaigns and strengthening health programmes	MOH, Dept. of Quality control and hospital cabinet of quality control	Adapt and adopt WHO tool kit and guidelines
SO 6: Promote patient safety research	National Institute of Health is in place	Establish mechanisms to promote research on patient safety

***Recommendations:***

The main recommendations made at the consultation and the next steps by countries in the South-East Asia Region and by WHO are as follows:

***For countries***

- Training of trainers' programmes on patient safety should be developed. Clinical auditing should also be developed and implemented on a priority basis at regional, national and HCF levels.
- Regular CME and performance reviews on patient safety should be carried out for all grades of health care professionals including the managerial staff at all levels of hospitals
- Information technology infrastructure and the capacity to use it in administrative and clinical processes should be developed. Software (such as Datix) can be used to report adverse events.
- Patient safety hospitals on the same lines as baby-friendly hospitals should be established.
- Workshops on hospital architecture and planning and ergonomics pertaining to patient safety should be organized.
- Regional conference on patient safety should be periodically organized to learn from best practices and share experience with other countries.

**For WHO**

- A regional accreditation board should be established for the South-East Asia Region and a regional network of patient safety.
- A resource centre on patient safety (guidelines, books and journals) and a resource directory should be established.
- Patient safety resources should be disseminated to Member States.
- A portal of communication through social media should be developed to facilitate countries and institutions to learn from each other.
- The Regional Offices for South-East Asia and the Western Pacific should collaborate on patient safety (WHO/OECD quality survey is one example).
- Technical support on patient safety should be provided to countries whenever requested.

**For WHO and countries**

- Funding and technical resources for patient safety activities should be explored. Special attention should be paid to research on patient safety which is a neglected area in the Region.

## **9.6 Closing session**

Dr Senanayake, Regional Adviser, concluded that there was a need to develop collaborations between countries and share resources. WHO collaborating centres in the area of patient safety should be developed, which can serve as centres of excellence. The Regional Office for South-East Asia and Western Pacific are working closely with OECD on quality and patient safety and the next meeting will be held in November 2014. All Member States will be invited to participate. He reminded that 5 May is the “Clean hands saves lives” day. On this day support and commitment to hand hygiene is celebrated in health-care institutions throughout the world. He encouraged hospitals that have not yet joined the programme to do so.

## **10. Summary and conclusions**

Patient safety was recognized as a fundamental and core issue in the delivery of health-care at all levels (primary, secondary and tertiary) and in all modalities of health-care (promotion, prevention, diagnosis, treatment, follow-up and rehabilitation) in the Region. The importance of establishing quality and patient safety as a priority in health-care is increasingly being realized by countries of the Region. Being multidisciplinary and cross-cutting, patient safety and quality requires well-developed health systems and coordination between health-care activities and processes. The countries in the Region are in different stages of development and the state of health-care reflects this heterogeneity.

The representatives from the countries at the consultation presented the current situation and the way forward. Thailand has a robust and well-developed infrastructure for patient safety. Indonesia has different systems and legislation in place for patient safety, but needs stronger integration and coordination of its activities and initiatives. India, the largest and most populous country of the Region, was not represented at the meeting by its national authorities, thus inputs from the national level and public sector could not be included. However, the corporate private health-care sector in India was well-represented and it was indicated that quality and safety is a priority area in India with an increasing number of hospitals being accredited. Accreditation institutes are in place and well-developed in Thailand and India. Myanmar would be setting up patient safety as a priority in its national policy and plans. Bangladesh had collaborated with WHO in the pilot programme under the multimodal strategy for improvement of hand hygiene from the first challenge for patient safety “Clean care is safer care”. However, there will be issues of sustainability and the country will proceed to develop a sound structure for patient safety at the national level. Bhutan, Democratic People’s Republic of Korea, Maldives and Timor-Leste have taken initiatives in the area of quality and safety, but are yet to develop the structure for patient safety. Nepal has adopted quality assurance as a priority and is in the process of developing a robust QA programme in its effort to improve patient safety.

All participating countries appreciated WHO’s initiative in developing a regional strategy for patient safety and provided valuable inputs at the meeting. The inputs were incorporated in the draft and the document was finalized with the consensus of the representatives from the Member States.

The participants agreed upon the six strategic objectives which would form the basis for national policies for patient safety. Further, the comprehensive interventions for each objective could guide the development of an action plan and implementation of patient safety at different levels of health-care. The guiding principles were reiterated at each stage of the discussion.

Strengthening health systems and effective implementation was seen as the key and could be made possible through national commitment and the coordination and integration of the activities of the cross-cutting areas and multiple stakeholders. The finalized regional patient safety strategy and the assessment tool incorporating the suggestions and recommendations made at the consultation will be distributed to the Member States. The assessment tool would be used as a benchmark to define the baseline situation and assess progress in the improvement at all levels.

Several recommendations were made to take the initiative forward. Action on the part of the Member States and the assistance required from WHO was defined.

## **Annex 1**

### **Fifty-fifth World Health Assembly WHA55.18**

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:**

- a) 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;

- b) 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;
- c) 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 healthcare providers that offer a benchmark for excellence in patient safety internationally;
- d) To encourage research into patient safety, including epidemiological studies of risk factors, effective protective interventions, and assessment of associated costs of damage and protection;
- e) To report on progress to the Executive Board at its 113th session and to the Fifty-seventh World Health Assembly.

## **Annex 2**

# **Promoting patient safety in health care**

### **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;

- a) 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;
- b) to develop national mechanisms to capture, share, respond, and learn from this information at all levels of the health system;
- c) to promote interventions that have been shown to improve patient safety;
- d) 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;
- e) 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;
- f) 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;
- g) to establish systems that respect the rights of both patients and providers, and
- h) 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 South-East Asia**

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 59th 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, 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 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 behavioral 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;
  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; integrate 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

### List of documents reviewed

#### **World Health Assembly resolutions and decisions and related documents for patient safety elements and implications for patient safety:**

- WHA55.18 Quality of care: patient safety
- WHA60.29 Health technologies
- WHA64.6 Health workforce strengthening
- WHA64.7 Strengthening nursing and midwifery
- WHA64.8 Strengthening national policy and dialogue to build more robust health policies, strategies and plans
- WHA64.9 Sustainable health financing structures and universal coverage
- WHA64.13 Working towards the reduction of perinatal and neonatal mortality
- WHA 64.24 Drinking water sanitation and health
- WHA65.19 Substandard/spurious/falsified/counterfeit medical products
- WHA65.22 Follow-up of the report of consultative expert working group on research and development
- EB132/42 **Progress report health systems:**
  - Patient safety (WHA55.18)
  - Drinking water, sanitation and health (WHA64.24)
  - Rational use of medicines(WHA60.26)
  - Health policy and systems research strategy

#### **Regional Committee resolutions for patient safety elements and implications for patient safety:**

- SEA/RC55/R4 Accessibility to essential medicines
- SEA/RC56/R6 Traditional systems of medicine

- SEA/RC56/R8 Water, sanitation and hygiene determinants of health – role of health ministries
- SEA/RC56/R7 Strengthening of nursing and midwifery workforce management
- SEA/RC58/R2 Skilled care at every birth
- SEA/RC59/R3 Promoting patient safety in health care
- SEA/RC59/R6 Strengthening the health workforce in South-East Asia
- SEA/RC59/R7 Public health, innovation, essential health research and intellectual property rights
- SEA/RC61/R3 Revitalizing primary health care
- SEA/RC62/R6 Measures to ensure access to safe, efficacious, quality and affordable medical products.
- SEA/RC62/R4 Engaging the private sector in providing health services to meet national health systems goal
- SEA/RC63/R4 Prevention and containment of antimicrobial resistance
- SEA/RC64/R5 National essential drug policy including the rational use of medicines
- SEA/RC66/R4 Health intervention and technology assessment in support of universal health coverage

### **Report of workshops/consultations on patient safety**

- Patient safety strategy : Recommendations of the expert committee workshop held on February 8–9, 2005, Quality Agency , Ministry of health and consumer affairs, Madrid, NIPO: 351-05-035-1.
- Promoting patient safety in healthcare institutions Report and documentation of technical discussion in conjunction with 43rd CCPDM 14–16 June 2006.
- First Regional workshop on patient safety, New Delhi, 12–14 July 2006, SEA-HSD-297.
- WHO Regional workshop on Patients for patient safety: Report of the workshop, Jakarta 17–19 July 2007.
- WHO Regional Patient Safety workshop on “Clean care is safer care” Report, Bangkok 20–22 June 2007.

- Core components for infection prevention and control programmes: Report of the second meeting of informal network on infection prevention and control in health care, WHO, Geneva, Switzerland, 26–27 June 2008.
- National consultation workshop on patient safety. Directorate General of Health Services MoHFW, Government of India, 10–12 May 2010.
- First global forum on medical devices: Recommendations, Bangkok, Thailand, 9–11 September 2010.
- Health-care quality, chapter 5 in Health at a Glance Asia/Pacific. 2012 OECD/WHO (2012), OECD publishing.  
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## **Blood safety**

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2. Universal access to safe blood transfusion  
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3. Clinical transfusion process and patient safety aide-memoire.[www.who.int/bloodsafety](http://www.who.int/bloodsafety)
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## **Annex 5**

# **Report of the Expert group meeting to draft regional strategy for patient safety for SEAR Member States, 10–11 October 2013, Regional Office for South-East Asia, New Delhi, India**

## **Introduction**

Patient safety is a fundamental issue in all aspects of health-care. The Regional Committee, through resolution SEA/RC59/R3 Promoting patient safety in health care, requested WHO 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 in the Region and worldwide”.

In alignment with World Health Assembly resolution WHA55.18 on Quality of care: patient safety and Regional Committee resolution SEA/RC59/R3 on patient safety and responding to the need to improve patient safety in the Member States of the South-East Asia Region, a draft regional strategy on patient safety was prepared by the HSM unit at the Regional Office. In order to review and finalize the draft, an Expert Group meeting was organised on 10-11 October 2013 in the Regional Office, New Delhi. The experts were from different fields of healthcare including health administration, accreditation and quality, clinical discipline, education, infection control and health research. The various technical units at the Regional Office with patient safety were also represented. The patient safety team from HQ participated through a video conference. The list of participants is in Annex 5a.

## **Objectives**

The general objective of the meeting was to review, make recommendations and finalize the draft regional strategy for improvement of patient safety, with the following specific objectives:

- (1) to deliberate on the progress in patient safety worldwide and in the Region;
- (2) to assess the global and regional situation and current knowledge on the subject;
- (3) to review and discuss the proposed draft regional strategy for patient safety; and
- (4) to finalize the draft regional strategy for patient safety for subsequent regional consultation.

## **Proceedings**

Dr Prakin Suchaxaya, Acting Director Health Systems Development, welcomed the experts and gave an overview of the importance of patient safety and its fundamental place in health care.

Dr Sunil Senanayake, Regional Adviser (Health Systems Management and Patient Safety), explained the objectives of the meeting and introduced the participants.

## **Global and regional situation on patient safety**

Dr Senanayake presented the global situation and the current status of patient safety in the South-East Asia Region. He referred to World Health Assembly and Regional Committee resolutions on patient safety and the Jakarta Declaration on Patients for Patient Safety. He quoted the WHO study on burden of harm 2009, which indicated that most evidence was from developed countries and there was little data from developing countries. The evidence available showed that the burden of unsafe care was much higher in the countries of the South-East Asia Region and the major challenge was weak health systems and shortage of human resources for health with six out of 11 countries in the South-East Asia Region are severely short of trained health-care workers. Control of health-care-associated infections was a major issue for focus and interventions in the Region along with problems of medication safety, injection safety and blood safety.

## **Video conference with patient safety team at HQ**

The patient safety team at HQ interacted with the group and discussion was based on various aspects covered by the draft document. Issues discussed included legal and regulatory framework, communication between health-care staff and staff and patients, the role of a hygienic environment, education in patient safety, development of safety culture, human factor ergonomics, decision-making in surgery, injection safety and transplantation (human organs) safety.

## **Review of draft regional strategy on patient safety**

Dr Geeta Mehta, Medical Officer (Patient Safety) presented the draft regional strategy, inviting suggestions and recommendations from the group. In order to improve patient safety and provide safe and quality health-care in the Region, seven strategic objectives had been suggested with sub-objectives and corresponding interventions. The document also referred to the WHO technical resources available for assistance.

The group reviewed the draft in detail, deliberated on the objectives and strategies and their suggestions and recommendations were accommodated.

## **Revision of the document based on recommendations and suggestions of the expert group:**

These suggestions and recommendations have been incorporated in the revised document: Regional strategy for patient safety (second draft). Some of these revisions are mentioned below;

- The WHO patient safety programme has been updated as per suggestions of the patient safety team at HQ
- The strategic objectives have been reduced from seven to six. Objective 5 (support and implement WHO campaigns in patient safety) has been merged with objective 4 and 6. The new objective 5 is “To Improve the implementation of global patient safety challenges and strengthen patient safety in all health programmes”. Objective 5.1 (improve hand hygiene in health-care facilities) has been merged with objective 4.1: strengthen

infection prevention and control structure and programmes across all health-care services and all levels of care. The earlier objective 5.2: safe surgical care is now objective 5.1.

- Other changes included the greater emphasis and elaboration of the intervention points under 4.1: strengthen infection prevention and control structure and programmes across all healthcare services
- Major changes have been made in the intervention points under medication safety, summarizing and incorporating particular suggestions by the Regional Adviser Essential Drugs and Other Medicines.

## **Way forward**

The revised Regional strategy (2nd Draft) for patient safety will be reviewed and finalized through a regional consultation inviting the 11 SEAR Member States. The time line for consultation is March 2014.

## List of participants

### India

Dr Gayatri Vyas Mahindroo  
Director  
National Accreditation Board for Hospitals  
and Healthcare Providers  
Quality Council of India  
New Delhi

### Indonesia

Dr Liliana Kurniawan  
Former Senior Researcher and Chairperson  
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### Sri Lanka

Dr Sathasivam Sridharan  
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Health-care Quality and Safety  
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## Annex 6

### List of participants

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## **Private hospitals**

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Dr Geeta Mehta  
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## **Annex 7**

### **Agenda**

- (1) Inaugural session
- (2) Global patient safety programmes, initiatives and campaigns
- (3) Regional situation of the patient safety programme
- (4) Presentation of draft regional strategy
- (5) Review and finalization of the regional strategy
- (6) Way forward and monitoring implementation
- (7) Conclusions and recommendations
- (8) Closing session

## **Annex 8**

### **Inaugural address by Dr Poonam Khetrapal Singh, Regional Director, WHO Regional Office for South-East Asia**

“The fundamental principle of healthcare is that it should do no harm. Hospitals and Healthcare facilities are the institutions people go when they are sick or need health services. They go there with trust that they will get better and become free of ailments. But if a patient is harmed in the hospital it is a great erosion of that trust. An essential aspect of health care quality is “Patient Safety” and it is mainly preventing medical errors that may lead to adverse events and harm. The safety of the patient has to be kept in forefront during all modalities of prevention, diagnosis, treatment, rehabilitation and follow up and in all levels of care: primary, secondary and tertiary. Due to complexity of healthcare and growing needs for healthcare in the population, the risk and potential for harm is increased.

As it is recognized that most of the harm is due to failures in design, organization and operation of systems, a systems approach for patient safety and putting in place essential elements of quality care are of paramount importance. Quality and Safety of healthcare provided is an enormous task to the service providers, institutions, hospitals and to the Ministries of Health. Governments and Ministries are adopting many different policies, strategies, techniques and methods to ensure quality and safety of the healthcare provided to the nation including strengthening legislation and regulations.

In developed countries, as many as one in ten patients are harmed while receiving healthcare. In developing countries there is even greater risk of harm and it has been estimated that it is 20 times higher than that of developed countries, mainly due to limitations in infrastructure, technologies and human resources. Unfortunately developing countries do not have adequate information to estimate the harm. Developed countries are spending millions of dollars every year for compensation payment as a result of harm happened to patients at healthcare institutions.

Taking cognizance of the fact that patient safety is a growing public health problem, in 2002, WHO Member States resolved to pay the closest possible attention to the issue of patient safety and the World Alliance for Patient Safety was formed. Promotion of Patient Safety was further endorsed by the regional committee in 2006 and the Member States of the WHO South East Asia Region resolved to support and enable health care institutions at all levels to implement systems changes and practices conducive to patient safety.

World Health Organization has developed many guidelines, checklists and programmes to ensure quality and safety of the healthcare provided and to minimize healthcare acquired infections, antimicrobial resistance, and medical mismanagements as well as to reduce hazards from clinical and biological waste among many other measures. All these guidelines need to be adopted by each and every healthcare institution to achieve the goals of patient safety in WHO South-East Asia Region.

I am very glad that “Health Systems Management and Patient Safety Unit” of the Regional Office initiated developing and adopting Regional Strategies for Patient Safety. It is important to note that these strategies need to be adopted by each and every healthcare facility in all Member Countries in our Region to achieve goal of providing safe good quality universal health care to all.

Ladies and gentlemen,

With these few words, I wish you success in your deliberations and wish you very pleasant stay in Colombo.

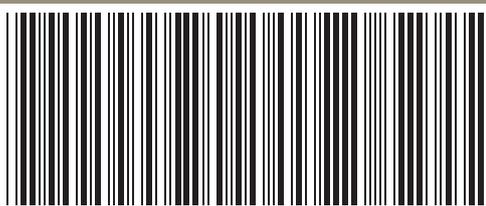
Thank you.”

The quality and safety of health care is of prime importance in health service delivery. Health services that are provided should be of high quality and should be safe for the service providers as well as service recipients. WHO HQ has designed and implemented many patient safety initiatives, but a comprehensive global strategy to address this important aspect of health-care delivery is yet to be developed. Considering the importance of patient safety in the South-East Asia Region, HSM Unit of the WHO Regional Office drafted a regional strategy for patient safety to be adopted by the Member States. This draft was circulated among all relevant technical units of the Regional Office as well as in HQ and improved by accommodating suggestions made by those units. The revised draft strategy was presented to an expert group constituted from the Region as well as from HQ and further improved upon. Based on the recommendations of the expert group, the draft was finalized after a regional consultation where all Member States were consulted. The regional consultation was held from 22-24 April 2014 in Colombo, Sri Lanka. Finalized regional strategy will be published as a separate publication.



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