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First Regional Workshop on Patient Safety

A Report
New Delhi, 12-14 July 2006



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1. Introduction

The first Regional Workshop on Patient Safety was held in New Delhi, India, from 12 to 14 July 2006. Participants included representatives from Bhutan, Indonesia, Maldives, Nepal, Sri Lanka and Thailand as well as representatives from several nongovernmental organizations (NGOs) in India. The WHO Secretariat included staff from its headquarters, the Western Pacific Regional Office (WPRO), the South-East Asia Regional Office (SEARO) and country offices of Nepal, Sri Lanka and Thailand. The programme and the list of participants are provided in Annexes 1 and 2.

Dr Dorji Wangchuk (Bhutan) and Dr Santawat Asavaroengchai (Thailand) were respectively nominated as Chairperson and Rapporteur of the workshop. Professor Didier Pittet, Leader of the First Global Patient Safety Challenge, Patient Safety Programme, WHO/HQ, and Mr Martin Fletcher, Technical Officer, Patient Safety Programme, WHO/HQ, were nominated as Technical Moderators.

2. Objectives of the workshop

The objectives of the meeting were:

- (1) To enhance an understanding of important concepts in patient safety, particularly the need for a systems approach;
- (2) To exchange information about patient safety initiatives under way in the Region and identify emerging areas for regional collaboration;
- (3) To identify and address issues related to the implementation of patient safety in the following four areas: health care associated infections, the frontline role of health care workers, the involvement of patients and their families, and the rational use of medicines.

In addition, participants had the opportunity to attend the official launch of the Patient Safety Challenge in India and to participate in a technical session on “Clean Care is Safer Care” which introduced the WHO (Advanced Draft) Guidelines on Hand Hygiene.

3. Opening session

Dr Poonam Khetrpal Singh, WHO Deputy Regional Director for South-East Asia, made the opening address on behalf of Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia, who could not be present.

Participants were reminded that “First, do no harm” is the cornerstone of medicine. However, unintentional harm does occur at all levels of the health system, both public and private. Despite the recognition that patient safety is a fundamental part of the drive to improve quality of care, insufficient resources had been invested to address the problem in a concerted and consequential manner. No country, rich or poor, could claim to have fully addressed the problem of patient safety.

The World Health Assembly had passed resolution WHA55.18 which called upon 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 patients’ safety and the quality of health care”. In 2004, the late WHO Director-General, Dr LEE Jong-Wook, had launched the World Alliance for Patient Safety to catalyze and coordinate global and national efforts to improve patient safety.

The Regional Director hoped that this workshop, which was the first of its kind to be held in the Region, would constitute an important step towards the development of a strategy on patient safety in health care in South-East Asia.

4. Global context of patient safety

4.1 The World Alliance for Patient Safety and its Programme of Action

In a video-taped presentation, Sir Liam Donaldson, Chair of the World Alliance for Patient Safety, said a few words about the Alliance and its programme of action. The Alliance aimed to fulfil the requirements of the World Health Assembly resolution WHA55.18 through international leadership. It sought to create an overarching strategy, action programmes and a coalition of nations, stakeholders and individuals to transform patient safety worldwide.

Improving patient safety required the highest level of commitment and action by all WHO Member States. Globally, action on patient safety was gaining momentum and it had truly become a global issue. An increasing number of countries were working actively to make patient safety a priority and to establish programmes of action. In this regard, he appreciated the work already under way in many countries in the Region, particularly in areas of injection and drug safety and health care waste management.

A growing body of research evidence pointed to the fact that adverse events in health care were common and knew no geographical boundaries. While their context may differ, no country – rich or poor – could claim to have come to grips fully with the problem of patient safety.

The current concepts of patient safety placed the prime responsibility for most adverse events on deficiencies in system design, organization and operation rather than on the negligence or poor performance of individual providers or individual products. Counter-measures based on changes in systems of care were, therefore, more productive as risk-reduction strategies than those that only targeted individual practices or products.

Safe patient care also required competent, conscientious and safety-conscious individuals at the frontline. Ensuring patient safety as a key component of educational curricula, training programmes and induction schemes was also vital.

Briefing was provided on some of the work being done by the World Alliance for Patient Safety in each of the six main action areas. The first was the Global Patient Safety Challenge. For the period 2005-2006, the work on Global Patient Safety Challenge was being focused on health care-associated infections with the theme “Clean Care is Safer Care”. Work in the area of “Patients for Patient Safety” entails harnessing the wisdom of patients and “patient-champions” in making health care safer and better for future patients. The third area of action aimed to establish effective reporting and learning systems in order to learn from past failures. The fourth area sought to develop taxonomy for patient safety to create better information-sharing about the number, types, causes and consequences of errors and adverse events. The fifth area aimed to facilitate research in order to have a better understanding of the extent and causes of patient harm and to develop appropriate solutions. The sixth area sought to create solutions by translating theoretical knowledge into practical action.

He also highlighted new areas of work planned for 2006 and 2007 that included: Technology for Patient Safety; Patient Safety and the Care of Acutely Ill Patients; a Second Global Patient Safety Challenge; Exemplar Hospitals; and Education for Patient Safety.

Sir Liam concluded his remarks by stating that though much was happening, much still remained to be done. He emphasized that realizing the benefits of this important programme of work would require the will and commitment on the part of every WHO Member State.

4.2 Key concepts in patient safety

Quoting Sir Liam Donaldson, Mr Martin Fletcher, Technical Officer, Patient Safety Programme, WHO/HQ, reminded the audience that “patient safety is not only about statistics but involves damage to the lives of real people”. Patients should therefore be at the heart of all patient safety strategies and programmes. Patients, health professionals and policy-makers must all work together to build a safer health system.

He emphasized the importance of a systems focus in patient safety. Drawing on an analogy to Swiss cheese, he described patient safety as a series of defences (slices of cheese) which prevent minor mishaps from turning into major failures. These include *procedures* such as the use of standardized treatment guidelines, *physical barriers* such as the special handling and dispensing of potentially harmful drugs when they are delivered into clinical areas, *pertinent information* such as information on a patient’s drug allergies, and *decisions* such as clinical judgments on patients made by the clinical staff based on their training and experience. He went on to liken the gaps and weaknesses in patient safety to the holes in Swiss cheese. These might include inadequate or ignored protocols, faulty equipment, missing information, or inadequate supervision. In such situations, the holes of the Swiss cheese can line up resulting in patient harm and sometimes death.

Mr Fletcher pointed out that big improvements in patient safety did not result from telling people to be careful, but from understanding the nature of the safety problems that occur and the factors that contribute to them, and most importantly, from taking actions to prevent or mitigate their re-occurrence. The ultimate aim should be to identify risks before they

actually harm patients. In this regard, it is a welcome development that patient safety reporting and learning systems are emerging as a major area of interest for many Member States. In order to help countries develop or improve their systems, WHO has produced “Draft Guidelines for Adverse Event Reporting and Learning Systems” which will be refined as more field experience is gained.

Mr Fletcher informed participants that in August 2005, the Joint Commission on Accreditation of Health Care Organizations and Joint Commission International were officially designated as a WHO Collaborating Centre on Patient Safety. The Centre is building an international network to identify, evaluate, adapt and disseminate patient safety solutions applicable to a wide variety of countries and health care settings.

He indicated that there was much to be learned from other high-risk industries such as aviation, nuclear energy and oil industry, which had a better record on safety than health care systems. In these industries there is a strong sense that safety is everyone’s business. These industries have placed a particular emphasis on staff reporting of ‘near-misses’ as a valuable source of learning about risk areas and developing solutions. The situation is very different in the health care industry where errors and system failures are widespread yet there is limited understanding of their causes, slow action to address known risks, and few examples of widely implemented strategies. A prevailing culture of blame and retribution, the lack of supportive feedback, and inadequate institutional support, all contributed to under-reporting of medical errors and adverse events.

5. Regional context

5.1 Magnitude of the problem

Dr Sultana Khanum, Director, Health Systems Development, WHO/SEARO, began her presentation by citing examples of adverse events resulting from faulty or contaminated medical devices, wrong and over-medication, unsafe blood or blood products, infections acquired in the course of care and surgical procedures, anaesthesia and obstetric trauma.

According to medical record audits, 1 in 10 persons in health care institutions in industrialized nations experienced some form of unintended harm.

While less well documented, the scope of the patient safety problem in developing countries including in the South East Asia Region, is believed to be far more serious. Based on existing information:

- The risk of acquiring a health care-associated infection is estimated to be 2 to 20 times higher in developing countries than in industrialized ones. Neonatal infections among hospital-born babies in developing countries were found to be 3 to 20 times higher than those reported in industrialized countries.
- WHO estimates that people residing in South East Asia receive more than 5 injections per year and 50% of the injections are 'unsafe'. Unsafe practices include reuse of syringes and needles in the absence of sterilization, and poor collection and disposal of dirty injection equipment which expose health care workers and the community to the risk of needlestick injuries.
- Furthermore, WHO estimated that countries in South-East Asia produce over 1,000 metric tons of health care waste including injection-related waste every day which is not properly disposed of.
- South-East Asia is a large producer of medical devices that are exported all over the world. However, the devices sold in the domestic market are often manufactured outside the regulatory framework and may not meet international standards.
- WHO estimates that developing countries account for around 77% of all reported cases of counterfeit and substandard drugs in the world and that over 50% of all medicines prescribed, dispensed or sold globally are not justified.

5.2 Technical discussions on patient safety

The WHO Director reported on the Technical Discussions on 'Promoting Patient Safety at Health Care Institutions' which took place in New Delhi on 16 June 2006 at the 43rd Consultative Committee for Programme Development and Management (CCPDM). The CCPDM had identified the following regional priority areas of work related to patient safety:

- Creating an enabling environment
- Addressing common communication barriers within the health care team and between health care professionals and patients

- Establishing national reporting systems and response mechanisms that are integral components of quality assurance programmes
- Implementing evidence-based interventions that reduce harm and improve patient safety
- Educating and training staff
- Learning from operational research linked to interventions.

In addition to the recommendation that the regional patient safety initiative be broadened beyond the confines of health care institutions to 'Promoting Patient Safety in Health Care', the CCPDM made the following recommendations to Member States and WHO:

For Member States:

- To assess the scope and nature of adverse events and the factors that contributed to them;
- To establish or improve detection and reporting systems;
- To establish national mechanisms to capture, share, respond to and learn from this information;
- To promote interventions that have been shown to be effective;
- To support and enable health care institutions, both public and private, to implement system changes;
- To create/implement policies and legislations conducive to sustainable health system-oriented solutions;
- To engage patients, consumer groups, health care workers and professional bodies in finding and implementing solutions;
- To establish systems that respect the rights of both patients and providers.

For WHO:

- To coordinate the development of a regional strategic framework and package of interventions for patient safety;
- To provide strong technical leadership and support to Member States in the design, implementation and monitoring of patient safety programmes;

- To ensure capacity building in different aspects of patient safety at the regional, sub-regional and country levels;
- To facilitate collaboration and exchange of information and best practices between Member States and the World Alliance on Patient Safety;
- To coordinate and facilitate research on patient safety;
- 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;
- To monitor and report on progress in the Region.

Dr Khanum stated that this programme of action will be considered by the WHO Regional Committee for South-East Asia in August 2006 as a supplement to the recommendations of the CCPDM.

5.3 People at the centre of care initiative

Referring to the WHO South-East Asia and Western Pacific bi-regional 'People at the Centre of Care Initiative', Dr Linda L. Milan, Director, Building Healthy Communities and Populations, WHO Western Pacific Regional Office (WPRO), said that patient safety was also a priority in the Western Pacific Region. In resolution WPR/RC54.R2, Member States have requested WPRO to support countries to improve the quality of health care, of which patient safety is an integral component. Patient safety is embedded in several domains of the bi-regional initiative including: empowering consumers, engaging patients (and their families) in their own care; training of health care professionals; improving the health services; and, strengthening the health system. Dr Milan pointed out that when a doctor has to look after 300 patients a day, patient safety is easily compromised. However, safety can be improved by changing the way that health care professionals are trained technically and emotionally, how their work is organized and how services are delivered. Patient safety therefore requires a comprehensive approach that takes into account the needs of consumers/patients, health care providers, health institutions and the health system at large, appropriate incentives and equitable access to health care for everyone.

6. Country experiences

Participants were invited to share their country's experience in patient safety focusing on the following areas:

- Major patient safety issues
- National patient safety initiatives and programmes under way
- Suggested priorities for regional collaboration.

6.1 Government sector

Bhutan

Dr Dorji Wangchuk, Director-General, Department of Medical Services, Ministry of Health (MoH), informed participants that the MoH had taken several measures to improve patient safety in the country. These included:

- Establishing a National Infection Control and Health Care Waste Management Programme.
- Instituting an Infection Control and Waste Management Committee in every district hospital to address: injection safety; safe work practices; prevention of accidents and injuries in the workplace; use of protective barriers; hand washing; proper decontamination, disinfection and sterilization practices; and, proper handling of health care wastes.
- Creating a Health Technology Committee in the Quality Assurance and Standardization Department (QASD) at the MoH to oversee the overall quality of care. The Committee establishes quality standards and benchmarks, sets specifications for medical devices and equipment. The committee also conducts maternal death audits to identify and address preventable causes of maternal mortality.
- A Drug Regulatory Authority (DRA) has been established to ensure the safety, effectiveness, and quality of drugs. The RGoB spends almost US\$ 2 million annually on importing essential drugs. Counterfeit drugs are a major issue as is the high-cost of non-generic drugs.

Other measures taken to enhance patient safety include:

- Revitalizing the Essential Drugs Programme and pharmacovigilance;
- Strengthening the health workforce both in terms of numbers as well as skill mix;
- Empowering patients by creating a partnership between them and health care professionals;
- Instituting a hospital accreditation process;
- Establishing a system of prequalification for medical devices (WHO should take the lead on this);
- Integrating patient safety into the curriculum of Health Assistants and General Nurse Midwives at the Royal Institute of Health Sciences (medical and advanced nursing education are obtained overseas);
- Instituting surveillance of health care harm;
- Designing health facilities that are safer and more user-friendly, and
- Implementing water sanitation projects to ensure safe water for patients and the community at large.

Indonesia

Dr Nico Lumenta, Chairman of the Indonesian Hospital Patient Safety Committee (IHPSC), gave the presentation. He shared the results of a point prevalence survey conducted in 2004 in 11 hospitals in the capital city of Jakarta, which found that 9.2% of patients had a hospital acquired infection, a figure that falls within the 6-16% range found in earlier surveys. He then described the important steps that Indonesia has taken to improve patient safety:

- The Indonesian Hospital Association (IHA) created the Indonesian Hospital Patient Safety Committee (IHPSC) in June 2005 with support from the Ministry of Health (MoH).

- The 'Patient Safety Movement' was launched by the MoH at the National Seminar of the Indonesian Hospital Association in Jakarta in August 2005.
- A Hospital Act was drafted in 2006 that will make patient safety programmes compulsory in hospitals and will ensure that incident reports are not subjected to disciplinary investigations or criminal sanctions by the courts.

The IHPSC is under the patronage of the Director-General for Medical Care, MoH. Its members include representatives of the Indonesian Hospital Association (IHA), the Hospital Ethics Committee and the Indonesian Commission on Hospital Accreditation (ICHA). The Committee has three divisions: Patient Safety Development, Patient Safety Program, and Education & Training.

In March 2006, the IHPSC published the National Guide for Hospital Patient Safety in collaboration with the MOH, the Indonesian Commission on Hospital Accreditation (ICHA), and the Indonesian Hospital Association (IHA). The Guide aims to:

- Create a patient safety culture in hospitals;
- Increase hospital accountability toward patients and society;
- Decrease adverse events in hospitals, and
- Implement programmes to prevent the recurrence of adverse events;

The Guide includes the following chapters:

- Concept of Patient Safety
- Hospital Patient Safety Standard
- Seven Steps toward Hospital Patient Safety
- Incident Reporting System and Form
- Hospital Patient Safety Glossary
- Instrument for Hospital Patient Safety Accreditation

The 'Seven Steps' guide toward patient safety will eventually become part of the hospital accreditation system. Over the next several months, a team from the MoH, ICHA, IHA and IHPSC, will tour 12 major cities to promote the use of the Guide in hospitals. The Guide will be piloted in 3-5 hospitals. The results of the pilot projects will be presented at the Indonesian Hospital Association Congress, 22-25 November 2006 in Jakarta.

In collaboration with the 'Institute of Clinical Risk', the IHPSC is offering training modules through hospital associations and medical, nursing and other health professional associations. In addition, the National College of Medical Education has agreed to develop and introduce patient safety into the medical curriculum.

Maldives

In her presentation, Ms Sofiya Abdulla, Ward Nurse at the Indira Gandhi Memorial (IGM) Hospital in Male, described the challenging geography of Maldives. The hundreds of widely scattered islands make it difficult to provide equitable access to quality health care to the population. The country has six regional hospitals, 10 atoll hospitals and one tertiary care hospital, the IGM hospital, in the capital city of Male. While there is currently no national policy on patient safety, a hospital infection control programme is being implemented at the IGM Hospital which should be expanded to more peripheral hospitals in the future. The following activities have been implemented to date:

- A multidisciplinary Infection Control Committee, which includes doctors, nurses and microbiologists, has been created.
- A manual on standard nursing care procedures has been developed. It is being periodically revised in the light of experience and evidence gained.
- Inservice seminars are organized to update nurses' knowledge.
- While there is no official system for reporting and recording of medication errors, an 'incident book' is kept at the ward level where nurses can report such incidents.

What is still lacking in the current programme is a continuous system of supervision, monitoring and inservice training. Other key areas for patient safety that need to be addressed in the wider health care system include:

- Drug safety: Good-quality medicines are not always available. The practice of self-medication with over-the-counter medicines is commonplace. Overuse and misuse of antibiotics has led to the development of antibiotic resistance.
- Environmental safety: hospitals are overcrowded; ventilation is inadequate; and, pests are not effectively controlled in the city.

The Senior Staff Nurse concluded her presentation with the following recommendations:

- Establish a reporting system for medical errors;
- Formulate a Health Act to enforce reporting;
- Introduce a hospital accreditation system, and
- Create a quality control unit.

Nepal

Dr L.L. Shah, Chief Surgeon at the Janakpur Zonal Hospital, indicated that there were no reliable data on the total burden of adverse events in Nepal. However, he noted that hospital-acquired infections are estimated to occur in around 5-7% of patients. According to the 2004 annual survey of the Department of Health Services, 40% of hospital equipment was non-functional. Counterfeit medications are of great concern in the country.

The surgeon attributed adverse events to:

- Severely understaffed hospitals
- Inadequately trained, unmotivated and underperforming administrative and clinical staff
- Poor working environment
- Inability to fire under-performing staff
- Overcrowding of patients in hospitals

- Unmanaged flow of visitors
- Lack of proper diagnostic tools
- Overuse of medicines (compounded by the lack of diagnostic tools)
- Long patient waiting times and treatment delays
- Deteriorating patient-provider relationships – can degenerate into physical violence against health care providers by patient’s family.

Nepal has taken, albeit on a limited scale, the following initiatives:

- a quality assurance policy has been drafted but has yet to be ratified;
- maternal and neonatal audits have been initiated at selected facilities;
- a leadership training programme has been developed for nurses;
- quality inspection of essential drugs is being strengthened, and
- a District Health System Initiative has been introduced which ensures that each of the 75 districts hospitals in the country will also have a public health officer.

Dr Shah concluded his presentation by proposing that WHO assist Member States to share information and experiences in the following areas:

- sensitizing policy-makers to the importance of patient safety;
- establishing national adverse event reporting and learning systems;
- promoting quality improvement;
- engaging professional associations in patient safety, and
- creating health consumer groups for patient safety.

Sri Lanka

In his presentation, Dr Terrance de Silva, Deputy Director-General of Medical Services of the Ministry of Health, stated that doctors’ decisions were never questioned in the past. Today consumers are better informed and have higher expectations from doctors. Patients’ rights groups have

emerged. Doctors are going on strike. The number of malpractice litigations against caregivers has increased dramatically as in other countries in the Region. The media, NGOs and political leaders have all become active on quality of care and patient safety issues. As in other countries of the Region, there was a serious resource constraint in patient care.

The Deputy Director-General of Medical Services delineated the areas of patient safety most relevant to Sri Lanka. These included safety of injections, blood, drugs, pregnancy, chemicals, transplants, clinical procedures, medical devices and immunization. Referring to the 2007 National Patient Safety Goals created by the Joint Commission International (JCI), he indicated that Sri Lanka was taking steps to fulfil the requirements to meet the following goals:

- To identify patients correctly
- To improve effective communication among caregivers
- To improve the safety of medications
- To reduce the risk of health care-associated infections
- To reconcile medications across the continuum of care
- To reduce the risk of patient harm resulting from falls
- To reduce the risk of influenza and pneumococcal disease in institutionalized older adults
- To reduce the risk of surgical fires
- To encourage patients' active involvement in their own care as a patient safety strategy
- To prevent health care-associated pressure ulcers (decubitus ulcers).

Other safety measures being introduced were in the areas of water, food and environmental sanitation (including waste disposal and elimination of stray animals) and building safety.

Thailand

Dr Santawat Asavaroengchai, Bureau of Policy and Strategy, Ministry of Public Health, who also participated in the Technical Discussions on Patient

Safety at the CCPDM in June 2006, described the patient safety situation in Thailand. Based on an audit of medical records at two major hospitals, the prevalence of hospital-related adverse events in Thailand is similar to that prevailing in industrialized countries: 10% of inpatients developed adverse events, 10% of adverse events led to death, and half of the events were preventable.

As in other countries in the Region, there has been a dramatic increase in the number of complaints and legal suits filed by patients with the Thai Medical Council. This trend has damaged the doctor-patient relationship and contributed to health care professionals' resistance to reporting adverse events. The fear of litigation has pushed the problem of medical errors and adverse events underground where it cannot be effectively addressed. The fear of blame and punishment is thus thwarting efforts to improve patient safety and the quality of care in Thailand. A more transparent and trusting environment needs to therefore be cultivated as a first step to addressing patient safety. It is only in such an environment that information on adverse events can be collected, the nature and underlying causes understood, and better policies formulated and implemented.

Efforts toward the development of a national quality of care policy were described. In 1996, the first Hospital Standard for Quality Improvement and Accreditation was introduced in 16 pilot hospitals. Many hospitals, at all levels of the health care system, are currently using this Standard as a guide for quality improvement. The major focus of the Standard is on clinical risk management. The latter entails:

- strong hospital leadership
- physician participation
- cross-functional teamwork
- total quality management

In 2002, a national health security Act was introduced which addressed the issue of compensation to patients for unintentional harm. This improved doctor-patient relationship in the context of the growing problem of litigation. In 2003, patient safety was chosen as the theme of the 4th National Forum for Quality Improvement to raise awareness about the safety of patients in the hospital quality improvement process.

In 2006, the Institute of Quality Improvement and Hospital Accreditation of Thailand established a set of national patient safety goals for hospitals. These focus on the following eight priority areas:

- Patient identification
- Operation safety
- Medication safety
- Health care-associated infection
- Maternal and neonatal morbidity
- Delayed rescue
- Acute coronary syndrome
- Communication failure

The presentation was concluded with a set of proposed activities and potential areas for regional collaboration. The proposed activities are:

- Establish effective, careful and participatory surveillance and evidence-based risk management strategies and systems;
- Build a strong governmental and societal commitment to creating a culture of patient safety, and
- Develop a regional strategic plan and patient safety 'movements' with active involvement of patient groups.

6.2 Nongovernmental sector

Hospital Infection Society-India (HISI)

Dr Geeta Mehta, President, HISI, made a brief presentation on the activities of the society. The organization, which was founded over a decade ago, serves as a technical resource to hospitals who are establishing infection control programmes. The organisation has collaborated with the Indian Ministry of Health and WHO to develop country-appropriate guidelines for the prevention of health care-associated infections including national guidelines that promote a six-step method for hand washing. HISI organizes training programmes on all aspects of prevention and control of hospital infections.

HISI's current activities include:

- Collecting data on health care-associated infections that are reliable, comparable between institutions and can be used for decision making;
- Introducing the concept of infection control to the more remote areas of India;
- Establishing national infection control standards, and
- Motivating health care providers to follow infection control guidelines.

Patient Safety – India

Mr Murrigan Thevar, Patient Champion, Patients for Patient Safety network of the World Alliance for Patient Safety, emphasized the pivotal role of a 'healthy' doctor-patient relationship in patient safety. This relationship has become less trusting and both parties have become more suspicious of the other. There is a widening gap between doctors and patients due to asymmetry in knowledge, socioeconomic status and educational levels. Increased reporting of medical errors in the media has also contributed to the polarization. In a small qualitative survey conducted at 10 public and 19 private health care facilities in Mumbai, patients perceived that doctors were too busy to listen to them, prescribed too many tests, and were more concerned about making money than healing them. Doctors, in turn, stereotyped patients as irresponsible for their own health, not following medical instructions, and delaying care until their disease had progressed to an advanced stage, and then expecting instant cures. Patients found doctors intimidating and did not dare to express their concerns or ask questions. Doctors in turn did not obtain the medical history they required to reach a proper diagnosis and to order appropriate tests. Patients did not understand the doctor's instructions regarding their medicines or follow-up. This communication gap severely hampers care. Blame and frustration on both sides have resulted in a downward spiral with, in extreme cases, patients physically threatening doctors and of doctors going on strike. The following interventions were offered to bridge the communication gap between doctor and patient:

- Recruit knowledgeable volunteers who can assist doctor-patient interactions;

- Establish help desks at health care facilities;
- Create telephone hotlines for major diseases;
- Provide audio-visual and printed educational materials in waiting rooms;
- Facilitate forums for open dialogue between doctors and patients, and
- Educate the media so that adverse events and patient harm are reported more responsibly.

7. Common issues and potential areas for regional collaboration

7.1 Common trends and issues

Issues that were raised during the discussions can be grouped into a few key areas. These are summarized below.

The changing relationship between health care provider and consumer

- Doctors no longer perceived as ‘gods’
- Communication gap between doctor and patient is increasing as health care becomes more complex
- Patient expectations are increasing
- Emergence of consumer groups
- Increase in number of complaints and litigation
- Under-reporting of adverse events for fear of blame, punishment and litigation
- Increased involvement of media and nongovernmental organizations to protect patient rights

In response, there is a need for:

- A more people-centred approach to care which addresses the needs of consumers, health care workers, health institutions and the health care system at large;

- Empowering patients through education, informed consent, informing them when things go wrong, and
- Creating partnerships between providers and consumers to improve the quality of health care.

An overburdened, under-skilled and unmotivated health workforce

In response, there is a need for:

- Improving how work is organized and services are delivered;
- Including patient safety in medical and nursing curricula;
- Strengthening the numbers, distribution and skills of the workforce, and
- Moving patient safety beyond the hospital to community-level care.

Patient safety as an outcome of health systems and an integral component of quality assurance

In addition to competent, conscientious and safety-conscious health care workers, patient safety requires a supportive health system and a conducive environment. There is a need for:

- Building patient safety into quality assurance programmes;
- Introducing non-punitive reporting and learning systems (“careful and participatory surveillance”);
- Introducing simple, cost-effective patient safety measures that are in line with available human, physical and financial resources;
- Improving infection control and waste management as components of quality assurance;
- Strengthening accreditation, monitoring and supervision systems, and
- Improving the physical design of health care facilities to support patient safety.

Need for leadership and governance

Participants acknowledged that without a strong and committed leadership and governance, improved patient safety cannot be achieved. Specifically, there is a need for:

- A better understanding of the size and nature of patient safety problems in the Region;
- Strong leadership at the government and institutional levels;
- Multi-disciplinary patient safety committees to formulate national priorities and actions;
- Transparent, non-punitive reporting and response systems which encourage reporting by health care workers and build public trust and confidence;
- Reviewing the legal, regulatory and policy environment that protects the rights of both patients and health care providers, and
- Educating and engaging the media and civil society as responsible partners.

7.2 Potential areas for regional collaboration

The above issues and areas of work can be formulated into the following questions:

- How to engage policy-makers and providers?
- How do we implement effective safety reporting systems which protect health care workers when they report errors and events?
- How do we involve patients in partnerships?
- How do we engage the media in a constructive way?
- How do we integrate patient safety programmes with existing quality assurance programmes and strengthen monitoring?
- How do we identify the 'right' regulatory, policy and legislative environment for patient safety in a country?
- What to teach the next generation of doctors and nurses to be more 'safety aware'?
- How to best learn from each other?

To answer the above questions, participants recognized that:

- countries are at different points of the patient safety spectrum, and
- there was a need to build on existing knowledge and guidelines and harness the work already under way in different countries.

Participants agreed that Member States:

- should first assess individual strengths and weaknesses in the area of patient safety, and
- collaborate to develop harmonized reporting systems, regulatory and legislative frameworks, and regional action plans.

Furthermore, WHO should:

- set up a regional network through which Member States can share expertise, information, experiences, and tools, and
- organize regional training workshops to build regional capacity.

8. Toward a programme of action

On the second day of the meeting, participants were divided into four groups and each group was assigned a topic for discussion. The groups were expected to: identify three key issues which were common to most countries in the Region; identify 3 to 5 potential areas of work to address those issues; within each of those areas of work to identify three action points that would move the agenda forward; and list areas where WHO/World Alliance for Patient Safety could help.

Working Group I – Fighting health care-associated infections (HAI) in resource-poor settings

The key issues identified in this area were:

- Most countries do not have hospital infection control programmes;
- Baseline data on HAI are not available and published information tends to be anecdotal;

- Inadequate training and education in infection control and the training that is available does not extend to all categories of health care professionals;
- Universal standards and protocols are difficult to apply where the infrastructure is weak and interruptions in the supply of standard materials are frequent;
- Many HAI are caused by structural weaknesses in aging and outdated health-care facilities including poor ventilation, dirty filters in air-conditioners and water leakages;
- Absence of a continuous supply of safe water is an issue in many settings as are basic sanitation and waste management.

The areas of work that required attention were:

- Establishing HAI surveillance, monitoring and response systems;
- Extending education and training on the prevention and control of HAI to all categories of health care workers including hospital administrators;
- Developing acceptable standards and procedures for prevention and control of HAI at the institutional, national and regional levels;
- Strengthening and maintaining logistical systems for the procurement and supply of standard infection control materials at all levels of the health system, and
- Designing proper health care waste management systems with minimum impact on the environment.

The action points suggested included the following:

- Sensitize all categories of health care workers including hospital administrators and policy makers;
- Establish multi-disciplinary infection control committees and infection control teams;
- Adapt existing infection control guidelines (including standards and practices) to suit local needs, context and resources;
- Design or adapt existing training modules;
- Educate and train health care workers with regular updates;

- Ensure a continuous and sustainable supply of standard and essential materials, and
- Develop a system to monitor HAI that enables regular feedback and improvement in quality of care;

The group urged WHO to:

- Establish a network for sharing information, experience and best practices in prevention and control of HAI;
- Make available applicable standards, protocols and guidelines;
- Organize training programmes with an emphasis on practical application and implementation;
- Provide technical assistance to countries when required; and,
- Establish an information system for surveillance in infection control.

Working Group II – Health care workers at the frontline of patient safety

The group identified the following key issues:

- Inadequate numbers of health care workers and their inequitable distribution;
- The health work force lacks the competencies to ensure a maximum level of patient safety;
- Patient care is not people-centred, and
- Teamwork in health care is weak.

The group identified the following two priority areas of work:

- Building the health workforce, and
- Creating an enabling work environment.

The group recommended the following specific action points:

- Develop a health workforce policy and plan that ensures appropriate numbers and skill mix;
- Integrate patient safety concepts into pre-service and in-service training programmes;

- Establish a policy that supports patient safety as a key goal of health systems;
- Create systems and processes that support and protect patient safety;
- Establish quality improvement and accreditation systems;
- Strengthen the monitoring and supervision of health care staff;
- Improve communication and interaction within the health care team, and
- Engage and empower patients in their own care.

The group urged WHO to:

- Promote people-centred health care;
- Collect and disseminate case studies and best practices for health workers' role in ensuring patient safety;
- Assist countries in developing systems for monitoring and evaluation of best practices regarding patient safety, and
- Facilitate the sharing of experiences, knowledge and tools through regional workshops.

Working Group III – Patients: passive victims or active partners?

The group identified the following key issues:

- The concept of patients' rights is not understood in the local context;
- The health care team, hospital administrators and policy makers do not know how to deal with the consequences of mistakes and harm when they occur;
- The hierarchical nature of the doctor-patient relationship makes effective communication difficult, and
- The perceived practical and ethical concerns health care professionals have in involving patients in decisions regarding their own care.

The group identified the following priority areas of work:

- Defining patients' rights in the context of patient safety;
- Moving from a paternalistic doctor-patient relationship to a partnership;
- Establishing incident reporting systems that are not punitive and that lead to a constructive response;
- Establishing complaint-handling and compensation mechanisms for patients and their families, and
- Establishing a statutory authority to protect patients' rights.

The group recommended the following specific action points:

- Create social awareness about patients' rights;
- Advocate for a patients' rights policy;
- Develop and disseminate educational messages and materials on patient safety and patients' rights through the media and schools;
- Promote policies within health care facilities that are patient-centred and ensure that patients are informed and empowered to exercise their rights;
- Create an enabling environment in health care facilities in which individuals feel safe to report incidents or 'near misses' when they occur;
- Encourage reporting of incidents by patients and their families by setting up mechanisms such as a hotline, and
- Provide counselling and support to patients and their families when harm occurs.

The group urged WHO to:

- Involve patients and consumer advocates as active partners in forums discussing patient safety;
- Encourage countries to involve patients and health consumer groups in patient safety committees, and
- Document and share experiences on patient safety and patients' rights among countries.

Working Group IV – Medicines: what are the risks and what can be done?

The group identified the following key issues:

- An inadequately informed public;
- Irrational drug prescribing behaviour of health care providers;
- The substandard quality of medicines and medical devices;
- Absence of systems to monitor adverse events and treatment failures associated to drugs and medical devices, and
- The improper disposal of unused/expired drugs, particularly in emergencies.

The areas of work that required attention were:

- Establishing or strengthening drug information units as well as drug therapeutic committees;
- Addressing the problem of counterfeit and substandard medicines, and
- Ensuring the quality of drug production;

The group recommended the following specific action points:

- Promote the use of standard treatment guidelines and formularies;
- Adapt Essential Drugs List to different levels of the health care system;
- Engage civil society, consumer groups and patient organizations to empower and educate patients about the risks and benefits of drugs;
- Strengthen regulatory mechanisms to ensure the quality of drugs and medical devices;
- Establish and enforce guidelines for the proper disposal of unused or expired drugs;
- Introduce sophisticated and reliable equipment to check the quality of medicines.

The group urged WHO to:

- Update Essential Drugs Lists;
- Establish or strengthen systems for prequalification of drugs and medical devices;
- Design tools and organize training programmes in the procurement of drugs;
- Provide technical assistance to countries to strengthen planning and management of medical technologies including their maintenance, and
- Provide forums for sharing of knowledge, experience and best practices at the regional level.

9. The global patient safety challenge in India

On the third day of the meeting, all workshop participants were invited to attend a ceremony held in New Delhi to launch the Global Patient Safety Challenge in India. India is the first country in the South-East Asia Region to launch the Challenge and to sign the 'Clean Care is Safer Care' pledge committing the country to addressing health care-associated infections.

On the occasion, the Honourable Minister of State for Health and Family Welfare, Mrs Panabaka Lakshmi, released the India Country Report on the Global Patient Safety Challenge. She informed the gathering that Indian experts had contributed to the development of the WHO guidelines on Hand Hygiene in Health Care. She announced that, based on the recommendations of an Expert Committee, eleven hospitals in eight states and Delhi are implementing waste management projects with support from WHO. Furthermore, hand hygiene and infection control will be integrated into the national medical curriculum and inservice training of health care workers. Other speakers included the Secretary, Health and Family Welfare, Mr Prasanna Hota, the Director-General of Health Services, Dr R.K. Srivastava, Prof. Didier Pittet, Leader of the Global Patient Safety Challenge, and Dr S.J. Habayeb, WHO Representative in India.

The launch was followed by a technical briefing on the prevention of health care-associated infections which was moderated by Prof. Didier

Pittet. Dr Agnes Leotsakos, Technical Officer, Patient Safety Programme, WHO/HQ, gave an overview of the “Clean Care is Safer Care” initiative. Ms Julie Storr, Project Manager, Global Patient Safety Challenge, introduced the advanced draft of the WHO Guidelines on Hand Hygiene in Health Care and reviewed the scientific evidence they are based on.

Dr Geeta Mehta, President of the Hospital Infection Society of India (HISI), presented the results of a study conducted at the Lady Hardinge Medical College and Hospital in New Delhi on the use of a locally prepared alcohol-based handrub to control the spread of hospital-acquired infections. The study found that the promotion of hand rubbing with an alcohol-based preparation was successful if staff perception of the product was positive. Furthermore, promoting the positive benefits of hand rubbing versus washing with soap and water in terms of accessibility and time saved, did yield good results. There was evidence of the benefit of handrub, which could also be used in the outpatient department.

The alcohol-based handrub used in the study was manufactured locally based on the WHO formulation. The cost of the raw materials was higher than anticipated, resulting in no significant cost advantage over commercially available products, and, in some cases, the in-house formulation was more expensive. However, a lengthy discussion relating to the type of ethanol purchased resulted in a consensus that it might be possible to drive down costs considerably by switching from laboratory to industrial quality ethanol. Possible skin allergies due to constant use of handrubs also needed to be considered, although alcohol-based handrubs did not cause more skin problems than soap. In the study, the increase in hand hygiene compliance was significant.

10. Closing session

10.1 Summary of the workshop proceedings

Dr Santawat Asavaroengchai, Rapporteur, presented a summary of the proceedings of the workshop from 12 to 14 July 2006. Participants obtained an overview of the problem of patient safety in the global and regional contexts. The participants had an opportunity to share country experiences and identify recurrent issues concerning patient safety.

Common issues and trends that emerged from the discussions included insufficient national leadership and commitment to patient safety, changing relationship between caregivers and patients, shortages, inequitable distribution and poor skill mix of health workers and fear of blame when an error or adverse event had taken place.

The four working groups identified common issues and developed areas of work and action points in the following four areas of patient safety:

- Engaging patients and their families
- Addressing health care-associated infections
- Promoting the rational use of medicines (and medical devices)
- Enhancing the performance of health workers at the frontline of patient safety.

The India launch of the Global Patient Safety Challenge was an opportunity for the participants to learn about patient safety initiatives that were under way in the country. The technical briefing on hand hygiene introduced the new WHO guidelines on the subject and gave an overview of the tools which could aid implementation.

Participants learned that patient safety was everybody's business and must be built into all aspects of health care. It was part of many existing programmes and the challenge lay in its implementation. Simple measures that can save lives like hand hygiene could be taken immediately. Health providers' behaviour that promoted patient safety required intervention at the levels of attitude, knowledge and skills, tools and work environment. Patient safety also required a safe reporting environment.

Blame and punishment tended to drive patient safety problems underground. Many of these problems were due to systems failure. Government and political support was necessary to encourage reporting of cases. The media could be an important player in this.

Patient safety required a partnership with patients, their families and communities. When patients were harmed, there was an erosion of public trust. Patients and their families must become informed partners in their care.

10.2 Closing remarks

Dr Poonam Khetrpal Singh, WHO Deputy Regional Director for South-East Asia, made the closing remarks on behalf of Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia, who could not be present. In his message, the Regional Director thanked participants for achieving the objectives of the workshop and outlining key action points in four priority areas of patient safety that will lead to the formulation of a regional programme for patient safety. The draft report of the workshop will be available to all delegates at the 59th session of the Regional Committee meeting in Dhaka in August.

The Regional Director selected a number of important activities which need to be implemented immediately:

First, awareness needed to be created and a commitment to action made. Member States need to build evidence on the scope and nature of adverse events as well as the factors that contribute to them. Without strong evidence, it was difficult to raise awareness and to have a committed leadership to lead the patient safety movement.

Second, programmes, standards and guidelines already exist to address many areas of patient safety such as nosocomial infections and irrational use of drugs in the Region. Nonetheless, it was striking that the same errors and system failures continue to occur. Ways and means had to be found to motivate the health workforce to implement existing guidelines and solutions.

Third, the capacity of the health workforce had to be built and an enabling work environment created for them. Member States need to incorporate patient safety concepts in their human resources development plans as well as preservice, inservice and continuing professional education. In addition, Member States need to establish a policy and regulatory framework that supports the implementation of patient safety.

Fourth, patients and communities needed to be engaged actively involved as partners in the process. Patients' rights needed to be promoted while also protecting providers' rights. In this regard, there is a need to establish a functional system to mitigate the consequences of adverse events, establish neutral bodies for mediation, and strengthen legal machinery for compensation, if deemed necessary.

The World Health Assembly resolution WHA55.18, urges Member States to pay the closest possible attention to patient safety. It implies that all those who are present here today have an obligation to promote patient safety. WHO is committed to work hand in hand with Member States to make health care safer in the Region.

With this, after thanking participants for their valuable contributions, the meeting was declared closed.

Annex 1

Programme

Wednesday, 12 July 2006

Day 1

- 08:30-09:00 Registration
- 09:00-09:30 **Opening Session**
- Inaugural address – Dr Poonam Khetrpal Singh, Ag Regional Director, WHO South-East Asia Regional Office
 - Objectives of the workshop and introduction of participants
 - Dr Gunawan Setiadi, STP Health Systems, HSD, WHO/SEARO
 - Nomination of Chair, Co-chairs and Rapporteur
- 09:30-10:30 **Plenary 1: Global context of patient safety**
- International context of patient safety
 - Sir Liam Donaldson, Chair, World Alliance for Patient Safety (video presentation)
 - Mr. Martin Fletcher, Secretariat, World Alliance on Patient Safety PSP WHO/HQ
- Q & A
- 11:00- 13:00 **Plenary 2: Regional context and country experiences**
- Promoting patient safety in health care in South-East Asia- Dr. Sultana Khanum, Director, HSD, WHO/SEARO
- Q&A
- Country presentations
- 14:00-15:30 Regional context and country experiences (cont'd)
- documentary on HIV and unsafe blood exposure, Norwegian Church Aid in cooperation with Tata Institute of Social Sciences, Bombay
 - country presentations
- 16:00-17.00 Discussion on emerging issues and areas for regional collaboration
- 17:00- 17:15 Preview of the next day

Thursday, 13 July 2006

Day Two

09:00-10:30 **Group Work on Patient Safety in Health care Institutions**
(simultaneous sessions)

Group Work-I

Topic: Fighting health-care associated infections in resource-poor settings (potential issues for discussion: educating and motivating all workers to adopt safer practices, integrating infection-control measures into in-service training and clinical practice, implementation of hand hygiene where clean water is scarce, monitoring nosocomial infections when diagnostic tools are limited)

Group Work-II

Topic: Health workers at the frontline of patient safety (potential issues include: staffing levels, the skill level of the nursing and midwifery workforce, nurse-physician relations, responsiveness of management to address problems in patient care identified by nurses at the bedside, quality of the nurse working environment)

Group Work-III

Topic: Patients—passive victims or active partners? (potential issues for discussion: practical and ethical concerns of involving patients in their own care, concerns about creating additional burdens on staff, dealing with the consequences of mistakes and harm when they occur, role of patients in identifying and reporting adverse events, patients' rights, consumer education, role of consumer associations)

Group Work-IV

Topic: Medicines—what are the risks and what can be done? (potential issues for discussion: irrational use, 'polypharmacy', overuse of injections, development of resistance, adverse effects, quality of drugs and treatment failures).

11:00-13:00 Group Work (cont'd)

14:00-15:30 **Plenary 3: Reporting on Group Work**

- Presentations of Group Work I and II
- Discussions

16:00-17:30 Reporting on Group Work (Cont'd)

- Presentations of Group Work III and IV
- Discussions

17:30- 17:45 Preview of the next day

Friday, 14 July 2006

Day Three

- 09.00 -11.30 **Inauguration of the Global Patient Safety Challenge in India**
(Venue: Nilgiri Room)
- 13:00 -15:30 **Technical briefing session on the “Clean Care is Safer Care” initiative**
(Venue: Nilgiri Room)
- 13.00 –13.15 Clean Care is Safer Care: An overview
(Dr Agnes Leotsakos, WHO)
- 13.15 –13.30 Hand Hygiene and Multimodal Strategies: The scientific evidence
(Ms Julie Storr, WHO)
Discussion
- 13.30 – 14.15 Tools and strategies for implementation
(Ms Julie Storr, WHO)
Discussions
- 14.15 – 14.45 Introduction to WHO Guidelines on Hand Hygiene in
Health Care (Advanced Draft) (Ms Julie Storr, WHO)
Preliminary observations on indigenously prepared alcohol-based handrub
for hand disinfection
(Dr Geeta Mehta, President, Hospital Infections Society, India)
Discussion
- 14.45 –15.30 Regional action on “Clean Care is Safer Care” - Group
discussion (Professor Didier Pittet, Leader of the First Global Patient Safety
Challenge, and Director, Infection Control Programme, University
Hospitals, Geneva)
- 16.00 -16:30 **Plenary 4: Closing session/Group photo**
- Summary of the workshop proceedings – Dr Santawat Asavaroengchai, Rapporteur
 - Closing remarks – Dr Poonam Khetrpal Singh, Ag. Regional Director, WHO South-East Asia Region
 - Group Photo

Annex 2

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