

# Promoting Patient Safety at Health Care Institutions

Report and Documentation of the Technical Discussions  
held in conjunction with the 43<sup>rd</sup> Meeting of CCPDM  
WHO/SEARO, New Delhi, 14-16 June 2006



**World Health  
Organization**

Regional Office for South-East Asia  
New Delhi

SEA-HS-227  
Distribution: General

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The report and recommendations of the Technical Discussions on Promoting Patient Safety at Health Care Institutions, held in conjunction with the 43<sup>rd</sup> meeting of the Consultative Committee for Programme Development and Management (CCPDM), held in WHO/SEARO, New Delhi, 14-16 June 2006 were presented to the Fifty-ninth session of the Regional Committee for South-East Asia. The Regional Committee noted the report and endorsed the recommendations. The Committee also adopted a resolution on the subject (SEA/RC59/R3).

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# Part I – Report<sup>\*</sup>

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<sup>\*</sup> Originally issued as “Report of the Technical Discussions on “Promoting Patient Safety at Health Care Institutions” (document SEA/RC59/Inf.4 dated 20 July 2006)



## **Introduction**

1. The Technical Discussions on Promoting Patient Safety at Health Care Institutions were held on 16 June 2006, in New Delhi, India in conjunction with the 43rd Meeting of the Consultative Committee for Programme Development and Management (CCPDM). H.E Prof. Mya Oo, Deputy Minister for Health, Ministry of Health, Myanmar, and Dr Bishnu Prasad Pandit, Chief Specialist, Ministry of Health and Population, Nepal, were elected Chairman and Rapporteur respectively. Special invitees, representing the local civil society, participated in the discussions in addition to the CCPDM participants.

## **Opening Remarks by the Chairman**

2. The Chairman, in his opening remarks, said that it was opportune that the topic for Technical Discussions this year was Promoting Patient Safety at Health Care Institutions as it was a critical component of quality of care. Patient Safety was recognized as an essential input for achieving national health targets and for improving the health of the population.

3. He pointed out that adverse events occurred at all levels of the health system, in both clinical and managerial domains, during both preventive and curative interventions, and in both public and private practice. An adverse event was defined as a discrete occurrence related to health care management that results in unintended injury, illness or death.

4. He noted that the magnitude and the nature of the problem of adverse events were not well documented in countries of the Region. The situation in developing countries was believed to be far more serious than in industrialized nations. Beyond the poor state of health care infrastructure and equipment, unreliable supply and quality of drugs, it was the poor performance of personnel and the severe under-financing of essential operational costs of health services that made the probability of adverse events that much greater in these countries.

5. The Chairman reminded participants that the subject of Patient Safety had been presented to the Executive Board of the World Health Organization (WHO) for the first time in January 2002. The discussions on the subject culminated in the adoption of a resolution by the Fifty-fifth World Health Assembly in May 2002. Resolution WHA55.18 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, including the monitoring of drugs, medical equipment, and technology".

6. The Chairman informed the participants that in October 2004, the Director-General of WHO launched the World Alliance for Patient Safety to galvanize and coordinate global and national efforts to improve patient safety.

7. The Chairman also recognized that the South-East Asia (SEA) Region of WHO had been working closely with Member States to ensure patient safety in the following interrelated areas: blood safety; injection and immunization safety; health care waste management; drug safety; making pregnancy safer; child health, and human resources for health.

8. He hoped that active deliberations during the session would result in practical recommendations that could be implemented at health care institutions in countries of the Region. He then introduced the video message of Sir Liam Donaldson, Chair of the World Alliance for Patient Safety (WAPS).

## **Remarks by the Chair of the World Alliance for Patient Safety**

9. In a video-taped presentation, Sir Liam Donaldson, Chair of the WAPS, thanked Dr Samlee Plianbangchang, Regional Director, WHO SEA Region, for the opportunity to set the global stage for patient safety and said a few words about the work of the Alliance. He welcomed efforts already under way in many Member countries of the SEA Region in areas such as injection safety, drug safety and health care waste management.

10. The Alliance aimed to fulfil the requirements of the World Health Assembly resolution 55.18 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.

11. 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 Member States were working actively to make patient safety a priority and to establish programmes of action.

12. A growing body of research evidence pointed to the fact that errors 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.

13. 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. Countermeasures based on changes in systems of care were, therefore, more productive as risk-reduction strategies than those that only targeted individual practices or products.

14. 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.

15. 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 area presented first was the Global Patient Safety Challenge. For the period 2005-2006, the work on Global Patient Safety Challenge is being focused on health care-associated infection with the theme Clean Care is Safer Care. Work in the area of Patients for Patient Safety is harnessing the wisdom of patients and “patient-champions” in making health care safer and better for future patients. The third area of action aims to establish effective reporting and learning systems in order to learn from past failures. The fourth area seeks 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 aims 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 seeks to create solutions by translating theoretical knowledge into practical action.

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

17. He 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.

## **Introduction to the Topic of Technical Discussions**

18. Dr Sultana Khanum, Director, Health Systems Development (HSD), WHO/SEARO, began her presentation with the following questions: Are we following the longstanding cornerstone of medicine “First, do no harm”? Are we unintentionally harming patients whom we are seeking to help? Do we know what burden of injury, illness or death in the world is due to unintentional harm? She gave examples of adverse events that occur in health care in association with:

- Medical devices (e.g. contaminated or unsafe injection);
- Medication (e.g. wrong drug, wrong dose, wrong patient, wrong route, unjustified prescription);
- Unsafe blood or blood product transfusion;
- Patient care (e.g. nosocomial infections, post-operative deep vein thrombosis), and
- Surgery, anaesthesia and obstetric trauma, etc.

19. The presentation was organized around three questions:

- Why is patient safety a regional priority?
- How to enhance patient safety?
- What needs to be done?

20. It was mentioned that at least one in 10 persons in health care institutions experienced some form of unintended harm. An estimated 50% of injections in developing countries were unsafe. Over 50% of all medicines prescribed, dispensed or sold globally were not justified – almost certainly more in poor countries. Compared to industrialized countries, the risk of acquiring a health care-associated infection was estimated to be 2-20 times higher and that of neonatal infections 3-20 times higher. Furthermore, in the SEA Region:

- Only 61% of blood donations were from volunteers — proven to be the safest donors;
- An estimated 1000 tons of health care waste were produced and improperly disposed of each day, and
- Medical devices may not meet international standards because they are produced outside of the regulatory framework.

21. It was conceded that while adverse events could not be eliminated entirely, they could be minimized:

- At least 50% of adverse events were preventable;
- Adverse events were primarily due to deficiencies in health care systems rather than due to human error, and
- Adverse events often have common root causes which can be generalized and corrected.

22. The importance of creating an environment and developing monitoring systems which would facilitate 'learning from failure' was underlined. Since individuals were not likely to report health care errors if they were to be punished, the focus should be on systems rather than on blaming individuals. In addition, transparent and effective reporting systems needed to be in place so that adverse events could be detected, reported, analysed and responded to. Finally, the experience and wisdom of patients and their families, health care workers and professional bodies, and consumers and consumer groups should all be harnessed towards making health care safer.

23. In this context, it was important for Member countries to: (i) Find out what harm was being done, to whom, where and why; and (ii) Identify and deliver solutions. At the same time, WHO should: (i) Provide technical leadership and support to Member countries in the design, implementation and monitoring of patient safety programmes; (ii) Ensure capacity building in different aspects of patient safety at the regional, sub-regional and country levels; (iii) Facilitate collaboration and exchange of information and best practices between Member countries and the World Alliance on Patient Safety, and (iv) Monitor and report on the progress made in the Region.

24. The presentation was concluded by reminding the audience that improving patient safety was clearly an issue of high significance for every country in the Region, from the richest to the poorest, and that commitment to patient safety will save many lives and prevent significant harm across the Region.

## **Discussions**

25. The following sections provide the highlights and conclusions of the discussions.

## **General discussion**

26. The participants expressed appreciation for putting patient safety on the agenda and hoped that the meeting would come up with a draft resolution to be approved by the Regional Committee. The importance of identifying a set of concrete actions to improve the quality of care in the Region was highlighted. Studies in Thailand had shown that 10% of disability and 10% of deaths could be attributed to adverse events and that 50% of such events were preventable. The number of medical malpractice suits filed with the Medical Council in Thailand had increased dramatically over the last 30 years. Not surprisingly, adverse events were a sensitive issue in Thailand and were perceived as a threat to health professionals, jeopardizing their relationship with patients and having the potential to lead to litigation. Several mechanisms to promote patient safety in Thailand, such as a hospital accreditation programme and medical record audit were in place. There was a need to develop measures appropriate to the Region. In this context, the following steps were proposed: Development of a participatory surveillance and evidence-based risk management system; Strong governmental and societal commitment to establish a culture conducive to patient safety, and Development of a regional strategic plan with active involvement of patient groups (to be approved by the Regional Committee).

27. Participants expressed their appreciation for the timely initiative. It was felt that many aspects of patient safety fell outside the realm of health institutions. Some of the failings of patient safety programmes can be attributed to weak regulation; understaffed, overworked and under-skilled health workers, and faults in the building design. More transparency was called for and there was a need to work closely with the public. Health professionals' fear of exposure to litigation as being the reason for their not coming forward was acknowledged.

28. The need to conduct problem analysis and identify the underlying societal and institutional determinants for the shortcomings in patient safety was highlighted. Adverse events are a multisectoral problem requiring multisectoral solutions.

29. The problem of low-quality medical devices, vaccines and drugs in the Region and the need for good procurement policies based on international standards, was noted.

30. Participants emphasized the need to recognize and build on existing interventions in the Region. Some of the measures being implemented in large hospitals in India were the establishment of various committees, including a committee to investigate deaths and take appropriate actions; a health care risk

management committee, and an infection control committee to monitor hospital-acquired infections, especially in intensive care units. There was a need to focus on identifying faults in the system and removing them rather than blaming individuals.

31. Inadequacy of information and research in patient safety in most countries of the Region was pointed out. Some of the measures under way to improve patient safety in Sri Lanka, such as a hospital infection control and quality assurance programme, and strengthening of a health information system to document patient safety issues were elaborated. A pilot project was under way in five major hospitals which will eventually be scaled up to other hospitals in the country.

32. The meeting recognized that patient safety was a very important issue, particularly in the areas of medical devices; drugs; waste disposal, and injection safety. Some of the policies and strategies adopted to improve patient safety in DPR Korea, such as requiring health care workers to adhere to the highest standards of health care practice; establishing a national reporting system on adverse events, and educating students on patient safety were highlighted. Participants called on WHO and the Alliance to assist Member countries in capacity building and in the development of safety guidelines, adequate reporting systems, and a standardized taxonomy.

33. The increasing concerns regarding quality of care and patient safety in Indonesia were highlighted. It was noted that the then existing medical practice laws in Indonesia gave an opportunity for patients to file a lawsuit. Some policy measures were implemented in Indonesia to enhance the quality of care and prevent misconduct and adverse events, such as laws and regulations on medical practices and hospital accreditation, and the partnership between health professionals and patients/other stakeholders.

34. It was noted that patient safety should not be confined to the walls of a health care institution. The meeting was reminded that adverse events included errors of omission as well as commission noting that not taking appropriate actions could also lead to patient harm.

35. Finally, at the close of the general discussion, the Chairman highlighted the fact that the first principle of patient care was quality care at individual and institutional levels. He underlined the need to practise professionalism i.e. by updating knowledge, improving skills, and being very critical in aiming for zero harm/defect. He also emphasized that regulatory measures needed to be developed and patient safety implemented, both in public and private settings. A committed teaching faculty was needed to provide role models. He also highlighted some measures which should be taken to improve patient safety, such as establishing a patient safety

committee in large institutions with a sub-committee on utilization, instituting professional audit, and improving the teaching curricula, focusing on simple measures, such as hand hygiene. The Chairman also underlined the need for a clean environment, and appropriate water and sanitation management.

### **Priority areas of work**

36. The priority areas identified during the group work are delineated below.

(1) Creating an enabling environment:

- Assessing the scope and nature of the problem;
- Raising awareness;
- Engaging stakeholders such as professional associations and medical councils;
- Establishing national policies and guidelines;
- Establishing enabling legislation, rules and regulations, and
- Ensuring adequate levels and effective use of financial and human resources.

(2) Addressing common communication barriers within the health care team and between health care professionals and patients such as:

- Fear of blame;
- Culture of 'not questioning';
- Gender barriers;
- Relationship imbalances;
- Lack of privacy and confidentiality, and
- Lack of cultural sensitivity.

(3) Establishing systems and mechanisms as an integral component of quality assurance:

- Monitoring and feedback;
- Incident reporting;
- Clinical audits and reviews;
- Management and logistic systems;
- Patient safety committees, and
- Institutional standards and accreditation.

- (4) Implementing interventions to reduce harm and improve patient safety:
  - Empowerment of patients through information and education;
  - Standard operating procedures;
  - Infection control including hand hygiene;
  - Blood safety;
  - Injection safety;
  - Environmental hygiene and waste management, and
  - Safety of medicines and medical devices.
- (5) Educating and training staff:
  - Induction of hospital staff, both clinical and non-clinical (administrative, managerial and support), on institutional policies and procedures related to patient safety, and
  - Inclusion of modules on patient safety in pre- and in-service training curricula and continuing health professional education.
- (6) Learning from operational research linked to interventions.

## Conclusions and Recommendations

37. In addition to the recommendation that the regional initiative be broadened from 'Promoting Patient Safety at Health Care Institutions' to 'Promoting Patient Safety in Health Care', the Group made the following recommendations (see also annex):

### For Member countries

38. It is recommended that Member countries should:
- (1) Assess the scope and nature of adverse events occurring at health care institutions, as well as of the contributing factors;
  - (2) Establish or improve, with the involvement of all stakeholders, systems for the detection and reporting of adverse events occurring at health care institutions with the primary focus to improve systems rather than attribute blame, and national mechanisms to capture, share, respond and learn from this information at all levels of the health system;
  - (3) Promote interventions that have been shown to improve patient safety;

- (4) Support and enable health care institutions, both public and private, from the primary health care level through the referral level, to implement changes in systems and practices conducive to patient safety;
- (5) 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;
- (6) 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;
- (7) Establish systems that respect the rights of both patients and providers, and
- (8) Allocate adequate resources to implement the above activities.

## **For WHO**

39. It is recommended that WHO should:

- (1) Coordinate, through an inclusive consultative process, the development of a strategic framework and package of interventions for strengthening patient safety at health care institutions, which builds on successful interventions and actions, both in the Region and worldwide,
- (2) Provide strong technical leadership and support to Member States in designing and implementing patient safety interventions and monitoring systems at health care institutions;
- (3) Ensure capacity building in different aspects of patient safety through training activities at the regional, sub-regional and country levels;
- (4) Facilitate collaboration and exchange of information and best practices between Member States and the World Alliance on Patient Safety;
- (5) 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;
- (6) 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
- (7) Monitor and report on the progress made in the Region.

Annex

## **Consideration of the Recommendations Arising out of the Technical Discussions on “Promoting Patient Safety at Health Care Institutions”\***

1. The Technical Discussions on Promoting Patient Safety at Health Care Institutions were held on 16 June 2006, in New Delhi, India in conjunction with the 43rd Meeting of the Consultative Committee for Programme Development and Management (CCPDM). H.E Prof. Mya Oo, Deputy Minister for Health, Ministry of Health, Myanmar, and Dr Bishnu Prasad Pandit, Chief Specialist, Ministry of Health and Population, Nepal, were elected Chairman and Rapporteur respectively. Special invitees, representing the local civil society, participated in the discussions in addition to the CCPDM participants.
2. Sir Liam Donaldson, Chair of the World Alliance for Patient Safety, had sent a video-presentation containing his remarks which was shown to the participants.
3. The detailed report of the Technical Discussions on Promoting Patient Safety at Health Care Institutions is provided in the document SEA/RC59/Inf.4.
4. In addition to the recommendation that the regional initiative be broadened from ‘Promoting Patient Safety at Health Care Institutions’ to ‘Promoting Patient Safety in Health Care’, the Group made the following recommendations:

### **Recommendations for Member countries**

5. It is recommended that Member countries should:
  - (1) Assess the scope and nature of adverse events occurring at health care institutions, as well as of the contributing factors;
  - (2) Establish or improve, with the involvement of all stakeholders, systems for the detection and reporting of adverse events occurring at health care

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\* Originally issued as “Consideration of the Recommendations Arising out of the Technical Discussions on “Promoting Patient Safety at Health Care Institutions” (SEA/RC59/11 (Rev.1) dated 20 July 2006

institutions with the primary focus to improve systems rather than attribute blame, and national mechanisms to capture, share, respond and learn from this information at all levels of the health system;

- (3) Promote interventions that have been shown to improve patient safety;
- (4) Support and enable health care institutions, both public and private, from the primary health care level through the referral level, to implement changes in systems and practices conducive to patient safety;
- (5) 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;
- (6) 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;
- (7) Establish systems that respect the rights of both patients and providers, and
- (8) Allocate adequate resources to implement the above activities.

## **Recommendations for WHO**

6. It is recommended that WHO should:

- (1) Coordinate, through an inclusive consultative process, the development of a strategic framework and package of interventions for strengthening patient safety at health care institutions, which builds on successful interventions and actions, both in the Region and worldwide,
- (2) Provide strong technical leadership and support to Member States in designing and implementing patient safety interventions and monitoring systems at health care institutions;
- (3) Ensure capacity building in different aspects of patient safety through training activities at the regional, sub-regional and country levels;
- (4) Facilitate collaboration and exchange of information and best practices between Member States and the World Alliance on Patient Safety;

- (5) 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;
- (6) 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
- (7) Monitor and report on the progress made in the Region.

7. The Technical Discussions Group proposed that the Fifty-ninth session of the Regional Committee may consider to adopt a resolution on this topic based on the above-mentioned recommendations.



**Part II – Resolution, Agenda  
and Working Paper**



# Resolution\*

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,

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\* Originally issued as "Promoting patient safety in health care" (document SEA/RC59/R3). As decided by the Fifty-ninth session of the Regional Committee the term "institutions" was dropped from the original title.

1. ENDORSES the recommendations contained in the report (SEA/RC59/11(Rev.1) and SEA/RC59/Inf.4);
2. URGES Member States:
  - (a) to assess the scope and nature of adverse events in health care institutions as well as the contributing factors;
  - (b) to establish or improve, with the involvement of all stakeholders, systems for the detection and reporting of adverse events with a primary focus on improving systems;
  - (c) to develop national mechanisms to capture, share, respond, and learn from this information at all levels of the health system;
  - (d) to promote interventions that have been shown to improve patient safety;
  - (e) to support and enable health care institutions, both public and private, from the primary health care level through the referral level, to implement systems changes and practices conducive to patient safety;
  - (f) to create, at all levels of the health care system, through awareness-raising and enabling policies and legislation, an open environment receptive to the operational changes needed to deliver safer care in health care institutions;
  - (g) to engage patients, consumer associations, health care workers, and professional associations, hospital associations, health care accreditation bodies and policy-makers, in building safer health care systems, and creating a culture of safety within health care institutions;
  - (h) to establish systems that respect the rights of both patients and providers, and
  - (i) to allocate adequate resources to implement the above activities, and
3. REQUESTS the Regional Director:
  - (a) to coordinate, through an inclusive consultative process, the development of a strategic framework and package of interventions for strengthening patient safety which builds on successful interventions and actions in the Region and worldwide;

- (b) to provide strong technical leadership and support to Member States in designing and implementing patient safety interventions and monitoring systems;
- (c) to ensure capacity building in different aspects of patient safety through training activities at the regional, sub-regional, and country levels;
- (d) to facilitate collaboration and the exchange of information and best practices between Member States and the World Alliance on Patient Safety;
- (e) to coordinate and facilitate research on patient safety in the Region, including baseline surveys on adverse events, and operational research to assess the cost-effectiveness of interventions;
- (f) to contribute to the development of a patient-safety taxonomy, systems for reporting and learning from adverse events, and best practices to improve patient safety, and
- (g) to monitor and report on progress in this area in the Region.



# Agenda<sup>\*</sup>

1. Introduction
2. Magnitude of the Problem
3. WHO's Response
4. Key Concepts and Strategic Directions
5. The Way Forward

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<sup>\*</sup> Originally issued as document SEA/PDM/Meet.43/TD/1.1 dated 5 June 2006



# Annotated Agenda<sup>\*</sup>

## 1. Introduction

- (a) Patient safety is a critical component of quality of care
- (b) Definition and examples of adverse events
- (d) Most adverse events are due to system failures and are preventable

## 2. Magnitude of the Problem

- (a) Epidemiology of adverse events
- (b) Costs and impact of adverse events

## 3. WHO's Response

- (a) WHO Geneva
  - Fifty-fifth World Health Assembly passed Resolution WHA55.18 on Patient Safety, May 2002
  - World Alliance for Patient Safety established and a Forward Programme with six areas of action developed, October 2004
  - First Global Patient Safety Challenge "Clean Care is Safer Care" launched to address health care-associated infections, October 2005
- (b) WHO South-East Asia Region
  - Patient safety cuts across several areas of work in the Region including blood safety, injection and immunization safety, health care waste management, drug safety, health care-associated infections, making pregnancy safer, child health, and human resources for health.

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<sup>\*</sup> Originally issued as document SEA/PDM/Meet.43/TD/1.2 dated 5 June 2006

## **4. Key Concepts and Strategic Directions**

- (a) A focus on systems rather than blaming individuals
- (b) Learning systematically from things that go wrong
- (c) Involving patients and communities
- (d) Translating evidence into sustainable health-system oriented solutions

## **5. The Way Forward**

- (a) Role and responsibilities of Member States
  - Assess the scope and the nature of adverse events at health care institutions as well as the factors that contribute to them;
  - Establish or improve national systems for the detection and reporting of adverse events in health care institutions, and a national mechanism to capture, share, respond, and learn from this information from all levels of the health system;
  - Support priority research aimed at improving patient safety;
  - Promote interventions that have been shown to improve patient safety;
  - Support or enable health care institutions to implement system changes and practices conducive to patient safety;
  - Create an environment receptive to change at all levels of the health care system through awareness-raising and enabling policies and legislation;
  - Engage patients, consumer associations, health care workers and professional associations in efforts to build safer systems within health care institutions;
  - Allocate adequate resources to implement the above activities.
- (b) Role and responsibilities of WHO SEA Region:
  - Through an inclusive consultative process, develop a strategic framework and package of interventions for strengthening patient safety in health care institutions, which builds on successful interventions and actions in the Region and worldwide;

- Provide technical leadership and support to Member States;
- Support capacity building efforts through training at the regional, sub-regional, and national levels;
- Facilitate collaboration and the exchange of information and best practices between Member States and the World Alliance on Patient Safety;
- Assist Member countries in establishing and coordinating regional research priorities;
- Support the global development of evidence-based norms, standards, and guidelines for quality of care and patient safety; and,
- Monitor and report on progress in the Region.



# Working Paper<sup>\*</sup>

## 1. Introduction

1. The longstanding cornerstone of medicine “first, do no harm” represents the medical profession’s understanding that human beings are fragile. Thus, patient safety has always been an important part of quality of care. Nevertheless, it is seen that health care systems around the world occasionally, but unintentionally, harm patients whom they are seeking to help. Every point in the management of a patient contains a certain inherent risk for harm.

2. Adverse events occur at all levels of the health system, in both clinical and managerial domains, during both preventive and curative interventions, and in both public and private practice. An adverse event is defined as a discrete occurrence related to health care management that results in unintended injury, illness, or death. Preventable events are events that could have been anticipated and prepared against but occur because of an error or other system failure. This can include acts of commission and omission. Examples of preventable adverse events include injury, disability or death associated with:

- surgery and anaesthesia (e.g. surgery performed on the wrong patient or the wrong body part, foreign body left during procedure, endotracheal tube misplacement)
- medication (e.g. wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- medical devices (e.g. contaminated or unsafe injections or blood collection)
- invasive investigations (e.g. mislabeled biopsy)

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<sup>\*</sup> Originally issued as document SEA/PDM/Meet.43/TD/1.3-Rev.1 dated 5 June 2006

- blood or blood product transfusion (e.g. hemolytic reactions due to ABO incompatibility, transmission of infectious agents such as HIV, hepatitis B or hepatitis C virus)
- patient care (e.g. post-operative deep vein thrombosis or pulmonary embolism, advanced stage pressure ulcers)
- failure to identify underlying conditions (e.g. hyperbilirubinemia in neonates)
- labour or delivery of a low-risk pregnancy (e.g. cases of birth and obstetric trauma)
- environmental (e.g. exposure to radiation, burns, electric shock, falls)

3. Published audits of adverse events in acute care suggest that around half of adverse events in industrialized nations are potentially preventable (1-5). The proportion of adverse events that are preventable is likely to be even higher in developing countries. Adverse events are primarily due to deficiencies in system design, organization and operation rather than due to individual providers. System and process changes can therefore result in dramatic improvements in patient safety all over the world, particularly in developing nations.

## **2. Magnitude of the problem**

4. Lapses in patient safety are remarkably common and have been exacting an enormous human and financial toll globally.

### **2.1 Epidemiology of adverse events**

5. The vast majority of data on the incidence of adverse events have been collected from reviews of medical records in industrialized nations and most of this evidence comes from hospitals even though adverse events occur in all health care settings including physicians' offices, nursing homes and pharmacies.

6. The magnitude of the problem of adverse events remained largely unrecognized until the early 1990s with the publication of the results of the Harvard Medical Practice Study in 1991 (6, 7). Since then, a body of evidence has emerged from medical record audits in Australia, the UK, Denmark, New Zealand, and Canada suggesting an incidence of adverse events ranging from 3.2 to 16.6 per 100 hospital admissions (1-5). National studies on the incidence of adverse events have

also been published in France recently and are underway in a number of other countries including Spain and Brazil (8). Extrapolating from all these studies would suggest that 1 in 10 patients receiving hospital care may experience some form of unintended harm. Despite continued debate about the exact size and nature of the problem, few would disagree that patient safety shortcomings are a significant source of patient morbidity and mortality in the world.

7. While less well documented, the situation in developing countries is believed to be far more serious. Beyond the poor state of the health care infrastructure and equipment, unreliable supply and quality of drugs, and short-comings in waste management and infection control, the health care workforce is severely overburdened and services are seriously underfinanced. These factors have a negative impact on the performance of the health care system as a whole and ultimately on health outcomes. In addition, many people in developing countries seek care from unqualified providers in the informal, largely unregulated sector.

8. Illustrating the above, the risk of acquiring a health care-associated (or nosocomial) infection, a prevalent patient safety problem, is estimated to be 2 to 20 times higher in developing countries than in industrialized ones (9,10). A review of hospital-acquired infection surveillance data collected between 1978 and 1980 at a large teaching hospital in Bangkok, Thailand, found an average incidence of 9.8 infections per 100 discharges (11). A cross-sectional survey conducted between 2001 and 2002 at two teaching hospitals in Indonesia reported that 1 in 14 hospitalized patients had one or more health care-associated infections and that 5-8% of patients who underwent surgery had such infections (12). The prevalence of health care-associated infections is probably much higher than reported in these studies due to limited diagnostic tools and under-reporting in medical records. A 2005 review of data from developing countries on rates of neonatal infections among hospital-born babies found rates that were 3 to 20 times higher than those reported in industrialized countries (13).

9. Nosocomial transmission of *Mycobacterium tuberculosis* (TB) is a global public health concern especially in HIV infected patients. A prospective blood culture survey conducted in an infectious disease hospital in Thailand and a general hospital in Malawi in 1997 revealed that 10% of febrile inpatients enrolled in the study had TB bacteraemia that went unrecognized although 80% had a cough and 45% had an abnormal chest radiograph or a positive sputum smear (14).

10. In 1999, WHO estimated that people residing in South-East Asia received more than 5 injections per capita per year and 50% of these injections were unsafe (15). Confirming these estimates, a cross-sectional survey in 2004, of a randomly selected sample of injection providers and community members, covering urban non-slum, slum and peri-urban areas of Delhi, India, found that the population received 5.1 injections per capita per year and that only 22.5% of injections were administered with a sterile syringe and needle (16). That same year, a nationwide assessment of injection practices in India found that every second prescription in outpatient clinics included an injection, over 60% of injections were unsafe, safety was poorest at immunization clinics, and only 51% of the disposal of injection-related waste was acceptable at health care facilities (17).

11. Regulation of medical devices is a serious concern in South-East Asia. The region is a large producer of medical devices that are exported all over the world. While statistics are lacking, the devices sold in the domestic market are manufactured outside the regulatory framework and often do not meet international standards.

12. In 1999, WHO estimated that developing countries accounted for around 77% of all reported cases of counterfeit and substandard drugs in the world (18). During that same year, WHO further estimated that over 50% of all medicines prescribed, dispensed or sold globally were not justified (19). A community-based study carried out in Chittagong, a metropolitan area of Bangladesh, in 1998, found a 73.5% prevalence of drug misuse in the treatment of acute diarrhoea among under-five children. What is worse, those who consulted health care professionals were at 5.7 times higher risk of receiving such drugs and experienced even longer episodes of diarrhoea (20). A retrospective review of medication errors conducted at a prominent children's hospital in Bangkok between 2001 and 2002, found that medication errors occurred in 1% of admissions – most commonly a prescription error (35%)—but that the majority (77%) of errors were detected and prevented before the drugs were administered to patients (21).

13. The above examples only give an idea of the scope of the patient safety problem in the Region. Many more baseline studies on the prevalence and nature of adverse events in the Region are needed.

## 2.2 Costs of adverse events

14. In addition to causing avoidable human suffering, the overall costs of adverse events can be considerable. These include:

- Damage to patients and their families made worse by the defensive and secretive way that many health care institutions respond in the aftermath of a serious event.
- Loss of confidence, motivation and job satisfaction within the health workforce which can lead to poor performance and attrition.
- Loss of reputation and credibility and trust within the communities served by health care organizations.
- Financial costs as a result of prolonged hospitalization, litigation claims, lost income, disability and medical expenses.

15. These constitute human, financial and opportunity costs that health systems can ill-afford in settings where resources and faith in the system are already stretched to their limit.

## 3. The response

16. Despite the recognition that patient safety is a fundamental part of the drive to improve quality of care, there have been insufficient resources invested to address the problem in a concerted and consequential fashion. No country, rich or poor, can claim to have fully come to grips with the problem of patient safety. Although there are examples of successful initiatives for reducing the incidence of adverse events within specific health care institutions, few have been scaled up to embrace an entire health system. Nonetheless, public concern has been mounting in recent years, and a growing number of medical practitioners, public health experts, patient advocates, health institutions, and Governments are working to address it.

### 3.1 WHO's response

17. The subject of patient safety was first presented to the Executive Board of the World Health Organization in January 2002. This culminated in the drafting of a resolution that was adopted by the Fifty-fifth World Health Assembly in May 2002. Resolution WHA55.18 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, including the monitoring of drugs, medical equipment, and technology" (22). Further, it requested the Director-General to develop global norms and standards; promote the framing of evidence-based policies and to develop mechanisms in order to recognize excellence in patient safety internationally; encourage research; and to support Member States in several key areas.

18. An intercluster working group on patient safety was set up in 2002 and was instrumental in bringing together all the relevant activities in WHO for consolidated action in response to resolution WHA55.18. WHO's work on patient safety falls under the following main areas: blood safety, injection safety, vaccine safety, drugs and medicines, making pregnancy safer and medical devices. Since the resolution was passed, WHO has established work programmes tackling several systemic issues. These include the absence of an agreed international taxonomy for patient safety events, methods to assist Member States estimating hazards within their own health care systems, and the development of reporting and learning systems to detect patient safety problems.

19. In May 2004, noting the progress made in implementing resolution WHA55.18 and recognizing that no single player could tackle the full range of patient safety issues on a worldwide scale, the Fifty-seventh World Health Assembly called for an international alliance for improving patient safety as a global initiative. Thus, in October 2004, the WHO Director-General launched the World Alliance for Patient Safety and with it the Forward Programme, to galvanize and coordinate global and national efforts to improve patient safety (23). The Alliance is chaired by Sir Liam Donaldson, Chief Medical Officer of the United Kingdom. The Secretariat of the Alliance is based at WHO Headquarters in Geneva. The Forward Programme identifies six main priority areas for international work including:

Action area 1	The Global Patient Safety Challenge (a biennial programme of events which focuses on one area of patient safety. The Challenge for 2005-06 is "Clean Care is Safer Care" and focuses on hand hygiene).
Action area 2	Patients for Patient Safety (working with users of health care around the world to gain patient involvement in the work of the Alliance).

Action area 3	International Patient Safety Taxonomy (a project aiming to standardize the various patient safety classification systems existing globally, to allow greater intersystem comparison and study).
Action area 4	Research in the field of patient safety (to develop an understanding of the various inputs and outputs that are required for the global patient safety agenda).
Action area 5	Solutions (finding ways to reduce the risk of health care and improve its safety).
Action area 6	Reporting and Learning (to identify areas of patient safety where there is the greatest need for action and to learn from these areas).

20. Every two years, under what it has named the Global Patient Safety Challenge Alliance, the Alliance will identify for action, an issue in patient safety that is relevant to all Member States. The theme selected for the first Challenge for 2005-2006 is "Clean Care is Safer Care" which tackles the issue of health care-associated infections (9). The focus was chosen in part because it presents all the main characteristics of a patient safety problem: It affects large numbers of patients worldwide; it has multiple causes, relating to systems and procedures as well as human error; there are proven ways to reduce it, yet, many health care institutions have not yet adopted the proven practices; and it offers a clear agenda for research and for monitoring and evaluation of the effectiveness of remedial actions.

### 3.2 WHO South-East Asia Region's Response

21. WHO's South-East Asia Region (SEAR) is working closely with Member States in the Region to ensure patient safety in the following inter-related areas: blood safety, injection and immunization safety, health care waste management, drug safety, making pregnancy safer, child health, and human resources for health. The following is an overview of regional efforts in these different areas:

22. *Blood safety*: An estimated 61% of blood donations in the Region are voluntary (24). WHO's Strategy for Safe Blood has been endorsed by all Member countries. The strategy promotes nationally coordinated blood transfusion services, collection of blood from voluntary donors, quality testing of blood through reliable laboratories to

ensure it is free of infectious agents, and rational use of blood in clinical settings. A 'Regional External Quality Assessment Scheme' for blood grouping and screening for HIV and hepatitis B and C has been established.

23. *Injection and immunization safety:* As mentioned earlier, WHO estimates that 50% of injections administered in the South-East Asia Region are unsafe (15). WHO is promoting the use of auto-disposable syringes for immunization in the Region and believes a similar policy is needed for the curative sector.

24. *Health care waste management:* Countries in the Region produce over 1,000 metric tons of health care waste every day which is not properly disposed of (25). Within the framework of WHO's new policy on health care waste management, a six-month distance certification course was launched at the Indira Gandhi National Open University (IGNOU) in New Delhi, India. Many training sessions of health care workers were conducted in tsunami-affected countries, particularly in Indonesia and Maldives.

25. *Drug safety:* As mentioned previously, it is estimated that over 50% of all medicines prescribed, dispensed or sold globally are not justified. WHO is intensifying efforts to promote the rational use of drugs and strengthen drug regulation in the Region.

26. Counterfeit medicines continue to be a highly visible issue in the Region and, as a result of WHO's efforts in this area, Member countries are beginning to take concerted action to address it. With regard to the largely unregulated sector of herbal medicines, WHO SEAR has published "Guidelines for Regulation of Herbal Medicines in the SEA Region" (26). WHO has supported national pharmacovigilance in several Member countries and some countries have become part of the global WHO Programme for International Drug Monitoring (27).

27. *Health care-associated infections:* All of the above areas are implicated in the prevention of health care-associated infections, a major source of patient harm, particularly in intensive care units. Airborne infections, in particular TB, are a major source of nosocomial infections and WHO is promoting best practices to prevent such infections through health education, isolation of infectious patients, adequate ventilation, and the safe induction of sputum (28). Health care-associated infections constitute an important source of neonatal morbidity and mortality and research on the prevention of such infections has been identified as a priority in WHO's regional strategy to improve newborn health (29).

28. *Making pregnancy safer:* In the framework of the Making Pregnancy Safer Initiative, WHO is providing technical support to countries in the Region to enhance the quality of maternal and newborn care. Activities include improving access to skilled birth attendants, the promotion of evidence-based norms and standards for maternal and neonatal care, and the rational use of drugs during pregnancy to protect both the mother and the unborn child.

29. *Child health:* WHO has initiated a hospital assessment process for improving referral care of children. The process entails an initial assessment of hospital care practices for children using a standardized tool. This leads to identification of deficiencies in processes including triage, clinical skills, and infrastructure, which are then rectified by appropriate action including training of health care providers.

30. *Strengthening human resources for health:* The performance of the health workforce is critical to a well-functioning health system and has an immediate impact on the quality of health service delivery and therefore on patient safety. There is a direct relationship between staffing levels and patient outcomes (30).

- WHO has collected data on the number and types of health care providers in Member Countries of the Region.
- Since nurses and midwives comprise the greater part of the health workforce in the Region, WHO has undertaken activities that focus on management of the nursing and midwifery workforce, training skilled birth attendants and community health nurses, and improving the quality of nursing education and services.
- Regarding medical training, WHO is actively promoting curriculum reform in medical schools in the Region to strengthen the psychosocial and ethics components of medical education (31).
- Finally, within the framework of the “South-East Asia Public Health Initiative (2004-2008)”, WHO is strengthening public health education programmes in the Region and has created the South-East Asia Public Health Educational Institutes Network (SEAPHEIN) to facilitate exchange of knowledge and resources within the Region (32).

## **4. Key concepts and strategic directions**

31. Safety is a fundamental principle of patient care and a critical component of quality management. Changing health care systems and redesigning the ways they work to reduce patient risks, is a formidable challenge. It demands a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care. It embraces nearly all health care disciplines and actors, and thus requires a comprehensive multifaceted approach to identifying and managing actual and potential risks to patient safety in individual services and finding broad, long-term solutions for the system as a whole.

32. Enhancing the safety of patients includes four complementary actions:

- preventing adverse events
- making them visible
- mitigating their effects when they occur
- reducing risk to future patients

These actions, in turn, are guided by a set of key concepts which are elaborated in the following paragraphs:

### **4.1 A focus on systems rather than on blaming individuals**

33. Thinking in terms of systems offers the greatest promise of sustainable solutions. This places appropriate emphasis on every component of patient safety, as opposed to solutions driven by narrower and more specific aspects of the problem.

34. Current conceptual thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design, organization and operation rather than on individual providers or individual products. Adverse events are provoked by “upstream systemic factors, which include the particular organization’s strategy, its culture, its approach towards quality management and risk prevention, and its capacity for learning from failures. Countermeasures based on changes in the system are therefore more productive than those that target individual practices or products.

35. The examples below illustrate weaknesses in health care organization and management systems that may lead to an adverse event.

- Organizational and managerial aspects such as lack of appropriate equipment and supplies, overload and inadequate supervision, low salary and motivation, poor interpersonal communication among providers and between patients and staff as well, and insufficient investment in management, organization systems and procedures.
- Inadequate health care operational practices, standard operating procedures, and culture of blame. Lack of appropriate technical expertise because of absence of a continuous training environment.

#### **4.2 Learning systematically from similar mistakes and minimizing risks in the future**

36. The fundamental principle of patient safety activities is learning from failure. Health care errors are often provoked by weaknesses in the systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and underlying patterns which may go unnoticed if incidents are not systematically reported, analysed, and, most importantly, responded to. This is why 'adverse event reporting and learning systems' is a cornerstone to national patient safety programmes.

37. In order to be successful, however, reporting must be safe i.e. individuals who report incidents must not be punished or suffer other ill effects from reporting. In order to be of value, reporting must lead to a meaningful response, ideally to changes in processes and systems that make health care safer. Finally, in order to aid research and the search for solutions at both the national and international levels, data should be comparable within and across countries. This is the purpose of the WHO draft guidelines for the development of 'adverse event reporting and learning systems' which establishes a common set of concepts, principles and norms for reporting and analysis (33).

#### **4.3 Involving patients and communities**

38. By definition, patients and consumers of health care are at the centre of the quest to improve patient safety: when things go wrong, they are the ones who suffer.

Patients and patient safety advocates play a vital role in identifying risks and devising solutions. There are many lessons to be learned from their experiences and much to be gained from their energy and motivation to find solutions.

39. There is now growing interest in the international medical and public health community about implementing patient-centered, systems-based health care. The voice of patients and families who have suffered preventable medical injury is a powerful motivational force for health care providers across the globe to improve patient safety.

40. Consumer associations, as patient advocates, have a tremendous opportunity to contribute to a safer health system by playing a central role as partners in reporting, research, solutions, and safety in general.

#### **4.4 Translating evidence into sustainable health systems-oriented solutions**

41. The most important knowledge in the field of patient safety is how to prevent harm to patients. The first step in turning this vision into reality is to ensure that successful interventions and actions are made widely available in a form that can be easily replicated.

42. Finally, national patient safety programmes should be built around the following principles:

- Strong and visible top level leadership with an explicit focus on improving systems of care to reduce sources of risk and their causes.
- Increased ability to learn from mistakes, through better reporting and detection systems, skilful investigation of incidents and responsible sharing of data.
- Related to the above, addressing barriers to greater openness among health care workers is vital as issues such as fear of blame and punishment drive problems underground.
- Greater capacity to anticipate mistakes and probe systemic weaknesses that might lead to an adverse event.
- Identifying existing knowledge resources, within and outside the health sector; to develop solutions to identified safety problems.

- Improvements in the health care delivery system itself to support implementation of safer practices (this may require that structures are reconfigured, incentives are realigned, and patient safety is placed at the core of the system).
- Engagement of frontline health care workers.
- Partnership with patients and consumers.

## 5. The way forward

43. The following are the main issues and challenges in strengthening patient safety:

- Limited evidence/knowledge base necessary to understand what exactly is happening, to whom, where and why, and to set national and regional priorities.
- Related to the above, lack of systems and methodological uniformity to identify and measure adverse events.
- Lack of awareness or will to improve patient safety among key players such as doctors, nurses, managers, allied health professionals, policy makers, civil society groups, and health care organizations.
- Although there are examples of successful patient safety initiatives, none have embraced all elements of patient safety or been scaled up to embrace an entire health system.

44. To overcome these challenges, there is much work to be done in the areas of advocacy, research, best practices, and monitoring, reporting and learning.

### 5.1 Role and responsibilities of Member States

45. First, Member States need to know exactly what harm is happening, to whom, where and why. More specifically, Member States need to:

- Assess the scope and nature of adverse events at health care institutions as well as the factors that contribute to them,
- Establish or improve systems for the detection and reporting of adverse events at health care institutions with a primary focus on promoting system learning rather than attributing blame, and national mechanisms to capture,

share, respond, and learn from this information at all levels of the health system, and

- Encourage and support priority research aimed at improving patient safety.

Second, Member States must begin to deliver solutions, in particular:

- Promote interventions that have been shown to improve patient safety, and
- Support and enable health care institutions, from the primary health care level through the referral level, to implement systems changes and practices conducive to patient safety.

In addition, to support the above, Member States should:

- 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,
- Engage patients, consumer associations, health care workers, and professional associations in educational programmes that promote a culture of safety and in other efforts to build safer systems within health care institutions, and
- Allocate adequate resources to implement the above activities.

## **5.2 Role and responsibilities of WHO**

46. To support Member States, WHO should:

- Through an inclusive consultative process, coordinate the development of a strategic framework and package of interventions for strengthening patient safety in health care institutions, which builds on successful interventions and actions in the Region and worldwide,
- Provide strong technical leadership and support to Member States in designing and implementing patient safety interventions and monitoring systems at health care institutions,
- Ensure capacity building in different aspects of patient safety through training activities at the regional, subregional, and country levels,
- Facilitate collaboration and the exchange of information and best practices between Member States and the World Alliance on Patient Safety,

- 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,
- 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
- Monitor and report on progress in the Region.

47. As a first step in the development of a regional strategic framework, WHO Regional Office for South-East Asia is organizing a Regional Workshop on Patient Safety in Health Care Institutions, 12-14 July 2006 in New Delhi, India. The workshop will bring together senior government representatives from the 11 Member States to discuss patient safety concepts and priorities and lay the groundwork for a programme of action for the Region.

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