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Regional strategy for enhancing patient safety

Contents

Executive summary

Patient safety is a system property and the foremost attribute of quality of care. As such, it is of organizational, managerial and economic concern, in addition to being a clinical concern of the health care system. Patient safety is becoming a global and regional public health issue affecting all types of health care system, whether developed or developing. Up to 75% of health care errors are estimated to be preventable. With an estimated average of 10% of all inpatient visits resulting in some form of unintended harm, the pressing need to tackle the issue of patient safety is clear. The increasingly complex interaction between humans and health systems has led to an inevitable risk to patients in the delivery of health services. Adverse events affect all processes of health care systems and levels of care, and all aspects from clinical to managerial, from curative to preventive, from the public sector to the private sector and from diagnosis to discharge. Patient safety is challenged not only by the complexity of care processes but also, first, by a culture of denial and blame, where these two characteristics have predominated over an environment of problem-solving and learning, and second, by an inconsistent reporting and learning system that has prevented the collection and dissemination of information in any meaningful way.

There are two key reasons why the issue of patient safety is of particular concern to health authorities in the Eastern Mediterranean Region. First, there is a greater probability that adverse events are more frequent in developing countries where the health care system is not well organized and coordinated and where there are gaps in coverage and loss of information. The number of inpatient visits made within the Region highlights the potential magnitude of unsafe practice. Health care actors typically operate as separate entities with no effective means of communication between health authorities, providers, public and private sectors, and research community. In resource-poor settings the challenge is even greater, with less funding for recurrent maintenance, insufficient infrastructural resources and outdated systems that are not regularly reviewed. Second, throughout the Region, the massive growth in privatization and in trade in health services signals the pressing need to establish mechanisms of quality assurance and control, benchmarking and guarantees for the safety of patients.

The overall cost of adverse events can be considerable. Loss of confidence within the clinical teams, and loss of reputation and credibility of services and facilities are just some of the ramifications of adverse events. As well as causing avoidable human suffering, the financial and opportunity costs to health services are substantial and estimated at between 5% and 10% of health expenditure. In resource-poor settings, the health system can ill-afford these costs in an environment where human and financial resources are already stretched.

WHO has recognized the growing importance of patient safety. Resolution WHA55.18 outlines the various responsibilities of WHO in providing technical support to Member States in developing reporting systems, reducing risk, formulating evidence-based policies, fostering a culture of safety and encouraging a research agenda on patient safety.

The purpose of this paper is to set the scene for creating a culture of patient safety in health care; making patient safety a leadership, organizational and management priority; creating a framework for identifying system vulnerabilities and informing improvement; and providing patient safety improvement tools for health professionals to use. To achieve these goals, five interrelated strategies are proposed: raising awareness of the magnitude of patient safety through a critical mass of influential figures; assessing the extent of unsafe practice showing its prevalence, disability, preventability; understanding and categorizing causes of unsafe practice; piloting models and frameworks; and eventually developing and running a large-scale patient safety programme.

Recommendations to enhance the safety of patients include complementary actions at policy level as well as managerial and clinical levels. Health authorities must begin develop an agreed upon vision, mission and set of organizational values within which to frame their patient safety strategic plan in line with regional strategies.

1. Introduction

1.1 Background

In 2002, the World Health Assembly, in resolution WHA55.18 Quality of care: patient safety, urged 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. This paper presents an agenda for partnership with Member States in response to that resolution. The paper envisages a long-term engagement of Member States and the WHO Regional Office for the Eastern Mediterranean for the purpose of: creating a culture of patient safety in health care; making patient safety a leadership and management priority; creating a framework for identifying system vulnerabilities and informing improvement; and providing improvement tools for health professionals to use.

The history of patient safety in the Eastern Mediterranean Region can be traced as far back as the ancient civilizations, the physician–patient relationship being referred to, for example, in the Hammurabi Code of Babylon. Clear religious teachings in Islam also made safety and the reduction of all types of harm in all settings a duty. In more recent times studies of adverse outcomes and harm to patients have been carried out for many years, and as far back as 1850. Confidential enquiries, medical audit and the rising rate of litigation in the 1970s and 1980s were all important stimuli to raising awareness of the problem of patient safety. In Australia, Canada, Denmark, Netherlands, New Zealand, Singapore, United Kingdom and the United States of America and elsewhere, this led to the development of risk-management programmes. Initially these had an almost exclusively legal and financial focus, aimed at protecting the institutions concerned. They gradually evolved to address clinical issues and acted as a gateway to the underlying problem of patient safety, ultimately revealed by retrospective record reviews, such as the Harvard Medical Practice Study [1]. The major legacy has been to reveal the scale of harm to patients from health care and to stimulate a number of similar studies.

The most powerful evidence of harm to patients from health care systems comes from a number retrospective reviews of case records in which clinicians assessed the presence or absence of adverse events—instances of harm to patients from health care management rather than disease. Findings emerging from the countries studied suggest a relatively high rate of adverse events—around 10% [2].

1.2 What do we mean by health care errors?

Adverse events affect all levels and all aspects of care, from clinical to managerial, from curative to preventive, from the public sector to the private sector, and from diagnosis to discharge. The following are some examples:

- **Failure to diagnose/wrong diagnosis and inappropriate treatment**: If symptoms are missed or wrongly interpreted, this can lead to the condition remaining untreated or the incorrect treatment schedule being selected. This can further arise from the failure to use or act upon the correct diagnostic test or device.
- **Medication errors**: Errors of medication may be related to professional practice, health care products, procedures, and systems. Disruption can occur at any stage of the process including prescribing; order communication; labelling, packaging and nomenclature; compounding; dispensing and distribution of medication; all of which can lead to the wrong medication being administered at the wrong dosage. Included within medication errors are adverse drug reactions which can occur following the administering of drugs and biologicals.
- **Health facility acquired infections (HAI)**: A lack of adequate infection control within facilities can lead to the transmission of communicable disease, including HIV/AIDS. Modes of transmission include unsafe injections, low levels of sterilization of used equipment, inadequate disposal of medical waste, soiled linen and clothing, poor hygienic practices such as the disinfecting of floors and surfaces and low compliance with hand-hygiene procedures.

- **Blood and body fluids safety**: The administering of unsafe blood and other fluids which have not been adequately screened for communicable disease can provide another mode of transmission of communicable disease.
- **Transfusion reaction**: Complications can arise following the transfusion of blood where there is an immune response against the transfused blood cells or other components of the transfusion.
- **Communication errors**: Breakdowns within the communication process can lead to a variety of errors including patient misidentification, erroneous assigning of test results, medication errors, transfusion errors due to the use of wrong blood types, and wrong-site surgery.
- **Surgical care**: Owing largely to its invasive quality and use of anaesthesia, surgery has long been associated with several risks and complications. This risk must be accounted for in both pre-operative and post-operative care, specifically in the correct administering of anaesthesia, and diagnosis and management of potential new symptoms following surgery.
- **Medical equipment**: Errors can occur following unsafe installation, and failure to maintain and operate accurately medical equipment. Furthermore, the absence of the appropriate accessories and supplies, such as specialist clothing or an inappropriate structural design and location can render the use of the equipment unsafe, e.g. in the use of radiation therapy.
- **Invasive diagnostic and clinical technologies**: The new generation of advanced technologies currently in use can pose a threat to patients due to the potential for internal damage and heightened risk of infection.
- **Non-medical equipment**: During movement within facilities, patients can be exposed to harm from non-medical equipment including beds, railings and steps owing to poor design and lack of maintenance. The safety of patients must further be considered during their transportation between facilities.
- **Physical environment**: If badly designed and built, facilities may pose a threat to the safety of patients through collapse, especially in areas prone to natural disasters. Many factors can impact upon the safety of the building and its environment, including the design of the building, nature and quality of building material used, its location, its access to amenities, supplies and capacity to dispose of medical and general waste. Air and water quality within the health facility must be maintained to a high level to reduce the risk of infection amongst patients and staff. Furthermore, patients and staff may face harm from third parties who may try to enter facilities, highlighting the need to provide a high level and availability of security.
- **Food safety**: Food hygiene constitutes a further risk to patients from lack of hygienic procedures in the procurement, preparation and disposal of food, while a further aspect of food safety is ensuring that food provided meets the specific dietary requirements of individual patients.

1.3 The construct of patient safety

Safety is a fundamental principle of health care and a critical component of quality management. The following definition of terms was adopted by the Institute of Medicine of the US National Academy of Sciences in its report *To err is human* [3].

Patient safety is ‘freedom from accidental injury’.

Adverse events are injuries related to medical management, in contrast to complications arising from disease, and are defined as ‘an injury resulting from a medical intervention’. Adverse events may stem from errors of commission and/or omission, and usually reflect deficiencies in the systems of care.

Error is defined as the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning).

Near misses are serious errors and mishaps, those with the potential to cause an adverse event, that fail to do so because of happenstance or because they are intercepted.

A sentinel event is “an unexpected occurrence involving death, serious physical or psychological injury”[4]. Examples are retained instruments or other material after surgery, requiring re-operation or

further surgical procedure; hypoxic brain damage probably attributable to anaesthesia, airway management or ventilator technique; maternal death or serious injury associated with labour or delivery in a low risk case; procedures involving wrong patient or body part; unexpected/unexplained serious neurological injury following spinal procedure that is likely to be permanent.

According to the Heinrich ratio, for each 1 major injury (sentinel event) known or reported there are 300 (near misses) which do not result in an injury. Near misses are important from the educational point of view to prevent future sentinel events.

1.4 The components of patient safety

System design and processes, whether managerial, organizational or clinical, are responsible for the safe performance of health care. Thus in order to understand the factors causing unintended harm, highlighted in section 1.2, a systemic approach is used to categorize the different types of patient safety. Three main categories of patient safety can be identified.

a) Product safety: drugs, devices, vaccines and other biologicals—examples are: drug reactions, labelling of medicines, reporting of laboratory results, blood safety and transfusion check, injection practices, checking equipment before usage, preventive equipment maintenance programmes, equipment failures, calibration, checking anaesthesia and design of recovery equipment.

b) Safety of services: inpatient and outpatient medical practices—examples are mortality review of wrong procedures, medical and surgical complications, anaesthesia adverse events, antibiotic usage, infection control, excess caesarean sections—as well as non-personal services such as filing procedures and recording of patient details.

c) Safe environment of care: facilities, waste management, environmental considerations, protection against falls and self-harm, fire safety.

2. Problem of patient safety in the Eastern Mediterranean Region

2.1 Magnitude of risk

Patient safety is a major public health problem of great magnitude caused by system failure. Studies have shown that adverse events in health care facilities affect a surprisingly high number of inpatients, with unintended harmful consequences occurring on average in 10% of acute admissions [5]. In the United States of America, for example, more people die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer and AIDS together [2]. Of the top 20 risk factors that account for 75% of all deaths annually, adverse in-hospital health care is ranked number 11 [6]. This figure might seem high, but an even greater concern is that between 50% and 80% of these events are potentially preventable [5]. Research conducted by WHO in seven countries of the Region (Afghanistan, Egypt, Iraq, Morocco, Pakistan, Sudan and Yemen) has shown that out of an average of 4 injections per person, 3 injections are unsafe, exposing patients to the risk of abscesses and the transmission of a wide range of infections, such as hepatitis B and C and HIV/AIDS [7].

Improvement in patient safety demands a complex system-wide effort, involving a wide range of actions relating to 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.

Thinking in terms of systems offers the greatest promise of definitive risk-reduction solutions, which place the appropriate emphasis on every component of patient safety, as opposed to solutions driven by narrower and more specific aspects of the problem, which tend to underestimate the importance of other perspectives.

2.2 Where and why adverse events occur

Medical interventions are, by their nature, high-risk procedures. The nature of medicine as a hands-on endeavour, and the essentially human basis for health systems with the inevitable error that it entails, mean that medical treatment is inherently risky. Most of the current evidence on adverse events comes from hospitals, because the risks associated with hospital care are high, strategies for improvement are better documented, and the importance of patient trust is paramount. However, many adverse events occur in other health care settings, such as physicians' offices, nursing homes, pharmacies and patients' homes. Recent literature highlights concerns about outpatients as well, but there are very few data on the extent of the problem outside hospitals.

Every point in the process of care-giving contains a certain degree of inherent unsafety: side-effects of drugs or drug combinations, hazards posed by a medical device, substandard or faulty products entering the health service, human shortcomings, or system failures (sometimes called latent factors). Adverse events may therefore result from problems in practice, products, procedures or systems of care.

Studies have shown that there are factors which make the practice of medicine relatively more unsafe. For example, it is more unsafe to be admitted to the intensive care unit than to ambulatory outpatient care. Other factors include the degree of vulnerability and debility of the patient; length of stay; type of hospital (whether general multispeciality or highly specialized, the latter being safer); complexity of the case; and at what stage of disease the patient presents.

The majority of incidents occur as a result of latent flaws within the system. While errors in individual medical practice contribute to patient harm, the underlying root causes of most adverse events relate to health systems design and management, environmental and operational factors, organizational design and interpersonal communications. It is estimated that up to 75% of adverse events have systemic causes rather than being attributable to individual error [8, 9]. In this regard, patient safety should be viewed from a systems perspective and strategies must be based on systems change that overhauls the culture and approach to quality and safety, rather than targeting of individual practitioners. For those who work on systems, adverse events are shaped and 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. Counter measures based on changes in the system are more productive than those that target individual practices or products.

2.3 Adverse events are more common in developing coutries

The situation in developing countries and countries in economic transition, including some countries of the Eastern Mediterranean Region, merits particular attention. The often poor state of infrastructure and equipment, unreliable supply and quality of drugs, shortcomings in waste management and infection control, poor performance of personnel because of low motivation or insufficient technical skills, and severe underfinancing of essential operating costs of health services make the probability of adverse events much higher than in industrialized nations. Developing countries account for around 77% of all reported cases of counterfeit and substandard drugs, according to WHO figures [10].

In developing countries, it is suggested that as much as 50% of all medical equipment is unusable, or only partly usable, at any given time [11]. This high figure has implications for the safety of patients and health workers alike. Evidence also points to the potential harm to patients from irrational and unplanned design of health facilities. In one study it was found that 40% of hospital beds were located in structures originally built for other purposes [12] with inevitable negative effects, such as hindering infection control and radiation safety.

Currently no data exist on the magnitude of the problem in the Region, however the numbers of people potentially affected in the Region can be estimated. Of the populations of Sudan, Morocco, Lebanon, Islamic Republic of Iran, Saudi Arabia, Oman and Jordan, 2%, 3%, 4%, 6%, 10%, 11% and 12%

respectively are annually admitted as inpatients to health facilities [1]. Working on the basis that at least 10% of all inpatient episodes result in unintended harm, this means that a significant number of people in the Region may be affected. The figure could be much higher in the least developed countries in the Region for the reasons stated above. A quick survey in one of the countries of the Region provided alarming results. The percentage of post-operative infection among cardiac surgery cases reached 60%; 50% of deaths in emergency cases were due to improper case management by physicians; 36.8% of antibiotic prescriptions were inappropriate; overall rate of hospital-acquired infection over 5 months ranged from 24.5% to 49%; and adherence to correct hand-washing practice was only 30%.

2.4 Consequences for health care systems

As well as causing avoidable human suffering, adverse events have a large financial cost in terms of additional treatment and extra days in hospital. The financial and opportunity costs to health services are estimated at between 5% and 10% of health expenditure. For example, additional hospital stays caused by adverse events cost the health service in the United Kingdom around 2000 million pounds Sterling every year, excluding the 2800 million pounds Sterling paid for claims, and existing and expected claims for litigation [5]. The wider costs of lost working time and disability benefits and the wider economic consequences are greater still. There is also an enormous human cost. Many patients suffer increased pain, disability and psychological trauma and may experience failures in their treatment as a terrible betrayal of trust. Staff may experience shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden. Doctors or nurses whose confidence has been impaired will work less effectively and efficiently; at worst they may abandon medicine as a career. The consequences of adverse events in advanced health care systems are therefore huge. In less developed health care systems they may be greater still in relation to the benefits derived from the system.

3. Experience of countries of the Eastern Mediterranean Region in patient safety

A safe health system is important for all countries, irrespective of their state of development. In 2003, the Regional Office distributed a questionnaire to all ministries of health to assess the awareness of and activities in patient safety, both at the level of the ministry of health and the facility. The data received will be updated regularly. The different aspects of patient safety covered in the questionnaire included the nature and extent of patient safety programmes and activities, internal and external incident reporting systems, efforts in risk assessment, availability of patient safety data, existence of patient safety guidelines and any recordable improvements made. The responses received showed that few health care systems have yet developed effective safety programmes that aim both to monitor and to react to safety issues and that proactively assess potential risks and hazards. Incident monitoring systems are now relatively common in a number of countries, but seldom systematically link to action at the clinical level for activities such as blood safety, injection safety, hospital-acquired infections and waste management. Three countries disseminate a standard procedure for adverse events and have developed guidelines. None so far have undertaken risk assessment of unsafe practice. In general, the patient safety interventions in the Region are sporadic and isolated, resulting in a paucity of available data.

Several countries have initiated quality improvement and assurance activities, including Bahrain, Egypt, Islamic Republic of Iran, Jordan, Kuwait, Lebanon, Morocco, Oman, Qatar, Saudi Arabia, Tunisia and United Arab Emirates. Some of these have launched health facility accreditation programmes. Thus patient safety as an attribute of quality is not totally new to many countries. WHO programmes, such as safe motherhood, safe waste disposal, safe injections, nosocomial infection control and safe blood, are sporadically implemented and with different degrees of depth and breadth. In no country of the Region are these programmes systematically organized in a national programme of patient safety with specific policies and managerial and clinical profiles. Information, training,

[1] This figure is calculated using the number of inpatient visits to hospitals in the public and private sector, and the total population, using the assumption of 1 visit made per person per year. Based on data provided to the Regional Office by ministries of health in the Region.

standards indicators, targets and strategies are divergent and sometimes even outside the direct responsibility of the Ministry of Health. Four countries (Islamic Republic of Iran, Qatar, Saudi Arabia and Sudan) reported having enacted a law or directive relating to patient safety standards. Patient safety guidelines have been developed in Bahrain, Kuwait, Lebanon, Sudan and United Arab Emirates.

4. Challenges

As shown by the survey of patient safety in the Region, and despite growing interest in the safety of patients, there is still widespread lack of awareness of the problem of adverse events. Capacity for reporting, analysing and learning from experience is still seriously hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, undue concerns over breaches in confidentiality of data, fear of professional liability, and weak information systems. Understanding and knowledge of the epidemiology of adverse events (frequency of occurrence, causes, determinants and impact on patient outcomes) and of effective methods for preventing them are still limited. Although there are examples of successful initiatives for reducing the incidence of adverse events, none has been scaled up to embrace an entire health system. Six main challenges are identified.

a) The most serious challenge is that of denial of the problem by medical practitioners. Typical statements such as “We do not have this problem” are detrimental to efforts to put patient safety in its place. Patient safety is a big issue in health systems of industrialized countries simply because it is recognized as a major problem. Denial is arrogance and leads to catastrophic results. It is an attitude that must be seriously addressed. It is important to note that in countries that have addressed patient safety, it has played a major role in securing confidentiality of reporting and in protecting providers who report errors.

b) Health systems are complex by nature and consist of thousands of interlinked processes, at any point of which there can be a system failure. However, many adverse events can be avoided. Some of the main reasons for system failure include: inadequate operational practices; lack of explicit protocols; lack of training; failures in communication; and poor technical design of medical equipment and packaging.

c) A key challenge in establishing a patient safety initiative is the wide scope and diversity of the factors involved, which include systemic, human and material factors. This variety of influences will require a comprehensive strategy that considers all factors at all levels of care and environmental settings. The types of incident that occur during treatment are diverse and frequent in all health care settings. They can include causes as varied as misdiagnosis, incorrect prescription, acquiring nosocomial infections, equipment failure, flaws in the information system and breaches of security with the innumerable factors of people, systems, products and procedures working in tandem. This wide scope poses many challenges in developing a reporting system in that it must account for many different scenarios that can occur within any medical specialty and at any level of care. Therefore, in addition to the guaranteeing of the correct diagnosis and treatment, there are innumerable other factors that contribute to safe medical outcomes. One particular area that requires special consideration with regard to patient safety is where medical procedures are performed on healthy people, i.e. immunization and preventive health care in general.

d) There is a prevailing culture of blame, where the assignment of blame has predominated over the creation of environments of problem-solving and learning. This has resulted in the magnitude of the problem being hidden and the creation of a punitive climate that discourages transparency in reporting of adverse events.

e) There is inconsistency in reporting and learning systems which has prevented the collection and dissemination of information in any meaningful way. This is the result of factors a,b,c,d above.

f) Other challenges include those implicitly mentioned in section 2.3. These are:

- structural: limited facilities and resources; low investment in system redesign; outdated and unsafe facilities;
- operational: inadequate standards of care; lack of evidence-based practice; lack of explicit protocols; poor technical design of medical equipment and packaging; limited use of information technology, due to high costs and privacy concerns; interpersonal communication failures; ineffective staffing due to lack of training and continuing training and lack of technical competence;
- organizational: inappropriate skill mixes; lack of equipment and supplies, insufficient time; inadequate supervision.

5. WHO response

The effective reduction of adverse outcomes for patients calls for a concerted international effort in which WHO would play a proactive leadership role, particularly as part of its important focus on enhancing health systems performance. The experience of countries that are heavily engaged in national efforts to improve health systems performance clearly demonstrates that, although health care systems differ from country to country, many threats to patient safety have similar causes and often similar solutions. There is great scope for collaboration in designing and implementing systems for patient safety. Globally, WHO has taken the lead in tackling some specific aspects of the problem. The WHO Programme for International Drug Monitoring, with its collaborating centre in Sweden, has instituted a coherent programme of action including pharmocovigilance, harmonization of drug regulations, monitoring of drug safety, bridging the gap between industry and regulatory authorities, and other important actions. The Immunization Safety Priority Project aims to establish a comprehensive system to ensure safety of all immunizations. In addition, the Global Advisory Committee on Vaccine Safety has been established to provide independent scientific assessment of vaccine safety issues. Another major effort centres on injection safety, where WHO coordinates the Safe Injection Global Network.

Action is also needed from a broader system perspective, wherein the safety of patients is viewed as a major element in improving the quality of care and enhancing the performance of health care providers.

At the regional level, guidelines for accreditation of hospitals were developed by the Regional Office in 2000. Patient safety standards comprise an important part of these accreditation standards. The Regional Office, together with the League of Arab States, has revised and elaborated standards on patient safety and a preliminary database is being established to follow up progress in implementing patient safety and. The Regional Office has supported Egypt, Morocco and Sudan to adapt and include these patient safety standards in their accreditation programmes. In collaboration with the Ministry of Public Health of Kuwait and the Executive Board of the Health Ministers' Council for the Cooperation Council States, work is in progress to launch the Regional Patient Safety Centre agreed upon at the regional consultation on patient safety in 2004.

6. Strategies to enhance the safety of patients

The Regional Office, in collaboration with the Executive Board of the Health Ministers' Council for the Cooperation Council States and the Ministry of Public Health of Kuwait, held an intercountry meeting in November 2004 on patient safety, in Kuwait. Experts from the field of patient safety and quality assurance of health care came together to review current activities on patient safety in the Region, develop a broad regional strategy for patient safety and establish a platform for action on improving patient safety, recognizing the framework of the WHO initiative, World Alliance for Patient Safety.

The consultation formulated regional strategic directions which covered five main areas related to: raising awareness; assessing the scope of patient harm; enhancing the understanding of the causes of patient harm; developing frameworks and models of patient safety; and organizing a fully operational national patient safety programme.

Two further outcomes of the meeting are acknowledged as major milestones in the enhancement of patient safety in the Region. First, the Kuwait Declaration on Patient Safety, issued jointly by the participants, called upon the regional scientific and civic community to join the efforts of WHO and ministries of health to attain safer care for patients. Second, consistent with its support to the Kuwait meeting and patient safety efforts in the Region, the Ministry of Public Health, Kuwait, undertook to establish, jointly with the Gulf Cooperation Council, WHO and the World Alliance for Patient Safety, a regional patient safety centre. The centre will act as a focal point for patient safety in the Region in the capacity of technical support and advocacy efforts.

In practice, progress towards a safe health care system is likely to come from a sustained attack on major sources of harm to patients and a gradual reduction in the level of hazards and instances of actual harm. This process can be helpfully divided into a number of stages which describe the actions required, and may also be used to assess the stage of development of a country or institution in the area of patient safety. These stages are all necessary and may proceed concurrently. For instance, a programme to reduce an immediately identified problem of nosocomial infection may proceed in parallel with a project to assess the overall scale of harm to patients within a country.

1) Raising awareness

Drawing attention to the harm caused by health care systems, or to the potential for harm, provides a receptive context for further studies and action on patient safety. Unless both policy-makers and clinicians are convinced that patient safety is a problem, progress in patient safety will not be sustained or effective. A fundamental question applicable to any environment and any health care system is: "What risks does this system pose to the people it is intended to help?" Collecting data on these issues should serve to make all stakeholders realize that reported hazardous situations are not isolated, but are probably more general and widespread.

Arguably the main task of the health authorities is to establish and foster a culture that is open to learning from errors and that strives for best practice implementation at all levels. Mistakes must be viewed within the context of opportunities for improvement, mitigation and prevention. This is a formidable task that requires a large-scale shift in the attitudes of individuals and organizations. The context needs to transform into one of process change and improvement, and away from a readiness to assign blame, culpability and liability. A critical mass of influential figures should be generated in which the public and private sectors and media need to be involved. A sense of direction and clarity of purpose will thus evolve among the patient safety stakeholders.

Raising awareness requires:

- improving capacity-building and identification of resources, especially of charismatic figures to lead and pioneer patient safety initiatives;
- continuous training programmes on patient safety issues for the different categories of health care providers to ensure their own safety as well as patients' safety;
- developing, updating and disseminating universal protocols and guidelines on evidence-based practices, and facilitating knowledge sharing to health care providers for different patient safety aspects;
- collecting and disseminating patient safety "success stories" from a range of different countries and contexts to stimulate further action and provide direction to countries with less developed patient safety programmes;
- establishing a learning network that facilitates the sharing of best practices and a proactive research agenda that anticipates risks and learns from adverse events in a synergistic and regular manner.

An advocacy strategy must continuously advocate for an open environment for safety and accountability. Another important aspect of raising awareness is the user/patient who should be equipped with knowledge on safe practice. Patients should know, for example, that before a doctor or

nurse touches them he/she should have washed his/her hands. Patients should demand safety as their right.

2) Assessing the nature and scale of harm to patients

The strategy for assessment of incidence, nature and impact of adverse outcomes will, of course, vary from country to country. Strategies in general will also vary in their range and depth. Planning and prioritizing effective safety interventions require, as does any public health problem, a thorough understanding of the nature of the problem. Countries must assess the overall burden on both the population and the health care system of harm to patients in order to guide policy. At the clinical level, understanding the specific problems particular to each specialty is necessary for effective intervention. In all cases, data collection is a necessary prelude to effective action but need not delay action on immediate and obvious patient safety problems. Review of data on incidence of harm, available from existing programmes and sources, should make patient safety the unifying theme and umbrella concept for all sources of harm from health care processes. Reviews should be conducted of the status of health care delivery and the frequency of adverse events addressed from the point of view of quality improvement. There are various tools available that can help in reviewing the frequency of adverse events including performance review, clinical audit, clinical risk management and managing and learning from complaints.

The mapping of unsafe practice will enable assessment of extent and categorization of harm, including near misses. The outcome of mapping will be: estimation of the prevalence of injury to patients caused by their health care; measurement of adverse events; judging preventability of these events; and assessing disability from these events.

3) Understanding the causes of harm

The causes of adverse outcomes must be clearly understood. In some instances, causes may be immediately apparent, while in others sophisticated methodologies may need to be employed. Root cause analysis (RCA) is the most widely applied tool to discover causes of unsafe practice. Acknowledgement of the overwhelmingly systemic causes of adverse events means that considerable attention must be focused on tackling systemic issues. Health authorities must be instrumental in establishing effective reporting and learning networks that communicate all relevant information between all health actors.

Digging deeper to understand the causes of harm should enable national health systems to develop a structured, integrated programme of patient safety initiatives at different levels in order to make a difference and to sustain improvement in patient safety. This will include:

- **policy level** actions that support standardization and consistency of practice; commitment to and investment in systems redesign and information technology/management; research to inform systems redesign and a culture that learns from its own mistakes and shares knowledge;
- **organizational/managerial level** actions that support best practice based on evidence, teamwork, credentialling and supervision, risk management, audit and reporting, and open disclosure when things go wrong; and
- **clinical level** initiatives that support people in doing the right thing as part of a safe and high quality system with appropriate accountability to individual patients, management and the community.

Within each of these levels, different action will be required depending on the patient safety area being addressed. For example, to produce early improvements in the system and show that progress is being made, it is critical to begin with initiatives addressing areas of known harm. These are areas where the need for measurable patient care improvements is most urgent, and where there is often already evidence about what works to improve patient safety.

4) Developing and piloting an accountability framework/model affecting safety and quality improvement at the policy, managerial and clinical levels

A framework or a model needs to be developed to guide the health facilities and workers on methods of prevention. While some methods with clear-cut benefits can be introduced immediately, others will require piloting and evaluation. Globally, experiences of nationwide patient safety programmes are limited, especially in the developing countries. At this stage, a limited scale model as research and development will need to be considered. Lessons learnt from this model will help later in developing a large-scale nationwide patient safety programme. The main features of this framework are as follows.

- Responsibilities for patient safety must be clarified and strengthened and the public fully informed about these accountabilities.
- Responsibilities for clinicians, managers and funders at all levels of the health care system (national, province, local and facility level) should be reviewed and aligned with best practice to create a new and nationally consistent accountability framework.
- The new accountability framework would support a more just, transparent and open safety culture in the national health care system, for example, by ensuring that health professionals are supported and provided with adequate protection when reporting on sentinel (serious) adverse events. Another example is that the new framework should be reflected in contractual agreements between those responsible for patient safety and their managers, to ensure it is embedded in day-to-day management and that it is on a par with accountabilities in place for financial management.
- Sustainable change is only likely to be achieved if there are improved and consistent governance processes guided by an appropriate focus on patients, close collaboration between stakeholders and learning-by-doing.

5) Organizing and running safety programmes

Passing through the different stages previously mentioned, and with a cumulative body of knowledge and experience, a country will be now in a position to opt for nationwide patient safety programmes. There are necessary large-scale changes for organizational shift that places patient safety and quality at the heart of health services. The following list is not exhaustive and a combination of two or more may be opted for to be implemented simultaneously.

1. Establish a National Task Force/Committee. This body will require sufficient authority and funding to take on the leadership role required of it. This national body should lead the process of patient safety, building consensus and developing leadership, and amassing all stakeholders including providers, consumer groups, public/private actors, nongovernmental organizations, insurers and the accrediting body. It can also contribute to: establishing national level policies and guidelines; preparing an interim plan; establishing mechanisms for overseeing coordination, implementation, monitoring and evaluation of the plan; and establishing a research body/network leading proactive assessment into high-risk areas within patient safety.
2. Develop, disseminate and implement a national reporting and notification system of patient safety, taking the following points into consideration: accountability of health facilities for effective reporting of adverse events; confidentiality of reporting; absence of blame and punishment; understanding the root causes of errors and incidents (adverse events); corrective actions and developing a system to minimize errors; promoting a learning environment; legislation to protect reporters.
3. Ensure high level political commitment for patient safety and rights through relevant legislation, rules and regulations and resources for patient safety.
4. Develop a set of standards and indicators for patient safety that refer to types of health care error, , such as failure to diagnose, medication errors, health facility acquired infections etc. (see section 1.2).

5. Develop national and local specific safety targets, such as to minimize medication errors, on infection control, etc.
6. Establish a system of patient rights and complaints.
7. Establish legislation for protection of health care providers' rights with regard to confidentiality in reporting and provide an effective regulatory environment. This step is crucial for successful implementation of patient safety.
8. Identify quality improvement methodologies that can be applied to resolve issues of patient safety, such as development of evidence-based standard operating procedures (SOPs)
9. Improve capacity for health care staff and managers for developing and implementing a patient safety plan.
10. Devise mechanisms and administrative processes for linking licensing, accreditation and the provision of health insurance to attaining high quality health care.

In short, national programmes must be proactive in that they anticipate risk, preventive in that they revise the design of vulnerable systems and ethical in that they place patients at the centre of the process.

7. Conclusions

A completely safe health care system is an ideal that may never be realized but it nevertheless provides a vision and expands our view of what might be achieved. The problem of patient safety is potentially immense, especially in developing countries. The nature and scale of harm from health care systems worldwide, including in the Eastern Mediterranean Region is largely uncharted. The experience of patient safety in the Region is only just being launched with a system perspective, and partnership with WHO is being established in this field. A regional framework for patient safety has been developed. 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. Similarly, most adverse events are not the result of negligence or lack of training, but rather occur because of latent causes within systems.

Enhancing the safety of patients must include complementary actions at policy level as well as at managerial and clinical levels. Initiatives at policy, managerial and clinical levels are required to redesign and simplify systems within and between health care services so that mistakes and accidents are less likely to occur in the first place, and to ensure that if problems do occur, they can be corrected before they cause harm to patients. It is not enough to have action at one level; the three levels must coordinate with and complement each other. This requires: a) increased ability to learn from mistakes, through better reporting systems, skilful investigation of incidents and responsible sharing of data; b) greater capacity to anticipate mistakes and probe systemic weaknesses that might lead to an adverse event; c) identification of existing knowledge resources, within and outside the health sector; and d) improvements in the health care delivery system itself, so that structures are reconfigured, incentives are realigned, and quality is placed at the core of the system. In general, national programmes are built around these principles.

In the long term, making health care safe may confer greater health gain than almost any other public health programme. WHO's work on patient safety will aim to bring the benefits of patient safety initiatives to all Member States. The recommendations proposed are targeted at enhancing the safety of patients focusing on three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. In order to expand the activities to stimulate action on patient safety in all WHO Member States, WHO should, where possible, support countries to carry out patient safety studies and programmes themselves. This would create local ownership and good prospects for subsequent development of programmes to enhance safety.

8. Recommendations

Member States

1. Introduce the concept of "patient safety" and make it a top priority on the health agenda of policy-makers and within the organizational structure of the health system through:

a) Performing continuous situation analysis of system performance in patient safety through improving data and information for safer health care;

b) Providing technical support to those who work in the health system to enable them to deliver safer patient care;

c) Involving consumers in improving health care safety;

d) Redesigning systems of health care to facilitate a culture of safety; and

e) Building awareness and understanding of health care safety.

2. Establish a national focal point/group for patient safety to develop a national action plan, guidelines, mechanisms of monitoring and follow-up of the different patient safety aspects, focusing especially on:

   a) Hand hygiene;
   b) Prevention of medication errors;
   c) Enhancing measures to prevent malpractice;
   d) Prevention of health care–acquired infection.

3. Collaborate with the Regional Patient Safety Centre in Kuwait.

4. Establish a national plan for continuous health training and education programmes for health care staff in the area of patient safety.

5. Take necessary active steps to implement and apply the regional strategic plan for patient safety.

Regional Office

6. Disseminate and follow up implementation of the regional strategic plan for patient safety with Member States.

7. Continue to provide technical support and advice to the Member States in the field of patient safety, as one of the important strategies to improve the quality of health care.

8. Make patient safety a priority of the collaborative programme planning between WHO and Member States for 2006–2007 and beyond, in order to implement the regional strategic plan for patient safety and achieve the regional expected results of the programme budget 2006–2007.

9. Strengthen cooperation between the member states and the Kuwait Regional Patient Safety Centre and the World Alliance for Patient Safety with a view to:

   a) supporting the development of patient safety policy, skills of staff and practice;
   b) enabling countries to assess their programme on patient safety;
   c) promoting research on major patient safety issues, and establishing an action team of researchers, who can lead and collaborate on research on patient safety in the Region;
   d) facilitating exchange of information between Member States on the action taken and main achievements in patient safety.

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