

# Patient Safety Friendly Hospital Initiative: from evidence to action in seven developing country hospitals

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## Abstract

**Quality problem.** Recent evidence in the level of patient safety from hospitals in six developing countries in the Eastern Mediterranean Region has demonstrated the high prevalence of adverse events, the excessive rate of death and permanent disability and their high preventability. The Patient Safety Friendly Hospital Initiative (PSFHI) has been launched to respond to these challenges.

**Initial assessment.** The principal approach of the PSFHI has been to develop an assessment manual that has 140 patient safety standards across five domains—leadership and management, patients and public involvement, safe evidence-based clinical practices, safe environment and lifelong learning.

**Choice of solution and implementation.** Ministries of health of seven countries—Egypt, Jordan, Morocco, Pakistan, Sudan, Tunisia and Yemen were asked to nominate one hospital for assessment and then follow-up with an improvement plan.

**Evaluation.** The standards are divided into critical (20), core (90) and developmental (30). The range of critical standards, the compulsory standards with which a hospital has to comply, achieved by participating hospitals was 8–78%. Overall, in the domain of leadership and management the highest compliance was 47%, for patients and public involvement 25%, for safe evidence-based clinical practice 53%, for safe environment 64% and for lifelong learning 27%.

**Lessons learned.** This is the first systematic multi-country initiative in the Eastern Mediterranean Region, which provides compelling evidence that assessment of patient safety standards is feasible and applicable in resource-poor settings and there are significant opportunities for improving the level of patient safety in these hospitals.

**Keywords:** quality measurement, quality management, external quality assessment, patient safety, hospitals

## Introduction

Improving the level of patient safety has a direct bearing on the number of lives saved and disabilities prevented as a result of the medical care provided to hospitalized patients in developing countries. Evidence is progressively emerging from many developing countries [1–3] and there is a slow but steady increase in the level of awareness of the risk of unsafe healthcare among policymakers and practitioners. The risk of healthcare-associated infection in some developing countries is as much as 20 times higher than in developed countries [4]. It seems imperative that in developing

countries efforts at gathering evidence related to unsafe care are undertaken in tandem with efforts at tackling this problem.

Countries of the Eastern Mediterranean Region (Eastern Mediterranean Region comprises 23 countries stretching from Morocco in the West to Pakistan in the East and covers a population of 550 million.), with support of the World Health Organization, have adopted a similar approach by way of the Patient Safety Friendly Hospital Initiative (PSFHI). This initiative was launched by the Eastern Mediterranean Regional Office of the World Health Organization (WHO EMRO) in 2007 to tackle the

enormous problem of unsafe healthcare in the region. The PSFHI follows an earlier effort to document the amount of harm inflicted on patients as a result of the healthcare they receive in hospitals. The study, which was performed in six countries of the EMR—Egypt, Jordan, Morocco, Sudan, Tunisia and Yemen demonstrated that up to 18% of inpatient admissions were associated with adverse events [5]. Moreover, the study called to attention the excessive rate of death and permanent disability, and high preventability related to adverse events. The PSFHI has been launched to respond to this challenge.

## The Patient Safety Friendly Hospital Initiative

The PSFHI is a WHO initiative aimed at assisting institutions in countries to launch a comprehensive patient safety program. Ultimately, it is hoped that this initiative will be owned by national institutions and ministries of health. Award of a certificate or award of achievement is at the discretion of the national authority, such as the ministry of health or a national accrediting body. All hospitals are eligible to participate, whether public or private, and can benefit directly from this initiative for benchmarking and self-improvement [6].

The objective of the PSFHI is to enhance patient safety by developing harmonized standards to which hospitals adhere and by encouraging the participation of hospital managers, clinicians and patients to collaborate in this effort. Furthermore, this initiative encourages national health authorities and medical and nursing schools to participate in the process of safe healthcare delivery to complement national, regional and global healthcare accreditation programs.

The overall approach adopted by the PSFHI has an assessment phase followed by an improvement phase. This paper focuses on the assessment of hospitals, which has two strands of work—first, development and validation of an instrument to systematically assess the practices related to patient safety; and secondly, assessment and measures introduced to improve the level of patient safety in selected hospitals in EMR countries.

### Development of instruments for assessment of patient safety

Recognizing the need to develop a valid and reliable instrument for the assessment of patient safety, adapted to developing countries, WHO EMRO embarked on a process of developing a patient safety assessment manual. This effort involved review of WHO clinical guidelines; systematic review of the literature on patient safety; review of different countries' accreditation standards, the Arab League for Quality in Healthcare accreditation standards, and research studies published in peer-reviewed journals.

A small team with experience and knowledge of the literature on patient safety was tasked to develop the first draft of

the manual that delineated patient safety standards categorized under various domains and subdomains. Effort was made to ensure that the standards are relevant, culturally appropriate and implementable in the regional setting. Each standard was operationally defined, and means identified for its measurement. For the latter, three methods—interview, observation and document review were employed. A scoring guide was developed, offering a detailed description of the criteria required to meet the standard. Thus for each standard the manual has specific information and has guidelines for the assessor on how to make an objective assessment.

### Pre-testing and external peer review

Pre-testing was conducted in two hospitals in Egypt, one in an urban and another in a rural setting. Each standard was discussed with hospital staff to test for feasibility and appropriateness as well as means for determining hospital compliance with the standard. This was performed through dialogue with hospital staff and by doing a mock assessment. On the basis of these findings and in response to feedback from the hospitals, the standards were modified to produce a second version of the manual.

A regional patient safety panel, representing regional and international experts in the field of quality, patient safety and accreditation, reviewed the patient safety assessment manual. The expert panel critiqued and endorsed the first edition of the patient safety assessment manual during a consultation held in early 2009.

### Patient safety standards

A total of 140 patient safety standards have been included across five domains: leadership and management, patient and public involvement, safe evidence-based clinical practice, safe environment and lifelong learning. Each domain comprises a number of subdomains, 24 in all (Table 1). Standards are categorized into critical (20), core (90) and developmental (30):

- (i) Critical standards are the minimum and compulsory standards with which the hospital has to comply to become enrolled in PSFHI (Table 2),
- (ii) Core standards are essential set of standards that the hospital should comply with to become safe for patients. It is not compulsory to meet 100% of the core standards in order for a hospital to be enrolled in PSFHI; however, the percentage of fulfilled standards determines the level of patient safety attained.
- (iii) Developmental standards are the desirable requirements that a hospital should comply with to demonstrate an enhanced level of safe care.

### Panel of regional surveyors

A group of 10 regional surveyors has been developed who are fully conversant with the standards and are eligible to assess a hospital. These experts have been selected from seven countries of the region based on their experience in

**Table 1** Patient safety domains, sub-domains and standards

Domains	Subdomains	Standards			
		Total	Critical	Core	Developmental
A. Leadership and management measures	6	36	9	20	7
B. Patient and public involvement measures	7	28	2	16	10
C. Safe evidence-based clinical practices measures	6	44	7	29	8
D. Safe environment measures	2	21	2	19	0
E. Lifelong learning measures	3	11	0	6	5
Maximum score	24	140	20	90	30

the area of quality and safety and their involvement with the development of the manual.

## Assessing patient safety in hospitals

The development of the assessment manual was followed by its implementation in one hospital in each of the seven countries in mid-2009. This served two purposes—first, to assess the adequacy of the patient safety program; and second, to pilot and further refine the PSFHI before rolling out to other countries.

### Selection of hospitals

Ministries of health of seven countries—Egypt, Jordan, Morocco, Pakistan, Sudan, Tunisia and Yemen were requested to nominate one hospital as a pilot site for the PSFHI. These hospitals ranged from large teaching to medium-sized public sector hospitals with the number of hospital beds varying from 162 to 1041 (Table 3).

### Assessment and data collection

The assessment was done by a team of two from among the regional experts. Each hospital and the concerned ministry of health were informed in advance of the visit and a set of questionnaires sent to allow the hospital to better prepare itself. The assessment was done in a non-threatening and non-judgmental manner. The team conducted interviews with the patient safety leader, patient safety coordinator, hospital managers, quality and safety coordinator, monitoring and evaluation team, infection prevention and control team, laboratory staff, blood bank manager, chief pharmacist, head nurse and selected patients and their relatives. Each hospital required an average of 3 days for assessment.

There were 143 different documents that could be requested ranging from the hospital's strategic plan for patient safety to guidelines for injection safety. Documents were reviewed and when not available, interviews were conducted to verify whether or not the hospital complied with patient safety measures. In addition, different departments were visited to observe the patient safety environment and to

substantiate the information acquired through interviews and documents.

Medical records were examined for appropriateness of patient identification, legibility of writing, documentation of treatment and presence of updated handover notes. Furthermore, several areas including inpatient wards, intensive care units, pharmacy, blood bank, laboratories, central sterilization unit, kitchen and medical record archive were observed. An observation checklist was prepared for different departments. For example, the checklist for inpatient department included observation of the medical records, hand hygiene practices, safe injection practices, appropriate use of a consent form, availability of hand rails, communication strategy, system for communication of pending and urgent test results and adequate patient information.

On average the time spent reviewing documents, conducting staff interviews and observing clinical processes was 25, 35 and 40%, respectively.

### Scoring, leveling and reporting

Scoring was not a challenge when the patient safety standard was met (score = 1) or not met (score = 0). In situations where the standard was partially met (score = 0.5), the assessors followed the structure, process and output approach. When only structure or process was found to be present, and agreed upon, the standard was considered partially met.

The final report including an executive summary with recommendations to improve patient safety was sent to the ministers of health and the relevant hospital in respective countries.

## What was the level of readiness for patient safety in these hospitals?

### Benchmarking of patient safety standards

Patient safety in the seven institutions was assessed according to critical, core and developmental standards (Table 4). The overall baseline assessment score varied in the range 14 and 41% across the seven countries. The achievement of critical standards ranged from 8 to 78% (Fig. 1). The latter are compulsory standards that a hospital has to comply with to become enrolled in PSFHI.

**Table 2** Critical standards for enrollment in PSFHI

Domain	Standard text
A. Leadership and management measures	<p>The hospital has Patient Safety as a strategic priority. This strategy is being implemented through a detailed action plan</p> <p>The hospital has designated a senior staff member with responsibility, accountability and authority for patient safety</p> <p>The leadership conducts regular Patient Safety Executive Walks to promote patient safety culture, learn about risks in the system, and act on patient safety improvement opportunities</p> <p>A designated person co-ordinates patient safety and risk management activities</p> <p>The hospital conducts regular at least monthly morbidity and mortality meetings</p> <p>The hospital ensures availability of essential equipment</p> <p>The hospital ensures that all reusable medical devices are properly decontaminated prior to use</p> <p>The hospital has sufficient supplies to ensure prompt decontamination and sterilization</p> <p>Qualified clinical staff, both permanent and temporary, are registered to practice with an appropriate body</p>
B. Patient and public involvement measures	<p>Before any invasive procedure consent should be signed by patients. He/she should be informed of all risks, pros and cons of procedure in advance</p> <p>All patients are identified and verified with at least two identifiers including full name and date of birth (and ensure that room number is not one of them) whenever a patient undergoes any procedure (e.g. laboratory, diagnostic or therapeutic procedures) or transfer or is administered any medication, blood or blood component</p>
C. Safe evidence-based clinical practices measures	<p>The hospital maintains clear channels of communication for urgent critical results</p> <p>The hospital has systems in place to ensure safe communication of pending test results to patients and care providers after discharge</p> <p>The hospital has an infection prevention control program including infection prevention and control policies, protocols and procedures and multidisciplinary committee</p> <p>The hospital ensures proper decontamination of all equipment with special emphasis on high-risk areas</p> <p>The hospital implements guidelines, including WHO guidelines, on safe blood and blood products</p> <p>The hospital has safe pre-transfusion procedures, e.g. recruitment, selection and retention of voluntary blood donors, blood screening (e.g. HIV, HBV)</p> <p>The hospital ensures availability of life-saving medications at all times</p>
D. Safe environment measures	<p>The hospital segregates waste according to the hazard level (see guidelines) and color code it</p> <p>The hospital conforms to guidelines on management of sharps waste, including WHO guidelines</p>

**Domain A: leadership and management measures**

In this domain the range of compliance to the relevant standards varied between 18 and 47% (Supplementary material, Appendix). This domain includes standards related to the presence of a patient safety program and policies and the leadership support dedicated to its implementation. The hospitals performed relatively better as regards the availability of essential functioning equipment and supplies to deliver services. On the other hand, few hospitals had policies, guidelines, standard operating procedures readily available for clinical or support services.

**Domain B: patient and public involvement measures**

In the domain of patient-centeredness none of the participating hospitals met the two critical standards—proper patient identification and building health awareness of patients and families. Achievement of core standards in this domain ranged from 9.4 to 40.6%. Less than 4% of developmental standards were found to be met.

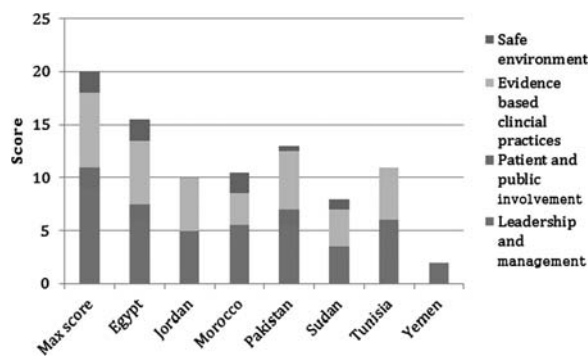
This domain assesses presence of family rights statement, building of health awareness, proper patient identification, paying attention to patients' voice and developing

**Table 3** Characteristics of participating hospitals

	Egypt	Jordan	Morocco	Pakistan	Sudan	Tunisia	Yemen
Hospital beds	252	921	162	1041	483	802	315
Daily outpatients	1200	1200	193	2140	238	905	610
Bed occupancy (%)	58	74	47	95	93	82	21
Daily admissions	70	200	26	120	65	85	35
Staff	1200	1968	308	3217	871	1410	491
Physicians	559	651	75	332	677	196	180
Nurses	193	1147	167	851	109	935	180
Paramedical	108	314	66	348	85	210	491

**Table 4** Patient safety baseline assessment scores for hospitals

Standards	Max score	Baseline scores achieved by hospitals						
		Egypt	Jordan	Morocco	Pakistan	Sudan	Tunisia	Yemen
Critical	20	15.5	10	10.5	13	8	11	2
		78%	50%	53%	65%	40%	55%	8%
Core	90	41.5	33.5	25.5	34.5	24.5	38	16.5
		46%	37%	28%	38%	27%	42%	18%
Developmental	30	0.5	3.5	2	3.5	1	6	1.5
		2%	12%	7%	12%	3%	20%	5%
Total score	140	57.5	47	38	51	33.5	55	20
		41%	34%	27%	36%	24%	39%	14%

**Figure 1** Achievement of critical standards across domains of patient safety.

mechanisms to communicate adverse events to patients (Supplementary material, Appendix).

### Domain C: safe evidence-based clinical practices measures

Most of the critical standards (mean 63%, range 14–86%) were met by many hospitals. The domain of evidence-based clinical practice includes standards related to common medical practices and procedures, such as injection safety, hand hygiene, safe blood transfusion, safe surgery and infection control (Supplementary material, Appendix).

Assessment of the standards related to infection control ranged from 5 to 23 out of a maximum of 36 (14–64%). All hospitals had an infection control unit and/or program. However, in many cases, surveillance of outbreaks within the hospital was found to be deficient. Also, in most hospitals, clear protocols were not available to guide action taken when the staff was infected, for example, with Hepatitis B virus.

### Domain D: safe environment measures

In the domain of safe environment several hospitals displayed deficient performance (Supplementary material, Appendix). While many hospitals had a waste management system in place, and demonstrated adherence to certain regulations and procedures related to biological and hazardous waste disposal, none met the physical and infrastructural standards that ensure safety of patients. Most hospitals failed to demonstrate a fire evacuation plan and even when such a plan existed, personnel were not trained to follow it.

### Domain E: lifelong learning measures

Lifelong learning was lacking or inadequate in all hospitals (Supplementary material, Appendix). There was no patient safety curriculum and most hospital staff were not provided patient safety orientation programs. Aside from the mortality committee, staff in all hospitals were not familiar with the

reporting procedure and steps to be taken during or after an adverse event.

## Next steps

At the country level, two streams are being followed to take this work further. The first relates to the national expansion and ownership in the seven countries in which the initiative was piloted; while the second relates to reaching other EMR countries in which the PSFHI has not been initiated.

For the first stream—the ministry of health expresses commitment to and owns the initiative, and selects 10 hospitals to participate in the launch and invites them to a national workshop. Each hospital is approached by the ministry of health with a briefing on the initiative and a description of the process, with emphasis on advancing patient safety. The hospital management assigns a task force for the initiative, including a physician, nurse and administrator and invites an independent team of assessors to undertake a baseline assessment. The results are shared with each hospital and the hospital is provided with key suggestions and recommendations for improvement. The hospitals are notified that they will be reassessed after 12 months and are assisted in drafting an action plan for the initiative. This process is currently going on successfully in Jordan. The second stream of work invites ministries of health of a second wave of countries to select one or two pilot hospitals where a similar process is repeated. Iraq is leading the second wave of PSFHI countries. WHO EMRO continues to provide technical backup and has outlined the necessary steps to participate in the initiative [6].

## Lessons learnt

Patient safety is a global problem that affects the developed and developing world [7]. The joint global initiative of the WHO and the World Alliance for Patient Safety (WAPS) has obliged developing countries to launch a concerted effort that would help assess the magnitude of the problem, identify the root causes, develop interventions; and stresses the need for greater advocacy and awareness among policy-makers, practitioners, patients and the public at large.

The PSFHI follows the effort to estimate the prevalence of adverse events among hospitals in six EMR countries and to respond to this daunting challenge [5]. The study provides a benchmark for future comparison. Although evidence on the prevalence of adverse events has largely been available from developed countries [8–14], it is progressively emerging from developing countries [2, 3].

The PSFHI relies primarily on expertise and experience from within the region. The African Partnerships for Patient Safety is another regional bi-directional initiative working with identified hospitals in Africa and Europe, which aims to establish sustainable partnerships focusing on patient safety and will be aligned with each country's individual health policy framework [15].

The patient safety manual adapted to developing countries has been a rewarding effort in assessing the level of patient safety in hospitals and offers several advantages. First, it allows systematic assessment and quantification of problems in hospitals across different patient safety domains; secondly, being a system-based approach, it permits comparison over time in terms of improvement in the level of patient safety-related structures, processes and outputs; thirdly, by identifying issues as systemic problems, it helps to introduce a non-blame and non-punitive culture; and finally it supports the long-term implementation of risk-reducing strategies that help to reduce the risk of harm to patients.

None of the hospitals achieved a baseline score of 50% across the five domains of patient safety. Commitment of the leadership and management was found to be wanting in all institutions. Leadership is a key element of a patient safety program that recognizes safe care as a system-related problem and promotes investment in developing systems that ensure the safety of patients [16].

The domains of patient and public involvement and life-long learning were found to be equally deficient. Patients are neither involved nor do they have a 'voice' in matters related to the care they receive. From the providers' perspective they have little opportunity to participate in staff development programs related to patient safety or to improve their clinical competencies. This necessitates developing interventions that tackle both the 'demand' as well as the 'supply' aspects of safe patient care. The London Declaration, endorsed by WHO and WAPS, calls for a greater role for patients to improve the safety of healthcare worldwide [17]. The potential for engaging patients in patient safety is considerable but requires further research to examine the influences on patient involvement, the limits and the possible risks [18, 19].

None of the seven hospitals assessed achieved the 20 critical patient safety standards that are necessary to enroll a hospital in the PSFHI. The shortcomings were consistently distributed across all domains, suggesting that any improvement initiative would need to be comprehensive and should address all critical areas.

Assessment is only the first step; the PSFHI aims at improvement by offering a package of interventions that address the safety of patients in healthcare settings. This improvement effort has been launched in several countries and expanded in others, and a toolkit to assist hospitals in improving patient safety is currently being developed. It is expected that the PSFHI will contribute to creating a conducive environment to address adverse events, encourage implementation of WHO-guided patient safety standards and contribute to building mutual trust and transparency between patients and providers of healthcare.

The PSFHI has certain limitations. First, despite regional adaptation of the standards, it is difficult to say whether all are valid and reliable. Indeed, these need to be reviewed as more experience is gained and include critical standards for all five domains. Secondly, there is limited number of regional patient safety experts who can perform the role of surveyors. Concurrent effort is being planned to increase the

number of surveyors within each country who could independently undertake such assessments. Thirdly, so far hospitals in the private sector have not been assessed. The initiative needs to be expanded to cover private institutions. Fourthly, the ownership of the ministries of health is critical. Not all countries have shown the same enthusiasm. However, where they have, such as Jordan and Iraq, the results have been promising.

Finally, there is always a question mark on the sustainability of initiatives launched by development agencies. Indeed, there is a window of opportunity that may last a few more years and in this period the initiative has to be institutionalized as a national program. Being aware of this challenge, the PSFHI has been launched with the involvement of the ministries of health to gain their ownership; some countries have shown commitment by allocating resources to national patient safety programs, while others are aligning it as part of the quality assurance programs. This initiative has so far been appealing to policymakers and it is no surprise that all countries in the region that have been offered this initiative have accepted it.

## Conclusions

The PSFHI provides compelling evidence that assessment of patient safety standards in hospitals is feasible and applicable in resource-poor settings. Implementation of the patient safety standards has increased the level of awareness of participating hospitals as well as patients. Indeed, the element of public engagement gives this initiative thrust in relation to other quality-related programs.

The ultimate aim of PSFHI is to improve patient safety in countries of the Eastern Mediterranean Region. While refinement of assessment tools and their use in countries will continue, the PSFHI has progressed from assessment to improvement. National expansion is being encouraged and is in progress in several countries. Future research will determine whether this initiative has improved patient safety in the hospitals of EMR countries.

## Supplementary material

Supplementary material is available at *INTQHC Journal* online.

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