

Assessment of Patient Safety in Hospitals

A Manual for Evaluators

DRAFT

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Foreword

Unsafe health care remains a problem of immense magnitude worldwide. While the past decade has witnessed remarkable progress towards improved patient safety, many gaps still exist and harm inflicted on patients by adverse health care events remains unacceptable. The WHO Eastern Mediterranean Region covers 22 countries and a population of over 3 billion. It is estimated that the Region has over 4500 public sector hospitals and over 1000 private sector hospitals, with approximately 800 000 hospital beds in the public sector. The number of hospital admissions is estimated to exceed 30 million each year. The high number of inpatients warrants special attention to patient safety in hospitals in the Region.

In response to increasing awareness and concern at the situation, the WHO Regional Office for the Eastern Mediterranean launched a patient safety programme in the Region. The programme was guided by a regional strategy comprising five approaches: awareness-raising; assessment of the scale of the problem; understanding the causes of error; developing and testing interventions of prevention; and organizing and running patient safety programmes. Patient safety research was conducted in six countries and the research network is being expanded to more countries of the Region. The development of solutions and initiatives aimed at driving change towards greater patient safety has become a pressing need, and is recognized by the public and professional community. As part of one such initiative—the patient safety friendly hospital initiative—the Regional Office developed a set of patient safety standards, with the aim of assessing and implementing patient safety programmes in hospitals and instilling a culture of safety.

Assessment based on the standards in this manual is not intended to be self-administered. Rather, it requires training and expertise. Development of a critical mass of trained assessors is essential and it is hoped that this manual will be used extensively within and outside the Region in the future. The manual has been through multiple rounds of revision by national and international experts. It has been pilot-tested and found to be valid and reliable. Nevertheless, there is room for improvement and contributions towards further development and constructive editing are invited.

I encourage ownership of the assessment tools in the manual by Ministries of Health, academic institutions and professional associations. WHO will continue to facilitate the assessment process to provide technical and capacity-building support. I hope that this manual will become a reference for all those who strive to improve patient safety in health care.

Hussain A. Gezairy M.
WHO Regional Director for the Eastern Mediterranean

Introduction

Overview

Patient safety is a global health concern, affecting patients in all health care settings, in developed or developing countries. Research studies have shown that an estimated 10% of all inpatient admissions result in a degree of unintended patient harm (1). It is estimated that up to 75% of these lapses in health care delivery are preventable. In addition to human suffering, unsafe health care exacts a heavy economic toll. Indeed, it is estimated that between 5% and 10% of expenditure on health is due to unsafe practices that result in harm. Most of this is due to system failures rather than the actions of individuals (2).

WHO has recognized the importance of patient safety and prioritized it as a public health concern. World Health Assembly resolution WHA55.18 outlined the various responsibilities of WHO in providing technical support to Member States in developing reporting systems, and reducing risk, framing evidence-based policies, promoting a culture of safety, and encouraging research into patient safety (3). In response to the pressing need for the development of interventions that address lapses in patient safety, the WHO Region for the Eastern Mediterranean launched the patient safety friendly hospital initiative.

This initiative involves the implementation of a set of patient safety standards in hospitals. Compliance with the standards ensures that patient safety is accorded the necessary priority and that facilities and staff implement best practice. The standards were developed and revised by a group of regional and international experts. The initiative was piloted in seven countries of the Region (Egypt, Jordan, Morocco, Pakistan, Sudan, Tunisia, and Yemen) and experts were trained to conduct initial baseline assessments, based on the standards and implementation guidelines, in one pilot hospital in each of the countries.

Patient safety friendly hospital assessment

Patient safety standards are a set of requirements that are critical for the establishment of a patient safety programme at hospital level. They provide a framework that enables hospitals to assess patient care from a patient safety perspective, build capacity of staff in patient safety, and involve consumers in improving health care safety.

Patient safety friendly hospital assessment is a mechanism developed to assess patient safety in hospitals. It provides institutions with a means to determine the level of patient safety, whether for the purpose of initiating a patient safety programme or as part of an existing programme. The assessment is conducted through an external, measurement-based evaluation. It is voluntary. For the moment, the WHO Regional Advisory Group on Patient Safety is the primary assessment team. The group will assess hospitals to determine whether or not they comply with the WHO patient safety standards and patient safety performance indicators. Assessment has a number of benefits for hospitals. It demonstrates commitment and accountability regarding patient safety to the public. It offers a key benchmark and delineates areas of weakness and encourages improvement to attain standard targets. It provides motivation for staff to participate in improving patient safety. The ultimate goal of the initiative is to improve the level of patient safety in hospitals by creating conditions

lead to safer care, thus protecting the community from avoidable harm and reducing events in hospital settings.

Role of WHO

The patient safety friendly hospital initiative is a WHO initiative aimed at institutions within countries to launch a comprehensive patient safety programme. Ultimately it is hoped that this initiative will be owned by the institutions and ministries of health. The manual provides necessary tools for professional associations, regulatory, accreditation oversight bodies and ministries of health, to improve patient safety. Award of a certificate of achievement is at the discretion of the national supervising body, such as the Ministry of Health. However, hospitals can benefit directly from this initiative through benchmarking and self-improvement.

The patient safety standards were developed through:

- systematic review of literature on patient safety;
- review of relevant WHO clinical guidelines;
- review of national accreditation standards;
- review of the League of Arab States quality in healthcare accreditation standards;
- review of patient safety initiatives and activities in countries of the Region;
- review of research studies published in peer reviewed journals;
- peer review in several regional meetings;
- expert panel critique and finalization of the first draft in a consultation meeting in Egypt.

Structure and organization of the manual

The manual is organized into two sections: 1) the patient safety standards; and 2) the patient safety friendly hospital assessment tools.

Section 1 comprises five domains divided into 24 subdomains. It also includes a guide for the evaluator including documents to be reviewed for each standard, relevant interview questions, observation guide, and scoring guidelines.

Section 2 comprises a set of tools to facilitate the assessment process, including a standard agenda for the assessment visit, interview questionnaires collated by interviewees, and a complete list of all documents required from the hospital.

The five domains under which the standards are organized are: A. Leadership and management; B. Patient and public involvement; C. Safe evidence-based clinical practice; D. Safe environment; and E. Lifelong learning. Each domain comprises a number of subdomains – 24 in total. A set of critical (20 in total), core (90 in total) and developmental (30 in total) standards (Figure 1) are distributed among the five domains.

Figure 1. Domains and contributing standards

Domains	Critical standards	Core standards	Developmental standards	Total standards in each domain
A. Leadership and management (6 subdomains: A1-A6)	9	20	7	36
B. Patient and public involvement (7 subdomains: B1-B7)	2	16	10	28
C. Safe evidence-based clinical practice (6 subdomains : C1-C6)	7	29	8	44
D. Safe environment (2 subdomains : D1-D2)	2	19	0	21
E. Lifelong learning (3 subdomains :E1-E3)	0	6	5	11
Total	20	90	30	140

Comment [e1]: I took out the subdomains column completely to avoid confusion

Critical standards are compulsory standards with which a hospital has to comply to enrolled in the patient safety friendly hospital initiative.

Core standards are an essential set of standards with which a hospital should become safe for patients. It is not compulsory to meet 100% of the core standards in a hospital to be enrolled in the patient safety friendly hospital initiative. However, the percentage of standards complied with will determine the level the hospital achieves. Furthermore, the percentage of core standards fulfilled is important for benchmarking, to document improvement over time.

Developmental standards are the requirements that a hospital should attempt to meet, based on its capacity and resources, to enhance safe care.

All patient safety subdomains and standards follow the same format. Each subdomain starts with a *Title*, which explains the areas it covers, followed by a *Measurement statement*, which describes the subdomain, followed by a *Rationale*, which explains why it was selected, and finally *Standards listed under the specific subdomain* that contributes to the composite (Figure 2).

Figure 2. Format of patient safety standards

Example from domain A: Leadership and Governance

A.1	Title	Leadership commitment	Key respondent	Final score	
subdomain	Measurement statement				
	Rationale				
	standards	Critical standard			
		Core standard			
	Developmental standard				

The WHO Regional Advisory Group on Patient Safety will review and update the regional patient safety standards and patient safety performance indicators every three

How to use the manual

Section 1 of the manual contains the patient safety standards divided among the five already described. For each standard, a set of critical, core and developmental standards used to indicate compliance with the standard. Against each criterion is a column indicates the key respondent from whom information on the criterion will be obtained. Section 2 provides a set of structured interviews comprising all standards relevant to the interviewee. For example, all the standards that can be determined by asking the infection control specialist will be found collated in the interview form with the infection control specialist.

Each standard is followed by an evaluator guide, which details the steps the evaluator to take to determine compliance with each of the standard. These steps include the documents to be reviewed by the evaluator for each standard. Section 2 provides the documents hospital needs to prepare for assessment.

Finally, there is a scoring guide at the end of each standard to assist the evaluator in determining the score for each criterion (depending on whether the score is totally met, partially met or not met) (Box 1).

Each criterion receives a score of 1 if found to be met, 0.5 if partially met and 0 if not

Box 1. Format of the standards

- subdomain and standards
- Documents to be reviewed for subdomain
- List of relevant interviews
- Scoring guide

Scoring requires adequate experience on the part of the assessment team (Box 2).

Box 2. Scoring
0 Criteria not met
0.5 Criteria met for structure and process
1 Criteria met for structure, process and output

Levels of compliance with patient safety standards

Hospitals will be scored as patient safety friendly based on four levels of compliance level 4 representing the highest attainable level (Figure 3).

Level 1: Compliance with 100% of critical standards and any number of developmental standards.

Level 2: Compliance with 100% of critical standards and 60% to 89% of core standards and any number of developmental standards.

Level 3: Compliance with 100% of critical standards and at least 90% of core standards and any number of developmental standards.

Level 4: Compliance with 100% critical standard and at least 90% of core standards and at least 80% of developmental standards.

Figure 3. Levels of compliance with patient safety standards

Hospital level	Critical standards	Core standards	Developmental standards
Level 1	100%	Any	Any
Level 2	100%	60-89%	Any
Level 3	100%	≥ 90%	Any
Level 4	100%	≥ 90%	≥ 80%

Conduct of assessment

All hospitals are welcome to participate, whether public or private. However, at present there is a limited number of regional experts who have the experience to undertake this assessment. At this stage, hospitals are being selected based on criteria developed by the Regional Office of the Ministry of Health, in collaboration with WHO country offices. The Regional Office is making concerted efforts to expand the number of trained evaluators and to ensure local ownership of the initiative by ministries of health or other recognized agencies in the region. Once this stage is reached, assessment of hospitals will be undertaken by national experts. The Regional Office will continue to provide technical support as and when required.

In the current phase of the initiative, the hospital receives the patient safety standards indicator documents that will be used for the evaluation before the assessment visit. The hospital management team is encouraged to inform the public, staff and patients, that

safety friendly hospital assessment evaluators will be assessing the hospital on the s
dates and should inform them of the purpose of the patient safety friendly hospital init

The assessment process

- The onsite assessment team and agenda will vary according to the hospital's prof
size, services, and location). The team will comprise a mix of national and inter
evaluators initially, and subsequently national evaluators. The team will be comp
at least a physician, a nurse and an administrator. Hospital staff will be trained to
their hospital internally for patient safety. The team will use a set of patien
indicators and standards to ensure that WHO patient safety standards are being me
- The report and recommendations for improvement in patient safety given by the
the senior managers of the hospital will be confidential and constructive. The re
the evaluation may be made public or may remain confidential at the discretio
hospital management.
- A hospital attaining level 4 must inform the Regional Office of any devi
compliance with the standards.
- Internal evaluation is suggested to be on a quarterly basis and external evalu
suggested on a two-year basis for level 1 and 2 hospitals and every three years fo
and 4 hospitals.

Criteria for selection of evaluators

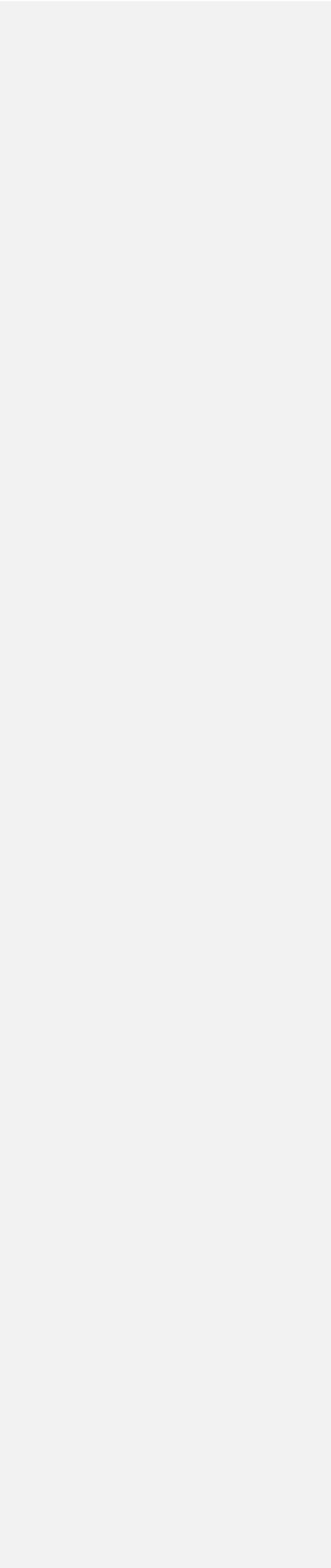
In the current phase of the study, evaluators will initially be selected by the Regiona
and may later be selected by the Ministry of Health or other national agencies. The fo
are suggested criteria for selection of evaluators:

- experts in the field with a minimum of 10 years of working experience and postg
studies (medicine, administration and nursing);
- knowledge of the patient safety friendly hospital assessment standards and meth
for evaluation;
- knowledge of performance improvement and patient safety methods.

Expansion at national level

Following the initial baseline assessment of one hospital, selected by the Ministry of
the following steps are suggested for national expansion.

1. The Ministry of Health expresses commitment to and ownership of the initia
selects 10 hospitals to participate in a launch and training workshop. Each ho
approached by the Ministry of Health with a briefing on the initiative and a descri
the process, with emphasis on its key objective, which is to advance patient safety
2. Hospital management assigns a task force for the initiative, including a physicia
and administrator.
3. A workshop on the initiative is held.
4. The baseline assessment in each of the 10 hospitals is initiated. Evaluators f
patient safety task force in one hospital perform the assessment in another hospita

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5. The results of the baseline assessment are summarized in a report for each (prepared by the evaluating team). Reports are shared with policy-makers at the of Health.
 6. The results are shared with each hospital and the hospital is provided with suggestions and recommendations for improvement. Technical support materials be provided by the Regional Office. The hospitals are notified that they will be assessed after 9 months and are assisted in drafting an action plan for the initiative.
 7. A workshop is held at a national level to share the results and raise more awareness nationwide.