

PROMOTING STANDARDS
IN THE PRIVATE HEALTH SECTOR

A Self-Assessment Guide for Health Care Organizations



QUALITY, SAFETY, ETHICS



IFC

**International
Finance Corporation**
World Bank Group

IFC'S Mission

IFC, a member of the World Bank Group, creates opportunity for people to escape poverty and improve their lives. We foster sustainable economic growth in developing countries by supporting private sector development, mobilizing private capital, and providing advisory and risk mitigation services to businesses and governments. For more information, visit www.ifc.org.

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FOREWORD

IFC produced this guide because improving standards in health care organizations is important. We believe that patients everywhere, including in developing countries, have a right to receive high quality care in a safe environment.

When IFC invests in health care organizations, we stake our reputation on our clients' commercial performance and their values and standards. We have seen that a commitment to high standards of quality, safety, and ethics makes good business sense.

This guide is for health care organizations of all sizes and complexities operating in emerging markets. Raising health care standards is about developing systems to ensure that appropriate care is provided to patients in a safe environment. And health care providers should not only seek to “do the right thing”, but aim to do it well, and to do it right “first time, every time”.

I hope that you will find this guide useful in improving quality, ethics, and safety standards in your organization.



Guy Ellena
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INTRODUCTION



Introduction

ABOUT IFC

The International Finance Corporation (IFC) is part of the World Bank Group. Our mission is to promote sustainable private sector investment in developing countries in order to reduce poverty and improve people's lives.

IFC fosters sustainable economic growth in developing countries by financing private sector investment, mobilizing capital in the international financial markets, and providing advisory services to businesses and governments.

In recent years IFC has become increasingly active in the private health sector in developing countries. We are now the largest multi-lateral investor in the private health sector worldwide. Since 2000 we have provided over US\$1.5 billion of financial support (mainly through debt and equity financing) to over 80 projects in more than 30 countries. This support has enabled some \$4 billion of investment in the private health sector.

Health care organizations supported by IFC provide employment for an estimated 35,000 people and treat 5.5 million patients annually. About one third of our health care clients are based in IDA countries (mainly poorer developing countries). And about one fifth have achieved some form of internationally recognized accreditation.

Typically our clients are private hospitals, but they also include other types of health care organizations including diagnostic centers, eye care chains, polyclinics, medical waste management firms and HMOs. More information is available at: www.ifc.org/che

PURPOSE OF THIS GUIDE

This Guide is designed to assist health care organizations in emerging markets to reach “international standards” of quality and patient safety. It will enable them to conduct an organizational self-assessment to identify how well they are meeting defined standards in five key areas:

- Governance and Leadership
- Ethics and Patient Rights
- Quality Measurement and Improvement
- Patient Safety
- Facility Safety and Emergency Management

The Guide will help them to gauge how much effort they need to make – and in which areas – to reach international standards.

The assessment is not, in itself, intended for use as an accreditation tool, although it is likely to be a useful tool for organizations that are actively considering international accreditation. If the organization has already attained international accreditation, the Guide may serve to reinforce its commitment to the process of continual improvement.

The document provides information regarding key principles underlying quality improvement initiatives. And it guides users through the important steps of undertaking a quality self-assessment. These include: getting organized, collecting data, identifying gaps and developing plans for meeting key standards.

WHY ARE STANDARDS IMPORTANT?

Why should private health care providers be interested in promoting standards of quality, safety and ethics?

Of course, the consequences of poor standards can be disastrous. Stories of unethical business practices are increasingly common in the news media and have resulted in the demise of individuals and whole health care organizations. No hospital executive wants to find their hospital or one of their staff in the news because of a patient being caused serious injury or death.

Ethical and responsible conduct is not only important for public relations, but it is also a necessary element in risk management. The reputation of a health care organization is critical in influencing patients seeking services. And, for those organizations aspiring to attract medical tourism, a good reputation is imperative. Hospitals with good reputations also benefit from lower recruitment and orientation costs, as staff retention is high and the most qualified professionals tend to seek jobs with them.

Solid, supportive leaders who work closely with the staff to improve standards also find that patient and staff satisfaction increase. These outcomes create a sense of achievement and pride in the organization.

Quality improvement is linked to performance improvement because improving quality tends to reduce costs. For example, when clinicians are uncertain about the best course of action to take, they tend to do more – e.g. more tests, more procedures and more observation. Therefore, health care organizations that undertake more analysis and promote evidence-based medicine are more likely to reduce waste. In fact, some health professionals state that “the opposite of quality is waste” — and waste reduction requires removing process flaws and non-value adding processes.

From a commercial perspective, all of these outcomes can translate into financial dividends.

GOVERNANCE AND STANDARDS

What is governance?

Good governance is of fundamental importance to improving standards of quality and safety.

Governance is defined as the rules, processes and laws by which an organization is operated. Typically, there are two groups that make up the governance structure of an organization:

- the governing body (e.g. board), and
- the chief executive officer (or president) and senior managers.

In the case of health care organizations, clinicians (e.g. medical and nursing staff) also play a key role in governance. For example, physicians who provide care in a health care facility are normally supervised by a licensed medical practitioner; accordingly hospitals have medical directors to fulfill this senior management oversight role. By driving the clinical decisions of the organization, physicians also control the use of resources — such as medications, procedures and tests — thereby making a significant impact on the business.

These groups share the responsibility of setting the strategic direction for the organization and for achieving its goals. They are accountable for the quality of services and the safety of the patients, visitors and staff.

The leaders of health care organizations carry out the responsibilities of governance through their planning, decision-making, and performance management functions.

PRINCIPLES OF GOOD GOVERNANCE

Principles of good governance include¹:

Stakeholder rights:	Stakeholders include investors and employees, as well as patients, community members and organizations, and vendors. Some rights are accorded by law and others may be established by the organization. Stakeholders should know their rights and have a means of redress for violation of their rights.
Integrity & ethical behavior:	Decisions are based on the values held by an individual or organization. It is important, then, that the organization defines and agrees on a shared set of values and code of conduct ² , such that decisions are based on a common understanding.
Disclosure & transparency:	The organization implements procedures to independently verify and safeguard the integrity of its operating and reporting systems. Disclosure of material matters concerning the organization should be timely and balanced to ensure that investors and other stakeholders have access to clear, factual information.
Performance orientation:	The organization should establish indicators to determine whether goals and objectives are being met. All aspects, including financial, management, and clinical performance, should be measured to provide an overall assessment of the organization.
Responsibility & accountability:	The leadership of a health care facility is ultimately responsible for providing safe, high quality care. It is accountable for its actions to the relevant stakeholders, e.g. investors, health authorities, community, and individual clients.
Mutual respect:	Leaders should demonstrate mutual respect and civility with a goal of building trust. ³

¹ OECD (2004) OECD Principles of Clinical Governance, OECD Publications: Paris. Available at www.oecd.org/dataoecd/32/18/31557724.pdf

² IFC's proposed Code of Conduct for Health Care Organizations is included in Appendix I.

³ The Governance Institute. (2009) Leadership in Health Care Organizations: A Guide to Joint Commission Leadership Standards. A Governance Institute White Paper. The Governance Institute: San Diego, Ca.

GOVERNANCE STRUCTURE FOR HEALTH CARE ORGANIZATIONS

There is no “right” governance structure for hospitals and other health care organizations. The structure will be based on the size and complexity of the organization. However, there are some basic elements that are recommended.

First, all leaders should have a job description outlining their roles and responsibilities.

Each individual has their own job to do and each leader has a responsibility to collaborate with the other leaders to make sure that the operations of the organization function smoothly. Achieving this aim requires a structure and process of communication through which leaders can share information and make decisions. Meetings and committees are two primary means of gathering the right people together to make decisions.

Management meetings need to be held frequently enough to communicate information and to make decisions. Top management teams, e.g. the chief operating officer, administrator, nursing director (or matron) and medical director, may meet on a weekly basis; whereas, meetings that include all department heads may meet monthly. These types of meetings are usually referred to as “standing” meetings as they are scheduled on a regular basis. It is customary to make a yearly calendar marking these dates in advance.

Committees, on the other hand, are organized around key tasks or functions. Most health care providers should have at least the following committees⁴:

- Quality and Patient Safety
- Infection Prevention and Control
- Pharmacy and Therapeutics
- Safety (environmental)
- Medical Records
- Clinical Privileging

Illustrative terms of reference for each of these committees are set out in Appendix II.

PRINCIPLES OF QUALITY IMPROVEMENT

Several principles guide quality improvement efforts: client-focused care, teamwork, leadership, systems, and data. These principles should be applied when developing policies and procedures and implementing quality improvement activities.

Client-focus

Client-focused care is directed toward meeting the needs of patients and their families. Some factors to take into consideration are:

Dignity and respect:

- Taking into account the values, beliefs and cultural backgrounds of patients during the planning and delivery of care.
- Resolving complaints and conflicts as soon as possible.

Information sharing:

- Encouraging patients to share their thoughts and questions.
- Health care professionals providing information regarding illness and treatment options in ways that each patient can understand.

Participation:

- Preparing and supporting patients and their families to participate in care at the level they choose.

Continuity:

- Providing care across the continuum of care, e.g. between home, hospital, primary health care, and the community.

Teamwork

Quality improvement activities are best carried out in multidisciplinary teams. Each member of the staff is valuable in the care and treatment of patients and each member has a role in providing quality care for the patient. Additionally each team brings a different set of knowledge, experiences and skills, providing better understanding of an issue or process. Teams are capable of providing a greater number of ideas for solutions than individuals. And, when people work together, they are usually more committed to the solutions agreed upon. Therefore involving all levels of staff in quality improvement initiatives creates a sense of accountability and ownership.

⁴ Institute for Healthcare Improvement. Some Questions To Ask When Forming A Board Quality Committee. Available at: www.ihl.org/NR/rdonlyres/FD638477-AB4A-43B1-A9D9-35486E931C45/7339/JimReinertsenQuestionsforBoardQualityComm.pdf

Leadership	Effective leadership is critical to the success of quality improvement efforts. Leaders provide the direction and support required to create a culture of quality. Leadership must incorporate “Quality” into the mission, vision and values of the organization. Leaders must be “present” and participate in quality improvement efforts, such as participating in quality-related training, committees, making rounds ⁵ , showing interest (e.g. by asking questions about activities and results), including Quality Improvement reports in meeting agendas, and giving recognition to individuals and groups.
Systems	Hospital services are provided within a system. The focus must be on improving the overall system and the processes within it to create an environment that meets the needs of the staff and patients. Quality standards assist the staff in looking at the various processes that affect the quality of care. For example, the process of maintaining an inventory has a direct effect on the availability of drugs. The focus is not on individual staff members but rather on how well the system is working and finding ways to improve it.
Data	Sound decisions are made with the appropriate information. Therefore, quality improvement efforts rely on collecting data to assess performance, to identify strengths and gaps in performance, and to find solutions to improve performance and meet set standards. The measure of success is based on comparing the baseline measurement with the measurement after an improvement has been implemented.

Utilization/workload measures

- No of inpatients
- No of outpatients
- No of procedures (surgical etc)
- No of tests

Efficiency measures

- Average length of stay
- Bed occupancy rate
- Day case rate
- Operating theater utilization

Quality/outcome measures

- Unplanned readmission rates < xx days
- Infections (e.g. MRSA and Clostridium Difficile)
- Patient falls
- Unplanned returns to operating theater
- Needle-stick injuries
- Pressure sores
- Complications rate
- Caesarian rate
- Deaths
- Sentinel events
- Patient complaints
- Patient satisfaction

Often, data such as these are collected, but frequently they are not aggregated, analyzed and used for decision-making. Thus, the first place to start is with the data that exist. Collating this basic information helps the organization to understand its patient population and provides a basis for planning service delivery and improvement.

RESOURCES

Organizations committed to Quality Improvement should familiarize themselves with the latest Patient Safety Guidance from the World Health Organization (WHO). This covers important issues such as Safe Surgery and Hand Hygiene – and can be found at: www.who.int/patientsafety.

And many useful materials can be found on websites such as that of the Institute for Healthcare Improvement: www.ihl.org

Throughout this Guide, useful information sources are identified. These include publications and websites, that may be used to learn and to build staff capacity. All online resources that are referred to are accessible free of charge.

WHERE TO BEGIN

When asked, health care staff can usually list the types of problems they face daily in providing patient care. However, often they do not believe that they have the accountability or power to do anything about it. And in many organizations, staff members have not been trained in the Quality Improvement approaches used to investigate and solve problems. Nonetheless, Quality Improvement methodology is increasingly being used effectively in many developing countries to help health care teams to identify problems and to find and implement solutions.

The key factor in this process is the use of data to support decisions. The type of data collected will vary from place to place, but commonly includes or relates to:

⁵ Patient Safety First, UK. Leadership for Safety, Supplement 1: Patient Safety Walkrounds. Available at: [www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/How%20to%20Guide%20for%20Leadership%20WalkRounds%20\(pdf\)](http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/How-to-guides-2008-09-19/How%20to%20Guide%20for%20Leadership%20WalkRounds%20(pdf))



PREPARING FOR THE SELF-ASSESSMENT



Preparing for the Self-Assessment

STEP 1: GET ORGANIZED

The first step towards improving standards of care and services is to form a Quality Assessment Team (or committee). Management should write the terms of reference for the team to provide the team members with the expectations for their work.

A team leader needs to be appointed who is responsible for organizing the group, assigning tasks and coordinating the effort. Several characteristics have been identified for an effective team leader; this is a person who is interested, respected by others, an effective facilitator, and can devote the necessary time required. This person is not necessarily a manager.

All main categories of staff (e.g. medical, nursing, pharmacy, housekeeping, and security) should participate on the team. A team of six to eight individuals is often considered to be most effective.

STEP 2: ORIENT THE TEAM

Who conducts the assessment?

The Quality Assessment Team is responsible for conducting the assessment. And they may also ask for assistance from any member of the staff. The assessment should be a participative process, so that ownership of the quality improvement process spreads throughout the organization. Community members also may be invited to participate. These might be individuals who hold specific positions, such as members of a community health committee (if one exists), parent-teachers' association, local council or non-governmental organization (NGO). Or they may be individuals who have had recent experiences in the hospital, as these individuals can provide insights from the users' perspective. When conducting assessments of the fire systems, the Civil Defense may be consulted with.

Team orientation

The team needs to be oriented to its purpose and objectives, as well as to key quality principles and methodologies. An introduction to the importance of quality improvement by the head of the facility will lend credence to the team's work. The team leader is a likely person to review the quality standards and assist the team in understanding how to conduct the assessment. If the organization has individuals who have been trained in Quality Improvement methods, they could be helpful in training the team.

STEP 3: CONDUCT THE ASSESSMENT

What areas does the Assessment cover?

The Self-Assessment Template that follows is based on a defined set of 31 standards, covering five key areas:

Clinical Governance and Leadership (CGL)

- Governance documents
- Management responsibility for operations
- Oversight of contracts
- Departmental scope of services and policies and procedures
- Space and equipment planning
- Staff recruitment, retention and development

Ethics and Patient Rights (EPR)

- Verification of professional staff credentials
- Processes to support patient and family rights
- Informed consent
- Framework for ethical management
- Organ and tissue donation
- Reproductive health policies/IVF
- Termination of pregnancy services
- Clinical research

Quality Measurement and Improvement (QMI)

- Clinical practice guidelines and pathways
- Leaders' involvement and support
- Infection prevention and control
- Medications use
- Sentinel events

Patient Safety (PS)

- Patient identification
- Effective communication
- High alert medications
- Correct site, procedure, and patient for surgery
- Health care associated infections
- Risk of falls

Facility Safety and Emergency Management (FSE)

- Environmental safety and security
- Hazardous materials plan
- Emergency management planning
- Fire/smoke plans
- Medical equipment maintenance
- Utilities management

Note. These standards were adapted from the JCI Accreditation Standards for Hospitals, 3rd Edition⁶. Thus, for those organizations seeking international accreditation; these standards will help set them on a path toward meeting internationally recognized standards.

HOW IS THE SELF-ASSESSMENT TEMPLATE ORGANIZED?

The Self Assessment Template lists each standard and an “intent statement” to help the team understand the standard and why it is important.

Compliance with each standard is evaluated against several “measurable elements”. There are 160 measurable elements in total and for each one there are four columns:

1) What is required?	The first column describes the measurable element.
2) How is this element assessed?	This question indicates what to look for when assessing the measurable element.
3) Score	The team will score each of the elements to establish a baseline and to measure ongoing progress. (See Table 1 below for scoring key).
4) Observations	This column provides space for writing comments or observations that are made, which is particularly useful when determining what action is needed to meet the standard.

References and free online resources that may be useful for meeting the standards are cited in the footnotes.

Table 1: Assessment Scoring Key

- 0 =** Not met
- 5 =** Some of the elements are in place, but the criteria is not fully satisfied
- 10 =** The element fully meets the criteria

WHAT METHODS CAN BE USED TO CONDUCT THE ASSESSMENT?

Several methods may be used for gathering information to complete the assessment. Some are outlined below.

1. Observation

Observation is typically used to monitor staff carrying out their duties. For example, observation is frequently used to assess infection control practices, counseling techniques and performance of treatment procedures. Observations can be made during safety rounds to establish that safety practices are carried out, e.g. management of hazardous materials. Observation is also used to assess the condition of the facilities, the availability of space for performing services efficiently, and the safety of the environment. (It is generally recommended that management and staff make safety rounds together weekly.)

2. Interviews

One-on-one interviews may be conducted with managers, staff and clients. Discussions might also be held with groups, such as the Infection Control or Pharmacy and Therapeutics committees (if these exist). These interviews should be guided by a set of questions but tend to be less formal. More formal interviews/questionnaires are intended to answer a specific set of questions – using a structured questionnaire or survey tool. Such tools are often used, for example, to collect data regarding staff and patient satisfaction^{7,8}.

3. Review of documents

Some information needs to be obtained by reviewing documents, e.g. patient registers, patient records, personnel files, policies, guidelines and protocols, reports, plans, and minutes of meetings.

⁶ Joint Commission International (2007) Joint Commission International Accreditation Standards for Hospitals, 3rd Edition, Oakbrook Terrace, IL, USA.

⁷ A range of patient survey questions can be found at: www.nhssurveys.org/Filestore/documents/Inpatient_2009_Core_Questionnaire_v5.pdf

⁸ Staff survey questions available at: www.cqc.org.uk/_db/_documents/quest_acute.pdf





THE SELF -ASSESSMENT TEMPLATE



The Self-Assessment Template

STEP 1: GET ORGANIZED

Self-Assessment – Quality and Safety

Date _____

Name of facility _____

Location: (town, district/province) _____

Name(s) of assessor(s) _____

CLINICAL GOVERNANCE AND LEADERSHIP (CGL)

Standard CGL.1 [Governance documentation]

Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out.

Intent of CGL.1

There is an entity (e.g. a holding company, a foundation, an owner), or a group of individuals (e.g. a board) that is responsible for overseeing the organization's operation and is accountable for providing quality health care services to its community or to the population that seeks care.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) The organization's governance structure is described in written documents.	A document or set of documents describes the mission, vision and values, purpose and goals, and structure of the organization (including the organizational chart). Also roles/responsibilities of the Chief Executive Officer, Board, etc. The title of the document may be "bylaws", "administrative manual", etc. The organization's mission is made public, e.g. posted.			
2) Strategic and management plans and operating policies and procedures are developed and approved by the organization's governing body.	Strategic and operational plans are written. The approval of the strategic and operational plans is documented in the minutes of the governing body. (The governing body may be the Board of Directors, or other such group).			
3) An annual budget is developed and approved to allocate the resources required to meet the organization's mission.	An annual budget is developed. The approval of the budget is documented in the minutes of the governing body.			
4) A license to operate the organization, as required, is obtained and posted.	A license to operate the facility, and any other licenses that are required, are displayed in public view.			

Standard CGL.2 [Senior manager responsible for operations]

A designated senior manager or director is responsible for managing the organization and ensuring compliance with applicable laws and regulations.

Intent of CGL.2

Effective leadership is essential for a health care organization to be able to operate efficiently and fulfill its mission. A senior manager or director is responsible for the organization’s overall, day-to-day operations. These include the procurement and management of essential supplies, maintenance of the physical facilities, financial management, quality management, patient safety, and other responsibilities.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) A senior manager or director manages the organization’s day-to-day operations, including human, financial and other resources.	A job description outlines the roles and responsibilities of the senior manager/director. Routine management meetings are held and the minutes show collaboration with department directors/managers in overseeing resource planning, financial management and quality improvement.			
2) The senior manager or director ensures compliance with approved policies.	Documents show that policies approved by the governing body have been implemented. These may include implementation plans, minutes of meetings, monitoring activities and reports to the governing body.			
3) The senior manager or director ensures compliance with applicable laws and regulations.	Copies of applicable laws and regulations are available. Compliance with laws and regulations is documented, e.g. reporting of notifiable contagious diseases, radiology safety logs.			
4) The senior manager or director responds to any reports from inspecting and regulatory agencies.	Reports from inspecting or regulatory agencies, e.g. accreditation, Civil Defence or Radiation Safety Councils, are kept on file. Minutes of meetings or reports show that actions have been taken to rectify any issues arising.			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
5) The organization's leaders plan services with recognized leaders in the community and other health care organizations.	Documents demonstrate involvement of community leaders and other health care organizations in planning services, e.g. strategic or program planning.			

Standard CGL.3 [Oversight of contracts]

The organization's leaders provide oversight of contracts for outsourced clinical and support services.

Intent of CGL.3

Organizations frequently have the option to either provide services directly or to arrange services through referral, consultation, contractual arrangements, or other agreements. Such services may range from diagnostic imaging services to financial accounting services. In all cases, there is leadership oversight for such contracts, or other arrangements to ensure that the services meet patients' needs. They are monitored as part of the organization's quality management and improvement activities. Department managers receive and act on regular reports from contracting agencies and ensure the reports are integrated into the organization's quality monitoring process when appropriate.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) Contracts and other arrangements are monitored, as appropriate to the nature of the contract, as part of the organization's quality management and improvement program.	Contracts with any vendor (e.g. housekeeping, laboratories) include expectations for quality and how it will be monitored. Documents show that quality monitoring is done, results are communicated to leadership and actions are taken as needed. All independent contractors providing clinical services (e.g. diagnostic, consultation or treatment) have been formally awarded documented privileges by the organization to provide such services.			
2) Services provided under contracts and other arrangements meet patients' needs.	Results of patient satisfaction surveys or complaints regarding contracted services are documented and followed up.			

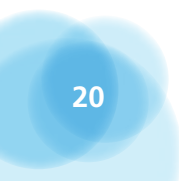
Standard CGL.4 [Departmental services specification]

The directors of each clinical department identify, in writing, the scope of services to be provided, policies and procedures for carrying out work, and the criteria for the department’s professional staff.

Intent of CGL.4

Each department has a document called a “Scope of Services” that describes the goals and services provided by the department. The scope also includes the types of staff required to assess and meet patient care needs. The document describes how clinical services are coordinated within each department as well as with other departments and services. Unnecessary duplication of services is avoided or eliminated to conserve resources. Policies and procedures are written to standardize clinical care. A consistent format is used for departmental documents.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) The scope of service and policies/procedures describe the current services provided by each department.</p>	<p>Each department has a written scope of services that describes the services provided in the department, hours of operation, main diagnoses and procedures, support services available, organizational structure (management, medical, nursing), etc.</p> <p>Each department has a set of policies and procedures specific to their departmental functions and processes. In clinical departments, these processes address patient assessments, admission and discharge criteria, discharge planning, transfer and referrals, and coordination with other departments.</p> <p>Organization-wide protocols are incorporated in the department manuals, such as fire safety, adverse event handling, infection control, emergency preparedness etc.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>



Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>2) There is coordination of services:</p> <p>a. within each department (e.g. through regular staff meetings, reporting mechanisms, development of admission/ transfer/ discharge criteria), and</p> <p>b. between departments.</p>	<p>Coordination is described in the departmental scope of services and policies/procedures. This could include regular staff meetings, grand rounds, interdisciplinary team meetings; reporting processes (e.g. shift reports). Coordination between key departments is also described, e.g. between an orthopedic unit and a physiotherapy department, or these might include outside services, e.g. the emergency department describes their process for coordinating with ambulance services. Admission and discharge criteria are written for each inpatient department.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3) The department director develops and applies criteria related to the required level of education, skills, knowledge and experience of the department's professional staff.</p>	<p>Job descriptions describe education, skills and knowledge required. A library of recognized medical qualifications is developed. Annual performance appraisals document staff competency. This information is used to plan staff training and development.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>4) The director ensures that there is a process for authorizing all medical professionals to admit and treat patients, commensurate with their training and qualifications (clinical privileges).</p>	<p>A list of the clinical privileges for each physician is available in the departments and other areas where they work.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Standard CGL.5 [Departmental resource planning]

Departmental directors/managers recommend space, equipment, staffing, and other resources needed by the department or service.

Intent of CGL.5

Each department’s leader communicates their human resources and other resource requirements to the organization’s senior managers. This helps ensure that adequate staff, space, equipment, and other resources are available to meet patients’ needs at all times. As these resource needs may change or may not be fully met, the departmental leaders need to have plans to respond to resource shortages to ensure safe and effective care for all patients.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) Department directors/managers recommend numbers and qualifications of staff, space, and equipment required to provide services.</p>	<p>A staffing plan is developed, based on the organization’s strategic plan and the department’s scope of services. The plan describes the methods used to ensure an adequate number and mix of staff. Staffing levels are based on appropriate utilization/workload information which is recorded periodically (e.g. daily patient census).</p> <p>A periodic assessment is undertaken to determine space and equipment needs.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) Department directors/managers have a process to respond to resource shortages.</p>	<p>Policies and procedures outline steps that are taken when shortages occur, e.g. of drugs or staff.</p>				<p>.....</p> <p>.....</p>

Standard CGL.6 [Staff recruitment, retention and development]

Organization leaders ensure that there are uniform programs for the recruitment, retention, development, continuing education, and health and safety of all staff.

Intent of CGL.6

An organization’s ability to care for patients is directly related to its ability to attract and retain qualified, competent staff. Leaders recognize that staff retention, more than recruitment, provides greater long-term benefit. Retention is increased when leaders support staff advancement through continuing education. Thus, the leaders plan and implement programs related to recruitment, retention, development, and continuing education for each category of staff. The organization’s recruitment program considers published guidelines such as those from the WHO, the International Council of Nurses, and the World Medical Association. The health and safety of an organization’s staff are critical for maintaining staff security, satisfaction, and productivity.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) There is a formal process for staff recruitment and retention.	Job descriptions are written for each category of staff, outlining the required educational qualifications, skills, knowledge and experience. The Human Resources department has a recruitment and retention plan that is developed collaboratively with department directors, and is updated annually. The effectiveness of the plan is measured, e.g. by monitoring staff turnover, absence and vacancy rates.			
2) Each department has established an orientation program for new staff.	A general orientation program is conducted for all new employees. A department-specific orientation is conducted as well as a job-specific orientation. The orientation program is documented, attendance is monitored, and successful achievement is recorded in each employee’s personnel file.			
3) There is a formal program for staff personal development and continuing education.	Each department determines staff training needs on an annual basis and develops a training plan. The plan may include in-service training/coaching as well as targeted outside education. Participation is documented in personnel files.			
4) The organization provides a staff health and safety program.	The program addresses both urgent and non-urgent health-related needs through direct treatment and referral. The program includes immunizations and vaccinations and appropriate follow-up care for staff exposed to infectious diseases and work-related injuries.			

ETHICS AND PATIENT RIGHTS (EPR)

Standard EPR.1 [Verification of credentials of professional staff]

The organization has an effective process for gathering, verifying, and evaluating the credentials (e.g. licenses, education, training, and experience) of those professional staff permitted to provide patient care.

Intent of EPR.1

Physicians, dentists, nurses, pharmacists and others who are licensed to provide clinical services represent those primarily responsible for patient care and care outcomes. Thus, the organization has the highest level of accountability to ensure that each of these practitioners is qualified to provide safe and effective care and treatment to patients. The organization assumes this accountability by:

- understanding the applicable laws and regulations that identify those permitted to work in these positions;
- confirming that the organization will only permit such practitioners to work within it;
- gathering all available credentials for each practitioner including:
 - at least evidence of education and training and evidence of current licensure,
 - evidence of current competence through information from other organizations at which the practitioner practiced,
 - letters of recommendation, and/or
 - other information the organization may require such as health history, pictures/ID, etc.;
- verifying of essential information such as:
 - current registry or licensure, especially when such documents are periodically renewed,
 - any certifications, and
 - evidence of completion of postgraduate education.

The organization needs to make every effort to verify essential information, especially when the education took place in another country and/or a significant time ago. Secure web-sites, documented phone confirmation from sources, written confirmation, and verification by trusted third parties, such as designated official governmental or nongovernmental agencies, may be used.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) Licensure, education and training are verified according to the parameters in the intent statement above.	A policy/procedure describes the process for verifying licensure, education and training. The verification is documented in each personnel file.			
2) There is a separate record maintained of the credentials of every professional staff member that contains copies of any required license, certification, or registration and other documents required by the organization.	A policy/procedure lists the required contents of personnel files. Personnel files contain the required documents.			
3) There is a standardized procedure to review each record at least every three years to assure current licensure, registration, etc.	A system is in place to verify that all licensure, certification and registrations are current. A Credentialing and Privileging Committee is one means of carrying out this function.			

Standard EPR.2 [Patient and family rights]

The organization implements processes that support patients’ and families’ rights during care.

Intent of EPR.2

An organization’s leaders are primarily responsible for how the organization treats its patients. Thus, the leaders need to know and understand patient and family rights and their organization’s responsibilities as identified in laws and regulations. The leaders provide direction to ensure that staff members throughout the organization assume responsibility for protecting these rights. To effectively protect and advance patient rights, the leaders work collaboratively and seek to understand their responsibilities in relation to the community served by the organization. The organization respects the right of patients (and in some circumstances the rights of the patient’s family) to have the prerogative to determine what information regarding their care would be provided to their families or others, and under what circumstances. For example, some patients may not wish to have a diagnosis shared with their family. Policies and procedures are developed and implemented to ensure that all staff members are aware of and respond to patient and family rights issues when they interact with and care for patients throughout the organization.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) Policies and procedures guide and support patient and family rights in the organization.</p>	<p>Policies and procedures are written and implemented regarding the rights of patients and their families. These may be based on a Patient Rights Charter. Specific expectations for each “right” need to be described. The rights should include at a minimum:</p> <ul style="list-style-type: none"> • respect for personal dignity and privacy during examinations, treatments and procedures, • informed consent, • information regarding cost of services, • access to medical records, and • information about their health care needs. <p>Patients and their families need to be informed about their rights in a form and language that they can understand.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) Vulnerable groups (e.g. children, disabled individuals, the elderly, and others identified by the organization) are protected against abuse.</p>	<p>Policies and procedures regarding vulnerable groups outline how to protect patients against possible abuse and what actions are taken when cases of abuse are suspected. Cases of reported or suspected abuse and actions taken to intervene are documented.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>3) The organization respects patients' health information as confidential.</p>	<p>Policies and procedures describe how patients' health information is protected and how breaches of confidentiality are dealt with. Incidents of breaches and actions taken are recorded.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>4) The organization informs patients and families about their rights to refuse or discontinue treatment and the available care and treatment alternatives in a manner that they can understand.</p>	<p>Interviews with patients indicate that they were provided with information regarding their right to refuse treatment. This information might be provided in a written document or verbally. When a patient has refused treatment, documentation on the medical record shows that they are provided information about available care and treatment alternatives.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>5) Patients are aware of their right to voice a complaint and the process to do so.</p>	<p>Interviews with patients show that they are aware of their right to make a complaint and how to do so. (This may also include the use of a suggestion box).</p>				<p>.....</p> <p>.....</p>

Standard EPR.3 [Informed consent]

Patients' informed consent is obtained through a process defined by the organization and is carried out by trained staff.

Intent of EPR.3

One of the main ways that patients are involved in their care decisions is by granting informed consent. To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Informed consent may be obtained at several points in the care process, e.g. when a patient is admitted for inpatient care, and before undertaking certain procedures or treatments for which the risks may be high. The consent process is clearly defined by the organization in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures. Patients and families are informed as to what tests, procedures, and treatments require consent and how they can give consent (e.g. verbally, by signing a consent form, or through some other means). Patients and families understand who may, in addition to the patient, give consent. Designated staff members are trained in how to inform patients and in how to obtain and document their consent.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) The organization has a clearly defined informed consent process described in policies and procedures.</p>	<p>Policies and procedures define the process for obtaining informed consent.</p>				<p>.....</p> <p>.....</p>
<p>2) Designated staff are trained to implement the policies and procedures.</p>	<p>Staff training for implementing the informed consent policy is documented. This may be part of staff orientation.</p>				<p>.....</p> <p>.....</p>
<p>3) Patients give informed consent consistent with the policies and procedures. Patients are informed of:</p> <ul style="list-style-type: none"> a. their condition, b. the proposed procedure(s) and treatment(s) and who is authorized to perform them, c. potential benefits and drawbacks to the proposed treatment(s) and possible problems related to recovery, d. possible alternatives to the proposed treatment(s) and possible results of non-treatment, e. the likelihood of successful treatment(s), and f. the identity of the physician or other practitioner responsible for care. 	<p>Consent forms are completed and located on the patient's medical record. Interviews with patients indicate that they have received all of the information required for informed consent.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>4) The organization has a process for when others can grant informed consent.</p>	<p>The policies and procedures indicate who may grant consent when the patient is unable to do so, e.g. for children or comatose patients. Signed consent forms show that the proper individuals have provided consent.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>5) Consent is obtained before high-risk procedures and treatments are undertaken.</p>	<p>The policies and procedures include a list of high- risk procedures and treatments for which consent is required. A consent form/record is located on records of patients who have undergone these procedures.</p>				<p>.....</p> <p>.....</p> <p>.....</p>

Standard EPR.4 [Ethical management]

The organization establishes a framework for ethical management that ensures that patient care is provided within business, financial, ethical, and legal norms and that protects patients and their rights.

Intent of EPR.4

A health care organization has an ethical and legal responsibility to its patients and its community. The leaders understand these responsibilities as they apply to the organization’s business and clinical activities. They create guiding documents to provide a consistent framework to carry out these responsibilities. The organization operates within this framework to:

- disclose ownership and any conflicts of interest;
- honestly portray its services;
- provide clear admission, transfer, and discharge policies;
- accurately bill for its services; and
- resolve conflicts when financial incentives and payment arrangements could compromise patient care.

The framework also supports the organization’s professional staff when confronted by ethical dilemmas in patient care such as disagreements between patients and their families, and between patients and their care providers, regarding care decisions, and inter-professional disagreements. These documents are readily available to provide such support.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) The organization’s leaders establish ethical and legal norms that protect patients and their rights.	A relevant policy, Code of Ethics, or Code of Conduct is established.			
2) The organization discloses its ownership.	Ownership of the organization is publicly displayed.			
3) The organization honestly portrays its services.	Services available are made known to the public, with no documented cases of misrepresentation. The scope of services is clearly defined. Transfer arrangements are in place for patients who do not match the organizations resources. Admission and discharge criteria, and registration processes are clearly defined.			
4) The organization accurately bills for services.	A price-list is available. Internal and external audits demonstrate accurate billing practices.			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>5) The organization discloses and resolves conflicts when financial incentives and payment arrangements may compromise patient care (e.g. payment of referral fees, informal or “under the table” payments, bribes or kickbacks).</p>	<p>The organization’s Code of Ethics and/or policies and procedures describe expectations and actions to be taken when posed with such conflicts. Situations that arise are reviewed for consistency in carrying out the policy.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>6) Staff are supported when confronted by ethical dilemmas in patient care and professional ethical issues.</p>	<p>An ethics committee or other structure is in place that oversees and provides guidance in dealing with ethical issues.</p>				<p>.....</p> <p>.....</p>
<p>7) The organizational structure(s) and processes support safe reporting of ethical and legal concerns.</p>	<p>The organization’s policies and procedures describe mechanisms to allow for safe reporting of ethical and legal concerns, e.g. hot lines.</p>				<p>.....</p> <p>.....</p>

Standard EPR.5 [Organ and tissue donation and transplantation]

The organization implements safeguards to ensure compliance with international guidelines.

Intent of EPR.5

Transplant services raise many important ethical issues. For organizations involved in or with links to organ donation and transplant programs:

- The organization supports the choice of patients and families to donate organs and other tissues for research or transplantation.
- Information is provided on the donation process.
- Policies and procedures are developed to guide the procurement and donation process and the transplantation process.
- The policies are consistent with laws and regulations and take account of social and ethical issues.
- Staff are trained in implementing the policies and procedures to support patient and family choices.
- The organization complies with recognized international guidelines on organ donation and transplantation^{9, 10, 11}. Staff are trained in these guidelines and in related contemporary concerns and issues. These include, for example information on organ and tissue shortages, the illegal trade in organs, the harvesting of organs without consent from dead patients (or executed prisoners).

The organization has a responsibility to ensure that valid consent is received from live donors. It ensures that adequate controls are in place to prevent patients from feeling pressured to donate. Controls also identify instances where there may be commercial arrangements between donors and recipients, including via third parties, e.g. agents and intermediaries. It cooperates with other organizations and agencies responsible for all or a portion of the procurement, banking, transportation, or transplantation process.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) The organization supports patient and family choices to donate organs and other tissues.	Medical records show family requests for donation are carried through. Data of potential candidates and rates of procurement are kept.			
2) Policies and procedures guide the procurement, donation and transplantation processes.	Policies and procedures describe procurement, donation and transplant processes. These comply with the WHO guidelines on organ transplantation.			
3) Staff are trained in the relevant policies and procedures and in ethical issues pertinent to organ transplantation.	Training records of staff in targeted areas, e.g. ICU, are maintained.			
4) Valid informed consent is obtained from live donors.	Appropriate checks, including interviews with potential donors, are conducted by trained staff.			

⁹ WHO Guiding Principles on Human Organ Transplantation (1989). Available at: www.who.int/ethics/topics/transplantation_guiding_principles/en/index.html

¹⁰ Joint Commission (2004) Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients. Available at: www.jointcommission.org/NR/rdonlyres/E4E7DD3F-3FDF-4ACC-B69E-AEF3A1743AB0/0/organ_donation_white_paper.pdf

¹¹ World Medical Association Statement on Human Organ Donation and Transplantation. (2006) Available at: www.wma.net/e/policy/wma.htm

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
5) The organization cooperates with relevant organizations and agencies in the community to respect and implement choices to donate.	Minutes of meetings, memos, or reports indicate cooperation with relevant community organizations and agencies.			
6) Staff are supported when confronted by ethical dilemmas in patient care and professional ethical issues.	An ethics committee or other structure is in place that oversees and provides guidance in dealing with ethical issues.			
7) The organizational structure(s) and processes support safe reporting of ethical and legal concerns.	The organization's policies and procedures describe mechanisms to allow for safe reporting of ethical and legal concerns, e.g. hot lines.			

Standard EPR.6 [Reproductive health practices/IVF]

The organization sets policies and oversees practices relating to fertility treatment.

Intent of EPR.6

Organizations providing fertility services develop and implement reproductive health policies for fertility treatment (e.g. IVF), which take account of legal, social and ethical considerations.

IVF services raise many important ethical issues that should be addressed in the policies. For example:

- When embryos are formed outside the body, what should be done with those that are not transferred?
 - Is it acceptable to use them for research?
 - Could they be donated to another infertile couple?
 - Should they be frozen for future use? Or should they be destroyed?
 - And who has the right to make these decisions?
- Donation of gametes (egg and sperm)
 - What criteria are used to determine who may donate and who may receive gametes (e.g. age, relationship status, family size, etc?)
 - What procedures are followed for recruiting, counseling and treating donors?
 - What rules apply to the compensation of donors?
 - What are the rules determining anonymity, or otherwise, of donors?
- Ethical questions concern the practice of transferring several embryos in order to increase the likelihood of pregnancy. (If all the embryos successfully implant, the woman faces the prospect of a high order multiple pregnancy, with its attendant increased risks of obstetric complications, premature birth and disability¹²).

Sex selection using IVF techniques presents a wide range of important ethical, legal and social implications. A significant ethical concern is that sex selection for non-medical reasons may reinforce discrimination, particularly against women and girls.¹³

Informed consent by women for all reproductive services is required. Services are carried out based on standardized procedures by qualified practitioners. And, a registry is kept to track the outcomes.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
1) Fertility treatment is integrated into a wider reproductive and child health package of services. ¹⁴	Fertility treatment is a part of the local maternal health scope of services.			
2) The organization has written policies regarding assisted reproductive health technologies that ensure that the rights of women as users of these technologies are within the boundaries of legal and ethical considerations.	<p>Policies and procedures address assisted reproductive health technologies, including IVF. These should address key ethical issues (e.g. including those outlined above) – especially in countries where regulations are not well-defined.</p> <p>Policies must include the rights of women, including egg donors (where applicable).</p>			

¹² WHO. (2003) Assisted reproduction in developing countries-facing up to the issues. Progress in Reproductive Health Research. No. 63. Available on: www.who.int/reproductive-health/hrp/progress/63/63.pdf

¹³ WHO Genomic Resource Center. Available at: www.who.int/genomics/gender/en/index4.html

¹⁴ See a discussion of policy regarding infertility treatment in India, available at: www.searo.who.int/LinkFiles/Reproductive_Health_Profile_infertility.pdf

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
3) Health care providers at each level are trained to perform screening, examination, diagnosis, referral and treatment services as appropriate.	Clinical practice guidelines, protocols and procedures are developed. Training records show that the staff performing the procedures have been deemed competent.			
4) Procedures and equipment for the techniques are standardized.	The equipment and procedures used to carry out these techniques are standardized.			
5) Prior to treatment, health personnel provide patients with full information of the risks and implications of the procedures. ¹⁵	Verbal explanations and written information are made available to patients. Patient interviews show that they received and understood the information.			
6) Where applicable, donors are provided with full information of the risks and implications of the procedure. (These may relate to physical and/or emotional implications and issues relating to confidentiality)	Verbal explanations and written information are made available to donors. Request to see written information provided to donors.			
7) A registry is kept of the results of direct treatment (e.g. pregnancy rates), pregnancy outcomes, child development and side effects of treatment for the women.	A register or log is kept of all fertility treatments. Quality and outcome indicators are identified. The data are aggregated monthly. Minutes of departmental meetings show that the data are reviewed and actions taken as required.			
8) Registries are linked, where possible, with national health registries.	If a national registry is kept, the organization contributes its data.			

¹⁵ WHO. Current Practices and Controversies in Assisted Reproduction. Report of a meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction" WHO headquarters, Geneva, Switzerland, 17-21 September 2001. Available at: www.who.int/reproductive-health/infertility/36.pdf

Standard EPR.7 [Termination of pregnancy services]

The organization sets policies and procedures relating to termination of pregnancy services.

Intent of EPR.7

Organizations providing termination of pregnancy services take account of legal, social and ethical considerations.

Informed consent by women is required.

Services are carried out based on standardized procedures by qualified practitioners.

Sex selection using termination of pregnancy presents a wide range of important ethical, legal and social implications. A significant ethical concern is that sex selection for non-medical reasons may reinforce discrimination, particularly against women and girls.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
1) Termination of pregnancy is integrated into a wider reproductive package of services ¹⁶ .	Termination of pregnancy is a part of the local reproductive health scope of services.			
2) The organization has written policies regarding termination of pregnancy that ensure that the rights of women as users of these technologies are within the boundaries of legal, social and cultural considerations.	Policies and procedures guide the organization's provision of termination of pregnancy services. These must include the rights of women.			
3) Staff at each level are trained to perform examination, referral and treatment services as appropriate.	Clinical practice guidelines, protocols and procedures are developed. Training records show that the staff performing the procedures have been deemed competent. These may be checklists or other performance based training documentation.			
4) Clinical procedures and equipment are standardized ¹⁷ .	The equipment and procedures used to carry out these services are standardized.			
5) Prior to treatment, health personnel provide patients with full information of the risks and implications of the procedure ¹⁸ .	Verbal explanations and written information are made available to patients. Patient interviews/records show that they received the information.			

¹⁶ Marie Stopes International. Resources for planning reproductive health services. www.mariestopes.org/Publication.aspx?rid=1

¹⁷ WHO. Preventing unsafe abortion: www.who.int/reproductivehealth/topics/unsafe_abortion/en/index.html

¹⁸ Marie Stopes International. Information for Women. www.mariestopes.org.uk/Womens_services/Abortion/Download_our_leaflets_on_abortion.aspx

Standard EPR.8 [Clinical research]

The organization informs patients and their families about how to gain access to clinical research, investigations or trials involving human subjects.

Intent of EPR.8

An organization that conducts research, investigations, or clinical trials involving human subjects provides information to patients and families about how to gain access to those activities when relevant to the patient’s treatment needs¹⁹. The organization does not commence trials until their purpose and benefits are clear and pertinent ethical issues have been fully considered. When patients are asked to participate, they are given information upon which to base their decision. Patients are informed that they can refuse to participate or withdraw participation and that their refusal or withdrawal will not compromise their access to the organization’s services. The organization has policies and procedures for providing patients and families with this information.

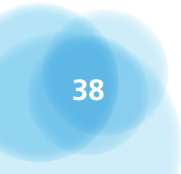
Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) Prior to commencement, the purpose of any clinical trial and its purported benefits are clear. Ethical issues relating to the trial are also fully considered. An ethics committee including independent external experts may be formed to approve trials.</p>	<p>Details of trials are documented. Objectives and purported benefits are clearly specified. Minutes of meetings of a clinical trial committee (and/or ethics committee) record discussion of ethical aspects, including formal approval to proceed.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

¹⁹ A global register of clinical trials is maintained at: www.clinicaltrials.gov

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>2) The organization has a committee or other mechanism to oversee all research within it. Oversight activities include:</p> <ul style="list-style-type: none"> a. a review process, b. a process to weigh relative risks and benefits to subjects, c. processes to provide confidentiality and security of research information, d. ensuring that informed consent processes and other ethical aspects are appropriate, e. ensuring compliance with all regulatory aspects of clinical research, f. monitoring serious adverse events, and g. intervening in the interest of patient safety if required. 	<p>The terms of reference for a research oversight committee (e.g. institutional review or ethics committee) include the required elements. Committee minutes demonstrate that the terms and policies and procedures are carried out.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3) Appropriate patients are identified and informed about how to gain access to research, investigations or clinical trials relevant to their treatment needs²⁰.</p>	<p>Public announcements are made for planned research. Criteria are established for patient selection based on research protocols.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>4) Policies and procedures guide the information and decision process.</p>	<p>There are written policies and procedures for all clinical research processes.</p>				<p>.....</p>

²⁰ Resource for patients. Candid experiences of patients involved in different aspects of clinical trials in the UK are available at: www.healthtalkonline.org/medical_research/clinical_trials

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>5) Written informed consent is obtained from participants and includes the following information:</p> <ul style="list-style-type: none"> a. expected benefits, b. potential discomforts and risks, c. alternatives that might help them, d. procedures that they must follow e. process for reviewing research protocols, f. process for withdrawing participation, and g. process for weighing the benefits and risks to the subjects. 	<p>Research files demonstrate that all patients were informed about the required elements. Patient interviews could be used to validate this requirement.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>6) Patients are assured that their refusal to participate or withdraw from participation will not compromise their access to the organization’s services.</p>	<p>Written documentation of this right is located in the research file for each patient.</p>				<p>.....</p> <p>.....</p> <p>.....</p>



QUALITY MEASUREMENT AND IMPROVEMENT (QMI)

Standard QMI.1 [Clinical practice guidelines]

Clinical practice guidelines and clinical pathways are used to guide clinical care.

Intent of QMI.1

The goals of health care organizations include:

- using evidence-based medicine;
- standardizing clinical care processes;
- reducing risks within care processes, particularly those associated with critical decision steps; and
- providing clinical care in a timely, effective manner using available resources efficiently.

The organization uses a variety of tools to reach these goals. It seeks to develop clinical care processes and make clinical care decisions based on the best available scientific evidence. Clinical practice guidelines are useful tools in this effort to understand and apply the best science to a particular diagnosis or condition.

The organization seeks to standardize care processes. Clinical care pathways (protocols, algorithms, etc) are useful tools in this effort to ensure effective integration and coordination of care and efficient use of available resources.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) Clinicians use recognized and reputable clinical practice guidelines and pathways to guide patient care processes.^{21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31}</p>	<p>Current evidence-based guidelines are adopted for the care and treatment of high-priority patient groups (e.g. involving high volume procedures, or high risk procedures). These may be in the form of a document, protocol, poster, check-list and/or other job aide.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

²¹ National Library for Health (NLH): www.library.nhs.uk

²² National Institute for Health and Clinical Excellence (NICE): www.nice.org.uk

²³ eGuidelines: www.eguidelines.co.uk

²⁴ Centre for Evidence Based Medicine: www.cebm.net

²⁵ Health Information Research Unit: <http://hiru.mcmaster.ca/hiru>

²⁶ Agency for Healthcare Research and Quality (AHCPR): www.ahrq.gov

²⁷ National Guideline Clearinghouse: www.guideline.gov

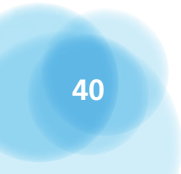
²⁸ Elsevier Clinical Decision Support: www.ClinicalDecisionSupport.com

²⁹ New Zealand Guidelines Group: www.nzgg.org.nz

³⁰ WHO and UNICEF Baby-friendly Hospital Initiative: www.who.int/nutrition/topics/bfhi/en/index.html

³¹ African Partnerships for Patient Safety: www.who.int/patientsafety/implementation/apps/en

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>2) The organization uses the following processes in implementing clinical practice guidelines and clinical pathways:</p> <ul style="list-style-type: none"> a. select from among those applicable to the services and patients of the organization (mandatory national guidelines are included in this process, b. if available);evaluate for their applicability and science; c. adapt when needed to the technology and other resources of the organization or to accepted national professional norms; d. formally approve or adopt by the organization; e. implement and monitor for consistent use and effectiveness; f. support with staff trained to apply the guidelines or pathways; and g. update periodically. 	<p>Policies and procedures outline the process for developing and implementing the clinical guidelines. Guidelines and pathways that have been developed reflect key patient populations. They are approved by identified authorities, e.g. department head or medical director, and dated. References are included on the documents that demonstrate recent evidence.</p> <p>Select an aspect of the guidelines to monitor to assure compliance. For instance, for a protocol regarding use of antibiotic prophylaxis, the timing of the dose or the amount and type of antibiotic could be monitored. Monitoring is done until the protocol is effectively implemented and sustained over time.</p> <p>An ongoing review process is followed to check that the guidelines are up-to-date. The review process is outlined in the policies and procedure and the date of review is noted on the guidelines.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3) At least one guideline or pathway is adapted, adopted or updated each year.</p>	<p>It is more important to implement a few guidelines well than many done poorly. Thus, the staff will prioritize the guidelines and work on a few at a time.</p>				<p>.....</p> <p>.....</p>



Standard QMI.2 [Leaders' collaboration]

The organization's leaders collaborate to carry out a Quality Improvement and Patient Safety program.

Intent of QMI.2

The organization's leaders play a key role in ensuring that the quality improvement and patient safety plans shape the organization's culture and make an impact on every aspect of operations. Leaders ensure the program involves:

- continuous system design and redesign in the quality improvement process;
- a multidisciplinary approach, with all departments and services in the organization included;
- coordination among the multiple organizational units concerned with quality and safety. These might include, for example,
 - a clinical laboratory quality control program,
 - a facility risk management program, or
 - a patient safety program.

(An inclusive program is necessary to improving patient outcomes because patients typically receive care from many different departments and services and/or types of clinical staff); and,
- a systematic approach, i.e. employing similar quality processes to carry out all improvement and patient safety activities across the organization.

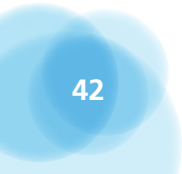
Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) The Quality Improvement and Patient Safety Program (or similar) employs a systematic approach to quality improvement and patient safety. ^{32, 33}	Quality and safety plans describes the quality improvement methods that are used (e.g. "Plan-Do-Study-Act").			
2) A multidisciplinary Quality Improvement and Patient Safety Committee ³⁴ meets on a regular basis to provide guidance to the quality improvement process.	A committee has been formed and a leader assigned. It meets at least monthly and keeps minutes. The minutes show that data relating to quality are discussed, decisions to improve quality are made and progress is followed.			
3) The leaders set priorities for quality improvement and patient safety activities and provide technology and support, consistent with the organization's resources.	An annual "Quality Plan" (or similar) outlines the quality objectives for the year. Minutes of the Quality Improvement and Patient Safety Committee (or similar group responsible for improvement) show the prioritization process and the participants involved. Senior management supports a budget for quality improvement and safety.			

³² University Research Corp (2004) A Modern Paradigm for Improving Healthcare Quality. Bethesda, MD, USA. Available at: www.qaproject.org

³³ Institute for Healthcare Improvement. www.ihl.org

³⁴ Draft terms of reference for a Quality and Patient Safety Committee are included in Appendix II.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>4) Those responsible for governance regularly receive and act on reports of the Quality Improvement and Patient Safety Program.</p>	<p>Leaders review the quality of clinical and non clinical services on a regular basis, e.g. at least quarterly. Action is taken that is supported by data and objective measures of performance. Cost effectiveness is also part of this review. Leaders track clinical audit results and take actions as indicated.</p> <p>There is a defined process for notifying leaders when a sentinel event has occurred and there is evidence that they are actively involved in resolving such situations.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>5) There is a training program for staff that is consistent with their role in the Quality Improvement and Patient Safety program.</p>	<p>A training plan (which may be a one-page table) outlines the quality training for different categories of staff. For instance, leadership receives training in quality awareness, management indicators and data for decision making, general staff are provided basic quality/safety awareness training, and staff involved in quality committees/teams receive more in-depth training on quality improvement methodologies.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>



Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>6) Leaders identify key measures (indicators) to monitor the organization’s clinical structures, processes and outcomes. These may include the International Patient Safety Goals³⁵ or similar. Clinical monitoring includes:</p> <ul style="list-style-type: none"> a. aspects of laboratory services, b. aspects of radiology and diagnostic imaging services, c. medication errors, adverse drug events and near misses, d. infection control, surveillance, and reporting, and e. clinical research (where applicable).³⁶ 	<p>The annual Quality Plan lists the indicators that are being measured for each of the required aspects of care. Minutes of the Quality Improvement and Patient Safety Committee meetings indicate the prioritization process. The organization carries out periodic assessments of its structures, processes and outcomes based on the standards in this Plan.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>7) Managerial/ administrative monitoring includes:</p> <ul style="list-style-type: none"> a. procurement of routinely required supplies and medications essential to meet patient needs, b. activities as required by law and regulation, c. risk management. 	<p>The annual Quality Plan lists the indicators that are monitored for each of the required aspects of management. (E.g. indicators for utilization management might include patient numbers, lengths of stay, bed occupancy etc).</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

³⁵ Information on International Patient Safety Goals available at: www.jointcommissioninternational.org/International-Patient-Safety-Goals/

³⁶ University Research Corp (2005) Health Manager’s Guide: Monitoring the Quality of Hospital Care. Bethesda, MD, USA. Available at: www.qaproject.org

Standard QMI.3 [Infection control]

There is a designated coordination mechanism for all infection control activities that involves physicians, nurses, and others as appropriate to the size and complexity of the organization.

Intent of QMI.3

Infection prevention and control activities reach into every part of a health care organization and involve individuals in multiple departments and services, e.g. in clinical departments, facility maintenance, food services, house-keeping, laboratory, pharmacy and sterilization services. There is a designated mechanism to coordinate the overall Infection Control program. That mechanism may involve a small working group, or a coordinating committee. Responsibilities include, for example, setting criteria to define health care-associated infections, establishing data collection and surveillance methods, designing strategies to address infection prevention and control risks, and reporting processes. Coordination involves communicating with all parts of the organization to ensure that the program is continuous and proactive. Whatever the mechanism chosen by the organization to coordinate the infection control program, physicians and nurses are represented and engaged in the activities with the infection control professionals. Others may be included as determined by the organization’s size and complexity of services (e.g. epidemiologist, data collection expert, statistician, central sterilization manager, microbiologist, pharmacist, housekeeping services manager, environmental or facilities services manager, operating theater supervisor).

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) There is a designated mechanism for the coordination of the infection control program that is based on current scientific knowledge, practice guidelines, and laws/regulations.</p>	<p>A staff member is assigned to oversee the infection control program. This may be a full time post or an assigned role. Their job description includes this responsibility. The terms of reference for an Infection Control Committee describes the roles and responsibilities of various staff members in the program.</p> <p>The organization has policies and procedures to ensure that all aspects of the infection control program are comprehensively addressed. Process controls, physical infrastructure and other regulatory aspects are adequately addressed.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) The organization’s leaders allocate adequate resources for the infection control program.</p>	<p>Observation of the facility and discussions with staff reveal that there are sufficient supplies, equipment and human resources necessary to carry out the infection control program.</p>				<p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>3) The infection control program includes systematic and proactive surveillance activities to determine usual (endemic) rates of infection and outbreaks of infectious diseases.</p>	<p>The infection control plan or policies/procedures describe the surveillance process. Surveillance data are documented.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>4) The organization has established the focus of the infection control program to prevent or reduce the incidence of health care–associated infections, e.g:</p> <ul style="list-style-type: none"> a. respiratory tract infections are included as appropriate to the organization,³⁷ b. urinary tract infections (UTI) are included as appropriate to the organization,³⁸ c. intravascular invasive devices are included as appropriate to the organization,³⁹ d. surgical wounds are included as appropriate to the organization,⁴⁰ e. epidemiologically significant diseases and organisms are included as appropriate to the organization and its community, and f. emerging or reemerging infections are included as appropriate to the organization and its community.⁴¹ 	<p>Hospital-associated infections are routinely monitored, e.g. pneumonia (particularly ventilator associated), UTI, blood stream infections and surgical wound infections. The data are collected and rates of infection graphed. Comparisons are made across time and against regional or international rates.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

³⁷ Coffin SE, Klompas M, et. al Strategies to prevent ventilator-associated pneumonia in acute care hospitals. Infection Control and Hospital Epidemiology. vol. 29, supplement . Available at www.azdhs.gov

³⁸ Lo E, Nicolle L, et.al Strategies to prevent catheter-associated urinary tract infections in acute care hospitals. Infection Control and Hospital Epidemiology. vol. 29, supplement 1

³⁹ Marschall J, Mermel LA, et al. (2008) Strategies to prevent central line–associated bloodstream infections in acute care hospitals. Infection Control and Hospital Epidemiology. vol. 29, supplement 1

⁴⁰ Anderson DJ, Kaye KS, et al. (2008) Strategies to prevent surgical site infections in acute care hospitals. Infection Control and Hospital Epidemiology. vol. 29, supplement 1

⁴¹ Dubberke ER, Gerding DN, et al. (2008) Strategies to prevent Clostridium difficile infections in acute care hospitals. Infection Control and Hospital Epidemiology. vol. 29, supplement 1. Available at: www.wvhidep.org/Portals/31/infection%20control/SHEA%20Prevent%20C%20dif%20in%20Acute%20Care%20Oct08.pdf

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
5) Equipment cleaning and sterilization methods are appropriate for the type of equipment. ⁴²	Policies and procedures for sterilization are based on manufacturer's recommendations and current practice. Staff performing sterilization are trained (documented in their file) and competency verified. The effectiveness of sterilization is monitored.			
6) Laundry and linen management are appropriate to minimize risk to staff and patients. ⁴³	Laundry department policies and procedures include infection prevention practices. Staff are trained (documented in their file). Compliance with these practices is recorded.			
7) Disposal of infectious waste and body fluids are managed to minimize transmission risk. ⁴⁴	Policies and procedures describe the disposal of infectious waste. All staff that deal with waste are trained to carry out these procedures correctly (documented in their file). Observation and monitoring of compliance is recorded.			
8) Sharps and needles are collected in dedicated, puncture-proof containers which are not re-used. ⁴⁵	Observations made during safety rounds indicate that appropriate containers are used for sharps disposal. These may be heavy plastic or thick cardboard containers. The opening does not allow withdrawal of items. The container is no more than 2/3 full. Containers are never emptied, but are sealed and put in a protected location until final disposal.			

⁴² Center for Disease Control (2008), Guideline for Disinfection and Sterilization in Healthcare Facilities. Available at: www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

⁴³ Healthcare Laundry Accreditation Council (2006) Accreditation Standards for Processing Reusable Textiles for use in Healthcare Facilities. Frankfort, IL, USA. Available at www.hlacnet.org

⁴⁴ Center for Disease Control (2003) Guidelines for Environmental Infection Control in Health-Care Facilities. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

⁴⁵ WHO Safe Injection Global Network. www.who.int/injection_safety/sign/en

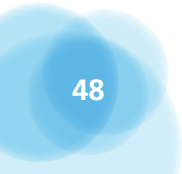
Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
9) Kitchen sanitation and food preparation and handling are appropriate to minimize infection risk.	Policies and procedures are written for kitchen sanitation. Staff are trained (document in file). Observation monitoring shows that staff carry out the procedures according to policy.			
10) The risks and impact of any renovation or construction on air quality and infection control activities is assessed and managed.	Minutes of meetings regarding construction projects indicate that infection control is considered and actions planned to reduce the potential for infection. During construction, safety rounds are made to observe whether safety practices are adhered to.			
11) Patients with known or suspected contagious diseases are isolated in accordance with organization policy and recommended guidelines. ⁴⁶	Isolation policies and procedures are in place. Observation of practice indicates proper implementation of isolation precautions.			
12) Universal procedures, including for gloves, masks, eye protection and hand disinfection, are appropriately implemented. ^{47, 48}	Observations show that staff use gloves and masks etc according to the defined policy and procedures.			
13) All staff are oriented to the policies, procedures, and practices of the infection prevention and control program.	Infection control procedures are incorporated into the general orientation program for staff. Annual training is provided for targeted staff groups.			
14) Patients and their families are educated about reducing the transmission of infectious diseases, e.g. immunizations, personal hygiene, hand washing, cough etiquette, as appropriate.	Policies and procedures describe expectations for educating patients and families regarding hygiene measures. Informational materials are made available to them and implementation of the policy is monitored.			

⁴⁶ Coia JE, Duckworth GJ, et al. (2006) Guidelines for the control and prevention of methicillin-resistant Staphylococcus aureus (MRSA) in healthcare facilities. Journal of Hospital Infection, 63S, S1-S44. Available at: www.his.org.uk/_db/_documents/MRSA_Guidelines_PDF.pdf

⁴⁷ Joint Commission (2009). Measuring Hand Hygiene Adherence: Overcoming the Challenges. Available at: www.jointcommission.org/NR/rdonlyres/68B9CB2F-789F-49DB-9E3F-2FB387666BCC/0/hh_monograph.pdf

⁴⁸ WHO (2009). WHO Guidelines on Hand Hygiene in Health Care. Available at http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>15) There is a comprehensive program and plan to reduce the risk of health care–associated infections in health care workers.</p>	<p>There is a policy on the provision of staff vaccinations and immunizations and a policy on the evaluation, counseling, and follow-up of staff exposed to infectious diseases.</p> <p>Staff are able to receive urgent and non-urgent care through direct care or referral. Needle stick injuries are tracked, with post-exposure prophylaxis medications available. Hepatitis B vaccine is available to staff.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>



Standard QMI.4 [Medications use]

Medications use complies with applicable laws and regulations and is efficiently organized to meet patient needs.

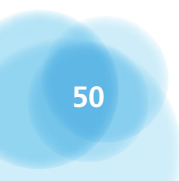
Intent of QMI.4

Medications, as important resources in patient care, must be organized effectively and efficiently. Medication management is not only the responsibility of the pharmaceutical service but also of managers and clinicians. How this responsibility is shared depends on the organization's structure and staffing. In those cases where a pharmacy is not present, medications may be managed on each clinical unit according to organization policy. In other cases, where a large central pharmacy is present, the pharmacy may organize and control medications throughout the organization. Applicable laws and regulations are incorporated into the operation of the medication management system. To ensure efficient and effective medication management and use, the organization conducts a systems review at least once a year. The review includes the medications selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring. The review considers evidence-based practices, monitoring activities, documentation of improvements, and safety systems.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) Policies guide all phases of medication management and medication use in the organization, including: <ul style="list-style-type: none">a. when generic or brand names are acceptable or required,b. the data necessary to accurately identify the patient,c. the required elements of the order or prescription,d. whether or when indications for use are required on a PRN (pro re nata, or "as needed") or other medication order,e. special precautions or procedures for ordering drugs with look-alike or sound-alike names,f. actions to be taken when medication orders are incomplete, illegible, or unclear,	A set of medication policies and procedures address all the required elements. There is evidence that the there is compliance with the policies and procedures. A multidisciplinary team guides the formulation, implementation, review and improvement of medication policies and procedures.			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>g. the use of verbal and telephone medication orders and the process to verify such orders,</p> <p>h. the types of orders that are weight based, such as for children,</p> <p>i. the types of orders that require additional information, such as vital signs or lab results,</p> <p>j. destruction of medications known to be expired or outdated, and</p> <p>k. special precautions and double verification while handling high risk medications - the list of which should include insulin, chemotherapy drugs, radioactive drugs, concentrated electrolytes, anti-coagulants, and sedatives.⁴⁹</p>					<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) The pharmacy or pharmaceutical service and medication use comply with applicable laws and regulations.</p>	<p>A copy of applicable laws and regulations are available in the pharmacy. The pharmacists and assistants are aware of the laws and regulations. These requirements are included in the policies and procedures.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>3) An appropriately licensed, certified, and trained individual supervises all activities.</p>	<p>Personnel records indicate that a licensed pharmacist supervises the pharmacy.</p>				<p>.....</p> <p>.....</p>

⁴⁹ Best Practice Committee of the Health Care Association of New Jersey, Medication Management Guideline. Hamilton, New Jersey, USA. Available at www.hcanj.org/bestpractices.htm and at the National Guideline Clearinghouse: www.guideline.gov



Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>4) A list of medications for prescribing and ordering is available and is appropriate to the organization's mission, patient needs, and services provided.</p>	<p>A formulary or other document lists the medications available.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>5) There is a process established for when medications are not available that includes a notification to prescribers and suggested substitutions.</p>	<p>A policy/procedure describes the process to be followed when medications are not available, e.g. notification of physician, identifying alternatives.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>6) Medications are protected from loss or theft throughout the organization.</p>	<p>A policy describes how medications are managed to prevent loss or theft.</p>				<p>.....</p> <p>.....</p>
<p>7) Medications are stored under conditions suitable for product stability.</p>	<p>Observations made in areas where medications are kept show that medications are stored properly. The temperatures of refrigerators are monitored daily; range limits are listed, and staff know what to do when the temperature is out of range. The "first in/first out" rule is applied to avoid wastage due to expiration.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>8) Controlled substances are accurately accounted for according to applicable law and regulation.</p>	<p>A log/record is kept for managing controlled substances.</p>				<p>.....</p> <p>.....</p>
<p>9) Emergency medications are available in the units where they will be needed or readily accessible within the organization to meet emergency needs.</p>	<p>During rounds, the emergency carts/boxes are found to be locked and the stocking sheets accurately completed.</p> <p>Adequate stocks of life critical medications are consistently maintained.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
10) Only those permitted by the organization and by relevant licensure, laws and regulations prescribe or order medications.	A policy and procedure outline who by law, etc. are permitted to prescribe/order medications.			
11) Medications prescribed or ordered are recorded for each patient and dose.	Each patient has a medication record and each dose of medication is recorded.			
12) Medications are prepared and dispensed in clean and safe areas; the process adheres to law, regulation and professional standards of practice.	During safety rounds, areas for preparing and dispensing medications are observed to be clean and separate from potential contaminants.			
13) Staff preparing sterile products are trained in aseptic techniques.	Documentation in personnel files shows that staff preparing sterile products have been trained in aseptic techniques. Observation of practice confirms compliance.			
14) There is a standardized medication dispensing and distribution system in the organization	Observation and interviews with staff indicate that the same process is used throughout the organization for dispensing and distributing medications. A recall process is outlined, e.g. when medications are pulled from the market.			
15) Medications are appropriately labeled after preparation.	During rounds, medications are noted to be properly labeled.			
16) Medication effects on patients are monitored, including adverse effects.	Documentation on medical records indicates the response to medications. E.g. if pain medication is given, the patient's pain relief is noted; if antibiotics are given, documentation indicates whether the infection resolves.			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
17) Adverse effects are reported in the time frame required by policy.	A policy/procedure describes reporting of adverse effects of medications. Adverse effects are monitored, e.g. by completing an incident report.			
18) Medication errors and near misses are reported in a timely manner using an established process.	A policy/procedure defines medication errors and near misses. A process for reporting and measuring error rates is implemented.			
19) The organization uses reported information on medication errors and near misses to improve medication use processes.	Data show that medication errors are being reported, and actions taken to reduce risks.			
20) An antibiotic policy is developed and implemented by clinical teams in collaboration with microbiology staff.	Policies and protocols are developed to guide appropriate use of antibiotics, e.g. antibiotic surgical prophylaxis. Adherence to the policies are monitored.			

Standard QMI.5 [Sentinel events]

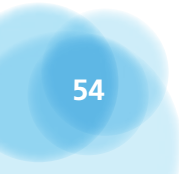
The organization uses a defined process for identifying and managing sentinel events.

Intent of QMI.5

The organization’s definition of a sentinel event includes events as may be required by law or regulation, and those viewed by the organization as appropriate. All events that meet the definition are assessed by performing a credible root cause analysis⁵⁰. When the root cause analysis reveals that systems improvements or other actions can prevent or reduce the risk of such sentinel events recurring, the organization redesigns the processes and takes whatever other actions are appropriate to do so. It is important to note that the term “sentinel event” does not always refer to an error or mistake, or suggest any particular legal liability.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) The organization has established a definition of a sentinel event that includes at least:</p> <ul style="list-style-type: none"> a. unanticipated death unrelated to the natural course of the patient’s illness or underlying condition; b. major permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition; and c. wrong-site, wrong-procedure, wrong-patient surgery. 	<p>A policy/procedure defines “sentinel event” and includes the required elements. Documents show that a root cause analysis was done and actions taken to respond to a sentinel event. (As these events do happen in hospitals all over the world, it would be unlikely that a hospital did not have a record/history of sentinel events.)</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) The organization has a process by which it identifies high-risk areas in terms of patient and staff safety.</p>	<p>A policy/procedure describes a process for identifying high risk areas/processes, e.g. pro-active risk assessment. Plans, minutes of meetings and reports demonstrate that the organization has identified potential risks and taken proactive actions to reduce them.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3) The organization’s leaders undertake a formal assessment of patient and staff safety risks at least once per year.</p>	<p>Minutes, reports or other documents show that the organization has conducted a formal assessment of risks and the management of risks on an annual basis.</p>				<p>.....</p> <p>.....</p> <p>.....</p>

⁵⁰ UK National Patient Safety Agency. A Guide to Root Cause Analysis. Available at: www.msnpsa.nhs.uk/rcatoolkit/course/iindex.htm



PATIENT SAFETY (PS)

Standard PS.1 [Patient identification]

The organization has established procedures for accurately identifying patients.

Intent of PS.1

Wrong-patient errors occur in virtually all aspects of diagnosis and treatment. Patients may be sedated, disoriented, or not fully alert; may change beds, rooms, or locations within the hospital; may have sensory disabilities; or may be subject to other situations that may lead to errors in correct identification. The intent of this goal is twofold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Policies and/or procedures are collaboratively developed to improve identification processes. In particular, these include the processes used to identify a patient: prior to surgery; when giving medications; blood, or blood products; taking blood and other specimens for clinical testing; or providing any other treatments or procedures. The policies and/or procedures require at least two ways to identify a patient, such as the patient's name, identification number, birth date, or other ways. The patient's room number or location cannot be used for identification. The policies and/or procedures clarify the use of two different identifiers in different locations within the organization, such as outpatient services, the emergency department, or operating theater. Procedures for identifying comatose patients who are not in possession of identification documents are also included.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) A collaborative process is used to develop policies and/or procedures that address the accuracy of patient identification.	Physicians, nurses and other health care workers work together to write and implement policies and procedures to accurately identify patients. Review minutes of meetings and talk with staff members regarding their involvement.			
2) The policies and/or procedures require the use of two patient identifiers, not including the use of the patient's room number or location. (Identifiers for neonates may be different from those defined for adult patients).	Review the policy and procedure.			
3) Patients are identified before administering medications, blood, or blood products;	Ask unit staff members how they identify patients prior to administering medications and blood. Determine if their response is consistent with the policy and procedure. Observe practice.			
4) Patients are identified before taking blood and other specimens for clinical testing.	As above			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
5) Patients are identified before providing treatments and performing procedures.	As above.			

Standard PS.2 [Effective communication]

The organization develops an approach to improve the effectiveness of communication among caregivers.

Intent of PS.2

Effective communication, which is timely, accurate, complete, clear, and understood by the recipient, reduces errors, and results in improved patient safety. Communication can be electronic, written, or verbal. The most error-prone communications are patient care orders given verbally, including those given over the telephone. (For example, an error-prone communication is the verbal report back of critical test results, such as a clinical laboratory telephoning a patient care unit to report the results of a STAT test).

The organization collaboratively develops a policy and/or procedure for verbal and telephone orders that includes:

- the writing down, or entering into a computer, of the complete order (or test result by the receiver of the information),
- the receiver reading back the order (or test result), and
- the confirmation that what has been written down and read back is accurate.

(This practice is sometimes referred to as “Listen, Write and Read”).

The policy and/or procedure identify permissible alternatives when the read-back process may not be possible, such as in the operating theater and in emergency situations.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) A collaborative process is used to develop policies and/or procedures that improve the accuracy of verbal and telephone communications.	Physicians, nurses and other health care workers work together to write and implement policies and procedures regarding verbal and telephone communications. Review minutes of meetings and talk with staff members regarding their involvement.			
2) Verbal and telephone orders or test results are written down by the receiver of the order or test result.	Review the policy and procedure. Review medical records to determine whether the relevant documentation is complete.			
3) Verbal/telephone orders or test results are read back by the receiver of the order or test result.	Ask staff members about their practice when receiving a telephone order or test result.			
4) The order or test result is confirmed by the individual who gave the order or test result.	Ask physicians, lab and radiology staff regarding their process of confirming orders and tests that they relay by phone.			

Standard PS.3 [High alert medications]

The organization develops an approach to improve the safety of high-alert medications.

Intent of PS.3

When medications are part of a patient treatment plan, appropriate management is critical to ensuring patient safety. A frequently cited medication safety issue is the unintentional administration of concentrated electrolytes (e.g. potassium chloride [2mEq/ml or more concentrated], potassium phosphate, sodium chloride [0.9% or more concentrated], and magnesium sulfate [50% or more concentrated]). This error can occur when a staff member has not been properly oriented to the patient care unit, when contract nurses are used and not properly oriented, or during emergencies. The most effective means to reduce or eliminate this occurrence is to remove the concentrated electrolytes from the patient care unit to the pharmacy. The organization collaboratively develops a policy and/or procedure that prevents the location of concentrated electrolytes in patient care areas where misadministration can occur. The policy and/or procedure specifies any areas where concentrated electrolytes are clinically necessary (such as the emergency department or operating theater); how they are clearly labeled; and how they are stored in those areas in a manner that restricts access to prevent inadvertent administration.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) A collaborative process is used to develop policies and/or procedures that address the location, labeling, and storage of concentrated electrolytes.</p>	<p>Physicians, nurses and other health care workers work together to write and implement policies and procedures to deal with concentrated electrolytes. Review minutes of meetings and talk with staff members regarding their involvement.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>2) Concentrated electrolytes are not present in patient care units unless clinically necessary. Actions are taken to prevent inadvertent administration in those areas where permitted by policy.</p>	<p>Make observations during safety rounds to ensure that concentrated electrolytes are not kept on the units, except where policy permits. In these permitted areas (e.g. emergency department, ICU) check that they are properly stored and labeled.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Standard PS.4 [Correct site, procedure, and patient for surgery]

The organization develops an approach to ensuring correct-site, correct-procedure, and correct-patient surgery.

Intent of PS.4

Wrong-site, wrong-procedure, wrong-patient surgery is a disturbingly common occurrence in health care organizations. These errors are the result of ineffective or inadequate communication between members of the surgical team, lack of patient involvement in site marking, and lack of procedures for verifying the operative site.

Frequent contributing factors include inadequate patient assessment, a culture that does not support open communication among surgical team members, problems related to illegible handwriting, and the use of abbreviations.

Organizations need to collaboratively develop a policy and/or procedure that is effective in eliminating these problems. Evidence-based practices include those described in the WHO Safe Surgery Checklist⁵¹ and the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery⁵².

The essential processes found in these protocols are:

- marking the surgical site;
- a preoperative verification process; and
- a time-out that is held immediately before the start of a procedure.

Marking the surgical site involves the patient and is done with an unambiguous mark. The mark:

- should be consistent throughout the organization;
- should be made by the person performing the procedure (i.e. the surgeon);
- should take place with the patient awake and aware, if possible; and
- must be visible after the patient is prepped and draped.

The surgical site is marked in all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). The purpose of the preoperative verification process is to:

- verify the correct site, procedure, and patient;
- ensure that all relevant documents, images, and studies are available, properly labeled, and displayed; and
- verify that any required special equipment and/or implants are present.

The time-out permits any unanswered questions or confusion to be resolved. The time-out is conducted in the location the procedure will be done, just before starting the procedure, and involves the entire operative team. The organization determines how the process is to be briefly documented, such as in a checklist.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) A collaborative approach is used to develop policies and/or procedures to ensure the correct site, correct procedure, and correct patient, including procedures done in settings other than the operating theater.</p>	<p>A multi-disciplinary team consisting of surgeons, anesthesiologists, surgical nurses and technicians, and surgical ward staff work together to develop an effective process to ensure the correct site, procedure and patient.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

⁵¹ Available at www.who.int/patientsafety/safesurgery

⁵² Available at: www.jointcommission.org/PatientSafety/UniversalProtocol

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>2) The organization uses a clearly understood mark for surgical site identification and involves the patient in the marking process.</p>	<p>Ask surgery staff members regarding the process that they use for marking the site. Make observations during safety rounds.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>3) The organization uses a process to verify that all documents and equipment needed are on hand, correct, and functional.</p>	<p>Review completeness of the checklist used by surgical staff to ensure all documents, equipment etc are in order. Ask surgical staff members regarding the process that they use to ensure all elements are confirmed.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>4) The organization uses a checklist and time-out procedure just before starting a surgical procedure.</p>	<p>As above</p>				<p>.....</p> <p>.....</p>

Standard PS.5 [Health care associated infections]

The organization develops an approach to reduce the risk of health care associated infections.

Intent of PS.5

Infection prevention and control are challenging in most health care settings, and rising rates of health care associated infections are a major concern for patients and health care professionals. Infections common to all health care settings include catheter-associated urinary tract infections, blood stream infections and pneumonia (often associated with mechanical ventilation). Central to the elimination of these and other infections is proper hand hygiene. Internationally acceptable hand hygiene guidelines are available from the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (US CDC) – see resources referenced in earlier footnotes 44 to 48.

The organization has a collaborative process to develop policies and/or procedures that adapt or adopt currently published and generally accepted hand hygiene guidelines, and for the implementation of those guidelines within the organization.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
1) The organization has adopted or adapted currently published and generally accepted hand hygiene guidelines.	Review the policy and procedures adopted. References used (e.g. WHO, US CDC, JCI) should be cited on the procedure and dated.			
2) The organization implements an effective hand hygiene program.	Make routine observations of hand hygiene practices. Clinical units should collect data for all levels of staff and report findings to the Infection Control/Prevention Committee.			

Standard PS.6 [Falls prevention]

The organization develops an approach to reduce the risk of patient harm resulting from falls.

Intent of PS.6

Falls account for a significant portion of injuries in hospitalized patients. The organization should evaluate patients' risk of falls and take action to reduce this risk and to reduce the risk of injury should a fall occur. The evaluation could include fall history, medications and alcohol consumption review, gait and balance screening, and walking aids used by the patient.

The organization establishes and implements a fall-risk reduction/prevention program. This is based on appropriate policies and/or procedures, and on physical modifications to the facilities (e.g. fitting of hand-rails, non-slip floor covering etc).

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) A collaborative process is used to develop policies and/or procedures aimed at reducing the risk of patient harm resulting from falls in the organization.</p>	<p>Physicians, nurses and other health care workers work together to write and implement policies and procedures to reduce the risk of falls. Review minutes of meetings and talk with staff members regarding their involvement.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>2) The organization implements a process for the initial assessment of patients for risk of falls. This includes reassessment of patients when indicated by a change in condition, medications, etc.</p>	<p>Review policies and procedures, e.g. fall risk assessment and protocol. Ask staff members regarding how they assess patients for risk of falls. Review medical records to determine if a fall assessment has been completed, and re-assessments done as indicated.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3) Measures are implemented to reduce fall risk for those assessed to be at risk.</p>	<p>Observe the use of fall-prevention measures during safety rounds. Ask staff regarding their knowledge of the fall risk protocol.</p> <p>Observe physical measures taken, e.g. handrails, non-slip floor surfaces etc.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

FACILITY SAFETY AND EMERGENCY MANAGEMENT (FSE)

Standard FSE.1 [Safety and security]

The organization plans and implements a program to provide a safe and secure physical environment.

Intent of FSE.1

The organization provides a safe and secure facility. Prevention and planning are essential to creating a safe and supportive patient care facility. To plan effectively, the organization must be aware of all of the risks present in the facility. This includes safety as well as security risks. The objectives are to:

1. prevent accidents and injuries;
2. maintain a safe and secure environment for patients, families, staff and visitors; and
3. reduce and control potential hazards and risks.

(These are particularly important during periods of construction or renovation).

In addition, to ensure security, all staff, visitors, vendors and others in the organization are identified and issued temporary or permanent badges or other identification. Areas intended to be secure (such as the newborn nursery) are secure and monitored. Periodic inspections of the facility check for potential hazards, e.g. sharp and broken furniture that could injure, locations where there is no escape from fire, or secure areas where there is inadequate monitoring/control. These periodic inspections are documented and help the organization to plan and carry out improvements and to plan for longer-term facility upgrading or replacement. By understanding the risks present in the organization's physical facility, the management can develop a proactive plan to reduce these risks for patients, families, staff, and visitors.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) The organization ensures that all staff, visitors and vendors are identified and all security risk areas are monitored and kept secure.	As a minimum, all staff are wearing ID badges. A process is in place to screen visitors and vendors. Check designated secure areas (e.g. nursery) for additional adequate security measures.			
2) The organization has a documented, current and accurate inspection report of its physical facilities.	An in-depth inspection of the facility has been undertaken within the past year. The inspection was carried out by a reputable individual/group, e.g. engineer.			
3) The organization implements a plan to reduce evident risks based on the inspection.	A plan has been developed and actions implemented to address the findings of the facility inspection.			
4) The organization plans and budgets for upgrading or replacing physical infrastructure needed for the continued operation of a safe and effective facility and to meet legal and regulatory requirements.	The organization's budget includes provision for necessary physical upgrading.			

Standard FSE.2 [Hazardous materials plan]

The organization has a plan for the inventory, handling, storage, and use of hazardous materials and the control and disposal of hazardous materials and waste.

Intent of FSE.2

The organization identifies and safely controls hazardous materials and waste according to a Hazardous Materials Management Plan (or similar). Such materials and waste include chemicals, chemotherapeutic agents, radioactive substances, hazardous gases and vapors, and other regulated medical and infectious waste.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>1) The organization identifies hazardous materials and waste and has a current list of all such materials within its facilities.</p>	<p>The list of hazardous materials and waste is current and comprehensive, and includes all departments.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>2) A Hazardous Materials Management Plan provides for:</p> <ul style="list-style-type: none"> a. the inventory of hazardous materials and waste, b. the proper labeling of hazardous materials and waste, c. safe handling, storage, and use of hazardous materials, d. procedures for coping with spills, exposures and other incidents, e. procedures for reporting and investigating of spills, exposures, and other incidents, f. procedures for proper disposal of hazardous waste, g. proper use of protective equipment, and h. documentation, including any permits, licenses, or other regulatory requirements. 	<p>A Hazardous Materials Management Plan (or similar) describes the processes for all of the required elements.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>3) Hazardous materials and waste are managed according to the Hazardous Waste Management Plan.</p>	<p>Interviews with staff indicate that they understand the Hazardous Materials Management Plan. Posters and signs remind staff of key procedures. During safety rounds, handling and disposal of hazardous materials and waste is observed to be carried out according to policy.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Standard FSE.3 [Emergency management plan]

The organization develops and maintains an Emergency Management Plan (or similar) and program to respond to likely community emergencies, epidemics, and natural or other disasters.

Intent of FSE.3

Emergencies, epidemics, and disasters may directly affect the organization. These might range, for example, from earthquake damage to patient care areas, to a flu outbreak that prevents staff from coming to work. To respond effectively, the organization develops an Emergency Management Plan and a program to manage such emergencies.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) The organization has identified the major internal and external disasters and major epidemic events which pose significant risks of occurring.</p>	<p>A document lists all the major internal and external disasters and epidemics that could pose a risk to the organization.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>2) The organization plans its response to likely disasters. The plan sets out processes for</p> <ul style="list-style-type: none"> a. determining the type, likelihood and consequences of hazards, threats, and events, b. determining the organization's role in such events, c. communicating strategies for events, d. the managing of resources during events, including alternative sources, e. the managing of clinical activities during an event, including alternative care sites, and f. the identification and assignment of staff roles and responsibilities during an event. 	<p>A disaster plan addresses actions to take for all the identified risks</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>3) The Emergency Management Plan is tested annually. Staff members participate in at least one emergency-preparedness test per year.</p>	<p>Staff training in the Emergency Management Plan is documented. The annual test of the Plan is documented with an analysis of the findings and a corrective action plan.</p>				<p>.....</p> <p>.....</p> <p>.....</p>

Standard FSE.4 [Fire/smoke safety plans]

The organization plans and implements a program to ensure that all occupants are safe from fire, smoke, or other potential emergencies in the facility.

Intent of FSE.4

Fire is an ever-present risk in a health care facility. Thus, every organization needs to plan how it will keep its occupants safe in case of fire or smoke. The organization adopts preventive measures including:

- safe storage and handling of potentially flammable materials (e.g. flammable medical gasses such as oxygen);
- use of early warning/early detection systems such as fire patrols, smoke detectors and fire alarms;
- provision of suppression mechanisms such as water hoses, chemical suppressants, and sprinkler systems;
- managing hazards related to any construction in or adjacent to the patient-occupied buildings; and
- ensuring safe and unobstructed means of exit for patients, staff and visitors in the event of a fire.

Such plans and safeguards are required no matter what the age, size, or construction of the facility.

Measurable Element	Look for	Score			Observations
		0	5	10	
What is required?	How is this element assessed?				Why did you give this score?
<p>1) The organization has a program to ensure that all occupants of the facility are safe from fire and smoke (or other non-fire emergencies). A Fire Safety Plan specifies</p> <ul style="list-style-type: none"> a. the frequency of inspecting, testing, and maintaining fire protection and safety systems, b. the procedures for safely evacuating the facility in the event of a fire or smoke, c. the process for testing (exercising all or a portion of the plan), at least twice per year, d. the necessary training of staff to effectively protect and remove patients when an emergency occurs, and e. the participation of staff members in at least one fire safety test per year. 	<p>A Fire Safety Plan contains all the required elements.</p> <p>There is evidence that the Plan is continually updated, e.g. based on regulatory changes, facilities development and corrective actions identified during regular testing of the Plan.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
<p>2) The program includes the assessment of fire risks during construction within or adjacent to the facility.</p>	<p>Minutes of the construction project team meetings and action plans describe how risks will be minimized during construction.</p>				<p>.....</p> <p>.....</p>
<p>3) Fire detection and abatement systems are inspected, tested, and maintained at a frequency determined by the organization.</p>	<p>A maintenance record indicates the inspection dates, test results and maintenance of fire systems.</p>				<p>.....</p> <p>.....</p> <p>.....</p>
<p>4) Staff are trained to participate in the Fire Safety Plan.</p>	<p>Staff training attendance records show the number of staff who participated. The percentage of staff attending is tracked.</p>				<p>.....</p> <p>.....</p>
<p>5) A fire and smoke safety evacuation plan is tested at least twice a year.</p>	<p>A report of the evacuation drill includes an analysis of the exercise and the corrective actions taken.</p>				<p>.....</p>
<p>6) Staff participate in at least one fire and smoke safety test per year.</p>	<p>Attendance records of staff participation are kept.</p>				<p>.....</p>
<p>7) The organization develops and implements a policy and plan to limit smoking. These:</p> <ul style="list-style-type: none"> a. apply to all patients, families, staff and visitors; and b. eliminate smoking in the organization's facilities or minimally limits smoking to designated non-patient care areas that are ventilated to the outside. 	<p>A smoking policy is written. No-smoking signs are clearly displayed. Observation of smoking behavior within the organization shows that the policy is followed.</p>				<p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>

Standard FSE.5 [Medical equipment maintenance]

The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results.

Intent of FSE.5

In order to ensure that medical equipment is available for use and functioning properly, the organization

- maintains an inventory of medical equipment;
- regularly inspects medical equipment;
- tests medical equipment as appropriate to its use and requirements; and
- undertakes preventive maintenance.

Qualified individuals provide these services. Equipment is inspected and tested when new and then on an ongoing basis, as appropriate to the equipment’s age and use, or based on manufacturers’ instructions. Inspections, test results, and any maintenance undertaken are documented. This helps ensure continuity of the maintenance process and supports capital planning for equipment replacements, upgrades, and other changes.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) There is a program to register, test and maintain all medical equipment.	An inventory with each item of equipment individually numbered/ identified is available. The inventory is updated when new equipment is added or when equipment is disposed of. New equipment is tested and logged into the inventory system. An inspection process is recorded. A label/tag with the inspection date is on each piece of equipment. Equipment is maintained according to manufacturers’ recommendations.			
2) Qualified individuals manage the medical equipment program.	A trained biomedical engineer maintains the equipment.			
3) Data are collected and analyzed for the medical equipment management program.	A report or register includes information regarding the state of the equipment, with recommendations.			

Standard FSE.6 [Utilities management]

Potable water, electrical power, and medical gases are available 24 hours a day, seven days a week, through regular or alternate sources, to meet essential patient care needs.

Intent of FSE.6

Patient care, both routine and urgent, is provided on a 24-hour basis, every day of the week in most health care organizations. Thus, an uninterrupted source of clean water and electrical power is essential to meet patient care needs. The organization continually endeavors to ensure uninterrupted supply of potable water and of electrical power. Regular and alternate sources may be used to achieve this.

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
1) Water quality is monitored regularly.	A log is kept of checks of water quality. Actions are taken if a problem is identified.			
2) Potable water, electrical power and medical gases are available 24 hours a day, seven days a week.	If availability is a problem, a log is kept regarding how often problems occur.			
3) The organization has identified the areas and services at greatest risk when power fails or water is contaminated or interrupted.	If availability of water or power is a problem, the organization has documentation that describes the areas and services that are at greatest risk, e.g. patients on ventilators or dialysis.			
4) The organization plans alternate sources of power and water in emergencies.	Based on the risks identified, the organization has a plan outlining what to do when these situations arise. An alternative power supply is maintained and tested on a regular basis. A maintenance log is kept.			
5) Key systems such as utility, medical gas, and ventilation are identified, inspected, tested and maintained by the organization.	Diagrams of the utility, medical gas and ventilation systems are available. Emergency services such as Civil Defense have copies of these diagrams in case of a fire or other emergency. A maintenance record is kept for all systems.			

Measurable Element	Look for	Score			Observations
What is required?	How is this element assessed?	0	5	10	Why did you give this score?
6) Data are collected and analyzed for the for the purposes of planning and improvement, e.g. under a medical utility management program.	Key indicators for effective functioning of the utility systems are kept. Reports or minutes show that the monitoring data are reviewed and used for improving the utility systems			

IFC information resources - Environmental, fire and life safety

More detailed resources are available online at:

IFC Environmental, Health and Safety Guidelines for Health Care Organizations

[www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_HealthCareFacilities/\\$FILE/Final+-+Health+Care+Facilities.pdf](http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_HealthCareFacilities/$FILE/Final+-+Health+Care+Facilities.pdf)

IFC Performance Standards on Social and Environmental Sustainability

[www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/pol_PerformanceStandards2006_full/\\$FILE/IFC+Performance+Standards.pdf](http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/pol_PerformanceStandards2006_full/$FILE/IFC+Performance+Standards.pdf)

IFC Environmental, Health and Safety General Guidelines (section on Life and Fire Safety in section 3.3, p79-81)

[www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_GeneralEHS/\\$FILE/Final+-+General+EHS+Guidelines.pdf](http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/gui_EHSGuidelines2007_GeneralEHS/$FILE/Final+-+General+EHS+Guidelines.pdf)





AFTER THE SELF-ASSESSMENT *NEXT STEPS*



After the Self-Assessment Next Steps

STEP 4: SCORE PERFORMANCE AND IDENTIFY GAPS

After completing the assessment, the team should calculate the scores and review the findings. The aim of this exercise is to identify the gaps toward meeting the standards in order to make improvements and take corrective actions. The process for doing this is described below.

The responses for each standard are summed to determine the level of achievement, as follows:

- 1. Enter the scores for each question/element in the Self-Assessment Template on the following pages. The Scoring Key is:**

0 = the organization does not meet the criterion

5 = yes, some elements are in place, but the criterion is not fully satisfied

10 = yes, the criterion is fully satisfied

- 2. Add the 0, 5 and 10 scores for all of the measurable elements.**
- 3. Determine overall achievement by adding together the scores for all the standards and dividing by 1,600* (the total score possible).**

** Note - The Highest Possible Score will be less if there are standards that are not applicable (e.g. IVF, organ transplantation). Subtract 10 from the Highest Possible Score for each element that is not applicable.*

The reason that the following score-tables have a “Baseline Score” column along with additional Score columns is to allow progress to be tracked over time, i.e. as future assessments are undertaken.

		Baseline Score	Score	Score
Clinical Governance and Leadership				
CGL.1	Governance documents, e.g. bylaws, policies/ procedures			
1	Structure described			
2	Strategic and operational plans			
3	Budget			
4	License to operate			
CGL.2	Senior manager responsible for operations			
1	Manages day-to-day operations			
2	Assures compliance with policies			
3	Assures compliance with laws and regulations			
4	Responds to reports of inspecting and regulatory agencies			
5	Plans services with community and other providers			
CGL.3	Oversight of contracts			
1	Quality oversight of contracts			
2	Contract services meet patient needs			
CGL.4	Departmental scope of services and policies and procedures			
1	Scope of service; policy and procedures			
2	Coordination and integration of services			
3	Criteria for professional staff qualifications			
4	Process for clinical privileging			
CGL.5	Department directors recommend space, equipment, etc			
1	Department directors recommend space, equipment, etc			
2	Processes to respond to resource shortages			
CGL.6	Programs for recruitment, retention and staff development			
1	Program for recruitment and retention			
2	Staff orientation program			
3	Staff personal development and continuing education plan			
4	Employee health and safety program			
Total	Highest Possible = 210			
	Percent achievement	%	%	%

		Baseline Score	Score	Score
Ethics and Patient Rights				
EPR.1	Credential verification of professional staff			
	1 Licensure, education and training verified			
	2 Separate records for professional staff			
	3 Records reviewed at least every 3 years			
EPR.2	Processes to support patient and family rights			
	1 Policies and procedures that support patient rights			
	2 Vulnerable groups are protected against abuse			
	3 Health information is confidential			
	4 Patients/families informed of their rights			
	5 Patients can voice complaints			
EPR.3	Informed consent			
	1 Informed consent policy/procedure			
	2 Staff trained to obtain informed consent			
	3 Informed consent given for high-risk procedures/treatments			
	4 Process when others can grant informed consent			
EPR.4	Framework for ethical management			
	1 Ethical and legal norms established			
	2 Disclosure of organizational ownership			
	3 Honest portrayal of service offered			
	4 Accurate billing of services			
	5 Discloses and resolves financial conflicts of interest			
	6 Staff are supported in dealing with ethical issues			
	7 Safe reporting of ethical and legal concerns			
EPR.5	Organ and tissue donation and transplantation			
	1 Patient/family supported in making decisions to donate			
	2 Organ and tissue donation policies and procedures			
	3 Staff are trained in policies and procedures			
	4 Valid informed consent from live donors			
	5 Organization cooperates with community organizations			

EPR.6	Reproductive health policies and procedures (IVF)			
1	IVF services are integrated into MCH services			
2	Policies and procedures for services support women's rights			
3	Staff are trained in examination, diagnosis, referral and transfer			
4	Procedures and equipment are standardized			
5	Patients are provided with full information			
6	Donors are provided with full information			
7	IVF registry maintained			
8	Register linked with national health registries			
EPR.7	Termination of pregnancy services			
1	Services are integrated into MCH services			
2	Policies and procedures for services support women's rights			
3	Staff trained in screening, exam, diagnosis, referral and transfer			
4	Procedures and equipment are standardized			
5	Patients provided with full information			
EPR.8	Clinical research trials			
1	Benefits and ethical issues fully considered prior to proceeding.			
2	Research committee oversight			
3	Appropriate pts identified and informed how to gain access			
4	Research policies and procedures			
5	Informed consent obtained			
6	Patients informed about refusal to participate			
Total	Highest Possible = 430			
	Percent achievement	%	%	%

		Baseline Score	Score	Score
Quality Measurement and Improvement				
QMI.1	Clinical practice guidelines and pathways			
	1	Clinicians use clinical practice guidelines and pathways		
	2	Process for implementing guidelines and pathways		
	3	One guideline or pathway developed each year		
QMI.2	Leadership involvement and support			
	1	Systematic approach to quality improvement		
	2	Multidisciplinary Quality Committee		
	3	Leaders set priorities for improvement activities		
	4	Leaders receive and act on quality reports		
	5	Quality improvement training program		
	6	Clinical indicators		
	7	Management indicators		
	8	Data aggregated, analyzed, and transformed into information		
	9	Improvements achieved and sustained		
QMI.3	Infection prevention and control			
	1	Coordinated infection control program		
	2	Adequate resources allocated		
	3	Systematic and proactive surveillance		
	4	Processes implemented to prevent or reduce infections		
	5	Equipment cleaning and sterilization		
	6	Laundry and linen management		
	7	Disposal of infectious waste		
	8	Sharps and needle disposal		
	9	Kitchen sanitation and food preparation		
	10	Risks and impact of construction is managed		
	11	Isolation procedures		
	12	Universal procedures		
	13	Staff oriented to infection control policies and procedures		
	14	Patients and families educated about reducing transmission		
	15	Reduce risk of hospital-associated infections in staff		

QMI.4	Medications use			
1	Medication policies and procedures			
2	Pharmacy services and medication use comply with laws			
3	Licensed, trained pharmacy supervisor			
4	List of medications			
5	Process to inform prescribers of unavailability of meds			
6	Medications protected from loss or theft			
7	Medications properly stored			
8	Controlled substances accounted for			
9	Emergency medications available			
10	Medications prescribed by licensed individuals			
11	Medications reviewed and verified for appropriateness			
12	Meds prepared and dispensed in clean, safe areas			
13	Staff trained in aseptic technique			
14	Uniform medication dispensing and distribution system			
15	Medications appropriately labeled after preparation			
16	Medication effects are monitored			
17	Adverse effects are reported			
18	Medication errors and near misses are reported			
19	Medical error reporting is used to improve processes			
20	Antibiotic policy			
QMI.5	Sentinel events			
1	Definition of sentinel event			
2	High risk areas are identified			
3	Patient and safety risks formally assessed annually			
Total	Highest Possible = 500			
	Percent achievement		%	%

		Baseline Score	Score	Score
Patient Safety				
PS.1	Patient identification			
	1 Collaborative process for development of policies/procedures			
	2 Use of two patient identifiers			
	3 Patient identified before giving medications, blood, etc.			
	4 Patient identified before taking blood or specimens			
	5 Patient identified before giving treatments or procedures			
PS.2	Safe communication			
	1 Collaborative process for development of policies/procedures			
	2 Complete verbal or telephone order written down			
	3 Read back of verbal or telephone order			
	4 Order or test result is confirmed			
PS.3	High alert medications			
	1 Collaborative process for development of policies/procedures			
	2 High alert medications not present on units			
PS.4	Correct site, procedure, patient for surgery			
	1 Collaborative process for development of policies/procedures			
	2 Clearly understood mark for surgical identification			
	3 Verification of documents, equipment on-hand, correct, functional			
	4 Checklist and time out procedure			
PS.5	Health associated infections			
	1 Hand hygiene guidelines			
	2 Effective hand hygiene program			
PS.6	Risk of falls			
	1 Collaborative process for development of policies/procedures			
	2 Fall risk assessments			
	3 Measures to reduce risk of falls			
Total	Highest Possible = 200			
	Percent achievement	%	%	%

		Baseline Score	Score	Score
Facility Safety and Emergency Management				
FSE.1	Program to provide safe and secure environment			
	1 Staff, visitor and vendor identification			
	2 Inspection of physical facility			
	3 Plan to reduce risks identified during inspection			
	4 Plans for upgrading and replacing systems			
FSE.2	Hazardous materials			
	1 List of hazardous wastes			
	2 Plan covers listed processes			
	3 Hazardous materials managed according to plan			
FSE.3	Emergency management plan			
	1 Identification of potential major internal and external disasters			
	2 Plan to respond to identified disasters			
	3 Plan tested annually			
FSE.4	Fire/smoke plans			
	1 Fire safety plan			
	2 Fire assessment during construction			
	3 Inspection of fire detection and abatement systems			
	4 Staff trained to participate in fire plan			
	5 Fire evacuation plan tested twice a year			
	6 Staff participate in one fire test per year			
	7 Smoking policies			
FSE.5	Medical Equipment Maintenance			
	1 Program to test, maintain and keep inventory of equipment			
	2 Qualified staff to manage medical equipment			
	3 Data for medical equipment management program			

FSE.6	Utilities Management			
1	Potable water, electrical power and medical gas 24/7			
2	Data for medical utility management			
3	Areas of risk identified			
4	Plans for alternate sources of power and water			
5	Utility systems identified, inspected and maintained			
6	Water quality monitored			
Total	Highest Possible = 260			
	Percent achievement	%	%	%

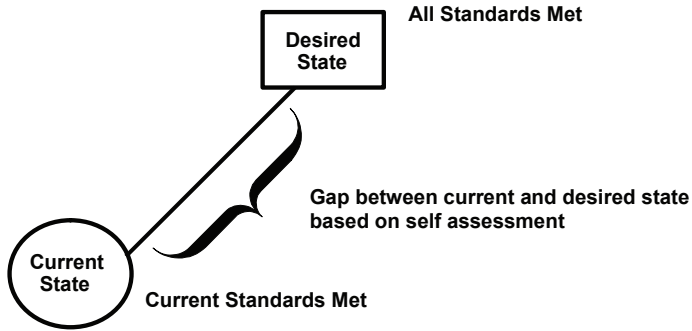
Overall Achievement of Standards – SCORE (Highest possible = 1,600)			
Overall Achievement of Standards – Percent	%	%	%

The team will be able to determine the percentage of the standards met for each category, as well as the overall percentage of standards met. This percentage will give the team a guide to where the main gaps are and where the organization needs to focus its attention. The team should graph the overall score and use this percentage as a measure of on-going progress.

STEP 5: DEVELOP AN ACTION PLAN

The team should develop an Action Plan to close the gaps to meet the standards. Each measurable element that is scored as “partially met” or “not met” requires an action.

Quality Gap Analysis



It is likely that some of the actions that need to be taken will be straightforward. For example, if a process for checking water quality is needed, then the action is clear – a procedure needs to be written identifying who checks the water, when, and how. In some cases, the way forward is likely to be less clear and the team may need to collect more information in order to understand the situation. For example, one hospital that investigated the reason for a higher rate of incomplete medication orders discovered that this occurred when new medical interns joined. This finding was clearly important in determining a solution to the problem.

Some issues arising may be difficult to resolve and require specialist assistance. In other instances there may well be internal resistance to change (e.g. relating to new working practices) and will require sustained, explicit management support. Colored graphs and charts showing progress on key indicators (e.g. infection rates, patient satisfaction) over time, displayed in departmental areas are also an effective way of promoting quality improvement efforts.

Action plans should be as specific as possible, e.g. regarding responsibilities and timetables.

Example: Action Plan

What needs to be done?	Who is going to do it?	When will it be done?
1. Develop a policy and procedure regarding obtaining informed consent.	Winona Amory, Senior Nurse, Surgical Ward	May 15

STEP 6: COMMUNICATE THE FINDINGS/ ACTIONS

The assessment findings and action plans should be shared with all key parties. A Communication Plan should include:

1. Who needs the information?

List all the individuals or groups that need the information, e.g. staff, board of directors, committees.

2. What information is needed?

Each group has a different need for the information. For instance, the infection control committee will be interested in the findings related to specific standards, whereas the board of directors is more likely to be interested in a summary of the findings.

3. How will the information be delivered?

The method that best suits the target group should be used. A formal report might be sent to the board of directors and a presentation might be made to the medical staff.

4. Who will convey the information?

The person selected for delivering the information must be an appropriate authoritative figure.

5. When will the information be given?

Specific dates need to be assigned so that the plan can be monitored.

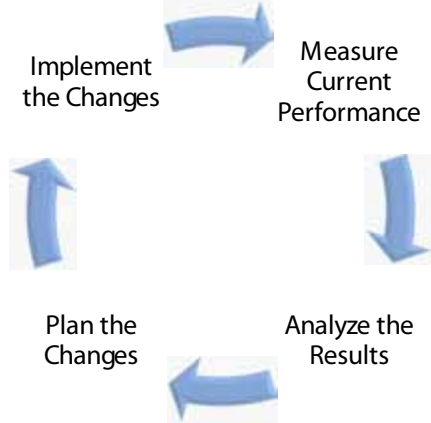
Example: Communication Plan

Who needs the information?	All clinical staff
What information is needed?	Informed consent policy and procedure
How will the information be delivered?	Formal presentation
Who will convey the information?	Winona Amory, Senior Nurse
When will the information be given?	June 30

STEP 7: SUSTAIN THE GAIN

Some organizations using this Guide may be conducting a self-assessment for the first time. In order to sustain improvement efforts, the initial baseline assessment should be conducted and then, further assessments performed at intervals to establish progress. Organizations may choose to begin by focusing their attention on a small number of standards in specified priority areas and meet these before going on to tackle additional ones. The action plans should be used to move the process forward. The full assessment might be done on a semi-annual or annual basis. The assessment should not be considered a “once off” activity – see the Quality Improvement Cycle below.

The Quality Improvement Cycle



Even when all of the standards have been met, organizations should conduct an assessment at least annually in order to sustain the improvement process.

Your views

IFC seeks to support health care organizations in developing countries to raise their standards to international levels.

What did you think of this Guide? And how was your experience of using it? We welcome your views, including ways you think we can make it even more useful and relevant.

Please send your views by email to: healthstandards@ifc.org



APPENDICES



APPENDIX I: IFC CODE OF CONDUCT FOR HEALTH CARE ORGANIZATIONS

PURPOSE

To establish a culture of openness, trust and integrity in business practices. This document will serve to guide behavior to ensure ethical conduct based on the values of the International Finance Corporation (IFC).

POLICY

Organizations receiving funds from the IFC are expected to maintain high standards of professional and business integrity, to comply with all applicable laws, rules and regulations, deter wrongdoing and to avoid situations and behaviors that could reasonably be foreseen to reflect negatively on the integrity or reputation of IFC.

Prior to financing agreements, officers of the organization are to receive this document and are required to execute a Code of Conduct Statement. This statement will indicate that the document has been read and understood, that the organization will conduct business to the expectations outlined, that prohibited conduct will be avoided, and any relevant conflicts will be disclosed.

The intent of these guidelines is not to attempt to foresee or define each situation that does or might involve a breach in ethics. The intent is rather to focus on situations that are viewed as likely to pose actual or potential concerns or to reflect negatively on the integrity or reputation of IFC. The intent is also to focus on IFC's expectation that, in questionable or unforeseen situations, timely disclosure will facilitate satisfactory resolution before any such situation becomes problematic.

During and, as applicable, subsequent to the agreement with IFC, the following issues shall be disclosed and avoided or managed as appropriate:

1. Compliance with Laws and Regulations

The organization will ensure all activity by or on behalf of the organization is in compliance with applicable laws and regulations.

2. Adherence to Ethical Standards

Organizations will accurately and honestly represent their services and will not engage in any activity intended to defraud any individual or organization of money, property or honest services.

3. Client focus

The organization has the responsibility to ensure that there are no compromises in delivering the highest standard of services and that every aspect of their operations promotes and reflects these standards. No one is to take unfair advantage of anyone through manipulation, concealment, abuse of privileged information or misrepresentation of material facts.

4. Non-discrimination

Discrimination or harassment on the basis of race, color, religion, gender, nationality, age or disability is not tolerated.

5. Confidentiality

The organization shall maintain the confidentiality of clients and that of their service users and other confidential information in accordance with applicable legal and ethical standards.

6. Records

All organizational records, documents and reports must be accurate, complete, and un-tampered.

7. Avoidance of conflicts of interest

Executives, managers, employees, and Board members owe a duty of loyalty to the organization. Persons holding such positions may not use their positions to profit personally or to assist others in profiting in any way at the expense of the organization.

8. Business relationships

Business transactions with vendors, contractors and other third parties shall be transacted appropriately, without offers, solicitation or acceptance of gifts and favors or other improper inducements in exchange for influence or assistance in a transaction. Business activities must be conducted on the basis of fair competitive practices. All purchases of services and supplies must be from qualified and reliable sources and be based upon objective factors, consistent with the organization's policies and procedures.

9. Occupational safety

The organization abides by all laws and regulations regarding occupational safety. This requires an active participation in maintaining a safe working environment and includes observance of established safety procedures and making recommendations for changes where they are needed.

10. Clinical research

The organization has a committee or other mechanism to oversee all research within the organization. Any person enrolled in clinical research is fully informed of the risks and benefits and their right to refuse to participate or drop out of the activity without risk of reprisal.

11. Organ donation and transplant

The organization complies with the WHO Guiding Principles on Human Organ Transplantation.

Organ retrieval from living persons is not undertaken where there are reasonable grounds to suspect that the donation is coerced or that a financial consideration is expected by the donor.

The organization permits the allocation of organs on the basis of morally relevant criteria only.

Transplantation is prohibited when the chance of success is insufficient to justify the risks.

The buying and selling of organs are not performed or condoned by the organization.

The harvesting of organs without prior consent from dead patients (or their legal representative) is not performed or condoned by the organization.

12. Gender selection

Sex selection, by selectively terminating a pregnancy for non-medical reasons, is not performed or condoned. This encompasses a number of related practices, including pregnancy ultrasound scanning, where there are reasonable grounds to suspect a risk of termination of pregnancy dependent upon the determined sex of the embryo or fetus.

13. Assisted reproductive technologies

Interventions of human procreative processes [e.g. invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), artificial insemination by donor (AID)] are carried out with due consideration to donor confidentiality, parental age limits, same sex couples, ownership of donated sperm/eggs, multiple embryo transfer and genetic testing. All such procedures are carried out within the laws and regulations of the country.

Exploitation of clients seeking reproductive assistance (e.g. non-required testing procedures or procedures unlikely to yield results), or of egg donors is prohibited.

Harvesting of stem cells must only be done with the express permission of the donor under the laws and regulations of the country.

14. Female genital mutilation

Female circumcision is not performed or condoned by the organization.

APPENDIX II: OUTLINE TERMS OF REFERENCE FOR KEY COMMITTEES IN HEALTH CARE ORGANIZATIONS

Quality and Patient Safety Committee

1. Ensure that policies and systematic processes are in place and working to assess and improve the quality of care and services provided to patients in the facility.
2. Assess safety risks and take actions to reduce potential injury.
3. Review reports on the evaluation of clinical and non-clinical quality indicators and of quality management programs and services of the organization.
4. Ensure that actions are taken to correct identified problems and improve the quality of care.
5. Ensure that processes are in place to facilitate implementation of quality standards.
6. Recommend or provide education programs concerning quality.

Infection Prevention and Control Committee

1. Develop standards, guidelines and/or best practices for infection prevention and control.
2. Provide infection prevention and control training and education, for both infection control professionals (ICPs) and non-ICP front-line health care workers.
3. Develop evaluation strategies for infection prevention and control programs, practices and procedures through the development of measures and indicators.
4. Supervise surveillance of infection risks, e.g. surgical site, urinary tract, and blood stream infections.

Pharmacy and Therapeutics Committee

1. Make recommendations on and formulate Hospital Policy regarding the safe, effective and cost-effective prescribing and use of medicines for the treatment of patients.
2. Review medication usage in the hospital and make recommendations or publish guidance as appropriate.
3. Monitor and review prescribing practices within the hospital and provide appropriate guidance or feedback as necessary.
4. Establish and maintain a Hospital Formulary or Preferred Prescribing Guide.

Safety Committee

1. Ensure hospital environment is safe and healthy for hospital personnel, patients and visitors by:
 - a) conducting risk assessment, risk communication and risk management,
 - b) conducting safety audits,
 - c) implementing safety programs,
 - d) providing technical advice to improve the facility environment,
 - e) developing plans for the management of hazardous waste materials and waste, and
 - f) developing plans for fire safety and general safety and security.
2. Ensure facility is well prepared in time of emergency by:
 - a) developing emergency/disaster plans, and
 - b) supporting the implementation of the plans.

Medical Records Committee⁵³

1. Ensure that accurate and complete medical records are kept and readily available for every patient treated in the hospital.
2. Help to ensure that medical staff complete all the medical records of patients under their care by recording a discharge diagnosis and writing a discharge summary.
3. Determine the standards and policies for the medical record services of the health care facility.
4. Recommend action when problems arise in relation to medical records and the medical record service.
5. Control new and existing medical record forms used in the health care facility.

⁵³ WHO (2002) Medical Records Manual: A Guide for Developing Countries. Available at www.ihro.org/9290610050.pdf

Clinical Privileging Committee

The Committee is charged with advising on credentialing and defining the Clinical Privileges of Medical Practitioners and Allied Health Professionals by:

1. Providing advice, guidance and/or endorsement to other clinical and advisory committees with regard to policies and procedures, clinical reviews, and safety, quality, audit and education processes.
2. Advising the Director of Medical Services on the range of clinical services, procedures and other interventions that can be provided safely in the Relevant Hospital setting.
3. Advising the Director of Medical Services on the minimum credentials necessary for a Medical Practitioner or Allied Health Professional to fulfill competently the duties of a specific position or Clinical Privileges, within the Relevant Hospital.
4. Advising the Hospital Director on the information that should be requested and provided by applicants for appointment to specific Medical Practitioner and Allied Health Professional positions or for specific clinical privileges.
5. Accepting requests to undertake the processes of credentialing and defining the clinical privileges in line with the range of clinical services, procedures and other interventions:
 - a) relevant to all Medical Practitioners applying for initial appointment,
 - b) from an Authorized Person, in respect of a review of the Medical Practitioner or Allied Health Professional and/or their clinical Privileges, and
 - c) from any Medical Practitioner or Allied Health Professional who requests a review of their clinical privileges.
6. Ensuring the credentials of each Medical Practitioner or Allied Health Professional are reviewed and verified in accordance with the organization's by-laws and policies.
7. Advising the Hospital Director of the committee's recommendations in relation to the clinical privileges of each Medical Practitioner and Allied Health Professional.

APPENDIX III: GLOSSARY

accreditation

1. The process in which an independent external “accrediting” organization (usually non-governmental) assesses a health care organization to determine if it meets a formal set of standards designed to improve the quality of care.
2. The positive formal decision by an accrediting organization that a health care organization meets an applicable set of standards.

adverse event

An unanticipated, undesirable, or potentially dangerous occurrence in a health care organization. Also see sentinel event.

client

A recipient of health care regardless of the state of health. Clients may, for example, include people receiving screening or preventative services. Patients’ families may also be considered as clients. Clients are sometimes classified as being “internal” and “external”; “internal” clients/customers are people who work inside the organization (e.g. physicians, staff, management) and “external” are those that use the services of the organization (e.g. patients, families, insurers, vendors).

clinical governance

The means by which organizations ensure the provision of quality clinical care by making individuals accountable for setting maintaining and monitoring performance standards.⁵⁴

clinical pathway

An agreed-upon treatment regime that includes all elements of care. (There are several terms used for clinical pathway - such as “care pathway” or “care map”).

clinical practice guidelines

Statements that help practitioners and patients choose appropriate health care for specific clinical conditions (for example, recommendations on the case management of diarrhea in children under the age of five years). The practitioner is guided through all steps of consultation (questions to ask, physical signs to look for, lab exams to prescribe, assessment of the situation, and treatment to prescribe).

clinician

A health professional, such as a physician, psychiatrist, psychologist, or nurse, involved in clinical practice (as distinguished from one specializing in research).

competence

A determination of an individual’s skills, knowledge, and capability to meet defined expectations, as frequently described in a job description.

confidentiality

1. The restricted access to data and information to individuals who have a need, a reason, and permission for such access.
2. An individual’s right to personal and informational privacy, including for his or her health care records.

continuum of care

Matching the individual’s ongoing needs with the appropriate level and type of care, treatment, and service within an organization or across multiple organizations.

continuity of care

The degree to which the care of individuals is coordinated among practitioners, among organizations, and over time.

contracted services

Services provided through a written agreement with another organization, agency, or individual. The agreement specifies the services or personnel to be provided on behalf of the applicant organization and the fees to provide these services or personnel.

credentialing

The process of obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization. The process of periodically checking staff qualifications is called recredentialing.

credentials

Evidence of competence, current and relevant licensure, education, training, and experience. Other criteria may be added by a health care organization. Also see competence; credentialing.

data

Facts, clinical observations, or measurements collected during an assessment activity. Data before they are analyzed are called “raw data.”

disaster

See emergency

discharge

The point at which an individual’s active involvement with an organization or program is terminated and the organization or program no longer maintains active responsibility for the care of the individual.

⁵⁴ Pietroni, *Advancing Clinical Governance* (1998). Available at: www.clinicalgovernance.scot.nhs.uk/documents/Clinical_Governance_Definitions.pdf

emergency

1. An unanticipated or sudden occasion, as in emergency surgery needed to prevent death or serious disability.
2. A natural or man-made event that significantly disrupts the environment of care (for example, damage to the organization's building(s) and grounds due to severe winds, storms, or earthquakes); that significantly disrupts care and treatment (for example, loss of utilities such as power, water, or telephones due to floods, civil disturbances, accidents, or emergencies in the organization or its community); or that results in sudden, significantly changed or increased demands for the organization's services (for example, bioterrorist attack, building collapse, or plane crash in the organization's community). Some severe emergencies are called "disasters".

ethical

Conforming to accepted standards of moral, social or professional behavior.

governance

The individual(s), group, or agency that has ultimate authority and responsibility for establishing policy, maintaining quality of care, and providing for organization management and planning. Other names for this group include "board," "board of trustees," "board of governors," "board of commissioners," and "governing body."

harvesting, of organs

Removal of an organ for means of transplantation.

hazardous materials and waste

Materials whose handling, use, and storage are guided or defined by local, regional, or national regulation, hazardous vapors, and hazardous energy sources. Although JCI considers infectious waste as falling into this category of materials, not all laws and regulations define infectious or medical waste as hazardous waste.

health care–associated infection(s) (HAI)

Also known as nosocomial infections. Any infection(s) acquired by an individual while receiving care or services in a health care organization. Common HAIs are urinary infections, surgical wound infections, pneumonia, and blood stream infections.

health care professional

Any person who has completed a course of study and is skilled in a field of health. This includes a physician, dentist, nurse, or allied health professional. Health care professionals are often licensed by a government agency or certified by a professional organization.

IDA

The International Development Association is the part of the World Bank that helps the world's poorest countries. Established in 1960, IDA aims to reduce poverty by providing interest-free credits and grants for programs that boost economic growth, reduce inequalities and improve people's living conditions.

indicator

A measure used to determine, over time, an organization's performance of functions, processes, and outcomes.

infectious waste

See hazardous materials and waste

informed consent

Agreement or permission accompanied by full information on the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins the procedure or treatment. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.

in-service education

Organized education, usually provided in the workplace, designed to enhance the skills of staff members or teach them new skills relevant to their jobs and disciplines.

inpatient

Generally, persons who are admitted to and housed in a health care organization at least overnight.

intent statement

A brief explanation of a standard's rationale, meaning, and significance, noted in this manual under the heading Intent. Intent statements may contain detailed expectations of the standard that are evaluated in the on-site survey process.

invasive procedure

A procedure involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body.

job description

Explanation of an employment position including duties, responsibilities, and conditions required to perform the job.

leader

An individual who sets expectations, develops plans, and implements procedures to assess and improve the quality of the organization's governance, management, clinical, and support functions and processes. The leaders described in these standards include at least the leaders of the governing body; the chief executive officer and other senior managers; departmental leaders; the elected and the appointed leaders of the medical staff and the clinical departments and other medical staff members in organizational administrative positions; and the nurse executive and other senior nursing leaders.

licensure

A legal right that is granted by a government agency in compliance with a statute governing an occupation (such as physicians, nurses, psychiatry, or clinical social work, or the operation of a health care facility).

measure

1. To collect quantifiable data about a function, system, or process (one "measures").
2. A quantitative tool. Also see "indicator"

medical equipment

Fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals.

medical record

See patient record/medical record

medical waste

See hazardous materials and waste

medication

Any prescription medications; sample medications; herbal remedies; vitamins; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; and intravenous solutions (plain, with electrolytes and/or drugs).

medication, high-risk or high-alert

Those drugs that carry a risk for errors that can lead to significant adverse outcomes.

medication error

Any preventable event that may cause inappropriate medication use or jeopardize patient safety. Also see sentinel event.

mission statement

A written expression that sets forth the purpose, or "mission," of an organization or one of its components. The generation of a mission statement usually precedes the formation of goals and objectives.

monitoring

The review of information on a regular basis. The purpose of monitoring is to identify the changes in a situation. For example, the health information specialist of the district health management team reports every month the cases of meningitis occurring in villages at risk.

multidisciplinary

Including representatives of a range of professions, disciplines, or service areas.

near miss

Any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a "near miss" falls within the scope of the definition of an adverse event. Also see adverse event.

nosocomial infection(s)

See health care-associated infection(s)

organizational chart

A graphic representation of titles and reporting relationships in an organization, sometimes referred to as an "organogram" or "organization table."

patient record/medical record/clinical record

A written account of a variety of patient health information, such as assessment findings, treatment details, progress notes, and discharge summary. This record is created by physicians and other health care professionals.

plan

A detailed method, formulated beforehand, that identifies needs, lists strategies to meet those needs, and sets goals and objectives. The format of the plan may include narratives, policies and procedures, protocols, practice guidelines, clinical paths, care maps, or a combination of these.

policy

A plan or course of action adopted by the organization intended to influence or determine decisions.

primary source verification

Verification of an individual health care practitioner's reported qualifications by the original source or an approved agent of that source. Methods for conducting primary source verification of credentials include direct correspondence, documented telephone verification, or secure electronic verification from the original qualification source or reports from credentials verification organizations that meet requirements.

privileging

The process whereby a specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization, based on evaluation of the individual's credentials and performance.

procedure

Step-by-step instructions on how to perform a technical skill.

process

A series of actions (or activities) that transform the inputs (resources) into outputs (services). For example, a rural health education program will require that staff develop an education strategy, develop educational materials, and deliver the education sessions.

program

Services designed to meet the needs of a particular patient population

protocol

Scientific treatment plan or study outline—including types of trial participants, schedule, procedures, medications and dosages, etc.—for using an experimental procedure or a new treatment with the intent of measuring human applications.

qualified individual

An individual or staff member who can participate in one or all of the organization's care activities or services. Qualification is determined by the following: education, training, experience, competence, applicable licensure, law or regulation, registration, or certification.

quality of care

The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Dimensions of performance include the following: patient perspective issues; safety of the care environment; and accessibility, appropriateness, continuity, effectiveness, efficacy, efficiency, and timeliness of care.

recruiting

Seeking; normally new employees or other members of an organization.

risk management program

Clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

root cause analysis

A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. Also see sentinel event.

safety

The degree that the organization's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, or visitors.

scope of practice

The range of activities performed by a practitioner in a health care organization. The scope is determined by training, tradition, law or regulation, or the organization.

scope of services

The range of activities performed by governance, managerial, clinical, and support personnel.

security

Protection from loss, destruction, tampering, or unauthorized access or use.

sentinel event

An unanticipated occurrence involving death or major permanent loss of function.

side effect

Pharmacological effect of a drug, normally adverse, other than the one(s) for which the drug is prescribed.

staff

As appropriate to their roles and responsibilities, all people who provide care, treatment, and services in the hospital (e.g. medical staff and nursing staff), including those receiving pay (e.g. permanent, temporary, and part-time personnel, as well as contract employees), volunteers, and health profession students.

clinical staff

Are those who provide direct patient care (physicians, nurses, etc.)

nonclinical staff

Are those who provide indirect patient care (admissions, food service, etc.)

standard

A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and service.

transfer

The formal shifting of responsibility for the care of a patient from (1) one care unit to another, (2) one clinical service to another, (3) one qualified practitioner to another, or (4) one organization to another organization.

utility system

Organization-wide system and equipment that support the following: electrical distribution; emergency power; water; vertical and horizontal transport; heating, ventilating, and air conditioning; plumbing, boiler, and steam; piped gases; vacuum systems; or communication systems, including data-exchange systems. May also include systems for life support; surveillance, prevention, and control of infection; and environment support.

variation

The differences in results obtained in measuring the same event more than once. The sources of variations can be grouped into two major classes: common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.

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