Essentials of Patient Safety

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The first step to proper healthcare

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Preface

Every hour of every day, patients and healthcare providers are affected by the decisions they make and their consequences, especially in the event of adverse results. Mediocre healthcare as well as the aftermath of healthcare mistakes have affected lives - sometimes directly, at other times indirectly. With the intention of bringing safety and quality to the forefront of healthcare in the Kingdom of Saudi Arabia, we have prepared this book. Even though this book has been prepared in a very brief manner, we intend to publish a second edition in the near future which will elaborate more on each section described; perhaps even include more topics as well.

In each section, there will be clinical scenarios that describe various issues and literature regarding patient safety and quality healthcare. Due to the complex nature of healthcare, we provide awareness of the multiple aspects that determine the quality and safety of healthcare as well as patient, nurse, and systems outcomes. Each of these 14 Sections presents clinical scenarios, learning objectives and key points along with references that will be very beneficial to the readers. Patient safety and quality care are at the core of healthcare systems and processes and are fundamentally dependent upon all healthcare practitioners as a team.

To achieve goals in patient safety and quality, and thereby improve healthcare throughout this nation, healthcare practitioners must assume the leadership role.
Introduction

Millions of patients suffer harmful injuries or death every year due to medical errors.¹ Behind these numbers lie the stories of many damaged lives, not to mention the billions of Saudi Riyals that are spent on prolonged hospital stay, corrective procedures, income loss, disability care and litigation, resulting from unsafe care.

Over the past decades, the Saudi healthcare system has introduced several measures in an attempt to improve patient safety nationally, such as the establishment of the following: Saudi Commission for Healthcare Specialties (SCFHS), the Saudi Central Board for Accreditation of Healthcare Institutes (CBAHI), and the Saudi Food and Drug Authority (SFDA) to name few initiatives. Recently, as part of the Saudi Vision 2030 initiatives, the Saudi Ministry of Health (MOH) is working on establishing a body called ‘Saudi Patient Safety Center (SPSC)’. This body is will be responsible for establishing the National Strategy to improve patient safety and reduce medical errors/harm through several strategies that engage the healthcare system’s stakeholders.

Recently, SCFHS has introduced CanMeds as the essential component that the postgraduate training and evaluation revolves around. One of the most important competencies integrated in CanMeds is Patient Safety. CanMeds, the initiative of the Royal College of Physicians and Surgeons in Canada, is a framework that outlines the different roles that should be held by a physician (Fig. 1).

This book is meant to be a practical guide for residents and fellows in the area of

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¹ Reference number should be included or replaced with a citation.
patient safety. Majority of the section titles were picked in accordance with the Patient Safety Curriculum Multi-Professional Guideline published by the World Health Organization (WHO). Each section starts with a clinical scenario (that resembles real-life cases), followed by brief description of the pertinent points related to the chapter topic, and finally each chapter ends with a summary of take home messages (Key Points) that are required for the trainee.

References
Section 1 - What is Patient Safety?

Clinical Scenario
You have been accepted to Urology Residency Programme, just a couple of months back. Today was your first day in the Operating Room (OR) helping one of the Senior Urologist in the hospital. The patient was a 45-year-old male who was scheduled to undergo a radical right nephrectomy for renal cell carcinoma. Before the procedure started, the OR nurses wanted to do a ‘time-out’ (see section 4), however, the consultant urologist was angry with the delay that took place in the holding area as well as epidural administration and told the nurse who started going through the standardized process of ‘time out’ to “Shut-up, we all know that we are doing a right nephrectomy!”.

“Time-out is important for patient safety”, the circulating nurse told the Urologist. The Urologist replied by saying, “I have been practicing urology for more than 30 years, and I don't need a lecture about my patient’s safety from a nurse!”.

The Urologist went through the case doing a beautiful and neat radical right nephrectomy with minimal blood loss. The whole procedure took only 2 hours. While fascia was closed and you were about to close the skin, the Senior Urology Resident entered the OR in a panic and told the Urologist the Following: “Doctor, I think we did the wrong procedure. This patient (Mr. Mohammed Alhazmi) had a renal cell carcinoma of the left kidney. The next patient on the list (Mr. Mohammed Alharbi) is the one who has right renal cell carcinoma!”.

“What are we going to do now?” said the Urologist.

Learning Objectives
1. Define patient safety.
2. List and describe the six quality dimensions of the Institute of Medicine (IOM).
3. Explain why safety is the leading quality dimension of the IOM.

Patient Safety Definition
‘The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare.’
The IOM sets out six dimensions for quality (Fig. 2), with safety leading the way as the dimension that is perhaps most critical to patients and their families.

- **Safe**: Avoiding injuries to patients from the care that is intended to help them.
- **Effective**: Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.
- **Patient-centred**: Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- **Timely**: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
- **Efficient**: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equitable**: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.¹

**Key Points**
1. Patient safety is the most important dimension of the IOM’s quality dimensions as it serves as the foundation for healthcare quality.
2. The IOM’s six quality dimensions are interdependent and complementary.
3. Patient safety is the responsibility of everyone in the healthcare facility.

**References**
Clinical Scenario
Dr. Almarwani is a 55-year-old Internist who has been practicing Internal Medicine for more than 30 years. Last year, the hospital board hired a new CEO with a mandate to improve quality and patient safety. One of his first decisions was to sign a multi-million SR riyals contract to buy an Electronic Health Information System (HIS). “I don't understand why we waste all this money on this computer system” Dr. Almarwani told himself.

Part of the preparation for launching the new HIS included training of staff on how to use the Electronic Health Record (EHR), however, Dr. Almarwani hated every minute of it. “It is much easier and safer to write the medication orders directly on the paper” said Dr. Almarwani.

Two months went by after the EHR was fully implemented in the hospital. “I remember the exact day like it was yesterday” recalls Dr. Almarwani. “Here's how he remembers the events of that day: I was running late in the morning clinic and had to run to the medical ward to write the admission orders for a patient who was just been admitted under my name that morning with a diagnosis of urinary infection (UTI). She was a 60-year-old female, known to have diabetes mellitus (DM), and high blood pressure, both controlled with medications. She had no known allergy, or that’s what I thought. I wrote ciprofloxacin 400 mg IV twice a day for 7 days duration. For whatever reason, the computer wouldn't accept my orders. I kept trying and trying with no luck. And then I realized that each time I clicked on the ‘Order’ icon, a warning came up at the top of the screen. The warning indicated that the medication cannot be ordered due to allergy. I kept complaining that this computer system was wasting my time and wrongly added an allergy list that the patient did not have!

Out of frustration, I went and asked the patient whether she had allergy or not and was shocked to find out that she had an anaphylactic reaction to ciprofloxacin 11 years ago! I went back and reviewed her history in the EHR,
and found out that she had a clear documented allergy to ciprofloxacin, in the form of anaphylaxis!

Dr. Almarwani finished his story by saying the following, “I could have killed that lady if she had gotten the ciprofloxacin. The only reason I could not order it was because the computer would not allow me since it was already documented as an allergy!”

Learning Objectives
1. To understand and explain the significance of human factors in systems and process design.
2. To understand the concept of Human-Machine Interface, Human-Environment Interface, Human-Human Interface, and Human-Software Interface.
3. To describe examples of important concepts in the application of human factors, engineering to improve patient safety.

Human Factors Definition
Human factors is a body of knowledge about human abilities, human limitations, and other human characteristics that are relevant to design. Human factors engineering is the application of human factors information to the design of tools, machines, systems, tasks, jobs, and environments for safe, comfortable, and effective human use.¹

Understanding human factors and the impact of their

Figure 3 - Organizational and human factors in healthcare systems (from Moray, 2000)
interplay on safety is very important for healthcare workers. There is an interesting field called ‘human factors engineering’ that is focused primarily on creating an environment that ‘makes doing the right things easy to do and the wrong things difficult to do’. Moray came up with a framework that explains interplay between: individuals, microsystem (within healthcare facilities), and the larger surrounding environment. Based on Moray’s model, the patient is placed at the center with the other factors surrounding him (Fig. 3).

One of the important concepts to understand in human factors engineering is the interface between different components, e.g. Human-Machine Interface, Human-Environment Interface, Human-Human Interface, and Human-Software Interface.

Outside the healthcare industry, human factors engineering has long been utilized to improve safety. Here are some of the industries where human factors engineering has been very effective: aviation, oil and gas, as well as space industry. The healthcare industry is considered a late comer when it comes to the application of human factors engineering.

A very useful strategy to improve Patient Safety is the introduction of ‘forcing functions’ at the level of the interface. Forcing functions: is a feature of the system design that prevents medical errors and/or harm from taking place. Here are some forcing functions examples:

- Inability to order a medication included in the allergy list using a Computerized Physician Order Entry (CPOE); see the clinical scenario above.
- Inability to order a medication without entering the patient’s weight using a Computerized Physician Order Entry (CPOE).
- Inability to use the electrosurgery pen, in case the electrode pads are not 100% attached to the skin.

**Key Points**

1. Human factors is a very important discipline that deals with the relationship of humans (healthcare professionals) with their environment
Section 2 - Human Factors and Patient Safety

(patients and families, medical devices, computers).

2. Human factors engineering is the application of human factors information to the design of tools, machines, systems, tasks, jobs, and environments for safe, comfortable, and effective human use.

3. Forcing functions: is an important example of human factors engineering that prevents medical errors and/or harm from taking place.

References
Section 3 - Understanding Systems and Effect of Complexity on Patient Care

Clinical Scenario
A 25-year-old obese patient has been recently admitted to the Intensive Care Unit (ICU) with the diagnosis of severe acute biliary pancreatitis. He developed acute respiratory distress syndrome (ARDS), and acute renal failure (ARF). He is intubated and on maximum ventilatory settings. In addition to starting haemodialysis for ARF, he is getting total parenteral nutrition (TPN), and is on multiple medications.

Here are the medical teams involved in his care:
- ICU Medical staff
- General Surgery
- Nephrology
- Infectious Diseases
- Endocrinology
- Respiratory Therapy
- Dietician
- Physiotherapy
- Nurses
- Social Workers
- Clinical Pharmacist

The above scenario is an example of how complex the care of some patients can get. How can we reduce risk to patients in complex situations?

Learning Objectives
1. To understand how systems thinking can improve patient safety and minimize patient adverse events.
2. To understand Donabedian’s model regarding systems.
3. To understand the impact of system’s complexity on patient safety and how this can be mitigated.
4. To explain why a systems approach to patient safety is superior to the traditional approach

According to Donabedian model, a system consists of structure/inputs, processes, and outputs/outcomes (Fig. 4).¹

The system is comprised of:
- Resources (structure) that are processed (process) in various ways (assessment, diagnosis, treatment) to generate outcomes.
- Outcomes:
  - Output (e.g., immunization), which in turn can produce:
    - Effects (e.g., immunity) on those using them, and longer term, more indirect impacts (e.g., reduced measles prevalence or reduced mortality rates) on users and the community at large

**Structure**
The resources used to carry out the activities:
- Supplies
- Equipment
- Numbers of staff
- Qualifications/credentials of staff
- Work space
- Policies

Example: A 50-year-old male with type I diabetes mellitus (DM), legally blind that presents to the ED with right foot gangrene.
Q. Is this a sign of failure of: Structure, Process, and/or Outcomes?

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Figure 4 - Donabedian’s Quality Framework, Source: sphweb.bumc.bu.edu
A. **Structure:** Family Physician, Endocrinologist, Ophthalmologist, and Dietician

**Process**

Process is the transformation of inputs into outputs

- Series of steps (procedures, operations, activities, tasks), performed repeatedly that turns or act on **inputs** (people, materials) from a “supplier” into **outputs** (products, services, care) for a “customer”
- Process can be simple and short, or complex and long

Clinical process examples:

- Taking history
- Conducting physical exam
- Making diagnosis
- Providing treatment
- Counselling

Example: A 50-year-old male with type I DM, legally blind that presents to the ED with right foot gangrene.

Q. Is this a sign of failure of: Structure, Process, and/or Outcomes?

A. **Process:** Lack of proper teaching about diet, insulin injection, and foot care. Failure to conduct annual funduscopic examination.

**Outcome**

The results of care processes (adverse or beneficial)

Outcomes may sometimes refer to:

- **Outputs:** the direct products or services produced by the process e.g., patients receiving therapy and counselling
- The more indirect **effects** on the clients (changes in knowledge, behaviour, and physiology that result from the outputs. (e.g., reduced case fatality, adjusted blood sugar level)
- **Impacts** are the long-term and still more indirect effects of the outputs.
Example: A 50-year-old male with type I DM, legally blind that presents to the ED with right foot gangrene.

Q. Is this a sign of failure of: Structure, Process, and/or Outcomes?

A. Outcome: Normoglycaemia, blindness, amputations, diabetes ketoacidosis (DKA), and death.

When it comes to system’s complexity, it is important that human factors engineering is implemented throughout the various components of the system to mitigate risk and allow prompt and early recognition of medical errors; hopefully before they cause harm. Strategies like: simplification, standardization, protocols, clinical pathways, and/or clinical practice guidelines are examples of effective strategies to promote patient safety and reduce risk.

**Key Points**
1. According to Donabedian model, a system consists of structure/inputs, processes, and outputs/outcomes.
2. A system is composed of multiple interdependent parts that should function together as a whole.
3. A system’s complexity can have a negative impact on patient safety.
4. A system’s complexity needs to be mitigated with proper clinical risk management strategies and system’s design improvements.
5. It is more productive to adopt system’s approach/thinking (just culture) rather than individual (shame and blame).

**References**
Section 4 - Being an Effective Team Player

Clinical Scenario
“May I have your attention please: ‘Code Blue, Code Blue’ in male medical ward” the switchboard employee announces through the public announcement system twice. Immediately, your Code Blue pager started beeping. You (a Senior Internal Medicine Resident) were just one floor above the male medical ward. As part of the Code Blue team, you started running down the stairs towards the male medical ward. Within 3 minutes, you were inside the patient’s room who just arrested! The nurse tells you the patient was admitted last night with diabetic ketoacidosis (DKA), and was started on treatment. According to the nurse, he was feeling a bit tired before he all of a sudden lost consciousness. CPR was started and patient advanced cardiac life support (ACLS) protocol was initiated. It didn't take too long before the room became very crowded with people (Nurses, Interns, Residents, Medical Students, and other bystanders). People were talking and it became difficult for nurses to hear your requests to give alternating doses of epinephrine and atropine. The code went for 45 minutes with no response and unfortunately, the patient ended up dying despite your great efforts. He was only 24-years-old but had type 1 DM for almost 22 years!

The thing that bothered you the most was the chaos that took place throughout the 45 minutes of the code. “It didn't feel like we were functioning as a team” you told your colleague!

The next time a Code Blue is announced, the most important question to answer is the following:

How can we prevent the situation from becoming chaotic? How can we work as a team?!

Healthcare is delivered by teams, not individuals. Each clinical team is comprised of: physicians, nurses, and allied healthcare professionals. Physicians belong to different clinical departments: Surgery, Medicine,
Paediatrics, as well as Obstetrics and Gynecology to name a few. Clinical departments have multiple smaller units. Each clinical unit (team) is comprised of (in a decreasing order): Consultant, Senior Registrar, Registrar, Residents (Senior and Junior). Not to mention, Clinical Interns, and Medical Students in academic hospitals.

The vast number of individuals involved in a patient’s care makes it essential to have robust *communications amongst* team members to ensure a quality healthcare is provided to patients and minimize medical errors.

Certain units within the hospital are known to have big and complex teams, e.g. the Operating Room (OR), and Intensive Care Unit (ICU), where proper and clear communication is paramount to avoid medical errors. See Fig. 5

![The Operating Room (OR), has large and complex teams.](image)

**Learning Objectives**

1. To know what teamwork exactly means.
2. To realize the value of the teamwork in your practice and its relationship to safety.
3. To practice the teamwork in the clinical activities at various settings such as: clinical ward, ICU, ER, OR to name a few important areas.
There are many tools that improve the effectiveness of teams. For example:

- **Surgical time out**: A safety process that gets done prior to starting the surgery, where the entire team in the OR pause to listen to the circulating nurse saying out loud (in a structured format) the name of the patient, medical record number (MRN), as well as the name of the procedure. The surgeon, anaesthesiologist, and other surgical team members have to verbalise their understanding and agreement with the surgical time out. It involves as well check points just before committing the surgical incision or inserting an invasive procedure/instrument. Check out the surgical safety checklist developed by the World Health Organization (WHO).¹

- **Medication reconciliation**: Standardized review of medications at the time of patients transfer from any unit to another and/or discharge.

- **Hand over meetings**.

- **Debriefings**.

**Key Points**

1. Teamwork is a very essential component of any medical provider communication.

2. Recent complexity of healthcare systems enforced the teamwork concept to take place in order to facilitate medical practice and enhance patient safety.

3. Effective teams practice effective communication techniques.

**Reference**

Section 5 - Learning from Errors to Prevent Harm

Clinical Scenario

“Did you do root cause analysis for the patient we discussed yesterday at the Morbidity and Mortality (M&M) Committee?” The Medical Director asked the Quality Department Head. “We are planning to start the process this afternoon” replied the Quality Department Head.

This was a case of a 45-year-old male who presented to the Emergency Department with one day history of left lower quadrant abdominal pain and fever. He underwent an abdominal and pelvic CT scan with oral and IV contrasts. The diagnosis of uncomplicated sigmoid diverticulitis was made but unfortunately, the patient developed a severe case of contrast nephropathy with acute renal failure, requiring him to undergo dialysis.

“The most important thing to me is: How can we learn from this? How can we avoid such an adverse event in the future? Is it preventable?” The Medical Director asked the Quality Department Head.

Learning Objectives

1. To realize the nature of errors in healthcare and how they happen.
2. To differentiate between the preventable and non-preventable errors as well as consequently how to deal with your staff.
3. To understand the importance of reporting incidents and near misses whether they occur to a patient, family, staff, or visitor as long as it occurs within the hospital amenities.
4. To learn from and communicate the reporting to the concerned staff.

One of the most important objectives of patient safety as a discipline is to learn from errors and prevent future harm. To be able to do that, the healthcare system has to function as an effective ‘learning organization’, i.e., risky behaviours, near-misses, and medical errors have to be reported, analysed, and then take-home messages have to be communicated to the remainder of the healthcare system in an effort to, hopefully, prevent harm from happening.
The most essential role of patient safety reporting systems is to promote patient safety by learning from previous failures and mistakes in the healthcare system. It is well-known that most problems are not just a series of random, unconnected coincidences but rather a result of weak systems, and in many cases, have common root causes that can be identified and rectified. If incidents (adverse events) are not reported and analysed, we risk repeating the same mistakes over and over again. We are all aware of many incidents that take place in nearby healthcare facilities, and sometimes within the same healthcare facility, without everybody learning from them.

**Key Points**

1. Some medical errors are unfortunately inevitable however majority of errors are of preventable nature and can be already prevented or mitigated.

2. Reporting errors whether incidents or near misses are very critical towards patient safety as it provides lessons to staff and consequently learn from these incidents and near misses to improve the system.

3. The paradigm shift in incident reporting may expose the staff for penalty for non-reporting and not the opposite. Health leaders should empower staff to report and to be transparent to improving the performance and not to reveal the name of involved staff. Let’s focus on the system root causes rather individual attribution to errors which is very rare.
Section 6 - Understanding and Managing Clinical Risk

Clinical Scenario
“Have you ever thought about becoming a Clinical Risk Manager?” the hospital CEO asked one of his junior medical staff. “What is clinical risk management?” asked the junior medical staff. “It is an important specialty by which the hospital can decide its priorities based on a risk register related to the clinical activities/scope of service” the CEO answered.

Learning Objectives
1. To know the proper definition of clinical risk management.
2. To understand the basic principles of clinical risk management.
3. To understand some practical risk management tools such as failure mode and effects analysis (FMEA) that can prevent and/or mitigate the risk.

Clinical Risk Management
“It is an approach to improving the quality and safety of healthcare by identifying what places patients at risk of harm and taking action to prevent or control the risks”.\[1\].

There are 4 principles of clinical risk management:
1. Identify risks that could affect patients and/or staff.
2. Assess the likelihood of risk happening: Mild, moderate, and severe.
3. Assess the impact of risks: Low, intermediate, and high.
4. Try to eliminate or mitigate risks.

Given the nature of healthcare system, risk is present in almost all levels whether strategic (planning, governance) or operational (direct patient care by frontline staff). Knowing that risk impacts everything in healthcare, it is important that all risks in clinical setting are identified and managed through structured evidence-based strategies that help maintain quality and patient safety.
For clinical risk management to be successful, we have to have full commitment to leadership. See Fig. 7.

The leadership’s role regarding clinical risk management can be summarised in the following:

- Ensuring proper definition and review of organizational risk management policies and procedures in order to make sure they are promoting quality and safety while ensuring that they are in alignment with the organizational mission, vision, and values.
- Identify and assign appropriate accountability and responsibility, for risk management, throughout all levels of the organization.
- Ensuring proper implementation and integration of best practice risk

- Ensuring effective communication of risk management to all stakeholders in the organization.

FMEA, is a very effective risk management strategy tool that gets used frequently in clinical settings to proactively assess certain processes (clinical or administrative).

FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)[2]

**Key Points**

1. With the complexity of healthcare systems, risk management has become an essential part in improving quality and safety for healthcare facilities, patients/families and staff from various hazards.
2. Risk management has 4 main principles: Risk identification, risk likelihood, risk impact, risk mitigation/prevention.
3. Healthcare leadership have to be committed to risk management.
4. Risk management tools such as FMEA can be proactively used to predict risk and prevent it from happening or at least mitigate the risk on occurring.

**References**

2. Institute for Healthcare Improvement. Failure modes and effects analysis (FMEA) tool. Cambridge, Massachusetts, USA. Available online: http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx
Clinical Scenario
You are the Chief Obstetrics and Gynaecology (OB/GYN) Resident in the department. Last week, when you were on-call, you had to handle a high risk case; a 22-year-old primigravida with twins. She never had antenatal care (i.e. un-booked), and presented with shortness of breath and abdominal pain. Her BP was: 170/110, HR: 130, and had bilateral lower limb oedema. Within 15 minutes of her presentation to the ED, she went into tonic-clonic seizure. ABC was done and magnesium sulfate was given to her but unfortunately, despite all of the resuscitative efforts, she ended up dying; both twins were non-viable as well (IUFD: Intrauterine Fetal Demise).

After you finished presenting the case to the departmental Morbidity and Mortality Committee, it was the consensus of the department members that the lack of antenatal care in such a high risk pregnancy (primigravida with twins), was the main contributing factor to this very unfortunate outcome!

“It is about time that we start our Mother and Child Safe Care campaign. We are hoping such an initiative, would dramatically improve the quality of obstetric services in the community” said the OB/GYN Department Head.

Learning Objectives
1. To know that quality improvement is a continuous never ending process.
2. To understand the origin of total quality management.
3. To know the types of quality improvement strategies: External and internal.
4. To implement quality improvement tools; e.g. plan-do-check-act (PDCA) in your hospital or healthcare facility.

More than six decades ago, Edward Deming, who is considered by many as ‘the father of quality improvement’ has proposed a concept called Total
quality management (TQM). TQM promoted continuous quality improvement through systematic analysis and measurement of various processes to promote positive outcomes.

Around 20 years ago, healthcare leaders borrowed strategies from the work of Deming\cite{1} in rebuilding the manufacturing businesses of post-World War II Japan. The TQM adopted the view that the entire healthcare organization has to be committed to quality improvement and patient safety.\cite{2}

Healthcare quality improvement can be divided in two main categories:

- **External**: Mostly, done by the government (regulators).
- **Internal**: Done by healthcare providers.

**External: From outside the organization**
1. Accreditation
2. Certification
3. Licensure
4. Peer-review
5. Mandatory clinical indicators reporting

**Internal: From within the organization**
1. Leadership commitment
2. Morbidity and mortality rounds
3. Internal clinical audits
4. Credentialing and privileging
5. Electronic Health Records
6. Others: Lean Six Sigma, PDCA, etc.

Examples:
- **Licensure**: It is the minimum quality standards. Currently, it is done by the Ministry of Health only for the private sector healthcare facilities.
- **Accreditation**: It is the optimal quality standards. It is intended for all healthcare facilities. See Fig. 8

![Accreditation vs. Licensure](image)
One of the most important tools used for quality improvement in all industries including healthcare is PDCA which is a 4-step success formula as follows:

- **Plan phase**: To prioritize the area for improvement in your system with base-line data collected. Following that, a team is composed of the most involved persons in the process. The team then further studies the area for improvement, variations, root cause analysis or why this problem could happen. Finally, the team formulates an action plan to correct the identified causes.

- **Do phase**: It is about testing the plan done previously by the team and other stakeholders. In other words, to implement the plan on a small scale and not rush into carrying out the plan on larger scale. This step is critical to identify the strengths and weaknesses of the plan when implemented in the real world.

- **Check phase**: In this phase, the team will measure what happened or the outcomes of the small scale implementation that was conducted in the Do phase. This phase helps a lot in improving the plan by doing the necessary changes and modifications. Keep in mind that check phase may take the team back to the ‘plan phase’ once again followed by another ‘do phase’ and then recheck again till the team feels comfortable with the results of the ‘check phase’.

- **Act phase**: This phase means the large-scale implementation of the plan.

You cannot imagine what consistent use of PDCA in your system can lead to in terms of improvement.

**Key Points**

1. Quality improvement is a journey not a destination.
2. Quality improvement has external and internal strategies.
3. External quality improvement strategies e.g. Accreditation, and licensure are done by the regulators.
4. Internal quality improvement strategies e.g. morbidity and mortality rounds are done by the healthcare providers.
5. PDCA, a 4-step success formula, is one of the important quality improvement tools.

References
Section 8 - Patient Empowerment and Community Engagement

Clinical Scenario
“I feel very good about this ‘Ask Me 3’ programme” said the head of the Outpatient Department (OPD). “What is ‘Ask Me 3’?” asked his Administrative Assistant. “Ask Me 3 is a brilliant initiative introduced by the National Patient Safety Foundation (NPSF) in the USA, as an effective strategy for patient and public empowerment” answered the OPD head. He went on to say that ‘Ask Me 3’ involves reminding patients and their families to ask 3 simple questions to their physicians. Here are the questions:
1. What is my problem?
2. What do I need to do?
3. Why do I need to do it?

Reminding patients and their families about it at the point of care would have a positive impact on making the encounter with healthcare workers a more productive one.

Learning Objectives
1. To learn the impact of patient empowerment and community engagement on patient safety.
2. To learn few practical examples of initiatives concerning patient empowerment and community engagement.

Patient-Centred Care
It is care that is “respectful of and responsive to individual patient preference, needs and values”.[1]

In 2005, the WHO established a very important unit called Patients for Patient Safety (PFPS). One of the main objectives of this unit was to empower patients and build their capacity together with their families as informed and knowledgeable healthcare partners.
Section 8 - Patient Empowerment and Community Engagement

Such an initiative is essential in implementing patient-centred care in the Kingdom of Saudi Arabia. The Saudi Patient Safety Centre (SPSC) is going to work through a national patient safety strategy framework. One of the main components of this strategy is using patient empowerment and community engagement as a lever to improve patient safety. Consequently, moving away from the traditional view of the ‘Paternalistic’ patient-physician relationship into the modern view which is ‘Partnership’, where patient-physician relationship is the main focus of the strategy.

Key Points
1. WHO introduced PFPS unit to promote safety through patient empowerment and community engagement.
2. Patient empowerment and community engagement is essential to implement Patient-Centred care.
3. Patient safety would be improved by empowering patients in their healthcare.

References
Section 9 - Infection Prevention and Control

Clinical Scenario
A 70-year-old gentleman was recently diagnosed with right colon cancer based on a colonoscopy screening. His staging workup did not show any signs of metastasis. He was otherwise well, except for diabetes mellitus (DM), which was controlled by oral hypoglycaemic medications. He underwent an uneventful right hemicolectomy.

In the first couple of days postoperatively, the patient seemed to be recovering well as far as the colectomy, but while on the surgical floor, he began showing signs of heart failure. The patient’s IV site had also showed signs of infection with arrhythmia and development of a lesion at the site which was cultured and came back positive for methicillin-resistant Staphylococcus aureus (MRSA). The IV was removed and the patient's MRSA was treated using peripherally inserted central catheter for antibiotic therapy. Over a span of 3-4 days the patient's heart failure signs and symptoms worsened and he became increasingly short of breath. A registered staff nurse assessed him at change of shift and noticed he was pale, diaphoretic and dyspnoeic which is secondary to congestive heart failure. The patient was seen by a cardiologist and an echocardiogram was done which revealed mitral valve regurgitation secondary to infective endocarditis. The patient had to be transferred to the ICU for further management. Subsequently, the patient was prepped for the catheter laboratory for valvular balloon pump insertion as well as for central line insertion. The patient improved with the balloon pump and was scheduled to be transferred to a tertiary care facility the next day for a valve replacement.

The above story is a perfect example of why it is important to follow proper infection prevention and control practices, such as cleaning the skin prior to peripheral IV cannula insertion and keeping the site clean.

Learning Objectives
1. To better understand the concept of infection prevention and control.
2. To abide by the policies, procedures, and updated guidelines of infection prevention and control.
3. To accelerate the awareness of global initiatives for hand hygiene.

Infection prevention and control (IPC) is an essential programme of any healthcare facility’s operation. Many problems could arise from poor IPC practices. Middle East respiratory syndrome coronavirus outbreak, healthcare associated infections (HAI) like central line associated bloodstream infections, and catheter associated urinary tract infections are few examples of HAI.

According to the World Health Organization (WHO), 70% of healthcare professionals and 50% of surgical teams do not practice proper hand hygiene on a regular basis.\[^1\] The WHO chose the day of May 5, as the global infection control day. It is the day for ‘SAVE LIVES: Clean Your Hands’ campaign. Each country is expected to observe this day and hold some practical activities to promote hand hygiene as a very important tool to prevent nosocomial infections.

As part of its commitment to promoting IPC, the WHO launched the First Global Patient Safety Challenge in October 2005. It was called: Clean Care is Safer Care! At the launch, several WHO Member States signed a statement committing themselves to addressing HAI in their country; Saudi Arabia was one of those countries.

The flagship programme for the First Global Patient Safety Challenge was termed Hand Hygiene. The WHO came up with a very effective tool called ‘5 Moments for Hand Hygiene’ See Fig. 10

**Key Points**

1. All healthcare professionals should adhere to proper infection prevention and control practices.
2. 5 Moments of Hand Hygiene is an effective tool introduced by the WHO to remind healthcare professionals about washing their hands.

References


Section 10 - Improving Medication Safety

Clinical Scenario
At 7 pm, a 28-year-old woman has just given birth to a healthy 3 kg baby girl. Both the pregnancy and labour were uneventful.

The treating Paediatrician ordered ranitidine because the baby seemed to be spitting up some saliva (vomiting).

Ranitidine was administered in an age and weight appropriate dose. Within a couple of minutes of the baby receiving the ranitidine intravenously, she became grey and went into cardiac arrest! Code Blue was announced and cardiopulmonary resuscitation was started. CPR continued for 60 minutes but unfortunately the baby girl could not be revived. The time of death was announced at 9:50 pm (less than 3 hours from the time she was born!).

A root cause analysis was carried out and it showed that instead of the baby girl receiving ‘ranitidine’, she got another medication, ‘atracurium’ a powerful muscle relaxant!

“Didn't we implement our look alike sound alike (LA/SA) and high alert medications policies recently” said the CEO angrily?!

Learning Objectives
1. To understand the impact of medication errors on safety.
2. To understand the different strategies that help reduce medication errors.
3. To learn about the concept of high alert medications.
4. To learn about LA/SA concept.

According to the National Patient Safety Agency (currently NHS Improvement), a patient safety incident is defined as: ‘any unintended or unexpected incident which could have or did lead to harm for one or more patients.’ (NPSA, 2007:9)
Medication errors are a major challenge to all countries. It is estimated that they cost more than $42 billion USD in both direct and indirect costs, annually.[1] However, the most serious price patients pay are errors that result in injury or harm. Medication-associated harm has been identified as a threat to patient safety and highlighted system failures that result in patient injury. Unfortunately, there is limited data regarding the true incidence of medication-associated harm, which means that the current burden is vastly underestimated. In response to the serious nature of medication-associated harm, medication safety has been identified as the topic for the third WHO Global Patient Safety Challenge (First was: ‘Clean Care is Safer Care’; Second was: ‘Safe Surgery Saves Lives’) with an overarching goal of reducing medication-associated harm by 50% worldwide by 2022.

Almost, all healthcare professionals deal with medications in one way or another. Whether prescription, transcription or administration; medication processes are complex and carry the risk of errors and/or harm to patients.

Adverse Drug Events (ADE) could take place in any setting whether inpatient or outpatient, within healthcare facilities or at home.

There are three main strategies to improving medication safety inside healthcare facilities:

- Design the system to prevent errors from occurring in the first place.
- Try to make errors more visible if they do occur.
- Design the system to mitigate and minimize the negative impacts of medication errors when they occur, consequently reducing harm to patients.

To improve medication safety, all healthcare facilities should have a LA/SA policy including the list of LA/SA medications and a standardized process of dealing with them. See Fig. 1

Figure 1 - Example of LA/SA “Look-alike vial alert by ISMP” (in this case, the two medications look alike)
Healthcare facilities should also have a clear policy on how to deal with high alert medications (which are medications that pose a heightened risk of causing significant harm if they are used improperly, e.g. heparin or warfarin.

1. In an effort to improve medication safety, the Institute for Safe Medication Practices (ISMP) issues on their website www.ISMP.org, a list of LA/SA and other high alert medications.

**Key Points**

1. Medication errors represent a major problem to patient safety.
2. LA/SA poses a potentially dangerous effect on safety and need clear policies and procedures to deal with them.
3. Healthcare facilities should have clear policies and procedures for high alert medications.

**References**

Section 11 - Patient Safety and Invasive Procedures

Clinical Scenario
Mr. Mohammed Almishal is a 50-year-old gentleman who presented to the Endoscopy Suite for colonoscopy screening. The nurse brought him some papers to sign before the procedure. His Gastroenterologist came in to greet him while he was waiting to be moved into the endoscopy room. “Anything I need to worry about Doc?” asked Mr. Almishal. “It will be a straightforward procedure” answered the Gastroenterologist.

Mr. Almishal underwent the colonoscopy where a polyp was removed from the sigmoid colon. The procedure lasted for 15 minutes, after which the patient was moved into the recovery room.

Two hours later, the patient was discharged to go home. That evening, Mr. Almishal did not feel well and was complaining of abdominal pain. At first, he told himself that this was probably gas pain from having the colonoscopy but that night, his pain continued to get worse and eventually he went to the Emergency Department. He underwent some blood work, abdominal and chest X-rays. The emergency room (ER) doctor came to him with a concerned look on his face. “There is free air under your diaphragm sir. You may have a perforated colon” said the ER doctor. “Perforated colon? Why did anyone not tell me this could happen?” shouted Mr. Almishal. “It says here they told you” answered the ER doctor, while browsing through Mr. Almishal’s medical records. “Have a look here. Isn’t this your signature? It shows here that you signed the informed consent which mentions bleeding and perforation as possible complications” said the ER doctor. “Informed consent? I am sure no one informed me about a possible hole in my colon, otherwise I would have not agreed to have the procedure done. After all, this was only a screening procedure!” said Mr. Almishal.

Learning Objectives
1. To understand the potential impact of invasive procedures on safety.
2. To understand the benefit of proper informed consent on patient safety.
3. To learn few examples of invasive procedures and their relationship to safety.

Many invasive procedures have the potential to cause harm to patients. Harm could come in different shapes and forms, whether physical, emotional, or psychosocial. To help minimize any harm caused by invasive procedures, it is essential that the person doing the procedure adheres to the following:

- **Informed consent**: A proper informed consent should have the following components: The reason for doing the procedure (indications), explanation of the procedure, possible complications, and presence or absence of alternatives to the procedure.
- **Competence to do the procedure**: Having the knowledge, skills, attitude needed to do the procedure safely.

These are the specialties that have invasive procedures as part of the training:

- **Surgical**: General Surgery, Orthopaedics, ENT, Ophthalmology, Neurosurgery, Plastic Surgery, Paediatric Surgery, Urology, and Cardiac Surgery
- Obstetrics & Gynaecology
- **Radiology**: Interventional Radiology
- **Internal Medicine**: Cardiology, Gastroenterology
- **Critical Care**: ICU, NICU, PICU.

**Key Points**

1. Invasive procedures carry an inherent risk to patient safety.
2. Any invasive procedure should be preceded by a properly written and communicated informed consent.
3. Informed consent is essential to patient empowerment and safety.
4. Health professionals are required to perform proper informed consent before performing any invasive procedure.
5. Informed consent is considered a patient’s right, and a very important educational tool for patients.
6. Informed consent should have the following components: The reason for doing the procedure (indications), explanation of the procedure, possible complications, and presence or absence of alternatives to the procedure.
Section 12 - National Patient Safety Improvement Efforts

Clinical Scenario
You are a senior Obstetrics and Gynaecology Resident, the anaesthesiologist just finished intubating a patient who is scheduled to have a myomectomy for fibroids. While you were prepping the skin, the patient all of a sudden became hypotensive. After going through the ABCs, the anaesthesia team ascertained the patient developed an anaphylactic shock secondary to a second generation cephalosporin that was given as prophylaxis. The procedure had to be postponed until the patient stabilizes.

At first, it was thought to be an allergic reaction, but root cause analysis, revealed there was a problem with the whole antibiotics batch that came under that specific lot number.

You ran into the anaesthesiologist the other day and he told you that he had to report this adverse event under the ‘Pharmacovigilance’. “Pharmacovigilance, what is it?” you asked him. “It is a programme introduced by the Saudi Food and Drug Authority (SFDA) that mandates all healthcare facilities to report drug-related adverse events. This is a very powerful strategy to improve medication safety” the Anaesthesiologist replied.

Learning Objectives
1. To identify the different national organizations concerned with patient safety in Saudi Arabia and their roles.

Since the establishment of the Ministry of Health (MOH) in 1950, the Saudi government has achieved some important milestones in its journey towards reducing medical harm and improving patient safety situation in the Kingdom of Saudi Arabia.

In 1992, the Saudi Commission for Healthcare Specialties (SCFHS) was established as the body that regulates the licensure of healthcare professionals. In 2001, the national health accreditation was started by the creation of
Makkah Region Quality Program, which later was expanded to include all the regions in the Kingdom of Saudi Arabia resulting in the creation of the Central Board of Accreditation for Healthcare Institutions (CBAHI) in 2005. In 2003, the SFDA was established as the main regulator for food, drugs, and medical equipment. See Fig. 11

![Milestones: Quality & Patient Safety in KSA!](image)

**Figure 11 - Patient Safety Milestones in Saudi Arabia**

All the above activities have shown the Saudi government’s commitment to improving the patient safety situation in the country, which culminated this year by announcing the establishment of the Saudi Patient Safety Center (SPSC). This centre will play a pivotal role in promoting patient safety by coordinating with all stakeholders (regulators, providers, and public) to minimize preventable harm to patients.

**Key Points**
1. The Saudi government established many regulatory health organizations to promote quality and patient safety.
2. Some of the organizations promoting patient safety in the Kingdom include the following: MOH, SCFHS, CBAHI, and SFDA.
3. Recently, the Saudi government announced its plan to establish the SPSC as the organization responsible for coordination national patient safety improvement efforts.
Clinical Scenario
As the Chief Resident in the Radiology Department, your Department Head gave you an important task in the upcoming Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) team’s accreditation visit scheduled for next week. In addition to being part of the Radiology Department staff, CBAHI surveyors were going to interview, you were also responsible for accompanying the surveyors as a guide through the different units of the Radiology Department.

You were having lunch with a group of Radiology Residents who you’re your friends, when suddenly a heated debate took place about accreditation. Half the group were sceptical of accreditation and thought it was just a big act! The other half thought it was helpful but could not clearly cite the evidence when asked to do so!

At that moment, it hit you, ‘What is the impact of accreditation?’ and you started asking yourself.

Learning Objectives
1. To understand the definition of accreditation and its positive impact on healthcare system.
2. To know about the ESR program introduced by CBAHI, as Saudi Arabia’s National Patient Safety Goals.

The CBAHI is the Kingdom’s national accreditation organization. Its mandate is to accredit all healthcare facilities in Saudi Arabia. CBAHI has 3 principal functions:
1. Establishing health quality standards.
2. Surveyors recruitment and development.
3. Healthcare facilities survey to assess compliance with standards.[1]
CBAHI’s Vision
To become the regional leader in improving healthcare quality and safety.

CBAHI’s Mission
To promote quality and safety by supporting healthcare facilities to continuously comply with accreditation standards.

CBAHI’s standards are grouped into the following main areas:
- Leadership
- Medical
- Nursing
- Provision of Care
- Infection Prevention and Control (IPC)
- Medication Management (MM)
- Human Resources
- Quality and Patient Safety
- Labs
- Patient and Family Rights/Education
- Facility Management and Safety (FMS)

CBAHI has 7-member teams: Leadership Surveyor, Medical Surveyor, Nursing Surveyor, MM Surveyor, IPC Surveyor, Lab Surveyor, and FMS Surveyor.

According to Donabedian Model, CBAHI standards are either: Structure, process, or outcomes standards.

CBAHI Milestones
- 2001: Makkah Region Quality Program (MRQP) was established.
- 2005: CBAHI was established as a ‘Voluntary’ programme.
- 2006: 1st edition of CBAHI National Hospital Standards were established.
- 2012: 2nd edition of CBAHI National Hospital Standards was certified by the International Society for Quality in Healthcare (ISQua).
• 2013: Cabinet of Ministers Decree changed CBAHI’s official name to the “Saudi Central Board for Accreditation of Healthcare Institutions”, also CBAHI’s accreditation became ‘Mandatory’.\[2\]

(source: CBAHI’s website)

**Essential Safety Requirements (ESR)**

In an effort to improve patient safety across the Kingdom, CBAHI introduced Essential Safety Requirements (ESR).

ESR is a list of 20 national standards for hospitals. They are considered to be the basic conditions that must be present to ensure patient safety. Hospitals will not be granted accreditation status without showing evidence of full compliance with ESR. ESR are considered the Kingdom’s National Patient Safety Goals.

**Key Points**

1. CBAHI is Saudi Arabia’s national healthcare accreditation organization.
2. CBAHI’s mandate is to develop standards for different types of healthcare facilities (hospitals, primary care centres, ambulatory centres, medical laboratories, blood banks), recruit/develop surveyors, and perform surveys in preparation for accreditation.
3. CBAHI conducts orientation programmes regarding the standards and survey process for healthcare facilities in the country in addition to public training programmes concerning the healthcare quality and patient safety.
4. ESRs are top priority standards developed by CBAHI to assess the healthcare facilities against these must-have prerequisites.
5. ESRs are the Kingdom’s National Patient Safety Goals.

**References**

2. Saudi Central Board for Accreditation of Healthcare Institutions website [http://www.who.int/gpsc/5may_advocacy-toolkit.pdf?ua=1](http://www.who.int/gpsc/5may_advocacy-toolkit.pdf?ua=1)
Section 14 - Research to Improve Patient Safety

Clinical Scenario
“I am not happy with the patient safety culture that we have in this hospital” the Surgical Ward Staff Nurse told the Nursing Supervisor. “Why do you say that? I thought our staff had very good safety training!” said the Nursing Supervisor. “What I meant was that we have many nurses that don't feel empowered to stand up to some risky behaviours from some physicians. Things like handling patients without washing hands, performing some bedside procedures under poor aseptic conditions to name a few examples” said the Staff Nurse.

“This is why I think we should perform a Patient Safety Culture Survey” added the Surgical Ward Staff Nurse. “What is Patient Safety Culture Survey” asked the Nursing Supervisor. “It is a very valuable type of Patient Safety Research that any organization uses to understand the hidden forces that govern patient safety within a healthcare facility in order to identify what could be done to improve the safety culture” answered the Staff Nurse. “Great. Let's go ahead and do it” said the Nursing Supervisor.

Learning Objectives
1. To understand the importance of patient safety research.
2. To acknowledge the continuous efforts in patient safety research in Saudi Arabia.
3. To identify some other research gaps healthcare professionals/trainees can recommend or contribute to.

Adverse events are not infrequent in the Saudi healthcare system, but the exact magnitude of the problem have yet to be determined because only a few studies in Saudi Arabia have addressed medical errors. Currently, CBAHI is conducting a study with the WHO to assess the country’s nationwide prevalence of adverse events. The results of this study should have a significant impact on patient safety in the country.
The Ministry of Health (MOH) has a reporting system for sentinel events (SE) where hospitals (MOH and Private) are required to report on a list of sentinel events within 48 hours of their occurrence (See Fig. 12). Despite the problems with underreporting, such a programme does provide value in drafting corrective action plans and strategies to minimize harm and promote safety. The MOH requires that each hospital that suffers an SE, submits a root cause analysis within a week from the incident (See Fig 13).

**Figure 12** - Nation-wide sentinel events (2010 - 2014) based on the MOH reporting system, Saudi Arabia

**Figure 13** - Root causes of the sentinel events between the 2012 - 2015, MOH, Saudi Arabia
Since the early 90s of the last century, adverse events to patients have started to be thoroughly studied.

The Harvard Medical Practice Study, published in February 1991, initiated this wave of patient safety research in the world. They use a structured retrospective medical records review to obtain results; followed by large-scale epidemiological studies in this field using the same methodology. EMRO study about the adverse events that occurred to hospitalized patients in 8 Middle Eastern developing countries was one example of this methodology. Last thing to be considered was that not all studies have been published or communicated to the international literature.

These are the patient safety research methodologies:
1. Retrospective record review methodology,
2. Incident reporting systems
3. Routine hospital data
4. Claims and complaints analysis
5. Central national/regional audits or enquiries

The aforementioned methods have all played a part in understanding the patterns and burden of patient safety in many countries.

**Key Points**
1. Research in patient safety has been initiated by Harvard Medical Practice Study published in early 1991 followed by a lot of research in measuring patient harm in the healthcare systems.
2. CBAHI, in Saudi Arabia, published a study about the prevalence of Sentinel Events in the country 2016.
3. In collaboration with WHO, CBAHI conducted the first study in Saudi Arabia to measure the adverse events and the preventability in the hospitals of the country.
4. A lot of research is still needed in patient safety filed in Saudi Arabia and the region.