

King Saud University
College of Business Administration
Department of Health Administration
Masters` Program

***PA 505 –The Quality of Healthcare First
Semester 1436/ 1437***

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IMPROVE PATIENT SAFETY

Patient Safety

After reading this chapter, you will be able to

- ❖ **Contrast quality management and patient safety,**
- ❖ **Recognize measures of patient safety,**
- ❖ **Use prospective risk analysis to improve the safety of healthcare processes,**
- ❖ **Use root cause analysis to improve patient safety,**
- ❖ **Describe patients' role in reducing adverse events.**

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- ❖ These are actions undertaken by individuals and organizations to protect healthcare recipients from being harmed by the effects of health-care services; also defined as freedom from accidental or preventable injuries produced by medical care.
- ❖ **Medical errors** are preventable adverse events or near misses during provision of healthcare services.

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Patient safety and professional ethics

- ❖ **People working in health care are bound by legal standards and professional ethical principles to do whatever they can to promote patient safe environment.**

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- ▶ ***Principles of Biomedical Ethics*** four core ethical principles:
 1. ***Autonomy*** (self determination or privacy)
 2. ***Nonmaleficence*** (not harming or do no harm)
 3. ***Beneficence*** (promote good)
 4. ***Justice*** (fairness)

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- ▶ Although all healthcare professionals espouse the principle “**First, do no harm,**” patients are occasionally harmed by caregivers’ actions—or inaction.
- ▶ Despite continued efforts by healthcare organizations to improve patient safety, however, potentially avoidable safety problems still exist.

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The 2011 National Healthcare Quality Report in the USA revealed several opportunities for improvement in HCOs (AHRQ 2012):

- ❖ **Sepsis, a severe bloodstream infection, occurs in 5 percent of emergency surgery patients and 2 percent of elective surgery patients.**
- ❖ **Almost 4 percent of hospitalized patients experience mechanical adverse events associated with central venous catheter placement.**

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The 2011 National Healthcare Quality Report in the USA revealed several opportunities for improvement (AHRQ 2012):

- ❖ **Approximately 150 deaths occur per 1,000 discharges with complications potentially resulting from care during hospitalization.**
- ❖ **Of long-stay nursing home residents, 11 percent developed pressure sores.**
- ❖ **An estimated 1.7 million healthcare-associated infections occur each year in hospitals, leading to approximately 100,000 deaths.**

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- ❖ Healthcare facilities have had **safety** programs in place for many years.
- ❖ The purpose of these programs is to provide an environment in which **hazards** are eliminated or minimized for employees, staff, patients, and visitors.
- ❖ Safety is promoted through several activities, including risk management, emergency preparedness, hazardous materials management, radiation safety, environmental safety and hygiene, security, and preventive maintenance.

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Risk Management

- ❖ **Risk management** is the understanding of legal principles to prevent legal liability and responsibility.
- ❖ The investigation and analysis of the frequency of causes of adverse incidents that injure patients, visitors, and staff and the development of measures to minimize risk and redesign systems to protect the financial assets of the organization against consequences and the costs of risk

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- ❖ **Historically, however, no organized approach has been taken to prevent medical errors that cause harm to patients.**
- ❖ **The prevention of mistakes in healthcare is not new, but it has long been taken for granted.**
- ❖ **Error prevention was essentially entrusted to individuals:**
- ❖ **The physicians, nurses, technicians, clerical staff, and others who provide care for patients or support patient care activities were expected to do the right thing—correctly—every time.**

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- ❖ When an error occurred, the person involved usually was blamed for being careless, incompetent, or thoughtless.
- ❖ Organizations focused on training and hiring competent people, believing they would be less likely to make mistakes.
- ❖ This reliance on healthcare professionals and support staff to perform faultlessly was misguided.

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- ❖ While the development of a competent staff is important, poor working conditions can make even the finest professionals prone to error.
- ❖ **Faulty system design** is also a factor in most medical incidents.
- ❖ While an individual may have made a mistake, the **root cause** of that mistake likely lies in the design of the patient care **system**.

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- ❖ Healthcare professionals' decisions and actions are influenced by multiple factors, including the **organizational culture**, personal attitudes and qualifications, the composition of the work group, the physical resources available, and the design of **work systems** and processes.
- ❖ Consider the event described in Critical Concept 8.1.

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Critical Concept 8.1. Patient Care Event Resulting in Patient Harm

- ❖ **A patient tells the radiology technician that she is feeling heat from the X-ray equipment. The technician dismisses the patient's concerns and continues with the exam because the X-ray procedure states that the machine should be turned off only if the equipment's malfunction warning bulb lights up. Because the mechanical warning system failed, the patient suffers burns.**

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Critical Concept 8.1. Patient Care Event Resulting in Patient Harm

Although the radiology technician erred by not responding to what the patient was saying, this mistake was encouraged by faulty equipment and a departmental procedure that failed to account for the possibility of an equipment malfunction. Healthcare professionals watch for errors and usually catch and correct them before patients are harmed, but if faulty system design causes numerous little mistakes, healthcare professionals can easily pass over a few without noticing.

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- ❖ **Healthcare systems that depend on perfect human performance are fatally flawed.**
- ❖ **Mistakes can be made by anyone. In general, they result from circumstances beyond the conscious control of the person who errs.**
- ❖ **To improve patient safety, systems and processes must be examined to see if changes are needed to reduce the chance that a patient will be harmed.**

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Patient safety improvement initiatives are focused primarily on the clinical aspects of patient care, but the same techniques used to protect patients from harm can be applied to any work activity, including billing, patient registration, plant maintenance, and housekeeping.

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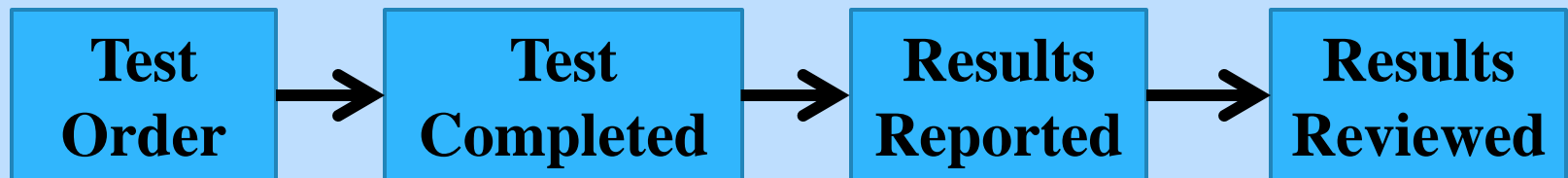
Preventing Mistakes

- ❖ **Most mistakes are not intentional but occur because a process is complex.**
- ❖ **Even simple patient care processes are complex in terms of the variables involved.**
- ❖ **Consider, for example, the hospital process of obtaining a blood specimen for laboratory testing illustrated in Exhibit 8.1.**

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Preventing Mistakes

- ❖ **Exhibit 8.1. High-Level Flowchart of Hospital Laboratory Testing**



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Preventing Mistakes

- ❖ **The variables in this process include the method used to order the test (handwritten or electronic), the patient's location, the method used to collect the specimen, the type of vials used to store the blood, the method of laboratory analysis, the manner in which results are reported, and many more.**
- ❖ **Considering all of these factors, the results are likely to be inaccurate at least some of the time.**

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Preventing Mistakes

- ❖ Unfortunately, elimination of all possible chances for error is not always feasible.
- ❖ In such cases, patient care processes should be redesigned so that the chances of harmful errors are minimized.
- ❖ By adding safeguards to a process, the likelihood of causing patient harm can be greatly reduced.

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Examples of patient care mistakes and safeguards

Mistakes

The phlebotomist starts to draw blood from the left arm of the patient, not knowing that the patient has just undergone a mastectomy on the left side and should not have blood drawn from that arm.

Safeguard

A red wristband on the patient's left arm alerts the phlebotomist that the left arm should not be used for blood draws.

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Examples of patient care mistakes and safeguards

Mistakes

A hospital dietary worker delivers an unmarked food tray to a patient room. He assumes he is delivering the tray to the correct room because it is the last tray on the cart and the patient in the room is the only patient in the nursing unit who has not yet received a meal.

Safeguard

A large sign indicating “nothing by mouth” is hung by the patient’s bed. The dietary worker sees the sign and does not leave the food tray for the patient.

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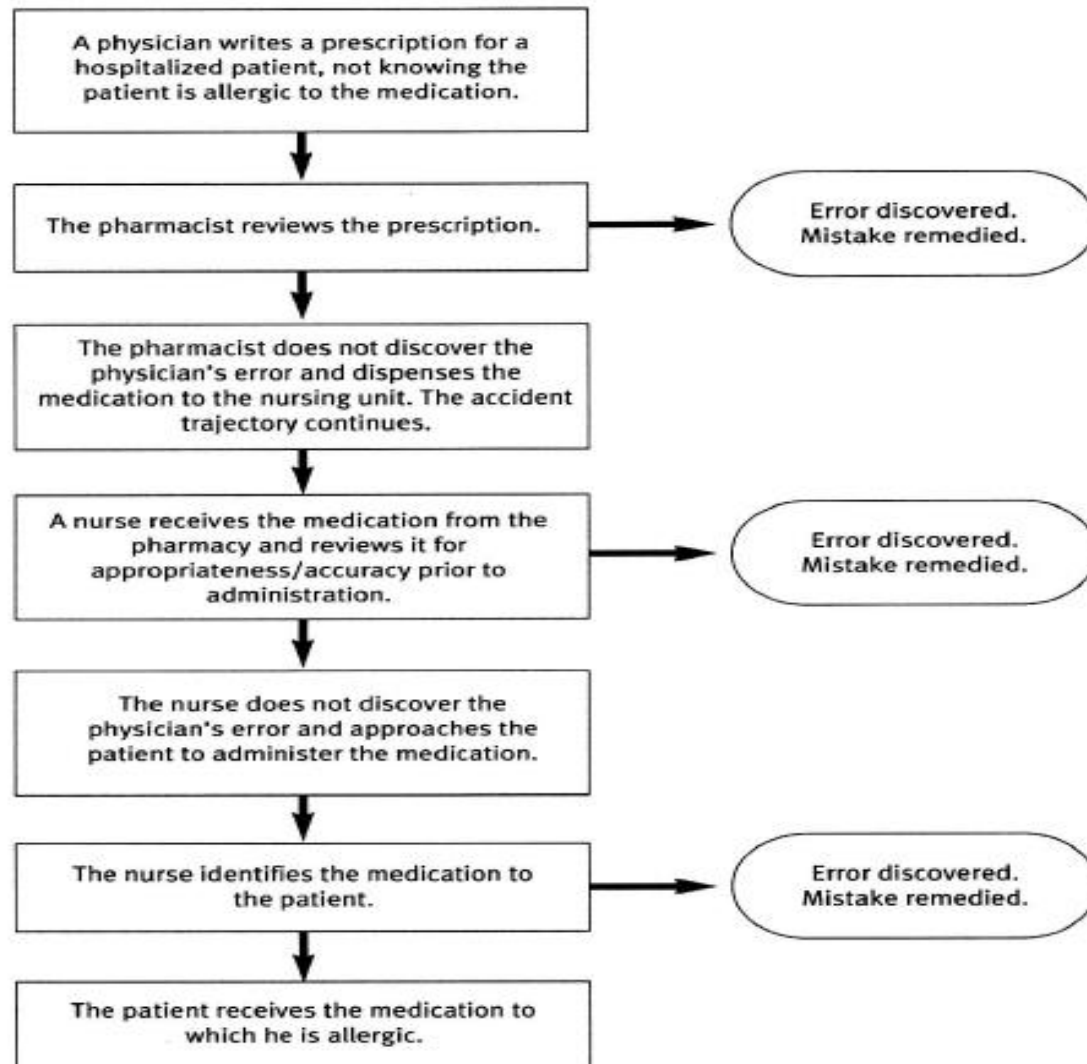
Preventing Mistakes

High-risk activities

- ❖ **Tasks or processes known to be error- prone or that have potential for causing significant patient harm should an error occur.**
- ❖ **High-risk activities usually incorporate several safeguards. Exhibit 8.3 is an illustration of a hospital's medication administration process and errors that could occur at various stages.**

EXHIBIT 8.3 IS AN ILLUSTRATION OF A HOSPITAL'S MEDICATION ADMINISTRATION PROCESS

EXHIBIT 8.3.
Hospital
Medication
Administration
Process



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Measuring Patient safety

- ❖ The purpose of patient safety performance measurement is to discover and fix problems before an **adverse event** occurs.
- ❖ Patient safety measures are no different from other healthcare performance measurements.
- ❖ Examples of patient safety topics and the system-level measures used to assess corresponding performance are shown in Exhibit 8.4.

EXHIBIT 8.4. EXAMPLES OF PATIENT SAFETY TOPICS AND THE SYSTEM-LEVEL MEASURES USED TO ASSESS CORRESPONDING PERFORMANCE

EXHIBIT 8.4. Patient Safety Topics and System-Level Measures

<i>Topic of Interest</i>	<i>Measure</i>
How often do patients develop an infection as a result of surgery?	Number of surgical cases in which patients developed an infection following surgery per 100 procedure days
How often do patients develop an infection as a result of a central venous catheter?	Average number of hospitalwide central venous catheter infections per 1,000 catheter line days
How often do patients develop pneumonia as a result of being on a ventilator?	Rate of pneumonia detected per 1,000 ventilator days in the intensive care units
How often do patients have an adverse reaction to a medication?	Average number of adverse drug events per 1,000 doses
How often do patients experience a sentinel event?	Number of sentinel events per 10,000 adjusted patient days*
How often do patients experience a fall?	Number of falls per 10,000 adjusted patient days*
How often do patients experience a medication error?	Number of medication errors per 1,000 doses of medication

* Adjusted patient days: quantity calculated by the financial department that is based on the sum of inpatient days and financial equivalent patient days, which is determined by applying a formula to outpatient treatments, thereby accounting for inpatients and outpatients in this quantity.

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Measuring Patient safety

- ❖ **Incident reports**, sometimes called occurrence reports, are paper or electronic forms used to document potential or actual patient safety concerns.
- ❖ Employees are asked to complete a report whenever a patient is involved in an event that has caused or has the potential to cause injury.

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Measuring Patient safety

Examples of reportable events:

- ❖ Error that occurs during the delivery of patient care (e.g., medication administration mistake, treatment error)
- ❖ Development of a condition seemingly unrelated to a patient's disease (e.g., infection, pressure ulcer)
- ❖ Adverse or suspected adverse reaction to a treatment, medication, or blood transfusion
- ❖ Serious injury or unexpected death of a patient
- ❖ Patient fall

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Measuring Patient safety

- ❖ The **incident reporting** process is not standardized among healthcare organizations.
- ❖ Facilities may define **reportable events** differently or use different mechanisms to document events.
- ❖ To streamline the reporting process, some organizations have created web-based **incident reporting** tools and telephone hotlines.

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Measuring Patient safety

- ❖ **Prompt identification of patient incidents enables an organization to immediately investigate the circumstances of the incident and, if necessary, modify the process or environment to prevent similar occurrences in the future.**
- ❖ **Incident reports** are also used to identify patterns of events that indicate unsafe conditions.
- ❖ **Various departments and committees in the organization review these reports on a regular basis.**

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Measuring Patient safety

- ❖ To ensure that staff members report patient incidents, managers must strive to maintain an environment that encourages people to report mistakes, admit problems, have different opinions, and exchange ideas.
- ❖ Experience has shown that when employees fear reprisal, they are less likely to report patient incidents; as a result, the organization loses a valuable source of information about patient safety (NAHQ 2012).

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Measuring Patient safety

The following five practices are important to increasing the quantity and quality of employee incident reports:

1. **Protect people involved against disciplinary proceedings (as far as is practical).**
2. **Allow confidential reporting or de-identify the reporter.**
3. **Separate the agency or department collecting and analyzing the reports from those that have the authority to institute disciplinary proceedings and impose sanctions.**
4. **Provide rapid, useful, accessible, and intelligible feedback to the reporting community.**
5. **Make reporting easy.**

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Measuring Patient safety

- ❖ An example of a form used to report the circumstances surrounding a patient fall is shown in Exhibit 8.5.
- ❖ The individual who witnessed, first discovered, or is most familiar with the incident usually completes the report.
- ❖ The reporter does not include his judgment on the cause of the event, only facts.
- ❖ The names of witnesses to the event and the employee involved in the incident (if not the reporter) are typically included in the report.

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Measuring Patient safety

- ❖ **Some countries have a standardized national reporting system for patient safety incidents.**
- ❖ **They also have national network of patient safety organizations (PSOs) for the purpose of gathering and analyzing information about patient incidents from providers in all HSOs.**
- ❖ **To qualify as a PSO, an organization must have expertise in identifying risks and hazards in the delivery of patient care, determining the underlying causes, and implementing corrective and preventive strategies.**

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LEARNING POINT Improving Patient Safety

Patient safety is one component of an organization's quality management activities. The same basic cycle of **measurement**, **assessment**, and **improvement** used in other quality management activities applies to patient safety initiatives. The safety of patient care is measured, the measurement results are assessed, and improvements are made.

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Improving Patient Safety

Projects aimed at improving patient safety follow the same steps as any other project does:

- 1. Define the improvement goal.**
- 2. Analyze current practices.**
- 3. Design and implement improvements.**
- 4. Measure success.**

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Improving Patient Safety

- ❖ Any of the models described in Chapter 5 can be used to improve patient safety.
- ❖ Two improvement models not described in Chapter 5 are used by healthcare organizations for the explicit purpose of making patient care safer:
 1. Failure Mode and Effects Analysis
 2. Root Cause Analysis

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- 1. Failure Mode and Effects Analysis (FMEA)** is a proactive risk assessment technique that involves a close examination of a process to determine where improvements are needed to reduce the likelihood of adverse events . The technique is considered proactive because the improvement project is undertaken to prevent an adverse event.

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Improving Patient Safety

Failure Mode and Effects Analysis (FMEA)

The **FMEA** technique promotes systematic thinking about the safety of a patient care process in terms of the following questions:

- ❖ What could go wrong?
- ❖ What will be the result if something goes wrong?
- ❖ What needs to be done to prevent a bad result when something does go wrong?

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Failure Mode and Effects Analysis (FMEA)

Risk or hazard potential is part of every process. The goal of an FMEA project is to find these hazards and make process changes to reduce the risk of error.

FMEA is a formal and systematic assessment process, but individuals informally use FMEA almost every day. Here is an example:

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Failure Mode and Effects Analysis (FMEA)

- You want to go and visit your family in *Abha* after the final exams, expecting to buy an airlines ticket at the airport.
- *What could go wrong:* The flight to Abha will be sold out.
- *Result:* You will miss the trip, and you will be disappointed because you have waited several months for this visit.
- *Prevent the bad result:* Buy a ticket in advance.

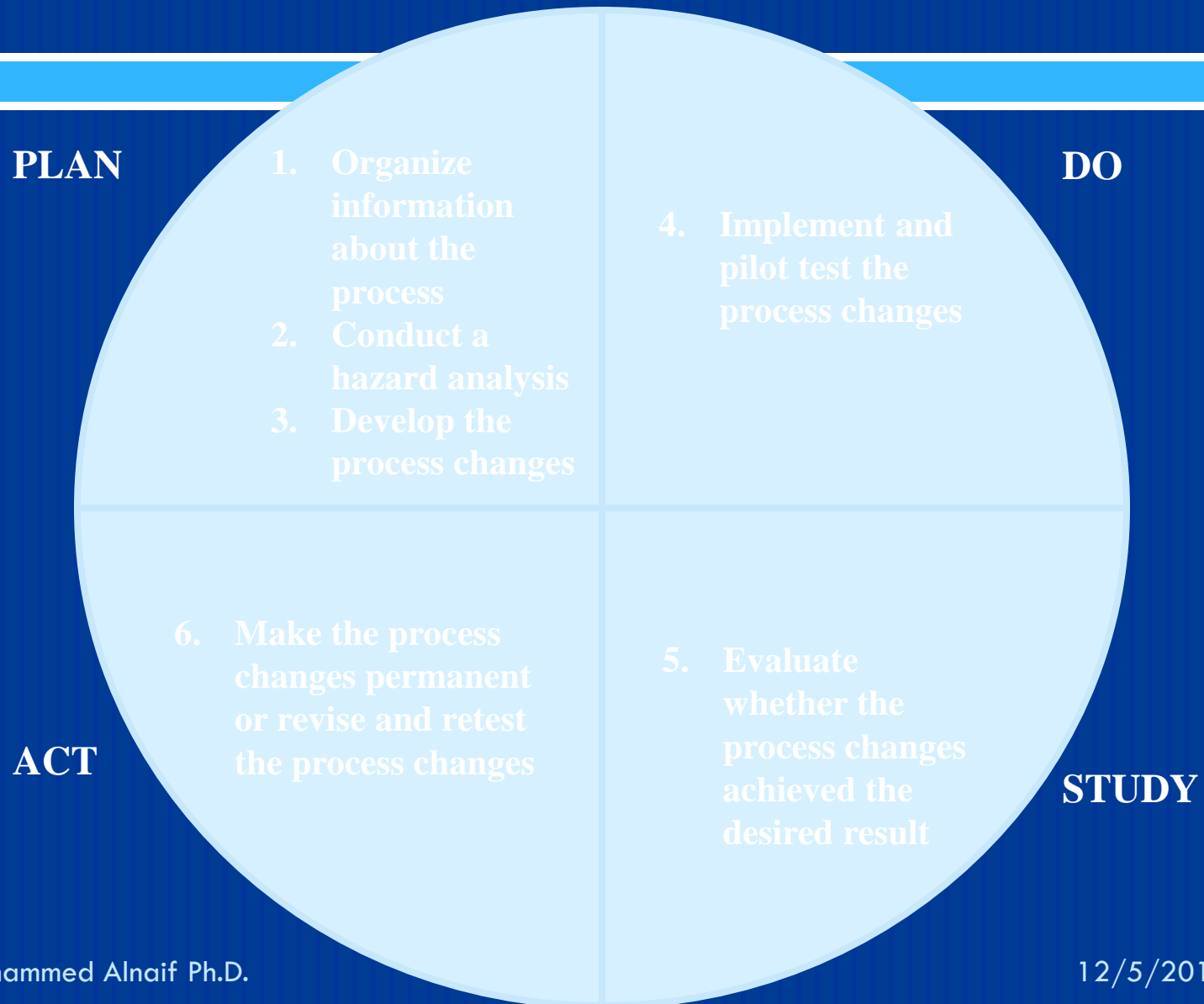
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Failure Mode and Effects Analysis (FMEA)

- ❖ The **six steps** of an **FMEA** project are sequenced similarly to those of the **Plan-Do- Study-Act** improvement model (see Exhibit 8.7).
- ❖ **FMEA** projects are undertaken by a team that has experience with the process under study; the team regularly carries out the activities and knows where the potential for error exists.
- ❖ To gain a fresh perspective, the **FMEA** project team may also include people who have no experience with the process.

Exhibit 8.7. FMEA Steps in Relationship to PDSA Cycle



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Failure Mode and Effects Analysis (FMEA)

- ❖ An FMEA project begins with the development of a clear understanding of the process.
- ❖ The team develops a flowchart to visualize each step.
- ❖ Next, the team conducts a **hazard analysis**, which involves a brainstorming session to develop a list of all failures that could occur in each step.
- ❖ The first two steps in the process of ordering outpatient laboratory tests for patients are shown in Exhibit 8.8.
- ❖ Listed below each step are the failure modes or errors that could occur.

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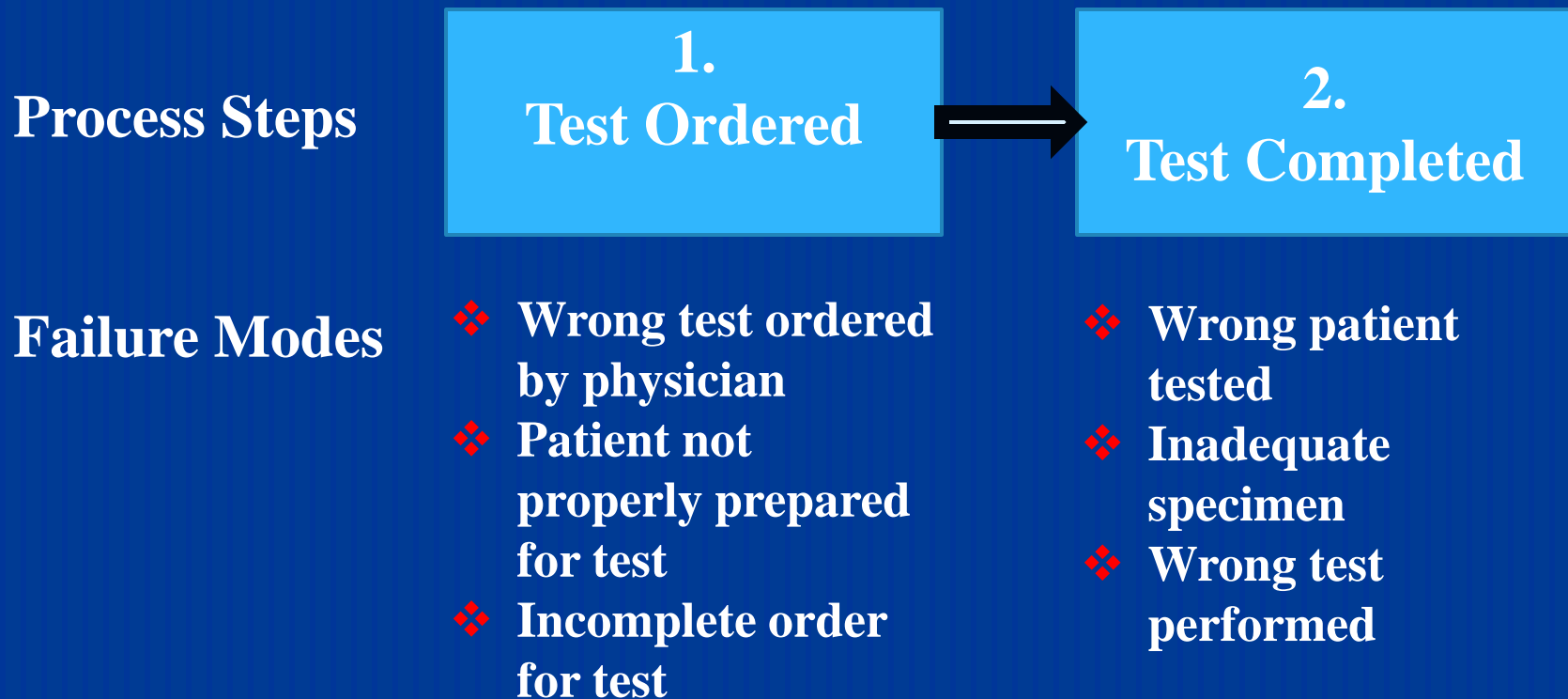
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Failure Mode and Effects Analysis (FMEA)

- ❖ After all potential failure modes or mistakes have been identified for each step; the team determines the risk or criticality of each failure mode to prioritize it for elimination. Different schemes are used to calculate risk.
- ❖ In some **FMEA** models a criticality score is assigned to each potential failure on the basis of the following criteria:
 1. ***Frequency***: the probability that the failure will occur
 2. ***Severity***: the degree of harm the patient will experience if the failure occurs
 3. ***Detection***: the likelihood that the failure will be detected before patient harm occurs

Exhibit 8.8. First Two Steps in Outpatient Laboratory Testing Process and Failure Modes

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Failure Mode and Effects Analysis (FMEA)

- ❖ Each criterion is rated on a scale of 1 to 5, with 1 being the lowest possible rating and 5 the highest.
- ❖ Once the rating process is complete, a **criticality** score is assigned to each potential failure.
- ❖ This score is calculated as follows:
$$\text{Frequency} \times \text{Severity} \times \text{Detection}.$$
- ❖ The potential failures with the highest criticality scores are considered the **critical failures** most in need of prevention.

Exhibit 8.9 is an FMEA worksheet for the first step in the laboratory test-ordering process

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Steps	Potential Failures	Effects	Frequency	Severity	Detection	Criticality
Test Ordered	Wrong test ordered by physician					
	Patient not properly prepared for test					
	Incomplete order for test					

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Failure Mode and Effects Analysis (FMEA)

- ❖ Once the critical failures are identified, the team determines what would cause these potential failures so that preventive actions can be taken.
- ❖ The following list provides examples of questions the team can ask about the critical failures to discover their root causes:
 - ❑ Who might experience this problem?
 - ❑ Would all the people who do the work experience it, or just some of them?
 - ❑ What is the specific problem?
 - ❑ Where might the failure occur?
 - ❑ Where is the failure unlikely to occur?

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Failure Mode and Effects Analysis (FMEA)

- ❖ The remaining steps of the FMEA project are the same as those of any improvement project.
- ❖ The process changes are implemented and tested to determine whether the desired results have been achieved.
- ❖ If the process changes reduce or eliminate the possibility that the critical failures will occur—the desired result of an FMEA project—they are incorporated into the process.

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Root Cause Analysis (RCA)

- ❖ **A structured process for identifying the underlying factors that caused an adverse event.**
- ❖ **Safety improvement teams use RCA after an adverse event has occurred to determine system deficiencies that led to the event.**
- ❖ **The six steps involved in RCA follow the Plan-Do-Study-Act Cycle**

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Root Cause Analysis (RCA)

- ❖ Since 1996, organizations accredited by The Joint Commission have been required to conduct an RCA following a **sentinel event**.
- ❖ A **sentinel event** is an incident in which death or serious harm to a patient occurred.
- ❖ The word **sentinel** reflects the egregiousness of the injury (e.g., surgery performed on the wrong patient) and the likelihood that investigation of the event will reveal serious safety problems

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Root Cause Analysis (RCA)

- ❖ The Joint Commission also encourages facilities to conduct an RCA following a **near miss**.
- ❖ A **near miss** is an incident that did not result in death or injury but could have; only by chance was the patient not harmed.
- ❖ These regulations require healthcare facilities to conduct formal investigations of serious adverse events.

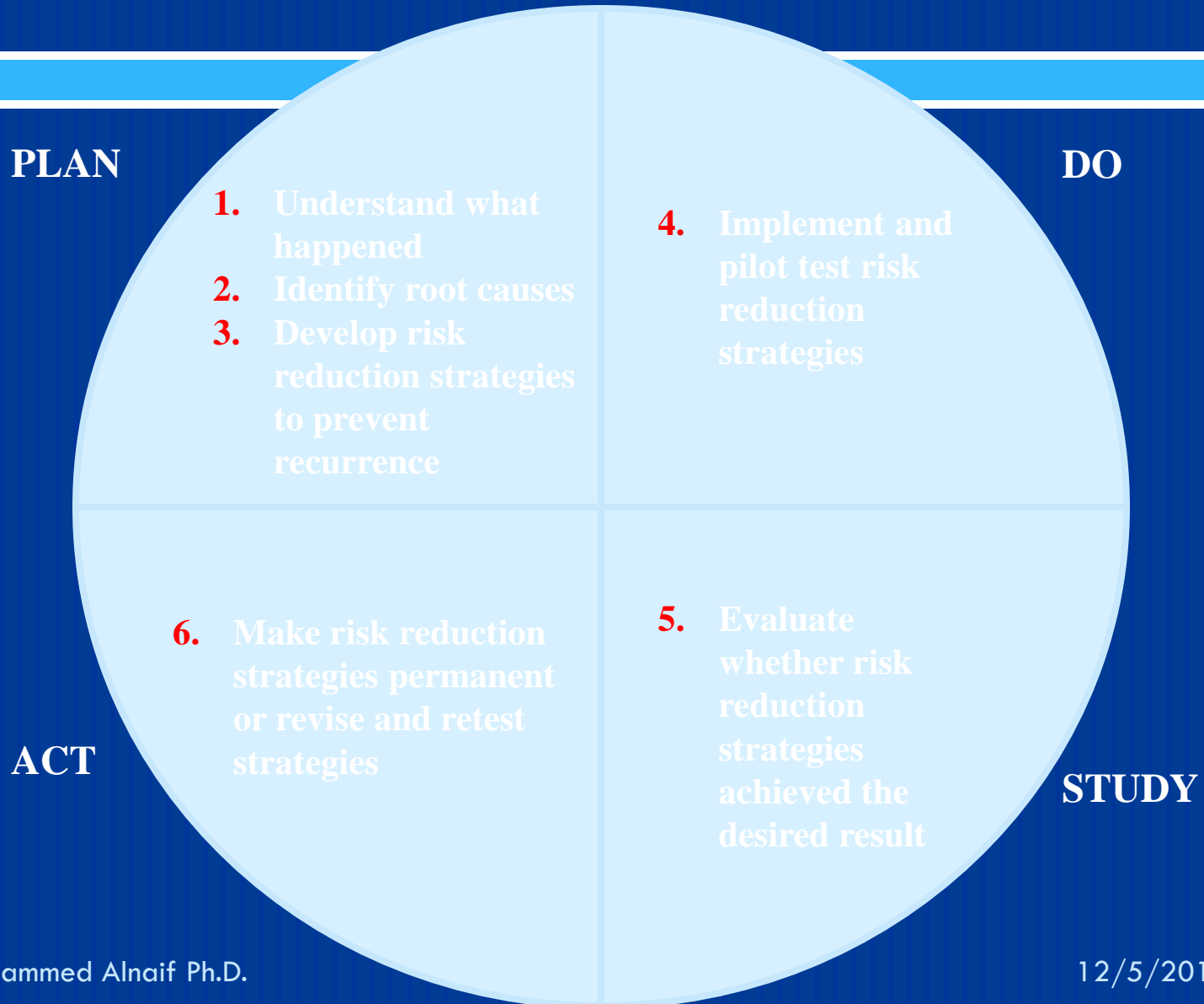
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Root Cause Analysis (RCA)

- ❖ **RCA begins promptly after a sentinel or adverse event takes place.**
- ❖ **As for all improvement projects, a team of people is assembled to conduct the investigation.**
- ❖ **The team is composed of those who witnessed the event and those with expertise in the processes involved.**
- ❖ **In some organizations, managers or senior leaders may also work with the RCA team.**
- ❖ **Ideally, the team leader is someone who has experience using the RCA investigation technique.**

Exhibit 8.11. The six steps involved in RCA follow the Plan-Do-Study-Act Cycle



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Root Cause Analysis (RCA)

Critical Concept 8.2. Page 199 is a description of a wrong-site surgery event. An arthroscopy should have been performed on the patient's right knee, but the procedure was done on his left knee.

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LEARNING POINT Root Cause Analysis (RCA)

Root cause analysis is an accident investigation technique undertaken to find and fix the fundamental causes of an adverse event. It is similar to any improvement method that follows the steps of the Plan-Do-Study-Act cycle.

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LEARNING POINT Consumer Involvement in Patient Safety

Patients and family members can promote their safety by speaking up when they encounter a potentially unsafe or out-of-the-ordinary activity, process, or alarm. In some organizations, patients and family members are involved in internal quality management efforts.

THANK YOU