PREVENTABLE ADVERSE EVENTS

ABSTRACT:

Patient safety in healthcare improvement and quality involves a wide range of activities to meet ever-increasing demands, which involves multiple stakeholders focused on healthcare safety, efficiency, and ethical outcomes.

Healthcare in the United States and countries represented by the World Health Organization (WHO) are actively engaged in health reform processes to improve health care quality initiatives. Despite increased advances in healthcare initiatives, in particular as it relates to standard organizational safety practices, failures continue to result in serious reportable medical or diagnostic errors. Health organizations focused on acute care and outpatient services are continuously confronted by material and human barriers to effective health team participation and accountability to meet the growing demands in healthcare, such as best practice education of health professionals, data collection and reporting. Professional roles are evolving in medicine and nursing with quality at the center of health system reform and trends to promote safe outcomes.

This article will discuss the definitions of patient safety in detail and the classification of various types of medication and diagnostic errors, which are both preventable and not. There will be an emphasis on the different recommendations and methods on how to improve the major problems in healthcare.

TARGET AUDIENCE AND LEARNING OBJECTIVES:

The target audience for this course is nurses and advanced practice nurses or other licensed health providers interested in issues of quality healthcare. Course learning goals for the learner includes being able to:

1. Explain the different medical errors and interventions intended to reduce them.
2. Differentiate between a preventable vs. non-preventable adverse event.
3. Identify processes to investigate the extent of drug-related medical errors.
4. Explain the different barriers in hands off-transfers by medical professionals.
5. Describe patient chart review processes of errors recorded by healthcare providers.
6. Identify the extent of inappropriate prescription to both child and adults.
7. Explain the importance of the Agency for Healthcare Research and Quality (AHRQ) reports on patient safety and of accepted AHRQ Hospital Patient Safety Indicators (HPSI).
8. Identify the common types of adverse events of post-discharge patients and recommendations to improve them.
9. Explain processes to investigate diagnostic errors in both clinical and hospital settings to detect the warning signs for possible errors, and ways to improve it.
10. Describe the key elements of electronic health records, and its importance to information flow between patients and healthcare providers.
1. PATIENT SAFETY DEFINITIONS
   Medical Errors
   Preventable vs. Non-preventable adverse event

2. DISCONTINUITIES IN CARE
   Hand-offs/transfers
   Interdepartmental communication

3. MAJOR AND COMMON HOSPITAL ADVERSE EVENT AND MEDICAL ERROR STUDIES
   Drug-related
   Non drug-related: adults vs. pediatrics

4. INSTITUTE OF MEDICINE AND AHRQ REPORTS ON PATIENT SAFETY
   Hospital Patient Safety Indicators (HPSI)
   Accepted Agency for Healthcare Research and Quality (AHRQ) HPSI
   Surgical
   Post-Op
   Medical

5. COMMON TYPES OF POST-DISCHARGE ADVERSE EVENTS
   Drug related
   Nosocomial
   Procedure related
   Pressure Ulcers
   Diagnostic Errors

6. DIAGNOSTIC ERRORS AND MISDIAGNOSES
   Statistics
   Types

7. CLINICAL SCENARIOS: INPATIENT/POST-DISCHARGE ADVERSE EVENTS AND MEDICAL ERRORS
   Adverse event clinical definitions (Unavoidable vs. Preventable)
   Unavoidable adverse event example
   Preventable adverse event example

8. RECOMMENDATIONS FOR IMPROVEMENT
   System Failures
   Improving transitional care
   Medication reconciliation
   Improved Electronic Medical Record (EMR) strategic use

9. IMPROVED SCREENING METHODS TO IDENTIFY PATIENTS WITH ADVERSE EVENTS

10. ON REFLECTION
The terms “adverse medical event”, “adverse medical outcome” or “medical error” are used in the lay press, scientific literature and mainly the web – to explain the cause or result of an injury to a patient because of a medical intervention, and not just any underlying medical illness. Ultimately, a preventable adverse event occurs *unintentionally* to a patient from any kind of healthcare management. [1]

Most adverse outcomes are due to failures traced to the healthcare delivery system as well as human error. Some adverse events occur due to unforeseen safety risks or as a result of new emerging technologies; whereas, others occur due to system failures such as poor communication, poor documentation, poor staffing or mismanagement of resources that lead to errors. Errors can also happen due to lack of necessary education to support health professional skills or knowledge-base, or may result due to fatigue, stress, or inability to keep up with the demands and flow of the healthcare system. [1]

**PATIENT SAFETY DEFINITIONS**

Patient safety during a patient’s course of care in a hospital or clinic setting has become a very important issue in healthcare delivery today. There are numerous studies that reveal unsafe practices with devastating outcomes occur in healthcare, and health organizations and providers have not appropriately addressed approximately 50% of various types of adverse events shown to be preventable. [2] Other studies have discussed solutions to improve patient safety by focusing on organizational team functions and their *culture of safety*, which is defined by the healthcare organization as the result of individual and group values, competencies, attitudes and behavior. These are the ones that influence patient safety. [2]

In order to achieve a positive safety environment, the organization should first evaluate their current culture on patient safety. Most *positive* safety culture organizations are bounded with openness and trust and values of the importance of safety. [2]

One of the biggest reasons why there are threats to patient safety is due to understaffing, most especially when it comes to nurses. It was researched that Dutch hospitals have shortages in operating room personnel, which is just about 23% of the population in the Netherlands, since this is “not the most satisfying or popular job” for nurses. [13]

Other reasons have been studied and reported. In Canada, clinic medical providers who participated in a research study revealed four major types of self-reported medical errors or incidents as the following: documentation (41.4%), medication (29.7%), clinical administration (18.7%) and clinical process (17.5%). It shows that medication has the largest percentage of threat for the health of the patient. [17]

Triage is also one of the threats to patient safety, but this is hardly noticed nor documented in any adverse effect studies. According to Smits et al., it was reported that there are approximately 9 out of 27 incidents (33%) identified in record review of primary care patients that were related to triage. The telephone triage nurses in Norway correctly
classified 82% of acute and 74% of urgent cases based on written documents. Based on this study, it was determined that nurses and physicians themselves perceive triage as a major threat to patient safety. Triaging patients for appointment is a difficult task that needs to be carefully analyzed and balanced. There should be regular trainings in triage as well as clear communication between physicians and nurses about triage processes in order to avoid medical errors. [17]

In order to promote patient safety in a primary care setting, identification of the most common types of errors should be prioritized first. There are different researchers who have studied different types of methodologies just to identify these errors; and, some approaches included reviewing medical reports from doctors, interviewing adult patients, doing observational prospective studies, and reviewing malpractice cases in hospitals. These different methodologies are the reasons for difficulty in comparing the rates of errors or even adverse events. Despite obstacles identified with the different methodologies, similar error categories and events have been identified to provide a classified system. According to one study, the following are the number of events reported: [29]

- 117 errors for 15 physicians in 83 visits across 7 offices over 3 half-day sessions
- 221 incidents from interviews with 38 patients asking them to recall events that occurred at any time in the past
- 344 incidents from 42 physicians over 20 weeks
- 940 incidents over 2 weeks across 10 practices
- 805 incidents occurring between October 1993 and June 1995 from 324 physicians
- 5,921 incidents from claims data for over a 15-year period
- 1,223 incidents from 4 articles published 1995-2002

**Types of error causing adverse events**

There are different types of errors that causes adverse events; and in one research it shows that the most common type of adverse event was caused by therapeutic error (34.2%, range 4-49%), followed by diagnostic error (19.1%, 12-41%) and operative adverse event (18.4%, 7-47%). *Therapeutic error* means that a diagnosis has been made but an appropriate therapeutic response was either not ordered or not delivered. *Diagnostic error* indicates either failure to make a diagnosis or to do so in a timely manner or the failure to make a correct diagnosis from provided information. *Operative adverse events* occurred more in the peri-operative period but this also includes those occurring during the actual procedure. [37]

The literature has little information in terms on what types of patient safety events the health care professionals or health care setting should focus or agree upon. There are diverse ways to focus attention on safer outcomes in terms of learning strategies, and creating change and improvement; and, there is no concise universal definition of what constitutes a medical error. In fact, the way front-line health care providers or managers understand and categorize different types of errors, adverse events and near misses and the kinds of events believed to be valuable for learning are not well understood. [50]
There are focus groups that may be utilized by a health organization to research how people in different healthcare settings understand the concepts of the different types of Patient Safety Events (PSEs) to gather knowledge and learning. Generally, a short questionnaire is developed by the focus group and mailed to each study participant for investigation and validation. In one such focus group, health care staff along with their managers divided adverse events into simple categories of major and minor events, and based upon harm or harm potential. Four themes surmounted from the gathered data, and are as follows: [50]

(1) Incidence study categories are problematic for those working in organizations;
(2) Preventable events should be the focus for learning;
(3) Near misses are an important but complex category, differentiated based on harm potential and proximity to patients;
(4) Staff disagrees on whether events causing severe harm or events with harm potential are most valuable for learning.

Misconception of patient safety terminology can lead to confusion for health care providers, creating barriers to needed reflection on a range of different PSEs for additional knowledge on ways to reduce harm and, ultimately, improve patient safety at the point of care. [50]

One study explored how front-line providers and managers categorized different types of errors, adverse events and near misses (collectively referred to here as patient safety events, or PSEs) with a focus on the kinds of events useful to a range of healthcare professionals. By learning, it involves processes of identifying PSEs, analyzing their causes and taking corrective action to reduce the reoccurrence of similar events. The researchers were able to examine how front-line providers and managers categorize PSEs and their reasons for doing so: [50]

First, organizations that intend to learn from PSEs will be presented with bigger opportunities, given past studies reporting on the incidence of adverse events among hospitalized patients. A classification scheme made by frontline healthcare providers and managers can help organizations make excellent decisions on which events to study. [50]

Second, it was discussed that self-reports tend to identify serious events with bad outcomes, while other events go unrecognized. When events are corrected before harm occurs, there is a potential system vulnerability, and important loss of learning opportunity. There must be a focus on those events with greater opportunities to create strategies and lessen harm on patients. [50]

Third, there are doubts about the way front-line providers or managers categorize types of PSEs and which type(s) are believed to present valuable learning opportunities with one recent exception. In one article some researchers found that PSEs are sometimes "defined away," thereby decreasing the opportunities to learn on how patient safety can be improved. [50]
Finally, studies gave priority to a lack of a common language and inconsistency in error identification that hinders systematic reporting of PSEs. It also limits the potential to learn from these events since the possibility for learning is directly related to how potentially dangerous events are understood, interpreted and categorized. [50]

**Medical Errors**

“Primum non nocere” or translated as “first, do no harm” is the universal medical caveat attributed to Hippocrates. Over the last 20 years, the U.S. healthcare system had positively increased awareness of the seriousness of medical errors. That is why in the year 2000, the Institute of Medicine (IOM) published its landmark study, “To Err is Human: Building a Safer Health System”. From here, it was reported to have raised the specter of Americans delaying and/or avoiding necessary health care intervention because of the knowledge and/or fear of being subjected to widespread medical errors. [7] Medical errors are traumatic for patients and also for healthcare professionals. The public does not realize the full toll medical errors have on healthcare professionals since patients or the victims receive more publicity than those in the healthcare field. [8]

The definition of medical errors may include adverse events or outcomes that can be prevented depending on the medical knowledge of the person involved. These medical errors are better understood as doing an actual harm to a person resulting in any kind of injury, accident or illness - but were also averted by timely intervention. [7] There are effective tools that have been discovered for the prevention of medical errors. [8]

According to Dr. Mamta Gautam, professional burnout symptoms of medical providers and other healthcare staff may initiate a vicious cycle of medical errors that increase burnout. It is then important to also focus on these healthcare professionals to help discuss the feelings and emotions with regards to medical errors and how to move on and continue doing their job. [8]

The concerns about medical errors in the U.S. healthcare system come from three categories: overuse intervention, underuse beneficial intervention and misuse, which is inappropriate intervention. [7] Several decades ago, medical errors were a well kept secret by medical practitioners, but since the release of the report “To err is human”, medical safety and the disclosure of errors have been revealed to the public’s knowledge. [6]

The disclosure of medical providers to medical errors is very important for the public, most especially the patients and other health care professionals. It is a normal reaction that providers may be hesitant to discuss the medical misdiagnosis or errors due to the fear of consequences as well as disciplinary actions or penalty charges they may face. [6]
PROGRAMS TO PREVENT MEDICAL ERRORS

Local Programs

Since the start of the twenty-first century, people became more focused on the quality of health care systems. Hospitals, clinics and even health insurers monitor and keep the data about specific cases or events of patients and treatment outcomes in order to improve their services. There are also several initiatives of implementing a well-designed infection control program, which can reduce nosocomial and acquired infections. [7]

Regional and National Programs

In the U.S., the following national programs known to help in preventing medical errors are the following: U.S. Food and Drug Administration (FDA) which is a mandatory program report for the medicines, vaccines, medical devices, and blood products; Centers for Disease Control (CDC) National Nosocomial Infections Surveillance System which is responsible for health care-related infections; State agencies of New York, Massachusetts, and Florida which monitors health parameters, and non-governmental organizations (NGOs) such as Joint Commission on Accreditation of Healthcare Organizations (JCAHO) oversee medical error reporting programs. [7]

Ideal Medical Error Reporting Programs

There are two programs that are successful in reducing its medical error rates. One is the Department of Anesthesiology and the other one is the US Department of Veterans Affairs. The anesthesiology team became successful by reducing its medical error rate from 25–50 per million patients to something of the order of 4–7 per million patients. This happened due to first initiating a system analysis of errors and then by constantly making improvements on technology, cooperation, simplification, standardization and adoption of the practice guidelines. The same is also the true for the U.S. Department of Veterans Affairs, which has reduced medication errors 70% by introducing a handheld, wireless medication bar coding system [7].

PREVENTABLE ADVERSE EVENT

There are reasons why despite the highest quality care for the patient, medical errors or poor treatment still happen. This is because of the different treatment outcomes or adverse effects that the patients are encountering. It is said that adverse responses to medical care may not necessarily imply the intervention of medical error. [7] Adverse events are “injuries that are related to medical treatment which can be measured by its disability”, while an unpreventable adverse event is mentioned as a “complication that cannot be prevented given the current state of medical knowledge”. [7]
Preventable or avoidable adverse events are defined as "a direct result of failure(s) to follow recognized, evidence-based best practices or guidelines at the individual and/or system level". [1]

The following may cause these avoidable or preventable adverse medical events: misdiagnosis, forgetting to diagnose the patient, a delay in treatment and diagnosis, delay in follow up and poor performance by medical practitioners. These all lead to medical liability. [1]

A study tried to identify the potential causes and contributing factors of preventable adverse drug events (ADEs) in a national sample of spontaneously reported ADEs, focusing in particular on the contribution of information management. A classification approach was being developed for types of ADEs, which included 11 main classes and their subclasses. Six of the main classes were identified from the study data and they found that ADEs occurring in the prescription, transcription and administration stages were most frequent, and human factors were the leading class of underlying cause. [29]

Data concerning patient complaints and reporting incidents have been used for research purposes with the advantage of covering the entire nation. Also, there are different sources of data, which gave different levels of detail especially with respect to system factors. Data in official statements typically have substantial information about these factors that can be used in order to understand complex phenomenon and their causes. The principle limitation of patient complaints is reporting bias, and under-reporting is a major issue. [29]

ADEs were found out to be common in the prescription, transcription and administration stages of the medication use process and human factors were important for all of these. Human factors issues as a cause were associated with a large proportion of preventable ADEs. In one study, Nuckols et al. found human factors to have a 46% of hospital incident report narratives, but their objective was to study the content of the narratives and ascertain whether or not they could find contributing factors. Some of the most common human factors issues were related to calculation, misunderstanding, inadequate knowledge and reliance on memory. The majority of human factors issues in information management errors fall into the categories of slips and lapses, which arise from informational problems, such as forgetting or incomplete knowledge. [25]

The importance of data in the medication management process is greatly emphasized. Omissions of use of patient data were another common cause for information management errors. This usually happens when no one in the healthcare team tends to review the patient’s records, which is accurate. One reason for omissions might be due to a hurried or rushed environment such as the setting of the emergency room, which involve deviations from safe practice commonly identified in health care. [32]

Information management errors are due to the following: documentation, copying the data or contraindicated prescriptions that happen in the prescription and transcription or admission phases. The typical contributing factors are the use of the copy–paste method and information transfer but duplicated documentation, lack of documentation, verification
of dictation, ignoring guidelines, work processes and availability of patient data also contributed to errors in information management. Even medication data are collected and stored in multiple phases, and information management is partly based on the copy–paste method, one that is prone to human errors. Utilizing the possibility of electronic data entries and structured documentation systems at the point of care should easily prevent this type of error. [32]

One research study carefully analyzed the funnel-shaped distribution data of adverse event (AE) and preventable adverse event (PAE) rates with sample size as a problematic consequence of variation. Further research is needed to explain the results of this study; however, it definitely affirmed that AE and PAE cause serious problems across all healthcare settings and medical procedures. [44]

In a hospital setting, the transfusion and clinical laboratory services are integral parts of inpatient and outpatient care that heavily affect outcomes and costs. Laboratory data may influence up to 70% of important decisions made throughout a hospital stay, and up to 2.7 million blood product transfusions occur yearly in the United States.

It is clearly defined that serious safety events arise. Preventable errors have been shown to cause patient suffering, permanent disability, and death. As a result, blood transfusion and clinical laboratory safety have been priorities for both governmental and accrediting healthcare organizations. [67]

In the U.S., the different responsibilities of health care organizations were reported relative to blood transfusion services. The FDA Center for Biologics Evaluation and Research (CBER) inspects facilities according to specific quality standards and the reporting of fatalities related to blood collection, transfusion, or medical device use is mandatory. The College of American Pathologists (CAP) provide comprehensive safety standard and The Joint Commission (TJC) prioritizes problems with incompatible blood transfusions, laboratory patient identification, and communication by designating them as National Patient Safety Goals. The incompatible blood transfusions are specified as “serious reportable events” and “never events” by the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF), respectively. [67]

One of the most effective monitoring techniques has been to use adverse event and “near-miss” data to direct and measure quality improvement efforts. There are numerous reports that many healthcare sites have voluntary reporting systems that capture various event types in either paper or electronic forms. The examination of data such as contributing factors, system failures, and outcomes may facilitate discovery of event trends that can be used to inform safety initiatives, broaden communication lines, and enhance patient care coordination. [67]
DISCONTINUITIES IN CARE

Hand-offs/transfers and Interdepartmental communication

Many hospitals, most especially teaching hospitals, are dependent on transfers of patient care to another medical provider just to abide a rule on duty hour restrictions, and this is called hand-offs. This actually impacts medical students to a great degree. [53] For example, a medical student who evaluates a patient initially is more likely to learn from the patient encounter than a student who received the patient as a hand-off the next morning after all the clinical and diagnostic tasks were done. [53]

There are also three analyses found in research that causes serious harm to the flow of handling patient care information during the hand-offs of nurses in a hospital. These are the following: (1) different ways in nurse documentation and communication; (2) easy accessibility of the patient's electronic health record, i.e., easily accessible by the entire care team; and (3) rarity of interdisciplinary communication. [55]

Hand-offs/Transfers

In the field of medicine and healthcare, interdisciplinary departments with varied team associates tend to involve communication processes that rely upon human memory and mental processing of information than other industries, which comes with a high risk of failures and errors. More often than not, these medical errors for information transfers among healthcare providers increase the possibilities of adverse effects or impacts, most especially when erroneous information becomes “fact” for the person or team receiving it. Research also shows that there are 70% cases for malpractice claims in teaching settings, and hand-off errors were the second most known problem due to lack of monitoring. Failure of good communication also contributed to 60% of the problems encountered in healthcare settings [61].

In a discussion of skill development in third-year medical students on a clerkship and subject exam performance, a group of researchers found a statistically significant but casual association of hand-offs between the numbers of new patients seen. It proposed that exposure to hand-off patients may have less educational value compared to learning from patients with undiagnosed presentations. However, this situation plays a less important role for the students who score higher on the subject exam and a more important role for students who score lower. [62]

There are several categories of skills reported which are involved in diagnostic reasoning, including data acquisition and reporting, problem representation, and generation of hypotheses, which involves searching for and selecting an illness script. These set of skills have been negatively influenced by hand-offs. An example would be a night float resident might admit a patient complaining of headache, weakness, poor appetite, generalized aches and a cough and then appropriately hypothesize that the patient has influenza. A student would likely have more difficulty sifting through these complaints, prioritizing them, and linking the other symptoms to the cough. The student will definitely learn from the diagnosis
and experience on initial assessment more than a student that will see the patient the next day. All night float residents performed usually the most important part, which includes data gathering on the patient, creating an assessment and differential diagnosis. This also includes creating an evaluation and treatment plan. It was observed that students who scored lower on the exam were more dependent on the hand-off than those practicing skills on new patients. [62]

A number of factors have been analyzed on the night float systems on the number of hand-off patients that students see and it may also include daytime system as well. According to the report given by five hospitals, students saw approximately 50% more hand-off patients if the teams admitted patients daily than if the teams admitted on an every 4th day call cycle. Also, residents may assign more stabilized hand-off patients to students whom they perceive as less proficient. [62]

One study was done to assess whether a modified "ABC-SBAR" mnemonic (airway, breathing, circulation followed by situation, background, assessment, and recommendation) improved handoffs by pediatric interns in a simulated critical patient scenario; further studies are needed to check handoff in an emergency situation. [56]

There is a real need to provide formal training in hand off quality early in medical residency training. General surgery trainees clearly prefer and performed better, though not perfectly, hand offs with the in-person method. [63]

A rule was implemented in 2003 to limit the hours of residents in the hospital but these had increased the cases of hand-offs while at the same time may have reduced the transferring of information. The rules have also increased the scheduling model tools like cross-coverage and night-float for resident medical providers. This had increased errors due to lack of familiarity to the case of patients [61].

Recent research found that there’s little effect or medication error to the pediatric residents with regards to hand-offs, but this created concerns about the impact of duty limit hours of hand-offs. A report done by the Institute of Medicine showed that it is necessary that resident doctors should learn the patient hand-offs and make this a priority research [61]. Hand-offs were grouped to qualitative and quantitative study.

**Qualitative study**

In a qualitative study, verbal interactive hand-offs predominated in internal medicine, obstetrics–gynecology and pediatrics, and all who were interviewed said that they believed they made up one-half of hand-offs in surgery.

During face-to-face hand-offs, resident providers only relied on written, verbal and non-verbal cues such as gestures and emphasis. Interviewees expressed a preference for verbal, interactive hand-offs. Most hand-offs without a face-to-face interaction were just conducted over the telephone, yet 15–20% of the hand-offs in surgery solely happened with the
outgoing resident leaving an electronic or paper summary or handwritten notes. Participants reported that the number of asynchronous hand-offs was increasing. [61]

It was also observed that hand-off quality is also dependent on residents’ clinical and diagnostic skills. Outgoing resident providers must have a good understanding of the clinical conditions and events for them to have a better focus on relevant information. This should make handwritten notes be shared by the incoming residents. Additional informal decision algorithms must also be used for more hand-off information. [61]

The residents admitted that trust and confidence to the hand-off participants are important and they usually made decisions based on the clinical diagnosis and interactions. The interviews found that confidence in hand-off participants’ abilities was important, with residents reporting they made judgments about the value of information based on prior clinical interactions. When using the formal data summaries, residents reported that the number of data items in the forms might distract from a focus on the information critical for managing patients. Handwritten notes focused on patients’ current status, likelihood of complications or events and “to do” lists for the upcoming duty period. [61]

One of the factors of having errors during hand-offs is when it lacked true two-way exchange of information between medical providers and other healthcare professionals. Examples would include hand-offs between residents not in good terms or not comfortable with each other, hand-offs just like or similar to the hand-off data form, and hand-offs during the first day of a rotation or when residents just came back from vacation. It could also be due to longer absences and by staff new in a setting more prone to errors. [61]

When some planned tasks were erased and wrong information was given on the patient, there were continued errors and communication problems in hand-offs. Outgoing shifts tend towards increased errors, delays in patient care and, hence, longer hospital stays. Its been reported that coordination problems mostly occur when there is no face-to-face hand-off and no form of notes given to the incoming duty resident. [61]

**Quantitative study**

According to one research, hand-offs lasted on average of just over 12 minutes, with a very small number of hand-offs lasting significantly longer than 20 minutes. An inverse relationship of the number of patients handed off and minutes per patient set the total time for the hand-off. Time constraints are determined by attempts to have hand-off efficiency with a large patient number, a fixed time to establish rapport, and hand-offs under cross-coverage with a large census; potentially occurring under a model of a reduced mandate for care and more limited information-sharing. [61]

In 2003, the Accreditation Council for Graduate Medical Education restricted residency duty hours; and, because of it, there developed much concern about the increased frequency of hand-offs whereby patient care responsibility is transferred from one resident who is leaving the hospital to another incoming resident. This resulted in a heightened focus on the importance of quality hand-offs. [60]
The hand-off process, also known as “sign-out,” can be a written or verbal transfer of patient care information. Each time a hand-off occurs the possibility for miscommunication arises. It is estimated that the contribution of communication failures to adverse events has been between 15% and 67%. [60]

Theories from the psychology of communication describe the quality of hand-offs as reflecting the mentality of people; the more knowledge that people have to share, the worse they communicate new material because they overestimate the knowledge of the other. These psychological processes could systematically affect the effectiveness of communication during hand-offs. [60]

A study made by pediatric medical interns of their hand-off communication showed that 40% of the time they failed to give pertinent information to their patients. From the examples used in the study, a correlation was found between communication psychologies to the poor hand-off communication. Residents also overestimated the fact that there would never be a problem to communication and therefore no double-check was made. This is also the reason why endorsements between outgoing residents or interns should be communicated carefully to incoming duty. [60] Since no formal hand-off curriculum was identified in the study, this suggests that senior residents are not that good in handling hand-off communication compared to interns. [60]

A review by the National Aeronautics and Space Administration reported that hand-off communication has been found to be most effective when it is driven by “problems, hypotheses, and intent” rather than long lists. It is much better to train interns to communicate better by using this framework, and avoid unnecessary knowledge items that cannot be remembered. This will prevent cognitive overload for on-call interns by tailoring information that is communicated. This is an area that requires additional studies [60].

**Interdepartmental communications**

As we know, hand-off communication is one good example of how a medical error in patient care occurs. This involves communication errors as the main underlying factor of adverse events and patient’s harm. Hand-off error greatly increased in the intensive care environment and the problem happened for two reasons: (1) residency work hour restrictions shows more incomplete or incorrect transfer of information and (2) handoffs are done by people who have not yet been given formal training for this process. [40]

There were many lapses to consider in communication in a multicenter study of hospitalists and non-hospitalists in six U.S. academic medical centers. There were a few primary care providers (PCPs), which had direct communication with the inpatient medical team during their patients’ hospitalizations; however, the problem was that more than half reported they had not received any discharge summary within 2 weeks. Almost, one quarter of PCPs did not have any knowledge that their patients had been admitted at all. [52]
There is a big difference between the rates of adverse effects of hospitals and hospital departments. There were more preventable adverse effects found in hospital departments as compared to hospitals in general. Patient safety at the hospital department level can still be improved independently of those reported between hospitals or hospital departments in general. [39]

A sample of patient groups with a higher risk of preventable adverse effects has been studied. The inter-departmental variance in both the rates of adverse events (AEs) and the rates of preventable AEs was mainly explained by differences in the patient mix and department type. Increasing age and higher co-morbidity were two associated factors with an increased risk of preventable AEs. Thus, patient safety interventions should give more priority to elderly patients and patients with co-morbidity. It is also considered that longer hospital stays were associated with an increased risk of preventable AEs, but still questionable whether length of stay is a cause or a result of the occurrence of preventable AEs. In addition, patients who undergo a surgical procedure are at a higher risk. Healthcare providers should obtain better documentation of surgical patients to prevent adverse outcomes because of the increased risk of adverse effects. [39]

There are recommendations on how to improve the overall patient safety within a hospital. Recommendations include there must be interventions tailored for individual hospital departments which are necessary to reduce their patient safety risks. In order to do this, there must be a deeper understanding of the nature and underlying causes of adverse effects of a particular department, since such understanding will facilitate implementation of effective interventions to reduce the variation. [39]

The hospital management team should be aware of the appropriate interventions and implementation strategies that will help limit the adverse effects and problems of specific hospital departments. Hospital managers should give importance to the high risk departments with higher preventable adverse effects to give the necessary safety programs for the patients such as elderly patients and patients that undergo surgical procedures. [39]

There was a study that found the majority of medical adverse events are secondary to errors in communication. There were approximately 5632 sentinel events that were reported to the Joint Commission (known until 2007 as the Joint Commission on the Accreditation of Healthcare Organizations) since January 1995, which revealed that 70% are the result of communication. Due to such an overwhelming number, the Joint Commission's 2009 national patient safety goals have challenged medical professionals along with hospital administrations to engage in continuous improvement of effective communication among caregivers. [43]

The Cincinnati Children's Hospital Medical Center (CCHMC) in 2007 was reviewed in terms of the root cause of non-perioperative serious safety events (SSEs) and found out that the common cause of these events is the failure in team communication or team situation awareness (SA). It was reported that four of seven SSEs (57%) involved poor recognition of abnormal vital signs or poor communication of parents’ or nurses’ concerns and these events usually occurred at night time when there are least number of resources, multiple
sign-outs of physicians and nurses, and communication among nurses, physicians, and patients’ families is less frequent. With the release of the new Institute of Medicine regulations about hours for residents and the potential for increased discontinuity of care and increased transfers of care (handoffs), there is really a need to improve SA and communication. [43]

A night discussion session was implemented in one study and they put great emphasis on standardized questions, formal discussion time, inclusion of nurses and residents, and follow-up discussion with the attending medical provider. The study was able to show that a combination of these components into a Night Talks approach significantly decreased the rate of near misses. It was observed that there are also additional effects on the culture of safety. Night-shift nurses reported feeling more a part of the team because they are now involved in the patients’ care plans. The residents also appreciate the attending providers supervising their decisions at a point in the night when they feel most vulnerable. Finally, the attending providers are more aware of the issues at night so that plans can be initiated earlier and adverse events can be prevented. [43]

It was also found out that a visible reminder in the workspaces of the medical residents and nurses helped. The addition of an administrative assistant to hand the forms to the pediatric chief resident each week improved the return. Convincing the pediatric chief residents that a phone call every night in the middle of the night would improve patient care and that patient safety is a continuing challenge helped to improve safe outcomes, as the data demonstrated an impact. [43]

Instituting a standardized Night Talk between the bedside nurse, PCP, intern, senior resident, and attending physician substantially reduced near-miss events in the neurosurgical patients on one unit. It was found out that a discontinuity of care occurs due to restriction in work hours, and medical practice evolving into more shift work, which in turn brings more discontinuity of care. By improving communication during high-risk times such as the night shift, as well as by improving team SA, adverse events can be substantially reduced. There should be more discipline and focus to meet the demands of the Joint Commission's national patient safety goals, in order to gain improvement in communication. [43]

In a study to improve the ophthalmic histopathology request form and its completion by ophthalmology staff at the Royal Hallamshire Hospital, Sheffield, improving written communication is important to the hospital for a number of reasons. Firstly, maximizing the relevant clinical information available to the histopathologist when specimens are reported enables them to investigate the specimen appropriately and can definitely provide the most likely clinical diagnosis and possible differentials, which allow clinicians to plan appropriate patient management. [65]

The quality and clarity of patient-provider communication in the hospital is of highest importance. Ineffective communication in the hospital contributes to poor care transitions and post-discharge complications. Patients commonly leave the hospital with a poor understanding of what transpired like diagnoses, treatment provided, or even major test
results and inadequate knowledge about the self-care activities that they must perform upon returning home, such as medication management, physical activity, and follow-up appointments. Poor communication is often cited as the main underlying and remediable factor behind medical errors, adverse events, and the readmissions that commonly occur after hospital discharge. The results of this study provided exact evidence, showing that patients often feel they have experienced suboptimal communication in the hospital setting. There must be more priority in improvement in care transitions and patient safety, particularly among patients with inadequate health literacy. [90]

Schillinger and colleagues found that patients with inadequate functional health literacy reported significantly worse communication on the domains of general clarity, explanations of processes of care, and explanations of condition and prognosis. Subsequent analyses by Sudore and colleagues demonstrated that patients with inadequate or marginal health literacy more often reported that physicians did not give them enough time to say what they thought was important, did not explain processes of care well, and did not ask about problems in following the recommended treatment. [90]

**MAJOR AND COMMON HOSPITAL ADVERSE EVENT/MEDICAL ERROR STUDIES**

There are identified problem areas that need to be solved in a hospital setting, which may affect medication therapy; these include hand hygiene and medication safety. According to the reports, errors happen because of the following reasons:

- Errors that happen during the prescription, preparation, and administration of medical drugs;
- Errors that happen because of wrong identification of a patient or procedure, miscalculation a drug, writing mistakes, reading mistakes, mishearing, or reaching for the wrong substance.

Also, some of the other problematic areas are the following:

- Patient information was lacking on one treating or specialty department to the next, and necessary treatments were not done properly or done in an erroneous manner;
- Patients and/or procedures have been mixed up due to confusion and one patient may have given the medication of another patient or have underwent a different operation not suited for the patient;
- Patients are often passive “consumers” because of their illness.

Studies from New York and Utah/Colorado showed statistics after retrospective patient chart review that 3.7% of patients (New York) and 2.9% of patients (Utah/Colorado) had experienced adverse events in the hospital. Additionally, 58% and 53% of these events were categorized as avoidable. [46] Another study investigated that increased workload and capacity utilization increase the occurrence of medical error, an effect that can be
offset by a positive safety climate but not by formally implemented safety procedures and policies. [79]

Patient safety remains to be one of the biggest challenges for the public health sector, which in reality is often affected by mistakes made in pre-hospital emergency care. A culture of safety is encouraged and health professionals have new tools at their disposal to help them maintain that safety. [81]

**Drug-related**

Medication use sometimes accidentally happens by unwanted adverse reactions that are very detrimental to a person’s health. It was documented in 2001 that over 4 million people experienced medication adverse events, which was 1.5 times the rate observed in 1995. The Institute of Medicine also has estimated that 1.5 million preventable adverse events occur every year and up to 50% could have been prevented by the modification of prescribing methods. There are also unknown risks and unpreventable side effect risks that were discussed. The FDA’s Safe Use Initiative (SUI) focuses on preventable risks that are significant and amenable to implementable interventions that have potential impact and measurable outcomes. [38]

It is very essential to find ways to reduce the harm from different medications or drugs and identifying, describing, and understanding the root cause of significant preventable risks are very important. FDA’s SUI describes four main categories of preventable risks and these are the following: [38]

1. Medication errors
2. Unintended/accidental exposure
3. Intentional misuse/abuse, and
4. Drug quality defects

Medication errors are broken into subcategories: [38]

1. Informational errors in prescribing or by patients/consumers
2. Procedure and process type errors

Procedure type errors usually happen in hospital settings. It was reported that in a critical care unit individual patients experienced 1.7 medication errors per day. A review of the literature focusing on hospital practices indicated that most medication errors occurred during administration (53%), but they also occurred during prescription (17%), preparation (14%), and transcription (11%). Though the procedural and process type errors are of concern, the major focus of FDA’s SUI is informational errors. [38]

Medication use remains to be a high-risk activity. A recent Institute of Medicine (IOM) report on this subject is that the rates and impact of medication errors have a great impact but are less understood. The President of the Institute of Safe Medication Practices (ISMP), Michael Cohen shared his thoughts to a committee of the US Congress, estimating that the dollar
Cost of adverse drug events was about $200 billion across all health care settings. In ambulatory settings, medication errors and adverse drug events (ADEs) are one of the most important safety issues. A study based on the National Ambulatory Medical Care Survey (NAMCS) found that office-based physicians prescribed at least one inappropriate medication to nearly 8% of the elderly who received prescriptions. There was also another study of ambulatory elderly patients with polymorbidity and associated polypharmacy that documented 35% reported experiencing at least one ADE within the previous year. [35]

In the United Kingdom (UK) and other countries, there have been tremendous deficits in the safety and quality of medication use to a degree that constitutes a public health threat. It has been found that 3% to 4% of all unplanned hospital admissions are caused by preventable adverse drug events. Antiplatelets, non-steroidal anti-inflammatory drugs (NSAIDs), oral anticoagulants, diuretics, and other potentially nephrotoxic agents account for approximately 60% of all preventable admissions. [35]

In accordance with research evidence, the "use of antiplatelets and oral NSAIDs in patients at increased risk of gastro-intestinal bleeding" and "use of oral NSAIDs in patients at increased risk of renal failure” were identified as key priorities for quality improvement in primary care by a Delphi (research) panel of primary care clinicians. [36]

More studies show that drug administration errors are among the highest medical errors. Children are always at risk for such medication errors because of the need to calculate doses depending on each body weight and height measurements. Pediatric doses that are ten times the correct amount (1000% of the correct dose) are occasionally given and can be life-threatening. In a pediatric emergency room, this type of error happens for every one of the thirty-two medications ordered. The highest error rates are to be expected in prehospital emergency medicine. [21]

Vaccines can prevent a disease from occurring in the first place and can also decrease the risk of complications and risk of transmission, which is why this became one of the most important developments in public health. It helps decrease the communicable diseases most especially in children. Due to its effectiveness, people became concerned about its safety and side effects. There are live vaccines such as BCG, DPT, Polio, Measles, Hepatitis B, Hib and their various combinations which cause transient minor adverse events including swelling, redness or soreness at the injection site, and low-grade fever, crying and irritability (in infants). [24]

The adverse events caused by an error in these vaccines are related to manufacturing, handling, cold chain maintenance, vaccination schedule or administrations, which are program errors. They are generally preventable and detract from the overall benefit of the immunization program. These incidents, which result in needless deaths or life-threatening illness and damage to vaccination programs are preventable if proper reconstitution of vaccines and proper handling procedures are followed. [24]

Some factors that also play a role to medication errors include labels, appearance and location of ampoules and syringes, inattention, poor communication, carelessness, and
fatigue on the part of the anesthesiologist. There is one case of drug error-induced polymyoclonus that happened due to injection of tranexamic acid for spinal anesthesia, as the two different ampoules had a similar appearance. The lesson learned is it is important to double-check the medication to reduce such errors. [12]

There are only few studies about the effect of direct intrathecal administration of tranexamic acid in humans. De leede et al. has reported a case of a 68-year-old man who accidentally received an intrathecal injection of 50 mg tranexamic acid. Immediately after the injection, he developed status epilepticus. The outcome was complicated, with hypotonic paresis of all four limbs, which resolved but resulted in residual bilateral peroneal palsy. Yeh et al. reported that seizures and refractory ventricular fibrillation after accidental intrathecal administration of 500 mg tranexamic acid were associated with fatal outcome. The exact mechanism by which tranexamic acid induces seizures or ventricular fibrillation is not known. There are, however, reports of neurotoxicity in experimental studies, and when applied topically to the cerebral cortex in animal studies, this drug is known to produce seizures. [12]

There were also case reports about medication errors that were due to confusion between hyperbaric Bupivacaine and tranexamic acid, since the ampoules of tranexamic acid and Bupivacaine were similar in appearance. The reports led the manufacturer to change the ampoule configuration of hyperbaric Bupivacaine so that such serious complications would cease to happen. [12]

According to statistics reviewed by the American Institute of Medicine, approximately 7000 people die every year in the U.S. because of medication errors, including self-medication and doctors’ prescriptions in patients of all ages. In hospitals, drug administration errors are one of the most common medical errors. Because of age group-specific contraindications and the need for personalized dose calculation, children can be expected to be particularly at risk of medication errors. There are certain improvement measures, which had already been put in place such as using an electronic prescription system and standardized drug preparation, most especially for children. In a prospective study, during simulated resuscitation by pediatric emergency physicians as many as one in every thirty-two prescriptions were found to contain a tenfold error. The type of real-time events identified in the simulated resuscitations had potential to cause immediate serious harm and in many cases prove fatal. [21]

A high error rate that is expected in the prehospital pediatric emergency care has been reported, and this is because neither exclusively pediatric staff nor treatment procedures optimized for pediatric patients can be provided. A retrospective analysis of 360 prehospital prescriptions in the U.S. also showed medication errors in 35% of all cases. There were also high doses of intravenous epinephrine given in amounts much higher than the recommended dose. No specific incidence rates from larger populations are available for emergency medicine but it is likely that a considerable number of pre-hospital medication errors are not reported. This means that the likely frequency and the consequences of medication errors in prehospital pediatric emergency care give rise to a substantial danger, which must be reduced [21].
Non drug-related: adults vs. pediatrics

Pediatrics:

Children with medical conditions in academic pediatric centers have been identified in adverse event reports, even after adjusting for the medical status before admission, such as controlling for level of medications, technological device dependency, and having a complex chronic condition. In general, there were 9.2% of children admitted to the hospital who had an adverse event. Adverse events related to surgery were the most frequent in this type of pediatric center, while in community hospitals diagnostic adverse events were due to “other clinical management” were more common [9].

In community hospital settings, adverse events in the emergency department were more common among children aged 1–5 years than among other age groups; and, medically related adverse events were significantly more common in children during the first year of life. Drug-related adverse events mostly occur in children aged greater than 1–5 years in academic pediatric centers as compared to other age groups. Children 5–18 years of age in community hospitals had the most adverse events related to surgery, diagnostics and drugs. [9]

There have been reports that various factors affect the higher rates of adverse events among children in pediatric centers in Canada. Such reports indicate that the adverse events can be due to several reasons, such as: complexity of care, higher number of caregivers, trainees and handoffs, and different standards of documentation. Children with complex medical conditions are the highest group with an increased vulnerability to adverse events. There are events that are related to surgery. This high incidence in academic pediatric centers could be explained by the Canadian practice of performing most surgery in children under 5 years of age in such facilities. [9]

In a comparison of community hospitals to academic pediatric centers, adverse events in community hospitals attributed to visits to the emergency department were more common as were diagnostic adverse events. Diagnostic errors are recognized hazards in pediatric emergency care, whereas, the issue of adverse events in community hospitals is partly owing to emergency department physicians being more familiar with adult medicine than pediatric medicine, and the lack of standardized emergency pediatric protocol. [9]

Everyone in health care is fully aware of the negative consequences when drugs that are potent chemicals are given to sick patients. The complex drug use process can be at fault, or the potent chemicals themselves can cause adverse drug events (ADEs). Both sources of problems are implicated in causing patient harm. It was believed that in order to solve problems health care workers voluntarily report events, both actual and near misses. However, in reality, voluntary reporting tends to be incomplete because of time pressure, fear of punishment, and other problems. One of the most common findings or actions after an ADE has been carefully described as “triggers.” Use of triggers allows more confident
detection of rates and characteristics of ADEs. A trigger tool finds events that have had a negative patient consequence, and generally, some action has been taken. [68]

**Adults:**

In cases involving adult patients, the elderly groups are the higher risk group for adverse effects due to their poor immune system. Elderly patients also are at high risk due to medical conditions, disabilities and polypharmacy. These issues are being discussed and explained in the outpatient department or during admission to the hospital. Prevention of adverse effects in the elderly population poses challenges to medical professionals because their disease presentation is often atypical and complex [25].

Studies have shown that hospitalizations among adults, ages 65 years old and above, due to adverse drug events have increased in the U.S., which led to more chronic medical conditions and the need to take more medications. Age-related physiological changes, a greater degree of frailty, a larger number of coexisting conditions, and polypharmacy have been associated with increased cases of adverse events. Older adults are nearly seven times as likely as younger persons to have adverse drug events that require hospitalization. [23]

The ultimate goal of the federal initiative “Partnership for Patients” which is amounting to one billion dollars is that preventable re-hospitalizations will decrease by 20% by the end of 2013; to reduce further harm and promote patient safety to patients as well as reduce healthcare costs. The focus of this partnership program is on clinical care and avoiding further adverse drug events. [23]

The elderly population is increasing which also has a concomitant increase in chronic diseases and functional impairment. As mentioned earlier, many elderly due to their poor immune system suffer from co-morbid conditions and disabilities that necessitate multiple medications or polypharmacy. [33]

Adverse drug events are more common in ambulatory care settings for elderly people, and up to 35% of high-risk elderly outpatients develop preventable adverse drug events. One causative factor of preventable adverse drug events is the prescription of inappropriate medications. Inappropriate medication prescription (IMP) are prescription(s) that introduce a significant risk of an adverse drug related event when there is evidence for an equally or more effective alternative medication. It is also known as the failure to achieve the optimal quality of medication use. IMP has been categorized as under-prescribing, mis-prescribing or over-prescribing. Several factors increase the risk of IMP to elderly persons, including physiological changes like reduction in renal and hepatic function, both of which are detrimental outcomes of drug metabolism, and other disabilities like visual and cognitive decline. [33]

Despite putting great efforts to scrutinize and improve the quality of medication prescription among elderly persons in the primary care setting, inappropriate medication prescriptions are still common. Approximately one in five prescriptions to elderly persons are inappropriate. Diphenhydramine and Amitriptiline are the most common inappropriately
prescribed medications with high-risk adverse events. These medications are good candidates for being targeted for improvement, for example, through the use of computerized clinical decision support. Focused and systematic interventions are needed to improve the quality of medication prescription in this patient group. [33]

INSTITUTE OF MEDICINE AND AHRQ REPORTS ON PATIENT SAFETY

Hospital Patient Safety Indicators (HPSI)

A current patient safety culture evaluation is the initial step to establish a positive patient culture. [2] The hospital setting involves a network of healthcare professionals when dealing with both inpatient and outpatient departments, either directly or indirectly. Once a patient is admitted, he/she will then receive diagnosis and treatment from different specialty medical providers and hospital medical sections, depending upon the type of diagnosis or condition of the patient. In hospital departments, a rapid and safe service for patients is needed 24/7, and since shifting service occurs in order to provide simultaneous services of the medical or hospital team, there are high risk complications that can happen. This is especially a concern relative to the diagnosis and treatment of the very young such as neonates and infants, and the very old who are critically ill or disabled patients. [46] Consequently, there should be certain safety rules developed for health teams caring for vulnerable groups at high risk of an AE. [71]

Hospital Acquired Infections And Sterilization Techniques:

One of the primary problems that threaten the safety of patients care is a healthcare-associated infection, which is an increasing worldwide concern. Surgical procedures conducted in hospital and other health care settings involve direct patient contact with a medical device or surgical instrument that can lead to severe life-threatening infections. Controlling this problem is a major criterion for hospital accreditation worldwide. Proper sterilization of instruments between patients is needed in order to remove all microbes and prevent harmful adverse effects as a result of cross contamination. [71]

There are different types of sterilization techniques available, and the most common method for sterilization of medical instruments is steam sterilization. However, neither steam sterilization nor autoclaving are guaranteed to be 100% effective in killing all microorganisms, so the quality of sterilized products should be assessed by physical, chemical, and biological indicators. According to the CDC and other medical programs, “to ensure heat penetration to all instruments during each cycle, a chemical indicator should be placed inside and in the center of a load of unwrapped instruments, routinely in every sterilization process”. Biological indicators are also used from time to time for monitoring of the quality of sterilization processes. [71]

During the past years, not all developing countries used both chemical and biological indicators. There were two studies that tried to determine the sterilization processes in various countries. One study gathered the history of sterilization processes of hospitals in
Poland between the years 1997 to 2000, which greatly revealed that more improvement was needed. In the year 2005, 30 indicators were created after assessing the sterilization process in Thailand hospitals. This report also showed that there is a greater need for attention to sterilization processes for both inpatient and outpatient hospital departments, and adequately trained medical personnel as well as national guidelines are immediately needed. The international studies mentioned above mainly focused on improving the sterilization process to gain knowledge and be consistent with the World Alliance for the Patient. Greater improvements can happen if there is a continuous training program. The use of chemical indicators has resulted in great improvements in sterilization control. [71]

Patient Safety Performance Indicators:

In Spain, the Patient Safety movement has influenced the Spanish National Health Service; the Spanish patient safety efforts was especially based on the Healthcare Cost and Utilization Project by the U.S. Agency for Healthcare Research and Quality (AHRQ) and the requirements made by the Organization for Economic Co-operation and Development (OECD) or the Healthcare Quality Indicators Project Overview. In one study, the Patient Safety Indicators (PSI) is well followed. Approximately five PSI has been considered for empirical validation in public hospitals across Spain. All acute care areas have manifested systematic variability or variation beyond chance, which was proven to have a cluster effect and that, importantly, detected hospitals above the expected. The empirical properties were seen as very useful to screen for healthcare performance in Spanish hospitals. [74]

As for the lessons learned from the aforementioned study, it was found that hospitals with more complex problems are signaled as poor hospital performers, especially if they have high incidences of secondary diagnoses. There are still several debates that need further clarification on hospital validity issues to fully trust using the Patient Safety Indicators (PSI). As for the Spanish National Health System (NHS), there is five PSI proven to have good performance, positive likelihood ratio (+LR). The studied even reported:

“The most conservative estimation yielded a + LR of 26.8 in decubitus ulcer, a + LR of 406.3 in catheter-related infection, a + LR of 149.3 in PE-DVT and a + LR of 25.32 in postoperative sepsis”.

The result showed a high + LR except in decubitus ulcer, which are affected by both underreporting or present admission cases, and either false negative or false positive cases. More studies are needed to evaluate the stability of PSI; taking this as a screening tool and assessing its limits in specified contexts might give us the intervention that hospitals truly need. [74]

Nurse overtime working hours is an issue affecting adverse outcomes in hospitals and were positively associated with the following nurse-sensitive patient safety outcome indicators: patient falls, decubitus/pressure ulcers, near errors in medication, medication errors, unplanned extubation, hospital-acquired pneumonia, and hospital-acquired urinary tract infections. Risks of patient falls, decubitus/pressure ulcers, unplanned extubation, hospital-acquired pneumonia, and hospital-acquired urinary tract infections significantly increased when the patient-nurse ratio exceeded 7:1. It was concluded that nurse workforce and nurse-sensitive patient outcome indicators are positively correlated. The results of this
study will help professional nursing groups and hospital managers define suitable nursing workforce standards for hospital settings. [78]

**Agency for Healthcare Research and Quality (AHRQ) HPSI**

The Agency for Healthcare Research and Quality (AHRQ) has developed various healthcare decision-making and research tools to be used by program managers, researchers, and others at the Federal, State and local levels. The Quality Indicators (QIs) are used for readily available hospital inpatient administrative data to be analyzed and measured. The QIs are helpful for potential quality concerns, in order to help identify areas that need further study and investigation, and track changes over time. [100]

AHRQ's Center for Quality Improvement and Patient Safety are integrally involved with patient safety initiatives, and their main responsibility is to support the Center for Primary Care, Prevention, and Clinical Partnerships. There are four elements that were made by AHRQ for patient safety and these are: identifying threats to patient safety; identifying and evaluating effective patient safety practices; teaching, disseminating, and implementing effective patient safety practices; and maintaining vigilance. [103]

Current AHRQ QI modules enumerate several aspects of quality surveillance, and these surveillance strategies include the following: [100]

- List hospital admissions in geographic areas that evidence suggests may have been avoided through access to high-quality outpatient care (first released November 2000, last updated March 2012)
- Reflect the hospital quality of care, including across geographic areas and inpatient mortality for medical conditions and surgical procedures (first released May 2002, last updated March 2012)
- Reflect hospital quality care as well as geographic areas, to focus on potentially avoidable complications and iatrogenic events (first released March 2003, last updated March 2012)
- Use indicators from the other three modules with adaptations for use among children and neonates to reflect quality of care inside hospitals, as well as geographic areas, and identify potentially avoidable hospitalizations (first released April 2006, last updated March 2012)

AHRQ has faced a bigger responsibility on improving patient safety given the recent problems facing the U.S. health care system today, as well as the limited support and resources needed. Utilizing AHRQ extensive experience, new processes to discover facts are needed to improve the use of safety practices in healthcare. [103]

Healthcare-associated infection (HAI) is the most frequent result of unsafe patient care worldwide, but only limited data is available from the developing world. The most obvious finding of one time-trend study was significant improvement in sterilization control especially in the development of the use of chemical indicators. [71]
Surgical

In a surgery department or in a surgical team in the hospital, professionals working in different departments create a team to support care for a specific patient; they contribute to patient care from different health science disciplines wherein both their training and end goal for the patient are different. This contributes to one reason for a lack of communication between the operating room personnel, and a primary basis for surgical errors to occur. [13]

There are approximately 43% of surgical errors that happened due to miscommunication involving different healthcare personnel. Most of the time, surgical errors occurring in the operating room were between surgeons, anesthesiologist, nurses and internist. [13]

In a recent analysis by the American College of Surgeons’ closed claims database, communication problems were traced back to not just happening during surgery but also before and after the surgery started. There are about 85% of adverse events solely on communication problems with only 4% on written communication. This is the reason why The Agency for Healthcare Research and Quality (AHRQ) and the Joint Commission (JC) both recommend the implementation of read backs among medical professionals specifically in the operating room setting. Read backs are recommended for telephone orders with regards to medication administration and verbal orders with highly critical results where there is no written documentation yet generated. [14]

Dr. Eddie Hoover eloquently described the surgery industry’s reticence to engage in read backs in a 2007 Archives of Surgery editorial when he noted that "Getting surgeons to read back orders and instructions will age you 10 years, yet the Navies of the world have demonstrated for eons that it improves efficiency, promotes safety, and saves lives.” [14]

The reports on surgical adverse outcomes are very important but it depends on the health system and underlying resources. For example, in the Netherlands and some other hospital systems with a complicated hospital registration system, there is much dependence on the accuracy of the reporting and documentation through various resources. [57] It was analyzed that the LHCR system (the acronym for national surgical adverse event registration in the Netherlands) was poorly reported or underreported and that less severe events tended to be reported less frequently, except in the nursing file, which was not designed to serve as input for the LHCR. The medical file rather than the nursing file seems the most appropriate additional resource for this purpose. [57]

There has been under-reporting due to reluctance or negligence among medical providers to report adverse outcomes. Particularly strong disincentives for reporting are shame, fear of liability, loss of reputation and peer disapproval. The awareness that medical errors, and also surgical complications, are frequently system errors rather than an individual liability has helped to abandon a shame-and-blame culture and has harnessed the medical professional to report errors and adverse outcomes. There is also an increase in patient
awareness and demand to expect safety and transparency in healthcare, creating more awareness within health administrations of the importance to contribute to safer outcomes, and a better quality of care. [57]

In one study, it was concluded that the registration, management and prevention of surgical adverse outcomes are not to be neglected in daily clinical practice, impacting the selection of patients to be treated and procedures to be performed. It was claimed that hospitals and clinicians should be willing to put effort into a structural and reliable means to list not only the beneficial but also the harmful effects of their professional activities or clinical management to improve the quality of care for their patients. [57]

Entry or admission nursing assessments of in-hospital patients are strongly associated with in-hospital mortality; and, predischARGE nursing assessments of in-hospital patients are associated with post discharge mortality. These assessments, part of what is termed as the ‘head-to-toe’ patient assessment, and which are a standard part of nursing school curricula, are collected and recorded at all hospitals. Simplified summaries of assessments can be constructed. Since nursing assessments are recorded at least every 12 hours throughout the patient's stay, they represent a changing indicator of patient condition. They are a real-time longitudinal sensitivity that no static measurement, such as demographics or principal diagnosis, can provide. [72]

It has been proven that this compact clinical data source in the EMR is a natural longitudinal source of information, which allows medical providers to have continuing insights of nurses as recorded throughout the patient's entire stay. Such dynamic information should allow medical providers to improve patient care. The latest observation on EMR technology does not allow quick and easy access to nurses’ observations and assessments, so changes in current record-keeping software or adjuncts to it will be necessary to make this information more accessible. [72]

**Post Op**

Two million surgical operations per year that have surgical site complications and approximately 30% of surgical patients resulted in patients experiencing sepsis. [101]

Studies on surgical site complications also showed outcomes whereby more than 40 million major surgical operations annually performed in the U.S. resulted in 800,000 to two million complications due to surgical site infections. [101]

There are two types of surgery that were being compared, and it was between elective and non-elective surgery. Comparing these two, sepsis and death were more likely to happen after non-elective than elective surgery. This was observed to increase significantly after elective and non-elective procedures over the last 17 years, and this may due to medical errors and poor outcome of the surgery. No improvement for the hospital mortality rate of patients having elective surgery has been revealed by some studies. There are also disparities in surgical outcomes being noted and these relate to age, sex, and ethnicity and the development of postoperative surgical sepsis. [101]
In the U.S. surgery patients are vulnerable to surgical sepsis, and reports suggest that surgical sepsis accounts for almost 30% of all septic patients. These are considered as high-risk patients since the surgical procedures they underwent promoted metabolic, hematologic, and immunologic responses in their body. The immune function after surgery pose increased patient vulnerability to experience perioperative bacterial infection, hemorrhage, blood transfusion, or anesthesia up to severe suppression that promotes sepsis. [101]

One study found that due to progress in surgical care on patients with greater utilization of surgical intensivists, alterations in the antibiotics or strategies employed, the overall mortality rate between surgical patients has dramatically improved. On the other hand, it was stated that elective surgery had the greatest increases in sepsis rates and worst severe sepsis cases. This type of surgery also failed to show a decrease in age-adjusted rates of death for postoperative sepsis over time. It is therefore important to start using population data for postoperative sepsis which may include the analysis of the specific procedures associated with sepsis and a focused evaluation of the various racial and sex disparities in the development of postoperative sepsis. [101]

Medical

AHRQ defined patient safety indicators (PSIs) have been shown to be an effective tool for monitoring and tracking safety events in the general hospitalized population. From a medical standpoint, one study showed that approved PSIs supported patient outcomes in the following: [102]

1. Complication of anesthesia
2. Death in low-mortality diagnosis-related groups
3. Decubitus ulcer
4. Failure to rescue
5. Foreign body left during procedure
6. Iatrogenic pneumothorax
7. Selected infections due to medical care
8. Postoperative hip fracture
9. Postoperative hemorrhage or hematoma
10. Postoperative physiologic and metabolic derangements
11. Postoperative respiratory failure
12. Postoperative pulmonary embolism or deep venous thrombosis
13. Postoperative sepsis
14. Postoperative wound dehiscence
15. Accidental puncture or laceration
16. Transfusion reaction

Additional experimental PSIs include:

1. Physiologic and metabolic derangements in all diagnoses among all discharges
2. Aspiration pneumonia
In a study focused on the medical condition of chronic kidney disease (CKD), it showed a lack of standardized PSIs were associated with undetected safety events, which are likely to contribute to adverse outcomes in this disease. This study sought to determine the proportion of CKD patients who experience multiple potentially hazardous events from varied causes and to identify risk factors for the occurrence of “multiple hits.” It referenced CKD patients in the Veterans Health Administration (VHA) that were retrospectively examined for the occurrence of one or more safety events from a set of indicators defined a priori, including AHRQ PSIs, hypoglycemia, hyperkalemia, and dosing for selected medications not accounting for CKD. [102]

Chronic kidney disease (CKD) is becoming rampant in the U.S. and CKD patients are very vulnerable to adverse outcomes that may be due to delivery of care by a medical professional. Hospitalized patients with CKD have greater risk for having AHRQ-defined PSIs than patients without CKD. Hyperkalemic and hypoglycemic events were individually found to be common adverse safety events as well as risk factors for mortality in patients with CKD. Also, medication errors are very common, which is the reason why patients with CKD are at risk of an assortment of safety events beyond the scope of those previously considered. [102] Patient safety events have costly consequences for patients and healthcare networks, increasing the length of stay, hospital readmissions, and the risk of death. Preventing these adverse events can improve quality of care and patient outcomes. Further studies are definitely needed on this type of condition. [102]

In patients admitted with acute coronary syndrome (ACS), significant discrepancies were observed between the medical record and patient self-report for 13 health conditions of importance to the care of ACS patients. Discrepancies are reported but since important treatment decisions in ACS patients are made based in part on information from the initial clinical history, the findings reported here are of great potential significance for these patients in particular. There is an urgent need for research that identifies the most effective and efficient means to obtain accurate health information. This may result in improved care for ACS patients, and improve the quality and safety of patient care more broadly. [73]

The linking of the 'maturity' of the hospitals' quality improvement system score (MI) to quality and patient safety outcomes in 43 Spanish hospitals are first analyzed in one study. The data suggests that adjusted hospital complications are associated with the development of the hospitals' quality improvement systems: hospitals with more mature quality improvement systems present lower complication rates. Similar results, although borderline significant and partly confounded by hospital size can be observed for adjusted hospital readmissions. [76]
COMMON TYPES OF POST-DISCARGE ADVERSE EVENTS

There are many adverse events that most likely happen after the patient has been discharged from the hospital, and these can be related to drugs or medications, nosocomial or hospital acquired infections, procedure related infections or problems, pressure ulcers and diagnostic errors.

In 2004, Baker and colleagues estimated that up to 23,750 Canadians die annually from preventable adverse events (AEs) and adverse drug-related events (ADREs) are the most common type of preventable AEs in patients admitted to hospital; and, ADRE’s cause up to 12% of visits to the emergency department (ED) in Canadian tertiary care centers. Research on drug-related morbidity has focused on inpatient and community settings, but not enough on the contribution of emergency physicians (EPs) to this problem. Emergency physicians practice in high-risk settings for medication errors and other AEs, treat high-acuity patients, work under time pressure, and treat patients based on incomplete information regarding medical history or medication consumption. [45]

In order to evaluate the tolerability of prescriptions given on discharge from the ED, it was observed that higher-acuity patients are more often admitted to hospital, evaluated serially by nurses, physicians and pharmacists for the development of ADREs, and tend to receive closer follow-up after discharge from the hospital or ED. In comparison, lower-acuity patients are more likely to be discharged from the ED without specific follow-up plans or monitoring in place for ADREs, even though they commonly receive prescriptions on discharge from the ED. The underlying assumption that these patients do not run into significant problems with medications prescribed on discharge from the ED has not been tested. [45]

In Australia, medication administration errors are common when patients are discharged from hospital to a residential care facility (RCF). This usually happens because it is compulsory that the primary treating provider needs to attend to the RCF at short notice just by documenting on a medication administration chart. If the doctor cannot attend, doses may be missed or delayed and a locum doctor may be called to document on a medication chart. [19]

It really puts a big challenge on healthcare professionals when it comes to the continuity of medication management because, more often than not, it is compromised when patients are discharged from hospitals to residential care facilities (RCF) such as ‘nursing homes’ and ‘care homes’. These are usually patients who have complex and intensive medication needs. The missed, delayed or incorrect medication administration is unfortunately common. An Australian study reported that patients discharged to RCFs were prescribed an average of 11 medications of which seven were new or had been modified during hospitalization. The median time between arrival at the RCF and the first scheduled medication dose was 3 hours, and ‘when required’ (prn) medications were sometimes needed sooner. [19]

A U.S. study revealed that most patients transferred to a RCF had one or more medication doses missed; on average, 3.4 medications per patient were omitted or delayed for an
average of 12.5 hours. In another U.S. study, medication discrepancies related to transfers to and from hospitals and RCFs resulted in ADEs in 20% of patients. An analysis of medication incidents that resulted in patient harm in Canadian long-term care facilities identified patient transfer as a common factor. [19]

The delays on the medication chart can be a cause of several adverse events; such as the RCF staff may withhold medications, administer them without a current medication chart or revert to pre-hospitalization medication regimens. When this happens, infections can develop due to inadequate medication management and the patient’s poor immune system. Procedure related problems tend to manifest because there is no recent medication chart, which is needed to support care of the patient. The clinical importance of delays or errors in medication administration depends on the clinical status of the patient, the nature of the medications involved, and the length of the delay.

Depending on a patient’s condition, in some cases, no adverse event occurs but then these delays in access to medications for symptom control (for example, analgesics and medications for terminal care) can greatly impact quality of life, and delays or errors with regularly scheduled medications (for example, anti-epileptics and antibiotics) may have serious consequences. Unplanned hospital readmissions have been reported as a result of failure to receive prescribed medications after transfer to a RCF. [19]

Older adults who are discharged home after a medical illness have an increased fall rate. Some researchers have suggested that a high risk for falls is not limited to the 65 and older post-hospitalized population. All adults who have fallen during their hospitalization have a high rate of falls during their immediate post-hospitalization period, especially patients who have fallen on more than one occasion during their hospitalization. One study suggests that weekly phone calls are well accepted by patients and may potentially be a feasible hospital-based surveillance system to monitor post-discharge fall risk factors, and could be utilized to test future interventions that reduce falls in this high-risk population. [91]

There should be a targeting exercise intervention program for people at increased risk without expensive large-scale screening programs. People who have been in hospital are known to be at increased risk of falls and disability so some health systems have developed an exercise program and recruitment strategy for this population. One exercise program allows for flexibility in exercise prescription to best cater to the needs of this population; it is optimally designed to address the major problems of falls and disability in older adults and could be readily translated into clinical practice. [92]

**DIAGNOSTIC ERRORS/MISDIAGNOSES**

**Statistics:**

Several studies have shown that patients and their medical providers consider medical errors, and particularly diagnostic errors, common and potentially harmful. Diagnostic errors are also accounted for about 50% of mistakes in such surveys although figures between
20% and 25% were also reported, depending on the medical setting and the materials used to determine the rate of diagnostic errors. The studies of clinical practice based on autopsies, second opinions, or case reviews yielded different diagnostic error rates, depending on each area or expertise or clinical discipline. In perceptual disciplines, such as dermatology, pathology, or radiology, diagnostic errors occurred in 2% to 5% of cases while in clinical fields requiring more data gathering and synthesis, up to 15% of patients might suffer from a diagnostic error. Schiff et al. reported that the most common missed or delayed diagnoses were pulmonary embolism (4.5%), drug reactions or overdose (4.5%), lung cancer (3.9%), colorectal cancer (3.3%), acute coronary syndrome (3.1%), breast cancer (3.1%), and stroke (2.6%). [93]

How many times adverse events happen due to diagnostic errors is difficult to assess. One study reported, “retrospective studies indicate that more than 8% of adverse events and up to 30% of malpractice claims are related to diagnostic errors, but prospective studies are lacking”. This is in contrast to other varied opinion about “the definition of diagnostic errors, since they may not be considered as such in some studies if there was no harm”. [93]

What are the mechanisms of diagnostic errors? In a study of 100 errors in internal medicine defined as “autopsy discrepancies, quality assurance activities, and voluntary reports,” a study made by Graber et al., the researchers tried to determine the contribution of system-related and cognitive aspects to diagnostic error. The causes of diagnostic errors involved cognitive causes in 28% of the cases, the context or the system in 19%, and mixed causes in 46%. Thus, cognitive factors, that is, how doctors think, were involved in almost 75% of the cases. This reinforces the importance of understanding physicians’ thinking, decision-making, and the processes of clinical reasoning, which will be addressed in the following section. [93]

Types

Diagnostic errors can also be defined as not intentional with regards to the mistake, delay or missed as judged from a definite information, and it is categorized as: false negative, false positive, and discrepant. [4]

A false negative diagnosis is frequently ruled out, such as an abnormality on the patient’s condition, but in fact it is indeed present. A false positive diagnosis is when the medical professional overanalyzes the diagnosis or stated an abnormality but actually there is none to talk about. A discrepant diagnosis is an entirely different diagnosis made from an actual diagnosis. [4]

According to a study of Schiff and colleagues, they found that failure or delay in considering the diagnosis was the most common failure in the diagnostic process. The most commonly missed diagnoses includes cancer, pulmonary embolus, coronary disease, aneurysms, appendicitis, which have all been documented in previous studies; but, little is known about the presenting complaints or initial (incorrect) diagnoses that precede these missed diagnoses. [5] There are medical providers who reported their own lessons in treating their
patients and the errors they have committed, and their reports could definitely help researchers and serve as a guide to develop preventive strategies. [5]

In other studies, diagnostic errors or misdiagnosis are discussed as serious problematic and detrimental to the health of the patient. It is actually a common error. Diagnostic errors include errors in diagnostic reasoning and judgment, inability to perform, interpret or even follow-up the test or failure to make an order from the start. Inability to choose the right treatment is also included. According to the *Harvard Medical Practice Study II* in one of the earlier studies, this type of diagnostic error is said to be the reason for 17% of preventable adverse events. [10]

Other of the important statistics by different researches is as follows:

1. There are 59% malpractice claims in a retrospective review analysis involved on diagnostic error that put the patient’s life in danger. [10]

2. For the self-reports of doctors with regard to diagnostic error, errors happened mostly in the phase of testing which is 44% and this includes failure to constantly order, report or follow-up the results; and, it is followed by errors on the medical professionals clinical judgment or assessment (32%), by poor history taking (10%), physical assessment (10%) and errors in consultation, referral and delays (3%). [10]

3. Cognitive factors by medical internists also contribute to this type of error by 74% of cases. [10]

When dealing with diagnostic errors or what we have called “misdiagnosis”, it is an embarrassment and unacceptable for healthcare professionals to be incompetent in their field. But we also have to remember that some diagnostic errors are hard to detect since it will take some time to determine if the diagnosis is incorrect depending on what happened in the patient’s case within a few months. It is important to consider that most empirical studies regarding the intervention of these diagnostic errors are not that successful, and unable to identify ways to eliminate harmful effects on patients. [10]

Diagnostic errors is proven to be cognitive in nature, not so much involving knowledge deficiency, but related to the appropriateness of data collection from the patient, as well as data integration and verification of diagnostic hypotheses. Their risk of occurrence increases in the real field of busy medical practice, which is assumed to be always under time pressure, when medical providers use reasoning shortcuts (heuristics) and are subject to biases. The latter is related to their personal traits (i.e., overconfidence), their mental representation of diseases (i.e., anchoring bias), and their environment. Many providers induce a premature diagnostic closure. Ways to prevent these errors involve the self-awareness of medical providers, training in medical education, and external support. [93]

There must be effective ways to reduce diagnostic errors. Certain conditions must be fulfilled to increase the chance that such interventions bring some change, and these are the following: [93]
First, medical providers should be enthusiastic about making diagnoses and decisions. They should adopt an evidence-based attitude towards medical education issues instead of relying merely on their own opinions.

Second, all the organizations and schools such as the teaching clinical structures and medical schools, as well as medical professional societies should support medical education research, train their clinicians as supervisors and teachers, and valorize clinical supervision and feedback in clinical contexts.

Finally, pre-, post-, and continuous education must be specific in training to help physicians detect and correct their own reasoning flaws. With all these conditions fulfilled, one may hope to really make a difference on the burden represented by diagnostic errors and thus increase patient safety.

CLINICAL SCENARIOS: INPATIENT/POST-DISCHARGE
ADVERSE EVENTS AND MEDICAL ERRORS

Two surgeons reviewed hospital records concerning surgical care with screening criteria and they used a standardized procedure within a structured electronic review form just to determine or identify if AE had occurred, and if they were preventable. The surgeons defined an AE based on three criteria: (1) an unintended physical and/or mental injury; (2) a result in temporary/permanent disability, death or prolongation of hospital stay; (3) caused by the patient’s medical management rather than the disease state. [26]

Adverse Event Clinical Definitions (Unavoidable vs. Preventable)

Preventable adverse events are defined as events that do not meet the current standard criteria of medical professionals or healthcare systems. Unavoidable adverse events are the events that cannot be prevented. Also, described as unavoidable injury due to appropriate medical care. An example is when an unknown drug reaction occurs in a patient who just received the appropriate administration of a particular drug for the first time. If a drug reaction occurred in a patient who knowingly had a previous allergic reaction to that particular drug, the adverse event would be considered preventable and might be considered negligent.

The causes, consequences and prevention strategies of adverse events must also be carefully studied. Like for example in one study surgeons were able to review the surgical adverse events or events that played a big factor in surgical treatment and care. The surgeons classified the surgical adverse events by the clinical procedure involved, such as diagnostic process, surgical procedure, drug/fluid, medical procedure, other clinical management, discharge, and other. Consequences were also assessed such as a prolonged hospital stay, extra treatment, a readmission to the hospital, extra outpatient care, a temporary or permanent disability at discharge, and death as a result of an adverse event. The type of injury also classified it, such as: bleeding, infection, shock, thrombosis, necrosis, fistula forming, and abnormal wound healing. This classification by injury was
according to the national reporting system of adverse outcomes developed by the Association of Surgeons in The Netherlands. [26]

We should also realize that an adverse event usually happens due to several causal factors, including technical, organizational, human, and patient-related factors. It is better to use the well-known tool called the *Eindhoven Classification Model of PRISMA-Medical*, a root cause analysis tool. In this study, causal factors of surgical AEs were judged to be predominantly human factors (65%) and less often organizational (13%) or technical (4%). [26]

The categories of the taxonomy are:

- Human factors which are skill-based, for example failures in the performance of highly developed skills, or, rule-based, for example an incorrect fit between an individual's training or education and a particular task, or, knowledge-based, for example inadequate application of existing knowledge;
- organizational factors, for example inadequate or unavailable protocols, management priorities, inadequate transfer of information and cultural aspects;
- technical factors, for example material defects, failures due to poor design of equipment, software, labels or forms;
- patient-related factors, for example, co-morbidity, age, and treatment compliance

Types Of Preventable Adverse Events:

There are about four studies that reported the types of preventable adverse events in acute hospitals. Three of these studies showed that most of the adverse events and preventable adverse events were associated with a surgical operation. [48] Key points from these studies are listed below:

1. *Operative* adverse events accounted for 24%–53% of adverse events and 20%–42% of preventable adverse events.

2. The errors in *evaluation and diagnosis* and errors in *treatment* (including drug treatment) were the next most common types of preventable adverse events.

3. *Therapeutic* adverse events accounted for 15% to 28% of preventable adverse events.

4. *Diagnostic* adverse events accounted for 9% to 21%.

5. *Drug related* adverse events were the next most frequent type, accounting for about 10% of preventable adverse events.

The most frequent type of preventable adverse drug event was error in medication dose, followed by error in method of use, inadequate monitoring or follow up, inappropriate drug use and administering a drug to the wrong patient. Preventable adverse drug events were
the most common cause of avoidable readmissions to ICU and readmissions due to preventable cardiac arrests. [48]

Although the rate of surgical preventable adverse events was highest, surgical adverse events were least likely to be preventable. There are about 75% to 100% of diagnostic adverse events and 50% to 77% of therapeutic adverse events that were preventable, whereas only 17% to 44% of operative adverse events were considered preventable. [48]

Contributing Factors:
Preventable adverse events were often associated with more than one contributing factor. Most are individual error and a large proportion of these caused serious patient harm or death. On the other hand, a small proportion of adverse events were associated with equipment failure, which rarely caused serious harm or death. The proportion of system failures contributing to preventable adverse events varied widely, ranging from 3% to 83%. Generally, studies, which used reporting data, interview or questionnaire, reported a higher rate of system failure than studies. [48]

**Unavoidable Adverse Event Example**

To follow are some case scenarios of unavoidable or non-preventable adverse events:

First case involves the drug *tacrolimus* in a patient with graft-versus-host disease after bone marrow transplantation for chronic myelogenous leukemia. After giving the prescribed medication fatal acute renal failure occurred resulting in death.

Second case is an anemic patient who is experiencing syncope and coronary artery disease and developed a severe life threatening transfusion related acute lung injury after receiving a red blood cell transfusion.

Third case is of a patient with pseudonomal pneumonia who was given *imipenem* for his treatment but during the time the patient was being given imipenem, despite appropriate antibiotic dosing, seizures ensued and after changing the prescribed antibiotic treatment the severe tonic-clonic seizures still occurred.

Fourth case is about a procedural complication. This is a case of a 55-year-old patient with known liver cirrhosis who presented with shortness of breath and distended abdomen. The patient underwent paracentesis in the ED and returned 2 days later, stating that fluid was leaking from paracentesis sites. AE severity: required an ED return visit. [42]

Fifth case relates to a nosocomial infection. This is a case of a patient who presented to the ED with 5 days of bilateral leg weakness followed by sudden onset of paresthesias. Spinal cord compression was diagnosed and a Foley catheter was inserted. Three days later, the patient developed urinary tract infection confirmed by culture. AE severity: required medical intervention. [42]
Preventable adverse event example

To follow are preventable adverse medical event examples: [1]

1. Wrong surgical procedure such as wrong surgical site, wrong patient and wrong surgical procedure

2. Retained foreign body left during surgery on the patient

3. Blood donor or organ transplant incompatibility

4. Infectious agent transmission to a patient

5. Administering incorrect medication or dosage

6. Trauma or accident in the hospital such as falls or burns

7. Heart conditions such as DVT (deep venous thrombosis) or PE (pulmonary embolus) without the right prophylactic treatment

8. A surgical site infection without giving any antibiotic prophylaxis

9. Pressure ulcers

10. Catheter-acquired infections

Additional detailed examples of preventable adverse events are described below:

An operating room setting: two factors were considered as a proximate cause for an error. One involved a process factor when a post-insertion chest x-ray was not obtained and second is a controllable environmental factor when the surgeon failed to realize that the guide wire was much shorter than expected on the patient. Before this happened, there was no policy requiring the surgeon to inspect the guide wire when it was pulled out. After this incident, there were three action plans made that required all medical staff must complete an in-service training program specifically for this procedure, all procedures must be performed under fluoroscopy and following immediately a chest x-ray is required, and audits of the administration or quality assurance department for ensuring complete compliance. [20]

An operating room setting: a human factor manifested regarding where to place the sponges as they are being counted. An additional system issue or human resource issue was identified and the reason is because the circulating nurse and the scrub technician did not perform their duties as expected such as counting the number of sponges being used during the operation. The surgeon in this case was not at fault. After this incident, new strategies were developed. Firstly, a Devon Bag-It sponge counter bag (Covidien, Mansfield, MA) was to be used in all operating rooms (which looks like a shoe holder that hangs on a
pole). Each slot holds one sponge that can be viewed by the scrub technician and by the circulating nurse as they are counting aloud and concurrently. Secondly, leadership accountability was identified to prevent drift from and workarounds of existing policies. Thirdly, adequate in-service education programs were provided. Finally, random audits by the quality assurance team were set in motion to ensure proper compliance procedure. [20]

According to the report project of medical accidents dated July 2010 to March 2011, which was issued by the Ministry of Health, Labour, and Welfare, in Canada, there were also several incidents involving radiological technologists that occurred among young and experienced technologists so this became the focus of discussion. The researchers sent out questionnaires to different radiological technologists and examined the causal relationship between years of their experience and their concerns about patient treatment and safety. They found that their concerns about patient treatment and safety are different depending on years of experience. New technologists were on a low level of caring relative to the philosophy "To err is human"; they stated that the causes of the errors were neither the devices nor the system of the devices. Comparing to mid-career technologists, the report stated that they identified the most common cause of errors is the liability of the person concerned. Experienced technologists stated that the cause of the error is excluding the person concerned; also, due to the devices, patients, or advanced specialization of the examinations. It was concluded that technologist education is an important factor to improve skills and the depth of concern about patient safety. [15]

Preventable case scenarios are described below with correlating AE severities: [42]

1. **Suboptimal follow-up**: A case of a 53-year-old patient with a history of smoking, hypertension and coronary artery disease presented with left-arm paresthesias and weakness. CT head, chest radiography and ECG were all negative. Discharged with neurology follow-up in 2 weeks. On telephone follow-up 2 weeks later the patient stated that the symptoms had worsened and that an appointment had not yet been received.
   **AE severity: symptoms only**

2. **Fall**: A case of a 98-year-old patient diagnosed with myocardial infarction and congestive heart failure. No documentation of universal fall precautions in place in the ED or on the ward. The next day the patient fell in the bathroom — no physical injury was documented. The fall was deemed related to poor vision and physical reconditioning. The patient received physiotherapy and occupational therapy treatment.
   **AE severity: required medical intervention**

3. **Unsafe disposition decision**: A case of a 70-year-old patient with a history of chronic obstructive pulmonary disease presented with increasing shortness of breath and fever. The patient was noted to be in moderate respiratory distress. No acute changes on ECG or chest radiograph. The patient was treated and discharged as COPD exacerbation. Returned 8 hours later and in severe respiratory distress.
   **AE severity: required admission**
4. **Diagnostic issue**: A case of a 55-year-old patient presented with chest pain similar to usual angina. The nurse noted the pain radiated to the patient's back and blood pressure was unequal between arms. ECG and chest radiograph were noted as nil acute and troponin T positive. The patient was referred to cardiology and there was a 7-hour delay in diagnosis of aortic dissection.
   
   ***AE severity: death***

5. **Medication adverse effect**: A case of a 28-year-old patient presented with a 1-week history of confusion. The patient was found to be hyperglycemic, attributed to recent course of steroids. The patient was treated with IV insulin infusion, and 2 serial levels of hypokalemia occurred before treatment initiation.
   
   ***AE severity: required medical intervention***

6. **Management issue**: A case of a 90-year-old patient who fell and sustained a hip fracture. The patient was admitted for conservative management without deep venous thrombosis prophylaxis. Two weeks later the patient developed pulmonary embolism and responded to heparin treatment.
   
   ***AE severity: required medical intervention***

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**RECOMMENDATIONS FOR IMPROVEMENT**

**System Failures**

Type of individual and system errors:

Technical errors were the most frequent cause of preventable adverse events followed by failure to request or arrange investigation or procedure: the failure to synthesize, decide or act on information and lack of care. Inexperience and communication errors were the two most frequent types of system failures. This pattern was reported by virtually all of the studies, which provided relevant data irrespective of the specialty, and the methods used. [48]

The review found out that preventable adverse events are often associated with more than one contributory factor, and mostly are associated with individual error and a significant proportion with system failure. While technical errors and cognitive failures were the most common types of error, lack of experience, inadequate supervision of junior staff and problems in communications were the most common types of system error. [48]

There are two factors associated with the wide variation in the proportion of system failure, and these are as follows: [48]

Firstly, the majority of preventable adverse events, which were associated with a system failure, were also associated with other factors related to individual human error. Even in studies in which a large proportion of adverse events were associated with a system failure, only a small number of reported system failures were identified as the main or the sole cause of an adverse event. Studies that reported a small proportion of adverse events due
to a system failure, only noted system failure when it was the main or the sole rather than a contributory cause of adverse events.

Secondly, the reported proportion of system failures was strongly related to the methods used. Studies using case note review to identify and analyze adverse events reported a significantly lower proportion of system failures than studies that used an interview, questionnaire or reporting system data. This is because the retrospective case note review often focuses more on the actions of clinicians in the frontline, and less on the actions of other staff or systems with a more supportive role. Some potentially important contextual events might not be recorded in the case notes. Hence, *retrospective case note review may not provide sufficient information to uncover the underlying causes of adverse events, such as system failures.* [48]

The data collected by the reporting system, interview, or questionnaire may be biased toward the role of system failure and focus less on the role of the individual error. Clinicians may report adverse events in a way that shifts the responsibility from the individual and toward system factors. Case note review, overestimates the role of individual human factors and underestimates the role of system factors, while reporting systems and interviews or questionnaire-based studies probably do the reverse. [48]

A well-established model to evaluate system failure is the *Swiss Cheese Model of Systems Errors.* In any system-based approach, in order to prevent system failure or an error, there must be enough barriers and defenses. Consider a slice of cheese as representative of each system barrier; in reality, different barriers present themselves as a gap, or the hole in a slice of Swiss cheese. Gaps or holes do happen because of either an active or latent failures in the system or both. When comparing active errors, these are the errors committed by the front liners. These front liners in the healthcare field are the medical providers, nurses and pharmacists. While latent errors are the conditions that surround the error. There may be long standing problems and loopholes that become visible due to triggering factors based on the active errors. The kinds of latent errors or failures in the healthcare system would be the organizational process itself and the management. This latter type of failure may be prevented if identified and corrected early. [105]

If the errors in diagnosis are not reported properly, systemic failures and immediate medical attention will not occur. This is very alarming because it can undermine patient safety and cause harm. The best way to detect avoidable error and prevent it from happening is to report right away known errors, and to try to find the reason for any errors or failures. Once the reasons for any errors are identified, the recommendation is to outline the arrangement of clinical events in chronological order and consider developing safe and effective solutions to reverse the possible outcome of a patient's condition. Its important to remember that human errors can be included in the chain of events and medical providers tend to forget this. [104]

Historically, the surgical morbidity and mortality conference (SMMC) has been a core educational venue, a quality-assurance (QA) tool, and a way to socialize a surgical trainee into the culture of surgery. But most of the times, it is focused on human errors and just
occasionally discusses system failures that are responsible for the vast majority of medical errors. More recently, health care delivery systems place greater emphasis on the root cause analysis (RCA), which is one of the most effective ways to analyze system failures and find possible solutions to them. Initial data showed RCA improved patient safety. The best thing to do is to combine using RCA results in SMMC to enhance surgical education, QA, and teaching of patient-safety skills in surgical settings. [20]

Root Cause Analysis

Root cause analysis is one of the effective tools to identify the potential system and organizational problems, which will lead to adverse event or events. Most of the RCA will not be that practical to use for every adverse event. In order for this to become effective, RCA must be performed at the onset of pattern of events or in every serious event. [104]

Transitional Care

Transitional care has three sets of priorities in mind and these are: goal-oriented, time-limited and therapy-focused. An example would be after a hospital stay when a patient is provided with a package of different services that includes low intensity therapy such as physiotherapy, occupational therapy, social worker and nursing support and/or personal care. Most transitional care helps people complete the entire healing process and develop back their functional capacity, while assisting them and their family to make long-term care arrangements. [106]

There are different transitional care programs that are specific for older people who would otherwise be eligible for residential aged care. This program can be organized by the hospital where the client has received their acute/sub-acute care. A transition care client can only enter transitional care directly upon discharge from hospital. [106]

There are two types of transitional care to choose from and it is either a home-like residential setting or in the community setting. The average duration of transitional care for the elderly is 7 weeks, with a maximum duration of 12 weeks that may in some circumstances be extended by a further 6 weeks. [106]

A transitional care program is designed to improve a patient’s independence and confidence after every hospital stay. It is very important to create a transitional care team, which includes a medical provider, nurse coordinator, dietician, pharmacist, psychologist, and social worker (most especially for elderly people). This team must follow the patient through inpatient and outpatient hospital settings as well as transitional interface. The transitional care team should contribute significantly to reduced readmissions, ER visits, deaths, adverse events, and cost of care. [104]

Medication Reconciliation

Medical Reconciliation is a process of detecting the most accurate list of medications of a patient that are a big part of patient care. This includes knowing the name of the medicine,
its dose, frequency, route as well as its uses and adverse effects. This information must be well known to provide proper medicines for patients. The process also needs to compare all the list of the patient’s current medications with the admitting notes of the medical provider, its transfer and discharge orders. [104]

A study noted that 7% of adverse drug events occur in acute care hospitals, and at least 58% of these can be prevented. These are resulting from incomplete drug information, prescribing or dispensing errors, and overuse or underuse of medications. It is very essential to have effective implementation of medication reconciliation in order to lessen the preventable adverse drug events occurring at transitions between community and hospital care.

To ensure that medication reconciliation is used for all high-risk patients, many hospitals today have a paper-based or electronic-based medication reconciliation process. This is also in compliance with the accreditation standards. It was noted that adherence of this is poor which is generally conducted in less than 20% of patients at risk. There are new electronically enabled discharge reconciliation processes that represent an innovative approach to this problem. [22]

One of the main barriers of medical reconciliation is time and the resources it requires to gather the data, such as the community drug list determination, most especially in the emergency departments (ED) where most patients are admitted. For a typical ED with 50,000 visits per year, it is reported that an estimated additional 2,900 hours of nursing time and 8,750 hours of pharmacist time would be required; not to mention, the added wages on these health care personnel of $349,500 at $30/hour just to complete the admission medication reconciliation for patient visits where it is required. It was also observed that at least 20% of patients died or were discharged before having complete information related to the community drug list. Healthcare departments for further improvement on medication reconciliation adherence and compliance must appropriately address this.

To overcome such inefficiencies to adherence, Brigham and Women’s Hospital established a prototype medication reconciliation module that integrated data from the ambulatory electronic medical record and discharge medication orders. This had improved adherence to 68.7% because more medical providers could reduce their time to complete the process by ten minutes. Another hospital that followed this method of medication reconciliation was Bellevue Hospital in New York, where the decision was made to block admission and discharge orders until medication reconciliation was completed. We should take note that this is possible only for hospitals with computerized prescriber order entry (CPOE), which represents less than 20% of hospitals in the United States, and even fewer in Canada [22]

**Improved Electronic Medical Record (EMR) Strategic Use**

Current healthcare systems are increasing and changing tremendously, and that is the reason why there is acceleration of diagnostic and therapeutic tools, multiplication of stakeholders, and an escalation of economical and societal challenges. This complexity leads
to inevitable discontinuities, and many gaps have been identified, including their impacts on the quality and safety of healthcare processes documented. [51]

Specifically in relation to the lack of safety in the healthcare industry, reports have highlighted the important contribution of various discontinuities in healthcare as a basis to develop corrections and reforms; and, simultaneously, addressing the potential role of information and communication technologies to help improve the situation. For example, in 2001, a recommendation for "... an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education..." [51]. The U.S. President’s Information Technology Advisory Committee in 2004 summarized the existing evidence and provided recommendations for a framework in the 21st century healthcare information infrastructure to lower cost, reduce errors and improve quality, based on four components: electronic medical records, clinical decision-support systems, computerized provider order entry (CPOE), and a secure, private, inter-operable health information exchange. [51]

Since the new health system vision was announced, the healthcare information technology (HIT) industry, has gone through various stages of what is called Gartner’s hype cycle: from a peak of inflated expectations, illustrated by the following statements: “... the potential of IT to improve the delivery of care while reducing costs is enormous...”; “... increased mortality after implementation of a commercially sold computerized physician order entry system ...” (an evolutionary stage in the cycle that reflects a period of disillusionment due to conflicting bad outcomes following implementation of a new COPE); and, “... hospitals with automated notes and records, order entry, and clinical decision support had fewer complications, lower mortality rates, and lower costs ...” (a slope of enlightenment that all is not as bleak or disruptive as described in the preceding phase of the cycle). The last stage of the Gartner's hype cycle, known as the “plateau of productivity”, has not been reached yet, as reflected in the existing literature for strong evidence of the impact of electronic medical records or CPOE. [51]

Presently, for the patient to be well informed, the increasing nature of information and communication technologies is enabling new developments in electronic medical records, with potential significant impacts on improving care transitions. Most people and consumers are getting ready and equipped with their “digital proxy”, a mobile that is always on, permanently connected, and with a context-aware device such as a smart phone. Now, homes can be made intelligent, aware and reactive to the wishes and needs of their inhabitants. There is rapid development of “ambient assisted living” tools occurring, providing intelligent technologies aimed at supporting ageing, chronically-ill populations that want to remain autonomous, at home, for as long as possible. With the ability to supervise and monitor this kind of healthcare task, there is correlating acceleration of the different responsibilities among medical professionals towards patients, and most especially their families and friends. [51]

In an increasingly consumer-oriented healthcare era, there is both opportunity and risk involved because it requires further personalization of healthcare services and of its ICT enabling tools. The opportunity exists to increase acceptance of consumer-adapted tools,
and to be able to make use of additional, personalized contextual information to enhance their relevance, accuracy and usefulness. The risk relates to further fragmented information and services, as witnessed when looking at all those small “apps” that are being installed on smart phones, each with a different purpose. If these become a success, we will move one step closer to providing personalized, adapted, coherent and interoperable electronic health services to individuals and their care professionals. [51]

The transitions in healthcare truly accounts for a significant share of preventable medical errors, but electronic health tools can totally help secure these transitions by improving communication and coordination; and, by involving and empowering patients and enabling new ways to access quality care. There are many challenges such as improving issues of trust amongst the multiple and diverse stakeholders. This involves being able to create a sustainable, open infrastructure on which innovative services can be developed, and to demonstrate their added value, return on investment, and contribution to improving healthcare and health outcomes. [51]

Patient harm resulting from medical care remains very common as validated by U.S. studies. There is little progress to no improvement, for example, only 1.5% of hospitals in the U.S. have implemented a comprehensive system of electronic medical records, and only 9.1% have even basic electronic record keeping in place. Only 17% of U.S. hospitals and clinics have computerized provider order entry (CPOE). Physicians-in-training and nurses alike routinely work hours in excess of those proven to be safe. The compliance with even the simplest interventions, such as hand washing, is poor in many health centers. [41]

A reliable measurement strategy is required to enhance patient safety and most medical centers are still dependent on voluntary reporting to track institutional safety, despite repeated studies showing the inadequacy of such reporting. The patient-safety indicators of the AHRQ are susceptible to variations in coding practices, and many of the measures have limited sensitivity and specificity. Recent studies have shown that the trigger tool has very high specificity, high reliability, and higher sensitivity than other methods. The only problem is the manual use of the trigger tool, which is time consuming; but, as electronic medical records become more widespread, automating trigger detection could substantially decrease the time required to use this surveillance tool. [41]

The CPOE systems are computer applications that allow direct, electronic entry of orders for medications, laboratory, radiology, referral, and procedures. CPOE systems for ordering medications are sometimes called electronic prescribing (e-prescribing) systems. CPOE systems are often implemented with clinical decision support (CDS) alerts to guide ordering. There is early research demonstrating the benefits of CPOE/CDS systems in reducing medication errors by as much as 55 – 86 % and subsequent adverse drug events (ADEs), although the latter occur less frequently and are more difficult to identify. [47]

There is evidence from several systematic reviews about the benefits of CPOE/CDS systems relative to medication safety. The studies included in these reviews overlap, and vary widely in design and results; few include randomized, controlled trials. The heterogeneity of the studies prevented all but one author from conducting a meta-analysis, but these authors
found CPOE/CDS systems were associated with a 66% reduction in the odds of an error occurring. The results of such studies show that even a basic CPOE system, without CDS alerts, can have a favorable impact on medication safety. That this work was conducted in an independent medical group practice suggests that CPOE implementation is associated with improved medication safety in the real-world setting. [47]

CPOE with CDS is a critical component of the EMRs order-management system. This order-management system must support the patient's care team as it cooperates in performing the sub-processes of:

1. care-plan development and communication (by medical providers, nurses, and pharmacists)
2. order planning (by medical providers, nurses, and pharmacists)
3. order entry (by nurses and medical providers)
4. order review, modification, and fulfillment (by pharmacists, nurses, and medical providers)
5. order review and administration (by nurses and medical providers)

CDS is an important feature of health IT. In the future, its effectiveness will depend not only upon the design and implementation of the CDS functionality but also upon consideration of changes to the work system in which it is implemented.

Electronic Medical Records (EMRs) have become very useful today. It helps automate the medical provider's workflow, and it generates a complete record of a patient with all the pertinent information needed; such as, patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. It also supports any clinical patient encounter as well as other health-care related activities, which directly or indirectly include evidence-based decision support, quality management, and outcomes reporting. [54] EMRs are useful in the healthcare setting due to their ability to have a single system that can store and generate all of the relevant information for a health team. EMRs have definite potential to improve efficiency, patient safety, and quality of care and to reduce barriers to effective communication between health providers. [54]

As a computer based system, EMRs use a prescription system wherein required doses, routes of administration, and frequencies are entered into a software program and the computer performs the calculation. This functionality has been shown to reduce the rate of incomplete prescriptions although in isolation it cannot reduce the rate of dangerous dosing errors. This is very helpful in the pediatric therapy database, which includes information on dosing recommendations; and, in one study focused on the use of a computerized prescription system it was shown it could save 45 minutes of time per day. [54]

Before the first introduction of this system in the U.S. in the 1970s, expectations about CPOE systems reducing medication errors and patient harm were high. There were reasons to suppose that CPOE/CDSS systems would be effective in reducing medication errors and adverse drug events, and thereby improving medication safety. A number of studies
(predominantly from the U.S.) showed CPOE/CDSS systems were indeed successful strategies for reducing medication errors, and there was some indication of patient harm being reduced. As mentioned earlier, there were also other studies that showed negative effects in the sense that new medication errors were being introduced through CPOE/CDS or that mortality increased after implementation of CPOE/CDSS in a Children's Hospital. [49]

Different studies that looked into the effect of electronic prescribing were predominantly performed in the U.S., because it was there that CPOE/CDSS was first introduced into clinical practice. The findings from these studies may not apply to the European hospital setting due to differences in computer systems and work processes between countries. Therefore, studies using an ITS design with segmented linear regression analysis in order to evaluate the effect that CPOE/CDSS has had on the incidence of medication errors, and to relate this to patient harm, is also underway in European hospital systems. [49]

Medical provider resistance is a major perceived barrier for hospitals to adopt EMR systems. As fully functional EMRs become more commonplace, having a single system that can store and generate all of the relevant information that a health team needs will become easier. Improved efficiency, patient safety, and quality of care with the use of such tools can hopefully reduce the barrier of medical provider resistance. [64]

It has been demonstrated that an EMR-generated rounding report could save medical provider’s time, increase satisfaction, and improve patient safety. Similar to the findings of Van Eaton research (mentioned earlier), junior medical residents reported significant time savings of 45 minutes per day. However, the system did not report any time savings for attending providers, and the time savings for senior residents was estimated at 30 minutes.

In contrast, it has also been reported that EMR-generated rounding provides a 45-minute time savings across all levels of provider training. This may be in part to the automated nature of some single system designs where the report has been fully integrated into the EMR, not as a separate system, and where users have remote access to allow notes. Some researchers believe this particular document format and the use of the EMR to generate all of the data for a Rounding Report to be unique. All previously reported systems in the literature describe a separate rounding and sign-out system from their EMR system. [64]

A very good example that EMR is useful relates to an EMR-derived automated adverse-event detection system as an efficient and effective method to identify hypoglycemia in hospitalized children. Hypoglycemia is a common adverse event in pediatric inpatients. NICU patients, premature and low birth weight infants, and patients receiving insulin therapy are at the highest risk for hypoglycemia. Although the results are based on a single institution’s experience, one study demonstrated how the EMR could significantly aid in the development of strategies to reduce hypoglycemia in hospitalized children. [69]

Patient flow delays occur during the implementation of an EMR in a busy pediatric ED. It is difficult to know how much benefit is gained through interventions of increased staffing and limited diversion of low acuity patients. [77] Every user of an EMR continues to make suggestions about their needs and requirements, and the EMR system has evolved to
optimize ease of use and special functionalities for particular groups of users and particular subspecialties. Based on some experiences and the lessons learned in the course of maintaining full-EMR systems, some researchers have suggested that the key goals to be considered for future EMR system development include the following: innovative new user-interface technologies, special extended functions for each user group's specific task-oriented requirements, powerful and easy-to-use functions to support research, new flexible system architecture, and, patient-directed functions. [82]

**IMPROVED SCREENING METHODS TO IDENTIFY PATIENTS WITH ADVERSE EVENTS**

The priority of research on patient safety and the transformation of the work environment have typically focused on inpatient acute care settings. The Institute of Medicine (IOM) reported clearly and recommended that work be done on “studies and development of methods to better describe, both qualitatively and quantitatively, the work nurses perform in different care setting”. [29] The recommendation is that research on patient safety needs to be addressed across care settings. Preventive services, primary care, and ambulatory care settings are areas where there is a more limited body of research related to patient safety.

There are two national task forces that have been commissioned to evaluate existing preventive services. The Agency for Healthcare Research and Quality (AHRQ) convened the United States Preventive Services Task Force (USPSTF), an independent body of experts, to evaluate and make recommendations for clinical preventive services. The Centers for Disease Control and Prevention (CDC) established the Community Task Force to evaluate public health prevention programs. Both task forces focus on establishing the efficacy of prevention strategies and also consider the relative harms and benefits of preventive services. [29]

Adverse events usually happens in one third of hospital admissions and reliance on detecting methods could lead to improper ways of improving patient safety. Recent studies showed that the adverse event detection methods commonly used to monitor patient safety in the U.S. today, such as performing reports voluntarily as well as using and helping out with the AHRQ’s Patient Safety Indicators, is flagged as very poor performance comparing to other screening methods. This fact is believed to be the cause of 90 % misses of adverse events. Researchers discovered that the Institute for Healthcare Improvement’s *Global Trigger Tool* is ten times more effective than other methods. [107]

There are many questions with regards to the reliability of automated measures on patient safety, and such measures can confuse quality teams if automated measures are neither sensitive nor specific to identify adverse events. There are some methods that only rely on the medical charts of providers and nurse reviews, and this approach was used in the Harvard Medical Practice Study of adverse events in hospital patients. Since this method is very time consuming, it only has limited use. [108]
Clinical surveillance has a lot of advantages over some adverse detection methods. It involves active surveillance and has an independent view on voluntary reporting; and, the collection of information relevant to case classification is timely and accurate, and it does not rely solely on what is documented in charts. The only problem is that it has not yet been used in multiple or various settings due to a lack of popular knowledge on its benefits. [27]

There are many countries that believe in and perform retrospective patient record review studies, and utilize this method as the most helpful way and solution to identify adverse events in their hospitals. However, there is recognition that this method has some disadvantages too, such as being time-consuming, pricey and laborious. [28]

According to one study, reporting sources are very helpful to hospitals, which can provide information on patient safety periodically and on demand. Incident reporting is recognized by a lot of medical providers and healthcare professionals. It is also true that relatives of patients can play an important role in signaling safety issues. [28]

The Vaccine Safety Datalink (VSD) project created a real-time active surveillance system that detects real safety problems, and in which problems can be investigated and ruled out internally without generating false alarms to the public. The VSD shared experience offers lessons that may be useful to others who are establishing similar systems. [31]

The VSD’s active surveillance system also improves as lessons are learned from past experience, and has already proven valuable. In 3 years of operation, there was detection of one vaccine-safety problem that led to a revised Advisory Committee on Immunization Practices recommendation for the MMRV vaccine. Nine other signals were fully investigated and ruled out. The different causes of these spurious signals were due to uncertainty in the estimated background rates, changes in true incidence or coding over time, other confounding, inappropriate comparison groups, miscoding of outcomes, and chance. It was reported, “Some of these causes are preventable and have been corrected in subsequent VSD analyses, whereas some will be problematic for any active surveillance system.” [31]

One of the most significant barriers to reducing errors and improving quality of care is lack of awareness of the type, the incidence, and consequences of errors in any setting. The most commonly used method for estimating vulnerabilities in healthcare is to retrospectively collect and count errors through voluntary reporting systems (often referred to as “incident reports”). These are fraught with difficulty due to underreporting (according to IOM’s 1999 report, only 5% of known errors are typically reported; and, then there are unknown errors) and abuse, for example, reports filed and counter filed as a means of retaliation against colleagues. Error reporting often does not promote understanding of the organizational structure and processes of care but it tends to be associated with blame and shame, and frequently results in antagonism between team members undermining mutual respect, trust, and cooperation. [35]

The Patient Safety and Quality Improvement Act (2005) was introduced in large part to stimulate increased error reporting through the creation of Patient Safety Organizations (PSOs). Bates and colleagues have described difficulties involved in defining and quantifying
errors. They report that even direct observational studies, which are highly labor intensive, often miss errors. An alternative approach that is prospective, rather than retrospective, and encourages involvement of all team members for identifying and prioritizing safety and quality problems invokes Failure Modes and Effects Analysis (FMEA). This has been widely used in other high-risk industries and has been advocated by the IOM9 as a means of analyzing a system to identify its weaknesses (“Failure Modes”), possible consequences of failure (“Effects”), and to prioritize areas for improvement. Some have adapted and tailored this methodology to allow for levels of resources and expertise available in ambulatory settings, and developed an instrument that has been shown to be effective in a variety of these settings. The details of the rationale and processes behind this instrument termed “Safety Enhancement and Monitoring Instrument that is Patient Centered” (SEMI-P) are described elsewhere. [35]

It is important to know that a vital step toward creating a strong safe medical model is to close the medical provider divide so as to maintain communication and coordination. This has drawn attention to the fact that currently practice meetings are “universally unpopular” despite their indispensability. The medical model that invokes a paradigm of complex adaptive systems is designed to aid formation of central “attractors” in the form of self-empowered effective learning teams, with a common vision to help their complex microsystems adapt. Thriving systems are endowed with simple rules, shared vision, and opportunities for team members to innovate. [35]

In order to be more practical, reliable and less time consuming, the Institute for Healthcare Improvement developed the Global Trigger Tool. This new method has been used widespread by hospitals in the U.S. and the U.K. The tool has also been used by organizations in need of quality assurance, and by U.S. regulators like the Department of Health and Human Services (HHS) Office of Inspector General, which has used it in a study to estimate the incidence of adverse events in hospitalized Medicare patients. [108]

The success of the study by the HHS Office of Inspector General has led to recommendations that the Centers for Medicare and Medicaid Services develop new detection methods for adverse events in hospitalized Medicare beneficiaries. The study has also informed ongoing work to evaluate and update national patient safety measures at the National Quality Forum, a nonprofit organization that seeks to build consensus around national performance measures for quality and to disseminate them. [108]

The Global Trigger Tool uses specific methods for reviewing medical charts. The closed patient review chart happens between two or three employees mainly nurses and pharmacists, who are trained to review the charts in a systematic and reliable manner by looking at discharge codes and summaries, medications, laboratory results, operation records, nursing notes, physician progress notes, and other notes or comments to determine whether there is a “trigger” or an abnormal laboratory result or medication stop in the chart. It there’s any trigger noticed then a medical provider who needs to examine and sign off on a chart review further investigates.
In one recent study, the three methods (the hospital’s voluntary reporting system, the AHRQ’s Patient Safety Indicators, and the Institute for Healthcare Improvement’s Global Trigger Tool) were examined in terms of utility to figure out any adverse events among hospitals in the inpatient department. The performance of each method was being compared and rated. Based on the findings, it was stated, “the Global Trigger Tool method had both high sensitivity and high specificity, the Patient Safety Indicators method had very low sensitivity and high specificity, and voluntary reporting systems seemed to be very insensitive.” [108]

The Global Trigger Tool is well developed, with adverse event detection rates of 3.9 percent and 2.7 percent, respectively, in New York and Utah/Colorado. The detection levels were also higher than those of adverse events with other methods in hospitalized patients from England, Australia, and Canada. [108]

Use of the European Foundation for Quality Management (EFQM) model to build the assessment tool allows information to be structured and to organize safety standards and indicators of security in a consistent manner. This methodology proposes a suitable tool for measuring patient safety in an extra-hospital situation. The application of this tool will identify areas for improvement related to patient safety. To create this tool use of the SENECA study (a European multicenter study) provides the foundation; and, the indicators were created using the Delphi Method (relying on a panel of experts). [81]

Despite that a decade has already passed since the Institute of Medicine report on patient safety, hospital adverse events have been reported to still be high and not fully managed. This observation should be an incentive for incoming policy makers, reviewers and researchers to evaluate methods for the detection of adverse events in hospital patients. Specifically, the results could influence the work of the Centers for Medicare and Medicaid Services and the AHRQ as they evaluate methods to detect patient safety problems in Medicare inpatients; as well, the ongoing work at the National Quality Forum to evaluate and develop new national measures of safety. A Global tool to identify adverse events and rates of organizational performance to a universal scale is a stepping-stone to progress toward a high level of patient safety. [108]

ON REFLECTION

The limited body of evidence on errors and adverse events in preventive services definitely supports the need for additional research to move ahead in the area of patient safety. Some of the evidence from studies in ambulatory and primary care will assist to provide future direction for research and subsequent evidence-based practice, for example, in preventive care. There are also unique errors and adverse events associated with preventive care. It is clear that there is potential for errors and adverse events in a preventive model or service, but additional evidence is needed to explicate what they are moving forward. The evidence that is available is largely from either descriptive studies or from randomized controlled trials examining the efficacy of preventive services to avoid adverse events, specifically in cancer screening. There is less systematic evaluation of some aspects of preventions, for
example, counseling interventions for prevention. The nature of preventive services and their outcomes and where they are delivered is exciting, yet increases the complexity of both establishing an evidence based program and implications for practice. The continued evaluation of using information technology to address risks and adverse events is a promising area for study and practice in future venues of health care, including prevention services. [29]

The main focus in safety and quality research in health care has been on preventable events rather than on preventive services. Screening, counseling, and chemoprophylaxis are the key elements of preventive services. The evidence relative to errors and adverse events in the area of preventive services is limited and needs to be developed to provide direction for practice. [29]

The need to eliminate health care–associated preventable harm by ensuring implementation of evidence-based recommendations for patient care is also essential and depends on a well-organized investment in research. Policy makers should start with the goal of eliminating preventable harm and work backward to fill in knowledge gaps necessary for attaining that goal. For national prevention programs to be fully successful and broadly implemented, resources must be available to support and develop all phases of the translational research process. This full investment will ensure that patients actually receive the benefits of evidence-based prevention practices, and reduce preventable harm. [30]

Medication errors can have a serious public health impact and can be extremely expensive. The Safe Use Initiative (SUI) is a non-regulatory effort within the FDA and one of its focus points is to identify areas where medication errors can be prevented. Through collaboration with key stakeholders, the SUI hopes to raise awareness of these issues and support the health care community to make changes. As a result of the combined efforts of SUI and its partners, a number of key areas have been identified as worth addressing, for example, in the optimization of pain therapy. Healthcare provider education on NSAID use is necessary for the protection of a patient’s wellbeing. Improving physician (and other healthcare providers) adherence to NSAID guidelines, and enhancing understanding of the pharmacology of NSAIDs in the geriatric population, is an essential step to reducing medication errors. Finding new and innovative ways to promote education and awareness should be a task that the entire health care community addresses. [38]

Despite documented success to reduce medical errors in both surgical anesthesia and the Veterans Health Administration Medication Delivery System, adverse events and medical errors continue to represent an indelible stain upon the practice, reputation, and success of U.S. health care improvement initiatives.

In that regard, what may be required to successfully attack the unacceptably high severity and volume of medical errors is a locally directed and organized initiative sponsored by individual healthcare organizations that is coordinated, supported, and guided by state and federal governmental and nongovernmental agencies.
Within such a comprehensive approach, trained and designated personnel at or consulting with diverse health care organizations would be able to undertake the following:

1. Detect and observe the manifestation of medical mistakes in identifiable patient groups at greatest risk, and comprehend their cognizable root causes;
2. Scrutinize, decipher, and distribute data to clinicians and interested parties;
3. Execute error diminution stratagems based upon reanalysis and restructuring of health care systems;
4. Where required, call upon health care experts for technical support and on-site surveys;
5. Evaluate the impact of newly implemented programs on patient safety.

Factors that presently reduce the efficacy of medical error prevention programs include:

1. Extant performance improvement and continuous quality improvement programs most often do not specifically address the issue of medical errors;
2. Initiatives aimed at medical error reduction traditionally operate in isolation;
3. Infection control and employee safety initiatives typically receive low priority at health centers;
4. Passive error reporting systems suffer from incomplete reporting and underreporting of identifiable medical errors;
5. Active reporting systems are expensive to implement and maintain. Furthermore, active reporting systems that hold individuals responsible understandably suffer from intentional underreporting of errors;
6. The new reduced working hours of house staff has resulted in the new dilemma of frequent patient handoffs to the new doctors coming on service. These handoffs have resulted in a new potential pitfall for errors that will need to be addressed in the upcoming years;
7. Despite the present mandate for electronic records so that medical information can be more easily shared by collaborating physicians and subspecialties, the varied types of electronic medical records and challenges with their ability to communicate, is causing electronic sharing of information to be potentially fraught barriers and necessary steps must be take to address implementation strategies and to avoid increased gaps in communication and patient safety.

The Quality Interagency Coordination Task Force has concluded the following:
“Systems designed to facilitate quality improvement through error reduction can generate effective, useful reporting if those individuals who report are assured of confidentiality, protected from legal liability resulting from the report, provided with
timely feedback on the data from the system, and are not unduly burdened by the effort involved in reporting.” [7]

There is continuous enhancement requests for the EMR Rounding Report than current resources can keep up with; and, a need is seen to expand the report to other services such as the special needs and requirements of the pediatric populations, nursing staff, emergency room, surgical subspecialties, intensive-care unit, and obstetrics. Health team members other than physicians and nursing staff, can utilize the rounding report as well as social services when transferring patients to outside facilities such as nursing homes. [54]

Ongoing studies support that improving the hand-off is important to enhancing the culture of safety and continuity of inpatient care. Without effective hand-offs, current and potential future added limits on shift work hours, such as those of medical residents in training, might result in an uncomfortable trade-off; such as, errors attributable to fatigue and errors due to inadequate transfer of information during the hand-off. Under team- and shift-based approaches to care, hand-offs are not limited to any one provider or health team member, and improving them is germane to safe and effective care. Thus, efforts ultimately will need to go beyond making learners, or any individuals, the repository and conveyors of this information through creation of reliable systems to manage and move information critical to patient care. This should include finding more effective approaches for asynchronous hand-offs, including systems to support information transfer and continuity of care when members of the health team cannot meet face to face.

Research also is needed to study the decision-making models and algorithms that underlie the hand-off and how these could be better understood and taught to promote safe care during end-off-shift hand offs and facility transfers. Related work includes efforts to enhance the salience of information in hand-offs through the use of three heuristics—“reduce, reveal and focus,” with this approach based on naturalistic approaches to enhance decision-making. Such research also may benefit the design of future hand-off summaries. Finally, work is needed to explore the best approaches to charge nurses, senior residents and faculty, and health team members in general to assist in the recovery of information lost or distorted in the hand-off. Research in all of these areas has a high potential of contributing to better approaches for hand-off teaching and practice. [61]

The communication issues implicated as a root cause in greater than 80% of reported adverse events represent an opportunity for the development of technological tools designed to improve the exchange of information. Specifically, computerized sign-out tools can facilitate standardization of the handoff process and access to clinical data. In doing so, these electronic sign-out applications have the potential to improve communication and reduce preventable adverse events. The benefits of using computerized sign-out tools to facilitate the handoff process have been demonstrated in various medical disciplines, including pediatrics and the newborn intensive care unit [40].

Clinical surveillance can also be an effective means of detecting patient safety issues. Although it was reported as effective, further evaluations are recommended. [27] First, it is recommended to compare the findings of clinical surveillance with other detection methods.
of identifying patient safety events. Second, economic analysis for the detection of adverse
events is also necessary to identify the best effective method. Third, an evaluation of this
method in different hospitals is also a priority. Finally, it is recommended further studies are
needed to determine if adverse event detection leads to improvement in patient outcomes.

There are many solutions that have been presented to prevent factors associated with the
risk of duplicate medication ordering errors. The solutions conform to the principles of
designing systems to do the following: support communication and collaboration among the
healthcare team; enhance error recovery by improving team and individual situation
awareness, particularly around shift changes and other hand-offs; improve teamwork with
regards to order entry; and, improve the usability and functionality of order entry screens
and medication alerts. [58]

Some other recommendations that needs to be considered in the long run include:

1. Manufacture medication databases to:
   a. Identify the same medication, regardless of combination, formulation, or route
      of delivery;
   b. Identify potentially additive medications regardless of medication class;
   c. Identify medication combinations (including doses) that could potentially be
      additive but have been demonstrated to be safe and effective, for example, the
      combination of aspirin 81–625 mg once a day with clopidogrel 75 mg a day.

2. Manufacture EHR algorithms for checking for potentially duplicate and additive
   medication orders.

3. Apply human factors design principles to make the patient's medication record —
   recently administered and planned — more accessible and comprehensible during
   order planning, entry, review, and administration.

4. Apply human factors design principles to create more accessible and
   comprehensible alerts.

5. Select, implement, and maintain health IT products and services for both safety
   and effectiveness.

6. Develop context appropriate policies for order entry. For example:
   a. Review all recent and planned medications before entering or fulfilling orders.
   b. Identify one person on a rounding team to enter orders during patient rounds
      and a supervising physician to review orders immediately after rounds.

7. Require hand-offs (for example, at change of shift and patient transfer) to include
   communication of recent and planned medication orders.
8. Review and optimize protocols for care processes likely to create duplicate or additive orders, for example, electrolyte replacement in patients on TPN, anticoagulation, or verbal orders.

To prevent an increase in duplicate medication orders will take the concerted efforts of multiple stakeholders, which include policy makers, medication database manufacturers, EHR manufacturers, healthcare organizations, healthcare teams, and individual clinicians. The availability of safe and effective medication databases and EMRs requires safety measures, such as certification requirements and additional software systems (i.e., medication databases) that align with certification schemes. Health IT manufacturers will need to enact the solutions listed above that are relevant to them. Healthcare organizations will need to include the above solutions in their efforts to maximize the benefits and decrease the risks when they implement information technologies.

Two demonstrated risks of CPOE are particularly relevant to medication safety: increased duplicate errors and alert fatigue. The EMR manufacturers must perform usability evaluations of CPOE and design the technology with the contexts of use in mind. Healthcare organizations must work with manufacturers to inform them about those contexts, ensuring that alerts encompass all predictable, relevant situations. Healthcare organizations should provide competency-based EMR training and feedback to users (as well as their supervisors) regarding the frequency of duplicate order entry. Of course, this reporting should not be seen as an adequate substitution for the more effective solutions above. Finally, definitions of healthcare professionalism will need to be extended to include the management of electronic patient information. [58]

Based on these findings, multiple improvement activities, particularly continuous improvement of any model of healthcare (care-delivery organizations, care teams, and clinicians) and the health IT organized to service them, are recommended. Systems factors such as teamwork, communication, organizational decision-making, and user-centered design of health IT represent important areas for further research and health team engagement. [58]

This study module has provided a domestic and international perspective on the progress of preventable adverse events. It has been emphasized that the standardization of patient safety data can enhance adverse event reporting, aggregation, and analysis. Certainly, the main goal is to attain a standardized safety model to produce accessible data for query and local and international comparisons. Meaningful safety data allow for the development of evidence-based actions that can be prospectively applied to patient care processes and provides a means for intervention validation. Those involved in health care quality and patient safety should concentrate on classification development and integration into health system reporting structures to ensure the application of meaningful data to improve patient safety in their organizations. A best practice classification can serve as a model to other health systems and organizations seeking to integrate standardized data collection into their operational functions. As health teams continue to work on patient safety initiatives, new funding avenues and opportunities may evolve to further incentivize and to reach out to a wider arena of patient safety leaders to improve terminology and future outcomes. [67]
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