FDOH Medical Errors: A Public Health Perspective

Learner Course Guide

To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.
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**Section Quiz**
The Public Health Practice Unit (PHPU) is pleased to be able to provide this training with a continuing education opportunity. This is a self-paced course which means that once the course is completed with an 80% or higher on the post assessment and the evaluation is completed and submitted back to the Public Health Practice Unit, continuing education credit will be turned in to CE Broker on the participant’s behalf.

In order to receive continuing education credit, the participant must complete the Evaluation Form (completed with participant’s name as it appears on the license and license number) attached to this course and return the form by fax (850-922-0462) or email.

Slide 2 – How to Use Navigation
In order to make your training experience as easy as possible during the course of this self-paced Training Course, we are providing these navigation instructions.

When a slide pauses you can do one of three things to advance the presentation:
You may click directly on the slide with your cursor;
You may click on the PLAY button on the bottom left of the screen;
or you may click on the FORWARD button, also located on the bottom left of the screen.
It’s a New Day in Public Health

If you need to review a previous slide, you may click the BACK button on the bottom left of the screen. Please keep these instructions in mind as you proceed with this training. You will need to advance the slide now.

As a Florida Board of Nursing approved provider of nursing continuing education, this course meets the Florida requirement for 2 hours of continuing education on prevention of medical errors for initial licensure and biennial renewal according to Florida Statute 456.013.

This course addresses the impact of medical errors on today’s healthcare system with a focus on the outpatient setting, root cause analysis, error reduction and patient safety. It further addresses medical errors that are relevant to the public health environment.

Information and research informing the content of this program has been derived from historical reports authored or published by the Institute of Medicine as well as scholarly literature review.
Slide 4

LEARNING OBJECTIVES
Upon completion of this course, you will be able to:

- Identify the scope of the problem
- List factors that increase the risk of medical errors
- Recommend general process changes which reduce errors and improve patient safety
- Discuss evidence-based strategies to decrease risk of medical errors

Continued…

Following completion of this course, it is expected that the participant will be able to:

- Identify the extent to which medical errors occur in the healthcare system;
- List factors that increase the risk of medical errors;
- Recommend process changes which reduce risk of errors;
- Discuss evidence-based strategies for reducing the risk of medical errors;

Slide 5

LEARNING OBJECTIVES
Upon completion of this course, you will be able to:

- Summarize internal and external reporting responsibility;
- Describe the importance of communication in preventing and identifying medical errors; and
- Explain the importance and role of root cause analysis in prevention and recurrence of medical errors.
DEFINITIONS

Adverse event – an injury resulting from a medical intervention rather than the underlying medical condition of the patient.

Medical error - the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.

Near miss - “any potentially harmful event that could have had an adverse result but, through chance or intervention in which, harm was prevented.” [§381.0271(7a.3), FS]

The Public Health Practice Unit offers definitions for various words and technical verbiage which the participant will see throughout the presentation and may want to reference at a later date. Definitions have been derived from historical reports authored or published by the Institute of Medicine.

Adverse event - an injury resulting from a medical intervention rather than the underlying medical condition of the patient. It is considered preventable and signals the need to ask why the error occurred.

Medical error - The failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.

Near miss - “Any potentially harmful event that could have had an adverse result but, through chance or intervention in which, harm was prevented.” [§381.0271(7a.3), FS]

Preventable harm - An adverse occurrence or event which results from insufficient vigilance or lack of prudence or forethought on the part of individual providers

Safety of care - Freedom from accidental injury

Sentinel event - An unexpected occurrence involving death, serious physical harm or psychological injury or risk thereof. It requires immediate response and investigation.
Publication of the Institute of Medicine’s (IOM) report, To Err is Human: Building a Safer Health System in 1999, brought the subject of patient safety and prevention of medical error to national attention. It reported the claim that approximately 98,000 people were dying annually from preventable medical errors and over one million people were being injured annually.

The primary conclusion of the report was that the majority of medical errors do not derive from recklessness or the actions of an individual or a particular group: they most commonly occur through the use of faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them.

The committee who created the report laid out a comprehensive strategy by which government, health care providers, industry and consumers could work together to reduce preventable medical errors. It struck a balance between regulatory and market-based initiatives and between the roles of professionals and organizations.
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The aim was to make health care safer through making it harder for people to do something wrong and easier for them to do something right.

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Crossing the Quality Chasm: A New Health System for the 21st Century (2001), a follow-up report from the IOM panel of the Quality Health Care project, focused on reinvention of the health care system to foster innovation and improve delivery of care. The committee presented a comprehensive strategy and action for the following decade.

Slide 13

The 2001 Crossing the Quality Chasm Report defined six aims for healthcare. Healthcare should be:

- Safe - avoiding injury to patients from the care intended to help them
- Effective - providing services based on scientific knowledge
- Patient centered - providing care that is respectful of and responsive to individual patient preferences, needs and values and allowed to guide clinical decisions
- Timely - reducing waits and harmful delays
It’s a New Day in Public Health

• Efficient - avoiding waste
• Equitable - providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location or socioeconomic status

Slide 14

10 Rules for Healthcare Redesign

1. Care should be based on continuous healing relationships
2. Care should be customized to patient needs & values
3. The patient should be the source of control
4. Clinicians & patients should share knowledge
5. Care should be evidence-based

Continued…

1. Patients should receive care whenever they need it, and in many forms, not just face-to-face visits.
2. The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.
3. Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them.
4. Patients should have unfettered access to their own medical information and to clinical knowledge.
5. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
6. Patients should be safe from injury caused by the care system.
7. The health care system should make information available to patients and their families that allow them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments.
8. The health system should anticipate patient needs, rather than simply reacting to events.
9. The health system should not waste resources or patient time.
10. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Patients should receive care whenever they need it, and in many forms, not just face-to-face visits. This rule implies that the healthcare system should be responsive at all times (24 hours a day, every day), and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits.
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#2 Rule for Healthcare Redesign
Care should be customized to meet patient needs and values

The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.

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Slide 18

#3 Rule for Healthcare Redesign
The PATIENT should be the source of control

Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision-making.

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Slide 19

#4 Rule for Healthcare Redesign
Clinicians and patients should communicate effectively & share knowledge

Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
Slide 20

#5 Rule for Healthcare Redesign
Care should be evidence-based

Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

Slide 21

#6 Rule for Healthcare Redesign
Systems should be designed to prevent & mitigate errors

Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

Slide 22

#7 Rule for Healthcare Redesign
The healthcare system should be Transparent in performance

The health care system should make information available to patients and their families that allow them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.
The health system should anticipate patient needs, rather than simply reacting to events.

The health system should not waste resources or patient time.

Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.
Suggested Areas of Change
- Application of evidence to health care delivery
- Utilization of information technology
- Alignment of payment policies with quality improvement
- Preparation of the workforce

Based on the premise that redesign of the health care delivery system is dependent on changing the structure and processes of the environment in which health care professionals and organizations function, four primary areas of change were suggested:
1. Application of evidence to health care delivery
2. Utilization of information technology
3. Alignment of payment policies with quality improvement
4. Preparation of the workforce

The past decade has seen numerous improvements to safety in health care delivery. Unfortunately, health care delivery continues to fall short of what it should be or what is desired. In 2007, the World Health Organization (WHO) reported that medical care errors continued to affect up to 10% of patients worldwide (WHO, 2010).

Recent study from the Journal of Patient Safety indicates death from preventable medical errors may be four times higher than was indicated in earlier reports: as many as 440,000 patients a year.
According to the World Health Organization, medical errors claim the spot as the third leading cause of death in the United States; following cancer and heart disease (Binder, 2013).

It is doubtful that the actual number of medical errors is accurately captured. Under-reporting, lack of a universal standardized reporting system, and fear of professional and legal penalties contribute to the hesitancy of health care providers to self-report medical errors or near misses.

The national annual cost of medical errors and resulting poor quality was estimated to be as high as $19.5 billion in 2008, which represented 30% of health care spending. Of that annual loss, $4.4 billion was attributed to Medicare cost.
Errors are also costly in terms of physical and psychological discomfort for patients, lost work productivity for patients who require extra care time, loss of trust in the healthcare system by patients as well as diminished satisfaction by patient and health professionals.

In 2009, approximately 10,739 malpractice payments were made on behalf of health care providers; 52.5% of those events occurred in the outpatient setting. Sixty-six percent of outpatient medical malpractice claims involved major injury or death.

Medical errors are commonly typed into one of four categories: diagnostic, treatment, preventive or other.
It is estimated that 7 to 10 billion laboratory tests are performed each year nationally to inform approximately 70% of medical decisions (MMWR, 2005).

Researchers from Johns Hopkins have determined that diagnostic errors account for the largest fraction of malpractice claim payouts, cause the most severe patient harm and the highest total of payouts. They estimate the number of patient suffering misdiagnosis-related, potentially preventable, significant permanent injury or death annually in the U.S. ranges from 80,000 to 160,000. They also determined that more diagnostic error claims were rooted in outpatient care than inpatient care (68.8 % vs. 31.2 %).
Diagnostic error can be defined as a diagnosis that is missed, wrong or delayed, as detected by some subsequent definitive test or finding. The ensuing harm results from the delay or failure to treat a condition which was present when the working diagnosis was wrong or unknown or from treatment provided for a condition not actually present. Failing to inform a patient of an abnormal outpatient diagnostic test result can be a serious error.

Breakdowns were found to occur in all 5 dimensions of the diagnostic process, and in 43.7% of cases more than one dimension was involved.
This chart illustrates the percentage of medical errors related to diagnostic process dimension.

Most commonly, breakdowns occurred during the patient-practitioner clinical encounter (78.9%). Breakdowns involving the patient-practitioner clinical encounter were most often judged to be due to data-gathering and synthesis problems (i.e., cognitive errors) related to the medical history (56.3%), physical examination (47.4%), ordering of diagnostic tests for further workup (57.4%), and failure to review previous documentation (15.3%).

Two additional documentation-related problems are notable. First, no differential diagnosis was documented at the index visit in 81.1% of cases. Second, practitioners copied and pasted previous progress notes into the index visit note in 7.4% of cases; of these cases, copying and pasting mistakes were determined to contribute to more than one-third (35.7%) of errors.

Outside the patient-practitioner encounter, process breakdowns also occurred in the areas of referrals, patient actions or inaction, follow-up and tracking of diagnostic information, and performance and interpretation of diagnostic tests.

<table>
<thead>
<tr>
<th>Percentage of Medical Errors Related to Diagnostic Process Dimension</th>
<th>% of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Related</td>
<td></td>
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<tr>
<td>Failure to provide an accurate medical history</td>
<td>16.3%</td>
</tr>
<tr>
<td>Patient did not seek medical care in timely manner</td>
<td></td>
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<tr>
<td>Patient-practitioner encounter</td>
<td>78.9%</td>
</tr>
<tr>
<td>Breakdowns occurred during the patient-practitioner clinical encounter</td>
<td>43.7%</td>
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<tr>
<td>Breakdowns involving the patient-practitioner clinical encounter</td>
<td>56.3%</td>
</tr>
<tr>
<td>Most often judged to be due to data-gathering and synthesis problems related to the medical history</td>
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</tr>
<tr>
<td>Physical examination</td>
<td>47.4%</td>
</tr>
<tr>
<td>Ordering of diagnostic tests for further workup</td>
<td>57.4%</td>
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<tr>
<td>Patients did not seek medical care in timely manner</td>
<td>15.3%</td>
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<tr>
<td>Error related to medical history</td>
<td></td>
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<tr>
<td>Error related to physician exam performance</td>
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<tr>
<td>Diagnostic tests</td>
<td></td>
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<tr>
<td>Problems ordering diagnostic test for follow-up</td>
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<td>Problems related to medical history</td>
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<td>Error related to medical history</td>
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<td>Error related to physician exam performance</td>
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<tr>
<td>Follow-up and tracking</td>
<td></td>
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<tr>
<td>Inadequate follow-up tracking system</td>
<td></td>
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<tr>
<td>No follow-up tracking system</td>
<td></td>
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<tr>
<td>Referrals</td>
<td>15.1%</td>
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<tr>
<td>Appropriate expert not contacted</td>
<td></td>
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<tr>
<td>Suboptimal weighing of critical history data</td>
<td></td>
</tr>
<tr>
<td>Involvement of more than 1 dimension</td>
<td>14.7%</td>
</tr>
</tbody>
</table>

(Singh, Giardina, Meyer, Purushotam, & Thomas, 2013)
The chart presented is illustration of the potential severity of injury associated with the delayed or missed diagnosis. In 86.8% of cases, the potential for injury was classified as moderate to severe. When errors in the diagnostic process were subjected to more in depth research, a modal severity rating of 5 across all 5 processes was determined.

Please take a moment to read this case study. It represents a multitude of medical errors which presented great potential for injury:

The specimen was labeled with the wrong patient identifiers. The situation has the potential to harm two patients—the patient whose urine was mislabeled as well as the patient who was incorrectly linked to that specimen. Both patients may have ended up with incorrect diagnoses, missed treatment, or treatment which was not indicated.

In addition to offering inaccurate diagnostic information, a mis-labeled urine could result in false evidence of infidelity or child abuse. For example, a sexually transmitted parasite, Trichomonas vaginalis, can be identified in urine and can raise suspicions of marital infidelity in adults or child abuse if the specimen was mistakenly labeled for a minor child.
Presented are four methods for the prevention of diagnostic errors.

Communication breakdown between providers and patients contributes to 80% of all errors.

Follow-up and tracking of diagnostic data accounts for 14.7% of diagnostic error; and performance and interpretation of diagnostic tests accounts for 13.7% of diagnostic error (Singh et al., 2013).

The use of point-of-care testing utilizes hand-held medical devices which are computerized to perform many diagnostics by people who may have little or limited experience and training. The devices used are often not covered by the regulations that govern tests performed in a laboratory setting and the personnel performing point-of-care tests are seldom required to undergo training. Although point-of-care tests have a small risk for erroneous results, the manufacturer’s instructions should be followed carefully to avoid risk of error. Errors in point-of-care testing such as glucose and prothrombin time can have serious consequences because medication dosages are frequently determined by test results. (Wolcott et al., 2008)

Failing to inform a patient of an abnormal outpatient diagnostic test result can be a serious error.

Finally, if it isn’t documented, it didn’t happen.
Misdiagnosis is considered a treatment error which affects more than 150,000 patients annually in the primary care setting.

Examples of common treatment errors are:
- Error in the performance of an operation, procedure or test;
- Error in administering the treatment;
- Error in the dose or method of using a drug;
- Avoidable delay in treatment or in responding to an abnormal test;
- Inappropriate care.

Take a moment to read this case study:
A 38-year-old man has an anal cyst (diagnosed as benign) surgically removed. The excised tissue is then microscopically analyzed and found to be cancerous. The primary care facility receives the pathology report and a new clerk files it before the nurse or the physician reviews it. The patient is not notified of the test results. In the interim, he has to return to the hospital four times because of continued pain and discomfort, but, because his records do not indicate that he has cancer and no one rechecks the pathology results, he is diagnosed as having a sexually transmitted disease.
Meanwhile, the cancer, which has been left untreated, continues to spread, and the man dies a year later. The case study provided represents a cascade of medical errors: diagnostic and treatment. When doctors fail to perform adequate tests or fail to properly diagnose illnesses, patients can suffer severe injury or wrongful death as a result.

Medication administration is a complex process. There is potential for errors to occur at any step in that process - from prescribing the medication to the provision of the drug to the patient. Common causes of medication errors include:

- Incorrect diagnosis,
- Prescribing errors,
- Dose miscalculations,
- Poor drug distribution practices,
- Drug device related problems,
- Incorrect drug administration,
- Failed communication, or
- Lack of patient education.
Treatment errors are commonly associated with incorrectly prescribed medication. There are a number of things which may contribute to an incorrect prescription:

- Illegible handwritten prescriptions,
- Insufficient or missing information about co-prescribed medications,
- Past dose-response relationships,
- Lab values and allergic sensitivities,
- Incorrect drug or dose is selected or the regimen is too complex,
- Telephone orders with failure to read back may result in prescription for sound-alike medication,
- Drugs with similar-looking names may be incorrectly dispensed when prescriptions are handwritten, or
- Failure to transmit prescription to the pharmacy.

The illustration provided is an example of a hand-written prescription for Metadate ER 10 mg tablets. Metadate is a drug used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Due to the similarity in name, poor penmanship and the omission of the modifier "ER", the pharmacist filled the prescription incorrectly and dispensed methadone 10 mg tablets. Methadone is a morphine-based product used as a heroin substitution therapy and analgesic. Methadone is **not** used for the treatment of ADHD.
LEGIBILITY
- EHRs have made illegible handwriting an anomaly rather than a norm.
- Remember, technology may be interrupted by Mother Nature, requiring the use of paper records.
- Make sure the opportunity for misinterpreting your documentation is minimal.

The use of electronic health records (EHRs) has offered reduction in medication errors. Illegible handwriting is rarely an issue and most systems are designed to incorporate information about the patient’s allergies, past dose-responses, and other significant information. The caveat to the usefulness of the EHR is that the information is only as accurate as the data which the user places in the system. Hurriedly placing a medication list into an electronic record but neglecting to list allergies may prove to be a work-around which results in medical error and patient harm.

Treatment Errors
Unclear communication regarding:
- Treatment rationale
- Drug name
- Drug appearance
- Dosage & length of therapy
- Common side effects

Unclear communication contributes to treatment errors. The following information should always be clearly relayed:
Drug name,
Drug appearance,
Why the drug has been prescribed,
How much and how often to take it,
when to take it,
How long to take it,
What common side effects may occur,
What the new drug replaced or supplements (Academy of Managed Care Pharmacy, 2010).

The prudent nurse who is unfamiliar with a medication to be administered will stop and familiarize her/himself with the medication and potential side effects prior to administering the medication. He/she will also ensure the patient has a firm understanding of a newly prescribed medication.
Recent study has revealed an alarming lapse in basic infection control practices associated with the use of syringes, needles, multi-dose vials, single-use vials and flush solutions.

Consider this case study. Practitioners often do not recognize or understand that single-dose vials do not contain any type of preservative. Once opened and accessed for use with a single patient, these vials should be disposed of immediately, regardless of the amount of product remaining in them.

Although today’s healthcare climate emphasizes cost containment, once opened and accessed for use with a single patient, these vials should be disposed of immediately, regardless of the amount of product remaining in them. Although disposing of multi-dose vials after one use might be difficult for some frugal users, keep in mind that the cost of a new vial per patient (unless it is a medication that is very difficult to obtain or expensive) is certainly less when compared with an outbreak in your facility (Paparella, 2011).
CASE STUDY

- As a young child, Josie had been given penicillin, turned blue, and was rushed to the hospital.
- She was 15 when she got strep throat, was given penicillin, and died.
- No one had asked her about medication allergies.

In 2008, the Pennsylvania Patient Safety Advisory cited more than 3800 cases in which patients received medications to which they had documented allergies. Breakdowns in communication of allergy information include "documentation of patient’s allergies on paper but not entered into the organization's computerized order-entry systems, and allergies arising during episodes of care but not documented in the medical record or communicated to appropriate staff."

VACCINE ADMINISTRATION

Vaccine administration errors
- patient harm
- inconvenience
- wasted vaccine
- wasted time

Historically, one of the cornerstones of public health medicine has been the administration of vaccines.

Errors in the administration of vaccinations may result in:
- Patient harm
- Inconvenience to the parties
- Wasted vaccine
- Wasted time
To ensure the accurate administration of vaccinations, consistently utilize the 6 “Rights” of Vaccine Administration.

- **Right vaccine** - Triple check the label to ensure you are administering the right medication. Always use the right diluent for the right vaccine.
- **Right patient** - Verify the patient’s information. Always ask for the patient’s name and date of birth prior to vaccination.
- **Right documentation** - Document the vaccine information statement date, vaccine manufacturer and lot number, clinic name and the person administering the vaccine.
- **Right dosage** - Split or partial vaccine doses are NOT recommended.
- **Right time** – Follow recommended intervals and age recommendations; administer vaccine before the expiration date.
- **Right route of administration** - Review the package insert to determine the correct route of administration.

There are several habits of safety which are conducive to prevention of medication errors:

- Utilize two identifiers on all patient information.
- Provide vaccine information sheets.
- Perform proper medicine and vaccine storage and management.
- Properly manage and store sample medications.
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**Vaccine Administration Safety Habits**
- Appropriate refrigerator labeling
- Documentation:
  - Full vaccine administration
  - Non-prescription
  - Prescription

(Continued)
- Make sure that refrigerated medications are appropriately labeled.
- Fully document vaccine administration without leaving blank spaces.
- Reconcile and accurately document the patient’s use of non-prescription and prescription medications in the patient’s medical chart.

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**PREVENTIVE ERRORS**
When it is clearly indicated that preventive actions should be taken, failure to do so is a medical error.

The failure to prevent a condition is a type of medical failing and may include:
- Inadequate monitoring or follow-up treatment,
- Failure to implement action which would prevent known complications of a diagnosed disease,
- Failure to treat family members or others exposed to infectious disease,
- Failure to address clear risk factors for various conditions.

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**CASE STUDY**
- An 8 year old child presents to the local county health department following a non-life threatening stray dog bite.
- The child is examined and no serious injury is detected.

Take a moment to review the offered case study. Does this case represent the occurrence of a medical error? YES

The State of Florida requires surveillance and investigation of dog bite incidents which may pose risk of rabies. Staff must have knowledge and judgment of rabies prevention and control procedures. They must also possess the skills necessary to follow and apply guidelines. Data about the animal bit exposure should have been collected upon receipt of the initial
report/patient visit and efforts should have been implemented to locate the stray animal in order to determine risk for rabies exposure.

If risk of rabies exposure was determined, animal isolation/quarantine and rabies testing should have been conducted with recommendation for human post exposure prophylaxis treatment as appropriate. Mandatory state reporting should have followed per Florida Statutes, Section 381.0011 authority (DOH/Disease Control/Epidemiology TAG 340-1-13).

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“An Ounce of Prevention is Worth A Pound of Cure.”
-Benjamin Franklin

Benjamin Franklin was accurate in his proclamation, “An ounce of prevention is worth a pound of cure.”
There are a number of precautions everyone should follow each day to avoid accident and injury to staff as well as patients:

- Fire safety - Know how to use a fire extinguisher
- Use of safety-type sharps containers - An overfilled sharps container is an accident waiting to happen for the curious child whose mother is temporary distracted
- Environmental safety - Pick up items which may present risk for falls
- Hand washing should be a routine habit for the prevention of spread of infection.

Another method for avoiding injury which can be prevented is assisting patients in avoiding the development of chronic disease:

- Ask patients about physical activity, stress levels
- Counsel patients on illness prevention
- Talk about healthy eating habits
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OTHER ERRORS

- Failure of communication
- Equipment Malfunction

Failure of communication and equipment malfunction are those errors which commonly fall under the category of Other Errors.

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FAILURE OF COMMUNICATION

There are a number of communication points at which medical error is more subject to occur:
- patient/family vs. clinician, office/clinic staff members
- the communication chain
- primary care vs. hospital
- handoff communications
- missing reports

There are a number of communication points at which medical error is more subject to occur. Special attention should be offered to these areas to ensure smooth and accurate information flow processes. Structured handoffs, proactive sharing of patient information, improved feedback and standardized processes for information handling may assist in the prevention of error.

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Equipment Malfunction

Occasionally, equipment failure will result in medical error. Users should ensure they follow manufacturer’s directions for use and are attentive for indicators that equipment is not functioning properly. Sterilization of equipment, improperly performed, may result in cross-contamination leading to the transmission of infectious agents and the spread of disease such as Hepatitis C, HIV and TB.
It is important that weight/other scales which require annual calibration be evaluated on a regular basis to ensure readings are consistent and accurate (Marsteller, Hsiao, Underwood, Woodward & Barr, 2010).

The process of informed consent is applicable to all medical care decisions where one or more alternatives exist.

A complete informed consent process consists of seven elements:
1. Discussion about the patient’s role in the decision-making process
2. Describing the clinical issue and suggested treatment
3. Discussing alternatives to the suggested treatment
4. Discussing risk and benefits associated with the suggested treatment and comparing them with the risks and benefits of alternative treatments
5. Discussion of related uncertainties
6. Assessing the patient’s understanding of the information provided
7. Eliciting the patient’s treatment preference (consent)
In an examination of the informed decision-making process in 1,057 audio-recorded outpatient encounters in the offices of primary care physicians and surgeons, regarding mostly low-risk decisions, only 9% were deemed to contain all the elements of complete informed decision-making.

The most common element missing was an explicit assessment of patient understanding. However, risks and benefits, and their associated uncertainties were also commonly not included in the discussions.

Multiple studies have shown that most patients are unable to recall or do not understand most of the information that is presented to them in the informed consent process. Lower levels of education are consistently associated with being less likely to recall information in the informed consent process. Older age and low level health literacy has been associated with being less likely to recall informed consent information. Patients with cognitive dysfunction are particularly vulnerable in the informed consent process.
Multiple potential methods have been proposed for improving the informed consent process. These methods include:

Providing patients with supplemental written materials, in simplified language, has been found to result in higher patient recall of informed consent information. Decision aids have been found to improve knowledge scores by an average of 15%, improve patients’ participation in decision making, resulting in lower decisional conflict, and increased accuracy of risk perceptions (Cordasco, 2013).

There are populations which are considered ‘vulnerable’ to medical errors. Those populations require extra vigilance in the provision of care.
The pediatric population is at increased vulnerability of medical errors due to physiological characteristics, developmental issues and dependence on others. Pediatric medications require weight dosing and careful consideration of dosing frequency; errors may occur when physicians/pharmacists convert dosage from pounds (for adults) to kilograms (for children). They may also occur due to misplaced decimal points in the drug dosage order.

As the most frequent users of medications, older adults are at substantial risk for medical errors. Physiological changes which are associated with the normal aging process disrupt or change the body’s ability to absorb, metabolize and excrete drugs. Visual and auditory decline frequently affect communication. Development of chronic disease such as arthritis or postural hypotension may create functional limitations and lead to falls.
Health literacy is the “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Individuals with limited health literacy skills or those who lack mastery of the English language may require additional or alternative forms of communication in order to ensure care is safely delivered and instructions for care fully understood.

The implementation of safe practices such as promoting and facilitating effective hand hygiene, establishing protocols for communicating critical lab values, standardizing procedures and reconciling medications has solved a number of systemic problems associated with care delivery; however, there is much to be done.

At-risk behaviors are those actions performed by healthcare providers which have potential to compromise patient safety. Healthcare personnel may engage in risky behaviors because the risk of patient harm seems remote. They may unknowingly engage in risky behaviors when they become comfortable and competent with a task and lose the perception of risk (NCCMERP, 2007).
Risky behaviors often emerge because of system-based problems in healthcare organizations. The perceived benefits of taking a risky shortcut lead to repeated at-risk behaviors, despite the healthcare provider’s possible knowledge, on some level, that patient safety could be at risk.

In addition, as one healthcare worker has apparent success with an at-risk behavior, they will likely influence fellow workers until that behavior becomes a standard practice (NCCMERP, 2007).

An organizational culture with a high tolerance of at risk behaviors is a system based problem which may lead to medical error and patient harm.

Unnecessary complexity in processes provides many opportunities for healthcare providers to take risks when providing care to a patient. The National Coordinating Council on Medication Error Reporting and Prevention (2007) made the presented recommendations to reduce medical errors associated with at-risk behaviors:

• Eliminate organizational tolerance of risk.
• Determine systems-based reasons for risk-taking behavior.
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MINIMIZING AT-RISK BEHAVIORS
- Increase awareness of at-risk behaviors.
- Eliminate system-wide incentives for at-risk behaviors.
- Motivate through feedback and rewards.

- Increase awareness of at-risk behaviors.
- Eliminate system-wide incentives for at-risk behaviors.
- Motivate through feedback and rewards.

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NATIONAL PATIENT SAFETY GOALS (NPSGs)
Goal 1 – Improve the accuracy of patient identification - use at least two patient identifiers

The National Patient Safety Goals (NPSGs) were established in 2002 to help accredited organizations address specific areas of concern in regards to patient safety.

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NATIONAL PATIENT SAFETY GOALS (NPSGs)
Goal 1 - Improve the accuracy of patient identification
- When administering medications, blood or blood components,
- When collecting blood samples and other specimens for testing, or
- When providing treatment or procedures
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Goal 2 - Improve the effectiveness of communication among and between caregivers.

- Report critical results of tests and diagnostic procedures on a timely basis.

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Goal 3 - Improve the safety of using medications:

- Label all medications and medication containers,
- Maintain and communicate accurate patient medication information,
- Reduce the likelihood of patient harm associated with the use of anti-coagulate therapy,

(Continued)

- Provide patient education to ensure the patient knows what medicines to take at home, and
- Maintain and communicate accurate patient medication information.
Goal 7 - Reduce the risk of healthcare associated infections:

- Use the hand cleaning guidelines from the Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines,
- Set goals for improving hand cleaning,
- Implement evidence based practices to prevent central-line associated bloodstream infections (CBI), surgical site infections and catheter-associated urinary tract infections (CAUTI)
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Goal 9 - Prevent residents and patients from avoidable falls.

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Goal 13 - Communication with residents and families about all aspects of their care, treatment or services is an important characteristic of a culture of safety. When residents know what to expect, they are more aware of possible errors and choices. Residents can be an important source of information about potential adverse events and hazardous conditions (2007).

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Goal 15 - Identify safety risks inherent in patient populations: Identify patients at risk for suicide and identify risks associated with patients who are utilizing home oxygen therapy.
To meet National Patient Safety Goals, primary care practices must implement some basic patient protections, including such activities as proper supply management, storage, labelling, instrument calibration and chart documentation, in addition to more complex efforts like ensuring appropriate training, practicing appropriate hand hygiene and reconciling old, current and new medication lists. Much of human error is preventable through improved system design to counteract error including the use of checklists, decreasing interruptions, preventing fatigue, avoiding task saturation and improved environmental conditions.

The use of point-of-care testing utilizes hand-held medical devices which are computerized to perform many diagnostic tests - once performed exclusively by trained healthcare personnel - outside of the laboratory or clinic by people with limited experience and training. The devices used are often not covered by the regulations that govern tests performed in a laboratory setting and the personnel performing point-of-care tests are seldom required to undergo training.
REDUCING DIAGNOSTIC ERRORS

- Manufacturer’s instructions should be followed carefully to avoid risk of error
- Errors can have serious consequences because medication dosages are frequently determined by test results (Wolcott et al., 2008).

Although point-of-care tests have a small risk for erroneous results, the manufacturer’s instructions should be followed carefully to avoid risk of error. Errors in point-of-care testing such as glucose and prothrombin time can have serious consequences because medication dosages are frequently determined by POC test results (Wolcott et al., 2008).

NPSGs-Reducing Diagnostic Errors

- Failing to inform of test results can be a serious error
- Failure to inform patients of abnormal outpatient test results are common
- Use of simple processes for managing results is associated with lower failure rates (Casalino, Durham, Chin, Bieder, Kistner, Karrison, Ong, Sarkar, McLaughlin & Meltzer, 2009). (Goal 1, 2, 13)

Failing to inform a patient of an abnormal outpatient diagnostic test result can be a serious error. Research indicates failures to inform patients or to document informing patients of abnormal outpatient test results are common; use of simple processes for managing results is associated with lower failure rates.

PUBLIC HEALTH PRACTICE & MEDICAL ERRORS

Increase of occurrence of medical errors in the outpatient setting offers relevance to the importance of being aware and proactive in the prevention of medical errors in the public health practice arena.

The focus of public health is on the safety and well-being of entire populations. A unique aspect of the field is that it strives to provide services that benefit the largest number of people.
When providing public health nursing care to the population-patient, structural failures and errors may lead to poor health outcomes and accidental harm. The diagram provided conceptualizes safety as the outcome for population-patients when no errors or failures of practice occur.

Operational failures are those structural aspects within the organization which make it difficult to avoid making errors. These may be described as problems leading to not having the necessary supplies or information. Disruptions, delays, risks and losses which are costly to the organization frequently occur as a result. Examples may include: insufficient vaccine supplies, improper staffing; insufficient staff training or supervision; lack of safety culture; failure to share community referral resources needed by other staff to efficiently provide care.
Systems failures are those structural aspects of inter-organizational and inter-agency networks that make it difficult to avoid errors. Examples may include: untimely distribution of infectious disease reports among agencies; inability to obtain or communicate information across agency boundaries; personnel restrictions which limit or restrict PHN involvement in community coalitions; lack of HIPAA agreement for patient data sharing and appropriate referrals.

Error by omission is the failure to engage in an act that would have otherwise prevented illness, distress or harm. Examples may include: inadequate outbreak investigation; failure to conduct a community needs assessment; failure to effectively participate in a community collaborative; failure to conduct outreach to vulnerable populations; failure to identify best practices for population level practices. An example of an error of omission is when the public health nurse fails to fully assess the specific population at risk for missed vaccinations and the underlying reasons for a locally low or declining immunization rate which results in outbreak of communicable disease.

Error of commission is engagement in an act that directly leads to or causes illness, distress, or unintentional harm. Examples may include: over-publicized health consequence of an outbreak, implementing a health program shown
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to be harmful, providing inaccurate data or health information to community groups (Example – A PHN distributes a poorly worded PHA that warns against a health behavior but sparks a widespread panic or anxiety; a patient is having his gallbladder removed but during the surgery, the intestine is nicked and the patient develops a serious infection).

Error of communication is the miscommunication or lack of communication which results in preventable harm. The error could occur between a provider and patient or between multiple providers. (Example – A cardiologist, aware the patient was not ready to resume normal activities, failed to warn a 19 year old patient not to run while diagnostics were pending following a syncopal episode; having not been warned, the patient resumed running and suffered sudden death while running.)

Each of us is responsible for creating a culture of safety.

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How Can Errors be Reduced and Patient Safety be Increased????

Create.....

A CULTURE OF SAFETY
Effective safety cultures have been defined as those in which there is shared commitment to safety, where engaging in safety-promoting behaviors is encouraged and reinforced by leadership and where near misses are valued as opportunities for learning and improvement (Weaver, Dy, Lubomski & Wilson, 2013).

Engaging patients more fully in their care is a primary task toward the creation of a culture of safety. Patient engagement entails involving and informing the patient in choosing treatment options, encouraging the patient to develop healthy habits, and educating and empowering the patient so that the patient feels confident making health related decisions. A patient who knows exactly what medications are prescribed, what the medication is for and also feels comfortable communicating with healthcare professionals might notice when a wrong medication is about to be given or when the dosage is incorrect and intercept the error.
Transparency is vital to creating a culture of safety. Patients should expect full access to their medical record, full explanation of all pricing/costs and open discussion of true outcomes. Safety experts and patient advocates agree that patients have a right to know all about their care, especially when things go wrong. Full explanation and complete honesty is the only way to deal with an error. When a medical error occurs, addressing the error should be focused on identifying factors that contributed to the error, rather than assigning blame to the person associated with the error (Riley, 2009).

Better understanding of the quality, safety and system problems encountered in the provision of care will allow focused application of patient safety solutions, including teamwork and effective communication. Understanding how and why a medical error occurred requires that the issue be examined.
One should look beyond a medical error and understand that there may be many factors associated with the error. To understand an error one must ask questions about the underlying factors and encourage others to consider an error from a systems perspective.

Asking ‘what happened’ rather than ‘who was involved’ is a methodology utilized to keep discussions about causes focused on the system rather than the person.

Root Cause Analysis (RCA) is an important component of quality improvement. It is a systematic process used to address problems and identify the underlying causes associated with variation in performance. The most important aspect of RCA is the use of a systematic approach in the examination of errors which removes focus from the individual involved in the error. The identification of causative factors allows formation of an action plan to identify strategies an organization can employ to prevent future occurrences.
To be thorough an RCA must be thorough and credible. A thorough RCA offers:
- Determination of related human and other factors;
- Determination of related processes and systems;
- Analysis of underlying cause and effect systems through a series of “why” questions;
- Identification of risks and other potential contributions; and
- Determination of potential improvement in processes or systems.

A credible RCA:
- Includes participation by organizational leadership as well as those most closely involved in the processes and systems;
- Is internally consistent; and
- Includes consideration of relevant literature.

The first step in the root cause analysis process is the formation of a team to answer the relevant questions:
What happened?
How did it happen?
Why did it happen?
What should be done to prevent it from happening again?
Collecting factual information includes:
- Establishing what happened and how in detailed, chronological order;
- Collecting as much information as possible from: written and computer records; personal testimony from those directly and indirectly involved (patients, relatives and colleagues).
- Determining what the impact was or what it could have been.

Why did it happen? Establish the main and underlying reasons contributing to why the event happened. Consider, for example, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event. Try to avoid simply focusing on superficial causes of events (for example, 'I forgot to pass on an important message about the condition of an elderly diabetic patient to the practice nurse'). Alternatively, if it is a positive event, what were the underlying factors that contributed to a successful outcome?
What was learned as a result of the occurrence?
Outline the learning needs identified from the event.
Demonstrate that reflection and learning have taken place on an individual or team basis.
Consider, for example: - a lack of knowledge and training - the need to follow systems or procedures - the importance of team working or effective communication.
The Agency for Healthcare Research and Quality (AHRQ) has determined that medical errors result most frequently from systems errors, health care delivery organization and the service delivery process. Health care professionals have historically viewed errors as a sign of the individual practitioner’s incompetence or recklessness. Rather than utilizing errors to improve systems and prevent reoccurrence, health care professionals were hesitant to admit mistakes or discuss “near misses” for fear of professional censure, administrative blame or personal embarrassment.

Another habit that dies slowly is the tendency to blame and punish individuals when they make a mistake. Although the science is irrefutable that almost all errors are caused by system failures, it has proved difficult for doctors and nurses to really accept this concept and to create a non-blaming environment. It is still unsafe to talk about your mistakes and the response is still to blame the individual rather than seek the underlying system failures.
Although health care organizations have expended substantial effort to promote incident reporting, studies suggest that underreporting is pervasive. Many observers attribute underreporting to the punitive (“name and blame”) approach that many health care organizations have taken with regard to safety incidents. By indoctrinating a sense of fear, the punitive approach discourages reporting and, in doing so, prevents organizational learning and improvement. Obtaining the information offered through reporting is considered crucial for identifying risky situations, analyzing underlying causes, taking corrective action, and implementing prevention efforts. Those directly involved in patient care are said to possess important safety-related information that cannot be obtained through retrospective peer review or computerized surveillance systems (Leape, 2009).

REMEMBER--The goal of reporting medical errors is to analyze the occurrence and identify methods for preventing reoccurrence.
Completion of incident reports is the expectation associated with occurrence of unusual events. To make incident reporting work, safety experts contend, health care organizations must establish a “just” culture—that is, an organizational context in which health professionals feel assured that they will receive fair treatment when they report safety incidents. A just culture has been defined as a “non-punitive” environment in which individuals can report errors or close calls without fear of reprimand, rebuke, or reprisal. At the same time, a just culture is not an environment wherein no accountability exists. Failing to discipline those who commit unsafe acts due to incompetence or recklessness is just as much a violation of widely accepted moral principles as is punishing those who commit honest mistakes (Leape, 2009).

Florida Department of Health (DOH) Policy provides guidelines for which employees are expected to report incidents as defined in DOH Policy and Procedures on Incident Reporting.
The employee(s) that were involved or were a witness to the incident should report the incident to the appropriate manager as soon as possible and no later than 5:00 p.m. the next workday. Even if the incident is promptly resolved, management and the Director’s Office must be notified of the incident and the status. The reporting employee(s) must complete the Initial Incident Report Form DH 1152.

Examples of ‘Category One’ incidents are:
- Non-serious accident/injury/illness: slips, trips, falls, etc.;
- Medication/Dispensing error without adverse consequence;
- Unintentional breach/violation of confidential information or patient privacy with no reasonable expectation of harm.

A Category Two incident is an incident of a more serious nature which must be sent to the Office of the Inspector General. Following approval by the appropriate parties at the local level, it must be encrypted and emailed to the IG via email account.

Examples of Category Two incidents are:
- Alleged abuse/neglect;
- Major dispute/altercation/fighting;
- Serious accident/injury/illness;
- Introduction of contraband/drugs/alcohol;
- Medication/Dispensing error with adverse consequences;
- Death, disability, or serious injury/illness of any client, patient, visitor, or other individual thought to
be a result of being provided or withheld health services or otherwise occurring on DOH property;
• Unauthorized transfer of bodily fluids;
• Unintentional breach/violation of confidential information or patient privacy or unintentional if reasonable expectation of harm towards a person exists.
Unavailable or unknown information relevant to the occurrence should not be a reason to delay timely submission of an Incident Report. Unavailable/unknown information can be submitted later once it is known.

Florida Statute 395.0197 mandates reporting of any adverse event which occurs within a healthcare organization. According to the statute, the definition of an “adverse incident” is “an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred” (Fla. Stat. 395.0197 (5)).
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There are a number of injuries which are considered “adverse events”
• Death;
• Brain or spinal damage;
• Permanent disfigurement;
• Fracture or dislocation of bones or joints;

(continued)
• Limitation of neurological, physical or sensory function which continues after release;
• A condition requiring specialized medical attention or surgical intervention which results from non-emergent medical intervention for which the patient has not given informed consent;
• A condition which requires the transfer of the patient to a unit providing a higher level of acute care as a result of the adverse event rather than the patient’s condition prior to the adverse incident.
All adverse incident reports must be filed with the organization’s internal risk management system within 3 days of the occurrence of the event. Designated organizational officials must then report the event to the Florida Agency for Health Care Administration (AHCA) in two types of reports:

- **Code 15 Report** - offers detailed report of serious patient injuries, the organization’s investigation of the injury and determination of if the factors causing or resulting in the adverse incident represents potential risk to other patients. A Code 15 report must be filed within 15 calendar days of the occurrence of the adverse incident;

- **Annual Report** - contains a summary of all adverse incidents and malpractice actions (new, pending and closed) which occurred in the organization during the course of the calendar year.

No matter the medical error one makes, it is probably not the first time it has occurred; reporting increases the likelihood that it may not happen again. Medical error reporting offers the opportunity to examine the system and correct that aspect which may contribute to recurrence of that particular medical error or similar ones. Making a medical error does not make one a bad health care professional, it makes one ‘human’. It offers the opportunity to make the health care system and the processes of health care delivery safer.
Prevention of medical errors requires emphasis on responsibility and safety at all levels of patient care delivery. Team effort assures a check and balance system which eliminates individual liability when there is system failure. Ensuring patient safety requires the establishment of operational systems that minimize the opportunity for errors to occur and maximize the interception of errors which are about to occur. Healthcare providers must work collaboratively in a patient-centered environment to improve patient safety through continuous evaluation and improvement of the processes through which care is provided. Individual providers and practitioners must be vigilant to ensure they are performing tasks in a cautious manner which can be expected to result in safe healthcare delivery. Medical error reporting offers the opportunity for system correction for prevention of its recurrence.

The goal in the PHPU is to support the health care professionals throughout the department. The PHPU would like to provide tools and resources which will offer assistance to field operations. PHPU welcomes the feedback and thoughts from the participants of this self-paced course.