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CPHRM Preparation Course

Week 4

Patient Safety and Regulatory Requirements

Agenda:

Question from Week 3
Significant Safety Events
Legal and Regulatory Environment

2/17/20

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Significant Safety Event

"Mistakes are at the very base of human thought, embedded there, feeding the structure like root nodules. If we were not provided with the knack of being wrong, we could never get anything useful done."

"We are built to make mistakes, coded for error … The capacity to leap across mountains of information and land lightly on the wrong side represents the highest of human endowments."

Lewis Thomas, 1974

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Sentinel Event

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

Serious injury specifically includes the loss of limb or function.

The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

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Sentinel Events

- Patient Safety event that reaches the patient and results in:
- Death
- Permanent harm
- Severe temporary harm and intervention required to sustain life

An event can be considered 'sentinel" even if the outcome was not death, permanent harm, severe temporary harm and intervention required to sustain live.

Signal a need for immediate investigation and response

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Adverse Event

Defined by AHRQ

- "Harm from medical care rather than an underlying disease

Preventable Adverse Event: Those that occurred due to error or failure to apply and accepted strategy for prevention

Ameliorable Adverse Events: Events that, while not preventable, could have been less harmful if care had been different

Adverse event due to negligence: Those that occurred due to care that fell below the standards expected of clinicians in the community

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Patient Safety and Quality Improvement Act of 2005

- Requires event reporting be collected and categorized by Patient Safety Organization (PSO)
- Standardized manner with common set of data elements
- Allows aggregation and analysis across all providers
- "Common Formats" capture event specific data
- 7 point scale with five categories

Scale for Harm

- A—**Death**: Dead at time of assessment
- B—**Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life
- C—**Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm
- D—**Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay
- E—**No harm**: Event reached patient, but no harm was evident
- F—**Unknown**

Scale for duration of harm to the patient

- A—**Permanent** (one year or greater)
- B—**Temporary** (less than one year)
- C—**Unknown**

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How to determine deviation:

Table 1: Deviation Decision Tool (see Table 2/page 13)

Clinical trial used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication/adverse outcome of trial.
- ✓ If deviation: It is classified as preventable—go to the Harm Classification Tool to determine level.

Evidenced-based practice used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication.
- ✓ If deviation: it is classified as preventable—go to the Harm Classification Tool to determine level.

Compliance with updated procedures, policies, protocols, standards of care used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication.
- ✓ If deviation: it is classified as preventable—go to the Harm Classification Tool to determine level.

Deviation from standard practice, yet appears justifiable and applicable for the situation

- ✓ Refer to peer review for majority decision using the reasonable person criteria—if deemed the deviation is appropriate—not classified as preventable, if harm classified as complication/adverse outcome
- ✓ If deviation is not considered justified, it is classified as preventable—go to the Harm Classification Tool to determine level.

Emergency situation to save life, limb, function where no other known established treatment exists

- ✓ Refer to peer review for majority decision using the reasonable person criteria—if deemed the deviation is appropriate—not classified as preventable, if harm classified as complication / adverse outcome.
- ✓ If deviation is not considered justifiable, classified as preventable—go to the Harm Classification Tool to determine level.

If there is harm from a known complication, was there timely intervention and treatment?

- ✓ If yes, the harm was not preventable
- ✓ If no, harm was preventable—go to the Harm Classification Tool to determine level.

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Deviation Determination Guide

The following guide will aid in determining action following an event.

When an Event/Adverse Outcome Occurs
• Was there a deviation?
❑ If Yes 1. Classify the level of harm—5 levels/1 near miss 2. Take action guided by the serious safety event classification (see Table 2/page13)
❑ If No 1. Likely a complication 2. Track/Trend
❑ Not Sure 1. Use peer review process and complication guide (see Table 1/page 8) • If deviation is yes—Classify the level of harm (use 5 levels of harm/1 near miss); take action guided by the SSE classifcation • If no to deviation—Likely a complication; track/trend

Things to consider:
- Determine the SSE rate of all events—SSE rate = frequency of preventable harm
- All deviation should be understood for future prevention
- This is intended to serve as a guide and is not prescriptive

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Known Complication as Preventable Harm

Known complications from the delivery of healthcare are inescapable. However, there are times when a known complication may also be considered preventable harm. When classifying such consider the following:

Harm occurred when risk of such was known?
❑ If Yes 1. Likely a complication 2. Track/Trend
❑ If No 1. Classify the level of harm—5 levels /1 near miss 2. Take action guided by serious safety event classification (see Table 2/page13)

Things to consider:
- Tracking and trending complications should be part of the peer review process and continuous performance improvement
- Determine the SSE rate of all events—SSE rate = frequency of preventable harm
- All deviation should be understood for future prevention
- This is intended to serve as a guide and is not prescriptive

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Healthcare Associated Preventable Harm Level Classification

Safety Event Class	Level of Harm	Code	Patient Outcome	Suggested Follow-Up Analysis
Serious Safety Event (Reaches the patient)	**Death**	**SSE-1**	Unexpected death not related to the natural or expected course of the patient's illness or underlying condition . On balance of probabilities, was caused by or brought forward in the short term by the incident.	RCA, including culpability / accountability review (CCA)
	Severe Permanent or Temporary Harm	**SSE-2**	Patient outcome is symptomatic, requiring life-saving intervention or major medical-surgical intervention, shortening life expectancy or causing major, permanent or temporary harm or loss of function.	RCA, including culpability / accountability review (CCA)
Safety Event (Reaches the patient)	**Moderate Permanent or Temporary Harm**	**SE-3**	Patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure, additional therapeutic treatment), an increased length of stay, or causing permanent or temporary harm, or loss of function.	**Options:** RCA, ACA, barrier analysis, including culpability/accountability review
	Mild Temporary Harm or None	**SE-4**	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate, but short-term, and minimal or no intervention (e.g., extra observation, investigation, review, or minor treatment), is required.	**Options:** ACA, barrier analysis, trending analysis, including culpability / accountability review
	No Detectable Harm/No Harm	**SE-5**	Patient outcome is asymptomatic. No symptoms are detected and no treatment is required. Not able to discover or ascertain the existence, presence, or fact of harm, but harm may exist; insufficient information is available, or unable to determine any harm. Harm may appear later.	**Options:** ACA, barrier analysis, trending analysis, including culpability / accountability review
Pre-Patient Event (Does not reach the patient)	**Almost Happened**	**PPE-6**	Error or capacity to cause harm was caught by an error detection barrier prior to reaching the patient. ✓ The system worked	Review barrier detection, celebrate success

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Protecting Sensitive Information

- Peer Review Privilege
  - MT Code Annotated 37-2-201
- Patient Safety and Quality Improvement Act of 2005

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EMTALA

EMTALA was passed as part of the Consolidated Omnibus Budget Reconciliation Act of 1986 and applies to all hospitals who receive Medicare funds and maintain an emergency department.

This act is also known as the "anti-dumping law," as it prohibits asking a patient about his/her financial information or method of payment until he/she is evaluated to determine whether he/she suffers from an emergency medical condition or is in active labor. If the patient is found to have a medical emergency or is in active labor, the hospital must provide necessary and appropriate treatment to stabilize him/her. Treatment cannot be delayed until the patient's financial status can be determined; treatment must proceed accordingly.

In addition, a specialty or higher level of care hospital cannot refuse to accept the patient as a transfer. Since these regulations are specific to patients seen in the emergency department, EMTALA no longer applies once the patient is admitted to the hospital. Therefore, it is important for case managers to understand EMTALA and its rules and requirements when transferring patients.

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COBRA

COBRA requires employers with at least 20 employees, who provide healthcare plans to those employees, to offer extended coverage for individuals at risk of losing their healthcare coverage due to:

- Job loss.
- Decreased work hours.
- Job transition.
- Death.
- Divorce.
- Other life-changing events.

Coverage under COBRA typically lasts 18 months, but can be extended up to 36 months in certain situations. An individual must elect COBRA within 60 days of his/her healthcare plan coverage terminating and may be required to pay the entire premium plus a 2% fee. Unfortunately, this high premium cost makes COBRA coverage impossible for many people.

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HIPAA

Enacted in 1996, HIPAA seeks to establish standardized mechanisms for electronic data interchange, security, and confidentiality of all healthcare-related data. The act mandates:

- Standardized formats for all patient health, administrative, and financial information.
- Unique identifiers for each healthcare entity, including individuals, employers, health plans, and health care providers.
- Security mechanisms to ensure confidentiality and data integrity for any information that identifies an individual.

Basically, HIPAA is intended to protect private personal health information from being released in any form (e.g., written, electronic, verbal) to anyone without the patient's consent. In addition to protecting a patient's privacy, HIPAA allows the flow of health information necessary to provide and promote high-quality individual health care while protecting public health and well-being.

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MEDICARE FRAUD AND ABUSE LAWS

Fraud and abuse of the Medicare system exists, costing taxpayers billions of dollars and jeopardizing the Medicare Trust Fund. Many of these laws address conflict of interest issues and govern provider self-referral. Unless this fraud and abuse of the system is controlled, the overall health and welfare of Medicare and Medicaid beneficiaries are at risk.

Federal laws governing Medicare fraud and abuse have been created for this reason and include the:

- False Claims Act (FCA).
- Anti-Kickback Statute (AKS).
- Physician Self-Referral Law (Stark Law).

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FALSE CLAIMS ACT

FCA → Protects the government from being overcharged or sold substandard goods or services.

EXAMPLE:

Knowingly submitting a Medicare claim for services that were not actually provided.

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ANTI-KICKBACK STATUTE

AKS → Protects against providers **knowingly** and **willfully** offering, paying, soliciting, or receiving any compensation directly or indirectly for referrals that are reimbursable by a federally funded health care program.

EXAMPLE:

A provider receives incentive payments for **intentionally** directing referrals to a particular postdischarge provider.

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PHYSICIAN SELF-REFERRAL LAW

STARK LAW

- The Stark Law is related to, but not the same as, the federal anti-kickback statute.
- Prohibits a physician from making a referral for certain health services to a company **in which he/she has ownership or investment, or receives compensation.**

EXAMPLE:

A provider **consistently refers** patients to a home health company of which he is part owner.

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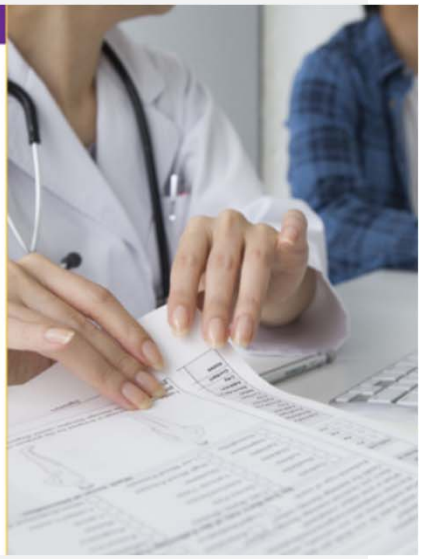
AFFORDABLE CARE ACT

The Patient Protection and Affordable Care Act (ACA), simply referred to as the Affordable Care Act or Obamacare, was signed into law in 2010. This comprehensive attempt at health reform focuses on several issues, the main one being to give Americans more access to quality, affordable health coverage while controlling the growth of healthcare spending.

In the effort to make insurance more available, health insurance marketplaces, or health exchanges, were created. These organizations help facilitate the purchase of health insurance in each state. In addition, each marketplace provides a set of government-regulated and standardized health care plans from which people can purchase coverage policies from federal subsidies.

Other high points to the ACA include improving the quality and efficiency of health care while preventing chronic disease and improving public health. These changes have spurred more of a population health focus, which involves moving from caring for patients as problems arise to actually working to prevent them in the first place.



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OSHA/CDC

The Occupational Safety and Health Administration was established by the Occupational Safety and Health Act and is considered the primary regulatory system for workplace health and safety. OSHA has instituted several safety rules and requirements for employers, such as maintaining injury records and providing employees with information about workplace hazards.

Another agency focused on regulating workplace safety is the CDC. The CDC is responsible for developing several comprehensive infection control recommendations. These include:

- Standard, contact, and airborne precautions.
- Proper hand hygiene.
- Injection safety.
- Health care–associated infections.
- Vaccination recommendations.

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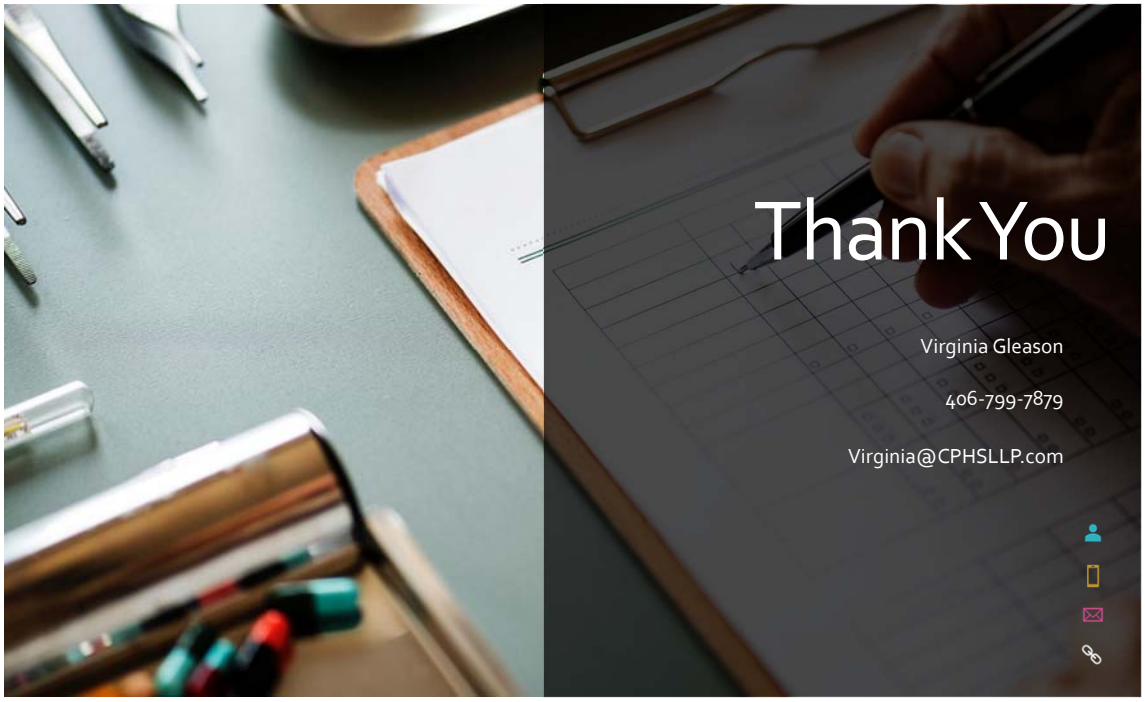

Thank You

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