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Question: 1

A hospital has opted to open an anticoagulation clinic. As this is a high-risk medication, a risk manager wants to conduct a risk assessment before opening the clinic. The BEST tool to use would be a

- A. root cause analysis RCA.
- B. failure mode and effects analysis FMEA.
- C. cause and effect diagram.
- D. scatter diagram.

Answer: B

Explanation:

Failure Mode and Effects Analysis FMEA is the most appropriate tool in this scenario because it is a proactive risk assessment methodology designed to identify and mitigate potential failures before harm occurs. According to Health Care Risk Management principles outlined by ASHRM and the American Hospital Association Certification Center, FMEA is specifically used when introducing new processes, services, or high-risk clinical operations, such as an anticoagulation clinic involving medications with narrow therapeutic indices and significant bleeding risks. FMEA systematically evaluates each step in a proposed process, identifies possible failure modes, analyzes their causes and effects, and prioritizes risks using severity, occurrence, and detectability scoring. This structured approach aligns with patient safety objectives by reducing preventable adverse events before implementation.

In contrast, Root Cause Analysis RCA is a retrospective tool used after an adverse event has occurred. A cause and effect diagram is a component often used within RCA or FMEA but is not a comprehensive risk assessment tool on its own. A scatter diagram is primarily used for statistical correlation analysis and does not evaluate process failures.

Therefore, for proactive risk identification and mitigation prior to clinic opening, FMEA is the best and most appropriate tool.

Question: 2

A risk manager is reviewing the hospital's incident reporting system and notices that very few medication errors are being reported despite known high volumes of medication administration. Which of the following is the MOST appropriate action?

- A. Discipline staff members for failure to report errors.
- B. Conduct a root cause analysis on the reporting system.
- C. Assess the organizational culture and barriers to reporting.

D. Notify the liability insurer immediately.

Answer: C

Explanation:

Within Health Care Risk Management frameworks supported by ASHRM and the American Hospital Association Certification Center, effective incident reporting systems depend heavily on organizational culture. When underreporting is identified, the most appropriate first step is to evaluate whether a just culture exists and whether staff perceive reporting as safe, nonpunitive, and constructive. Fear of retaliation, lack of feedback, time constraints, and unclear reporting procedures are common barriers that suppress reporting rates.

A punitive response such as disciplining staff may further discourage transparency and undermine patient safety initiatives. Conducting a root cause analysis may be appropriate if a specific adverse event occurred, but in this scenario the systemic issue is underreporting itself, which is primarily cultural and operational in nature. Immediate notification of the liability insurer would not address the underlying safety system weakness.

Health care operations objectives emphasize creating a culture of safety that encourages voluntary reporting, learning, and system improvement. By assessing and strengthening reporting culture, leadership can improve data accuracy, enhance early risk identification, and support proactive patient safety management.

Question: 3

All of the following are examples of an adverse drug event EXCEPT

- A. administration of a drug by the wrong route.
- B. a drug reaction experienced by the patient.
- C. controlled substance inventory discrepancy.
- D. an error in ordering or dispensing a drug.

Answer: C

Explanation:

Under Health Care Risk Management principles defined by ASHRM and the American Hospital Association Certification Center, an adverse drug event refers to patient harm or potential harm related to the use of medication. This includes medication errors and adverse drug reactions that directly affect patient safety. Administration of a drug by the wrong route is a medication error that may result in patient harm and therefore qualifies as an adverse drug event. A drug reaction experienced by the patient is, by definition, an adverse drug reaction and falls within the broader category of adverse drug events. Similarly, an error in ordering or dispensing a drug represents a medication error that may cause or has the potential to cause harm to a patient. In contrast, a controlled substance inventory discrepancy relates to regulatory compliance, diversion risk, or financial accountability, not direct patient injury. While such discrepancies are

serious and fall under legal, regulatory, and operational risk domains, they do not constitute an adverse drug event unless patient harm occurs.

Clinical and patient safety objectives emphasize distinguishing between medication-related patient harm and regulatory or operational issues. Therefore, the controlled substance inventory discrepancy is not an adverse drug event.

Question: 4

A hold-harmless agreement is an important component of which of the following aspects of a risk financing program?

- A. risk transfer
- B. risk retention
- C. first-party liability insurance
- D. third-party liability insurance

Answer: A

Explanation:

Within Health Care Risk Management frameworks established by ASHRM and the American Hospital Association Certification Center, risk financing strategies include risk retention, risk transfer, and insurance mechanisms. A hold-harmless agreement is a contractual provision in which one party agrees to assume responsibility for certain liabilities and to protect another party from claims or losses arising from specified activities. This mechanism is a classic example of risk transfer.

Through hold-harmless or indemnification clauses, an organization shifts potential financial responsibility for loss to another party, often a contractor, vendor, or service provider. This contractual allocation of liability reduces the organization's exposure without necessarily purchasing insurance. It is therefore categorized under noninsurance risk transfer.

Risk retention, by contrast, involves assuming and financing losses internally, such as through self-insurance or deductibles. First-party liability insurance addresses losses sustained directly by the insured organization, while third-party liability insurance covers claims made by others against the organization. Although insurance is also a method of risk transfer, the specific instrument described in the question is a contractual transfer mechanism rather than an insurance product.

Accordingly, a hold-harmless agreement is most directly associated with risk transfer within a comprehensive risk financing program.

Question: 5

A hospital's Ethics Committee is seeking advice on a case involving the elective sterilization of an adolescent patient who is developmentally disabled. One of the parents is refusing consent. The risk manager should evaluate which of the following?

who has consent authority
competency level of the patient
diagnosis of the patient
state statutes and laws

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

Answer: B

Explanation:

Under Health Care Risk Management principles outlined by ASHRM and the American Hospital Association Certification Center, cases involving sterilization of minors, particularly those who are developmentally disabled, raise significant legal and regulatory concerns. The risk manager's primary responsibility is to ensure compliance with applicable consent laws and protect patient rights while minimizing organizational liability.

First, determining who has legal consent authority is essential. When parents disagree, state law typically governs whether both parents must consent, whether one parent's consent is sufficient, or whether court involvement is required. Second, evaluating the competency level of the patient is critical because decision-making capacity influences whether the patient can participate in consent or assent processes. Capacity assessments may require clinical and legal evaluation.

Third, state statutes and laws are highly relevant, as many jurisdictions impose strict legal requirements or court approval for sterilization of minors or individuals with developmental disabilities. These laws are designed to protect vulnerable populations.

The patient's diagnosis alone is not the determining legal factor; rather, decision-making capacity and statutory requirements are central. Therefore, the risk manager must evaluate consent authority, competency, and applicable state laws to ensure regulatory compliance and ethical integrity.

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