administered; the planned surgical procedure may or may not have been carried out.

PRODUCT OR DEVICE EVENTS:
6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility. Included are generally detectable contaminants in drugs, devices or biologics regardless of the source of contamination or product.

7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:
(A) Catheters
(B) Drains and other specialized tubes
(C) Infusion pumps
(D) Ventilators

8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

PATIENT PROTECTION EVENTS:
9. Infant discharged to the wrong person.

10. Patient death or serious disability associated with patient elopement.

11. Patient suicide or attempted suicide resulting in serious disability, while being cared for in the facility, defined as events that result from patient actions after admission to the facility.

Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

CARE MANAGEMENT EVENTS:
12. Patient death or serious disability associated with a medication error, for example, errors involving the wrong:
(A) Drug
(B) Dose
(C) Patient
(D) Time
(E) Rate
(F) Preparation
(G) Route of administration

Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.

13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.

14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the facility. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:
(A) Pulmonary or amniotic fluid embolism
(B) Acute fatty liver of pregnancy
(C) Cardiomyopathy

15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the facility.

16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

17. Stage 3 or Stage 4 pressure ulcers acquired after admission to the facility. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

18. Patient death or serious disability resulting from joint movement therapy performed in the hospital.

19. Artificial insemination with the wrong donor sperm or wrong egg.

ENVIRONMENTAL EVENTS:
20. Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excludes events involving planned treatment, such as electrical countershock or elective cardioversion.

21. Any incident in which a line designated for oxygen or another gas to be delivered to a patient:
(A) Contains the wrong gas: or
(B) Is contaminated by toxic substances.

22. Patient death or serious disability associated with a burn incurred from any source while being cared for in the facility.

23. Patient death or serious disability associated with a fall while being cared for in the hospital.

24. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the facility.

CRIMINAL EVENTS:
25. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

26. Abduction of a patient of any age.

27. Sexual assault on a patient within or on the grounds of the facility.

28. Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the facility.

Indiana Medical Error Reporting System

What You Need To Know

Need to report a situation involving the safety of a patient or visitor? Fill out an incident report via the MyIUHealth team portal (https://team.myiuhealth.org/) or call IU Health Risk Management – available 24/7/365. A committee will decide if the incident qualifies to be a state reportable event.

Adapted from https://www.in.gov/isdh/23433.htm
More information on the MERS is also available there.

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Indiana Medical Error Reporting System

What: Indiana's Medical Error Reporting System requires that hospitals, ambulatory surgery centers, abortion clinics, and birthing centers report a serious adverse event that occurs within that facility. Indiana's medical error reporting system is based on the National Quality Forum's twenty-eight (28) serious reportable events. The National Quality Forum selected those consensus standards to represent a wide range of healthcare issues.

Why: On January 11, 2005, Indiana's Governor issued an Executive Order requiring the Indiana State Department of Health to develop and implement a medical error reporting system. The purpose of the reporting system was to obtain data that could be used towards reducing the frequency of medical errors, revealing the causes of medical errors, and empowering healthcare professionals to design methods to prevent or discover errors before patients are harmed.

Medical errors generally are not the sole result of actions of individuals but rather the failure of the systems and processes used in providing healthcare. The Indiana Medical Error Reporting System reports are available online, on the Indiana State Department of Health Web site, on the Medical Error Reporting System home page at www.in.gov/isdh/23433.htm.

DEFINITIONS

The requirements for the Indiana Medical Errors Reporting System are codified in the Indiana Administrative Code (IAC). The following are definitions used in the reporting system and are found at 410 IAC 15-1.1, 410 IAC 26-1 and 410 IAC 27-1.

"ASA Class I patient" means a normal, healthy patient.

"Biologics" means a biological product, such as:
(1) A globulin;
(2) A serum;
(3) A vaccine;
(4) An antitoxin
(5) Blood
(6) An antigen
used in the prevention or treatment of disease.

"Burn" means any injury or damage to the tissues of the body caused by exposure to any of the
following:
(1) Fire
(2) Heat
(3) Chemicals
(4) Electricity
(5) Radiation
(6) Gases

"Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so.

"Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate.

"Hypoglycemia" means a physiologic state in which:
(1) The blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) Physiological or neurological, or both, dysfunction begins.

"Immediately postoperative" means within twenty-four (24) hours after either of the following:
(1) Administration of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.

"Joint movement therapy" means all types of manual techniques, to include:
(1) Mobilization (movement of the spine or a joint within its physiologic range of motion);
(2) Manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
(3) Any other type of manual musculoskeletal therapy;
regardless of their precise anatomic and physiologic focus or their discipline of origin.

"Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

"Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:
(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.

"Neonates" means infants in the first twenty-eight (28) days of life.

"Serious disability" means either of the following:
(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
(A) Not present on admission and requiring continued treatment; or
(B) For which there is a high probability of long term or permanent lifestyle change at discharge.
(2) Unintended loss of a body part.

"Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3.

"Surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure ends when the surgical incision has been closed or operative devices, such as probes, have been removed. The procedures include, but are not limited to, the following:
(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.
The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters.

REPORTABLE EVENTS

The following are the twenty -eight (28) reportable events included in the Indiana Medical Error Reporting System.

SURGICAL EVENTS:

1. Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(A) That occur in the course of surgery; or
(B) Whose exigency precludes obtaining informed consent; or both

2. Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

3. Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(A) That occur in the course of surgery
(B) Whose exigency precludes obtaining informed consent; or both

4. Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
(A) Objects intentionally implanted as part of a planned intervention
(B) Objects present before surgery that were intentionally retained
(C) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws

5. Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was