



Indiana State
Department of Health

Indiana Medical Error
Reporting System



Final Report
for 2016

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EXECUTIVE SUMMARY

On January 11, 2005, Indiana Governor Mitchell E. Daniels Jr. 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.

This Report for 2016 is the tenth Indiana Medical Error Report and presents information about reportable events occurring in Indiana health care facilities from January 1, 2016 through December 31, 2016. The Indiana Medical Error Report for 2016 is based on data received by the Indiana State Department of Health prior to August 31, 2017.

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. For 2016, there were a total of two hundred eighty one (281) facilities required to report. One hundred twenty seven (127) events were reported for 2016. One hundred twenty two (122) events occurred at hospitals while five (5) events occurred at ambulatory surgery centers.

One hundred twenty seven (127) is the most reported events for a year since the beginning of medical error reporting in 2006. The average number of reportable events per year has been one hundred six (106). The most reported event for 2016 was stage 3 or 4 pressure ulcers (also known as bed sores) acquired after admission, followed by retention of a foreign object in a patient after surgery, surgery on the wrong body part and serious disability or death associated with a fall. These were the same top four (4) reported events in all but two (2) of the years of medical error reporting.

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. A serious reportable event may include events resulting in death or serious disability or any surgical event involving a wrong patient, body part, or procedure. Indiana was the second state to develop a medical error reporting system based on the National Quality Forum consensus standards.

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 requirement to report events identifies persistent problems, encourages increased awareness of patient safety issues and assists in the development of evidence-based initiatives to improve patient safety.

INTRODUCTION

This report is the Indiana Medical Error Reporting System Report for 2016. This report presents information about reportable events occurring in Indiana health care facilities from January 1, 2016 through December 31, 2016. The report is based on data received by the Indiana State Department of Health prior to August 31, 2017.

Indiana has a tradition of excellence in healthcare. Indiana's health care facilities are among the most advanced in the country. Indiana colleges and universities are recognized leaders in healthcare education and research. Healthcare professionals are often recognized for the dedicated and outstanding care provided to Hoosiers. It is imperative that Indiana continue to lead the way in improving patient care and health outcomes. The reduction of medical errors is an important component of continuing the Hoosier tradition of quality healthcare.

The goal of the Indiana State Department of Health is that this data will increase focus on these issues and promote the development of evidence-based initiatives designed to improve patient safety. With the growth and technical advancement of the healthcare system, maintaining and improving patient safety has become a complex and long term process. Patient care today involves a large number of healthcare professionals and health care facilities. With this larger and decentralized system, there is an increased potential for medical errors. While individuals may, and do, make independent mistakes, medical errors are more often a system failure resulting from inconsistent care practices between professionals or facilities or communication lapses within or between the many health care professionals or facilities providing care to a patient.

The data on medical errors reinforces the need for health care facilities and providers to collaborate on quality. In today's healthcare system, patient care is generally not limited to a single provider or facility. The reduction of medical errors requires care coordination to promote consistent healthcare practices and ensure appropriate communication between providers. The medical error reporting system is intended to encourage a culture in which health care providers report potentially unsafe situations without fear of reprisal in collaboration towards improved healthcare.

This report is 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. The site includes this report as well as previous reports.

BACKGROUND ON MEDICAL ERROR REPORTING

History of Medical Error Reporting

Reports on medical errors can be traced back to the 1970's, when a physician-attorney named Don Mills analyzed more than 20,000 medical charts concluding that one patient in twenty was harmed by treatment.¹ A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Leape, and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality.²

The Institute of Medicine of the National Academy of Sciences

The Institute of Medicine was chartered in 1970 as a component of the National Academy of Sciences in Washington, D.C. It is a nonprofit organization providing evidence-based analysis and guidance on matters of biomedical science, medicine, and health.

In 1998 the Institute of Medicine appointed the Committee on the Quality of Health Care in America to identify strategies for achieving a substantial improvement in the quality of healthcare delivered to Americans. In 1999 the Institute of Medicine published a landmark report on medical errors entitled *To Err Is Human: Building a Safer Health Care System*.³ The report estimated that between 44,000 and 98,000 patients die each year as a result of medical errors. The report estimated that a medication error occurs for two of every one hundred patients admitted to a hospital. The report further estimated that the total cost of preventable medical errors to be between 17 and 29 billion dollars per year.⁴

The 1999 Institute of Medicine report significantly increased awareness of medical errors and brought attention to the need for reliable data on the number of medical errors occurring in health care facilities. A subsequent Institute of Medicine report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, reinforced the need for reliable data and cited the need for evidence-based policies and practices.⁵

The Institute of Medicine report cited several causes of medical errors including the following:⁶

- Lack of reliable data on the number of medical errors which limits the ability to identify origins of the problem and develop initiatives to resolve the problem
- Medical errors are often a system failure where care practices are inconsistent between healthcare professionals leading to mistakes

¹ D.H. Mills, *Medical Injury Information: A Preparation for Analysis and Implementation of Prevention Programs*, 236(4) Journal of the American Medical Association, pp. 379-381 (1976).

² Agency for Healthcare Research and Quality, *Medical Errors: The Scope of the Problem* (2000), Retrieved February 17, 2007 from <http://www.ahrq.gov/qual/>.

³ Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

⁴ *Id.*

⁵ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (National Academy Press, 2001).

⁶ Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

- With larger, decentralized, and fragmented health care facilities and an increase in the number of health professionals providing care to a patient, there is an increased potential for medical errors
- Access to patient information by health care providers
- Lack of legible handwriting or conversely data entry mistakes
- Use of acronyms or abbreviations
- Inadequate documentation
- Patient loads placed on staff resulting in timing issues in the delivery of care
- Competition between facilities resulting in the lack of development of communication systems between health care providers

The National Quality Forum

In a 1998 report, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposed creation of the National Quality Forum as part of an integrated national quality improvement agenda. The National Quality Forum was incorporated as a new organization in May 1999. The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.⁷

The National Quality Forum is a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting. The National Quality Forum, a public-private partnership, is made up of all parts of the healthcare system, including national, state, regional, and local groups representing consumers, public and private purchasers, employers, healthcare professionals, provider organizations, health plans, accrediting bodies, labor unions, supporting industries, and organizations involved in healthcare research or quality improvement.⁸

In 2002, the National Quality Forum published a report titled *Serious Reportable Events in Healthcare*. The report identified twenty-seven (27) events that are serious, largely preventable, and of concern to both the public and health care providers. The report recommended that these twenty-seven events be reported by all licensed health care facilities. The National Quality Forum suggested that analysis of reported events could provide caregivers and patients with important information about the safety of healthcare and opportunities for improvement.⁹ In 2007, the National Quality Forum added a twenty-eighth (28th) event.

⁷ National Quality Forum, http://qualityforum.org/About_NQF/Mission_and_Vision.aspx.

⁸ *Id.*

⁹ *Serious Reportable Events in Healthcare*, National Quality Forum (2002).

INDIANA MEDICAL ERROR REPORTING SYSTEM

Development of the Indiana Medical Error Reporting System

On January 11, 2005, Governor Mitchell E. Daniels Jr. issued Executive Order 05-10 requiring the Indiana State Department of Health to develop and implement a medical error reporting system. The Executive Order cited successfully implemented medical error report systems for 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.

Prior to 2006, the Indiana State Department of Health did not collect medical error data. The Indiana State Department of Health initiated development of a medical error reporting system and adopted rules requiring hospitals, ambulatory surgery centers, abortion clinics, and birthing centers to report medical errors. The Indiana State Department of Health began collecting reportable event data on January 1, 2006.

Purposes of the Medical Error Reporting Initiative

Purposes of reporting requirement:

- Increase awareness of the problem of medical errors
- Collect and analyze data on medical errors to determine whether there are areas where mistakes could be reduced
- Provide ability to analyze data to assist health care providers in reducing medical errors
- Provide information to patients so that they understand their role in helping to prevent errors
- Promote the sharing of successful solutions and improvements between health care providers
- Culture of open discussion. The goal is not to fix blame but to encourage reporting of errors so that initiatives may be developed to prevent mistakes.
- Develop best practices aimed at reducing medical errors
- Reduce healthcare costs through elimination of errors and duplication

Responsibility for quality care

There is a tendency to attach blame when bad things happen. A “culture of blame” tends to decrease the communications needed to address something that is generally a system-based issue. By not communicating on quality issues, competing health care facilities have created inconsistent processes and procedures that have resulted in confusion among healthcare professionals as they move between facilities. The Indiana State Department of Health encourages collaboration on quality. This report is intended to encourage a healthcare culture that looks beyond blame and supports patient safety through collaboration and responsibility.

Requiring the reporting of these twenty-eight (28) events is not meant as a way of identifying and punishing those responsible for the event. Studies have indicated that most medical errors were not the result of actions of individuals but rather the failure of the systems and processes used in providing healthcare. By reporting the most serious events, persistent problems can be identified and actions can be taken to prevent these events from occurring in the future. The requirement to report serious events encourages the movement towards increased awareness of patient safety issues and encourages work towards evidence-based initiatives to improve patient safety.

This report is not intended to place blame or focus attention on specific facilities or individuals. Such an approach would be counterproductive because the reality is that medical errors are usually the

result of a system failure. A medical error that occurs in one facility may have actually begun in another facility. For instance, a pressure ulcer may have started in one long term care facility or hospital and increased in severity during a stay in another hospital. The event becomes a reportable event for the hospital if it reaches a stage 3 or 4 level while the patient is admitted to that hospital. The solution to this situation requires increased care coordination and assessments by multiple health care providers. This illustrates the systemic nature of medical errors. Commercial manufacturers, health care facilities, clinics, healthcare professionals, professional organizations, government agencies, researchers, and patients all have responsibilities towards improving patient safety.

Healthcare licensing and certification surveys

The Indiana State Department of Health is the licensing authority for Indiana health care facilities. As part of the state licensing and federal certification program, the agency conducts regular health surveys at health care facilities. During the course of a survey, surveyors often review facts surrounding a possible medical error to determine whether there was a breach of health care facility regulations.

In developing the Indiana Medical Error Reporting System, one of the concerns of facilities was that a reportable event could be used to instigate a health survey of a health care facility. Such an action would likely discourage health care facilities from complete reporting as the reporting of an event could result in punitive action through the survey process. Incomplete reporting would reduce the reliability of the data and inhibit the development of quality of care initiatives. A goal of the system is to promote the reporting of events so that the data can be analyzed to determine areas where mistakes may be reduced.

To address this issue, the Indiana State Department of Health separated the Medical Error Reporting System from the health care facility survey program. The events reported by health care facilities via the Medical Error Reporting System are not received or reviewed by health care surveyors. Events are reported through an online system that goes to the agency's health information and data program. Surveyors are not provided with the reported events and therefore cannot base their investigations on events reported by a health care facility through the Medical Error Reporting System.

The licensing and certification program regulations require the Indiana State Department of Health to investigate complaints concerning health care facilities. Surveyors will investigate any complaint received through the licensing and certification complaint system. Surveyors may therefore investigate potential reportable events discovered as part of existing standard survey procedures or as part of a complaint survey that is based on an event.

Survey process for determining whether events were reported as required

During the course of a survey at a health care facility, Indiana State Department of Health surveyors will review whether the facility has implemented a process for determining and reporting reportable events as required by state rule. The survey process is as follows:

- Surveyors will first review and determine whether the health care facility has an effective, organized, facility-wide, comprehensive quality assessment and improvement program as required by rule [see, for example, 410 IAC 15-1.4-2(a)].
- Surveyors will review and determine whether the health care facility has implemented a process for reporting to the Indiana State Department of Health each reportable event that is

determined by the facility's quality assessment and improvement program to have occurred in the facility [see, for example, 410 IAC 15-1.4-2.2(a)(2) and 2.2(b)].

- Surveyors will review and determine whether reportable events identified by the facility's quality assessment and improvement program were reported in a timely manner [see, for example, 410 IAC 15-1.4-2.2(c)].
- Surveyors will review whether the facility took appropriate action to address the opportunities for improvement found through the facility's quality assessment and improvement program and whether the outcome of the action was documented as to its effectiveness, continued follow-up, and impact on patient care [see, for example, 410 IAC 15-1.4-2(b)].

If during the course of a survey surveyors become aware of an event that constitutes a reportable event, the surveyors will inform the ISDH Director of Acute Care who will verify that the reportable event was reported within the appropriate time requirements. The Indiana State Department of Health may take enforcement action if it finds that a health care facility failed to report a reportable event as required by the rule or failed to perform the actions described above.

Event Terminology

There is no accepted universal terminology for the events described in this report. A definition of applicable terms was not adopted during the rule promulgation process. In reviewing the issue, the Indiana State Department of Health found that a wide variety of terminology has been used to describe unexpected or unplanned events that result in injury to a patient. The following are definitions utilized by various organizations.

The Joint Commission on the Accreditation of Healthcare Organizations encourages the voluntary reporting to the Commission of "sentinel events" and any root cause analysis performed by a hospital. The Joint Commission defines a sentinel event, root cause analysis, near miss, and adverse event as follows:¹⁰

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes 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. Such events are called "sentinel" because they signal the need for immediate investigation and response.

Root cause analysis is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. It progresses from special causes in clinical processes to common causes in organization processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such improvement opportunities exist.

¹⁰ Joint Commission on the Accreditation of Healthcare Organizations, *Sentinel events*, Comprehensive Accreditation Manual for Hospitals Update 4 (November 2004).

Near miss is used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a “near miss” falls within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.

Adverse event is an untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.¹¹

The Institute of Medicine defined the terms “error” and “adverse event” as follows:¹²

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a “preventable adverse event.” Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).

The National Patient Safety Foundation defined “healthcare error” as follows:¹³

An unintended healthcare outcome caused by a defect in the delivery of care to a patient. Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting.

The Institute of Medicine defined the term “patient safety” as follows:¹⁴

Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.

The National Patient Safety Foundation defined “patient safety” as follows:¹⁵

The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.

¹¹ *Adverse Health Events in Minnesota, Second Annual Public Report*, at p. 73 (Minnesota Department of Health, February 2006).

¹² Institute of Medicine, *To Err Is Human: Building A Safer Health System*, at p. 28 (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

¹³ National Patient Safety Foundation, <http://www.npsf.org/>.

¹⁴ *Adverse Health Events in Minnesota, Second Annual Public Report*, at p. 73 (Minnesota Department of Health, February 2006). See also, Institute of Medicine, *To Err Is Human: Building a Safer Health System*, at p. 58 (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

¹⁵ National Patient Safety Foundation, <http://www.npsf.org/>.

OVERVIEW OF THE INDIANA MEDICAL ERROR REPORTING SYSTEM

Who is required to report?

Indiana rules (410 IAC 15-1.4-2.2, 410 IAC 15-2.4-2.2, 410 IAC 26, 410 IAC 27) require that hospitals, ambulatory surgery centers, abortion clinics, and birthing centers report events as defined in the rules. A copy of each set of rules is included in the appendices to this report.

What are the essential components of the reporting system?

The Indiana Medical Error Reporting System was organized based on several general principles. The following is a description of the general principles and how the reporting system addresses them:

- Preserve patient confidentiality. Identifying information about a patient is not reported to the Indiana State Department of Health. The only information reported is the category of event, the quarter in which the event occurred, and the facility in which the event occurred. The report does not include the quarter in which the event occurred to further limit the linking of an event with a patient. The inclusion of the quarter in the data is to assist facilities in identifying reported events to prevent duplication of reported events.
- Consensus standards. The standards were developed by the National Quality Forum through a collaborative process with representatives from throughout the healthcare system. The consensus standards provide a means for measuring and publicly reporting on performance, and attaining healthcare goals.
- Timely. Events are reported through an online system. The health care facility may review their reported events at any time throughout the year to ensure correct reporting. By having an online system with constant access, this allows the Indiana State Department of Health to assemble the data quickly at the end of the reporting period and produce a report.
- Not punitive. The Indiana Medical Error Reporting System is intended to help find solutions to healthcare quality problems by promoting collaboration and communication between providers towards improving quality of care. As discussed above, information from reported events on the Indiana Medical Error Reporting System is not reviewed by surveyors as part of the survey process. The only punitive element is a failure to report reportable events.
- Transparency. Data will be available on the internet and available to the public. Each year the Indiana State Department of Health will publish a report. The report will include the reported data for each health care facility. The report will be published on the Indiana State Department of Health Web site.
- Health care facilities to share best practices. The Indiana State Department of Health will be working with health care providers and associations to identify initiatives designed to provide solutions to events identified in the data.

What is the health care facility required to report?

The above health care facilities are required to report any reportable event as defined by the rules that occurs within that facility. Once a health care facility has determined that a reportable event has occurred it must send the Indiana State Department of Health the following information:

- (1) Which of the twenty-eight reportable events occurred;
- (2) The health care facility where the reportable event occurred; and
- (3) The quarter and year within which the event occurred.

The facility submitting the reportable event is not to include any identifying information regarding:

- (1) a patient;
- (2) a licensed healthcare professional; or
- (3) a facility employee involved.

The facility submits the reportable event in an electronic format. The Indiana State Department of Health has established an internet portal system that allows a facility to register and then submit the required reports electronically. The system does not allow for the submission of information identifying a patient or healthcare professional.

What is not included in the Indiana Medical Error Reporting System?

The Indiana Medical Error Reporting System only collects data on the number and category of reported events. The Indiana System does not include the following:

- Specific information about the event. The health care facility only reports the category of the event. The facility does not provide the Indiana State Department of Health with a description of the event. The agency therefore does not have the ability to analyze each event. Each event must be reviewed by the facility's Quality Improvement and Assessment Program.
- A way to distinguish between events that resulted in death and events resulting in serious disability. Reports to the Indiana Medical Error Reporting System do not distinguish between death and serious disability. Data reported does not reflect the number of deaths resulting from such events.
- Events that resulted in less than death or serious disability. The threshold for some events is an event resulting in death or serious disability. For those events, an event that occurs but results in no harm or injury or harm to a patient at less than death or serious disability is not a reportable event.
- "Near misses." Near misses are events that were caught before the event occurred. For instance, the wrong patient is taken to the surgery department but it is caught before surgery is performed on the patient. The Indiana Medical Error Reporting System does not include near misses.
- Root cause analysis. Some states require a facility to perform a root cause analysis for each event and provide that analysis to the state department of health. Indiana's rule

requires events to be reviewed by the facility's Quality Improvement and Assessment Program but does not require a report to the Indiana State Department of Health.

How does a health care facility determine whether a specific event is a reportable event?

Health care licensing rules require health care facilities to have an effective, organized, and comprehensive quality assessment and improvement program in which all areas of the facility participate (see, for example, 410 IAC 15-1.4-2). The facility is required to take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program. The Indiana Medical Error Reporting System requires the facility's quality assessment and improvement program to establish a process for reporting a reportable event that occurs within that facility.

The procedure for reporting a medical error is as follows:

- The health care facility must have a process in place for accurately and timely determining the occurrence of a potential reportable event
- When an event occurs that may constitute a reportable event, the event is referred to the health care facility's quality assessment and improvement program for review
- If the facility's quality assessment and improvement program determines that a reportable event occurred, the facility must report the event within fifteen days of the program's determination that a medical error occurred and not later than four months after the potential event is brought to the program's attention
- The reportable event is submitted to the Indiana State Department of Health via an online system. An individual is designated by each facility to report events and is provided access to the online system. The facility reports the category of the event and the quarter in which the event occurred.

What are the responsibilities of the health care facility towards correcting the medical error?

Health care licensing rules require health care facilities to have an effective, organized, and comprehensive quality assessment and improvement program in which all areas of the facility participate (see, for example, 410 IAC 15-1.4-2). The facility is required to take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program. The facility's quality assessment and improvement program is required to conduct in-depth analyses of events that may have been caused by medical error.

After conducting the analyses, the facility is required to develop and implement a plan to correct the problem. In developing corrective actions, the Indiana State Department of Health encourages collaboration between providers to develop consistent care practices that will reduce confusion and result in fewer medical errors. The Indiana Medical Error Reporting System is intended to promote the development of best practices that are shared across the provider community.

How will the Indiana State Department of Health enforce the reporting requirements?

The reporting requirements are included as part of the health care facility licensing rules. For violation of health care facility licensing rules, the Indiana State Department of Health may impose the following enforcement actions:

- issue a letter of correction
- issue a probationary license
- conduct a resurvey
- deny the renewal of the license
- revoke the license
- impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000) per violation

If the Indiana State Department of Health becomes aware that an event was not reported as required by rule, the agency will conduct an investigation. If the investigation determines that an event occurred and was not reported, the Indiana State Department of Health may issue an enforcement action.

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; or
 - (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 Report for 2016.

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; or
 - (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 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; or
 - (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 State 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.

REVISIONS TO REPORTING REQUIREMENTS

INITIAL 2006 REPORTING STANDARDS

Indiana's Medical Error Reporting System is based on the National Quality Forum's serious reportable events. Indiana adopted its initial reporting requirements in 2005 with reporting beginning on January 1, 2006. In the initial reporting requirements, Indiana followed the National Quality Forum's then 27 events but added language to clarify a few of the events and added definitions of terms to provide further clarification. Indiana was the second state, following Minnesota in 2003, to develop a medical error reporting system based on the National Quality Forum serious adverse reportable events. These initial requirements were in effect for 2006 through 2008.

2009 REPORTING REVISIONS

In May 2007 the National Quality Forum published *Serious Reportable Events in Healthcare 2006 Update*. The update identified a 28th adverse event as well as further refinement of the initial list of events. The 28th adverse event was "artificial insemination with the wrong donor sperm or wrong egg."

In March 2008 the Indiana State Department of Health began promulgation of a proposed rule that would update the rules for the Indiana Medical Error Reporting System. Final rules were adopted and became effective for reporting purposes on January 1, 2009. Changes in the reporting requirements at that time included the following:

- Added the 28th event "artificial insemination with the wrong donor sperm or wrong egg"
- Clarified when a surgical procedure ends
- Clarified the retention of foreign objects to exclude objects intentionally left in when the risk of removal exceeds the risk of retention
- Clarified medication administration to include 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
- Added serious disability to the falls event

2016 REPORTING REQUIREMENTS

There were no changes to the 2016 reporting requirements and standards.

READING THIS REPORT

Using this report

The best use of this report by consumers is as a guide for increasing awareness of patient safety issues. Informed consumers are better prepared to ask questions about issues that are important to them and contribute to achievement of their healthcare goals. By learning about patient safety issues, patients may be better able to communicate with their health care providers. If patients have questions or concerns about their medical care, patients should not hesitate in discussing these questions with their health care provider or facility and ask what he or she can do to assist in the prevention of medical errors. The Indiana State Department of Health has created an on-line course for patients and providers to help them speak up to improve patient safety. That on-line course “Speak up to Prevent Infection” can be found on the Health Care Quality Resource Center at <http://www.in.gov/isdh/24555.htm>.

Patients should inquire of their health care facilities about possible consumer groups or activities that promote healthcare quality and patient safety. Collaboration of consumers with facilities is an important part of improving the quality of healthcare and many facilities have a wide variety of programs and resources designed to promote and improve public health. Links to healthcare quality organizations are provided at the end of this report. Many of these links provide information as to how patients can assist in ensuring their safety.

It is important to remember that this report should not be used to make comparisons of the safety or quality of the facilities. The number and type of reported events can vary based on factors other than differences in safety or quality of care, including:

- Size of the facility.
- The scope, complexity, and number of procedures performed at a facility.
- Interpretation differences of reportable events by each facility.

How to read this report

The data used in this Report for 2016 is based on data received prior to August 31, 2017 and covers the reporting period of January 1, 2016 through December 31, 2016. The rules require an event to be reported within fifteen days of the program’s determination that a medical error occurred and not later than four months after the potential event is brought to the program’s attention. Reportable events discovered and reported after the report for the year the event occurred has been issued will be included in the report for the next year. When a facility has reported any events that occurred in or before a year where the report has been issued, the events thus reported will be noted in the report.

A table of reported events is provided for every Indiana health care facility that was required to report 2016 events. The individual tables are grouped according to the type of facility and the county of the facility. Appendix A is a summary of health care facilities that reported at least one event. Appendix B is the reported events for hospitals and begins with hospitals located in Adams County. Appendix C is the reported events for ambulatory surgery centers. Appendix D is the reported events for abortion clinics and Appendix E is the reported events for birthing centers. All licensed health care facilities in the above facility types that were open for any period of time during 2016 are included in the Appendices.

Licensed health care facilities often include a wide range of services. A hospital, for instance, might include under their license a hospital, home health service, off-site clinics, and a long term care unit.

Any reportable event occurring in any service included under a given license is reported under that license.

Facilities report by licensed facilities. In some cases, hospitals have more than one hospital under one license. The individual facility tables found in the appendices will indicate if there is more than one hospital included under that license.

Data on number of procedures performed at a facility

The reports for individual hospitals found in Appendix B provide the number of hospital inpatient discharges, the number of hospital outpatient visits, and the number of combined inpatient and outpatient surgical procedures performed at each hospital. This data is provided for the purpose of comparison of how many patients are treated and how many surgical procedures are performed by each hospital in relation to the number of events reported. This data is required to be reported by hospitals to the Indiana State Department of Health through the Indiana Hospital Association no later than 120 days after the end of each calendar quarter. More information on this data is found at the beginning of Appendix B.

The Indiana State Department of Health has separated inpatient discharges from outpatient visits. Some of the reportable events apply only to an individual admitted to a hospital. By separating the data for inpatient discharges and outpatient visits, a more appropriate comparison with the specific reportable event is possible. The Indiana State Department of Health has limited the “surgical procedures” number to the primary procedures rather than all procedure codes. This improves clarity and accuracy by accounting for multiple codes applying to a specific procedure.

Appendix C similarly includes data for each ambulatory surgery center. For each ambulatory surgery center, the number of surgical procedures performed at the facility is listed. This data is reported to the Indiana State Department of Health by each ambulatory surgery center as part of their annual report.

In order to eliminate mistakes in the report and give facilities the opportunity to review their data for accuracy, in June, 2017 the Indiana State Department of Health sent to each facility their draft report page for 2016. Facilities were instructed to review their data for correctness and completeness. Facilities then returned to the Indiana State Department of Health a verification of data. In July 2017, the Indiana State Department of Health contacted all facilities that had not returned their verification form to request that the form be returned. The report for each facility reflects whether the data was verified by the facility.

INDIANA MEDICAL ERROR REPORT FOR 2016

Table 1 (2016): Number of health care facilities included in this report

Type of Health Care Facility	Number of Facilities
Hospitals	140
Ambulatory Surgery Centers	130
Abortion Clinics	6
Birthing Centers	5
TOTAL	281

Table 2 (2016): Total number of reported events by type of health care facility

Type of Health Care Facility	Total Number of Reported Events
Hospitals	122
Ambulatory Surgery Centers	5
Abortion Clinics	0
Birthing Centers	0
TOTAL	127

Table 3 (2016): Total number of reported events by categories for all facilities

Category of Event	Number of Reported Events	Percentage of all Reported Events
Surgical	51	40.1%
Product or Device	1	0.8%
Patient Protection	2	1.6%
Care Management	58	45.7%
Environmental	13	10.2%
Criminal	2	1.6%
TOTAL	127	100%

Table 4 (2016): Total number of health care facilities reporting one or more events

Type of Health Care Facility	Total Number of Facilities Reporting at Least One Event	Number of Facilities	Percent of Facilities Reporting at Least One Event
Hospitals	45	140	32.1%
Ambulatory Surgery Centers	5	130	3.8%
Abortion Clinics	0	6	0%
Birthing Centers	0	5	0%
TOTAL	50	281	17.8%

Table 5 (2016): Total 2016 reported events by all facilities by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		51
1. Surgery performed on the wrong body part	26	
2. Surgery performed on the wrong patient	1	
3. Wrong surgical procedure performed on a patient	3	
4. Retention of a foreign object in a patient after surgery	21	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		1
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	1	
PATIENT PROTECTION		2
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	2	
CARE MANAGEMENT		58
12. Death or serious disability associated with medication error	1	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	57	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg	0	
ENVIRONMENTAL		13
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	0	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	13	
24. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		2
25. Care ordered by someone impersonating a health care provider	0	
26. Abduction of patient of any age	0	
27. Sexual assault of a patient on the facility grounds	1	
28. Death / injury of patient or staff from physical assault occurring on facility grounds	1	
TOTAL NUMBER OF REPORTED EVENTS		127

Table 6 (2016): Total reported events by abortion clinics by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		0
1. Surgery performed on the wrong body part	0	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	0	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg	0	
ENVIRONMENTAL		0
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	0	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	0	
24. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
25. Care ordered by someone impersonating a health care provider	0	
26. Abduction of patient of any age	0	
27. Sexual assault of a patient on the facility grounds	0	
28. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		0

Table 7 (2016): Total reported events by birthing centers by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		0
1. Surgery performed on the wrong body part	0	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	0	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg	0	
ENVIRONMENTAL		0
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	0	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	0	
24. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
25. Care ordered by someone impersonating a health care provider	0	
26. Abduction of patient of any age	0	
27. Sexual assault of a patient on the facility grounds	0	
28. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		0

Table 8 (2016): Total reported events by ambulatory surgery center by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		5
1. Surgery performed on the wrong body part	3	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	0	
4. Retention of a foreign object in a patient after surgery	2	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		0
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	0	
PATIENT PROTECTION		0
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	0	
CARE MANAGEMENT		0
12. Death or serious disability associated with medication error	0	
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	0	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg.	0	
ENVIRONMENTAL		0
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	0	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	0	
24. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
25. Care ordered by someone impersonating a health care provider	0	
26. Abduction of patient of any age	0	
27. Sexual assault of a patient on the facility grounds	0	
28. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		5

Table 9 (2016): Total reported events by hospitals by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		46
1. Surgery performed on the wrong body part	23	
2. Surgery performed on the wrong patient	1	
3. Wrong surgical procedure performed on a patient	3	
4. Retention of a foreign object in a patient after surgery	19	
5. Intra-operative or post-operative death in a normal, healthy patient	0	
PRODUCTS OR DEVICES		1
6. Death or serious disability associated with contaminated drugs, devices, or biologics	0	
7. Death or serious disability associated with misuse or malfunction of device	0	
8. Death or serious disability associated with intravascular air embolism	1	
PATIENT PROTECTION		2
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	2	
CARE MANAGEMENT		
12. Death or serious disability associated with medication error	1	58
13. Death or serious disability associated with hemolytic reaction	0	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	
15. Death or serious disability associated with hypoglycemia	0	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	57	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg.	0	
ENVIRONMENTAL		13
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	0	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	13	
24. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		2
25. Care ordered by someone impersonating a health care provider	0	
26. Abduction of patient of any age	0	
27. Sexual assault of a patient on the facility grounds	1	
28. Death / injury of patient or staff from physical assault occurring on facility grounds	1	
TOTAL NUMBER OF REPORTED EVENTS		122

ANALYSIS OF REPORTED EVENTS FOR 2016

Analysis of reported events

This is the eleventh report of the Indiana Medical Error Reporting System. The number of reported events, one hundred twenty seven (127), is the highest number reported in a year.

The most reported event for 2016 was stage 3 or 4 pressure ulcers. There were fifty-seven (57) of those events reported. Over the eleven (11) year period of the report, there has been fluctuation in the number of pressure ulcers reported. The most reported previously was forty-five (45) in 2013 and the least reported, twenty-two (22) in 2009. The fifty-seven (57) events reported was a significant increase over the thirty-seven (37) events reported for 2015.

The second most reported event for 2016 was surgery performed on the wrong body part. There were twenty six (26) such events reported; twenty three (23) reports by hospitals and three (3) by ambulatory surgery centers. A total of twenty (20) such events were reported for 2015.

Surgery on the wrong body part includes many medical results. If surgery was begun (the insertion of a needle into the skin for anesthesia, for example) and then stopped after recognition that the anesthesia was at the wrong site or body part, that event must be reported as surgery on the wrong body part. As surgery is defined in the rule a reportable surgery on the wrong body part encompasses all stages of surgery from, for example, numbing the wrong leg before catching the error, to completed surgery on the wrong leg.

The ISDH encourages hospitals and ambulatory surgery centers to adopt a standardized checklist and ensure its use for all surgical procedures.

The third most reported event for 2016 was retention of a foreign object in a patient after surgery. There were twenty one (21) of these events reported. This is a sizeable decrease over what was reported last year. There were thirty three (33) retention of a foreign object events reported in 2015.

The fourth most reported event for 2016 was a death or serious disability associated with a fall which was reported thirteen (13) times.

One hundred twenty seven (127) events were reported for 2016. One hundred twenty two (122) events occurred at hospitals while five (5) events occurred at ambulatory surgery centers.

In looking at the number of reported events by individual facilities, the licensing status of a health care facility is a consideration in analyzing the number of events occurring at a specific facility. Reports for individual facilities are by health care facility license. A facility may have more than one (1) hospital under the license. One health care facility, Indiana University (IU) Health accounted for ten (10) of the reported events. In analyzing that information it should be noted that IU Health includes several hospitals and services under their license. Any reportable events occurring at IU Health Methodist Hospital of Indianapolis, IU Health University Hospital, IU Health Riley Hospital for Children, and IU Health Saxony Hospital are reported under their one (1) license.

No reportable events were submitted by abortion clinics or birthing centers for calendar year 2016. No reportable events have been reported by these facilities over the eleven (11) years of reporting. That is expected as abortion clinics and birthing centers have very limited services. Many of the twenty-eight (28) reporting categories would not be applicable to an abortion clinic or birthing center.

Because abortion clinics and birthing centers are limited in services and the scope is much smaller than even an ambulatory surgery center, the Indiana State Department of Health expected to have few, if any, reported events by these facilities. The data continues to be consistent with that expectation.

DATA TABLES

TABLE 10 (2016): 2016 Hospital Inpatient Discharges, Outpatient Visits and Procedures

HOSPITAL DATA		
Data Category	Definition	Total Number Reported
Inpatient Discharges	Inpatient Discharge means the discharge of an individual who had been admitted to the hospital as an inpatient. It does not include hospice, skilled nursing facility and observation patients.	742,807
Outpatient Visit	Outpatient Visit refers to a visit to a facility for the purpose of emergency services, outpatient surgery, occupation and physical therapy/rehabilitation, cardiac diagnostic and treatment procedures, or psychiatric and social services. These classifications are based on selected billing or diagnosis codes.	9,828,427
Procedures	Procedure includes any surgical procedure coded "00.30" to "86.99" inclusive in the principal procedure field as reported by the hospital for both inpatient discharges and outpatient visits.	1,384,210

TABLE 11 (2016): 2016 Ambulatory Surgery Center Procedure Data

AMBULATORY SURGERY CENTER DATA		
Data Category	Definition	Total Number Reported
Procedures	Procedure includes any procedure reported by the ambulatory surgery center.	605,538

TABLE 12 (2016): Top Four (4) Reported Events in Indiana for 2016

Event	Number of Reported Events	Percent of Total Number of Reportable Events	Ratio of Number of Reported Events to Total Number of Discharges or Surgical Procedures
Stage 3 or 4 pressure ulcers acquired after admission	57	44.9%	1 event per 13,032 hospital inpatient discharges
Surgery performed on the wrong body part	26	20.5%	1 event per 76,529 surgical procedures performed in hospital and ambulatory surgery centers
Retention of foreign object in patient after surgery	21	16.5%	1 event per 94,750 surgical procedures performed in hospital and ambulatory surgery centers
Death or serious disability associated with a fall	13	10.2%	1 event per 57,139 hospital inpatient discharges

TABLE 13 (2016). Comparison of reported events for surgical procedures for hospitals and ambulatory surgery centers (ASC)

Event	Number of ASC Reported Events	Ratio of Number of Reported Events to Number of Surgical Procedures	Number of Hospital Reported Events	Ratio of Number of Reported Events to Number of Surgical Procedures
Surgery performed on the wrong body part	3	1 event per 201,846 surgical procedures performed in ambulatory surgery center	23	1 event per 32,296 surgical procedures performed in hospital
Wrong surgical procedure performed on a patient	0	0 event per 605,538 surgical procedures performed in ambulatory surgery center	3	1 event per 461,403 surgical procedures performed in hospital
Retention of foreign object in patient after surgery	2	1 event per 302,769 surgical procedures performed in ambulatory surgery center	19	1 event per 72,853 surgical procedures performed in hospital

COMPARISON OF ANNUAL REPORTS

This report for 2016 is the eleventh report of the Indiana Medical Error Reporting System. The following tables provide a few comparisons between the past years' reported events.

TABLE 14 (2016): Total number of reported events by type of health care facility for 2006 - 2016

	Hospitals	Ambulatory Surgery Centers	Abortion Clinics	Birthing Centers	TOTAL
Number of Reported Events for 2006	79	6	0	0	85
Number of Reported Events for 2007	101	4	0	0	105
Number of Reported Events for 2008	99	6	0	0	105
Number of Reported Events for 2009	89	5	0	0	94
Number of Reported Events for 2010	102	5	0	0	107
Number of Reported Events for 2011	94	6	0	0	100
Number of Reported Events for 2012	88	12	0	0	100
Number of Reported Events for 2013	102	9	0	0	111
Number of Reported Events for 2014	102	12	0	0	114
Number of Reported Events for 2015	114	4	0	0	118
Number of Reported Events for 2016	122	5	0	0	127
Average per year	99.3	6.7	0	0	106

TABLE 15 (2016): Top Five (5) Reported Events in Indiana for 2006 through 2016

	Stage 3 or 4 pressure ulcers acquired after admission	Retention of foreign object in patient after surgery	Surgery performed on the wrong body part	Death or serious disability associated with medication error	Death or serious disability* associated with a fall
Number of Reported Events for 2006	26	23	11	6	4
Number of Reported Events for 2007	27	24	23	8	5
Number of Reported Events for 2008	33	30	16	7	8
Number of Reported Events for 2009	22	29	17	3	8
Number of Reported Events for 2010	34	33	14	0	17
Number of Reported Events for 2011	41	17	18	3	12
Number of Reported Events for 2012	30	19	15	0	14
Number of Reported Events for 2013	45	27	18	0	12
Number of Reported Events for 2014	44	27	21	4	10
Number of Reported Events for 2015	37	33	20	2	14
Number of Reported Events for 2016	57	21	26	1	13
Average per year	36	25.7	18.1	3.1	10.6

* = “serious disability” added in 2009

TABLE 16 (2016): Combined total number of reported events by categories for 2006 - 2016

Category of Event	Surgical	Product or Device	Patient Protection	Care Management	Environmental	Criminal	TOTAL
Reported Events For 2006	39	4	0	33	6	3	85
Reported Events For 2007	49	2	2	38	5	9	105
Reported Events For 2008	48	3	4	42	8	0	105
Reported Events For 2009	51	5	2	27	9	0	94
Reported Events For 2010	50	1	1	36	18	1	107
Reported Events For 2011	40	0	2	44	12	2	100
Reported Events for 2012	41	11	2	30	16	0	100
Reported Events for 2013	48	3	0	48	12	0	111
Reported Events for 2014	52	2	0	50	10	0	114
Reported Events for 2015	60	0	1	41	15	1	118
Reported Events for 2016	51	1	2	58	13	2	127

TABLE 17 (2016): Comparison of reported events for surgical events for 2006 - 2016

Event	Surgery performed on wrong body part		Surgery performed on the wrong patient		Wrong surgical procedure on patient		Retention of foreign object after surgery		Intra-operative or post-operative death in a normal healthy patient	
	ASC	Hospital	ASC	Hospital	ASC	Hospital	ASC	Hospital	ASC	Hospital
Reported Events for 2006	6	5	0	2	0	3	0	23	0	0
Reported Events for 2007	4	19	0	0	0	1	0	24	0	1
Reported Events for 2008	3	13	0	0	0	1	2	28	1	0
Reported Events for 2009	4	13	0	1	0	2	1	28	0	2
Reported Events for 2010	2	12	0	1	0	2	3	30	0	0
Reported Events for 2011	3	15	0	0	1	3	2	15	0	1
Reported Events for 2012	2	13	0	2	3	2	0	19	0	0
Reported Events for 2013	5	13	0	0	0	2	2	25	0	1
Reported Events for 2014	9	12	0	0	1	3	2	25	0	0
Reported Events for 2015	2	18	0	0	1	6	0	33	0	0
Reported Events for 2016	3	23	0	1	0	3	2	19	0	0

TABLE 18 (2016): Total reported events by all facilities by reportable event categories for 2006 - 2016

Reportable Event	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
SURGICAL- Total Reported Events	39	49	48	51	50	40	41	48	52	60	51
1. Surgery performed on the wrong body part	11	23	16	17*	14*	18	15	18	21	20	26
2. Surgery performed on the wrong patient	2	0	0	1	1	0	2	0	0	0	1
3. Wrong surgical procedure performed on patient	3	1	1	2	2	4	5	2	4	7	3
4. Retention of foreign object in patient after surgery	23	24*	30	29*	33*	17	19*	27*	27*	33*	21*
5. Intra-operative or post-operative death in a normal, healthy patient	0	1	1	2	0	1	0	1	0	0	0
PRODUCTS OR DEVICES- Total Reported Events	4	2	3	5	1	0	11	3	2	0	1
6. Death or serious disability associated with contaminated drugs, devices, or biologics	1	0	0	0	0	0	7	2	0	0	0
7. Death or serious disability associated with misuse or malfunction of device	3	1	2	2	1	0	1	0	2	0	0
8. Death or serious disability associated with intravascular air embolism	0	1	1	3	0	0	3	1	0	0	1
PATIENT PROTECTION – Total Reported Events	0	2	4	2	1	2	2	0	0	1	2
9. Infant discharged to wrong patient	0	0	0	0	0	0	0	0	0	0	0
10. Death or serious disability associated with patient elopement	0	0	1	0	0	0	0	0	0	0	0
11. Suicide or attempted suicide resulting in serious disability	0	2	3	2	1	2	2	0	0	1	2
CARE MANAGEMENT – Total Reported Events	33	38	42	27	36	44	30	48	50	41	58
12. Death or serious disability associated with medication error	6	8	7	3	0	3	0	0	4	2	1
13. Death or serious disability associated with hemolytic reaction	0	1	0	0	0	0	0	0	0	1	0
14. Maternal death or serious disability associated with low	0	1	0	0	1	0	0	0	1	0	0

risk pregnancy labor or delivery											
15. Death or serious disability associated with hypoglycemia	1	1	2	2	1	0	0	3	1	1	0
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	0	0	0	0	0	0	0	0	0	0
17. Stage 3 or 4 pressure ulcers acquired after admission	26	27*	33	22	34	41	30	45	44	37	57*
18. Death or serious disability due to joint movement therapy	0	0	0	0	0	0	0	0	0	0	0
19. Artificial insemination with the wrong donor sperm or donor egg	n/a	n/a	n/a	0	0	0	0	0	0	0	0
ENVIRONMENTAL- Total Reported Events	6	5	8	9	18	12	16	12	10	15	13
20. Death or serious disability associated with electric shock	0	0	0	0	0	0	0	0	0	0	0
21. Wrong gas/contamination in patient gas line	0	0	0	1	0	0	1	0	0	0	0
22. Death or serious disability associated with a burn	2	0	0	0	0	0	0	0	0	0	0
23. Death or serious disability associated with a fall	4	5	8	8	17	12	14	12	10	14	13
24. Death or serious disability associated with restraints or bedrails	0	0	0	0	1	0	1	0	0	1	0
CRIMINAL – Total Reported Events	3	9	0	0	1	2	0	0	0	1	2
25. Care ordered by someone impersonating a health care provider	0	0	0	0	0	0	0	0	0	0	0
26. Abduction of patient of any age	0	1	0	0	0	0	0	0	0	0	0
27. Sexual assault of a patient on the facility grounds	2	6	0	0	1	2	0	0	0	1	1
28. Death/injury of patient or staff from physical assault occurring on grounds	1	2	0	0	0	0	0	0	0	0	1
TOTAL NUMBER OF REPORTED EVENTS	85	105	105	94	107	100	100	111	114	118	127

*Includes at least one (1) event that occurred before report year, but was reported after the previous report was issued.

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ADDITIONAL INFORMATION ON MEDICAL ERRORS AND PATIENT SAFETY

There are numerous organizations that are a resource for information on patient safety. The following is a list of Web sites that provide information on patient safety. This list provides only a fraction of the resources available. There are many more resources available for consumers, health care providers, and policy makers.

Agency for Healthcare Policy and Research (AHRQ): www.ahrq.gov/consumer

The mission of the federal Agency for Healthcare Policy and Research is to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans. Information from this agency's research helps people make more informed decisions and improve the quality of healthcare services.

Centers for Medicare and Medicaid Services: www.cms.hhs.gov/

The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and works in partnership with the states to administer the Medicaid program. CMS has developed a number of quality improvement initiatives that can be found at this site.

Consumers Advancing Patient Safety: www.patientsafety.org

Consumers Advancing Patient Safety is a consumer-led nonprofit organization, formed to be a collective voice for individuals, families and healers who wish to prevent harm in healthcare encounters through partnership and collaboration. In addition to the organization resources available on their Web site, this site also provides several links to other patient safety Web sites of interest to consumers.

National Academies of Science, Engineering and Medicine (formerly IOM):
<http://www.nationalacademies.org/hmd/>

A nonprofit organization specifically created for science-based advice on matters of biomedical science, medicine, and health as well as an honorific membership organization, the Institute of Medicine (IOM) was chartered in 1970 as a component of the National Academy of Sciences. On March 15, 2016, the division of the National Academies of Sciences, Engineering, and Medicine (the Academies) that focuses on health and medicine was renamed the Health and Medicine Division (HMD) instead of using the name Institute of Medicine (IOM).

Institute for Safe Medication Practices: www.ismp.org/Tools/default.asp

Alerts for Patients page containing a listing of frequent medication errors and how to avoid them, general information and advice on medication safety for consumers.

Joint Commission: http://www.jointcommission.org/topics/patient_safety.aspx

The Joint Commission evaluates and accredits more than 15,000 healthcare organizations and programs in the United States. Its mission is to continuously improve the safety and quality

of care provided to the public. A number of patient safety tips for patients and consumers can be found at their website.

Leapfrog Group: www.leapfroggroup.org

The Leapfrog Group is an initiative driven by organizations that buy health care who are working to initiate breakthrough improvements in the safety, quality and affordability of healthcare for Americans. The Leapfrog Website provides quality and safety information about hospitals that consumers can search.

Minnesota Alliance for Patient Safety: www.mnpatientsafety.org

The Minnesota Alliance for Patient Safety was established in 2000 as a partnership between public and private health care organizations working together to improve patient safety. Information about Minnesota's patient safety coalition can be found at this site.

Minnesota Department of Health: www.health.state.mn.us/patientsafety/publications/index.html

This site provides information on Minnesota's Adverse Health Event Annual Reports.

National Academy for State Health Policy: www.nashp.org

The National Academy for State Health Policy is a non-profit, non-partisan organization dedicated to helping states achieve excellence in health policy and practice. The organization provides resources to compare patient safety initiatives and approaches across the states.

National Coordinating Council for Medication Error Reporting and Prevention: www.nccmerp.org

This organization is an independent body comprised of twenty-three national organizations. The mission of the National Coordinating Council for Medication Error Reporting and Prevention is to maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting and promotion of medication error prevention strategies.

National Patient Safety Foundation: www.npsf.org

The Foundation's mission is to improve the safety of patients through efforts to: identify and create a core body of knowledge; identify pathways to apply the knowledge; develop and enhance the culture of receptivity to patient safety; raise public awareness and foster communications about patient safety; and improve the status of the Foundation and its ability to meet its goals.

National Quality Forum: www.qualityforum.org

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

Pressure ulcer information

Mayo Clinic: <http://www.mayoclinic.org/>

This site provides information from the Mayo Clinic, the world's first and largest integrated group medical practice.

Medline Plus: www.nlm.nih.gov/medlineplus/pressuresores.html

Medline Plus is a service of the U.S. National Library of Medicine and the National Institutes of Health

Quality Assurance Performance Improvement (QAPI):

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html>

QAPI is a data-driven, proactive approach to improving the quality of life, care, and services in nursing homes. The activities of QAPI involve members at all levels of the organization to: identify opportunities for improvement; address gaps in systems or processes; develop and implement an improvement or corrective plan; and continuously monitor effectiveness of interventions.

Quality Interagency Coordination Task Force: www.quic.gov/report/

The Quality Interagency Coordination Task Force was established in 1998 in accordance with a Presidential directive. The purpose of the Task Force was to ensure that all federal agencies involved in purchasing, providing, studying, or regulating health care services were working in a coordinated manner toward the common goal of improving quality care.