



Indiana State
Department of Health

Indiana Medical Error
Reporting System

Final Report for 2009

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Indianapolis, IN 46204**

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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.

The first report of the Indiana Medical Error Reporting System was released in August 2007. This Report for 2009 is the fourth Indiana Medical Error Report and presents information about reportable events occurring in Indiana health care facilities between January 1, 2009 and December 31, 2009. The Report for 2009 is based on data received by the Indiana State Department of Health prior to August 1, 2010.

For 2009, there were a total of three hundred and six (306) facilities required to report. Ninety-four (94) events were reported for 2009. Eighty-nine (89) events occurred at hospitals while five (5) events occurred at ambulatory surgery centers.

The ninety-four (94) reported events for 2009 is a decrease from the 105 events reported for 2007 and 2008. The most reported event for 2009 was retention of a foreign object in a patient after surgery. The number of retained objects and wrong body part surgeries remained nearly constant from 2008.

Most significant for the Report for 2009 was the decrease in the number of reported stage 3 or 4 pressure ulcers in hospitals. The number of pressure ulcers fell to its lowest level in the four years of reporting and dropped from the most reported event to the second most reported event. The decrease in the number of pressure ulcers is likely linked to the Indiana Pressure Ulcer Initiative. The Initiative began in June 2008 and concludes in September 2010. Over 230 health care facilities and agencies participated in the Initiative and implemented system-based prevention improvements.

Indiana's medical error reporting system is based on the National Quality Forum's twenty-eight serious reportable events. Only the most serious events are reportable events under this system. A serious event includes 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.

Requiring the reporting of these twenty-eight events is not meant as a way of identifying and punishing those responsible for the reportable event. 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.

Indiana's Medical Error Reporting System requires that hospitals, ambulatory surgery centers, abortion clinics, and birthing centers report any reportable event as defined by the rules that occurs within that facility. The facility is required to report which of the twenty-eight reportable events occurred, the health care facility where the reportable event occurred, and the calendar quarter and year within which the event occurred.

INTRODUCTION

This report is the Indiana Medical Error Reporting System Report for 2009. This Report for 2009 presents information about reportable events occurring in Indiana health care facilities between January 1, 2009 and December 31, 2009. The report is based on data received by the Indiana State Department of Health prior to August 1, 2010.

This report shows that retention of a foreign object in a patient after surgery, stage 3 or stage 4 pressure ulcers acquired after admission to the hospital, and surgery performed on the wrong body part were the three most common reported events for 2009. These three events have been the top three reported events in all four of the Indiana Medical Error Reports although, in the 2009 report, retention of a foreign object replaces pressure ulcers as the top reported event.

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 for 2009 is available online on the Indiana State Department of Health Web site at www.in.gov/isdh. The Medical Error Reporting System home page is found at www.in.gov/isdh/23433.htm and 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, DC. It is a nonprofit organization providing evidence-based analysis and guidance on matters of biomedical science, medicine, and health.³

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*.⁴ 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.⁵

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.⁶

The Institute of Medicine report cited several causes of medical errors including the following:⁷

- 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

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 of the National Academies, Retrieved February 12, 2007 from <http://www.iom.edu/About-IOM.aspx>.

⁴ 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).

⁵ *Id.*

⁶ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (National Academy Press, 2001).

⁷ 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).

- Medical errors are often a system failure where care practices are inconsistent between healthcare professionals leading to mistakes
- 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.⁸

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.⁹

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.¹⁰

Indiana's Medical Error Reporting System is based on the National Quality Forum's twenty-seven serious reportable events. Indiana added language to clarify a few of the events and added definitions of terms to provide further clarification. Indiana is the second state, following Minnesota in 2003, to develop a medical error reporting system based on the National Quality Forum serious adverse reportable events. Like Minnesota's system, the Indiana Medical Error Reporting System has been a collaborative effort with strong support from Indiana's healthcare community and a shared goal of improving patient safety.

⁸ National Quality Forum, http://qualityforum.org/About_NQF/Mission_and_Vision.aspx.

⁹ *Id.*

¹⁰ *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 error
- 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-seven 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 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:¹¹

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

¹¹ Joint Commission on the Accreditation of Healthcare Organizations, *Sentinel events*, Comprehensive Accreditation Manual for Hospitals Update 4 (November 2004).

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.

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.¹²

The Institute of Medicine defined the terms “error” and “adverse event” as follows:¹³

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:¹⁴

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.

¹² *Adverse Health Events in Minnesota, Second Annual Public Report*, at p. 73 (Minnesota Department of Health, February 2006).

¹³ 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).

¹⁴ National Patient Safety Foundation, <http://www.npsf.org/au>.

The Institute of Medicine defined the term “patient safety” as follows:¹⁵

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:¹⁶

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

¹⁵ *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).

¹⁶ National Patient Safety Foundation, <http://www.npsf.org/au>.

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 appendix 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 calendar 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. The Indiana State Department of Health anticipates that patient safety centers will become an evaluator of reported events once those centers are developed.
- 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 are not reportable events.
- "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 six 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 2009.

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.

INDIANA MEDICAL ERROR REPORT FOR 2009

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.

This report provides information about activities that have been implemented by facilities and coalitions to improve patient safety. 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 2009 is based on data received prior to August 1, 2010 and covers the reporting period of January 1, 2009 through December 31, 2009. The rules require a facility to report events within six months of discovery.

A table of reported events is provided for every Indiana health care facility that was required to report 2009 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 during 2009 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 are reported 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 in this report 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 directly 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, the Indiana State Department of Health sent to each facility their draft Report for 2009. 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 2009, the Indiana State Department of Health contacted all facilities that had not returned their verification form to request that the form be returned. A few facilities failed to return the verification prior to the publishing of the report. The report for each facility reflects whether the data was verified by the facility.

Changes for 2009

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 is “artificial insemination with the wrong donor sperm or wrong egg”.

In March 2008 the Indiana State Department of Health promulgated 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. For events occurring in 2009, health care facilities and clinics used the revised reporting rules that added the 28th adverse event and revised events to National Quality Forum events.

Combined 2009 Data for All Health Care Facilities

TABLE 1 (2009): Number of health care facilities included in this report

Type of Health Care Facility	Number of Facilities
Hospitals	147
Ambulatory Surgery Centers	146
Abortion Clinics	9
Birthing Centers	4
TOTAL	306

TABLE 2 (2009): Total number of reported events by type of health care facility

Type of Health Care Facility	Total Number of Reported Events
Hospitals	89
Ambulatory Surgery Centers	5
Abortion Clinics	0
Birthing Centers	0
TOTAL	94

TABLE 3 (2009): Total number of reported events by categories for all facilities combined

Category of Event	Number of Reported Events
Surgical	51
Product or Device	5
Patient Protection	2
Care Management	27
Environmental	9
Criminal	0
TOTAL	94

TABLE 4 (2009): 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	42	147	28.6%
Ambulatory Surgery Centers	5	146	3.4%
Abortion Clinics	0	9	0%
Birthing Centers	0	4	0%
TOTAL	47	306	15.4%

Combined Data for All Facilities

Table 5 (2009): Total 2009 reported events by all facilities by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		51
1. Surgery performed on the wrong body part	17**	
2. Surgery performed on the wrong patient	1	
3. Wrong surgical procedure performed on a patient	2	
4. Retention of a foreign object in a patient after surgery	29**	
5. Intra-operative or post-operative death in a normal, healthy patient	2	
PRODUCTS OR DEVICES		5
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	2	
8. Death or serious disability associated with intravascular air embolism	3	
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		27
12. Death or serious disability associated with medication error	3	
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	2	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	22	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg	0	
ENVIRONMENTAL		9
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	1	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	8	
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		94

** At least one event occurred in 2008, but was reported after the 2008 Report was issued.

Combined Data for Hospitals

Table 6 (2009): Total reported events by hospitals by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		46
1. Surgery performed on the wrong body part	13**	
2. Surgery performed on the wrong patient	1	
3. Wrong surgical procedure performed on a patient	2	
4. Retention of a foreign object in a patient after surgery	28**	
5. Intra-operative or post-operative death in a normal, healthy patient	2	
PRODUCTS OR DEVICES		5
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	2	
8. Death or serious disability associated with intravascular air embolism	3	
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		27
12. Death or serious disability associated with medication error	3	
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	2	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	22	
18. Death or serious disability due to joint movement therapy	0	
19. Artificial insemination with the wrong donor sperm or wrong egg	0	
ENVIRONMENTAL		9
20. Death or serious disability associated with electric shock	0	
21. Wrong gas / contamination in patient gas line	1	
22. Death or serious disability associated with a burn	0	
23. Death or serious disability associated with a fall	8	
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		89

** At least one event occurred in 2008, but was reported after the 2008 Report was issued.

Combined Data for Ambulatory Surgery Centers

Table 7 (2009): 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	4	
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	1	
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

Combined Data for Abortion Clinics

Table 8 (2009): 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

Combined Data for Birthing Centers

Table 9 (2009): 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

ANALYSIS OF REPORTED EVENTS FOR 2009

Significant Findings for 2009

- The total number of reported events decreased from the previous two years
- The number of pressure ulcer events declined to its lowest number over the four years of reporting
- The number of retained foreign objects replaced pressure ulcers as the most reported event
- The number of medication errors resulting in death or serious disability declined to its lowest level in the four years of reporting
- Through the Indiana Pressure Ulcer Initiative, there was a significant decrease in the number of pressure ulcers in health care facilities

Analysis of reported events

This is the fourth report of the Indiana Medical Error Reporting System. The number of reported events declined in 2009 as compared to the previous two years. Based on experiences of other states, the Indiana State Department of Health expected an increase to occur in the second year with a leveling off to occur in either the third or fourth year of the report. A decrease in the fourth year of reporting is consistent with the experiences of other states with mandatory reporting.

Most significant for the Report for 2009 was the decrease in the number of reported stage 3 or 4 pressure ulcers. The number of pressure ulcers fell to its lowest level in the four years of reporting and dropped from the most reported event to the second more reported event. The decrease in the number of pressure ulcers is perhaps linked to the Indiana Pressure Ulcer Initiative. The Initiative began in June 2008 and concludes in September 2010. Over 230 health care facilities and agencies participated in the Initiative. A more complete discussion of the Initiative is included later in this Report for 2009.

The most reported event for 2009 was retention of a foreign object in a patient after surgery. The number of retained objects and wrong body part surgeries remained nearly constant from 2008. The ISDH has not seen improvement in the number of reported surgical events. In recent years several organizations have introduced surgical safety checklists. The ISDH will be closely reviewing 2010 data to determine whether the use of checklists resulted in fewer surgical events. The ISDH encourages hospitals and ambulatory surgery centers to adopt a standardized checklist and ensure its use.

The Report for 2009 showed a decrease in medication errors resulting in death or serious disability. The number of reported events was the lowest in the four year reporting. This may be in part a result of increased awareness among providers to medication errors resulting from widespread publicity of a few recent medication error events. The reporting threshold for this event only requires reporting of events resulting in death or serious disability so it may not necessarily be a statistically significant result. From our survey process, the ISDH continues to identify medication errors in health care facilities and agencies.

Ninety-four (94) events were reported for 2009. Eighty-nine (89) events occurred at hospitals while five (5) events occurred at ambulatory surgery centers. That data is consistent with the scope of the facilities. Because an ambulatory surgery center does not have overnight stays and performs limited services, many of the twenty-eight (28) reporting categories would not be applicable to an ambulatory

surgery center. The unlikely occurrence of many events at an ambulatory surgery center reduces the expected number of reported events at those facilities. The data is consistent with that expectation.

There was one (1) retained foreign object event at ambulatory surgery centers in 2009 as compared to twenty-eight (28) such events at hospitals. Hospitals continued to report more foreign object events than ambulatory surgery centers. Some of the difference may perhaps be attributable to the complexity of some hospital surgeries and the types of surgeries performed at the two types of facilities. It is still however a significant finding that there is a significant difference in foreign objects retentions between the two types of facilities.

In looking at the number of reported events by individual facilities, the licensing status of a health care facility likely 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 hospital under the license. One health care facility, Clarian Health Partners, accounted for eighteen (18) of the reported events. In analyzing that information it should be noted that Clarian includes several large hospitals and services under the Clarian Health Partners license. Any reportable events occurring at Methodist Hospital of Indianapolis, Indiana University Hospital, and Riley Hospital for Children are reported under that one license.

No reportable events were submitted by abortion clinics or birthing centers for calendar year 2009. There have not been any reported events at these facilities over the four years of reporting. That is expected as abortion clinics and birthing centers have very limited services. Many of the twenty-eight 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 is consistent with that expectation as there were no reported events.

Data Tables

TABLE 10 (2009): 2008 Hospital Discharges, Visits and Procedures

2009 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.	809,600
Outpatient Visits	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.	3,878,619
Procedures	Procedure includes any surgical procedure coded "01.00" to "86.99" inclusive in the principal procedure field as reported by the hospital for both inpatient discharges and outpatient visits.	1,277,994

TABLE 11 (2009): 2008 Ambulatory Surgery Center Procedure Data

2009 AMBULATORY SURGERY CENTER DATA		
Data Category	Definition	Total Number Reported
Procedures	Procedure includes any procedure reported by the ambulatory surgery center on the ASC Utilization Report, State Form 49933	436,606

TABLE 12 (2009). Top Five Reported Events in Indiana for 2009

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
Retention of foreign object in patient after surgery	29	30.9%	1 event per 59,000 surgical procedures performed in hospital and ambulatory surgery centers
Stage 3 or 4 pressure ulcers acquired after admission	22	23.4%	1 event per 37,000 hospital inpatient discharges
Surgery performed on the wrong body part	17	18.1%	1 event per 101,000 surgical procedures performed in hospital and ambulatory surgery centers
Death associated with a fall	8	8.5%	1 event per 586,000 hospital inpatient discharges and outpatient visits
Death or serious disability associated with medication error	3	3.2%	1 event per 1,562,000 hospital inpatient discharges and outpatient visits

TABLE 13 (2009). Percentage of Category of Events

Category of Event	Number of Reported Events	Percentage of all Reported Events
Surgical	51	54.3%
Product or Device	5	5.3%
Patient Protection	2	2.1%
Care Management	27	28.7%
Environmental	9	9.6%
Criminal	0	0.0%
TOTAL	94	100%

TABLE 14 (2009). 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	4	1 event per 109,000 surgical procedures performed in ambulatory surgery center	13	1 event per 98,000 surgical procedures performed in hospital
Surgery performed on the wrong patient	0	0 event per 436,606 surgical procedures performed in ambulatory surgery center	1	1 event per 1,277,994 surgical procedures performed in hospital
Wrong surgical procedure performed on a patient	0	0 event per 436,606 surgical procedures performed in ambulatory surgery center	2	1 event per 639,000 surgical procedures performed in hospital
Retention of foreign object in patient after surgery	1	1 event per 436,606 surgical procedures performed in ambulatory surgery center	28	1 event per 46,000 surgical procedures performed in hospital
Intra-operative or post-operative death in a normal, healthy patient	0	0 event per 436,606 surgical procedures performed in ambulatory surgery center	2	1 event per 639,000 surgical procedures performed in hospital

COMPARISON OF ANNUAL REPORTS

This Report for 2009 is the third report of the Indiana Medical Error Reporting System. The following tables provide a few comparisons between the 2006, 2007, 2008, and 2009 reported events.

TABLE 15 (2009). Top Five Reported Events in Indiana for 2006 through 2009

Event	Number of Reported Events for 2006	Number of Reported Events for 2007	Number of Reported Events for 2008	Number of Reported Events for 2009
Stage 3 or 4 pressure ulcers acquired after admission	26	27	33	22
Retention of foreign object in patient after surgery	23	24	30	29
Surgery performed on the wrong body part	11	23	16	17
Death or serious disability associated with medication error	6	8	7	3
Death associated with a fall	4	5	8	8

TABLE 16 (2009): Total number of reported events by type of health care facility for 2006 - 2009

Type of Health Care Facility	Number of Reported Events for 2006	Number of Reported Events for 2007	Number of Reported Events for 2008	Number of Reported Events for 2009
Hospitals	79	101	99	89
Ambulatory Surgery Centers	6	4	6	5
Abortion Clinics	0	0	0	0
Birthing Centers	0	0	0	0
TOTAL	85	105	105	94

TABLE 17 (2009): Combined total number of reported events by categories for 2006 - 2009

Category of Event	Number of Reported Events For 2006	Number of Reported Events For 2007	Number of Reported Events For 2008	Number of Reported Events For 2009
Surgical	39	49	48	51
Product or Device	4	2	3	5
Patient Protection	0	2	4	2
Care Management	33	38	42	27
Environmental	6	5	8	9
Criminal	3	9	0	0
TOTAL	85	105	105	94

TABLE 18 (2009): Comparison of reported events for surgical events for 2006 - 2009

Event	Type of facility	Number of Reported Events For 2006	Number of Reported Events For 2007	Number of Reported Events For 2008	Number of Reported Events For 2008
Surgery performed on the wrong body part	ASC	6	4	3	4
	Hospital	5	19	13	13
Surgery performed on the wrong patient	ASC	0	0	0	0
	Hospital	2	0	0	1
Wrong surgical procedure performed on a patient	ASC	0	0	0	0
	Hospital	3	1	1	2
Retention of foreign object in patient after surgery	ASC	0	0	2	1
	Hospital	23	24	28	28
Intra-operative or post-operative death in a normal, healthy patient	ASC	0	0	1	0
	Hospital	0	1	0	2

Combined Data for All Facilities

TABLE 19: Total reported events by all facilities by reportable event categories for 2006 - 2009

Reportable Event	Number Reported for 2006	Number Reported for 2007	Number Reported for 2008	Number Reported for 2009
SURGICAL - Total Reported Events	39	49	48	51
1. Surgery performed on the wrong body part	11	23	16	17**
2. Surgery performed on the wrong patient	2	0	0	1
3. Wrong surgical procedure performed on a patient	3	1	1	2
4. Retention of a foreign object in a patient after surgery	23	24*	30	29**
5. Intra-operative or post-operative death in a normal, healthy patient	0	1	1	2
PRODUCTS OR DEVICES – Total Reported Events	4	2	3	5
6. Death or serious disability associated with contaminated drugs, devices, or biologics	1	0	0	0
7. Death or serious disability associated with misuse or malfunction of device	3	1	2	2
8. Death or serious disability associated with intravascular air embolism	0	1	1	3
PATIENT PROTECTION – Total Reported Events	0	2	4	2
9. Infant discharged to wrong person	0	0	0	0
10. Death or serious disability associated with patient elopement	0	0	1	0
11. Suicide or attempted suicide resulting in serious disability	0	2	3	2
CARE MANAGEMENT – Total Reported Events	33	38	42	27
12. Death or serious disability associated with medication error	6	8	7	3
13. Death or serious disability associated with hemolytic reaction	0	1	0	0
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	0	1	0	0
15. Death or serious disability associated with hypoglycemia	1	1	2	2
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	0	0	0
17. Stage 3 or 4 pressure ulcers acquired after admission	26	27*	33	22
18. Death or serious disability due to joint movement therapy	0	0	0	0
19. Artificial insemination with the wrong donor sperm or wrong egg	n/a	n/a	n/a	0
ENVIRONMENTAL – Total Reported Events	6	5	8	9
19. Death or serious disability associated with electric shock	0	0	0	0
20. Wrong gas / contamination in patient gas line	0	0	0	1
21. Death or serious disability associated with a burn	2	0	0	0
22. Death associated with a fall	4	5	8	8
23. Death or serious disability associated with restraints or bedrails	0	0	0	0
CRIMINAL – Total Reported Events	3	9	0	0
24. Care ordered by someone impersonating a health care provider	0	0	0	0
25. Abduction of patient of any age	0	1	0	0
26. Sexual assault of a patient on the facility grounds	2	6	0	0
27. Death / injury of patient or staff from physical assault occurring on facility grounds	1	2	0	0
TOTAL NUMBER OF REPORTED EVENTS	85	105	105	94

* Includes one event that occurred in 2006 but was reported after the release of the Report for 2006

** At least one event occurred in 2008, but was reported after the 2008 Report was issued.

ISDH HEALTH CARE QUALITY INITIATIVES for 2009

As part of its mission to promote public health and provide health care leadership, the Indiana State Department of Health partners with providers, associations, advocate groups, and academic institutions to develop and implement health care quality improvement programs. The Indiana Health Care Quality Initiative has developed programs to address health care issues such as Alzheimer's, falls, restraints, and pressure ulcers. The resulting healthcare improvement campaigns include the following components:

- Evidence-based to promote proven solutions
- Implementation of system-based approaches
- Collaboration between providers on quality issues
- Transparency through the utilization of metrics that can be tracked
- Care coordination to assure communication between facilities
- Incorporation of culture change to include consistent assignments and patient-centered care
- Improved education and training on patient safety and quality issues
- Educating patients/residents and families as to their role in improving health care quality
- Implementation of common assessment tools to be used across facilities

The following are some of the health care quality initiatives implemented by the Indiana State Department of Health in the past year.

Indiana Pressure Ulcer Initiative

The development of stage three or four pressure ulcers while admitted to a hospital was the number one reported event in the Indiana Medical Error Reporting System for the first three years of the report. To address this problem, the Indiana State Department of Health developed and implemented the Indiana Pressure Ulcer Initiative to promote the prevention of pressure ulcers.

As part of the Government Performance Responsibility Act (GPRA), the Centers for Medicare and Medicaid Services (CMS) in 2005 established pressure ulcers and restraints as their two GPRA goals. The GPRA data includes all Indiana nursing homes. The Indiana State Department of Health (ISDH) continues to monitor progress on preventing pressure ulcers.

Initiative Overview

In early 2007 the Indiana State Department of Health (ISDH) began development of a statewide campaign to prevent pressure ulcers. The campaign was initiated in response to data indicating that Indiana health care facilities had a high rate of pressure ulcers. Pressure ulcers are a challenging health care problem. For health care providers, pressure ulcers are difficult to prevent, assess, and treat. For residents and their families, pressure ulcers are a serious detriment to quality of life.

The ISDH planned a three-part initiative to assist with the prevention of pressure ulcers. The three-part initiative included the following parts:

1. The Indiana Pressure Ulcer Quality Improvement Initiative formally kicked off on October 30, 2007 with a Leadership Conference focusing on pressure ulcers. The conference was attended by nearly 1,100 participants from over 400 health care facilities.
2. The ISDH purchased a high-end pressure redistribution mattress and wheelchair cushions for every Indiana nursing home and provided training on their use. This was intended to promote awareness and ensure the availability of at least one mattress at every nursing home for immediate needs of at-risk residents at the time of admission. Distribution of the products occurred in January 2008.
3. The ISDH implemented a 15-month collaborative initiative utilizing a system-based approach to preventing and treating pressure ulcers. The collaborative initiative included nursing homes, hospitals, and home health agencies. The collaborative initiative began in June 2008 and ended in August 2009. A second phase of the collaborative initiative began in August 2009 and ends in September 2010.

Indiana Pressure Ulcer Initiative

The ISDH selected the University of Indianapolis Center for Aging & Community to coordinate the collaborative initiative. The Center for Aging and Community has a history of academic excellence along with experience in collaborative efforts to improve healthcare. The Center is one of Indiana's leading centers for aging studies, with an interdisciplinary approach to developing partnerships between higher education, business organizations and the community to improve the quality of life for older adults.

A collaborative team was assembled in June 2008 to plan the initiative. The collaborative team consists of over twenty healthcare quality associations and organizations and has continued to meet on a monthly basis throughout the Initiative. The evidence-based initiative was designed to assist

health care facilities to implement improved pressure ulcer prevention and care coordination systems. A component of the initiative was that direct assistance would be provided to participating facilities and families by expert faculty.

In developing the initiative, the collaborative team identified the following benefits of participation:

- First and foremost, increased patient quality of life for Hoosiers
- Improved care coordination between hospitals, home health agencies, and long term care facilities
- Educational opportunities for health care providers and caregivers
- Opportunity for improved quality of care through the prevention of pressure ulcers
- Opportunity for improved reputation within the community
- Opportunity to work with and learn from expert faculty
- Cost savings from fewer pressure ulcers requiring treatment

Participants

In the summer of 2008, the collaborative team invited Indiana health care facilities and agencies to participate in the initiative. Selected for the first phase of the Initiative were 95 nursing homes, 40 hospitals, and 28 home health agencies. In the summer of 2009, the ISDH offered a second phase of the Initiative to health care facilities and agencies. All interested facilities and agencies were included in the Initiative. The second phase included 80 facilities to include approximately 64 nursing homes, 8 hospitals, and 8 home health agencies. Also participating in the initiative were representatives from state surveyors and health care organizations. The total participation was approximately 240 facilities and agencies consisting of around 1,000 individuals.

Resources Provided

This initiative included many activities and resources. The following are a few of the resources provided to participants through the initiative:

- Participating facilities received a tool kit that included assessment and coordination tools.
- Participating facilities were provided onsite technical assistance in implementing the initiative.
- Three one-day in-person regional learning sessions with expert faculty were provided for representatives of participating facilities to discuss their experiences and identify solutions.
- Six online education modules on pressure ulcer prevention were developed and provided to all Indiana nursing homes.
- A consumer guide/brochure was developed and published to provide information on pressure ulcers to residents, patients, family, and resident representatives.

Outcomes

On August 26, 2009, the Indiana State Department of Health hosted an Outcomes Congress for the first phase of the Indiana Pressure Ulcer Initiative. Initiative data suggested approximately a 30% decrease in pressure ulcers for participating facilities and agencies. Anecdotal evidence of decreases was significant.

One nursing home had 68 pressure ulcers in 2008 that included over 30 residents. The nursing home participated in the Indiana Pressure Ulcer Initiative and implemented system-based improvements. The facility also brought in a wound care physician to review all residents to assess risk and make

care recommendations. The outcome was that the nursing home only had one pressure ulcer in 2009 and has subsequently maintained this prevention level.

One intensive care unit at a hospital documented fourteen (14) pressure ulcers in its unit in 2008. The unit participated in the Indiana Pressure Ulcer Initiative and implemented system-based improvements. The outcome was that the unit had no pressure ulcers in 2009.

GPRA pressure ulcer data for Indiana nursing homes (includes all nursing homes):

<u>Quarter/Year</u>	<u>IN Rate</u>	<u>IN Rank</u>	<u>National Rate</u>	<u>Region V Rate</u>
Q4 2008	8.3%	35th	8.0%	7.4%
Q1 2009	8.0%	29th	8.2%	7.6%
Q2 2009	7.6%	27th	7.9%	7.2%
Q3 2009	7.3%	26th	7.6%	6.9%
Q4 2009	7.8%	32nd	7.7%	7.1%
Q1 2010	7.6%	29th	7.8%	7.1%

Since the beginning of the GPRA pressure ulcer data report going back to 2003, Indiana has had the highest pressure ulcer rate in CMS Region V. The first quarter of 2009 was the first time since the start of data in 2003 that Indiana was below the national average.

Data indicates a decrease in pressure ulcers in nursing homes of about 250-300 residents per quarter. While this is a significant improvement in quality of life for residents, it is a significant cost savings. A stage one or two pressure ulcer may cost around \$10,000 to heal. A stage three or four pressure ulcer may cost up to \$40,000 and take a year to heal. At an average of \$20,000 per pressure ulcer, the reduction of 300 residents in a quarter would account for a cost savings of \$6,000,000. Adding in multiple quarters and patients from other providers, the Initiative likely resulted in a cost savings of \$15-20 million dollars.

The Medical Error Reporting data showed a decrease of eleven (11) stage 3 or 4 pressure ulcers in Indiana hospitals in 2009. At \$40,000 per ulcer to heal, the decrease represents a health care cost savings of around \$440,000.

The ISDH is pleased with the progress made by Indiana facilities over the past year. It is a step in the right direction. The ISDH encourages facilities to review their pressure ulcer prevention systems and implement improvements. The ISDH Pressure Ulcer Resource Center provides useful resources and best practices and is found at <http://www.in.gov/isdh/24558.htm>.

GPRA Restraint Rates

The use of restraints is a serious medical problem. For many years, restraints were a common practice in the prevention of falls. Evidence suggested however that patients and residents were often more seriously injured by the restraints than by falls. A number of deaths or injuries occurred from patients becoming entangled in siderails or lapbelts.

The ISDH along with the Centers for Medicare and Medicaid Services (CMS) implemented an initiative to reduce the use of restraints in nursing homes. In October 2005, CMS began its GPRA initiative on restraints. In June 2007, the ISDH conducted a Leadership Conference on the prevention of falls. The purpose was to provide potential interventions in fall prevention in order to safely remove restraints. In March 2008, the ISDH conducted a Leadership Conference on the topic of behavior management and restraint reduction. The outcomes for restraint reduction in nursing homes are described below.

GPRA pressure ulcer data for Indiana nursing homes (includes all nursing homes):

<u>Quarter/Year</u>	<u>IN Rate</u>	<u>IN Rank</u>	<u>National Rate</u>	<u>Region V Rate</u>
Q4 2007	4.4%	31st	4.8%	4.0%
Q1 2008	4.0%		4.5%	3.8%
Q2 2008	3.6%		4.2%	3.6%
Q3 2008	3.4%		4.0%	3.6%
Q4 2008	3.1%	27th	3.9%	3.4%
Q3 2009	2.5%	23rd	3.3%	3.0%
Q4 2009	2.3%	21st	3.1%	2.9%
Q1 2010	2.2%	25th	2.9%	2.7%

The Indiana restraint rate in nursing homes continues to decline. Beginning in Q4 of 2008, Indiana improved from fourth in the region to third. Indiana remains ranked third in the region.

Leadership Conference: Health Care Staffing

The Indiana State Department of Health held its sixth Long Term Care Leadership Conference on September 17, 2009. The conference focused on staffing issues at nursing homes. There were 1,001 registrants for the conference to include staff from comprehensive long term care facilities (nursing homes), consultants, health care organizations, and state surveyors.

Leadership Conference: Healthcare Associated Infections

The Indiana State Department of Health held its seventh Long Term Care Leadership Conference on March 2, 2010. The conference focused on healthcare associated infections and served as the kickoff for the Indiana Healthcare Associated Infections Initiative. A representative from the Centers for Disease Control and Prevention was among the speakers at the one-day event. There were over 1,200 registrants for the conference that included staff from comprehensive long term care facilities (nursing homes), hospitals, consultants, health care organizations, and state surveyors.

Indiana Healthcare Associated Infection Initiative

INTRODUCTION

The Indiana State Department of Health (ISDH) is leading a state collaborative initiative to prevent healthcare associated infections. The Indiana Healthcare Associated Infection Initiative is a two-year initiative. The Initiative is part of a national initiative developed by the Centers for Disease Control and Prevention.

The prevention of healthcare associated infections is an important health issue. Evidence suggests that healthcare associated infections are an increasing healthcare problem in part resulting from multi-drug resistant organisms. For instance, reported cases of *Clostridium difficile* infections increased annually in Indiana hospitals from 2002 to 2007.

Indiana has been active in recent years in addressing healthcare associated infections. The Indiana State Department of Health, health care organizations, and individual provider systems have conducted numerous initiatives directed at preventing infections. Most recently, the Indiana State Department of Health utilized a collaborative process to address Methicillin-resistant *Staphylococcus aureus* (MRSA) exposures and provide Indiana communities with the most current MRSA information and necessary tools to promote strategies for the prevention of *Staphylococcus aureus* infections. The state involvement in this new initiative extends and complements previous efforts to prevent healthcare associated infections.

There are actually two new state initiatives directed at healthcare associated infections. The Indiana Ambulatory Surgery Center Healthcare Associated Infection Initiative focuses solely on ambulatory surgery centers and increases certification survey standards related to infection control. An overview of the Ambulatory Surgery Center Initiative may be found on the ISDH Healthcare Associated Infection Resource Center Web site.

The goals of the Indiana Healthcare Associated Infection Initiative are:

- Improve the identification of healthcare associated infections by health care providers
- Reduce the number of healthcare associated infections
- Increase public and healthcare worker awareness of healthcare associated infections

The Indiana Healthcare Associated Infection Initiative is a collaborative initiative with three primary objectives:

- Develop a state plan for preventing healthcare associated infections
- Develop and implement a surveillance and monitoring system for healthcare associated infections
- Develop and implement a prevention initiative for healthcare associated infections

The Centers for Disease Control and Prevention Healthcare Associated Infection Initiative identified six healthcare associated infections:

- Central line associated bloodstream infections
- Catheter associated urinary tract infections
- *Clostridium difficile* infections
- Methicillin-resistant *Staphylococcus aureus*
- Surgical site infections
- Ventilator associated pneumonia

In their respective State Plans, each state selected two of the six healthcare associated infections as a focus for the state prevention initiative. Indiana selected *Clostridium difficile* and catheter association urinary tract infections as a focus for the Indiana Healthcare Associated Infection Initiative.

DATES OF INITIATIVE

Start date: September 1, 2009

End date: December 31, 2011

INDIANA PLAN FOR THE PREVENTION OF HEALTHCARE ASSOCIATED INFECTIONS 2010-2012

The Health and Human Services (HHS) Action Plan to Prevent Healthcare Associated Infections (HAIs) represents a culmination of several months of deliberation by subject matter experts across HHS to identify key actions in the prevention of healthcare associated infections. The initial version of the Action Plan was released in January 2009. Since that time, HHS solicited public comment, and the June 2009 revision to the Action Plan incorporates feedback received during this initial comment period. Links to the HHS Action Plan and State Plan Template are provided on the Indiana Healthcare Associated Infections Web page.

At part of the Initiative, the ISDH developed an Indiana Plan for the Prevention of Healthcare Associated Infections. The preliminary Indiana Plan was released on December 30, 2009 with the final plan released on May 14, 2010. Links to the Indiana Plan are provided on the Indiana Healthcare Associated Infections Resource Center page.

THE PREVENTION INITIATIVE

In 2008, the ISDH and its collaborative partners put together a prevention initiative to address pressure ulcers. The Indiana Healthcare Associated Infection Initiative will be structured in a similar model. The Initiative will utilize a collaborative model. The Initiative intends to provide evidence-based best practices to participating facilities, agencies, and centers. Clinical and medical experts in the assessment and treatment of healthcare associated infections will provide education and training, consultation and technical assistance throughout the initiative.

The prevention initiative phase began in July 2010. Nearly 200 nursing homes, hospitals, home health agencies, hospice agencies, ambulatory surgery centers, and dialysis clinics have enrolled to participate in the Initiative. The prevention initiative phase will last for 12-15 months and conclude in the fall of 2011.

This initiative is planning to include many activities and resources. The following are a few of the resources scheduled to be provided to participants through the initiative:

- Participating facilities will receive a tool kit that includes assessment and coordination tools.
- Participating facilities will be provided assistance in implementing the initiative.
- Three one-day implementation (learning) meetings with expert faculty will be provided for representatives of participating facilities to discuss best practices, experiences, and identify solutions.

INDIANA PATIENT SAFETY and HEALTH CARE QUALITY IMPROVEMENT ORGANIZATIONS

Statewide Organizations

Health Care Excel
2901 Ohio Boulevard, Ste. 112
Post Office Box 3713
Terre Haute, IN 47803-0713
(812) 234-1499
www.hce.org

Indiana Patient Safety Center
Director: Betsy Lee, RN, MSPH
1 American Square, Suite 1900
Indianapolis, IN 46282
317/423-7795
blee@ihaconnect.org
www.indianapatientssafety.org

ORGANIZATION AND PROVIDER PATIENT SAFETY ACTIVITIES IN 2009

Numerous health care facilities and organizations conducted patient safety activities during 2009 and 2010. The following are patient safety activities and initiatives provided to the Indiana State Department of Health that were conducted subsequent to the Report for 2008 and through the date of publication of this report.

STATE AND FEDERAL QUALITY CARE INITIATIVES

CMS Hospital Quality Indicators

The Centers for Medicare and Medicaid Services (CMS) Hospital Quality Alliance (HQA) is a public-private collaboration that collects and reports hospital quality performance information. This effort is intended to make critical information about hospital performance accessible to the public and to inform and invigorate efforts to improve quality. Participating hospitals are voluntarily reporting the data. The goals are to promote the best medical practices associated with the targeted clinical disorders, prevent or reduce further instances of these selected clinical disorders, and prevent related complications. The Indiana State Department of Health added these quality measures to its hospital consumer report. The hospital consumer reports may be found at <http://www.in.gov/isdh/reports/QAMIS/acc/hosrpt/index.htm>.

CMS GPRA Goals

The Government Performance and Results Act of 1993 (GPRA) emphasized the identification of meaningful outcome-oriented performance goals that address the fundamental purpose of federal programs. In 2005, the Centers for Medicare and Medicaid Services established an 18-month program to focus on pressure ulcers and restraints in nursing homes. The GPRA initiative and outcomes were previously discussed in this report.

INDIANA PATIENT SAFETY CENTER

Indiana health care providers, hospitals, and communities are partnering to improve the safety and quality of health care. The Indiana Hospital Association (IHA) launched the Indiana Patient Safety Center (IPSC) in July 2006 to provide a resource for patient safety policy, education, and collaboration. Over the past four years, the Indiana Patient Safety Center has established a reputation for leadership in patient safety throughout the state. As evidenced by its support and promotion of regional patient safety coalitions, a consistently robust educational calendar, and the provision of a consistent measurement system for evaluating cultures of safety in hospitals, the IPSC has raised awareness related to patient safety and provided front-line care givers and managers access to evidence-based practices for improving quality and safety.

The IPSC's strategic vision and plan aim to make Indiana the safest state in the nation for patients to receive health care.

Vision: By 2015 the Center will lead Indiana hospitals and other care providers and systems to create the safest health care in the United States.

Mission: To engage and inspire health care providers to create safe cultures and reliable systems of care to prevent harm to patients in Indiana.

The Indiana Patient Safety Center strives to elevate and expand its efforts as the leading resource for assisting Indiana hospitals, physicians, nurses, pharmacists, and other provider organizations in preventing harm to patients through improving the cultures of their organizations and spreading evidence-based practices and designs. In order to accelerate patient safety efforts throughout the state, the IPSC activities in the past year align with four specific strategies central to improving patient safety in Indiana. These include:

1. Collaborative Learning and Education: Promote accelerated safety improvement through collaboration and coalition-building.

The Indiana Patient Safety Center activities between July 2009 and June 2010 supported the above goals offered a variety of educational programs to promote collaborative learning and highlight successful strategies for improving safety.

IPSC offered the following educational programs and collaboratives:

- Offered basic patient safety tools training based upon the National Patient Safety Improvement Corps curriculum, including: root cause analysis (RCA), healthcare failure modes and effects analysis (FMEA), and error proofing. In addition, IPSC offered advanced training in socio-technical probabilistic risk assessment (ST-PRA) as part of the Just Culture Initiative started in 2008, based on the work of David Marx and his colleagues at Outcomes Engineering.
- Hosted the Inaugural Indiana Patient Safety Summit in March 2010, with over 250 attendees from across the state. Featuring national and Indiana speakers, the program focused on optimizing technology to prevent central-line associated blood stream infections, enhancing

access to specialists in rural areas through the use of telemedicine, and utilizing simulation for intra-professional education.

- Coordinated Indiana hospitals participating in the national On the CUSP: Stop BSI initiative, in collaboration with the Agency for Healthcare Research and Quality, the Health Research and Educational Trust, and the Johns Hopkins University faculty. This national initiative expands the success of the Michigan Keystone project to reduce central line-associated blood stream infections.
- Offered a one-day program at the 2009 IHA Annual Meeting featuring national patient safety speakers, Sorrel King and Rosemary Gibson, in addition to best practices in patient safety, clinical quality improvement, and service excellence from Indiana hospitals.
- Partnered with the Indiana State Department of Health, the University of Indianapolis, and other stakeholders in the Pressure Ulcer Congress and Phase II of the Pressure Ulcer Initiative.
- Partnering with the Indiana State Department of Health, the University of Indianapolis, and other stakeholders to plan the Indiana Healthcare Acquired Infection Initiative.
- Taught an intra-professional patient safety course for the fourth consecutive year in the for masters' level students in nursing, health administration, and public health.

2. Communication and Culture Change: Achieve safe cultures and heightened system “mindfulness” among leaders, patients, and front-line caregivers.

Communications plays a key role in patient safety improvement. The strategic communications goals of the Indiana Patient Safety Center are to accelerate the dissemination of existing evidence-based safety knowledge, to create a new safety culture in Indiana, and to provide Indiana with patient safety leadership.

To accomplish this, the Center has established regular communication channels with numerous stakeholder groups that have an interest in patient safety. Information is communicated through web sites, direct email, newsletters, educational meetings, media relations, stakeholder group meetings, statewide and national learning collaboratives, and regional safety coalitions.

The web site (www.indianapatientssafety.org) was redesigned in 2010 to offer advanced capabilities. The web site provides toolkits and access to state and national resources. While the IPSC continually shares global safety knowledge and developments, it also showcases the innovative safety improvement programs in Indiana.

3. Measurement and Analysis: Improve the performance of Indiana hospitals and health systems in processes and outcomes of care as reflected by relevant clinical quality and patient safety indicators and data regarding patterns of error, harm and common causes.

The Indiana Patient Safety Center offers all Indiana hospitals the opportunity to conduct employee patient safety culture surveys using a web-based application of the Agency for Healthcare Research and Quality (AHRQ) safety culture instrument. The AHRQ survey allows hospital leaders to gain insight into the perceptions of employees and physicians related to the culture of patient safety within each hospital. Participation in the statewide employee safety culture survey using a common database allows hospitals to compare their results to the state and national comparative data. Since 2007 over eighty-five Indiana hospitals have utilized the survey with nearly 65,000 Indiana hospital employees and physicians assessing the cultures of their work units.

4. Alignment and Sustainability: Align existing and new partners to promote Indiana's strengths to fight harm.

The Indiana Patient Safety Center fosters partnerships and relationships with local, regional, state, and national organizations. Current collaborating stakeholders include Indiana State Department of Health; VHA Central; Indiana Organization of Nurse Executives; Indiana State Medical Association, Indiana Association of Practitioners in Infection Control; Health Care Excel; the licensing boards for medicine, nursing and pharmacy; Indiana University; Purdue University; University of Indianapolis; Indiana Nursing Workforce Development Coalition; Indiana Health Information Exchange, and many others.

IHA's most significant strategy to promote alignment and sustainability in the past year has been to encourage the development and spread of regional patient safety coalitions in communities around the state. Such coalitions currently exist in six different areas the state: Indianapolis, Evansville, Northeast Indiana, Northwest Indiana, Central Southwest and the Michiana region. These regional patient safety coalitions foster the engagement of front-line nurses, physicians, and other health care providers in efforts to improve reliability in care and increase safety. In the past year, the Indiana Patient Safety Center has increased efforts to promote sharing between the regional coalitions. The IHA Board approved a strategy to intentionally expand the number of regional patient safety coalitions in the state and to create a network for sharing safety improvements.

The Indiana Hospital Association and the Indiana Patient Safety Center encourage alignment among hospitals in areas where increased standardization can promote safer patient care. Examples of such standardization include the use of common color codes to designate patient conditions, common emergency codes, and regional standardization for surgical safety practices, intravenous medication concentrations, and other high risk practices.

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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.

Institute of Medicine of the National Academies: www.iom.edu

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 was chartered in 1970 as a component of the National Academy of Sciences.

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 on the Accreditation of Health Care Organizations (JCAHO):
www.jointcommission.org/PatientSafety/

The 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: www.mayoclinic.com/health/bedsores/DS00570

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

Protecting 5,000,000 Lives from Harm Campaign: www.ihl.org/IHI/Programs/Campaign

The Institute for Healthcare Improvement is a Cambridge, Massachusetts based not-for-profit organization. The Institute launched the Campaign to Protect 5 Million Lives from Harm, the next phase after their Campaign to Save 100,000 Lives.

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.