Indiana State Department of Health

Indiana Medical Error Reporting System

Report for 2007

August 25, 2008

Indiana State Department of Health
2 North Meridian
Indianapolis, IN 46204

Judith A. Monroe, M.D.
Indiana State Health Commissioner

Mary Hill, R.N., J.D.
Deputy State Health Commissioner

This report was prepared by:

Terry Whitson, J.D.
Assistant Commissioner
ISDH Health Care Quality Commission

Burton Garten, J.D.
Director of Program Development
ISDH Health Care Quality Commission

Mary Azbill, M.T.
Director of Acute Care
ISDH Health Care Quality Commission

This report was published by the Indiana State Department of Health on August 25, 2008 and may be found online at www.in.gov/isdh. For more information on this report contact:
Office of Public Affairs
Indiana State Department of Health
2 North Meridian
Indianapolis, IN 46204
Phone: (317) 233-7254
Email: kseverson@isdh.in.gov

TABLE OF CONTENTS

Executive Summary ……..…. …… 2

Introduction ……..…….. 3

Background on Medical Error Reporting ……..…..... 4

Indiana Medical Error Reporting Initiative ……..…….. 6

Overview of the Indiana Medical Error Reporting System ……..... 11

Definitions …….. 15

Reportable Events ……... 17

Report for 2007 ……..……...….... 20

Analysis of Report for 2007 ……..……... 29

Comparison of Annual Reports ……... 33

ISDH Health Care Quality Initiatives for 2007 ……..……. 36

Indiana Patient Safety and Quality Improvement Organizations …… 39

Patient Safety Activities in 2007 ……..…… 40

References …… 47

Additional Information on Medical Errors and Patient Safety ..…….. 49

Appendices

Appendix A: Summary of Facilities Reporting Events for 2007 …… Appendix 1
Appendix B: Hospital Reported Events ……... Appendix 3
Appendix C: Ambulatory Surgery Center Reported Events …… Appendix 142
Appendix D: Abortion Clinic Reported Events ……... Appendix 285
Appendix E: Birthing Center Reported Events …… Appendix 295
Appendix F: Hospital Reporting Rule ……..…… Appendix 298
Appendix G: Ambulatory Surgery Center Reporting Rule ….…… Appendix 302
Appendix H: Abortion Clinic Reporting Rule ……..…… Appendix 306
Appendix I: Birthing Center Reporting Rule ……..…… Appendix 310

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 and included events occurring in 2006. This Report for 2007 presents information about reportable events occurring in Indiana health care facilities between January 1, 2007 and December 31, 2007. Two events occurring in 2006 were identified by health care facilities subsequent to the release of the 2006 report and are included in 2007 reported events. The Report for 2007 is based on data received by the Indiana State Department of Health prior to August 15, 2008.

Indiana's medical error reporting system is based on the National Quality Forum's twenty-seven 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-seven 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-seven reportable events occurred, the health care facility where the reportable event occurred, and the calendar quarter and year within which the event occurred.

For 2007, there were a total of 291 facilities required to report. One hundred and five (105) events were reported for 2007. One hundred and one (101) events occurred at hospitals while four (4) events occurred at ambulatory surgery centers.

Three reported events stand out as significant in the number of reports. The most reported event was twenty-seven (27) events of stage 3 or 4 pressure ulcers acquired after admission to the facility. Twenty-seven events represent approximately 1 event per 29,000 hospital inpatient discharges. The second most reported event was twenty-four (24) events of retention of a foreign object in a patient after surgery or other invasive procedure equating to 1 event per 75,000 surgical procedures performed in hospitals and ambulatory surgery centers. There were twenty-three (23) events of wrong body part surgery equating to 1 event per 78,000 surgical procedures.

The 105 reported events for 2007 is an increase from the 85 events reported in 2006. Stage 3 or 4 pressure ulcers were also the top reported event in 2006. The increase in the number of events was anticipated reflecting increased awareness of the reporting requirements and improved facility procedures to identify potential reportable events.

INTRODUCTION

This report is the Indiana Medical Error Reporting System Report for 2007. This Report for 2007 presents information about reportable events occurring in Indiana health care facilities between January 1, 2007 and December 31, 2007. The Indiana State Department of Health received two events subsequent to the release of the Report for 2006 that occurred in the 2006 reporting period. Those reported events are included in this Report for 2007 as part of the 2007 data. The report is based on data received by the Indiana State Department of Health prior to August 15, 2008.

This report shows that stage 3 or stage 4 pressure ulcers acquired after admission to the hospital, retention of a foreign object in a patient after surgery, and surgery performed on the wrong body part are the three most common reported events.

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.

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/errback.htm.
[3] Institute of Medicine of the National Academies, Retrieved February 12, 2007 from http://www.iom.edu/CMS/AboutIOM.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/mission.asp.
[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 begin development of 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/html/about_npsf.html.

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/html/about_npsf.html.

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 in included in the appendix to this report. For 2007, there were a total of 291 facilities required to 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-seven 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 event 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 Error 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) Induction 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. Such procedures include, but are not limited to:

(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-seven (27) reportable events included in the Indiana Medical Error Reporting System Report for 2007.

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) Retention of broken microneedles.

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 facility. Excluded are deaths 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.

13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-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 due to joint movement therapy performed in the facility.

ENVIRONMENTAL EVENTS:

19. Patient death or serious disability associated with an electric shock while being cared for in the facility. Excluded are events involving planned treatment, such as electrical countershock.

20. 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.

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

22. Patient death associated with a fall while being cared for in the facility.

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

CRIMINAL EVENTS:

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

25. Abduction of a patient of any age.

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

27. 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.

REPORT FOR 2007

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 2007 is based on data received prior to August 15, 2008 and covers the reporting period of January 1, 2007 through December 31, 2007. The rules require a facility to report events within six months of discovery. There were two 2006 events that were discovered after the release of the 2006 report. Those two events are included in this Report for 2007. The report indicates those two events as occurring in 2006.

A table of reported events is provided for every Indiana health care facility that was required to report 2007 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 2007 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 2007. 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 late July 2008, the Indiana State Department of Health called 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.

Combined 2007 Data for All Heath Care Facilities

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

Type of Health Care Facility	Number of Facilities
Hospitals	138
Ambulatory Surgery Centers	142
Abortion Clinics	9
Birthing Centers	2
TOTAL	291

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

Type of Health Care Facility	Total Number of Reported Events
Hospitals	101
Ambulatory Surgery Centers	4
Abortion Clinics	0
Birthing Centers	0
TOTAL	105

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

Category of Event	Number of Reported Events
Surgical	49
Product or Device	2
Patient Protection	2
Care Management	38
Environmental	5
Criminal	9
TOTAL	105

TABLE 4: 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
Hospitals	48
Ambulatory Surgery Centers	3
Abortion Clinics	0
Birthing Centers	0
TOTAL	51

Combined Data for All Facilities

TABLE 5: Total 2007 reported events by all facilities by reportable event categories

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

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

Combined Data for Hospitals

TABLE 6: Total 2007 reported events by hospitals by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		45
1. Surgery performed on the wrong body part	19	
2. Surgery performed on the wrong patient	0	
3. Wrong surgical procedure performed on a patient	1	
4. Retention of a foreign object in a patient after surgery	24*	
5. Intra-operative or post-operative death in a normal, healthy patient	1	
PRODUCTS OR DEVICES		2
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	1	
8. Death or serious disability associated with intravascular air embolism	1	
PATIENT PROTECTION		2
9. Infant discharged to wrong person	0	
10. Death or serious disability associated with patient elopement	0	
11. Suicide or attempted suicide resulting in serious disability	2	
CARE MANAGEMENT		38
12. Death or serious disability associated with medication error	8	
13. Death or serious disability associated with hemolytic reaction	1	
14. Maternal death or serious disability associated with low risk pregnancy labor or delivery	1	
15. Death or serious disability associated with hypoglycemia	1	
16. Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates	0	
17. Stage 3 or 4 pressure ulcers acquired after admission	27*	
18. Death or serious disability due to joint movement therapy	0	
ENVIRONMENTAL		5
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	5	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		9
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	1	
26. Sexual assault of a patient on the facility grounds	6	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	2	
TOTAL NUMBER OF REPORTED EVENTS		101

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

Combined Data for Ambulatory Surgery Centers

TABLE 7: Total 2007 reported events by ambulatory surgery centers by reportable event categories

Reportable Event	Number Reported	Totals
SURGICAL		4
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	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	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. Death / injury of patient or staff from physical assault occurring on facility grounds	0	
TOTAL NUMBER OF REPORTED EVENTS		4

Combined Data for Abortion Clinics

TABLE 8: Total 2007 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	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. 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: Total 2007 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	
ENVIRONMENTAL		0
19. Death or serious disability associated with electric shock	0	
20. Wrong gas / contamination in patient gas line	0	
21. Death or serious disability associated with a burn	0	
22. Death associated with a fall	0	
23. Death or serious disability associated with restraints or bedrails	0	
CRIMINAL		0
24. Care ordered by someone impersonating a health care provider	0	
25. Abduction of patient of any age	0	
26. Sexual assault of a patient on the facility grounds	0	
27. 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 2007

Analysis of reported events

This is the second report of the Medical Error Reporting System. As compared to the Report for 2006, there were an increased number of reported events. There were a total of 85 events reported in 2006 as compared to the 105 events reported in 2007. This increase was anticipated. Minnesota experienced a similar increase in the first several years of its reporting system. The increase can likely be attributed with increased awareness of the reporting requirement, improved organization of health care facility quality review systems for reviewing potential reportable events, and increased comfort of health care facilities with the reporting system.

For 2007, three reported events stand out as significant in the number of reports. There were twenty-seven (27) reported events of stage 3 or 4 pressure ulcers acquired after admission to the facility. The second most reported event was twenty-four (24) events of retention of a foreign object in a patient after surgery or other invasive procedure. Both of these events included one event that occurred in 2006 but was reported subsequent to the release of the Report for 2006 so was included in 2007 data. The third most reported event was surgery performed on the wrong body part. This event accounted for twenty-three (23) of the one hundred and five (105) reported events. The top three events accounted for over 70% of the reported events.

One hundred and five (105) events were reported for 2007. One hundred and one (101) events occurred at hospitals while four (4) 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-seven reporting categories would not be applicable to an ambulatory surgery center. The unlikely occurrence of many events at an ambulatory surgery center significantly reduces the expected number of reported events at those facilities. The data is consistent with that expectation.

In 2006, there were a comparable number of surgeries performed on the wrong body part between the two types of facilities. Considering that ambulatory surgery centers performed less than one-third of the total number of surgical procedures, the 2006 rate for ambulatory surgery centers for that event was significantly higher than for hospitals. The 2007 reported events show an increase in the number of wrong body part surgeries at hospitals and a slight decrease in the number of wrong body part surgeries at ambulatory surgery centers. There were 23 hospital wrong body part events in 2007 representing 1 event per 53,000 hospital surgical procedures. There were 4 ambulatory surgery center wrong body part events in 2007 representing 1 event per 146,000 surgical procedures. For 2007, hospitals had nearly a three times rate of wrong body part surgeries as compared to ambulatory surgery centers.

In 2007, there were 1,217,474 reported surgical procedures, both outpatient and inpatient, performed at hospitals. There were 584,939 surgical procedures reported performed at ambulatory surgery centers. The number of ambulatory surgery center procedures is significant as it represents nearly a 100,000 increase in the number of surgical procedures from the 2005 data. This is consistent with the increase in the number of ambulatory surgery centers in recent years and likely also reflects improved data collection.

There were significant differences between the two types of facilities for retention of a foreign object in a patient after surgery. Hospitals reported twenty-four (24) events where a foreign object was retained in a patient after surgery. Ambulatory surgery centers reported no events in that category. 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 were no foreign objects retained in ambulatory surgery center procedures.

Forty-eight (48) hospitals and three (3) ambulatory surgery centers reported at least one reportable event. This represents 35% of hospitals and 2% of ambulatory surgery centers. For the same reason as discussed above, this is an expected result. Ambulatory surgery centers have a more limited scope and many of the events would not apply to those facilities. For ambulatory surgery centers, the number of centers reporting at least one event was half the number in 2006.

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 ten 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 2007. Abortion clinics and birthing centers have very limited services. Many of the twenty-seven 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: 2007 Hospital Discharges, Visits and Procedures

2007 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.	785,731
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.	3,281,604
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.	1,217,474

TABLE 11: 2007 Ambulatory Surgery Center Procedure Data

2007 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	584,939

TABLE 12. Top Four Reported Events in Indiana for 2007

Event	Number of Reported Events	Percent of Total Number of Reportable Events	Ratio of Number of Reported Events to Total Number of Discharges or Surgical Procedures
Stage 3 or 4 pressure ulcers acquired after admission	27	25.7%	1 event per 29,000 hospital inpatient discharges
Retention of foreign object in patient after surgery	24	22.9%	1 event per 75,000 surgical procedures performed in hospital and ambulatory surgery centers
Surgery performed on the wrong body part	23	22.0%	1 event per 78,000 surgical procedures performed in hospital and ambulatory surgery centers
Death or serious disability associated with medication error	8	7.6%	1 event per 508,000 hospital inpatient discharges and outpatient visits

TABLE 13. Percentage of Category of Events

Category of Event	Number of Reported Events	Percentage of all Reported Events
Surgical	49	46.7%
Product or Device	2	1.9%
Patient Protection	2	1.9%
Care Management	38	36.2%
Environmental	5	4.7%
Criminal	9	8.6%
TOTAL	105	100%

COMPARISON OF ANNUAL REPORTS

This Report for 2007 is the second report of the Indiana Medical Error Reporting System. While it is too soon to identify data trends, the following tables provide a few comparisons between 2006 and 2007 reported events.

TABLE 14. Top Four Reported Events in Indiana for 2006 and 2007

Event	Number of Reported Events for 2006	Number of Reported Events for 2007
Stage 3 or 4 pressure ulcers acquired after admission	26	27
Retention of foreign object in patient after surgery	23	24
Surgery performed on the wrong body part	11	23
Death or serious disability associated with medication error	6	8

TABLE 15: Total number of reported events by type of health care facility for 2006 - 2007

Type of Health Care Facility	Total Number of Reported Events for 2006	Total Number of Reported Events for 2007
Hospitals	79	101
Ambulatory Surgery Centers	6	4
Abortion Clinics	0	0
Birthing Centers	0	0
TOTAL	85	105

TABLE 16: Total number of reported events by categories for all facilities combined for 2006 - 2007

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

Combined Data for All Facilities

TABLE 17: Total reported events by all facilities by reportable event categories for 2006 - 2007

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

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

ISDH HEALTH CARE QUALITY INITIATIVES for 2007

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 campaigns implemented by the Indiana State Department of Health in the past year.

Alzheimer's and Dementia Care

With an aging population, Alzheimer's and dementia have become increasingly important care issues. Health care providers frequently do not receive specific education and training on Alzheimer's and dementia through their initial training. To address this issue, the Indiana State Department of Health has partnered with the Alzheimer's Association of Greater Indiana to develop educational and training resources for health care personnel. Beginning in 2003, the Indiana State Department of Health and Alzheimer's Association developed eight training courses and provided training to over 2,000 long term care providers.

In 2007, the Alzheimer's Association and Ivy Tech Community College launched a Dementia Professional Certification Program. This certification is the first of its kind in Indiana and recognizes health care professionals that have furthered their study in dementia care. The courses provide realistic best practices to provide quality dementia care. To earn the Dementia Professionals Certification, health care professionals must have 40 hours of course work from courses offered through this program. This includes five core courses that are four hours each and twenty hours of electives.

The Indiana State Department of Health, Division of Long Term Care, has provided funding to the Alzheimer's Association of Greater Indiana to provide 50 scholarships for this certification program. The Indiana State Department of Health would eventually like to have at least one certified individual in every acute care and long term care facility.

The Alzheimer's Association and Indiana State Department of Health are continuing to expand educational opportunities on Alzheimer's and dementia care. The following are programs developed in 2007 with plans for implementation in 2008:

- To address difficulties of rural health care providers in accessing training programs, the Alzheimer's Association will present educational programs in two rural Indiana communities. The programs will provide over sixteen hours of educational activities.
- A seminar series by national speakers will be presented at 18 sites throughout the state. Each seminar will be a six-hour workshop consisting of ways to improve the quality of dementia care along with best practices.
- Two online educational programs will be developed and made available to health care providers. This improves the ability of health care professionals to access accurate and quality education on Alzheimer's and dementia care.

Leadership Conference: Pressure Ulcers – Strategies for the Reduction of Pressure Ulcers

On October 30, 2007 the Indiana State Department of Health conducted its second Leadership Conference. The topic of the conference was the reduction of pressure ulcers. The conference was attended by 1167 hospital and long term care professionals. Speakers included Dr. Judy Monroe, Indiana State Health Commissioner; Sharon White, Centers for Medicare and Medicaid Services; Dr. Elizabeth Ayello, Aline Holmes, and Theresa Edelstein discussing the New Jersey pressure ulcer initiative; and Karen Clay of Massachusetts providing best practices.

Leadership Conference: Strategies for Behavior Management and the Reduction of Restraints

The Indiana State Department of Health's third Long Term Care Leadership Conference was held Tuesday, March 18, 2008 and addressed behavior management and the reduction of restraints. There were 1,145 people registered for the conference to include staff from comprehensive long term care facilities, long term care associations, consultants, interested associations, and state long term care surveyors and staff.

Speakers included Beryl Goldman, Ph.D., MS, RN, NHA, Director of Kendal Outreach of Kennett Square, Pennsylvania, discussing a restraint free future and the Pennsylvania Restraint Reduction Initiative. State staff provided an overview of the regulatory requirements of restraints along with several case studies of the use of restraints. Joanne Rader, RN, MN, FAAN, consultant and Associate Professor of Gerontological and Mental Health Nursing at the Oregon Health Sciences University School of Nursing, presented the case for "Creating a Restraint Free Environment." Finally, Dr. John Wernert, a practitioner of Geriatric Psychiatry, and Gerald H. Roesener, RPh, CGP, FASCP, President of the Indiana Academy of Long Term Care Pharmacists, discussed the benefits of the Behavior Team Model that can be used in managing behaviors and psychiatric issues.
The Indiana State Department of Health provided all conference participants with a resource manual and a book ("Geriatric Medication Handbook"). All facilities also received a copy of the book and CD-Rom, "Bathing Without A Battle."

Indiana Pressure Ulcer Reduction Campaign

The Indiana Medical Error Reporting System Report for 2006 indicated that the most reported event was the development of a stage 3 or stage 4 pressure ulcer after admission to a facility. A purpose of the reporting system is to identify those areas where attention needs to be focused and develop solutions to the problem.

Pressure ulcers have been an ongoing challenge for health care facilities such as hospitals and nursing homes. While nursing homes are not included as part of the Medical Error Reporting System, data from the Centers for Medicare and Medicaid Services indicated that the rate of pressure ulcers in nursing home residents was 8.4% in 2006. Pressure ulcers are an example of a problem that requires a system-based approach.

To address the pressure ulcer problem, the Indiana State Department of Health partnered with health care associations to develop a quality improvement initiative. The initiative was kicked off by the October Leadership Conference on pressure ulcers attended by hospital and nursing home representatives. The conference provided best practices aimed at reducing the incidence of pressure ulcers.

A critical time in the health care system is when a patient transfers between facilities. The time required to implement care often contributes to the development of a pressure ulcer. This is particularly a problem when a patient transfers to a nursing home. The Indiana State Department of Health found that a pressure reducing mattress is generally not available for a new resident admitted to a nursing home who perhaps is at risk for pressure ulcers. It may take up to 48 hours after admission to secure needed equipment. The Indiana State Department of Health therefore purchased a high-end pressure redistribution mattress for every nursing home to ensure that needed equipment is available. The Indiana State Department of Health also purchased four wheelchair pressure cushions for each facility to highlight the daily lesser actions that need to be taken by facilities to prevent pressure ulcers. Having such equipment on hand will provide immediate care for new admissions and help to prevent pressure ulcers.

The third phase of the initiative is to provide direct expertise to hospitals and nursing homes in implementing a system-based approach to reducing the incidence of pressure ulcers. The Indiana State Department of Health is partnering with the University of Indianapolis Center for Aging and Community to lead a state initiative to decrease the incidence of pressure ulcers. The initiative began on July 1, 2008. The initiative will include numerous partners to include Health Care Excel, Indiana Patient Safety Center, United Senior Action, Hoosier Owners and Providers for the Elderly, Indiana Association of Homes and Services for the Aged, Indiana Health Care Association, and Indiana Hospital Association. The initiative will have many components. These components will include:

- Formation of an advisory panel on pressure ulcers
- Development of a consumer brochure on pressure ulcers
- Development of a tool kit on pressure ulcers for facilities
- Development of online training modules that will be available to all facilities through a learning management system
- Providing a community-based outreach program consisting of conference calls by patient advocates with residents and families
- Providing hands-on, highly interactive education and training for approximately 100 facilities who participate in the initiative
- Providing regional training activities across the state

Indiana Public Health and Medicine Day: Building Bridges

The Indiana State Department of Health hosted the Second Indiana Public Health and Medicine Summit in June 2008. The Public Health and Medicine Summit brought together the Public Health Nurses Conference and the Public Health and Medicine Day. The summit encouraged collaboration among public health professionals and health care providers and provided information on current public health issues and programs.

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.indianapatientsafety.org

Regional Organizations

Community Patient Safety Coalition (Southern Indiana)
Contact: Aprile Sandefur
Aprile_Sandefur@deaconess.com

Indianapolis Coalition for Patient Safety
Director: Carol Birk, RPh, MS
cebirk@purdue.edu
www.indypatientsafety.org

PATIENT SAFETY ACTIVITIES IN 2007

Numerous health care facilities and organizations conducted patient safety activities during 2007 and 2008. The following are patient safety activities and initiatives provided to the Indiana State Department of Health that were conducted subsequent to the Report for 2006 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 initiative was led by state quality improvement organizations. Indiana's efforts were led by Health Care Excel. The initial focus period was completed in 2007.

The two performance goals in this initiative were for pressure ulcers and restraints. Prior to 2005, Indiana's pressure ulcer rate was as high as 9.7%. In 2005 the rate was 8.6% as compared with a national rate of 8.5% and a regional rate of 7.8%. At the conclusion of the third quarter in 2007, Indiana's rate decreased to 8.1% as compared to the national rate of 8.1% and the regional rate of 7.5%. While Indiana has continued to show improvement in reducing pressure ulcers in nursing homes, Indiana continues to have the highest pressure ulcer rate in the regional states.

For restraints, Indiana's baseline restraint rate in 2005 was 5.8% as compared with a national rate of 6.4% and regional rate of 4.8%. At the conclusion of the third quarter in 2007, Indiana had a restraint rate in nursing homes of 4.4% as compared with the national average of 5.0% and the regional rate of 4.1%. While Indiana had the third highest percent of restraint use in regional states, Indiana has shown a significant reduction in the past 18 months and is below the national rate.

NATIONAL PATIENT SAFETY INITIATIVES

Institute for Healthcare Improvement - Protecting 5 Million Lives from Harm Campaign:

Building on the success of the Campaign to Save 100,000 Lives, the Institute for Healthcare Improvement launched the Campaign to Protect 5 Million Lives from Harm. This next phase of national campaign activity will reinforce the six interventions from the 100,000 Lives Campaign and add six new recommended interventions to prevent harm to patients to include:[17]

- Preventing harm from high alert medications (including anticoagulants such as heparin and warfarin, narcotics, sedatives and insulin)
- Preventing pressure ulcers by reliably using science-based guidelines for their prevention
- Reducing surgical complications by reliably implementing all of the changes recommended by the Surgical Care Improvement Project (www.medqic.org/scip)
- Reducing Methicillin-Resistant *Staphylococcus Aureus* (MRSA) infections by reliably implementing scientifically proven infection control practices
- Delivering reliable, evidence-based care for congestive heart failure to avoid readmissions
- Getting boards of directors involved in quality and patient safety efforts.

INDIANA PATIENT SAFETY ORGANIZATIONS

Indiana Patient Safety Center

The following are activities of the Indiana Patient Safety Center:

- *Statewide Safety Culture Survey:* Since February 2007 the Indiana Patient Safety Center has offered to Indiana hospitals the opportunity to conduct employee and physician safety culture surveys using a web-based application of the Agency for Healthcare Research and Quality (AHRQ) Hospital Culture of Safety instrument. The AHRQ survey allows health care leaders to gain insight into the perceptions of nurses, doctors, and other employees related to the culture of patient safety within hospitals. Participation in the statewide employee safety culture survey using a common database allows hospitals to compare their results to comparison groups within the state as well as state and national aggregates. The results will provide baseline data from which to measure the impact of hospital-specific and statewide safety interventions. As of July 31, 2008 over 23,000 health care providers and support personnel from 68 Indiana hospitals have taken the survey. Data related to the safety culture surveys will be used to prioritize educational and collaborative patient safety activities throughout the state.

- *Educational Support for Serious Adverse Event Reporting:* The Indiana Hospital Association and the Indiana Patient Safety Center provided education and support to Indiana hospitals with respect to the rule for mandatory reporting of serious adverse events. The Indiana Patient Safety Center has provided consultation and support for hospital with respect to registration for the state reporting portal and clarification of questions related to the reporting requirements.

[17] Protecting 5,000,000 Lives from Harm Campaign: www.ihi.org/IHI/Programs/Campaign

- *Indiana "Node" for the Institute for Healthcare Improvement's 5 Million Lives Campaign*: Building on the success of the Institute for Healthcare Improvement Campaign to Save 100,000 Lives, the Indiana Patient Safety Center serves as the Indiana "node" or organizing hub for the Institute for Healthcare Improvement's 5 Million Lives Campaign (http://www.ihi.org/IHI/Programs/Campaign). This phase of national campaign activity will reinforce the six interventions from the 100,000 Lives Campaign and add six new recommended interventions to prevent harm to patients. Ninety-eight percent of Indiana's short term acute hospitals are enrolled in the campaign. Additionally, numerous long term acute hospitals and some mental health facilities have enrolled.

- *High-Alert Medications Educational Program*: On July 17, 2007, the Indiana Patient Safety Center, in collaboration with the Indiana Hospital Association and VHA Central, launched a year-long collaborative among 40 teams across the state on high-alert medications, specifically aimed at reducing harm from anticoagulants, such as heparin and warfarin. One hundred thirty-six representatives from these hospitals participated in a one-day learning session with a national faculty expert and experts from Indiana hospitals. This session was followed by regular conference calls and on-going support from IPSC, IHA, VHA Central and the Institute for Healthcare Improvement.

  As a product of this collaborative effort, the Purdue University PharmaTAP, the Indiana Patient Safety Center, and VHA Central produced the *Anticoagulant Toolkit: Reducing Adverse Drug Events and Potential Adverse Drug Events with Unfractionated Heparin, Low Molecular Weight Heparins and Warfarin*. This useful resource can be accessed at the following web link: http://www.purdue.edu/dp/rche/pharmatap/resource.php.

- *MRSA Educational Programs*: On January 22, 2008, health care providers from across the state joined together to prevent transmission of methicillin-resistant Staphylococcus aureus in a state-wide collaborative effort. Speakers from the Centers of Disease Control in Atlanta, the Plexus Institute, the Indiana State Department of Health and several Indiana infection control practitioners shared best practices to prevent MRSA in hospitals and communities. Periodic telephone conference calls assisted hospitals in implementing strategies to prevent MRSA transmission.

  The Indiana Patient Safety Center participated with the Indiana State Department of Health, the Indiana Association of Practitioners of Infection Control, and an array of stakeholders on an ISDH task force to develop communication strategies and a tool kit for the prevention of methicillin-resistant staphyloccus aureus in the Fall of 2007.

- *Medication Safety Summit*: The Indiana Patient Safety Center, in collaboration with VHA Central, the Indianapolis Coalition for Patient Safety, Purdue University PharmaTAP, and Cardinal Health, held a session entitled "Joining Forces: A Medication Safety Summit." This educational session focused on preventing harm from high alert medications, including anticoagulants, insulin, and narcotics. In addition, information was shared about how to establish regional patient safety coalitions.

- *Leadership for Patient Safety*: In June 2007 the Indiana Hospital Association Leadership Conference focused on leadership strategies to promote patient safety. Noted national safety experts, Michael Leonard, M.D. and Allan Frankel, M.D., conducted a one-day program for hospital leaders and a one-day team training program for clinical teams in high risk areas, such as operating rooms, obstetrics, and the emergency department. Topics addressed at the

meeting included the role of human factors in patient safety, communication strategies, team behaviors, just culture, reliability, and health literacy. Over 350 hospital leaders, doctors, nurses and other health care professionals attended one or both days.

- *National Dialog Group*: The Indiana Patient Safety Center, the Indiana Hospital Association, and Health Care Excel convened a group of hospital leaders throughout the state to participate in a national "dialog group" to provide input to a new Hospital Leadership and Quality Assessment Tool (HLQAT) under development by a consortium of national organizations including the Centers for Medicare and Medicaid Services (CMS), the American Hospital Association (AHA), the Institute for Healthcare Improvement, several state hospital associations and quality improvement organizations, and researchers.

- *Trustee Leadership Conference*: On July 16-18, 2008, the Indiana Hospital Association and the Kentucky Hospital Association offered a joint Trustee Leadership Conference, including speakers who focused on the role of hospital board members in promoting patient safety and quality.

- *Patient Safety Improvement Corps Training*: An Indiana team including the Director of the Indiana Patient Safety Center and three hospital-based physician leaders participated in the Patient Safety Improvement Corps (PSIC), a patient safety training program co-sponsored by the Agency for Healthcare Research and Quality (AHRQ) and the Veterans' Health Administration National Patient Safety Center.

  Several modules from PSIC training were presented for Indiana hospitals. On July 29 and 30, 2008, The Indiana Patient Safety Center conducted two one-day training sessions for Team STEPPS™, a program developed by AHRQ and the Department of Defense to promote teamwork and communication among health care teams. On July 31, 2008, the IPSC offered a one day session of PSIC tools for patient safety professionals, nurses, doctors, and health care leaders to provide training in risk analysis and prevention tools, such as root cause analysis, health care failure modes and effects analysis, and error proofing.

- *Web Site and Communication Strategy*: The Indiana Patient Safety Center launched a Web site in March 2007 to support health care providers and inform the public about patient safety activities and information. With the assistance of the communications and information technology staff at the Indiana Hospital Association, in addition to web site development support from Purdue University, the Center launched its web site in March 2007. In addition to the web site, www.indianapatientsafety.org the Center has worked to develop contact lists to disseminate relevant patient safety announcements to a broad group of clinicians and health care leaders.

- *Building Key Alliances*: Over the past two years, the Indiana Patient Safety Center has formed alliances with leaders across the state to promote patient safety activities. These include the Indiana State Department of Health; business leaders; academic leaders at Indiana University, Purdue University, Butler University, University of Indianapolis, and the University of St. Francis; VHA Central; the Indiana chapters of the Association of Practitioners in Infection Control, the Indiana Organization of Nurse Executives, and the Indiana Association of Healthcare Quality; the Indiana State Medical Association; and others.

- *Expansion of Regional Coalitions to Support Patient Safety Improvement*: As part of its strategy to disseminate best practices in patient safety, the Indiana Patient Safety Center has

encouraged the development of regional patient safety coalitions across the state. Active coalitions exist in Indianapolis, Evansville, and the northern Indiana region around South Bend. Additional coalitions are being investigated or are forming in the northwestern part of the state, the Ft. Wayne area, and the Terre Haute region.

Indianapolis Coalition for Patient Safety

Since being founded in 2003, the Indianapolis Coalition for Patient Safety provides a forum for Indianapolis-area hospitals to share information about 'best practices' and work together to solve patient safety issues in Indianapolis and surrounding county hospitals. The Indianapolis Coalition for Patient Safety is comprised of chief executive, medical, nursing and pharmacy officers from Clarian Health, Community Health Network, Richard L. Roudebush VA Medical Center, St. Francis Hospitals and Health Centers, St. Vincent Health, and Wishard Health Services. Coalition membership recently expanded to include the Suburban Health Organization hospitals (Hancock Regional Hospital, Hendricks Regional Health, Henry County Hospital, Morgan Hospital and Medical Center, Riverview Hospital, Witham Health Services and Westview Medical Campus). In addition, there is participation by entities such as Eli Lilly, WellPoint, Inc, Indiana and Purdue Universities, and the Regenstrief Institute, Inc.

The following are key milestones of the Indianapolis Coalition for Patient Safety in focusing on solutions to patient safety issues:

- *Expansion of Regional Patient Safety Efforts*: Suburban Health Organization (SHO), composed of St Vincent Health and eight Indianapolis surrounding county hospitals, joined the Indianapolis Coalition for Patient Safety Summer 2008. SHO has a long-standing commitment to improving patient safety and pooled their expertise with the Coalition to demonstrate their continuing commitment to patient safety throughout central Indiana and to accelerate safety improvements through a community-wide effort.

- *High-Risk Drugs:* Anticoagulants (blood thinners), insulin, narcotics/opiates, etc. are commonly used in hospitals, but are considered by experts to be "high risk drugs".

    - Anticoagulants**:** The Joint Commission of Accreditation of Healthcare Organizations has established safe use of anticoagulants (heparins, warfarin) as a national patient safety goal. A city-wide list of anticoagulant patient safety practices was developed and implemented with assistance from the Institute for Safe Medicine Practices (ISMP).

    - IV Pump High Risk Drug Alerts: The Coalition applied for and received a research grant from Cardinal Health Corporation to study infusion pump alerts for selected high risk drugs. The goal of the research is to conduct a common cause analysis by trending root causes for alerts and overrides and to take action to further reduce risk with use of high risk medications.

    - Insulin**:** Eli Lilly and Company sponsored two Six Sigma work teams to address insulin safety in the hospitals. A team of experts from Lilly led a "be the vial" exercise with hospital teams from Wishard Health Services and from the Indiana Heart Hospital. Participants included front line health care practitioners and hospital leadership. Strategies to eliminate potentially unsafe process steps were implemented

and ongoing measurement continues to sustain the changes made to insure a safer environment for patients and staff.

- Standardizing names, concentrations, and dosage units for high risk IV infusion medications: Standardizing IV infusion drug concentrations among Coalition hospitals will reduce the chance of error as nurses frequently travel between systems. Tools and resources to assist hospitals with implementation are in development.

- *Surgical Safety:* Indianapolis Coalition for Patient Safety member institutions have largely implemented a standard set of best practices for surgery and procedure safety to include Site Marking and a Time Out Policy based on best current practice known at the time. In addition to applying the best evidence to all member hospitals, the standardized set of practices will provide continuity to physicians and staff who travel between hospitals. Site Marking verifications include marking the operative site/side with the mark 'yes' and marking prior to any sedative or anesthesia being administered in a standardized manner. Time Out Policy procedures verify the correct patient, correct procedure, correct site and other relevant information before any surgery begins.

- *Peer Reviewed Root Cause Analysis Review:* Building on the work of the Indiana Medical Error Reporting System, Indianapolis Coalition for Patient Safety, as a peer review organization, has shared information from adverse events to facilitate member learning so as to prevent the same event from occurring in other member hospitals.

- *Institute for Healthcare Improvement "100,000 Lives Campaign"***:** the Coalition hospitals pledged to cooperate and implement the initiatives aimed to protect patients from incidents of medical harm in U.S. hospitals. Work groups led by front line healthcare representatives from each of the organizations were established to collaborate and implement safe practices recommended under the IHI Campaign.

- *"Targeting Severe Sepsis"***:** the Coalition uses comparative mortality data to identify significant safety improvement opportunities. Sepsis emerged as a priority area due to increased patient length of stay and high mortality risk. Mid-2008 the Sepsis Team obtained administrative support from all Coalition hospitals to improve utilization and implementation of evidence based treatment order sets and evidence based tools to screen for Sepsis.

- *MRSA (Methicillin Resistant Staphylococcus Aureus)*: Coalition hospitals participated in the IU Center for Health Services and Outcomes Research collaborative project aimed at reducing MRSA infection rates in Indianapolis hospitals. The project helped improve preventive practice adherence and resulted in a significant reduction in MRSA infection rates on study units.

- *Patient Safety "Hero" Awards*: annually the Coalition recognizes an individual or a group within each member hospital that has championed a specific patient safety project. The awards are presented by the CEO of each organization during a Coalition awards luncheon. The 2007 award winner topics by hospital are listed below:
  - Clarian: "Safe Passages" program for patient safety
  - Community Health Network: Ventilator Acquired Pneumonia
  - Richard L Roudebush VA Medical Center: Safe Use of Anticoagulants
  - St Francis Hospital and Health Services: Emergency Heart Attack Response Team

- St Vincent Health: “Creation of Foley Free Zones” to reduce urinary tract infections
- Wishard Health Services: Insulin Six Sigma Team

The hospital system chief executive officers meet on a regular basis to discuss the implementation of the above activities, among other items. The Indianapolis Coalition for Patient Safety also has a multi-disciplinary executive team of key members in roles related to patient safety activities. Additionally, the Indianapolis Coalition for Patient Safety has a director responsible for the administration and overall direction of the organization.

EDUCATIONAL PROGRAMS OFFERED

IUPUI Course on Quality and Patient Safety

Multidisciplinary team-based improvements are a key principle for improving safety and reducing harm to patients. Health care leaders of the future will achieve positive quality outcomes and safe patient care through working together in interdisciplinary leadership teams. For the second year, an inter-professional course was offered during the spring semester at Indiana University Purdue University at Indianapolis School of Public and Environmental Affairs for graduate level learners in medicine, nursing, public health, informatics, health administration and other health related disciplines. The course content included an introduction to evidence-based quality and patient safety programs. The content and practical applications focused on the current science of patient safety and best practices, essential leadership skills, and techniques and tools for measurement and analysis.

The course was co-taught by a team of faculty from the Indiana Patient Safety Center, the Indiana University Schools of Nursing and Medicine, and Purdue University Regenstrief Center for Healthcare Engineering. The format and curriculum of the course was presented to the Institute for Healthcare Improvement Inter-professional Education conference in October 2007.

REFERENCES

2006 Update on Consumers' Views of Patient Safety and Quality Information, Kaiser Family Foundation / Agency for Healthcare Research and Quality (September 2006).

Accountability: Patient Safety and Policy Reform (Virginia A. Sharpe, ed., Georgetown University Press, 2004).

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

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

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals, United States Government Accountability Office GAO-04-850 (July 2004).

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).

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

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).

Jill Rosenthal and Maureen Booth, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, National Academy for State Health Policy (October 2005).

Jill Rosenthal and Maureen Booth, *State Patient Safety Centers: A new approach to promote patient safety*, National Academy for State Health Policy (October 2004).

Jill Rosenthal and Trish Riley, *Patient Safety and Medical Errors: A Road Map for State Action*, National Academy for State Health Policy (March 2001).

Jill Rosenthal, Trish Riley, and Maureen Booth, *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*, National Academy for State Health Policy (April 2000).

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

Lynda Flowers and Trish Riley, *State-based Mandatory Reporting of Medical Errors*, National Academy for State Health Policy (March 2001).

Lynda Flowers and Trish Riley, *How State are Responding to Medical Errors: An Analysis of Recent State Legislative Proposals*, National Academy for State Health Policy (September 2000).

Medical Errors: Practicing Physician and Public Views, Kaiser Family Foundation / Harvard School of Public Health (December 2002).

Mimi Marchev, *Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears*, National Academy for State Health Policy (December 2003).

National Patient Safety Foundation, http://www.npsf.org/html/about_npsf.html.

National Survey on Consumers' Experiences with Patient Safety and Quality Information, Kaiser Family Foundation / Agency for Healthcare Research and Quality / Harvard School of Public Health (November 2004).

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

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/Pages/Consumer.html

> 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.ihi.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.