

VERMONT2008

Patient Safety Surveillance and Improvement System

Report to the Legislature on **Act 215**
January 15, 2008



DEPARTMENT OF HEALTH
Agency of Human Services

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Executive Summary

This report is submitted in accordance with Act 215 (2006), 18 V.S.A. § 1913(e), which requires the Commissioner of Health to submit an interim report describing the following: 1) Status of the Patient Safety Surveillance and Improvement system (PSSIS), 2) Effectiveness in improving patient safety and health care quality and 3) Cost savings.

I. Status of Patient Safety Surveillance and Improvement System - Following enactment of the law, the Department was actively involved in the rule making process and met with a broad range of public and private partners to review the draft proposed rule. The intentional unsafe act provisions of the law became effective on 7/1/06 and eight (8) intentional unsafe acts have been reported to the Department. The PSSIS collaborated with the reporting hospitals and assured all events were reported to appropriate authorities. Upon adoption of the rule on 1/1/08, the remaining provisions of the law became effective and the PSSIS was fully implemented.

II. Effectiveness in improving patient safety - As of 1/1/08, the PSSIS will analyze reportable events, identify statewide trends and strategies to improve patient safety, and provide on-going monitoring and compliance audits of hospitals. Hospitals will also identify, track, and trend adverse events and near misses that are not reportable. Identification of events and implementation of solutions to prevent reoccurrence is a key activity in improving patient safety.

III. Cost Savings - To assess efforts in Vermont, hospital discharge data coupled with specific adverse event information collected will be utilized in an aggregated analysis of statewide specific adverse event incidence. This analysis will allow for comparison with other State and national data where available and inform ongoing patient safety and quality improvement efforts in Vermont.

healthvermont.gov/hc/patientsafety.aspx

Introduction

This report is submitted in accordance with Act 215 (2006), 18 V.S.A. § 1913(e), which requires the Commissioner of Health to submit an interim report describing the following: 1) Status of the Patient Safety Surveillance and Improvement system, 2) Effectiveness in improving patient safety and health care quality and 3) Cost savings.

Background

- In 1999, the Institute of Medicine (IOM) published, *To Err is Human: Building a Safer Health System*, which increased awareness of the quality and safety of health care delivery systems. The report estimated that between 44,000 and 98,000 people die in hospitals every year as a result of preventable medical errors, more than the number of combined deaths from motor vehicle accidents, breast cancer or AIDS.
- In 2005, the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) was signed into law in response to growing concern about patient safety in the United States and the 1999 Institute of Medicine (IOM) publication.
- In 2006, the State of Vermont enacted Act 215 (2006), 18 V.S.A. Ch. 45A, the Patient Safety Surveillance and Improvement System (PSSIS). This statute requires the Vermont Department of Health to establish a comprehensive patient safety surveillance and improvement system for the purpose of improving patient safety, eliminating adverse events in Vermont hospitals, and supporting and facilitating quality improvement efforts by hospitals.
- On 1/1/08, following adoption of the rule, the PSSIS was fully implemented. Key components of the system include 1) internal hospital reporting and analysis of all adverse events and near misses, 2) external hospital reporting of the National Quality Forum's twenty-eight (28) serious reportable events (Appendix A) and intentional unsafe acts to the PSSIS, 3) hospital disclosure to patients of adverse events that result in patient death or serious bodily injury, 4) analysis of reportable events and compliance monitoring by the PSSIS. Information obtained by the PSSIS is

confidential unless specifically authorized by law. The Department will work with the Department of Banking, Insurance Securities and Health Care Administration (BISHCA) and other interested stakeholders concerning which data should be included in the hospital community reports.

Status and Accomplishments

Since the law was enacted, the Department accomplished the following:

- Beginning in the fall of 2006, actively sought input concerning the draft proposed PSSIS rule through collaboration with a broad range of public and private partners, including Vermont Association of Hospitals (VAHHS), Vermont Medical Society, BISHCA, a consumer advocate and individual hospitals.
- Promulgated the final rule, approved by the Legislative Committee on Administrative Rules (LCAR) on 10/31/07, with an effective date of 1/1/08.
- Conducted outreach to assist hospitals in preparing for the effective date of the rule through 1) individual meetings with hospital staff and 2) statewide conference calls in collaboration with VAHHS.
- Held informational meetings concerning the law and the new rule with the Department for Children and Families, Department of Disabilities, Aging and Independent Living, Office of Professional Regulation and Board of Medical Practice.
- Obtained a contract for a secure electronic reporting system that enables hospitals to submit reportable events electronically to the PSSIS.
- Developed a paper based reporting tool for hospitals choosing not to submit the reportable events electronically to the PSSIS.
- Developed audit tools to be utilized by the PSSIS during routine periodic monitoring and focused compliance reviews at hospitals.
- Developed tools to be utilized by PSSIS staff for reviewing causal analyses and corrective action plans.

- Developed a reporting tool for submission of intentional unsafe acts.
- Issued interim intentional unsafe act guidance to hospitals on 12/11/06 pending adoption of the rule.
- Received eight (8) intentional unsafe act reports from hospitals since 7/1/06.
- Collaborated with reporting hospitals to assure all intentional unsafe acts were reported to appropriate authorities.

Effectiveness in Improving Patient Safety

Vermont hospitals are actively involved in promoting patient safety within their facilities. The PSSIS enhances these efforts by providing standards for hospitals to establish internal policies and reporting procedures for all adverse events and near misses.

The PSSIS will analyze reportable events, identify statewide trends and strategies to improve patient safety, and provide on-going monitoring and compliance audits of hospitals. Hospitals will also identify, track and trend adverse events and near misses that are not reportable. Identification of these events and implementation of solutions to prevent reoccurrence is a key activity in improving patient safety.

Cost savings

Cost savings analysis associated with reportable adverse events requires balancing the following three financial components which are difficult to quantify: 1) costs associated with an actual event, 2) expenditures associated with implementing system improvements to prevent an event from occurring, and 3) estimating cost savings for an event that did not occur.

The determination of a defined and measurable cost variable warrants consideration of the following possible cost components: facility operational costs which would be treatments required to correct the specific type of adverse event, administrative costs which would include system's correction and future prevention activities; punitive costs

including average malpractice awards for the specific type of adverse event; and societal costs, or expenses to the family including burial, loss of employment income, and disability payments.

An extensive review of the current analyses of other State patient safety and adverse event reporting systems found neither cost savings analyses nor proposed cost savings methodologies associated with those efforts. Empirical data from these States does provide evidence, however, that the implementation of patient safety and adverse event reporting programs are effective in improving patient care by decreasing medical errors and strengthening hospital systems of care. Therefore, the primary benefit of implementing a patient safety and adverse event reporting system is the promotion of effective and proven practices that result in better patient care.

To assess efforts in Vermont, hospital discharge data coupled with specific adverse event information will be utilized in an aggregated analysis of statewide specific adverse event incidence. This analysis will allow for comparison with other State and national data where available and inform ongoing patient safety and quality improvement efforts in Vermont.

Conclusion

Vermont is a proactive state poised to implement a statewide Patient Safety Surveillance and Improvement System (PSSIS). This important initiative will enhance statewide patient safety efforts, eliminate adverse events and support quality improvement efforts by Vermont hospitals.

A final report will be submitted 1/15/09 and will contain 1) Status of the Patient Safety Surveillance and Improvement system, 2) Effectiveness in improving patient safety and health care quality in the state, 3) Cost savings and 4) Recommendations regarding expansion of the system to include health care facilities other than hospitals.

Appendix A

**LIST OF NATIONAL QUALITY FORUM
SERIOUS REPORTABLE EVENTS**

1. SURGICAL EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Surgery performed on the wrong body part	<p>Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.¹</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>
B. Surgery performed on the wrong patient	<p>Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
C. Wrong surgical procedure performed on a patient	<p>Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>
D. Unintended retention of a foreign object in a patient after surgery or other procedure	<p>Excludes a) objects present prior to surgery that were intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as micro needles, broken screws).</p>
E. Intraoperative or immediately post-operative death in an ASA Class I	<p>Includes all ASA Class I patient deaths in situations in which anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p>

patient	Immediately postoperative means within 24 hours after surgery or other invasive procedure was completed, or after administration of anesthesia (if surgery not completed).
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2. PRODUCT OR DEVICE EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used for functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

3. PATIENT PROTECTION EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance)	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability while being cared for in a healthcare	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare

facility.	facility.
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4. CARE MANAGEMENT EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).	Excludes reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.	<i>Hyperbilirubinemia</i> is defined as bilirubin levels >30 mg/dl. <i>Neonate</i> refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy.	

H. Artificial insemination with the wrong donor sperm or wrong egg.	
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5. ENVIRONMENTAL EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.	Excludes events involving planned treatments such as electric countershock /elective cardioversion.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.	
D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility.	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.	

6. CRIMINAL EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.	
B. Abduction of a patient of any age.	
C. Sexual assault on a patient within or on the grounds of the healthcare facility.	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility.	

Appendix B

Program Evaluation/Cost Savings Methodology and Analysisⁱ

The following methodology will be employed to evaluate the incidence of twenty-eight (28) serious reportable events in Vermont during calendar year 2008.

1. Summarize serious reportable events based on category of event as detailed in Appendix A, number of reported events, and percentage of reported events.
2. Establish baseline statewide and hospital demographics and utilization patterns based on annual total number of discharges and total number of patient days by inpatient, outpatient, and emergency department use within the baseline time period.
3. Formulate the baseline time period for analysis based on the availability and appropriateness of a variety of datasets.
4. Define reference diagnosis (ICD-9-CM) codes closely corresponding medical errors to serious reportable events based on recommendations and accepted use from other state and national reporting. For example, the following codes have been used to analyze adverse events in other states:

ICD-9 Code	Description
998.4	Foreign body accidentally left during a procedure
998.7	Acute reaction to foreign substance accidentally left during a procedure
E871	Foreign object left in body during procedure
E874	Mechanical failure of instrument or apparatus during procedure
E875	Contamination or infected blood, other fluid, drug, or biological substance
E876	Other and unspecified misadventures during medical care

5. Determine numbers and rates of reportable adverse events in Vermont based on numbers of events per discharge. A pre-determined level of confidence and consideration of small numbers of reportable incidences will be utilized in the reporting of this data.
6. Compare the incidence of adverse events in Vermont with national and other state data where available.

ⁱ The scope of patient safety is much broader than what is represented by the incidence of these 28 reportable adverse events so an analysis of these events informs rather than defines patient safety efforts in Vermont. Adverse event incidence reporting does not compare the safety or quality of facilities in Vermont. The number of reported events can vary based on many factors other than differences in the safety of care including the size of the facility, differences in interpretation on which events qualify as reportable, and staff awareness of situations that require reporting.

