

VERMONT2008

Patient Safety, Surveillance, and Improvement System

Report to the Legislature on
Act 215 (2006), 18 V.S.A. § 1913(e)



DEPARTMENT OF HEALTH
Agency of Human Services

108 Cherry Street, PO Box 70
Burlington, VT 05402
1.802.863.7341
healthvermont.gov

Table of Contents

Executive Summary	3
Introduction	4
Status and Accomplishments	4
Effectiveness in Improving Patient Safety	5
Cost Savings and Plans for Expansion	6
Conclusion	7
Appendix A: List of National Quality Form Serious Reportable Events	8
Appendix B: Program Evaluation and Analysis	13

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, 3) Cost savings and 4) Recommendations for expansion of the system to include health care facilities other than hospitals. Upon adoption of the rule on 1/1/08, all provisions of the law became effective.

I. Status In 2008, the following key PSSIS components were fully implemented: 1) internal hospital reporting and analysis of all adverse events and near misses, 2) external hospital reporting of the National Quality Forum's (NQF) twenty-eight (28) serious reportable events (Appendix A) and intentional unsafe acts (IUA) to the PSSIS, 3) hospital disclosure to patients of adverse events that result in patient death or serious bodily injury, 4) reportable event analysis and on-site compliance monitoring.

II. Effectiveness The PSSIS reviewed hospital submissions of reportable events, and provided feedback on causal analysis and corrective action plans. In addition, hospitals identified, tracked, and trended non-reportable adverse events and near misses. Identification of non-reportable events and implementation of solutions to prevent reoccurrence is a key PSSIS component to improve patient safety.

III. Cost Savings To assess efforts, reportable event information collected was utilized in an aggregated analysis of statewide specific adverse event incidence. The analysis compared other State and national data where available and informed ongoing patient safety and quality improvement efforts in Vermont.

IV. Expansion Agency stakeholders supported the concept of the PSSIS proposal to expand the program to include long term care facilities and ambulatory surgical centers. Due to fiscal constraints, the Department recommends postponing expansion at this time.

Introduction

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 required 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.

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 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. (See Appendix A: List of National Quality Forum Reportable Adverse Events).

Status and Accomplishments

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

- 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.
- Implemented the PSSIS through active collaboration with individual hospitals, regulatory entities and external partners.
- Designed an electronic and paper-based reporting system which accepts reports from hospitals in any format to decrease duplication of reporting efforts.
- Implemented the secure electronic reporting system which enables hospitals to submit reports electronically and oriented all hospitals to the system.
- Reviewed hospital submissions of reportable events and provided feedback on corrective action plans aimed at eliminating the occurrence of adverse events.

- Initiated hospital onsite audits to review compliance with the PSSIS Statute, rule, and implementation of corrective action plans.
- Collaborated with regulatory entities concerning the reporting of Intentional Unsafe Acts (IUA) to the PSSIS. Decreased duplication of hospital reporting efforts by accepting IUA reports in any format submitted to regulatory entities.
- Planned for expansion of PSSIS to healthcare facilities other than hospitals.

Effectiveness in Improving Patient Safety

The aim of the PSSIS is to ensure a statewide patient safety system is in place which promotes the health and safety of all hospitalized Vermonters, meets legislative requirements and is maintained over time. In order to assess the program's effectiveness in meeting this aim, hospital event reporting capacity and PSSIS program function were evaluated and all objectives were met. (See Appendix B for Program Evaluation and Analysis).

The PSSIS requires hospitals to report NQF events to the system. The system regards these reports in a non-punitive manner but requires that the hospitals make a substantive analysis of the cause of the event, and establish a meaningful corrective action to prevent reoccurrence.

In 2009, the PSSIS is poised to fully realize its aim through the following activities:

- Develop recommendations concerning inclusion of patient safety data in hospital community reports through collaboration with BISHCA, VAHHS, and interested stakeholders.
- Continue routine periodic reviews to evaluate hospital compliance with the statute and rule, including disclosure of reportable events to patients.
- Continue focused hospital compliance reviews as warranted, including the implementation of a specific corrective action plan for a reportable event.

- Identify hospitals facing similar risks and develop collaborative Quality Improvement initiatives to enhance Vermont hospital capacity to prevent occurrences of reportable events.
- Begin building a baseline for Vermont reportable events over three years, beginning with the 2008 implementation year and adding 2009-2010 data.

Cost savings

In Vermont, the rate of NQF serious event reporting is consistent with results in other States. As expected, some reportable events resulted in increased patient monitoring and extended lengths of stay. Hospital identification of these events and causal analysis is expected to improve patient safety, outcomes and increase efficiencies in Vermont's healthcare system over time. The continuous quality improvement environment that PSSIS supports promotes the discovery of systemic issues adversely affecting patient safety and health outcomes. As the individual hospital uncovers the systemic issues associated with its reportable events and makes its corrective action, better patient care and improved outcomes will follow. The statewide view afforded PSSIS will allow statewide system improvements, shared learning and collaborative efforts with hospitals.

Quantifying the resulting cost savings, however, remains an elusive goal. An extensive review of other state patient safety and event reporting systems did not reveal a system that is reporting cost savings or has proposed a methodology for making a cost analysis. However, empirical data from these states does provide evidence that implementation of patient safety and event reporting programs effectively improve patient care by decreasing medical errors and strengthening hospital systems of care. (See Appendix B: Program Evaluation and Analysis).

Plans for Expansion

The Department of Health has explored expanding the PSSIS to include Vermont's long term-care facilities and ambulatory care centers. Such an expansion would extend the

benefits of improved patient safety, eliminate serious adverse events and expand effective quality improvement systems to Vermonters receiving care in these non-hospital environments. The Department is poised to make this expansion when funding becomes available.

Conclusion

Vermont's PSSIS was fully implemented in 2008 through active collaboration with VAHHS, BISCHA, hospitals, other State entities and external partners.

Hospitals are actively engaged in promoting patient safety within their facilities. The PSSIS enhances and supports these efforts by 1) identifying statewide trends and strategies to improve patient safety, 2) analyzing causal analysis reports and corrective action plans submitted by hospitals and 3) providing on-site compliance monitoring of the patient safety rule and statute.

Annually, the Department will reassess the appropriateness of expanding the scope of the program until a final determination is made.

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.</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 patient	<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. Immediately postoperative means within 24 hours after surgery or other invasive procedure was completed, or after administration of anesthesia (if surgery not completed).</p>

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 facility.	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.

4. CARE MANAGEMENT EVENTS	
EVENT	ADDITIONAL SPECIFICATIONS
<p>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).</p>	<p>Excludes reasonable differences in clinical judgment on drug selection and dose.</p> <p>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.</p>
<p>B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.</p>	
<p>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.</p>	<p>Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.</p>
<p>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.</p>	
<p>E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.</p>	<p><i>Hyperbilirubinemia</i> is defined as bilirubin levels >30 mg/dl.</p> <p><i>Neonate</i> refers to the first 28 days of life.</p>
<p>F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.</p>	<p>Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.</p>
<p>G. Patient death or serious disability due to spinal manipulative therapy.</p>	
<p>H. Artificial insemination with the wrong donor sperm or wrong egg.</p>	

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 and Analysis Reporting period 1/1/08 - 9/30/08

1. Hospital Event Reporting Capacity and PSSIS Program Function

A. Hospital event reporting capacity:

- 87.5% (14/16) hospitals submitted events electronically.
- 56% (9/16) hospitals reported one or more event.
- Of the hospitals reporting an event:
 - 100% submitted an initial report within 7 calendar days after discovery or recognition of the reportable event.
 - 100% completed a causal analysis and corrective action plan within 60 calendar days from submission of the initial report.
 - 100% disclosed the event to the patient and/or family.

B. PSSIS program function:

- 100% of submitted initial reports received follow-up within 7 days.
- 100% causal analysis and corrective action plans submitted by hospitals were reviewed within 30 calendar days and included written recommendations for improvement as indicated.
- 100% corrective action plans submitted were approved within 60 calendar days.

2. Event analysis per patient bed days and discharges:

For this reporting period, the PSSIS identified the following:

- 5.9 reportable events were submitted per 100,000 patient bed days.
- 4.7 reportable events were submitted per 100,000 discharges.

Total patient bed days and hospital discharges are utilized as denominator data in the analysis of reportable events. Inpatient hospital total patient bed days are available annually from hospital licensing.

Hospital discharge data renders a more complete picture of total hospital utilization upon which adverse events can be reported. Total Vermont hospital discharges include inpatient, emergency department and outpatient services discharges.

3. Baseline for reportable events:

- Reportable event analysis aligns with hospital patient bed day data submitted through hospital licensing. This data runs from October 1st of a given year through September 30th of the following year. The PSSIS will utilize existing data without creating additional data collection burden on the hospitals.
- A baseline for Vermont reportable events will be built over three years beginning with the 2008 implementation year data and adding 2009 and 2010 as they transpire.

4. Disaggregated data based on diagnosis codes:

- This analysis is unfeasible due to the small numbers of reportable events in Vermont. Statewide data will be aggregated over multiple years to allow comparison of Vermont results with results in other states.