Sentinel EVENTS

CY 2008

Annual Report to the Maine State Legislature

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■ Executive Summary

In 2002 Maine enacted Public Law 2001, Chapter 678 establishing a mandatory sentinel event reporting system. The law requires licensed General and Specialty Hospitals, Ambulatory Surgical Centers, End-Stage Renal Disease Facilities/Units, and Intermediate Care Facilities for Persons with Mental Retardation to report certain serious events, referred to as sentinel events, to the State. The law further requires an annual report to the Legislature and public.

Key Findings

- Maine continues to significantly under-report sentinel events based on estimates from national studies.
- Changes to the statutory language have been proposed to the Legislature, LD 1435, that reduce ambiguities concerning how and what must be reported, aligns requirements for root cause analysis with the Joint Commission, adds sentinel events from the National Quality Forum to those, which are now captured by Maine's reporting statutes, adds voluntary reporting of near misses, increases penalties for failure to report, and requires an affirmative statement of compliance with reporting requirements. In addition, the bill provides further clarification of protections from disclosure for suspected events to address concerns of providers.
- Maintaining a commitment to a collaborative approach among all stakeholders for identifying, reporting, and sharing aggregate data for all sentinel events offers the best opportunity for preventing recurrences.
- A total of 147 sentinel events have been reported and reviewed since the inception of the program in 2004. The overwhelming majority are unanticipated patient deaths.
- 43 sentinel events were reported in 2008 a 50% increase over 2007 due in part to discovery

through auditing by the Sentinel Event Team.

Goal of Reporting System

Maine's sentinel event reporting system is designed to encourage reporting, yet under-reporting persists. The confidentiality of reports, the public disclosure of only aggregate reports without hospital identifiers, and the separation of reporting from the hospital licensure process are embedded in the system as ways to promote reporting, collaboration and shared learning. Understanding that it is not possible to solve problems that are not identified, Maine's sentinel event reporting system was intended to look beyond blame and promote patient safety through collaboration and shared responsibility. An important precept is to provide a non-punitive environment for reporting so that others can learn from mistakes and prevent their recurrence. Essential to the success of the program is confidence that full reporting is taking place.

Definition of Sentinel Event

Sentinel events are outcomes determined to be unrelated to the natural course of the patient's illness or underlying condition, or proper treatment of that illness or underlying condition, or that results from the elopement of a hospitalized inpatient that lacks capacity. The law further characterizes sentinel events as:

- Unanticipated death;
- A major permanent loss of function that is not present when the patient is admitted to the health-care facility;
- Surgery on the wrong patient or wrong body part;
- Hemolytic transfusion reaction involving administration of blood or blood products having blood group incompatibilities;
- Suicide of a patient in a healthcare facility where the patient receives inpatient care;
- Infant abduction or discharge to the wrong family; and
- Rape of a patient.

State Review

The Sentinel Event Team conducted an onsite review at each facility reporting a sentinel event to analyze the incident and to ensure that all relevant factors were considered in the development of an action plan. This process provides an independent assessment that augments the facility's own internal review of the incident.

Confidentiality Provisions

By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within the State. Since the inception of the program, there have been no complaints of any breaches in the firewall.

Sentinel Events Reported in 2008

Forty-three sentinel events were reported in 2008. Thirty nine were reported by licensed hospitals, two by Intermediate Care Facilities for Persons with Mental Retardation (ICF/MR), two by Ambulatory Surgery Centers and none from End Stage Renal Disease Centers (ESRD). This number is a 50% increase over events reported in 2007. A total of 80% of Maine hospitals have reported at least one sentinel event since the inception of the program. Eight hospitals have never reported a single sentinel event.

A breakdown of the 43 reported sentinel events is as follows:

- 31 unanticipated deaths
- 3 wrong site surgeries
- 7 major loss of function
- 1 patient rape
- 1 patient suicide

There were no reports of infant abduction, discharge to the wrong family, or hemolytic transfusion reaction. The overwhelming majority of cases (34 of 43) were the result of mistakes, or cognitive errors, suggesting the need for training or educational programs. Forty one (95%) sentinel events included non-clinical circumstances, including errors associated with patient hand-off, chain of command, weekends or holidays, or associated with new practitioners. Aspects of thirty-six (84%) reported sentinel events raised concerns about the clinical management of a patient. There is a wide range of contributing factors in these cases including misdiagnosis and failure to rescue.

In 2008, root cause analysis results indicated that lack of education and inadequate documentation were the most prevalent causative factors. Thirty eight of thirty nine events attributed the root cause to those factors. Facilities reported policies and procedures and communication next in frequency. In those cases thirty four of thirty one cases respectively cited those root causes. Human factors and standards of care explained twenty two and nineteen cases, respectively.

Five Year Retrospective 2004-2008

A total of 147 Sentinel Events have been reported and analyzed since the inception of the

program in 2004. As part of a five-year retrospective we will report aggregate data and trends from all of the reported events later in 2009. We have identified characteristics of the cases and areas for future focus. Included in the data are reported features such as type of event, location of the event, age, gender, and contributing factors.

The National Quality Forum (NQF)

The NQF is a national, consensus-driven private-public partnership aimed at developing common approaches to quality improvement, including identification of events that are serious in nature and have been determined to be largely preventable. Increasingly, states are using the NQF list of serious events as the basis of their mandatory reporting systems. Comparability of definitions enhances clarity about what must be reported and provides benchmarks for comparing experiences across states. The Agency for Healthcare Quality and Research is also promoting standardized reporting of events, including the NQF list of serious events, and Maine's efforts in this regard will be compatible with national initiatives.

The Maine Quality Forum commissioned a review of the impact if Maine was to adopt the NQF list of serious reportable events in lieu of its current list. The study found a major distinction between Maine's reportable events and those of the NQF. NQF events are known to be primarily preventable and/or serious in nature and therefore, *a priori*, must be reported. According to Maine law, events must be reported when they are unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition.[2] The 'proper treatment clause' enables facilities to review sentinel events and determine whether they are the result of improper treatment. This discretion may lead to under-reporting, particularly if facilities lack appropriate methods of identifying these cases, or when the culture in the facility does not support individuals coming forward with concerns about proper treatment. Maine is in the very early stages of having a culture of safety in each health care facility.

Context for Reviewing Maine's Sentinel Events

There are many reasons for differences in the rate of adverse events, only some of which are indicative of variations in quality. Studies of other state mandatory reporting systems show that hospital systems for identifying and reporting events improve over time, yet the number of reported events in Maine had remained notably static until 2008. In 2008 there was an increase of 50% in reported events. This increase is due in large part to the on site audit process that was undertaken by the Sentinel Event Team. Ten (10) of the forty three (43) sentinel events reported in 2008 were discovered by the Sentinel Event Team as part of the onsite audit process. The 2007 Sentinel Event Annual Report included a review of literature that suggested methodologies for appropriate

levels of reporting against actual reported events. The magnitude of the discrepancy suggests continued serious under-reporting in Maine and the need to address this through enforcement or legislative means is highlighted by the number of events discovered by the Sentinel Event Team in reviewing only three Maine Hospitals.

Sentinel Event Program Highlights

The sentinel event program, in partnership with Maine Medical Center, was selected to participate in the National Patient Safety Improvement Corps (PSIC). Co-sponsored by the Agency for Health Care Quality (AHRQ) and the Veterans Administration (VA), the PSIC is a unique collaborative of public and private entities dedicated to reduce medical errors and improve patient safety.

The effort was culminated with two state wide Patient Safety Conferences for all 41 Maine hospitals, including Maine's state-owned psychiatric hospitals. These full day programs were co sponsored by the Division of Licensing and Regulatory Services and Maine Medical Center and were offered to senior leaders from each hospital. More than 150 attendees participated. Dr. Allan Frankel, a nationally recognized expert in the field of safety in healthcare delivery was the featured faculty. The outcome of this effort was a unanimous agreement to form a statewide coalition to continue the team training techniques necessary to reduce communication and handoff errors across the state.

In an effort to improve awareness of the State's sentinel event system and to assist facilities in discovering sentinel events onsite audit visits were made to three hospitals in 2008. That process identified ten sentinel events that had not been identified by the facilities, and not reported as sentinel events. Sentinel Event Team members focused these visits on reporting requirements, their relationship to the facility's own risk management program, and the process for reporting. Findings from these visits indicate that serious events continue to go unrecognized and unreported.

Conclusions and Recommendations

Maine's sentinel event reporting system focuses on identifying and deterring serious, preventable incidents. Due to their serious nature, the State has a vested interest and responsibility for assuring that everything possible is done to address them when they happen, and to ensure practices needed to prevent their recurrence are widely understood and adopted. Mandatory reporting is the primary tool for the State to hold facilities accountable for disclosing that an event has occurred and that appropriate action has been taken to remedy the situation.

LD 1435 proposes to amend the current sentinel event statute. The bill introduced by Senator Bowman will not be acted upon in the current legislative session prior to the

publication of this report. The goal of this bill is to reduce ambiguities about what must be reported and how, increase reporting of serious preventable events, add voluntary reporting of "near misses", and standardize the review process to better capture lessons learned across the state.

In the coming year, the sentinel event program will continue to work closely with hospitals and others to strengthen the reliability of reporting.

- The State is utilizing Maine's all-payer database to identify potentially reportable sentinel events in order to validate that all events are being reported.
- Protocols for conducting audits within hospitals have been developed to validate that all sentinel events are identified and have been reported.
- The Sentinel Event Team will continue to assess the adequacy of hospitals' internal systems for detecting and reporting events and to explore why some hospitals have not reported.
- Complaint data will continue to serve as a cross-check on the reporting system for those incidents that rise to the level of a reportable event.

Finally, the program will continue to maintain ongoing communications with Maine hospitals and stakeholders concerning reporting requirements and lessons that can be learned to prevent events from being repeated. The State is committed to maintaining a collaborative approach for identifying serious adverse events and finding joint solutions for reducing their occurrence. However, the overarching goal of the reporting system is to improve the quality of care and to honor our pledge to the Maine people that the State is a credible overseer of the quality of care in Maine.

Endnotes

[1] Exceptions include cases of a complaint investigation or if the hospital is selected by the Medicare program for a survey to validate Joint Commission findings.

[2] Me. Rev. Stat. Ann. tit. 22, § 8753 (2003). Definitions at http://janus.state.me.us/legis/statutes/22/title22sec8752.html

Background

This report is submitted in accordance with Maine law (22 M.R.S.A. §§8751-8756) which requires the Division of Licensing and Regulatory Services (the Division) to annually report to the Legislature, health care facilities and the public on the aggregate number and type of sentinel events for the prior calendar year, rates of change, causative factors, and activities to strengthen patient safety in Maine (see Appendix A for details of the law). This report is designed to:

- Build awareness of Maine's sentinel event reporting requirements and the follow-up process used by facilities and the State when events occur;
- Provide aggregate information on the number and nature of sentinel events reported;
- Identify patterns and make recommendations to improve the quality and safety of patient care; and
- Describe efforts to address under-reporting and enhance the role of sentinel event reporting in improving patient safety.

The report begins with a summary of Maine's sentinel event reporting requirements and the process used for reviewing reported events. This is followed by a brief description of how the system fits within other hospital oversight activities and national patient safety initiatives. A summary of sentinel events reported in 2008 is presented, followed by an analysis of statewide trends and observations. The report concludes with a context for assessing reporting levels under Maine's sentinel event reporting system, major program highlights during 2008, and recommendations for enhancing the sentinel event reporting system going forward.

Maine Sentinel Event Reporting and Review Process

The Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System* (Kohn, et al, 1999) heightened awareness of the serious injuries and deaths that occur every year from preventable medical errors. The IOM report proposed a combination of strategies to reverse these trends, among them:

- The establishment of state-based mandatory reporting systems, tied to systems of accountability, for the most serious medical errors that may cause harm and death.

- The encouragement of voluntary reporting systems for the broad spectrum of errors and near misses to better understand why and how events happen and what can be done to prevent their recurrence.
- The promotion of non-punitive systems within hospitals that encourage reporting at all levels and develop system solutions for their prevention.
- The promulgation of national efforts to standardize reporting, study patient safety trends, and disseminate best practices for reducing medical errors.

In 2002, Maine enacted Public Law 2001, Chapter 678 establishing a mandatory sentinel event reporting system. As implemented in subsequent regulations, the law requires licensed General and Specialty Hospitals, Ambulatory Surgical Centers, End-Stage Renal Disease Facilities/Units, and ICFs/MR to report certain serious events, referred to as sentinel events.

Definition of a Sentinel Event

Sentinel events include outcomes determined to be unrelated to the natural course of the patient's illness or underlying condition, or proper treatment of that illness, or underlying condition, or that results from the elopement of a hospitalized inpatient that lacks capacity. The law further characterizes sentinel events as:

- Unanticipated death;
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- Surgery on the wrong patient or wrong body part;
- Hemolytic transfusion reaction involving administration of blood or blood products having blood group incompatibilities;
- Suicide of a patient in a healthcare facility where the patient receives inpatient care;
- Infant abduction or discharge to the wrong family; and
- Rape of a patient.

Reporting Requirements

Facilities must notify the Division within one business day of discovering an event. Through a confidential telephone exchange of information, the Sentinel Event Team determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation that the event must be reported, the facility is required to submit a brief description of the incident via a restricted fax to the Division. A facility that knowingly violates any provision of the requirements is subject to a civil penalty.

Within 45 days of discovering a reportable event, the facility is required to share a written report with the State and the facility's quality improvement committee describing key elements of the event, the circumstances surrounding its occurrence, the

actions taken or proposed to prevent its recurrence, methods for communicating the event, and planned risk reduction actions.

The Sentinel Event Team conducts an onsite review at each facility reporting a sentinel event to assess the incident and to ensure that all relevant factors are considered in the development of an action plan. The on-site review occurs shortly after the incident is first reported so that findings can be incorporated into the facility's action plan. The facility's Chief Executive Officer (CEO) is briefed during this time by the Sentinel Event Team to assure his/her active engagement in understanding factors leading to the event and plans for mitigating its recurrence. The entire medical record of the patient is reviewed during the site visit to identify contributing factors that may have gone unnoticed and have affected the outcome before, during and after an event. This process provides an independent assessment that augments the facility's own internal review of the incident.

Throughout their review of a sentinel event, the Sentinel Event Team studies relevant standards of care and evidence-based research to help inform their review of the facility's response to an event. Depending on the nature of the event, content experts may also be consulted to expand understanding of the possible system failures or other factors that may have contributed to a sentinel event.

Upon receipt of the facility's full written report, the Sentinel Event Team confirms that direct causal factors have been examined by the facility and that corrective actions are appropriate, comprehensive, and implemented. If the report is accepted, a letter attesting to that fact is sent to the facility's CEO. Should more information be required, a letter requesting specific details is sent to the Risk Manager with a copy to the CEO. When this report is complete, a final approval letter is sent to the facility. Should it be necessary, the Sentinel Event Team may return to the facility to follow-up on the implementation of the action plan. A flow chart diagramming the sentinel event case review process can be found in Appendix C.

Information collected on sentinel events and their reviews are entered into a confidential database. This database is the primary source for identifying and generating aggregate statistics and trends through the Annual Report.

2008 Revised Rules Governing Sentinel Event Reporting

On January 1, 2009, revised reporting rules became effective. Key objectives in the rule changes were to reduce redundancy, improve reporting, streamline definitions for ease of use, and reduce ambiguity. Change highlights include:

The consolidation of the previously fragmented and diverse sentinel event rules into one free standing rule. The definition of a reportable event was reorganized to increase clarity. The definition of Root Cause Analysis (RCA) was included with a requirment that it be 'thorough and credible'.There is a clarification regarding the report of rape cases.Finally, there is a new requirement for an annual statement from each CEO or

Administrator from each facility affirming that all events have been reported .

Confidentiality Provisions

By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within the State. The Sentinel Event Team is responsible for reviewing the initial reported event, conducting on-site reviews, ensuring that all contributing factors to an event are identified, and that action plans are appropriate and implemented.

Relationship of Mandatory Reporting to Other Hospital Initiatives

Maine's mandatory reporting system fits within a broader system of oversight of patient safety within hospitals. This section focuses on oversight of hospitals since the vast majority of sentinel events nationally occur within hospitals and hospitals accounted for thirty nine of the forty three sentinel events reported in 2008.

Hospitals, their staff, and providers serve as the initial safeguard against adverse events through their credentialing processes, risk management programs, and quality improvement systems. These internal systems are essential underpinnings to early detection and resolution of quality problems.

The State is responsible for licensing healthcare providers to assure that their internal procedures and systems of care meet public expectations of quality. The State survey team conducts on-site visits to monitor compliance with licensure requirements, compliance with requirements for participation with Medicare and Medicaid programs, and to investigate complaints. The Medicare program relies on two types of external reviews to assure that hospitals are providing quality care: accreditation by the Joint Commission and certification by state agencies for those hospitals not accredited.

The Joint Commission is a voluntary program that accredits a hospital based on an evaluation of its performance compared to operational standards associated with a quality performing facility. In 2007, the Maine State Legislature mandated the Division accept Joint Commission accreditation as also satisfying State licensing requirements for hospitals (see Appendix D for 22 M.R.S.A. §1816). The purpose of the legislation was to reduce duplication and burden in that many of the standards are equivalent between State hospital licensing and the Joint Commission. Nothing in this new statute eliminates the legal duty of Maine hospitals to report sentinel events to the State. The effect of this legislation, however, means that regular onsite visits to accredited hospitals are no longer conducted by the State as part of its licensing function.[1] . Currently, 24 of Maine's 41 hospitals are Joint Commission accredited and thus exempt from routine State licensing oversight.

The Joint Commission accreditation program includes the voluntary reporting of specified reviewable sentinel events, many of which are similar to reportable events in Maine. Although

the definition of reportable events is similar, there are stark contrasts between the Joint Commission and Maine sentinel event reporting systems in other respects.

First, the Joint Commission reporting system is voluntary while the Maine system is mandatory. Between 1995 and 2008, the Joint Commission's website indicates that a total of 18 reviewable events were submitted by Maine hospitals (Joint Commission, 2007). This compares to the over 147 events reported under Maine's mandatory system since it began in 2004.

Second, the Joint Commission does not validate that events are being reported. The Joint Commission's website specifically states that "surveyors are instructed not to seek out specific sentinel events beyond those already known to the Joint Commission" (Joint Commission, 2007, July).

As will be discussed later in this report, Maine's Sentinel Event Team works actively with hospitals with a history of limited reporting to assure that internal systems are in place to detect serious adverse events. In the coming year the Sentinel Event Team will continue to target facilities with a high probability of under-reporting.

Third, the two systems are distinguished by the extent of follow-up to a reported event. No on-site review is conducted by the Joint Commission to assure an examination of all causative factors. In contrast, Maine's Sentinel Event Team visits each reporting facility and actively works with them to make certain that action plans adequately address the root causes and are implemented to prevent a recurrence.

The purpose of this section was to underscore the heightened significance of Maine's sentinel event reporting system. In an environment where the State now has a radically reduced presence in some hospitals, mandatory reporting provides an important window into the quality and patient safety issues of Maine hospitals.

Sentinel Events Reported in 2008

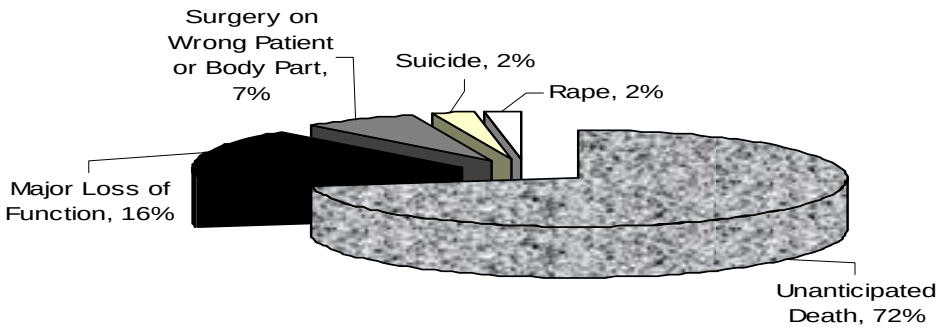
Forty-three sentinel events were reported to the Division in 2008. This represents a 50% increase over 2007 when twenty eight sentinel events were reported. A total of ten (23%) of the 2008 cases were identified by the Sentinel Event Team during onsite hospital audits. The Sentinel Event Team also reviewed over 215 complaints from the public to determine whether they met the statutory definition of a sentinel event. Two of those complaints did meet the definition of a Sentinel Event and they were reported as such.

Confidentiality provisions restrict the State from disclosing further information about these events given the small numbers and the potential to trace events to individual patients or hospitals. There were no reports of infant abduction or discharge to the wrong family or hemolytic transfusion reaction.

Demographics

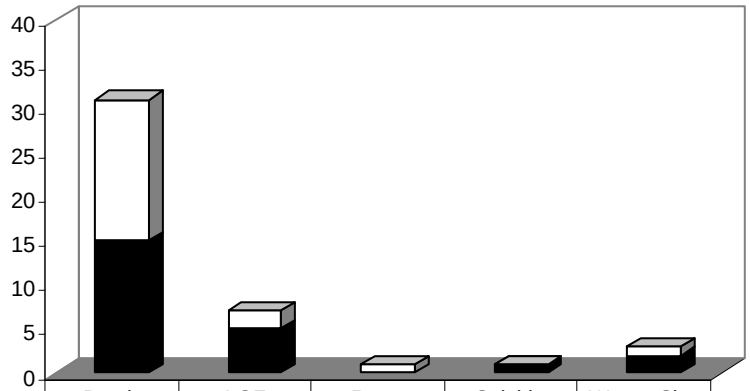
In 2008 the overwhelming majority, thirty one (72%) of the reported Sentinel Events were unanticipated patient deaths (e.g., falls, hospital acquired infection). This statistic is similar to previous years' data. Unanticipated deaths have constituted the largest number of cases every year since the inception of the program in 2004. Of the remaining twelve cases, seven (16%) resulted in permanent loss of function, three were wrong site surgeries, one was a patient rape, and one a patient suicide. There were no reports of infant abduction, discharge to the wrong family, or hemolytic transfusion reaction.

Figure 1: 2008 Sentinel Events by type of event



There were no significant differences, in any of the reporting categories, between male and female patients involved in Sentinel Events. The next most frequent type of sentinel event reported was Loss of Function (LOF) involving a total of seven (16%).

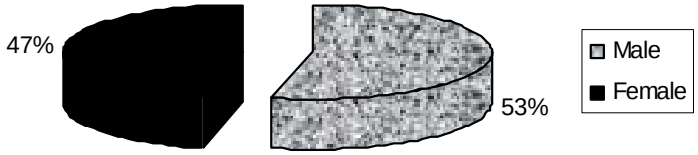
Figure 2: 2008 Sentinel Events by event type and gender



	Death	LOF	Rape	Suicide	Wrong Site
Female = 20	16	2	1	0	1
Male = 23	15	5	0	1	2

In 2008, Sentinel Event reports involving male patients were higher than those involving female patients. Twenty three patients (53%) were male and twenty (47%) female.

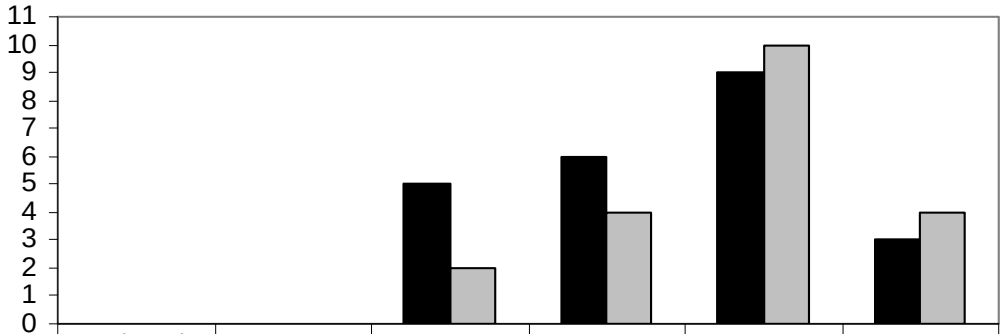
Figure 3: 2008 Sentinel Events by gender



Male = 23 Female = 20

In 2008, the 66-85 age group suffered the largest number of sentinel events nineteen (44%) of the cases. There were no reported cases involving children aged 10 or less.

Figure 4: 2008 Sentinel Events by patient age and gender



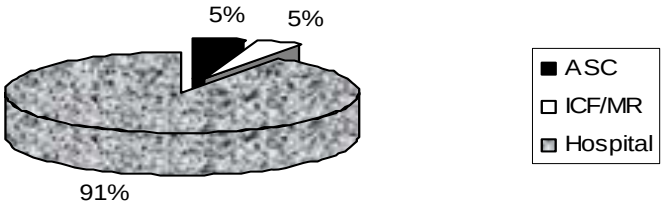
	Fetal Death	0-10	11-45	46-65	66-85	86-100
Male	0	0	5	6	9	3
Female	0	0	2	4	10	4

Male = 23 Female = 20

As in previous years, the overwhelming majority, thirty nine (91%), of the reported sentinel events were from hospitals. Ambulatory Surgery Centers continue to identify a small number of

events, in 2008 two (5%) cases were reported. Nationally, there have been reports of serious adverse events in the Ambulatory Surgery setting, most recently involving iatrogenic infections. Ambulatory Surgery Centers should have a systematic approach to identify complications that arise following patient discharge. ICFs/MR reported two (5%) of the 2008 sentinel event cases.

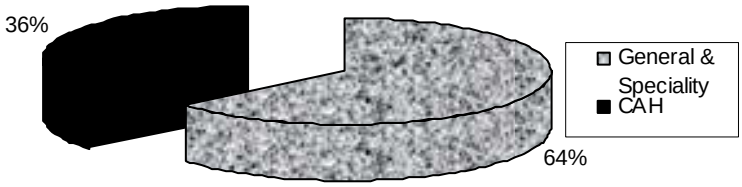
Figure 5: 2008 Sentinel Events by provider type



Ambulatory Surgical Center (ASC) = 2, Intermediate Care Facility for Mental Retardation (ICF/MR) = 2, Hospital = 39

Of the sentinel events reported by hospitals in 2008, twenty six (67%) were from General and Specialty Hospitals and thirteen (33%) were from Critical Access Hospitals.

Figure 6: 2008 Sentinel Events by hospital type



General and Specialty Hospital = 25, Critical Access Hospital = 14

As shown in Table 1, thirty three (80%) of Maine hospitals have reported at least one sentinel event since the inception of the program. Eight hospitals have not reported a single event. Other states report that the number of reporting hospitals generally increases when facilities see the relevance of reporting to improving patient safety within their own institutions and the state (Rosenthal, et al, 2001). It is for that reason that changes have been made in the case review process to ensure that visits are scheduled soon after the event. Findings resulting from a review

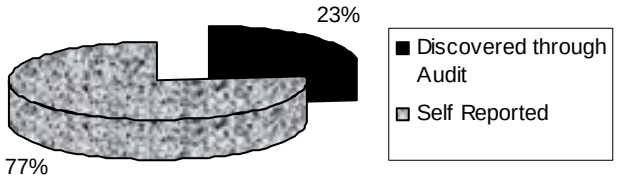
of the medical record are then shared with the facility leaders to enhance the RCA process.

Table 1: Reporting versus Non-Reporting Hospitals

	2004	2005	2006	2007	2008
	No. %	No. %	No. %	No. %	No. %
Reporting hospitals	11 27%	20 49%	25 61%	32 78%	33 80%
Non-reporting hospitals	30 73%	21 51%	16 39%	9 22%	8 20%
Total	41 100%	41 100%	41 100%	41 100%	41 100%

The Sentinel Event Team conducts on site visits across the state to facilities both to investigate a reported event and to educate and inform their leadership. During those on site visits, medical records and related documents are reviewed to help identify the effectiveness of the current systems to detect such occurrences. For example in only three auditing visits in 2008 ten additional previously unreported sentinel events were discovered representing 25% of all reported sentinel events in 2008.

Figure 7: 2008 Sentinel Events discovered through audit versus self reported



10 were discovered through audit, 33 were self reported

National Quality Forum

At the request of the Maine Quality Forum, each year the Sentinel Event Team reports Maine's events by categories of adverse events adopted by the National Quality Forum (NQF). The NQF is a national, consensus-driven private-public partnership aimed at developing common approaches to identification of events that are serious in nature and have been determined to be

largely preventable.(National Quality Forum, 2002).[2] Sometimes referred to as "never events," the NQF list increasingly has become the basis for states' mandatory reporting system (Rosenthal, 2007). The list of NQF serious events is intended to capture events that are clearly identifiable and measurable, largely preventable, and of interest to the public and other stakeholders. Comparability of definitions enhances clarity about what must be reported and provides benchmarks for comparing experiences across states.

NQF serious events are structured around six categories: surgical, product or device, patient protection, care management, and environmental.

The Maine Quality Forum commissioned a review of the impact if Maine was to adopt the NQF list of serious reportable events in lieu of its current list (Booth et al, 2005). The use of a nationally accepted standardized list of events generally was seen as offering greater specification on what constitutes a reportable event as well as the opportunity to compare Maine's experience with that of other states. Currently, half of the 26 state mandatory reporting systems use the NQF list or a close approximation (National Academy for State Health Policy, 2007). The study concluded that use of the NQF list would lead to the reporting of some events that are not currently or explicitly included in the Maine sentinel event list (e.g., State retention of a foreign object in a patient after surgery or other procedure unless it causes death or permanent injury). In other cases, there are events that Maine currently collects that would not be required under the NQF definition of sentinel event (e.g., NQF list is quite specific in defining which types of unanticipated deaths are reportable; Maine requires the reporting of all unanticipated deaths, subject to the 'proper treatment' clause).

Of Maine's forty-three (43) reported events, eleven (11) (39%) met NQF criteria. The remaining seventeen (17), (61%), did not meet NQF criteria and would not have resulted in a report or ensuing root cause analysis if NQF definitions alone were applied (National Quality Forum, 2002).

Table 2: State of Maine Sentinel Events Captured by NQF Criteria

Year	2005		2006		2007		2008	
	No.	%	No.	%	No.	%	No.	%
Yes	7	25%	8	32%	11	39%	13	30%
No	21	75%	17	68%	17	61%	30	70%
Total	28	100%	25	100%	28	100%	43	100%

Note: Maine data was not compiled into NQF categories in 2004.

Statewide Trends

In this section, we probe to seek common themes across events that can help us identify opportunities for reducing their occurrence. These observations are based on the onsite reviews conducted by the Sentinel Event Team following each reported event; the documentation

provided by facilities in their analyses of circumstances surrounding an event; and a review of patient safety literature. In this analysis, we looked to identify contributing factors throughout the entire episode of care and did not limit ourselves to the primary cause of an event.

Non-clinical Trends

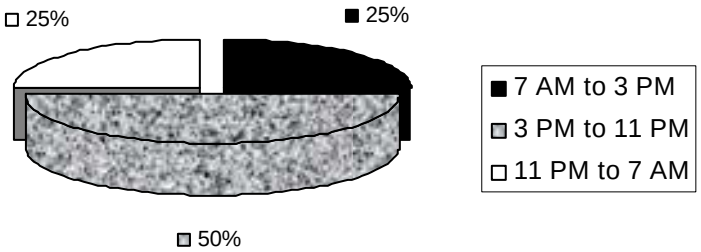
The Sentinel Event Team continues to track and analyze cases to assess the impact of time of day and day of week characteristics. This follows research that has demonstrated that patients admitted to the hospital on the weekend have a higher risk of mortality. (Becker, 2007) In Maine in 2008, the majority of reported sentinel events (44%) occurred between the hours of 3PM and 11PM. A total of thirty eight sentinel events (65%) occurred during 'off hours', 3 PM to 7 AM.

Figure 8: 2008 Sentinel Events by time of occurrence

7 AM to 3 PM = 15, 3 PM to 11 PM = 19, 11 PM to 7 AM = 9

When elective surgeries, or scheduled cases, are removed from the sample, the majority of sentinel events occurring between 3PM and 11PM increases to 50%. When including all 'off hours' for this new sample a total of twenty four (75%) took place between the hours of 3PM and 7AM.

Figure 9: 2008 Sentinel Events by time of occurrence excluding all elective cases

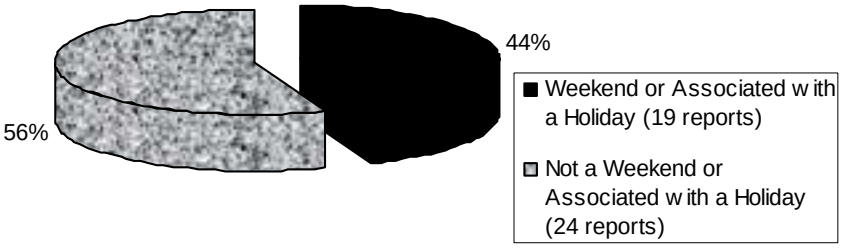


7 AM to 3 PM = 8, 3 PM to 11 PM = 16, 11 PM to 7 AM = 8

As first reported in the 2007 Sentinel Event Annual Report, the frequency of cases occurring during the weekend, or associated with a holiday, is disproportionately high. In 2008 a total of nineteen cases (44%) occurred on the weekend or associated with a holiday. That is an increase over nine cases (33%) events in 2007. Based on the literature and the observations of these events it is recommended that the 'weekend factor'

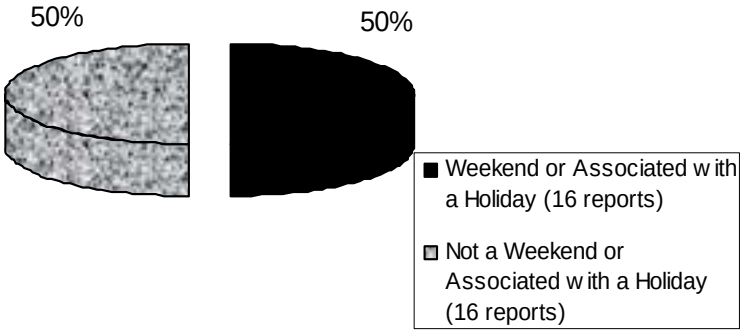
should be considered in the treatment plan of high risk cases (Bendavid, 2007) and when reviewing adverse events, or near miss cases (Becker, 2007).

Figure 10: Sentinel Events by day of the week characteristics 2008



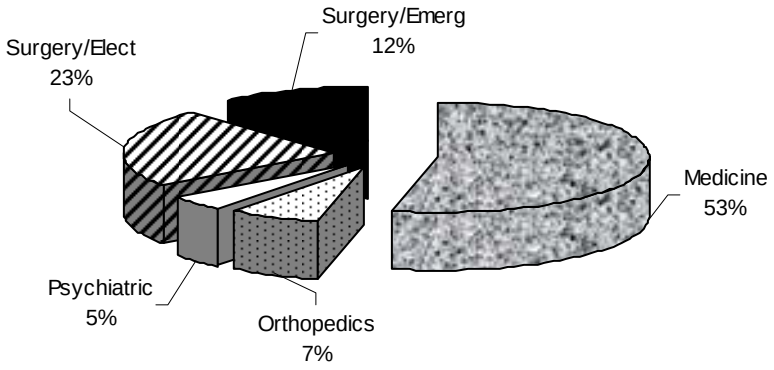
When the elective surgeries or scheduled cases, are removed from the sample, the number of weekend and holiday cases grows to sixteen (50%).

Figure 11: Sentinel Events by day of the week characteristics 2008 excluding elective cases



In 2008 we reviewed reported sentinel events by service. The majority of cases twenty-three (53%) were patients admitted to the medical service. General, orthopedic, emergency, and elective surgery cases comprised another eighteen (42%).

Figure 12: 2008 Sentinel Events by type of service

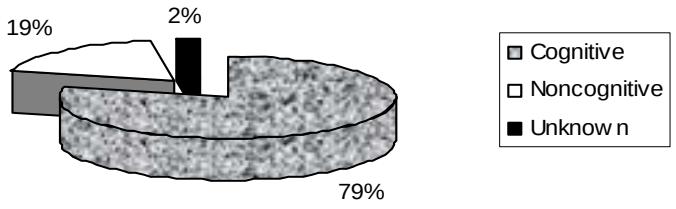


Medicine = 23, Elective Surgery = 10, Emergency Surgery = 5, Orthopedics = 3, Psychiatric = 2

Sentinel events are considered preventable and occur as the result of error. Errors can fall into two distinct groups: cognitive errors or 'mistakes', and non-cognitive errors or 'slips or lapses'. Mistakes reflect incorrect judgments or choices. Mistakes typically involve insufficient knowledge of, or failure to correctly interpret available information. Examples include ordering the wrong test or misinterpreting a laboratory result.

A non-cognitive error or 'slip' on the other hand, involves forgetting. An example would be failure to check a patient's identification prior to administering the medication. In 2008, the majority of cases, thirty four, (79%) involved cognitive errors. Only eight (19%) involved non-cognitive errors or 'lapses'.

Figure 13: 2008 Sentinel Events by type of error



Noncognitive = 8, Cognitive = 34 Unknown = 1

For hospitals, the "hand-off" has long been the "Bermuda Triangle" of health care (Landro 2006). Hand-off errors involve the period of time during which there is a transfer of rights, duties and obligations for a patient from one person or team to another. Hand-off issues include cross coverage/on call, nursing shift change/break relief, and transfer to another facility (e.g., tertiary

center, long term care facility). Ineffective hand-off can lead to wrong treatment, delay in diagnosis, and serious adverse events.

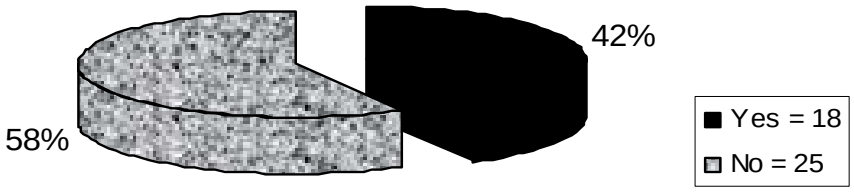
Eighteen (42%) of the forty three sentinel events reported in 2008 reflected problems in the transfer of knowledge from shift-to-shift report, or from physician-to-physician transfer of on-call responsibilities. In several instances, the information included critical laboratory or radiology tests ordered by one provider, and results going undetected by the incoming covering physician. Other examples of hand-off issues included incomplete or erroneous information relayed from the outpatient setting to the inpatient facility prior to a scheduled procedure.

Patients who are transferred to a higher level of care, a tertiary or secondary setting, are vulnerable to communication failures. Despite efforts to the contrary, there may be a breach in continuity of care in the process of transfer following discharge, or after the patient's return to the community (Wachter, 2004). Often there is no process in place to communicate back to the sending institution regarding results of treatment or issues surrounding the patient's care. This failure can contribute to error, and challenge the ability of the hospital to identify areas for improvement (Leonard, 2004).

In a number of cases, a sentinel event occurred and resulted in the need to transfer to a tertiary center. A technicality in the State's definition of a sentinel event does not place responsibility on the facility to report an event if the individual dies in another facility. The accountability for the patient's outcome and the reportability of the event thus may become ambiguous.

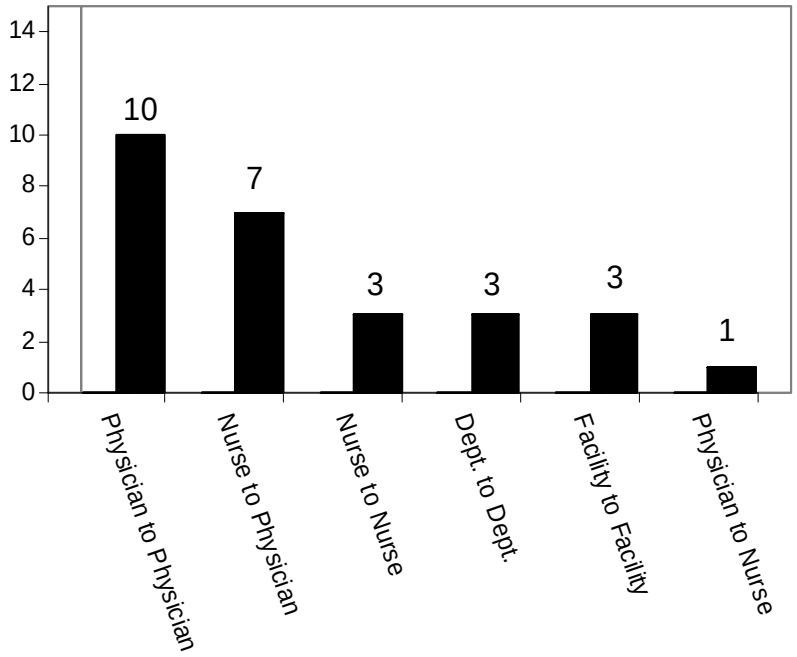
In 2008, hand off errors accounted for eighteen cases (42%) of all sentinel events reported. Of the eighteen cases, nine or (50%) had two types of handoff errors.

Figure 14: 2008 Sentinel Events with evidence of at least one handoff error



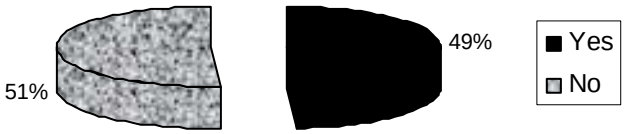
In 2008, seventeen (63%) of all handoff errors occurred in physician to physician communication or nurse to physician communication. In a study at the Massachusetts General Hospital, if the patient was coming from the Emergency Department or from another hospital, problematic handoffs were more likely. (Massachusetts General Hospital, 2008)

Figure 15: 2008 Sentinel Events by type of handoff error



In 2008, twenty one (49%) of reported sentinel events were characterized with a delay in treatment. The Joint Commission issued Sentinel Event Alert, Issue 26, "Delays in Treatment", in 2002. The report identified that there are many reasons for delays in treatment, the most common being misdiagnosis (42%). Other delaying factors included: delayed test results (15%); physician availability (13%); delayed administration of ordered care (13%); incomplete treatment (11%); delayed initial assessment (7%); patient left unattended (4%); paging system malfunction (2%); and unable to locate ER entrance (2%). The Joint Commission experience indicates that just over one half of the delays in treatment occur in the Emergency Department. In 2008 six of the twenty two (27%) sentinel events with evidence of delay in treatment were patients in the Emergency Department.

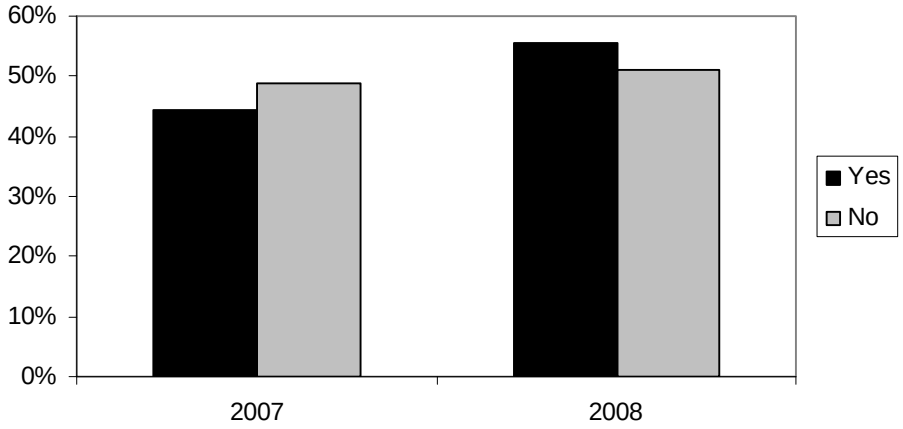
Figure 16: 2008 Sentinel Events with evidence of a delay in treatment



Yes = 21, No= 22

We first began to study cases for signs of delay in treatment preceding the sentinel event and contributing to the root cause in 2007. The number and rate grew to over 50% for sentinel event cases reported in 2008.

Figure 17: 2007 to 2008 Sentinel Events with evidence of a delay in treatment



12 cases had evidence of a delay versus 15 without in 2007
21 cases had evidence of a delay versus 22 without in 2008

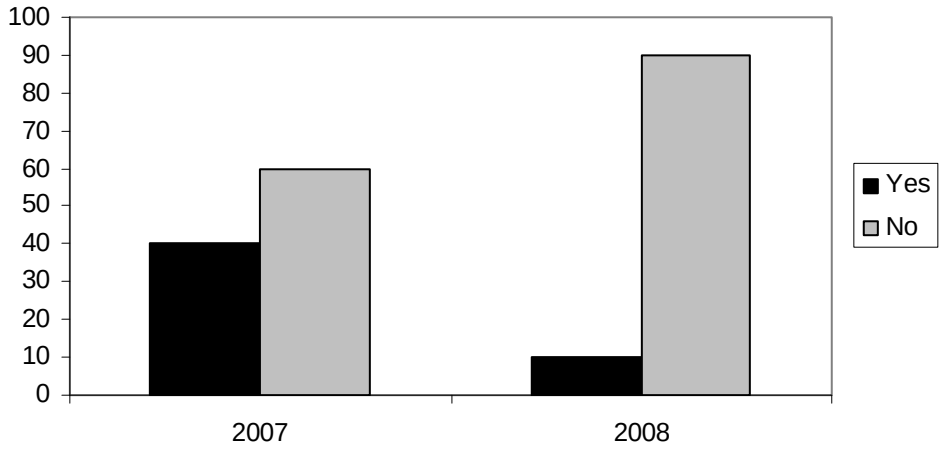
Sometimes steps are not taken in a timely manner to assure that the right person(s) is brought in to mediate a situation or to direct a proper course of action. This was a factor in seventeen (17) sentinel events reported in 2007. In several cases, a reluctance to involve the physician/provider resulted in a delay in treatment. Some of these situations occurred late at night or on the weekend when the provider was not available on-site.

Studies show that nurses are sometimes reluctant to activate the chain of command (Dougherty, 2007). Nationally, facilities are using evidence-based teamwork building systems, such as TeamSTEPPS™, to improve communication and teamwork skills among healthcare professionals (Agency for Healthcare Research and Quality, 2007 November). The goal of these programs is to create an atmosphere where people communicate without hierarchical barriers or

fear of reprisal. The Hospital Survey on Patient Safety Culture, sponsored by the Agency for Healthcare Research and Quality (AHRQ), assesses how well an environment or culture encourages health professionals to communicate about problems or share information about actions that can be taken to make care safer (Agency for Healthcare Research and Quality, 2007).

In 2008 there was evidence of failure to utilize the chain of command in only four (9%) cases. This improvement may be a sign of the success of the team training initiatives across the state.

Figure 18: 2007 and 2008 Sentinel Events with evidence of failure to utilize the chain of command

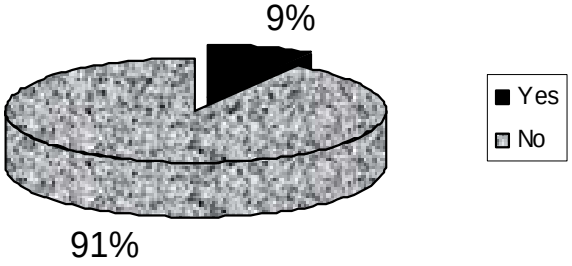


17 cases had a breach in the chain of command and 15 did not in 2007
4 cases had a breach in the chain of command and 39 did not in 2008

In 2007, we saw for the first time a trend involving patients well known to the Emergency Department and suffering a sentinel event. Although these patients are not easily identifiable, we continued to seek to find patients where that connection was recognized in 2008. We discovered an additional four patients (9%) who were well known to the Emergency Department and suffered a sentinel event.

This phenomenon has been characterized as a bias, or an inclination to prejudge a situation without fully reviewing the facts (Groopman, 2007). In these cases, familiarity with the patient seemed to be associated with a false sense of confidence or overconfidence that the problem was not new and that interventions applied in the past should be used.

Figure 19: 2008 Sentinel Events where the patient was well known to the ED



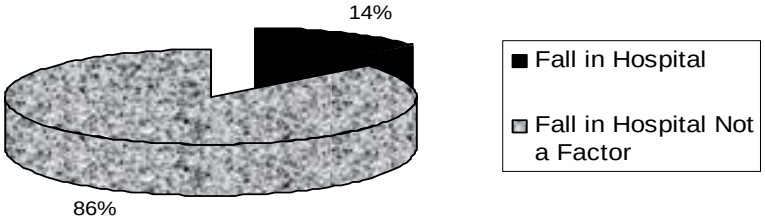
Well known = 4, No evidence of patient being well known = 39

Clinical Trends

In 2008, thirty six (84%) of all reported sentinel events identified issues with the clinical management of the patient. The trends listed below were not identified by the facility as the primary or only cause of a sentinel event. However, they all are thought to have contributed to the complexity of the situation and/or are important to understanding opportunities for future training and improvement.

Patient falls continue to be included in our sample and resulting in a sentinel event. In 2008, six (14%) of the reported sentinel events involved a patient who suffered a fall in the facility.

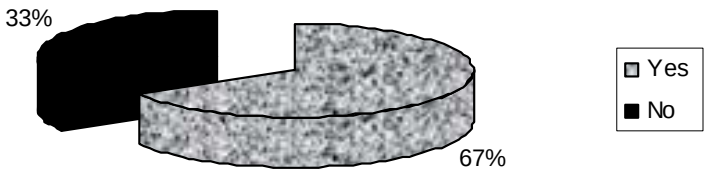
Figure 20: 2008 Sentinel Events where a fall in the facility was a factor



Falls = 6, No Fall = 37

For the first time we are reporting the frequency of anticoagulants involved in the patient fall resulting in a sentinel event. In 2008 four (67%) of the patient falls involved patients receiving anticoagulants.

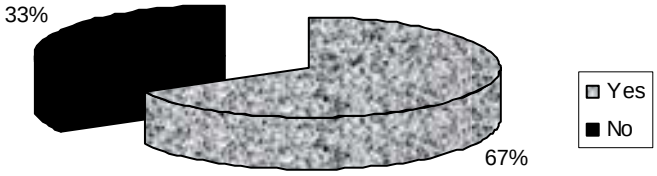
Figure 21: 2008 patients receiving anticoagulants and suffering a fall resulting in a Sentinel Event



Yes = 4, No = 2

In 2008 patient fall cases were studied for co-morbidities and found that four (67%) of the cases had a history of obesity and/or psychiatric history.

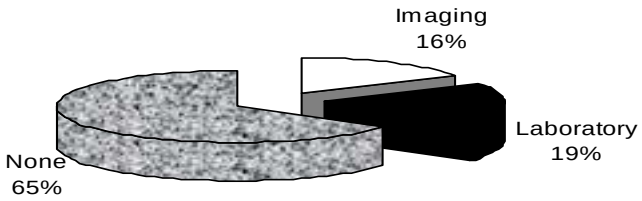
Figure 22: 2008 patients with co-morbidities, including obesity and/or psychiatric history that suffered a fall resulting in a Sentinel Event



Yes = 4, No = 2

In 2008, we identified for the first time, a trend in cases where a critical finding preceded sentinel events. These critical findings were found to be contributing factors in the root cause of the event. A critical finding is a diagnostic test result that requires immediate intervention. In these cases there may be a resulting delay in treatment or hand off error associated with the critical finding. A total of fifteen (35%) of reported sentinel events had evidence of a critical finding preceding the event. The Massachusetts Coalition for the Prevention of Medical Errors has developed Safe Practice Recommendations to promote successful communication of results, and a "starter set" of test results sufficiently abnormal to be widely agreed to be considered critical (Hanna, 2005).

Figure 23: 2008 Sentinel Events with evidence of a critical finding contributing to the cause of the event

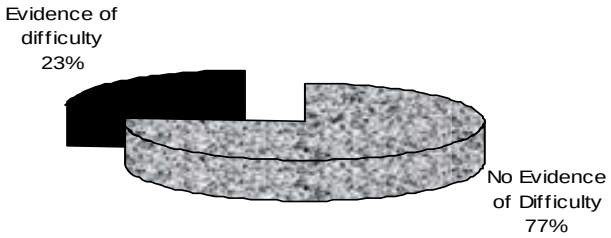


Imaging = 7, Laboratory = 8, None = 28

In 2007 difficulties encountered during tracheal intubation were identified as a pervasive problem in a variety of locations. In most instances it is not the causative factor for the sentinel event but a proximate cause. In 2008, seven (23%) of all of the sentinel events in which tracheal intubation was attempted were characterized with difficulties or failure. As in 2007, problems identified during intubation included:

- Misplacement of the tube, including esophageal intubation as well as tube placement in the right bronchus. In some cases, the incorrect placement of the tube was not immediately assessed or detected.
- Difficulty visualizing the vocal cords was cited following aspiration.
- Equipment availability, in particular specific blade or endotracheal tube sizes.
- Lack of familiarity with intubation equipment cited as an issue during the resuscitation attempt.

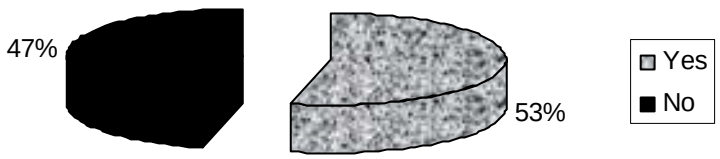
Figure 24: 2007 and 2008 Sentinel Events with documented intubation (or attempted intubation)



No difficulty = 23, Difficulty = 7, Total = 30

In 2007 a trend was identified in which patients involved with Sentinel Events were characterized with social and/or medical issues that raised questions about non-compliance, possibly 'difficult patients', or disenfranchised in the community. The 2008 Sentinel events were reviewed for those specific characteristics. Over half, twenty-two cases (53%) of the reported sentinel events had a history complicated by co-morbidities of obesity, substance abuse, mental retardation disability or psychiatric history. Research supports that people in minority groups and in lower social-class positions have higher morbidity and mortality rates from virtually every disease. (Syme, 2008)

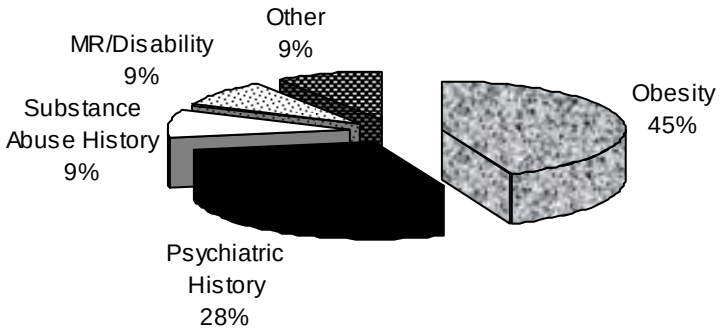
Figure 25: 2008 Sentinel Events with evidence of at least one of the following: obesity, psychiatric history, substance abuse history, MR/ disabled or noncompliant



Yes 22 =, No = 20

Specific characteristics for this group of patients associated with 2008 sentinel events are identified in the figure below.

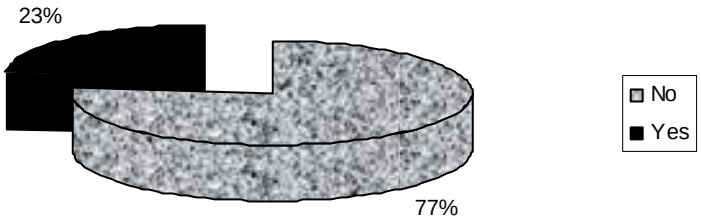
Figure 26: 2008 Sentinel Events with evidence of co-morbidities as demonstrated in Figure 25



Obesity = 14, Psychiatric History = 9, Substance Abuse History = 3, MR/Disabled = 3, Other = 3
Eight patients had more than one of the co-morbidities

In 2008 the sentinel event case reviews revealed a new finding in which low urine output was identified prior to the actual event. In none of these cases was the low urine output associated with the root cause or with the admitting diagnosis.

Figure 27: 2008 Sentinel Events with evidence of low urine output preceding the event



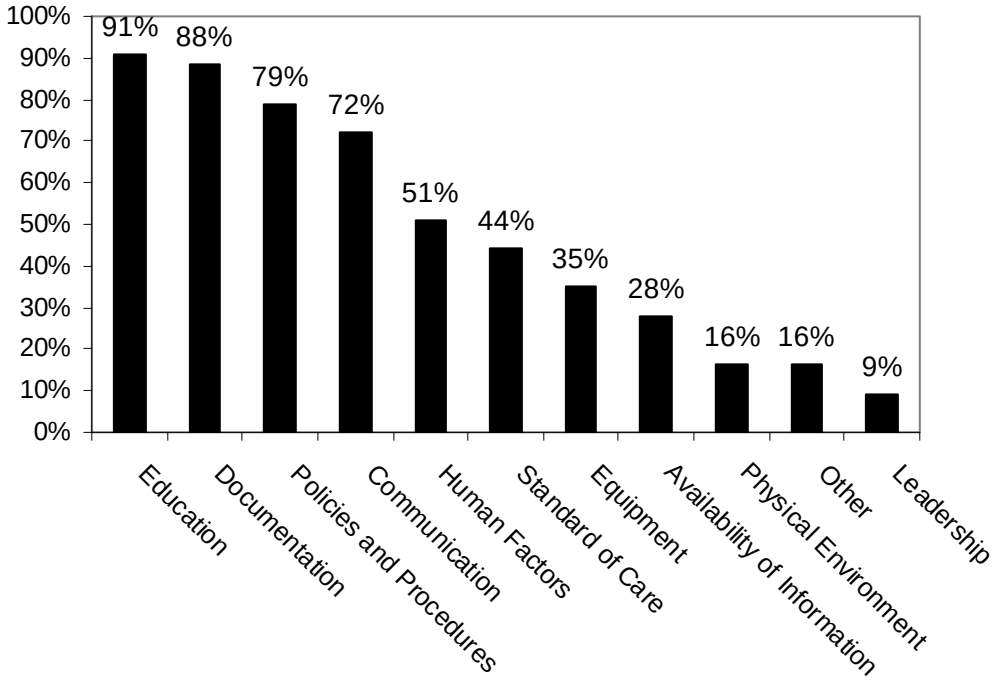
Yes = 10, No = 33

We will continue to study the clinical factors and events surround this finding.

■ Root Cause Analysis

After reporting an event, the facility is required to complete an analysis of root causes and a plan to prevent their recurrence. In 2008 root cause analysis results indicated that lack of education and inadequate documentation were the most prevalent causative factors. Thirty eight and thirty nine events attributed the root cause to those factors. Facilities reported policies and procedures and communication next in frequency. In those cases thirty four and thirty one case respectively cited those root causes. Human factors and standards of care explained twenty two and nineteen cases.

Figure 28: 2008 Sentinel Events facility reported root causes



Below we summarize summarizes the specific nature of root causes and action plans reported by facilities under each major category.

2008 Sentinel Events Facility-Reported Root Causes

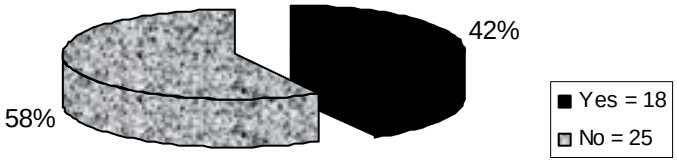
• **Cited Root Causes**
• Communication (number of events =10)
• Hand off communication failure • One-on-one communication failure • Incomplete Emergency Department record. No date/time, History and Physical • , inconsistent patient information and assessments • Delay in documentation in electronic Medical Record due to limited number of computers • Orders not dated or timed, incomplete consents, time out requirements not met • Unsigned physician orders • Inadequate communication from Emergency Department regarding pain assessment • Failure to communicate change in clinical status • Failure to communicate clinical information at change of shift
• Education/Training (number of events = 4)
• Lack of competency for tracheotomy care • Not all staff trained in Fall Risk Assessment • New personnel; unfamiliar forms
• Policy and Procedures (number of events = 6)
• No face to face pre-admission testing encounter, lack of formal anesthesia consult
• Documentation (number of events = 10)
• Pre-operative form inadequate to cover necessary aspects of surgical risks • Fall Risk Assessment does not incorporate pain medications, muscle relaxants, or antidepressants • Incomplete and inadequate forms and tools • Documentation deficiencies
• Human Factors (number of events = 12)
• Improper ordering and administration of pain medication • Staffing was not at optimal level • Physician not called for a critical lab value • Inadequate hand hygiene, resulting in transmission of c-difficile • Duplicate surgical marking
• Standard of Care (number of events = 6)
• Physician failed to assess patient • Mental Status issues not addressed in the Emergency Department
• Availability of Information (number of events = 2)
• Inconsistency among floors and units in executing post operative and discharge orders • Surgical area incorrectly identified due to lack of X-Ray films
• Equipment (number of events = 3)
• Surgical tray complete, but has a lot of equipment on it, leading to error • Failure to change time to identify Daylight Savings Time • Inpatient electronic medication ordering system would not generate an alert if drugs given in combination would have a synergistic effect with pain med

2008 Sentinel Events Facility-Reported Action Plans

Communication (number of events =13)
• Pharmacy to add strong dosing alerts to electronic system regarding the use fentanyl. • Pharmacist to follow up with prescriber for orders for contraindicated medications. • Pharmacist to follow up on orders for patches if ordered within first 72 hours
Education/Training (number of events = 16)
• Institute annual Fall Risk Assessment quiz for annual competency • Insure that all new and per diem staff are oriented to new forms • Development of a collaborative effort with area Skilled and Long Term Care facilities regarding infection control • Community outreach to schools regarding hand hygiene
Policy and Procedures (number of events = 16)
• Create in-house patient transport policy. Develop parameters for safe transport including the ability to provide oxygen, suction, and ability for patient to communicate with staff, and maintenance of current levels of clinical care during transport • Need to formalize leadership and oversight for assisted ventilator unit to be current with current best practice • Develop protocol for "critical" information transfer as part of Hand Off procedure • Pre-admission testing revised. Utilize a computerized web based application containing comprehensive medical questionnaire. New screens will prompt nursing to ask additional questions or request further tests. Designed to enhance clinical judgment. • Final verification will be changed to have a step added for the circulator nurse to view the surgeon's marking • Policy development and education for the labeling of specimens in the OR that will include active participation of the surgeons • Review DNR policy to best communicate patient's wishes
Documentation (number of events = 10)
• Revision of pre-operative form to incorporate discussion and documentation of explanation of high risk for surgery for both surgeon and anesthesiologist • Provide educational sessions on defensive documentation and specifically address blood transfusions consents, additions and deletions to documentation, dating and timing of orders and entries • Incorporation of tracheotomy care plan documentation as part of permanent record
Human Factors (number of events = 3)
• Implementation of an acuity tracking tool to review staffing patterns and identify opportunities for improvement in real time • Memos to all clinical staff regarding importance of meticulous hand hygiene and cleaning of equipment
Standard of Care (number of events = 4)
• Emergency Department staff reminded of alternative pain assessment tools [facial grimace scale] • Re-evaluate current Swing Bed Criteria and enforce appropriate use
Availability of Information (number of events = 2)
• Unit secretaries will receive checklists for medication discharge process at all computer station • Laboratory determined that digital films will be used routinely future cases
Equipment (number of events = 3)
• Electronic system now has mandatory fields for pain assessment/reassessment • Implementation of 1:10 dilution of bleach for routine cleaning to eradicate c-difficile

In 2008 a review was done to determine the tools that were being used by facilities to conduct root cause analyses. In the majority of cases, twenty five (58%) neither the Joint Commission nor Veterans Administration forms were being used. These tools are considered an industry standard and are found to be effective guides for the root cause process.

Figure 29: 2008 Sentinel Events where a Joint Commission or Veterans Administration Form was used



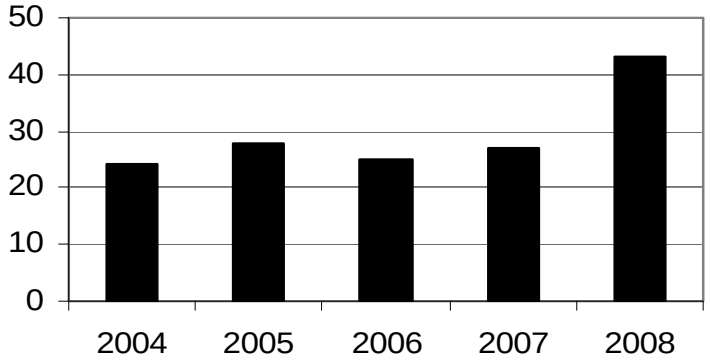
The use of standard tools assists in data gathering and sharing lessons learned to reduce the likelihood of recurrence

■ 5-Years Sentinel Event Retrospective 2004-2008

A total of one hundred and forty seven sentinel events have been reported since the inception of the program in 2004. Our internal medical record review process, the patient safety field, and the knowledge of events have developed during this time period as well. Specific findings and areas for research have been reported and recommendations for process improvements have been recommended nationally. In the state of Maine, we have identified specific attributes of cases and trends and have continued to add them to our data as they are recognized. It is for that reason that certain elements, for example delay in treatment, do not have data for the early years of the program.

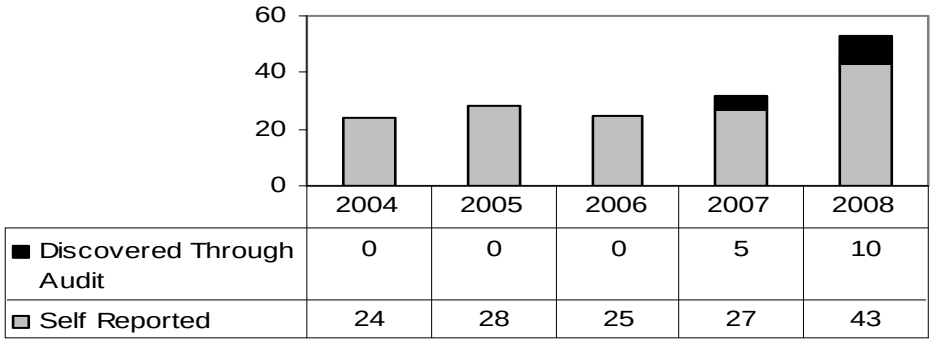
Reporting in the first four years of the program remained fairly static until 2008. A 50% increase in the number of reported Sentinel Events occurred in 2008, for a total of 43.

Figure 30: Number of Sentinel Events reported by year



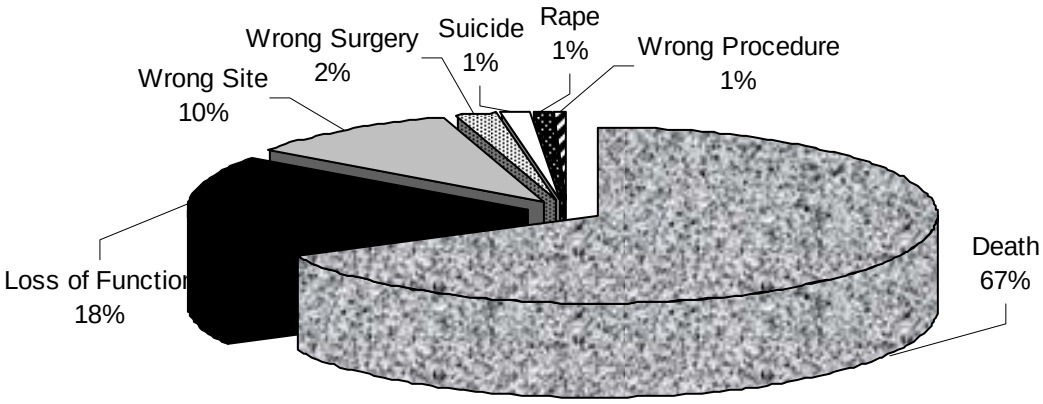
In 2007 and 2008, onsite audits were conducted by the Sentinel Event Team for the purpose of education and discovery. During that process a total of 15 unreported Sentinel Events were discovered.

Figure 31: Sentinel Events discovered through audit versus self reported



Throughout this five year period, unanticipated patient deaths represented the greatest number of reported sentinel event (99 out of the 147 sentinel events reported). This is consistent with the Joint Commission experience.

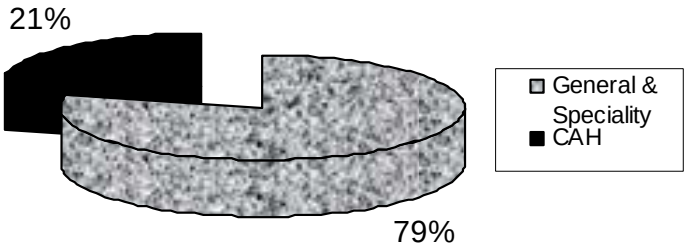
Figure 32: Sentinel Events by type 2004 to 2008



Total Reports = 147

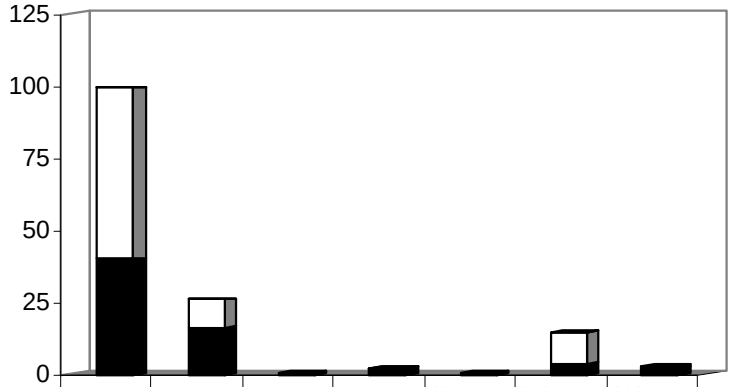
Out of a total of forty-one (41) hospitals in the state, fifteen (15) are Critical Access Hospitals, the remaining twenty-six (26) are general and specialty hospitals. In 2008, 79% of the total number of events were reported by general and specialty hospitals.

Figure 33: Sentinel Events by hospital type 2004 to 2008



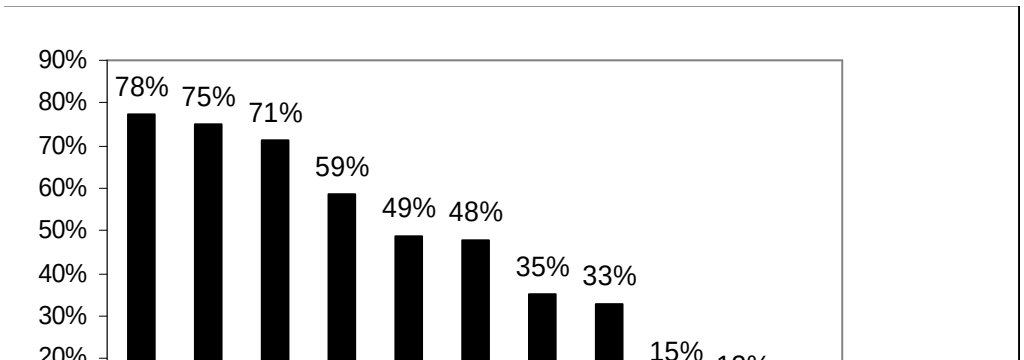
General and Specialty Hospital = 110
Critical Access Hospital = 30

Figure 34: Sentinel Events by gender and event type 2004 to 2008



	Death	LOF	Rape	Suicide	Wrong Proced	Wrong Site	Wrong Surg
Female = 83	59	10	1	0	1	11	1
Male = 64	40	16	0	2	0	4	2

Figure 35: Facility reported Sentinel Event root causes 2004 to 2008



Context for Reviewing Maine's Sentinel Events

A common response when reviewing findings from a state's adverse event reporting system is to question whether the numbers are good or bad, complete or incomplete, and how they compare to benchmarks. These are reasonable questions that cannot be easily or definitively answered. At best we are able to show how Maine's 43 reported events fit within a range of estimated adverse events to assess our relative standing. Even then, we are not able to determine the nature of any variation or why it exists.

There are many reasons why differences in the rate of adverse events may exist, only some of which are indicative of variations in quality.

- Adverse events are defined differently across states and within the research community. Thus, in the aggregate, rates of adverse events will differ. Even within a single category of event (e.g., unanticipated death) interpretations of what must be reported may vary thus leading to a different number of reported events.
- The number and type of adverse events are affected by the mix of hospital size, volume and patient acuity – factors that vary within and across states.
- Low numbers of adverse events should not automatically be interpreted as improved performance. In cases of a hospital that rarely reports or persistently reports no events, failure to report may indicate the lack of an effective internal system for detecting problems or learning from mistakes.
- Similarly, high numbers of adverse events are not necessarily indicative of poor care.

State reporting systems generally have low rates of adverse event reporting when first implemented. The number of adverse events typically increases within hospitals as their systems for identifying and reporting events improve and they better understand the requirements for what constitutes a reportable event (Rosenthal et al, 2001). Contrary to these national trends, reporting levels have remained fairly static in Maine since the program began in 2004.

Maine's sentinel event reporting system was designed to encourage reporting. The confidentiality of reports, the public disclosure of only aggregate reports without hospital identifiers, and the separation of reporting from the hospital licensure process were embedded in the system as ways to promote reporting, collaboration and shared learning. Understanding that it is not possible to solve problems that are not identified, Maine's sentinel event reporting system was intended to look beyond blame and promote patient safety through collaboration and shared responsibility. An important precept of the system has been to provide a non-punitive environment for reporting so that others can learn from mistakes and prevent their recurrence.

With these goals in mind, Maine has looked for ways to determine how well the State is doing in identifying and reporting events and thus learning from the mistakes that are occurring. The following two tables estimate the potential upper and lower bounds for the number of adverse events that may be occurring in Maine's hospitals based on national studies. There is wide variation in findings among the studies, given how each study defined a "reportable event". Some studies captured a broad net of events, including near misses or all adverse events, not just those defined as serious adverse events under Maine's reporting system.

The purpose of Table 10 is to illustrate the range of events that may be occurring in Maine hospitals. A total of 43 adverse events were reported under the sentinel event reporting system in 2008. Table 10 should not be used to determine how well Maine's reporting system is capturing reportable events given variations in how an adverse event is defined by the studies compared to reporting requirements in Maine. However, the magnitude of the discrepancy suggests serious under-reporting in Maine.

Table 3. The Expected Rate of Events in Maine Using Estimates Derived from National Studies

Study	Rate of Adverse Events	Maine 2006* Expected Number **
Sari *et al* (2007) Random sample of 1006 hospital admissions in 2004 in a large national health service hospital in England. Focus was on the full range of adverse events.	8.7 per 100 admissions	12.915
Nuckols *et al* (2007) Review of 16,575 randomly selected patients from an academic and community hospital in the US in 2001. Focus was on the full range of adverse incidents occurring in hospitals.	17 per 1000 patient days*	11,437
Baker *et al, (2004)* Review of incidence of adverse events among 1 teaching, 1 large community and 2 small community hospitals in each of 5 Canadian provinces in	7.5 per 100 admissions* *	11,133

2000. Focus was on the full range of adverse incidents occurring in hospitals.		
Davis *et al* (2002) Review of 6579 records in 13 public hospitals with 100 beds or more in New Zealand, 1998. Focus was on preventable adverse events.	6.3 per 100 admissions	9,352
Brennan *et* al (1991) Harvard Medical Practice Study. Review of 30,124 randomly selected records from 51 randomly selected acute care, non-psychiatric hospitals in NY in 1984. Focus was on injuries caused by medical management.	3.7 per 100 hospital discharges	5,492
Thomas *et a*l (2002) Review of 15,000 medical records from 28 hospitals in Utah and Colorado in 1992. Focus on injury caused by medical management those results in prolonged hospital stay or disability at discharge.	2.9 per 100 admissions	4,305

Data provided by the Maine Health Data Organization (MHDO) for the CY 2006, the most recent full year of data available.**Estimates derived by applying the rate adverse events found in each study to applicable Maine data for CY 2006. Note that discharges and discharge days were used in place of admissions and patient days. Discharges and discharge days do not include codes related to mental illness and disorders, alcohol and drug abuse.

Table 11 looks at only the subset of adverse events related to deaths. Each of the identified studies focused on identifying deaths that were caused by medical management and could have been prevented. Definitions used in these studies for "probably preventable" approximate the reportable event under Maine's reporting system known as "unanticipated death".

Table 4: The Expected Rate of Unanticipated Deaths in Maine Hospitals Using Estimates Derived from National Studies

Study	Rate of Adverse Events	Maine 2006* Expected Number **
Dubois and Brook (1988). Reviewed 182 deaths from 12 hospitals to assess those that were preventable	27% of deaths might be preventable; **14% probably preventable**	1026 deaths might be preventable; 532 deaths probably preventable
Hayward and Hofer (2001). Reviewed records on 111 hospital deaths at 7 VA Centers, 1995-96.	22.7% of deaths might have been preventable; **6.0% probably preventable**	1008 deaths might be preventable; 224 deaths probably preventable

* Data provided by the Maine Health Data Organization (MHDO) for the CY 2006, the most recent full year of data available.
** Estimates derived by applying the rate of deaths in each study to total number of deaths occurring in Maine

hospitals for CY 2006.

The actual number of unanticipated deaths reported in Maine was 14 in 2006, 20 in 2007, and 31 in 2008. Tables 3 and 4 help put Maine's sentinel event reporting system within a broader context and raise questions about whether the current system is effective in identifying all serious events. Later we discuss plans for the coming year to strengthen the program and to work more closely with hospitals to improve the detection and disclosure of reportable events.

Conclusions and Recommendations

Maine's sentinel event reporting system focuses on identifying and deterring serious, preventable incidents. Mandatory reporting is the primary tool for the State to hold facilities accountable for disclosing that an event has occurred and that appropriate action has been taken to remedy the situation. The system was designed to learn from mistakes, not punish individual practitioners or providers. To be effective, the system requires the participation of all hospitals and other reporting entities. Only by understanding the full scope of the problem can strategies be developed to improve patient safety throughout the State. However, findings suggest that there is serious under-reporting in Maine.

In the coming year, the sentinel event program will work closely with hospitals and others to strengthen the reliability of reporting.

- The State will continue to utilize Maine's all-payer database to validate whether all events are being reported. The State will work with the Maine Health Data Organization, the Maine Quality Forum and Maine hospitals to identify reportable events that can reliably be detected through administrative data and to develop the specifications for doing so. Results from this analysis will be used for case finding.

- Onsite audits with hospitals and other facilities will be used to validate that all sentinel events have been reported.

- The Sentinel Event Team will continue to assess the adequacy of hospitals' internal systems for detecting and reporting events and to explore why some hospitals have not reported.

- Complaint data will continue to serve as a cross-check on the reporting system for those incidents that rise to the level of a reportable event.

Finally, the program will continue to maintain ongoing communications with Maine hospitals, other licensed facilities and stakeholders regarding reporting requirements and lessons that can be learned to prevent events from being repeated. The State is committed to maintaining a collaborative approach for identifying serious adverse events and working toward joint solutions for reducing their occurrence in a non-punitive environment. However, the overarching goal of the reporting system is to improve the quality of health care and to honor our pledge to the Maine people that the State is a credible overseer of the quality of care in Maine.

Endnotes

[1] Exceptions include cases of a complaint investigation or if the hospital is selected by the Medicare program for a survey to validate Joint Commission findings.

[2] Since the original publication of the NQF list of serious reportable events, additional events have been added.

[3] Me. Rev. Stat. Ann. tit. 22, § 8753 (2003). Definitions at http://janus.state.me.us/legis/statutes/22/title22sec8752.html

References

Agency for Healthcare Research and Quality. (2007, November). TeamSTEPPS™: Strategies and tools to enhance performance and patient safety. Rockville, MD: AHRQ. http://www.ahrq.gov/qual/teamstepps/

Agency for Healthcare Research and Quality. (2007, April). Patient Safety Culture Surveys. Rockville, MD: AHRQ. MACROBUTTON HtmlResAnchor http://www.ahrq.gov/qual/hospculture/

Baker, G.R., Norton, P.G., Flintoft, V. et al. (2004). The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. CMAJ, 17, 1678-1686

Becker, D.J. (2007). Do hospitals provide lower quality care on weekends? Health Services Research, 42,1589-1612

Bendavid, E., Kaganova, Y., & Needleman, J. (2007, May). Complication rates on

weekends and weekdays in US hospitals. American Journal of Medicine, 120,422-428

Booth, M., & Rosenthal, J. (2007, May). An assessment of the Maine sentinel event reporting system. A report prepared for the Maine Quality Forum.

Brennan, T.A., Leape, L.L., Laire, N.M., Hebert, L. et al. (1991). Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study. New England Journal of Medicine,324,370-376.

Davis, P., Lay-Yee, R., Briant, R., Scot, A., Ali, W., & Schug, S. (2002). Adverse events in New Zealand public hospitals: Occurrence and impact. New Zealand Medical Journal, 115(1167), 1-9.

Dougherty, S., Whaley, J., Youngblood, A., & Pickoff, R. (2007). Respect, communication, and best practices. Patient Safety & Quality Healthcare, 4(6), 32-38.

Dubois, R.W., & Brook, R.H. (1988). Preventable deaths: Who, how often, and why? Annals of Internal Medicine, 109(7), 582-589.
Groopman, J. (2007). How doctors think. Houghton Mifflin Co: New York.

Hanna, D., Griswold, P., Leape, L.L., Bates, D.W. (2005, Feb.). Communicating critical test results: Safe practice recommendations [abstract].
http://www.ncbi.nlm.nih.gov/pubmed/15791766

Hayward, R.A., & Hofer, T.P.(2001). Estimating hospital deaths due to medical errors: Preventability is in the eye of the reviewer. JAMA, 286(4),415-420.

Joint Commission. (2007, July). Sentinel Events Policy and Procedures. [Online] Accessed Feb. 13, 2008.URL
http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se.pp.htm.

Kohn, L.T., Corrigan, J.M., Donaldson, M.S. eds. (2000). To err is human: Building a safer health system. Washington, DC: National Academy Press.

Landro, L. (2006, June 28) Hospitals combat errors at the hand-off. [Online] Pittsburgh Post-Gazette. www.post-gazette.com/pg/06179/701770-114.stm

Massachusetts General Hospital (2008, Sept. 23). Residents Report Patient-Handoff Problems Common, can Lead to Patient Harm http://www.massgeneral.org/about/pressrelease.aspx?id=1057

National Academy for State Health Policy (2007). 2007 guide to state adverse event reporting systems, State Health Policy Survey Report, Vol. 1, No.1. Portland, ME: National Academy for State Health Policy

National Quality Forum. (2002). Serious reportable events in healthcare: A consensus report. Washington, DC: The National Quality Forum

Nuckols, T.K., Bell, D.S., Liu, H., Padock, S.U., & Hilborne, L.H. (2007). Rates and types of events reported to established incident reporting systems in two U.S. hospitals. Quality and Safety in Health Care, 16(3), 164-168

Rosenthal, J., Booth, M., Flowers, L., & Riley, T. (2001). Current state programs addressing medical errors: An analysis of mandatory reporting systems and other initiatives. Portland, ME: National Academy for State Health Policy

Rosenthan, J., & Takach, M. (2007, December). 2007 guide to state adverse event reporting systems. (State Health Policy Survey Report, Vol. 1, No.1). Portland, ME: National Academy for State Health Policy. http://www.nashp.org.Files/shpsurveyreport_adverse2007.pdf.

Sari, A., Sheldon, T., Cracknell, A., Turnbull, A., & Dobson, & Y. (2007). Extent, nature and consequences of adverse events: results of a retrospective case review in a large NHS hospital; Quality and Safety in Health Care, 16, 164-168.

Syme, L. (2008). Reducing Racial and Social-Class Inequalities in Health: The need for a New Approach. http://www.medscape.com/viewarticle/574455

The Joint Commission (2002). Sentinel Event Alert, Issue 26, Delays in Treatment. www.**jointcommission**.org/SentinelEvents/SentinelEventAlert/sea

Thomas, E.J., Lipsitz, S.R., Studdert, D.M., & Brennan, T.A. (2002). The reliability of

medical record review for estimating adverse event rates. Annals of Internal Medicine,136(11), 812-816.

Wachter, R.M., Shojania, K.G. (2004). Internal bleeding: The truth behind America's terrifying epidemic of medical mistakes. New York: Rugged Land Publishing.

Appendix A

Chapter 1684: SENTINEL EVENTS REPORTING (HEADING: PL 2001, c. 678, §1 (new))

§8751. Sentinel event reporting

There is established under this chapter a system for reporting sentinel events for the purpose of improving the quality of health care and increasing patient safety. [2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

§8752. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [2001, c. 678, §1 (new); §3 (aff).]

1. Division. "Division" means the Division of Licensing and Certification within the Bureau of Medical Services.

[2001, c. 678, §1 (new); §3 (aff).]

2. Health care facility. "Health care facility" or "facility" means a state institution as defined under Title 34-B, chapter 1 or a health care facility licensed by the division, except that it does not include a facility licensed as a nursing facility or licensed under chapter 1665.

[2001, c. 678, §1 (new); §3 (aff).]

3. Major permanent loss of function. "Major permanent loss of function" means sensory, motor, physiological or intellectual impairment that requires continued treatment or imposes persistent major restrictions in activities of daily living.

[2001, c. 678, §1 (new); §3 (aff).]

4. Sentinel event. "Sentinel event" means:

A. One of the following that is determined to be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition or that results from the elopement of a hospitalized inpatient who lacks the capacity, as defined in Title 18-A, section 5-801, subsection (c), to make decisions:

(1) An unanticipated death; or

(2) A major permanent loss of function that is not present when the patient is admitted to the health care facility;

[RR 2001, c. 2, Pt. A, §37 (cor); §38 (aff).]

B. Surgery on the wrong patient or wrong body part; [2001, c. 678, §1 (new); §3 (aff).]

C. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; [2001, c. 678, §1 (new); §3 (aff).]

D. Suicide of a patient in a health care facility where the patient receives inpatient care; [2001, c. 678, §1 (new); §3 (aff).]

E. Infant abduction or discharge to the wrong family; or [2001, c. 678, §1 (new); §3 (aff).]

F. Rape of a patient. [2001, c. 678, §1 (new); §3 (aff).]

[RR 2001, c. 2, Pt. A, §37 (cor); §38 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).
RR 2001, Ch. 2, §A37 (COR).
RR 2001, Ch. 2, §A38 (AFF).

§8753. Mandatory reporting of sentinel events

A health care facility shall report to the division a sentinel event that occurs to a patient while the patient is in the health care facility as provided in this section. [2001, c. 678, §1 (new); §3 (aff).]

1. Notification. A health care facility shall notify the division of the occurrence of a sentinel event by the next business day after the sentinel event has occurred or the next business day after the facility determines that the event occurred. The notification must include the date and time of notification, the name of the health care facility and the type of sentinel event pursuant to section 8752, subsection 4.

[2001, c. 678, §1 (new); §3 (aff).]

2. Reporting. A health care facility shall file a written report no later than 45 days following the notification of the occurrence of a sentinel event pursuant to subsection 1. The written report must be signed by the chief executive officer of the facility and must contain the following information:

A. Facility name and address; [2001, c. 678, §1 (new); §3 (aff).]

B. Name, title and phone number of the contact person for the facility; [2001, c. 678, §1 (new); §3 (aff).]

C. The date and time of the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

D. The type of sentinel event and a brief description of the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

E. Identification of clinical and organizational systems or processes that may have contributed to the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

F. Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and [2001, c. 678, §1 (new); §3 (aff).]

G. A brief description of any corrective action taken or planned. [2001, c. 678, §1 (new); §3 (aff).]

[2001, c. 678, §1 (new); §3 (aff).]

3. Cooperation. A health care facility that has filed a notification or a report of the occurrence of a sentinel event under this section shall cooperate with the division as necessary for the division to fulfill its duties under section 8754.

[2001, c. 678, §1 (new); §3 (aff).]

4. Immunity. A person who in good faith reports a sentinel event pursuant to this chapter is immune from any civil or criminal liability for the act of reporting or participating in the review by the division. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. This subsection may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

[2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

§8754. Division duties

The division has the following duties under this chapter. [2001, c. 678, §1 (new); §3 (aff).]

1. Initial review; other action. Upon receipt of a notification or report of a sentinel event, the division shall complete an initial review and may take such other action as the division determines to be appropriate under applicable rules and within the jurisdiction of the division.

The division may conduct on-site reviews of medical records and may retain the services of consultants when necessary to the division.

[2001, c. 678, §1 (new); §3 (aff).]

2. Procedures. The division shall adopt procedures for the reporting, reviewing and handling of information regarding sentinel events. The procedures must provide for electronic submission of notifications and reports.

[2001, c. 678, §1 (new); §3 (aff).]

3. Confidentiality. Notifications and reports of sentinel events filed pursuant to this chapter and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.

A. Privileged and confidential information under this subsection is not:

(1) Subject to public access under Title 1, chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;

(2) Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or

(3) Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

[2001, c. 678, §1 (new); §3 (aff).]

B. The transfer of any information to which this chapter applies by a health care facility to the division or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established under this chapter or other laws of this State. [2001, c. 678, §1 (new); §3 (aff).]

C. The division shall take appropriate measures to protect the security of any information to which this chapter applies. [2001, c. 678, §1 (new); §3 (aff).]

D. This section may not be construed to limit other privileges that are available under federal law or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this subsection. [2001, c. 678, §1 (new); §3 (aff).]

E. For the purposes of this subsection, "privileged and confidential information" does not include:

(1) Any final administrative action;

(2) Information independently received pursuant to a 3rd-party complaint investigation conducted pursuant to department rules; or

(3) Information designated as confidential under rules and laws of this State.

[2001, c. 678, §1 (new); §3 (aff).]

This subsection does not affect the obligations of the department relating to federal law.

[2001, c. 678, §1 (new); §3 (aff).]

4. Report. The division shall develop an annual report to the Legislature, health care facilities and the public that includes summary data of the number and types of sentinel events of the prior calendar year by type of health care facility, rates of change and other analyses and an outline of areas to be addressed for the upcoming year. The report must be submitted by February 1st each year.

[2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

§8755. Compliance

A health care facility that knowingly violates any provision of this chapter or rules adopted pursuant to this chapter is subject to a civil penalty payable to the State of not more than $5,000 per unreported sentinel event to be recovered in a civil action. Funds collected pursuant to this section must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education. [2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

§8756. Rulemaking

The department shall adopt rules to implement this chapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter II-A. [2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

Appendix B

Rules Governing the Reporting of Sentinel Events

10-144 CMR Chapter 114
Effective Date January 1, 2009

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Statutory Authority ..... **A**

Purpose. The Regulations Governing the Reporting of Sentinel Events create a system for reporting all sentinel events to improve the quality of healthcare and increase patient safety. The reporting system focuses the attention of a health care facility on understanding the causes that underlie the event and on changing systems and processes to reduce the probability of future events.

Section 1. **Definitions**. As used in these rules, unless the context otherwise indicates, the following terms have the following meanings.

1.1 **DLRS.** "DLRS" means the Division of Licensing and Regulatory Services, Maine Department of Health and Human Services. The Sentinel Events Team (SET) is a unit of DLRS.

1.2 **Health Care Facility.** "Health care facility" or "facility" means the following:

1.2.1 State institutions including the Riverview Psychiatric Center and the Dorothea Dix Psychiatric Center (34-B M.R.S.A. Chapter 1);

1.2.2 All hospitals licensed pursuant to 22 M.R.S.A. Chapter 405, including all service locations as indicated on the hospital license application;

1.2.3 Ambulatory surgical facilities licensed pursuant to 22 M.R.S.A. Chapter 405;

1.2.4 Intermediate Care Facilities for Persons with Mental Retardation - Nursing (ICF/MR Nursing) licensed pursuant to 22 M.R.S.A. Chapters 1 and 405, and the Elizabeth Levinson Center (34-B M.R.S.A. Chapter 1); and

1.2.5 End-stage renal disease (ESRD) facilities licensed pursuant to 22 M.R.S.A. Chapter 412.

1.2.6 Health care facility does not include a facility licensed as a nursing facility pursuant to 22 M.R.S.A. Chapter 405, or assisted housing programs licensed pursuant to 22 M.R.S.A. Chapter 1664.

1.3 **Major Permanent Loss of Function**. "Major permanent loss of function" means sensory, motor, physiological or intellectual impairment that

1.3.1 requires continued treatment or

1.3.2 imposes persistent major restrictions in activities of daily living.

1.4 **Root Cause Analysis.** "Root cause analysis" (RCA) means a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. RCA focuses primarily on systems and processes, not on individual performance. RCA progresses from causes in clinical processes to causes in organizational systems. Improvements are identified that would tend to decrease the likelihood of such events in the future.

1.5 **Sentinel Event**. A "sentinel event" means:

1.5.1 An unanticipated death that is determined:

1.5.1.1 to be unrelated to the natural course of the patient's illness or underlying condition; or

1.5.1.2 to be unrelated to the proper treatment of the patient's illness or underlying condition; or

1.5.1.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).

1.5.2 A major permanent loss of function, as defined in section 1.3, that is not present when the patient is admitted to the health care facility that is determined:

1.5.2.1 to be unrelated to the natural course of the patient's illness or underlying condition; or

1.5.2.2 to be unrelated to the proper treatment of the patient's illness or underlying condition; or

1.5.2.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).

1.5.3 Surgery on the wrong patient or wrong body part;

1.5.4 Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities;

1.4.5 Suicide of a patient in a health care facility where the patient receives inpatient care;

1.5.6 Infant abduction or discharge to the wrong family; or

1.5.7 Rape of a patient. Rape, as a reportable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the health care facility, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ or object. One or more of the following must be present to determine reportability:

1.5.7.1 Any staff-witnessed sexual contact as described above.

1.5.7.2 Sufficient clinical evidence obtained by the health care facility to support allegations of unconsented sexual contact.

1.5.7.3 Admission by the perpetrator that sexual contact, as described above, occurred on the premises.

1.6 Sentinel Events Reporting System. **"**Sentinel events reporting system" means a system for reporting sentinel events for the purpose of improving the quality of health care and increasing patient safety.

Section 2. Mandatory Reporting of Sentinel Events

2.1 Sentinel Events Team. The Sentinel Events Team (SET), a unit of the Division of Licensing and Regulatory Services (DLRS), is assigned the responsibility to implement these rules.

2.2 Mandatory report. A health care facility is mandated to notify the SET of a sentinel event that occurs in the health care facility as defined in Section 1.2 of these rules. If a facility has reasonable cause to believe that a sentinel event may have occurred, it may confer with the SET, which shall determine whether the event is reportable.

2.3 **Notification.** The health care facility must notify the SET of the occurrence of a sentinel event by the next business day after the sentinel event occurred or the next business day after the facility determines that the event occurred. The written notification must include the following information:

2.3.1 Name of the health care facility;

2.3.2 Type of sentinel event as defined in Section 1.5 above;

2.3.3 Date and time of the sentinel event; and

2.3.4 Date and time of notification.

2.4 **Written report.** A health care facility must file a written report with the SET no later than forty-five (45) days following the notification of the occurrence of a sentinel event. The written report must contain the following information:

2.4.1 The health care facility name and address;

2.4.2 The name, title, telephone number, email address, and fax number of the contact person designated by the health care facility;

2.4.3 The date and time of the sentinel event;

2.4.4 The type of sentinel event, as defined in Section 1.5 above, and a brief description of the sentinel event;

2.4.5 A copy of a thorough and credible RCA. See Section 1.4.

2.4.6 Identification of changes that could be made to reduce the risk of the sentinel event occurring in the future;

2.4.7 A brief description of any corrective action taken or planned;

2.4.8 The signature of the chief executive officer of the health care facility.

2.5 **SET acceptance of report.** The SET will determine if the written report is acceptable.

2.6 **Immunity.** A person who in good faith reports a sentinel event in accordance with these rules is immune from any civil or criminal liability for the act of reporting or participating in the review by DLRS. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. These rules may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

2.7 **Annual notification.** By January 30 of each year, on a form provided by the SET, each health care facility must send the SET a written notice that contains an affirmative statement that it reported, in accordance with Section 2.2, all sentinel events that occurred in the prior calendar year.

Section 3. SET Review Procedure of Sentinel Events

3.1 **Cooperation.** A health care facility that has filed a notification or a report of the occurrence of a sentinel event, as required by these rules, must cooperate with the SET as necessary for the SET to fulfill its duties.

3.2 **Initial review.** Upon receipt of a notification or report of a sentinel event, the SET shall complete an initial review and may take other action that the SET determines is appropriate according to these rules.

3.3 **On-site reviews.** The SET may conduct on-site reviews of medical records and may retain the services of consultants when determined necessary by the SET.

3.4 **Annual SET Report.** On or before February first of each calendar year, the SET shall submit an annual sentinel events report to the Legislature, health care facilities, and the public. The report must include summary data of the number and types of sentinel events for the prior calendar year, including

3.4.1. a compilation of data by type of health care facility;

3.4.2 a compilation of data by rates of change and other analyses; and

3.4.3 an outline of areas to be addressed during the next 12 months.

3.5 **Civil Penalties.** A health care facility that knowingly violates any provision of the sentinel events reporting law or rules is subject to a civil penalty payable to the State of not more than $5000 per unreported sentinel event to be recovered in a civil action. Funds collected pursuant to this rule must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

Section 4. Confidential and Privileged Information

4.1 **Access.** The SET has access to all licensed facility records necessary to carry out the provisions of these rules. The records obtained by the SET are not available to the public except as allowed by law.

4.2 **Federal law.** These rules do not affect the obligations of the department relating to Federal law.

4.3 **Confidential and privileged information.** Notifications and reports of sentinel events filed pursuant to these rules and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.

4.3.1 **Not subject to public access, discovery, or admissible as evidence.** Privileged and confidential information subject to these rules is not:

4.3.1.1 Subject to public access under 1 M.R.S.A. Chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;

4.3.1.2 Subject to discovery, subpoena or other means of legal compulsion for release to any person or entity; or

4.3.1.3 Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

4.3.2 **Not a waiver of privilege.** The transfer of any information subject to these rules by a health care facility to the SET or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established by these rules, the sentinel events reporting law, or other applicable Maine laws.

4.3.3 **Other privileges**. These rules may not be construed to limit other privileges that are available under federal and state laws that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided by the Sentinel Events Reporting statute.

4.3.4 **Exclusions.** For the purposes of these rules, "privileged and confidential information" does not include:

4.3.4.1 Any final administrative action;

4.3.4.2 Information independently received pursuant to a third party complaint investigation conducted pursuant to department rules; or

4.3.4.3 Information designated as confidential under rules and laws of this State.

4.3.5 Security of information. The SET shall take appropriate measures to protect the security of any information that is subject to these rules.

Statutory Authority

22 M.R.S.A. Chapter 1684
22 M.R.S.A. §42
22-A M.R.S.A. §205

Regulatory History

Public Law 2001, chapter 678, established laws governing the reporting sentinel events and instructed the department to adopted rules to implement chapter 678.

ADOPTED

Deleted sentinel events reporting provisions in the following:

10-144 C.M.R. Ch. 112	Regulations for the Licensure of General and Specialty Hospitals in the State of Maine.
10-144 C.M.R. Ch. 118	Regulations Governing the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation.
10-144 C.M.R. Ch. 125	Regulations Governing the Licensing of Ambulatory Surgical Facilities.
10-144 C.M.R. Ch. 126	Regulations Governing the Licensing and Functioning of End Stage Renal Disease Units/Facilities.

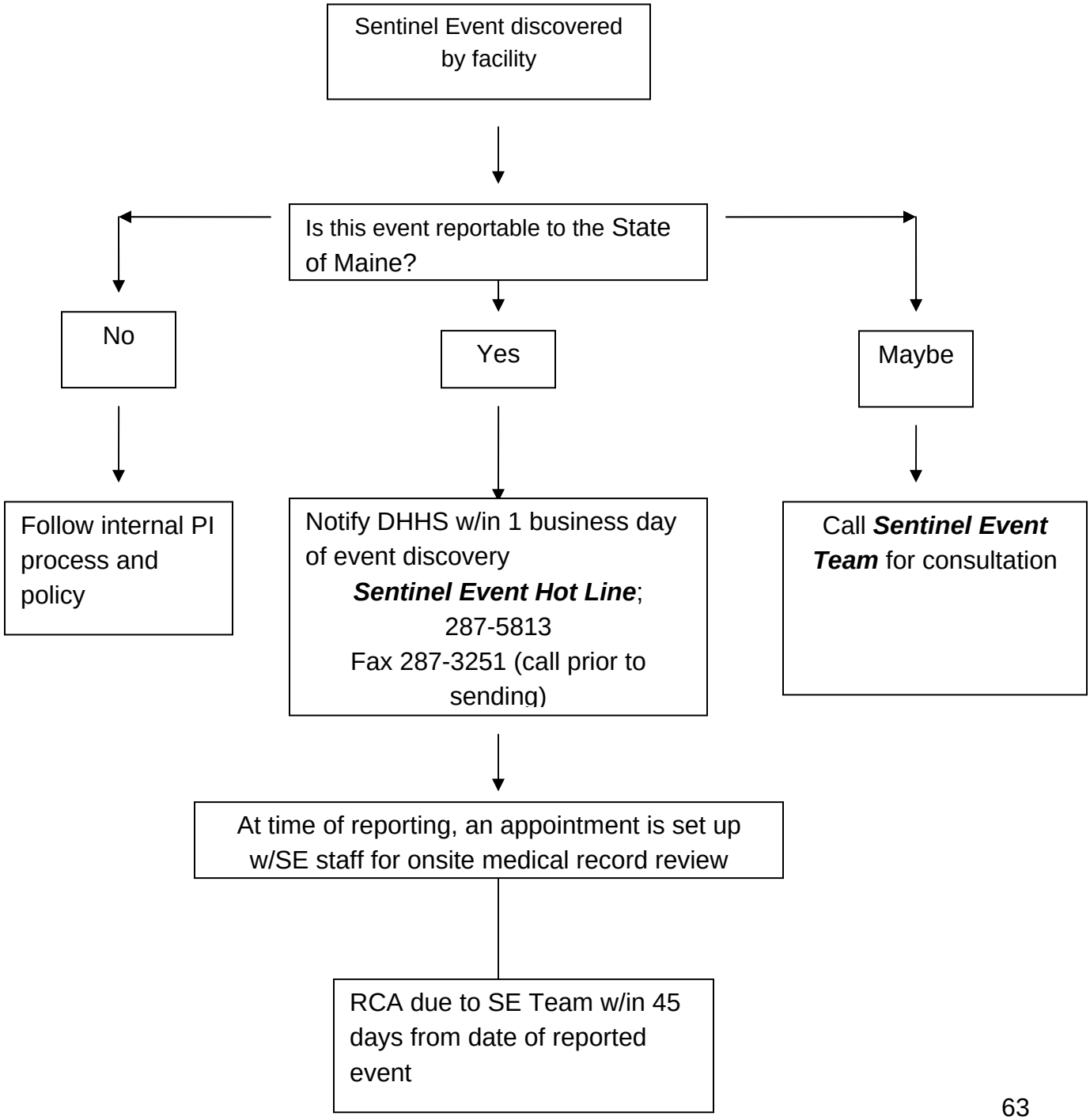
ADOPTED **[New]** 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, replaces the sentinel events reporting provisions in 10-144 C.M.R. Chapters 112, 118, 125, and 126.

Effective date: January 1, 2009

Appendix C

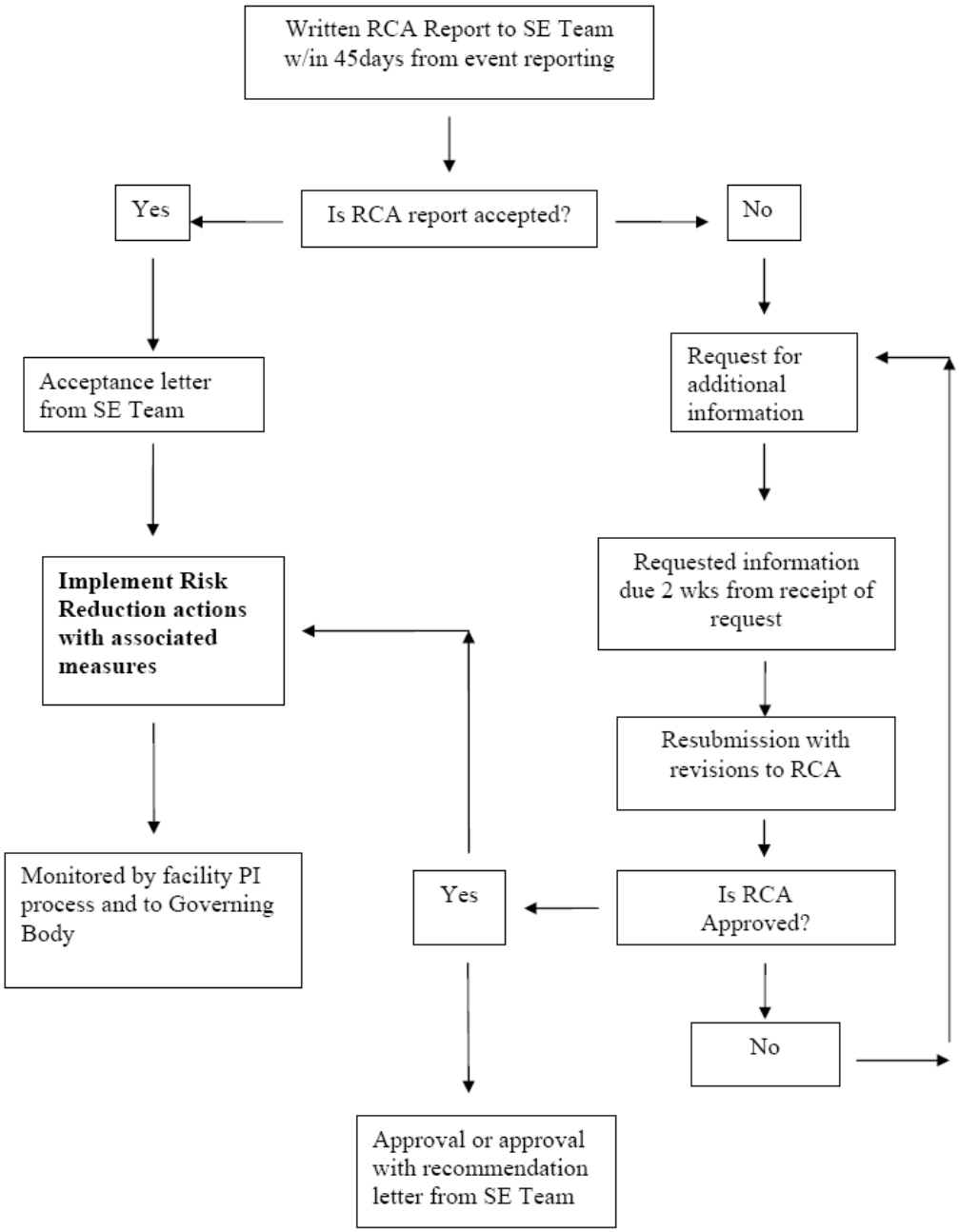
State of Maine
Department of Health and Human Services
Division of Licensing and Regulatory Services
Sentinel Event Process Flow

Part 1



Sentinel Event Process Flow

Part 2



Appendix D

PUBLIC Law, Chapter 314, 123rd Maine State Legislature
An Act To Prevent Duplication in Certification of Hospitals

An Act To Prevent Duplication in Certification of Hospitals

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1816, as amended by PL 1997, c. 488, §2, is further amended by adding at the end a new paragraph to read:

A hospital licensed under this chapter is exempt from department inspection requirements under this chapter if the hospital is certified by the Centers for Medicare and Medicaid Services for participation in the federal Medicare program and holds full accreditation status by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services. If a hospital is certified to participate in the federal Medicare program and not accredited by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services, the department shall inspect the hospital every 3 years for compliance with the Centers for Medicare and Medicaid Services' conditions of participation. The provisions of this paragraph do not exempt a hospital from an inspection by the department in response to a complaint or suspected violation of this chapter or of the Centers for Medicare and Medicaid Services' conditions of participation or an inspection by another state agency or municipality for building code, fire code, life safety code or other purposes unrelated to health care facility licensing or accreditation. For purposes of this paragraph, "Centers for Medicare and Medicaid Services" means the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Sec. 2. Effective date. This Act takes effect July 1, 2008.

Appendix E

Patient Safety Links

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was created by President Clinton to "advise the President on changes occurring in the health care system and recommend such measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." The site offers information on upcoming meetings and information released by government agencies on health care quality issues

Agency for Health Care Research and Quality (AHRQ) provides a range of information on patient safety and medical errors, including information on ongoing research and information for consumers

American Society of Health-System Pharmacists - ASHP's Research and Education Foundation helps pharmacists and others understand and prevent medication errors and adverse drug events.

American Society for Healthcare Risk Management - Focuses on the role risk management plays in patient safety.

The Anesthesia Patient Safety Foundation - Seeks to ensure patients are not harmed by the effects of anesthesia.

Aviation Safety Reporting System - a cooperative program established by the Federal Aviation Administration's Office of the Assistant Administrator for System Safety, and administered by NASA. It is a good example of an effective solution of anonymous reporting that has resulted in reduction of error.

Doing What Counts for Patient Safety:
Federal Actions to Reduce Medical Errors and Their Impact - Report of the Quality Interagency Coordination Task Force (QuIC) to the President, February, 2000

Federal Aviation Safety Data - a model for addressing the recording of patient safety data provided by the practitioner.

Flight Safety Foundation - An international organization for everyone concerned with the safety of flight.

Food and Drug Administration - Here you can find the Spontaneous Reporting System (SRS) for adverse drug reactions

Human Error Website - A repository for data on error rates in human cognitive processes.

Institute for Healthcare Improvement - Offers resources and services to help health care organizations make dramatic and long-lasting improvements that enhance clinical outcomes and reduce costs.

The Institute for Safe Medication Practices - Extensive experience in medication error prevention methods and maintains reference articles covering this subject.

Joint Commission on the Accreditation of Healthcare Organizations - Sentinel Events section includes policy, procedures, flow charts, publications, a glossary, and more.

MedWatch - The Food and Drug Administration's medical products reporting program.

National Committee for Quality Assurance - Information to make more informed decisions about choosing a managed health care plan by comparing plans based on quality.

National Patients Safety Foundation - Among the goals of the NPSF are: to assure patient safety in the delivery of health care, promote research on human and organizational error and prevention of avoidable patient injuries in health care, promote the application of knowledge to enhance patient safety, develop information, collaborative relationships and educational approaches that advance patient safety, and raise awareness and foster communications and dialogue to enhance patient safety.

The National Quality Forum (NQF) has released a draft report with a lengthy list of evidence-backed safety practices (*Making Healthcare Safer for Patients: Evidence-based Practices*). NQF also developed a list of recommended events that should require public reporting (*Serious Reportable Events in Healthcare*).

National Safety Council - A nonprofit, nongovernmental, international public service organization dedicated to improving the safety, health and environmental well-being of all people.

National Transportation Safety Board - An independent investigating body whose methods for applying their safety recommendations to the transportation environment has distinct applications in health care.

North American Thrombosis Forum (NATF) - is a multi-disciplinary organization founded with the objective of improving patient care through the advancement of thrombosis education.

Premier "Safety Share" is a service of the Premier Safety Institute. The Web site is designed to provide you with a valuable resource for healthcare-related information and tools that enhance patient, worker, and environmental safety.
To Subscribe: http://www.premierinc.com/all/safety/publications/subscribe.jsp

Quality Indicator Project - A project of the Maryland Hospital Association that serves as a tool to assist hospital leadership in overseeing patient care quality and identifying opportunities for improvement.

USP Center for Advancement of Patient Safety (CAPS) seeks to improve patient safety by increasing awareness of medication errors, encouraging medication error reporting, and creating programs that help prevent and reduce medication errors. For more information on CAPS, visit the USP web site at www.usp.org or e-mail mediarelations@usp.org.

U.S. Pharmacopeia - Promotes public health by establishing and disseminating official standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients and consumers.

VA Palo Alto HCS /Stanford University Simulation Center for Crisis Management Training in Health Care - An educational tool that has resulted in the reduction of error by simulating crisis for medical students.

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