

Sentinel EVENTS

CY 2009

Annual Report to the Maine State Legislature



Paul R. LePage, Governor

Mary C. Mayhew, Commissioner

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This report was prepared by
The Division of Licensing and Regulatory Services
Department of Health and Human Services
41 Anthony Avenue
11 State House Station
Augusta, ME 04333-0011

For further information please contact:

Anne Flanagan, M.S., R.N.
Assistant Director
(207)287-9334
Anne.Flanagan@maine.gov

or

Elizabeth Harwood, R.N.
Sentinel Events Health Services Supervisor
(207) 287- 4462
Elizabeth.Harwood@maine.gov

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This report may be found on the internet at:

http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

The Maine Sentinel Event Reporting Statute may be found on the internet at:

<http://www.mainelegislature.org/legis/statutes/22/title22ch1684sec0.html>

The Rules Governing the Reporting of Sentinel Events may be found on the internet at:

<http://www.maine.gov/sos/cec/rules/10/144/144c114.doc>

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.
- Amendments to the statutory language have been enacted by the Legislature, effective September 12, 2009. These changes 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 192 sentinel events have been reported and reviewed since the inception of the program in 2004. The majority are in the category of unanticipated patient deaths.
- 45 sentinel events were reported in 2009 indicating a continued increase in reporting over previous years.

Sentinel Events Reported in 2009

Forty-five sentinel events were reported in 2009. All of these cases were reported by licensed hospitals. This number is a 4% increase over events reported in 2008. A total of 37 or 90% of Maine hospitals have reported at least one sentinel event since the inception of the program. Four hospitals have never reported a single sentinel event.

A breakdown of the 45 reported sentinel events is as follows:

- 25 unanticipated deaths
- 9 major loss of function
- 7 wrong site surgeries
- 2 pressure ulcers
- 1 patient suicide
- 1 hemolytic transfusion reaction

There were no reports of infant abduction, discharge to the wrong family, or rape in a health care facility in 2009. The overwhelming majority of cases 42 (92%) were the result of mistakes, or cognitive errors, suggesting the need for training or educational programs. Forty two (92%) of the sentinel events reported included non-clinical circumstances, including errors associated with patient hand-off, chain of command, weekends or holidays, or associated with new practitioners. Aspects of 36 (80%) reported sentinel events raised concerns about the clinical management of a patient. There is a wide range of contributing factors in these cases including delays in treatment, misdiagnosis, and failure to rescue.

In 2009 root cause analysis results indicated that lack of education, inadequate documentation and policies and procedures were the most prevalent causative factors. Thirty seven, thirty four and thirty four events attributed the root cause to those factors. Facilities reported human factors and communication next in frequency. In those cases thirty cited those root causes. Standards of care and equipment explained twenty five and nineteen cases.

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

Effective September 2009, Maine expanded the definition of reportable Sentinel Events. The new definition has added the twenty seven Serious Reportable Events as defined by the National Quality Forum. (Appendix E). The original definition remains unchanged as follows: 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 result from the elopement of a hospitalized inpatient that lacks capacity. The law further requires reporting for patients transferred to another facility for reasons unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition.

The most frequently reported Sentinel Events include:

- 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;
- Suicide of a patient in a healthcare facility where the patient receives inpatient care;
- Rape of a patient; and
- Hemolytic transfusion reaction.

State Review

The Sentinel Event Team conducts onsite reviews at the 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 to reduce the likelihood of a recurrence. 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.

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. 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.

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;
- 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.

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.

2009 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 requirement 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.

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. There was a slight increase to 45 cases in 2009.

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. 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. 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 2009

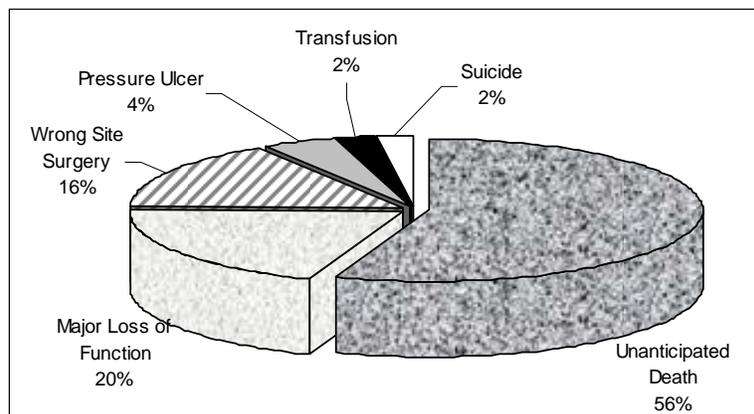
Forty-five sentinel events were reported to the Division in 2009. This represents a 4% increase over 2008 or two additional cases. It also represents a continued increase over reporting in the previous six years of the history of the program. A total of three (6%) of the 2009 cases were identified by the Sentinel Event Team during two onsite hospital audits.

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 rape.

Demographics

In 2009 the majority, twenty five (56%) 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 twenty cases, nine (20%) resulted in permanent loss of function, seven were wrong site surgeries, two were pressure ulcers, one transfusion and one a patient suicide. There were no reports of infant abduction or discharge to the wrong family.

Figure 1: 2009 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.

Figure 2: 2009 Sentinel Events by event type and gender

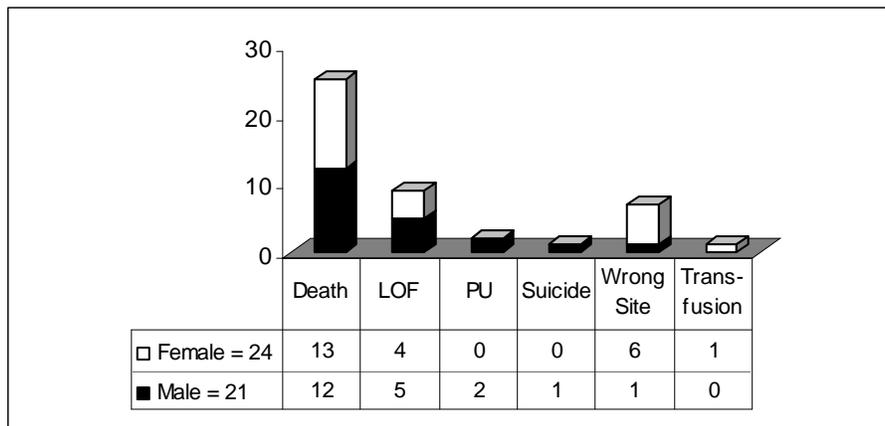
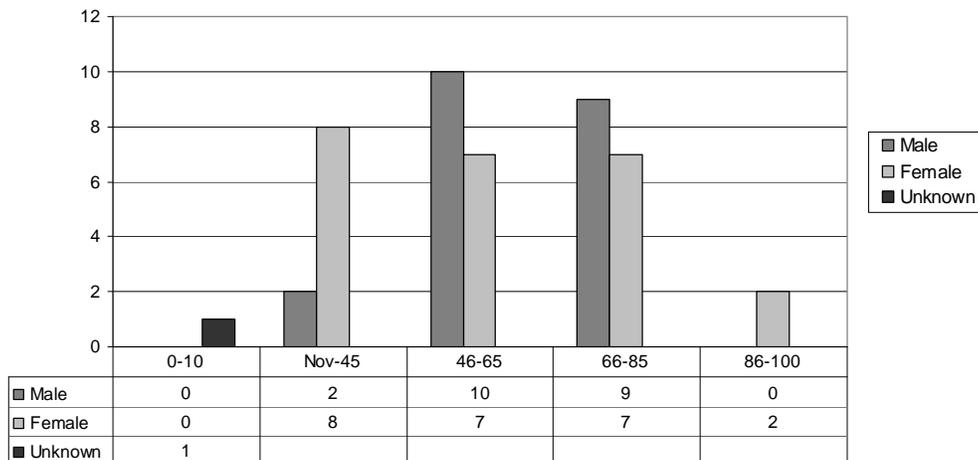


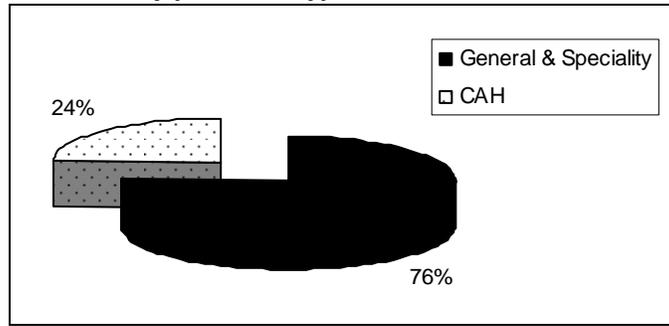
Figure 3: 2009 Sentinel Events by patient age and gender



As in previous years, the overwhelming majority, 100% of the reported sentinel events were from hospitals. There were no reported sentinel events from Ambulatory Surgery Centers or ICF/MRs. Nationally, there have been reports of serious adverse events in the Ambulatory Surgery setting, most recently involving iatrogenic infections. Ambulatory Surgery Centers are advised to have a systematic approach to identify complications that arise following patient discharge.

Of the sentinel events reported by hospitals in 2009, thirty four (76%) were from General and Specialty Hospitals and eleven (24%) were from Critical Access Hospitals.

Figure 4: 2009 Sentinel Events by provider type



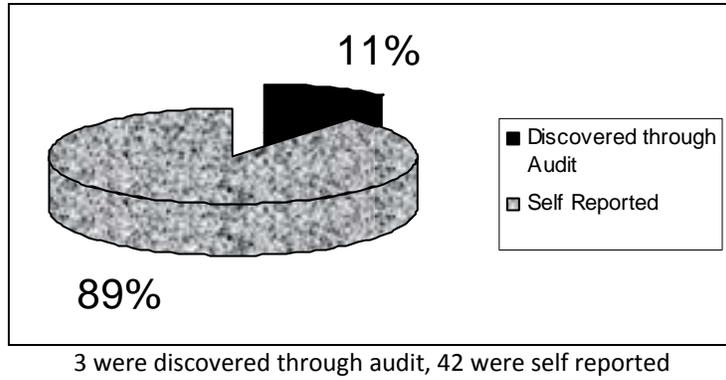
As shown in the figure below, thirty eight (93%) of Maine hospitals have reported at least one sentinel event since the inception of the program. Three hospitals have not reported a single event. Other states report that the number of reporting hospitals generally increases when facilities see the relevance 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.

Figure 5: Reporting versus Non-Reporting Hospitals

	2004		2005		2006		2007		2008		2009	
	No.	%										
Reporting hospitals	11	27%	20	49%	25	61%	32	78%	33	80%	38	93%
Non-reporting hospitals	30	73%	21	51%	16	39%	9	22%	8	20%	3	7%
Total	41	100%	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. On sites are also conducted to audit the facility to ensure that all sentinel events are being reported. 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. In 2009, three unreported sentinel events were discovered through the audit process.

Figure 6: 2009 Sentinel Events discovered through audit versus self reported



National Quality Forum

The National Quality Forum (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.

Of Maine’s forty-five (45) reported events, twelve (27%) met NQF criteria. The remaining thirty-three (73%), 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).

Figure 7: State of Maine Sentinel Events Captured by NQF Criteria

Year	2005		2006		2007		2008		2009	
	No.	%								
Yes	7	25%	8	32%	11	39%	13	30%	12	27%
No	21	75%	17	68%	17	61%	30	70%	33	73%
Total	28	100%	25	100%	28	100%	43	100%	45	100%

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

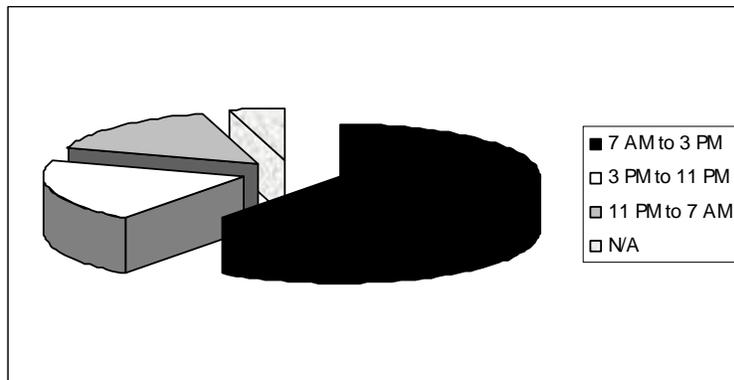
Statewide Trends

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 2009, 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.

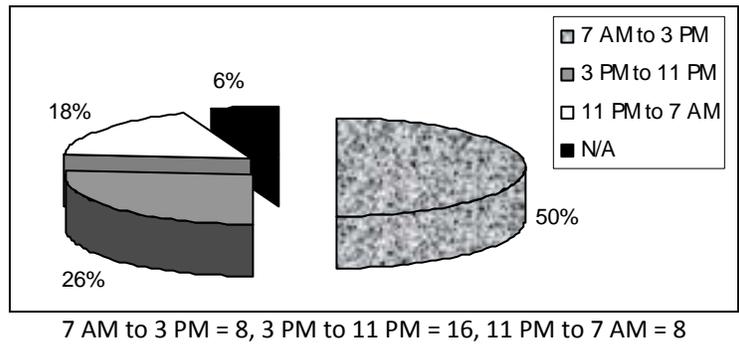
Figure 8: 2009 Sentinel Events by time of occurrence



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

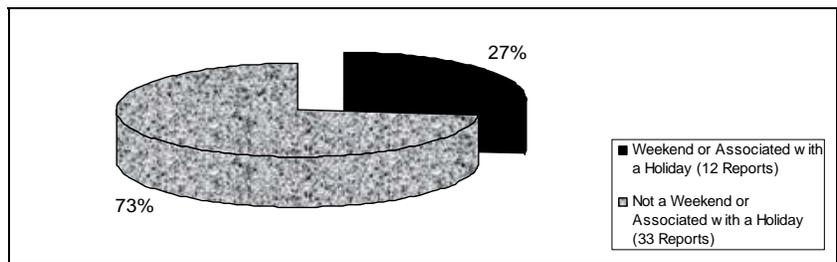
When elective surgeries, or scheduled cases, are removed from the sample, the majority of sentinel events occurring between 3PM and 11PM increases to 50%. When including all 'off hours' for this new sample a total of twenty four (75%) took place between the hours of 3PM and 7AM.

Figure 9: 2009 Sentinel Events by time of occurrence excluding all elective cases



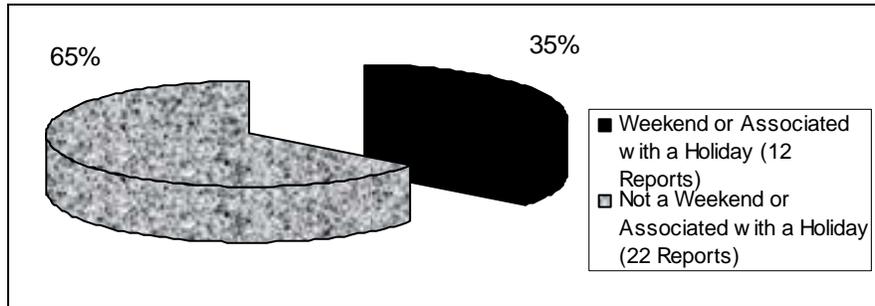
First reported in the 2007 Sentinel Event Annual Report, the frequency of cases occurring during the weekend, or associated with a holiday, was disproportionately high. This finding was confirmed in 2008. In 2009 only twelve cases (27%) occurred on the weekend or associated with a holiday. Based on the 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: 2009 Sentinel Events by day of the week characteristics



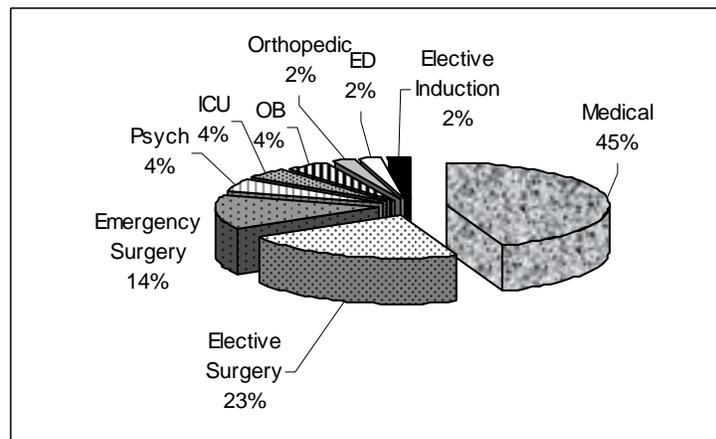
When the elective surgeries or scheduled cases, are removed from the sample, the number of weekend and holiday cases remains at 12 (27%). The earlier sentinel events trend demonstrating a 'weekend factor' was not found in the cases reported in 2009.

Figure 11: Sentinel Events by day of the week characteristics 2009 excluding elective cases



In 2009 reported sentinel events were reviewed by service. Patients admitted to the medical service accounted for twenty (45%) cases. Orthopedic, emergency surgery, and elective surgery cases comprised another eighteen (39%).

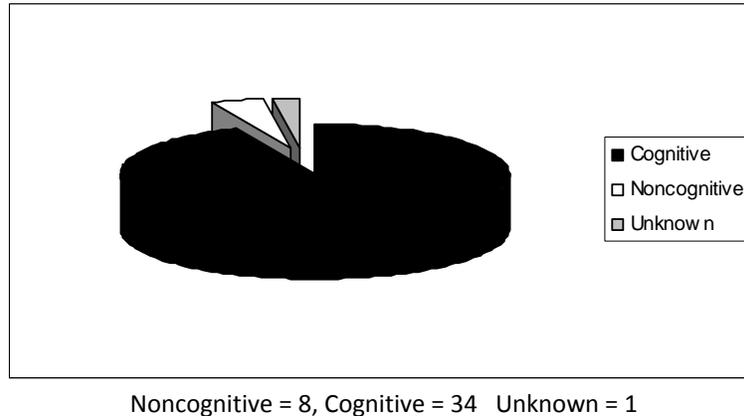
Figure 12: 2009 Sentinel Events by type of service



Sentinel events are generally 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 2009, the majority of cases, thirty four (79%) involved cognitive errors. Only eight (19%) involved non-cognitive errors or 'lapses'.

Figure 13: 2009 Sentinel Events by type of error



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.

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. Previously a technicality in the State's definition of a sentinel event did not place responsibility on the facility to report an event if the individual died in another facility. The accountability for the patient's outcome and the reportability of the event thus became ambiguous. Statutory changes now require reporting of unanticipated transfers on all patients.

In 2009, hand off errors accounted for forty one cases (91%) of all sentinel events reported, with some cases involving more than one hand off error.

Figure 14: 2009 Sentinel Events with evidence of at least one handoff error

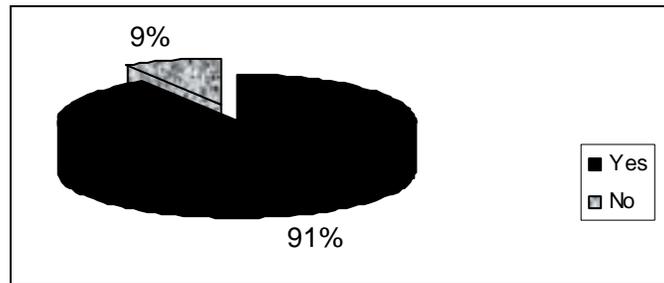
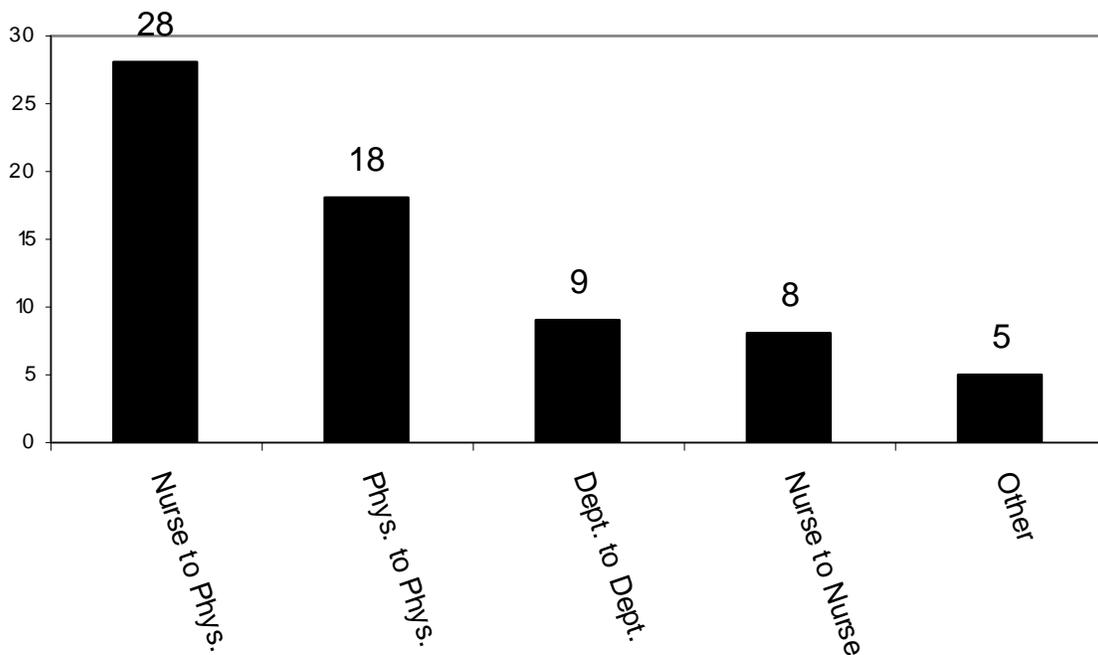
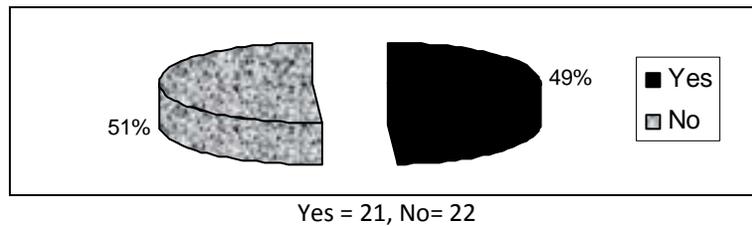


Figure 15: 2009 Sentinel Events by type of handoff error



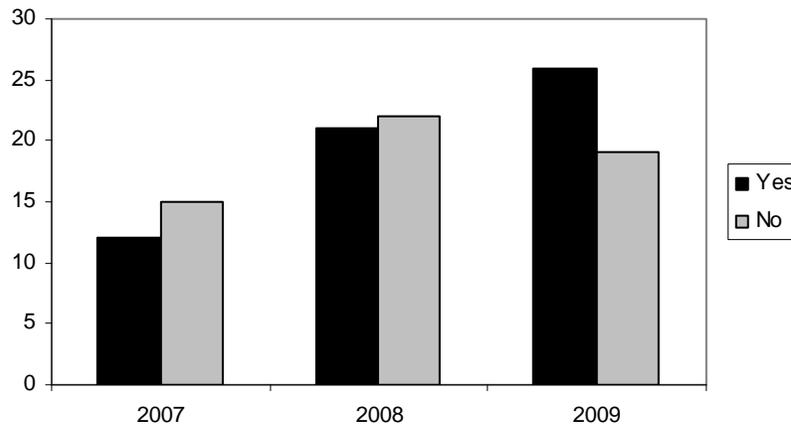
In 2009, twenty one (49%) of reported sentinel events were characterized with a delay in treatment. The Joint Commission issued Sentinel Event Alert, Issue 26, “Delays in Treatment”, in 2002. The report identified that there are many reasons for delays in treatment, the most common being misdiagnosis (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.

Figure 16: 2009 Sentinel Events with evidence of a delay in treatment



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 and continued to rise to 58% in 2009.

Figure 17: 2007 to 2009 Sentinel Events with evidence of a delay in treatment



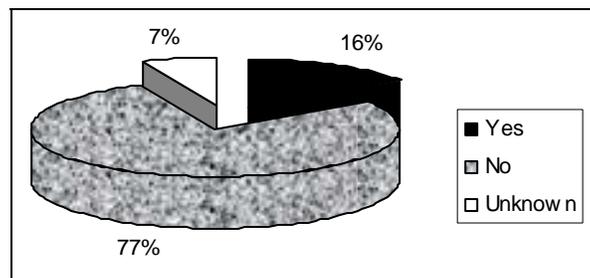
12 cases had evidence of a delay versus 15 without in 2007
 21 cases had evidence of a delay versus 22 without in 2008
 26 cases had evidence of a delay versus 19 without in 2009

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. 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 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 and 2009.

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 18: 2009 Sentinel Events where the patient was well known to the ED



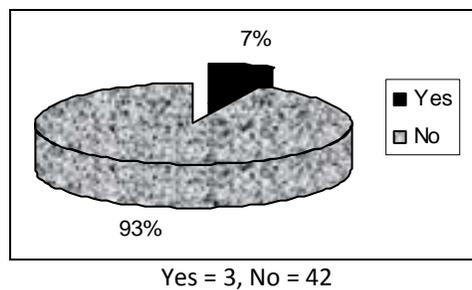
Well known = 4, No evidence of patient being well known = 39

Clinical Trends

In 2009, a majority of all reported sentinel events identified issues with the clinical management of the patient. The trends listed below were not necessarily 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 a factor in reported sentinel events. In 2009, three (7%) of the reported sentinel events involved a patient who suffered a fall in the facility.

Figure 19: 2009 patients suffering a fall resulting in a Sentinel Event



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 thirty (67%) of reported sentinel events in 2009 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 20: 2009 Sentinel Events with evidence of a critical finding contributing to the cause of the event

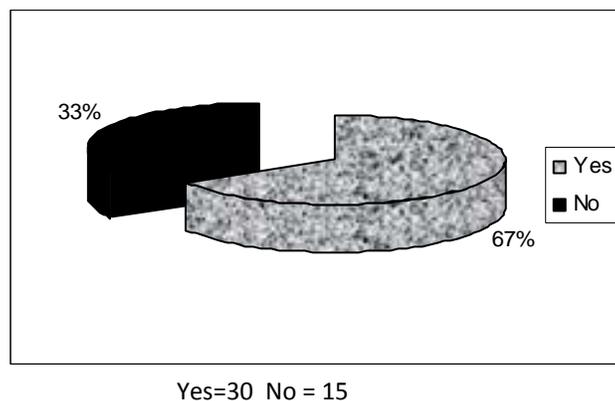
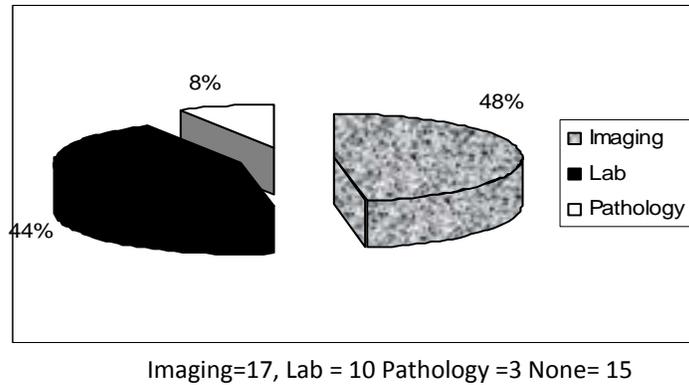
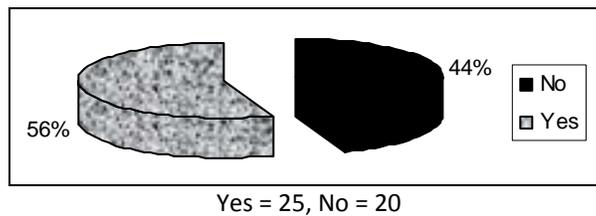


Figure 21: 2009 Sentinel Events with evidence of a critical finding by type



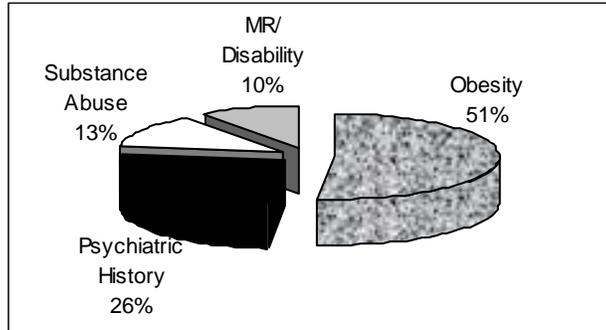
In 2007 a trend was identified in which patients involved with Sentinel Events were characterized with social and/or medical issues that raised questions about non-compliance, possibly 'difficult patients', or disenfranchised in the community. In 2009 sentinel events were reviewed for those specific characteristics. Over half, twenty-five cases (56%) 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 22: 2009 Sentinel Events with evidence of at least one of the following: obesity, psychiatric history, substance abuse history, MR/ disabled or noncompliant



Specific characteristics for this group of patients associated with 2009 sentinel events are identified in the figure below.

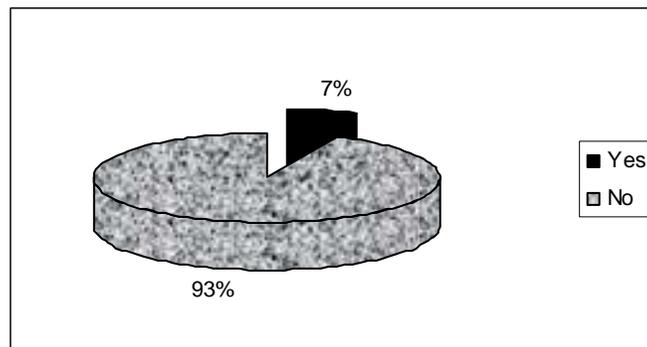
Figure 23: 2009 Sentinel Events with specific co-morbidities



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 2009, we continued to identify cases with this finding. In all of these cases low urine output was unrelated to the admitting diagnosis and identified as a new complication.

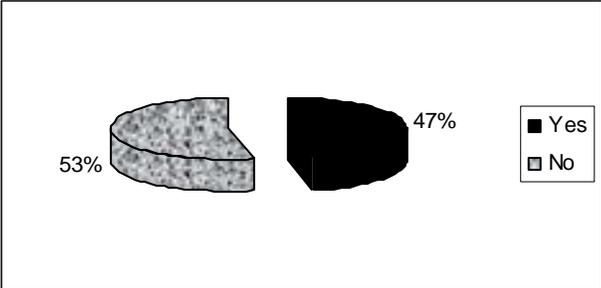
Figure 24: 2009 Sentinel Events with evidence of low urine output preceding the event



Yes = 3, No = 42

Almost half of the sentinel events reported in 2009 were cases where the patient had been seen in the emergency department prior to the admission where the sentinel event occurred.

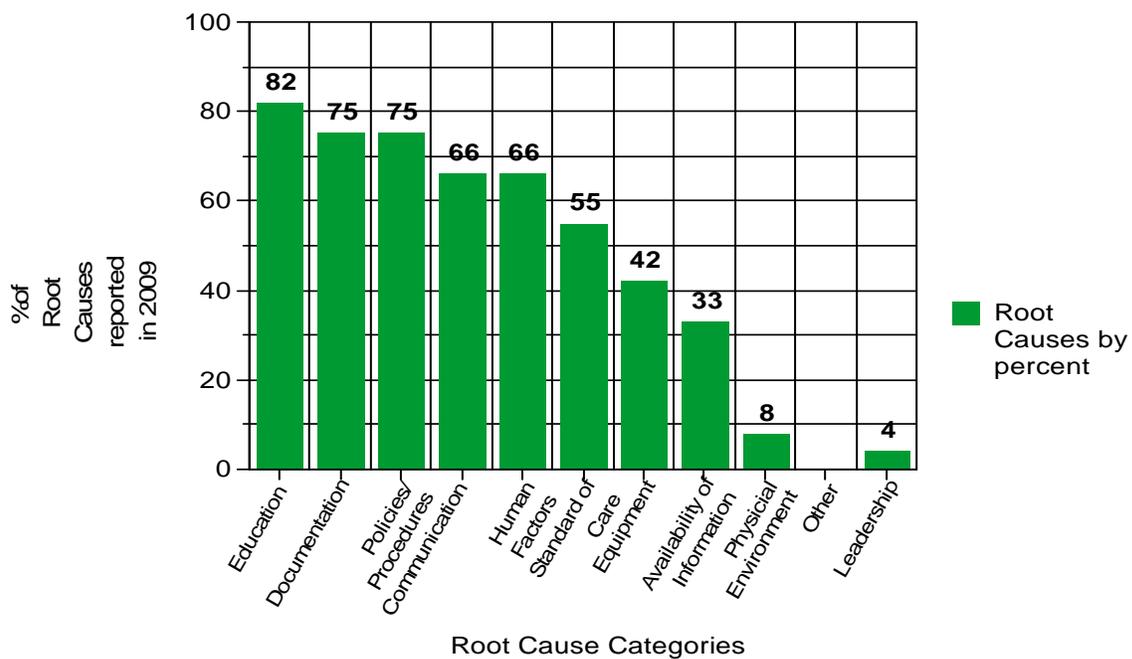
Figure 25: 2009 Sentinel Events Precipitated by an ED visit



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 2009 root cause analysis results indicated that lack of education, inadequate documentation and policies and procedures were the most prevalent causative factors. Facilities reported human factors, communication, standards of care and equipment follow in frequency.

Figure 26: 2009 Sentinel Events facility reported root causes



Sentinel Events reported in 2009 State of Maine

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

2009 SENTINEL EVENTS FACILITY-REPORTED ROOT CAUSES

• Cited Root Causes
<ul style="list-style-type: none"> • Communication
<ul style="list-style-type: none"> • Communication between transferring facilities provider to provider • Communication between surgeon and staff about surgical site • Communication about patient's safety status • Communication between physician and nurse about a patient's current status • Communication between physicians resulting in delay in transfer of patient
<ul style="list-style-type: none"> • Education/Training
<ul style="list-style-type: none"> • Staff unfamiliar with code cart equipment • Staff unfamiliar with PCA pump • Float staff not trained to assist with a procedure
<ul style="list-style-type: none"> • Policy and Procedures
<ul style="list-style-type: none"> • Too many cases booked in the OR on a day • Fall policy does not address fall risk assessment • EMTALA policy too general
<ul style="list-style-type: none"> • Documentation
<ul style="list-style-type: none"> • Discharge instructions missing documentation • Blank areas on nursing assessment • Date and time missing on physician's orders • Patient chart missing documentation about patient's current status
<ul style="list-style-type: none"> • Human Factors
<ul style="list-style-type: none"> • New physician unfamiliar with procedure • Critical thinking with high risk low frequency situations • Float nurse unfamiliar with standard of care
<ul style="list-style-type: none"> • Standard of Care
<ul style="list-style-type: none"> • Anticoagulation standard of care not followed after surgery • Fall risk assessment not complete • Vital sign frequency standard for post op not followed
<ul style="list-style-type: none"> • Availability of Information
<ul style="list-style-type: none"> • Old EKG missing from patient's records • EMR missing identifiers when entries made in certain areas of the record
<ul style="list-style-type: none"> • Equipment
<ul style="list-style-type: none"> • 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

2009 SENTINEL EVENTS FACILITY-REPORTED ACTION PLANS

Communication
<ul style="list-style-type: none"> • Nursing home discharge process to include physician to physician communication • Communication of critical lab results to physician revised
Education/Training
<ul style="list-style-type: none"> • Unit specific education for fall risk assessment • Nursing staff will be educated about triage levels • Core competencies reviewed annually and upon hire (including float staff)
Policy and Procedures
<ul style="list-style-type: none"> • Patient transfer policy revised • New procedure for stool specimen collection • Rapid response policy revised
Documentation
<ul style="list-style-type: none"> • Re-educate staff on documenting in the electronic medical record • Shift chart checks and sign off at handoffs • 24 hour chart checks by night shift
Human Factor
<ul style="list-style-type: none"> • Role clarification for code teams
Standard of Care
<ul style="list-style-type: none"> • Surgeon must review H&P prior to marking surgical site • Adopt ACC and AHA guidelines for VTE/DVT prophylaxis • Time outs will be lead by physician
Availability of Information
<ul style="list-style-type: none"> • Medication reconciliation will occur upon admission to ER and unit • Old records will be obtained upon admission to the ER
Equipment
<ul style="list-style-type: none"> • Foley catheter utilization and management • PCA instructions will be attached to machines • Checklist to ensure instruments in appropriate kits

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 45 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 45 adverse events were reported under the sentinel event reporting system in 2009. 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.

Figure 27. The Expected Rate of Events in Maine Using Estimates Derived from National Studies

Study	Rate of Adverse Events	Maine 2006* Expected Number **
Sari <i>et al</i> (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 <i>et al</i> (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 <i>et al</i> , (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 2000. Focus was on the full range of adverse incidents occurring in hospitals.	7.5 per 100 admissions* *	11,133
Davis <i>et al</i> (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 <i>et al</i> (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 <i>et al</i> (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.

The figure below 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”.

Figure 28: 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, 31 in 2008 and 25 in 2009. These tables 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>

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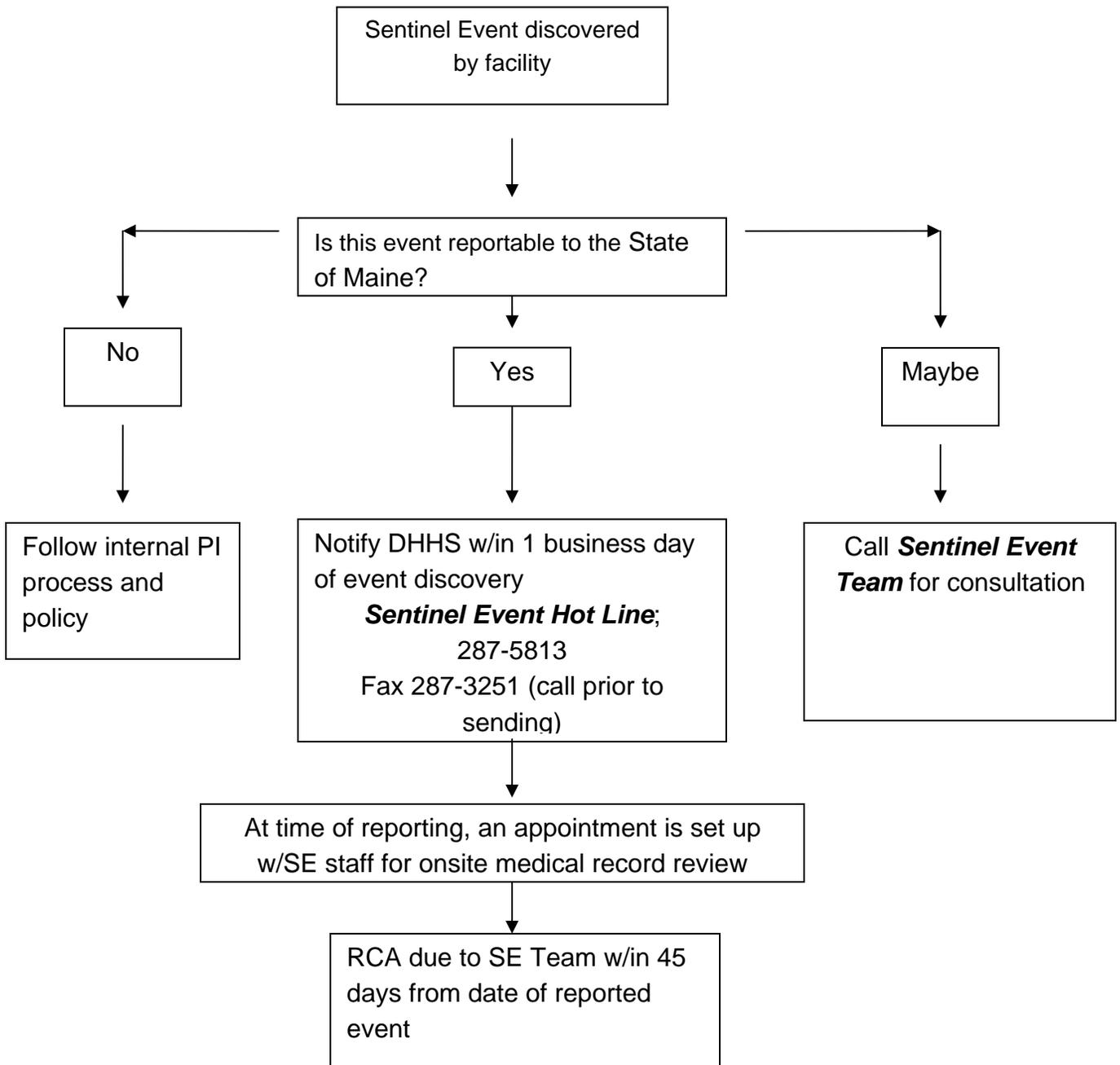
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Appendix A

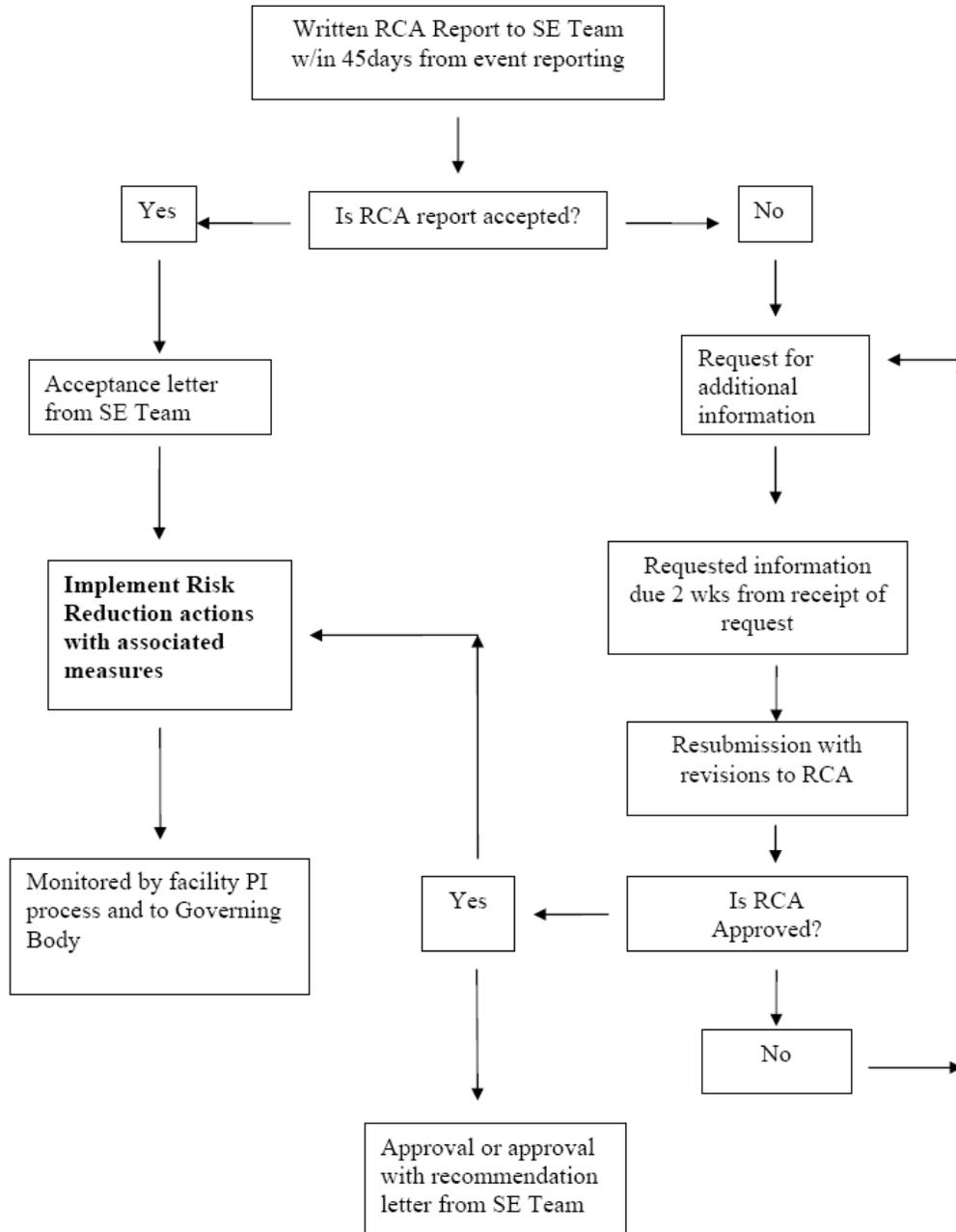
State of Maine
Department of Health and Human Services
Division of Licensing and Regulatory Services
Sentinel Event Process Flow

Part 1



Sentinel Event Process Flow

Part 2



Appendix B

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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