SENTINEL EVENT
ANNUAL REPORT TO THE LEGISLATURE
CY 2006

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Events Reported January 2006 through December 2006

BACKGROUND

Following the Institute of Medicine (IOM) Report, "To Err is Human" published in 2000, Americans became aware that thousands of deaths occurred because of preventable medical errors[1]. The report gave credibility to the belief that medical errors are due to a failure of various complex systems and processes in the healthcare environment and not because of a particular provider. In addition, the IOM recommended a mandatory reporting system where serious events would be reported, persistent safety problems identified, and appropriate action taken to prevent recurrence of these errors.

Since the IOM report, the Institute of Healthcare Improvement (IHI) launched the 100K Lives Campaign, enlisting hospitals to participate in preventing 100,000 avoidable deaths. Over thirty-five Maine hospitals joined the challenge, and ultimately more than 3000 hospitals participated in this venture. Patient safety improvement was made based on implementation of six (6) key changes:

1. Delivery of reliable evidence-based care for Acute Myocardial Infarction;
2. Preventing adverse drug events;
3. Preventing central line infections;
4. Preventing surgical site infections;
5. Preventing Ventilator-Associated Pneumonia; and
6. Deploying Rapid Response Teams.

Phase One of this campaign ended in June 2006, with more than 123,000 lives saved.

In Maine, mandatory reporting began in response to consumer interest generated by the IOM Report. LD 1363 was first introduced in 2001, and required some redrafting to address provisions of confidentiality to protect data, and to apply the specific elements of the mandated report. The bill was signed into law by Governor Baldacci in 2002. Under Section 1, 22 M.R.S.A., Chapter 1684, § 8751-8756, the Mandatory Sentinel Event Reporting statute became effective in May 2003. Maine established a law requiring licensed healthcare facilities, as defined under Title 34-B, Chapter 1 (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. The statute defines these occurrences as "sentinel events", and they are 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 capacity as defined in Title 18-A, section 5-801, paragraph C.

They include:

- Unanticipated death;
- Major permanent loss of function that is not present upon admission to the health-care facility, and surgery on the wrong body part or wrong patient;

- 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; and
- Infant abduction or discharge to the wrong family, or rape of a patient.

By law, all sentinel event (SE) information submitted to the Division of Licensing and Regulatory Services (the "Division") is considered privileged and confidential. No information about facilities or providers is discoverable or made public. The focus of the SE Program is to encourage voluntary reporting and identify those systems and processes which impact safe patient care for the citizens of Maine.

The Division of Licensing and Regulatory Services within the Department of Health and Human Services is responsible for the implementation and ongoing oversight of this program. Registered Nurses staff the program. To improve the effectiveness of the program, reallocation of resources within the Division of Licensing and Regulatory Services will enable the Division to add one (1) additional nurse to the two-member team in CY 2007.

Once a sentinel event has occurred, the facility must report this information to the Division within one (1) business day. A written report must be submitted within forty-five (45) days, using the key elements of a root cause analysis (RCA). The internal investigation must include the following:

- Identification of the systems or processes that may have impacted the event;
- A corrective action plan that will focus on preventive risk reduction measures; and
- The process for monitoring the effectiveness of their plan.

In addition, the document must show participation by leadership of the facility, and how the correction plan will be communicated to members of the performance improvement committee.

RCA is a commonly used methodology that enables facilities to ask (in a structured objective manner) "why", in order to help reveal the causal factors that led to the sentinel event. Its core principle is to target systems issues to prevent similar incidents from happening and does <u>not</u> place blame on an individual. Most Maine facilities utilize RCA criteria from the Joint Commission[2] or the Veterans Administration National Center for Patient Safety[3] as guidelines in preparing analysis reports.

Some objectives of the Sentinel Event Annual Report for calendar year 2006 are to:

- Identify patterns of SE events and where possible make recommendations to improve the quality and safety of patient care;
- Increase general knowledge about SE events, causes and prevention strategies;
- Provide an overview of issues identified in reported SE; and
- Provide aggregate information pertaining to SE reviewed during calendar year 2006.

INTRODUCTION

This report presents information about reported sentinel events for January 1, 2006 to December 31, 2006. The facilities which have submitted data for this report have conducted an in-depth analysis as to why these events occurred, which in turn has revealed some common factors. These results confirm what research has shown; that most sentinel events are not always caused by negligence of a single provider, but by a systems breakdown. This report reflects such issues as policies that are inconsistent or unclear, communication breakdowns between providers, and issues surrounding the need for better documentation. The lessons learned will help to encourage systems changes, that provide a safer healthcare environment for patients in the State of Maine. Understanding why an event occurred and how it can be prevented from recurring is important, not only for those who provide the care, but for patients and their families.

In an effort to improve patient safety, many facilities are changing their focus from the "traditional" blame and punishment of staff involved in the incident, to establishing a culture that supports patient safety by encouraging communication across clinical disciplines, and establishing a non-punitive approach to reporting events. This "just" culture is defined as one that supports the discussion of errors, so that lessons can be learned from them.[4] A supportive environment can increase teamwork, and a collaborative independence among clinicians, which may contribute to an environment that places patients in an improved position of safety.

Action plans for CY 2007 will include enhancements to capture potential under-reporting by medical facilities, as well as follow-up onsite visits to provide further consultative oversight of improvement plans related to specific events. Maine will continue to aggregate and trend data for learning opportunities to improve the quality and safety of patient care with medical facilities in Maine.

ACTIVITIES 2006

In January, the SE Team continued its participation in the second session of the Patient Safety Improvement Corps (PSIC) Program. This course was sponsored by the Agency for Healthcare Research and Quality and the Veterans Administration National Center for Patient Safety.[5] In 2005, the SE team, along with a representative from Henrietta D. Goodall Hospital, was selected to participate in this program, offering training to State field staff and hospital partners. Some of the goals of this offering were to provide participants with various statistical tools to analyze patient safety data and measure changes, apply a conceptual understanding of the steps of Healthcare Failure Mode and Effect Analysis (HFMEA), and to identify patient safety indicators, in order to properly evaluate a patient safety program.

The second Annual SE Report was developed and sent to the State Legislature in February 2006. This activity is a requirement under 22 M.R.S.A., Chapter 1684, §8754, and requires a report to be made to the Legislature, healthcare facilities, and the public. This report must provide a summary of aggregate data, inclusive of the number, category and type of healthcare facility in which the events occurred. Data trending analyses and areas of targeted focus for the upcoming year are outlined in this report.

In March, the SE Team was invited by the Perinatal Nurse Managers of Maine to provide education on the sentinel event reporting regulations and how they impact perinatal providers. In response, the team also provided aggregate information on the root causes of unanticipated death and permanent disability associated with obstetrics. Issues such as communication, competency, staff orientation and training, inadequate or unavailable fetal monitoring equipment were discussed. Some risk reduction recommendations made at that time included team training to enhance communication, clinical drills to prepare for emergent situations, and the development of clear guidelines for monitoring high-risk obstetrical patients. The SE Team also stressed the importance of the development of nursing protocols for the interpretation of fetal heart tracings, and a comprehensive plan for transfers to tertiary care. The presentation was well received and was attended by a large group of managers, both onsite and via satellite.

Also in March, the SE Team presented to the Maine Hospital Association. A general review of the Annual SE Report was conducted. Risk reduction actions taken by various facilities in response to their reported events were addressed and shared. The major area of discussion centered on types of patient falls causes, fall-risk assessment tools and prevention.

The 2005 Annual SE Report to the Legislature is made available on the Maine State website:

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

The Annual SE Report for 2006 will soon be available on the new website for the Division of Licensing and Regulatory Services:

http://www.maine.gov/dhhs/dlrs/

In May, The SE Team attended the third series of the PSIC course. This segment provided the participants with the knowledge and skills necessary to implement, sustain, and evaluate an effective patient safety program. Tools were provided to assist with the recognition of proactive risk assessments with an emphasis on underlying system causes, and the development, measurement and evaluation of integrated system changes. During this time, the SE Team presented the State of Maine patient safety project to the group. The presentation showed how the Team provided SE education, including the regulations, reporting process, criteria, and the RCA process to all licensed Intermediate Care Facilities for Persons with Mental Retardation (ICF-MR) and End Stage Renal Disease (ESRD) Centers throughout the State.

By July, the SE Team completed educational sessions for all seventeen (17) ESRD Centers in the State. The program included a power-point presentation reviewing the regulations and reporting requirements for SE. It also provided information on the SE review process and included tools to perform a complete RCA. Benefits derived from these forums gave ESRD staff and SE Team the opportunity to open communications with each other for future event reporting and consultation needs.

A final “Train the Trainer” seminar was provided to all the participants of the PSIC Program in September. Upon completion, the group was able to utilize various teaching strategies to enhance

instruction, design patient safety training for various audiences, and apply lessons learned by the VA and other PSIC members who have implemented patient safety programs in their respective areas. The SE Team was able to attend the entire Patient Safety Improvement Corps program with the assistance of Federal funding.

During December, the SE Team met with members of the Maine Association for Healthcare Quality (MAHQ). The MAHQ mission is to improve the quality of healthcare by advancing the theory and practice of quality management in healthcare organizations and to support the professional growth, development, and education of healthcare quality management professionals. The SE Team contributed information regarding the reporting of SE, reviewed a sample of a de-identified complete RCA reports compared to one that was less thorough, and shared lessons learned from risk reduction files.

Throughout the year, the SE Team performed onsite reviews for all SE reported to the Division. The SE Team had the opportunity to meet and dialogue with key staff, obtain information related to the event from the clinical record, and share lessons learned. All RCA reports were analyzed for identification of causal factors, appropriateness of risk reduction plans and implementation of corrective actions.

Ongoing responsibilities for the SE Team include providing consultation to facilities as needed and performing literature searches, in order to keep abreast of current clinical guidelines and standards of care, to assist in the evaluation of RCA reports. The SE Team would benefit from the opportunity to attend national training programs.

During the calendar year 2006, over three hundred and fifty (350) hospital complaints were received by the Division. A complaint is a report made to the Division by anyone other than the administrator or authorized official for a provider, alleging noncompliance with state/federal laws and regulations. Each of these was reviewed by the SE Team to cross reference individual licensed facilities reporting of SE against consumer generated reports. For SE purposes, reviews of these complaints are based on State laws. It did not reveal under reporting by facilities.

In addition, all SE reported in Maine in 2006 were matched against the National Quality Forum (NQF) core set of twenty-seven (27) Serious Reportable Events Criteria.[6] This comparison was done in response to requests made by the Maine Quality Forum, Maine SE Ad Hoc Committee. This committee was formed at the request of the Governor's Office to assess opportunities for strengthening Maine's SE reporting system. The NQF developed its standardized list to facilitate uniform data collection and reporting of serious events, with the goal of improving healthcare safety on a national level. The events are grouped into six (6) categories: surgical, product or device, patient protection, care management, environmental, and criminal acts. During the 2006 calendar year, twenty-five (25) sentinel events were reported in Maine. In comparing these twenty-five (25) events to the NQF criteria, the NQF criteria recognized eight (8) events or 32%. Therefore, seventeen (17) cases would not have been reported if Maine adopted the NQF criteria. (refer to Appendix B). For the second year, the NQF core standards identified fewer serious reportable events, compared with the Maine SE criteria.

During the year, The SE Team took the opportunity to research other states' SE forms. In order to collect standard information, revisions were made to the State's format. Additional details included were the physical location where the event occurred, admission/discharge diagnosis codes, any immediate corrective action taken, and how the event was discovered (refer to SE form in Appendix G).

An evaluation form was also developed for use by the SE Team, to assist in the internal tracking of RCA reports. Information such as the timeliness of reporting, strength of submitted corrective action plans, and documentation of monitoring process, is collected.

The SE Team provided consultation on an additional eleven (11) events and determined the incidents were non-reportable under the SE statute. The facilities reported that they followed their internal review processes, which included a RCA, and provided follow up with their individual quality programs and performance improvement committees.

All reported events were made within one (1) business day of recognition of the incident. RCA written reports were received within the mandated forty five (45) day timeframe, and no fines were imposed for noncompliance with the statute.

FINDINGS 2006

Reported events have remained somewhat stable since regulations have been in effect. No dramatic changes in the number of reportable events have been noted since informational sessions were completed for all licensed facilities in 2006 (refer to Appendix F). However, Maine has forty-one (41) licensed hospitals, and for CY 2004 through CY 2006, only twenty-four (24) hospitals have reported a sentinel event to the Division. This information has led to planned revisions of the regulatory language, clarifying that the Division may conduct random reviews of facility records, to ensure compliance with the statute.

There were a total of twenty-five (25) reportable SE between January 2006 and December 2006.Twenty-four (24) events occurred in an acute hospital setting, and one (1) in an Ambulatory Surgical Center (refer to Appendix E). Of these twenty-five (25), fourteen (14) were deaths, seven (7) were permanent loss of function, three (3) were wrong site surgery and, one (1) was a suicide (refer to Appendix D). There was a decrease of three (3) cases from CY 2005. One (1) suicide, two (2) neonatal, and one (1) pediatric death are included in the total number of deaths accounting for 56% of the events, wrong site surgery 16%, and permanent loss of function was 28%. Patient genders were equally divided. A breakdown of patient ages is as follows:

- Nine (9) patients or 36% were between the ages of sixty (60) to ninety (90);
- Eight (8) patients or 32% for patients aged between forty (40) and fifty (50);
- Five (5) patients or 20% were aged between twenty (20) and thirty (30) years; and
- Three (3) patients or 12% were newborn to one (1) year old.

In April 2006, Governor Baldacci released the 2007 State Health Plan. This report explains how stronger bonds with community coalitions will help to bring about a more organized system to deliver preventative services and public health across the state. Maine residents had the opportunity to participate in meetings, and help to identify top priorities for the plan. Obesity, nutrition and exercise were targeted areas to receive focused attention. Information in this report is cited from 2002, and compares the rate of obesity in Maine to the nation. At that time, Maine ranked 25th highest with 55.9% of the population considered obese, versus the national rate of 56%. More recent data from the CDC-BRFSS (Centers for Disease Control and Prevention-Behavioral Risk Factor Surveillance System) documents 61% of Maine adults are overweight or obese.[7]

During the course of 2006, the SE Team also identified increased weight as a potential risk factor for poor patient outcomes. Retrospectively, it was interesting to note that in eighteen (18) adult events related to permanent loss of function or unanticipated death, five (5) had documentation of admission weights greater than three hundred (300) pounds or notation in the record that patients were "morbidly obese". This represents 27.7% of the adult reviews. It is public knowledge that obesity has become a major health care problem in the United States. According to the American Obesity Association, "Persons with obesity are at risk of developing one or more serious medical conditions, which can cause poor health and premature death.[8]"

Obese patients are at higher risk for postoperative complications. Advance planning and a comprehensive preoperative teaching plan will help to prevent an adverse outcome. Staff in the operating room, recovery room, and other patient care units may require notification ahead of time that they will be receiving a patient with special needs. This would allow the opportunity to obtain necessary equipment to properly assess the patient and provide a safe environment. Some practical suggestions include:

- A larger/wider bed, equipped with pressure prevention surface;
- Additional staff to properly position, maneuver, or transfer the patient;
- Staff education to ensure knowledge of related complications;
- Equipment such as appropriately sized blood pressure cuff, abdominal binders, patient gowns, etc.;
- Sequential compression devices to accommodate larger leg size;
- Adequate pain medication dosage calculated on patient's actual weight; and
- Maintaining patient integrity throughout inpatient experience.

For CY 2006, 4% of reported events related to patient falls. These resulted in various types of permanent loss of function. There were no deaths associated with falls. Permanent injury related to falls decreased from 35% reported for CY 2005. It is important to note that while the number of reported events limit in depth statistical analysis, there are noteworthy data comparisons. This decline may be attributable to increased diligence in the healthcare setting to perform frequent, accurate assessments of patients at risk for falls, more thorough communication of a patient's condition at time of shift–to-shift hand-off reporting, consistent attention to environmental hazards for all patients, and adopting a proactive fall prevention program that has been conveyed to all caregivers in the facility.

During this year, the SE Team reviewed a death associated with suicide. This event occurred in a non-psychiatric acute care setting. The American Foundation for Suicide Prevention[9] provides education containing statistics and risk factors for suicide highlighting suicide prevention research. Some information they provide consists of the following:

- Suicide is the fourth leading cause of death for adults between the ages of eighteen (18) and sixty-five (65);
- There is no typical suicide victim: patients come from all races, income and educational levels; and
- Should always take a comment about suicide seriously.

Individuals living alone, retired/unemployed, history of major recent physical illness, family history of death by suicide, or smoker/drug/alcohol are risk factors that may lead to suicide. Additional warning signs include hopelessness, anxiety, sleep problems and recent impulsiveness.

Since 1995, the Joint Commission has collected SE statistics in a database. Updated information from the 2006 database shows suicide as the most frequently reported SE. The report documents that most of the suicides occurred in psychiatric hospitals, followed by general hospitals, and residential care facilities. Of those cases reported from general hospitals, many occurred in medical, surgical units or in the Emergency Room. In most events, the method of suicide was a hanging in a bathroom, bedroom or closet. Others resulted from patients jumping from a roof or window.

Risk reduction factors recommended by Joint Commission[10] include:

- Using a standardized methodology to revise suicide risk assessment/reassessment procedures;
- Enhancing staff orientation/education incorporating suicide risk factors;
- Updating policies and procedures for patient observation;
- Redesigning, retrofitting or introducing security measures (for example, locking mechanisms, patient monitors and alarms);
- Identifying and removing or replacing non-breakaway hardware;
- Weight testing all breakaway hardware;
- Implementing education for family/friends regarding suicide risk factors; and
- Revising information transfer procedures.

In conclusion, lessons learned and recommendations from unanticipated death related to suicide, especially in a non-psychiatric setting, are that education and staff training are essential components necessary to recognize signs and risk factors that a patient may present with at the time of admission to the facility. It is interesting to note that one of the Joint Commission National Patient Safety Goals for 2007 is requiring acute care hospitals, along with behavioral health and psychiatric organizations, to identify patients at risk for suicide.[11] The objective of this goal is to identify those critical areas where patient safety can be

improved. Review of RCA data of an inpatient suicide reveals communication, environmental safety and security along with staff orientation and training are major contributing factors.

ROOT CAUSE ANALYSIS FINDINGS

The SE Team reviewed the RCA findings for all SE's occurring in CY 2006. For those cases with completed information received and reviewed, communication failure was cited in 36% of the reported events, compared to 67.86% in 2005. This decrease may be due to the efforts facilities have made to improve patient information reporting during handoffs from one healthcare professional to another. This dialogue can take place between nursing at shift changes, physician to physician, ancillary services such as laboratories, and radiology to physicians, and during patient transfers from one facility to another. Policies and procedures issues decreased from 64.29% in 2005 to 24%. Documentation issues decreased from 35.71% to 24%. Education and training issues also improved from last year, however remained somewhat high at 44%. The category for available information remained similar to the last reporting year with, 24% (refer to Appendix C).

Three (3) of the highest RCA findings reported by the Joint Commission in 2005 were communication, patient assessment and policy and procedure compliance.[12] Data from other states such as New Jersey, Pennsylvania and Minnesota report similar results.[13] [14] [15]

Samples of risk reduction action plans submitted by health care facilities in response to events have been collected, categorized, and are listed below.

COMMUNICATION

- Leadership working to improve communications with direct care providers after realizing facility staff was not aware of the National Patient Goals;
- Hand off communication to other providers to include information about patient risk for falls;
- Modification of bedside communication tool to include a "safety plan" category;
- Posting of signs for patient and public to contact staff for any patients needing assistance;
- Certified Registered Nurse Anesthetist (CRNA) to review patient notes and flow sheets, and communicate directly with patient's nurse, for all patients with epidural catheters;
- Ambulatory Surgical Unit call-back nurse to notify surgeon, if patient has not passed flatus on first post operative day;
- Hand off communication between two or more care providers to include a patient's risk for fall;
- Physician to physician to communicate among other providers when co-managing patients;
- Each provider to initial a flow sheet documenting they have read each other notes;

- Admitting department to notify responsible physician when admission process is delayed due to lack of available patient bed;
- Obtain additional information from the patient family regarding substance abuse history.

POLICY/PROCEDURE

- Autopsy policy strengthened to support providers when asking a family for permission for an autopsy in situations such as a sudden death occurring from an unknown cause. This revision stated that the hospital would cover autopsy expense at no cost to family;
- Revision of standing orders for the management of patients with epidural catheters, to include when to notify anesthesia for further instructions;
- Fall risk assessments to be placed in specified area of patient record for accessibility to all services, along with prompts based on fall risk to document any changes in patient treatment plan;
- Post operative discharge instructions for patients to remain on clear liquid diet until passing flatus or at least for twenty-four (24) hours. Patient to call physician if no change after forty-eight (48) hours;
- Physician to perform daily call back to patients having incisional hernia surgery;
- Review/evaluate and revise all current patient fall risk policies and procedures;
- Development of more comprehensive policy and procedure for the selection, insertion, maintenance, and timely removal of Peripherally Inserted Central Catheter (PICC) lines for pediatric patients;
- Establishment of a standardized patient assessment procedure to include all disciplines.

PHYSICAL ENVIRONMENT

- Reduce patient movement between rooms, thereby decreasing transfer of detected/undetected Clostridium Difficile;
- Environmental service staff supervisor to perform quality checks on at least one (1) known Clostridium Difficile room cleaning per week, to ensure competency and consistency of room cleaning process;
- Those areas not intended for unsupervised patient use will be identified and locked.

STANDARDS OF CARE

- Patient fall risk assessment re-evaluated with appropriate interventions to prevent injury from falls;
- Implementation of a standardized training program for management of epidural catheters, to include uniform methods of assessing motor and sensation response;
- Investigate and evaluate other forms of analgesia instead of epidural catheter;
- All laparoscopic incisional herniorrhaphy surgery to be reviewed by surgical service committee;
- All current patient fall risks will be re-evaluated, with appropriate interventions with information entered into the patient teaching plan;
- Staff to follow approved list of codes when describing frequent visual checks of patients indicating when patient is sleeping;
- Auditing of PICC line care;

- Appropriate and timely assessment/reassessment of patient with medical status changes;
- Accurate patient assessment during sleep hours, while patient on fifteen minute checks.

EDUCATION/TRAINING

- Assess and improve medical/surgical skill set competencies (e.g., diabetes management, initial and serial neurological and respiratory assessments), for psychiatric nursing staff;
- Plan to clarify practice during surgical site verification documentation that surgical site marking is not required for surgery planned on a unilateral site;
- Annual competency for nurses to include patient assessment and sensation response to epidural catheters for pain management;
- Epidural catheter management to include patient care, assessment, documentation, and required communication with anesthetist;
- Annual update with review of patient care for laparoscopic incisional hernia repair;
- Additional education on expected course and behavior of patients with co-occurring treatment for depression and mood disorders during substance abuse detoxification;
- Identification of "red flags" during detoxification process to indicate changes in patient behavior that may impact patient care and assessment;
- Providers encouraged to contact other providers who have an established relationship with a patient, in an effort to obtain more clinical information;
- Review lock systems on bathroom doors, how to gain access in an emergency, and how to remove doors if necessary;
- All staff review of facility fall risk assessment tool, and associated procedure;
- Revision of process to ensure adequate documentation of vital signs in electronic medical record;
- Review patient search and visitation process to reduce likelihood that contraband is missed.

EQUIPMENT

- Explore and evaluate purchase of disposable patient gowns and blood pressure cuffs to reduce cross contamination;
- Revision of CPOE (Computerized Physician Order Entry) system to assist/prompt the prescriber to order the initial dose of an antibiotic as a "STAT" (medical abbreviation implying urgent) order for patients with community acquired pneumonia;
- Upgrade wheel chair alarms to incorporate a chair sensor pad and a cord pull-tab which attaches to the patient;
- All patient equipment with an alarm system will be tested for audibility and recognition.

LEADERSHIP

- Chief Medical Officer will address Chiefs of Staff to recognize and fulfill hospital obligation to notify Risk Management Department of a potential SE, thereby promoting timely mandated reporting;
- Clarify roles and expectation of Emergency Department staff when a patient need arises from another unit;
- Reinforce compliance with medical bylaws regarding requests for consultation, with the elimination of nursing staff to act as liaison between providers.

DOCUMENTATION

- Development of a standard plan for interdisciplinary teams to chart individual patient safety plan and goals in one location for team reference;
- Providers and Emergency Department staff to use the facility standard Sepsis Order Sheet;
- Review procedure in computerized system for documentation of frequent patient observation checks.

CONTINUING EFFORTS TO IMPROVE PATIENT SAFETY

Maine hospitals continue to participate in the ongoing IHI 100,000 Lives Campaign, working towards the goal to annually reduce morbidity and mortality rates by 100,000.[16]

The IHI has continued to search for more ways to improve patient safety. They estimate that fifteen million incidents of medical harm occur each year in the United States. Based on that information derived from data collection, it launched the Five Million Lives Campaign in December 2006, with the goal of protecting patients from five million incidents of medical harm over the next two years.[17] It is anticipated that Maine hospitals will join this venture, and continue to strive towards improved patient outcomes for all our Maine patients.

ACTION PLANS 2007

1. Reallocation of resources within the Division of Licensing and Regulatory Services to allow the addition of one (1) additional Registered Nurse for the SE Team.

2. Recommend revision to the following regulations within The Hospital Licensing Reform Committee to:

    a. The Governing Board (Chapter VI) of the *Regulations for the Licensing of General and Specialty Hospitals in the State of Maine* to include criteria for what is a credible and thorough Root Cause Analysis;
    b. The Governing Board (Chapter VI) of the *Regulations for the Licensure of General and Specialty Hospitals in the State of Maine* to include, "The Division may conduct random audits of any and all healthcare facilities, and review facility data/records to assure compliance as outlined in the statute";
    c. The Quality Management Process (Chapter XXI) of the *Regulations for General and Specialty Hospitals in the State of Maine* to include a requirement regarding Failure Mode and Effects Analysis (FMEA), (1. A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome; (2. A systematic approach to identify and prevent product and process problems before they occur).[18]

3. Evaluate the need to similarly revise the licensing regulations for Ambulatory Surgical Centers, End Stage Renal Disease Facilities and Intermediate Care Facilities for Persons with Mental Retardation.
4. Categorize all CY 2007 SE data utilizing the NQF[10] core set of reporting standards, and include the NQF categories in the *Annual Report*.
5. Conduct random follow-up reviews of reported SE to assess implementation of corrective action plans.
6. Conduct follow-up reviews on events identified as having a potential for high risk of recurrence, significant impact on a high volume of healthcare services, or at high risk for death or serious injury if corrective action is not taken.
7. Continue to conduct periodic review of all complaints captured in healthcare entities as defined in the statute.
8. Continue to offer consultation services to licensed facilities and welcome the opportunity to provide education to staff on the SE reporting process.
9. Continue to collect, review and analyze reported sentinel events and share aggregated data and risk reduction measures to Maine facilities.

FUTURE CHALLENGES OF THE SENTINEL EVENT TEAM

1. To access training is essential to remain apprised of new clinical guidelines and standards of care.

2. Increased attendance at healthcare quality improvement programs would allow Team members the chance to meet, collaborate and interchange ideas on patient safety with participants from Maine and elsewhere.

3. Access to appropriate clinical literature, and access to on-line professional journals help the SE team remain current and prepared with the tools necessary to perform their duties.

4. Identify an appropriate platform for the sentinel event database. This would assist in compiling and analyzing data, and preparing for expanded networking capabilities with other states' databases.

5. Access to various clinical consultative staff as needed.

APPENDICES

Appendix A

USEFUL RESOURCES

U.S. Department of Veterans Affairs, National Center for Patient Safety: www.patientsafety.gov

National Patient Safety Foundation: www.npsf.org

National Academy for State Health Policy: www.nashp.org

Maine Quality Forum: www.mainequalityforum.gov

The Leapfrog Group: www.leapfroggroup.org

The Joint Commission: www.jointcommission.org

U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality: www.ahrq.gov/consumer/

Office of MaineCare Services: www.maine.gov/dhhs/bms/providerfiles/sentinel_reporting_forms.htm

G. P. Clagett, et als. Prevention of Venous Thromboembolism, Chest 1998; 114: 531S-560S; (journal on line) available from:

http://www.chestjournal.org/cgi/search?pubdate_year=1998&volume=114&firstpage=531&DOI=&author1=Clagett%2C+GP&author2=&title=&andorexacttitle=and&titleabstract=&andorexacttitleabs=and&fulltext=&andorexactfulltext=and&journalcode=chest&fmonth=Jan&fyear=1998&tmonth=Dec&tyear=1998&fdatedef=1+January+1946&tdatedef=1+January+2007&flag=&RESULTFORMAT=1&hits=10&hitsbrief=25&sortspec=relevance&sortspecbrief=relevance&sendit=Search. (Internet access; 16 January 2007.)

Helpful Hints on Preventing Inpatient Suicide from Oregon Association of Hospitals and Health Systems: http://www.aracnet.com/~oahhs/issues/safety/suicidehints.htm

Appendix B

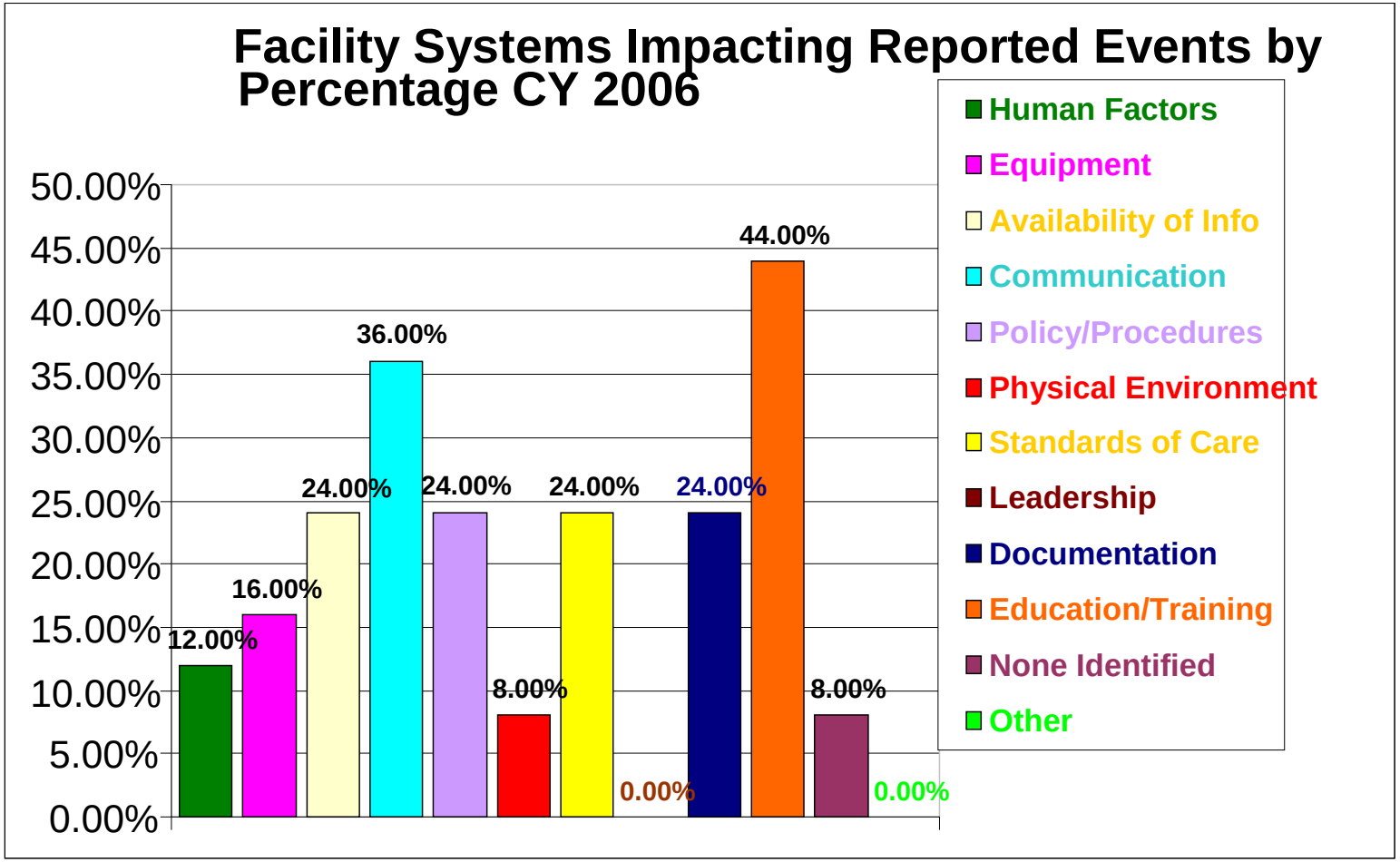
Maine Sentinel Events Reported During CY January 2006-December 2006 Utilizing NQF Serious Reportable Events Criteria

SURGICAL EVENTS	
A. Surgery performed on the wrong body part	3
B. Surgery performed on the wrong patient	0
C. Wrong surgical procedure performed on a patient	0
D. Retention of a foreign object in a patient after surgery or other procedure	0
E. Intraoperative or immediately post operative death in an ASA I patient	1
PRODUCT OR DEVICE EVENTS	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	0
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used for functions other than is intended	0
Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	0
PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	0
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	0
C. Patient suicide or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	1
CARE MANAGEMENT EVENTS	
A. Patient death or serious disability associated with a medication error (e.g., errors involving wrong drug, wrong dose, wrong patient, wrong rate, wrong preparation or wrong route of administration)	3
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO incompatible blood or blood products	0
C. Maternal death or serious disability associated with labor and delivery in a low-risk pregnancy while being cared for in a healthcare facility	0
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0

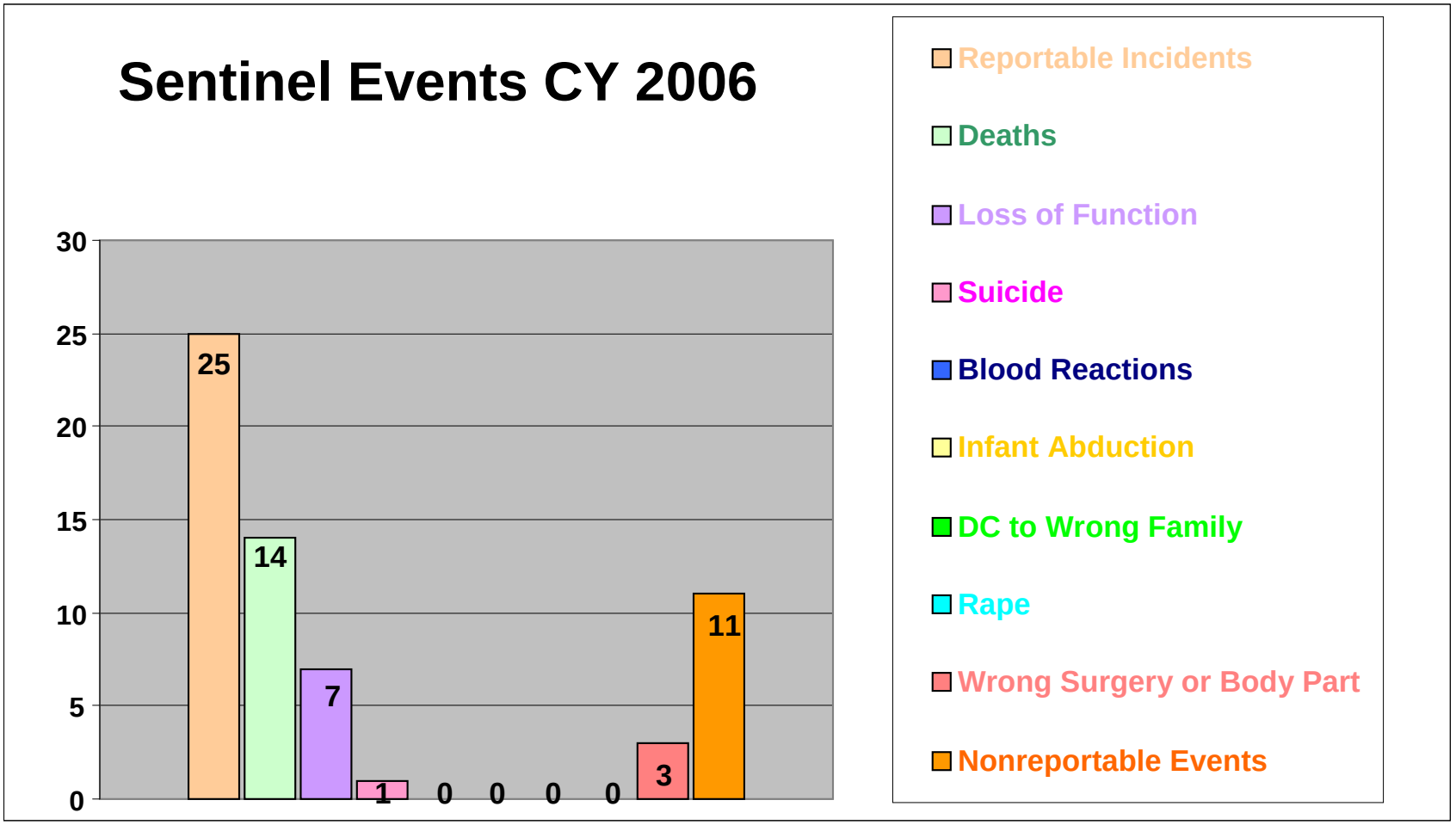
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	0
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	0
G. Patient death or serious disability due to spinal manipulation therapy	0
ENVIRONMENTAL EVENTS	
D. Patient death associated with a fall while being cared for in a healthcare facility.	

OTHER	
1. Events that could potentially meet NQF criteria with additional information	0
2. Events that did not meet NQF criteria	17

Appendix C


Facility Systems Impacting Reported Events by Percentage CY 2006
50.00%
45.00%
40.00%
35.00%
30.00%
25.00%
20.00%
15.00%
10.00%
5.00%
0.00%
12.00%
16.00%
24.00%
36.00%
24.00%
8.00%
24.00%
0.00%
24.00%
44.00%
8.00%
0.00%
Human Factors
Equipment
Availability of Info
Communication
Policy/Procedures
Physical Environment
Standards of Care
Leadership
Documentation
Education/Training
None Identified
Other

Appendix D


Sentinel Events CY 2006
30
25
20
15
10
5
0
25
14
7
1
0
0
0
0
3
11
Reportable Incidents
Deaths
Loss of Function
Suicide
Blood Reactions
Infant Abduction
DC to Wrong Family
Rape
Wrong Surgery or Body Part
Nonreportable Events

Appendix E

Facility Specific Data CY 2006

FACILITY TYPES	Deaths	Loss of Function	Suicide	Blood Reactions	Infant Abduction	DC to Wrong Family	Rape	Wrong Surgery or Body Part	Totals by Facility Type
Acute Hospitals	14	7	1					2	24
ASC								1	1
ESRD									0
ICF/MR									0

Appendix F

COMPARISONS BETWEEN REPORTED EVENTS FOR CY 2004, 2005 AND 2006
Hospitals, ASCs, ESRDs, ICFs-MRs

Classification of event	Frequency		
	2004	2005	2006
Unanticipated death	15	20	14
A manor loss of function	5	5	7
Surgery on wrong patient/body part	4	3	3
Hemolytic Transfusion reaction	0	0	0
Suicide of a patient	0	0	0
Infant abduction/discharge to wrong family	0	0	0
Rape of a patient	0	0	0
Total	24	28	25

Maine Department of Health & Human Services
Division of Licensing and Regulatory Services
Mandatory Reporting of Sentinel Events

Sentinel Event Reporting Form

Section I

This information is protected from public disclosure.

This form is required to meet the regulations pursuant to Section 1, 22 MRSA, Chapter 1684, Sentinel Events Reporting, § 8756
Regulations for Governing the Licensing of Ambulatory Surgical Facilities, Chapter 4.B. Compliance Requirements-Mandatory Reporting of Sentinel Events; the Licensing of General and Specialty Hospitals, Chapter VI.T. Governing Board-Mandatory Reporting of Sentinel Events; Critical Access Hospitals, Chapter XXVII C.1.b) (4); the Licensing of End Stage Renal Disease Units/Facilities, Chapter 4.F. Administration-Mandatory Reporting of Sentinel Events; the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation, Chapter 5.D.11 Mandatory Reporting of Sentinel Events

I. Each facility (general acute hospital, critical access, and specialty hospital, ambulatory surgical facility, end stage renal disease, intermediate care for mental retardation) shall report (to the Division) all patient sentinel events.

II. Patient Sentinel Events include:

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 that results from the elopement of a patient who lacks the capacity, as defined in Title 18-A, section 5-801, paragraph C, to make decisions:

1) An unanticipated death; or
2) Major loss of physical or mental function not related to the natural course of the patient's illness or underlying condition.

b. Surgery on the wrong patient or body part;
c. Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities;
d. Infant abduction or discharge to the wrong family;
e. Rape of a patient;
f. Suicide of a patient in a healthcare facility where the patient receives inpatient care.

02/20/07

Section II

Part I: *To be submitted or called to the Division at (207) 287-287-4325 by the next business day after the sentinel event occurred or the next business day after the hospital determines that an event occurred.*

Name of facility	
Type of Sentinel Event	
Date of Event	
Time of Event	
Date of detection (date event identified by facility)	
Date event reported to State	
Physical location of patient when SE occurred	
How was event discovered?	
Describe any immediate corrective action taken?	
Patient's Age	
Patient's Gender	
Admitting Diagnosis	
Admitting ICD-9 Codes	
Discharge ICD-9 Codes	
Name, title and contact information of person submitting report (Phone and confidential e-mail)	

Part II: Narrative Report *To be submitted in writing forty-five (45) days from the date the event was reported to the Division. (**May include attachments if all information is provided.**)*

Name of facility and address	
Name, title and contact information of person submitting report (phone and *confidential e-mail)	
Date and time of event	
Type of event	
Detailed Narrative Report to include:	1. Description of event 2. Clinical or organizational systems or processes that may have contributed to the sentinel event 3. Identification of changes to reduce the risk of reoccurrence, and all corrective actions taken or planned 4. Identifies who will be responsible to implement and measure/monitor effectiveness of risk reduction measures 5. Identifies when the proposed actions begin, and how frequently will they be assessed 6. Describes how corrective actions will be communicated to all levels of facility quality improvement process 7. Includes documentation of a relevant literature search related to systems/process improvement 8. Includes signature of the Chief Executive Officer/Administrator of the hospital.

Part III: Detailed Narrative Report

Please submit via fax to 207-287-3251, e-mail (carole.kennally@maine.gov), or mail (suggest Return Requested).

Confidential to Carole Kennally RN, HSC

Maine Department of Health & Human Services
Division of Licensing and Regulatory Services
#11 State House Station
41 Anthony Ave
Augusta, Maine 04333-0011

02/20/07

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