Maine Quality Forum

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Evaluation of Maine's: Sentinel Event Reporting System:

Is It Working for Maine?

January 9, 2006

Maine Quality Forum
Dennis Shubert M.D., Ph.D., Director

Maine Quality Forum Advisory Council
Rebecca Colwell R.N., B.S.N., M.B.A., Chair

MQF-AC Ad Hoc Committee for Evaluation of Maine's Sentinel Event Reporting System
Jonathan Beal Esq., Chair

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I. CHARGE

At the request of the Governor's Office, the Maine Quality Forum and the Maine Quality Forum Advisory Council formed an ad hoc committee to evaluate Maine's present mandatory sentinel event reporting system. The Advisory Council asked Representative Trahan to participate in recognition of his significant contribution to the present system. Rebecca Martins, who also was a significant contributor to the present system, participated through her seat on the Advisory Council and membership on the Ad Hoc Committee. All identifiable stakeholders were invited to participate including the Department of Health and Human Services.

The present system is supported by the two person sentinel event team functioning within the Division of Licensure and Certification of Department of Health and Human Services.

II. FINDINGS AND RECOMMENDATIONS

A. MAJORITY SUMMARY (4 Ad Hoc Committee members support; majority Advisory Council members support)

The Committee and the MQF Advisory Council found:

- Maine's present sentinel event statute is a tribute to the determination of forward looking dedicated people. The present statute reflects the consensus thinking around sentinel events at the time of its drafting.
- We acknowledge and are pleased by the positive effect Maine's sentinel event reporting law has had on promoting reporting, building of culture of safety by providers and building public awareness of the issue of healthcare safety.
- Maine's present sentinel event system with its use of a Sentinel Event Team excluded from other state government functions and protected from public disclosure laws, provides the intended mechanism for state support of thorough analysis of reportable events but limited required sharing of learnings among Maine providers.
- The sentinel event definitions in Maine's present statute require two levels of provider judgment (underlying condition, proper medical care) that introduce opportunity for marked variability that threatens the credibility of the reported sentinel events for the purpose of public accountability at the state health care industry level.
- Presently the Division of Licensure and Certification has not established the level of compliance with Maine statute. The Division's ability to establish compliance is made difficult by the inherent vagaries in the definitions and limitations on state resources.
- There is a national voluntary consensus standard sentinel event reporting taxonomy available and in the early stages of adoption.
- The National Quality Forum (NQF) 27 never events are examples of well defined serious reportable events useful for public accountability through public reporting.

- Providing the Maine Sentinel Event Team with the ability to forward de-identified descriptions of standardized sentinel events to national patient safety organizations partially fulfills Maine's obligation to the national greater good without imposing any identifiable burden or exposure to Maine's providers.
- The committee is concerned that there is an indeterminate amount of underreporting within Maine's system.

RECOMMENDATIONS

- Maintain present level of confidentiality and accountability to continue to promote reporting.
- Add the National Quality Forum's never events to Maine's sentinel event reporting statute.
- The Maine Sentinel Event team annual report shall confirm completion of planned corrective and preventive actions related to previous reported events.
- Through rule making, require providers to use the sentinel event taxonomy developed by the Joint Commission for Accreditation of Healthcare Organizations and endorsed as a national voluntary consensus standard by the National Quality Forum.
- Allow the state to forward de-identified summaries of Maine's events to Patient Safety Organizations recognized by the Federal Patient Safety Act of 2005.
- Require the Division of Licensure and Certification to adopt a protocol to assess compliance with the sentinel event statute.
- Encourage the sentinel event team to follow up and collect data on implementation of provider planned system corrections to system failures responsible for prior sentinel events.
- Provide the Maine Sentinel Event team and the Division of Licensure and Certification adequate resources to fulfill these recommendations as well as its existing statutory mandates. (Funding request details Appendix E)

B. MINORITY SUMMARY (1 committee member supports)

- As the legislature found just months ago, the current sentinel event program is working well and it is premature to significantly change the program or even create a legislative study around possible changes.
- The Division of Licensing and Certification, the state agency with the expertise and responsibility for the program, made recommendations that would improve but not substantially alter the program. These are the only changes that should be made at this time.
- Layering on the NQF list of reportable events to the existing law does nothing to address the majority's contention that the current statutory language is too variable to be a stable database. Adding additional reporting requirements simply adds more variability and distorts the baseline data collected to date.

- The national consensus standard taxonomy can be adopted by the department through rule-making when appropriate.
- It is premature to amend the statute to allow forwarding of aggregated, de-identified data to a national patient safety organization since they do not yet exist.

III. BACKGROUND AND PROCESS

It is important to understand why so much effort was invested in this appraisal. The evaluators agreed that the background for this effort is summarized by:

- Preventable patient injury and death, caused in large part by the failure to support inherently safer systems of care, occur often in the U.S. and Maine. The exact number is unknowable presently.
- The interim goal of any effort to reduce preventable patient injury and death is to promote adequate investment in personnel, training and systems by Maine's healthcare providers. The investment in supporting systems needs to match the recognized determination by providers to avoid preventable patient injury and death.
- Quality improvement science and common sense converge on accepting the statement that "you can not improve what you do not measure".
- Maine must have a reliable measure of success of avoiding preventable patient injury and death to fulfill state government's commitment and providers' commitment to their citizens/patients.

Given the fact of the ongoing nature of the challenge with avoidable injuries and deaths occurring in Maine, time is of the essence.

NARRATIVE OF THE PROCESS

Jon Beal, the Ad Hoc Committee chair called together staff support for the review effort on September 20, 2005. Attending the organizational meeting were also Lou Dorogi and Denise Osgood, from the Department of Health and Human Services, providing their insight on how the study effort should proceed.

The first meeting of the Ad Hoc Committee was convened on October 19, 2005. Mr. Beal outlined to the committee and the public the charge to the committee. Mr. Beal explained that the enthusiastic response to call for participants forced him to formalize the proceedings. He pointed out that the voting members of the Ad Hoc Committee would be the Advisory Council members who volunteered to participate in addition to Dr. Shubert and Representative Trahan. Representative Trahan had been invited to participate because of his major part in drafting the statute in force.

Mr. Beal outlined changes in the environment addressed by the Muskie School of Public Service and the National Academy of State Health Policy (NASHP) report integral to this document. The discussion is summarized in the summative notes appended. Mr. Beal requested written comments from public attendees which are also appended.

The second committee meeting took place telephonically to specifically review a survey of Maine physicians to address the issues of variability introduced into the sentinel event system by the proper medical care clause and the concern about under-reporting. It was decided to continue to refine the survey and test with the provider group.

The third committee meeting convened on November 29. At that time the draft report from Muskie/NASHP was reviewed by the committee with minor suggestions offered to the report itself. The committee then reviewed draft findings which it discussed and accepted public comment. The findings were accepted with one dissenting vote. The meeting was continued until December 1 at which time the committee worked through the draft recommendations which received committee and public comment and then was adopted with one dissenting vote. The committee also endorsed statements offered by Dr. Shubert with the intent of gaining common agreement on why the review effort was so important. Those statements were adopted by the committee.

The Maine Quality Forum staff was asked to provide an analysis of implementation of the committee recommendations that would be included in the report of the committee.

APPENDICES

APPENDIX A: Research Report

An Assessment of the Maine Sentinel Event Reporting System

December 2, 2005

Prepared by:

Maureen Booth, Muskie School of Public Service, University of Southern Maine
Jill Rosenthal, National Academy for State Health Policy

Prepared for:

Maine Sentinel Event Ad Hoc Committee
Maine Quality Forum Advisory Council

I. Background

I.1. Purpose of Ad Hoc Committee and This Report

In September 2005, the Maine Quality Forum through the Maine Quality Forum Advisory Council established the Maine Sentinel Event Ad Hoc Committee to assess opportunities for strengthening Maine's sentinel event reporting system through:

- alignment of Maine's reporting requirements with the National Quality Forum's list of serious reportable events
- use of a nationally accepted taxonomy to facilitate analysis and reporting of events
- sharing of data with a patient safety organization to be designated by the federal Agency for Healthcare Research and Quality.

Following a general discussion on the purpose of mandatory adverse event reporting, this report reviews five major issues that impact on the nature and scope of the Maine sentinel event reporting system:

- Adoption of the National Quality Forum (NQF) 27 Serious Event List
- Use of the "Proper Medical Care and Underlying Condition Clauses" in Maine
- Endorsement of a taxonomy by the NQF for reporting serious events
- Legislation to establish Patient Safety Organizations (PSO)
- Staffing and resources

The paper provides a general background on each of these developments, a discussion for possible implications for the Maine sentinel event reporting system, and options for consideration. After a brief discussion on issues of state capacity and resources, the paper concludes with a list of recommendations.

Through its cooperative agreement with the Muskie School of Public Service at the University of Southern Maine, the Maine Quality Forum requested Maureen Booth of the Muskie School and Jill Rosenthal of the National Academy for State Health Policy provide assistance to the Ad Hoc Committee in assessing the Maine sentinel event reporting system in light of the above issues. This report is largely a product of their efforts and was used by the Ad Hoc Committee in making their final recommendations to the Maine Quality Forum Advisory Council.

I.2. Purpose of Mandatory Reporting of Sentinel (or Adverse) Events

According to the Institute of Medicine (IOM), medical errors rank as a leading killer in the United States, with as many as 98,000 people dying each year as the result of errors in hospitals alone. The 1999 IOM report *To Err is Human* called on every state government to create a mandatory reporting system to collect standardized information about adverse events that result

in death or serious harm to identify and learn from errors.[1] Almost half of all states (24) have passed legislation or regulation to operate mandatory reporting systems.[2]

Mandatory reporting systems serve various functions.[3]

- Mandatory reporting systems can help identify system weaknesses. Single incidents may indicate that facility error-prevention mechanisms are not working effectively and warrant an immediate response. Identification of system weaknesses is the first step in driving improvements in patient safety.
- Mandatory reporting systems can complement other oversight functions. States that cannot routinely inspect hospitals for licensure requirements rely on investigations triggered by incident reports to provide an important window into hospital patient safety practices.
- Mandatory reporting systems serve the interests of the public who expect state governments to be aware of and investigate reports that may put a patient's safety in jeopardy.
- Mandatory reporting systems create an important check and balance to assure that a facility's internal patient safety activities are working.
- Public reporting of findings from mandatory reporting systems can allow the public and policy makers to follow the success of provider safety efforts.

According to the IOM, the overriding reason to establish a mandatory reporting system is to hold healthcare facilities accountable for preventable adverse events that result in serious injury or death. Accountability is achieved by investigating an adverse event, providing expertise or information to help remedy the problem, and insuring that appropriate changes are made and sustained to avoid the problem in the future.[4]

As the guardian of public safety, consumers assume that a state is aware of serious events when they occur and takes measures to protect them against possible recurrence. Although not all adverse events result from errors, states are able to conduct independent investigations to determine or validate their root cause and to take collective action by alerting other facilities when it is found that future events could likely be prevented.

A secondary purpose of a mandatory reporting system may be to collect and aggregate information across facilities to improve overall quality and patient safety. Many mandatory reporting systems emphasize accountability but also incorporate aspects of a quality improvement model. They do so by sharing with all facilities the lessons learned from individual reported incidents so that similar mistakes can be avoided in the future.

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[1] Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999), 9.

[2] See www.nashp.org for a list of states

[3] For more information, see Jill Rosenthal, Maureen Booth, How Safe Is Your Health Care? A Workbook for States Seeking to Build Accountability and Quality Improvement Through Mandatory Reporting Systems (Portland, ME: National Academy for State Health Policy, 2001).

[4] Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Washington, D.C.: National Academy Press, 1999), 86.

Function	Pros	Cons
Accountability *and* Quality Improvement	Aligns with state regulatory functions Provides information to reporting facilities for internal quality improvement processes Provides an opportunity for states and facilities to work collaboratively	May be seen as conflicting with state's regulatory role Requires enhanced analytic and educational resources

I.3. Major National Developments in Patient Safety

Maine enacted a system for reporting sentinel events in 2003 for the purpose of improving the quality of health care and patient safety. Since the enactment of the Maine system, the patient safety environment has changed in many ways. Patient safety reporting has changed as well, including:

- A concerted effort nationally to standardize patient safety reporting systems, including the development of a NQF list of 27 serious preventable adverse events recommended to be the basis of state reporting systems, the development of a nationally endorsed patient safety taxonomy, and the enactment of the federal Patient Safety and Quality Improvement Act of 2005, all explained in more detail later in this report.
- Development of reporting systems in additional states and improvements in the systems of existing state systems, including adoption of the NQF list in 5-6 states (NQF adopted in CT, IL, MD, MN, NJ, and under consideration in IN).

The establishment of the Maine Sentinel Event Reporting System Ad Hoc Committee by the MQF was intended to assess Maine's system in light of these developments. The following sections provide detail about these issues and whether and how they may impact Maine's existing sentinel event legislation.

II. NQF List of Serious Reportable Events

II.1. Background

The IOM report urged Congress to designate the NQF as the entity responsible for establishing and maintaining a core set of reporting standards to be used by states.[5] Through a voluntary consensus process with representatives across the spectrum of healthcare stakeholders, the NQF developed a list of 27 serious, preventable adverse events that should be reported by all licensed healthcare facilities. The NQF list is relatively short, includes only clearly defined events, and uses standardized terminology to encourage consistent implementation within and across states.

[5]The National Forum for Health Care Quality Measurement and Reporting (National Quality Forum or NQF) is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. See www.qualityforum.org.

As the NQF indicates, the list of serious reportable events is not intended to capture all events that may impact patient safety. Items were chosen based on the following criteria:

- Of concern to both the public and healthcare professionals and providers,
- Clearly identifiable and measurable, and
- Of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.

To qualify for the list, events were required to be serious, usually preventable, and any of the following:

- Indicative of a problem in the healthcare facility's safety systems, and/or
- Important for public credibility or public accountability given the serious nature of the event.[6]

States have identified several advantages of the national core set of reporting requirements. First, it would minimize conflicting requirements on hospitals and help benchmark hospital efforts to reduce error. Second, nationally aggregated data could help identify larger trends in serious events. Since these serious events are relatively rare, aggregate data may provide information that cannot be trended on a state-by-state basis. Once identified, quality improvement efforts might be tailored to address them.[7]

II.2 Implications of Adopting the NQF Event List in Maine

This section compares the NQF events to those required under Maine's Sentinel Event Reporting Law. The following section addresses the issue of Maine's "proper treatment" clause and how it aligns with the intentions of NQF.

Figure 1 compares NQF events with those required in Maine. As shown on this chart, Maine's adoption of the NQF list of serious reportable events would lead to the reporting of some events that are not currently or explicitly included in the Maine sentinel event list ("no state equivalent" or "more broad than NQF"). In other cases, there are events that Maine currently collects that are not required by the NQF. Aligning the Maine events with those of NQF is complicated by Maine's "proper care" clause which limits reporting to events found to have been the result of improper care by the facility. Thus, although actual event types may be broader than those of NQF, it may not yield more events.

[6]The National Quality Forum, Serious Reportable Events in Healthcare, (Washington, D.C.: National Forum for Health Care Quality Measurement and Reporting, 2002), page 6-8.

[7] Jill Rosenthal, Maureen Booth, Defining Adverse Events: A Guide for States Tracking Medical Errors (Portland, ME: National Academy for State Health Policy, 2003)

Figure 1 - Overview of Differences Between NQF and ME Sentinel Events

NQF Serious Reportable Events	*ME Sentinel Events*			
	More broad than NQF	Equi-valent	More narrow than NQF	No State equiva lent
I. SURGICAL EVENTS				
A Surgery performed on the wrong body part		X		
B Surgery performed on the wrong patient		X		
C Wrong surgical procedure performed on a patient				X
D Retention of a foreign object in a patient after surgery or other procedure				X
E Intraoperative or immediately post operative death in an ASA Class I patient	X			
II. 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	X			
B Patient death or serious disability associated with the use or function of a device in patient care in which the device is used for functions other than as intended	X			
C Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	X			
III. PATIENT PROTECTION EVENTS				
A Infant discharged to the wrong person		X		
B Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	X			
C Patient suicide or attempted suicide resulting in serious disability, while being cared for in a healthcare facility.			X	
IV. 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 time, wrong rate, wrong preparation or wrong route of administration)	X			
B Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	X			
C Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	X			
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	X			
E Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	X			
F State 3 or 4 pressure ulcers acquired after admission to a healthcare facility				X
G Patient death or serious disability due to spinal manipulative therapy	X			
V. ENVIRONMENTAL EVENTS				
A Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	X			
B Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances				X
C Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	X			
D Patient death associated with a fall while being cared for in a healthcare facility	X			
E Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	X			
VI. CRIMINAL				
A Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed healthcare provider				X
B Abduction of a patient of any age			X	
C Sexual assault on a patient within or on the grounds of the health care facility			X	
D Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of the healthcare facility	X			

NQF Events Not Currently or Explicitly Included under Maine Sentinel Events

- Wrong surgical procedure reported on a patient (potentially captured using the current list but not an explicit criteria)
- Retention of a foreign object in a patient after surgery or other procedure (potentially captured using the current list if the retained foreign object causes death or significant permanent injury but not an explicit criteria)
- *Attempted* suicide (only suicide is currently reportable)
- Stage 3 or 4 pressure ulcers acquired after admission to a health care facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider (reportable under other Maine reporting requirements)
- Abduction of patients who are not infants (infant abduction is currently included)
- Sexual assault on a patient that does not constitute rape (rape is currently included)

Hospitals and other stakeholders point to the fact that many of the above events are collected under Maine's broad language of "unanticipated death or major permanent loss of function" are reported to other agencies, or that they can be accounted for through an analysis of hospital discharge data. A review of 2004 hospital discharge data found that no wrong site surgeries were performed. Information reported by Licensure and Certification indicates that four wrong site or body part surgeries were reported under Maine's sentinel event system, indicating that hospital discharge data alone may fail to identify serious avoidable events. These numerical discrepancies may in part be attributable to challenges of coding or barriers to the flow of sensitive information within a healthcare provider.

Discrepancies aside, the purpose of a sentinel event reporting system as envisioned by the IOM and NQF is not simply to account for the number of adverse events but to have meaningful and standardized information about each event, the authority to investigate and act on findings relative to each event, and the commitment to share information broadly across facilities to reduce their reoccurrence. Data reported to the Food and Drug Administration or hospital discharge data base, while potentially providing a raw count of events, do not satisfy this broader mandate for investigation and action on the part of the state when serious events occur, or shared learning across all Maine hospitals.

Maine Sentinel Events Not Included under NQF

Maine's adoption of the NQF list would narrow the list of reportable events in other ways. While Maine requires the reporting of all unanticipated deaths and major permanent loss of function in general terms, the NQF list is quite specific in defining which types of unanticipated deaths and serious disabilities are reportable. For instance, according to the NQF list, a death or serious disability associated with a low-risk pregnancy is reportable, but not if it is associated with a high cost.

Impact of Adopting NQF List on Actual Adverse Event Reporting in Maine

A separate but related analysis in determining the implications for Maine of adopting the NQF list is to compare ACTUAL events reported under the current system to those required under the NQF. Maine Licensure and Certification reviewed all events submitted over a 23-month period from January 2004 through November 2005 and found that 56 percent fell within NQF categories. In descending order of frequency, the most common NQF categories were:

- Death with fall
- Wrong surgery
- Medication error with injury or death
- ASA I death
- Device related to death or injury.

Given the "proper care" filter, this analysis cannot provide a definitive judgment on what events would be "lost" or "gained" if Maine was to adopt the NQF list. It suggests, however, that approximately 50 percent may not be captured.

Pros of adopting the NQF list	Cons of adopting the NQF list
A clearly defined list is essential for the development of a national system compiled of data from state systems and for comparative purposes.	Because of its limited intent, the NQF list may not meet all of the states needs for regulatory authority and reporting requirements.
Standardization may increase reporting. Underreporting of events has been attributed in other states in part to a lack of clear definitions and ambiguity for what must be reported. Clarity allows the Division of Licensure and Certification to validate full reporting.	The specificity of the NQF list would result in exclusion of some events that are currently reportable under the Maine sentinel event list.
Adoption of the NQF would clarify some events that may not currently be reported under the Maine sentinel event list	Requires statutory or regulatory change
The IOM report *To Err is Human* called for Congress to require all health organizations to report standardized information to state governments	Providers would have the option of not subjecting an unanticipated death to full root cause analysis with follow-up.
Efficiently and effectively targets resources of providers and state staff who collect the data	

II.3. Options for Consideration

Four options have been identified for maintaining the current system or modifying it in minor or substantive ways.

1. Make no changes in how a reportable event is defined.
2. Retain the present reporting requirements of the Maine statute. Publicly report in aggregate only those that are equivalent to NQF events. This would restrict public accountability to only those specific events that are clearly preventable and typically result from medical error.
3. Change the statute to include only NQF events thereby standardizing reportable events. This option helps to target Maine efforts and resources to those events known to be highly preventable, and around which there are established guidelines and benchmarks for evaluating. It could also substantially reduce reporting burden on the part of hospitals.
4. Change the statute to include both the NQF list of events and the current Maine list. This option, with no other changes, would increase reporting burden of the hospitals by an unknown amount.

Concern about "opening up" Maine's statute for revision focuses on the possibility that gains made by the state in patient safety through its reporting system may be jeopardized. This was a legitimate concern during the time that Maine first adopted its sentinel event reporting system after a hard-won battle in 2003. At that time, there were no national consensus standards for reportable events. Each state was on its own in making the case for its mandated event reporting system. Opponents feared loss of hospital confidentiality and the onset of a blame mentality among the media. Today, there is far more convergence among patient safety experts, regulators, healthcare providers and the public about the legitimate role of the state in knowing when serious adverse events occur and acting on that data to assure the public that every effort is being made to avoid their reoccurrence in the future. There is also a growing consensus about what constitutes a preventable adverse event and the information that is needed to understand underlying causes and potential remedies.

At the same time, any proposed change to Maine's statute must come with assurances of not changing strong confidentiality protections necessary to the reporting and analysis process or changing the present level of accountability. Every effort must also be made to work with the media to understand and educate others to understand how patient safety findings should be interpreted.

III. Proper Medical Care and Underlying Condition Clauses

III.1. Background

The NQF includes a list of 27 events that are known to be primarily preventable and/or serious in nature and which, *a priori,* must be reported. The NQF taxonomy also proposes that facilities conduct thorough analyses of the causal factors believed to have led to the event and to submit those findings to the state for review and validation.

According to Maine law, 1) unanticipated deaths and 2) major permanent loss of function that is not present when the patient is admitted to the health care facility are reportable when 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.[8]

III.2. Implications for Maine

The proper treatment clause enables facilities to review sentinel events and determine whether they are the result of proper treatment before determining whether they are reportable. A similar event that occurs in two facilities may result in different outcomes. For example, if a death occurs in a facility and is determined to be unrelated to the natural course of the patient's illness or underlying condition and the facility believes the patient received proper treatment, the event would not be reportable. If another facility experiences a similar situation in which a patient dies and it is determined to be unrelated to the natural course of the patient's illness or underlying condition but the facility believes the patient did not receive proper care, the event would be reportable. The determination of proper treatment may be the result of a judgment based on the thoroughness of a root cause analysis or other factors. In simplest terms, the very circumstances that led to an adverse event (poor judgment or quality oversight) may, under Maine statute, be the determining factor in deciding whether or not to report the event. Maine's present statute introduces major opportunities for variability that cause concern about trending the rates of events over time. Also, the Maine system makes it almost impossible for the Division of Licensure and Certification to establish adequate reporting in that they do not have the expertise and resources to second guess providers in very complicated cases that may also be numerous.

According to an analysis of the existing state mandatory reporting systems, only Kansas includes a proper treatment clause similar to Maine's clause. The remaining systems require reporting of events regardless of the facilities' judgment about proper care.

Pros of the proper care clause	Cons of the proper care clause
Reduces the number of reportable events to avoid overwhelming state staff who collect the data	Introduces variability by basing the decision on whether to report an event on a judgment as opposed to having clearly identifiable and measurable events. Introducing variability into what is reported reduces the usefulness of the data for analysis and also for follow up investigation.
Narrows the list of reportable events to those that the facility believes are the result of improper care, which makes the list of reportable events closer to "errors"	Makes a judgment of root cause before reporting occurs, which eliminates the ability of the state system to aggregate and identify issues that may not be perceived at the facility level
	Reduces standardization with other reporting systems nationwide.
	Makes assessment of completeness of reporting very difficult

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

III.3. Options for Consideration

In considering options with regard to the proper treatment clause, it becomes necessary to consider adoption of the NQF list simultaneously. The NQF list includes clearly identifiable and measurable events, while the proper treatment clause introduces variability. Eliminating the proper treatment clause but retaining the current list of reportable events could dramatically increase the list of reportable events, overburdening facilities and state staff. Eliminating the proper treatment clause while simultaneously adopting the NQF list would reduce the list of reportable events.

1. Keep the current list of events with the "proper treatment" clause.

2. Keep the current list of events but remove the "proper treatment" clause, leading to more events being reportable to the state.

3. Adopt the NQF list of serious reportable events and discontinue present state definition of reportable events, likely leading to the same or fewer events being reportable to the state and with more national standardization.

4. Adopt the NQF list of serious reportable events, continue present state definition of reportable events and do not apply the "proper treatment" clause to the NQF list. This option would likely lead to a greater number of events being reported.

IV. NQF Taxonomy

IV.1. Background

On August 3, 2005, the National Quality Forum (NQF) endorsed the National Voluntary Consensus Standard for a Patient Safety Event Taxonomy. The taxonomy was developed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) with the assistance of a work group and represents the consensus of more than 260 healthcare providers, consumer groups, professional associations, purchasers, federal agencies, and research and quality improvement organizations. It establishes the nation's first standardized integrative classification system for healthcare errors and other patient safety problems.

The principal purpose of a taxonomy is to support better decision making and the prevention of harm by provider organizations by enabling information to be collected and aggregated across information systems within a health care setting about factors related to events. A secondary purpose is to enhance analysis by reporting systems to support healthcare improvement efforts at all levels, from individual providers to national policy. While there are many taxonomies in current use, the absence of a standardized taxonomy is a major barrier to understanding where and how problems occur. The selection of the JCAHO taxonomy followed a comprehensive "Call for Taxonomies" and was based on selection criteria including:

- Addresses near misses as well as adverse events
- Designed to encompass multiple clinical domains and settings of care

- Compatibility with other more focused taxonomies and with electronic information systems
- Brings with it continual improvement and updating capacity
- Designed to support both reporting and analytic efforts and to cover a wide spectrum of healthcare services and settings[9]

The taxonomy includes 5 primary classifications for an event:

1. ***Impact*** – the outcome or effects of medical error and systems failure, commonly referred to as harm to the patient.
2. ***Type*** – the implied or visible processes that were faulty or failed.
3. ***Domain*** – the characteristics of the setting in which an incident occurred and the type of individuals involved.
4. ***Cause*** – the factors and agents that led to an incident.
5. ***Prevention and Mitigation*** – the measures taken or proposed to reduce incidence and effects of adverse occurrences.

Each of the primary classifications are further divided and subdivided to allow for finer distinctions among the factors that affect patient safety. For example, subdivisions for the primary classification of **domain** would provide the following type of uniform information:

Setting: The event occurred within a hospital, in the emergency room.

Period: The date of the event was November 24, 2005, a holiday. The time was 6:15 a.m.

Staff: The physician was a resident. The nurse was an LPN. There was also a radiation technician present when the event occurred.

Patient: The patient is 67 years, male, primary diagnosis of cardiac heart failure, previously unidentified, coexisting condition of diabetes.

Target: The original clinical reason why the patient entered the emergency room was therapeutic.

Maine statute requires facilities to provide a written report on each event containing the following information:

- Facility name and address
- Name, title and phone number of the contact person for the facility
- Date and time of the sentinel event
- Type of sentinel event and a brief description of the sentinel event
- Identification of clinical and organizational systems or processes that may have contributed to the sentinel event
- Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and
- Brief description of any corrective action taken or planned.

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[9] NQF, *Standardizing a Patient Safety Taxonomy: A Consensus Report*, February 9, 2005.

There is no required format for reporting in Maine or any standardization to how the above elements should be described.

IV.2. Implications of the NQF Taxonomy for Maine

Adoption of the taxonomy in Maine would add to upfront time in reporting and analyzing events but provide potential time savings both within facilities as they conduct their internal root cause analysis and by the state Sentinel Event Team as it evaluates the nature of a reported event, its implications for further investigation, and the aggregation of event knowledge across facilities for broader lessons. Adoption of the taxonomy would require the state to modify its data collection mechanism in order to enhance its analysis capabilities. The taxonomy could be used for both reporting of the NQF list of events as well as the broader list of unanticipated deaths required in Maine.

IV.3. Options for Consideration

1. Adopt statewide the NQF taxonomy. The taxonomy was created by and is supported by the JCAHO which means it will be mandatory for JCAHO accredited organizations in the near future.
2. Do not adopt the NQF taxonomy.

V. Patient Safety and Quality Improvement Act of 2005

V.1. Background

The IOM's Committee on Data Standards for Patient Safety has noted the need for national leadership to establish and maintain standards for patient safety databases. Its recommendations include developing standards for the collection, exchange, and reporting of data to support patient safety and standardizing report formats and terminology to capture and report data related to medical errors.[10] These recommendations led to the National Patient Safety and Quality Improvement Act of 2005, which seeks to encourage health care providers to report medical errors and adverse events through a voluntary and protected mechanism to patient safety organizations (PSOs), independent nationally certified organizations which will compile and analyze the data. The legislation also allows the Secretary of the Department of Health and Human Services to determine common formats, including data elements and definitions, for PSOs to use.[11] Currently, no PSOs have been designated. The methodology for establishing PSOs and collecting patient safety information has not yet been developed.

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[10] Institute of Medicine, *Patient Safety: Achieving a New Standard for Care* (Washington, D.C: National Academy Press, 2004), 11.

[11] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ041.109

V.2. Implications of PSOs for Maine

The confidentiality provisions of the Patient Safety and Quality Improvement Act may provide incentive for state reporting systems to share their information with PSOs to facilitate enhanced data analysis and learning. However, to do so, violates the "voluntary" nature of PSO reporting unless there is explicit agreement with Maine hospitals to have their data reported. While it may be possible under revised statute for the state to submit de-identified data to the PSO or other body, it may fracture provider support for robust reporting.

The state itself may apply for PSO designation, an unlikely decision given the size and resources of other potential competitors.

V.3. Options for Consideration

1. Keep the Maine sentinel event system completely separate from future PSO developments
2. Adopt statutory language that would enable the Maine sentinel event reporting system to report de-identified data to a PSO.
3. Negotiate voluntary agreements with hospitals for the Maine Sentinel Event Reporting System to submit de-identified, statewide data to the PSO.
4. Consider the potential for the Maine sentinel event system to also function as a PSO.

VI. State Capacity and Resources

VI.1. Background

Throughout the work of the Ad Hoc Committee, issues came to light that raise questions about the adequacy of resources available to Maine Licensure and Certification, the division responsible for administering Maine's sentinel event reporting system, to appropriately implement and oversee the reporting system. By its own acknowledgement, the division has been unable to validate the accuracy or completeness of reporting, the thoroughness of root cause analyses conducted internally by facilities, or the effectiveness of remedies. Actual or perceived "fire walls" prevent findings from being shared with state surveyors to help target and focus routine licensure reviews. Current licensure requirements fail to provide sufficient safeguards that assure facilities are doing all they can to prevent errors before they occur. Although fulfillment of reporting requirements is a condition of licensure, the division has not assured that facilities are meeting this requirement.

The division has made recommendations to the committee regarding opportunities to improve the system within the current statute. In order to implement the changes, additional resources in the form of personnel, training, database preparation, and consultant expertise are required.

VI.2. Implications

Many of the issues raised in this report directly relate to the availability of resources. Regardless of what action is taken on revising Maine's statute or regulations to address the NQF and PSO, focus should be directed at assuring that sufficient resources are available to meet the challenge of improving patient safety throughout the state. Considerations to alter the current system should similarly take resources into account. As previously noted, some other state reporting system administrators have advocated for the adoption of a national standard, taxonomy and guidelines to strengthen and focus their state reporting system on known and preventable events.

VI.3. Options

The level of funding will directly affect the capacity of the Sentinel Event Team to meet its statutory obligations. The movement to a standardized event list and taxonomy can ease the validation process and enhance analytic capacity through the use of commercial software applications currently on the market.

This project did not include an assessment of the operations of the Sentinel Event program with respect to staffing and resource allocation. Resource needs will vary based on final recommendations and should be delineated in close coordination with the Sentinel Event Team to assure that they have the training, supports and expertise to fulfill their requirements.

APPENDIX B: Implementation Options

Change	Without Legislation	Not Achieved Without Legislation	Achieved With Legislation
Implement NQF Never Events	Categorize events in the annual report by NQF Never Event Categories	5/27 Not included, Future National Consensus Events not included, Proper care clause introduces variability into multiple events	Adopt present and future NQF National Consensus Standard Events; events collected without provider judgment of proper care thereby establish state level responsibility and trending indicator.
More Clearly define and require root cause analysis	By adoption in the hospital Licensing Manual		
Require sentinel event team follow up of corrective actions	Department Policy		
Review received complaints to licensing for unreported sentinel events	Department Policy		
Establish provider compliance with the sentinel event reporting statute at the time of licensing visits and random visits	Department Policy and changes to Licensing Manual		
Adopt NQF/Joint Commission Taxonomy	By Department rule change		
Report deidentified aggregated events to a national Patient Safety Organization	None		Language to allow
Provide adequate resources to sentinel event team	Can't, but separate from sentinel event statute itself		Possible

APPENDIX C: Minority Report

Submitted by Representative Trahan

As the sponsor of the original legislation leading to Maine's sentinel event reporting law, I appreciated the opportunity to participate in the Maine Quality Forum Advisory Council's Ad Hoc Committee on Maine Sentinel Event Reporting. While I support the Committee's recommendations to improve the current program by adopting the Division of Licensing and Certification's recommendations and providing the necessary staffing and resources for the state's Sentinel Event Team, I oppose the majority report's recommendation of legislation this session to add to the current list of reportable events. I also oppose the majority report's premature recommendations to implement a nationally-endorsed patient safety taxonomy at this time and provide the state authority to forward reported data to entities that have yet to be established.

Maine's sentinel event reporting law has two goals: to establish accountability at the industry level by publishing de-identified reports on the occurrence of certain sentinel events and to provide helpful information back to the provider community so that they can learn from one another how to best avoid the occurrence of sentinel events. It is a new program that just released its first annual report this year. I'm very proud of the collaborative effort that created this program, one of the first in the nation. We carefully considered every component and ultimately modeled the sentinel event definitions after the national standard set by the Joint Commission on Accreditation of Healthcare Organizations.

According to the Division of Licensing and Certification and the hospital community, the program is working well. This assessment is consistent with the conclusion reached by the legislative Health and Human Services Committee just months ago when the Maine Quality Forum first asked for these changes to be made to the statute. The legislature also rejected a proposal to study the law, again noting that more experience with the new program was needed.

The majority report makes several recommendations based on the majority's views that there is a new and improved national standard for defining sentinel events, that Maine's law lacks clarity because there is variability around when certain reporting standards are met, and the majority's perception that there may be under-reporting of sentinel events under the current statute. I disagree with both the basis for the majority's recommendations, as well as some of their recommended actions.

First, the majority report advocates adding the National Quality Forum's list of 27 serious reportable events to Maine's current definition of reportable events. However, the Committee discussed incorporating the National Quality Forum's list of reportable events by reference, rather than listing the 27 specific events, because they acknowledged that the NQF list was likely to change this year, and be revisited routinely. Given that the NQF list is expected to change soon, and periodically, I don't believe the NQF current

list should be incorporated into Maine's statute, either as it currently exists or incorporated by reference.

Changing the list of reportable events at this early state of the program's operation also would render the baseline experience of the first two years meaningless. The first annual sentinel event report was well received, by the media, consumers, providers and the legislature, and I look forward to the second annual report in early 2006. To substantively change the list of reportable events at this point would effectively distort the newly established baseline and force the entire effort to begin anew, rather than building on the success to date.

Maine's definition of sentinel events accomplishes its intended purpose, which is to encompass a substantial portion of the sentinel events due to medical error. The Maine definitions do not cover every conceivable sentinel event; nor does the NQF list. But the current law provides extensive valuable information to the public and to the provider community, and could be enhanced even further by adopting the Division's recommendations.

Second, the majority report contends that Maine's current definitions of sentinel event improperly allow for variability and provider judgments because the reporting of unanticipated deaths or loss of function is limited to those events "unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition." This phrase is intentionally part of Maine's sentinel event reporting program because improper care is a key factor in reporting these events for several reasons. Certainly Maine's program is consistent with the national focus around sentinel events, which is the prevention of medical errors. Also, the Maine administration, consumers and the media all refer to Maine's sentinel event reporting system as a report on improper care. I've attached the newspaper articles provided to the committee by the Maine Hospital Association to illustrate this point. This connection to medical errors is precisely why Maine's law contains the link to proper care and underlying condition. Given that the Maine program is clearly and irrevocably seen as a report on provider blunders, this phrase is critically important so that events beyond the control of the health care system are not attributed to the reporting provider as an error.

I also believe that the NQF list of reportable events also has intrinsic ambiguity. For example, on the NQF list of reportable events, whether a "device" was used "for functions other than as intended" would certainly be the subject of provider discussions and judgment. Not only do I believe that such ambiguities are inherent in any list of reportable events, but I think they stimulate invaluable discussions within the reporting facilities that assist in their efforts to implements system changes that will prevent recurrence of the event. I must also note the provider community's periodic collaborative educational programs with the state's Sentinel Event Team to discuss this and any other questions that may arise around Maine's reportable events helps provide some interpretive clarity and reporting consistency.

The committee was also concerned that such variability would render the state's annual reports useless for trending and comparing performance from one year to the next. While the current Maine law and the NQF list both have some events that are unequivocally reportable, e.g. "surgery performed on the wrong patient", both lists also have events that are not so clearly defined and I don't see this fact as a fatal flaw. The intrinsic variability of both the Maine and NQF lists is another reason I disagree with the proposed recommendation to add to the NQF list to the existing program. Simply adding additional reportable events, with their own definitional issues, does nothing to address any perceived variability in the system.

Some Committee members also thought that the unavoidable variation might also result in the potential for under-reporting of sentinel events. While I didn't see any clear evidence of under-reporting, nor do I understand why simply adding more reportable events to the Maine statute would address this issue, I wholeheartedly support fully funding the state's sentinel event division so that they may perform audits to assure full reporting. I understand that some Committee members are concerned that the state may not reach the same conclusions as a facility did with regard to the reportability of some sentinel events, but I believe that the audit process will fairly reveal any patterns of under-reporting that may exist.

I also believe the current program will be enhanced when the Sentinel Event Team has adequate resources to follow-up with reporting facilities as recommended by the Division of Licensing and Certification. While the current public reporting system serves as an accountability tool, the ultimate goal of preventing sentinel events will benefit from continued state oversight.

When the legislature approved the original bill, it called for funding four state positions. Unfortunately, despite my best efforts, only two positions were funded so the state has been unable to entirely fulfill the statutory intent. I continue to support the four positions, which are necessary to maximize the reporting program as it was originally designed. I've attached the Division of Licensing and Certification budget estimates of what may be necessary to fully implement their recommendations, which have my unqualified support.

The majority report makes two other recommendations: to adopt the sentinel event taxonomy created by the Joint Commission for the Accreditation of Health Care Organizations and endorsed by the National Quality Forum and to amend Maine's law so that the state can send de-identified reports to federally certified "Patient Safety Organizations." The sentinel event taxonomy may be adopted through rulemaking *when* it is publicly available to all providers required to report sentinel events. Currently, JCAHO hospitals have access to the taxonomy, but the final NQF-endorsed taxonomy is not publicly available. According to Maine Hospital Association comments, the NQF is in the process of finalizing the taxonomy and developing national implementation guidelines. Therefore, I believe that requiring use of the taxonomy at this time is premature, although I support its use when it becomes available and note that legislation is not required to mandate or permit its adoption.

Congress recently passed legislation authorizing the creation of federally certified Patient Safety Organizations that would collect patient safety data voluntarily submitted by providers. The federal law directs the Secretary of the Department of Health and Human Services to issue rules specifying the details for the operation and certification process for the Patient Safety Organizations. I believe amending Maine's statute to allow state transmission of information to the Patient Safety Organizations is very premature, given that no regulations have yet been issued for public comment. It will likely be years before the regulatory process is complete, the certification process is in place and the first Patient Safety Organization is in operation.

If, after the recommendations I endorse are fully implemented, new facts emerge that may warrant amending the sentinel event reporting statute, I strongly recommend that a legislatively convened study group be charged to review the program. The original program was developed collaboratively, with all stakeholders having an equal voice at the table. I believe the success of this program was the direct result of this collaborative effort.

APPENDIX D: Meeting Summaries

SUMMARY NOTES
MQFAC Ad Hoc Committee
Maine Sentinel Event Reporting System
October 19, 2005

Participants: Jonathan Beal (Ad Hoc Committee Chair), Dennis Shubert, MD (Maine Quality Forum), Becky Colwell (Maine Quality Forum Advisory Council), Lou Dorogi and Denise Osgood (Licensure and Certification), Rep. Lisa Miller, Becky Martins (National Patient Safety Commission), Pat Philbrook (Maine State Nurses Association), Rep. David Trahan, Elsie Freeman, MD (DHHS, Adult Mental Health), Sandra Parker (Maine Hospital Association), and David White (Maine Quality Forum). Taryn Bowe (Muskie School) provided staff support.

Background

Jonathan Beal made introductions and identified that the purpose of the Ad-Hoc Committee is to review the Maine Sentinel Event Reporting System in light of several national developments

The meeting agenda was revised due to the absence of Maureen Booth and Jill Rosenthal, the meeting's two scheduled presenters. The group briefly reviewed the structure of the committee. Although voting is limited to appointed committee members, meetings are open to the public and interested persons are encouraged to attend and share their ideas.

Dr. Shubert outlined the charge of the committee and clarified that the committee's intent is to:

> Review how the Maine sentinel event reporting system aligns with the events and taxonomy of the National Quality Forum (NQF);
>
> Assess the impact of the Patient Safety and Improvement Act of 2005. In particular is the question of whether and how events that are reported under Maine's reporting system could be reported into a PSO so that learning and quality could be improved.
>
> Propose legislation that places the Maine system into closer alignment with the NQF and Patient Safety and Improvement Act.

The purpose of the committee is <u>not</u> to:

> Change the confidentiality requirements or remediation processes that are currently in law.

Current Status of Mandatory Hospital Reporting in Maine

Lou Dorogi provided an overview of Maine's current sentinel event reporting system. Before Maine's sentinel event system was established, patient safety issues were dealt

with through state and federal licensing and certification reviews on a site-specific basis. Within the past year, the two-person sentinel event team within the Division of Licensing and Certification has been collecting baseline data on sentinel events. The data collected is kept confidential within the Sentinel Event Team, and the rest of licensing is not able to access it. In total, 24 sentinel events have been reported in the past year, primarily from hospitals.

The Division feels that Maine's sentinel event system is working. Hospitals have gotten on board rapidly and professionally, and there is a healthy exchange of information. The keys to the current system are confidentiality and reporting without punishment. A weakness is that there is no way of validating that all events are being reported.

The team is prepared to address system-wide quality improvement by observing trends over time and staying tuned-in to developments in other states that may prompt changes in Maine's own system.

Issues for Consideration when Aligning Maine Sentinel Events with NQF

The following general issues related to adopting NQF's events and taxonomy were discussed:

Determine whether and how critical incidents on behavioral health side will be addressed in the system and included in any future reporting to PSOs.

- Assess the capacity of the current Sentinel Event Team to adapt to new reporting categories. This will involve estimating whether the number of reported events would increase, decrease or remain the same using NQF criteria and determining what, if any, additional technical resources are needed to aggregate data for reporting to PSOs.

- Decide how to address Maine's unanticipated deaths that are not otherwise specified by NQF categories.

Other Concerns

- ***Quality of aggregate data.*** The general consensus was that PSO data would be helpful for Maine in examining and identifying areas of risk. However, some committee members questioned the integrity of the data seeing as it would come from states with different types of reporting systems (mandatory vs. voluntary) and potentially with different understandings of event category definitions.

- ***Concern with changing current system.*** Hospitals played an integral role in developing Maine's sentinel event system that was subsequently placed into current law. There is concern that the system's original intent and key stone (i.e. confidentiality) will be compromised if the statute is introduced back into the legislative process. (Licensure and Certification, Rep. Trahan)

- ***Concern with lack of definition and clarity around PSOs.*** The PSO legislation does not include standardized definitions for the reporting of sentinel events thus making comparisons and aggregation difficult.
- ***The state's role.*** Hospitals did not object to voluntarily reporting NQF events to the PSOs. There was, however, hesitancy to adopt a policy in which there would be mandatory reporting of this information by hospitals to the state.

Follow up Actions

1. Committee members and other interested parties were asked to formulate their thoughts and recommendations and send proposals for aligning Maine Sentinel Events with NQF to Maureen no later than October 31. Maureen will compile this feedback and bring it to the next Ad Hoc committee meeting.

2. The Muskie School will revise its comparison chart to include a column on JCAHO's performance measurements. At the next meeting, committee members will go through this chart item by item and discuss specific sentinel events where modifications may be necessary.

3. The Muskie School will prepare a visual that outlines the issues and concerns raised and maps out how these are related to the committee's primary charges.

Date for Next Task Force Meeting

The next meeting was scheduled for November 2, 2005 from 1:00 – 3:00 at the Dirigo Health Agency. Maureen will send out notice to participants.

SUMMARY NOTES

MQFAC Ad Hoc Committee
Maine Sentinel Event Reporting System
November 2, 2005

Participants: Jonathan Beal (Ad Hoc Committee Chair), Dennis Shubert, MD (Maine Quality Forum), Becky Colwell (Maine Quality Forum Advisory Council), Lou Dorogi and Denise Osgood (Licensure and Certification), Rep. Lisa Miller, Becky Martins (National Patient Safety Commission), Pat Philbrook (Maine State Nurses Association), Rep. David Trahan, Sandra Parker (Maine Hospital Association). Maureen Booth (Muskie School) and Jill Rosenthal (National Academy for State Health Policy) provided staff support.

October 19, 2005 Summary Notes

Summary notes from the Committee's October 19, 2005 meeting were accepted as distributed.

Activities since Last Meeting

Jonathan Beal thanked the Maine Hospital Association and State Licensure and Certification for submitting comments since the last meeting regarding thoughts and recommendations for changing Maine's sentinel event reporting system. It was also noted that comments were also submitted by OMNE, copies of which were handed out to members.

Overview of Committees Charge and Issues

Maureen Booth referenced Attachment B which identified the Committee's 4-point charge and issues that have surfaced in discussion to date. Jonathan Beal indicated that this was the second of the Committee's three meetings, after which a report and recommendations will be submitted to the Advisory Council of the Maine Quality Forum for review.

Review of Differences between the Maine Sentinel Event Reporting System and the National Quality Forum

Maureen Booth and Jill Rosenthal reviewed Attachment C, a chart showing differences between NQF and Maine Sentinel Events. Corrections to the chart are discussed below.

Attachment C (Abstract)

No	Item	Discussion
I.C.	Wrong surgical procedure performed on a patient	Although there is no Maine equivalent, it was noted that incidence could be abstracted from claims data. It was also noted that claims data must be requested, that there is a charge for such analysis, and that information is not publicly available.
I.D.	Retention of a foreign object in a patient after surgery or other procedure	Same as I.C.
IV.B	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	It was consensus of participants that the Maine event is not equivalent to that of NQF but is essentially "more broad" in that it includes all unanticipated deaths.
V.B	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.	While there is no State equivalent under the sentinel event reporting system, such events are reported to the FDA.
V.E	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health car facility.	Serious disability as a result of restraint in a gerry chair is reportable.
VI.A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.	While there is no State equivalent under the sentinel event reporting system, such events must be reported to law enforcement.

An additional major difference between the NQF and the Maine sentinel event reporting system was discussed. According to Maine law, anticipated deaths and major permanent loss of function are reportable when they are determined to be unrelated to the natural course of the patient's condition or underlying condition or proper treatment of that illness or underlying condition. Determining "proper treatment" is at the discretion of the healthcare provider based on their review and investigation of an event.

Participants generally felt that the Maine statute cast a broader net than that of NQF and focused on reports that fall clearly in the category of medical error, as determined by the healthcare provider. Opponents of that position argued that the NQF list focused clearly on events that were preventable and were inherently considered errors.

The question also arose as to whether in fact, given the "proper treatment" clause, Maine's statute in fact captured more events than the NQF. Although definitionally Maine terminology seems broader, we cannot tell how many events are not reported

because the hospital determined that proper treatment was rendered. This substantially degrades the utility and value of the Maine sentinel events program for tracking and trending events.

A compromise position was discussed which would keep the events as currently required but analyze them in accordance with the NQF categories and taxonomy. This option would provide a means to more clearly track and monitor the specific nature of adverse events in Maine, where those events are currently reported, and benchmark them to national standards. The NQF 27 events would stand alone or have to be added to the definitions of sentinel events where currently omitted [e.g., Pressure sores, gas line errors, etc], and the "proper treatment" filter would need to be eliminated in order to assure that all NQF events made it into the net.

Patient Safety Organization (PSO)

The Patient Safety and Quality Improvement Act of 2005 provides for the designation of patient safety organizations by DHHS to compile and analyze data related to medical errors and adverse events that are voluntarily submitted by health care organizations. The Committee discussed whether to amend Maine statute to allow the Maine Sentinel Event Team to report de-identified data collected under its reporting system to a PSO for learning purposes.

Participants expressed concerns that such action was premature given that so little is currently known about PSOs and that methodologies for establishing PSOs and collecting patient safety information has not yet been developed. There was also reservation about whether the PSO could accept data that had been collected under a mandatory reporting system. To the extent that data was reported to the PSOs, many felt that it should be done on a hospital-specific basis and/or through collective agreement via the Maine Sentinel Event Team.

NQF Taxonomy

The NQF has endorsed the National Voluntary Consensus Standard for a Patient Safety Event Taxonomy that provides the structure and values for reporting aspects of an event such as the location, where an event occurred, the likely clause of the event, etc. This taxonomy further specifies broad language currently included in Maine's statute about information that must be included when reporting an event.

It was generally agreed that use of the NQF taxonomy would require regulatory change and could not be adopted through policy or guidance.

Jeopardy

The question was raised as to the implications of re-opening the Maine statute for revision and the possible loss of existing gains. Participants agreed that current confidentiality protections should not be threatened and that accountability should stay at the industry level. However, at the industry level, accountability could be enhanced through more resources and focus within the Sentinel Event Team on root cause analyses, validation and enforcement. Whether or not statutory changes are proposed to adopt the NQF list and taxonomy, recommendations should address the issue of capacity to adequately perform the full range of responsibilities of the Maine Sentinel Event Team within the Division of Licensure and Certification.

Next Meeting

The next meeting was scheduled for 9:30 a.m. – noon on Tuesday, November 29, 2005. The location of the meeting was subsequently changed to the Maine Health Data Organization, 151 Capital Street, Augusta.

SUMMARY NOTES

MQFAC Ad Hoc Committee
Maine Sentinel Event Reporting System
November 29, 2005

Participants: Jonathan Beal (Ad Hoc Committee Chair), Dennis Shubert, MD (Maine Quality Forum), Becky Colwell (Maine Quality Forum Advisory Council), Rep. Lisa Miller, Rep. David Trahan, David White, Maureen Booth (Muskie School), and Jill Rosenthal (National Academy for State Health Policy), Those in attendance representing stakeholders were Kellie Miller (Maine Osteopathic Association), Gordon Smith (Maine Medical Association), Sandra Parker (Maine Hospital Association), and Mary Mayhew (Maine Hospital Association). Also in attendance were Lou Dorogi and Denise Osgood (DHHS).

November 2, 2005 Summary Notes
Summary notes from the Committee's meeting of November 2, 2005 meeting were reviewed and accepted as distributed.

Draft Committee Report
Maureen Booth and Jill Rosenthal presented their draft committee report going through the six sections individually. The attached report reflects the changes suggested by the committee addressing non-substantive suggestions. Review of the report engendered significant discussion but the chair channeled into the review of committee findings and recommendations. Dr. Shubert went through the committee findings item by item. New item 8 was added different from the list distributed. The appended report suggested wording changes. The list of findings was accepted by the committee 4 yeas and 1 nay with Dr. Shubert not voting.

Draft Recommendations
Dr. Shubert then started to lead the committee through the draft recommendations. There was not time to complete the recommendations and accept them. The appended draft recommendations included suggested changes in items 1 and 2.

Preliminary Physician Survey
The chair reserved time to discuss the preliminary physician survey. Dr. Shubert explained that the survey had two goals. One goal was to assess the degree of variability in reporting in Maine's present system as well as assess degree of under reporting unrelated to variability and interpreting the proper medical care clause. The committee agreed that Maine's present system has a great deal of variability therefore diminishing the ability of the present system to allow the division of licensure and certification or the Sentinel Event Team to establish degree of under reporting and also to prevent the creation of a stable indicator of progress on reducing serious events. Since the committee agreed to the findings that the survey was intended to document there was a consensus that the survey should not be utilized.

Proposed Budget for Strengthening of the Sentinel Events System
The Division of Licensure and Certification distributed proposed budget for strengthening of the sentinel events system and redistributed its proposed changes that would not require statutory changes. Those are appended.

Next Meeting
The chair recognized the inability to complete the agenda and scheduled a follow-up meeting for Thursday, December 1, 2005 at 2:00 PM at the Maine Quality Forum offices located at 211 Water Street.

SUMMARY NOTES

MQFAC Ad Hoc Committee
Maine Sentinel Events Reporting System Statute
December 1, 2005

Participants: Jon Beal, Chairman, Dennis Shubert, Lisa Miller, David White, Maureen Booth, David Trahan.

Guests: Lou Dorogi, Sandra Parker

This meeting was a continuation of the November 29, 2005 meeting that was adjourned because of time limits. The committee continued to work through draft recommendations. Recommendations were gone through in sequence with language changes noted on the final document. All seven recommendations were adopted with a 4 to 1 vote with Rep. Trahan the nay vote.

The committee also worked through a list of statements offered by Dr. Shubert to help anticipated readers of the committee's report to understand the context for the committee's work and its importance. The committee accepted that language as appropriate for the final report.

The committee discussed how to incorporate Rep. Trahan's request for a minority report. It was agreed upon the Rep. Trahan would provide a summary of his minority that would be included in the summary of the report itself as well as a minority report which would be included. Rep. Trahan made the point that he was concerned that the effort to change the statute that he was so instrumental in drafting and adopting that would potentially alienate providers and interfere with the function of the statute itself.

The proposed physician in quality improvement personnel survey was discussed. It was agreed that the survey would not be sent as it was the full agreement of the committee that the present ME Sentinel Events statute process did indeed introduce a variability into the functioning of the sentinel event process and as noted in the committee recommendations whose agreement that it was likely under reporting.

During the meeting the committee accepted multiple public comments.

Mr. Beal thanked the committee for their effort in what he characterized as an intellectually honest effort and there was clear acceptance on the behalf of all committee members that each person's viewpoint and position was appropriately acknowledged.

APPENDIX E: Public Comments

Hospital Licensing & Certification Recommendations, October 2005

The following are recommendations for working within the current ***Sentinel Event Reporting*** Statute, 22 M.R.S.A., and Sections 8751-8756:

1. Categorize all current /future Sentinel Event data utilizing the NQF core set of reporting standards. Include the NQF reporting categories in the public reporting of events, to include the *Annual Report to the State Legislature.*

2. Revise ***The Governing Board*** (Chapter VI) Regulations for General and Specialty Hospital to include criteria for what is a **credible** and **thorough** Root Cause Analysis:

a) Is facilitated by an individual trained in the root cause analysis process;

b) Involves, if necessary, consultation with internal of external experts;

c) Involves the active participation of leadership; and includes consideration of relevant and available literature.

d) Involves a complete review of the event, to include a flow chart of events;

e) Includes interviews with all readily identifiable witnesses and participants;

f) Includes a thorough review of all related documentation;

g) Identifies the human and other factors in the chain of events leading to the event;

h) Identifies system limitations related to the occurrence;

i) Involves a thorough literature search related to the event to assist in determining potential improvement in processes or systems and where redesign might reduce risk;

j) Makes reasonable attempts to identify trends of similar events which have occurred in the facility;

k) Identifies specific process and system improvements; and

l) Identified corrected action is documented with a clear assignment of responsibilities and corrective action time frames.

3. Conduct random follow-up reviews of identified Sentinel Events to assess implementation of corrective action plans.

4. Conduct follow-up reviews on events identified as having a potential for ***a high risk of reoccurrence, significant impact on a high volume of healthcare services***, or ***at high risk for death or serious injury*** if corrective action is not implemented.

5. Conduct periodic (minimum of quarterly) review of all complaints captured in health care entities defined in Statute. The purpose of this audit process would be to identify any potential Sentinel Events and review for appropriate reporting.

6. Revise ***The Governing Board*** (Chapter VI) Regulations for General and Specialty Hospital language to include: The Division may conduct random audits of any and all applicable health care facilities, and review facility data to assure compliance as outlined in this Statue. This review may include, but will not be limited to, review of organizational event logs, review of organizational records and periodic audits of complaints received by the Division.

7. Consider adding to the ***Quality Management Process*** (Chapter XXI) of Regulations for General and Specialty Hospital a requirement regarding FMEA (Failure Mode and Effects Analysis). **FMEA (Failure Mode and Effects Analysis)** can be defined as a systematic way to identify, prioritize and eliminate known or potential errors before they occur.

OMNE-Nursing Leaders of Maine, October 31, 2005

OMNE – Nursing Leaders of Maine appreciates the opportunity to provide comment on changes under consideration to the Maine Sentinel Events Reporting Law. Our comments are based upon the initial discussion held by the Ad Hoc Committee on October 19, 2005.

Aligning Maine Sentinel Event Reporting with NQF

In reviewing the existing sentinel event reporting criteria defined in Maine statute in comparison to the NQF standards, Maine actually captures more information overall particularly related to unanticipated death reporting. Rather than limit the reporting criteria, DHHS Licensing & Certification along with providers could categorize the unanticipated death events given the existing broad statutory definitions. The NQF events not captured in the existing reporting requirements to DHHS are captured elsewhere in hospital reporting to MHDO and other entities. During the presentation provided by Licensing & Certification, it became clear that the law is working, hospitals are reporting and there is an exchange of information between the state and hospitals when events are researched. We do support the need for additional resources for the Division of Licensing & Certification as was originally envisioned when the reporting law was passed. Fundamental to the success of reporting compliance is the confidentiality protections carefully crafted in the Maine sentinel event reporting statute. While comments were expressed by Ad Hoc committee members stating that removal of the confidentiality protections were not on the table for discussion, once the issue of sentinel event reporting moves back to the legislature, it will be subject to agendas outside of MQF control, and thus subject to removal. ***OMNE opposes any Legislative initiative that seeks to amend the mandatory reporting law.***

JCAHO Patient Safety Event Taxonomy

We support a general long term goal for utilization of the JCAHO taxonomy to enhance sentinel event reporting. Once the NQF has completed their review and published implementation guidelines, we would welcome the opportunity to evaluate implementation of the taxonomy tool here in Maine.

Reporting of Sentinel Events to the National PSO

It was in this year, 2005, that Congress passed the Patient Safety and Quality Improvement Act. Rules implementing the legislation will be promulgated in the Federal Register for public comment and later in final format. We support the MQF monitoring the federal rulemaking process, providing comment as appropriate and upon finalization of the rules that define the PSO program operations evaluating the potential role of MQF. Noting that this process generally takes two to three years, it is premature for Maine to impose any reporting criteria to entities that do not exist.

Maine Hospital Association, October 31, 2005

On behalf of all Maine's community non-profit hospitals, the Maine Hospital Association offers these comments on the Committee's proposed changes to Maine's sentinel event reporting law.

Maine's sentinel event reporting program is relatively new, but as the Committee heard at its first meeting, it is working well from both the regulators' and the hospitals' perspective. The discussions between the hospitals and the state staff, both at the individual facility level and also at statewide meetings hosted by the MHA, have provided the necessary clarity to the broad statutory language. In fact, Maine's law arguably captures more sentinel events than the National Quality Forum's list of 27, which in many cases, is overly specific. Our state's first annual report also provides a valuable baseline for trending forward, which will be lost if the statutory scheme is altered. Finally, while we understand that removing the confidentiality protections will not be one of the Committee's recommendations, we remain concerned that opening this statute to amendment will provide others with the opportunity to destroy the protections which are critical to the success of the system. Congress recently reaffirmed the value of confidentiality when they voted to protect the information reported to the Patient Safety Organizations. To truly support a culture of safety, hospital staff must rest assured that their reports will not be used against them so confidentiality is key to encouraging the reporting of sentinel events.

Regarding the details of the National Quality Forum list of 27 reportable events, we note that the majority of events are covered under Maine law, with state law definitions being slightly more or less inclusive. Exceptions include information that is already externally reported to other entities. Specifically, "wrong surgical procedure performed on a patient," and "retention of a foreign object in a patient following a surgery or other procedure" are both captured on the administrative claims data sent to the Maine Health Data Organization. The "stage 3 or 4 pressure ulcers acquired after admission," while very rare occurrences given the decreasing lengths of stay, should be largely captured by the mandatory reporting of the nursing sensitive measures. "Any instance of care ordered by or provided by someone impersonating a physician or other licensed healthcare provider" would be immediately reported to law enforcement. Finally, "any incident in which a line designated for oxygen or other gas contains the wrong gas or is contaminated" is required to be reported to the U.S. Food and Drug Administration. They have issued advisories to providers on this very issue, as a result of the mandatory reports.

We also note that statutory changes are not necessary in order for hospitals and the state staff to utilize the nationally-endorsed taxonomy, when it becomes available. We are pleased to see that the National Quality Forum is taking the initiative to fine-tune the taxonomy and issue implementation guidelines. We agree with the Committee that using the taxonomy will improve the value of reported sentinel events, not only in Maine, but

nationally in the Joint Commission on Accreditation of Healthcare Organizations' sentinel database as well as the Patient Safety Organizations' database network, when it is created.

We look forward to the Secretary's regulations that will create and set certification standards for Patient Safety Organizations. Since the PSOs do not yet exist, we believe statutory changes referencing PSOs would be premature and inadvisable. Further, we don't believe it is necessary for the state to forward Maine's data to a PSO, however, as the federal statute clearly states that PSOs will be set up to accept voluntary submissions of a wide range of information from providers. Should the state forward the de-identified reports, there would be a danger of duplicate submission if the hospital inadvertently included data it sent to the state, along with other information that the PSO might accept.

Finally, with regard to the Division of Licensing and Certification's concerns, we will continue to work with their staff to improve the state's reporting program and provide the forum for educational sessions on the data. We believe that the state currently has the requisite authority to follow-up after a reported event, which may be accomplished by submission of minutes or other documentation to conserve state staff time. We will also continue to work with our members and the state to encourage appropriate submission of all reportable events.

Therefore, we do not believe the proposed amendments are necessary or desirable at this time. Thank you for the opportunity to comment.

Maine Hospital Association, November 8, 2005

On behalf of all Maine's community non-profit hospitals, and in response to concerns raised at the November 2nd meeting, the Maine Hospital Association offers these additional comments regarding Maine's sentinel event reporting law.

Committee leadership voiced considerable concern regarding a clause in current Maine law that limits reportable events to those "unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition". First, we are appalled and offended at the characterization of that descriptor as an "escape clause" that is used to avoid reporting sentinel events. The statutory language was not accidental; it deliberately and accurately reflects the intent and function of the sentinel event reporting program.

The mandatory reporting program has two purposes: accountability at the industry level and improving the quality of care by requiring the analysis necessary to identify system changes to prevent recurrence of any of these events, and then implementing the appropriate changes. Health care providers' obligations under Maine's law do not end with the identification and report of a sentinel event. The law requires that each event be subject to extensive analysis to identify processes that may have contributed to the event, identify changes that could be made to reduce the risk of recurrence and then providing a description of the specific corrective action taken. To meet the dual goals of the law, the statutory language requires this analysis and action for those sentinel events that hold the greatest potential for hospitals to reduce future risk—those events unrelated to the illness or underlying condition or proper treatment thereof.

The issue of error or improper care is a key factor in reporting these events. The Institute of Medicine[12], the current state statute and the new federal law[13] on patient safety and quality improvement all premise their work on *error prevention.* Even the first two words in the preface to National Quality Forum's publication of the 27 reportable events are "Healthcare error..." and the report goes on to state that their charge was to come up with a list of "preventable adverse events".
Deleting the clause relating the reportable event to the underlying condition or proper care would also be in conflict with the state and public view of this reporting scheme, which is that the state's database of reported sentinel events are all due to medical errors. This perspective is clearly reflected in the sample of attached media reports as well in the more recent Maine Public Radio interview with Dr. Shubert where it was reported that: "Last year fifteen people died in Maine hospitals from causes attributable to medical errors." The current statutory language is a reasonable attempt to capture only those sentinel events attributable to medical errors.

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[12] The IOM describes "*To Err Is Human*" as a publication that "breaks the silence that has surrounded medical errors and their consequence..."

[13] The White House Press Release announcing the Patient Safety and Quality Improvement Act states: "And by providing doctors with information about what treatments work and what treatments cause problems, we will reduce medical errors that injure and cause the deaths of thousands of Americans each year."

Expanding the list of reportable events to include *all* unanticipated deaths or major permanent loss of function would be misleading, unfair to providers, and potentially alarming for consumers. For example, a patient may be admitted for a surgical procedure, receive optimal care in all respects and still unexpectedly die from a heart attack. Falsely attributing this event to medical error, either explicitly or implicitly, would be inaccurate and be a disservice to providers and consumers.

Expanding the list of reportable events to include *all* unanticipated deaths or major permanent loss of function would also overwhelm the dedicated staff of the Department of Licensing and Certification and put the providers in the untenable position of performing analyses of events where they cannot identify any hospital process that contributed to the sentinel event, cannot identify any changes that could be made to reduce the recurrence of the event and cannot describe any corrective action that they could take. While we support the broader language of Maine's law that captures *any* unanticipated death or major permanent loss of function unrelated to the patient's illness or proper treatment of that illness, we object to inappropriately expanding the list of reportable events. In these times of limited resources, we must efficiently and effectively target our efforts, in both the public and private sectors. The current law strikes the appropriate balance.

An additional benefit of relating the reportable event to "proper care" is that the clause has been the spark for health care professionals to engage in debates around potentially reportable events as part of the requisite analysis. These discussions appropriately focus on a retrospective analysis of the care provided and identifying any possible changes that could be made to improve the care and prevent the recurrence of the untoward event. No one involved in the care is permitted to walk away from the discussion by simply dismissing the event as unrelated to their individual role in the patient's care.

It's important to note that Maine's sentinel event reporting statute was not intended to replace all existing mandatory and voluntary reporting schemes, such as the U.S. Food and Drug Administration's mandatory reporting of deaths and serious injuries associated with the use of medical devices or JCAHO's sentinel event reporting program. While Maine's hospitals support transparency and the opportunity to share information that might assist in preventing sentinel events, we do not support unnecessarily duplicative reporting requirements.

Thank you for the opportunity to comment.

Budget Request DHHA (Sentinel Event Team)

General Fund

To fund the SFY-07 requirements for the Sentinel Events Program and receive, review and report serious medical errors, the following General Fund appropriation are needed:

2 Health Services Consultant (HSC) positions in the Medical Facilities unit of the Division of Licensing and Certification to support receipt, review and reporting of serious medical errors.

1 additional Health Services Consultant position to conduct follow up reviews for identified medical error resolution, random reviews to validate reporting of sentinel events and provide planning research and database support and analysis.

	2007	**2008**
Positions (HSC)	(3.000)	(3.000)
Personal Services	150,718	155,239
Fringe	72,345	74,514
Training	10,000	10,500
Programming Assessment/ DB Preparation	25,000	10,000
Consultants	3,000	3,000
Travel	4,250	4,500
Total	264,773	257,753

Training consists of one (1) out of state training per HSC and additional state training.

Consultation consists of access to physician specialists at an estimated $100.00/hour.

Travel is computed for last year's experience, plus addition of a third HSC.

Programming consists of assessment and construction of a database.