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Landscape of Maine Patient Safety Activities: A Report to the Dirigo Health Agency's Maine Quality Forum

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"Patient safety refers to the freedom from accidental or preventable injuries produced by medical care. Practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events." (Agency for Healthcare Research and Quality)

The purpose of this report *Landscape of Maine Patient Safety Activities* is to provide the Maine Quality Forum and the Dirigo Health Agency with baseline information that identifies the scope and depth of current patient safety initiatives in Maine. The State Health Plan identified the need to document the current patient safety efforts and compare Maine's patient safety efforts to similar efforts in other states.

The landscape review of patient safety activities in Maine includes data collected through three different lenses. First, the team completed an environmental scan of patient safety activities in other states and explored the various configurations of formal organizational patient safety activities. Second, a convenience sample online survey was conducted with Maine healthcare stakeholders to gather specific information about activities and needs for additional efforts. Finally, follow-up interviews were conducted with key informants to gain a deeper understanding of the Maine landscape of patient safety activity.

Environmental Scan of State Patient Safety Activities

Patient safety is an area of focus for all healthcare organizations. While some organizations address patient safety on their own, within their own profession, or within their organizational setting, some states have organizations that include a broader stakeholder involvement. To understand the context in which Maine's patient safety activities are currently occurring, a review was conducted of how other states are approaching patient safety.

- Maine's patient safety activities are primarily structured through healthcare provider groups, organizations and systems. Other patient safety activities occur through partnership and collaborative groups, state agencies, professional and trade associations and grant projects.
- States typically address patient safety and quality using different types of organizations, partnerships, and funding mechanisms. All states are involved in patient safety to some extent, but many are specific in focus. A few states support patient safety in a comprehensive population-based agency with public funds.
- Most privately supported patient safety organizations target specific types of healthcare providers or settings of care.
- Patient Safety Organizations (PSOs) were developed as a part of the federal Patient Safety Act of 2005 to provide legal protection for reporting patient safety and quality data. The Agency for Healthcare Research and Quality oversees the designation. Currently there are 30 states that have designated PSOs, which often have more than one PSO, since PSOs may target a very

specific population (76 PSOs total). PSOs primarily focus on data collection and analysis of patient safety data (adverse events).

- Maine has only one organization with the federal designation PSO. Specialty Benchmarks, located at Pineland Farms, is a private, for-profit firm which contracts with anesthesiology practices across the country to collect and analyze quality data.

While some states have organized themselves to provide broad spectrum and population-based structure to patient safety activities, most states rely on partnerships with stakeholders for patient safety infrastructure. These public-private partnerships bridge diverse and specific activities through many different organizations and provider groups. Specific topic-driven patient safety activities are often dependent upon funding by the healthcare setting, trade associations, or grant funds. Groups with the federal designation "Patient Safety Organization" typically engage with targeted settings of care and may choose to focus entirely on data collection and analysis of adverse events, rather than undertake improvement activities or provider and consumer education. Funding sources of the various organization types are subject to grant availability, public fund support and membership fees. Financial sustainability varies from model to model, yet infrastructure support remains a concern for most models of patient safety organizations.

Online Survey

An online survey was designed by the research team in consultation with Dirigo Health Agency and Maine Quality Forum staff. The purpose of the survey is to expand understanding of the involvement, scope and impact of patient safety activities from the perspective of individuals who are involved in the provision of healthcare in Maine. In September 2011, 758 people and 26 key contacts at organizations/groups were sent emails and invited to participate in the survey. The online survey was "live" for 2.5 weeks and 316 respondents completed the entire survey.

- For organizations that are involved in patient safety activities, the top three types of activities involve quality improvement, communication improvement, and staff education and training.
- Most organizations use their own budget to support patient safety activities, but about a quarter receive funding from grants and about ten percent receive government funding and/or fees. Half reported a dedicated staff person to patient safety, while some others report using a committee
- About two-thirds of organizations that are involved with patient safety activities engage consumers in patient safety activities. Of those who engage consumers in patient safety activities, about two-thirds share their patient safety data with Maine consumers.
- Most organizations provide or participate in training on patient safety (93%). The majority of these trainings on patient safety are designed and conducted at the organizational level. About three quarters of respondents belong to a collaborative that addresses patient safety (73%).

- The top five priority areas in patient safety were infection control and prevention, medication errors, adverse events, patient safety culture, teamwork and communication. These five areas were top priorities at both the organizational and state level. Infection control and prevention is the topic of highest interest and activity
- Survey respondents indicated interest in a state role with training for healthcare providers, and education for both healthcare providers and consumers.
- Participants report organizational activities and training focused on infection control and prevention; infection control and prevention is high priority area for additional activity.

Key Informant Interviews

The key informant interviewees included quality and safety leaders from hospitals, home health, primary care, healthcare organizations, and state agencies, as well as, hospital administrators and clinicians. The purpose of the interview was to expand upon the findings of the online survey and ask some clarifying and follow-up questions. Each key informant was asked to discuss the five most mentioned topics of interest from the survey: infection control, medication errors, adverse events, patient safety culture, and teamwork and communication. The three emergent themes from the qualitative interviews are summarized below.

Patient safety education represents a new and developing discipline which presents a challenge for Maine's healthcare community to catch up and keep up with this growing body of knowledge, skill set and attitudes.

- Educational institutions in Maine should be preparing the healthcare professional workforce to enter the field with patient safety knowledge, skills and attitudes.
- Current Maine healthcare professionals need training to gain basic patient safety competencies. There is widespread interest and demand for ongoing professional education in specific topics or best practices.

The Maine healthcare community is facing a tremendous challenge to *engage, empower and educate Maine consumers* regarding patient safety and quality.

- It is difficult to figure out how to get the public's attention about patient safety. Attempts to engage, empower, and educate patients, families and consumers at the point of care are challenging, particularly during the window provided in the acute care setting.
- Care of the patient occurs across an evolving continuum. Most patient care occurs outside of the acute care hospital, yet the focus on patient safety is primarily in-patient.

As patient safety policies, programs, and activities have taken hold in the Maine healthcare community, *many efforts are segmented* in silos with organizational or professional boundaries that diminish the economies of effort, the spread of best practices and the benefits derived from common data sharing.

- Clinical roles and silos influence practices in patient safety. Topic-driven collaborations by healthcare systems, professional organizations and grant activities have been very successful in improving patient safety practices in Maine.
- There is some consensus that state agencies and state-wide organizations could boost local and regional efforts to improve patient safety through coordination of healthcare professional training, public outreach, uniform reporting standards, and policy dialogue.
- The State or another state-wide organization can play an important role in providing infrastructure for improvement efforts

Conclusions

This report provides a view of patient safety efforts in Maine through three different lenses. The environmental scan suggests that state agencies and the Maine healthcare community are very active in addressing certain patient safety topics. Other states offer a more comprehensive approach, notably partnerships that bring broad based financial and human resource support to population-based improvement strategies. Maine currently does not have an organization with Patient Safety Organization (PSO) federal designation other than one private firm which contracts with anesthesiology practices around the country.

Survey results indicated extremely strong interest in basic education and training in patient safety both for current healthcare professionals and those individuals in the higher education pipeline. Patient safety is a recent discipline and there is in fact, some catching up to do. These results were confirmed by the key informant interviews. Many respondents believe that there is strong value in state-wide educational efforts and see a role for state leadership to drive this endeavor. The importance of sharing data to learn from errors and near misses was a recurring theme and may require the impartiality of a state-supported or PSO group to achieve wide-spread and transparent usefulness.

The control and prevention of infections has become one of the most pressing patient safety problems in healthcare due to the emergence of antibiotic resistant organisms.[11] The federal government and other healthcare payers are exerting financial pressure on healthcare providers as they begin to reduce or stop payment for services related to healthcare associated infections. With the delivery of healthcare services continuing to move from hospitals to ambulatory care, homes, and other settings, infection and infection control cannot be understood as clinical issues to be contained within the walls of the hospital. Infection control and prevention and antibiotic resistance are now a community concern that requires coordinated and sustained action through partnerships of stakeholders empowered through community-specific data and evidence-based strategies. As surveillance and incidence data and measures and become more standardized and available to providers, payers and consumers are driving increasing attention to the problem and urging action.

The overwhelming expression of interest and need for infection control and prevention education and improvement work may reflect the "canary" of the patient safety infrastructure within Maine. Healthcare associated infections are essentially moving targets with evolving clinical guidelines, diagnoses and treatments. Both healthcare providers and consumers have knowledge deficits and have yet to fully embrace best practices that can help control the spread of infection. Yet, at the same time, state agencies and healthcare organizations have devoted significant resources to prevent healthcare associated infections. Without the infrastructure of a comprehensive and population-based organization, these efforts may not be as effective as they could be. The expressed needs and frustrations of the survey respondents can be considered a symptom of a fragmented approach that falls short of addressing a significant and urgent patient safety issue.

Specific recommendations are detailed in a separate section in the report.

INTRODUCTION

Background

"Patient safety refers to the freedom from accidental or preventable injuries produced by medical care. Practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events." (Agency for Healthcare Research and Quality)

It has been twelve years since the Institute of Medicine issued To Err is Human.[1] Since then, the distinct discipline of patient safety has exploded, spawning new research, tools, training, policies, legislation, accreditation requirements, even a whole industry of professionals and public and private organizations devoted to improving patient safety. However, as many have noted on the ten year anniversary of the report, frustratingly few victories have emerged despite all the efforts.[2] Healthcare providers and organizations have devoted significant time and effort to improving patient safety over the last ten years in the context of a fragmented and paper-based healthcare delivery system.[3] It has become clear that improvements in patient safety cannot occur in silos of healthcare settings or provider groups. Many of the most successful patient safety improvement initiatives have been framed through partnerships and communication across the continuum of care.[4-10]

Research Activities

The purpose of this report *Landscape of Maine Patient Safety Activities* is to provide the Maine Quality Forum and the Dirigo Health Agency with baseline information that identifies the scope and depth of current patient safety initiatives in Maine. The State Health Plan identified the need to document the current patient safety efforts and compare Maine's patient safety efforts to similar efforts in other states.

The landscape review of patient safety activities in Maine includes data collected through three different lenses. The research team conducted three distinct activities to gather data for this report. First, the team completed an environmental scan of patient safety activities in other states and explored the various configurations of formal organizational patient safety activities. Included in the Environmental Scan section is a brief description of current Maine activities and organizations focused on patient safety. Second, a convenience sample online survey was conducted with Maine healthcare stakeholders to gather specific information about activities and needs for additional efforts. Finally, follow-up interviews were conducted with key informants to gain a deeper understanding of the Maine landscape of patient safety activity.

ENVIRONMENTAL SCAN

Patient safety is an area of focus for all healthcare organizations. While some organizations address patient safety on their own, within their own profession, or within their organizational setting, some states have organizations that include a broader stakeholder involvement. To understand the context in which Maine's patient safety activities are currently occurring, a review was conducted of how other states are approaching patient safety. Information was collected through a review of state websites and links from the Agency for Healthcare Research and Quality (AHRQ) website. As the landscape of patient safety organizations and partnerships is ever-changing, the following review intends to highlight some examples of how states are addressing patient safety. The report starts with an overview of Maine's patient safety landscape, and then expands to other state examples of how other states have approached patient safety.

Maine's approach to patient safety

Maine's patient safety activities are primarily structured through healthcare provider groups, organizations and systems. Other patient safety activities occur through partnership and collaborative groups, state agencies, professional and trade associations and grant projects. A representative (not exhaustive) list of some major patient safety activities are presented below.

- **Maine Critical Access Hospital Collaborative** - works on common issues related to patient safety and quality improvement. The Collaborative is supported by the Maine Quality Forum, the Maine Office of Rural Health and Primary Care, and the Muskie School of Public Service. The Collaborative was awarded a two-year grant from the Maine Health Access Foundation in 2008 to address medication errors. The Collaborative is also a key participant in a federal grant award to the Muskie School SAFER to demonstrate improvements in transitions of care between nursing facilities and rural hospitals. The Collaborative includes all 16 Maine Critical Access Hospitals and stakeholders from a variety of state agencies, organizations and educational institutions. Discussions of the sustainability of the Collaborative beyond federal grant participation are underway.
- **Patient Safety Academy** – interdisciplinary educational annual conference for healthcare professionals on patient safety topics. The conference is sponsored by the Maine Office of Rural Health and Primary Care and is hosted by the Maine Critical Access Hospital (CAH) Patient Safety Collaborative.
- **Maine Quality Forum** – part of the Dirigo Health Agency and the Dirigo Health Reform. The Maine Quality Forum works to improve the quality of healthcare in Maine through collecting research, promoting best practices, collecting and publishing comparative quality data, promoting electronic technology, promoting healthy lifestyles and reporting to consumers and the Legislature. Under its Chapter 270 authority, the Maine

Quality Forum requires hospitals to submit patient safety related data such as healthcare associated infections.

- **Quality Counts** - regional health care collaborative working to improve healthcare through leading, collaborating, and aligning improvement efforts. Examples of their work include involvement in the Aligning Forces for Quality Transforming Care at the Bedside (TCAB) Initiative and a pressure ulcer initiative.
- **Maine Office of Rural Health and Primary Care -** works on health personnel recruitment and retention programs, helps communities receive grants to improve the health care system, and facilitates communication on health care issues affecting rural and underserved communities. Services include collecting and analyzing data about resources, makes recommendations for filling gaps, and works to increase access to primary medical care, behavioral health and oral health care services for underserved areas and populations.
- **Maine Infection Prevention Control Collaborative** – voluntary statewide collaborative whose mission is to improve the health of the people of Maine by reducing health care-associated infections and the burden of drug resistant organisms. Membership also includes the Association for Professionals in Infection Control and Epidemiology (APIC), Pine Tree Chapter, Maine Quality Forum, the Northeast Health Care Quality Foundation (NHCQF) and the Maine Centers for Disease Control and Prevention. MIPC members meet regularly to learn together, share resources, data, and successes and failures.
- **Maine Centers for Disease Control, Infectious Disease Division** – infection control and prevention focus. The Maine CDC has developed the Healthcare Associated Infections (HAI) Program in the Division of Infectious Disease. This work includes establishing a multidisciplinary advisory group to guide and support program prevention and surveillance activities, recruiting and training HAI program staff, and developing a State HAI Prevention Plan.
- **Maine State Licensing and Regulatory Services** – provides licensing and regulation to healthcare facilities in Maine, and maintains the state's adverse event reporting system.
- **Maine Hospital Association** – provides ongoing education for Association membership and leads and participates in quality improvement activities, many of which pertain to patient safety
- **Northeast QIO -** The Northeast Health Care Quality Foundation (NHCQF) is a non-profit, educational health care organization, headquartered in Dover, New Hampshire. NHCQF is designated by the Centers for Medicare & Medicaid Services (CMS) to serve as the Medicare Quality Improvement Organization (QIO) for the states of Maine, New Hampshire, and Vermont. Recent topics addressed in the scope of work include prevention of pressure ulcers and healthcare associated infections.

State approaches to patient safety

States typically address patient safety and quality using different types of organizations, partnerships, and funding mechanisms.

There a variety of ways in which a state may address patient safety in terms of organizations and partnerships. Some of these types of organizations or partnerships may focus on a very specific healthcare provider setting, such as hospitals and physicians. Other organizations take a broader population-based approach. States generally have more than one organization or group addressing patient safety.

- Public
- Private (profit and non-profit)
- Partnerships
    - Public-private partnerships
    - Partnerships in-state or multi-state by profession or organizational setting

All states are involved in patient safety to some extent, but many are specific in focus. A few states support patient safety in a comprehensive population-based agency with public funds.

Publically supported

All states provide some patient safety activity through their public health infection control, and licensing and regulations governing sentinel events. A minority of states have information on their websites about involvement in patient safety activities. It is common to find state supported activities with a specific focus on a particular aspect or topic area of patient safety. While a broader focus usually involves a public-private partnership, some states have shown leadership through their government supported or mandated organizations. Some examples are shared below.

Pennsylvania Patient Safety Authority (independent state agency) analyzes and evaluates adverse events and incidents (near-misses) reported by all hospitals, birthing centers, ambulatory surgical facilities and certain abortion facilities. The Authority has expanded its focus to include infection control, providing consumer tips, and providing educational resources for facility staff on patient safety topics.

Illinois Department of Public Health (independent state agency) has been involved with hospital and ambulatory surgical centers public reporting of performance data, infection prevention, consumers guide, and electronic prescribing.

Oregon Patient Safety Commission (semi-independent state agency) has an adverse event reporting program for hospitals, ambulatory surgery centers, nursing facilities, and pharmacies.

Most privately supported patient safety organizations target specific types of healthcare providers or settings of care.

Private (profit and non-profit)

Most states have private organizations that address patient safety which can include both for-profit and non-profit entities. These organizations typically focus on a particular population, provider type or setting of care as hospitals or physicians. Funding to support the organizations may include membership fees, trade association support, foundations, and grants. Some organizations may be a quality improvement organization (QIO) or a designated patient safety organization (PSO). While some organizations with the PSO designation provide comprehensive and broad patient safety improvement activities, other organizations with the PSO designation only perform targeted activity for a specific provider type and others only collect data and provide data analysis.

Tennessee Center for Patient Safety was founded by the Blue Cross Blue Shield Tennessee Foundation, and is under the direction of the Tennessee Hospital Association clinical and professional practices department. The Center has been involved in reducing healthcare-acquired infections, implementing a unit-based safety program, the Tennessee Nursing Partners Collaborative, and the Tennessee NSQIP Surgical Quality Consortium.

Maine has only one organization with the federal designation PSO. Specialty Benchmarks, located at Pineland Farms, is a private, for-profit firm which contracts with anesthesiology practices across the country to collect and analyze quality data.

Patient Safety Organizations

(PSOs) were developed as a part of the federal Patient Safety Act of 2005 to provide legal protection for reporting patient safety and quality data. The Agency for Healthcare Research and Quality oversees the designation. Currently there are 30 states that have designated PSOs, which often have more than one PSO, since PSOs may target a very specific population (76 PSOs total). PSOs primarily focus on data collection and analysis of patient safety data (adverse events). More complete information concerning PSO designation is provided in the Appendix.

Partnerships can promote a comprehensive approach to patient safety.

Partnerships

Partnerships can include public and private organizations working together on patient safety. These partnerships usually result in a more comprehensive approach to patient safety due to the engagement of multiple stakeholders. Some states have taken their collaborative activities beyond state lines and now participate in a multi-state collaborative. Examples of different types of state partnerships are given below.

In-state partnership

Mississippi Patient Safety Coalition focuses on developing a statewide culture of safety. Organizations involved include Blue Cross Blue Shield, Department of Health, associations (healthcare, hospital, nurses, pharmacists, medical), the state's academic health science center, AARP, and the state QIO.

Public-private partnership

Minnesota Alliances for Patient Safety focuses on patient safety issues that can be addressed by a collaborative approach. This partnership includes the Minnesota Hospital Association, Minnesota Medical Association, Minnesota Department of Health and more than 50 other public-private health care organizations.

Multi-state partnership

Mountain-Pacific Quality Health, which collaborates with Montana, Wyoming, Hawaii and Alaska, is a physician-sponsored organizational network of quality improvement organizations in these states.

Patient Advocacy Groups

As with public and private patient safety groups across the states, patient advocacy groups concerned with patient safety vary significantly. There are organizations formed by families of victims of medical error such as the Josie King Foundation or Mothers Against Medical Error (MAME). Some patient advocates and groups have formed regional coalitions such as the New England Voices for Error Reduction (NEVER). NEVER plans to develop a regional outreach plan to offer a patient safety curriculum, including speakers, to medical and nursing students. There is also planning going on for public information campaigns to provide the consumer with patient safety information. Examples of Maine patient safety advocacy efforts include Consumers for Affordable Healthcare, Voice 4 Patients, and McCleary MRSA Prevention. Some advocacy groups are included in formal public, public-private, and private patient safety organizations, however, not all groups include consumer or advocate representation.

Summary

While some states have organized themselves to provide broad spectrum and population-based structure to patient safety activities, most states rely on partnerships with stakeholders for patient safety infrastructure. These public-private partnerships bridge diverse and specific activities through many different organizations and provider groups. Specific topic-driven patient safety activities are often dependent upon funding by the healthcare setting, trade associations, or grant funds. Groups with the federal designation "Patient Safety Organization" typically engage with targeted settings of care and may choose to focus entirely on data collection and analysis of adverse events, rather than undertake improvement activities or provider and consumer education. Funding sources of the various organization types are subject to grant availability, public fund support and membership fees. Financial sustainability varies from model to model, yet infrastructure support remains a concern for most models of patient safety organizations.

SURVEY OF MAINE HEALTHCARE PROFESSIONALS

Overview

The purpose of the survey is to expand understanding of the involvement, scope and impact of patient safety activities from the perspective of individuals who are involved in the provision of healthcare in Maine. This section of the report provides a summary and key findings of the survey results. *Appendix A contains the complete survey responses.*

Methods of the Online Survey

An online survey was designed by the Muskie School research team in consultation with Dirigo Health Agency and Maine Quality Forum staff. The survey process provided an opportunity for individuals to indicate current patient safety activities in their organization and comment on areas of need and recommendations to fill those needs. The research team developed a list of potential stakeholders. Individuals affiliated or employed by healthcare organizations were solicited to participate. In September 2011, 758 people and 26 key contacts at organizations/groups were sent emails and invited to participate in the survey. A request was made to key contacts at organizations/groups to forward the survey link to their members. The survey was "live" for two and a half weeks. A reminder email was sent to all after the first week. As this survey was a convenience sample, more than one person at an organization may have filled out the survey about their organization. This was anticipated and encouraged, as different roles within an organization will have different knowledge and involvement with patient safety activities. Additionally, the online access gave multiple users access from a single computer to compensate for computer access limitation at certain provider locations. At the close of the brief survey period, we logged a total of 326 respondents, of which 10 only filled out the question describing the type of organization they worked for. These 10 incomplete surveys were omitted and *316 survey participants* were used in the data analysis.

To set the stage for the responses in both the online survey and key informant follow- up interviews, the following definition of patient safety from the Agency of Healthcare Research and Quality was provided to the participants:

"Patient safety refers to the freedom from accidental or preventable injuries produced by medical care. Practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events." (AHRQ)

Key Findings

What are the characteristics of organizations addressing patient safety represented in this survey?

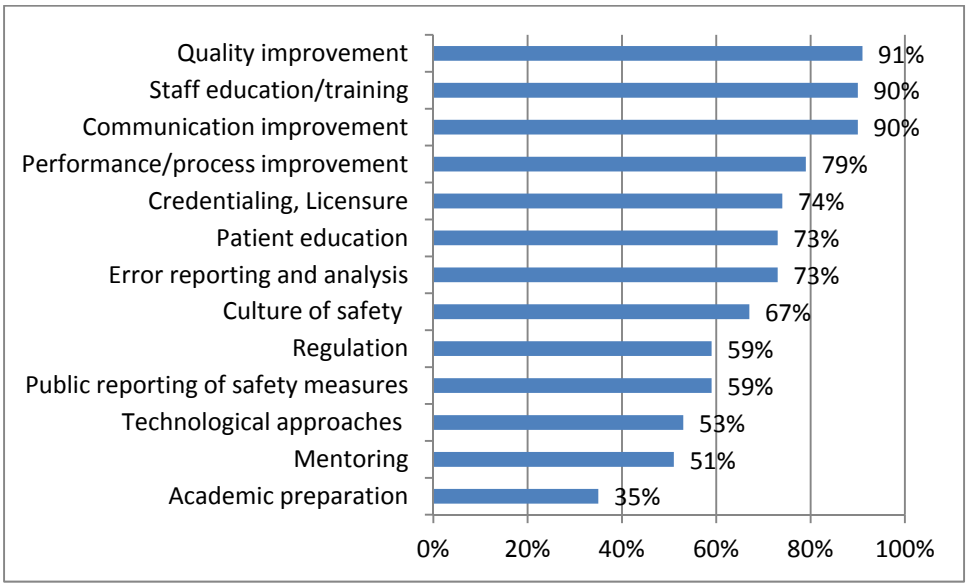
Of the 316 survey participants, most reported that their organization is involved in patient safety activities (79%, 247 respondents). Approximately two-thirds of respondents indicated that they were located in rural locations, and worked in hospitals or emergency medical services. The organizations in Maine represented by the participants that address patient safety can be categorized into five types of affiliation:

- hospitals,
- physician practices,
- emergency medical services (EMS),
- other community providers, and
- organizations that do not provide direct patient care.

What patient safety topics are addressed by organizations represented in this survey?

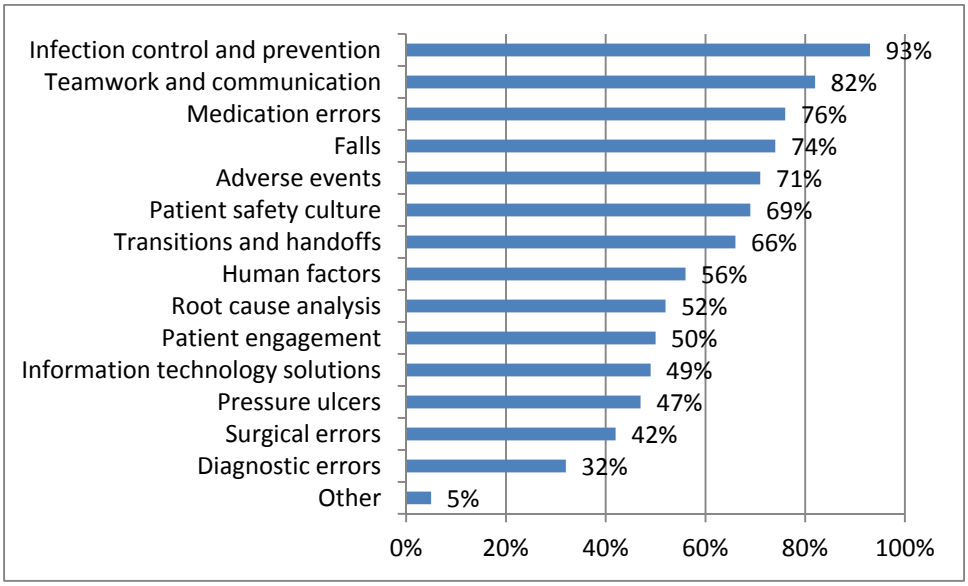
For organizations that are involved in patient safety activities, the top three types of activities involve quality improvement, communication improvement, and staff education and training. All three types of activities represent the key areas of focus for most organizations (see Figure 1).

Figure 1. Types of patient safety activities conducted by Maine organizations (n=230) Note: more than one type of activity could be selected.



Participants were asked to indicate patient safety topics that their organization addresses. As depicted in Figure 2, *infection control and prevention is the topic of highest interest and activity.* Teamwork and communication is another strong area of activity, followed closely by medication errors, falls and adverse events.

Figure 2. Patient safety topics addressed by organizations (n=199) Note: more than one response may be reported.



What is the structure of patient safety activities?

Participants were asked to indicate who takes lead responsibility for patient safety activities in their organization. About half responded that there is a dedicated staff person, while some others report using a committee. A portion of organizations (15%) reported their organization has both a dedicated staff person and a committee to lead patient safety activities. *Most organizations use their own budget to support patient safety activities, but about a quarter receive funding from grants and about ten percent receive government funding and/or fees.* Some organizations use more than one type of funding source to support patient safety activities.

Patient safety activities are directed at primarily patients, families and health care providers. Most organizations have more than one audience for their patient safety activities.

How are consumers involved in patient safety?

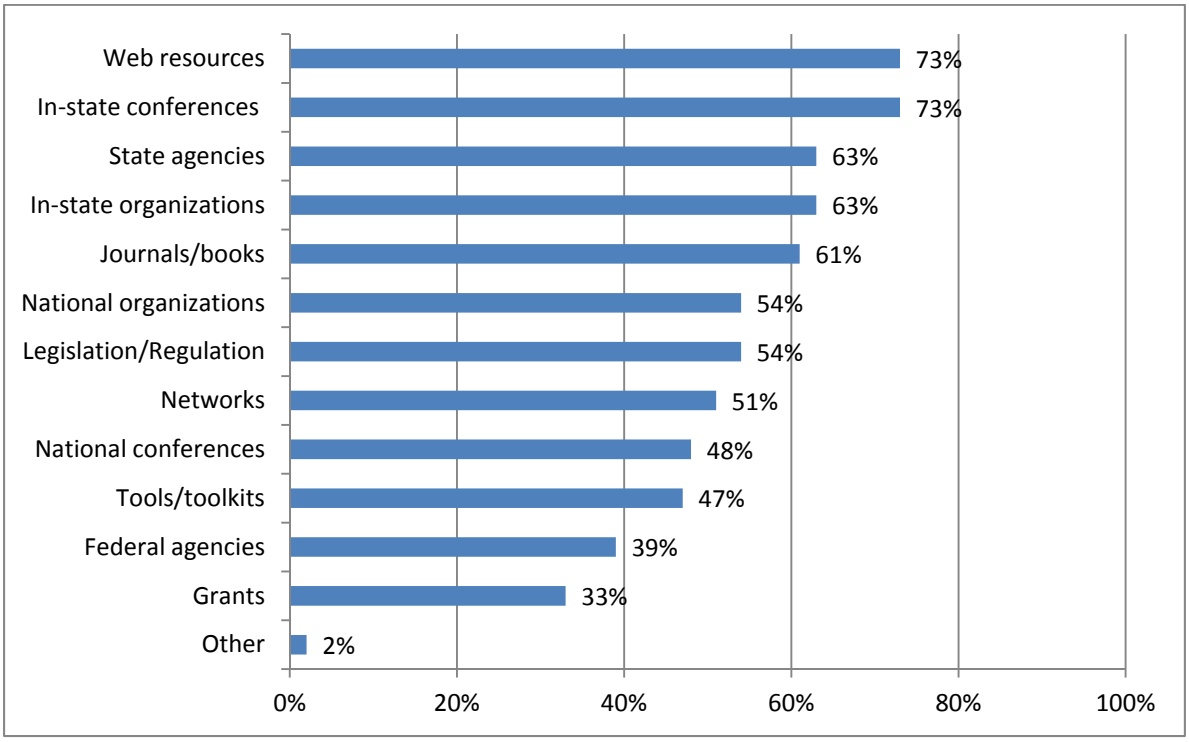
About two-thirds of organizations that are involved with patient safety activities engage consumers in patient safety activities. Of those who engage consumers in patient safety activities, about *two-thirds share their patient safety data with Maine consumers*. Some respondents mentioned sharing

information about falls, precautions, medication safety and infections. For those that engage consumers in patient safety activities, most use a website, print material and verbal means to communicate patient safety data.

What resources are used in training and education?

Most organizations provide or participate in training on patient safety (93%). The majority of these trainings on patient safety are designed and conducted at the organizational level. *About three quarters of respondents belong to a collaborative that addresses patient safety (73%).* In-state conferences and web resources are most commonly reported by respondents (see Figure 3). Examples of in-state conferences include the annual Patient Safety Academy and the Quality Counts Annual Conference. As depicted in Figure 3, multiple resources are common.

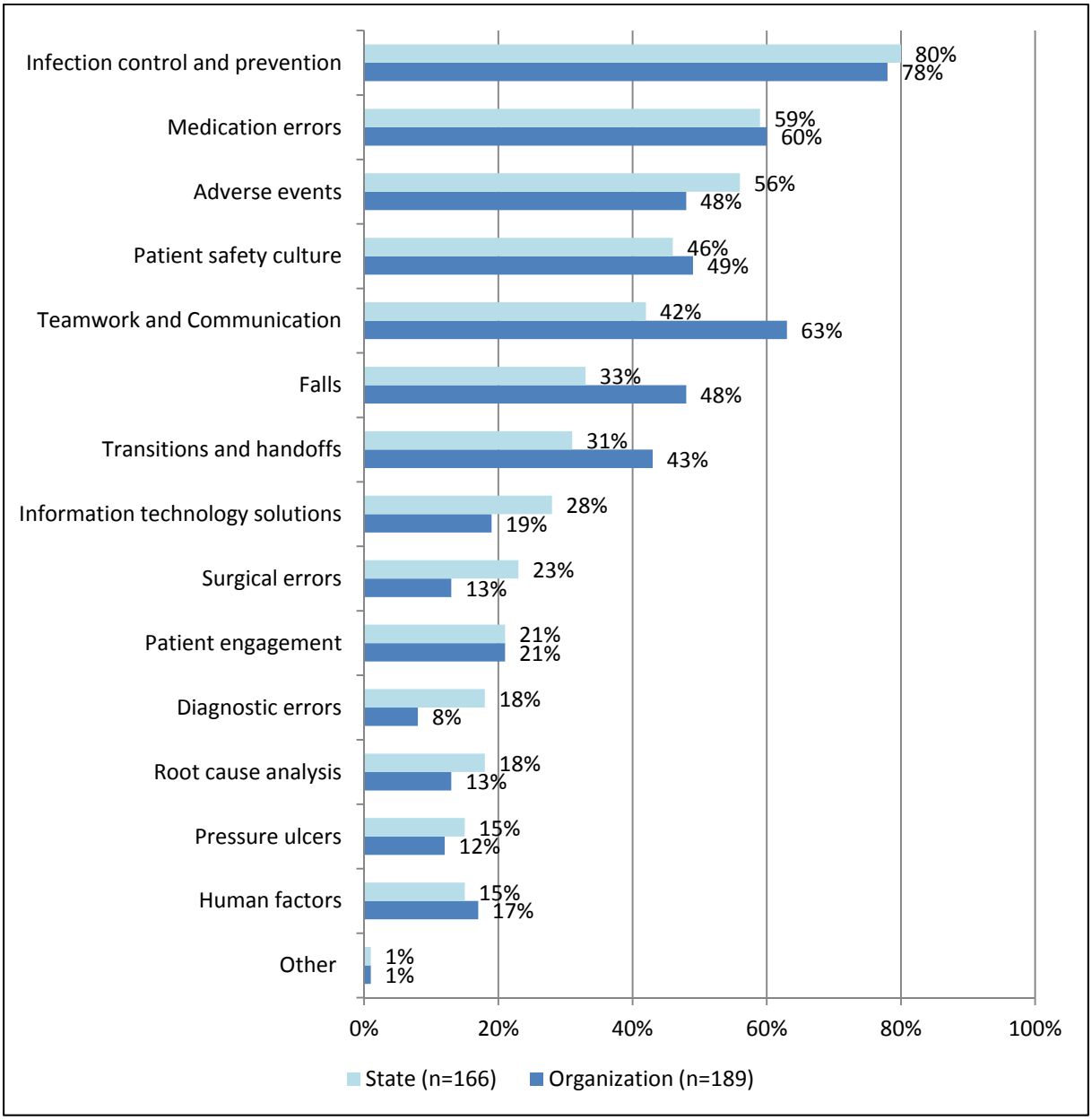
Figure 3. Resources used to address patient safety (n=186) Note: more than one response could be reported.



What are the priority needs for patient safety?

Respondents were asked to identify patient safety priorities for their own organization and for the state. The top five priority areas in patient safety were *infection control and prevention, medication errors, adverse events, patient safety culture, teamwork and communication*. These five areas were top priorities at both the organizational and state level. Other key areas of interest are displayed in Figure 4.

Figure 4. Top five highest priority patient safety topics at the organizational and state levels



Finally, survey respondents were asked to consider ways in which the state should be involved in patient safety activities. Most indicated interest in a state role with training for healthcare providers, and education for both healthcare providers and consumers. Public access to patient safety data and licensing/regulation were also noted, but to a lesser extent than the interest in state involvement in education and training.

Recommendations from survey participants

Sixty-eight respondents to the survey provided suggestions for improving patient safety. These recommendations were then categorized into several themes, with training and education being the most prominent.

Training/education	43%
Consumer focus	24%
Collaboration	19%
Data collection/monitoring	9%
Accountability/regulation	6%
Reimbursement/funding issues	6%
Technology	3%
Best practices	3%
Other	24%

These findings suggest the need for increased focus on training and education for both healthcare providers and consumers. The participants suggest a preference for trainings in the form of state and regional conferences and web resources. The annual Patient Safety Academy and Quality Counts conferences could be example of opportunities for training and education. Of special interest to the survey participants are increased access to Web resources, including webinars that easily reach healthcare professionals in Maine's rural regions.

Topics of significant interest for trainings and educational resources include infection control and prevention, medication errors, and consumer engagement. By far, however, the survey responses indicate a pressing desire for increased educational training and resources regarding infection control and prevention. It is important to note that e*ven though most participants report organizational activities and training focused on infection control and prevention, the majority still consider this a high priority area for both their organization and the state to address through additional activity.*

KEY INFORMANT INTERVIEWS

The Process

The Patient Safety Activities Survey included an item asking respondents to indicate their willingness to participate in a follow-up phone interview with the research team. Fifty-nine (59) individuals provided their names and contact information. We sorted the respondents into categories for professional role, organization and geographic region. Our intention was to interview individuals from differing professions and healthcare settings. We contacted 28 individuals and successfully interviewed 20 key informants. The key informant interviewees included quality and safety leaders from hospitals, home health, primary care, healthcare organizations, and state agencies, as well as, hospital administrators and clinicians. This qualitative survey was conducted by phone and the conversation ranged from 30 to 45 minutes. The interview template is provided in the Appendix.

The purpose of the interview was to expand upon the findings of the online survey and ask some clarifying and follow-up questions. We asked the participants to describe patient safety activities in which they or their organization have participated. Each key informant was asked to discuss the five most mentioned topics of interest from the survey: infection control, medication errors, adverse events, patient safety culture, and teamwork and communication. The interviewees considered these topics through the lens of their current affiliation and provided ideas or comments on how to address these topics at a state level.

Three central themes emerged from these qualitative interviews. The following section summarizes each theme and expanded subthemes. We are sharing relevant key informant comments related to the themes, as well as summarized recommendations.

Emerging Themes:

- Patient safety education represents a new and developing discipline which presents a challenge for Maine's healthcare community to *catch up and keep up* with this growing body of knowledge, skillset and attitudes.
- The Maine healthcare community is facing a tremendous challenge to *engage, empower and educate Maine consumers* regarding patient safety and quality.
- As patient safety policies, programs, and activities have taken hold in the Maine healthcare community, *many efforts are segmented* in silos with organizational or professional boundaries that diminish the economies of effort, the spread of best practices and the benefits derived from common data sharing.

Theme One

Patient safety education represents a new and developing discipline which presents a challenge for Maine's healthcare community to catch up and keep up with this growing body of knowledge, skill set and attitudes.

The discipline of patient safety represents a new knowledge base for much of the current healthcare workforce. The evidence base, skill sets, and best practices were not part of past educational preparation. The last decade has brought an explosion of new information and tools that can be deployed by healthcare professionals, but many lack the basic framework to apply this new information and these new tools. The Maine healthcare workforce is challenged to catch up by several factors: an older workforce whose preparation did not include basic patient safety training, a newer workforce arriving with some training that may or not coordinate with practices in the field. The rapid advancement of the patient safety discipline has made it difficult for institutions and organizations to keep up with current best practices. Some institutions struggle to provide appropriate, timely, and effective training and continuing education and seek support and partnership through peer institutions, professional and state organizations, and the government.

Subtheme: Educational institutions in Maine should be preparing the healthcare professional workforce to enter the field with patient safety knowledge, skills and attitudes.

- Curricula should include basic patient safety competencies.
- Educational institutions should have coordinated dialogue with the healthcare community to prepare students accordingly.
- Educational institutions could assist healthcare community with training for current professionals to bring them up to speed.

We should work on the curriculum of the health care professional in our educational institutions.

We need to encourage patient safety culture to be taught as part of nursing and allied health education. People need to be trained in techniques prior to being in the workforce.

Start at the schools. There needs to be training on teamwork and communication as a part of education and training for nurses and doctors.

It starts in the educational institutions – putting the consumer voice in training – to change the tide for the future.

Subtheme: New models are needed to train current Maine healthcare professionals in basic patient safety competencies.

- Educational institutions could assist healthcare community with training for current professionals to catch them up to speed.
- The healthcare community could benefit from proficiency training to advance the patient safety competencies of the workforce.
- Multi-modal delivery of education is essential.
    - Webinars, both live and archival
    - Regional training and conference meetings
    - Clearinghouse of evidence-based practices and best practices
    - Interdisciplinary education
    - Grand rounds and CME activities

I think that webinars are great for staff education – they can be watched live or you can review them at a later time. There are too many full-day seminars that people just can't get to. Video conferencing is another option.

Safe delegation is an issue that needs to be addressed. Communication between hospital administrators, nurses and practitioners can be a challenge where there is often a hierarchy. Nurses are sometimes put in a place that is not safe and unsafe delegation can lead to patient injuries.

We need intensive communication training courses for entire staff.

Teamwork and the use of checklists are more familiar methods to staff who were recently in school than those who have been out of school awhile.

The younger staff and hospitalists are more on-board. These are new topics for the older staff.

We have no formal training in patient safety. Shortcuts are taken – and humans make mistakes. We look at near miss events and see how the issues can be addressed.

People don't always understand the difference between a mandate and a best practice.

Education around adverse events is needed. Education about professional responsibility to detect error is also needed.

Subtheme: There is widespread interest and demand for ongoing professional education in specific topics or best practices.

- Infection control and prevention is a topic of high interest. Common needs for education and support for local initiatives could be met through Maine CDC.
- Other topics of keen interest include teamwork and communication, patient safety culture, adverse events and medication errors.

People are very interested in teamwork and communication. Webinars at various times during the day would be great – we are so isolated. The concept is very important. We don't have a lot of information about it, but want it.

There are evolving issues in infection control and prevention with a continual need for ongoing education.

It's so hard at the local level, especially if you are small, to do this on your own.

We could use some universal form of training in infection control. It is challenging for organizations that are on the smaller side of the scale.

We need more education about how to manage violence in the emergency department, especially with small numbers of staff in the ED. This involves safety for the patient, other patients and the staff. We would like to know some models that have been used in other small facilities.

MRSA screenings are now required by law for hospitals to test high risk patients. A lot of screening is done, but what do you do with the results? Guidance is needed. A standardized approach of what to do with the results would be helpful.

Suggestions from Key Informants:

- Engage higher education institutions in a dialogue with the healthcare community to ensure that patient safety knowledge, skills and attitudes are part of the curriculum for tomorrow's healthcare professionals.
- Coordinate professional training to increase the efficiency of continuing education.

Theme Two

The Maine healthcare community is facing a tremendous challenge to engage, empower and educate Maine consumers regarding patient safety and quality.

All of our key informants remarked on the difficulty that they face to engage, empower and educate the patients, families and caregivers that they serve. Certainly, the same issues that professionals face in catching up to speed on a rapidly developing field play some role for consumers as well. However, the issues run deeper and reflect concerns such as literacy, informed consent, access to understandable patient safety data, and less than optimum communication between patients and providers. The interviewees feel that these issues are universal across settings of care and that a population-based approach is advisable. They believe that messaging should be consistent and that consumers as well as healthcare institutions and organizations need help to learn how to "put the patient in patient safety".

Subtheme: It is difficult to figure out how to get the public's attention about patient safety.

- How to get the public interested in public reporting?
- How can we do effective mass education to train/inform consumers?
- There is a significant need to engage the consumer in medication safety, infection prevention such as hand hygiene, and patient/provider communication, in particular.

It is likely that the publically available incidence rates represent underreporting – we need to work on validation of the data. Consumers should be familiar with reporting websites to get information.

What are the gaps in patient safety activities in Maine? We need to patients more involved in their care, but I just not sure how to reach the public.

I don't think that public reports have a wide reach to the consumer. Are people really encouraged to look at the information?

Consumers are not aware of how to be involved or don't want to be involved. The consumer is not the power player and the power players like it that way. Healthcare is complex, but consumers deserve a big place at the table.

Subtheme: Attempts to engage, empower, and educate patients, families and consumers at the point of care are challenging, particularly during the window provided in the acute care setting.

- Role of consumers in patient safety advisory councils
- Review of patient care processes
- Patients have short acute care stays when they are sick and stressed – not the optimum time for engaging, educating and empowering.
- Informed consent and literacy are issues that many provider organizations struggle to improve.

I believe that we need to work hard to engage patients in patient safety. You can work on ways to build safe care together. This includes asking about hand hygiene, keeping an up-to-date medication list, bringing an advocate along with you to the hospital, knowing your providers, and understanding your discharge instructions.

Patients are here (hospital) for such a short time, and are so sick when they're here that they don't often understand what you are talking about when you are trying to engage them.

People don't want to upset the apple cart. They see the staff as too busy and they don't want to distract them from their work. Sometimes they are just invalidated by attitudes or responses. Everyone is too busy – we need to change attitudes. We can train patients to be persistent and assertive and how to put that into practice with actual behavior.

Subtheme: Care of the patient occurs across an evolving continuum. Most patient care occurs outside of the acute care hospital, yet the focus on patient safety is primarily in-patient.

- After discharge from the hospital, many patients fall between the cracks and consumers don't know how to coordinate the care themselves.
- Coordination between community providers is challenging.
- Community providers have less patient safety training and improvement activities.
- Community providers usually don't have trained staff dedicated to patient safety.

Most of the patient touches happen in the community setting. We need to look at safety in the doctor's office – this has not been fully developed or explored.

At the level of the physician practice, patient safety is not really thought about. Really, the culture of safety needs to be brought to the forefront – it has happened in the hospitals and nursing facilities, but not in facilities like ours. I think the Patient Centered Medical Home will help drive that direction. It is the accreditation, reimbursement and certification issues that bring it into focus.

Health care organizations could do a better job educating the public around infections and hand hygiene. It is a challenge for us to do public education activities that are not revenue generating.

Sharing information across settings is also needed, so that patients have continuous treatment regardless of the setting. We need to discuss sharing information between providers, the sharing of results and processes.

Suggestions from Key Informants:

- Coordinated and consistent messaging to Maine consumers may help to raise awareness about the role of patients, consumers and caregivers play in patient safety.
- Maine healthcare providers could use some guidance on best practices to engage, empower and educate consumers.
- Healthcare professionals can enhance the objective to engage, empower and educate consumers by exploring and addressing personal, professional and organizational barriers.
- Efforts to improve patient safety have to extend beyond the acute care setting. These community healthcare providers should be at the table of patient safety improvement efforts and training
- Coordination of care (both within the healthcare setting and between healthcare settings) is a key element of providing safe healthcare and should be a priority in future initiatives
- Health literacy, informed consent and patient education about issues such as hand hygiene, medication reconciliation and patient/provider communication are common needs across all setting.

Theme Three

As patient safety policies, programs, and activities have taken hold in the Maine healthcare community, many efforts are segmented in silos with organizational or professional boundaries that diminish the economies of effort, the spread of best practices and the benefits of common data sharing.

Patient safety programs have blossomed in the acute care setting and the major healthcare systems have taken the initiative to apply these programs in their affiliated healthcare settings. However, some healthcare settings are on the outside of this loop and struggle to provide this same level of resources to patient safety issues. Within institutions, it is not uncommon to hear that patient safety work occurs in silos and that the responsibility for patient safety activities falls to a few individuals.

There are many success stories in patient safety in Maine. Numerous topic-specific initiatives have attracted strong participation and new-found partnerships. Many disparate professional organizations, state agencies, and grant activities drive these initiatives. Some express hope for greater coordination of activities so to avoid competition for precious human and fiscal resources. There is interest in a comprehensive approach to patient safety that meets the needs of consumers and healthcare providers across the continuum of care.

Subtheme: Clinical roles and silos influence practices in patient safety.

- Some clinical departments embrace patient safety innovations and others may not. Even within one institution, the application of best practices may be uneven.
- Hospitals are very focused on patient safety practices, yet these practices may not extend into the community settings.
- Whose job or role is patient safety? Some look to specific individuals such as infection preventionists and quality improvement staff to "do" patient safety. There is a need to have everyone at the same table to affect change.
- It has been a challenge to engage physicians in patient safety activities. Many community providers do not participate in grand rounds or other educational events.

The culture is threaded through the institutions and questions need to be encouraged all the way through. Staff need to be encouraged to be open and demonstrate through their behavior.

I think that we need to take a population health approach to patient safety. We should remove the feeling that everybody is just too busy to pay attention.

We have to engage the front line to get to zero (infections) and let everyone know that they have a role in this. Hierarchy is an issue within the hospital setting of care.

We struggle with learning from near-misses. Patterns are important clues that something needs to be addressed. We need to share near misses and adverse events with other organizations.

There is so much competition between health care systems. Health care systems are concerned that the other systems will use the (adverse event) information against them.

Subtheme: Topic-driven collaborations by healthcare systems, professional organizations and grant activities have been very successful in improving patient safety practices in Maine.

- There are many fine examples of successful programs that show promising results
  - Quality Counts – Transforming Care At the Bedside (TCAB), Pressure Ulcer Initiative
  - Maine Hospital Association education sessions
  - Maine Infection Prevention Consortium
  - Maine Quality Forum data reports
  - TeamSTEPPS – Maine Health
  - Maine CAH Patient Safety Collaborative
  - Falls Prevention programs - A Matter of Balance
- There is significant enthusiasm for the synergy of collaboration and the support that arises from shared experiences and problem-solving.
- Funding, sustainability and spread of best practices is a hurdle for most programs
- Without coordination, even some of the best programs compete with each other for the time and attention of the staff leading the efforts
- Collaborative activities face geographic challenges as staff struggle to arrange both travel and meeting time

We are learning new skills such as redesigning work flow and process improvement and we are working on improving our culture of teamwork. We have initiatives going in team training, Microsystems training, improving the patient experience, communication with the caregiver, medication reconciliation, and the quietness of the healing environment.

The Transforming Care at the Bedside project has had a positive impact on increasing communication to members of the team. The hospital quality network has reduced readmissions through communication and having all the providers involved.

The Pressure Ulcer Prevention Initiative has learned how to bridge care settings and develop innovative relationship that haven't existed in the past between long term care, home care and acute care hospitals.

We have utilized literacy volunteers in the community. They have helped with the discharge process, assimilating discharge instructions so that they're meaningful to the patient, and help with visual cues for appointments.

We use a balance program, an evidence-based program, and provide it for people who have a fear of falling. There should be more programs like this.
We are looking for resources, recommendations, areas of excellence and best practices. We would appreciate articles, conferences, standardization tools and the ability to steal successes shamelessly from our colleagues.

Subtheme: There is some consensus that state agencies and state-wide organizations could boost local and regional efforts to improve patient safety through coordination of healthcare professional training, public outreach, uniform reporting standards, and policy dialogue.

- Public policies may be more effective than legislation.
- Access to federal agency expertise and other resources can be coordinated through state agencies.
- State agencies should communicate to make sure that regulations and policies do not compete.
- Data collection standardization and transparency of blinded or aggregated data for public review and best practice discussion would be helpful.

The State could sponsor national speakers for education and training. We need to train people to implement ways to change the culture. It is inspiring to hear patient stories.

It would be so helpful if we could see each other's (medication errors) data – if it were blinded data we could learn so much from each other.

The Sentinel Event Reporting program is not as helpful as it could be and the yearly reports could be improved to identify issues to address through education and programs. Extracted data could really help other hospitals. We could also spend some time looking at the costs of errors such as falls and infection – the State could help by leading the effort on this.

I don't think legislation is the way to improve safety. Facilities need to take the initiative. If the facilities have no input into the format of safety improvement there will be problems with the buy-in and implementation.

The Maine Quality Forum has done important work. It's been critical that MQF was a neutral data collector and presented the data in a non-blaming manner. There are other special interest groups collecting data that have an agenda and are not neutral.

We need to have licensure and regulations (State) departments talking to each other and collaborating.

There is a healthcare system database to look at adverse drug events. One hospital may report 15 things and the other might report 75 things. The hospital (with 75 things) may be reporting incidents with more detail than the other hospital, so you really can't say one hospital is worse than the other. The definitions for reporting have differing interpretations.

Suggestions from Key Informants:

- State agency collaboration regarding patient safety issues, licensures and regulations
- Data collection by neutral party for purposes of benchmarks, best practices and review of adverse events and near misses
- Centralized clearinghouse of resources for providers of healthcare
- Commitment by healthcare providers, systems and other stakeholders to work together to improve patient safety and not use it as a competitive edge
- Interdisciplinary initiatives have greater impact potential
- Topic-driven initiatives have been very successful within Maine, yet we need to work on sustainability of effort and spread of successful activities
- The State or another state-wide organization can play an important role in providing infrastructure for improvement efforts

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

This report provides a view of patient safety efforts in Maine through three different lenses. The environmental scan suggests that state agencies and the Maine healthcare community are very active in addressing certain patient safety topics. Many other states offer a more comprehensive approach, notably partnerships that bring broad based financial and human resource support to population-based improvement strategies. Maine does not currently have an organization with Patient Safety Organization (PSO) federal designation other than one private firm which contracts with anesthesiology practices around the country.

Survey results indicated extremely strong interest in basic education and training in patient safety both for current healthcare professionals and those individuals in the higher education pipeline. Patient safety is a recent discipline and there is in fact, some catching up to do. These results were confirmed by the key informant interviews. Many respondents believe that there is strong value in state-wide educational efforts and see a role for state leadership to drive this endeavor. The importance of sharing data to learn from errors and near misses was a recurring theme and may require the impartiality of a state-supported or PSO group to achieve wide-spread and transparent usefulness.

The control and prevention of infections has become one of the most pressing patient safety problems in healthcare due to the emergence of antibiotic resistant organisms.[11] The federal government and other healthcare payers are exerting financial pressure on healthcare providers as they begin to reduce or stop payment for services related to healthcare associated infections. With the delivery of healthcare services continuing to move from hospitals to ambulatory care, homes, and other settings, infection and infection control cannot be understood as clinical issues to be contained within the walls of the hospital. Infection control and prevention and antibiotic resistance are now a community concern that requires coordinated and sustained action through partnerships of stakeholders empowered through community-specific data and evidence-based strategies. As surveillance and incidence data and measures and become more standardized and available to providers, payers and consumers are driving increasing attention to the problem and urging action.

The overwhelming expression of interest and need for infection control and prevention education and improvement work may reflect the “canary” of the patient safety infrastructure within Maine. Healthcare associated infections are essentially moving targets with evolving clinical guidelines, diagnoses and treatments. Both healthcare providers and consumers have knowledge deficits and have yet to fully embrace best practices that can help control the spread of infection. Yet, at the same time, state agencies and healthcare organizations have devoted significant resources to prevent healthcare associated infections. Without the infrastructure of a comprehensive and population-based organization, these efforts may not be as effective as they could be. The expressed needs and frustrations of the survey respondents can be considered a symptom of a fragmented approach that falls short of addressing a significant and urgent patient safety issue.

Recommendations

- Assemble a state-wide stakeholder group that includes consumers, payers, state agencies, trade organizations, healthcare providers, and academic institutions to form goals and strategies for the coordinated and comprehensive patient safety education of current and future Maine healthcare professionals.
- Consider and promote an appropriate home for a Patient Safety Organization in Maine that analyzes patient safety events for the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care.
- Encourage state agencies that play a role in patient safety activities with Maine's healthcare community and consumers to coordinate their efforts in data collection, regulation and education.
- Support state-wide patient safety education efforts to engage, educate and empower Maine's consumers with consistent messaging, transparent reporting, and provider partnerships. Should patient safety become a competitive differentiation between providers, Maine's consumers will not be well-served.
- Healthcare associated infections represent a priority issue for Maine's healthcare community and should be the focus of further attention by the Dirigo Health Agency and the Maine Quality Forum.

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GLOSSARY

Adverse Event: Any injury caused by medical care. Identifying something as an adverse event does not imply error, negligence, or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process.

Benchmark: A benchmark in health care refers to an attribute or achievement that serves as a standard for other providers or institutions to emulate. Benchmarks differ from other standard of care goals, in that they derive from empiric data—specifically, performance or outcomes data. For example, a statewide survey might produce risk-adjusted 30-day rates for death or other major adverse outcomes. After adjusting for relevant clinical factors, the top 10% of hospitals can be identified in terms of particular outcome measures. These institutions would then provide benchmark data on these outcomes. For instance, one might benchmark "door-to-balloon" time at 90 minutes, based on the observation that the top-performing hospitals all had door-to-balloon times in this range. In regard to infection control, benchmarks would typically be derived from national or regional data on the rates of relevant nosocomial infections. The lowest 10% of these rates might be regarded as benchmarks for other institutions to emulate.

Checklist: A checklist is an algorithmic listing of actions to be performed in a given clinical setting, the goal being to ensure that no step will be forgotten. Although a seemingly simple intervention, checklists have a sound theoretical basis in principles of human factors engineering and have played a major role in some of the most significant successes achieved in the patient safety movement.

Competency: Having the necessary knowledge or technical skill to perform a given procedure within the bounds of success and failure rates deemed compatible with acceptable care. The medical education literature often refers to core competencies, which include not just technical skills with respect to procedures or medical knowledge, but also competencies with respect to communicating with patients, collaborating with other members of the health care team, and acting as a manager or agent for change in the health system.

CPOE: Computerized provider order entry (CPOE) refers to any system in which clinicians directly enter medication orders (and, increasingly, tests and procedures) into a computer system, which then transmits the order directly to the pharmacy. These systems have become increasingly common in the inpatient setting as a strategy to reduce medication errors. A CPOE system, at a minimum, ensures standardized, legible, and complete orders and thus has the potential to greatly reduce errors at the ordering and transcribing stages.

Error: An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome.

Evidence-Based: Use of the phrase "evidence-based" in connection with an assertion about some aspect of medical care—a recommended treatment, the cause of some condition, or the best way to diagnose it—implies that the assertion reflects the preponderance of results from relevant studies of good methodological quality.

Healthcare-Associated Infections: Health care–associated infections (HAIs) are the most common complication of hospital care. According to the Centers for Disease Control and Prevention (CDC), nearly 1.7 million HAIs occur yearly, leading to approximately 99,000 deaths every year. Such infections were long accepted by clinicians as an inevitable hazard of hospitalization. However, recent efforts have demonstrated that relatively simple measures can prevent the majority of common HAIs, and as a result, hospitals and providers are under intense pressure to reduce the burden of these infections.

Health Literacy: Individuals' ability to find, process, and comprehend the basic health information necessary to act on medical instructions and make decisions about their health.

Informed Consent: Refers to the process whereby a physician informs a patient about the risks and benefits of a proposed therapy or test. Informed consent aims to provide sufficient information about the proposed treatment and any reasonable alternatives so that the patient can exercise autonomy in deciding how to proceed.

Medication Error: Any preventable event that may cause or lead to unintended and incorrect medication use or patient harm, while the medication is in the control of the health care professional or patient.

Medication Reconciliation: The process by which health care providers collect a list of the medications that a patient is taking, using that information to make treatment decisions, and ensuring that all other caregivers who need to know are informed of changes to those medications.

Near Miss: An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart).

Patient Safety: Fundamentally, patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.

Root Cause Analysis (RCA): A structured process for identifying the causal or contributing factors underlying adverse events or other critical incidents.

Safety Culture: Safety culture and culture of safety are frequently encountered terms referring to a commitment of safety that permeates all levels of an organization, from front-line personnel to executive management. More specifically, "safety culture" calls up a number of features identified in studies of high reliability organizations, organizations outside of health care with exemplary performance with respect to safety. These features include:

- Acknowledgment of the high-risk, error-prone nature of an organization's activities
- A blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- An expectation of collaboration across ranks to seek solutions to vulnerabilities
- A willingness on the part of the organization to direct resources for addressing safety concerns

SBAR: Situation, Background, Assessment, and Recommendation. A specific, structured technique that provides a framework for communication between members of the health care team about a patient's condition, particularly for critical conversations requiring a clinician's immediate attention and action.

Sentinel Event: An adverse event in which death or serious harm to a patient has occurred; usually used to refer to events that are not at all expected or acceptable (e.g., an operation on the wrong patient or body part). The choice of the word "sentinel" reflects the egregiousness of the injury (e.g., amputation of the wrong leg) and the likelihood that investigation of such events will reveal serious problems in current policies or procedures.

Spread: The intentional and methodical expansion of the number and type of people, units, or organizations using the improvements.

Teamwork Training: Providing safe health care depends on highly trained individuals with disparate roles and responsibilities acting together in the best interests of the patient. The need for improved teamwork has led to the application of teamwork training principles, originally developed in aviation, to a variety of health care settings.

Workarounds: A deviation from the expected pattern of work to achieve an end result, bypassing safety features. Workarounds should be considered symptoms of a poorly designed process or equipment. Although workarounds may help achieve the immediate result, they are not system improvements; they leave the system unaltered, thus continuing to present potential safety hazards for future patients.

Source:
Agency for Healthcare Research and Quality (AHRQ). The AHRQ Web M&M Glossary page. Available at: http://www.webmm.ahrq.gov/glossary.aspx

APPENDIX

Patient Safety Activities in Maine Survey

Background

The online survey was sent to stakeholders in Maine that have potential involvement in patient safety activities. In September 2011, 758 people and 26 key contacts at organizations/groups were sent emails asking for participation in the survey. Key contacts at organizations/groups were asked to send the survey to their members. It was requested the survey be filled out within two and a half weeks. A reminder email was sent to all after the first week. There were a total of 326 respondents, of which 10 only filled out the question describing the type of organization they worked for. These 10 were omitted, leaving 316 responses for analysis.

More than one person at an organization may have filled out the survey about their organization. This was anticipated and encouraged, as different roles within an organization will have different knowledge and involvement with patient safety activities. The survey allowed more than one person to fill out the survey from a computer to allow for participants with limited computer access at their organization to fill out the survey.

Survey Responses

1. What category best describes your organization? (n=316)

EMS	33%
Critical Access Hospital (25 or less beds)	17%
Community Hospital (26-99 beds)	7%
Health Care System	6%
Large Hospital (100+ beds)	5%
Specialty Practice (i.e. orthopedics, podiatry, etc.)	4%
Primary Care Practice (3-5 providers)	3%
Primary Care Practice (6+ providers)	3%
Home Care	3%
Community Organization	3%
Academic Institution	3%
Federally Qualified Health Center/Rural Health Clinic	2%
State Agency	2%
Collaborative/Network	2%
Ambulatory Care	1%
Primary Care Practice (1-2 providers)	1%
Dental Practice	1%
Mental Health Provider	1%
Trade Association	1%
Nursing Facility	0.30%
Veteran's Administration	0.30%
Lab and Radiology Services	0.30%
Other (please specify)	3%
Rehabilitation Hospital	-
Indian Health Services	-
Pharmacy	-
School Health	-
Consumer Organization	-

Other included family planning, health information exchange, public health organizations, and substance abuse providers.

Organizational categories were developed to highlight the types of organizations represented in this survey. (n=316)

EMS	33%
Hospital	29%
Physician practice	13%
Other community provider	13%
Agency/organization not providing direct care	12%

2. In what county is your organization located? (n=313)

Cumberland County	22%
Penobscot County	17%
Kennebec County	9%
York County	8%
Androscoggin County	6%
Hancock County	5%
Oxford County	5%
Somerset County	5%
Aroostook County	4%
Franklin County	4%
Piscataquis County	4%
Washington County	4%
Knox County	3%
Lincoln County	3%
Waldo County	3%
Sagadahoc County	0.30%

3. Is your organization located in a rural or urban setting? (n=311)

Urban (Augusta, Bangor, Lewiston, Auburn, Portland)	38%
Rural	62%

4. Is your organization involved in patient safety activities? (n=314)

Yes	79%
No	12%
Don't Know	10%

Note: The remaining questions were only asked of respondents who reported their organization is involved in patient safety activities.

5. What category best describes your organization? (n=316)

EMS	33%
Critical Access Hospital (25 or less beds)	17%
Community Hospital (26-99 beds)	7%
Health Care System	6%
Large Hospital (100+ beds)	5%
Specialty Practice (i.e. orthopedics, podiatry, etc.)	4%
Primary Care Practice (3-5 providers)	3%
Primary Care Practice (6+ providers)	3%
Home Care	3%
Community Organization	3%
Academic Institution	3%
Federally Qualified Health Center/Rural Health Clinic	2%
State Agency	2%
Collaborative/Network	2%

Ambulatory Care	1%
Primary Care Practice (1-2 providers)	1%
Dental Practice	1%
Mental Health Provider	1%
Trade Association	1%
Nursing Facility	0.3%
Veteran's Administration	0.3%
Lab and Radiology Services	0.3%
Other (please specify)	3%
Rehabilitation Hospital	-
Indian Health Services	-
Pharmacy	-
School Health	-
Consumer Organization	-

Other included family planning, health information exchange, public health organizations, and substance abuse providers.

6. In what county is your organization located? (n=313)

Cumberland County	22%
Penobscot County	17%
Kennebec County	9%
York County	8%
Androscoggin County	6%
Hancock County	5%
Oxford County	5%
Somerset County	5%
Aroostook County	4%
Franklin County	4%
Piscataquis County	4%
Washington County	4%
Knox County	3%
Lincoln County	3%
Waldo County	3%
Sagadahoc County	0.30%

7. Is your organization located in a rural or urban setting? (n=311)

Urban (Augusta, Bangor, Lewiston, Auburn, Portland)	38%
Rural	62%

8. Is your organization involved in patient safety activities? (n=314)

Yes	79%
No	12%
Don't Know	10%

Note: The remaining questions were only asked of respondents who reported their organization is involved in patient safety activities.

5. Please check all the types of patient safety activities that apply to your organization. (n=230)

Quality improvement	91%
Communication improvement (i.e. teamwork, communication between providers, provider-patient communication)	90%
Staff education/training	90%
Performance/process improvement	79%
Credentialing, Licensure	74%
Error reporting and analysis	73%
Patient education	73%
Culture of safety (i.e. culture survey - learning organization)	67%
Public reporting of safety measures	59%
Regulation	59%
Technological approaches (i.e. bar coding, telemedicine, computerized adverse event detection)	53%
Mentoring	51%
Academic preparation	35%

6. Who takes lead responsibility for patient safety activities in your organization? (n=228)
*Note: More than one response could be selected.

Dedicated staff person	50%
Committee	53%
Other (please specify)	20%

Thirty-five respondents (15%) reported their organization has both a dedicated staff person and a committee to lead patient safety activities.

Most "other" responses mentioned all staff as responsible for patient safety. Other responses included nursing leadership, operations manager, owner, workgroups/teams, quality improvement director, and volunteer deputy chief.

7. What is the source(s) of funds used to support your patient safety activities? (check all that apply) (n=220)

Organization budget	90%
Grant	26%
Government	12%
Fees	8%
Other (please specify)	5%

Other included town funds, dues, personal funds, no funds being needed, volunteer, private fundraising, and departmental budgets.

8. Who is the primary target audience for your patient safety activities? (check all that apply) (n=222)

Patients and Families	76%
Health Care Providers	72%
Health Care Executives and Administrators	27%
Non-Health Care Professionals	23%
Government	14%
Other (please specify)	3%

Other included nurses, nursing students, the community, all staff, and insurance companies.

9. Do you engage consumers in patient safety activities? (n=222)

Yes	64%
No	23%
Don't Know	14%

10. Are your patient safety activities shared with Maine consumers? (n=143)

Yes	67%
No	13%
Don't Know	20%

For those that engage consumers in patient safety activities, about two-thirds share their activities with Maine consumers.

11. What type of information is shared with Maine consumers? (n=62)

For those that engage consumers in patient safety activities, the following are common types of information shared. Note – open-ended responses categorized for themes. Responses could be categorized into more than one group.

Data	44%
Falls	18%
Precautions	16%
Medication safety	15%
Infections	13%
Improvement project status/updates	10%
Accident prevention	8%
Committee reports	6%
Vaccinations	3%
General patient safety topics	44%

12. How is information shared with Maine consumers? (n=72)
For those that engage consumers in patient safety activities, the following are common types of information shared. Note – open-ended responses categorized for themes. Responses could be categorized into more than one group.

Website	44%
Print	28%
Verbal	22%
Public events/press	17%
Visual/posters	9%
Articles	6%
Courses/training	5%
Other	39%

Other included involvement of consumers in committees, public and organizational reports, and by request.

13. Does your organization provide or participate in training on patient safety? (n=215)

Yes	93%
No	4%
Don't Know	3%

14. How does your organization provide or participate in training on patient safety? (Check all that apply) (n=197)

Designs and conducts trainings at your organization	92%
Participates in trainings provided externally	71%
Sponsors trainings to external audience	27%
Other (please specify)	2%

Other responses included supervisors making home visits with clinicians, online information, and participation in meetings where related patient safety topics are introduced.

15. Does your organization participate in networks or collaboratives that address patient safety topics?

Yes	73%
No	13%
Don't Know	13%

16. Please list the networks or collaboratives with which your organization participates.

17. What resources do you use to address patient safety? (check all that apply) (n=186)

In-state conferences (i.e. Quality Counts, Patient Safety Academy)	73%
Web resources	73%
In-state organizations (i.e. Infection Control Collaborative)	63%
State agencies	63%
Journals/books	61%
Legislation/Regulation	54%
National organizations (i.e. Institute for Healthcare Improvement)	54%
Networks	51%
National conferences	48%
Tools/toolkits	47%
Federal agencies	39%
Grants	33%
Other (please specify)	2%

Other included registries, state certified instructors to teach classes, and local and state EMS offices.

18. What patient safety topics have you addressed? (check all that apply) (n=199)

Infection control and prevention	93%
Teamwork and Communication	82%
Medication errors	76%
Falls	74%
Adverse events	71%
Patient safety culture	69%
Transitions and handoffs	66%
Human factors	56%
Root cause analysis	52%
Patient engagement	50%
Information technology solutions	49%
Pressure ulcers	47%
Surgical errors	42%
Diagnostic errors	32%
Other (please specify)	5%

Other included lab procedures, physical safety, staffing and credentialing, environmental safety, trauma analysis, and quality improvement.

19. What five patient safety topics are the highest priority? Please check five for your organization. (n=189)

Infection control and prevention	78%
Teamwork and Communication	63%
Medication errors	60%
Patient safety culture	49%
Adverse events	48%
Falls	48%
Transitions and handoffs	43%
Patient engagement	21%
Information technology solutions	19%
Human factors	17%
Surgical errors	13%
Root cause analysis	13%
Pressure ulcers	12%
Diagnostic errors	8%
Other (please specify)	1%

Other included medication reconciliation.

20. What five patient safety topics are the highest priority? Please check five for the state. (n=166)

Infection control and prevention	80%
Medication errors	59%
Adverse events	56%
Patient safety culture	46%
Teamwork and Communication	42%
Falls	33%
Transitions and handoffs	31%
Information technology solutions	28%
Surgical errors	23%
Patient engagement	21%
Diagnostic errors	18%
Root cause analysis	18%
Human factors	15%
Pressure ulcers	15%
Other (please specify)	1%

Other included prevention.

21. What role should the state play in patient safety activities? (Check all that apply) (n=193)

Health care provider education and training	85%
Consumer education	75%
Public access to patient safety data	61%
Licensing/Regulation	55%
Other (please specify)	4%

Other included none, develop a statewide health plan, oversight of unsafe practices, public reporting of infections, controlling infection outbreaks, resource library, provide information on best practices, provide literature searches from sentinel events.

22. What suggestions do you have for improving patient safety in Maine? (n=68)

Responses were open-ended. The following show some common areas mentioned in the written responses.

Training/education	43%
Consumer focus	24%
Collaboration	19%
Data collection/monitoring	9%
Accountability/regulation	6%
Reimbursement/funding issues	6%
Technology	3%
Best practices	3%
Other	24%

Other included raising awareness, fostering communication, coordinating care, prevention, mental health focus.

23. Are you willing to be contacted for a brief phone conversation about patient safety activities in your organization? (N=187)

Yes	32%
No	68%

For those who were willing to be contacted for an interview, the following information was requested:

- Name of your organization
- Name and job title
- Email address
- Organization's website address

Key Informant Interview Script

Thank you so much for taking the time to speak with me today. The purpose of the interview is to expand our understanding of some of the results from the Patient Safety Activity Survey that you recently participated in. As you may remember, the Muskie School is preparing a report concerning the scope and impact of patient safety activities currently underway in the State of Maine. I expect that this interview will take about 30 minutes and I will be taking notes from our conversation.

As in the electronic survey we will be using the definition of patient safety from the Agency for Healthcare Research and Quality which is:

Patient safety refers to the freedom from accidental or preventable injuries produced by medical care. Practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.

1. Could you please describe some of the activities that your organization is doing to improve patient safety?

2. The following topics were mentioned as high priorities to address at the state level. For each of these areas, what would be the best way to impact these areas at the state level? What activities would be helpful to your organization on this topic area?

    a. Infection control and prevention
        - Best way to impact at state level
        - What activities would be helpful to your organization in this area

    b. Medication errors
        - Best way to impact at state level
        - What activities would be helpful to your organization in this area

    c. Adverse events
        - Best way to impact at state level
        - What activities would be helpful to your organization in this area

    d. Patient safety culture
        - Best way to impact at state level
        - What activities would be helpful to your organization in this area

    e. Teamwork and communication
        - Best way to impact at state level
        - What activities would be helpful to your organization in this area

3. I am interested in how you (your organization) have engaged consumers in patient safety activities. Tell me about the most effective ways you have found to engage patients or consumers in patient safety.

   What are some of the challenges or barriers to engage patients or consumers in patient safety?

4. Many of the survey respondents expressed a desire for education and training around patient safety topics. In your opinion, what might be the best ways to achieve patient safety education here in Maine?

5. Before we close, I would like to ask you if there is something else you would like to add about patient safety activities in Maine whether at your organization level or the state level.

Patient Safety Organization (PSO) General Information

Source: PSO Fast Facts http://www.pso.ahrq.gov/psos/fastfacts.htm#ff01

What is a PSO?

A PSO is an entity or a component of another organization (component organization) that is listed by AHRQ based upon a self-attestation by the entity or component organization that it meets certain criteria established in the Patient Safety Rule.

The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care. See 42 CFR 3.102 for the complete list of requirements.

What are "patient safety activities"?

There are eight patient safety activities that are carried out by, or on behalf of a PSO, or a health care provider:

- Efforts to improve patient safety and the quality of health care delivery
- The collection and analysis of patient safety work product (PSWP)
- The development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices
- The utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk
- The maintenance of procedures to preserve confidentiality with respect to PSWP
- The provision of appropriate security measures with respect to PSWP
- The utilization of qualified staff
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system

Why are the terms "safety" and "quality" used in conjunction when describing the role of PSOs?

The term "safety" refers to reducing risk from harm and injury, while the term "quality" suggests striving for excellence and value. By addressing common, preventable adverse events, a health care setting can become safer, thereby enhancing the quality of care delivered. PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data, thus identifying and reducing the risks and hazards associated with patient care and improving quality.

What is the purpose of a PSO?

The Patient Safety Rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Rule outlines how PSOs can be a source of confidential and privileged external advice for health care providers seeking to understand and minimize the risks and hazards in delivering patient care.

What is Patient Safety Work Product?

PSWP is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSWP may identify the providers involved in a patient safety event and/or a provider employee that reported the information about the patient safety event. PSWP may also include patient information that is protected health information as defined by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (see 45 CFR 160.103).

Do PSOs receive Federal funding?

PSOs do not receive Federal funding.

What are the benefits to health care providers who work with a PSO?

PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

The protections of the Patient Safety Rule enable PSOs that work with multiple providers to routinely aggregate the large number of patient safety events that are needed to understand the underlying causes of patient harm from adverse events and to develop more reliable information on how best to improve patient safety.

The uniform Federal protections that apply to a provider's relationship with a PSO are expected to remove significant barriers that can deter the participation of health care providers in patient safety and quality improvement initiatives, such as fear of legal liability or professional sanctions.

What is the difference between the "Listed PSO" logo and the "AHRQ Common Formats" logo?

PSOs that are currently listed by the HHS Secretary are entitled to display the "Listed PSO" logo. This logo is intended to identify entities whose PSO certifications have been accepted in accordance with Section 3.104(a) of the Patient Safety Rule. Before working with a PSO, however, health care providers are encouraged to review AHRQ's geographic or alphabetical directories to confirm that the entity being considered is still a listed PSO.

The "AHRQ Common Formats" logo may be displayed by any organization that is using the Common Formats developed by AHRQ. Such entities do not need to be listed as a PSO by the HHS Secretary to employ the Common Formats and thus display the logo. The Common Formats are available in the public domain to facilitate their widespread adoption and implementation. Entities that display the logo should use the Common Formats as a whole; however, entities that have a limited focus may use the Common Formats that pertain only to that area.

HHS Agency Roles

Which agencies within the Department of Health and Human Services (HHS) implement the Patient Safety Act?

AHRQ is responsible for the provisions dealing with the listing of PSOs such as administering the certification processes for listing; verifying that PSOs meet their obligations under the Patient Safety Rule; working with PSOs to correct any deficiencies in their operations; and, if necessary, revoking the listing of a PSO that remains out of compliance with the requirements. The Office for Civil Rights (OCR) administers and enforces the confidentiality protections provided to PSWP.

Why is AHRQ responsible for the regulation of PSOs?

Congress vested the authority for implementing the Patient Safety Act with AHRQ by incorporating its provisions into AHRQ's authorizing statute. As the lead Federal agency for patient safety research, AHRQ is an appropriate partner for PSOs and health care providers.

How does AHRQ ensure that a listed PSO is in compliance with the statutory requirements as outlined in the Patient Safety Rule?

The Patient Safety Rule establishes in Subpart B the requirements that an entity must meet to seek listing, and remain listed, as a PSO. The Patient Safety Rule relies primarily upon a system of attestations, which places a significant burden for understanding and complying with these requirements on the PSO. However, the Patient Safety Rule also authorizes AHRQ to conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ developed a Patient Safety Organizations: A Compliance Self-Assessment Guide to suggest approaches for thinking systematically about the scope of these requirements and what compliance may mean for an individual PSO.

What role will OCR have regarding the Patient Safety Rule?

OCR is responsible for the investigation and enforcement of the confidentiality provisions of the Patient Safety Rule. OCR will investigate allegations of violations of confidentiality through a complaint-driven system. To the extent practicable, OCR will seek cooperation in obtaining compliance with the confidentiality provisions, including providing technical assistance. When OCR is unable to achieve an informal resolution of an indicated violation through voluntary compliance, the HHS Secretary has the discretion to impose a civil money penalty (CMP) of up to $10,000 against any PSO, provider, or responsible person for each knowing and reckless disclosure that is in violation of the confidentiality provisions.

What is AHRQ's role in providing technical assistance?

AHRQ provides additional information and clarification on the PSO listing process, listed PSOs, the Patient Safety Rule, and other PSO activities, such as the Common Formats. PSOs, health care providers, and other interested parties should contact AHRQ at pso@ahrq.hhs.gov or (301) 427-1111 with requests for technical assistance.

Listing Process and Requirements

Who can seek listing as a PSO?

The Patient Safety Rule permits many types of entities—either an entire organization or a component of an organization, a public or private entity, a for-profit or not-for-profit entity—to seek listing as a PSO. Both the *mission* and the *primary activity* of the entity (or component) must be to conduct activities to improve patient safety and the quality of health care delivery (42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)).

The Patient Safety Rule requires an entity to certify that it meets 15 distinct statutory requirements; a component of another organization must attest that it meets another three statutory requirements; and each entity or component organization must comply with several additional regulatory requirements.

What are the requirements to be a PSO?

Every entity seeking to be a PSO must certify to AHRQ that it has policies and procedures in place to perform the eight patient safety activities specified in the Patient Safety Rule.

In addition, an entity must also, upon listing, certify that it will comply with the following seven additional criteria specified in the Patient Safety Rule:

- The mission and primary activity of the entity are to conduct activities that improve patient safety and the quality of health care delivery
- The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals
- The entity, within each 24-month period that begins after the date of the initial listing as a PSO, will establish two bona fide contracts, each of a reasonable period of time, with more than one provider, for the purpose of receiving and reviewing PSWP
- The entity is not, and is not a component of, a health insurance issuer
- The entity shall fully disclose—
    i. any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and
    ii. if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity
- To the extent practical and appropriate, the entity collects PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers
- The entity uses PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk

The Patient Safety Rule also establishes several additional requirements (see 42 CFR 3.102(a)).

Are there additional requirements for a component organization?

If the entity seeking listing is a component of another organization, the entity must also certify that it is, and will be in compliance with, three additional requirements specified in the Patient Safety Rule:

- The entity maintains PSWP separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the PSWP
- The entity does not make an unauthorized disclosure of PSWP to the rest of the organization in breach of confidentiality
- The mission of the entity does not create a conflict of interest with the rest of the organization

Are any entities excluded from being listed as a PSO?

The Patient Safety Act excludes a health insurance issuer or a component of a health insurance issuer from becoming a PSO. The Patient Safety Rule also excludes the following entities: regulatory agencies; organizations that serve as agents of regulatory agencies (e.g., entities that carry out inspections or audits for a regulatory agency); accreditation and licensure entities; and entities that administer a Federal, State, local, or tribal patient safety reporting system to which health care providers are required to report by law or regulation (see 42 CFR 3.102(a)(2)(ii)).

What is the primary activity requirement for initial listing as a PSO?

Entities submitting certifications for initial listing need to attest that they meet the requirement that both their mission and their primary activity are to conduct activities to improve patient safety and the quality of health care delivery (42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)).

What can an entity do if it does not meet this primary activity requirement?

A multi-purpose entity with a broader scope can create or designate a component that more clearly meets the mission and primary activity criterion. The component of that entity can then seek listing.

What requirements does a PSO need to meet regarding their staff?

There are two requirements relating to PSO staff in the Patient Safety Rule. PSOs must have policies and procedures in place to conduct each patient safety activity, for which PSOs are required to use qualified staff (42 CFR 3.102(b)(1)(i)). Second, PSOs must have an appropriately qualified workforce, including licensed or certified medical professionals (42 CFR 3.102(b)(2)(i)(B)). AHRQ has interpreted this language to mean that each PSO has a qualified staff with relevant medical experience available. The language does not require every member of a PSO's workforce to have this expertise, but at least one individual

must have medical credentials and experience. Such a workforce can include individuals who serve on a volunteer basis, as well as those who are paid as employees or serve under contract.

It is desirable that the medical experience reflects the type of patient safety events reported to and analyzed by the PSO. For example, a PSO that receives patient safety event information related to the delivery of hospital care would want to have a physician as part of their workforce; a PSO that primarily deals in adverse drug events would likely benefit from having a pharmacist as a member of their workforce. The over-arching requirement is that the qualified staff works under the direct supervision of the PSO.

How does an entity apply to become a PSO?

AHRQ has prepared a *PSO Certification for Initial Listing* form that an entity must use to certify that it meets the requirements to become listed as a PSO. To access this form go to: http://www.pso.ahrq.gov/forms/certfm.htm

What is the deadline for submitting the forms to become a PSO?

There is no deadline for applying to be listed as a PSO. Applications for PSO status will be accepted at any time and will be reviewed as expeditiously as possible.

Does a PSO listing expire?

A PSO is listed for a period of 3 years. To renew its listing for an additional 3 years, the PSO will be required to complete and submit a *PSO Certification for Continued Listing* form before the expiration of its period of listing. The PSO must certify that it is performing, and will continue to perform, each of the patient safety activities and that it is complying with, and will continue to comply with, the other requirements of the Patient Safety Rule. The PSO's 3-year period of listing will automatically expire at midnight of the last day of the PSO's listing period if AHRQ has not received and approved the PSO's continued listing form.

Privacy and Confidentiality Protections

What are the privacy and confidentiality protections for PSWP?

The Patient Safety Act and Rule make PSWP privileged and confidential. Subject to certain specific exceptions, PSWP may not be used in criminal, civil, administrative, or disciplinary proceedings. PSWP may only be disclosed pursuant to an applicable disclosure exception (see 42 CFR 3.206).

Can original provider records be protected as PSWP?

A patient's original medical record, billing and discharge information, and any other original patient or provider records cannot become PSWP. Copies of selected parts of original provider records may become PSWP.

Can a health care provider work with more than one PSO? If so, is the PSWP protected?

The Patient Safety Rule permits a health care provider, such as a hospital, to work with more than one PSO. Any information that is eligible to become PSWP reported to a PSO by a health care provider is protected. The definition of PSWP (42 CFR 3.20) provides important detail on what information is eligible for protection and when those protections apply.

Is information submitted to the NPSD safe?

Yes. PSWP must be nonidentified before it is submitted to the NPSD. Nonidentification requires that the information identifying individual and institutional providers, patients, and provider employees reporting patient safety events be removed from the PSWP.

What is the importance of the privacy and confidentiality protections for PSWP?

The Patient Safety Act makes PSWP privileged and confidential. The Patient Safety Act and the Patient Safety Rule generally bar the use of PSWP in criminal, civil, administrative, or disciplinary proceedings except where specifically permitted. Strong privacy and confidentiality protections are intended to encourage greater participation by providers in the examination of patient safety events. By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

What is the relationship between the Patient Safety Rule and the HIPAA Privacy Rule?

PSWP may contain individually identifiable health information as defined in the HIPAA Privacy Rule. Health care providers that are HIPAA-covered entities must comply with the use disclosure exceptions for PSWP as well as the permissions and disclosure requirements concerning protected health information (PHI) set forth by the HIPAA Privacy Rule, as well as the limitations on the disclosure of information found in the Patient Safety Rule when disclosing PSWP. PSOs that are business associates of HIPAA-covered entities are subject to the limitations on the use and disclosure of PHI. Also, a PSO is a business associate of a HIPAA-covered provider subject to the business associate requirements of the HIPAA Privacy Rule.

If a PSO is revoked for cause (i.e., noncompliance with the requirements that each PSO must meet) and a health care provider inadvertently submits data to that entity, is the data protected?

If a PSO's listing is revoked for cause, health care providers may continue to submit data to the delisted PSO for 30 calendar days, beginning on the date and time that the PSO is delisted and ending 30 days thereafter. Data submitted during this 30 day period are treated as PSWP and are subject to the confidentiality and privilege protections of the Patient Safety Act.

For example, if a PSO is delisted for cause at midnight on March 1, a health care provider can continue to submit data to the delisted PSO until midnight on March 31 and the data will be protected. Data submitted to the former PSO after midnight on March 31 would not be protected. All PSWP submitted to a former PSO in accordance with provisions of the Patient Safety Act and Patient Safety Rule remains protected after the PSO ceases operations.

Common Formats and the Network of Patient Safety Databases (NPSD)

What are the Common Formats?

Common Formats are common definitions and reporting formats used to facilitate the collection and reporting of patient safety events. AHRQ developed Common Formats for use by health care providers and PSOs. other organizations dedicated to improving care quality.
Currently, the Common Formats are limited to patient safety reporting in two settings of care—acute care hospitals and skilled nursing facilities. Future versions of the Common Formats are being developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. AHRQ most recently released a beta version of the Venous Thromboembolism (VTE) Common Format, which includes Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). This version (dated November 1, 2011) is currently available for public review and comment. AHRQ plans to incorporate the

VTE Common Format into the next version of the Common Formats for both acute care hospitals and skilled nursing facilities.

To learn more about the Common Formats, please go to http://www.pso.ahrq.gov/formats/commonfmt.htm. To access the most current versions of the Common Formats, please go to www.psoppc.org.

What is the development and version history of the Common Formats?

In collaboration with the Federal Patient Safety Workgroup (PSWG), AHRQ has developed Common Formats for two settings of care – acute care hospitals and skilled nursing facilities.

To develop the Common Formats, AHRQ first reviewed existing patient safety event reporting systems from a variety of health care organizations. Working with the PSWG and Federal subject matter experts, AHRQ and the PSWG developed, piloted, drafted, and released Version 0.1 beta of the Common Formats (for acute care hospitals) in August 2008.

Through a contract with AHRQ, the National Quality Forum (NQF) solicited feedback on Version 0.1 beta from private sector organizations and individuals. The NQF, a nonprofit organization that focuses on health care quality, then convened an expert panel to review the comments received and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revised the Common Formats and released Version 1.0 in September 2009.

The review process above was repeated to further refine the Common Formats and to incorporate any public comments on Version 1.0 prior to finalization of the technical specifications for electronic implementation. These modified formats for acute care hospitals were made available as Version 1.1 in March 2010.

In conjunction with the PSWG, AHRQ revised the device event-specific Common Format (available in Version 1.1) to include patient safety events related to HIT. This Common Format, *Device or Medical/Surgical Supply including HIT Device*, was released in October 2010 and will be incorporated into the next version of the Common Formats (Version 1.2) for acute care hospitals.

In March 2011, AHRQ and the PSWG released Common Formats for skilled nursing facilities. AHRQ anticipates that the refinement of the Common Formats for skilled nursing facilities will emulate the evolution of the acute care hospital Common Formats.

Most recently, AHRQ and the PSWG developed a Common Format for Venous Thromboembolism (VTE) that includes both Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). This Common Format [released November 1, 2011] is currently available as a beta version for public review and comment.

AHRQ plans to incorporate the VTE Common Format into the next version of the Common Formats for both acute care hospitals and skilled nursing facilities.

Will the general public ever have access to the trending data collected or aggregated from PSOs?

The Patient Safety Act authorizes AHRQ to facilitate the development of a network of patient safety databases (NPSD), to which PSOs, health care providers, or others can voluntarily contribute nonidentifiable PSWP. The Patient Safety Act directs AHRQ to incorporate the nonidentifiable trend data from NPSD in its annual *National Health Care Quality Report (NHQR*). The NHQR is available in hard copy and electronically on the AHRQ Web site at http://www.ahrq.gov/qual/qrdr10.htm.

Why should PSOs contribute PSWP to the NPSD?

By enabling PSOs to aggregate PSWP on their own and to contribute nonidentifiable PSWP to the NPSD, the stage has been set for breakthroughs in our understanding of how best to improve patient safety. The NPSD will facilitate the aggregation of sufficient volumes of patient safety event data to identify more rapidly the underlying patterns and causes of risks and hazards associated with the delivery of health care services. By contributing nonidentifiable PSWP to the NPSD, PSOs can accelerate the pace at which the NPSD can advance our knowledge and provide an important adjunct to a PSO's own analyses.

What information are PSOs required to submit to the NPSD?

PSOs are not required to submit any information to the NPSD.