A Conversation

with

PATIENT SAFETY OFFICERS

PATIENT SAFETY AUTHORITY
An Independent Agency of the Commonwealth of Pennsylvania

PA PSRS
Pennsylvania Patient Safety Reporting System

"I think I can state that patient safety is probably the one area where we would all agree that we should be cooperating and not competing."

—Pennsylvania Patient Safety Officer

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March 2007

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Insight for the Future

From late 2006 to early 2007, the Patient Safety Authority and the Pennsylvania Patient Safety Reporting System (PA-PSRS) conducted three regional group discussions with Patient Safety Officers (PSOs) from healthcare facilities throughout Pennsylvania. The purpose of these meetings was to gain insight on how PA-PSRS can best help PSOs improve patient safety and to seek feedback on the current and future direction of PA-PSRS.

Background

The Authority is an independent state agency established under Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. It is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities. The Authority's role is nonregulatory and nonpunitive.

The Authority operates under an 11-member Board of Directors: a physician appointed by the Governor who serves as board chair, 6 other members appointed by the Governor to fill seats designated for specific professional occupations, and 4 members appointed by the General Assembly. Current membership includes three physicians, three attorneys, two nurses, a pharmacist, and an executive with a health insurance company.

Under Act 13, all hospitals, birthing centers, and ambulatory surgical facilities must report what the Act defines as "Serious Events" (i.e., actual adverse events) and "Incidents" (i.e., near misses). Act 30 of 2006 extended this requirement to qualifying abortion facilities. In turn, the Authority analyzes and evaluates those reports so it can learn from the data reported in order to advise facilities and make recommendations for changes in healthcare practices and procedures which may be instituted to reduce the number and severity of Serious Events and Incidents.

To provide a mechanism for the collection and analysis of data related to Serious Events and Incidents, the Authority developed and implemented PA-PSRS, a secure, Web-based, data collection and analysis system. PA-PSRS was developed under contract with ECRI, a Pennsylvania-based independent, nonprofit health services research agency, in partnership with EDS, a leading international, information technology firm, and the Institute for Safe Medication Practices (ISMP), also a Pennsylvania-based, nonprofit health research organization. All information submitted through PA-PSRS is confidential, and no information about individual facilities or providers is made public. In addition, Act 13 contains whistleblower protections as well as provisions that allow healthcare workers to submit what are called "Anonymous Reports" if they believe that healthcare facilities are not acting appropriately in response to a Serious Event within the facility.

Statewide mandatory reporting went into effect in June 2004, making Pennsylvania the first state in the nation to require the reporting of both actual adverse events and near misses. By the end of 2006, Pennsylvania healthcare facilities had submitted nearly 425,000 reports of Serious Events and Incidents through PA-PSRS.

Purpose of the Group Discussions

The Authority continuously evaluates PA-PSRS, as both the Authority and individual facilities gain experience in using PA-PSRS. Above all, the Authority remains committed to assuring that PA-PSRS is a user-friendly, nonredundant system that provides valuable feedback to facilities for their

internal patient safety and quality improvement activities. The Authority also recognizes that reporting systems alone do not improve patient safety. It is what we do with the information we learn from reporting systems that holds the potential for real improvement. To this end, the Authority and PA-PSRS invited a diverse, representative sample of PSOs to participate in these discussions. In Pennsylvania, the PSO is the individual primarily responsible for patient safety and PA-PSRS's primary contact within each facility.

The Authority and PA-PSRS see these group discussions as a valuable format to facilitate organized discussion among selected representatives of the Pennsylvania healthcare facilities mandated to report data to PA-PSRS. Though PA-PSRS also obtains feedback through other means, such as annual surveys and ad hoc communications from facilities, the group discussions yielded additional detail and context that could not be obtained by these other means. It was not among the Authority's goals for these group discussions to have participants arrive at consensus on the issues explored. Rather, the discussions were aimed to elicit either consensus or divergent opinions where they existed and to either validate or challenge pre-existing assumptions.

Design of this Report

This report contains general observations of participants' discussion centering on three topics: (1) the PSO's role in their facilities, (2) additional support from which they would benefit, and (3) the means of measuring improvement or judging success in patient safety improvement. This report provides the methods by which PA-PSRS selected participants and conducted the discussion groups, as well as observations on PSOs' responses. Because of the informal nature of these discussions, this report takes a qualitative approach and does not contain statistical analysis of the participants' responses. Rather, results are presented using descriptive terms that reflect general observations (e.g., few, some, majority, all). All information contained herein is confidential as to who provided it. Specific quotes and points of view are not attributed to individuals by name, facility, or region.

The Authority and PA-PSRS originally intended to provide this report solely to the Authority Board of Directors to inform their deliberations about future endeavors for the Authority. However, due to requests from participants and the insight from these group discussions, this report has been made public. This report serves as a window into the day-to-day challenges and concerns of PSOs in Pennsylvania.

While the role of the PSO in Pennsylvania is shaped by specific legal requirements, healthcare facilities across the nation have embraced the concept of the PSO and designated a single individual with primary responsibility for patient safety. We believe the needs and challenges of PSOs in Pennsylvania are not unique to this state, and this report can help to inform a much broader audience about how PSOs view their role, whether they have the resources they need to be effective, and how they know they are making a difference.

Patient Safety Officer Discussion Groups

Background

The Authority and PA-PSRS conducted three group discussion sessions with PSOs representing healthcare facilities throughout Pennsylvania. PSOs' participation was sought because they are the primary individuals responsible for patient safety in their facilities, and they are PA-PSRS's primary contacts within their facilities. The purpose of these sessions was to obtain PSOs' feedback on the current efforts of PA-PSRS and guidance on the focus of future efforts. Participating PSOs comprised a diverse, representative sample of PSOs statewide.

The sessions occurred at regional locations in the state during late 2006 into early 2007. Discussion topics were intended to (1) draw out consensus and divergent opinions and (2) validate or challenge assumptions about PSOs.

Participating PSOs discussed the following questions:

1. What is the role of the PSO at your facility?
2. What more could the Authority/PA-PSRS do to help PSOs be more effective?
3. How do we know we are making a difference in improving patient safety?

Collective Responses

With their responses, some PSOs' validated assumptions held by the Authority and PA-PSRS, while others offered interesting suggestions for future efforts. Results from the discussion groups are summarized below:

The Role of the PSO

- Most PSOs come from a risk management or quality management background, although some are physicians.
- Typically, facilities employ PSOs in multiple positions (e.g., PSO and risk manager), which can contribute to conflict in responsibilities.
- Most PSOs are mid-level managers in their healthcare facilities.
- Most PSOs have adequate access to senior administration but not to boards of trustees.
- PSOs act as "keeper of patient safety issues," but many have limited resources to fulfill this role.
- PSOs are able to get clinicians' attention for patient safety problems when needed, but some report difficulty sustaining momentum on long-term initiatives that compete with patient care for individuals' time and effort.

What More Could the Authority and PA-PSRS Do to Help Improve Patient Safety?

- Help educate senior administration and boards of trustees
- Provide education and training to front-line caregivers to help augment PSOs' limited resources
- Standardize the reporting requirements of the Mcare Act to (1) reduce variability among reporting facilities and (2) provide a base of consistent advice from the Authority and the Pennsylvania Department of Health (DOH)
- Help engage physicians in patient safety, and provide guidance on disclosure of Serious Events to patients
- Provide benchmarking data and improve capability of analytical tools
- Help communicate to the public about patient safety

How to Measure Improvement in Patient Safety

PSOs' guidance on establishing metrics to track improvement in patient safety includes the following:

- Changes in clinical processes and systems will be more reliable than trying to measure outcomes.
- When looking at the success of a specific initiative, PSOs use several methods concurrently to determine positive change (e.g., surveys, chart reviews, direct observation).
- There are some preventable events, such as wrong-side surgery, that could be completely eliminated.
- Focused projects/statewide initiatives may induce change and result in measurable improvements.

Discussion

Many PSOs identified the Authority and PA-PSRS as reliable sources of appropriate and relevant patient safety information and education. Some PSOs' requests and queries served to validate the current direction of PA-PSRS and, to some degree, provided evidence behind preliminary goals for future efforts. The Authority and PA-PSRS will carefully consider PSOs' observations and suggestions, including requests for additional education, training, and resources; standardized reporting requirements; alignment/partnering of related organizations; and opportunities for future such discussion groups and networking opportunities.

The Design and Scope of the Group Discussion Sessions

PA-PSRS staff developed the model used for the three group discussion sessions based on research of the available literature and existing examples of how focus groups are organized and implemented. The resulting model drew on elements of successful focus groups (e.g., limited duration, group moderator, structured questions) conducted by other entities. Because some aspects of traditional focus group methodology were rejected as inappropriate for our purposes (e.g., concealed observation of participants, a disinterested facilitator), we refer to these meetings in this report as "group discussions" rather than "focus groups." Preparation for the three group discussion sessions began in June 2006.

Choice of Regional Locations

PA-PSRS chose locations in Pennsylvania's eastern, central, and western regions to ensure regional diversity. The meetings were conducted in Harrisburg, Valley Forge, and Pittsburgh, on December 15, 2006, December 18, 2006, and January 12, 2007, respectively.

Facility Representation

For the discussion groups, PA-PSRS desired representation from the various facility types that report to PA-PSRS, with some consideration for the extent to which different types of facilities report to PA-PSRS. For example, since hospitals account for about 99% of all reports to PA-PSRS, it was appropriate that nearly all participants were PSOs from hospitals. These facility types include: healthcare systems, acute tertiary, acute community, behavioral health, rehabilitation, ambulatory surgical, and birthing center.

PA-PSRS envisioned that 10 to 12 representatives would attend each session, representing the above facility types. Diverse representation was desired to properly represent the different observations, ideas, and experiences of the different reporting facilities.

To ease the time demands made on PSOs (i.e., leaving their facilities for a morning), PA-PSRS limited selection of participants to those who could travel one hour or less to the selected locations.

Of the 60 PSOs invited to participate in one of the three sessions, 26 attended, representing to some degree all facilities that report to PA-PSRS. (See Table 1 and Figure 1 for the number and percentage, respectively, of facilities that participated from each facility category.) Eighteen PSOs failed to respond to the invitation; 11 PSOs declined but expressed interest in attending future sessions; and 5 accepted but were unable to attend at the last minute.

Some PSOs were unable to attend themselves but requested to send delegates in their stead. The Authority approved these types of requests depending on the delegates' job title and role.

PA-PSRS also intended the group of participating facilities to be representative by facility size. Figure 2 compares, according to bed size, facilities participating in the group discussions and hospitals statewide. While

Table 1. Number of Participating Facilities by Facility Type

Type	Number
Acute tertiary hospital	7
Acute community hospital	7
Health system	6
Rehabilitation hospital	4
Behavioral health hospital	1
Ambulatory surgical facility	1

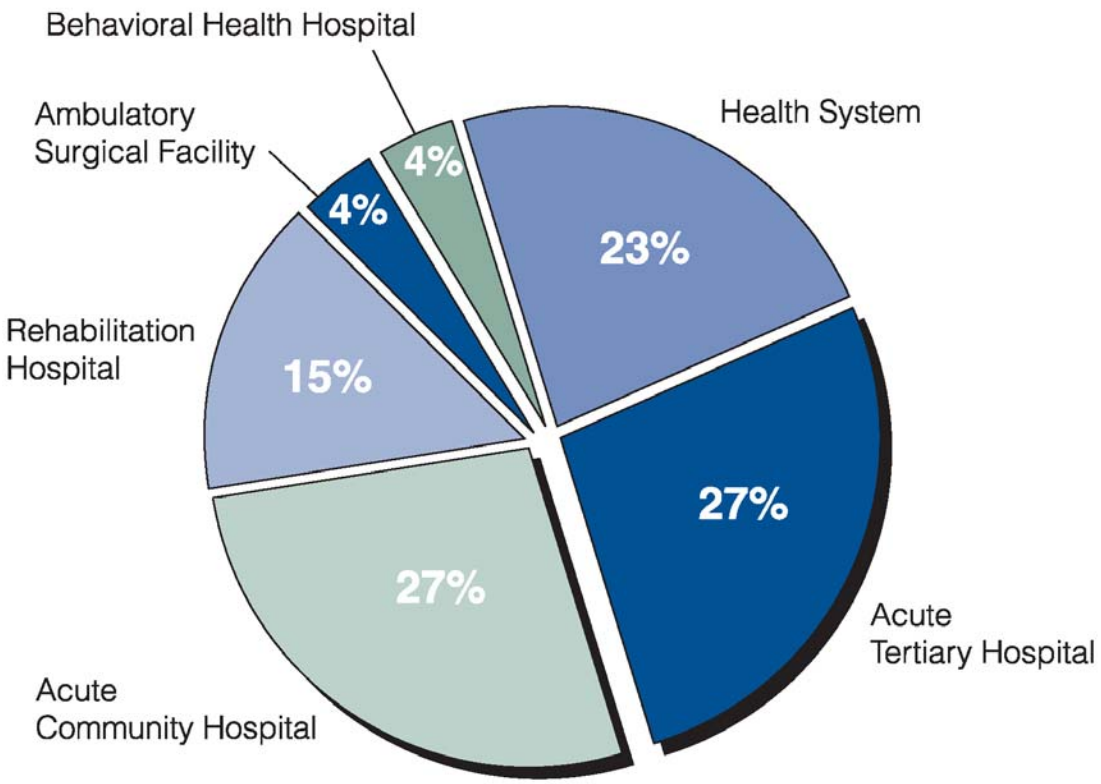

Figure 1. Percentage of Participating Facilities in Attendance

several size categories are either under- or over-represented, the group of participating facilities does include representatives in each category.

Group composition was also intended to include PSOs whose facilities represented a wide range of report volumes to PA-PSRS. Some PSOs represented relatively high-volume reporters, while others were medium- or low-volume reporters, measured as reports-per-bed. Figure 3 illustrates the distribution by report volume of participating facilities.

Authority and PA-PSRS Representation

For the most part, the Authority and PA-PSRS representatives who attended the group discussions were present to observe, answer questions, and document the discussions. The PA-PSRS project manager participated as the moderator.

Topic Discussion

The Authority and PA-PSRS chose topics for the group discussions. The following 3 topics were selected from an initial list of 10. Under each major question are subsidiary questions the moderator used to prompt discussion.

1. What is the role of the PSO at your facility?
   a. How do you effect change in your facility?
   b. What barriers to change do you encounter?
   c. What are the PSO's duties and responsibilities
   d. How does your patient safety committee operate?

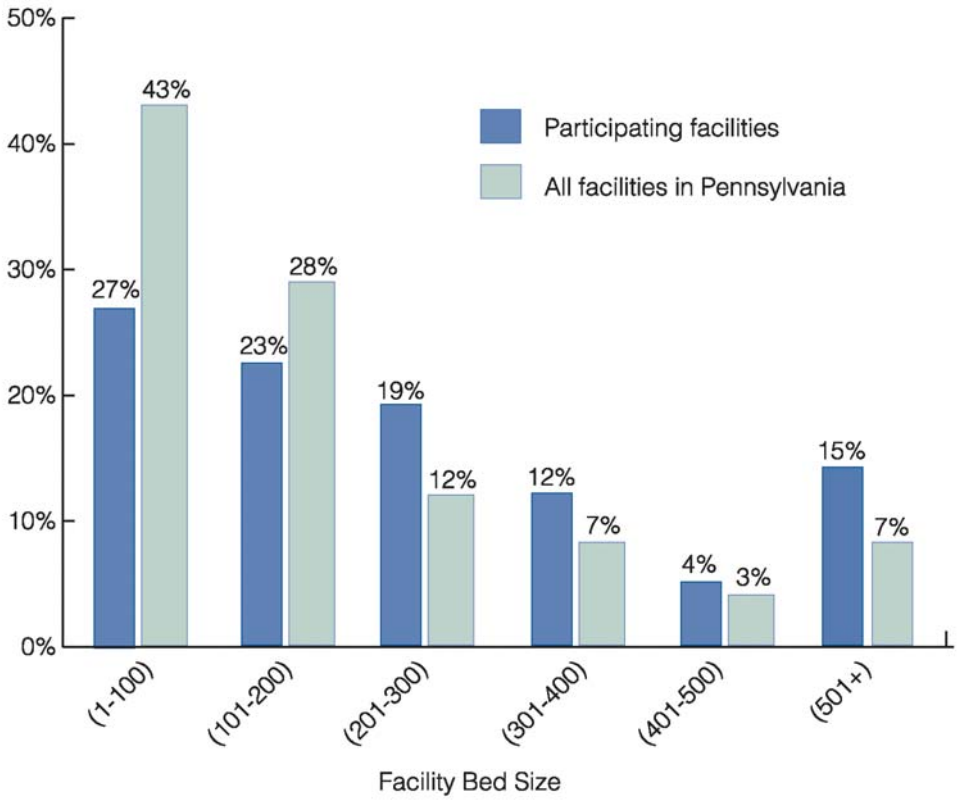

Figure 2. Comparison of Participating Facilities' and Statewide Facilities' Bed Size

2. What more could the Authority/ PA-PSRS do to help PSOs be more effective?

   a. How useful are the Authority's/ PA-PSRS's current activities?
   b. What is the Authority or PA-PSRS not doing that would be helpful to you?
   c. Is there an interest in collaborative projects?
   d. If you could change something about PA-PSRS, what would it be?

3. How do we know we are making a difference in improving patient safety?

   a. What measures of success do you use at the facility level?
   b. How do you use PA-PSRS analytical tools?
   c. How could we measure success in patient safety improvement at the state level?

Total discussion time was limited to two hours. After the discussion groups adjourned, participants were encouraged to contact the Authority or PA-PSRS with any additional comments or questions.

Limitations

The results of these group discussions cannot be construed as the observations of all PSOs, nor was this the intent. The Authority and PA-PSRS did, however, aim to bring together a representative group of PSOs to help ensure that the most important concerns were discussed. Due to factors such as limited attendance, it is possible that such a sample might not have been achieved. Likewise, the observations in this report might not

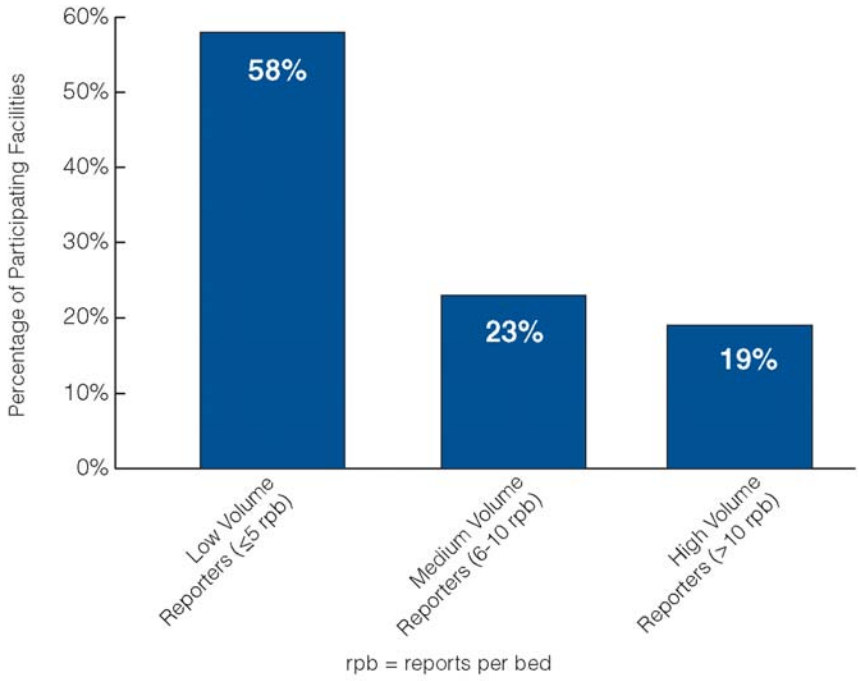

Figure 3. Participating Facilities' Reports Volume (June 2004-September 2006)

accurately reflect everything that every PSO had to say about his or her role, needs, and measures of success. Despite these limitations, the Authority and PA-PSRS staff believe these sessions can help guide improvement efforts for PA-PSRS and patient safety.

Patient Safety Officers' Roles, Needs, and Measures of Success

During the three group discussion sessions conducted December 15 and December 18, 2006, and January 12, 2007, in Harrisburg, King of Prussia, and Pittsburgh, respectively, participating PSOs discussed three topics posed to them by Authority and PA-PSRS representatives:

1. What is the role of the PSO in your facility?
2. What more could the Authority and PA-PSRS do to help improve patient safety?
3. How do we know we are making a difference in improving patient safety?

Presented below are the PSOs' responses relevant to these discussion topics. Analysis of PSOs' responses revealed that many PSOs considered these topics to be closely related.

The Role of the PSO

The role/function of a designated PSO was, in essence, created by Act 13 and represented a structural change in the majority of Pennsylvania healthcare systems. Prior to the Mcare Act, some facilities in Pennsylvania had empowered individuals to act in the interest of patient safety; however, the Act clarified and set specific standards for this emerging role.

According to the Mcare Act, the Patient Safety Officer of a medical facility has the following responsibilities:[1]

- Serve on the patient safety committee
- Ensure the investigation of all reports of Serious Events and Incidents
- Take such action as is immediately necessary to ensure patient safety as a result of any such investigation
- Report to the patient safety committee regarding any action taken to promote patient safety as a result of investigations that were conducted

As was apparent from responses during the three group discussions, PSOs recognize the Act's definition of their responsibilities; however, most noted that there are additional aspects of their roles in their facilities.

Key Roles

- Most Patient Safety Officers (PSOs) come from a risk management or quality management background, though some are physicians.
- Typically, facilities employ PSOs in multiple positions. This "multiple hat" role of the PSO can contribute to conflict in responsibilities (e.g., while addressing a patient safety issue, a PSO who is also the healthcare risk manager may have to consider facility interests).
- Most PSOs are mid-level managers in their healthcare facilities.
- Most PSOs have adequate access to senior administration but not to boards of trustees.
- PSOs act as "keeper of patient safety issues," but many have limited resources to fulfill this role. For example, a PSO without the help of additional employees (e.g., patient safety analysts) may have to prioritize data entry into PA-PSRS and/or facility reporting systems over other tasks.
- PSOs are able to get clinicians' attention for patient safety problems when needed, but some report difficulty sustaining momentum on long-term initiatives that compete with patient care for individuals' time and effort.

Wearing Multiple Hats

The role of the PSO varies by facility, but it is typically an added responsibility to the existing duties of an individual who already serves one or more roles in the institution. (See the sidebar article "Who (Else) is the PSO?") The PSOs communicated that their multiple responsibilities and roles, at times, require them to wear "multiple hats." In general, PSOs' responsibilities comprise a trio of sister issues to patient safety: risk management, healthcare quality, and performance improvement. Most PSOs are organized in "middle management" and typically hold several positions at their facilities. Some participants' accounts from the group discussions are listed below.

Example 1. "I'm the Patient Safety Officer for multiple facilities," one PSO said. According to the PSO, her role in the healthcare system has evolved over the years. In the beginning, the system had to define who the PSO would be and define his or her role and job description. Today, one of the primary responsibilities of the PSO is to ensure compliance with the Mcare Act, according to the PSO. "All of the reporting, the determination of Serious Events, all of that falls within the PSO's job responsibilities," she said.

In the healthcare system in which she also serves as director of risk management, the PSO and patient safety is organized under a single division that includes aspects of performance improvement, risk management, care management, infection control, data reporting, and analysis. All told, the healthcare system employs more than 100 individuals to support safety initiatives such as Institute for Healthcare Improvement (IHI) campaigns, initiatives discussed in the *PA-PSRS Patient Safety Advisory*, and the Joint Commission's National Patient Safety Goals.

Example 2. Another participant recounted that the PSO position, a supervisor position at his facility, fell to him because he was already the facility's quality manager. As PSO,

Who (Else) is the PSO?

The following list includes examples of the many titles and roles held by Patient Safety Officers (PSOs) *in addition to* their role as the PSO, as reported to the Pennsylvania Patient Safety Reporting System in its 2006 user survey of Pennsylvania healthcare facilities:

- Chair, patient care committee
- Chief executive officer
- Chief medical officer
- Chief quality officer
- Clinical nursing supervisor
- Compliance officer
- Director of case management
- Director of education
- Director of infection control
- Director of patient safety
- Director of performance improvement
- Director of quality management
- Director of risk management
- Director of survey readiness
- Disaster coordinator
- Employee health manager
- Environment of care manager
- Executive director for hospital and intensive residential services
- In-house counsel
- Medication safety coordinator
- Operating room manager
- Pharmacy manager
- Privacy officer
- Respiratory supervisor
- Risk manager
- Secretary of medical staff
- Staff development coordinator
- Vice president
- Workplace safety officer

Source: Pennsylvania Patient Safety Reporting System. 2006 user survey.

he works in tandem with a nurse who is also in quality management. A nurse/risk manager enters the data into PA-PSRS. The PSO primarily is involved as a liaison during investigation and oversight, especially when physicians are involved. He is also responsible for presenting PA-PSRS report data to various committees.

Example 3. "I'm actually a dedicated Patient Safety Officer, and that's all I do all day," another PSO said. He sees himself as a liaison between the risk management and quality departments at his facility. Some of his other duties include disseminating patient safety information and reports to various committees and educating front-line staff. "Even though I am the Patient Safety Officer, I still feel there is so much work to be done in changing the culture and just getting that information out—the job is never-ending."

Example 4. Another PSO is a high-placed physician leader at his facility. He counts himself as fortunate in his particular position because he reports on patient safety directly to the facility's board of trustees, "which hasn't heard the appropriate message in many institutions," he said. According to this PSO, his facility was proactive in creating the PSO role even before the Authority was established.

"Even though I am the Patient Safety Officer, I still feel there is so much work to be done in changing the culture and just getting that information out— the job is never-ending."

Example 5. In communicating her role, another PSO said her facility made a similar decision to appoint a PSO before Act 13 was enacted. "We made the decision to do it at an executive level because of the need to interact with some of our physicians," she said. Her facility has bifurcated the PSO position into an administrative role, which she fulfills, and a medical role filled by a physician. At this facility, patient safety is separate from risk management, although the two interact. "We view patient safety as the quality improvement arm of risk management, if you will, but we really want to be proactive and not hung up on the risk management side," she said.

Depending on how a facility or system is structured, the multiple hats PSOs wear sometimes conflict, particularly between risk management and patient safety. "Sometimes, it is very hard to distinguish between the two roles," a PSO said. "You really have to stop and make a conscious decision about whether you're wearing one hat or another."

Several PSOs had similar thoughts. One presented the "what if" scenario of an adverse event. "Part of you wants to learn from that as the Patient Safety Officer and make any changes you need to make to ensure it doesn't happen again," she said. "The other part of you needs to think about protecting the financial resources of the hospital, and it's a difficult situation to find yourself in." Another PSO framed this issue as both a workload (e.g., reporting to PA-PSRS) and patient safety conflict. "You struggle daily, you know, 'Is this just an Incident, is this a Serious Event?' . . . and you're talking to your patient rep, you're talking to your risk manager, and you're usually the same person having multiple conversations with yourself."

Despite these perceived conflicts, there are perceived benefits to the multiple-hat issue, at least according to one PSO. "The one thing I do like about the combined role of the Patient Safety Officer and the risk manager is that now our conversations are protected, whereas before they were not," she said. The PSO added that because of her dual roles, she feels as though she can investigate and interview staff members without counsel present.

Deciding between the 'Urgent and the Important'

I wish I could do patient safety full time, but unfortunately the reality is that unless there is some grant money or reimbursement of some kind, that's probably never going to happen.

The preceding statement from one PSO captures a consensus of the participants in the discussion group sessions. With some exceptions, PSOs held the general opinion that while they are perceived as "the institutional keeper of patient safety," they often have limited resources with which to address patient safety issues. For example, one PSO felt her limited time often forced her to choose between the "urgent and the important."

PSOs said they tackle the problem of limited resources in various ways, depending on their facility structure and organization, including the following:

Prioritizing issues. The PSO who offered this solution said her facility's patient safety committee helps determine the priority of most patient safety issues. Items of high priority (e.g., Joint Commission Sentinel Events) get immediate attention, while items of low priority may reside on a "to-do" list for a period of time. Patient safety issues are compiled from a variety of sources.

Delegating responsibilities. Several PSOs reported that their facilities employ individuals to help with various patient safety tasks. For example, one PSO said that she has a part-time employee to submit reports to PA-PSRS. Another said that in addition to splitting the PSO position (i.e., administrative and medical positions), her facility employs several professional staff in subordinate positions to facilitate reporting, investigating, and analyzing the facility's 500 to 600 incidents per month; this job structure allows the PSO to focus on higher-order patient safety issues and spend more time on activities such as facilitating root cause analyses [RCAs]).

Harvesting available resources. Other PSOs spoke of making full use of whatever employees, resources, and/or skills were available. For example, in one PSO's experience, she has developed working relationships with knowledgeable individuals at her facility; as a result, "I guess I have the resources of everybody who works there at the hospital," she said. Some PSOs work at the "30,000-ft level"—ensuring that their patient safety committees are well attended and supported and distributing and disseminating the committee's recommendations to appropriate departments. In contrast, another PSO engages in daily meetings with the pharmacy director and the infection control coordinator to address individual Serious Events and Incidents.

Requisition and allocation of resources, despite the preceding accounts, remains a difficult task. For example, the PSOs who have delegates for data entry into PA-PSRS and internal reporting systems—and consider themselves fortunate to have this arrangement—nevertheless were quick to point out that these additional employees are an added expense. Even with such resources, one PSO, speaking for her facility, said that the important task of patient safety requires more attention. "We do believe we have a really good handle on what's going on across the organization as far as reportable Incidents, but wish I had time to make patient safety rounds," she said.

Obtaining Leadership Buy-In

I can't say as the PSO that I can wave my magic wand and all of a sudden we are doing the right thing. It's really a leadership expectation that safety is going to be the priority.

Although PSOs reported varying levels of leadership buy-in on patient safety, they agreed across the board that leadership is key to ensuring that patient safety filters down through the ranks to front-line practitioners. PSOs addressed two key areas of requisite buy-in: the physician and the board of trustees.

Most PSOs, particularly those who are not physicians, reported that accessing and/or communicating with physicians in their facilities can be difficult but that this is critical to the success of patient safety initiatives. Perceived challenges to working with physicians included the following:

- Finding common concepts to communicate because "they [physicians] think differently"
- Finding time in physicians' busy schedules to have them participate in patient safety committees
- To a lesser degree, combating physicians' worries over specific aspects of reporting and disclosure, pursuant to the Mcare Act (e.g., reporting near misses)
- Demonstrating the benefit of a proactive, systems approach.

Many PSOs reported some successes in reaching physicians, such as the following accounts:

- PSOs who experienced difficulty with communicating certain problems (e.g., use of unapproved abbreviations contributing to medication errors) to some physicians said that they encountered an attitude of "it hasn't happened to me." PSOs said that their peers need to demonstrate that if an event occurred only once, even in another facility, it justifies making system changes where necessary to ensure that a similar event does not occur closer to home. Sometimes, this means demonstrating the impact of even a single event. "It was kind of startling for them to actually see the process traced from the identification of an issue, through how it impacted the patient, to how it impacted the organization economically, and how, ultimately, the potential was there to impact the physician from a litigious scenario," one PSO said of communicating with physicians.
- PSOs said that physicians also respond to the following approaches:
  - Summarizing issues for physicians in one or two pages and making use of tools such as algorithms or diagrams
  - Demonstrating important patient safety issues through the use of the actual patient case/chart for which physicians were either primary or consulting caregivers
  - Avoiding humiliation or ambush tactics
  - Consulting with medical executive committees to set ground rules for communication

Ultimately, physicians are responsive to efforts to reach them, according to a majority of PSOs. Indeed, several PSOs reported that physicians at their facilities actively participate in patient safety, while other PSOs report directly to physicians and/or work with physicians who chair the patient safety committees. "I think our physicians get it, I really do," a PSO said. "They become involved, and we can actually drill down to find a cause or a problem that relates to their interactions with patients, staff, or family, and then they are more willing to buy into it. But, I think a key point is their time. If you can present a concise argument, they are more than happy to cooperate with you."

"I think our physicians get it, I really do. If you can present a concise argument, they are more than happy to cooperate with you."

Regarding communicating patient safety issues to the board of trustees for large facilities and systems, PSOs said that they would appreciate additional methods and means to do so.

One PSO who successfully attained access to the board at his facility, said he worked five years to achieve this goal. He now meets once a month with the board chair to discuss

patient safety goals for the facility. For example, the PSO said he received permission to take a number of caregivers and some board members to a national healthcare conference that focused on safety and quality. The effect on the attendees has been impressive: "They are incredibly energized by having gone to this and seeing what can happen," he said.

In addition, the PSO said that one of the most important things people working in patient safety need to accomplish is to convince boards of trustees that patient safety is just as important as cash-flow statements. However, the PSO noted that relationships with boards may be difficult for other PSOs to achieve, often due to multiple organizational layers separating boards from PSOs and patient safety committees. Furthermore, PSOs must recognize that the nonhealthcare background of many board members influences their decisions and actions, he said. For example, when a Serious Event occurs, board members with a corporate background may believe the appropriate response is to terminate employment of the caregiver(s) involved; for such board members, nonpunitive or similar approaches may seem completely alien.

> ***"It looks great to a JCAHO inspector for a board member to say that 'Yes, we have the core measures, but we also have all this data that comes from the Patient Safety Authority that we review.'"***

In contrast, at least one PSO was surprised to learn of his fellow PSOs' problems with obtaining board buy-in because, in his experience, regulatory bodies (e.g., Joint Commission) assume that board members are aware of and involved with initiatives related to patient safety. For example, during a recent Joint Commission inspection at the PSO's facility, a surveyor asked board members about their knowledge of the core measures. "It looks great to a JCAHO inspector for a board member to say that 'Yes, we have the core measures, but we also have all this data that comes from the Patient Safety Authority that we review,'" he said. (For information about Joint Commission core measures, visit http://www. jointcommission.org.)

Complying with the Mcare Act

Some PSOs addressed the impact of the Mcare Act on them and their facilities. Comments regarding the Act's impact tended to fall into two categories: (1) working with DOH surveyors on compliance issues and (2) complying with and/or interpreting the intent of the "Mcare disclosure letters" (i.e., written notification provided to patients; see definition below).

Working with surveyors. PSOs had somewhat divergent views of their experiences working with DOH surveyors. While some PSOs were somewhat critical of their surveyors' priorities, others clearly see their surveyor as a valuable resource. A few PSOs expressed frustration that their surveyors tend to focus on "the minutia" of compliance issues and that this diverts time and energy away from improving patient safety. They felt that their surveyors could play a useful role, while still meeting their obligations as regulators, if they focused less on minor irregularities in administrative processes and instead helped the PSO to define attainable goals for performance improvement or to share lessons learned from their work surveying other facilities. "We spend a lot of time trying to follow the rules, and it has nothing to do with improvement; it has nothing to do with patient safety," one PSO said. "It has to do with getting the letters out, making sure I have a lot of documentation . . . If we get cited because of the noncompliance with the Mcare law, I'm the one who is held accountable."

Other PSOs felt they had good working relationships with their facility surveyors. One PSO spoke of his organization's

teamwork with DOH and said, "I don't find them [to be] that big of an obstacle to us as far as patient safety." For example, when an incident occurs and the PSO and other involved individuals would like to learn of DOH's potential reaction, they contact the department. According to the PSO, "We call them up and say, you know, this kind of incident occurred, or this happened—we are looking at it this way, how would you look at it? And surprisingly, we are much more stringent on it than they are."

Preparing Mcare disclosure letters. The other issue that PSOs identified with the Act concerns section 308(b) (i.e., the duty to notify the patient of a Serious Event.) This section states the following:[2]

> A medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee within seven days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian shall be notified in accordance with this subsection. The notification requirements of this subsection shall not be subject to the provisions of section 311(a). Notification under this subsection shall not constitute an acknowledgement or admission of liability.

Discussion about the letters prompted different responses. Concerns include the following:

- Patients and medical staff seem confused about the purpose of the letters, particularly when patients receive them by mail after patients and physicians participate in disclosure conversations that are documented in patients' medical records.
- The letters have prompted phone calls from patients' attorneys about the meaning of the letters and have surfaced during litigation.
- Legal counsel and risk management departments question PSOs about the meanings of the letters.

"My issue is more around are we doing a service to our clients, to our patients, to their families, and I don't think we are with that letter," one PSO summarized. "I think we are doing a disservice with that letter."

In contrast, other PSOs spoke of positive patient reactions to the letters and, rather than express concerns, discussed their approaches to compliance. One PSO said that she had not "had anybody confused;" however, issuing the letters had prompted interesting conversations with patients (e.g., one patient responded with a thank-you letter). "Maybe we are unique, but I don't think we're great at disclosure," the PSO said. "I think as a result of the Act and the required letter, we have gotten better at it."

Another PSO mentioned that the letters have prompted additional meetings with patients and their families to discuss the patients' medical records.

PSOs' strategies for the letters included the following:

- Accomplishing disclosure in a conversation between the physician and the patient and treating the letters merely as documentation that the disclosure conversation occurred and explaining to physicians that this is the purpose of the letters
- Discussing the letters during initial conversations with patients and issuing the letters to patients before discharge
- Seeking help and concurrence from DOH surveyors about the content and scope of letters

Improving Patient Safety

The majority of comments made by PSOs indicated two main themes about their efforts to improve patient safety: (1) most PSOs are

actively involved in making and evaluating changes and (2) while PSOs' patient safety initiatives elicit cooperation from staff and workers, patient safety is still something that people must make time for, rather than a mindset. The latter theme, while an apparent challenge, was still seen as progress. For example, one PSO attributed patient safety progress to the impact of the Mcare Act and the Authority. "We are so far ahead of the curve in the state of Pennsylvania, and I think a lot of it has to do with the Patient Safety Authority as well as the Mcare Act, because we don't have the issues that other entities have, internationally and nationally, with patient safety because it is set forth in the state of Pennsylvania," she said. "I think we have moved forward more than I could ever say we have moved backward."

Regarding beneficial changes that they or others have undertaken to improve patient safety, PSOs presented several accounts, including the following:

- Staff on the behavioral health unit at one PSO's facility reported problems with patient falls. A task force was convened, and its members discussed the issue with staff. The task force found that carpeting in the hallway contributed to depth-perception problems for certain patients; the carpeting was removed. In addition, the task force discovered that some patient falls resulted from "sticky floors." The tacky floors were traced to certain cleaning solutions used by environmental staff; the environmental staff was told of the problem, and different cleaning solutions were recommended for use, reducing the unit's fall rate.

- After reading recently published information on the risk of bed entrapment, a technician on a unit in a PSO's facility took the initiative to assess all beds on the unit. In due course, the beds were updated or changed to reflect the recommendations in the recently published information. "I was just so pleased that that came from a tech," the PSO said.

- In another PSO's facility, misinterpretation of labeling reportedly contributed to a medication error. A patient presented to the emergency department with prescription medications that had been filled by the pharmacy of a department store chain. Pharmacies under this chain labeled medications according to a specific system of numbers; however, at the time, the numbers appeared on the labels in the same location that a majority of pharmacies communicated dosage information. A misinterpretation of the label information resulted in an overdose to the patient. Following the overdose, the PSO's facility contacted the Institute for Safe Medication Practices, which contacted the pharmacy to discuss its labeling practices.

- After learning of the risks of using color-coded patient wristbands to communicate patient information from a supplementary issue of the *PA-PSRS Patient Safety Advisory*, a PSO's facility conducted a failure mode and effects analysis (FMEA) project to determine whether the identified risks were present at their facility. Subsequently, they joined a task force to implement and standardize safe practices for this issue.

Despite a consensus that more work remains to communicate the patient safety mindset to staff and others, a few PSOs reported signs, including the following, that patient safety concepts have gained recognition from individuals other than PSOs:

- Physicians have requested FMEAs on specific issues.

- Physicians have become actively involved with RCA investigations.

- Patient safety committees have attracted the interest of front-line caregivers, including not only physicians and nurses but also technicians and aides.

Finally, PSOs offered strategies from their own facilities to further ingrain the patient safety mindset into peoples' daily activities, including the following:

- Making patient safety "everyone's problem" (For example, one PSO reported that his system undertook to make patient safety issues the responsibility of whoever discovers them. The system has, in effect, designated sub-PSOs to recognize and report issues to the facility PSO.)
- Offering continuing medical education credits to physicians who attend patient safety committee meetings or participate in FMEA and RCA efforts
- Basing compensation on achieving patient safety goals ("Part of my compensation is based on our infection rate, our medication error rate, and our fall rate," said a PSO. "So are the unit managers who work for me and for the patient care services department. That gets peoples' attention.")
- Obtaining senior administration buy-in to patient safety principles and support for patient safety initiatives

What More Could the Authority and PA-PSRS Do to Help Improve Patient Safety?

PSOs provided varied responses during this topic discussion, ranging from expansive lists (e.g., more help with education, training, leadership buy-in, and resources) to specific queries (e.g., explanation of Act 13 reporting requirements). While similar topics arose during all three group discussions, sessions differed from one another in that participants focused on different aspects of and/or proposed different solutions to similar topics. For example, PSOs at each session, to some degree, requested action (e.g., clarification, standardization) on the Act's reporting requirements. However, proposed solutions varied in occurrence and degree, including to standardize reporting requirements among facilities (i.e., all facilities have the same definition of what is reportable), to issue advice or guidance on reporting that is consistent with that of other agencies (e.g., alignment of the Authority and DOH), and to provide education and training on reporting and disclosure (e.g., to physicians, to DOH surveyors).

Key Requests

- Help educate senior administration and boards of trustees on patient safety issues
- Provide education and training to front-line caregivers to help augment PSOs' limited resources
- Standardize the reporting requirements of the Mcare Act to (1) reduce variability among reporting facilities and (2) provide a base of consistent advice from the Patient Safety Authority and the Department of Health
- Help engage physicians in patient safety, and provide guidance on disclosure of Serious Events to patients
- Provide benchmarking data and improve capability of analytical tools
- Help communicate to the public about patient safety

In addition, many PSOs asked for help with some of the difficult issues that they discussed while they explained how their facility had implemented the PSO role.

Standardize and Clarify Interpretation of the Mcare Act and Reporting Requirements

As indicated previously, PSOs acknowledged that reporting and analyzing patient safety event data comprises a substantial part of their job description. However, many PSOs stated that lack of standard and clear

reporting requirements contributes to different interpretations of the requirements among individuals, facilities, and agencies. These different interpretations are perceived to contribute to several issues.

Different definitions of Incidents and Serious Events. A salient topic discussed during all three sessions was the difficulty in determining whether a particular occurrence is reportable. In particular, PSOs requested clarification of definitions for Incidents and Serious Events, as well as agreement among the Authority and DOH on these definitions. A few PSOs mentioned the July 2006 PA-PSRS program memorandum from PA-PSRS, "Interpretation of the Definition of Serious Events Used by the Pennsylvania Patient Safety Reporting System Analysts During Analyses of Anonymous Reports."* Some PSOs found the memorandum and the decision algorithm that it contained to be helpful, but noted that some DOH surveyors disagreed with the guidance or were unfamiliar with it. While a few PSOs agreed that the memorandum "was a great idea" and an attempt at achieving consistency in determinations of Serious Events, at least one PSO termed the guidance as "circulatory" and said that application of the decision algorithm resulted in Serious Event classification for nearly every occurrence to which they applied it.

Inconsistent data reported. PSOs voiced concerns about potential inconsistent reporting practices among facilities reporting to PA-PSRS (e.g., different event classifications, underreporting) and inconsistent reporting criteria among different reporting systems (i.e., internal systems, PA-PSRS, and others). On the former issue, a PSO suggested that the Authority consider broadening the reporting requirements beyond the Authority's intent for each facility to define in its patient safety plan its interpretation of reportable events. Another PSO provided evidence of the latter issue in an account of her facility's pharmacy staff; she said they are dissatisfied with noted inconsistencies (i.e., terms, report criteria) between PA-PSRS and the other systems, such as the Pennsylvania Health Care Cost Containment Council (PHC4) reporting system.

Incidence of multiple/redundant reports. Some PSOs requested clarification about whether or why they should report events that are noted upon admission to their facilities, particularly when the patients are transferred to their facilities for treatment of an injury resulting from the potentially reportable event. Besides potential creation of multiple and redundant reports (i.e., reports about the same event from the transferring and admitting facilities), the PSOs questioned why they should account for events that either occurred during transport or before the patients were transferred from other facilities.

Misinterpretation of the Mcare disclosure letters. As noted above, PSOs experienced several issues regarding these letters, including patient misinterpretation and physician and administration resistance. "The level of anxiety over these letters is still pretty high," a PSO said. During this topic discussion, PSOs questioned whether the legal aspects of these letters had been fully considered, as several PSOs had received queries from patient attorneys about the letters and were aware that the letters have shown up in court. "How does the Patient Safety Authority help us there?" another PSO asked. "Perhaps in leading the charge for protection of these letters in terms of legislation."

Expand Use of PA-PSRS Data

In addition to standardizing reporting practices, many PSOs suggested that the Authority and PA-PSRS expand the use and

* This program memorandum describes interpretations used by PA-PSRS analysts during their review of anonymous reports submitted to PA-PSRS. The interpretations are not legal definitions and should only be used by healthcare facilities as guidance into the process used by PA-PSRS staff in evaluating an anonymous report. It is the responsibility of each reporting facility to determine whether an event meets the Act 13 definition of a Serious Event. The program memorandum is available to reporting facilities upon login to PA-PSRS (click on "Program Memorandum" under "Resources").

availability of PA-PSRS data. Although individual facility data was acknowledged as useful, some PSOs requested valid comparative and benchmarking data. There was a consensus that senior administration often requested this type of information from PSOs to get a sense of "where do I stand."

Some PSOs argued that the value of PA-PSRS lies in recognition and communication of serious patient safety issues, not in comparison of the number and type of reports. One PSO said she did not want PA-PSRS to become another rating system. "You know, your hospital is better than my hospital because you have fewer events," she said. Another noted that benchmark data on certain events may hold little value. "Anymore, the average is not great," he said. "When you're willing to accept a benchmark, you're saying that it's inevitable that this is going to happen."

Others suggested building better analytical tools for those facilities that are data driven, such as easier and better data export and drill-down capabilities. One PSO theorized that such improvements would help her unearth desired results on a timely basis, rather than handing off data-export requests to her facility information technology department.

Similarly, some PSOs requested additions or improvements to the reporting system, such as new event type categories. One request focused on medication errors. The PSO said that there is often not enough data to adequately fill in the PA-PSRS report and suggested a "Medication-EZ" form that would gather less data but might be reported more reliably.

Some PSOs addressed the Authority's initiative to interface PA-PSRS with their internal reporting systems. The data interface allows reporting facilities to submit reports to PA-PSRS directly through their existing internal incident reporting systems.* PSOs who have worked with the interface spoke favorably of it; others asked for updates and said the interface would help them free up time to analyze data. Reporting system vendors are starting to take notice of PA-PSRS, too, according to one PSO, who spoke of her experience at an American Society for Healthcare Risk Management conference. "I don't know if you got an opportunity to talk to a lot of vendors—they all say 'You're from Pennsylvania? We'll interface with PA-PSRS.'"

In addition, some PSOs addressed the content of the *PA-PSRS Patient Safety Advisories*. There was consensus that the *Advisories* contain valuable information that is useful for educational purposes; however, a couple of PSOs requested that the *Advisories* address topics relevant to their specialty units and facilities, as well as more content of interest to physicians to help further engage them in patient safety.

Provide More Education and Training

Many PSOs saw more training and education as the best way to achieve improvement in patient safety. The PSOs suggested that the Authority and PA-PSRS could help by educating front-line staff, managers, physicians, and senior administration.

One PSO said that patient safety was too large a challenge for just the PSO or a patient safety committee and that they wanted to create a "patient safety army" throughout their facility, with someone on every unit and in every department who could be the local patient safety expert. This PSO said the Authority could make a difference by developing the core curriculum and tools for those individuals. Giving them the skill sets for safety and quality improvement, these individuals would be able make, measure, and adjust small changes on their units, which will help improve the facility's overall performance.

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* More information about facilities interfacing with PA-PSRS is available from the Authority's Web site at http://www.psa.state.pa.us/psa/cwp/view.asp?a=1296&Q=446127&psaNav=|.

Educating and training physicians and administrators about important concepts, such as disclosure of adverse events and systems approaches to safety improvement may go a long way, too, according to some PSOs. For example, one PSO requested formal education for physicians about the Mcare disclosure letters. As noted above, some PSOs reported that physicians had problems with the disclosure letters; in particular, physicians questioned the point of the letters and were offended by the mandate that disclosure must occur in writing, since many already abided by a long-standing practice of having disclosure conversations with their patients. Regarding systems approaches, another PSO noted that additional education is needed to convey that a systems approach is a more productive response to an event than blaming the clinician. "Trying to beat that drum and have people understand—that is always a major barrier and something that I have worked very hard at," he said.

Partner with Health-Related Organizations

PSOs suggested that the Authority and PA-PSRS partner with or encourage alignment among other health-related agencies (e.g., DOH, PHC4, IHI) both at the state level and nationally to ensure that the like-minded goals of patient safety do not conflict. For example, PSOs requested consistent guidance from DOH and the Authority on reportable events, as well as help to reduce variability among reporting facilities.

One PSO said that factors such as misalignment and/or nonalignment with other agencies have clearly hindered the Authority's growth. "I think they do need to be stronger," he said. "I think it is not as effective as it wants to be, could be, philosophically should be." Beyond alignment, there could be some other benefits to partnering with other agencies, the PSO said, such as promoting patient safety to boards of trustees. For example, the Authority could partner with the Hospital Association of Pennsylvania and offer board retreats, or request representatives from IHI to speak. "I think that's how you get their attention," the PSO said of hospital board members.

Other PSOs saw these suggested partnerships as a means to accomplish joint goals, such as implementing "Just Culture"*,[3] statewide, similar to efforts undertaken in other states. "I believe that Just Culture is our next step," one PSO said of fellow PSOs and his facility. "We've been nonpunitive, now it's time to be just." In their requests for Just Culture, perhaps PSOs recalled the 2006 Patient Safety Symposium sponsored by the Hospital & Healthsystem Association of Pennsylvania (HAP), in which the Authority underwrote a keynote address by David Marx, J.D., author of "Patient Safety and the 'Just Culture:' A Primer for Health Care Executives." (More information about this symposium is available from HAP at http://www.haponline.org/quality/safety/symposium/, as well as the March 2006 *PA-PSRS Patient Safety Advisory*, available at http://www.psa.state.pa.us/psa/lib/psa/advisories/mar_2006_advisory_v3_n1.pdf.)

Facilitate More Networking/ Group Discussion

Noting the apparent productiveness of the group discussions and citing other models of productive group efforts (e.g., the collection of healthcare facilities in Northeastern and Central Pennsylvania that comprise The Color of Safety Task Force), many PSOs called for the Authority and PA-PSRS to sponsor more such forums. "I think you've earned our respect, and that's not easy to

* Just Culture refers to the environment in facilities that adopt a modified approach to nonpunitive error reporting to balance the need to learn from mistakes with the need to take disciplinary action for reckless conduct. In the "Patient Safety and the 'Just Culture': A Primer for Health Care Executives," David Marx, J.D., discusses the application of four behavioral concepts—human error, negligence, reckless conduct, and intentional rule violations—in determining disciplinary action to events that threaten patient safety.

do," answered one PSO when questioned about why PSOs would like the Authority to sponsor such programs. She also referenced an RCA training course conducted in the spring of 2006. "Even the root cause analysis that was sponsored by PA-PSRS was excellent," she said. "Any opportunity to get together to network, to sharpen your skills, to know what other entities are doing . . . Because you know we live in our own little worlds, and we think we are doing it right. Then, I start hearing what other people are doing, and I may change a bit on how I look at things."

At least one PSO mentioned that future group forums would be an opportunity for the Authority and PA-PSRS to go beyond the scope of analysis presented in the *PA-PSRS Patient Safety Advisories*. By examining the details about specific events, she said, small groups of representatives from similar facilities across the state would be able to look at the data from a deeper process perspective and arrive at process changes. Many PSOs felt that it would be beneficial to share solutions resulting from such efforts with their peers. "As soon as they can figure it out, I don't have to, and with the limited amount of time that we have, the more we can learn as a group together, the better we all are," a PSO said. "I think I can state that patient safety is probably the one area where we would all agree that we should be cooperating and not competing."

To be effective, any universal improvement strategies (e.g., The Color of Safety Task Force strategies to standardize the meaning of color wristbands in facilities across the state) produced during future patient safety group initiatives would benefit from statewide implementation, according to PSOs. Lack of universal implementation or misalignment of strategies or recommendations between state agencies could result in further patient safety issues, they said. To prevent such confusion, at least one PSO suggested that the Authority could mandate such strategies; however, others pointed out that such actions could result in the perception of the Authority as a regulatory entity.

> ***"I think I can state that patient safety is probably the one area where we would all agree that we should be cooperating and not competing."***

PSOs felt that because the Authority was in a unique position of having earned the facilities' trust, PSOs might be willing to share information with one another through the Authority. Sharing the results of FMEA projects was one such opportunity, according to some PSOs. For example, a PSO whose facility conducted an FMEA on Phenergan after reading an *Advisory* article, asked, "Why not share it?" Sharing FMEAs might lead others to consider issues that they might have missed, the PSOs said. While PSOs would be comfortable sharing FMEAs with each other via the Authority and PA-PSRS, they would be less comfortable sharing the results of RCAs performed on actual events.

Market Patient Safety Further

During one session, PSOs suggested that the Authority's limited public profile with front-line practitioners and the public might present an opportunity to further promote patient safety. It may be time for the Authority to present "a face" for facilities and the public to identify with, they said. PSOs mentioned that other entities such as DOH (i.e., through the presence of its surveyors at facilities) and PHC4 (i.e., through its print and broadcast media exposure) garner more recognition than the Authority and PA-PSRS. Representatives speaking to facility staff and the public may help, according to one PSO, show "that you're real, something more than a logo." With regard to the public, another PSO envisioned facilities getting help with communicating their efforts to their surrounding communities. "I would like to see the Patient

Safety Authority be the support group of the hospital—to help share with the public that we do pay attention to patient safety, that we are concerned with it, and that we are working with you to try to identify what our problems are and the corrections," she said.

How to Measure Improvement in Patient Safety

PSOs acknowledged the difficulty of measuring improvements in patient safety and arriving at valid measures. They noted that it is more than simply a reduction in the number of reports about a certain type of event, because such a reduction could be simply the result of reporting noncompliance, rather than a reduction in incidence of the event. Common consensus was that appropriate process measures are more important than outcomes.

Measures of Improvement at Individual Facilities

PSOs rely on multiple methods of measuring success at improving specific patient safety problems, in large part because individual methods, when used in isolation, are of questionable validity. They seem to triangulate problems and determine whether all indicators are "pointing in the same direction."

The methods PSOs use to measure improvement include the following:

- Staff perception appeared to be a frequent factor in determining whether an implemented change produced positive results; however, at least one PSO mentioned that staff perception could be inaccurate and cited examples where perceptions of improvement did not match evidence from the reports they had submitted to PA-PSRS.
- Some PSOs rely on survey responses of staff and/or patients to determine if patient safety has improved.
  - — One PSO's facility conducted a patient safety culture survey during National Patient Safety Awareness Week in March. In 2006, the facility achieved a more than 30% response rate by offering gifts for participation. In terms of their results, leadership and teamwork on patient safety initiatives received high marks, but handoff communication scored poorly.
  - — Another PSO said her facility contracted an outside specialty service to conduct culture of safety surveys. Results were similar; leadership scored well, but staff perceived communication as poor.
- Some PSOs said that they rely on specific metrics (e.g., rate of falls with harm; medication errors causing harm; infections, including device-related and clean surgical site infections) as indicators of improvement resulting from change management programs. Those who use these metrics acknowledged that they are comfortable relying on them because they have educated staff consistently throughout their

Key Measures of Success

Patient Safety Officers provided the following guidance to the Patient Safety Authority on establishing metrics to track improvement in patient safety in Pennsylvania:

- Changes in clinical processes and systems will be more reliable than outcomes.
- When looking at the success of a specific initiative, PSOs use several methods concurrently to determine positive change (e.g., surveys, chart reviews, direct observation).
- There are some preventable events, such as wrong-side surgery, that could be completely eliminated.
- Focused projects/statewide initiatives may induce change and result in measurable improvements.

facility on the definitions of these events and that there is not a similar consistency among institutions at the state level.

- Others rely on combinations of methods, such as verbal audits of staff compared to internal or PA-PSRS report data. With regard to using PA-PSRS to identify and monitor progress, one PSO said she found it useful to examine the variations and trends in report data to monitor overall facility progress.

- Other methods mentioned included chart review, direct observation of clinical or administrative processes, and patient safety walk-arounds.

One PSO offered this account of changes that produced positive outcomes. She noted a sudden increase in the number of medication errors, investigated it, and identified transcription errors as the problem. She took the problem to the nursing staff and decided to switch from a multiday review of the medication administration record (MAR) review to a daily review of the MAR. Under the new system of review, medication errors related to transcription errors dropped by 87%. The PSO said that the noted reduction was not due to lack of reporting; rather, the errors were just not occurring at their previous rates.

In contrast, as an example of proactive change that does not produce evidence of an immediate positive outcome, a PSO revisited her story of a technician who implemented changes to beds on a unit because of recently released information about the risk of bed entrapment. The PSO said that she could not provide outcome data to prove that the changes resulted in reduced bed entrapments because her facility never experienced a bed entrapment, either before or after the change. However, because of the changes, she was "absolutely convinced that we dodged a bullet."

Statewide Measures of Success

In discussing what may be valid measures of success at a statewide level, some PSOs turned to "never events" (i.e., serious, identifiable, and preventable events in healthcare that should never happen).*,[4] Discussion followed on whether it was reasonable to set statewide goals of zero occurrences for certain types of events. PSOs drew on existing examples of good safety records in their discussion. For example, one PSO said, "I liken it to the airline industry. The airline industry is touted for its quality and safety of its passengers, but it isn't zero. You can still get on a plane and die, and we all know this." PSOs noted, however, the difference between healthcare and the aviation industry ("You're far more likely to be killed in healthcare," a PSO said), mainly that the industry is near perfect in safety and quality efforts, while healthcare is still struggling.

> ***"I think you can have a goal of zero for some things, understanding that, yes, they are going to crop up. But, there are certain things that you have a campaign to reduce them."***

Drawing on this model, reasonable goals could be achieved for certain preventable events. "I think you can have a goal of zero for some things, understanding that, yes, they are going to crop up. But, there are certain things that you have a campaign to reduce them," the same PSO said. As examples, he offered wrong-side surgery, central line infections, and preventable obstetrical injuries. He also noted that zero target rates, while ambitious, may be OK in certain circumstances; for example, his facility reduced the incidence of a particular type of infection to zero for

* The National Quality Forum developed and maintains a list of "never events," events which should never occur because they are preventable; examples include wrong-site surgery, retained foreign bodies, and preventable postoperative deaths.

more than one year. "You may not have zero forever, but if you can do it for a year at one hospital, any hospital . . .," he said. According to the PSO, focus on these types of events could yield true measurable improvements.

PA-PSRS Success

When asked whether PA-PSRS and other efforts by the Authority have benefited them, their facilities, and patient safety, almost all PSOs cited examples of improvements.

The system itself has helped improve patient safety, starting from its implementation, according to PSOs. For some smaller facilities, PA-PSRS helped them establish their first electronic systems, including "forcing computers in the door," according to one PSO. "At the smaller facilities, where they didn't have an established system, this was a godsend," she said.

The system and the Authority also helped promulgate the value of reporting near misses; some PSOs reported that physicians have started to buy in to this idea after realizing there is no risk of discovery surrounding near misses because they never progressed further. "The near misses have been an excellent idea that I think the Patient Safety Authority helped put in the forefront as important," a PSO said.

While recalling the need for standardization and improved export and drill-down capabilities, PSOs nevertheless said they find PA-PSRS data and the system itself to be useful. "It's a tool that you can use, as you have designed it, to look at something going on in your institution," a PSO said. Some PSOs noted that they and others in their facilities give far more weight to PA-PSRS data than other state reporting systems' data because PA-PSRS incorporates clinical perspective in its analyses.

As an example of ideas progressing from PA-PSRS analysis into system changes, a PSO again mentioned The Color of Safety Task Force. More such process and system efforts would lead to true measurable outcomes, she said. "These are the things that aren't real sexy, but really will make a difference," she said.

"The near misses have been an excellent idea that I think the Patient Safety Authority helped put in the forefront as important."

The *PA-PSRS Patient Safety Advisories* received praise. PSOs felt that the *Advisories* are well-received in their facilities and that they are useful as an educational tool. Reported uses of the *Advisories* ranged from reading and disseminating the articles to expanding upon the important issues and strategies. One PSO said her facility extracts the *Advisory* articles and republishes them in an internal newsletter. Another said an *Advisory* article prompted his facility to develop a systematic approach to certain IV complications. "We took, for example, the article you had on extravasation, and we developed, I think, a terrific system in the hospital," he said. Lack of hard data makes it difficult to show improvements; however, "I have no doubt that we have a much better system in place because of that," he said.

PSOs reported their use of the toolkits that accompany certain *Advisory* articles (e.g., including single copies of the specific article, training videos, and sample policies and procedures) was mostly limited to distributing the information to relevant clinical staff.

Finally, PSOs reported that the current group discussions were seen as an important success, and more opportunities to provide feedback to the Authority would be appreciated. "I'd just like to thank you for having this session," a PSO said. "Up until this point, I think we have just been given information or we have had sessions to try and clarify things, but I don't think you really sought input from us. Hopefully, you heard what we said and we'll see something from it."

Notes

1. Medical Care Availability and Reduction of Error (Mcare) Act of Mar. 20, 2002 Pub. L. 154, No. 13, 40. Ch. 3, Sec. 309. Also available from the Patient Safety Authority's Web site: http://www.psa.state. pa.us/psa/lib/psa/act_13/act_13.pdf.
2. Medical Care Availability and Reduction of Error (Mcare) Act of Mar. 20, 2002, Pub. L. 154, No. 13, 40. Ch. 3, Sec. 308(b). Also available from the Patient Safety Authority's Web site: http://www.psa.state.pa.us/psa/lib/psa/act_13/act_13.pdf.
3. Marx D. Patient safety and the "just culture:" a primer for health care executives. [online]. 2001 Apr 17 [cited 2007 Jan 25]. Available from Internet: http://www.usuhs.mil/cerps/documents/ps_justculture.pdf.
4. Centers for Medicare & Medicaid Services. Eliminating serious, preventable, and costly medical errors—never events [press release]. 2006 May 18 [cited 2007 Jan 19]. Available from Internet: http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863.

Moving Forward

In undertaking these discussion groups, the Authority and PA-PSRS hoped to gain insight into the daily challenges and concerns of PSOs in Pennsylvania healthcare organizations and to find opportunities for improvement. The three topics—the role of the PSO, how to better support PSOs, and how to measure improvement in patient safety—were designed to initiate an open, constructive dialogue that would point the way forward. (For a take-away list of such comments, refer to "Patient Safety Commentary.") The Authority and PA-PSRS staff found these discussions to be provocative and productive, and we believe the PSOs who participated would agree. Several PSOs suggested that the Authority host similar forums in the future.

Discussion

The Role of the PSO

Although there was some indication of the level of work and commitment behind implementing patient safety initiatives, it was instructive to actually hear the details from the individuals who are responsible for this work. Clearly, there is no one standard way to implement the role of the PSO, and facilities have experimented with a variety of models. Many have placed the role of the PSO in the domain of risk management or quality improvement, a few have given this responsibility to physicians, and some have divided the role among individuals within these disciplines. Most—though not all—PSOs have multiple roles within their facility, and full-time PSOs were the exception rather than the rule. PSOs are all personally involved with making important changes in their facilities. Most felt their ability to implement changes could be improved by having greater buy-in from senior leaders and additional resources at their disposal.

Helping PSOs Be More Effective in Improvement Efforts

Going forward, PSOs suggested the next challenge they would like the Authority to help them meet is the need to educate and engage senior leadership, trustees, physicians, and other front-line practitioners in patient safety principles germane to their roles. They suggested the Authority could also make an important contribution to PSOs' effectiveness by clarifying Mcare requirements so that the Authority and the DOH provide consistent guidance on compliance with reporting and disclosure requirements. Reducing variability among facilities about the reporting requirements may also enhance the usefulness of PA-PSRS data in analyzing patient safety issues. PSOs also suggested that the Authority could serve as a facilitator of statewide or regional initiatives that would allow facilities to cooperate with one another in solving shared problems. PSOs also felt the Authority could play a valuable role in educating the public about patient safety issues and how they can help to ensure safer care for themselves and their families.

Measuring Improvements

All PSOs struggle at times with demonstrating positive outcomes for changes undertaken at their facilities. Many PSOs indicated in comments cited in this report that the Authority and PA-PSRS have helped improve patient safety by raising awareness of significant issues and providing resources to address them. In their individual facilities, PSOs monitor changes using multiple inputs and methods to determine whether or not a change was successful. Process and/or system changes were seen as a valid measure of impact, given the difficulties associated with

Patient Safety Commentary

The following commentary concerning the topics of the group discussion sessions provided excellent take-home points of Patient Safety Officers' roles, needs and concerns, and measures of improvement.

The Role of the PSO

— "I'm actually a dedicated Patient Safety Officer, and that's all I do all day, for all intents and purposes. Even though I am the Patient Safety Officer, I still feel there is so much work to be done in changing the culture and just getting that information out—the job is never ending."

— "You struggle daily, you know, 'Is this just an Incident, is this a Serious Event?' . . . and you're talking to your patient rep, you're talking to your risk manager, and you're usually the same person having multiple conversations with yourself."

— "We do believe we have a really good handle on what's going on across the organization as far as reportable Incidents, all those kinds of things, but wish I had time to make patient safety rounds."

What More Could the Authority or PA-PSRS Do

— [Regarding Mcare Act duty to disclose adverse events to patients] "How does the Patient Safety Authority help us there? Perhaps in leading the charge for protection of these letters in terms of the legislature."

— [Regarding benefits of a systems approach to analyzing adverse events] "Trying to beat that drum and have people understand—that is always a major barrier and something that I have worked very hard at."

— [Regarding benefit of future forums and sharing of ideas] "As soon as they can figure it out, I don't have to, and with the limited amount of time that we have, the more we can learn as a group together, the better we all are. I think I can state that patient safety is probably the one area where we would all agree that we should be cooperating and not competing."

Measuring Improvements

— [Regarding preventable events]"I think you can have a goal of zero for some things, understanding that, yes, they are going to crop up. But, there are certain things that you have a campaign to reduce them."

— "The near misses have been an excellent idea that I think the Patient Safety Authority helped put in the forefront as important."

— "I'd just like to thank you for having this session. Up until this point, I think we have just been given information or we have had sessions to try and clarify things, but I don't think you really sought input from us. Hopefully, you heard what we said and we'll see something from it."

measuring outcomes in safety. Statewide initiatives to eliminate certain types of adverse events that are universally accepted as preventable also have merit and warrant further investigation.

In the Future

The Authority and PA-PSRS will seek to address the observations and suggestions raised by PSOs during these sessions in future efforts. The meaningful dialogue we initiated through these discussion groups was clearly beneficial to the Authority and PA-PSRS staff, and we hope to continue to receive such thoughtful feedback and productive suggestions from those working in patient safety throughout the healthcare community.

Phone: 717-346-0469

Fax: 717-346-1090

E-mail: patientsafetyauthority@state.pa.us

Web site: www.psa.state.pa.us

Office Location
539 Forum Building
Harrisburg , PA 17120

Mailing Address
P.O. Box 8410
Harrisburg, PA 17105-8410