

April 30, 2009

PENNSYLVANIA PATIENT SAFETY AUTHORITY

2008 ANNUAL REPORT



PATIENT
SAFETY
AUTHORITY

An Independent Agency of the Commonwealth of Pennsylvania

Analyzing, Educating, and Collaborating for Patient Safety

Letter from the Board Chair



An independent agency of the Commonwealth of Pennsylvania

April 30, 2009

Dear Fellow Pennsylvanians:

In 2008, the Pennsylvania Patient Safety Authority implemented many portions of its 2007 Strategic Plan to continue fostering a patient safety culture from one of blame to one of change--change that is needed to reduce and eliminate medical errors in Pennsylvania's 500-plus healthcare facilities.

This year we hired a Director of Educational Programs and a Patient Safety Liaison in the northeast region of Pennsylvania to further our educational initiatives and build the Patient Safety Liaison program. The PSL program will eventually have six clinical staff designated in regions across the state to work with individual facilities to remove barriers, implement guidance and discuss strategies to improve the culture of safety within their facility. With feedback obtained from the northeast Patient Safety Officers, the Authority has developed new educational programs, discussed further in this annual report, to support their needs and help them prevent and reduce medical errors.

In February 2008, hospitals began reporting healthcare-associated infections to the Centers for Disease Control and Prevention (CDC). The Authority, along with other state agencies, receives these reports to continue its mission to reduce infections in Pennsylvania's hospitals. In June 2009, Pennsylvania's nursing homes will begin reporting healthcare-associated infections through the Pennsylvania Patient Safety Reporting System (PA-PSRS). The Authority will analyze the reports and provide guidance through the award-winning *Pennsylvania Patient Safety Advisory* to help them reduce infections in their facilities.

In October 2008, the Authority held the first of four pilot sessions developed to educate hospital CEOs and administrators about patient safety and its significance in reducing medical costs. The session was well received and provided valuable insight for future programs.

As chair of the Pennsylvania Patient Safety Authority's Board of Directors, I'm pleased with the progress we've made, but I am also looking forward to the year ahead and the benefits healthcare facilities will yield from the work we will do together to reduce medical errors and improve patient safety in the Commonwealth of Pennsylvania.

On behalf of the Board, I am pleased to submit this annual report for your review.

Ana Pujols-McKee, MD
Chair
Board of Directors



An independent agency of the Commonwealth of Pennsylvania

Board of Directors

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Franchesca Charney, Director of Educational Programs
Megan Shetterly, Patient Safety Liaison, Northeast Region
Judy Marpoe, Project Manager
Barbara J. Holland, Esq., Legal Counsel

* * *

Office Location/Mailing Address

539 Forum Building
Harrisburg, PA 17120

Phone: 717-346-0469

Fax: 717-346-1090

Email: patientsafetyauthority@state.pa.us

Web site: www.patientsafetyauthority.org

What Pennsylvania Facilities Are Saying About the Patient Safety Authority

"The Patient Safety Authority has been a very valuable resource for us here at Pocono Medical Center. The Patient Safety Authority supported our efforts to create a clinical-service based Patient Safety Liaison program, educating our clinical staff to become patient safety champions. The Patient Safety Advisories have been excellent resources for our staff, and we've posted them both on our intranet site and in paper form in each of our clinical departments and units. Most importantly, Patient Safety Authority education staff is always available to us when we have questions about reporting or "best practices." We have tapped into their expertise on many occasions as we work to continually improve patient safety and quality."

*Shari VanderGast, JD, LCSW
Interim Patient Safety Officer
Pocono Health System*

"I am a new risk manager and also new to the state of Pennsylvania. As a new risk manager with limited resources and a scant orientation to the role, I have come to depend on the PSA. I have learned a great deal from the publications and the event reporting process. I have always received a quick response from the Authority when I have had questions about event reporting. I include PSA as a standing agenda item at my Patient Safety Committee meetings. The value of PSA to my role as risk manager is immeasurable."

*Karen E. Stark, RN,BSN, LNCC
Risk Manager/Patient Safety Officer
Jennersville Regional Hospital.*

"Pennsylvania is so fortunate. We have access to wonderful resources through the Patient Safety Authority. The Advisories share information and provide best practice/"lessons learned" to avoid similar events. Many are unusual and would never be recognized by the facilities without the PSA. Examples include "CT Contrast Media Power Injectors Can Rupture Conventional IV Sets" (December 2008) and "Pneumatic Tubes: A Possible Patient Safety Vacuum?" (March 2008). Another benefit is the personal messages they send in response to events relating to previous articles in the Advisories that may be of interest based on submissions. With the advent of the Patient Safety Liaison program, I look forward to possibly participating in statewide initiatives to further improve safety and raise awareness of errors."

*Lee Patrick, RN, MBA, CPHRM
Corporate Director / Patient Safety Officer
Good Shepherd Specialty Hospital*

"Patient safety is one of the most challenging, rewarding, and vital functions in healthcare. For me and for my facility, Charles Cole Memorial Hospital, the Patient Safety Authority has been a constant and invaluable patient safety resource continually making available to us new ideas and best practices. With the Authority as a resource, we have advanced our patient safety program through participation in the color-coded wristband initiative and the patient safety practices self-assessment. The Authority's user friendly Web site contains a wealth of information within its library of Patient Safety Advisories which we share with our staff and our Patient Safety Committee and access when responding to an event, undertaking a project, or reviewing a policy. We have also used the Advisories, such as the recent Advisory on Living Wills and DNRs, in staff training. Clearly, the Authority is a valuable partner and a driving force in patient safety. Where shall we go from here?"

*Lucia M. Lajcsak
Patient Safety Officer, Charles Cole Memorial Hospital
Certified in Patient Safety, CPHRM, CPHQ, CHCQM, CQIA, CHC*

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Executive Summary

The Pennsylvania Patient Safety Authority is an independent state agency established under Act 13 of 2002, the Medical Care and Reduction of Error “MCare” Act. It is charged with taking steps to reduce and eliminate medical errors by indentifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities, birthing centers and certain abortion providers. In June 2009, the Authority will begin collecting infection reports from nursing homes. The Authority’s role is non-regulatory and non-punitive.

The Authority initiated statewide mandatory reporting in June 2004, making Pennsylvania the only state in the nation to require the reporting of Serious Events *and* Incidents (near misses). All reports are confidential and non-discoverable, and they do not include any patient or provider names.

The 2008 Annual Report focuses on five healthcare domains that the Authority data shows need process changes for improved patient safety and ultimately a reduction in medical errors. The five domains include: leadership and patient safety, medication safety, safe surgery, infection prevention and device safety. Much of this report is based on information derived from a survey given to Pennsylvania healthcare facilities reporting under Act 13 of 2002 and Act 30 of 2006. While measuring patient safety is difficult for any organization, the Authority attempts to establish a baseline through the survey process for future annual reports, ongoing analysis and education initiatives.

Aggregate data from 2008 facility data reports will also be given for report volume, patient demographics, patterns in reports and information on new educational initiatives, such as the Patient Safety Liaison Program, developed to improve communication with facilities, provide the Authority with feedback and develop targeted educational programs.

For copies of the 2008 Annual Report go to www.patientsafetyauthority.org.

Measuring Improvement

The Authority’s most challenging question since it began educating healthcare facilities through *Pennsylvania Patient Safety Advisories* is whether healthcare in Pennsylvania is becoming safer. This question is not unique to Pennsylvania. It is a national concern not only for the United States but in other countries as well. Experts in patient safety are forced to admit that while we have made progress since the 1999 publication of the Institute of Medicine’s *To Err Is Human*, we are just at the beginning of a journey and we have a long way to go.

A number of strategies are being employed statewide to promote safety. For example, Pennsylvania’s Medical Care Availability and Reduction of Error Act of 2002 (MCare) made significant structural changes in the healthcare system, including the establishment of the Pennsylvania Patient Safety Authority, implementation of reporting requirements and the requirement for disclosing Serious Events to patients. Both public and private payers are beginning to decline reimbursement for potentially preventable adverse events. Healthcare quality information is increasingly available to the general public in an effort to promote patient selection of higher quality healthcare facilities and providers. The current national economic crisis and the continuing escalation of healthcare costs have renewed policymakers’ calls for a payment system that rewards efficiency. We have also witnessed the significant efforts of healthcare providers throughout Pennsylvania striving to solve the safety problems they identify in their own facilities.

For example, the Authority conducted a survey this year in which a total of 200 Pennsylvania healthcare facilities participated, including 118 hospitals (59%), 80 ambulatory surgical facilities (40%), one birthing center (0.5%), and one abortion facility (0.5%). For confidentiality purposes, the birthing center and abortion facility responses were included among ASFs.

One of the survey domains was safety leadership. Conducting formal patient safety walkarounds with members of the Board of Trustees provides senior leaders the opportunity to listen to the patient safety issues identified by staff. Regular walkarounds provide a forum to learn about issues related to team practice, communication, and a transparent culture in order to create improvements. The Authority asked participating healthcare facilities how often they performed patient safety walkarounds with a member of the Board of Trustees during the past year. Among hospitals, about one-third (32%) had done this at least once during the year, but the majority (68%) have not instituted this practice. This is one of the processes we will continue to monitor to ensure facilities are getting the support needed from leadership improvement.

Another question related to patient safety leadership is how often Patient Safety Officers (PSOs) participate in Board of Trustees meetings. Senior leaders can demonstrate their leadership on safety by inviting PSOs to address their Board of Trustees and to make safety a standing item on the board agenda. Doing so demonstrates that management and Trustees view safety as an important component of the Trustee's oversight responsibility. Among participating hospitals, nearly half (47%) responded that they attended four or more Board of Trustees meetings, while in one-third (31%), the PSO did not attend any. Responses were similar among ASFs and other facilities, with 44% reporting PSO participation in four or more board meetings and 24% reporting none. Overall, 46% of participants reported that their PSO attended four or more board meetings over the past year, suggesting that this practice has gained acceptance in many facilities.

Finally when participating facilities were asked whether they have adopted a "just culture" in their institutions, the majority of hospitals (70%) reported some level of implementation. A "just culture" is one that does not punish individuals for honest mistakes or for reporting safety concerns and injuries. It also does not go to the opposite extreme by permitting repeated, intentional rule violations. Rather, a just culture seeks a middle ground that tries to find system or engineering solutions to reduce inevitable human errors, while holding individuals accountable for intentionally violating safety policies or procedures. In the Authority survey, each facility was asked if they had written instructions for staff about error reporting which include "Just Culture" principles. These principles incorporate open communication with all staff and include accountability to promote a safe environment to learn from mistakes. As mentioned, a majority of hospitals report some level of implementation of "Just Culture" principles, with 59% reporting full implementation hospital-wide. One-third of hospitals (30%) report that they have not yet implemented these principles. Similar results were found for ASFs and other facilities, with 72% reporting some level of implementation, while 28% have not adopted this approach. For the complete results of the survey, please go to page 11.

But how do we know whether these efforts are actually making the healthcare system safer?

The ultimate measures of safety are the number of lives saved or the number of injuries prevented, but these concepts are notoriously difficult to measure in practice. Medicine is imprecise, and we don't always know whether bad outcomes are the results of errors, or whether they would have turned out better if we had done something differently.

There are many sources of data on patient safety, all of which suffer from significant biases and flaws. The most reliable way to collect data on the number of adverse events that occur is to have independent providers observing every healthcare encounter, but obviously this is impractical. The "gold standard" used in many safety studies is retrospective chart review, in which trained clinicians review individual medical charts looking for specific complications or errors, but even this is resource-intensive and therefore too expensive to do on a routine basis. Administrative data—information on the diagnoses made and procedures performed on patients—is available from hospitals, but these data are subject to unreliable coding practices that are used primarily for billing rather than monitoring adverse events.

In this annual report, in addition to summarizing the results of the facility surveys, we also discuss the related problems identified through PA-PSRS data, and the results of the Authority's analysis of adverse event reports and potential solutions published in the *Pennsylvania Patient Safety Advisory*.

For participating facilities, following publication of this annual report, the Patient Safety Authority will provide a detailed report comparing their level of adoption of these practices with that of similar facilities. We have encouraged Patient Safety Officers and CEOs to share these reports with their Patient Safety Committees, their senior leadership and their Board of Trustees. We anticipate that these reports will highlight for each institution their own successes as well as areas for further improvement.

Any set of safety practices would be, by definition, incomplete. However, as one window into the processes in place in Pennsylvania healthcare facilities, we believe they provide a useful view of the current state of safety in the healthcare system.

Standardization of Reporting Update

In its 2007 Annual Report, the Authority discussed at length variations in reporting by facilities. The Authority outlined many potential explanations for the disparity such as that Act 13 of 2002 includes several ambiguous terms that define what should be reported (e.g. ‘unanticipated’) and some facilities may have more evolved cultures of safety that encourage higher levels of Incident reporting. In a focus group of Patient Safety Officers in 2007, the PSOs also requested more guidance on what events should be reported.

In its 2007 Annual Report, the Authority outlined its plan to attempt to close the gap on the reporting variations. One of the main objectives of the plan was to work with the Department of Health to explore both organizations’ interpretations of Act 13 of 2002 requirements, with the goal of providing interpretive guidance that can be used by facility PSOs, Patient Safety Committees and Department of Health surveyors.

In the past year, the Authority has worked with the Department of Health to develop some standardization of reporting through a guiding principles document.

The Patient Safety Authority Board of Directors discussed the guiding principles at its September 2008 meeting. The board did not reach consensus on several issues and asked that the document be revised and discussed in future board meetings. In January 2009, a revised document was presented to the board and the Deputy Director of Quality Assurance from the Department of Health also gave a presentation on the standardization document.

During this time, the Authority also sent letters to 50 facilities that fell into the lowest tranches of reporting. This prompted one facility to contact the Authority for assistance with patient safety education. Another facility contacted the Authority to inquire about help in increasing Incident reports. In a recent analysis of the reporting patterns among those facilities that received the letter, we compared their reporting during the last quarter of 2008 and the first quarter of 2009. We found that the number of reports overall from this group increased by 58%. Reporting of Serious Events rose 9%, while reporting of Incidents rose 53%.

The Authority also published an editorial in the 2008 December *Pennsylvania Patient Safety Advisory* extolling the benefits of reporting Incidents.

In February 2009, the public comment period began on the draft standardization principles developed by the Authority and the Department of Health. A copy of the document containing draft guidance was published in the *Pennsylvania Bulletin* Saturday, February 28. The Authority also sent emails to PSOs with a link to the document in the *Pennsylvania Bulletin*. The public comments are being tabulated as of the writing of this report.

Concurrently with issuing a draft guidance document for public comment, we incorporated in our annual survey of PSOs the example scenarios used in the draft guidance document to help us understand the level of consensus that might exist around the draft interpretations.

We asked PSOs from hospitals to consider each example scenario and designate them as whether they believed their facility would classify the event as a Serious Event (harm), as an Incident (no harm) or not reportable at all. Participants could also respond that they needed more information to make a determination. Definitions of a Serious Event and Incident were not provided. The respondents had to rely on the experience of their positions in order to formulate their opinions.

Overall, the results of these questions demonstrate continued extensive variability in PSOs' interpretations of MCare's reporting requirements. A chart summarizing responses is presented in Figure 38 on page 57.

The Authority discussed in the 2007 Annual Report the wide variation in facilities' rates of reporting, and the survey results support the position that this variation is the result of differences in interpretations of the reporting requirements.

The Authority believes this level of variation is unacceptable and will continue to work towards improvement. However, the Authority is not the regulating agency that monitors patient safety reporting. Only the Department of Health has the authority to ensure facilities are reporting properly. The Authority will continue to work with the department to establish a more appropriate reporting framework.

The Authority anticipates some form of final approval guidance to be drafted by the Board of Directors and forwarded to the Department of Health who would have to approve and implement guidance. Once approved by the Department of Health, the department as the regulator of Act 13 of 2002 will be responsible for ensuring the facilities are reporting according to the guidance.

The Authority will provide education and training to healthcare facilities reporting through the Pennsylvania Patient Safety Reporting System and Department of Health licensure surveyors based upon the standardization document.

Education Mission – Moving Forward

The Authority has been fulfilling its mission of educating its stakeholders not only through its *Pennsylvania Patient Safety Advisory* but also through its outreach and collaboration efforts. The Patient Safety Liaison (PSL) pilot program, begun in 2008, has allowed the Authority and individual facilities one-on-one visits to help tailor patient safety improvement programs. Along with the PSL program, the Authority began educating Boards of Trustees and top level management through another pilot program developed in partnership with the Hospital and Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA). The Authority has also reached out to several state associations to provide continuing education credits for physicians, nurses and pharmacists.

The Patient Safety Liaison Program

Fulfilling a critical component of its mission and the 2007 strategic plan, the Authority hired a Director of Educational Programs to oversee its educational initiatives including the Patient Safety Liaison (PSL) program.

At the request of Patient Safety Officers for "more of a presence" from the Authority, the Patient Safety Liaison program was developed. The PSL acts as a consultant to Pennsylvania's healthcare facilities to ensure they are aware of the numerous educational resources available to them from the Authority. While acting as a liaison between the Authority and healthcare facilities, the PSL also serves as a liaison between healthcare facilities within the region.

The first Patient Safety Liaison was hired in August 2008 in the northeast region of Pennsylvania. The northeast region has 71 medical facilities, hospitals, birthing centers, ambulatory surgical facilities (ASF) and certain abortion facilities. There are currently 66 PSOs overseeing these 71 medical facilities. The reception of the medical facilities to the PSL has been welcoming and forthcoming. The attendance at the first meetings is varied

from leadership (CEOs), middle management, owners of facilities and PSOs. Topics discussed are varied but consistent themes related to patient safety. These themes include identified opportunities for improvement, strategies being employed, successes, barriers and sharing of information. The PSL also takes this opportunity to share with the audience resources currently available to the PSO through the Authority and other organizations. These resources include items such as toolkits, *Pennsylvania Patient Safety Advisory* articles, patient safety information from other entities, consumer tips and availability of continuing education credits in patient safety. The PSL also solicits feedback from Patient Safety Officers to understand what they need from the Authority to improve patient safety in their specific facility.

New education programs and sessions were developed by the Authority at the request of the northeast facilities. These programs and sessions will be instituted statewide once the other regional Patient Safety Liaisons are on board.

The Authority developed a basic patient safety program, called the “Patient Safety Officer Foundation Curriculum” to discuss the specifics behind patient safety and Act 13 of 2002. Personnel attending the program included CEOs, management staff and PSOs from hospitals and ambulatory surgical facilities. Feedback was very positive and there were numerous requests for additional educational sessions regarding patient safety leadership and insights, such as human factors, highly reliable organizations (HRO), crew management and proactive risk reduction strategies (FMEA). The Authority is developing a second program called “Beyond the Basics” to coincide with the basic program.

Through the northeast PSL’s interactions with PSOs of various care settings, educational needs regarding specific health care topics have been identified. For example, in April 2009 a half-day session on methicillin-resistant *Staphylococcus aureus* (MRSA) was given to ambulatory surgical facility employees in the northeast region. The session was well received. More HAI sessions are planned throughout the state once the other PSLs are on board.

The PSL and Director of Educational Programs also speak to numerous professional healthcare organizations about the PSL program to ensure it is utilized by the healthcare facilities. In February 2009, a presentation about the PSL program was given to the Council for Small Hospitals at the Hospital and Healthsystem Association of Pennsylvania (HAP). The program was embraced as a resource to help educate staff at no additional costs to their facility.

Currently it is projected that three (3) additional PSLs will be hired for the northwest, southwest and south central regions of Pennsylvania for FY 08-09. The Authority is in the first steps of the selection process and expects to have the three new hires in place in late spring (May-June 2009). The full complement of six (6) PSLs is projected for FY 09-10.

Patient Safety Training for Trustees

This year the Authority put its strategic plan initiative to educate executive management and Boards of Trustees into action. The initiative is designed to raise awareness and increase responsibility for patient safety by bringing it to the board level.

The Patient Safety Authority partnered with the Hospital and Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) to begin a pilot program. An advisory panel composed of executive leaders and trustees from hospitals and health systems assisted the Patient Safety Authority and HAP to develop a customized educational program that would help foster the kind of senior level and board engagement needed for improved patient safety. A business model was developed and the Authority provided the funding needed to host four training sessions in which a total of about 300 persons would participate.

Dr. John Combes of the American Hospital Association's Center for Health Care Governance developed the four pilot trustee training sessions that include:

- One session for a group of 3 or 4 small/rural hospitals
- One session for a group of 3 or 4 community hospitals
- One session for a stand-alone community hospital
- One session for a multi-hospital system

The first conference was held for the Board of Trustees at Susquehanna Health in Williamsport in the fall of 2008 with positive feedback.

The President and CEO of Susquehanna Health attended the conference and made several patient safety improvements to its organization as a result of the program.

"This conference provided the material and motivation necessary to complete a thorough review of our trustees' role in quality and safety. I fully endorse the program for all hospital and health system trustees charged with or interested in quality and safety of the services their organizations provide...Susquehanna Health anticipates using a modified version of this curriculum for future programmatic evaluation and strategic planning. We are grateful that this program helped stimulate our thinking and provided us with the motivation to make these changes."

*Steven P. Johnson, FACHE
President and CEO
Susquehanna Health*

Additional sessions will be scheduled by HAP limiting the size and presentation length to allow more interaction with participants. More updates of the program's success will follow. At the conclusion of the pilot sessions, the Authority hopes to support this training for all hospitals in Pennsylvania.

Pennsylvania Healthcare Organizations to Offer Continuing Education Credits through Patient Safety Advisories

The Patient Safety Authority has collaborated with healthcare associations throughout the state to provide continuing education credits for their memberships.

The Authority and the Pennsylvania Medical Society have been working together for several years providing doctors across Pennsylvania with continuing medical education credits. This year the medical society has asked the Authority to work with them to tailor the *Pennsylvania Patient Safety Advisory* articles so physicians can more readily choose articles that pertain to their discipline.

The Authority also met with the Pennsylvania State Nurses Association (PSNA) to provide continuing education hours for Pennsylvania nurses through its Web site. Licensed nurses in Pennsylvania will be required to have 30 continuing education hours for renewal in 2010. The Authority will provide current and retrospective articles to the PSNA and they will be posted on the PSNA Web site. The hours can be obtained by members and non-members of the PSNA. The Authority expects members to be able to obtain the continuing education hours through its June 2009 *Pennsylvania Patient Safety Advisory*.

The Pennsylvania Pharmacists Association (PPA) is also interested in partnering with the Authority to provide continuing education credits for Pennsylvania pharmacists. Their current partner will no longer provide material

for continuing education giving the Authority the opportunity to fill a gap for Pennsylvania pharmacists to obtain their patient safety credits that will be required for license renewal. Currently, the PPA has a year of continuing education material for their bi-monthly journal but they welcome the Authority's partnership to provide more options for their members to obtain patient safety credits.

Healthcare-Associated Infection (HAI) Reporting – What's Next

In July 2007, legislation was signed into law as Act 52 to prevent and reduce healthcare-associated infections in hospitals and nursing homes. The Pennsylvania Patient Safety Authority has been working with the various healthcare agencies (Pennsylvania Department of Health, Pennsylvania Healthcare Cost Containment Council and the Centers for Disease Control and Prevention) since then to implement the new law and move toward eradicating all HAI in Pennsylvania. Act 52 of 2007 requires the Authority to perform a significant amount of activities to support healthcare-associated infection elimination efforts. Many of these activities are related to preparing for HAI reporting by nursing homes.

In July 2007, Act 52 was signed into law.

Key provisions of the bill include the following.

Hospitals must:

- Develop infection control plans outlining the steps they will take to prevent and reduce infections.
- Educate healthcare workers as to how they can prevent infections.
- Screen high-risk populations for methicillin-resistant *Staphylococcus aureus* (MRSA), a type of infection that cannot be cured with many available antibiotics.
- Report infections to the Patient Safety Authority, Department of Health (DOH), and the Pennsylvania Healthcare Cost Containment Council (PHC4), through the CDC's National Health Safety Network (NHSN).

Nursing Homes must:

- Develop infection control plans
- Submit reports of HAI events to the Authority and the Department of Health

Act 52 of 2007 also requires the Department of Health to set risk-adjusted benchmarks for the purpose of data comparison, which will be introduced in 2009.

While the Authority, PHC4 and DOH all have access to NHSN data, DOH, as the regulating agency, is working with hospitals on data integrity and fixing identifiable reporting errors. To this end, DOH sent a series of reports to the hospitals identifying HAI reports submitted from July 1, 2008 through December 31, 2008 that needed modification. This activity was completed in April 2009. At this point, DOH locked down the data. It is this data that is presented in the Authority's annual report. As the Authority has just received this information, we are now beginning to perform more detailed analyses that will lead to additional educational opportunities. We will publish the results of some of these analyses in future issues of the *Pennsylvania Patient Safety Advisory*.

Hospitals entered a total of 18,307 HAI events into the NHSN database between July 1 and December 31, 2008. The DOH infections and report totals are included in Table 3 on page 35 of this annual report. This information and data in this report is not comparable to the Authority's 2007 annual report nor is it comparable to other Pennsylvania HAI data sources. For example, PHC4's annual HAI reports differ because facility and infection types vary between PHC4 data collection and what is currently being reported by hospitals through NHSN as a result of Act 52 of 2007.

The following hospital types are included in NHSN reporting: all acute care hospitals, children's hospitals, long-term care hospitals, psychiatric hospitals and rehabilitation hospitals. The PHC4 data is limited to acute care hospitals.

In addition, current reporting through NHSN includes more types of HAI reporting that was collected previously by PHC4.

PHC4 HAI reports **do not** include the following HAI events:

- Cases for children less than or equal to one year of age
- Cases assigned to major diagnostic category (MDC) 19 Mental Diseases and Disorders or MDC 20 Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders
- Cases with burns
- Cases with organ transplants or complications of transplants
- Any HAIs identified as:
 - systemic infections
 - eye, ear, nose, throat, or mouth infections, including upper respiratory infections
 - surgical site infections identified during readmissions

The DOH in consultation with the Authority and PHC4 developed calculation/benchmarking areas which include catheter-associated urinary tract infections (CAUTIs), central line-associated blood stream infections (CLABSIs), and select surgical site infections (abdominal hysterectomy, cardiac surgery, and hip and knee replacements).

The Authority looks forward to future DOH data reports to include CAUTIs and CLABSIs rates, select cardiac surgeries and device-associated infections.

The Authority's efforts have been focused on establishing the HAI reporting infrastructure for hospitals and nursing homes. We have also published HAI-related articles in the *Pennsylvania Patient Safety Advisory* and are giving presentations on reducing healthcare-associated infections. Infection prevention is also one of the domains of care included in our patient safety measurement project which is a primary focus of this annual report. A complete timeline of the tasks the Authority has undertaken to date for Act 52 of 2007 include:

September 2007 – The Authority establishes the Healthcare-Associated Infection Advisory (HAI) panel made up of infection control experts from throughout the state.

December 2007 – Draft HAI reporting requirements for hospitals were published in the *Pennsylvania Bulletin*. The Authority collected and distributed the public comments from facilities regarding the draft document. The HAI Advisory Panel reviewed comments and developed a final reporting document for hospitals based upon their expertise and the public comments.

February 2008 – Hospitals began mandatory reporting of HAIs using the Centers for Disease Control and Prevention's National Health Surveillance Network (NHSN).

March 2008 – Final reporting requirements for hospitals were published. The Authority embarked upon an extensive education and outreach program to ensure that Pennsylvania healthcare facilities understood the reporting requirements. Several presentations were given by Authority staff throughout 2008 to hospitals and nursing homes regarding Act 52.

March-April 2008 – The Authority and the HAI Advisory Panel worked with the Department of Health to develop the list of reportable infection events and reporting criteria for nursing homes. These infections will be

tracked by the Authority and the Department of Health through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

May 2008 – The draft reporting requirements for nursing homes were published in the *Pennsylvania Bulletin* and open for comment. The Authority received over 60 comments from nursing home organizations from across the state.

September 2008 – The final reporting requirements and criteria for nursing home HAI reporting was published in the *Pennsylvania Bulletin*.

December 2008 – The Authority conducted a Web conference attended by over 600 long-term care facilities to define and outline the criteria for infections that will be tracked in nursing homes.

January – March 2009 – The Authority completed 30 training sessions for 1250 nursing home employees throughout the state to prepare them for mandatory reporting. An HAI training curriculum, including an extensive Users Guide and Training Manual, was delivered in the training sessions.

April 2009 – A pilot reporting session will be held for two weeks with volunteer nursing home facilities to test the new system and ensure any problems are addressed prior to mandatory reporting in June.

May 2009 – A Webinar training session will be held for those facilities that could not make the live training sessions.

September 2008 – May 2009 – The nursing home HAI reporting system was developed as a subset of the Pennsylvania Patient Safety Reporting System (PA-PSRS). This process was lengthy because the PA-PSRS system had to be rebuilt specifically for nursing home reporting. The addition of nursing homes expands the number of facilities reporting through PA-PSRS to two and a half times the current amount of facilities reporting to the Authority.

June 2009 – Mandatory reporting of nursing homes begins.

Since Act 52 of 2007 was signed into law, the Authority has been educating the hospitals and nursing homes through *Pennsylvania Patient Safety Advisories*. The *Advisories* are based upon data collected in PA-PSRS. Once the nursing homes begin reporting in June the Authority expects to have more information specifically geared toward nursing home infections to pass on to the facilities as guidance.

Highlights of Data Submitted to the Patient Safety Authority

Other highlights regarding the data submitted to the Pennsylvania Patient Safety Authority during calendar year 2008 are listed below. For more detailed information and graphics, please see the “Data Collection and Analysis” section of the full report beginning on page 51.

- 525 hospitals, birthing centers, ambulatory surgical facilities, abortion facilities and birthing centers were subject to Act 13 of 2002 and Act 30 of 2006 reporting requirements. They submitted 219,874 reports of Serious Events and Incidents to the Authority, an increase of 7,891 reports from 2007.
- Approximately 96% of all reports were Incidents, or did not cause harm to the patient; approximately 4% of all reports were Serious Events, which indicates that the patient received some level of harm, ranging from minor, temporary harm to death.
- The number of Incident reports averaged 17,602 per month, an increase of 3% from 2007. Serious Event reports averaged 720 per month, representing a 19% increase from 2007. A significant portion of this increase can be traced to healthcare-associated infections reported by law as a Serious Event earlier in the year as a result of Act 52 of 2007.
- Reports from hospitals accounted for 98.6% of all reports submitted. However, reports submitted by ambulatory surgical facilities increased from 10.7 reports per facility in 2007 to 11.8 reports per facility in 2008.
- When evaluated regionally, the largest numbers of reports come from the southeastern and southwestern counties, which is consistent with the population within Pennsylvania. When report volume is adjusted for patient days, facilities in the north central counties appear to be more aggressively reporting events. Serious Events submitted in the north central region were 7.6%, significantly larger than the statewide average of Serious Events (3.5%). These higher numbers could be due to several factors including: a higher number of actual patient safety events; differences in the ability to identify patient safety events (especially Incidents); and differences in the way facilities report patient safety events based on Mcare law interpretation.
- Statewide, the most frequently reported events in hospitals involved Errors related to Procedures/Treatments/Tests (23%) and Medication Errors (22%). However, Errors related to Procedures/Treatments/Test comprise only 8% of reports involving harm or death and Medication errors comprise only 4% of events involving harm and 1% of events contributing to or resulting in death.
- Conversely, while Complications related to Procedures/Treatments/Tests comprise only 13% of reports overall in 2008, they comprise 43% of the reports of events involving harm and 59% of all reports of events resulting in or contributing to the patient’s death.
- Patients over age 65 were especially vulnerable to Serious Events and Incidents, representing more than half (52%) of all reports submitted to the Authority. In 2008, approximately 60% of all Falls and 73% of all reports related to Skin Integrity involved older patients. Falls reports for older patients are down by 4% since mandatory reporting began in 2004. Skin integrity reports remain the same. Skin integrity reports include pressure sores, bruises and other skin-related conditions.
- In a recent survey, 218 Patient Safety Officers (PSOs) reported making 607 changes in their facilities in 2008 as a result of specific *Pennsylvania Patient Safety Advisory* articles. PSOs from hospitals (115) cited 484 changes, while PSOs from ASFs (103) cited 123. Please see page 89 for more information about this survey.

Patient Safety in Pennsylvania Healthcare Facilities

Introduction

Since the Patient Safety Authority first launched the Pennsylvania Patient Safety Reporting System (PA-PSRS) in June 2004, the most challenging question we have faced is whether healthcare in Pennsylvania is becoming safer. This question is not unique to Pennsylvania. It is a national concern not only for the United States but in other countries as well. Experts in patient safety are forced to admit that while we have made progress since the 1999 publication of the Institute of Medicine's *To Err Is Human*, we are just at the beginning of a journey and we have a long way to go.

It is a major accomplishment that the healthcare community is now focused on patient safety like never before. Healthcare practitioners—and the public—increasingly view safety as a *fundamental* goal rather than one that should compete with other goals like reducing costs and increasing efficiency. In Pennsylvania, the Medical Care Availability and Reduction of Error Act of 2002 (MCare) made significant structural changes in the healthcare system. It required healthcare facilities to establish a Patient Safety Committee, to designate a Patient Safety Officer who would be accountable for patient safety, and to disclose healthcare-associated injuries to patients and their families. It required healthcare practitioners to report not only events in which patients were injured but also those that could have resulted in harm, and it required healthcare facilities to share those reports with other institutions through the Patient Safety Authority.

But how can we tell whether these changes—and the significant efforts of healthcare providers to improve the safety of specific clinical processes in their own facilities—have actually made us safer?

There are many organizations that attempt to quantify the quality of care given by facilities. These include Healthgrades, the Agency for Healthcare Research and Quality (AHRQ) with the patient safety indicators, Pennsylvania Healthcare Quality Alliance and others. Each attempts to paint a valid picture of quality and safety. However, data used to show safety has several limitations. Many outcome-based indicators are determined by administrative data and can be skewed by billing practices. Direct observation is the best way to assess patient safety. Unfortunately, it is not practical to assign an individual to monitor each patient's health care as it is happening.

The number of reports we receive of different types of injuries is one indicator of safety, but it is not an ideal one. Following publication in the *Pennsylvania Patient Safety Advisory* of some types of problems and suggested guidance facilities can follow to improve, we have seen the number of reports decline substantially, suggesting that actions taken in healthcare facilities are effective. Yet, in other cases we have publicized a problem and seen reports increase markedly, suggesting that we have raised awareness and that the problem was larger than the number of reports would indicate.

While the ultimate measures of safety are the number of lives saved or the number of injuries prevented, the next best alternative is to measure whether Pennsylvania healthcare facilities have adopted practices we believe are linked with patient safety.

To that end, we invited Pennsylvania healthcare facilities to participate in a statewide initiative to measure the level of adoption of selected process and structural safety practices advocated in the *Advisory* over the past several years. The specific practices we chose to measure are not arbitrary. While we might have chosen others that would be equally valid and important, we selected those that were related to existing national patient safety priorities, such as the National Patient Safety Goals advocated by the Joint Commission and the National Quality Forum's "Safe Practices for Better Healthcare" and "Serious Reportable Events."

The safe practices are organized into the following domains:

- Safety Leadership
- Medication Safety
- Safe Surgery
- Infection Prevention
- Device Safety

In this report, in addition to summarizing the results of the facility surveys, we also discuss the related problems identified through PA-PSRS, and the results of the Authority's analysis of adverse event reports and potential solutions published in the *Pennsylvania Patient Safety Advisory*.

For participating facilities, following publication of this annual report, the Patient Safety Authority will provide a detailed report comparing their level of adoption of these practices with that of similar facilities. We have encouraged Patient Safety Officers and CEOs to share these reports with their Patient Safety Committees, their senior leadership and their Board of Trustees. We anticipate that these reports will highlight for each institution their own successes as well as areas for further improvement.

Any set of safety practices would be, by definition, incomplete. However, as one window into the processes in place in Pennsylvania healthcare facilities, we believe they provide a useful view of the current state of safety in the healthcare system.

Methodology

In July 2008, the Authority conducted telephone interviews with eight facility Patient Safety Officers (PSOs) to identify factors that influence their reporting to PA-PSRS. The goal was to identify strategies used by these facilities to create opportunities for more active reporting by all Pennsylvania front-line clinicians and other staff. As a result of the eight PSO interviews, the Authority developed a statewide survey to measure the level of adoption of specific patient safety practices.

These practices were defined by (and in some cases exceeded) the requirements of the Centers for Medicare and Medicaid Services Hospital-Acquired Conditions, the Joint Commission's 2009 National Patient Safety Goals, and the National Quality Forum's Serious Reportable Events and Safe Practices for Better Healthcare. For example, the National Patient Safety Goal 3E – Reducing Harm from Anticoagulation Therapy requires some form of anticoagulation management and the survey included a specific patient safety practice related to the use of an anticoagulation management service. The survey included practices relevant to hospitals, ambulatory surgical facilities, birthing centers and abortion facilities.

The voluntary electronic survey was pilot tested by several facility PSOs recruited by the Authority's Patient Safety Liaison in northeastern Pennsylvania. It was subsequently distributed to all 525 Pennsylvania facility PSOs in mid-January 2009, with a request for survey completion within 14 days, which was extended an additional seven days. For most facilities, the surveys required coordination with other departments for completion. A total of 200 facilities statewide completed the survey, including 118 hospitals (59%), 80 ambulatory surgical facilities (40%), one birthing center (0.5%) and one abortion facility (0.5%). Statewide results are presented here in the Authority's 2008 Annual Report and comparative reports for participating facilities are scheduled for distribution in the second quarter of 2009.

Response rates for individual facility types, as a percentage of active facilities are as follows:

- Hospitals (49%)
- ASFs (31%)
- Birthing Centers (20%)
- Abortion Facilities (6%)
- Overall (38%)

This survey, like all surveys, has some limitations. The facilities represented in these results constitute over one-third (38%) of the healthcare facilities in the state, among those required to report adverse events and near misses to the Authority. Since facilities that participated were self-selected, the results may not reflect the adoption of these practices statewide. PSOs who thought their facilities would fare well in a comparison with their peers may have felt a greater incentive to participate and may therefore be disproportionately represented in the results. Despite refinement of the practices chosen and the wording of the survey questions following pilot testing, there may be variation in different individuals' interpretations of the questions. The small number of birthing centers and abortion facilities participating recommends strongly against generalizing their responses to other facilities of that type. For confidentiality reasons, their responses are combined with those from ASFs.

Safety Leadership

Successful execution of strategic quality improvement goals depends on a genuine sense of shared responsibility. According to the Institute for Healthcare Improvement (IHI), the duty of a leader is to unite their organization around carefully chosen goals. Research and development conducted by IHI and Associates in Process Improvement in 2008 has produced a new theory for the successful execution of strategic aims by leaders. This theory includes the achievement of strategic goals that are aligned with organizational priorities, a plan for daily management of local improvement projects to support or sustain breakthrough aims and daily operations, and the continual development of employees who are capable of leading initiatives to produce system-level results and supervisors who are capable of managing improvement in their local areas.¹

In 2008, the Joint Commission (TJC) added a new leadership standard that required healthcare facility leaders to formally establish a culture of safety. This standard requires facility leadership to change leadership structure, relationships, organizational policy, operations and culture, and focus on patient safety. This standard enables healthcare leaders to focus on patient safety by becoming the supporting foundation of patient safety, to develop a culture of safety and help the board to get focused and actively involved in quality and safety activities, using quality and safety data.²

Real change stands a better chance if it is driven from the top down through the leaders of the organization. The Authority is committed to increasing Trustee awareness of patient safety and one of the Authority's Board of Directors strategic initiatives has included facility board education. The purpose of the Leadership Safety Measure or domain is to engage facility boards and executive management in discussions to champion patient safety within their organizations. The leadership domain will increase the profile of patient safety and raise the priority of patient safety at the board level.

¹ Bisognano M. Institute for Healthcare Improvement. Leadership's role in execution. Change must happen organizationwide to be successful. Healthcare Executive [online]. 2008 Mar-Apr [cited 2009 Feb 18]. Available from Internet: <http://www.ihl.org/NR/rdonlyres/163519D3-BB7A-496B-9C10-C345B81462FB/0/BisognanoLeadershipsRoleinExecutionACHEMar08.pdf>.

² The Joint Commission. Accreditation program: Hospital leadership (pre-publication version) [online]. 2009 Jan 1 [cited 2009 Feb 18]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/D53206E8-D42B-416B-B887-491B6D5AA163/0/HAP_LD.pdf.

Patient Safety Walkarounds

Conducting formal patient safety walkarounds (See Figure 1) with members of the Board of Trustees provides senior leaders the opportunity to listen to the patient safety issues identified by staff. Regular walkarounds provide a forum to learn about issues related to team practice, communication and a transparent culture in order to create improvements. They also provide an opportunity for senior leaders, including board members, to demonstrate their commitment to their organization's patient safety efforts.

We asked participating healthcare facilities how often they performed formal patient safety walkarounds with a member of the Board of Trustees during the past year. Among hospitals, about one-third (32%) had done this at least once during the year, but the majority 68% have not instituted this practice. The practice has gained slightly more acceptance among participating ASFs and other facilities, with 45% having conducted walkarounds with Trustees within the past year. Overall, 17% of participating facilities report conducting walkarounds four or more times, suggesting that for these facilities the practice has become a common activity for their boards.

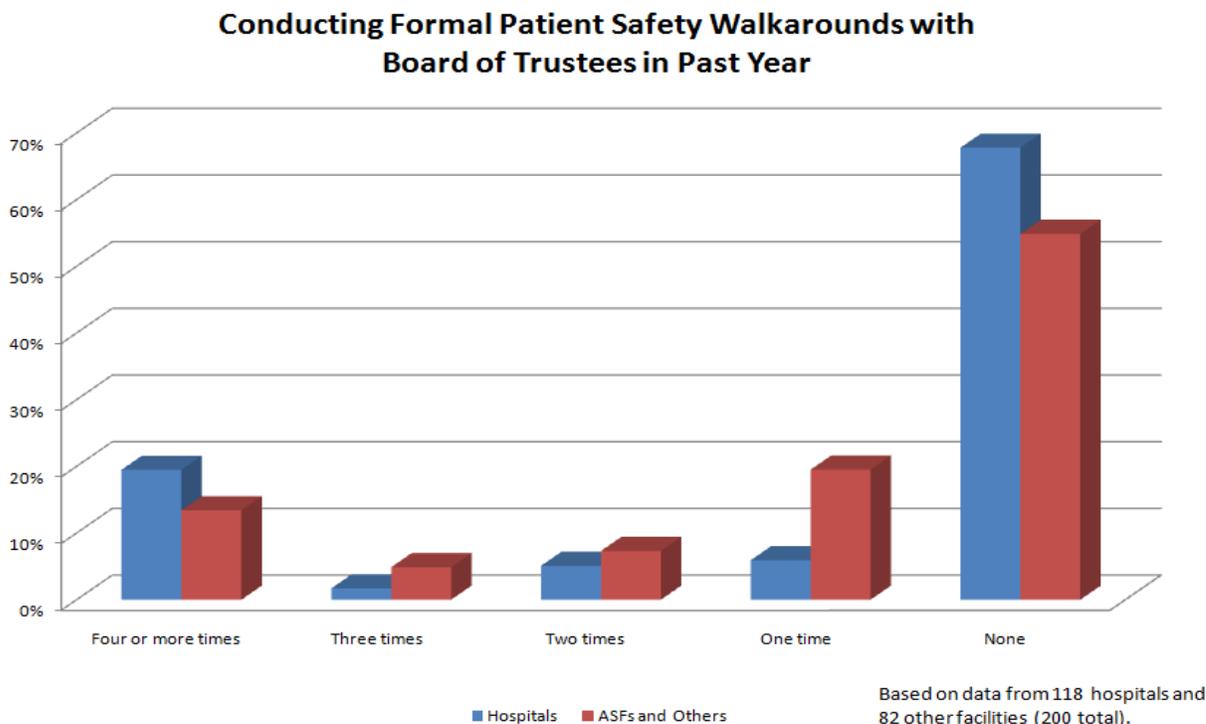


Figure 1.

Patient Safety Officer Participation in Board of Trustees Meetings

Senior leaders can also demonstrate their leadership on safety by inviting PSOs to address their Board of Trustees and to make safety a standing item on the board agenda. Doing so demonstrates that management and Trustees view safety as an important component of the Trustee’s oversight responsibility. It allows the board to hold management accountable for safety and to ensure that management allocates appropriate resources to safety within the institution. Without insight into what the organization is doing to correct problems that are identified or to improve clinical processes, board members cannot effectively monitor patient safety.

We asked participating facilities how often their PSO had attended board meetings over the past year. (See Figure 2) Among hospitals, nearly half (47%) reported that they attended four or more Board of Trustees meetings, while in one-third (31%), the PSO did not attend any. Responses were similar among ASFs and other facilities, with 44% reporting PSO participation in four or more board meetings and 24% reporting none. Overall, 46% of participants reported that their PSO attended four or more board meetings over the past year, suggesting this practice has gained acceptance in many facilities.

Patient Safety Officer Attendance at Board of Trustees Meetings in Past Year

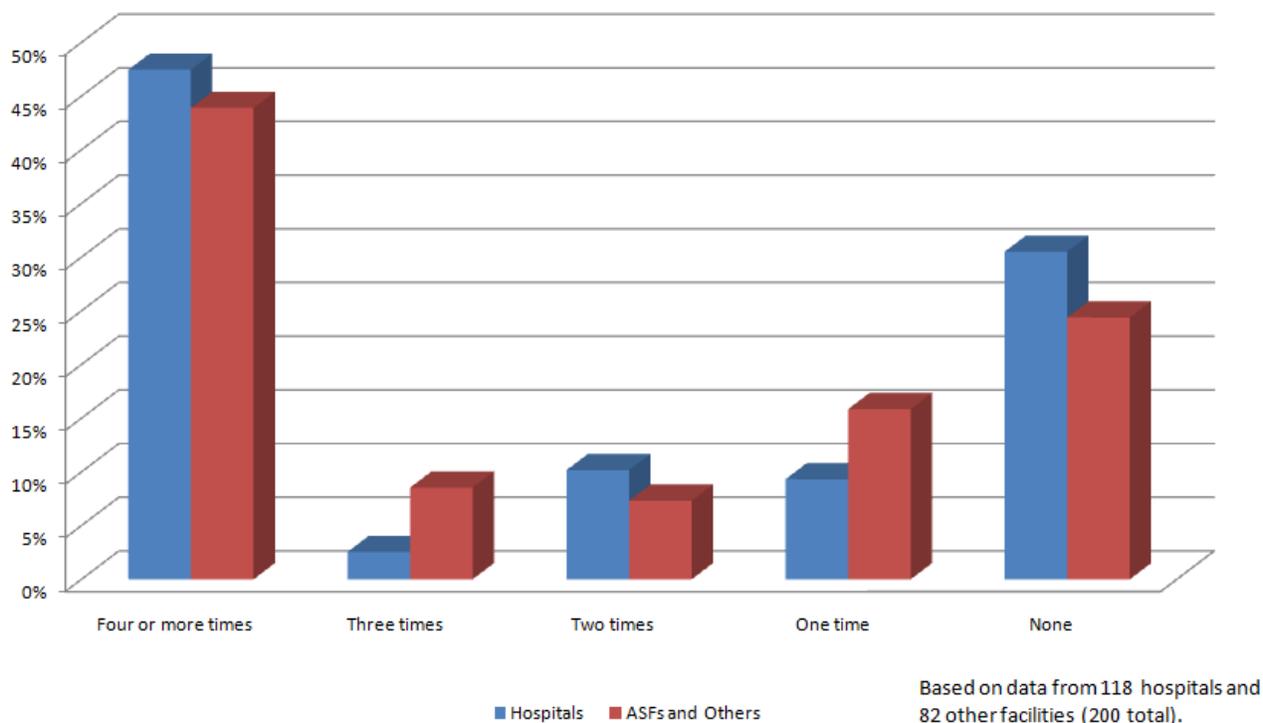


Figure 2.

Adoption of “Just Culture” Principles

In patient safety we recognize that a healthcare organization’s culture exerts a strong influence on how it responds to patient safety concerns and how it treats individuals who raise issues about safety and those involved in adverse events. There is a tension between the need to hold individuals accountable for safety while creating an environment in which they are comfortable acknowledging mistakes and working to fix the problems that cause them.

A “just culture” is one that does not punish individuals for honest mistakes or for reporting safety concerns and injuries. It also does not go to the opposite extreme by permitting repeated, intentional rule violations. Rather, a just culture seeks a middle ground that tries to find system or engineering solutions to reduce inevitable human errors, while holding individuals accountable for intentionally violating safety policies or procedures. This balance is a fair compromise between a punitive approach that encourages people to hide their mistakes and a “blame free” approach that tolerates deliberate poor performance.

We asked each facility if they have written instructions for staff about error reporting which include “Just Culture” principles. These principles incorporate open communication with all staff and include accountability to promote a safe environment to learn from mistakes. The majority of hospitals (70%) report some level of implementation of Just Culture principles, with 59% reporting full implementation hospital-wide. One-third of hospitals (30%) report that they have not yet implemented these principles. We found similar results for ASFs and other facilities, with 72% reporting some level of implementation, while 28% have not adopted this approach. (See Figure 3)

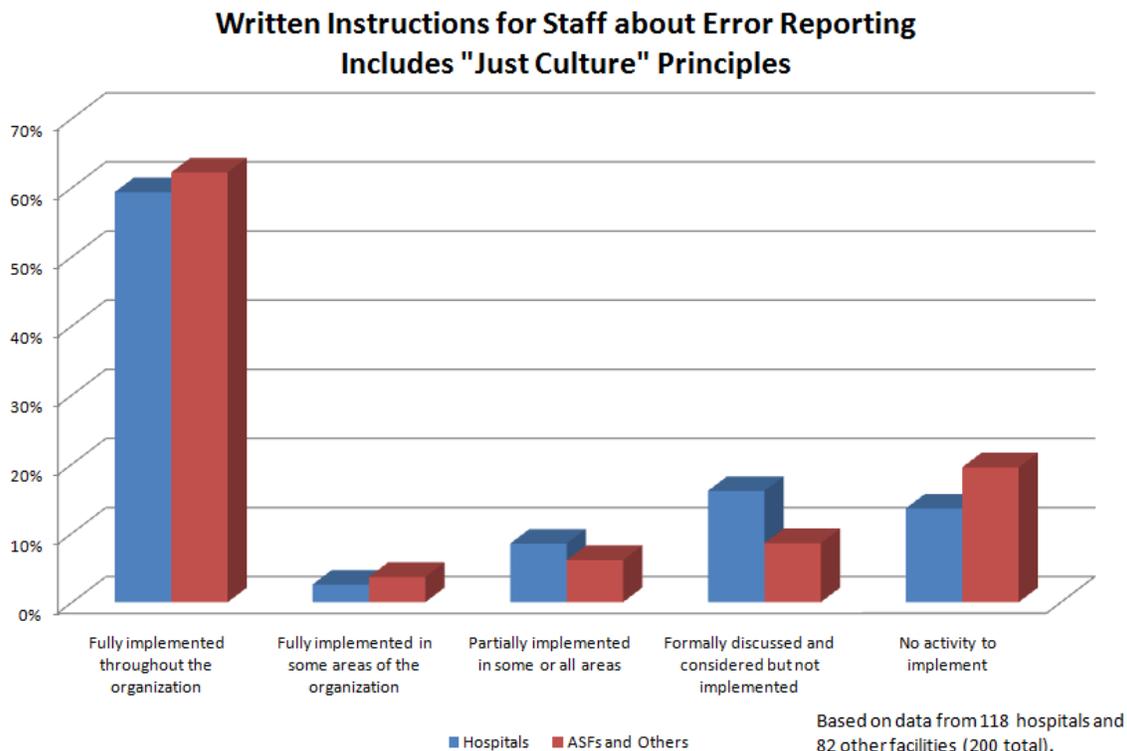


Figure 3.

Reward and Recognition Program

A reward and recognition program formally acknowledges the positive contribution of staff who identify error-prone situations that may adversely affect patient safety. These programs reward desired behavior, improve staff morale, increase retention and motivate employees to reach a higher level of performance. This program elevates staff members as positive role models, encouraging others to follow their example. They also demonstrate the organization’s commitment to act on safety problems brought to light, giving staff further incentive to voice their concerns when safety is at stake.

We asked each facility if their organization’s leadership had adopted a formal reward and recognition program for the identification of error-prone situations. Only about one in 10 participating hospitals (12%) have fully implemented a formal rewards and recognition program, while 36% report at least partial implementation. The majority of hospitals (64%) have not implemented this item. Among ASFs and other facilities, one in five (15%) report full implementation, and 20% report at least partial implementation. Most (80%) have not implemented a reward and recognition program for identifying safety concerns. (See Figure 4)

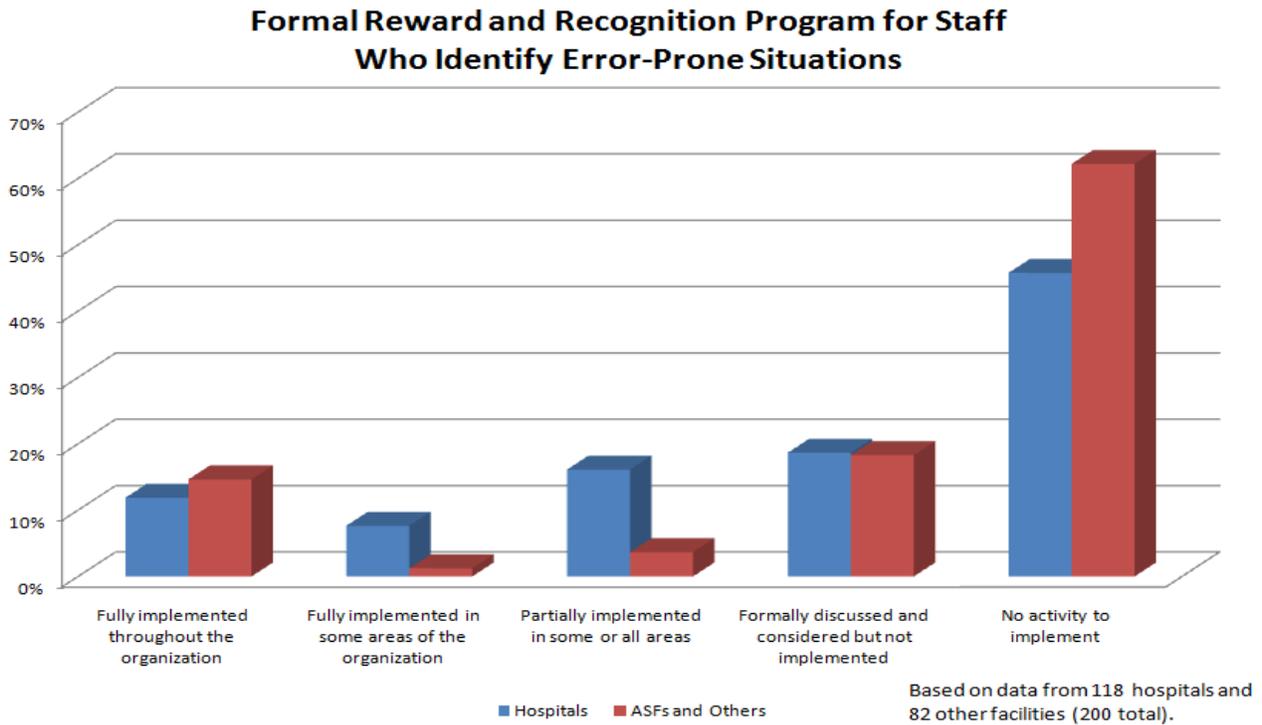


Figure 4.

Reports to the Authority

Reports submitted to the Authority are not overtly identified as related to organizational leadership. The disposition of a Serious Event is a required field for all reports submitted of this event type but is not necessary for the reporting of Incidents (near misses and other non-harmful events). In 2008, of the 211,229 reported Incidents, 39% were referred for a higher level of scrutiny.

Options for event disposition include referring the report to the medical director, peer review committee, Joint Commission, quality improvement/monitoring committee, risk management/safety committee, patient safety committee, medication event review committee or medical staff committee. The membership of these committees is frequently by those individuals who are in leadership roles or have regular contact with leadership. These data suggest that organizations are making a significant effort to provide closer scrutiny to these events and to learn from events that could have harmed patients, not only those in which harm has occurred.

Recent *Advisory* Articles Related to Leadership

Leadership Series:

[Is Your Institution Leaving Patient Safety Information at the Bedside?](#)

(Dec 2008)—Hospitals not capturing near-miss, or “Incident,” events are hurting their ability to identify and correct problems before they harm patients.

Leadership Series: [UPMC’s](#)

[Experience with Disclosure of](#)

[Medical Errors](#) (Sep 2008)—

At UPMC, physicians keep lines of communication open and remain available and accessible to their patients after medical errors occur that result in harm.

Leadership Series:

[Executive Patient Safety](#)

[Walkrounds](#) (Jun 2008)—

Abington Memorial Hospital's patient safety staff members have been conducting patient safety walkrounds for several years and have witnessed an increasing level of popularity in the exercise from trustees and executives.

Leadership Series:

[Meaningful Engagement in](#)

[Patient Safety Improvement](#)

(Mar 2008)—The Pennsylvania Patient Safety Authority Board of Directors chair, discusses getting “boards on board,” specifically, the trustees’ level of engagement in patient safety.

[The Role of Empowerment in](#)

[Patient Safety](#) (Dec 2004)—

Procedures will only improve patient safety if team members feel empowered to act when they believe the procedures are not being followed.

Medication Safety

Medications are a blessing if healthcare providers prescribe, prepare, dispense and administer them to patients safely and appropriately. However, because healthcare providers are human, they are fallible. Despite their expertise and commitment to quality, errors and other adverse events with medications occur and sometimes cause human suffering. One example that garnered national attention in 2007 was a harmful medication error involving three infants at one of the most reputable hospitals in California. These children, two of them newborn infants of actor Dennis Quaid, received a 1,000-fold overdose of heparin, a medication used to prevent blood clots. Vials containing 10,000 units/mL instead of 10 units/mL were used in error to flush the infants' vascular access lines. While this incident received national attention due to Dennis Quaid's celebrity, accidents like this could happen in any U.S. hospital.

With the 1999 release of the Institute of Medicine (IOM) report *To Err is Human*, healthcare practitioners, as well as the general public, learned that errors involving prescription medications kill up to 7,000 Americans a year and that the financial costs of drug-related morbidity and mortality may be nearly \$77 billion a year.³ A second report from the IOM, *Preventing Medication Errors*, determined that a hospital patient can expect on average to be subjected to more than one medication error each day.

Medication Safety Measures

Anticoagulation Management Service

Healthcare organizations have increasingly recognized the benefits of anticoagulation management services (AMS) in the inpatient and outpatient settings to monitor the effects of "blood thinning" medications like Coumadin (warfarin). The benefits of an AMS program include a reduction in mortality rates and bleeding complications, decreased adverse drug events, and shortened hospital stays. We asked Pennsylvania healthcare facilities about their degree of use of anticoagulation management services. Half (50%) of participating hospitals have established an AMS throughout their institution, while 70% report at least partial implementation in some areas. Fourteen percent of responding hospitals, including behavioral and rehabilitation hospitals, reported that they do not utilize AMS or that this measure was otherwise not applicable. Most ambulatory surgical facilities (ASFs) and other facilities (76% of 82 respondents) report not using AMS or that this measure did not apply, though 14 ASFs have established AMS throughout their institutions. (See Figure 5)

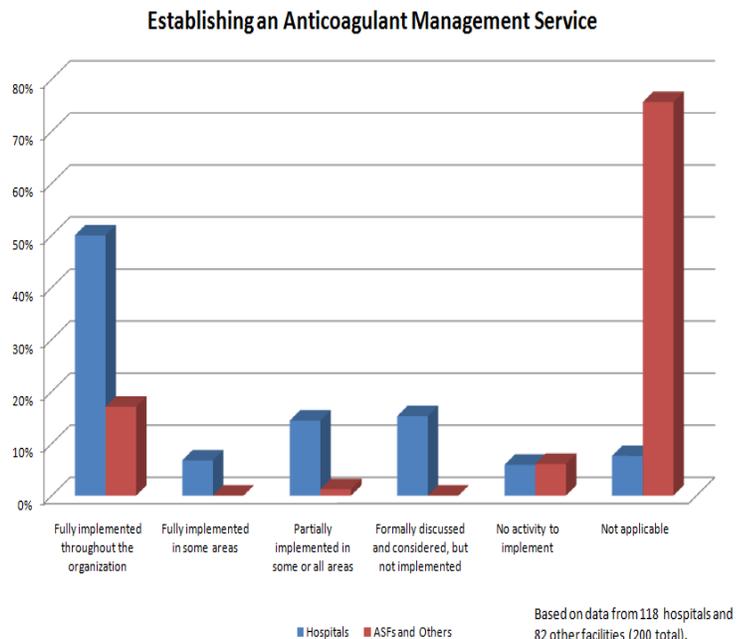


Figure 5.

³ Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine Report, November 29, 1999.

Pharmacist Evaluation of Medications as Part of Fall Risk Assessment

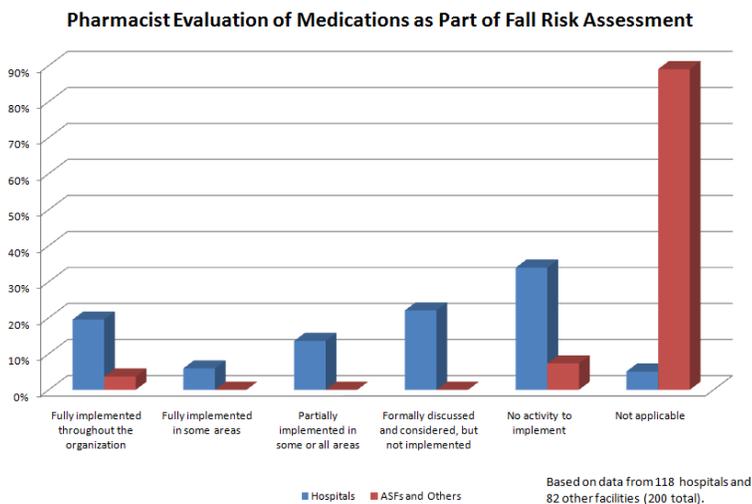


Figure 6.

facilities include a pharmacist in this process. Only 19% of hospitals have fully integrated a pharmacist in the fall risk assessment throughout the organization, and 39% report some level of implementation. Sixty-one percent (61%) of hospitals reported that they have not implemented this practice or that this measure is not applicable to their practice setting. The large majority of ASFs and other facilities (96%) reported no activity to implement or that this measure did not apply. (See Figure 6)

Proactive Risk Assessment for New Drugs

Too often, safety competes with other priorities when healthcare facilities add new drugs to their formulary, such as costs and contractual agreements with purchasing groups or vendors. Healthcare practitioners who would use the medication often are not included in the evaluation process and the potential for error may not be considered ahead of time. This may lead to unexpected problems, such as medication errors due to drug names that look- or sound-alike or drug labels that can be confusing to read. These problems can be avoided by proactively looking at the possibility for errors before deciding to add a new drug. This assessment allows for a multidisciplinary team, including doctors, nurses and pharmacists, to examine the use of new drugs to identify potential problems before any error actually occurs. We asked Pennsylvania healthcare facilities about their use of formal risk assessments when considering a new drug for addition to their formulary. The majority of participating hospitals (81%) reported that this is their standard practice throughout the organization, and 89% report at least partial implementation. However, 11% of hospitals reported they have not implemented proactive risk assessments for new drugs as a standard practice. Over half of ASFs and other facilities (57%) report using risk assessment for a new drug. In contrast to hospitals, a larger percentage (43%) of these facilities has not implemented this measure. (See Figure 7)

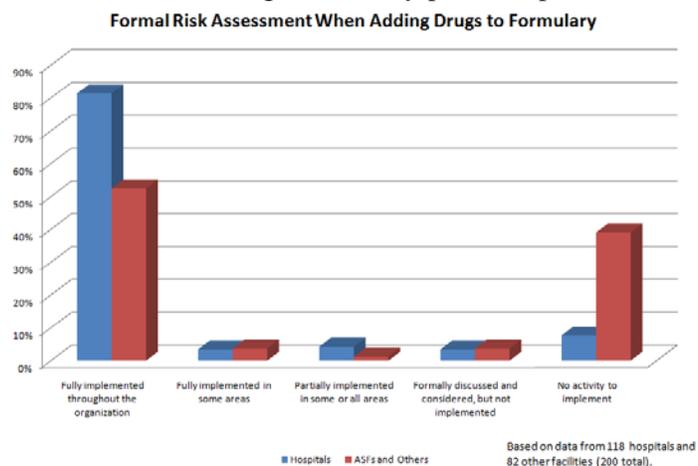


Figure 7.

Many drugs may increase a patient’s risk for falling, and considering medications as part of the overall fall risk assessment may help reduce this risk or may serve to initiate fall precautions. Involving a pharmacist in an interdisciplinary fall prevention program can help to address this gap. Pharmacists can proactively identify drugs that may increase a patient’s risk of falls during routine screening of medication orders. This medication screening data can then be included in the fall risk assessment and help direct any fall prevention strategies. While fall risk assessments are not new in healthcare, few responding Pennsylvania

Pharmacy Computer System Testing

A robust pharmacy computer order entry system that screens new drug orders for unsafe dosages or potential drug interactions is an important tool in preventing serious injury from medication errors. The Authority has received many reports suggesting that pharmacy computer systems in Pennsylvania facilities are not detecting unsafe drug orders as well as they could. In order to ensure their pharmacy computer system is catching errors, facilities can routinely test their systems using simulated unsafe medication orders. If the system is not able to identify unsafe orders, pharmacy and information technology staff can work with the computer system vendor in modifying the system to prevent future errors.

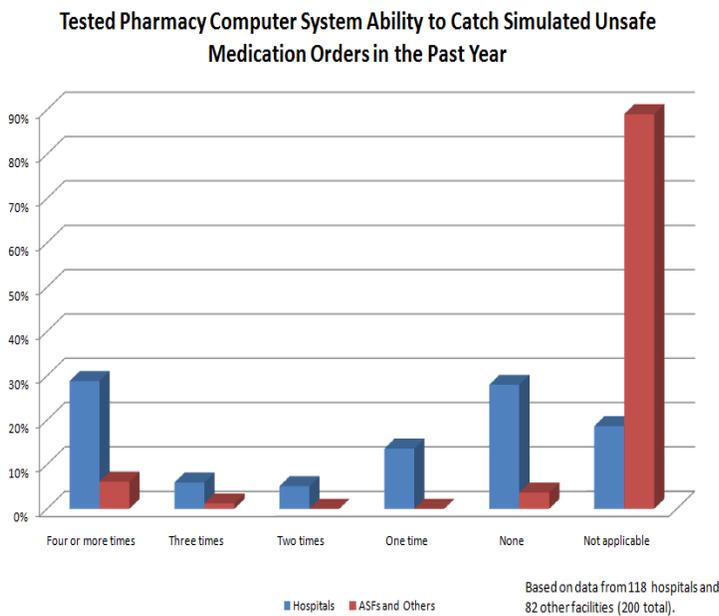


Figure 8.

We asked Pennsylvania healthcare facilities how often they have tested their pharmacy computer system's ability to catch simulated unsafe medication errors in the past year. Just over half (53%) of participating hospitals have tested their pharmacy computer system with simulated unsafe medication orders at least once during the past year, while 28% report that they have not done so and 19% report that this measure is not applicable. Given that most ASFs, birthing centers and abortion facilities do not have on-site pharmacy services, it is not surprising that 89% of these facilities reported that this measure was not applicable to their organization. However, six of the 80 responding ASFs reported they have tested their pharmacy computer system three or more times during the past year. (See Figure 8)

Using Patient-Specific Medication Vials to Prevent Cross-Contamination

Patients may be at risk for infections when healthcare practitioners re-use or re-enter vials of injectable medications with needles or syringes previously used on another patient. Up to 24% of healthcare practitioners re-enter vials with syringes that were just injected into patients.⁴ The end result of sharing multi-dose vials was dramatically illustrated by an occurrence that made national news. In February 2008, the Southern Nevada Health District reported findings from an investigation arising from a cluster of hepatitis C virus (HCV) infections in their area.

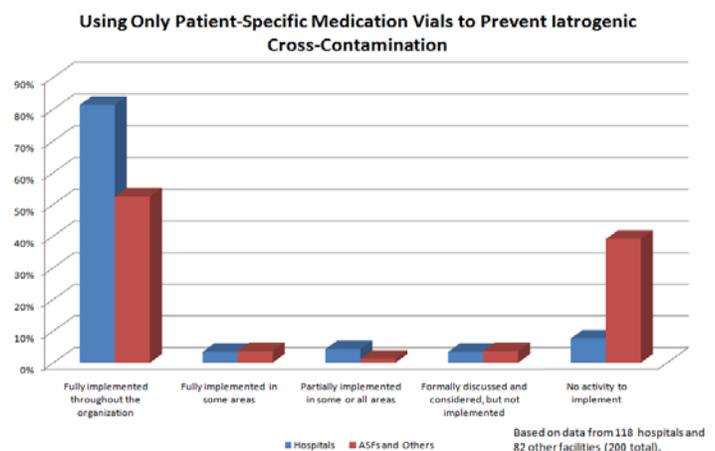


Figure 9.

⁴ Plott RT, Wagner RF, Tying SK. Iatrogenic contamination of multi-dose vials in simulated use. *Arch Dermatol* 1990 Nov;126(11):1441-4.

The health district’s investigation uncovered that six patients infected with HCV had undergone procedures at an endoscopy center in southern Nevada. As a result of these infections, 40,000 patients were informed they should be tested for HCV, as well as for hepatitis B and HIV. As of May 2008, results show 77 individuals were likely exposed to HCV from a procedure performed at the clinic. We asked Pennsylvania healthcare facilities if they use only patient-specific medication vials to prevent cross-contamination. The majority of hospitals (53%) indicated that they use only patient-specific medication vials throughout their organization, and 91% report at least partial adoption in some areas. Nine percent (9%) of hospitals report not having adopted this practice. Among ASFs and other facilities, half (50%) report at least partial adoption. (See Figure 9)

Use of Pre-Filled Heparin Flush Syringes

One of the ways to reduce the risk of medication errors is to limit the number of different drug formulations and concentrations available. The fewer choices available to us, the lower the chance we will choose the wrong one. The blood thinner heparin is routinely used to keep intravenous (IV) lines open. Having concentrated heparin

available in patient care areas and relying on nurses to dilute it for flushing IV lines runs the risk that the wrong concentration will be chosen or that the dilution will be incorrect. Heparin overdoses are extremely dangerous and can result in uncontrolled bleeding or death. A safer practice is to eliminate heparin vials in patient care areas and to use only pre-diluted heparin flush syringes for flushing IV lines.

We asked healthcare facilities if they have removed heparin vials from patient care areas and adopted pre-filled heparin flush syringes.

The majority of hospitals indicated that they have adopted this practice throughout their

organization (59%), and 81% report at least partial adoption in some areas. Nearly one in five (19%) have not adopted this practice. Among ASFs and other facilities, 22% report full or partial implementation, with 78% reporting that they have not implemented this practice. (See Figure 10)

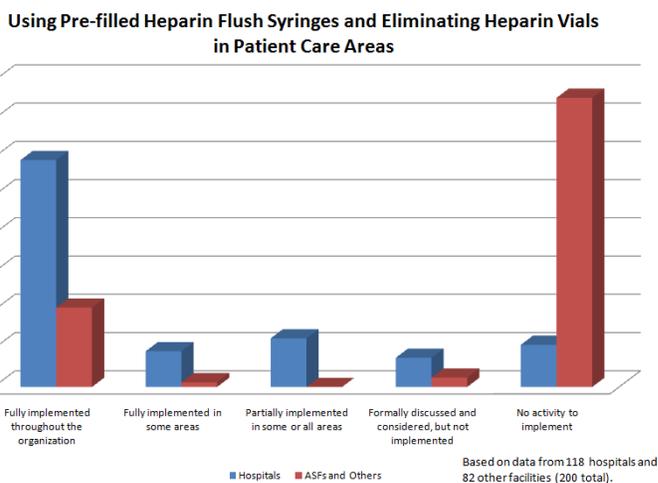


Figure 10.

Propofol Infusion Syndrome

Propofol is an intravenous anesthetic commonly used in both inpatient and outpatient surgeries, and it is used as a sedative for treatment of agitation in mechanically ventilated patients in intensive care units (ICUs). Pennsylvania facilities have submitted reports to the Authority involving propofol infusion syndrome (PRIS), a rare, potentially fatal complication from propofol. It is usually associated with high doses of propofol (greater than 5 mg/kg/hr) for prolonged periods (greater than 48 hours). We asked Pennsylvania healthcare facilities about whether they assess patients prescribed propofol for their risk or PRIS.

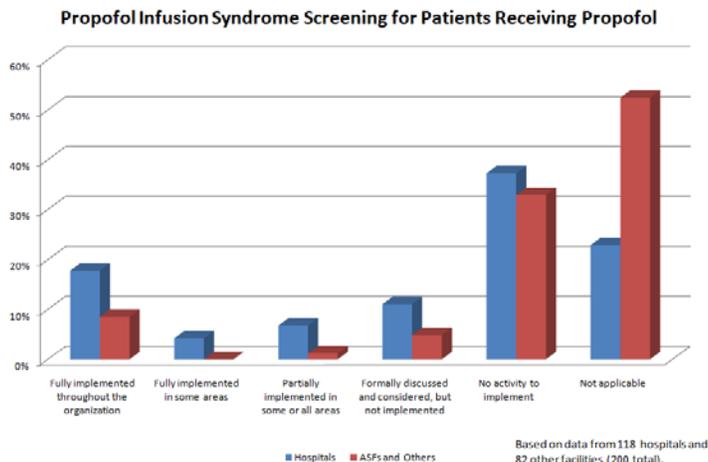


Figure 11.

Twenty-nine percent (29%) of responding hospitals report at least partial implementation of screening for PRIS, while 48% have not instituted screening, and 23% felt this measure was not applicable. Since many patients in other settings (ASFs, birthing centers and abortion facilities) do not receive infusions of propofol over an extended period, a majority of those respondents reported that this measure (52%) was not applicable to those organizations. However, 10% of these facilities did report full or partial implementation. (See Figure 11)

Telephone and Verbal Medication Orders

Verbal orders—those spoken aloud in person or by telephone—offer more room for error than orders that are written or sent electronically. Interpreting speech can be a problem because of different accents, dialects and pronunciations. Background noise, interruptions, and unfamiliar drug names and terminology often increase the problem. Once received, a verbal order must be written down, adding another step to this process and increasing

the risk of error. Medications with sound-alike names also affect the accuracy of verbal orders. There have been numerous reports submitted to the Authority in which drug name pairs have been misheard.

A national accrediting organization, the Joint Commission, established a National Patient Safety Goal to address the error-prone procedure of verbal orders. Their goal states that the receiver of the verbal or telephone order should write down the complete order or enter it into a computer, then read it back, and receive confirmation from the individual who gave the order or test result. We asked Pennsylvania facilities if they had established explicit,

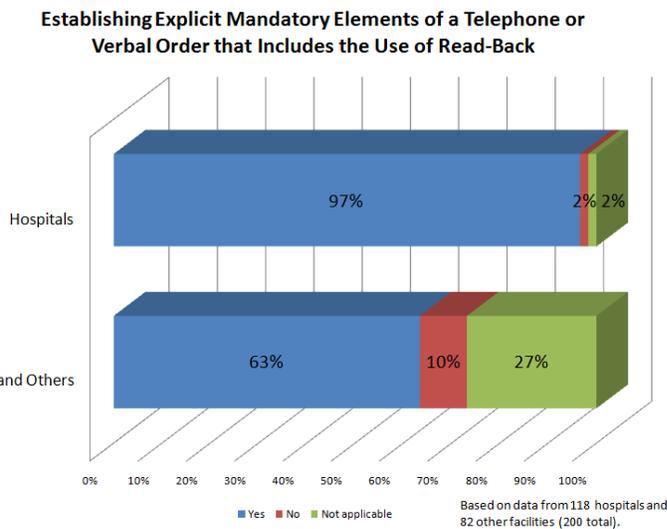


Figure 12.

mandatory elements of a telephone or verbal order that includes the use of read-back. Almost all responding hospitals (97%) indicated they have implemented this process. In addition, a majority of other reporting facilities (63%) indicated that they use this process as well. (See Figure 12)

Assessment for Topical Skin Patches in the Emergency Department

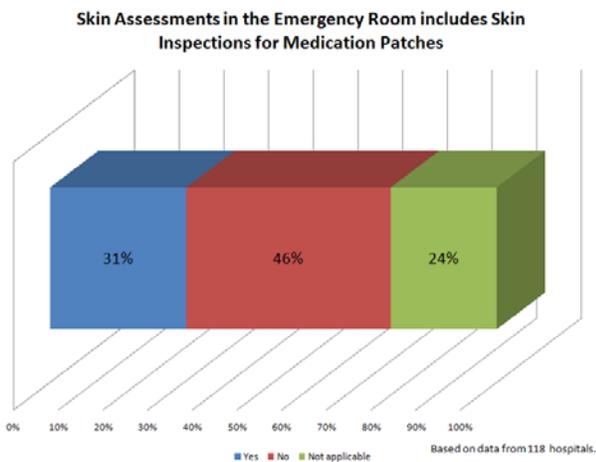


Figure 13.

The number of medications and the ways in which they can be administered have expanded dramatically over the years. One such advance has been the development of transdermal patch delivery systems. These medication-containing patches release active ingredients that are absorbed through the skin. Examples of medications available in patch form include nicotine replacement patches for smoking cessation, drugs for blood pressure, pain killers and drugs to prevent motion sickness. Medication error reports submitted to the Authority and reports from national databases include many examples of practitioners applying new patches without removing the old patch, which continues to deliver medication. While all of the drugs mentioned above have been cited in reports to the Authority, errors associated with the use of fentanyl (DURAGESIC®)

patches pose the greatest risk of harm. Fentanyl is considered a high-alert medication. While not necessarily more prone to error, if an error does occur, there is a greater risk of patient harm or death. However, the Authority has received numerous reports of multiple fentanyl patches being found on patients.

We asked Pennsylvania healthcare facilities if they had policies in place to look at a patient’s skin for medication patches when they are admitted into their emergency department (ED). Among hospitals, about one-third (31%) report that skin assessments in the ED include inspections for transdermal patches. Nearly half of hospitals (46%) have not done so, and another 24% reported that this measure was not applicable as not all hospitals have an ED. (See Figure 13)

Removal of Sterile Water for Injection from Patient Care Areas

Severe hypernatremia, a high level of sodium in the blood, can be challenging to treat, especially in patients with high blood sugars which may seem to limit treatment options. Unfortunately, some healthcare practitioners have failed to recognize the danger of infusing plain sterile water intravenously to treat this condition. Administering sterile water by direct IV infusion can lead to hemolysis or breaking open of red blood cells. There have also been cases reported to the Authority of accidental use of sterile water for injection. For example, bags of sterile water for injection and inhalation have been mistaken for other IV solutions when they are stocked on patient care units. We asked facilities whether they have removed sterile water from patient care areas to prevent accidental IV administration. The majority of hospitals (64%) have fully implemented this practice throughout their facility, and 78% report at least partial implementation. One in five hospitals (22%) have not implemented this practice. Nearly half (48%) of ASFs and other facilities also reported at least partial implementation. (See Figure 14)

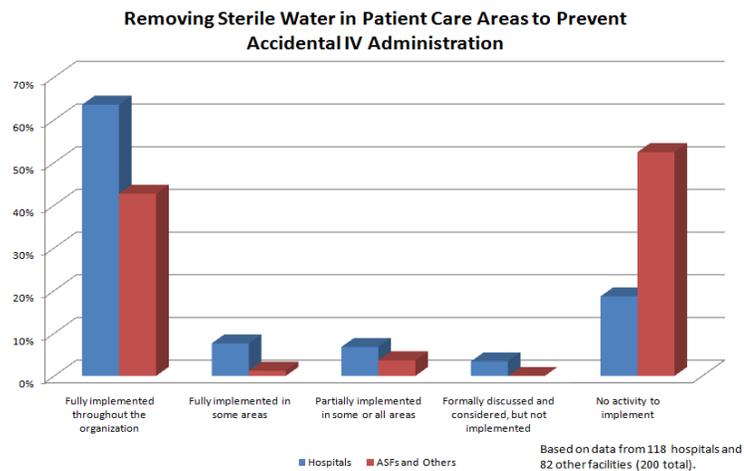


Figure 14.

Segregation of Insulin Syringes

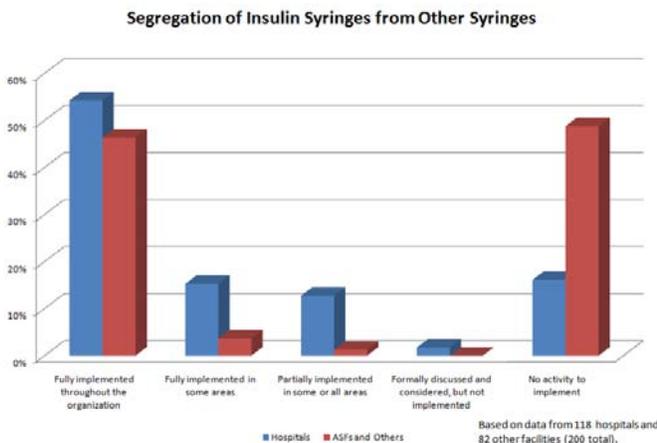


Figure 15.

For patients who require insulin to treat diabetes, special insulin syringes are used to withdraw the medication from a vial. Vaccines, on the other hand, are administered with a small syringe, often referred to as a “tuberculin” (TB) syringe. Unfortunately, the Authority has received several reports describing errors in which TB syringes were used in place of insulin syringes. One reason for the error may have been the resemblance in packaging of the TB syringe and the insulin syringe. The TB syringe is packaged in a white wrapper with black and orange print with an orange plunger tip—the same color used for many years on insulin syringes. A mix-up between these two syringes can lead to a 10-fold overdose of insulin. For example, in one report, a

nurse selected a TB syringe instead of an insulin syringe, intended to give 9 units of insulin, but gave 0.9 mL, which equaled **90 units** of insulin, and resulted in a 10-fold overdose.

We asked facilities if they physically segregated insulin syringes from all other syringes in the pharmacy and on patient care units. Fifty-four percent (54%) of responding hospitals stated that this action was fully implemented, with 82% reporting at least partial implementation in some areas. Nearly one in five hospitals (18%) has not implemented this practice. More than half of ASFs and other facilities (51%) report full or partial implementation.

Reports to the Authority

Reports submitted to the Authority that are labeled as problems related to “Medication Error” have consistently been one of the largest percentage of reports overall, generally about 25%. (See Table 1) However, a lower percentage of medication errors are reported as Serious Events than any other event type. “Adverse Drug Reaction” is another event type Pennsylvania healthcare facilities use to report medication-related events.

The Authority received 48,630 reports in 2008 that the reporting organization classified as a Medication Error. A majority of these reports did not harm the patient (99.3%), but there were 319 cases reported as a Serious Event, representing 0.7% of all medication error reports. The most common types of medication errors submitted were drug omissions (23.5%), wrong drug (9.6%) and wrong dose/over dosage (8.1%). The event types involved in most Serious Events were wrong dose/over dosage (25.1%), wrong drug (14.7%) and “other” (9.4%).

Table 1. Reports Classified as Medication Error (2008)

Event Type	Subcategory	Number	%
1. Dose Omission		11,443	23.5%
2. Extra dose		3,369	6.9%
3. Wrong	a. Dose/over dosage	3,932	8.1%
	b. Dose/under dosage	2,374	4.9%
	c. Drug	4,680	9.6%
	d. Dosage form	581	1.2%
	e. Duration	522	1.1%
	f. Rate (IV)	1,110	2.3%
	g. Route	1,296	2.7%
	h. Strength/concentration	705	1.4%
	i. Technique	417	0.9%
	j. Time	2,349	4.8%
	k. Patient	2,298	4.7%
4. Prescription/refill delayed		1,390	2.9%
5. Medication list incorrect		1,754	3.6%
6. Monitoring error (includes contraindicated drugs)	a. Drug-drug interaction	138	0.3%
	b. Drug-food/nutrient interaction	2	0.0%
	c. Documented allergy	1,092	2.2%
	d. Drug-disease interaction	29	0.1%
	e. Clinical (lab value, vital sign)	655	1.3%
	f. Deteriorated drug/biologic	19	0.0%
	g. Contaminated drug/biologic	6	0.0%
	h. Other (specify)	197	0.4%
7. Unauthorized drug		1,322	2.7%
8. Inadequate pain management		54	0.1%
9. Other		6,896	14.2%
Total		48,630	100.0%

Case Study: Medication Errors Associated with Known Patient Allergies

Problem: In the September 2008 issue of the *Pennsylvania Patient Safety Advisory* we published on a number of reports in which patients received a medication to which they were allergic. More than 3,800 cases had been submitted since reporting began in June 2004. Issues that led to patients receiving a medication to which they were allergic included:

- Breakdowns in patient information, in which the patient's allergy was not known to the prescriber, pharmacist or nurse at the time of prescribing, dispensing or administering.
- Breakdowns in drug information, in which critical drug information, including information regarding drug-drug contraindications and cross allergies, is not available at the time of prescribing, dispensing or administration.

Solutions: Current, complete, and accurate allergy information is critical to reduce the risk of inappropriate drug selection. To improve the collection of allergy information, documentation, communication and maintenance, organizations can consider the following:

- Standardizing locations to document and retrieve complete allergy information, including description of the reaction(s).
- Developing a process to make sure updates to allergy information is documented if the patient's allergies change, and establishing a process to verify and update archived allergy information upon each readmission or patient encounter.
- Upon admission to a facility, documenting patient allergies, *as well as a description of the reaction to the allergen*, and if possible, the date that the reaction took place on all admission order forms.
- Making the allergy reaction selection a mandatory entry in the organization's order-entry systems for prescribers and pharmacists.
- Eliminating the practice of writing drug allergens on allergy wristbands. Instead, have the single red allergy bracelet act as an "alert" to the practitioner, identifying at the point of care that the patient *has an allergy*, requiring further investigation of the patient, medical record and MAR.

For more information, see *Medication Errors Associated with Documented Allergies (Sep 2008)*.

Recent Advisory Articles Related to Medication Safety

[Medication Errors Occurring with the Use of Bar-Code Administration Technology](#)

(Dec 2008)—Medication errors in organizations that use bar-code systems for administration can result from failures to use this technology appropriately.

[Anticoagulation Management Service: Safer Care, Maximizing Outcomes](#) (Sep 2008)—

Healthcare organizations have increasingly recognized the benefits of anticoagulation services in the inpatient and outpatient settings.

[Hazardous Spills: The Safe Handling of Hazardous Drugs](#) (Sep 2008)—

Safe handling of hazardous drug spills is different from other healthcare spills. Exposure extends beyond patients and healthcare practitioners when nonclinical staff are involved with containment and disposal.

[Sterile Water Should Not be Given Freely](#) (Jun 2008)—

Sterile water is hypotonic. Serious patient harm, including hemolysis, can result when it is administered by direct intravenous infusion.

[Icodextrin in Peritoneal Dialysis Solution May Cause Falsely High Blood Glucose Readings](#) (Jun 2008)—

Blood containing maltose, galactose or xylose can falsely elevate results from point-of-care glucose meters using a particular enzyme/indicator test method.

[Dangers Associated with Shared Multidose Vials](#) (Jun 2008)—

As recent national news has illustrated, multidose vial use in any patient care area is risky, with an ever-present danger for iatrogenic cross-contamination.

[Medication Assessment: One Determinant of Falls Risk](#) (Mar 2008)—

The absence of assessments may result in patients who are at risk for falls receiving medications that increase falls risk.

Safe Surgery

The vast majority of surgical procedures in Pennsylvania hospitals and ambulatory surgical facilities (ASFs) each year are performed safely and result in improved quality of life for the patients who undergo them. However, even simple surgical procedures involve many complex steps, each with the potential to fail and cause unintended injury. For example, based on reports submitted by Pennsylvania hospitals and ASFs, the Patient Safety Authority estimates that:

- One out of every 40,000 surgical procedures may involve an unintended retained foreign body, such as a surgical sponge, needle or other instrument.
- One of every 52,000 procedures may involve surgery on the wrong patient, the wrong body part or performing the wrong procedure.
- One of every 88,000 procedures may involve a surgical fire.⁵

While these events are rare, they are almost always preventable, and surgical teams must take steps before and during each procedure to ensure they do not occur. While patients must accept the risk inherent in all procedures that their disease or condition may not be cured, they should not have to accept the risk of these avoidable adverse events.

Safe Surgery Indicators

Consent Forms for Surgical Procedures

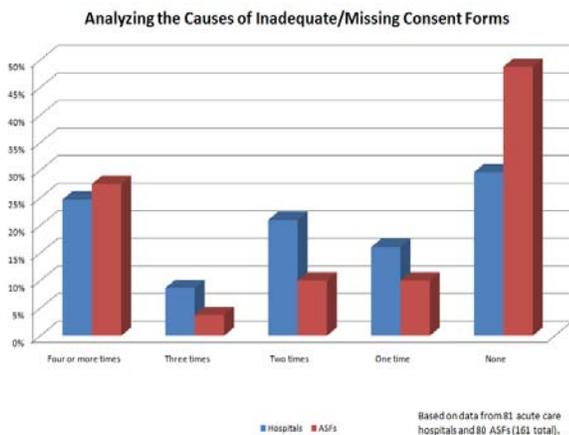


Figure 16.

Before undergoing surgery, the patient must give their informed consent for the procedure. Giving informed consent means that the patient has been fully informed of their diagnosis, the type of procedure, the risks and benefits of the procedure, and any alternatives to the procedure. Prior to surgery, the patient signs a consent form. A surgical consent form is essentially a permit for surgery and documents that the patient (or their representative) has granted permission to proceed. The consent form is also used as one source of information about the procedure for the healthcare team. This indicator does not look at the adequacy of the consent discussion, but focuses on the consent form as an information tool.

Inadequate or missing consent forms for surgical procedures are a potential source of error during the surgical process. Reasons that a consent form may be inadequate include when the side for the surgical procedure isn't included or is listed incorrectly. A consent form may be missing if the surgeon's office does not send the consent form to the hospital or the consent form is placed on another patient's chart. An inadequate or missing consent form is a risk to patient safety because the patient may have the wrong surgical procedure or a surgical procedure on the wrong side or body site. We asked Pennsylvania facilities if they have analyzed the cause of an inadequate or missing surgical consent form during the past year. Seventy percent (70%) of responding acute care hospitals and 51% of ambulatory surgical facilities have evaluated the causes of inadequate or missing consent forms at

⁵ Three "never complications of surgery" are hardly that. *PA PSRS Patient Saf Advis* 2007 Sep:4(3):82.

least once over the past year. Almost a third of acute care hospitals (30%) and about half (49%) of ambulatory surgical facilities have not done so over the past year. (See Figure 16)

Prohibition of Unlabeled Basins, Bowls and Cups in Procedure Areas

During a surgical procedure, many containers, such as basins, bowls or cups, are placed in the surrounding area. Errors may occur if medications and/or other solutions are removed from their original containers and placed in unlabeled containers. For this reason, many facilities do not allow staff to use unlabeled basins, bowls and cups in the operating room or in any area where an invasive procedure is performed. This process helps to reduce the risk that unidentified drugs and/or solutions are used in error. We asked Pennsylvania facilities whether unlabeled basins, bowls and cups are prohibited in the operating room or in any area where invasive procedures may be performed. Nearly all hospitals (96%) have at least partially implemented this measure, and the majority of them (80%) have fully implemented it throughout the organization. The practice has also been adopted in ASFs, with 76% reporting full implementation, and the remaining 24% reporting that the measure has not been implemented. (See Figure 17)

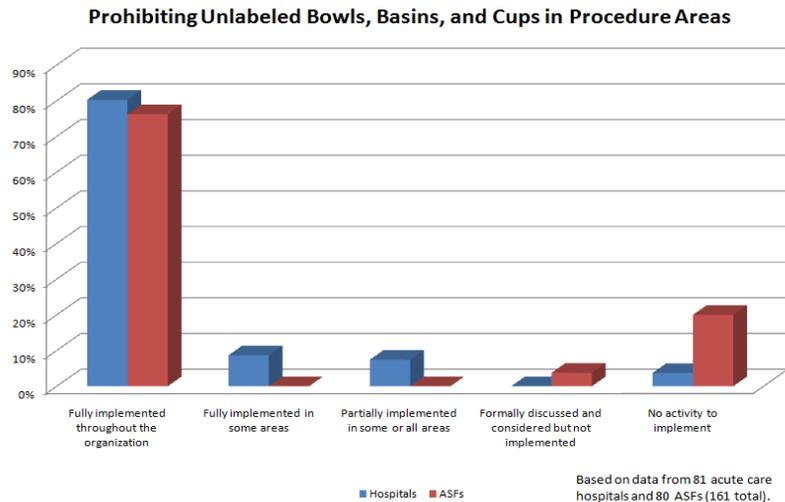


Figure 17.

Including Latex Sensitivity on the OR Pre-operative Checklist

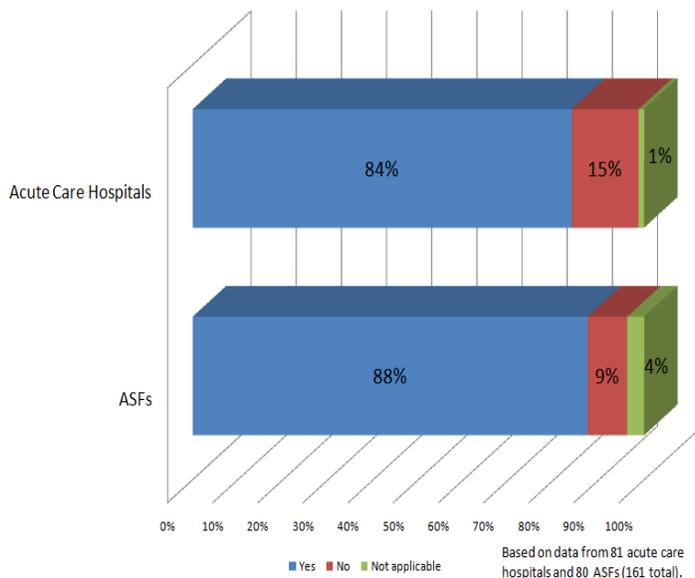


Figure 18.

OR Checklist Including Verification of Latex Sensitivity

Latex is found in many consumer products from household items to toys. Many devices and supplies in the OR also may contain latex, such as adhesive tape, gloves, oxygen masks and syringes. Reactions to latex range from mild, such as a skin rash or itching, to severe, such as shock leading to cardiac or respiratory failure. Surgical procedures may cause some of the most severe reactions to latex because latex comes into direct contact with moist areas of the body and internal surfaces. One way to keep patients with latex sensitivity safe in the OR is to verify if a patient has a latex sensitivity prior to the surgical procedure. This can be accomplished by including latex sensitivity on a preoperative checklist. When the sensitivity is identified measures can be taken to avoid the use of latex in the OR.

We asked Pennsylvania facilities if their organization’s OR check list included verification of latex sensitivity. The majority of acute care hospitals (84%) and ASFs (88%) do include latex sensitivity on their OR checklist. Only 15% of hospitals and 9% of ASFs do not include this information on their OR checklists. (See Figure 18)

Sponge, Sharps and Instrument Counts in Interventional Radiology

Many sponges (gauze pads), sharps (i.e., surgical blades and needles) and instruments (i.e., scissors, forceps) are typically used during a surgical procedure. Leaving a sponge, sharp or instrument inside of a patient who undergoes a surgical procedure may cause serious patient harm. These items may be left in a patient during procedures in the OR and following minimally invasive procedures performed outside of the OR, such as in interventional radiology.

Minimally invasive procedures such as biopsies, varicose vein treatments, and treatments to restore blocked blood flow to the legs typically involve small incisions. Even though the incision is small, an item, such as a sponge, may be left behind. Counting sponges, sharps and instruments before, during and after any procedure involving an incision or a puncture of the skin is an established way to prevent these items from being left inside of a patient. While these counts are routine for more invasive surgery, we asked Pennsylvania facilities if sponge, sharps and instrument counts are performed before, during and after each invasive interventional radiology procedure. A third (46%) of participating acute care hospitals perform these counts, a quarter (25%) of hospitals do not, and 30% reported that this measure is not applicable. The majority (75%) of ambulatory surgical facilities reported that this measure is not applicable to their facility, while 22% report that they do perform these counts. (See Figure 19)

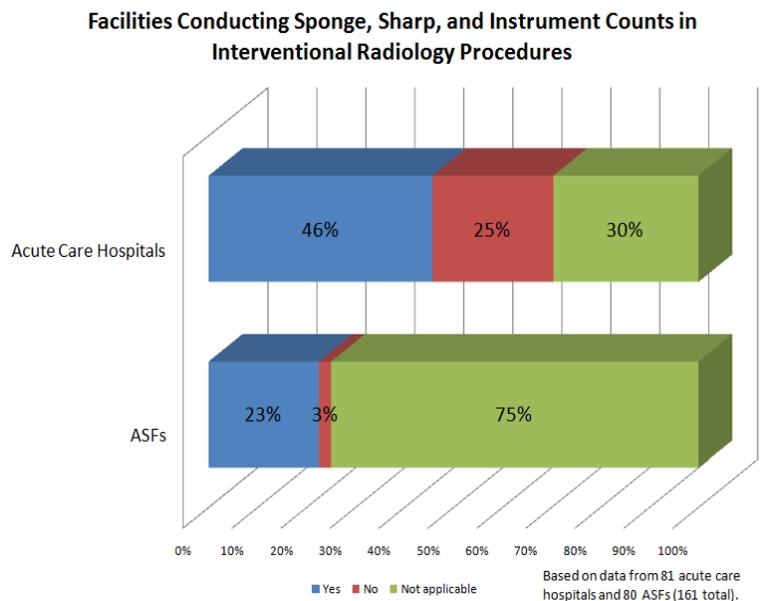


Figure 19.

Identification of the Surgical Site and Side

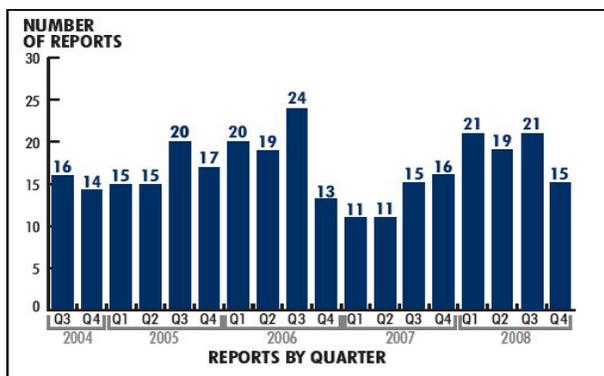


Figure 20.

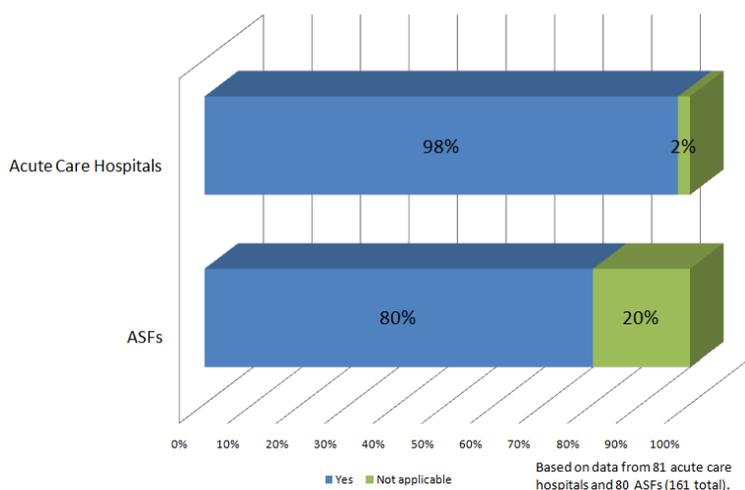
Wrong-site surgery involves all surgical procedures performed on the wrong patient, wrong body part, wrong side of the body, or wrong level of a site, such as the spine. Wrong-site surgery happens once a week in Pennsylvania. Over a 51-month period, 286 reports of wrong-site surgeries were submitted to the Authority—about one every five to six days. Overall, 76 wrong-site surgeries have been reported during 2008.⁶ These figures do not include near misses that were corrected before the patient was harmed. (See Figure 20)

⁶ Quarterly update on preventing wrong site surgery. *Pa Patient Saf Advis* 2009 Mar:6(1):33-35.

From August 2007 through August 2008, Pennsylvania facilities were asked to contribute to a statewide initiative to prevent wrong-site surgery by completing a detailed assessment form about events involving wrong-site surgery. Based on information submitted by facilities, we learned that the greatest potential for system improvement to prevent wrong-site surgery is compliance with the Universal Protocol, which involves standardized steps in the OR process, and radiologic (x-ray) confirmation of the correct level during spinal surgery.⁷ Incorrect information communicated when scheduling a procedure, sometimes included on the consent or in the history and physical may also be a patient safety risk.

Based on observations we have done at volunteer Pennsylvania facilities, we noted considerable variation in how the Universal Protocol has been implemented—how perioperative information is verified, how operative sites are marked, and how time outs are done—and all of the other steps of taking a patient through the OR, including scheduling the procedure.

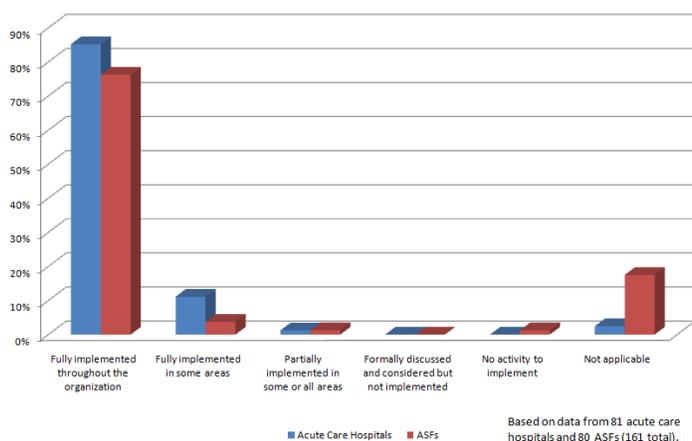
Facilities Requiring Patient Involvement in Site Confirmation and Site Making Prior to Sedation



We asked Pennsylvania facilities if their organization requires the patient’s (or their representative) involvement in marking the surgical site and that the site marking was done prior to sedating the patient. Almost all participating hospitals (98%) have implemented these measures, while the remaining 2% reported that this measure is not applicable to their facility. While 80% of ASFs have implemented this measure, 20% reported the measure is not applicable to their facility. (See Figure 21)

Figure 21.

Indicating Surgical Site/Side When Scheduling a Procedure



We also asked if the surgical site and side if applicable is indicated and documented at the time of scheduling an operating room for a procedure. Eighty-five percent (85%) of participating acute care hospitals report fully implementing this measure, and 11% report implementing it in some areas of the hospital. Among ASFs, 76% have fully implemented this measure, 4% have implemented the measure in some areas, and 18% reported this measure does not apply to their facility. (See Figure 22)

Figure 22.

⁷ Joint Commission. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery [online]. 2003 [cited 2007 Oct 31]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf.

World Health Organization Surgical Safety Checklist

To help promote surgical safety, the World Health Organization (WHO) developed a Surgical Safety Checklist to help ensure that OR teams consistently follow critical safety steps in the surgical process.⁸ The goal of the checklist is to minimize the most common and avoidable risks that may endanger surgical patients. When this checklist was pilot tested in eight hospitals in cities around the world, the rate of death decreased from 1.5% to 0.8%, and the rate of complications decreased from 11% to 7%.⁹ We asked Pennsylvania facilities if their organization uses the WHO Surgical Safety Checklist. Over two-thirds of participating hospitals (68%) do not use the WHO Surgical Safety Checklist, while 30% do use the checklist at their facility. Thirty-nine percent (39%) of ASFs use the WHO Surgical Safety Checklist and 44% do not use the checklist in their facility. Two percent (2%) of hospitals and 18% of ASFs do not consider the checklist applicable to their facility. (See Figure 23)

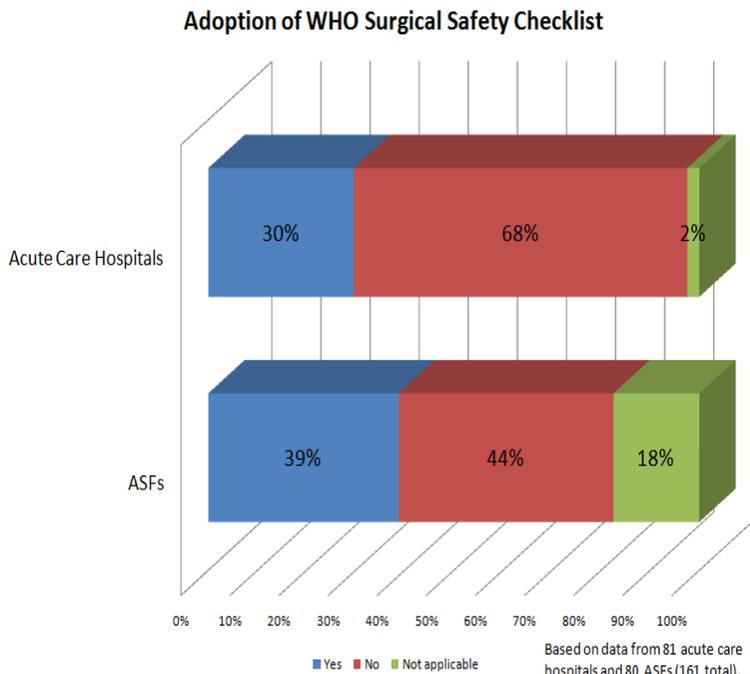


Figure 23.

Reports to the Authority

Reports submitted to the Authority that are labeled as “Errors Related to Procedures/Treatments/Tests” are a large percentage of reports overall, representing 23% of overall reports submitted in 2008. Events related to surgery and invasive procedures are the second largest category of events reported under this event type. The Authority received 9,792 reports in 2008 that were classified as errors related to a surgery or invasive procedure (see Table 2). Problems related to surgery and invasive procedures have great potential to result in harm to a patient. Examples of these types of events include surgery performed on the wrong side of the body and the retention of a foreign object after surgery, such as a surgical sponge (gauze) or an instrument.

⁸ World Health Organization Surgical Safety Checklist. First Edition [online]. [cited 2009 Feb 25]. Available from Internet: http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf.

⁹ Hanes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *NEJM* 2009 Jan 29;5(360):491-9.

Table 2. Reports Classified as Problems with Surgery/Invasive Procedures (2008)

Category	Number	%
Break in sterile technique	327	3.3%
Consent missing / inadequate	1322	13.5%
Count incomplete / not performed	366	3.7%
Count incorrect - Needles	1042	10.6%
Count incorrect – Sponges	454	4.6%
Count incorrect – Equipment	732	7.5%
Foreign body in patient	194	2.0%
Preparation inadequate / wrong	343	3.5%
Procedure not ordered	111	1.1%
Procedure cancelled or not performed	1574	16.1%
Procedure delayed	733	7.5%
Procedure not completed	153	1.6%
Unintended laceration or puncture	494	5.0%
Wrong procedure	27	0.3%
Wrong patient	91	0.9%
ID missing / incorrect	227	2.3%
Wrong site	48	0.5%
Wrong side (L vs R)	80	0.8%
Other Surgery/invasive procedure problem	1474	15.1%
Total	9792	100%

Wrong-site surgery is considered a “never event,” which means that it is an event that is considered preventable. Wrong-site surgery may have devastating consequences for a patient. The Authority received 246 reports in 2008 about problems related to the wrong procedure, patient, site or side. Of these reports, 76 indicated a wrong-site operative procedure reached the patient.

Another type of event that can cause serious harm is the retention of a foreign object, when a sponge, sharp or instrument is left in a patient’s body following surgery. The Authority received 194 reports of a retained foreign object in 2008. The most frequently reported retained foreign objects are instruments, with retained sponges reported almost as frequently. Guidewires, used to help insert a catheter (tube) into a blood vessel, are the most frequently reported retained instrument. Retained sponges have been found in many areas of the body, including the chest, abdomen, vagina and wounds of the extremities. Of the reports related to a retained foreign object in 2008, 84 (43%) were discovered after the patient left the OR.

Case Study: Perioperative Hypothermia

Problem: In the March 2008 issue of the *Pennsylvania Patient Safety Advisory*, we published an article on over 50 reports about patients experiencing hypothermia in the operating room. Hypothermia is defined as a core body temperature of less than 36°C (96.8°F). Patients can develop hypothermia during surgery as a result of factors in the operating room environment or the response of the body to anesthetic agents. Mild hypothermia may be planned and has been shown to be beneficial after cardiac arrest and may lower intracranial pressure after traumatic brain injury. However, unplanned perioperative hypothermia is associated with serious complications involving circulation of blood, coagulation, wound healing and drug metabolism.

Factors in the operative environment that may lead to unplanned hypothermia included:

- Exposure of a large body surface area to the typical low temperature and humidity in the OR environment;
- Administration of cold intravenous (IV) fluids;
- Evaporation of body fluids from surgical sites;
- Administration of unwarmed irrigation fluid; and
- Use of certain skin preparation methods that result in evaporation.

Certain patients may be at increased risk of developing hypothermia before, during or after a surgical procedure, including older adults, neonates, infants and children. The event data showed that in the majority of reports of hypothermia in the operating room interventions to prevent hypothermia were not in place.

Solution: To prevent hypothermia, the body's heat loss must be balanced with heat gained either from the body's own heat production or from an external source. There are a number of strategies that may be used to prevent hypothermia including:

- Minimizing skin exposure by covering body parts not involved in the surgery;
- Pre-warming the patient for 15 minutes immediately prior to administration of anesthesia;
- The use of passive insulation, which includes cotton blankets, surgical drapes and plastic drapes;
- The use of active warming devices, such as forced air, circulating water and electric blankets;
- Warming of blood, IV and irrigation fluids; and
- Monitoring of the patient's temperature on a continuous basis before, during and after the surgical procedure.

Recent Advisory Articles Related to Safe Surgery

[Surgical Site Markers: Putting Your Mark on Patient Safety](#) (Dec 2008)—Review of pen performance and sterility may provide insight for evaluating surgical site marking pens.

[Malignant Hyperthermia: Is Your Facility Prepared to Treat This Rare Condition?](#) (Sep 2008)—While occurrence of malignant hyperthermia is rare, the need for rapid response requires planning and advance preparation.

[Prevention of Inadvertent Perioperative Hypothermia](#) (Jun 2008)—Hypothermia may occur in any patient and may result in serious complications affecting the cardiovascular system, coagulation, and wound infection and healing.

[Colon Perforations Complicating Colonoscopies: What is the Best Known Evidence for Prevention?](#) (Jun 2008)—Identifying modifiable risk factors associated with colon perforation during colonoscopy could lead to fewer perforations.

[Preventing the Retention of Foreign Objects during Interventional Radiology Procedures](#) (Mar 2008)—Despite the minimally invasive nature of interventional radiology procedures, foreign objects may still be retained.

[Reducing Complications from Interscalene Blocks](#) (Dec 2007)—This anesthetic technique has many advantages, but it is associated with certain complications, such as seizure and arrhythmia. Specific risk reduction strategies before, during, and after ISB may help patients realize the benefits of ISB without the associated complications.

[Three Never Complications of Surgery Are Hardly That](#) (Sep 2007)—When undergoing an operation, a patient should never have to accept these three complications as risks of surgery.

Hypothermia may occur in any patient and may result in serious postoperative complications. Fortunately, a number of methods are available to detect and prevent hypothermia, allowing the prevention of perioperative hypothermia to be an obtainable goal.

For more information, see “**Prevention of Inadvertent Perioperative Hypothermia**” (Jun 2008).

Healthcare-Associated Infections

Healthcare-associated infections (HAIs) compromise patient safety at varying levels and account for billions of dollars in unanticipated medical costs in the United States. These infections remain one of the most significant public health challenges.¹⁰ During 2007, the Pennsylvania Health Care Cost Containment Council (PHC4) noted that acute care hospitals reported 27,949 patients who contracted an infection during their hospitalization, a rate of 17.7 per 1,000 cases which is a 7.8 percent decrease from the 19.2 per 1,000 cases reported for 2006.¹¹

In July 2007, legislation was signed into law as Act 52 to prevent and reduce healthcare-associated infections in hospitals and nursing homes. The Pennsylvania Patient Safety Authority has been working with the various healthcare agencies (Pennsylvania Department of Health, Pennsylvania Healthcare Cost Containment Council and the Centers for Disease Control and Prevention) since then to implement the new law and move toward eradicating all HAI in Pennsylvania. Act 52 of 2007 requires the Authority to perform a significant amount of activities to support healthcare-associated infection elimination efforts. Many of these activities are related to preparing for HAI reporting by nursing homes.

Key provisions of the bill include the following.

Hospitals must:

- Develop infection control plans outlining the steps they will take to prevent and reduce infections.
- Educate healthcare workers as to how they can prevent infections.
- Screen high-risk populations for methicillin-resistant *Staphylococcus aureus* (MRSA), a type of infection that cannot be cured with many available antibiotics.
- Report infections to the Patient Safety Authority, Department of Health (DOH), and the Pennsylvania Healthcare Cost Containment Council (PHC4), through the CDC’s National Health Safety Network (NHSN).

Nursing Homes must:

- Develop infection control plans
- Submit reports of HAI events to the Authority and the Department of Health

Act 52 of 2007 also requires the Department of Health to set risk-adjusted benchmarks for the purpose of data comparison, which will be introduced in 2009.

While the Authority, PHC4 and DOH all have access to NHSN data, DOH, as the regulating agency, is working with hospitals on data integrity and fixing identifiable reporting errors. To this end, DOH sent a series of reports to the hospitals identifying HAI reports submitted from July 1, 2008 through December 31, 2008 that needed

¹⁰ McKibben L, Horan T, Tokars JI, et al. Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. *Am J Infect Control* 2005 May;33(4):217-26.

¹¹ Hospital Acquired Infections in Pennsylvania: Annual Report 2007 [Cited 2009 Mar 3]. Available from Internet: <http://www.phc4.org/reports/hai/07/docs/hai2007report.pdf>.

modification. This activity was completed in April 2009. At this point, DOH locked down the data. It is this data that is presented in the Authority's annual report. As the Authority has just received this information, we are now beginning to perform more detailed analyses that will lead to additional educational opportunities. We will publish the results of some of these analyses in future issues of the *Pennsylvania Patient Safety Advisory*.

Hospitals entered a total of 18,307 HAI events into the NHSN database between July 1 and December 31, 2008. The DOH infections and report totals are included in Table 3.

Table 3. Pennsylvania DOH Report of NHSN Data, July 1 to December 31, 2008

Events	Total
Urinary tract infection	7,721
Surgical site infection	3,126
Gastrointestinal infection	2,563
Bloodstream infection	1,990
Pneumonia	1,493
Skin and soft tissue infection	454
Lower respiratory tract infection (other than pneumonia)	421
Eye, ear, nose, throat or mouth infection	354
Cardiovascular system infection	77
Reproductive tract infection	62
Central nervous system infection	38
Bone and joint infection	7
Systemic infection	1
Grand Total	18,307

This information and data in this report is not comparable to the Authority's 2007 annual report nor is it comparable to other Pennsylvania HAI data sources. For example, PHC4's annual HAI reports differ because facility and infection types vary between PHC4 data collection and what is currently being reported by hospitals through NHSN as a result of Act 52 of 2007.

The following hospital types are included in NHSN reporting: all acute care hospitals, children's hospitals, long-term care hospitals, psychiatric hospitals, and rehabilitation hospitals. The PHC4 data is limited to acute care hospitals.

In addition, current reporting through NHSN includes more types of HAI reporting that was collected previously by PHC4.

PHC4 HAI reports **do not** include the following HAI events:

- Cases for children less than or equal to 1 year of age
- Cases assigned to major diagnostic category (MDC) 19 Mental Diseases and Disorders or MDC 20 Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders
- Cases with burns
- Cases with organ transplants or complications of transplants
- Any HAIs identified as:
 - systemic infections
 - eye, ear, nose, throat, or mouth infections, including upper respiratory infections
 - surgical site infections identified during readmissions

DOH, in consultation with the Authority and PHC4 developed calculation/benchmarking areas which include catheter-associated urinary tract infections (CAUTIs), central line-associated blood stream infections (CLABSIs), and select surgical site infections (abdominal hysterectomy, cardiac surgery, and hip and knee replacements).

The Authority looks forward to future DOH data reports to include CAUTIs and CLABSIs rates, select cardiac surgeries and device-associated infections.

Infection Prevention Measures

Patient Safety Committee Involvement in HAI Prevention

Traditionally, HAI prevention in many healthcare facilities has not been well integrated into broader patient safety activities, and one of the goals of Act 52 of 2007 was to clarify that HAIs were considered Serious Events under the MCare Act. Our survey uncovered evidence that, at least in Pennsylvania, HAIs are seen as a patient safety concern and that the separate “silos” of infection prevention and patient safety may be less prevalent. We asked participants whether the Patient Safety Committee reviews data or reports on healthcare-associated infections. The overwhelming majority of facilities (almost 93%) responded positively that HAIs are reviewed by their Patient Safety Committee. Only seven hospitals and one ASF responded negatively to this question. (See Figure 24)

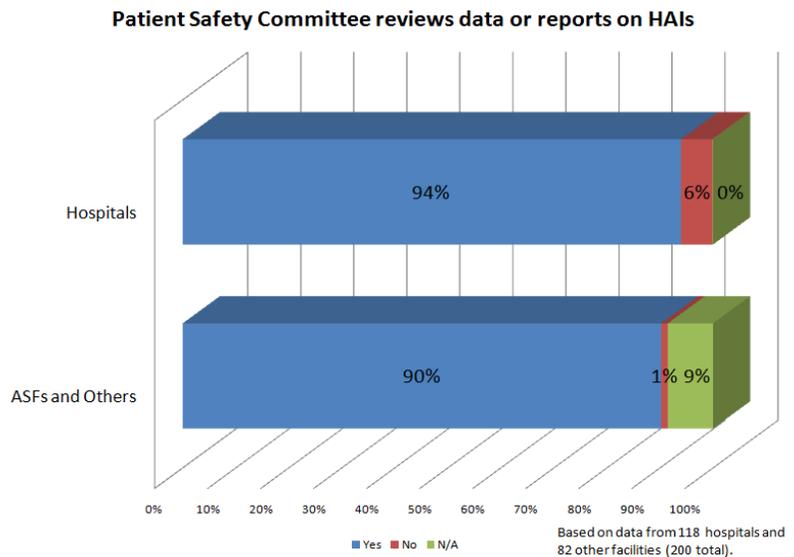


Figure 24.

Inspection Frequency of Handwashing and Sterile Supplies

The single most important thing healthcare workers can do to reduce infections is to consistently and reliably wash their hands. For busy practitioners caring for multiple patients, this can mean washing your hands 60 to 100 times a day. A frequent complaint of healthcare workers, and a reason they often cite for failing to wash their hands or to use necessary sterile precautions, is that the necessary supplies were unavailable. We asked participating facilities whether their formal Infection Control Plan specifies the inspection frequency of patient care areas for handwashing capabilities and availability of other supplies such as full alcohol hand rub dispensers, gloves and gowns. Overall, 79% of facilities specify how often supplies should be inspected to enable healthcare workers to wash their hands and use sterile supplies when necessary. (See Figure 25)

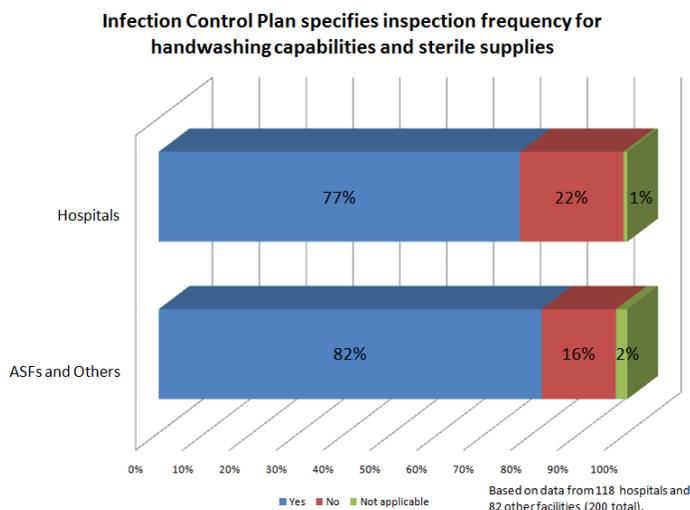


Figure 25.

Written Patient Information about Hand Hygiene

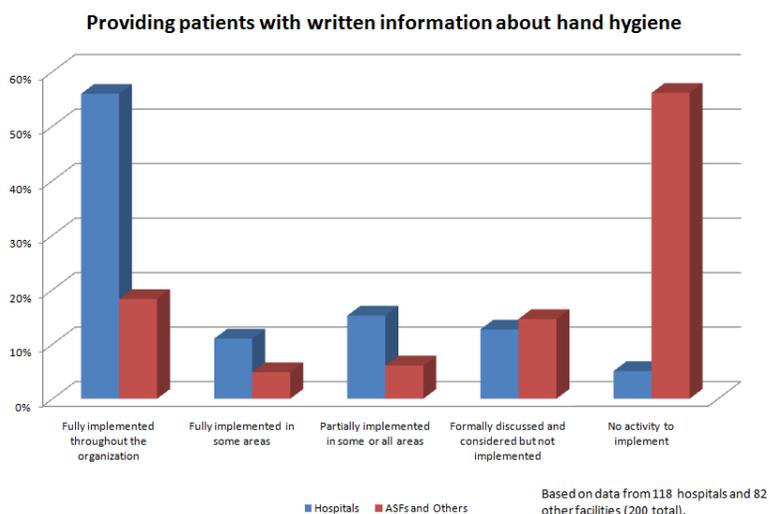


Figure 26.

Many healthcare facilities have enlisted the help of patients in promoting hand hygiene among their staff, including providing written information to patients encouraging them, for example, to ask staff if they have washed their hands. Most hospitals (82%) have at least partially implemented this practice, compared to only 29% of ASFs and other facilities. A significant number of hospitals (18%) and a majority of ASFs and other ambulatory facilities (71%) have not implemented this practice. (See Figure 26)

Case Study: Multidrug-Resistant Organisms (MDROs)

Problem: In the December 2008 *Pennsylvania Patient Safety Advisory* we published an article on multidrug-resistant organisms (MDROs) and the challenges faced by the infectious disease and infection control community. MDROs are defined by the Centers for Disease Control and Prevention (CDC) as “microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.”

A search of the PA-PSRS database revealed more than 700 reports from 2004 through 2007 that indicated inconsistencies relating to isolation precautions and identification of patients who tested positive for MDROs. The most common inconsistencies cited in submitted reports include: improper use of isolation garb or inadequate hand hygiene, untimely initiation of isolation, and improperly labeled active surveillance culture specimens.

Of particular note is a report by a patient’s family members highlighting conflicting instructions regarding their need to adhere to contact precautions as the patient was moved from the ICU to a medical-surgical unit. The family members indicated that the healthcare workers’ use of personal protective equipment, such as gowns and gloves, was inconsistent. The family reported that while some staff members did wear gowns and gloves, others did not—including a dialysis nurse who provided direct patient care. This report illustrates how inconsistencies and mixed messages to patients and their families can erode confidence in healthcare providers’ ability to deliver appropriate care and prevent the spread of MDROs. It also demonstrates the role patients and their families can play in enforcing isolation protocols when they understand the requirements.

Solutions: A multi-disciplinary approach to changing the culture and subsequent behavior in hospitals by introducing evidence-based practices incorporating risk reduction strategies have resulted in favorable results in certain hospitals. MDRO reduction and other HAI-related success stories will be published in the *Advisories* during 2009. Successful infection control programs incorporate key concepts detailed in the Association for Professionals in Infection Control and Epidemiology’s “Guide to the Elimination of Methicillin-resistant *Staphylococcus aureus* (MRSA) Transmission in Hospital Settings,” including:

- A baseline *risk assessment* for MDROs as a means to determine the incidence among the patient population
- Active surveillance cultures for patient care settings as mandated by state regulation, Pennsylvania Act 52 of 2007, requires that hospitals develop procedures necessary for requiring cultures and screenings for

Recent Advisory Articles Related to HAIs

[Multidrug-Resistant Organisms—Strategies to Reduce Infection](#) (Dec 2008)—Implementing critical risk reduction strategies (e.g., baseline risk assessment, ongoing compliance monitoring) is essential to prevent, control and eliminate multidrug-resistant organisms in healthcare settings.

[Hand Hygiene Practices and the Use of Alcohol-Based Sanitizers](#) (Sep 2008)—Use of alcohol hand sanitizers appears to be superior to traditional handwashing when the caregiver’s hands are not visibly soiled.

[Forcing Functions of Antibiotic Prophylaxis](#) (Sep 2008)—Forcing functions can help improve physician behavior associated with use of prophylactic antibiotics in preventing surgical site infections, according to a program undertaken at Temple University Hospital.

[Dangers Associated with Shared Multidose Vials](#) (Jun 2008)—Using a single, multidose drug vial for multiple patients creates the potential for cross-contamination.

[Act 52 of 2007: the Authority’s Role, Progress to Date and Future Goals](#) (Jun 2008)—Hospitals and nursing homes are required by 2007 legislation to report healthcare-associated infections (HAIs) to the Pennsylvania Patient Safety Authority. Ongoing collection and analysis of HAI-related data from more than 250 hospitals and 800 nursing homes will assist the Authority in identifying trends, patterns, and potential process or system failures.

[Prompt Identification and Effective Communication of Status May Reduce MRSA Infections](#) (Dec 2007)—Failure to adequately identify and/or communicate patients’ MRSA statuses can perpetuate MRSA infection and transmission. Limiting the risk of MRSA transmission involves developing a comprehensive program that includes components such as active surveillance and ongoing evaluation of processes.

nursing home residents admitted to a hospital, as well as procedures for identifying other high-risk patients admitted to the hospital.

- Evaluation of colonized nursing home residents for prompt placement and initiation of facility-specific precautions
- A well-established *hand hygiene program* that includes readily available alcohol-based handrubs
- Prompt initiation of *contact precautions* for acute care patients with either a positive culture or a known history of positive cultures for MDROs
- An effective method to *communicate* a patient's MDRO status across the healthcare continuum
- A system to *monitor staff compliance* with contact precautions and hand hygiene
- A system to provide feedback and education to staff
- An environmental *cleaning checklist/audit* tool to prevent/control the spread of MDROs via surfaces and patient care equipment¹²

The Authority's Role in Act 52 of 2007

The Authority's efforts have been focused on establishing the HAI reporting infrastructure for hospitals and nursing homes. We have also published HAI-related articles in the *Pennsylvania Patient Safety Advisory* and are giving presentations on reducing healthcare-associated infections. Infection prevention is also one of the domains of care included in our patient safety measurement project which is a primary focus of this annual report. A complete timeline of the tasks the Authority has undertaken to date for Act 52 of 2007 include:

September 2007 – The Authority establishes the Healthcare-Associated Infection Advisory (HAI) panel made up of infection control experts from throughout the state.

December 2007 – Draft HAI reporting requirements for hospitals were published in the *Pennsylvania Bulletin*. The Authority collected and distributed the public comments from facilities regarding the draft document. The HAI Advisory Panel reviewed comments and developed a final reporting document for hospitals based upon their expertise and the public comments.

February 2008 – Hospitals began mandatory reporting of HAIs using the Centers for Disease Control and Prevention's National Health Surveillance Network (NHSN).

March 2008 – Final reporting requirements for hospitals were published. The Authority embarked upon an extensive education and outreach program to ensure that Pennsylvania healthcare facilities understood the reporting requirements. Several presentations were given by Authority staff throughout 2008 to hospitals and nursing homes regarding Act 52.

March-April 2008 – The Authority and the HAI Advisory Panel worked with the Department of Health to develop the list of reportable infection events and reporting criteria for nursing homes. These infections will be tracked by the Authority and the Department of Health through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

May 2008 – The draft reporting requirements for nursing homes were published in the *Pennsylvania Bulletin* and open for comment. The Authority received over 60 comments from nursing home organizations from across the state.

¹² Association for Professionals in Infection Control and Epidemiology, Inc. Guide to the elimination of methicillin-resistant *Staphylococcus aureus* (MRSA) transmission in hospital settings [online]. 2007 Mar [cited 2009 March 3]. Available from Internet: <http://www.ihatoday.org/issues/quality/apicguide.pdf>.

September 2008 – The final reporting requirements and criteria for nursing home HAI reporting was published in the *Pennsylvania Bulletin*.

December 2008 – The Authority conducted a Web conference attended by over 600 long-term care facilities to define and outline the criteria for infections that will be tracked in nursing homes.

January – March 2009 – The Authority completed 30 training sessions for 1250 nursing home employees throughout the state to prepare them for mandatory reporting. An HAI training curriculum, including an extensive Users Guide and Training Manual, was delivered in the training sessions.

April 2009 – A pilot reporting session will be held for two weeks with volunteer nursing home facilities to test the new system and ensure any problems are addressed prior to mandatory reporting in June.

May 2009 – A Webinar training session will be held for those facilities that could not make the live training sessions.

September 2008 – May 2009 – The nursing home HAI reporting system was developed as a subset of the Pennsylvania Patient Safety Reporting System (PA-PSRS). This process was lengthy because the PA-PSRS system had to be rebuilt specifically for nursing home reporting. The addition of nursing homes expands the number of facilities reporting through PA-PSRS to two and a half times the current amount of facilities reporting to the Authority.

June 2009 – Mandatory reporting of nursing homes begins.

Since Act 52 of 2007 was signed into law, the Authority has been educating the hospitals and nursing homes through *Pennsylvania Patient Safety Advisories*. The *Advisories* are based upon data collected in PA-PSRS. Once the nursing homes begin reporting in June the Authority expects to have more information specifically geared toward nursing home infections to pass on to the facilities as guidance.

Patient Safety Authority HAI Accomplishments in 2008

Continuing our work from 2007 to establish the infection reporting requirements for hospitals, the Authority managed the public comment process following publication of the draft reporting requirements in December 2007 in the *Pennsylvania Bulletin*. Hospitals began mandatory reporting of HAIs using the Centers for Disease Control and Prevention's National Health Surveillance Network (NHSN) in February 2008. Final reporting requirements for hospitals were published in March 2008.

Throughout 2008, the Authority has worked with the Department of Health to educate hospitals to use NHSN and to ensure the integrity of the data hospitals are submitting. In addition to guidance documents published during the year, the Department and the Authority have developed online video tutorials available on the DOH Web site to demonstrate the use of NHSN. The DOH Infection Prevention Section and the Authority Help Desk staff assist facilities in meeting their requirements.

The Authority embarked on an extensive education and outreach program to ensure that Pennsylvania healthcare facilities understood the reporting requirements. Between September and December 2008, the Authority's Infection Control Analyst and other Authority staff met with infection control practitioners, Patient Safety Officers and trade associations throughout the state, giving 12 presentations on the HAI reduction goals and legal requirements of Act 52 of 2007. Among the groups the Authority provided education for are Pennsylvania-based chapters of the Association for Practitioners of Infection Control, the Pennsylvania Medical Directors Association (PMDA), Pennsylvania Health Care Association (PHCA), Hospital Council of Western Pennsylvania, the Hospital and the Healthsystem Association of PA (HAP), the Philadelphia Area Society for Healthcare Risk Management (PASHRM) and Highmark Blue Shield. We also contributed articles on Pennsylvania's HAI reduction initiative for the PMDA and Pennsylvania State Nurses Association (PSNA) newsletters.

The Authority worked with the Department of Health and the HAI Advisory Panel to develop the list of reportable infections that will be tracked in nursing homes as well as the criteria nursing homes will use to identify those infections. These infections and criteria were published in draft form for public comment in the *Pennsylvania Bulletin* in May 2008, and the reporting requirements were modified in response to suggestions provided in over 60 public comments. The final infection list and criteria were published in the *Pennsylvania Bulletin* in September 2008.

In December 2008, the Authority conducted a Web conference attended by over 600 long-term care facilities to define and outline the criteria for infections that will be tracked in nursing homes. We also developed an HAI training curriculum, including an extensive Users Guide and Training Manual, for nursing homes that were delivered to participants in 30 live training sessions throughout Pennsylvania in February and March 2009.

Device Safety

In healthcare environments, and increasingly even in our homes, medical devices surround us. They include sophisticated medical imaging equipment like computed tomography (“CAT scans”) or magnetic resonance imaging (MRI) but also everyday devices like needles and blood glucose meters. The vast majority of the time these devices are necessary and useful tools in providing high quality healthcare. However, patient safety can be compromised when these devices malfunction or break, when they are used incorrectly, or when they are used for purposes other than those intended.

There are also many advances in medical devices currently in use that make them safer than earlier models. For example, some infusion pumps (used to deliver drugs intravenously) have “free-flow protection,” an internal mechanism that prevents medications in IV bags from “flowing freely” into the patient and causing a drug or fluid overdose. While most infusion pumps sold in the US today have this type of protection, many older models are still in use without this safety feature.

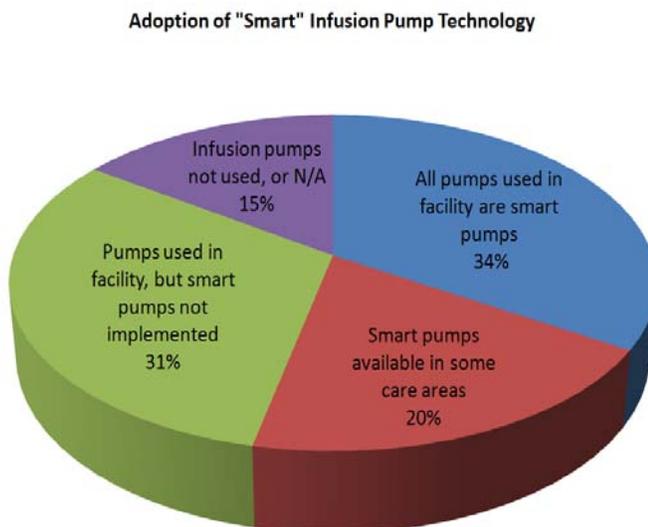
Device Safety Measures

Smart Infusion Pumps

“Smart” infusion pumps are computerized drug delivery devices that deliver IV drugs and other fluids at specific rates that are appropriate for the type of drug, the strength or concentration and the dose that is prescribed. The pumps are programmed by a nurse using a touch-screen to deliver the right dose over the right time period. What makes these pumps “smart” is that they have a library of drugs in memory, and if the nurse programs a dose that is beyond the dose limits in the library, the pump will either generate an alert or not allow the drug to be given.

We asked Pennsylvania healthcare facilities about their adoption of smart pump technology. Specifically, we asked whether or how widely smart pumps were available and how often they reviewed the pumps’ computer logs to evaluate the performance of the drug library and dose limits.

Over one-third (34%) of participating hospitals have implemented smart pump technology throughout their institution, while another 20% have provided these pumps in some areas. Almost one-third (31%) of hospitals report that they do use infusion pumps in their facility, but they have not yet adopted smart pumps. Fifteen percent of responding hospitals, including behavioral and rehabilitation hospitals, reported that they do not use any infusion pumps or that this measure was otherwise not applicable. (See Figure 27)



Based on data from 118 hospitals.

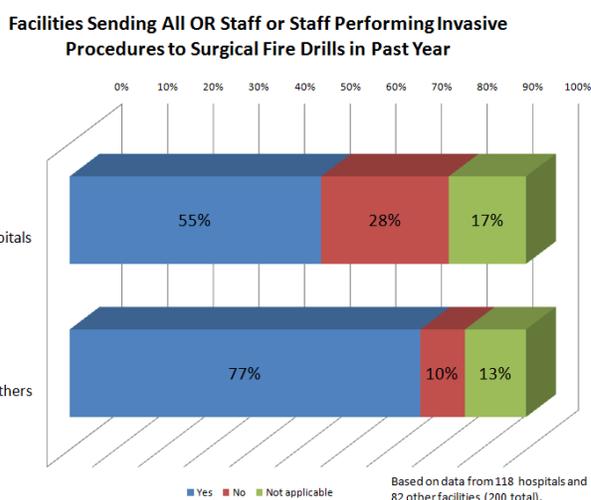
Figure 27.

Most ambulatory surgical facilities (ASFs) and other facilities (68% of 82 respondents) report not using infusion pumps or that this measure did not apply, though one ASF uses only smart pumps and three others have them available in some areas. Nine (11%) use infusion pumps but have not implemented smart pumps.

We asked each facility whether they had reviewed the computer logs from their smart pumps to evaluate the performance of the drug library and dose limits. If the system is performing poorly it may be unable to catch some unsafe orders, or if the dose limits are overly restrictive it could lead to too many unnecessary alerts, leading practitioners to ignore or override them. Of the 63 facilities that reported having at least some smart pumps, 34 (54%) have reviewed the computer logs in the past year to improve the smart pumps' performance. Three of the four ASFs who report using smart pumps did so as well.

Surgical Fire Drills

Fires during surgical procedures, while rare, can have tragic consequences both for patients and healthcare workers. These events are also completely preventable, and the Authority has raised awareness of this issue through several related articles in the *Patient Safety Advisory*. While we have published guidance on surgical fire prevention, operating room (OR) staff should also be prepared to respond quickly to extinguish fires when they occur. One method of preparedness is to have OR staff participate in surgical fire drills. As in any crisis, people are better equipped to handle emergencies if they periodically rehearse their response to emergency situations.



We asked each PSO whether their facility had conducted surgical fire drills with all OR staff in the past year. More than half of all hospitals (55%) and three out of four ASFs and other facilities (77%) had done so. While some facilities such as behavioral health and rehabilitation hospitals do not perform surgery, a substantial proportion of hospitals and a smaller proportion of ASFs had not conducted drills in the past year. (See Figure 28)

Figure 28.

Prohibition on Using Defibrillators for Routine Monitoring

The Authority has published on the hazards of using defibrillators for routine cardiac monitoring. Defibrillators are devices that deliver a shock to a patient's heart in response to certain abnormal heart rhythms. We have received reports in which defibrillators have been used as auxiliary physiologic monitors when regular monitors have been unavailable. Leaving a defibrillator connected to a patient for extended periods for monitoring places the patient at risk of receiving a shock unintentionally, and this has occurred in some cases reported to the Authority. In a 2005 *Patient Safety Advisory* article, the Authority provided guidance on preventing this adverse event.¹³ One element of this guidance was for facilities to consider prohibiting the use of defibrillators as auxiliary monitors. Based on the results of our survey, this prohibition is in place in most responding facilities, with 69% of facilities reporting full implementation throughout their organization. (See Figure 29)

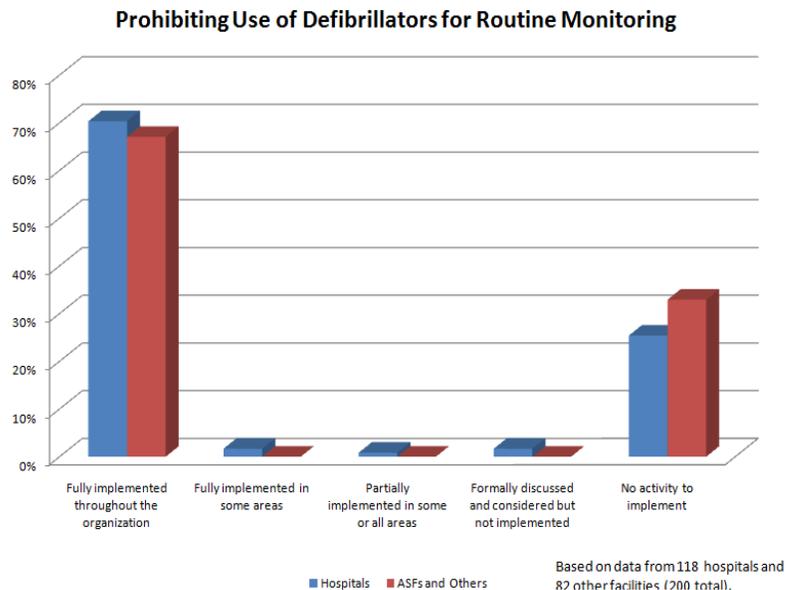


Figure 29.

Preventing Tourniquets from Being Left on Patients

In the June 2005 issue of the *Patient Safety Advisory*, the Authority reviewed 125 reports of tourniquets being left on patients, most for longer than 30 minutes and some for as long as 18 hours. Tourniquets are used when starting an IV or drawing blood, but if they are left in place longer than necessary they can cause significant and sometimes permanent damage to nerves, blood vessels or tissues. We asked facilities whether they had evaluated within the past year the causes of tourniquets being left on patients. Among hospitals, less than one-third (27%) had evaluated the causes of this problem, while the remaining hospitals either had not done so or felt this measure was not applicable in their facility. This practice was less common among ASFs and other facilities, with only 7% reporting that they had analyzed the causes of tourniquets left in error. (See Figure 30)

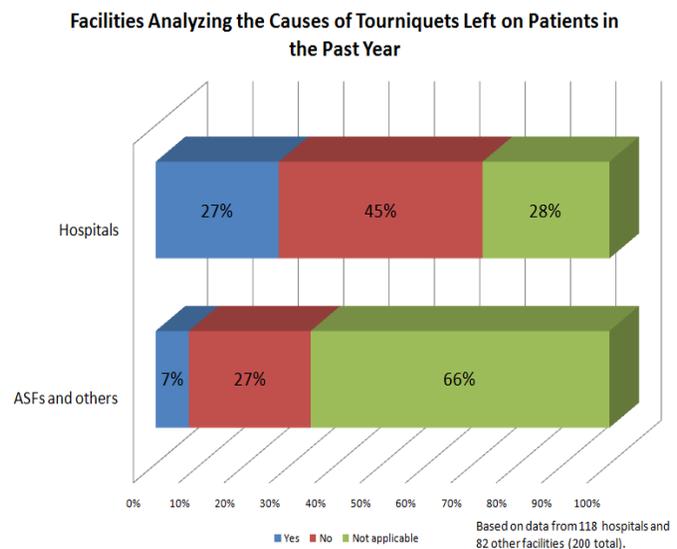


Figure 30.

¹³ Patient receives shock during defibrillator operational check. *PA PSRS Pat Saf Advis* 2005 Sep;2(3):19-20.

Skin Assessments during Pulse Oximetry

Pulse oximetry is a routinely used non-invasive technology for monitoring the level of oxygen in the blood. A sensor clipped to the patient’s finger is considered safe for up to eight hours if the application site has normal blood flow. If left on for longer periods, or on a patient with poor circulation, these devices can cause burns or injury from decreased blood flow. We asked facilities whether they had established a policy or protocols for periodic assessments of the skin around the oxygen sensor site when pulse oximetry is in use. Approximately one-third (35%) of hospitals and 18% of ASFs and other facilities reported partial to full implementation of this practice. The majority of facilities in both groups (65% of hospitals and 82% of ASFs and others) have not implemented this practice. (See Figure 31)

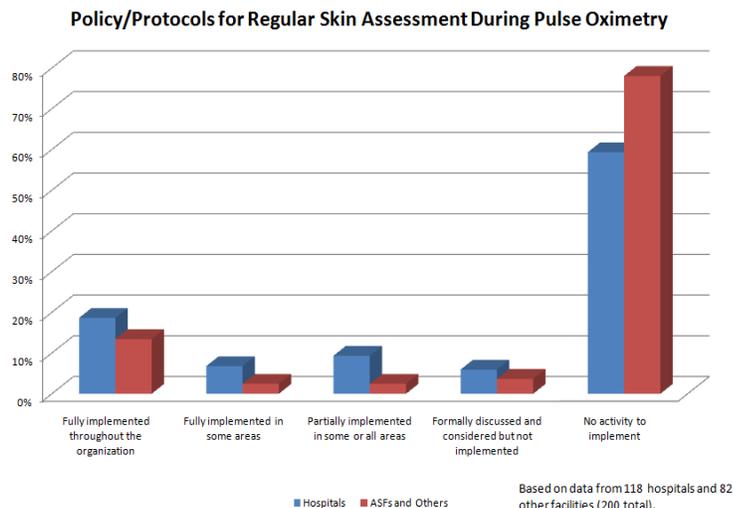


Figure 31.

Reports to the Authority

Reports submitted to the Authority that are labeled as problems related to “Equipment/Supplies/Devices” have consistently been a small percentage of reports overall, generally about 2%. However, medical devices play a significant role in Serious Events and Incidents categorized throughout PA-PSRS. For example, reports of equipment breaking, being inadequately prepared, or being unavailable during surgery are often categorized as problems related to the surgical procedure. Problems with infusion pumps are often classified as medication errors. The Authority received 3,343 reports in 2008 that the person reporting classified as related to Equipment/Supplies/Devices (see Table 4). The most frequently reported problems involved equipment malfunctions, equipment that was not available when it was needed, broken equipment and improperly sterilized equipment. (See Figure 32)

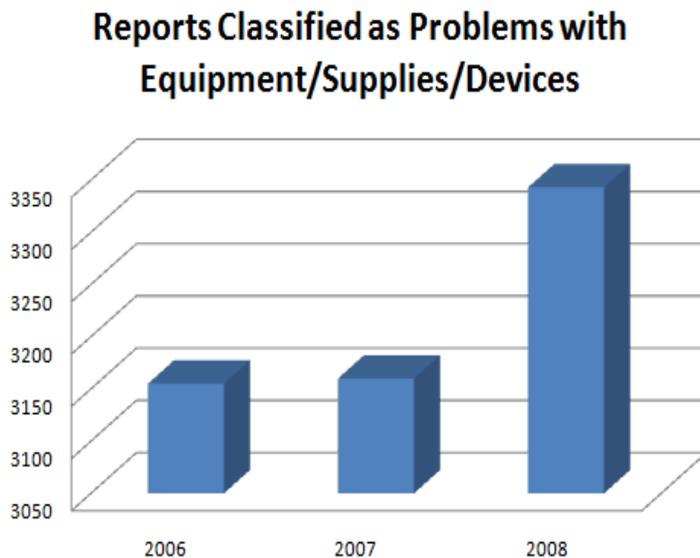


Figure 32.

Table 4. Reports Classified as Problems with Equipment/Supplies/Devices (2008)

Category	Number	%
Equipment disconnected	138	4.1%
Electrical problem	39	1.2%
Equipment not available	348	10.4%
Equipment malfunction	1,253	37.5%
Equipment wrong or inadequate	98	2.9%
Equipment misuse	113	3.4%
Inadequate supplies	163	4.9%
Medical device problem	155	4.6%
Equipment safety situation (failure to perform preventive maintenance, device failing standard procedures)	82	2.5%
Broken item(s)	279	8.3%
Outdated item(s)	38	1.1%
Sterilization problem	240	7.2%
Other equipment problem	397	11.9%
Total	3,343	100%

Reports Related to MRI Safety

Magnetic resonance imaging (MRI) is a breakthrough diagnostic technology, allowing us to visualize the structure and function of the body with much greater detail than computed tomography (CT) or traditional x-rays, without the undesirable radiation associated with these other tests. MRI works by creating a magnetic field around the patient, and this magnetic field requires unique precautions so that metallic objects do not enter the surrounding area. If they do, they can be drawn toward the magnet, potentially injuring the patient and staff and damaging the MRI machine. This also makes MRI unsuitable for patients with certain implanted devices. (See Figure 33)

Reports of Contraindicated Patients or Objects Reaching the MRI Suite

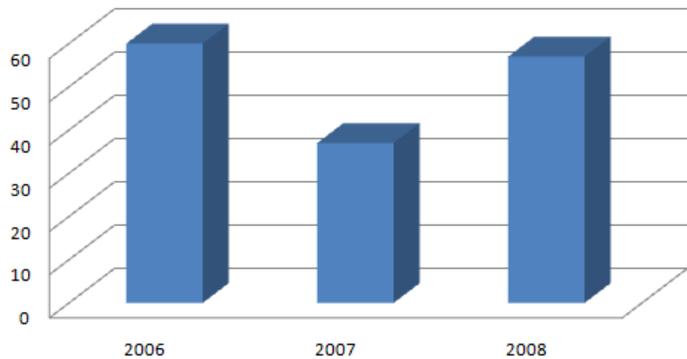


Figure 33.

From 2006 through 2008, the Authority received 154 reports in which patients who typically cannot have MRIs reached the MRI suite. In many of these cases, this error was caught in final screening by the MRI technician or in which the test was stopped after a metal device was evident on the scan. There are many more reports in which

the error was caught prior to sending the patient to the MRI suite, in which the physician ordered an MRI for a patient who was not a candidate for this type of test. The most frequently reported examples of this type of error involved patients with implanted defibrillators, pacemakers or aneurysm clips. During this same period, the Authority received 22 reports of metallic objects brought into the MRI suite in error which were drawn toward the MRI machine or into the bore of the magnet. Examples of objects cited in these reports include an oxygen tank, IV pole, stretcher, wheelchair parts, stethoscope, scissors and knives.

Reports of Objects Drawn toward MRI or into Magnet Bore

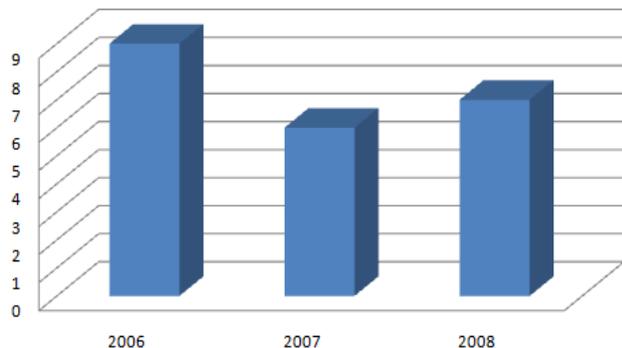


Figure 34.

Reports of Surgical Fires and Perioperative Burns

During the past three years, the Authority received 44 reports involving surgical fires¹⁴ and 274 reports involving perioperative burns. These categories are not mutually exclusive; some involve both a fire and burns to the patient. A majority of these reports (61%) identify an electrosurgical unit (ESU) or other device used to cut or fuse tissue as being implicated in the fire or burn. Many of these burns and fires can be prevented by simple measures such as using a holster for the device and/or putting the devices in standby mode when not in use.

Reports Involving Perioperative Burns

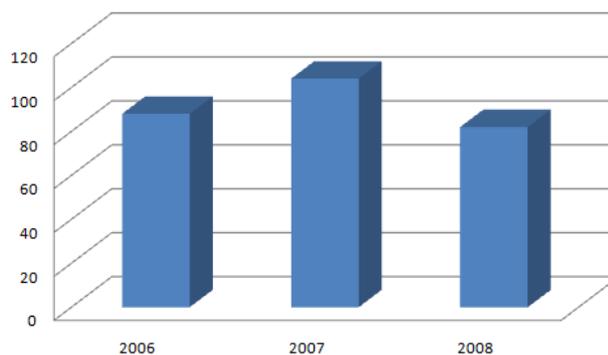


Figure 35.

For more information about how to prevent surgical fires, refer to the following *Patient Safety Advisory* articles:

- [Airway Fires during Surgery](#) (March 2007)
- [Electrosurgery Safety Issues](#) (March 2006)

¹⁴ Surgical fires were defined conservatively, counting only reports from the operating room that explicitly describe a fire or flame, or mention igniting or extinguishing burning objects. Reports describing only smoke, sparks, or burns were not considered fires.

Case Study: Errors with Intraocular Lens Implants

Problem: In the March 2005 issue of the *Patient Safety Advisory* we published on a number of reports in which the wrong intraocular lens was implanted, often during cataract surgery. In the June 2008 issue we published an analysis of 48 cases reported from mid-2004 through 2007. In about seven out of 10 cases additional surgery was required to implant the correct lens. (See Figure 36)

Figure. PA-PSRS Wrong Intraocular Lens Implant Reports by Quarter

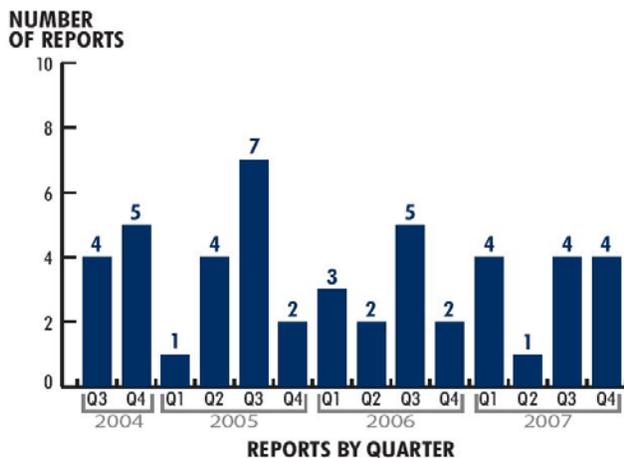


Figure 36.

Issues that led to implanting the wrong lens included:

- The physician or his or her office staff gave information from the wrong patient's office chart regarding the lens to be used.
- Surgical team members were inattentive during the pre-surgical time-out, in which essential elements of the case are verified.
- The surgeon's office record was not available in the operating room to review during the time-out.
- The nurse picked up the wrong lens.
- More than one lens was available in the operating room (OR).
- The sequence of the scheduled patients was changed without corresponding changes to their respective verification processes.

Recent Advisory Articles Related to Medical Devices

[Tubular Dressing Retainer: Retention without Restriction](#) (Dec 2008)—Improper application of the retainer and use of incorrect size, especially on fingers, has caused harm to patients.

[CT Contrast Media Power Injectors Can Rupture Conventional IV Sets](#) (Dec 2008)—A ruptured intravenous set can expose a patient or staff member to the contrast solution or blood and fluid.

[Icodextrin in Peritoneal Dialysis Solution May Cause Falsely High Blood Glucose Readings](#) (Jun 2008)—Blood containing maltose, galactose, or xylose can falsely elevate the results obtained from point-of-care glucose meters using a particular enzyme/indicator test method.

[Alarm Interventions during Medical Telemetry Monitoring: A Failure Mode and Effects Analysis](#) (Mar 2008)—This overview of telemetry monitoring alarm response processes and related failures can help to develop facility-specific risk reduction strategies.

[Smart Infusion Pump Technology: Don't Bypass the Safety Catches](#) (Dec 2007)—Using smart pumps to their fullest potential involves not only implementing this technology but also heeding alerts at the bedside.

[CT Scans May Affect Implantable Electronic Devices](#) (Dec 2007)—Not knowing if a patient has an implanted electronic device before conducting a computed tomography scan could potentially harm the patient.

[IV Infiltration: Be Alarmed Even When Your Infusion Pump Isn't](#) (Sep 2007)—Reports of infiltration and extravasation indicate that some clinicians may misunderstand the role of occlusion alarms on infusion pumps.

[Airway Fires during Surgery](#) (Mar 2007)—Following safe practices can help reduce the likeliness of fires during airway surgery that involves ignition sources such as electrosurgical units.

The event data shows that the verification process is central in the majority of the reports.

Solutions: After implanting the wrong lens, one Pennsylvania facility took specific steps to reduce the risk of this error recurring. The facility found that the staff had multiple inconsistent processes for verifying the lens before implantation. The facility found that standardizing on a single consistent process has been effective in reducing the risk of implanting the wrong lens. This process includes:

- The surgeon sends the office chart to the OR before the surgery.
- During the preoperative visit on the day of surgery, the circulating nurse verifies that tests used to determine what lens the patient needs are in the record and that the tests are for the patient undergoing the procedure.
- Immediately before surgery, the surgeon visits the patient, reviews the tests, selects the lens and hands the lens to the circulating nurse. Selecting the lens before the procedure is eliminated because a change in schedule may lead to the wrong lens being set up for the wrong patient.
- Once in the room, a time-out is performed with the entire OR team. The patient, procedure, site and lens are verified by the surgeon and the scrub nurse. The staff has the patient's office chart, surgical medical record, lens and lens box available to review during the time-out.
- The circulating nurse and surgeon double-check the lens power together before beginning the surgery.

Other healthcare facilities in Pennsylvania include such safety procedures as having only the current patient's medical record and lens available in the OR at the time of surgery, using the medical record from the physician's office during the time-out, and having the surgeon select the lens and place it on the patient's medical record before the procedure and announcing it to the nurse when handing it into the sterile field.

For more information, see **“Still Not Seeing Clearly—A Second Look at Intraocular Lens Implant Events” (Sep 2008)**.

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Data Collection and Analysis

The Reporting System

The Pennsylvania Patient Safety Reporting System (PA-PSRS) is a secure, Web-based system that permits healthcare facilities to submit reports of what Act 13 of 2002 (MCare Act) defines as “Serious Events” and “Incidents.” Statewide mandatory reporting through PA-PSRS went into effect on June 28, 2004. All information submitted through PA-PSRS is confidential. By law, reports do not contain any identifiable information and no information about individual patients and providers is collected. In addition, no information about individual facilities is made public.

As defined by Act 13 of 2002, PA-PSRS is a facility-based reporting system.¹⁵ All reports are submitted by facilities through a process identified in their patient safety plans, as required by the Act. However, Act 13 of 2002 provides for one exception to this facility-based reporting requirement. Under this exception, a healthcare worker who feels that his or her facility has not complied with Act 13 of 2002 reporting requirements may submit an anonymous report directly to the Authority. (See the section on Anonymous Reports on page 96)

To access PA-PSRS, facilities need only a computer with Internet access (i.e., access to the World Wide Web). There is no need for a facility to procure costly equipment or software to meet statutory reporting requirements, and only minimal self-directed training is necessary to learn how to navigate the PA-PSRS system. However the Authority provides user manuals and annual new user training.

In submitting a report, a facility responds to 21 core questions through check boxes and free-text narrative. The system directs the user through the process, offering drop-down boxes of menu options and guiding the user to the next series of questions based on the answers to previous questions. The system is very user-friendly, despite the software’s underlying complexity.

Among questions are those related to demographic information, such as a patient’s age and gender, the location within a facility where the event took place, the type of event and the level of patient harm, if any. In addition, the report collects considerable detail about “contributing factors,” details related to staffing, the workplace environment and management and clinical protocols. The facility is also asked to identify the root cause of a Serious Event and to suggest procedures and processes that can be implemented to prevent a reoccurrence.

Once a report is submitted, the Authority’s clinical team initiates its analysis. This team includes professionals with degrees and experience in medicine, nursing, law, pharmacy, health administration, risk management, product engineering and statistical analysis, among other fields. In addition, through our contract staff, the Authority has access to a large pool of subject matter experts in virtually every medical specialty.

¹⁵ It is important for Pennsylvania consumers to recognize that there are other complaint and error reporting systems meant for individuals. The Department of Health can issue sanctions and penalties, including fines and forfeiture of license, to healthcare facilities as appropriate. Citizens can file complaints related to hospitals and ambulatory surgical facilities by calling the Department of Health at 1-800-254-5164; for complaints related to birthing centers, they can call the Department of Health at 1-717-783-1379. Complaints against licensed medical professionals can be filed with the Department of State’s Bureau of Professional and Occupational Affairs at 1-800-822-2113. For web sites that compare healthcare facilities on measures of quality, refer to the Pennsylvania Health Care Cost Containment Council (www.phc4.org), the Pennsylvania Health Care Quality Alliance (www.phcqa.org), and the federal Department of Health and Human Services’s Hospital Compare (www.hospitalcompare.hhs.gov) and Nursing Home Compare (www.medicare.gov/NHCompare/home.asp).

After the system electronically receives and prioritizes each report, the clinical team performs additional review, following up with individual facilities as necessary. The team's primary role is to identify situations of immediate jeopardy and to identify trends or improvements that can be implemented to improve patient safety.

As a result of this comprehensive analysis, the Authority issues *Pennsylvania Patient Safety Advisories* based on data submitted through PA-PSRS, supplemented by a scholarly search of the medical and clinical literature. *Patient Safety Advisory* articles are directed primarily to healthcare professionals for use by both clinical and administrative staffs. The Authority encourages these providers to use the articles as learning tools for patient safety and continuous quality improvement. In a recent survey, a majority (58%) of all responding facilities and 77% of respondents from hospitals indicated that they have implemented improvements within their facilities as a result of information contained in this year's *Advisories*. The 218 Patient Safety Officers responding to the 2008 survey cited 607 process or system changes they had made as a result of *Advisory* articles. More information about this survey is in the section "*The Authority's Annual Survey of Patient Safety Officers*" (see page 89).

Primary distribution of the *Advisories* is through electronic emails, enabling the Authority to circulate the *Advisories* to thousands of individual healthcare providers, hospitals and government and healthcare organizations around the world, including national patient safety and quality improvement organizations. As a result, the Authority is able to generate considerable interest in Pennsylvania's approach to promoting patient safety and in the lessons learned through the PA-PSRS system. In addition, all copies of the *Patient Safety Advisory* are accessible on the Authority's recently redesigned Web site, www.patientsafetyauthority.org.

Another component of the PA-PSRS system is the set of analytical tools available to reporting facilities. These tools provide patient safety, quality improvement and risk managers with detailed reports analyzing data related to their specific facilities. Many reports can also be exported to other software programs for inclusion in facility publications or in reports and presentations to trustees and senior management. In addition, facility personnel have the ability to export all, or any portion, of their facility's data. Managers can use this information for their internal quality improvement and patient safety activities.

These analytical tools are an essential component of patient safety improvement efforts in Pennsylvania. While the PA-PSRS system allows the Authority to focus on analyzing statewide aggregate data, the analytical tools within the system provide immediate, real-time feedback to individual facility managers that will help them identify trends and actual or potential adverse patient outcomes within their institutions.

PA-PSRS was developed under contract with ECRI Institute, a Pennsylvania-based independent, non-profit 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, non-profit health research organization.

Interpreting PA-PSRS Data

Considerable caution is advised when interpreting data from PA-PSRS. Many factors influence the number of reports submitted by any particular facility or any group of facilities, of which safety and quality are just two. Additional factors include facility size, utilization or volume, patient case mix, severity of illness, differences in facilities' understanding of what occurrences are reportable, differences in facilities' success in detecting reportable occurrences and others.

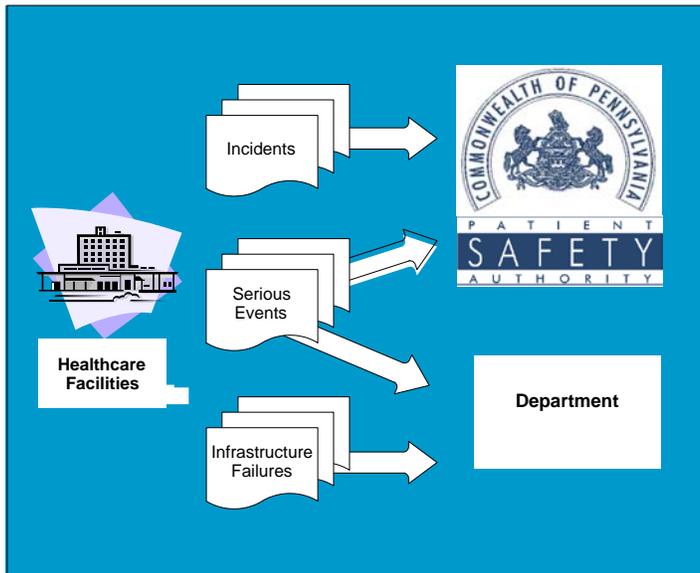


Figure 37. Submission of PA-PSRS Reports

Even if the data were adjusted for volume, patient factors, and all other factors but safety and quality, PA-PSRS data would still be an inaccurate “report card” for individual healthcare facilities. For example, if Facility A has substantially more reports than a similar facility (Facility B), this would not mean that Facility A is necessarily less safe than Facility B. In fact, Facility A could be *safer* than Facility B, because they may have better systems in place for recognizing and reporting actual and potential adverse events.

Numbers by themselves do not provide complete answers. For example, the number of incorrect medications administered is not meaningful without knowing the total number (known as the “denominator”) of all medications administered. In other words, 10 incorrect medications out of a total

of 50 administered doses are much different than 10 incorrect medications out of 10,000 administered doses.

Additional considerations when reviewing PA-PSRS data presented in this report include the following:

- Data presented in this report include only reports of Serious Events and Incidents. While PA-PSRS also collects reports of Infrastructure Failures, these reports are submitted only to the Department of Health. The Authority does not receive reports of Infrastructure Failures.
- Unless otherwise noted, data presented in this report are based on reports submitted to PA-PSRS between January 1, 2008, and December 31, 2008.
- Unless specifically noted, numbers of reports in different categories are actual “raw numbers” and have not been adjusted for any facility or patient-related factors that may influence differences in report volume among different facilities.
- The data are not adjusted to account for healthcare facility openings, closings or changes of ownership.

Caution is advised when comparing data contained in this report with data published by other patient safety reporting systems. The PA-PSRS program was developed within the context of Act 13 of 2002, which has its own unique definitions for what is and what is not reportable to PA-PSRS. It also uses a specific list of Event Types that may be different than the lists used by other systems. Most important, PA-PSRS is the only mandatory program collecting data on “near misses”—events which did not harm patients.

Many factors may influence differences between data from various patient safety reporting systems. The key comparisons to make are those made by individual healthcare facilities, as they monitor their own performance over time and in relation to specific patient safety goals relevant to their healthcare setting.

Definitions

Act 13 of 2002 (MCare) requires healthcare facilities to submit reports of the following three kinds of occurrences:

- **Serious Event**—An adverse event resulting in patient harm. The legal definition, from Act 13 of 2002 (MCare), reads: “An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an Incident.”
- **Incident**—A “near miss” in which the patient was not harmed. Act 13 of 2002 defines this as: “An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a Serious Event.”
- **Infrastructure Failure**—A potential patient safety issue associated with the physical plant of a healthcare facility, the availability of clinical services or criminal activity. Act 13 of 2002 defines this as: “An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.” Reports of Infrastructure Failures are not addressed in this report because these are submitted only to the Department of Health.

Reports of Serious Events and Incidents are submitted to the Patient Safety Authority for the purposes of learning how the healthcare system can be made safer in Pennsylvania. In contrast, reports of Serious Events and Infrastructure Failure are submitted to the Department of Health for the purposes of fulfilling their role as a regulator of Pennsylvania healthcare facilities.

Act 13 of 2002 (MCare) requires the following types of facilities to submit reports of Serious Events, Incidents and Infrastructure Failures to the Patient Safety Authority through PA-PSRS:

- **Hospital**—The Health Care Facilities Act (35 P.S. §448.802a) defines a hospital as “an institution having an organized medical staff established for the purpose of providing to patients, by or under the supervision of physicians, diagnostic and therapeutic services for the care of persons who are injured, disabled, pregnant, diseased, sick or mentally ill, or rehabilitative services for the rehabilitation of persons who are injured, disabled, pregnant, diseased, sick or mentally ill. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific medical specialties, but not facilities caring exclusively for the mentally ill.” For the purposes of this report, at the end of 2008, there were 241 Hospitals in the Commonwealth of Pennsylvania.
- **Ambulatory Surgical Facility**—The Health Care Facilities Act defines an ambulatory surgical facility as “a facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. Ambulatory surgical facility does not include individual or group practice offices or private physicians or dentists, unless such offices have a distinct part used solely for outpatient treatment on a regular and organized basis. Outpatient surgical treatment means surgical treatment to patients who do not require hospitalization but who require constant medical supervision following the surgical procedure performed.” For the purposes of this report, at the end of 2008, there were 261 ambulatory surgical facilities in the Commonwealth of Pennsylvania.

- **Birth Center**—The Health Care Facilities Act defines a birthing center as “a facility not part of a hospital which provides maternity care to childbearing families not requiring hospitalization. A birthing center provides a home-like atmosphere for maternity care, including prenatal, labor, delivery, postpartum care related to medically uncomplicated pregnancies.” For the purposes of this report, at the end of 2008, there were five birthing centers in the Commonwealth of Pennsylvania.
- **Abortion Facility**— Act 30 of 2006 extended the reporting requirements in Act 13 of 2002 to abortion facilities that perform more than 100 procedures per year. For the purposes of this report, at the end of 2008, there were 18 qualifying abortion facilities in the Commonwealth of Pennsylvania.

The abortion facilities required to submit reports to the Authority are determined by the Department of Health. This information is forwarded to the Authority for the Authority to include in PA-PSRS. The Department of Health is responsible for notifying the Authority of any change in facility status.

Other pertinent definitions used in this report include:

- **Medical Error**—This term is commonly used when discussing patient safety, but it is not defined in Act 13 of 2002. The word “error” appears in the PA-PSRS system and in this report. For example, one category of reports discussed is “Medication Errors.” In PA-PSRS the word “error” is used in the sense intended by the Institute of Medicine Committee on Data Standards for Patient Safety, which defined an error as:

The failure of a planned action to be completed as intended (i.e., error of execution), and the use of a wrong plan to achieve an aim (i.e., error of planning). It also includes failure of an unplanned action that should have been completed (omission).¹⁶

Within Act 13 of 2002, the term medical error is used in the *Declaration of Policy*: “Every effort must be made to eliminate medical errors by identifying problems and implementing solutions that promote patient safety.” It is also used in defining the scope of Chapter 3, Patient Safety: “This chapter relates to the reduction of medical errors for the purpose of ensuring patient safety.”

While PA-PSRS does include reports of events that result from errors, the program’s focus is on the broader scope of actual and potential adverse events.

- **Patient Safety Officer**—Act 13 of 2002 requires each healthcare facility to designate a single individual to serve as that facility’s Patient Safety Officer. Under Act 13 of 2002, the Patient Safety Officer is responsible for submitting reports to the Patient Safety Authority. Act 13 of 2002 also assigns other responsibilities to the Patient Safety Officer.

¹⁶ Institute of Standards for Patient Safety. Patient safety: Achieving a new standard for care. Washington DC: National Academies Medicine, Committee on Data Press; 2004.

Standardization of Reporting

In its 2007 Annual Report, the Authority discussed at length variations in reporting by facilities. The Authority outlined many potential explanations for the disparity such as that Act 13 of 2002 includes several ambiguous terms that define what should be reported (e.g. ‘unanticipated’) and some facilities may have more evolved cultures of safety that encourage higher levels of Incident reporting. In a focus group of Patient Safety Officers in 2007, the PSOs also requested more guidance on what events should be reported.

In the 2007 Annual Report, the Authority outlined its plan to attempt to close the gap on the reporting variations. One of the main objectives of the plan was to work with the Department of Health to explore both organizations’ interpretations of Act 13 of 2002 requirements, with the goal of providing interpretive guidance that can be used by facility PSOs, Patient Safety Committees and Department of Health surveyors.

In the past year, the Authority has worked with the Department of Health to develop some standardization of reporting through a guiding principles document.

The Patient Safety Authority Board of Directors discussed the guiding principles at its September 2008 meeting. The board did not reach consensus on several issues and asked that the document be revised and discussed in future board meetings. In January 2009, a revised document was presented to the board and the Deputy Director of Quality Assurance from the Department of Health also gave a presentation on the standardization document.

During this time, the Authority also sent letters to 50 facilities that fell into the lowest tranches of reporting. This prompted one facility to contact the Authority for assistance with patient safety education. Another facility contacted the Authority to inquire about help in increasing Incident reports. In a recent analysis of the reporting patterns among those facilities that received the letter, we compared their reporting during the last quarter of 2008 and the first quarter of 2009. We found that the number of reports overall from this group increased by 58%. Reporting of Serious Events rose 9%, while reporting of Incidents rose 53%.

The Authority also published an editorial in the 2008 December *Pennsylvania Patient Safety Advisory* extolling the benefits of reporting Incidents.

In February 2009, the public comment period began on the draft standardization principles developed by the Authority and the Department of Health. A copy of the document containing draft guidance was published in the *Pennsylvania Bulletin* Saturday, February 28. The Authority also sent emails to PSOs with a link to the document in the *Pennsylvania Bulletin*. The public comments are being tabulated as of the writing of this report.

Concurrently with issuing the draft guidance document for public comment, we incorporated in our annual survey of PSOs the example scenarios used in the draft guidance document to help us understand the level of consensus that might exist around the draft interpretations.

We asked PSOs from hospitals to consider each example scenario and designate them as whether they believed their facility would classify the event as a Serious Event (harm), as an Incident (no harm) or not reportable at all. Respondents could also respond that they needed more information to make a determination. Definitions of Serious Event and Incident were not provided. The respondents had to rely on the experience of their positions in order to formulate their opinions.

Overall, the results of these questions demonstrate extensive variability in PSOs’ interpretations of MCare’s reporting requirements. A chart summarizing responses is presented in Figure 38. Six of the 10 proposed events had a single response category above 50%, indicating at least a majority opinion among respondents. However, only two of the 10 sample cases elicited a response rate of 75% in a particular category, which could be considered a comfortable level of consensus.

The Authority discussed in the 2007 Annual Report the wide variation in facilities' rates of reporting, and these survey results support the position that this variation is the result of differences in interpretations of the reporting requirements.

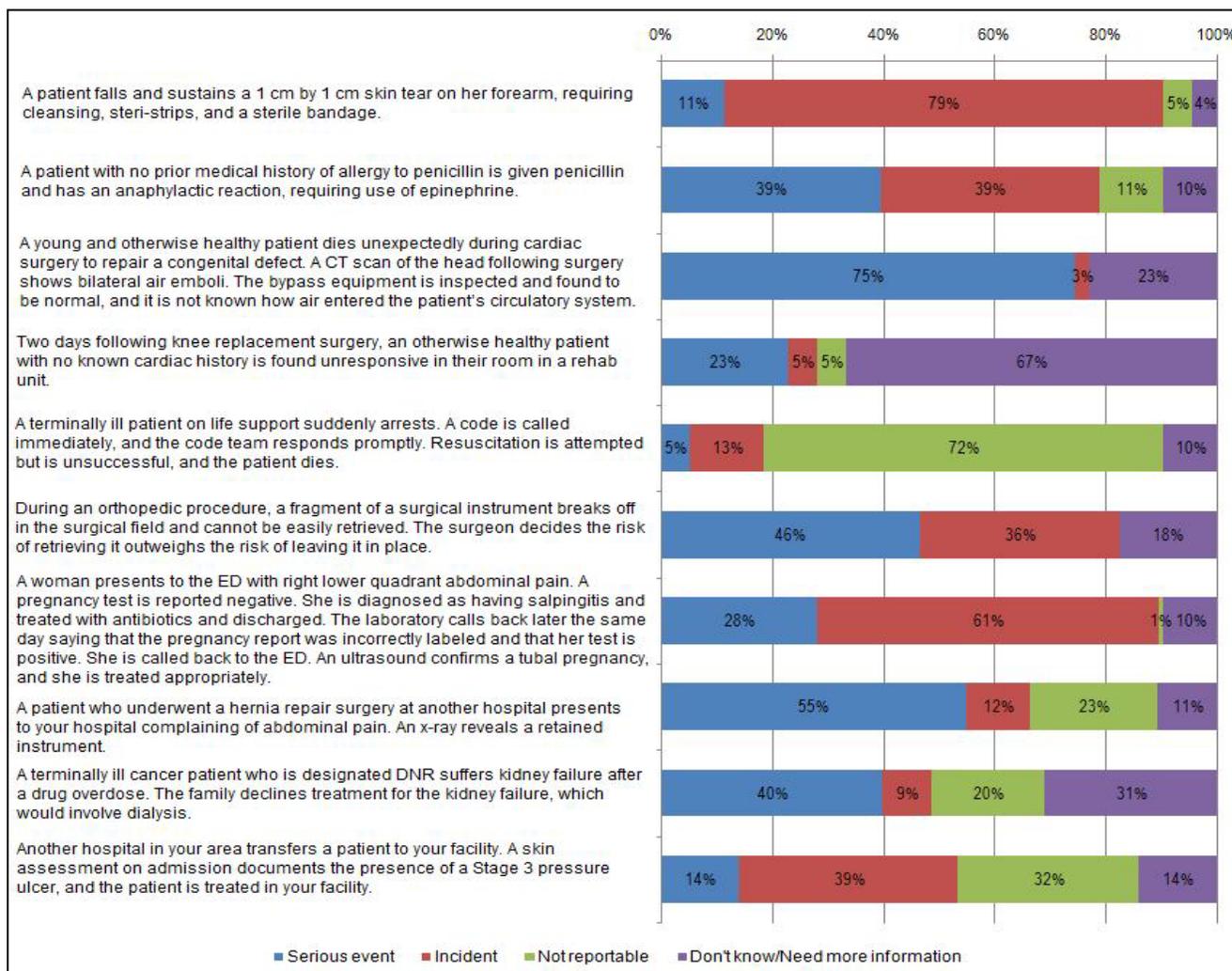


Figure 38. Responses by Percentage to Possible Reportable Scenarios, Posed to Hospital PSOs

The Authority believes this level of variation is unacceptable and will continue to work towards improvement. However, the Authority is not the regulating agency that monitors patient safety reporting. Only the Department of Health has the authority to ensure facilities are reporting properly. The Authority will continue to work with the department to establish a more appropriate reporting framework.

The Authority anticipates some form of final approval guidance to be drafted by the Board of Directors and forwarded to the Department of Health who would have to approve and implement guidance. Once approved by the Department of Health, the department as the regulator of Act 13 of 2002 will be responsible for ensuring the facilities are reporting according to the guidance.

The Authority will provide education and training to healthcare facilities reporting through the Pennsylvania Patient Safety Reporting System and Department of Health licensure surveyors based upon the standardization document.

Report Volume

Reports by Month and Submission Type

Between January 1, 2008, and December 31, 2008, Pennsylvania facilities submitted 219,874 reports to PA-PSRS, bringing the number of reports submitted since the program's inception to 867,612. Table 5 shows the distribution of submitted reports by month for calendar year 2008.

Table 5. Reports Submitted to PA-PSRS in 2008, by Month

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Serious Events	832	818	671	752	691	723	726	714	692	740	610	676	8,645
Incidents	19,749	18,240	17,800	18,531	15,766	15,361	19,386	17,120	16,900	18,200	16,226	17,950	211,229
Total	20,581	19,058	18,471	19,283	16,457	16,084	20,112	17,834	17,592	18,940	16,836	18,626	219,874

Approximately 3.9% of submitted reports were Serious Events, while 96.1% were Incidents. In 2008 the Authority received 18,323 reports per month on average, an increase of 3.7% from 2007. The number of Incident reports averaged 17,602 per month, an increase of 3.2% compared to the previous year. The number of Serious Event reports averaged 720 per month, which represents an 18.9% increase from 2007. Part of the increase can be traced to a certain event type, Healthcare-Associated Infections (HAI), which was reported into the PA-PSRS system early in the year. The mandatory reporting of these events into the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) began in February, and a corresponding decline in HAI submitted to PA-PSRS was observed.

Even after accounting for the temporary increase in HAI reporting before the transition to NHSN, the overall level of Serious Event reporting seems to have risen among other types of events as well. In part, this is to be expected with rising admissions. It may also demonstrate that the attention the Authority has given to the variation in reporting is reinforcing facilities' willingness to disclose Serious Events.

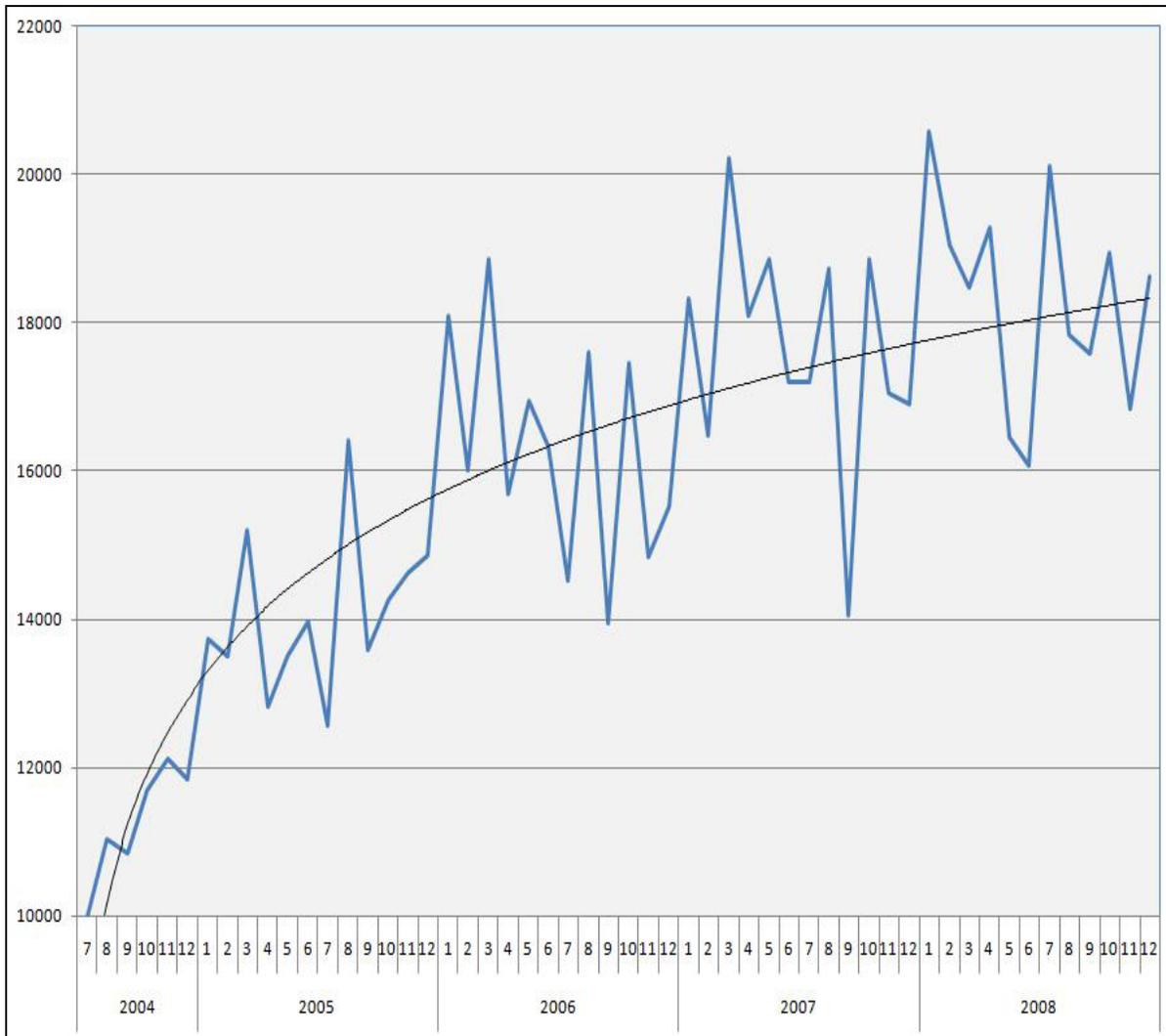


Figure 39. Number of Submitted Reports since Inception of PA-PSRS, by Month

Figure 39 demonstrates that the overall volume of reports submitted to the Authority each month has generally climbed since inception and may now be leveling off somewhat. The increase is primarily due to increases in Incident reporting. This can be due to several factors including: an increased number of actual events; improved recognition of Incidents by facilities; and improved Incident reporting by facilities. The number of reports submitted in January 2008 exceeded 20,000, the most in a single month since the inception of the program. This was offset somewhat by the 15% drop in submitted reports from April to May.

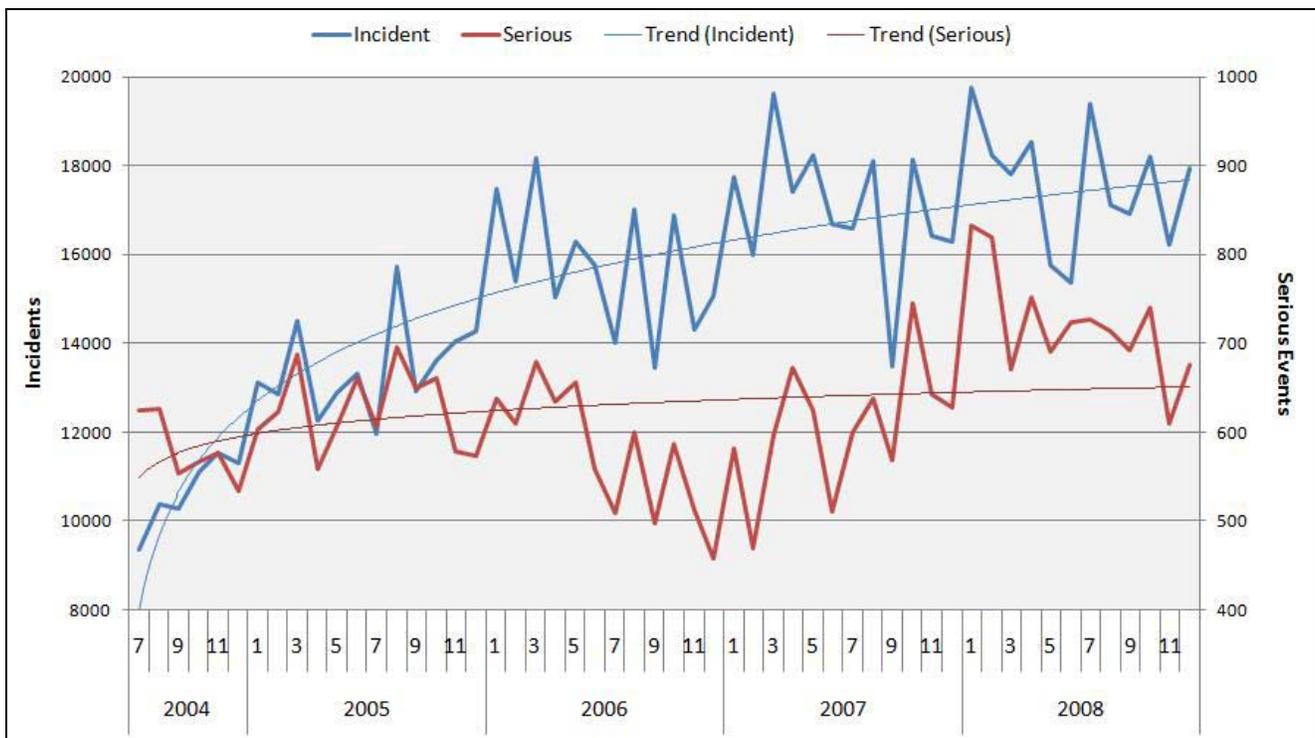


Figure 40. Number of Serious Event and Incident Reports since Inception of PA-PSRS

Figure 40 shows a more constant level of reporting by facilities in recent years. Depicting the volume of Serious Events and Incidents on a relative scale (24:1 given that Serious Events have been on average 4% of all submitted reports) shows that the volume of Incidents may be stabilizing somewhat entering the fifth full year of the program.

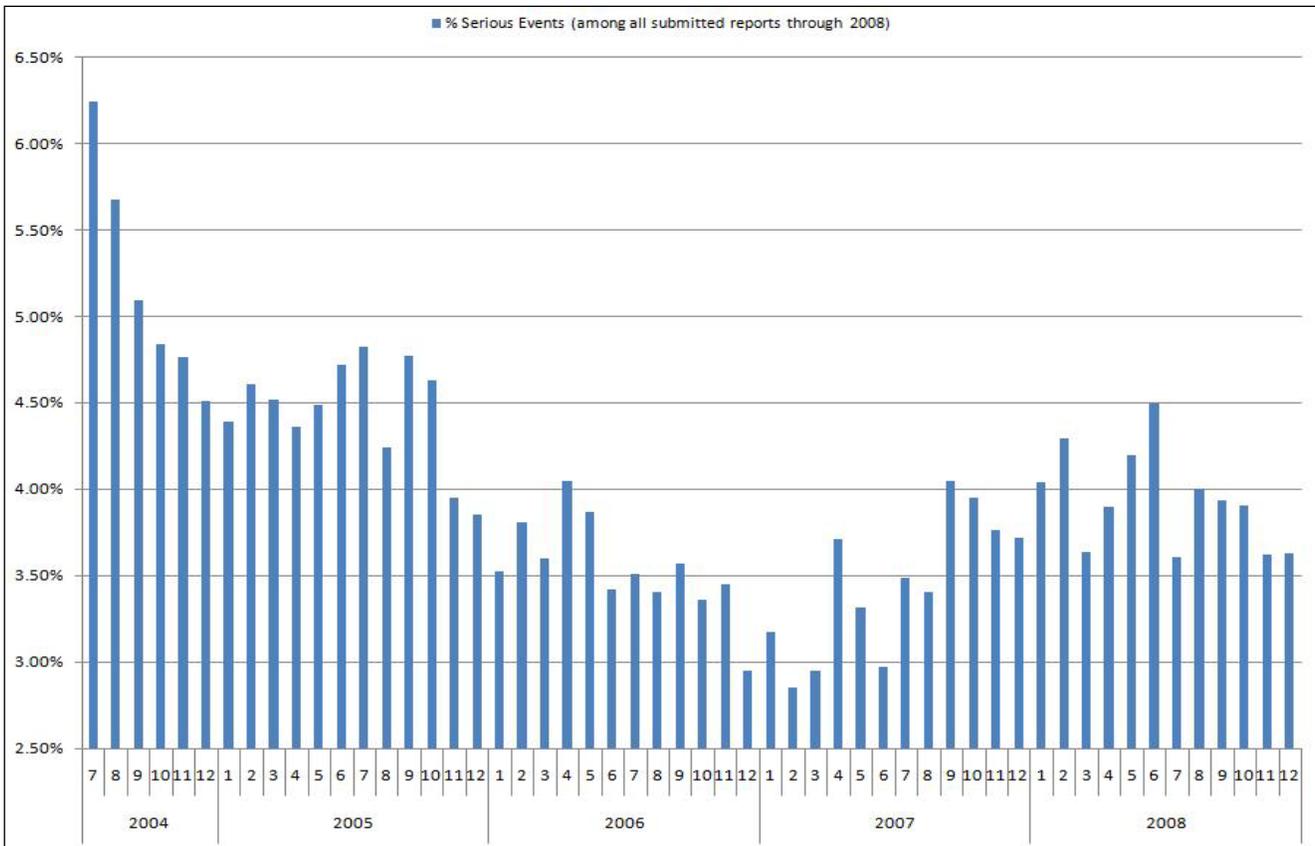


Figure 41. Percentage of Serious Event Reports (2004-2008)

Figure 41 illustrates the percentage of Serious Events among all submitted reports since the inception of the program. There were several months in 2008 where this percentage rose above 4%. In January and February, the explanation for this rise is the submission of HAIs into PA-PSRS instead of NHSN, as detailed above.

This corresponds with the large percentages of HAI-related Serious Events in those months, as seen in Figure 42. Figure 43 also demonstrates a comparison between Incidents and Serious Events over the past four years.

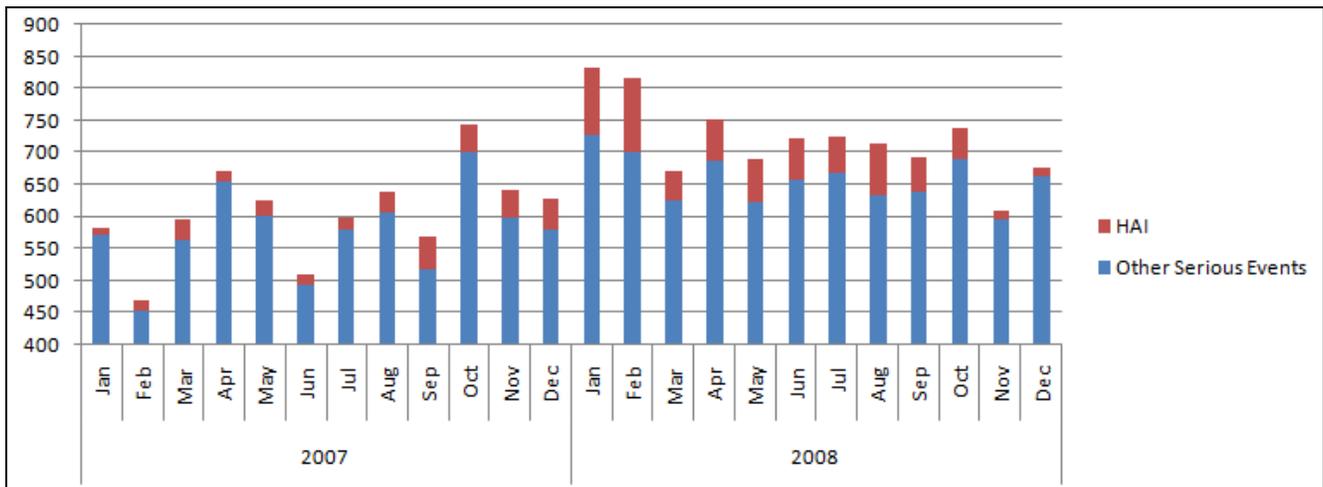


Figure 42. Serious Events by Month (2007-08), HAIs and Others

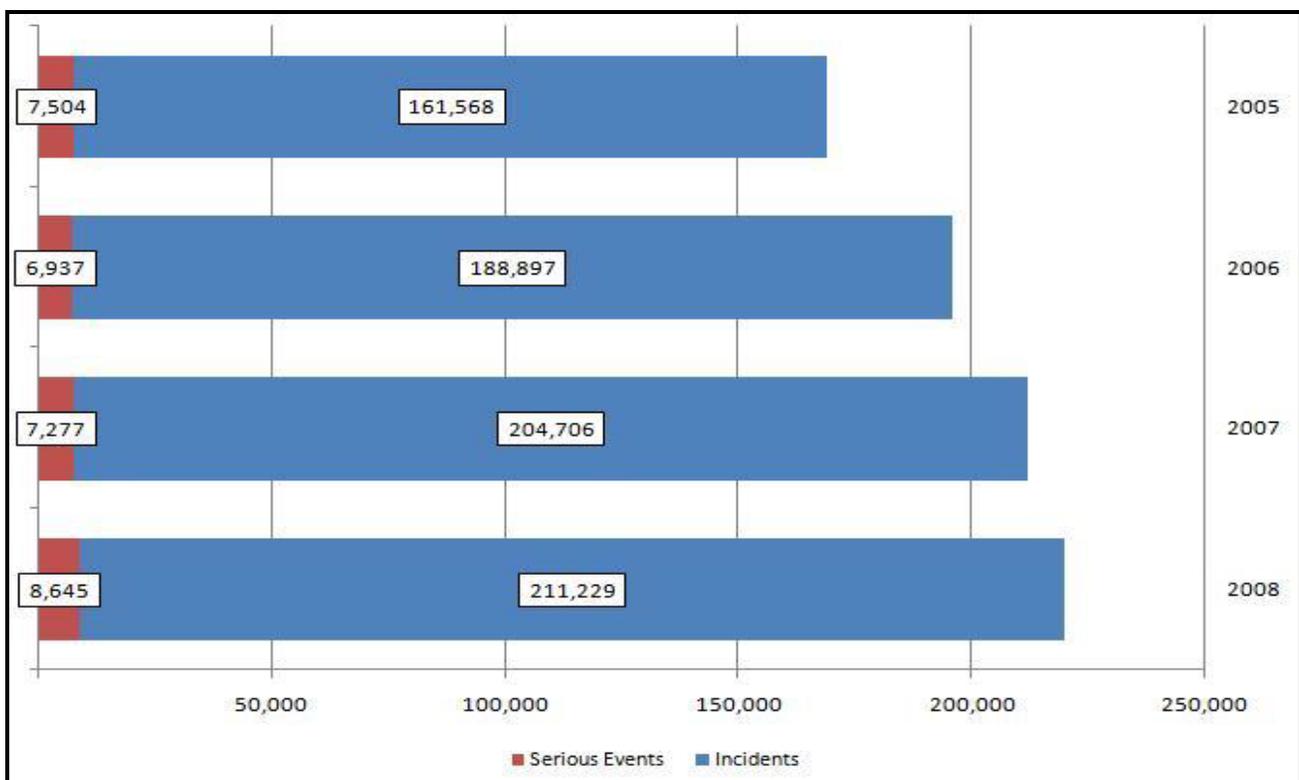


Figure 43. Comparison by Year of Serious Events and Incident Reports of PA-PSRS (2005-2008)

Reports by Event Type

When reporting an event to the Authority, a facility uses a classification system to characterize the occurrence they are reporting. This is usually referred to as the “taxonomy.” At the outset, a facility classifies a report by identifying what PA-PSRS defines as the “Event Type.” The Event Type essentially answers the most basic question about an occurrence: “What happened?”

At its most basic level, PA-PSRS contains the following nine Event Types:

- Medication Errors
- Adverse Drug Reactions (not a medication error)
- Equipment, Supplies, or Devices
- Falls
- Errors Related to Procedures, Treatments, or Tests
- Complications of Procedures, Treatments, or Tests
- Transfusions
- Skin Integrity
- Other / Miscellaneous

These categories are further broken down into second- and third-level subcategories. For example, the category “Falls” includes a series of subcategories such as:

- Falls while Lying in Bed
- Falls while Ambulating
- Falls in the Hallways of the Facility
- Other Types of Falls

The complete Event Type dictionary is a three-level, hierarchical taxonomy with 212 distinct Event Types. This Event Type dictionary is one way PA-PSRS classifies and looks for patterns and trends in submitted reports.

Figure 44 shows the percentage of reports submitted under each top-level Event Type. The most frequently reported occurrences were Errors Related to Procedure/Treatment/Test (23%) and Medication Errors (22%). These two Event Types account for 45% of all reports submitted. While Errors Related to Procedure/Treatment/Test was the Event Type most frequently reported to the Authority, they were not the ones most frequently associated with Serious Events.

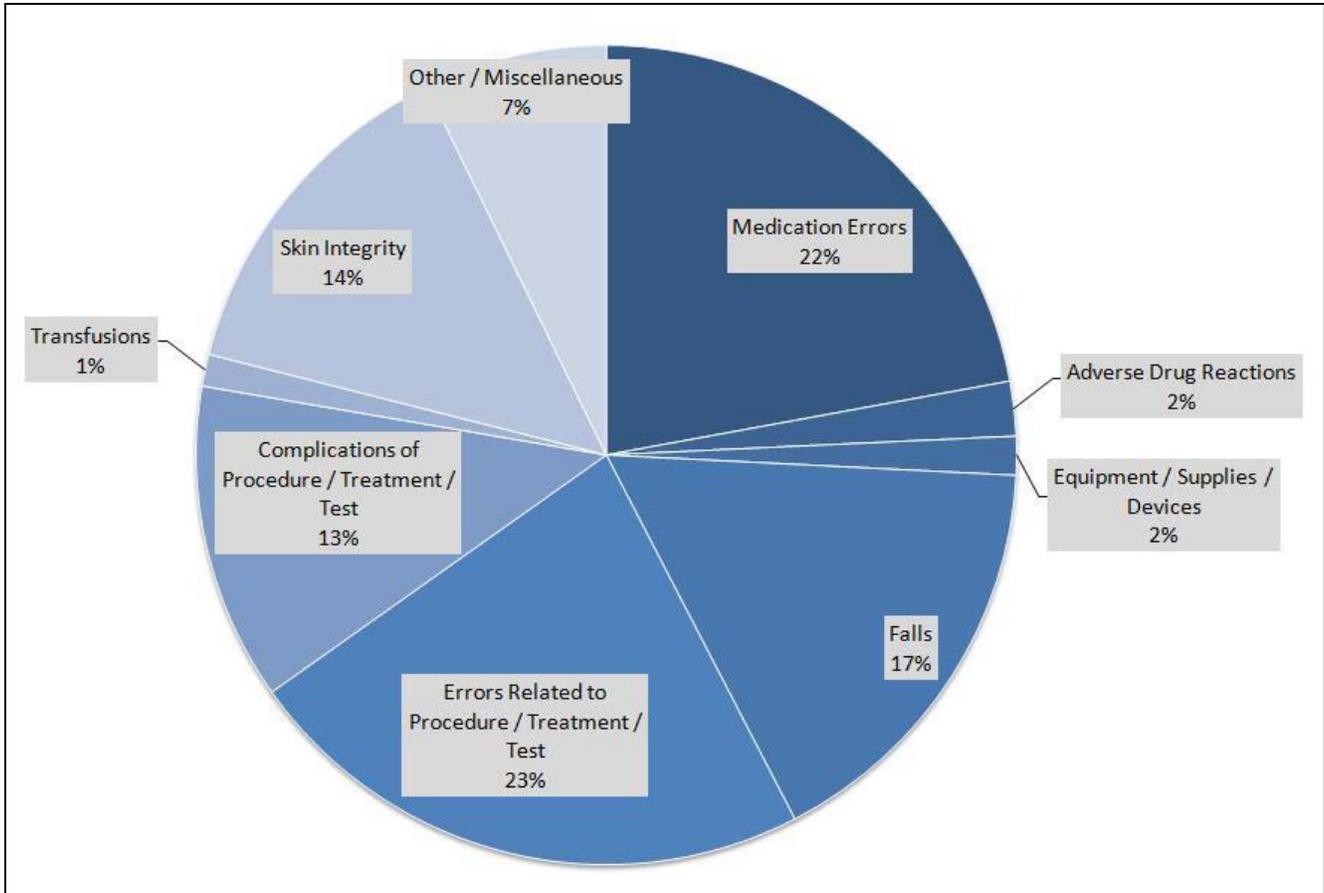


Figure 44. Percentage of Reports by Event Type (2008)

As shown in Table 6, the largest number of Serious Event reports was under the Event Type category Complications of Procedures/Treatments/Tests, followed by the category for Falls. These Event Types accounted for 42% and 18% of all Serious Event reports, respectively. Relative to the overall average of 4% of reports indicating harm, harm was significantly less likely to be reported under Errors Related to Procedure/Treatment/Test (1%).

Table 6. Reports by Event Type and Submission Type for 2008

Event Type	Serious Events		Incidents		Total	Percent of Total
	No.	%	No.	%		
Medication Errors	319	1%	48,311	99%	48,630	22%
Adverse Drug Reactions (not a medication error)	253	5%	4,473	95%	4,726	2%
Equipment / Supplies / Devices	77	2%	3,266	98%	3,343	2%
Falls	1,320	4%	35,190	96%	36,510	17%
Errors Related to Procedure / Treatment / Test	685	1%	49,447	99%	50,132	23%
Complications of Procedure / Treatment / Test	3,751	14%	23,737	86%	27,488	13%
Transfusions	42	2%	2,717	98%	2,759	1%
Skin Integrity	1,016	3%	29,356	97%	30,372	14%
Other / Miscellaneous	1,182	7%	14,732	93%	15,914	7%
Total	8,645	4%	211,229	96%	219,874	100%

Figure 45 demonstrates that a large decline in Serious Events from 2005 to 2008 occurred in Skin Integrity, the Event Type in which Pressure Ulcers are typically submitted. Perhaps due to greater awareness of Pressure Ulcers in regard to Centers for Medicare & Medicaid Service (CMS) reimbursement, a renewal of submissions was evident. Serious Events of report type Complications of Procedure/Treatment/Test increased once again in 2008; the event type includes Healthcare-Associated Infections, which hospitals are now submitting to the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN).

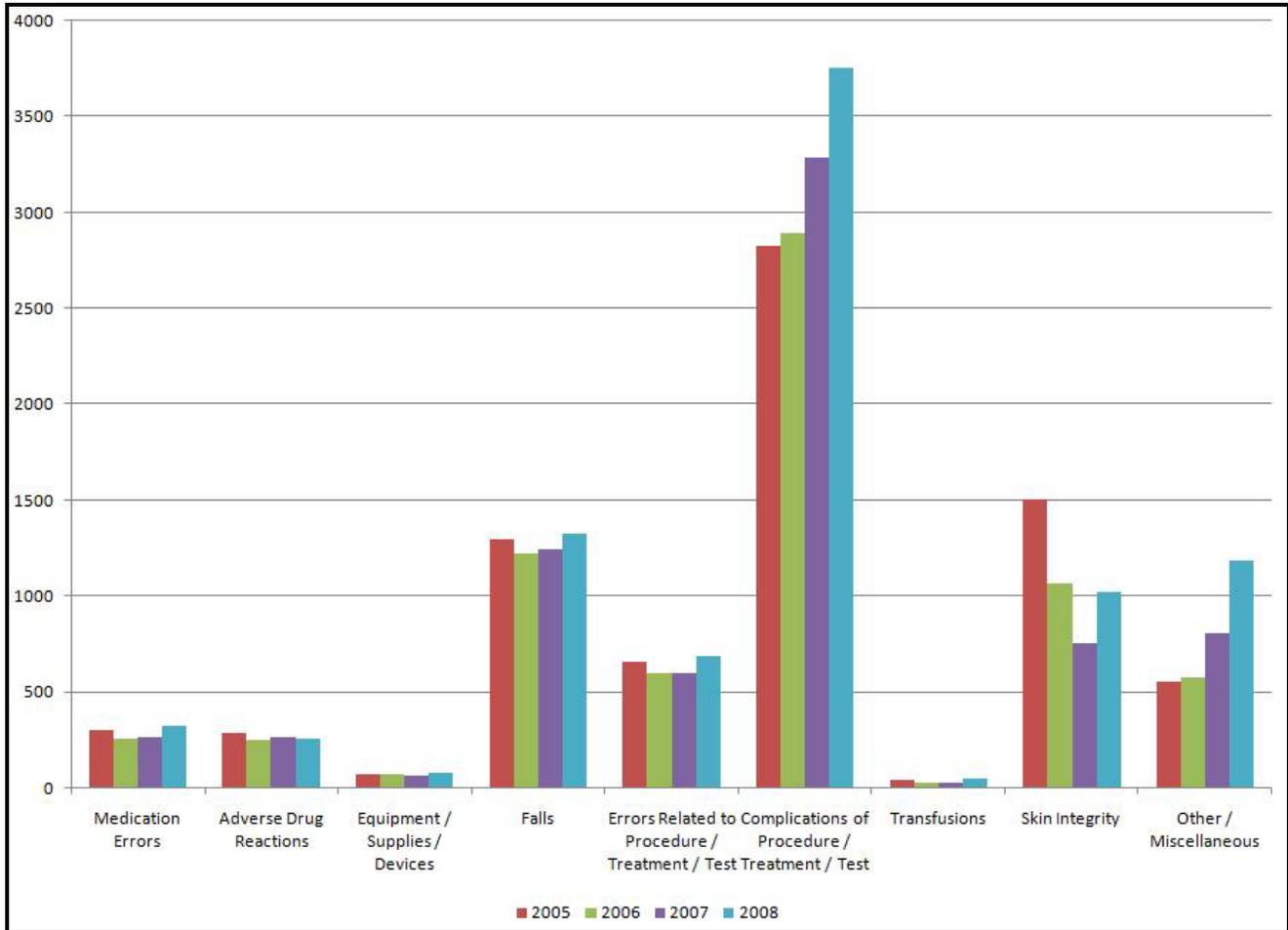


Figure 45. Reports Classified as Serious Events by Event Type (2005-2008)

A closer look at Serious Events of report type Complications of Procedure/Treatment/Test actually shows a decrease from 2007 to 2008 when excluding the Serious Events submitted as HAI, as shown in Figure 46.

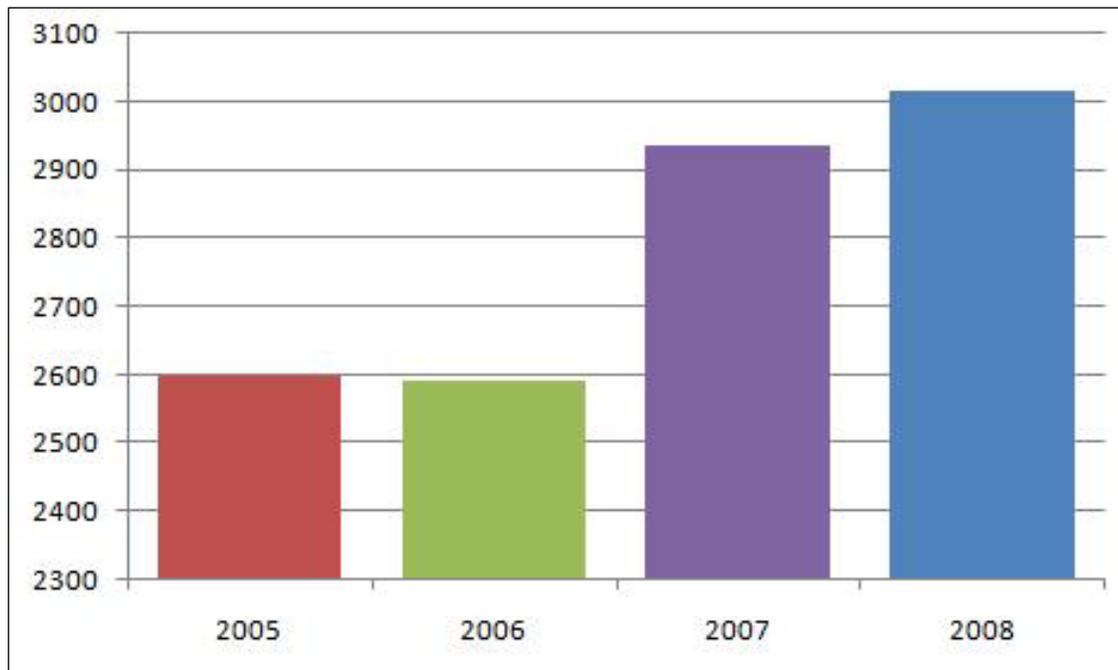


Figure 46. Detail of Serious Events of Report Type Complications of Procedure/Treatment/Test, Excluding HAI Reports Submitted as Serious Events (2005-2008)

Figure 47 below illustrates the submission of HAI as Serious Events into PA-PSRS in 2007 and 2008, by month.

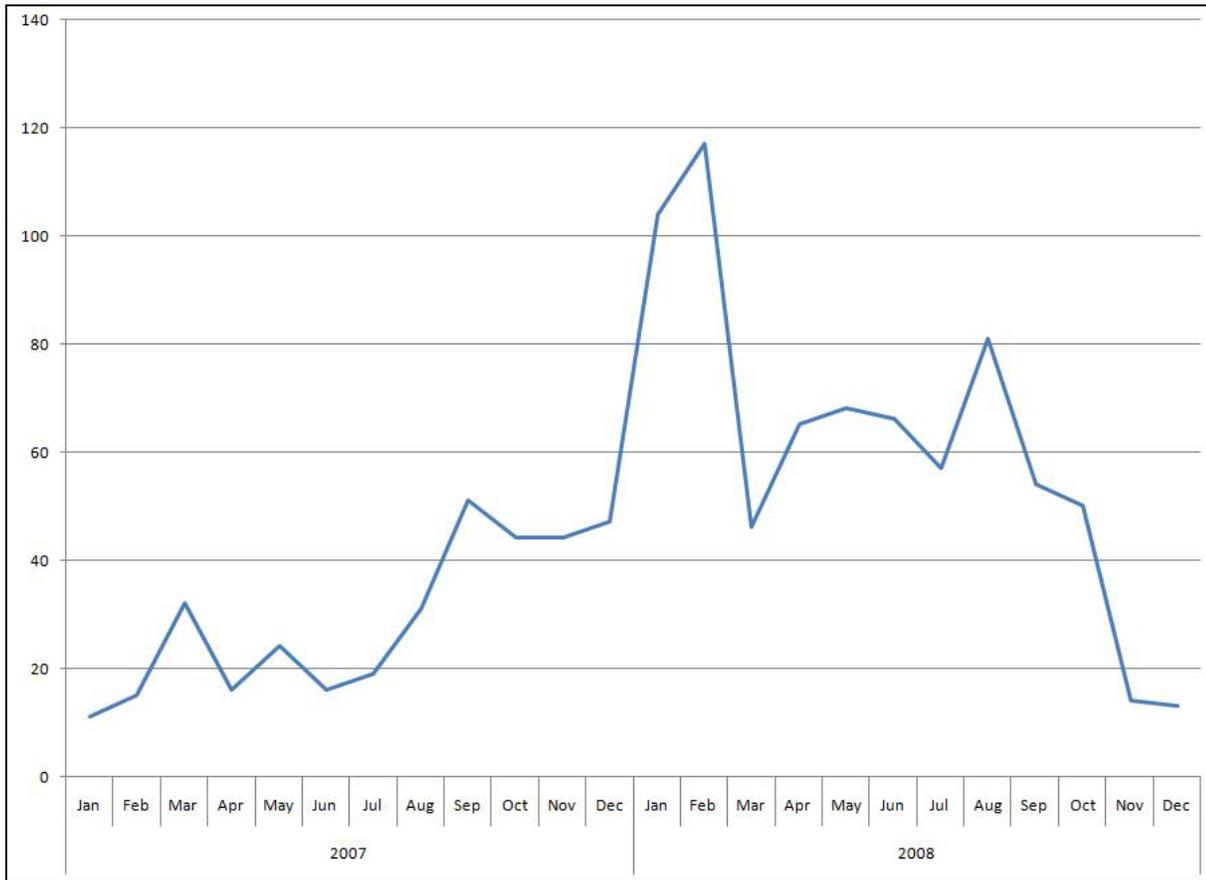


Figure 47. HAI Reports Submitted as Serious Events by Month (2007 and 2008)

Adjusting the report volume for a measure of healthcare utilization paints a different picture. Figure 50 shows, by region, the number of reports from hospitals per 1,000 patient days.¹⁷ This figure shows that, after accounting for the differences in the volume of healthcare provided in each region, facilities in the northcentral region reported more per 1,000 patient days than any other region. Also of note, the northwest region submitted a significantly greater proportion of Serious Events (7.6% of their reports) than the statewide average (3.5%).

It is difficult to draw conclusions about regional safety from these reporting patterns. As noted previously, the results shown could be due to several factors including: an increased number of actual patient safety events; differences in the ability to identify patient safety events (especially Incidents); and differences in the way facilities report patient safety events.

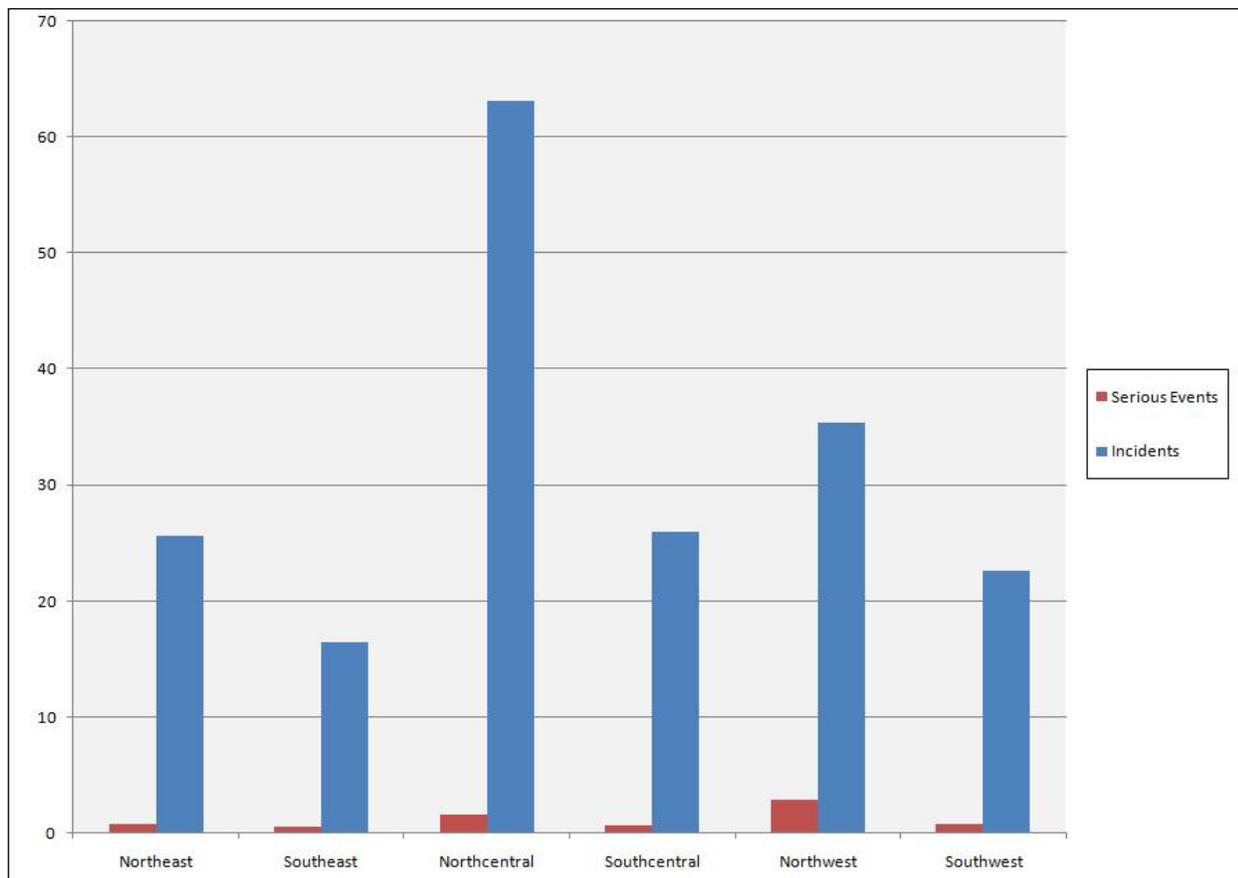


Figure 50. Reports from Hospitals per 1,000 Estimated Patient Days by Region (2008)

¹⁷ Patient days are a commonly used measure of healthcare utilization or volume. A patient day is defined as one calendar day of healthcare provided to a hospital inpatient. Patient days for each region were calculated based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.phc4.org). In each region, the number of reports submitted by hospitals from January through December 2008 was divided by the number of patient days estimated for 2008. Since only partial data is available for 2008, we estimated figures for the year using seasonal decomposition to account for any seasonal fluctuations in utilization. Further, data provided by PHC4 is based on patient home region, not necessarily the region of the facility in which the patient was treated. Inter-regional treatment accounts for 12.7% of admissions, based on calculations performed on a sample of 10% of Pennsylvania counties.

Comparing year to year, there is an observable increase across the regions of hospital reports per 1,000 patient days, as seen in Figure 51. The lone exception is a slight decrease in the southwest region from 2007 to 2008, where reporting declined 6.9%. There was an average increase per region of 3.4 hospital reports per 1,000 patient days from 2007 to 2008.

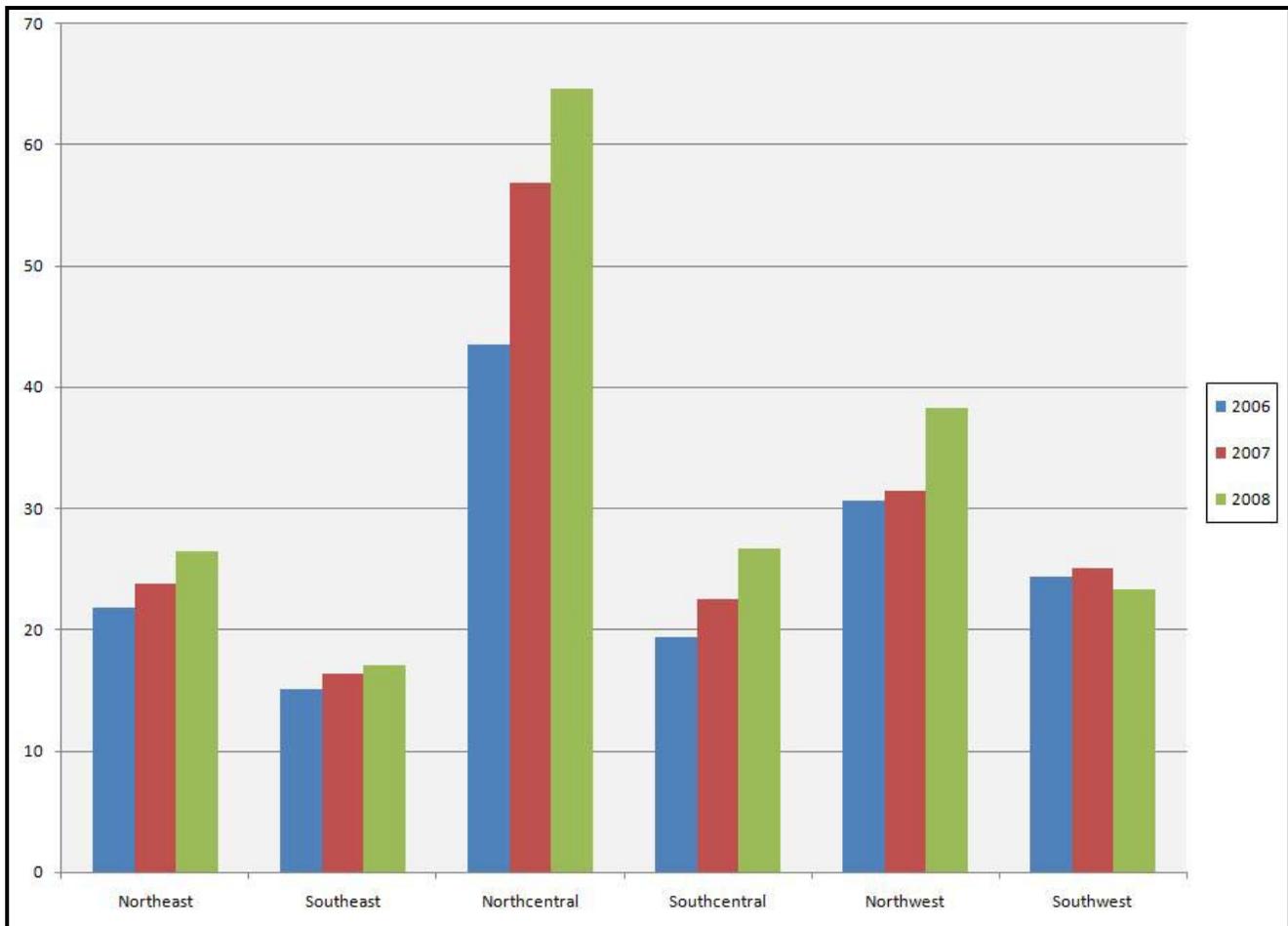


Figure 51. Reports from Hospitals per 1,000 Patient Days by Region (2006 through 2008)

Reports by Facility Type

As shown in Table 7, the vast majority of reports (98.6%) submitted to the Authority were submitted by hospitals.

Table 7. Reports through PA-PSRS by Facility Type (2008)

Facility Type	Hospitals	Ambulatory Surgical Facilities	Birthing Centers/Abortion Facilities	All
Number of Reports Submitted	216,732	3,089	53	219,874
Number of Facilities Active for year ending Dec. 31, 2008	241	261	23	525

Table 8 shows reporting rates among non-hospital facilities (ASFs/BCs/ABFs) compared to hospitals from year to year. An increase in the percentage of reports submitted from non-hospitals is attributable to an increased number of ambulatory surgical facilities and greater reporting from those facilities. Ambulatory facilities submitted 11.8 reports per facility in 2008 compared to 10.7 reports per facility in 2007. Overall, the number of reports from all facilities continues to rise.

Table 8. Reports by Facility Type since Inception of PA-PSRS

Year	Hospitals		Ambulatory Surgical Facilities/ Birthing Centers/Abortion Facilities		All Facilities Total
	No.	% of Facility Type	No.	% of Facility Type	
2004*	69,926	98.69%	925	1.31%	70,851
2005	166,998	98.77%	2,074	1.23%	169,072
2006	193,262	98.69%	2,570	1.31%	195,832
2007	209,285	98.73%	2,698	1.27%	211,983
2008	216,732	98.57%	3,142	1.43%	219,874
Total	856,203	98.69%	11,409	1.31%	867,612

*The PA Patient Safety Authority began mandatory reporting statewide on June 28, 2004.

Reports by Level of Patient Harm

For every report submitted to PA-PSRS, the healthcare facility applies a 10-item scale to measure whether an event “reached” the patient and, if so, how much harm it caused.¹⁸ This scale ranges from “unsafe conditions” (e.g., look-alike medications stored next to one another) to the death of the patient and can be summarized as follows:

- Unsafe Conditions—Circumstances that could lead to an adverse event (accounting for 8% of all reports)
- Event, No Harm—An event that either did not reach the patient or did reach the patient but did not cause harm (often called a “near miss,” accounting for 88% of all reports)
- Event, Harm—An event that reached the patient and caused temporary or permanent harm (3.76%)
- Event, Death—An event occurred that resulted in or contributed to death (0.17%)

Table 8 shows the reports received during 2008 categorized by the level of harm (as described above) and by Event Type. For the most part, the reports at each level of harm follow a similar distribution by Event Type as they do in the database as a whole. There are exceptions to this, however. For example, while complications comprise 13% of reports overall in 2008, they comprise 43% of the reports of events involving harm and 59% of all reports of events resulting in or contributing to the patient’s death.

At the other end of the spectrum, while medication errors comprise 22% of reports in 2008, they only comprise 4% of events involving harm and 1% of events contributing to or resulting in death. Reports of errors related to procedures/treatments/tests were also associated with harm or death at a frequency lower than their representation in the database as a whole; while they comprise 23% of reports in 2008, they comprise only 8% of reports involving harm or death.

A certain portion of the reports could be referred to as examples of Unsafe Conditions, meaning that there was an observed situation in which some harm was a possibility if corrective action was not taken. Unsafe Conditions were cited in 8% of the reports submitted in 2008. As shown in Table 9, the event types in which Unsafe Conditions were most often reported were Error related to Procedure/Treatment/Test (25%) and Skin Integrity (29%). The event type where Unsafe Conditions were least reported by percentage was Adverse Drug Reactions. Of all reports of the Adverse Drug Reactions event type, 0.3% were reported as Unsafe Conditions.

¹⁸ For example, an event in which a phlebotomist goes to draw blood from the wrong patient but catches the error by checking the patient’s wristband, would be an event that did not reach the patient.

Table 9. Reports by Event Type and Level of Patient Harm (2008)

Event Type	Unsafe Conditions		Event, No Harm		Harmful Event		Death Event		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Medication error	1,890	10%	46,422	24%	316	4%	2	1%	48,630	22%
Adverse Drug Reaction	55	0%	4,418	2%	241	3%	12	3%	4,726	2%
Equipment / Supplies / Devices	413	2%	2,853	1%	75	1%	2	1%	3,343	2%
Fall	448	2%	34,742	18%	1,309	16%	11	3%	36,510	17%
Error related to Procedure / Treatment / Test	4,603	25%	44,844	23%	666	8%	19	5%	50,132	23%
Complication of Procedure / Treatment / Test	1,224	7%	22,515	12%	3,534	43%	216	59%	27,489	13%
Transfusion	349	2%	2,367	1%	41	0%	1	0%	2,758	1%
Skin Integrity	5,249	29%	24,107	12%	1,016	12%	0	0%	30,372	14%
Other / Miscellaneous	4,100	22%	10,632	6%	1,079	13%	103	28%	15,914	7%
Total	18,331	8%	192,900	88%	8,277	3.76%	366	0.17%	219,874	100%

Also, to repeat figures shown above, only 3.93% of all reports submitted involve harm to the patient, ranging from a simple laceration to a life-threatening situation and death. A subset of reports are classified as having contributed to or resulted in the patient's death. These account for only a fifth of one percent of all submitted reports.

In looking at particular event types, although 14% of all reports in 2008 were attributed to Complications of Procedure/Treatment /Test, 59% of all reports involving the patient’s death were of that event type. Figure 52 illustrates that the vast majority of reports do not result in Patient Harm.

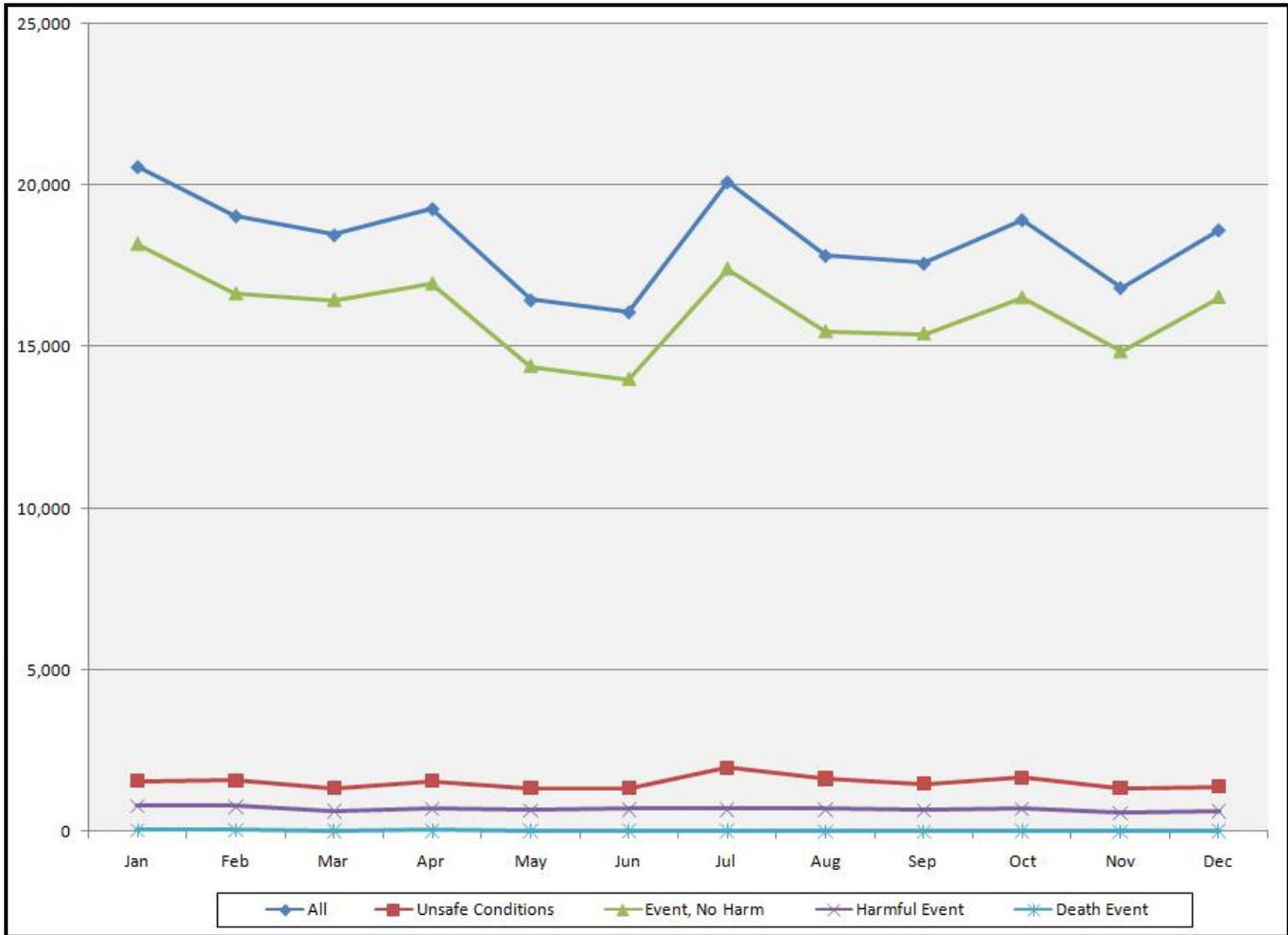


Figure 52. Reports by Level of Harm by Month (2008)

Reports Involving the Patient’s Death

In 2008, PA-PSRS received 366 reports of events that may have contributed to or resulted in the patient’s death. Not all of these patient deaths were preventable, and they did not necessarily involve an error on the part of a healthcare provider to be reportable under Act 13 of 2002.

These account for a fifth of one percent of all submitted reports. In terms of particular event types, although 14% of all reports in 2008 were attributed to Complications of Procedures/Treatments/Tests, about 59% of all reports involving the patient’s death were of that event type. Of these reports involving death associated with complications, the majority describe patients who died following surgery or another invasive procedure (49%) or patients who suffered cardiopulmonary arrest outside the ICU setting (22%). A further 12% involved maternal or neonatal injury associated with childbirth.

Table 10. Reports Involving the Patient’s Death, by Event Type (2008)

Event Type	No.	%
Medication error	2	0.5%
Adverse Drug Reaction	12	3.3%
Equipment / Supplies / Devices	2	0.5%
Fall	11	3.0%
Error related to Procedure / Treatment / Test	19	5.2%
Complication of Procedure / Treatment / Test	216	59.0%
Transfusion	1	0.3%
Skin Integrity	0	0.0%
Other / Miscellaneous	103	28.1%
Total	366	100%

Many reports involving the patient’s death were reported with the primary event type of “Other/Miscellaneous.” This category in the taxonomy contains a subcategory “Other unexpected death,” which explains the extensive use of this category. Many of these reports involve patients who were found unresponsive, who went into respiratory arrest and resuscitation efforts failed, or who were admitted to the hospital and died of their disease.

Patient Demographics

PA-PSRS collects few demographic details about patients because the Authority is not authorized to collect individually identifying information. In general, most reports include only information on patient gender and age. Table 11 presents the number of reports received in 2008 by patient gender and age cohort.

Table 11. Reports Submitted by Age Cohort and Gender (2008)

Age Cohort	Female		Male		All Patients		% Patients
	No.	%	No.	%	No.	%	Female
0 - 4	3,632	3.07%	4,888	4.81%	8,520	3.87%	42.63%
5-14	1,428	1.21%	1,801	1.77%	3,229	1.47%	44.22%
15-24	5,926	5.01%	3,545	3.49%	9,471	4.31%	62.57%
25-34	7,464	6.31%	3,953	3.89%	11,417	5.19%	65.38%
35-44	8,717	7.37%	6,609	6.50%	15,326	6.97%	56.88%
45-54	13,028	11.02%	12,593	12.39%	25,621	11.65%	50.85%
55-64	15,485	13.09%	16,856	16.59%	32,341	14.71%	47.88%
65-74	18,704	15.82%	18,616	18.32%	37,320	16.97%	50.12%
75-84	25,875	21.88%	22,117	21.77%	47,992	21.83%	53.92%
85+	18,002	15.22%	10,635	10.47%	28,637	13.02%	62.86%
Total	118,261	100.00%	101,613	100.00%	219,874	100.00%	53.79%

Patient Gender

Of the 219,874 reports submitted in 2008, 118,261 (53.8%) involved female patients, and 101,613 (46.2%) involved male patients. This pattern is consistent with our observations since 2004. During childbearing years women are more likely than men to have encounters with the healthcare system, and because women have a longer life expectancy than men, there are simply more women in the general population in the older age cohorts.

The proportion of reports classified as Serious Events differed slightly according to the patient's gender, with 4.1% of reports involving female patients classified as Serious Events, compared to 3.7% for reports involving males.

Table 12 shows the distribution of reports by patient gender and Event Type. Many of the same patterns observed in 2007 are evident this year as well. The proportion of reports involving female patients was significantly higher among reports of Adverse Drug Reactions and significantly lower among reports of Falls, compared to reports overall.

Table 12. Reports Submitted by Gender and Event Type (2008)

Event Type	Female		Male		All Patients	
	No.	%	No.	%	No.	% of Total
Medication Errors	26,779	55.1%	21,851	44.9%	48,630	22.1%
Adverse Drug Reactions	3,000	63.5%	1,726	36.5%	4,726	2.1%
Equipment / Supplies / Devices	1,722	51.5%	1,621	48.5%	3,343	1.5%
Falls	18,427	50.5%	18,083	49.5%	36,510	16.6%
Errors Related to Procedure / Treatment / Test	27,053	54.0%	23,079	46.0%	50,132	22.8%
Complications of Procedure / Treatment / Test	15,576	56.7%	11,913	43.3%	27,489	12.5%
Transfusions	1,558	56.5%	1,200	43.5%	2,758	1.3%
Skin Integrity	15,788	52.0%	14,584	48.0%	30,372	13.8%
Other / Miscellaneous	8,358	52.5%	7,556	47.5%	15,914	7.2%
Total	118,261	53.8%	101,613	46.2%	219,874	100%

Patient Age

Figure 53 shows the proportion of reports through PA-PSRS, from hospitals only, by gender and by patient age cohort. As noted above, this chart also illustrates that women are more likely than men to have encounters with the healthcare system during childbearing years. Patients aged 65 and older account for 52% of all reports from hospitals to the Authority in 2008. Also shown on this figure is the proportion of hospital inpatient admissions as reported by the Pennsylvania Healthcare Cost Containment Council (PHC4).¹⁹ However, this chart does not suggest that older patients are necessarily more likely than younger patients to be involved in a Serious Event or Incident. Rather, older patients' larger representation in the database simply reflects their larger representation in the healthcare system.

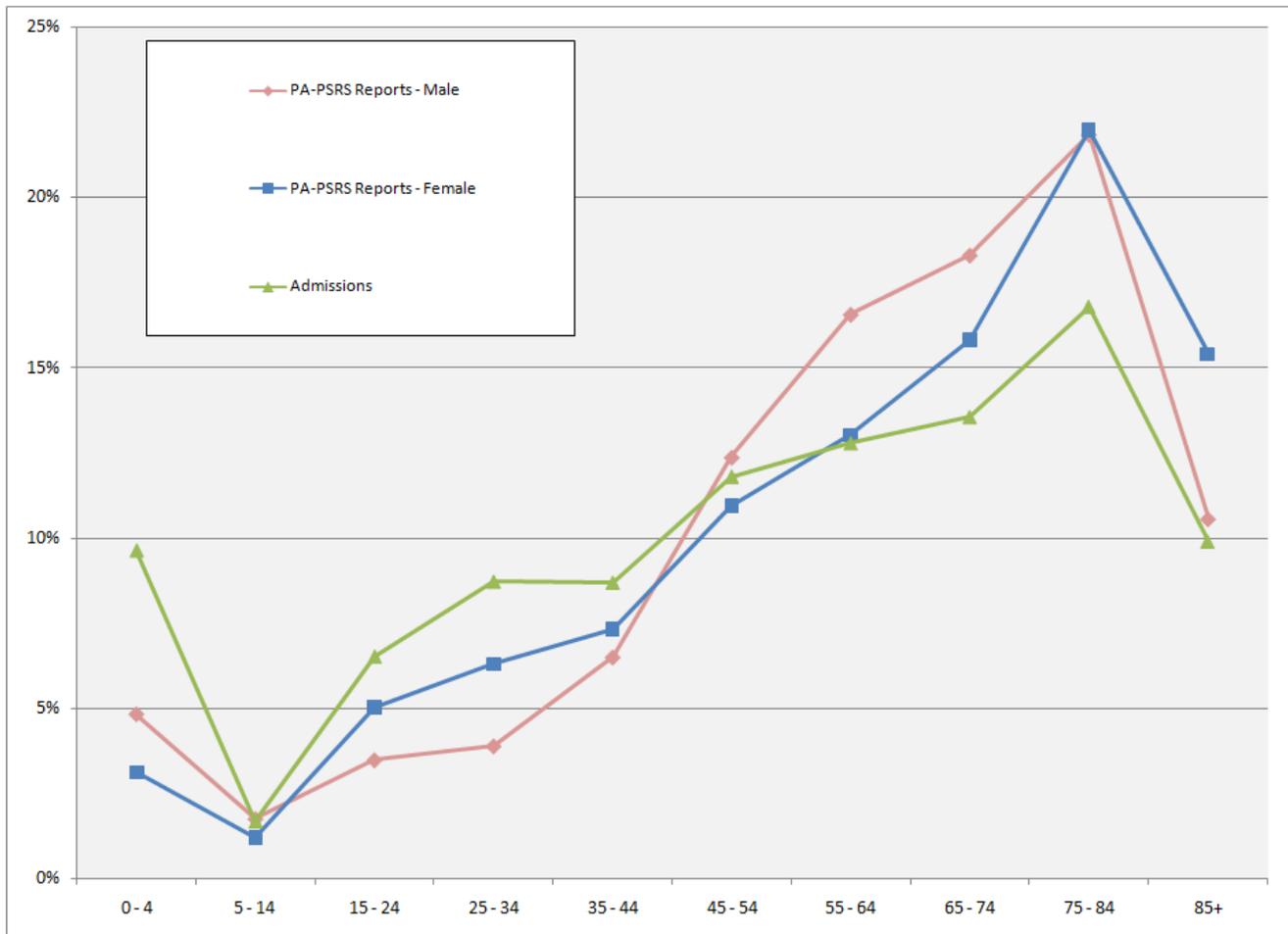


Figure 53. Proportion of Hospital Reports through PA-PSRS by Gender and Age Cohort (2008)

¹⁹ Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council (www.PHC4.org). Estimates were based on statewide inpatient data from the third quarter 2007 through second quarter 2008.

Patients Most at Risk by Age

Elderly Patients

In the Authority's previous annual reports, we identified several patterns of interest in reports involving elderly patients (65 and older), including a decrease in the percentage of reports. For example, in 2007, more than half of all reports (52.7%) involved patients 65 and older. In 2008, this figure dropped slightly to 51.8%. Elderly patients accounted for 64% of Falls in 2004 and 2005. This figure fell slightly to 62.4% in 2006 and further in 2007 to 61.2%. In 2008, this figure has dropped to 60.2%. Elderly patients accounted for 73.1% of reports related to Skin Integrity in 2006; this figure increased slightly to 73.5% in 2007; it is back down to 73.1% in 2008.

Perinatal Patients

There were 4,107 reports involving perinatal patients (those aged 20 days or younger), a decrease of 30% from 2007, which is a notable reversal of last year's 10% increase. However, 4.8% of perinatal reports were classified as Serious Events, higher than the overall percentage of 3.9%.

Just as last year, two thirds (66.7%) of reports for these patients were related to Errors or Complications of Procedures, Treatments or Tests. This does not necessarily mean that these patients are more likely to experience errors or complications. Rather, they may not be as prone to other types of events (e.g., falls, problems with skin integrity) as older patients.

About a fifth (19.4%) of reports involving perinatal patients was related to Medication Errors. This compares to 20% in 2007, 21% in 2006, 22% in 2005 and 19% in 2004. Complications of Procedures, Treatments and Tests accounted for 78.3% of the Serious Events in this age group.

Children and Adolescents

There were 7.8% more reports submitted to the Authority in 2008 involving children and adolescents (i.e., aged 21 and younger) than in 2007. As was the case last year, Errors Related to Procedures, Treatments and Tests were the most commonly submitted type of report, accounting for 30.8% of the reports of this population. However, event type Complications of Procedures, Treatments and Tests made up 55.9% of all Serious Events for this age group.

Education, Outreach and Collaboration



The Pennsylvania Patient Safety Authority has been fulfilling its mission of educating its stakeholders not only through its *Pennsylvania Patient Safety Advisory* but also through its outreach and collaboration efforts. The Patient Safety Liaison (PSL) pilot program begun in 2008 has allowed the Authority and individual facilities one-on-one face time to help tailor patient safety improvement programs. Through facility feedback, the Authority has developed two new educational programs. Through the visits, the Authority has also been able to make facilities aware of various educational tools available to them. In 2009, the Authority will expand the program to reach more facilities individually. Along with the PSL program, the Authority began educating Boards of Trustees and top level management through another pilot program developed in partnership with the Hospital and Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA). The Authority has also reached out to several state associations to provide continuing education credits for physicians, nurses and pharmacists. Presentations to various stakeholders and interested publics have also grown in 2008. Also, collaborations with stakeholders continue so the Authority can ensure the data it has collected is being used to improve patient safety as much as possible. More details on these educational efforts

are provided below along with updates on the Patient Safety Knowledge Exchange (PasSKEy) program and the Authority's new Web site. The Authority's efforts to reach out to its stakeholders have grown in 2008 with the expectation that we've only just begun.

The Patient Safety Liaison Program – Bringing the Authority's Educational Resources to Pennsylvania's Healthcare Facilities

Fulfilling a critical component of its mission and the 2007 strategic plan, the Authority hired a Director of Educational Programs to oversee its educational initiatives including the Patient Safety Liaison (PSL) program.

At the request of Patient Safety Officers for "more of a presence" from the Authority, the Patient Safety Liaison program was developed. The PSL acts as a consultant for Pennsylvania's healthcare facilities to ensure they are aware of the numerous educational resources available to them from the Authority. While acting as a liaison between the Authority and healthcare facilities, the PSL also serves as a liaison between healthcare facilities within the region.

The first Patient Safety Liaison was hired in August 2008 in the northeast region of Pennsylvania. The northeast region has 71 medical facilities, hospitals, birthing centers, ambulatory surgery facilities (ASF) and certain abortion facilities. There are currently 66 PSOs overseeing these 71 medical facilities. The reception of the medical facilities to the PSL has been welcoming and forthcoming. The attendance at the first meetings is varied from leadership (CEOs), middle management, owners of facilities and PSOs. Topics discussed are varied but consistent themes related to patient safety. These themes include identified opportunities for improvement, strategies being employed, successes, barriers and sharing of information. The PSL also takes this opportunity to share with the audience resources currently available to the PSO through the Authority. These resources include items such as toolkits, *Pennsylvania Patient Safety Advisory* articles, patient safety information from other entities, consumer tips and availability of continuing education credits in patient safety. The PSL also solicits feedback from its Patient Safety Officers to understand what they need from the Authority to improve patient safety in their specific facility.

New education programs and sessions were developed by the Authority at the request of the northeast facilities. These programs and sessions will be instituted statewide once the other regional Patient Safety Liaisons are on board.

The Authority developed a basic patient safety program, called the “Patient Safety Officer Foundation Curriculum” to discuss the specifics behind patient safety and Act 13 of 2002. Hospital staff attending the program included CEOs, management staff and PSOs from hospitals and ambulatory surgical facilities. Feedback was very positive and there were numerous requests for additional educational sessions regarding patient safety leadership and insights, such as human factors, highly reliable organizations (HRO), crew management and proactive risk reduction strategies (FMEA). The Authority is developing a second program called “Beyond the Basics” to coincide with the basic program.

Through the Northeast PSLs interactions with PSOs of various care settings, educational needs regarding specific health care topics have been identified. For example, in April 2009 a half-day session on MRSA was given to ambulatory surgical facility employees in the northeast region. The session was well received. More HAI sessions are planned throughout the state once the other PSLs are on board.

The PSL and Director of Educational Programs also speak to numerous professional healthcare organizations about the program to ensure it is utilized by the healthcare facilities. In February 2009, a presentation about the PSL program was given to the Council for Small Hospitals at the Hospital and Healthsystem Association of Pennsylvania (HAP). The program was embraced as a resource to educate staff at no additional costs to their facility.

Currently it is projected that three additional PSLs will be hired for the northwest, southwest and south central regions of Pennsylvania for FY 08-09. The Authority is in the first steps of the selection process and expects to have the three new hires in place in late spring (May-June 2009). The full complement of six PSLs is projected for FY 09-10.

Patient Safety Training for Trustees

This year the Authority put its strategic plan initiative to educate executive management and Boards of Trustees into action. The initiative is designed to raise awareness and conversation around patient safety by bringing it to the board level.

The Patient Safety Authority partnered with the Hospital and Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) to begin a pilot program to include various hospitals and health systems. An advisory panel composed of executive leaders and trustees from hospitals and health systems assisted the Patient Safety Authority and HAP to develop a customized educational program that would help foster the kind of senior level and board engagement needed for improved patient safety. A business model was developed and the Authority provided the funding needed to host four training sessions in which a total of about 300 persons would participate.

Dr. John Combes of the American Hospital Association's Center for Health Care Governance developed the four pilot trustee training sessions that include:

- One session for a group of 3 or 4 small/rural hospitals
- One session for a group of 3 or 4 community hospitals
- One session for a stand-alone community hospital
- One session for a multi-hospital system

The first conference was held for the Board of Trustees at Susquehanna Health in Williamsport in the fall of 2008 with mostly positive feedback.

The President and CEO of Susquehanna Health attended the conference and made several patient safety improvements to its organization as a result of the program.

"This conference provided the material and motivation necessary to complete a thorough review of our trustees' role in quality and safety. I fully endorse the program for all hospital and health system trustees charged with or interested in quality and safety of the services their organizations provide...Susquehanna Health anticipates using a modified version of this curriculum for future programmatic evaluation and strategic planning. We are grateful that this program helped stimulate our thinking and provided us with the motivation to make these changes."

*Steven P. Johnson, FACHE
President and CEO
Susquehanna Health*

The Susquehanna Health patient safety improvements include:

- Elevating the importance of the Health System's Quality and Safety Committee by appointing the system board's vice chairman to the role of Quality and Safety Committee chairman;
- Decentralizing the two city hospitals' Quality and Safety Committee from a monthly combined venue to individual hospital Quality and Safety committees to allow a more tailored focus, as well as additional time for each of the respective hospital's quality and safety activities;
- Reformatting the entire hospital/system dashboard reports to facilitate more focus on quality and safety, easier interpretation of the material and better follow-up;
- Expanding the amount of board meeting time dedicated to quality and safety and re-sequenced the agenda so this topic always precedes the finance report;
- Recognizing the corporate staff to create a full-time Vice President of Quality and Safety;
- Moving the quality and safety initiatives from a second tier initiative to a top tier priority and made quality and safety a primary component of the business model value proposition;
- Modifying our senior managements' incentive compensation program to reflect quality and safety as the most important single category of those items reviewed annually.

Additional sessions will be scheduled by HAP limiting the size and presentation length to allow more interaction with participants. More updates of the program's success will follow.

Pennsylvania Healthcare Organizations to Offer Continuing Education Credits through Patient Safety Advisories

The Patient Safety Authority has collaborated with healthcare associations throughout the state to provide continuing education credits for their memberships.

The Authority and the Pennsylvania Medical Society have been working together for several years providing doctors across Pennsylvania with continuing medical education credits. This year the medical society has asked the Authority to work with them to tailor the *Pennsylvania Patient Safety Advisory* articles so physicians can more readily choose articles that pertain to their discipline.

The Authority also met with the Pennsylvania State Nurses Association (PSNA) to provide continuing education hours for Pennsylvania nurses through its Web site. Licensed nurses in Pennsylvania will be required to have 30 continuing education hours for renewal in 2010. The Authority will provide current and retrospective articles to the PSNA and they will be posted on the PSNA Web site. The hours can be obtained by members and non-members of the PSNA. The Authority and the PSNA are in the final stages of an agreement finalizing the duties of each organization for making the hours available. The Authority expects members to be able to obtain the continuing education hours through its June 2009 *Pennsylvania Patient Safety Advisory*.

The Pennsylvania Pharmacists Association (PPA) is also interested in partnering with the Authority to provide continuing education credits for Pennsylvania pharmacists. Their current partner will no longer provide material for continuing education giving the Authority the opportunity to fill a gap for Pennsylvania pharmacists to obtain their patient safety credits that will be required for license renewal. Currently, the PPA has a year of continuing education material for their bi-monthly journal but they welcome the Authority's partnership to provide more options for their members to obtain patient safety credits.

The Authority has also reached out to the Pennsylvania Society of Health-System Pharmacists (PSHP) and the Pennsylvania Ambulatory Surgical Association to discuss making continuing education credits available to members of their organizations through the *Pennsylvania Patient Safety Advisory*.

Professional Nurses Can Earn Continuing Education Hours through the Authority's Educational Programs and Sessions

Pennsylvania law requires that all professional nurses in the state will need to acquire 30 hours of continuing education by October 31, 2010 in order for them to renew their license.

Through the efforts of the Hospital and Healthsystem Association of Pennsylvania (HAP), a provision was added to the new law that allows licensed nurses to obtain continuing education hours (CEs) through activities sponsored by federal and state agencies, including the Patient Safety Authority educational conferences and sessions.

For those who attended the Authority's "Patient Safety Officer Foundation Curriculum" held in February 2009 or the methicillin-resistant *Staphylococcus aureus* (MRSA) half-day session held in April 2009 you should have received a certificate from the Authority for continuing education hours. If you attended either course and did not receive a certificate please contact the Authority at 717-346-0469. All participants are asked to keep all completed continuing education certificates for five years.

Patient Safety Knowledge Exchange (PasSKEy) Update

The Patient Safety Knowledge Exchange (PasSKEy) is an initiative designed to provide Pennsylvania Patient Safety Officers with an electronic confidential forum to share information, ideas and solutions among themselves. The Authority learns about success stories on a regular basis from Pennsylvania's healthcare facilities. PasSKEy allows PSOs to share these success stories to help one another implement processes and protocols that have worked in each other's facilities.

The Authority has developed a work plan with its subcontractor, EDS, and will continue meetings to discuss the hierarchy of the Web page. The Authority invited Patient Safety Officers to become members of a peer group called the PasSKEy Development Council. The council will help the Authority create the best forum for them to exchange information. The PasSKEy initiative is expected to be available for PSOs in late 2009.

Patient Safety Authority Unveils New Web Site

The Authority unveiled its new Web site and design in January 2009. The new site, www.patientsafetyauthority.org, features an enhanced search engine with easier navigation and features allowing users to share patient safety information more readily.

The site also features a new tagline for the Authority: "Analyzing, Educating and Collaborating for Patient Safety." The tagline represents the Authority's mission to improve patient safety by analyzing data, educating stakeholders and collaborating with healthcare facilities and organizations to further use the data.

Specifically, the improved site makes it easier for users to find and distribute information in the following ways:

- Offers Pennsylvania-based healthcare information that is easier to read and find online with an enhanced search engine;
- Gives immediate access to the most recent information from the homepage featuring a spotlight section of "What's New";
- Allows users to browse-by-topic hundreds of *Pennsylvania Patient Safety Advisory* articles;
- Provides users with the means to distribute important Pennsylvania patient safety information through an "e-mail-to-a-friend" feature and;
- Offers a vast collection of educational tools and resources for healthcare providers and community groups to improve patient safety in Pennsylvania healthcare facilities.

Prior to the new Web site launch, a small number of PSOs were given access to test its new features. They gave high marks to the site particularly for the new features that give Patient Safety Officers the ability to search *Pennsylvania Patient Safety Advisory* articles by discipline and topic and then e-mail any information to leaders and staff.

Collaborations and Educational Conferences

The Patient Safety Authority collaborates with state and national healthcare organizations by sharing the information contained in nearly one million reports of Serious Events and Incidents submitted by Pennsylvania's healthcare facilities. The partnerships have covered numerous topics including patient falls, wrong-site surgery, pressure ulcers, high-alert medications, central line infections and ventilator-associated pneumonia (VAP).

Health Care Improvement Foundation (HCIF) Falls Collaboration

The Authority and the Health Care Improvement Foundation (HCIF) have signed a memorandum of understanding in which the Authority agrees to provide periodic, de-identified data on selected patient safety issues to HICF for prioritizing potential future initiatives and tracking the progress on current initiatives among Delaware Valley hospitals.

In 2007, HCIF selected fall prevention as one of its goals for 2007 which has continued into 2008. The Authority has provided data that southeastern hospitals can use in measuring their progress on reducing falls and/or harm from falls.

Health Care Improvement Foundation (HCIF) Wrong Site Surgery Collaboration

The Authority also provided aggregate wrong-site surgery data to the Partnership for Patient Care's Wrong-Site Surgery Prevention Program (PPC), under the Health Care Improvement Foundation. The main component of the PPC program focused on a regional approach to conducting proactive risk analyses to strengthen patient safety by targeting high-risk error prone clinical processes for improvement. Interventions targeted several crucial processes for preventing wrong-site surgery that include: scheduling, verification and reconciliation of essential patient information before surgery, site marking, time outs and OR turnover.

More than 20 southeastern hospitals in the study also implemented action goals (or proposed interventions) aimed at addressing vulnerabilities and potential failures. As the study progresses, the Authority will provide more information in its *Pennsylvania Patient Safety Advisory* quarterly wrong-site surgery updates.

Patient Safety Officer Foundation Curriculum

As mentioned, the Authority developed a basic patient safety program, called the "Patient Safety Officer Foundation Curriculum" to discuss the specifics behind patient safety and Act 13 of 2002. Specifically, the objectives of program: provide a historical prospective of patient safety; examine the importance of infrastructure in patient safety; apply Act 13 of 2002 and Act 52 of 2007 to the culture of safety; and recognize the importance of communication in patient safety. Hospital staff attending the program included CEOs, management staff and PSOs from hospitals and ambulatory surgical facilities. Feedback was very positive and there were numerous requests for additional educational sessions regarding patient safety leadership and insights, such as human factors, highly reliable organizations (HRO), crew management and proactive risk reduction strategies (FMEA). The Authority is developing a second program called "Beyond the Basics" to coincide with the basic program.

Methicillin-Resistant *Staphylococcus aureus* (MRSA) Session

The northeast Patient Safety Liaison (PSL) and the Authority's Director of Educational Programs developed a half-day educational session on MRSA at the request of ambulatory surgical facilities' patient safety officers. The objectives of the session include: discussing the clinical features of MRSA; understanding the mode of transmission; learning infection prevention strategies; recognizing high risk patients; indentifying surveillance measures and reviewing general care guidelines. The session was well received. More MRSA sessions are planned throughout the state once the other PSLs are on board.

Patient Safety Liaison Program Session

The Authority's Director of Educational Programs and northeast region Patient Safety Liaison (PSL) also speak to numerous professional healthcare organizations about the PSL program to ensure it is utilized by the healthcare facilities. In February 2009, a presentation about the PSL program was given to the Council for Small Hospitals at the Hospital and Healthsystem Association of Pennsylvania (HAP). The program was embraced as a resource to educate staff at no additional costs to their facility.

The Authority will continue to work with other healthcare and state organizations to educate healthcare providers through regional conferences covering topics such as disclosure, the philosophy behind reporting adverse events and near misses, and root cause analysis and failure mode and effects analysis (FMEA) training.

Speakers Bureau and Consumer Awareness Opportunities

For healthcare facilities and organizations, community and consumer groups, the Authority offers a speakers bureau. When appropriate a representative of the Patient Safety Authority will come speak about the current healthcare issues facing healthcare providers and consumers based upon data submitted to the Authority and national trends. The Authority can tailor the information based upon the needs of your organization. The Authority also attends healthcare fairs and other healthcare related events with an informational booth at your request. Please call the Authority at 717-346-0469 for more information about its speakers bureau and informational booth.

Helping Patients Participate in Their Healthcare

Although the primary work of the Authority is focused specifically on healthcare facilities, it is obvious patients are the center of all patient safety activities. The Authority is committed to providing consumers of the healthcare industry with information they can use to ensure they receive quality care as a patient. The Authority offers consumer tip sheets containing valuable medical information that is easy to understand. Topics include but are not limited to: medication errors, wrong-site surgery, falls, healthcare-associated infections and the risks associated with color-coded wristbands. These tips and other consumer brochures are based upon data received by the Authority from Pennsylvania healthcare facilities. The Authority data also shows patients have prevented medical errors by speaking up and participating in their healthcare.

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The Authority's Annual Survey of Patient Safety Officers

In February 2009, the Authority invited the registered Patient Safety Officers (PSOs) in the Commonwealth to participate in an online survey. The intent of the survey was to solicit their feedback on the Authority's activities and the performance of the Pennsylvania Patient Safety Reporting System (PA-PSRS). The survey also solicited their opinions on topics that would influence the Authority's direction and focus over the coming year, such as:

- Their interpretations of MCare reporting requirements for Serious Events.
- Their preparedness for preventing adverse events for which CMS will exclude reimbursement.
- The use of the National Health Surveillance Network (NHSN) for reporting HAIs from hospitals.

Responses were collected over a 16-day period. Of the 525 invitees, PSOs from 115 hospitals (HSPs), 102 ambulatory surgery facilities (ASFs), one birthing center (BC) and no abortion facilities (ABFs) responded, resulting in a 41.5% response rate. For purposes of data analysis, the birthing center was grouped with the ASFs when comparing responses from different types of facilities.

Pennsylvania Patient Safety Advisory

As in previous surveys, PSOs collectively gave the *Pennsylvania Patient Safety Advisory* high marks on usefulness (98%), relevance (97%), readability (99%), scientific quality (97%) and educational value (99%).

In the year since the last survey, the *Advisory* had undergone some enhancements, which were generally seen as useful improvements. The changes were thought to be at least somewhat useful in 90% of responses, and more than half of those responses called the changes "Very useful." See Figure 54 for details.

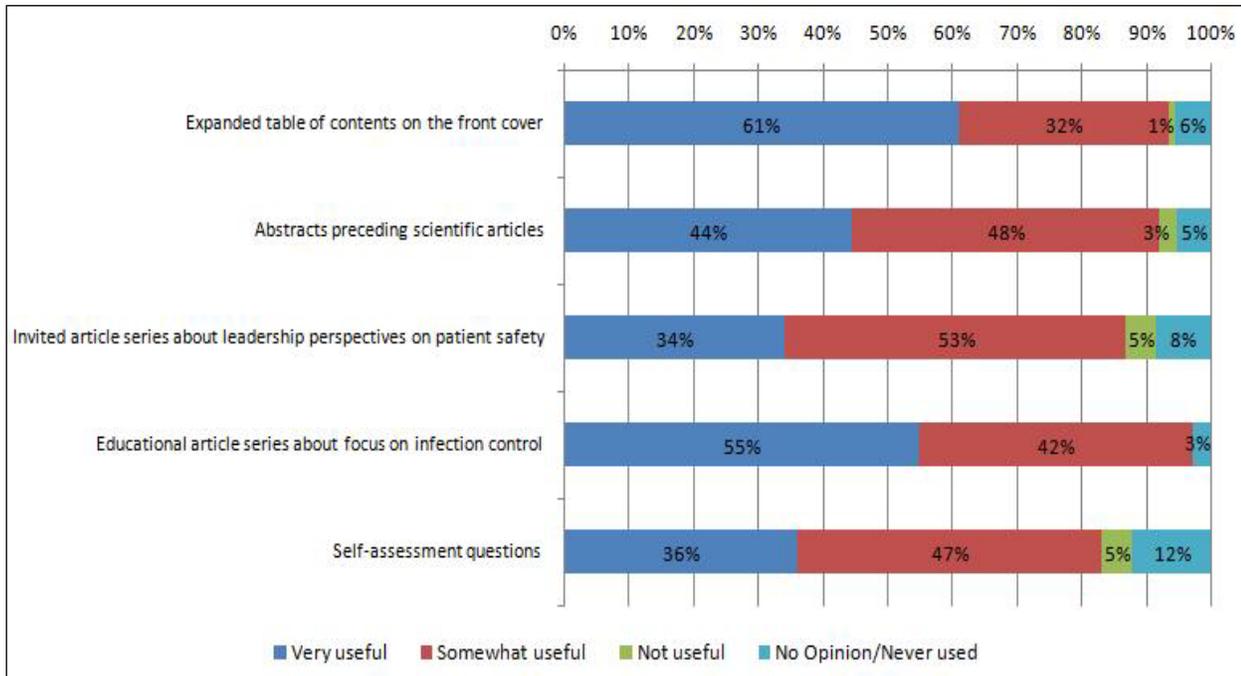


Figure 54. Responses by Percentage to Enhancements to the *Pennsylvania Patient Safety Advisory*

The Patient Safety Authority Strives to Educate

Among PSOs participating in the survey, 62% report making or planning to make changes based on a *Pennsylvania Patient Safety Advisory* article. This suggests that the Authority continues to achieve one of its' original objectives of providing healthcare facilities across the state with useful feedback through the *Advisory*. This result is likely due in part to *Advisory* articles' inclusion of specific suggestions for improvement. The 218 participants of the survey reported making 607 changes in their facilities as a result of specific *Advisory* articles, as seen in Figure 55. PSOs from hospitals (115) cited 484 changes, while PSOs from ASFs (103) cited 123.

Examples of the kinds of improvements facilities made include:

- Launching campaigns to promote and maintain hand hygiene compliance ([Hand Hygiene Practices and the Use of Alcohol-Based Sanitizers](#))
- Developing additional anticoagulation services and creating Anticoagulation Committees ([Anticoagulation Management Service: Safe Care, Maximizing Outcomes](#))
- Introducing or adding walkrounds ([Leadership Series: Executive Patient Safety Walkrounds](#))
- Enhancing fall prevention by including medication assessment in the fall reduction program ([Medication Assessment: One Determinant of Falls Risk](#))
- Revised protocols for medical screening exams in pregnancy related conditions ([Triage of the Obstetrics Patient in the Emergency Department: Is There Only One Patient?](#))
- Adopting the standardized color-coded wristbands program ([Update on Use of Color-Coded Patient Wristband](#))
- Reviewed designs prior to installation of tube system ([Pneumatic Tubes: A Possible Patient Safety Vacuum?](#))

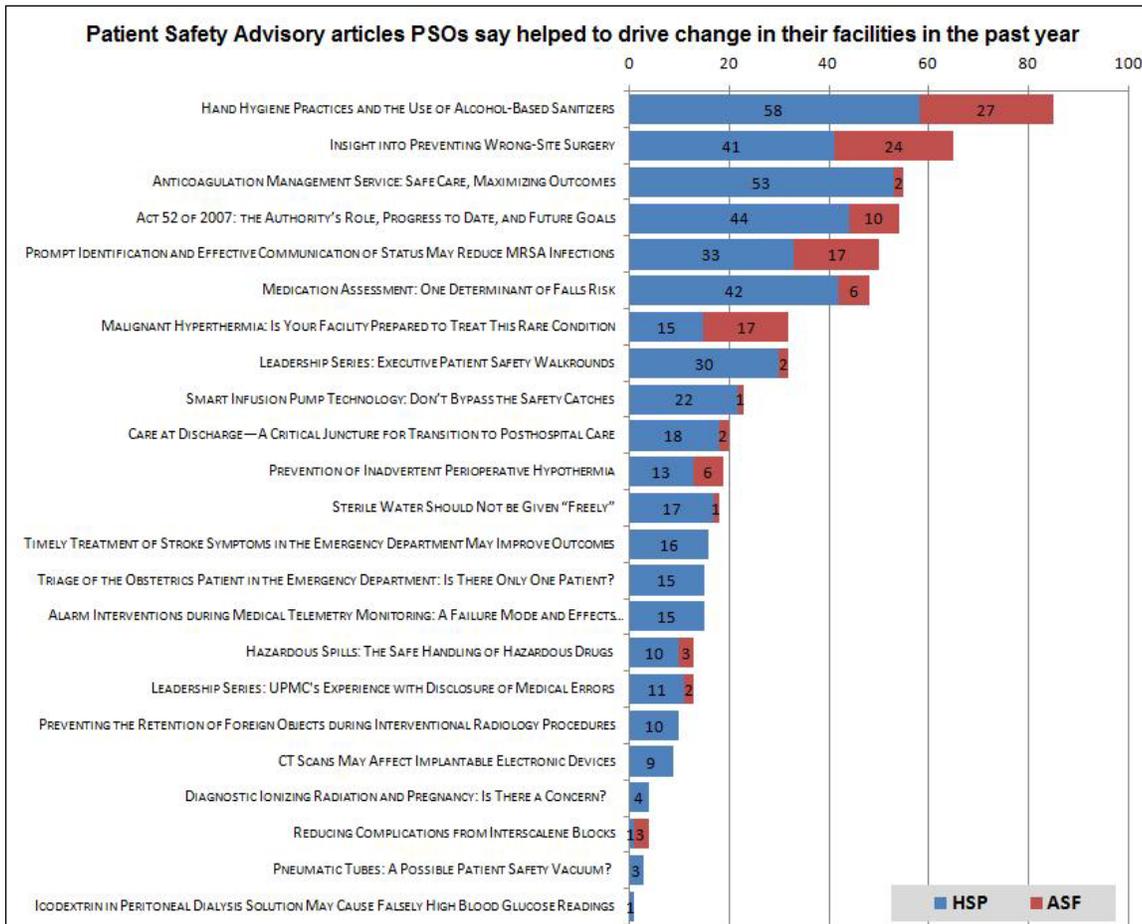


Figure 55. Pennsylvania Patient Safety Advisory Articles Cited by PSOs as Prompting Them to Make Changes in 2008

Last year, the Authority introduced a process in which Web links to relevant *Pennsylvania Patient Safety Advisory* articles would be sent to facilities in response to submitted reports from that facility. This provides real-time feedback for the facility to take advantage of “teachable moments” with the parties involved in the reported event. More than 60% of respondents noted to have received an email like this, with 91% saying that it was helpful.

Some comments on this process:

“Great idea. Used the material for adjunct to in-service education purposes.”

“That link saved me time I would have had to spend searching for relevant information on the site.”

“Reviewed with all the doctors who found it very informative.”

“I felt that the PSA was truly interested in helping to improve facilities and not just ‘police’ ASCs.”

“We have found these extremely useful and share them with the entire staff. The connection between reporting something and receiving this feedback brings home the fact that we are not reporting into a void and someone ‘out there’ is paying attention.”

Web Site Redesign

As mentioned in last year’s annual report, Patient Safety Officers (PSOs) voiced their opinions on what they would be interested in seeing on the Authority Web site, www.patientsafetyauthority.org. These insights contributed to the redesign plans, along with the Authority’s desire to increase awareness of the *Pennsylvania Patient Safety Advisory* and use of the many resources based on it. We surveyed the PSOs this year about the redesign and received generally positive responses, as shown in Figure 56. Out of a cumulative 972 opinions, there were only 13 responses expressing disagreement with any of the six given statements, a rounded calculated average of 1%. Strong agreement with the statements averaged 22%, with an additional 52% stating agreement. One PSO remarked, “Love the new Web site, much more user friendly, efficient and packed with useful information.”

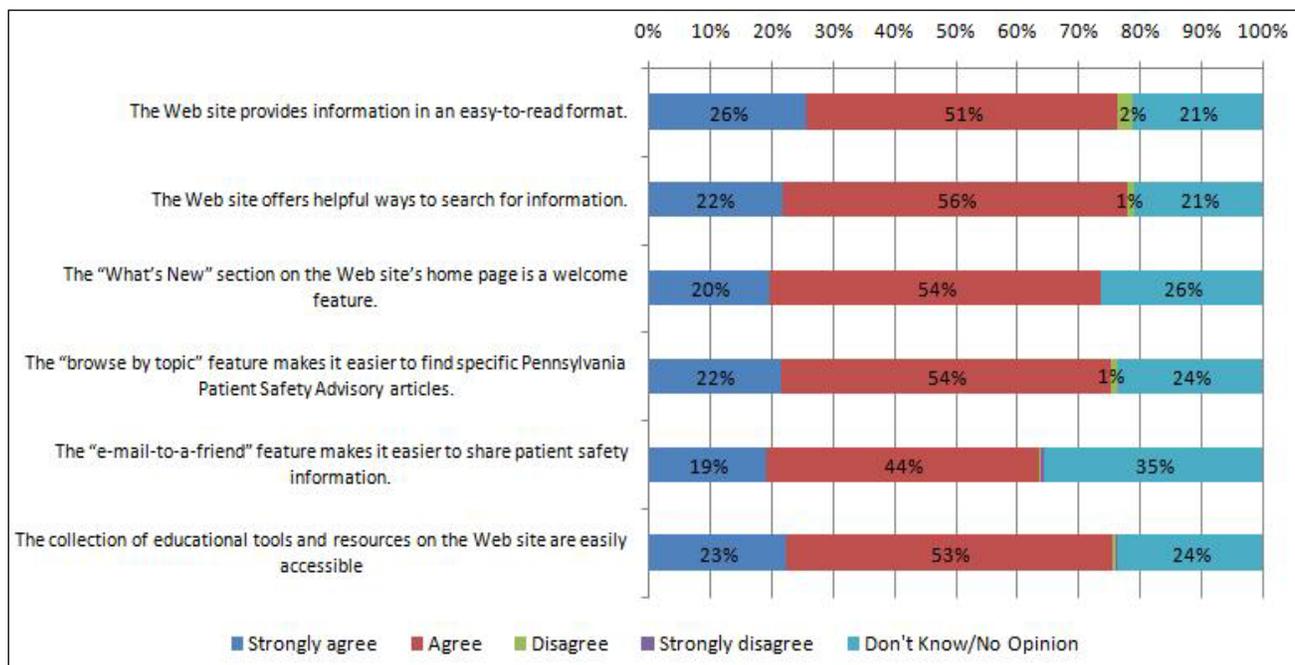


Figure 56. Responses by Percentage to Enhancements to the Pennsylvania Patient Safety Authority Web Site

Additional comments from PSOs regarding the Authority:

“We are a new facility and as I begin to utilize the site more often I have been very impressed by the level of content. I wasn’t aware of the various programs available and now I will communicate this to the physicians.”

“It is an excellent tool for ambulatory surgical centers.”

“It is helpful in assisting facilities to monitor and maintain patient safety practices.”

“Keep up the excellent work.”

“Excellent resource, if there are ways to get more involved please let me know.”

Preparedness for Preventing Non-Reimbursable Events

In 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a new policy in which they will no longer reimburse healthcare providers for the costs associated with treating selected adverse events. Patient Safety Officers (PSOs) from hospitals were asked to assess their facilities’ level of preparedness to be held accountable for selected non-reimbursable events. Responses were generally positive; for each of the five events, at least 54% of PSOs describing their facilities as “fully prepared.” PSOs felt best prepared to address pressure ulcers and catheter-associated urinary tract infections. Very few facilities reported feeling their facilities were “not prepared at all.” this response was chosen only eight times across all five types of events. See Figure 57 for more details.

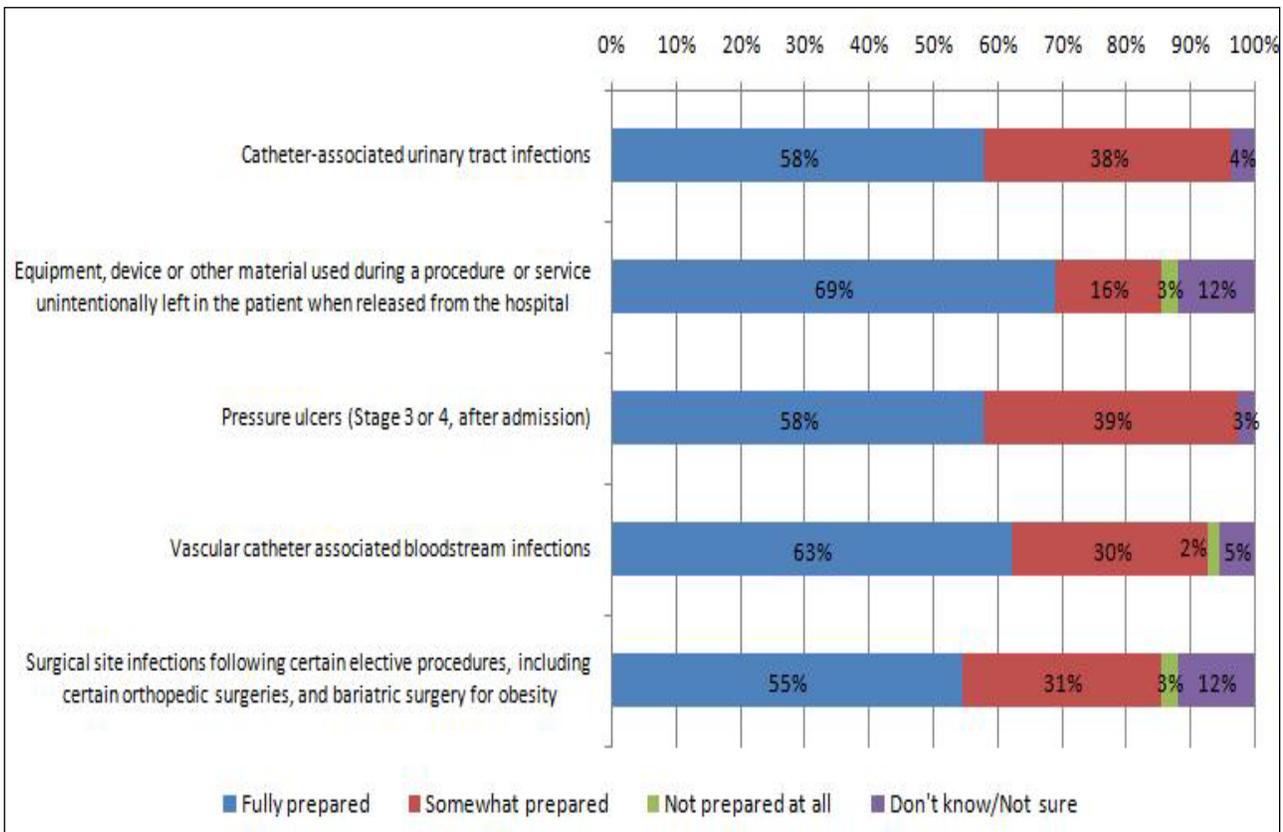


Figure 57. Responses by Percentage to Possible Reportable Scenarios, Posed to Hospital PSOs

Healthcare-Associated Infection Surveillance Using NHSN

Act 52 of 2007 was designed to help reduce and eliminate healthcare-associated infections (HAIs) in Pennsylvania. The Act required hospitals to begin reporting HAIs through the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). Reporting requirements for hospitals was implemented in early 2008. PSOs from hospitals were asked to rate their agreement with several statements regarding the NHSN system and its impact on infection prevention in their facilities (see Figure 58).

While respondents find the NHSN system difficult to use, a majority of respondents (60%) felt that use of NHSN had improved their facility's ability to track infections, and about half (49%) reported that infection control had improved since implementation of NHSN. A majority (65%) also felt that infection control had taken a higher priority in their patient safety committee meetings since NHSN implementation, and 61% felt that infection reporting through NHSN would benefit their hospital in the long run.

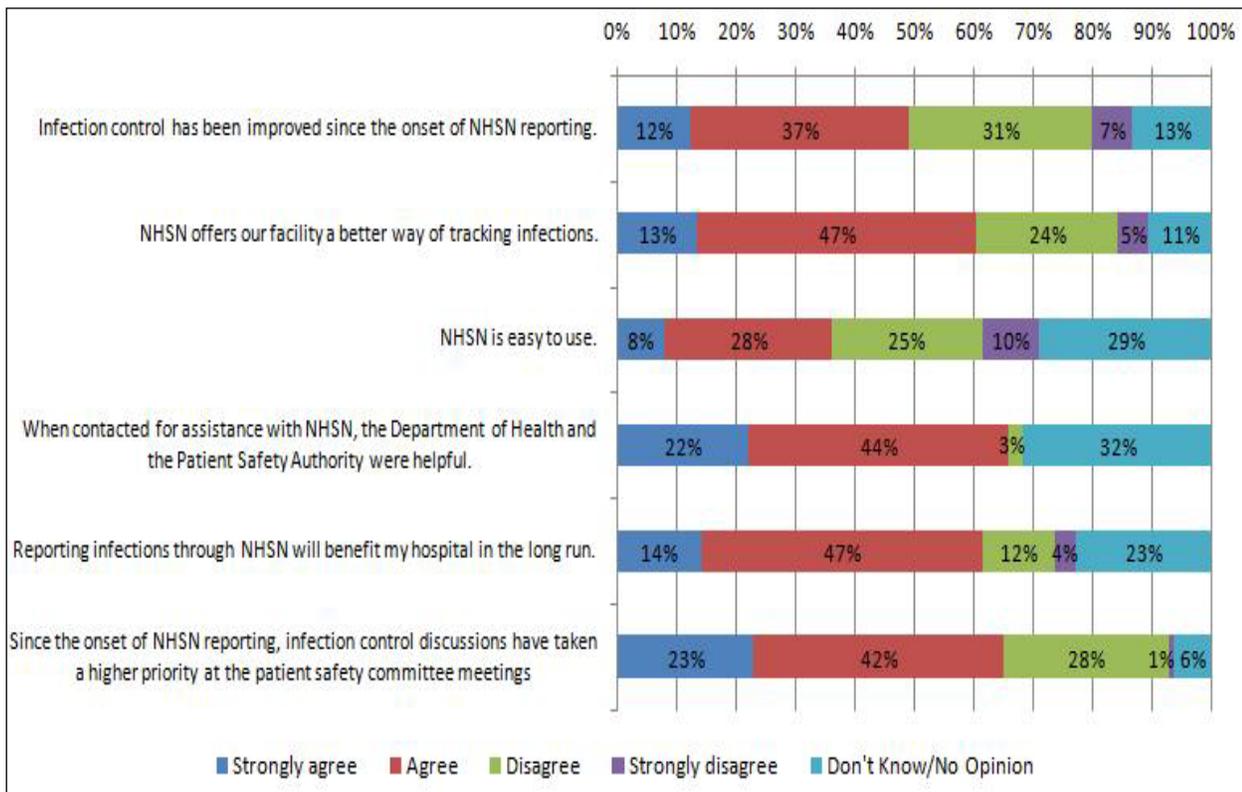


Figure 58. Responses by Percentage to Use of NHSN, Posed to Hospital PSOs

Summary

In our 2007 survey of Patient Safety Officers, respondents voiced their opinion that they would like guidance on reportable events. To that end, the Authority, in coordination with the Department of Health, published the draft Guidance for Healthcare Facility Determination of Serious Events under Act 13 of 2002 in the *Pennsylvania Bulletin*.²⁰

²⁰ Pennsylvania Bulletin: Draft Guidance for Healthcare Facility Determination of Serious Events under Act 13 of 2002. Pa.B. Doc. No. 09-383. File for public inspection February 27, 2009. Online: www.pabulletin.com/secure/data/vol39/39-9/383.html.

PSOs indicated that their facilities are at least somewhat prepared for the withdrawal of CMS reimbursement for certain preventable healthcare-associated conditions. They have also accepted the CDC's NHSN system for reporting Healthcare-Associated Infections (HAI).

As with previous years' surveys, our 2008 survey finds that the *Pennsylvania Patient Safety Advisory* is still highly regarded and benefits Pennsylvania healthcare facilities by:

- Generating useful patient safety information.
- Providing material to be used in education.
- Spurring process assessment and improvement.

To increase awareness and use of other resources based on the *Pennsylvania Patient Safety Advisory*, the Authority redesigned its Web site and have introduced a process to provide immediate feedback based on submitted reports. Along with expansion of the Authority's Patient Safety Liaison program, the Authority has established an extended reach to provide patient safety guidance to Pennsylvania healthcare facilities.

Other Items

Federal Legislation

Congress enacted the Patient Safety and Quality Improvement Act of 2005, P.L. 109-42, 42 U.S.C. 299b-21—b-26 (the “Act”) to provide a framework for entities that collect health information on patient safety events from health care providers to become listed and certified as federally recognized Patient Safety Organizations (“PSOs”). As a PSO, these entities will be able to share information relating to patient safety events with other PSOs with the aim of improving patient safety and the quality of care nationwide. Pursuant to the Act, the federal Department of Health and Human Services (“HHS”) published proposed rules on February 12, 2008, and final rules on November 21, 2008.

Importantly, the Act focuses on creating a voluntary system through which health care providers can share sensitive information relating to patient safety events without fear of liability, thereby leading to improvements in patient safety and in the quality of patient care. Neither the Act nor the proposed rules, however, addressed the circumstances under which an entity under a state mandate to collect similar patient safety information could become listed and certified as a PSO. The final rules addressed this issue.

The final rule expressly precludes entities collecting patient safety information pursuant to a mandatory reporting system established under state law from becoming listed and receiving certification as a federally recognized PSO. The final rule at 42 C.F.R. § 3.102(a)(2) provides:

Exclusion of certain entities. The following types of entities may not seek listing as a PSO:

(ii)(D) An entity that operates a Federal, state, local or Tribal patient safety reporting system to which health care providers (other than members of the entity’s workforce or health care providers holding privileges with the entity) are required to report information by law or regulation.

(III) A component of an entity listed in paragraph (q)(2)(ii) may seek listing as a component PSO subject to the requirements and restrictions of paragraph (c)(1)(ii) of this section.

Because the Authority is an entity operating a state reporting system to which providers are required to report under Pennsylvania law, the Authority is ineligible under current federal regulations from listing and certification as a federally recognized PSO.

Patient Safety Legislation

In July 2007, Act 52 became law charging the Authority, the Department of Health (DOH) and the Pennsylvania Healthcare Cost Containment Council (PHC4) with reducing and eliminating healthcare-associated infections in Pennsylvania. The Centers for Disease Control and Prevention (CDC) provide the reporting tool, but the Authority added reporting components to the CDC reporting system (NHSN) to meet Act 13 of 2002 (MCare) reporting requirements and prevent facilities from duplicate reporting. Along with hospitals, nursing homes are required to report infections to the Authority and DOH. The Authority must analyze the infection data and provide all healthcare facilities mentioned in the Act with information similar to that contained in *Pennsylvania Patient Safety Advisories*. Hospitals began reporting infection data to the CDC February 14, 2008. Nursing homes are expected to begin reporting through PA-PSRS in June 2009.

In May 2006, House Bill 1591 was signed into law as Act 30 requiring certain abortion facilities and providers to report through the Pennsylvania Patient Safety Reporting System (PA-PSRS). The law requires abortion facilities and providers that perform 100 or more procedures annually to report Serious Events, Incidents and Infrastructure Failures. The 18 qualifying facilities began reporting in early 2007, in accordance with the law.

Recommendations for Statutory or Regulatory Change

Act 13 of 2002 (MCare) calls upon the Authority to suggest recommendations for statutory or regulatory changes that may help improve patient safety in the Commonwealth. At this time, the Board does not have any formal recommendations for statutory or regulatory change.

Anonymous Reports

Act 13 of 2002 (MCare) includes an important provision that permits individual healthcare workers to submit what the MCare Act defines as an “Anonymous Report.” Under this provision, a healthcare worker who has complied with section 308 (a) of the Act may file an anonymous report regarding a Serious Event.

Act 13 of 2002 requires facilities to make anonymous report forms available to healthcare workers. The Authority also makes those forms available on the PA-PSRS Web site, which is accessible without a password. The reporting form is a simple, one page questionnaire. At the request of Patient Safety Officers, the Authority developed an Anonymous Report pamphlet. The pamphlet includes an anonymous report form with guidelines for filing a report so PSOs can make them easily accessible for hospital staff. The Authority’s Patient Safety Liaisons also ensure PSOs are making the anonymous report forms accessible to employees while making their routine visits to facilities in their region.

Healthcare workers are able to submit an anonymous report according to the protocols established through the PA-PSRS system. Persons completing the form do not need to identify themselves, and the Authority assigns professional clinical staff to conduct any subsequent investigations. The Authority encourages healthcare workers to submit anonymous reports when they believe their facility is not responding appropriately to Serious Events.

Act 13 of 2002 requires that the annual report include the number of anonymous reports filed and reviews conducted by the Authority. The Authority received one anonymous report in 2008 that complied with Act 13 of 2002 requirements.

Referrals to Licensure Boards

Act 13 of 2002 requires the Authority to identify the number of referrals to licensure boards for failure to submit reports under the Act’s reporting requirements. No such situations were identified during 2008. However, it is important to note that the Patient Safety Authority is unlikely to receive information related to a referral to a licensure board. That information is more appropriately referred to the Department of Health or will be reported directly by a facility to a specific licensing board.

Patient Safety Discount Program

Section 312 of Act 13 of 2002 provides for what the Act defines as a Patient Safety Discount. Under this provision, facilities may be eligible for a reduction in medical liability insurance premiums if they can demonstrate a reduction in Serious Events as a result of adopting a program recommended by the Authority.

In previous years, the Authority has recommended the National Patient Safety Foundation’s (NPSF) “Stand Up™ for Patient Safety” program and the “100,000 Lives Campaign” of the Institute for Healthcare Improvement.

While the Authority is not aware that any individual facility has applied for a patient safety discount under these programs, we are hopeful that hospitals and other facilities throughout the Commonwealth will eventually consider adopting some or all of these programs, both to promote patient safety and to reduce associated insurance costs.

Board of Directors and Public Meetings

Members of the Board of Directors are appointed by the Governor and the General Assembly, according to certain occupational or residence requirements. Current members, as of April, 2009 include:

- Physician appointed by the Governor, who serves as Chair: Ana Pujols-McKee, MD
Residence: Philadelphia (Philadelphia County)
- Appointee of the President pro tempore of the Senate: Marshall W. Webster, MD
Residence: Pittsburgh (Allegheny County)
- Appointee of the Minority Leader of the Senate: Cliff Rieders, Esq.
Residence: Williamsport (Lycoming County)
- Appointee of the Speaker of the House: Stanton N. Smullens, MD
Residence: Philadelphia (Philadelphia County)
- Appointee of the Minority Leader of the House: William F. Goodrich, Esq.
Residence: Pittsburgh (Allegheny County)
- Nurse appointed by the Governor: Joan M. Garzarelli, RN, MSN
Residence: Irwin (Westmoreland County)
- Pharmacist appointed by the Governor: Gary A. Merica, RPh
Residence: Red Lion (York County)
- Hospital employee appointed by the Governor: Roosevelt Hairston, Esq.
Residence: Malvern (Chester County)
- Health care worker appointed by the Governor: Anita Fuhrman, RN, BS
Residence: Lebanon (Lebanon County)
- Non-health care worker appointed by the Governor: Lorina L. Marshall-Blake
Residence: Philadelphia (Philadelphia County)
- Physician appointed by the Governor: Vacant

Act 13 of 2002 requires the Board of Directors to meet at least quarterly. During 2008 the Board met frequently to assess and develop future patient safety educational and advocacy activities including implementation of Act 52 of 2007 and its Patient Safety Liaison Program. Representatives of healthcare, consumer and other stakeholder groups, including the General Assembly, have attended and spoken at public meetings. Following are the dates of all public board meetings held by the Authority during 2008:

January 8, 2008
February 12, 2008
March 11, 2008
April 8, 2008
May 12, 2008
June 10, 2008
July 22, 2008
September 9, 2008
October 28, 2008
December 9, 2008

Minutes of the public meetings are available on the Authority's Web site at www.patientsafetyauthority.org or through PA PowerPort, Keyword: Patient Safety

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Fiscal Statements and Contracts

Act 13 of 2002 establishes the Patient Safety Trust Fund as a separate account in the State Treasury. Under Act 13, the Authority, which has sole discretion to determine how those funds are used to effectuate the purposes of the patient safety provisions of the Act, administers funds in the Patient Safety Trust Fund.

Funds for the Patient Safety Trust Fund come from assessments made by the Department of Health on certain medical facilities. The department has 30 days following receipt of those moneys to transfer them to the Trust Fund.

The Authority recognizes that Pennsylvania hospitals, birthing centers, ambulatory surgical facilities and certain abortion facilities bear financial responsibility for costs associated with complying with mandatory reporting requirements. Accordingly, the Authority has focused on two fiscal goals: to be moderate in the use of moneys contributed by the healthcare industry and to assure that healthcare facilities paying for the Pennsylvania Patient Safety Reporting System (PA-PSRS) receive direct benefits from the system in return.

In this regard, in designing PA-PSRS, the Authority included within the system a variety of integral and analytical tools that provide immediate, real-time feedback to facilities about their own adverse event and near miss reports and activities and a report that aggregates reports in the National Patient Safety Goal categories. Facilities can use these tools for their internal patient safety and quality improvement programs. The Authority also publishes the *Pennsylvania Patient Safety Advisory*, a scholarly journal issued quarterly that includes detailed analysis and identification of trends of reports submitted through PA-PSRS. Finally, the Authority has provided numerous training and education programs including topics such as regional root cause analysis, failure mode effect and analysis, reduction of MRSA in ambulatory surgical facilities, and a new educational session for Patient Safety Officers to name a few. These programs are generally offered for free or at a greatly reduced cost to facilities. As identified elsewhere in this report, the Authority is expanding its services to be increasingly collaborative with reporting facilities and other patient safety-centric organizations. By directly offering clinical guidance, feedback, and educational programs to providers about actual events that occurred in Pennsylvania, the Authority provides a valuable “return on investment” to the healthcare industry that funds this program.

Act 13 of 2002 sets a limit of \$5 million on the total, aggregate assessment of healthcare facilities for any one year, beginning in 2002, plus an annual increase based on the Consumer Price Index for each subsequent year. During the Authority’s first year of operation (FY2002-2003), at the Authority’s recommendation, the Department of Health issued a facility assessment for the full \$5 million. The Authority had very few expenditures in this fiscal year and was able to establish a funding surplus. Therefore, in several subsequent years, the Authority had recommended a partial assessment of \$2.5 million each year because that reduced amount had been adequate for ongoing operations, including numerous new programs, of the Patient Safety Authority. This partial assessment reduced the cost to Pennsylvania’s healthcare facilities.

The assessment was kept at \$2.5 million for four years. This amount was lower than the actual expenditures for each of those years. This level of assessment was possible due to the significant surplus that had built up in the first year of operation. However, this policy led to the Authority getting close to eliminating all surplus in FY 06-07 and on the verge of a funding deficit. Therefore, the FY 07-08 assessment was significantly higher than in previous years and more closely reflects the budget for the fiscal year.

Act 13 of 2002 requires that the annual report include a summary of fund receipts and expenditures, including a financial statement and balance sheet. Following are several tables detailing this information.

Facility Assessments

Fiscal Year	Number of Facilities assessed by DOH	Total value of assessments	Total Assessments received by DOH ²¹
2002-03	356	\$ 4,999,922	\$ 4,663,000
2003-04	377	\$ 2,562,938	\$ 2,542,316
2004-05	414	\$ 2,500,159	\$ 2,508,787 ²²
2005-06	450 ²³	\$ 2,499,906	\$ 2,500,149
2006-07	270	\$ 2,500,034	\$ 2,500,034
2007-08	526	\$ 5,400,000	\$ 5,391,583

Act 52 provided the ability for the Department of Health to assess the nursing homes up to \$1.0 million per year. The Department of Health assessed 725 facilities FY 2008-09 in the year 2008. This annual assessment includes the annual cost of living adjustment. This money can only be spent on activities related to HAI and implementation and maintenance of Act 52.

Nursing Home Assessments

Fiscal Year	Number of Facilities assessed by DOH	Total value of assessments	Total Assessments received by DOH
2008-09	725	\$1,000,782	\$1,000,782

²¹ Amounts assessed and amounts received will differ because a few facilities may have closed in the interim or are in bankruptcy. In a few cases, the Department of Health is pursuing action to enforce facility compliance with Act 13's assessment requirement.

²² Total Assessments received are greater than assessments made because some funds received were late payments for the previous year's assessment.

²³ The number of facilities assessed by the Department of Health differs from the number of Act 13 facilities cited elsewhere in this report due to the differences in the dates chosen to calculate the number of facilities for these two different purposes.

Actual Expenditures for 2008

Major Object Code	Amount
100: Personnel	\$264, 253. 25
300: Operating	\$3, 903, 013.31
400: Fixed Assets	\$ 0
TOTAL:	\$4, 167, 266.56

Act 13 of 2002 requires the Authority to identify a list of contracts entered into pursuant to the Act, including the amounts awarded to each contractor.

During the calendar year 2008, the Authority received services under the following contracts. Please note: While contract amounts are given for the fiscal year, actual amounts expended are given for the calendar year.

ASAP Software

PO#4300139821

PO Amount \$2,588.40

Amount Expended in 2008: \$2,588.40

PO#4300112910

PO Amount: \$43,097.40

Amount Expended in 2008: \$43,097.40

ASAP Software

PO#4300055878 dated December 4, 2007

(One time purchase – MS Project Professional 2003)

PO Amount: \$537.04

Amount Expended in 2008: \$537.04

Computer Aid, Inc.

PO#4500351099 dated September 1, 2006

(Staff Augmentation for Senior Consultant 9/1/06 – 7/25/08)

Contract Amount: \$412,457.56

Amount Expended in 2008: \$138,040.95

PO#4300124813 dated 07/1/2008 to 8/31/2008

PO Amount: \$52,984.00

Amount Expended in 2008: \$47,063.04

PO#4300116999 dated 9/1/08 to 10/31/08

PO Amount: \$52,984.00

Amount Expended in 2008: \$46,062.97

Computer Aid, Inc.

Contract 4600007811

PO#4300021201 dated June 27, 2007

(Staff Augmentation for Program Manager 4/10/2005 to 4/11/08

Contract Amount: \$126,060,000

Amount Expended in 2008: \$50,390.72

PO#4300085035 dated 4/11/2008 to 6/30/2008

PO Amount: \$38559.36

Amount Expended in 2008: \$24,691.52

PO#4300124814 dated 07/01/08 to 08/31/08

PO Amount: \$33,824.00

Amount Expended in 2008: \$26,382.72

PO#4300116999 dated 9/1/08 to 10/31/08

PO Amount: \$33,824.00

Amount Expended in 2008: \$13,529.60

Dell Marketing

PO#4300137194

PO Amount: \$7,955.00

Amount Expended in 2008: \$7,955.00

ECRI

FC#4000053248 dated September 19, 2003 to June 30, 2008

(Five-year contract for technical and clinical assistance in developing and implementing a statewide reporting system as required under ACT 13)

Contract Amount \$13,409,170 over 5 years

Amount Expended in 2008: \$1,711,473.90

FC# 3 month contract extension - dated July 1, 2008 to September 30, 2008

FC Contract Extension Amount: \$909,344.93

Amount Expended in 2008: \$909,344.93

Emergency Contract Extension PO#4300125232 October 1, 2008 for 1 month

FC Amount \$302,320.63

Amount Expended in 2008: \$302,320.63

Total Amount Expended in 2008: \$2,923,139.46

ECRI

FC # 4000013036 dated November 2008 to June 30, 2013

(Five-year contract for Program Administration, Clinical Analysis, Training and Data Collection and Reporting Infrastructure Services)

Contract Amount \$18,932,654 over 5 years

Amount Expended in 2008: \$496,373.04

OCE Imagistics Inc

PO 4500279371 \$248.84/month, \$2,986.08/yr

Amount Expended in 2008: \$2,986.08

PRK MOR, Inc.

FC#4900000796 dated January 21, 2004
(Parking at the Forum Place – yearly commitments
Contract Amount: \$2,880.00
Amount Expended in 2008: \$2,880.00

York Stenographic Services

PO # 4300061329 dated 1/2/2008 to 12/23/2008
Contract Amount: \$8,579.00
Amount Expended in 2008: \$3,981.37

The following Balance Sheet reflects the status of the Patient Safety Trust Fund as of December 31, 2008

Patient Safety Trust Fund Balance Sheet (Unaudited)

As of December 31, 2008

ASSETS	
Cash	\$ 0.00
Cash in Transit	(4,272.32)
Short Term Investments @ Market (Pool98)	3,900,826.13
Short Term Investments @ Market (Pool99)	344,972.41
TOTAL ASSETS	\$ 4,241,526.22
LIABILITIES AND FUND BALANCE	
Liabilities:	
Accounts Payable and Accrued Liabilities	\$ 101,024.65
Invoices Payable	54,934.67
Accrued Payables Goods Receipt	229,834.07
TOTAL LIABILITIES	\$ 385,793.39
FUND BALANCE	
Reserved for Encumbrances	\$ 4,797,839.71
Unreserved - Undesignated	(942,106.88)
TOTAL FUND BALANCE	\$ 3,855,732.83

TOTAL LIABILITIES AND FUND BALANCE	\$ 4,241,562.22

The Authority acknowledges the assistance provided by the Central Services Comptroller Office, Governor's Office of the Budget, in preparation of the Balance Sheet.



P A T I E N T
S A F E T Y
A U T H O R I T Y

An Independent Agency of the Commonwealth of Pennsylvania.

Phone | 717-346-0469

Fax | 717-346-1090

E-mail | patientsafetyauthority@state.pa.us

Web site | <http://www.patientsafetyauthority.org>

Address

539 Forum Building
Harrisburg, PA 17120