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# Patient Safety Authority

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2006 Annual Report



PATIENT  
**SAFETY**  
AUTHORITY

# Letter from the Board Chair



An Independent Agency of the Commonwealth of Pennsylvania

April 30, 2007

Dear Fellow Pennsylvanians:

The year 2006 has proven to be one of change for many reasons at the Patient Safety Authority. But one constant with the Authority is that it continues to work to help reduce and eliminate medical errors by identifying problems and offering solutions that promote patient safety.

During 2006, the Authority collected almost 196,000 reports of adverse events and near-misses which were submitted by healthcare facilities through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

The Authority's clinical staff analyzed and researched those reports and their findings were published in the Authority's *Patient Safety Advisory*, which in 2006 carried approximately 40 scholarly articles on specific events reported through PA-PSRS. Pennsylvania's healthcare facilities continue to use these articles to implement changes in their institutions that improve patient safety.

Pennsylvania was recognized with the prestigious John M. Eisenberg Award in October because of its educational initiatives, like the Advisory, in improving patient safety. These educational initiatives increased in 2006 through collaborations with statewide and national patient safety organizations. In 2007, the Authority will partner with the Governor's Office of Healthcare Reform to reduce hospital-acquired infections as outlined in the governor's "Prescription for Pennsylvania" plan.

As a new member and chair of the Authority's Board of Directors, I am committed to taking the Authority to the next level and continuing the tremendous good work already begun. My fellow board members and staff of the Authority and PA-PSRS are all conscientious and dedicated individuals who know the work of the Authority that lies ahead will entail a tremendous amount of additional hard work, but I can safely say we are up for the challenge.

On behalf of the Board, I am pleased to submit this Annual Report.

Ana Pujols-McKee, MD  
Chairperson  
Board of Directors



An Independent Agency of the Commonwealth of Pennsylvania

Board of Directors

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## ***What People Are Saying About the Patient Safety Authority***

*“Pennsylvania’s Patient Safety Authority has set the standard for state patient safety organizations. A concrete example of this is their publication of the Patient Safety Advisory which serves as a valuable resource for health care organizations of all types.”*

James P. Bagian, MD, PE  
Department of Veterans Affairs National Center for Safety

*“The Pennsylvania Patient Safety Authority is a model of state innovation in addressing patient safety. The PSA’s collection, analysis, and feedback of data related to adverse events and near-misses play a key role in identifying problems and recommending solutions that promote patient safety.”*

Jill Rosenthal  
National Academy for State Health Policy

*“The Pennsylvania Patient Safety Authority has demonstrated convincingly the value of a broad-based electronic reporting network that uses a common language. Their efforts have led to the identification of rare but serious events, as well as identifying the common causative factors for events occurring regularly in multiple locations. The insights of their analytic team have led to improvements in patient safety not only for patients in Pennsylvania but across the nation. We look forward to completing a project now underway about events related to anticoagulants that will combine the information from PSA’s statewide network with UHC’s information from over 40 teaching hospitals across the country.”*

Mark A. Keroack, MD, MPH  
Vice President and Director  
Clinical Practice Advancement Center  
University HealthSystem Consortium (UHC)

*“Since its inception, the Pennsylvania Patient Safety Authority has been a leader in researching and educating the medical community about medical errors and system maldesign. Today, their advisories provide useful and timely information to help prevent such occurrences. Plus, through a collaborative effort between the Authority and the Pennsylvania Medical Society, Pennsylvania physicians are able to keep up with their continuing medical education related to patient safety.”*

Mark A. Piasio, MD, MBA  
President, Pennsylvania Medical Society

*“The Pennsylvania Patient Safety Authority...fosters learning and has produced high-quality Patient Safety Advisories which detail salient findings, analysis of data...and useable information, tools, and recommendations to improve quality and safety...”*

Paula Bussard  
Hospital and Healthcare Association of Pennsylvania (HAP)

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# Executive Summary

The Patient Safety Authority is an independent state agency established under Act 13 of 2002, the Medical Care Availability and Reduction of Error “Mcare” Act. It is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities, birthing centers and most recently certain abortion providers. Its role is non-regulatory and non-punitive.

The Authority initiated statewide mandatory reporting in June 2004, making Pennsylvania the first state in the nation to require the reporting of both actual adverse events and near-misses. All reports are confidential and non-discoverable, and they do not include any patient or provider names. All submitted reports receive varying levels of review and analysis by experts in medicine, nursing, pharmacy, medical equipment, and risk management.

By many measures, the Pennsylvania Patient Safety Reporting System (PA-PSRS) system has elevated Pennsylvania to the forefront of patient safety activities around the country. At the end of 2006, PA-PSRS had collected nearly 436,000 reports, making it one of the largest databases of its kind. The Authority and PA-PSRS are featured prominently in national studies of state patient safety systems. The PA-PSRS database has generated interest not only throughout the United States but also as far as the United Kingdom, Norway and Switzerland.

During 2006, the Patient Safety Authority continued to focus on its data collection, analysis and educational outreach activities that promote its goal of reducing and eliminating medical errors. In May, the Authority offered an intensive two-day Root Cause Analysis seminar for patient safety officers and senior managers and provided educational toolkits with selected *Patient Safety Advisory* articles to assist facilities in educating staff. These and other educational resources helped facilities implement real change in their institutions.

## 2006 John M. Eisenberg Award Winner

In October, the Patient Safety Authority received the prestigious 2006 John M. Eisenberg Award for advancing patient safety and quality in the Commonwealth. Presented jointly by the Joint Commission and the National Quality Forum (NQF), the award acknowledges the Authority’s impact in patient safety on a regional and national level. The award also recognizes the Authority’s efforts to make the Pennsylvania Patient Safety Reporting System (PA-PSRS) into a nationally recognized resource for education and learning about patient safety. The award highlights the accomplishments and impact the Patient Safety Authority has in the eyes of its peers in the national patient safety community.

The accomplishments of the award recipients are linked to the principles that Dr. Eisenberg promoted throughout his career. These include a dedication to improving the quality of health care and patient safety, leadership in advancing methods for measuring and reporting health care quality, expanding the public’s capacity to evaluate the quality and safety of health care, and promoting health care choices based upon information about safety and quality.

This is the fifth year for the Eisenberg awards program, which recognizes major achievements of individuals and organizations in improving patient safety and quality. The annual awards include an individual lifetime achievement award and awards in the categories of system innovation (local and national) or research. In addition to the Patient Safety Authority, other Eisenberg award winners for 2006 include: Donald Berwick, MD, president, CEO and cofounder of the Institute for Healthcare Improvement (IHI) in Boston, for Individual Achievement; Jerry Gurwitz, MD, nationally recognized expert in geriatric medicine and professor at the University of Massachusetts School of Medicine, for Research; Minnesota Alliance for Patient Safety for Innovation in Patient Safety and Quality at a Regional Level; and the Wichita (KS) Citywide Heart Care Collaborative for Innovation in Patient Safety and Quality at a Local Level.

Some congratulatory messages from friends and colleagues of the Authority:

“...The efforts of the Patient Safety Authority and its contractor, ECRI, truly have made a difference in patient safety in Pennsylvania. Again, congratulations on this well-deserved recognition!” –Carolyn Scanlan, president, Hospital and Healthcare Association of Pennsylvania (HAP)

“Just saw the press release from JCAHO and NQF on the Eisenberg Award. Congratulations! Finally, they get what PA is doing and that it is making a difference in patient safety. You can feel proud of your work and that of the Authority!” –Paula Bussard, Senior Vice President, Hospital and Healthcare Association of Pennsylvania (HAP)

“...Congratulations to everybody at PSA and especially to all of your staff who have worked so diligently over the past years in the establishment and operation of PA-PSRS...” –James Steele, Deputy Counsel, PA Department of Health

“Heartiest congratulations. John Eisenberg was one of my favorite people...ever. He was instrumental in helping us get PRHI off the ground. The JHF contributed to this award and how nice to see it come ‘back home’ to a PA presence!”—Dr. Karen Feinstein, president, Jewish Healthcare Foundation, CEO, Pittsburgh Regional Healthcare Initiative

“I think this is great. I hope the PSA will acknowledge the hard work the facilities have done to help make this a success for our state and the impact this has on the safety of patients.”—Gary Grant, Director of Quality Improvement, Hanover Hospital, Hanover, PA

“Congratulations on your award! The Authority has led the nation towards improving patient safety—Kudos.” –Bonnie Haluska, associate vice president, Allied Services, Scranton, PA

“Congratulations on winning the prestigious Eisenberg Award! Kudos to Pennsylvania as one of the innovators of patient safety!! Our efforts are evident across the country!!”—Roseann Castanaro, Risk Manager/Patient Safety Officer, The Reading Hospital and Medical Center

“Congratulations on a job well done! It’s great to be a part of this very important program. Thank you for all your work.”—Betsy Krueel, RN, Lowry Surgicenter, Jeannette, PA

“...I wanted to extend my congratulations to the Board and staff of the Authority on receiving the very prestigious John M. Eisenberg Patient Safety and Quality Award. The award is well deserved and this recognition from NQF and JCAHO underscores the diligence, passion and commitment of the Authority to improve patient safety and quality for the residents of the Commonwealth. I commend the Authority for its collaborative and constructive approach in working with providers to achieve the patient safety goals that we all desire. In addition, I appreciate the Authority’s participation as a member of the Pennsylvania Node in the IHI 100k Lives Campaign.”—Joseph I. Morris, vice president, Health Care Improvement Foundation (HCIF).

## **Patterns and Trends in PA-PSRS Reports**

The Authority’s core mission is to collect and analyze reports of Serious Events and Incidents. The Authority accomplishes this through the Pennsylvania Patient Safety Reporting System, known as PA-PSRS—a secure, web-based, data collection and analysis system.

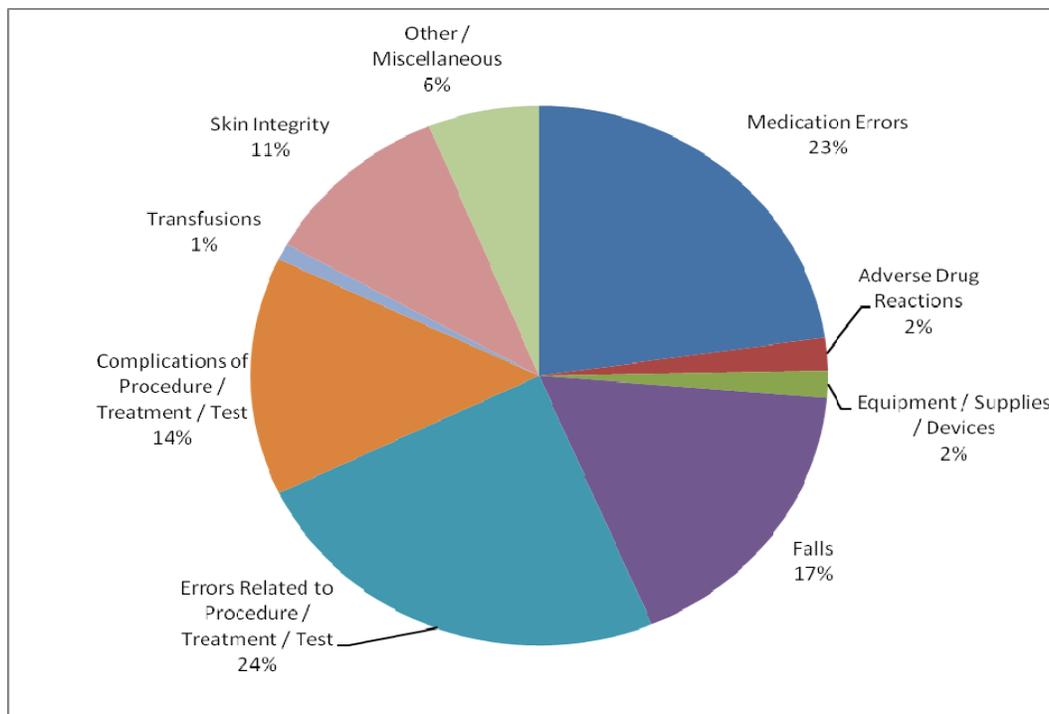
The Authority collected and analyzed data submitted by Pennsylvania’s 460 hospitals, ambulatory surgical facilities and birthing centers. These facilities submitted 195,832 reports: 6,937 of Serious Events (actual adverse events) and 188,895 of Incidents (often called near-misses) through PA-PSRS in 2006. Approximately 96% of the events were classified as Incidents.

Patterns and trends are evaluated in this Annual Report according to the recovery rate. The recovery rate is the percentage of reports without reported harm (Incidents) compared to all reports. The desired result is that the recovery rate increase. Increases will be due to a decrease in Serious Event reports, which is desirable, and/or an increase in reports of detected events that did not harm the patient (Incidents), which is also considered desirable by patient safety experts.

Report volume in 2006 showed an increase of almost 26,000 reports over 2005, with a decrease in Serious Events and a slight increase in the recovery rate.

When reporting an event to PA-PSRS, a facility uses a classification system or “taxonomy” to characterize the occurrence they are reporting. 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?” While there is considerable detail within the taxonomy, at its most basic level, the PA-PSRS classification contains nine Event Types.

Figure 1 presents the percentage of reports submitted in 2006 by their Event Type.



**Figure 1. Percentage of Reports by Event Type (2006)**

Other highlights of data submitted through PA-PSRS during the calendar year 2006 are:

- 464 hospitals, ambulatory surgical facilities and birthing centers were subject to Act 13 reporting requirements. They submitted 195,832 reports of Serious Events and Incidents through PA-PSRS, an increase of almost 26,000 reports over 2005.
- Incidents, in which the patient was not harmed, accounted for 96.5% of all reports; 3.5% of all reports were Serious Events, which indicates that the patient received some level of harm, ranging from minor, temporary harm to death. This represents an increase in the recovery rate.
- Reports from hospitals accounted for 98.7% of all reports submitted.
- Reports by region show the largest number of reports come from the southeastern and southwestern counties, which is consistent with the centers of population within Pennsylvania. When report volume is adjusted for population, facilities in the Northcentral region counties submitted a greater number of Incidents (no harm to the patient): 98.5%, compared to the statewide average of 96.8%, representing a higher recovery rate.

- Reports of healthcare associated infections (HAI) from 2005 and 2006 increased by 63% which may be the result of the Authority's efforts at the end of 2005 to encourage facilities to regard infections as a significant patient safety issue. Reporting increased in almost every HAI subcategory, as well as in each region of Pennsylvania. Overall, HAIs are one of the top three complications most frequently reported to PA-PSRS. Despite this increase in reporting of HAI's, this still represents a small portion of those that actually occur.
- Statewide, the most frequently reported events in hospitals involved Errors related to Procedures/Treatments/Tests (24%). However, these are not the ones most frequently associated with Serious Events (events that cause harm).
- Complications related to procedures, treatments, or tests accounted for 42% of all Serious Events.
- Patient Falls accounted for 17% of all reports, and 4% of Falls were considered Serious Events.
- Consistent with last year, patients over age 65 were especially vulnerable to Serious Events and Incidents, representing more than half (53%) of all reports submitted through PA-PSRS. In 2006, 64% of all Falls and 73% of all reports related to Skin Integrity involved older patients. Skin integrity reports include pressure sores, bruises and other skin-related conditions.
- Reports of children and adolescents (aged 21 and younger) increased 33% in 2006. Errors related to procedures, treatments and tests were the most commonly submitted type of report, accounting for 35% of the reports for this population.
- Reports involving perinatal patients (those aged 20 days or younger) increased 14.6% from 2,885 in 2005 to 3,305 in 2006. About one-fifth (20.5%) of the perinatal reports were related to Medication Errors.
- Medication Errors accounted for 23% of all reports (down from 2005), and 1% of Medication Errors were considered Serious Events. That means that, in almost 99% of Medication Errors, the patient was not harmed. One in four (25%) medication errors involves a high alert medication—these drugs carry risk of significant harm to the patient if used incorrectly.

The complete Annual Report, as well as more information about the Authority and access to issues of the *Patient Safety Advisory*, is available on the Authority's website, [www.psa.state.pa.us](http://www.psa.state.pa.us).

## Improving Reporting by Enhancing the PA-PSRS System

Because facilities are required to submit reports of all Serious Events and Incidents, the Authority is committed to improving the PA-PSRS software to make reporting easier for facilities. Numerous system enhancements were implemented during the year.

The most substantial enhancement was the implementation of a data interface developed to support facilities in reporting to PA-PSRS. The Authority provided significant resources to facilitate implementation of the electronic interface to PA-PSRS for those facilities with existing electronic reporting systems. The interface allows facilities to submit reports to multiple systems while entering report data only once and still meet their obligations under Act 13. It is anticipated that by May 2007, one-third of all Incident reports submitted to PA-PSRS will come through the interface. This represents over 5,000 reports per month.

The Authority promotes reporting by conducting meaningful research to give valuable "lessons learned" back to Pennsylvania facilities; educating facilities about the importance of creating a learning culture instead of a punitive one; and ensuring the PA-PSRS system is collecting data as efficiently as possible and providing the necessary tools for facilities to study their own data and make the necessary improvements in-house.

To increase the value of the data to reporting facilities, the Authority developed and provided analytical reports which help track reports they've submitted to PA-PSRS while correlating them to specific Joint Commission

National Patient Safety Goals. The report allows facilities to see which reports correspond to each particular goal. The Authority encourages facilities to utilize this tool as part of their overall quality improvement initiatives and for reports to senior managers and boards of trustees.

A sample of other enhancements implemented during 2006 includes the following:

- The PA-PSRS system can now generate a preprinted form that facilities can submit to the Food and Drug Administration's (FDA) MedWatch reporting program for drug and medical device problems. By electronically inserting data taken directly from the PA-PSRS report form, this process eliminates the need for a facility to re-enter the information on a blank FDA form, thus saving labor and avoiding redundant reporting.
- Facilities can run aggregate reports by facility type. Requested by facilities in the user survey, this addition enables a facility to compare its data to cumulative data for facilities more similar to their own.

## Using PA-PSRS Data to Provide Guidance and Promote Change and Safety

The Authority's professional staff of clinical analysts reviews and analyzes all Serious Event and Incident reports. Their research is published in the *Patient Safety Advisory*, a quarterly publication directed primarily to healthcare professionals and facility administrators. *Advisory* articles provide clinical guidance about process improvements facilities can adopt to improve patient safety and reduce potential patient harm. To date, more than 100 scholarly articles about specific events submitted through PA-PSRS have been published. In 2006, generated from an Incident in PA-PSRS data, facilities in northeastern and central Pennsylvania spearheaded a grassroots effort to reduce patient harm by creating the "Colors of Safety Task Force" which implemented and standardized a number of safe practices throughout their facilities. The *Advisory* is distributed electronically throughout the Commonwealth and around the country. It is also accessible on the Authority website. For synopses of selected *Advisory* articles from 2006, refer to "Patient Safety Guidance Based on Report Analysis and Research" (page 47).

Through a survey conducted by the Authority in the fall of 2006, patient safety officers confirmed the *Advisories* were a valuable resource and an impetus for change. Of hospital respondents, 77% said they had implemented changes in their facility's practices as a result of information from the *Advisory*. On average, each hospital had implemented approximately five significant policy/process changes based on guidance provided in the *Advisory* articles.

In 2006, PA-PSRS added a significant enhancement to the *Advisories* by introducing toolkits that help healthcare facilities implement the guidance offered in the *Patient Safety Advisory*. For example, In June 2006, the article "Improving the Safety of Telephone or Verbal Orders" was accompanied by a self-running, narrated online presentation appropriate for front-line clinicians; a sample policy and procedure around verbal orders; and a poster to help reinforce key messages with staff. The August 2006 *Supplementary Advisory* "Update on Use of Color-Coded Wristbands" was accompanied by a similar toolkit developed by the Colors of Safety Task Force, which was consistent with guidance from PA-PSRS.

Research findings highlighted through *Patient Safety Advisory* articles include issues that:

- Raised awareness of problems associated with the use of the sedation drug propofol by highlighting cases where the drug was not administered or monitored properly putting patients at risk and even in some cases causing death.
- Focused attention on the increased risk of medication errors when drugs are ordered verbally over the telephone instead of using a read-back procedure in which the person receiving the order writes it down, reads it back and gets confirmation that they understood the order correctly. An educational toolkit accompanied the article that included a poster, a slideshow and sample policy procedures for implementation to help further educate staff.

- Highlighted ways to avoid painful skin injuries, known as skin tears, and to treat them when they occur. Guidance to practitioners on how to avoid skin tears and provide proper techniques when treating them were included in a toolkit to educate staff and family.
- Identified rare cases of intraoperative deaths during hip replacement due to Bone Cement Implantation Syndrome (BCIS) in which five out of six of the patients died. Several risk reduction strategies in the article include evaluating and monitoring the patient’s condition before and during surgery. The six BCIS cases would most likely not have been noticed had it not been for the aggregation of the cases over the last two years through the PA-PSRS reporting system.
- Focused attention on the dangers of hospital bed rail entrapment and measures facilities can take to prevent injury and death from entrapment. A toolkit was also provided for front-line caregivers to help them implement changes within their facilities to reduce the risk of patients being trapped in their bed rails.

The Authority’s research findings are disseminated widely through the *Patient Safety Advisories*. The importance of distributing the *Advisories* to all appropriate staff cannot be emphasized enough so that the facility can benefit fully from the “lessons learned.” While several of Pennsylvania’s patient safety officers have commented on the usefulness of *Patient Safety Advisories*, one facility in particular encompassed the purpose of the *Advisory* overall:

*“Your Advisory publications are extremely helpful in educating all staff as well as giving the facility a focus to prevent future occurrences.”*

*--Patient Safety Officer  
Pennsylvania healthcare facility*

## **Education and Outreach Efforts Increase “Cultures of Safety”**

The Authority continues to embark on new education and outreach initiatives to improve patient safety in Pennsylvania’s healthcare facilities.

In the three years since mandatory reporting was initiated in Pennsylvania, PA-PSRS has received almost half of a million reports, a significant database that validates the utility of mandatory reporting, especially the mandatory reporting of near-misses. The point of mandatory reporting is not merely to collect reports but to learn from past experiences in one’s own facility and from the experiences of other facilities. Hospitals have responded to clinical guidance contained in the *Patient Safety Advisory* by implementing new, safer procedures and protocols.

By many measures, the PA-PSRS system has elevated Pennsylvania to the forefront of patient safety activities around the country. The PA-PSRS database has generated interest from throughout the United States and as far as the United Kingdom, Norway and Switzerland.

Adverse event reporting is a first step in dealing with issues of quality and safety. The action of submitting a report is an acknowledgement that something actually or almost happened, but the next steps are important—learning why it happened and implementing steps to prevent it from happening again. The Authority recognizes this is no easy task, but it’s a challenge that everyone from hospital CEOs to the maintenance workers in every facility should accept.

The Authority understands an integral part of making facilities safer involves reaching out to facilities and encouraging them to develop a “culture of safety” within their institutions that includes: 1) full and open disclosure of events; 2) investigations into “why” an event occurred; and 3) improvements and prevention measures to ensure an event does not occur again.

For its part in educating facilities, the Authority gave frequent patient safety lectures to physicians, nurses, pharmacists, hospital administrators and other healthcare workers; participated in statewide patient safety training sessions and conferences; participated in the establishment of new statewide collaborative organizations such as the PA eHealth Initiative and the Patient Safety Forum; collaborated with other statewide organizations to develop new research projects and initiatives using PA-PSRS data; and facilitated access to continuing education credits related to patient safety for physicians and other healthcare professionals.

News media around the Commonwealth, including the state's major newspapers, carried articles about the Authority's research and publications. In addition, several medical, clinical and professional journals, reprinted or cited articles that originally appeared in a *Patient Safety Advisory*. Among the publications and organizations that picked up articles from the *Advisory* are the *Joint Commission Perspectives on Patient Safety*, *Contemporary Surgery*, *Outpatient Surgery Magazine*, *HealthLeaders Magazine*, the Robert Wood Johnson Foundation website, *Patient Safety Net* (published by the U.S. Agency for Healthcare Research and Quality), *MedSun* (published by the Federal Drug Administration's Medical Device Surveillance Network), *Medical News Today*, *Patient Safety and Quality Healthcare*, *OR Manager*, *Physicians News Digest*, *Infection Control Today*, *Nursing Spectrum*, and the newsletters of numerous professional associations such as DecisionHealth, HC Pro, the Association for the Advancement of Medical Instrumentation (AAMI), Towers-Perrin RX Collaborative newsletter, the American Organization of Nurse Executives and the American Association of Critical-Care Nursing. Clinical staff also published articles in the *American Surgeon*, *American Journal of Surgery*, *AORN Journal* and *Medicare Patient Management Journal*.

The Patient Safety Authority Board continues to expand its focus on educational programs, like the Root Cause Analysis Seminar held in 2006, and by sponsoring an intensive two-day workshop on Failure Mode and Effects Analysis (FMEA) in May and June 2007. The workshop will allow Pennsylvania healthcare facilities to learn how to mitigate potential risks and develop control strategies where risk is present within their own healthcare facilities.

Results from the Patient Safety Authority's annual Fall 2006 survey suggest that Act 13 and the Patient Safety Authority have continued to help promote a culture of safety in Pennsylvania healthcare facilities. More than 87% (up from 80% in 2005) of the patient safety officers responding to the Authority's annual survey credited Act 13 with improving the culture of safety within their facilities. Equally important, 72% of survey respondents indicated that the PA-PSRS system improved their ability to monitor patient safety within their facilities.

Consistent with these efforts, the Board established several priorities in 2006 for the future that include promoting a culture of safety within individual healthcare facilities. The Authority met with Pennsylvania government officials to discuss plans for encouraging a culture of safety throughout the healthcare community. Those discussions continue into 2007 with plans for implementation underway. Three groups targeted for these education and outreach efforts include: patient safety officers and risk managers; clinicians representing the spectrum of healthcare professionals from physicians and nurses to pharmacists, laboratory workers and technicians; and healthcare executives, with a focus on CEOs and trustees.

## Program Administration

In 2006, many significant administrative changes occurred at the Patient Safety Authority.

In May, Dr. Ana Pujols-McKee, was appointed by Governor Ed Rendell to serve as chair of the Authority. Dr. McKee serves as chief medical officer and associate executive director of the Penn Presbyterian Medical Center in Philadelphia. She holds a bachelor's degree in psychology from the State University of New York at Binghamton, a medical degree from Hahnemann Medical College and Hospital and a specialty certification from the American Board of Internal Medicine. Dr. McKee is a member of numerous healthcare and community organization boards, including most recently the Pennsylvania Healthcare Cost Containment Council (PHC4). In 2004, Dr. McKee was named a Distinguished Daughter of Pennsylvania.

In December, Alan B.K. Rabinowitz, resigned as administrator of the Authority. Mr. Rabinowitz was named the Authority's first administrator in November 2002. Under his tenure, the Authority developed and implemented PA-PSRS, most recently recognized with the 2006 John M. Eisenberg Award. He also initiated the publication of the *Patient Safety Advisory*, recognized throughout the country as an educational resource. While the Authority conducts a search for a successor to Mr. Rabinowitz, Michael C. Doering, former PA-PSRS project manager, will serve as interim administrator.

The Authority also said goodbye to one of its founding board members, Dr. Nathan J. Zuckerman. Dr. Zuckerman served on the board since its inception in 2002.

The Authority's Board of Directors held nine public meetings throughout the year with guest speakers who gave presentations about medication errors, projects aimed at reducing infections and efforts made throughout the central and northeastern part of the state to standardize color-coded wristbands. PA-PSRS data contributed to the efforts and project initiatives that ultimately strive to improve patient safety.

More strategic planning sessions were held by the Board to focus on clarifying the agency's mission, identifying short-term and long-term goals and establishing priorities for the coming year. The Board created new committees to facilitate the Board's policy development, including committees dedicated to Strategic Planning, Data and Research, a Budget and a Search committee to find a permanent administrator.

Several objectives were established by the Board for implementation over the coming years. They include: increased collaboration with other healthcare organizations to better leverage the Authority's resources and more aggressively promote patient safety throughout the Commonwealth; sponsoring education and training initiatives targeting hospital boards of trustees and specific professional groups of healthcare workers; and working collaboratively to improve consistency of PA-PSRS reporting. In 2007, the Board continued planning activities and is developing a strategic plan to operationalize their objectives.

Finally, the governor signed House Bill 1591 into law in May. The measure, which became Act 30 of 2006, mandates abortion facilities that perform 100 or more procedures annually to follow Act 13 reporting requirements. See page 71 for more detailed information about this and other legislation impacting patient safety in Pennsylvania.

# Background

## The Patient Safety Authority

The Patient Safety Authority is an independent state agency established under Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. It is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities, birthing centers and in 2007 certain abortion facilities. The Authority’s role is non-regulatory and non-punitive.

The Authority operates under an 11-member Board, seven appointed by the Governor and four appointed by the General Assembly. Current membership includes three physicians, three attorneys, two nurses, a pharmacist and an executive with a health insurance company. At the time this report went to press, there was one board vacancy.

Under Act 13, all hospitals, birthing centers, ambulatory surgical facilities and certain abortion facilities—currently totaling approximately 475 facilities—must report what the Act defines as “Serious Events” (actual adverse events) and “Incidents” (so-called “near-misses”). In turn, the Authority analyzes and evaluates those reports so it can learn from the data reported in order to advise facilities and make recommendations for changes in healthcare practices and procedures which may be instituted to reduce the number and severity of Serious Events and Incidents.

To provide a mechanism for the collection and analysis of data related to Serious Events and Incidents, the Authority developed and implemented the Pennsylvania Patient Safety Reporting System, known as PA-PSRS, a secure, web-based, data collection and analysis system.

All information submitted through PA-PSRS is confidential, and no information about individual facilities or providers is made public. In addition, Act 13 contains whistleblower protections as well as provisions that allow healthcare workers to submit Anonymous Reports if they believe that healthcare facilities are not reacting appropriately in response to a Serious Event within the facility.

Statewide mandatory reporting went into effect in June 2004, making Pennsylvania the first state in the nation to require the reporting of both actual adverse events and near-misses. By the end of 2006, Pennsylvania healthcare facilities had submitted a total of nearly 436,000 reports of Serious Events and Incidents through PA-PSRS, with average monthly reports over 16,000 in 2006 (up from a 13,000 per month average in 2005).

## What is Patient Safety?

Patient safety can be defined as “freedom from accidental injury.” Within the academic and healthcare community, patient safety is also defined as the avoidance and prevention of unanticipated and undesirable patient outcomes. These patient outcomes are commonly called “adverse events” or, sometimes, “medical errors.”

It is important to recognize that not every adverse event is the result of an error. For example, if a patient receives the wrong medication, that can be classified as an error. But what if a patient has a bad reaction to a medication that he or she never received before? In the latter example, while the drug reaction should be classified as an unanticipated adverse event, it should not be considered an error *per se*.

The goal of patient safety is to reduce the likelihood of any unanticipated adverse event, whether it is considered a medical error or not. Patient safety advocates strive to understand the way healthcare is delivered and to develop protocols that will reduce the likelihood of future adverse events that result in patient harm.

The concept of patient safety received considerable public attention following the release of the Institute of Medicine’s important study, *To Err Is Human*, in 1999. That report estimated that up to 98,000 people die in hospitals each year from medical errors. In 2006, the IOM issued *Preventing Medication Errors*, the latest report in its *Crossing the Quality Chasm* series, citing the frequency and potentially tragic consequences of medication errors.

More and more national publications are reporting on the importance of patient safety or lack thereof. The federal government is also actively engaged in issues of quality and patient safety.

The potential for errors and other unanticipated outcomes is much greater today than it was in previous decades due to the combination of human factors, high-tech electronic equipment and sophisticated, often dangerous, medications and procedures. On the other hand, we can reduce medical errors by identifying where mistakes might happen before they actually occur. The key is to create a “culture of safety” where people and institutions encourage full and open disclosure to patients, acknowledging mistakes while implementing procedures to prevent future errors.

In September 2006<sup>1</sup>, Dr. James P. Bagian, Director of the Department of Veterans Affairs National Center for Safety, spoke about his experience transforming safety in Veterans Affairs hospitals nationwide. In the monthly perspectives article for the Agency of Healthcare Research and Quality (AHRQ), Bagian cited a survey he had done upon arriving with the VA that showed almost one quarter of the employees did not believe patient safety was important because they didn’t believe they, themselves, to be unsafe. “. . .It was this inappropriate confidence—the feeling that they were safe. It was that *other* physician, that *other* nurse, the *other* floor, the hospital down the street, yeah, they have problems, but *I* don’t have problems. Well, I always say that the person who thinks it can never happen to them is the most dangerous person in the room, because they’re in denial. In industries like aviation, space flight, and nuclear power, everybody knows that given the right set of circumstances it could happen to any of us.”

## Definitions used in this Report

Act 13 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, 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 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 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.

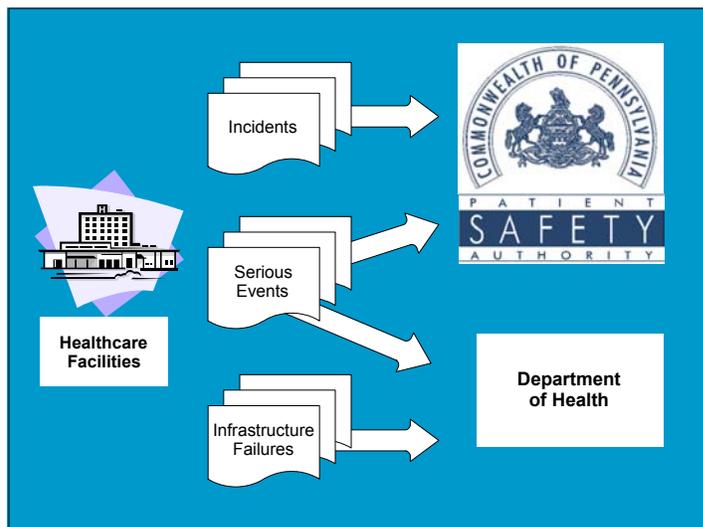
As shown in Figure 2, reports of Serious Events and Incidents are submitted to the Patient Safety Authority for the purposes of learning how the healthcare system can be made safer in Pennsylvania. In contrast, reports of Serious Events and Infrastructure Failure are submitted to the Department of Health for the purposes of fulfilling their role as a regulator of Pennsylvania healthcare facilities.

Act 13 requires the following types of facilities to submit reports of Serious Events, Incidents, and Infrastructure Failures to PA-PSRS:

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<sup>1</sup> Agency for Healthcare Research and Quality (AHRQ) Morbidity and Mortality Rounds on the Web. 2006 Sept. “*In Conversation with...James P. Bagian, MD.*” Available from the Internet: <http://webmm.ahrq.gov/perspective.aspx?perspectiveID=30>

**Figure 2. Submission of PA-PSRS Reports**



the purposes of this report, at the end of 2006, there were 239 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 2006, there were 220 Ambulatory Surgical Facilities in the Commonwealth of Pennsylvania.
- Birthing 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 2006, there were five Birthing Centers in the Commonwealth of Pennsylvania.

Act 30 of 2006 extended the reporting requirements in Act 13 to abortion facilities that perform more than 100 procedures per year. However, these facilities were not required to report during calendar year 2006; therefore, no data from these facilities is included in this report.

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. The word “error” appears in the PA-PSRS system and in this report. For example, one category of reports discussed is “Medication Errors.” PA-PSRS uses the word “error” 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).<sup>2</sup>

<sup>2</sup> Institute of Medicine, Committee on Data Standards for Patient Safety. Patient safety: Achieving a new standard for care. Washington DC: National Academies Press; 2004.

Within Act 13, 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. See the related discussion in “What Is Patient Safety?” on page 9.

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

# PA-PSRS Annual Survey of Patient Safety Officers

In November 2006, the PSA 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 opinions on topics such as the culture of safety in their facilities and their view and handling of healthcare associated infections (HAIs), along with feedback regarding the Pennsylvania Patient Safety Reporting System (PA-PSRS) and its role in their facilities. Responses were collected over a twelve-day period. Of the 419 invitees, PSOs from 109 hospitals (HSPs), 76 ambulatory surgery facilities (ASFs) and one birthing center (BC) responded, resulting in a 44% response rate. For purposes of data analysis, the birthing center was grouped with the ASFs when comparing responses from different types of facilities.

## Culture of Safety

In response to general questions regarding safety in their facilities, PSOs felt positive about their facilities' culture of safety, but they do allow that there is room for improvement. PSOs from ASFs/BCs rated their facilities' culture of safety more positively than PSOs from hospitals (see Figure 3). On a scale of 1 (poor) to 5 (excellent), PSOs from ASFs/BCs rated their facilities' safety culture on average at 4.6, compared to an average of 3.8 among PSOs from hospitals.



**Figure 3. PSOs' Global Ratings of Culture of Safety, by Facility Type**

More specific questions regarding culture of safety were adapted from a Patient Safety Culture survey instrument developed by Westat under contract to the Agency for Healthcare Research and Quality (AHRQ).<sup>3</sup> As shown in Figure 4 below, PSOs from ASFs/BCs seem to feel slightly more positive about their culture of safety than PSOs from hospitals, but differences based on facility type are modest. The largest disparity between facility types is in regard to the question of whether they believe patient safety is ever sacrificed for efficiency. Nearly all of the PSOs from ASFs/BCs felt that patient safety is never sacrificed for efficiency, whereas more than 1 in 5 PSOs from hospitals disagreed with this premise.

<sup>3</sup> Sorra JS, Nieva VF. Hospital Survey on Patient Safety Culture. (Prepared by Westat, under Contract No. 290-96-0004). AHRQ Publication No. 04-0041. Rockville, MD: Agency for Healthcare Research and Quality. September 2004.

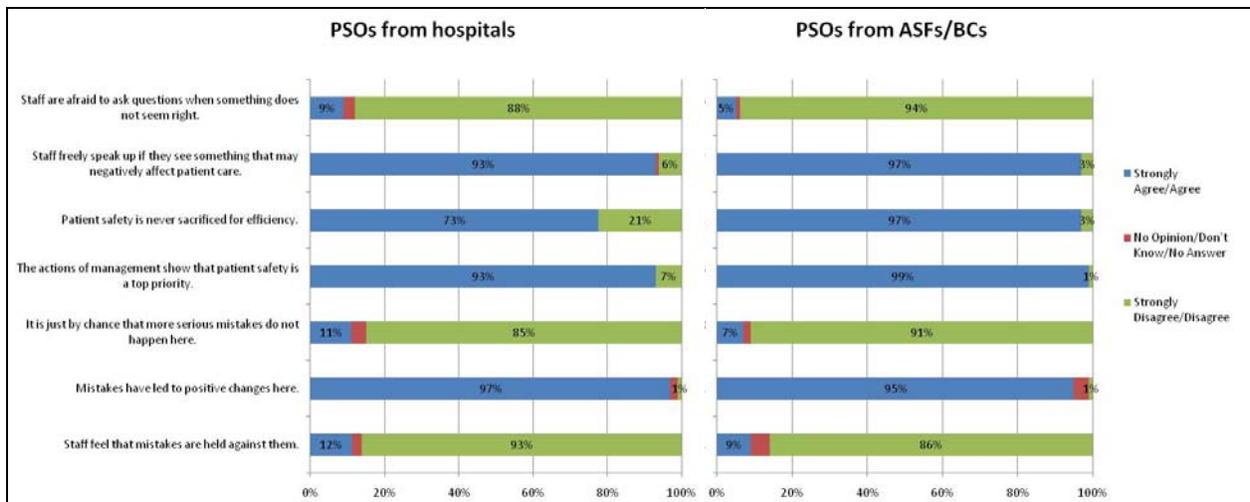


Figure 4. Comparison of PSO response to questions on Culture of Safety

## Healthcare Associated Infections

PSOs indicated that preventing healthcare associated infections is viewed as a patient safety issue, as evidenced in Figure 5 below. However, PSOs' opinions that their facility's staff view infection rates as "relatively low" suggests that there is room for improvement by making infection control a greater priority. If we accept that infections are an expected complication of medical care, we can become complacent in our efforts to prevent them. The report *Hospital-acquired Infections in Pennsylvania* (November 2006), published by the Pennsylvania Healthcare Cost Containment Council, highlighted the significant patient harm and expense associated with these infections.<sup>4</sup> While most Patient Safety Committees address infections, those in hospitals may be less likely to do so than those in ASFs/BCs, possibly due to hospitals' use of infection control practitioners. ASFs/BCs are less likely to have personnel who specialize in infection control on their Patient Safety Committees.

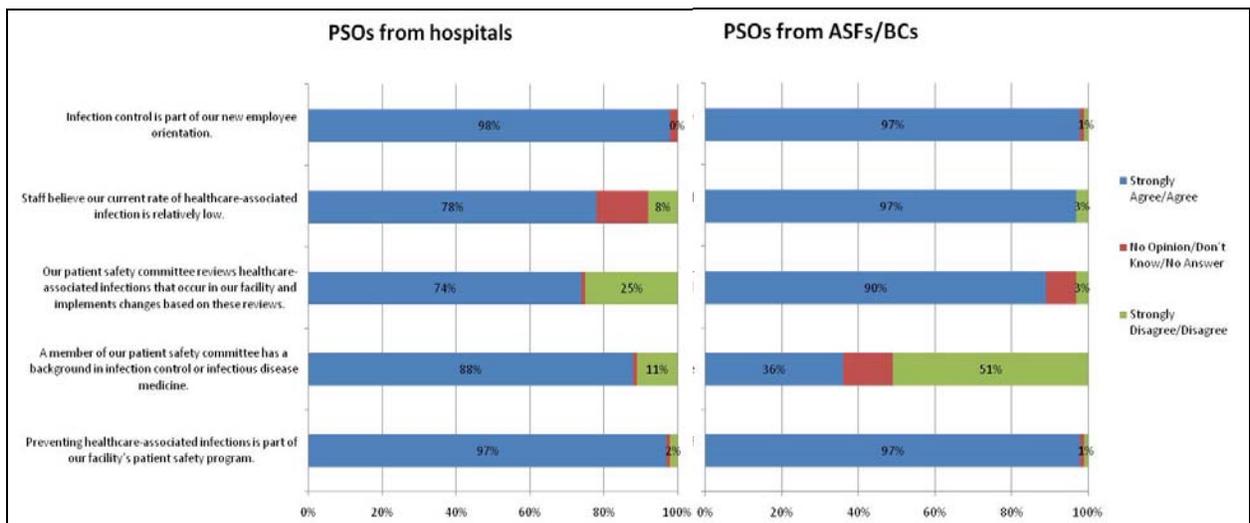


Figure 5. Comparison of PSO response to questions on Healthcare Associated Infections

<sup>4</sup> The report is available online at <http://www.phc4.org/reports/hai/05/docs/hai2005report.pdf>.

## Patient Safety Advisory

The *Patient Safety Advisory* is viewed by PSOs as being of good scientific quality and educational value (Figure 6). As in previous surveys, PSOs collectively gave the *Advisory* high marks on usefulness (98%), relevance (97%) and readability (98%).

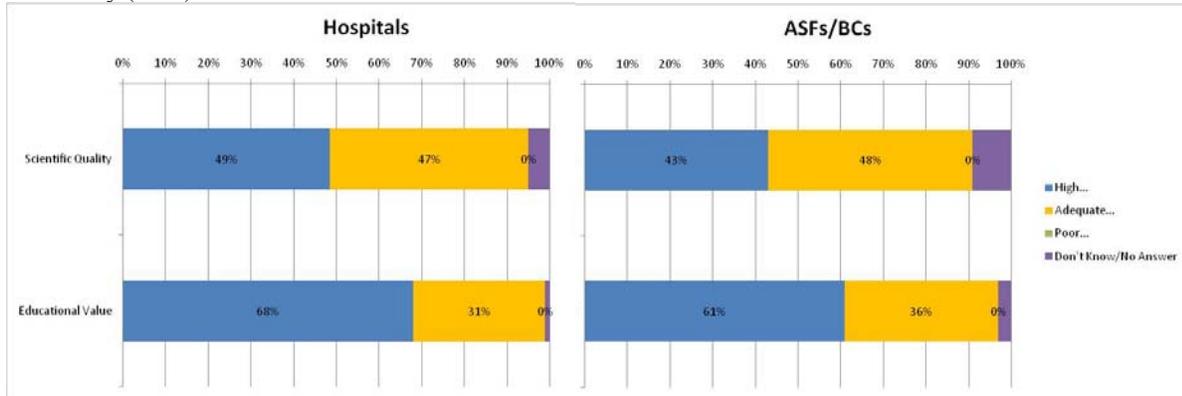


Figure 6. Comparison of PSO views of *Patient Safety Advisory* Quality

## New Features Offered by PA-PSRS

Several new features accompanying the *Patient Safety Advisory* were introduced in 2006. These were viewed as useful by those familiar with them when responding to the survey. As Figure 7 demonstrates, many PSOs are not familiar with these new features, and more can be done to boost awareness.

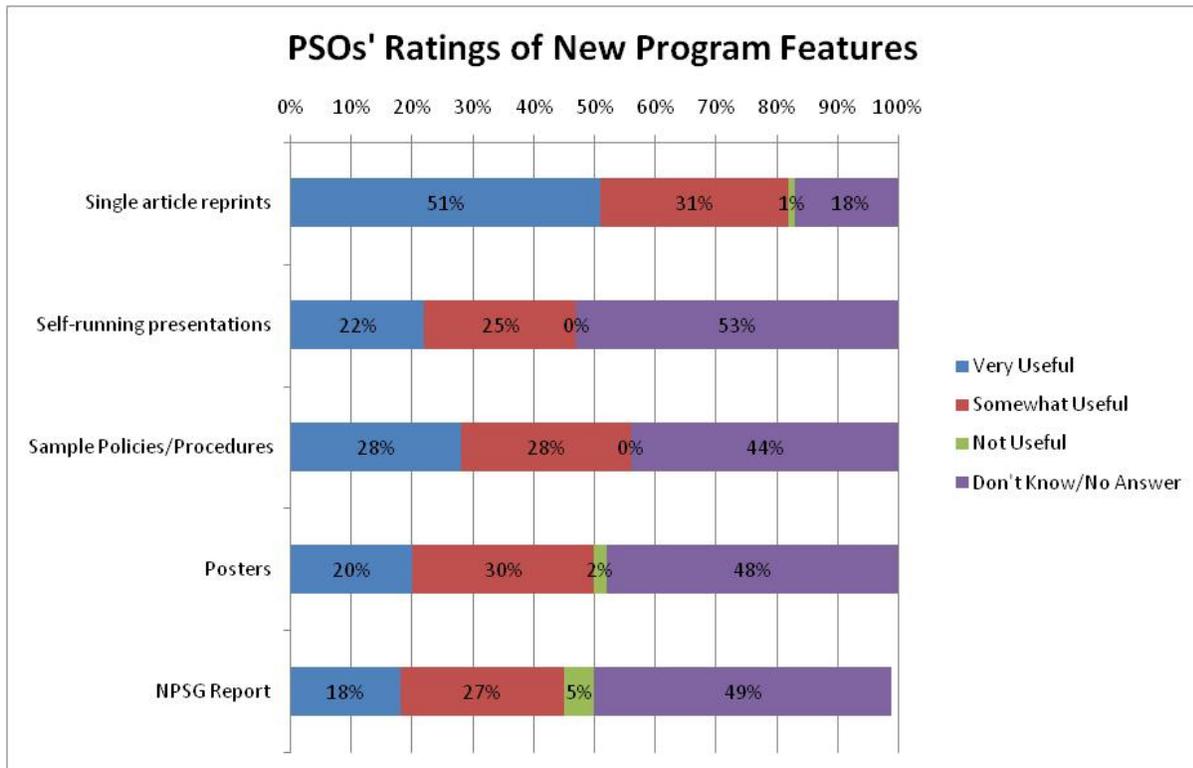


Figure 7. PSO ratings of New Program Features

These new features include:

- Each clinical article published in the *Patient Safety Advisory* is also available as a single-article reprint, making it easier for people to share specific articles via email or hardcopy.
- Brief self-running presentations with audio narration based on selected articles from the *Advisory*, which PSOs can use to train clinical staff.
- Sample policies and procedures based on guidance from *Advisory* articles, which PSOs can adapt to their facilities and patient populations.
- Posters based on selected *Advisory* articles, which PSOs can post throughout their facility to heighten awareness or reinforce key safety messages.
- A new analytical report available within the PA-PSRS reporting system that tracks and trends the facility's submitted reports related to specific National Patient Safety Goals.

## Reach of PA-PSRS and the *Patient Safety Advisory*

PSOs report that information from PA-PSRS reaches many individuals in Pennsylvania healthcare institutions. PSOs use PA-PSRS data and the *Patient Safety Advisory* for internal reports and education, as shown in Figure 8. Comments mentioned use in patient safety committees, management meetings, presentations to staff and administration, along with use in specific quality improvement projects and committees charged with addressing specific patient safety issues.

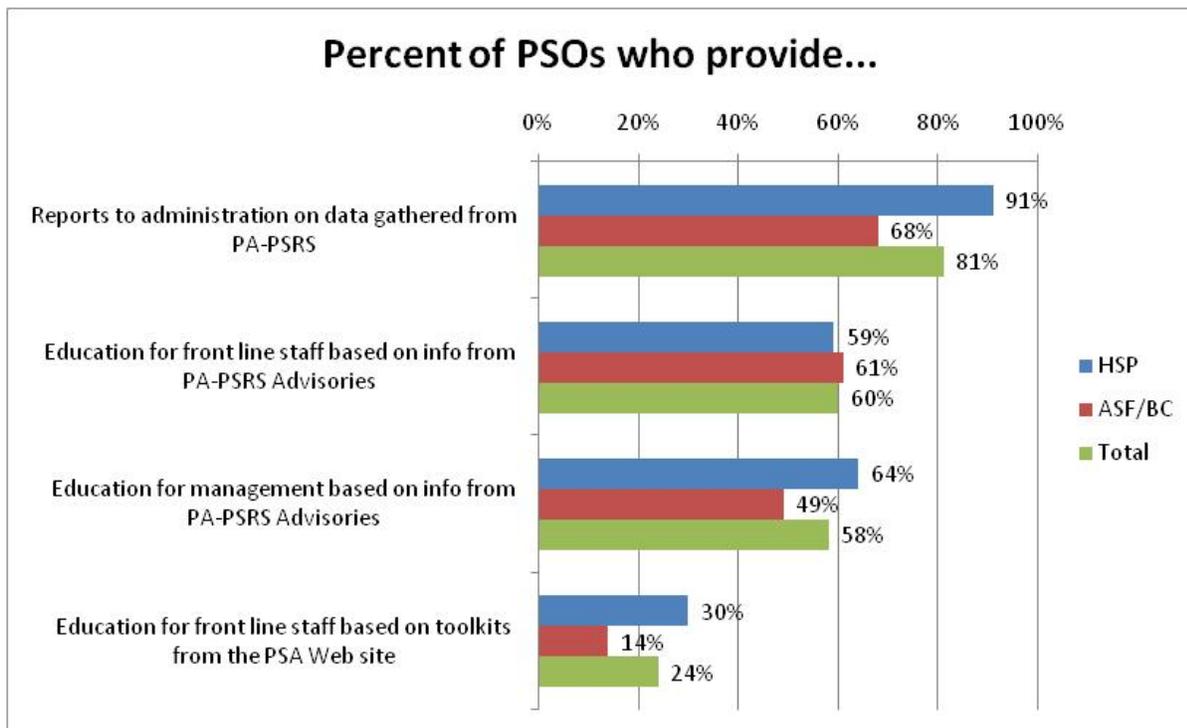


Figure 8. PSO Use of PA-PSRS Data and the *Patient Safety Advisory*

## PA-PSRS: Driving Change

The *Patient Safety Advisory* may be driving change more than individual facilities' PA-PSRS data. Among PSOs participating in the survey, 63% report making or planning to make changes based on an *Advisory* article, compared with 13% who report making or planning changes based on their facility's PA-PSRS data. This suggests that PA-PSRS has achieved one of its' original objectives of helping healthcare facilities across the state learn from adverse events and near misses that occur in other facilities. The 186 participants of the survey reported making 526 changes in their facilities as a result of specific *Advisory* articles, as seen in Figure 9. PSOs from hospitals (109) cited 391 changes, while PSOs from ASFs/BCs (77) cited 135.

Examples of the kinds of improvements facilities said they had made in response to *Advisory* articles include:

- Adopting PA-PSRS guidance on using color-coded patient wristbands to communicate clinical information, such as when a patient has drug allergies or to identify those who are at risk of falling.
- Forming a skin integrity task force to create a core group of clinicians who specialize in wound care and prevention of skin injuries such as pressure ulcers or skin tears.
- Restricting the use of propofol, a sedating agent that can suppress respiration, to the anesthesia department.
- Reducing the use of verbal orders, which can be more easily misinterpreted than written orders.
- Implementation of a “time out” prior to surgery to verify the patient’s identity, the procedure to be performed, the surgical site, and other critical information.

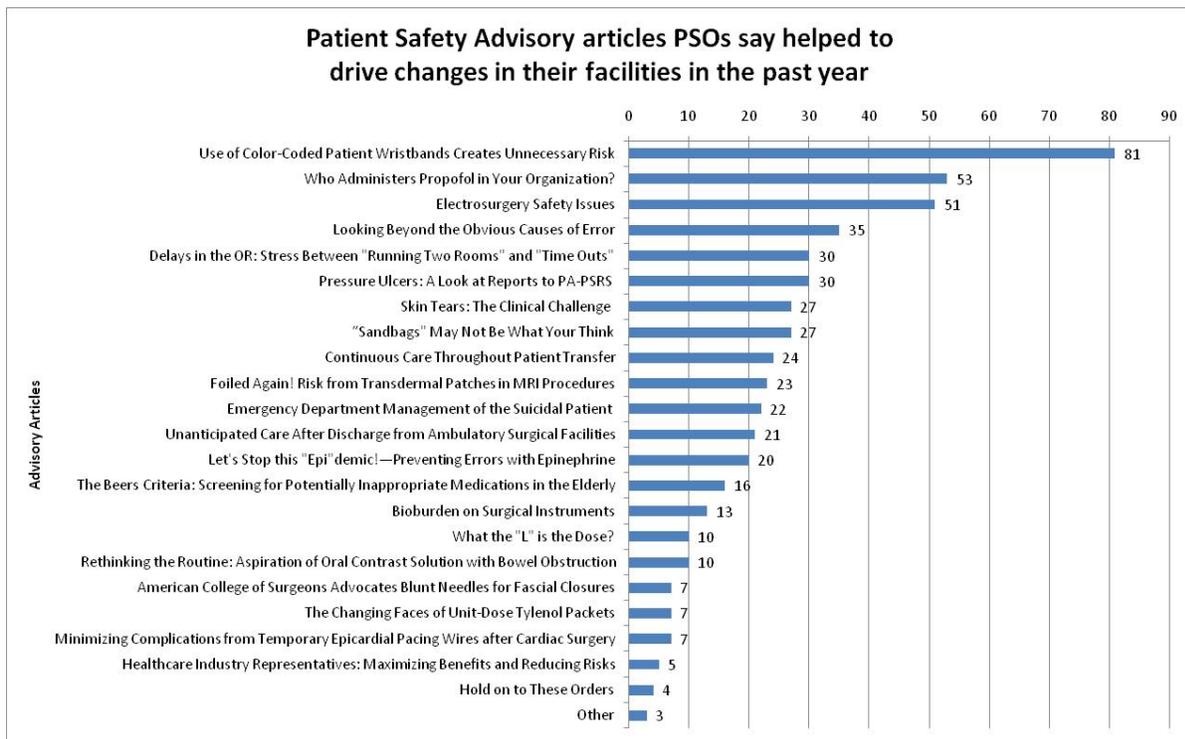


Figure 9. *Patient Safety Advisory* Articles Cited by PSOs as Prompting Them to Make Changes in 2006

## Summary

As with last year's survey, our 2006 survey of Patient Safety Officers finds that the *Patient Safety Advisory* is highly regarded and benefits Pennsylvania healthcare facilities by:

- Helping to set the patient safety agenda
- Prompting numerous process changes
- Being used extensively in education.

Though PSOs feel positively about their facilities' culture of safety and infection control efforts, there is room for improvement in both areas.

We also found out that we need to increase awareness and use of other resources based on the Advisory. The posters, self-running presentations, and sample policies and procedures are available on the PSA website and are intended to be resources for not only the PSOs but ultimately for all healthcare providers throughout the state.

# Data Collection and Analysis

## The Reporting System

### *Introduction*

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 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, PA-PSRS is a facility-based reporting system.<sup>5</sup> All reports are submitted by facilities through a process identified in their patient safety plans, as required by the Act. However, Act 13 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 reporting requirements may submit an Anonymous Report directly to the Authority. (See the section on Anonymous Reports on page 63.)

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.

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, management and clinical protocols. The facility is also asked to identify the root cause of a Serious Event and to suggest procedures that can be implemented to prevent a reoccurrence.

Once a report is submitted, the PA-PSRS 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, PA-PSRS has access to a large pool of subject matter experts in virtually every medical specialty.

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 *Patient Safety Advisories* based on data submitted through PA-PSRS, supplemented by a scholarly search of the medical and clinical literature. *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 (63%) of all responding facilities and 77% of respondents from hospitals indicated that they have implemented improvements within their facilities as a result of information

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<sup>5</sup> 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.

contained in this year's *Advisories*. The 186 Patient Safety Officers responding to the 2006 survey cited 526 process or system changes they had made as a result of *Advisory* articles.

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 country, 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.

More information about the *Patient Safety Advisories* and the data collected through PA-PSRS is in the section "Patient Safety Advisories" (see page 15). In addition, all copies of the *Advisory* are accessible on the Authority website, [www.psa.state.pa.us](http://www.psa.state.pa.us).

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 now 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, 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.

## ***Improving PA-PSRS***

The Authority introduced several new releases of the PA-PSRS software during the year that included more than 70 system changes to enhance the electronic data collection and analysis system. Many of these were technical changes to improve PA-PSRS operations and efficiency, but others were system changes requested by facilities to improve the utility and functionality of the system from the user's perspective.

For example, the Authority has reduced the staff time associated with reporting to PA-PSRS for many facilities that have internal, electronic reporting systems in addition to PA-PSRS. In response to requests from facilities, the Authority developed an interface capacity that allows facilities to transfer data to PA-PSRS from their internal reporting systems. Many hospitals and health systems, representing both large and small facilities throughout all regions of the Commonwealth, are participating in this initiative. While this software development requires considerable staffing and resource commitment by both the Authority and individual institutions, building an interface has enhanced hospital efficiency, decreased redundancy and duplicate reporting, saved facility staff time and resources, and promoted patient safety at the point of care.

The PA-PSRS system was also enhanced through the addition of new analytical tools embedded within the system. New data options provide improved data export capabilities. These tools provide immediate, real-time feedback to healthcare facilities, and enable them to perform evaluations and assessments of adverse events and near-misses involving their institutions. Facilities use these tools for their internal quality improvement and management review activities. For example, PA-PSRS added an analytical report which helps facilities track reports they've submitted that are related to specific Joint Commission National Patient Safety Goals. Some examples of the patient safety goals include the accuracy of patient identification, improving the safety of using medications and reducing the risk of patient harm from falls. The report also allows facilities to see which reports are falling into each particular goal category. The Authority encourages facilities to utilize this tool as part of their overall quality improvement initiatives and for reports to senior managers and boards of trustees.

In 2005, the system was modified to include the names of more than 6,000 generic and brand-name medications from a list maintained by the Federal Drug Administration (FDA). This drop-down menu on the electronic PA-PSRS report submission form helps to promote accuracy and clarity when a facility submits a report that involves a medication error or adverse drug reaction. In 2006, the drug dictionary was modified allowing for the capability to delete or add new drugs to the system.

In 2006, PA-PSRS added a feature that generates a preprinted form that facilities can submit to the FDA's MedWatch reporting program. By electronically inserting data taken directly from the PA-PSRS report form, this process eliminates the need for a facility to re-enter the information on a blank FDA form, thus saving labor and reducing redundant reporting.

Related to reporting, facilities were also given a guide or "algorithm" used by the Authority when evaluating Anonymous Reports to determine if an occurrence is a Serious Event or Incident. The document, sent to all patient safety officers in July 2006, is meant as a "here's how *we* do it" piece, not as a "here's how *to* do it" piece. The Authority will continue to work to provide facilities with more tools to develop a greater consistency in reporting events.

## ***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.

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, ten incorrect medications out of a total of 50 administered doses is much different than ten 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, 2006, and December 31, 2006.
- 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, 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.

## ***Using this Report: Guidance from the Clinical Director***

Information collected through PA-PSRS throughout 2006 on Incidents and Serious Events in Pennsylvania is reported in the following analyses of volumes, trends, and patterns, including those involving special populations of patients. This information has been contributed confidentially by the 464 facilities providing acute medical care in the state (as of December 31, 2006) under the requirements of Act 13 of 2002, the Mcare Act.

The following data analysis summarizes over 188,000 accounts of Incidents without indication of patient harm from their medical care and over 6,900 Serious Events in which patients were harmed as a result of their medical care.

The citizens of Pennsylvania may be concerned about the number of Serious Events and Incidents and how facilities are using the reporting system to make healthcare safer. However, healthcare consumers should know what they can and cannot validly conclude from the report:

- An Incident means a patient was not harmed by their medical care. The vast majority of reports PA-PSRS receives were not associated with harm to patients. Based on the reports, 96.5% of reported problems were either caught by healthcare providers before harm could occur or were not serious enough to produce harm that required additional treatment. These Incidents were submitted to identify situations in which unsafe actions might occur, but before they cause any significant harm.
- Not all Serious Events were due to unsafe actions. As an example, an allergic reaction is not the result of an unsafe action if the patient was not aware of any allergies, but it could be reported as a Serious Event nevertheless. This is particularly true for deaths, many of which are reported because care was given, even when all evidence leads to the patient's disease as the cause of the death. A report of a Serious Event does not always mean bad care.
- One wants to see a reduction in Serious Events, whether or not they are the result of unsafe actions. In keeping with the focus on the recovery rate, increases in the number of Incidents reported can be seen positively. The nature of the Incidents, however, provides important educational insights into improving the quality of care—without waiting for harm to occur.
- A knowledgeable observer wants to see diligence in reporting Incidents, not a decrease. Experts recognize that harmless, but unsafe actions are a sign of weaknesses in the system that can be improved before harm occurs. Paradoxically, reports of Incidents may be higher in a facility that is vigilant in searching for potential problems. Such facilities may actually be safer than facilities that do not look diligently for problems. Extrapolation from the most vigilant facilities suggests the potential for a 50% increase in the number of Incidents reported to PA-PSRS—with a concomitant increase in opportunities for learning about system weaknesses without patients being harmed first.

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- The numbers themselves are meaningless without knowing the number of patients seen, the inherent risks of the procedures undertaken, and the diligence with which the facility finds—and shares—information about unsafe actions and bad outcomes.
- For experts in safety, the key statistic is not the number of Incidents or the number of Serious Events, but the “recovery rate.” This is the percentage of reported events that are not associated with harm. A high recovery rate indicates a low percentage of Serious Events, a high percentage of Incidents that do not go on to harm the patient, or some combination. This will be listed in the tables that follow as the “% Incidents.”
- Note that the same clinical occurrence may be legitimately classified under several Event Type categories. For example, if two patients sharing a hospital room receive one another’s medications, these occurrences may be reported as “Medication Error, Wrong Patient,” or as “Medication Error, Wrong Drug.” This is not problematic because it does not hamper the PA-PSRS clinical staff from identifying significant patient safety issues across categories, and while one wants to encourage consistency in reporting, this is a lower-priority goal than encouraging facilities to submit reports.
- There is some variation in different facilities’ interpretations of the Act 13 reporting requirements. Patient Safety Officers have asked for the Authority to standardize the reporting requirements of the Mcare Act to (1) reduce variability among reporting facilities and (2) provide a base of consistent advice from the Authority and the Department of Health (DOH).

The Patient Safety Authority was established for the specific purpose of learning about *system* problems in the delivery of health care that can be improved by sharing the experiences of acute healthcare facilities across the state. The Patient Safety Authority has the responsibility of asking how the healthcare system can keep an unsafe act from harming a patient—no matter whether it is an honest, occasional mistake by an excellent provider or aberrant behavior by an unsafe provider. Serious Events that are sent to the Patient Safety Authority are also sent to the Department of Health for possible investigation by their surveyors. However, in compliance with the Mcare Act, the Patient Safety Authority is not allowed to collect information that would identify either an individual patient or an individual providing care.

The citizens of Pennsylvania have the right to expect reductions over time in the number of reports of Serious Events across the state and increases in the recovery rates of reported events. Facilities serious about patient safety should be judged by comparing their results over time, not by comparing their results to those of other facilities.

John R. Clarke, M.D.  
Clinical Director  
Pennsylvania Patient Safety Reporting System

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.

## Summary of Report Volume Submitted in 2006

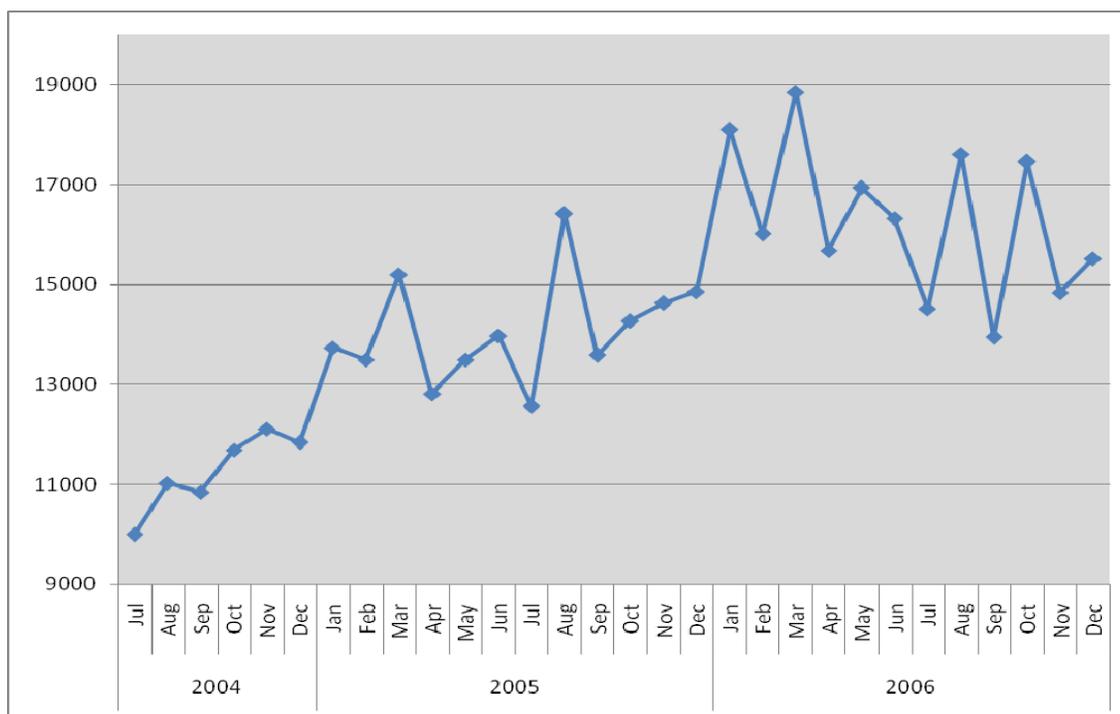
### Reports by Month and Submission Type

Between January 1, 2006, and December 31, 2006, Pennsylvania facilities submitted 195,832 reports to PA-PSRS. Table 1 shows the distribution of submitted reports by month for calendar year 2006.

**Table 1. Reports Submitted to PA-PSRS in 2006, by Month**

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Serious Events	638	610	678	635	655	558	509	600	498	586	512	458	6,937
Incidents	17,466	15,404	18,179	15,051	16,280	15,772	14,010	17,014	13,452	16,870	14,328	15,069	188,895
Total	18,104	16,014	18,857	15,686	16,935	16,330	14,519	17,614	13,950	17,456	14,840	15,527	195,832

Approximately 3.5% of submitted reports were Serious Events, while 96.5% were Incidents. On average, PA-PSRS received 16,320 reports per month, an increase of 15.8% from 2005. The number of Incident reports averaged 15,741 per month, an increase of 16.9% compared to the previous year. The number of Serious Event reports averaged 578 per month, which represents a 7.6% decrease from 2005 and an increase in the recovery rate.



**Figure 10. Number of Reports since Inception of PA-PSRS**

Figure 10 demonstrates that the overall volume of reports submitted to PA-PSRS has generally climbed since inception. We interpret this rise not as an increase in the number of reportable events occurring, but rather as continuously improving detection on the part of Pennsylvania healthcare facilities in recognizing and reporting Serious Events and Incidents.

Figure 11 supports the proposition of improved vigilance. Depicting the volume of Serious Events and Incidents on a relative scale shows that the increase in the volume of reports is attributable mostly to increased reporting of Incidents.

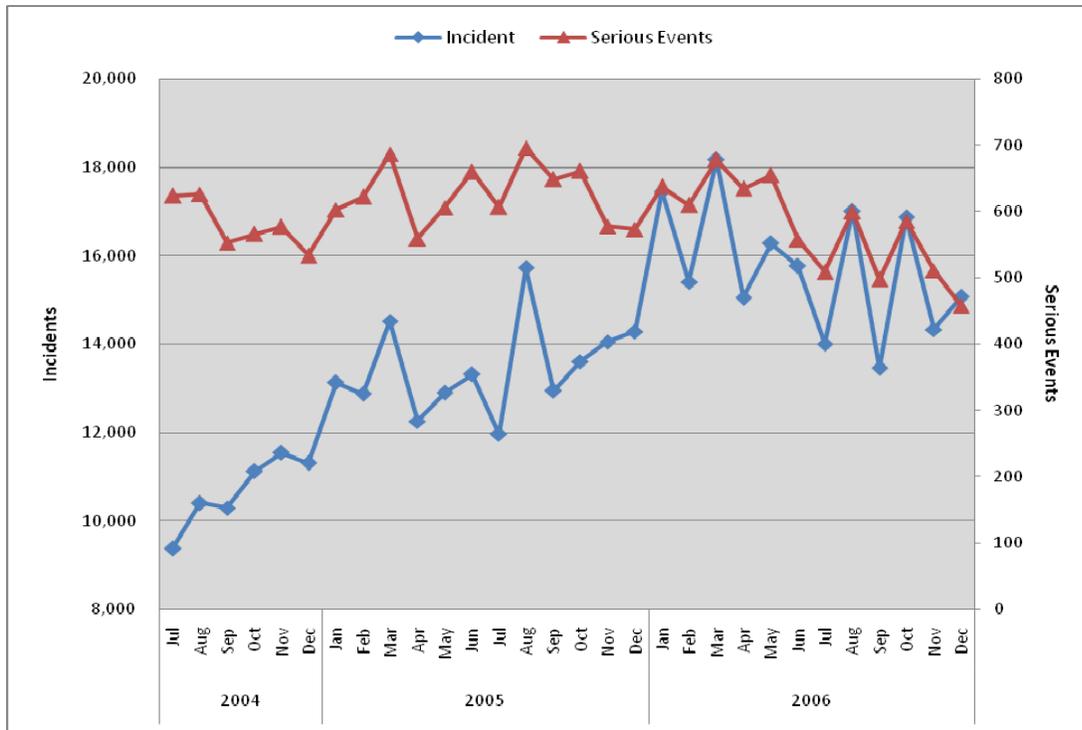


Figure 11. Number of Serious Event and Incident Reports since Inception of PA-PSRS

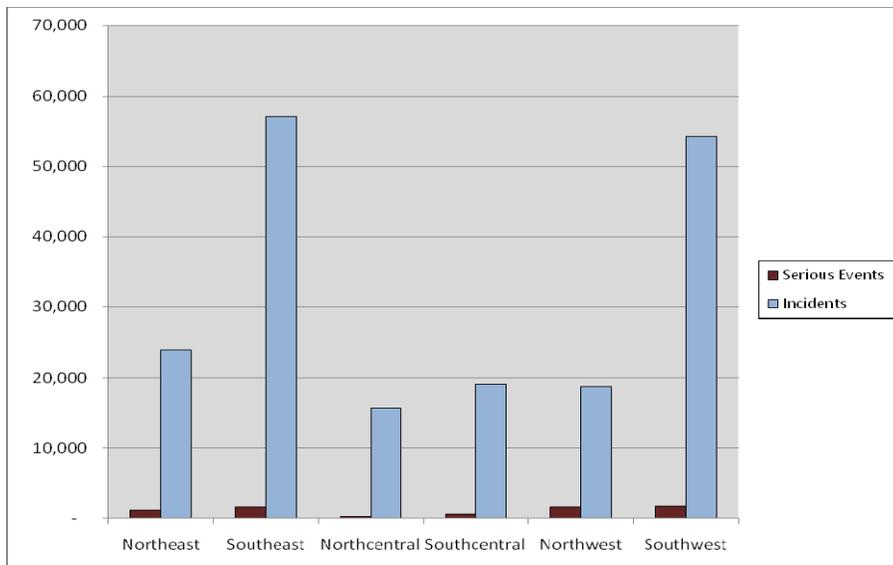
### Reports by Region and Submission Type



Figure 12. Pennsylvania Public Health Regions

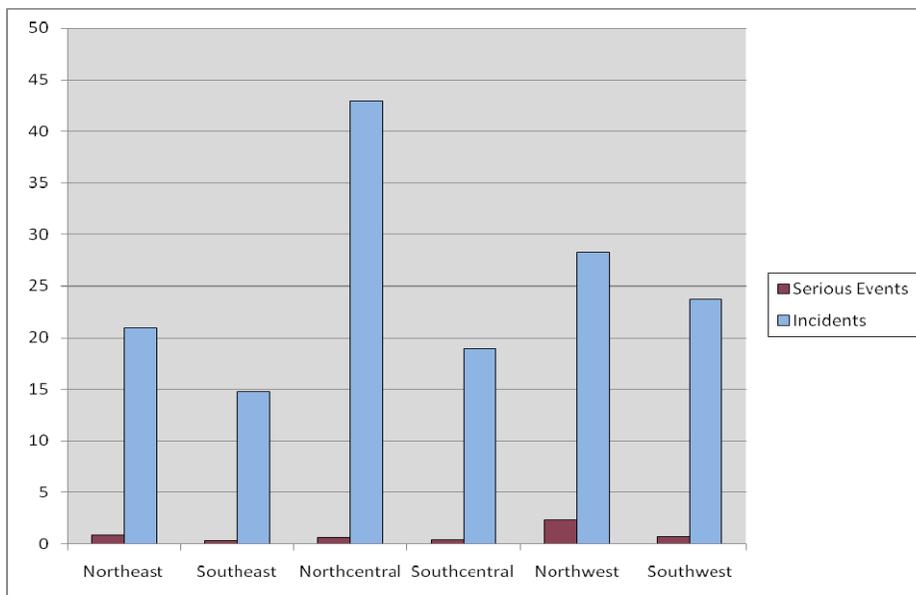
For the purposes of this report, the Patient Safety Authority Board of Directors has adopted a geographic breakdown of the Commonwealth into six regions, as shown in Figure 12. This breakdown is based on the Department of Health’s Public Health Districts.

The variation in the number of reports submitted to PA-PSRS by geographic region (see Figure 13) is consistent with the populations and number of facilities in these areas. The regions with the largest numbers of reports (Southeast and Southwest) were those with the Commonwealth’s two largest population centers: Philadelphia and Pittsburgh, respectively.



**Figure 13. Number of Serious Event and Incident Reports by Region (2006)**

Adjusting the report volume for a measure of healthcare utilization paints a different picture. Figure 14 shows, by region, the number of reports from hospitals per 1,000 patient days.<sup>6</sup> This figure shows that, after accounting for the differences in the volume of healthcare provided in each region, facilities in the Northcentral region reported a significantly greater proportion of Incidents (98.5% of their reports) than the statewide average (96.8%). It is not possible to determine from these data to what extent this variation in report volume results from genuine differences in safety or from differences in detection and reporting of adverse events and near misses.



**Figure 14. Reports from Hospitals per 1,000 Estimated Patient Days by Region (2006)**

<sup>6</sup> Patient days is 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](http://www.phc4.org)). In each region, the number of reports submitted by hospitals from January through December 2006 was divided by the number of patient days estimated for 2006. Since only partial data are available for 2006, we chose to use estimated figures for the year using seasonal decomposition to account for any seasonal fluctuations in utilization. Data available from PHC4 are based on the patient's region of residence, which is not necessarily the same as the region of the facility in which the patient was treated. We estimate that inter-regional treatment accounts for approximately 5.2% of admissions, based on calculations performed on a random sample of 10% of Pennsylvania counties.

Comparing year to year, keeping in mind that PA-PSRS data reflects the fact that PA-PSRS began collecting data only in June 2004, there is an observable increase across the regions of hospital reports per 1,000 patient days, as seen in Figure 15. The lone exception is a decrease in the Southcentral Region from 2005 to 2006, where reporting declined 1.5%. There was an average increase per region of 2.7 hospital reports per 1,000 patient days.

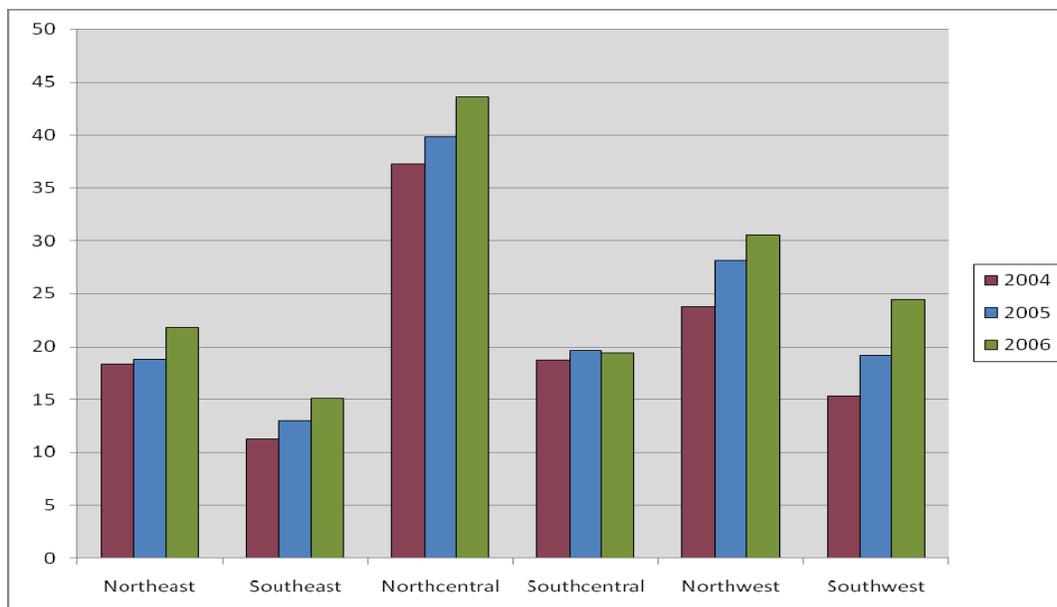


Figure 15. Reports from Hospitals per 1,000 Patient Days by Region (July 2004 through December 2006)

### Reports by Facility Type

As shown on Table 2, the vast majority of reports (98.7%) submitted to PA-PSRS were submitted by hospitals. However, Table 3 demonstrates that there has been a greater increase in the reporting rate among ASFs/BCs from 2005 to 2006 (23.9%) compared to hospitals (15.7%).

Table 2. Reports to PA-PSRS by Facility Type

Facility Type	Hospitals	Ambulatory Surgical Facilities/ Birthing Centers	All
Number of Reports Submitted	193,262	2,570	195,832
Number of Facilities Active at year's end Dec. 31, 2006	239	225	464

Table 3. Annual Reports by Facility Type since Inception of PA-PSRS

Year	Hospitals		Ambulatory Surgical Facilities/Birthing Centers		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
Total	430,186	98.72%	5,569	1.28%	435,755

\*PA-PSRS began mandatory reporting statewide on June 28, 2004.

## 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 4 presents the number of reports received in 2006 by patient gender and age cohort.

**Table 4. Reports Submitted by Age Cohort and Gender (2006)**

Age Cohort	Female		Male		All Patients		% Patients
	No.	%	No.	%	No.	%	Female
0 - 4	3,191	3.0%	4,292	4.7%	7,483	3.8%	42.6%
5-14	1,514	1.4%	1,897	2.1%	3,411	1.7%	44.4%
15-24	4,888	4.6%	3,083	3.4%	7,971	4.1%	61.3%
25-34	5,909	5.6%	3,304	3.7%	9,213	4.7%	64.1%
35-44	8,167	7.7%	6,034	6.7%	14,201	7.3%	57.5%
45-54	10,943	10.4%	10,820	12.0%	21,763	11.1%	50.3%
55-64	13,578	12.9%	14,262	15.8%	27,840	14.2%	48.8%
65-74	17,436	16.5%	16,569	18.3%	34,005	17.4%	51.3%
75-84	24,835	23.5%	20,867	23.1%	45,702	23.3%	54.3%
85+	14,999	14.2%	9,244	10.2%	24,243	12.4%	61.9%
Total	105,460	100.0%	90,372	100.0%	195,832	100.0%	53.9%

## Patient Gender

Of the 195,832 reports submitted in 2006, 105,460 (53.9%) involved female patients, and 90,372 (46.1%) involved male patients. This pattern is consistent with our observations in 2004 and 2005. 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 3.7% of reports involving female patients classified as Serious Events, compared to 3.3% for reports involving males.

Table 5 shows the distribution of reports by patient gender and event type. Many of the same patterns observed in 2005 are evident this year as well. The proportion of reports involving female patients was significantly higher among reports of Adverse Drug Reactions and Complications and significantly lower among reports of Equipment-related events and Falls.

**Table 5. Reports Submitted by Gender and Event Type (2006)**

Event Type	Female		Male		All Patients		Ratio of Reports Involving Female to Male Patients
	No.	%	No.	%	No.	% of Total	
Medication Errors	24,737	55.5%	19,802	44.5%	44,539	22.7%	H
Adverse Drug Reactions	2,411	62.9%	1,423	37.1%	3,834	2.0%	H
Equipment / Supplies / Devices	1,633	51.8%	1,522	48.2%	3,155	1.6%	L
Falls	16,847	49.7%	17,035	50.3%	33,882	17.3%	L
Errors Related to Procedure / Treatment / Test	25,510	53.8%	21,949	46.2%	47,459	24.2%	
Complications of Procedure / Treatment / Test	15,706	56.3%	12,204	43.7%	27,910	14.3%	H
Transfusions	1,071	55.3%	865	44.7%	1,936	1.0%	
Skin Integrity	11,189	53.4%	9,756	46.6%	20,945	10.7%	
Other / Miscellaneous	6,356	52.2%	5,816	47.8%	12,172	6.2%	L
Total	105,460	53.9%	90,372	46.1%	195,832	100.0%	

H=significantly higher than overall average of 53.9%; L=significantly lower than overall average of 53.9%.

## Patient Age

Figure 16 shows the proportion of reports to PA-PSRS, from hospitals only, by patient age cohort. Patients aged 65 and older account for 53.1% of all reports from hospitals to PA-PSRS in 2006. Also shown on this figure is the proportion of hospital inpatient admissions as reported by the Pennsylvania Healthcare Cost Containment Council (PHC4).<sup>7</sup> 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.

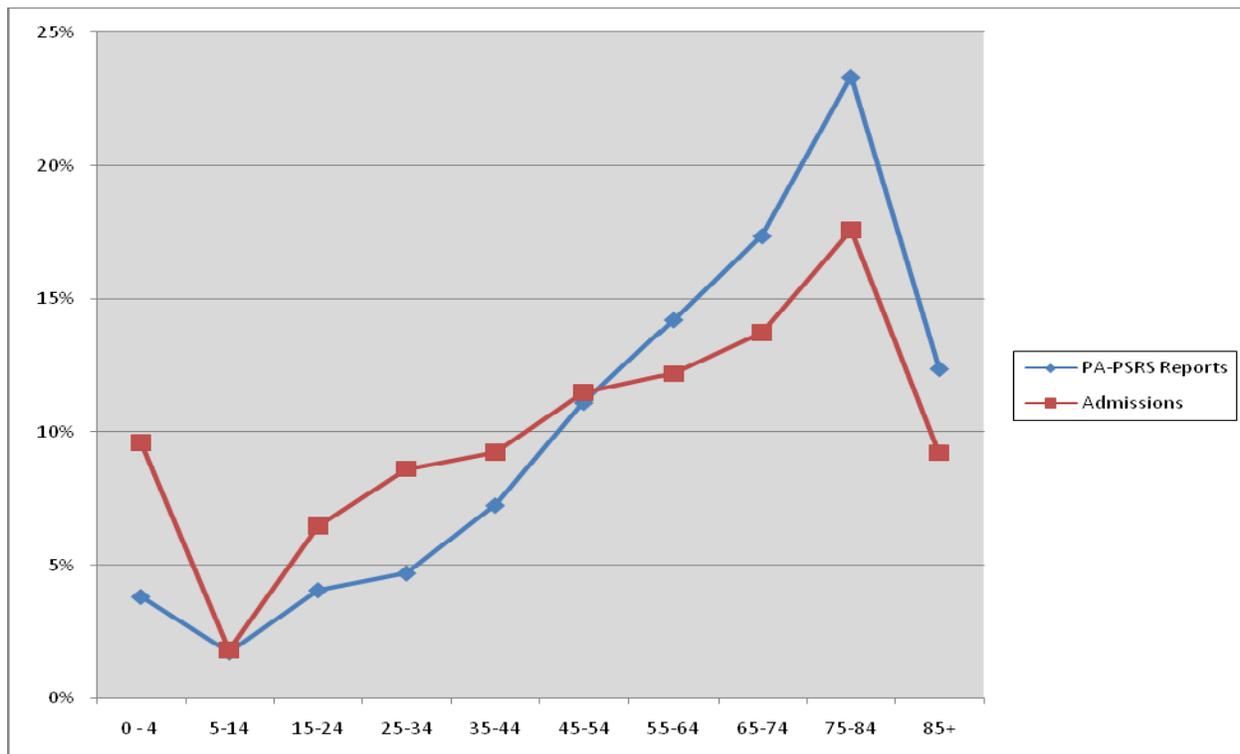


Figure 16. Proportion of Hospital Reports to PA-PSRS by Age Cohort (2006)

## 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). These patterns have remained consistent through 2006. For example, in 2005, more than half of all reports (53%) involved patients 65 and older. In 2006, this figure rose only slightly to 53.1%. Elderly patients accounted for 64% of Falls in 2004 and 2005. This figure fell slightly to 62.4% in 2006. Elderly patients accounted for 73% of reports related to Skin Integrity in 2005; this figure increased slightly to 73.1%.

### Perinatal Patients

In 2005, PA-PSRS received 2,885 reports involving perinatal patients (those aged 20 days or younger). There were 3,305 such reports in 2006, a 14.6% increase, which is less than the 15.8% increase in all submitted reports. Just as last year, two thirds (66.8%) 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.

<sup>7</sup> Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council ([www.PHC4.org](http://www.PHC4.org)). Estimates were based on statewide inpatient data from the third quarter 2005 through second quarter 2006.

About one-fifth (20.5%) of reports involving perinatal patients were related to Medication Errors. This compares to 22% in 2005 and 19% in 2004.

### **Children and Adolescents**

There were 7.5% more reports submitted to PA-PSRS in 2006 involving children and adolescents (i.e., aged 21 and younger) than in 2005. This is a smaller increase than the 15.8% increase in reports overall. As was the case last year, Errors Related to Procedures, Treatments, and Tests were the most commonly submitted type of report, accounting for 35.3% of the reports of this population.

## **Patterns in Reports to PA-PSRS**

### ***Reports by Event Type***

When reporting an event to PA-PSRS, 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:

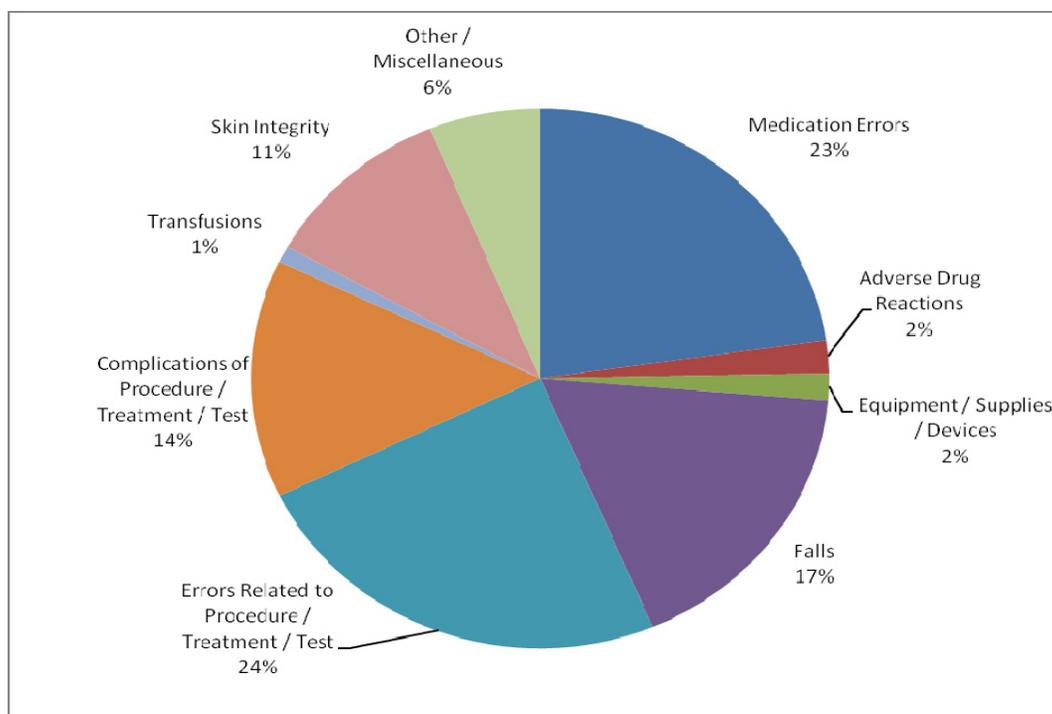
- Medication Errors
- Adverse Drug Reactions (not a medication error)
- Equipment, Supplies, or Devices
- Falls
- Errors Related to Procedures, Treatments, or Tests
- Complications of Procedures, Treatments, or Tests
- Transfusions
- Skin Integrity
- Other / Miscellaneous

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 over 212 distinct Event Types. This Event Type dictionary is one way PA-PSRS classifies and looks for patterns and trends in submitted reports.

Figure 17 shows the percentage of reports submitted under each top-level Event Type. The most frequently reported occurrences were Errors Related to Procedure/Treatment/Test (24%) and Medication Errors (23%). These two Event Types account for 47% of all reports submitted. While Errors Related to Procedure/Treatment/Test was the Event Type most frequently reported to PA-PSRS, they were not the ones most frequently associated with Serious Events.



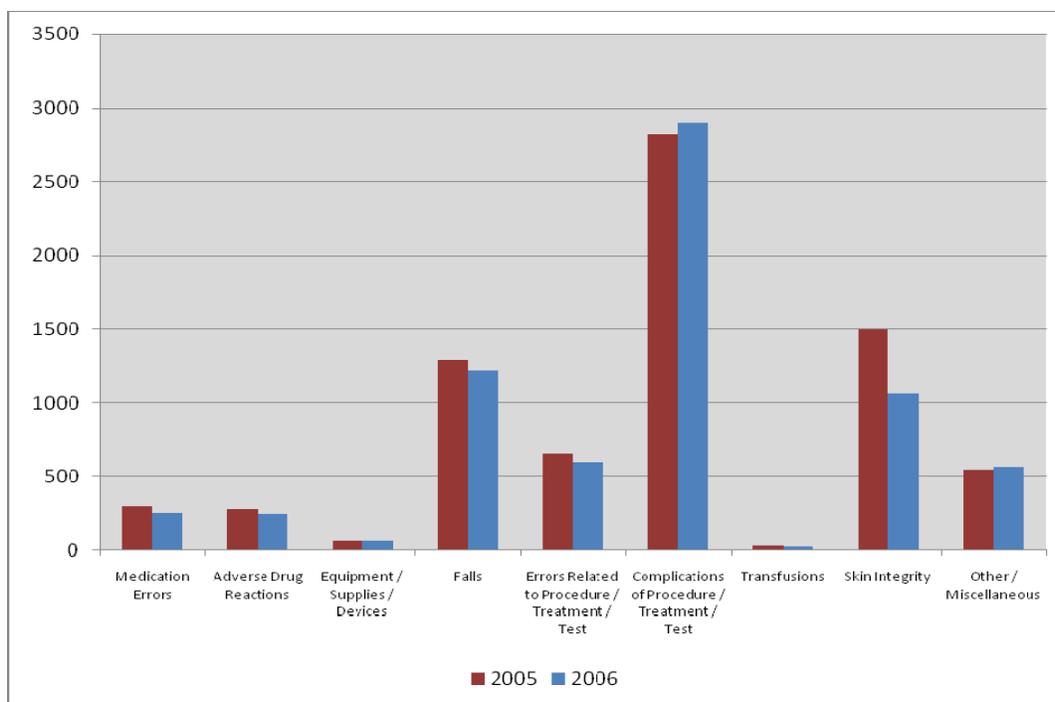
**Figure 17. Percentage of Reports by Event Type (2006)**

As shown in Table 6 below, the largest number of Serious Event reports was under the Event Type category Complications of Procedures/Treatments/Test, 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%). Figure 18 compares the volume of reports of Serious Events by Event Type for the past two years.

**Table 6. Reports by Event Type and Submission Type for 2006**

Event Type	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Medication Errors	253	1%	44,286	99%	44,539	23%	L
Adverse Drug Reactions (not a medication error)	245	6%	3,589	94%	3,834	2%	H
Equipment / Supplies / Devices	68	2%	3,087	98%	3,155	2%	L
Falls	1,219	4%	32,663	96%	33,882	17%	
Errors Related to Procedure / Treatment / Test	597	1%	46,862	99%	47,459	24%	L
Complications of Procedure / Treatment / Test	2,895	10%	25,015	90%	27,910	14%	H
Transfusions	25	1%	1,911	99%	1,936	1%	L
Skin Integrity	1,063	5%	19,882	95%	20,945	11%	H
Other / Miscellaneous	572	5%	11,600	95%	12,172	6%	H
<b>Total</b>	<b>6,937</b>	<b>4%</b>	<b>188,895</b>	<b>96%</b>	<b>195,832</b>	<b>100%</b>	

H=significantly higher than overall average of 4%; L=significantly lower than overall average of 4%.



**Figure 18. Reports Classified as Serious Events by Event Type (2005-2006)**

Because the vast majority of reports submitted to PA-PSRS were submitted by hospitals, the distribution of all reports by Event Type closely mirrored the distribution by Event Type in hospitals. However, the Event Types most frequently reported by hospitals were different from those most frequently reported by Ambulatory Surgical Facilities and Birthing Centers (see Table 7).

**Table 7. Reports by Event Type and Facility Type**

Event Type	Hospitals			Ambulatory Surgical Facilities/Birthing Centers			Proportion of Reports from ASFs/BCs versus Hospitals
	No.	% of Reports	% of Event Type	No.	% of Reports	% of Event Type	
Medication Errors	44,467	23%	99.84%	72	3%	0.16%	L
Adverse Drug Reactions (not a medication error)	3,751	2%	97.84%	83	3%	2.16%	H
Equipment / Supplies / Devices	3,087	2%	97.84%	68	3%	2.16%	H
Falls	33,813	17%	99.80%	69	3%	0.20%	L
Errors related to Procedure / Treatment / Test	46,923	24%	98.87%	536	21%	1.13%	L
Complications of Procedure / Treatment / Test	27,078	14%	97.02%	832	32%	2.98%	H
Transfusions	1,935	1%	100%	1	0%	0.05%	L
Skin Integrity	20,822	11%	99.41%	123	5%	0.59%	L
Other / Miscellaneous	11,386	6%	93.54%	786	31%	6.46%	H
Total	193,262	100%	98.69%	2,570	100%	1.31%	

H=significantly higher than overall average of 1.31%; L=significantly lower than overall average of 1.31%.

While reports of Medication Errors and Falls combined accounted for 40% of all reports submitted by hospitals, these categories accounted for only 6% of reports from Ambulatory Surgical Facilities and Birthing Centers. Over half (53%) of reports from these facilities involved Complications of Procedure/Treatment/Test or Errors Related to

Procedure/Treatment/Test. These differences are expected because these facilities provide specialized services of a more limited scope and generally treat a healthier patient population than do hospitals.

While the proportion of reports in each Event Type has remained relatively consistent since inception of PA-PSRS, Table 8 demonstrates that reports of certain Event Types are increasing at greater rates than others. While the overall number of reports submitted in 2006 increased 16% from 2005, the rise in reports of Skin Integrity problems and Errors related to Procedure/Treatment/Test was more than twice that percentage. Meanwhile, submissions of Falls and Medication Errors increased, but at a rate well below average. Due to efforts by PA-PSRS staff to reduce misclassification of submitted reports, the percentage classified as Other/Miscellaneous is decreasing, with more reports being submitted into an appropriate Event Type.

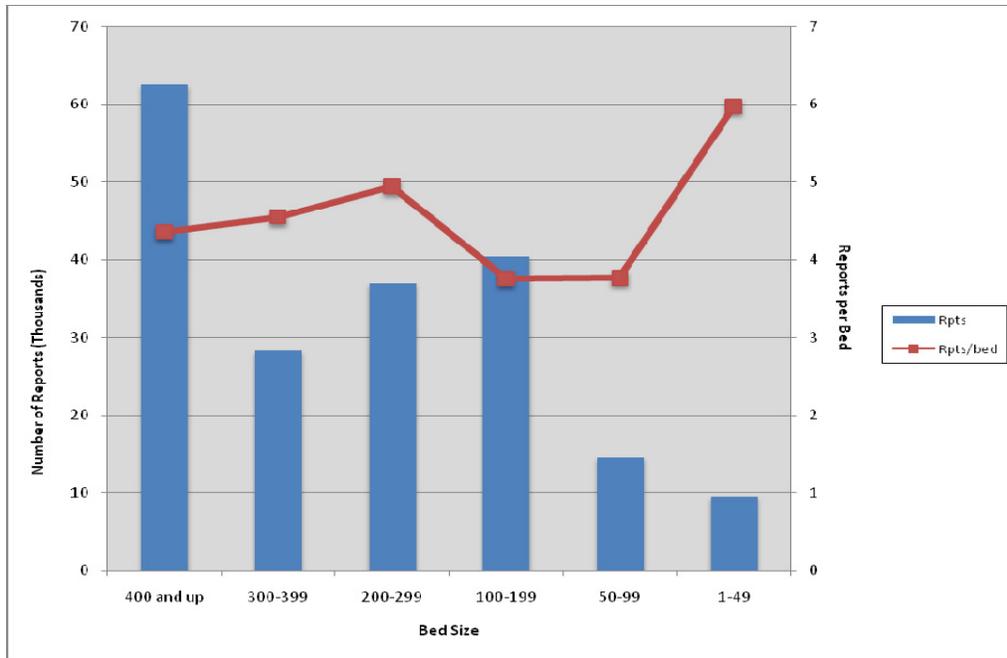
**Table 8. Reports by Event Type by Year**

Event Type	2004		2005		2006		% Increase from 2005 to 2006
	No.	% of Reports	No.	% of Reports	No.	% of Reports	
Medication Errors	17,499	25%	42,371	25%	44,539	23%	5%
Adverse Drug Reactions (not a medication error)	1,378	2%	3,358	2%	3,834	2%	14%
Equipment / Supplies / Devices	1,442	2%	2,547	2%	3,155	2%	24%
Falls	14,769	21%	33,654	20%	33,882	17%	1%
Errors Related to Procedure / Treatment / Test	12,620	18%	35,603	21%	47,459	24%	33%
Complications of Procedure / Treatment / Test	11,424	16%	23,057	14%	27,910	14%	21%
Transfusions	781	1%	1,634	1%	1,936	1%	18%
Skin Integrity	5,003	7%	15,115	9%	20,945	11%	39%
Other / Miscellaneous	5,935	8%	11,733	7%	12,172	6%	4%
Total	70,851	100%	169,072	100%	195,832	100%	16%

### **Reports from Hospitals by Event Type and Facility Size**

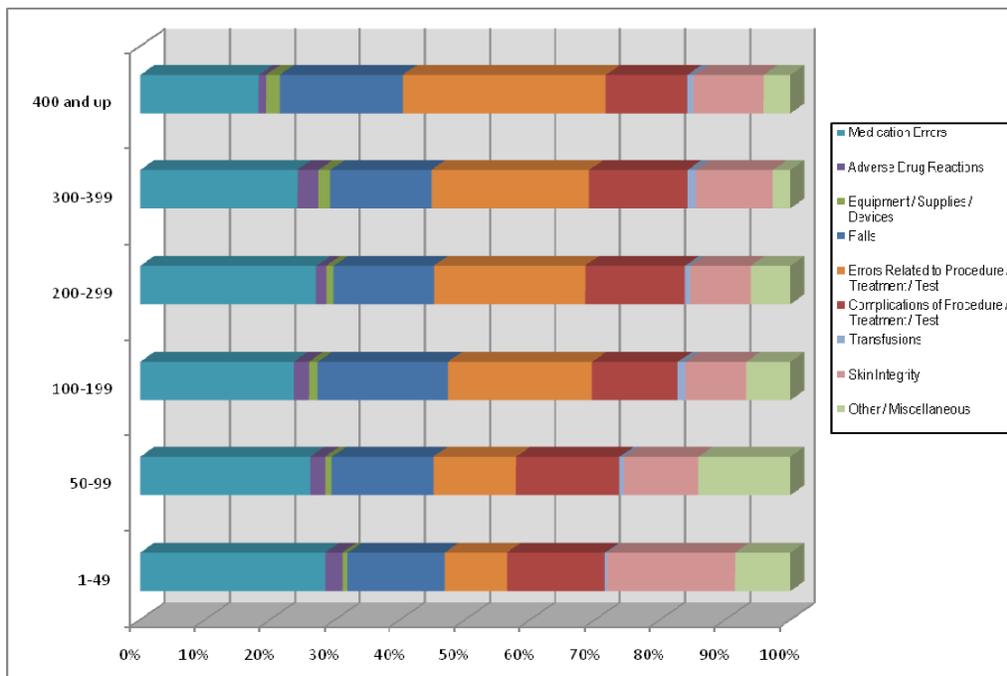
There is clearly a fundamental difference between hospitals and other types of facilities in terms of the types of reports they submit, as shown in Table 8 above. People sometimes assume there is also a substantial difference in the types of reports submitted among hospitals of varying sizes. For example, one might expect the reports from a large tertiary care hospital with a teaching program to be fundamentally different from the reports submitted by a 150-bed community hospital.

As shown in Figure 19, larger facilities submitted about a third of all reports to PA-PSRS in 2006 and the rate of reports per bed was at the average for hospitals of all sizes (4.3 reports per bed). The group of hospitals with the least number of beds had the highest submission rate related to size. Note that there is not necessarily a relationship between the submission rate and safety. It may mean that the healthcare providers in these facilities were better at identifying and reporting potential patient safety issues.



**Figure 19. Number of Reports and Reports per Bed by Facility Size (2006)**

The proportion of reports in each event type is relatively consistent across hospitals of different sizes (Figure 19). Hospitals with fewer than 100 beds reported proportionally fewer Errors Related to Procedure/Treatment/Test than larger hospitals, perhaps because they are performing fewer or less complicated procedures and in general have a healthier patient population. Hospitals in the 50-99 bed range submitted proportionally fewer reports related to Transfusions, and they were more likely to categorize their reports as “Other”. Aside from these few distinctions, the proportions of reports in each category from different size hospitals are similar.



**Figure 20. Reports from Hospitals by Facility Size and Event Type (2006)**

When looking at Figure 20, Transfusions can be easily overlooked. Looking at the data in another way, Figure 21 reveals that about 30% of Transfusion related reports come from the largest hospitals. One can also see a similar proportion of reports related to Equipment/Supplies/Devices were submitted by largest hospitals to the number from hospitals with less than 300 beds.

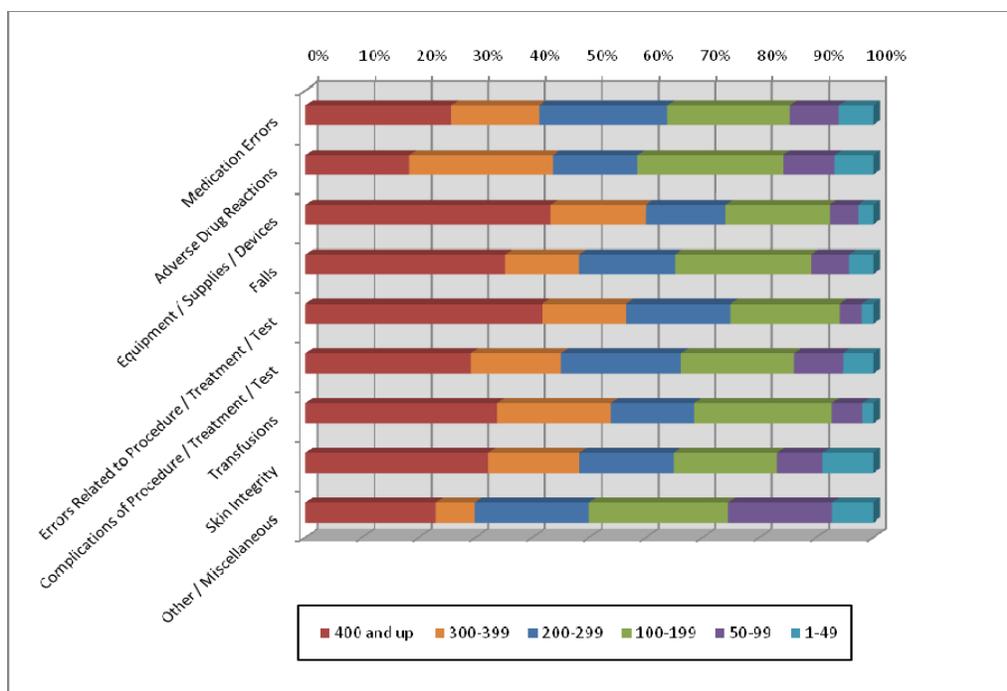


Figure 21. Reports from Hospitals by Event Type and Facility Size (2006)

## 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.<sup>8</sup> 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 9% 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%)
- Event, Death—An event occurred that resulted in or contributed to death (0.2%)

Table 9 shows the reports received during 2006 categorized by the level of harm (as described above) and by Event Type. Some Event Types are more likely to result in harm than others. For example, while complications comprise 14% of reports overall in 2006, they comprise 41% of the reports of events involving harm and 56% 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 23% of reports in 2006, they only comprise 4% of events involving harm and 2% of events contributing to or resulting in death. Reports of Errors Related to Procedure/Treatment/Test were also associated with harm or death at a frequency lower than their representation in the database as a whole.

<sup>8</sup> 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 before inserting the needle, would be an event that did not reach the patient.

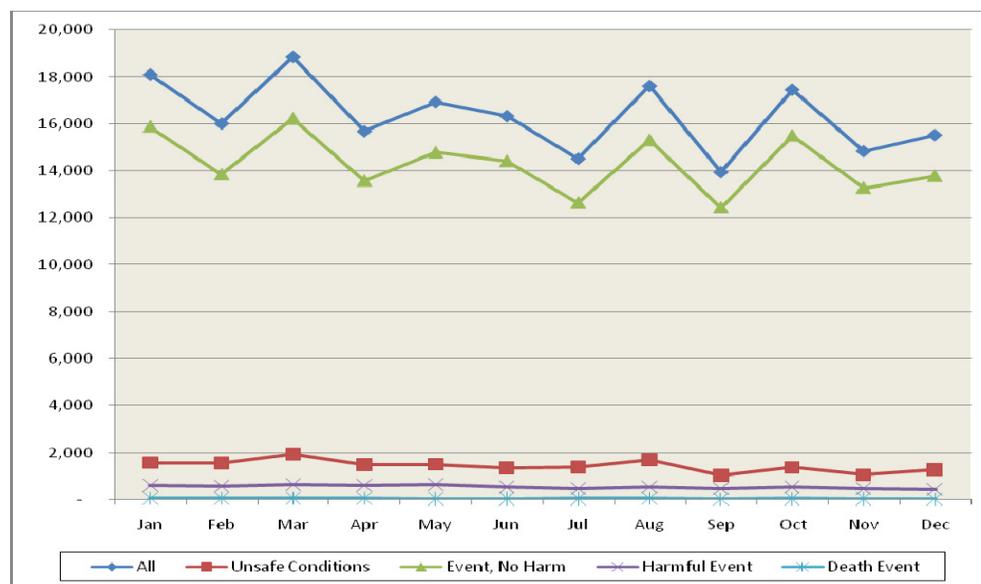
A certain portion of the reports could be referred to as examples of Unsafe Conditions, meaning that there was an observed situation in which some harm was a possibility if corrective action was not taken. Unsafe Conditions were cited in 9% of the reports submitted in 2006. As shown in Table 9, the event types in which Unsafe Conditions were most often reported were Errors related to Procedure/Treatment/Test (25%) and Skin Integrity (21%). 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, 0.29% were reported as Unsafe Conditions.

**Table 9. Reports by Event Type and Level of Patient Harm (2006)**

Event Type	Unsafe Conditions		Event, No Harm		Harmful Event		Death Event		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Medication error	2,457	14%	41,829	24%	246	4%	7	2%	44,539	23%
Adverse Drug Reaction	49	0%	3,540	2%	237	4%	8	2%	3,834	2%
Equipment / Supplies / Devices	406	2%	2,681	2%	66	1%	2	1%	3,155	2%
Fall	559	3%	32,104	19%	1,196	18%	23	6%	33,882	17%
Error related to Procedure / Treatment / Test	4,228	25%	42,634	25%	576	9%	21	6%	47,459	24%
Complication of Procedure / Treatment / Test	2,720	16%	22,295	13%	2,695	41%	200	56%	27,910	14%
Transfusion	272	2%	1,639	1%	25	0%	0	0%	1,936	1%
Skin Integrity	3,605	21%	16,277	9%	1,063	16%	0	0%	20,945	11%
Other / Miscellaneous	2,866	17%	8,734	5%	473	7%	99	28%	12,172	6%
Total	17,162	100%	171,733	100%	6,577	100%	360	100%	195,832	100%

Also, to repeat figures shown above, 3.5% 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 called Death Events can be isolated from other reported events. Death Events, as the term implies, are reports of events classified as having contributed to or resulted in the patient's death. These account for a fifth of one percent of all submitted reports. In looking at particular event types, although 14% of all reports for the year were attributed to Complications of Procedure/Treatment /Test, 56% of all Death Events were of that event type.

Figure 22 illustrates that the vast majority of reports do not result in Patient Harm.



**Figure 22. Reports by Level of Harm by Month (2006)**

## Reports Involving the Patient's Death

In 2006, PA-PSRS received 360 reports of events that may have contributed to or resulted in the patient's death (see Table 10). This represents a decrease of 21% compared to 2005. These account for approximately 5% of all Serious Events. In terms of particular event types, although 14% of all reports in 2006 were attributed to Complications of Procedure/Treatment/Test, about 56% 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 (21%). A further 10% were associated with healthcare-associated infections, and 8% involved maternal or neonatal injury associated with childbirth.

**Table 10. Reports Involving the Patient's Death, by Event Type (2006)**

Event Type	No.	%
Medication error	7	1.9%
Adverse Drug Reaction	8	2.2%
Equipment / Supplies / Devices	2	0.6%
Fall	23	6.4%
Error related to Procedure / Treatment / Test	21	5.8%
Complication of Procedure / Treatment / Test	200	55.6%
Transfusion	0	0.0%
Skin Integrity	0	0.0%
Other / Miscellaneous	99	27.5%
Total	360	100.0%

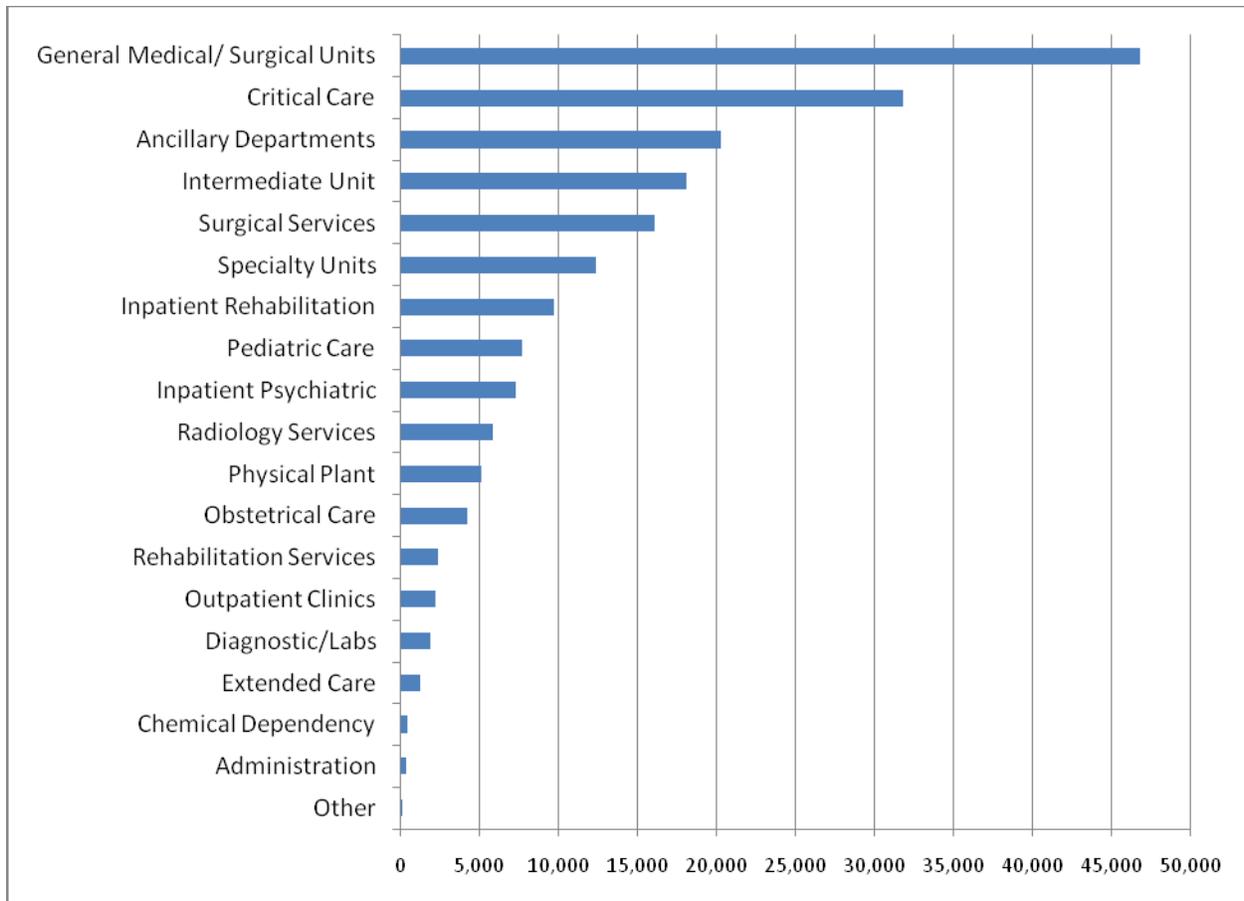
Many reports involving the patient's death were reported with the primary event type of "Other/Miscellaneous." This category in the taxonomy contains a subcategory "Other unexpected death," which explains the extensive use of this category. Many of these reports involve patients who were found unresponsive, who went into respiratory arrest and resuscitation efforts failed, or who were admitted to the hospital and appeared to have died of their disease. PA-PSRS staff has also looked at reports involving the death of the patient in ASFs and will be reporting on this in an upcoming *Advisory*.

## Reports by Location/Department (Hospitals Only)

PA-PSRS has 155 designated Care Areas for hospitals. These are the Locations or Departments of the hospital in which a patient receives care or is exposed to in the process of receiving care. As we see in Figure 23, General Medical/Surgical Units were cited as the location for the greatest number of all reports submitted in 2006, generating almost a quarter (24.2%) of the total. Other hospital departments with high report rates are Critical Care (16.4%), Ancillary Departments (10.5%), Intermediate Unit (9.3%), and Surgical Services (8.3%).

Examples of Care Areas by Department:

- General Medical/Surgical Units
  - General Medicine Ward
  - Medical/Surgical/Oncology Unit
- Critical Care
  - Emergency Department
  - Burn Unit
  - Medical/Surgical ICU
- Ancillary Departments
  - Laboratory
  - Pharmacy
  - Respiratory Care-Diagnostic/Therapeutic



**Figure 23. Reports by Location/Department (Hospitals Only, 2006)**

### ***Contributing Factors and Root Causes Cited in Reports***

When a healthcare facility submits a report to PA-PSRS, they are asked to identify the things that may have contributed to the event (the contributing factors) and the thing that ultimately caused the event (the root cause).

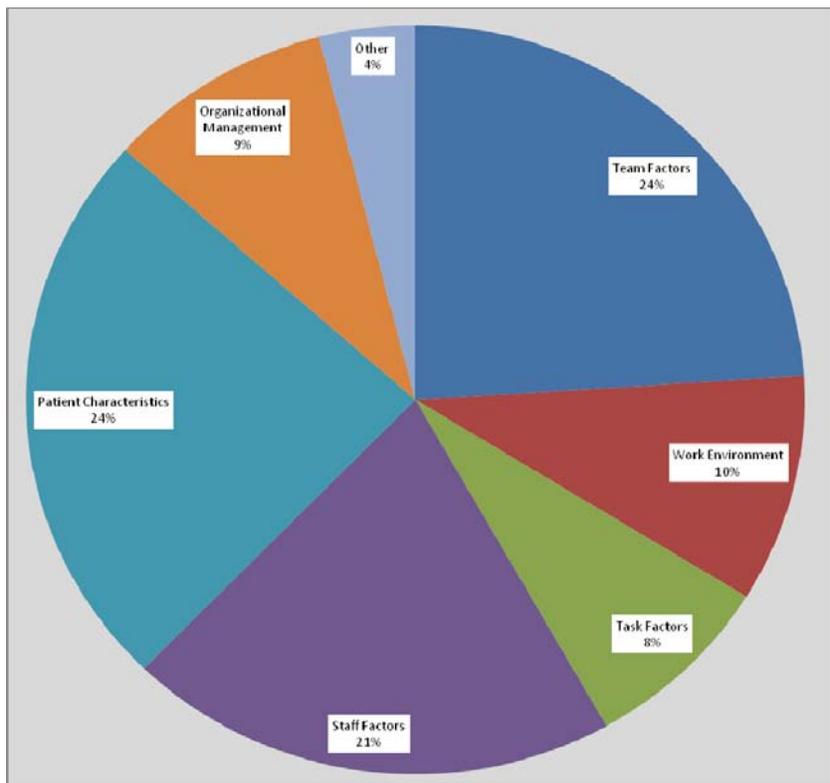
PA-PSRS lists nearly 40 potential contributing factors that may have precipitated an event, and these are grouped into factors related to:

- Teamwork among healthcare providers
- The healthcare working environment
- The specific task being performed
- The adequacy of staff
- Patient characteristics
- The organization and management of the facility as a whole.

As shown in Figure 24, Patient Characteristics and Team Factors (24% each) were the groups of contributing factors cited most often in reports submitted in 2006. This was also the case in 2005, although the frequency was at a slightly higher rate (27% and 26%, respectively).

“Communication problem between providers” was the most frequently cited Team Factor in these reports. Communication was viewed as problematic most often in conjunction with reports of Medication Errors and Errors in Procedure/Treatment/Test. These two Event Types accounted for about two out of three of all reports mentioning provider communication as a contributing factor. Problems with provider communication encompasses a wide

range of issues, including confusing or incomplete orders, verbal orders that are misinterpreted, illegible handwriting and many others.



**Figure 24. Leading Contributing Factors by Category (2006)**

As in 2005, “Lack of patient compliance/adherence” was the most frequently mentioned patient-related factor and was most associated with Event Types of Falls and Complications of Procedure/Treatment/Test. These Event Types accounted for almost three quarters of all reports that mentioned this factor. Patient adherence to instructions can influence a patient’s likelihood of falling, if, for example, the patient does not request nursing assistance for toileting or does not use assistive devices while ambulating.

Another frequently mentioned Contributing Factor is “Issue related to proficiency” as a Staff Factor. Nine of ten reports citing this factor were Errors in Procedure/Treatment/Test and Medication Errors. Proficiency issues come forth in the healthcare setting when a laboratory specimen is mislabeled or not labeled, the wrong test is ordered for a patient, the patient receives a wrong dose of medication or given the wrong drug altogether. PA-PSRS sees these cases as opportunities for education.

As in last year’s Annual Report, communication was the most frequently cited “root cause” in reports submitted in 2006, mentioned in almost two thirds of reports with this information. Other frequently mentioned root causes include orientation and training of staff, patient physical assessment, patient observation procedures and care planning procedures. With the exception of patient observation procedures, these are four of the most commonly cited root causes of Sentinel Events reported to the Joint Commission (formally known as JCAHO).<sup>9</sup>

<sup>9</sup> The Joint Commission. Sentinel event statistics, root causes of sentinel events (all categories; 1994-2005). Available from internet: [www.jointcommission.org/NR/rdonlyres/FA465646-5F5F-4543-AC8F-E8AF6571E372/0/root\\_cause\\_se.jpg](http://www.jointcommission.org/NR/rdonlyres/FA465646-5F5F-4543-AC8F-E8AF6571E372/0/root_cause_se.jpg). Accessed January 31, 2007.

## Medication Errors

Analysis of medication errors submitted to PA-PSRS is performed by the clinical analysts on multiple levels. Patterns are identified by the review of individual reports and groups of reports on a daily basis. In addition, a topical review of the database helps locate patterns of problems involved with medications. This information is then collected and analyzed. Advisory articles are produced based on the analysis of data as well as aggregation of similar problems and recommendations found through literature searches.

Medication related events that stood out, based upon analysis of the aggregate PA-PSRS data include errors involving “high-alert” medications, problems with look-alike drug names, and medications with suffixes.

While all medications have a level of risk if used incorrectly, a small number of medications bear a heightened risk of significant patient harm when they are used in error. These drugs are commonly referred to as “high-alert” medications. Though mistakes may or may not be more common with these drugs, the consequences of errors with these medications are more devastating to patients.<sup>10</sup>

A review of all medication-related events involving high-alert medications from the beginning of reporting to PA-PSRS in June 2004 to December 2006 shows that about one in five of all medication errors reported involve high-alert medications. Among all medication error reports submitted:

- 8.3% involved opiates/narcotics.
- 7.4% involved anticoagulants such as heparin and warfarin.
- 4.4% involved insulin products.

Medication errors that result from confusion between two drug names are another common problem. In fact, approximately 25% of medication errors reported to national medication error reporting programs result from confusion with drug names that look or sound alike.<sup>11</sup> A similarity of characters in brand drug names, generic names, and brand-to-generic names can lead to confusion. Similar-sounding drug names present additional problems. These similarities are compounded by practitioners attempting to keep up with the vast array of new products introduced to the marketplace, illegible handwriting, orally communicated prescriptions, similar labeling or packaging of medications, and incorrect selection of drug names that may appear in close proximity when entering orders into electronic order entry systems.<sup>12</sup>

An earlier review of reports in PA-PSRS showed that 11% of the medication error reports submitted to PA-PSRS were classified as wrong drug errors, where one drug was prescribed, dispensed, or administered in place of another drug. Of those reports, 34% were due to confusion between similar medication names. In addition:

- One of the most commonly confused name pairs reported to PA-PSRS has been morphine and HYDROMorphone, with 32% of the opiate/narcotic look-alike name reports include these two drugs. This topic will be addressed in an upcoming issue of the *PA-PSRS Patient Safety Advisory*.
- 6% of all reports of name confusion occurred between alprazolam and lorazepam.
- Mix-ups between similar names of insulin products such as:
  - NovoLog Mix 70/30 and Novolin 70/30
  - Humalog and Humalog Mix 75/25
  - Humulin N and Humulin R
  - Humalog Mix 75/25 and Humulin 70/30
  - NovoLog and Novolin R

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<sup>10</sup> PA-PSRS. Patient Safety Advisory. Focus on high alert medications. Sep 2004;1(3):6.

<sup>11</sup> ISMP Medication Safety Alert! 19 Apr 2000;(5)8.

<sup>12</sup> PA-PSRS. Patient Safety Advisory. Medication errors linked to drug name confusion. Dec 2004;1(4):7-8

Analysis of events involving mix-ups between medications with look-alike names in 2006 shows that out of 2,382 reports, mix-ups between morphine and HYDROMORPHONE are most common, followed by confusion between alprazolam and lorazepam, then oxycodone and OXYCONTIN. Eleven percent (11%) of these reports involve similar names of insulin products.

The practice of adding “suffixes” or “modifiers” (e.g., ER, CD, XL) to medication names is used by manufacturers to maintain brand awareness while signifying that the formulation is different from the immediate-release version of the product. One problem identified upon analysis of PA-PSRS reports is that health professionals accidentally omit the suffix when communicating drug names that have suffixes. This occasionally results in patients getting the immediate-release version and thus, an entire day’s dose at one time, sometimes with adverse effects.<sup>13</sup>

Analysis of wrong drug medication errors in 2006 reveals that 463 reports involved confusion between medications with suffixes. The most common mix-ups between products with suffixes have been:

- Effexor and Effexor XR – 11%
- Wellbutrin and Wellbutrin SR or XL – 8.2%
- Cardizem and Cardizem CD or LA – 6%

Many problems have been identified with the use of medications based on the manual review of individual cases submitted to PA-PSRS. Examples of events that caused or could lead to harm to patients include:

- A report submitted to PA-PSRS describes a situation in which a patient presented was ordered nimodipine to be administered via a nasogastric (NG) tube. A nurse withdrew nimodipine from the capsule using a parenteral syringe and needle. The nurse gathered up this syringe with a collection of other syringes to take to the patient’s bedside for administration and inadvertently administered the oral nimodipine IV push instead of via the NG tube.
- PA-PSRS has received several reports describing errors in which (TB) syringes were used in place of insulin syringes. For example, one nurse selected a TB syringe instead of an insulin syringe and administered 0.9 mL (90 units) of insulin, which resulted in a ten-fold overdose.<sup>14</sup>
- Many reports of ADRs and falls involving the elderly cite medications that appear on the Beers criteria, explicit criteria for certain medications that may lead to ADEs and were considered to be inappropriate for use in the elderly population.<sup>15</sup>

The *Patient Safety Advisory* provides a number of methods for reducing the risk of the types of medication errors described here. These include making changes to purchasing, labeling, and storage practices, as well as administrative and clinical processes.

## ***Patient Safety in Mental Health: Reports from Behavioral Health Hospitals***

Through a Memorandum of Understanding with the Department of Health, behavioral health hospitals (BHHs) licensed by the Department of Public Welfare are required to submit reports to PA-PSRS. While some patterns reflect the uniqueness of BHHs, there are also similarities with other facility types.

Overall, BHHs submit fewer reports to PA-PSRS than other hospitals, even after adjusting for differences in the volume of care delivered (see Figure 25).

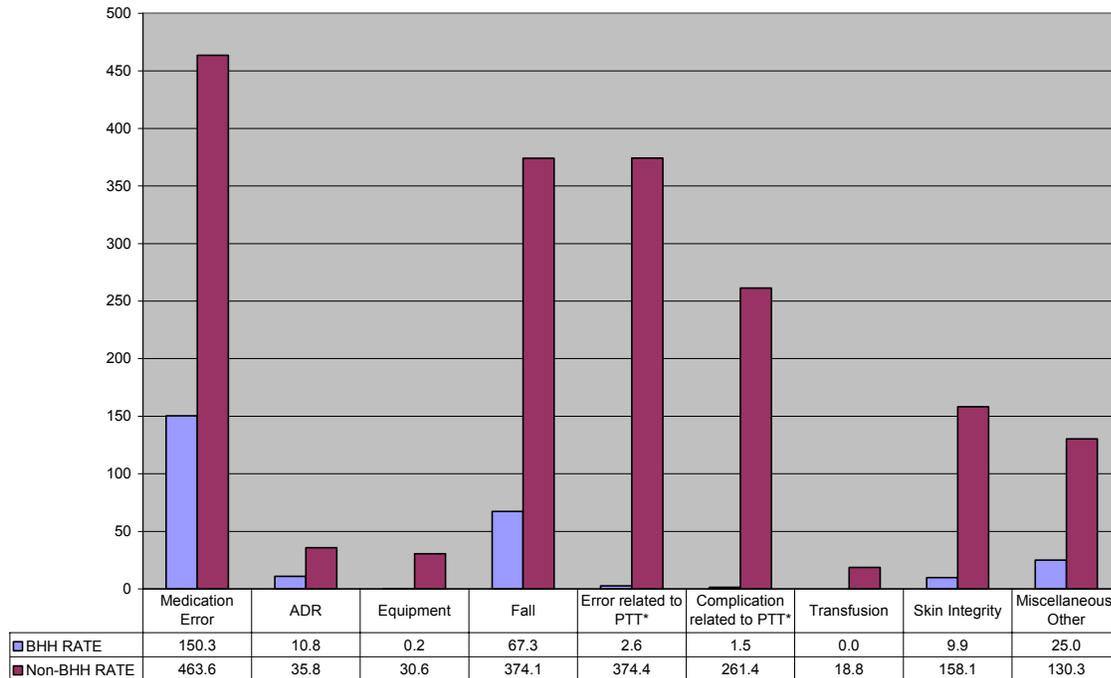
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<sup>13</sup> PA-PSRS. Patient Safety Advisory. Drug name suffix confusion is a common source of errors. Dec 2004;1(4):17.

<sup>14</sup> PA-PSRS. Patient Safety Advisory. Overdoses caused by confusion between insulin and tuberculin syringes. 28 Oct 2004;1(S1).

<sup>15</sup> PA-PSRS. Patient Safety Advisory. The Beers criteria: Screening for potentially inappropriate medications in the elderly. Dec 2005;2(4):11-5.

**Figure 25. Reports to PA-PSRS by Behavioral Health and Non-Behavioral Health Hospitals per 100,000 Patient Days (Jul 2004-Dec 2005)**



\*PTT is an abbreviation for "Procedure, Treatment, or Test."

Examining the distribution of reports by Event Type reveals some similarities and differences between these care settings. BHHs have submitted reports for all major Event Type categories except Transfusion. As in BHH facilities, Medication Errors and Patient Falls are the most prevalent types of reports. In contrast, BHHs report proportionately fewer of the following: Errors and Complications Related to Procedure/Treatment/Test, Skin Integrity and Equipment issues. Proportionately, 85% of reports submitted to PA-PSRS by BHHs are Medication Errors, Adverse Drug Reactions, and Patient Falls, compared to 47% of the non-BHH reports.

### Medication Errors

Fifty-five percent (55%) of BHH reports are medication errors, compared to 25% from non-BHH facilities. Predominant types of errors included dose omissions, extra dose, wrong drug, and wrong patient errors. Some patient safety strategies include:

- Posting lists of brand and generic drug names, as well as names of look-alike, sound-alike drugs that are commonly used in behavioral health.
- Developing consistent mechanisms to ensure administration of medications at bedtime and when patients return from passes/other departments.
- Reducing the need for recopying medication administration records.
- Having Pharmacy dispense medications labeled with both generic and brand names.
- Regularly sharing medication dispensing error information with the Pharmacy to encourage investigation and process improvement.

- Moving to Pharmacy-dispensed unit dosing that is administered individually to one patient at a time, rather than pre-pouring medications for several patients at once.
- Consistently applying a protocol to ensure that ordered parenteral medications are given when patients refuse oral medications.
- Implementing a system to flag/remind healthcare workers to follow up when medications require clarification.
- Using tall-man lettering system and/or unique labels – and separately storing – look-alike, sound-alike and regular versus extended release medications.
- Using two patient identifiers and asking patients to state their names, rather than asking “Are you X?”

### **Adverse Drug Reactions (ADRs)**

Almost two-thirds of ADRs reported to PA-PSRS from BHHs involved one of six medications: Risperdal, Haldol, Seroquel, Lithium, Lamictal, or Trazodone. Three-fourths of the symptoms reported were extrapyramidal reactions and/or rashes. Two life-threatening ADRs were also reported. A psychotropic medication resulted in neuromalignant syndrome. In another case, an antibiotic was associated with toxic epidermal necrolysis.

Risk reduction strategies included heightening staff awareness about:

- Medications most frequently associated with ADRs in BHH facilities.
- Symptoms and interventions related to extrapyramidal symptoms and neuromalignant syndrome.
- Symptoms and interventions associated with ADRs from non-psychotropic medications to reduce risk in life-threatening circumstances.

### **Patient Falls**

Compared to non-BHHs, a greater proportion of BH reports of patient falls occurred while ambulating, in hallways, and on the grounds of the facility. One-half of the fall reports did not indicate completion of a fall risk assessment or implementation of fall precautions. Yet, two-thirds of these reports specified medications given prior to the fall that may produce symptoms that increase fall risk (benzodiazepines, anti-seizure medications, and/or antipsychotics). Of fall reports specifying medications, 40% indicated that patients received multiple drugs prior to the fall.

Interventions to reduce falls or the harm associated with falls include:

- Adjusting medications to reduce dizziness, lightheadedness, loss of balance.
- Evaluating circumstances surrounding falls associated with elimination/use of bathrooms.
- Evaluating activities and correcting patient safety hazards to reduce injuries in recreational areas, smoking areas, courtyards, sidewalks/walkways.
- Securing furniture and equipping ambulatory aids with anti-tip devices when available.
- At night, using partial side rails when the patient is asleep and keeping patient items within reach.
- Because of symptoms associated with commonly prescribed medications, assessing all behavioral health patients for fall risk.

- Implementing fall precautions consistent to level of risk assessed, particularly with patients taking multiple medications, benzodiazepines, and anticonvulsants.

## Healthcare Associated Infections

PA-PSRS received 5,378 reports related to infection control in 2006, and healthcare associated infections (HAIs) are among the complications most frequently reported to PA-PSRS. Others are IV site complications and complications following surgery or invasive procedures.

Reports of HAI from 2005 and 2006 increased by 63%, which may have been encouraged by efforts at the end of 2005 to address low volume reporters. Reporting increased in almost every HAI subcategory, as well as in each region of Pennsylvania. For the past two years, the most frequently reported infections were antibiotic-associated diarrhea and wound or surgical site infections. In the third quarter of 2005, a new event sub-category was introduced, urinary tract infection, which became the third most commonly reported type of HAI in 2006.

However, there are significant variations in reporting among different regions in Pennsylvania. These variations may be due to two factors:

- Variations in facilities' interpretation of Act 13 reporting requirements. The definition of a Serious Event and Incident include the concept of an "unanticipated injury". In many cases, healthcare workers may consider HAIs as anticipated because of factors that place the patient at high risk, such as comorbid conditions, age, or length of hospital stay. Therefore, the facility's Patient Safety Officer may consider the occurrence as not reportable to PA-PSRS.
- Heightened awareness and willingness to report to PA-PSRS because of regional initiatives. For example, the southwestern region has a higher HAI reporting rate than any other region in the state. For several years, the Pittsburgh Regional Healthcare Initiative – a collaborative effort in the Pittsburgh area – has concentrated on reducing HAIs.

PA-PSRS does not receive reports of all HAI cases that occur in Pennsylvania, as evidenced by comparing its 2006 reporting rate per 10,000 patient days (5.86) with a national estimate of all the HAIs that occur (98). The occurrence must meet the facility's interpretation of the Act 13 definition of a Serious Event or Incident before it is reportable to PA-PSRS.

Even with such variations, the small proportion of infections reported to PA-PSRS has provided a foundation for a large number of *Patient Safety Advisory* articles that have been generated over the past two-and-a half years.

A brief look at HAI reports submitted to PA-PSRS in 2006 reveals the following:

TYPE OF INFECTION	PREDOMINANT SITE	PREDOMINANT ORGANISMS
Intravascular catheter infection	20% were central line-related	Methicillin resistant staphylococcus aureus (MRSA), Vancomycin resistant enterococcus (VRE), Staphylococcus aureus
Wound or surgical site infection	Groin, knee, sternum, PEG tube site	Pseudomonas aeruginosa, MRSA, Staphylococcus aureus
Pneumonia	16% were ventilator-associated	MRSA
Sepsis 48 hours post admission	Blood	Staphylococcus epidermidis, Klebsiella pneumonia, Pseudomonas aeruginosa
Antibiotic-associated diarrhea	Stool	50% of reports indicated Clostridium difficile; no organism was specified in remaining reports
Antibiotic resistant organism		VRE, MRSA

<b>TYPE OF INFECTION</b>	<b>PREDOMINANT SITE</b>	<b>PREDOMINANT ORGANISMS</b>
Urinary tract infection	Urine	Escherischia coli, Enterococcus faecalis, Pseudomonas aeruginosa, VRE

Other PA-PSRS Event Types capture additional infection control-related occurrences, as well, which have been sources of feedback to Pennsylvania facilities. For example, reports reflect healthcare workers not wearing personal protective equipment, or using stethoscopes or bandage scissors without disinfecting them between patients. Ineffective handwashing has been reported, such as a healthcare worker refusing to remove rings prior to performing a surgical scrub. Healthcare industry representatives have placed contaminated items on sterile fields or provided inaccurate advice about the time required to autoclave an instrument. Infection outbreaks caused by drug resistant organisms have sometimes resulted in deaths. Reports of communication gaps are regularly received, such as a patient requiring a specific type of isolation arrives to the operating room while OR staff is unaware and unprepared to implement the required isolation precaution. Many reports of breaks in sterile technique have been reported to PA-PSRS, involving: bioburden discovered on sterilized instruments; patient tissue inadvertently dropped on the floor; contaminated instruments placed on the sterile field or in the patient before checking sterility indicators or expiration dates; and insects on the sterile field. Moreover, reports originally submitted as infectious outbreaks in eye surgery centers were later determined to actually be inflammatory responses: toxic anterior segment syndrome.

As a result of these reports, PA-PSRS has published the following evidence-based infection control-related articles to provide feedback to healthcare facilities on this component of patient safety:

- Threat of cornea transplant contamination (June 2006)
- Bioburden on surgical instruments (March 2006)
- Healthcare industry representatives: Maximizing benefits and reducing risks (March 2006)
- Clostridium difficile: A sometimes fatal complication of antibiotic use (June 2005)
- Emerging strain of C. difficile (June 2005)
- A different look at scissors safety: Infection control (December 2004)
- Keeping an Eye on Toxic Anterior Segment Syndrome (December 2005)

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# Patient Safety Guidance Based on Report Analysis and Research

The primary way the Patient Safety Authority communicates with healthcare facilities about the significant trends identified in PA-PSRS reports is through the *Patient Safety Advisory*, a quarterly research publication with periodic supplements. The *Advisory* is widely distributed via e-mail and is also available online at the Authority's web site ([www.psa.state.pa.us](http://www.psa.state.pa.us)). Since the first *Advisory* was issued in March 2004, the Authority has published dozens of articles on a variety of clinical issues. In 2006, the Authority published four quarterly issues of the *Advisory* and two supplements, comprising more than 40 articles. Following are summaries of selected articles published during 2006. Refer to the original articles for more detail and for sources from the clinical literature.

## Feeding Tube Placement

Volume 3, Number 4—December 2006

While traditional bedside methods of verifying proper placement of feeding tubes are not reliable, these methods are still used despite the availability of more reliable, evidence-based practices to confirm proper placement. Of greatest concern, errors have been reported to PA-PSRS even when the gold standard of confirmation, a radiograph (x-ray) of the chest, has been done but misinterpreted by a patient's physician.

Injuries from feeding tube misplacement reported in the clinical literature include aspiration pneumonia, pneumothorax, perforations, empyema, broncho pleural fistula, and even death. The following three methods have traditionally been used to verify feeding tube placement at the bedside:

1. Auscultation involves instilling air into the feeding tube with a syringe while using a stethoscope placed over the stomach to listen for rushing air. However, this method cannot differentiate between tube placement in the stomach or the lung/bronchial tree. Misinterpretation of auscultation of air insufflation is known as pseudoconfirmatory gurgling.
2. Bubbling involves observing bubbles when the end of the feeding tube is placed under water; the appearance of bubbles is thought to indicate that the feeding tube is misplaced in the respiratory tract. Bubbling can also occur when feeding tubes are placed in the gastrointestinal tract.
3. Aspirate Appearance involves assessing the color of aspirate from the tube. Small bowel aspirates are golden yellow or greenish brown (intestinal fluid stained with bile); in contrast, gastric aspirates are often grassy green, off-white, or tan. However, respiratory secretions can be white, yellow, straw-colored, or clear. Because both respiratory and gastrointestinal aspirates may be similar in color, they may be easily misinterpreted.

The gold standard for nasogastric feeding tube placement is radiographic confirmation with a chest x-ray. The gold standard for nasoenteric feeding tube placement is radiographic confirmation with chest and abdominal x-rays. While radiographs are the preferred method of confirmation for small bore feeding tubes, they are not always done when large, rigid nasogastric tubes are inserted. However, some sources recommend radiographic confirmation of all blindly inserted tubes for feedings or administration of medications in high-risk patients. Barriers to radiographic confirmation include the expense of confirmatory x-rays, the effort involved, and radiation exposure to the patient. Moreover, x-rays have been misinterpreted as well.

The following PA-PSRS report indicates misinterpretation by nonradiologists: A house physician inserted a Keofeed tube in a geriatric patient. Both the nurse and physician confirmed placement by auscultating insufflated air. The physician confirmed placement after reading the x-ray. Tube feedings were begun. The patient was found dead.

Confirmation that the feeding tube is properly placed in the stomach or small bowel involves documenting the following on a chest x-ray:

1. The tube follows a straight course down the midline of the chest to a point below the diaphragm.
2. The tip of the tube is below the diaphragm.
3. The tube is not coiled anywhere in the chest.
4. The tube does not follow the path of a bronchus.

If the tube is intended to be placed in the small bowel, an abdominal x-ray is needed to determine where the ports are situated. Small bowel feedings are needed when patients cannot tolerate gastric feedings because of significantly delayed gastric emptying, demonstrated chronic aspiration of gastric contents, or a known incompetent lower esophageal sphincter.

Both endoscopy and fluoroscopy accurately verify placement of feeding tubes, but these methods can be cost-prohibitive, time-consuming, and pose additional risks, such as transporting patients to special procedures areas or imaging departments. Because fluoroscopy produces clinically significant radiation exposure, this technique is used for feeding tube placement only as a last resort. Another reliable method for ongoing tube placement verification is determining the pH of the fluid aspirated from feeding tubes. If the pH of the feeding tube aspirate is greater than or equal to 6, the tube may be inadvertently located in the respiratory tract.

However, several conditions can affect the pH of aspirates, resulting in misinterpretation of the placement of a feeding tube. For example, respiratory secretions may be acidic in patients with esophageal rupture, acid reflux, or a pleural infection such as empyema. Also, gastric pH will rise temporarily when the patient is receiving acid-inhibiting medications or when tube feedings are in progress. In spite of the possibilities for misinterpretation, pH continues to be the most reliable bedside method for ongoing feeding tube placement confirmation.

Several investigational studies have identified other methods to verify feeding tube placement:

- Combining bedside pH testing with laboratory testing of either bilirubin concentration or pepsin and trypsin of tube feeding aspirates provides a reasonably reliable method of verifying gastric placement of feeding tubes.
- Many institutions now regularly use confirmatory x-rays to ensure that a nasogastric tube's ports end in the stomach instead of the esophagus to minimize risk for aspiration of formula or medications administered via the tube.
- Patients at greatest risk for misplacement are those with diminished mental status and decreased cough or gag reflexes. Critically ill, obtunded, uncooperative, debilitated patients and those with maxillofacial or craniofacial trauma and craniofacial surgery are at greater risk for feeding tube misplacement.

An algorithm is available on the Patient Safety Authority website at: [www.psa.state.pa.us](http://www.psa.state.pa.us) for minimizing the risk of nasogastric or nasoenteric feeding tube misplacement.

## **Propofol Administration**

**Volume 3, Number 1—March 2006**

Healthcare facilities in Pennsylvania and across the country are asking: What are the necessary credentials for administering propofol (DIPRIVAN) for moderate and deep sedation? The American College of Gastroenterology and others contend that the safety profile of propofol is such that a gastroenterologist, registered nurse under their supervision, and other “qualified medical professionals” can safely and effectively administer the drug without specific training in the administration of general anesthesia. However, drug manufacturers and several anesthesiology professional organizations believe this may place patients at undue risk.

Propofol, an injectable emulsion, is a high-alert medication according to ISMP. Use of propofol is growing during endoscopic, radiologic, and other procedures in hospitals, ambulatory surgical facilities and physician offices across the country. Propofol offers certain advantages over other drugs used for sedation when used by trained and credentialed practitioners because it:

- Has a rapid onset and a short duration of action.
- Allows patients to wake up, recover, and return to baseline activities and diet sooner than some other sedation agents.
- Reduces the need for opioids, resulting in less nausea and vomiting.

Some disadvantages of propofol are:

- Unlike other agents used for sedation (e.g., midazolam, morphine) propofol has no reversal agents.
- Propofol dosing and titration can vary, as it is based on the patient's response and tolerance to the drug. Profound changes in respiratory status can occur rapidly. A patient can go from breathing normally to a full respiratory arrest in seconds, even at low doses, without warning from typical assessment parameters.

Practitioners may develop a false sense of security, allowing the perceived safety profile of propofol to influence their belief that the drug poses minimal risk. In untrained hands, propofol can be deadly. Manufacturers of propofol state in the product labeling that the drug should be administered only by individuals trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure.

The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received over 100 medical and medication error reports in which the use of propofol has been cited. Sixteen percent (16%) of these reports have been classified as Serious Events, including four patient deaths in which propofol may have played a role. The largest number of events involving propofol received by PA-PSRS occurred in the ICU and OR—practice settings designed with constant supervision in place.

There is a difference in opinion among professional societies about the necessary credentials for individuals administering propofol for sedation. In brief, the American Society of Anesthesiologists (ASA), American Association of Nurse Anesthetists, and American Association for Accreditation of Ambulatory Surgery Facilities believe that safe administration of propofol to non-ventilator-assisted patients is limited to individuals trained in the administration of general anesthesia who are not simultaneously involved in the procedure. In contrast, the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and Society of Gastroenterology Nurses and Associates endorse nurse-administered propofol under the direction of a physician if state regulations allow it, if the nurse is trained in the use of drugs causing deep sedation, and if the nurse is capable of rescuing patients from general anesthesia or severe respiratory depression. Further complicating the situation is that several insurance companies have decided that propofol administration in the office setting by gastroenterologists or their assistants is acceptable and safe for some procedures.

The Joint Commission Standard PC.13.20 requires the administration of moderate or deep sedation, that a sufficient number of staff, in addition to the person performing the procedure, be present to perform the procedure and monitor and recover the patient. The person administering the sedative agent must be qualified to manage the patient at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. While there may be a need for additional monitoring personnel for the procedure, the person administering the sedation must be qualified to monitor the patient.

The following strategies may help to reduce the incidence of complications from propofol. These strategies include:

- Review state regulations to determine which practitioners may or may not be able to administer propofol within their respective scope of practice.

- Evaluate the literature and various position statements available from professional societies such as the ASA, American Association of Nurse Anesthetists, and others.
- Establish policies and practice guidelines for the administration of propofol to non-ventilator-assisted patients undergoing minor surgical or diagnostic procedures.
- Define qualifications of professionals who can administer propofol to non-ventilator-assisted patients during procedures.
- If nurse-administered propofol is agreed upon as acceptable, specify the circumstances and required education and mentorship to be accomplished beforehand and competencies to be evaluated and met periodically.
- Evaluate locations where propofol administration is appropriate, and ensure that those areas are able to follow the developed criteria for administration, including expertise and availability of equipment to intubate patients. Also, ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.
- Define and document the intended level of sedation that patients should receive. Ensure that all patients, even if moderate sedation is intended, are able to be monitored and rescued from deep sedation.

While the debate will continue over the appropriate credentials for administering and monitoring propofol, one thing is clear: whenever propofol is used for sedation/anesthesia, it should be administered only by persons who are capable of recognizing and treating any untoward effects with this largely beneficial, but potentially deadly, agent.

## **Bone Cement Implantation Syndrome**

**Volume 3, Number 4—December 2006**

PA-PSRS has received reports of six intraoperative cardiac arrests in patients—five resulting in death—associated with hip arthroplasties using bone cement to implant prostheses. While hip surgery is a common procedure among the elderly and generally considered safe and effective, mortality most often occurs postoperatively, usually from cardiopulmonary causes such as myocardial infarction or pulmonary emboli.

Intraoperative deaths during hip arthroplasty occur less frequently but are almost exclusively associated with cementing of the femoral prosthesis. Although cardiac arrest and death are the most catastrophic symptoms associated with cemented arthroplasty, bone cement implantation syndrome (BCIS) is a well-recognized complex of sudden physiologic changes that occur within minutes of the use of methyl methacrylate cement to secure a prosthetic component into the femur. The cardiopulmonary complications of BCIS can be reduced through modern cementing techniques, appropriate anesthesia interventions, and adequate patient preparation, as well as avoiding the use of cement altogether.

Methyl methacrylate toxicity was considered the major cause of hemodynamic instability during arthroplasty surgery. However, this hypothesis has not been confirmed by animal studies. While absorbed monomer temporarily lowers blood pressure after insertion of bone cement, there is little evidence indicating that monomer causes severe systemic reactions. Methyl methacrylate monomer is no longer considered the cause of cardiopulmonary dysfunction during procedures using cemented components.

BCIS is now considered to be caused by the hemodynamic effects of medullary fat embolism, rather than the toxic effects of the cement itself. Cementing prior to prosthesis insertion causes sealing and pressurization of the femoral canal when the prosthesis is inserted. This leads to high intramedullary pressure, forcing medullary fat into the vasculature. This embolic load produces acute pulmonary hypertension that can lead to right ventricular dysfunction, ischemia, hypotension, and even sudden death. The severity of these symptoms does not correlate with the amount of methyl methacrylate used. Moreover, this syndrome occurs in the absence of methyl methacrylate use. Noncemented arthroplasty produces lower intramedullary pressures, fewer emboli, and much less hemodynamic

disturbance. Cementless stem fixation has become more durable and clinically effective over the past two decades. A review of 10,299 primary total hip arthroplasties in the North American Hip and Knee Registry revealed that cement use for stem fixation declined from 66.2% of the procedures in 1995 to 38.6% in 2001 ( $p < 0.001$ ).

Elderly patients with underlying cardiovascular disease who are undergoing cemented arthroplasty for repair of a fracture are at greatest risk for developing BCIS. Advanced age has been associated with a higher mortality rate. Severe osteoporosis may place a patient at higher risk also because osteoporotic bones have enlarged porous cavities and vascular spaces, which may allow marrow contents to enter the venous system more easily. Pathologic fractures are a risk factor. This may be due to the many co-morbid conditions associated with fractures that may increase mortality risk, compared to those patients undergoing elective hip replacement. Those with fractures have greater blood loss preoperatively, contributing to hypovolemia and hypotension. Patients are susceptible to cardiac ischemia if their preoperative cardiopulmonary reserve is limited by pre-existing pulmonary hypertension, right ventricular dysfunction, or coronary artery disease. Femoral tumors or cancer also place a patient at risk because of potential alterations in the femoral vascular architecture that may increase the risk of marrow embolization. Patients with large femoral canals (21 mm or more) are at risk for hypotension when cement is inserted into the femoral canal because of an increased vascular surface and a greater amount of embolizable intramedullary contents.

Among the surgical techniques presented in the article that may help reduce incidence of BCIS are:

- 1) Changing from a cemented to an uncemented prosthesis to minimize embolic load if the patient's mean arterial pressure decreases by 20 to 30% below baseline during canal reaming or plugging.
- 2) Conducting thorough, pulsatile, high pressure, high-volume lavage and brushing and drying of the intramedullary canal of the femoral shaft to remove tissue prior to cement insertion reduces disturbances in pulmonary function and prevents microembolization of marrow contents and the embolic response, thereby reducing the risk of fat embolism and minimizing circulatory changes.
- 3) Using a venting hole in the distal femur reduces distal trapping of debris and reduces pressurization by creating intramedullary drainage. However, drilling a venting hole may reduce the prosthesis stability or increase the risk of fracture.
- 4) During cement preparation, working the cement to remove volatile vasodilator compounds and use low viscosity to reduce intramedullary canal pressures.
- 5) Inserting the prosthesis stem into the cemented femoral canal slowly to reduce pressurization. Implant insertion produces maximum pressure, not cement insertion.

In order to get this information into the hands of physicians who perform hip replacement surgery, PA-PSRS developed a brief pocket guide summarizing the article, which was sent along with a reprint of the full article to every member of the Pennsylvania Orthopaedic Society. A similar mailing was sent to OR Managers of Pennsylvania hospitals where this procedure is performed.

## Verbal Orders

Volume 3, Number 2—June 2006

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 is inherently problematic because of different accents, dialects, and pronunciations. Background noise, interruptions, and unfamiliar drug names and terminology often compound the problem. Once received, a verbal order must be transcribed as a written order, which adds complexity and risk to the ordering process.

When the recipient records a verbal order, the prescriber assumes that the recipient understood correctly. No one except the prescriber, however, can verify that the recipient heard the message correctly. Sound-alike drug names and numbers are easily misheard and affect the accuracy of verbal orders. Numerous reports submitted to PA-PSRS have confirmed this for example:

- A misheard verbal order led to a patient receiving erythromycin instead of azithromycin.
- A phone order mistaken for Toradol 50mg was administered prior to the pharmacy review, when the intended dose was 15mg.
- A telephone order relayed to pharmacy by a nurse for “Viscerol” was clarified by pharmacy as Vistaril.

Medication errors can also occur when communicating a patient’s lab values verbally. In reports submitted to PA-PSRS, many of these types of errors involved misinterpretation of blood sugar levels for patients on insulin therapy. Another significant problem that arises with the use of verbal orders is a breakdown in the communication of relevant patient information, such as the current medication list, diagnoses, or co-morbid conditions and allergies. When medications are ordered verbally and the normal pharmacy check systems are not in place (such as when medications are available in unit stock, or when pharmacy is closed but accessible by non-pharmacy staff), more issues can arise.

The Joint Commission recently added a National Patient Safety Goal to address the error-prone procedure of verbal orders. The 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. Reports submitted to PA-PSRS include errors that could have been prevented if this technique had been used.

Faxes, electronic mail, and point-of-care computerized prescriber order entry are reducing the need for verbal orders in non-emergent situations. However, it is very unlikely that they will ever be totally eliminated. Sharing the following safe practices with nurses, pharmacists, and physicians in your facility may help you stimulate discussion and evaluate your practice.

- Limiting verbal communication of prescription or medication orders to urgent situations in which immediate written or electronic communication is not feasible.
- For prescribers, enunciating verbal orders clearly.
- For order recipients, writing down the complete order or entering it into a computer, reading it back, and receiving confirmation from the individual who gave the order.
- Including the purpose of the drug to ensure that the order makes sense in the context of the patient’s condition.
- Including the mg/kg dose along with the patient’s specific dose for all verbal neonatal/pediatric medication orders.
- Having a second person listen to a verbal order whenever possible. Students or other inexperienced staff may require special supervision when handling verbal orders.
- Limiting the number of personnel who may receive telephone orders to help ensure familiarity with facility guidelines and the ability to recognize the caller, which reduces the potential for fraudulent telephone orders.

PA-PSRS developed a toolkit in conjunction with this article, to help facilities implement these safe practices. The toolkit includes: a poster summarizing the read-back procedure, a sample policy on verbal or telephone orders, a survey that can help Patient Safety Officers assess compliance with the safe practices, and other items. The toolkit is available on the Patient Safety Authority web site at: [www.psa.state.pa.us](http://www.psa.state.pa.us).

# Colon Perforations During Colonoscopy

Volume 3, Number 4—December 2006

During the first year of reporting, PA-PSRS received 125 reports of perforations of the colon during colonoscopy and another 27 reports in which the diagnosis was uncertain or the situation was otherwise unclear. These results indicate that between 125 to 152 perforations were reported as complications of colonoscopies during the first full year of reporting to PA-PSRS. The actual number is likely higher. We know that perforations may occur in doctors' offices and not be reported by the hospitals because they did not occur in a defined medical facility. Additionally, there may be under-reporting of events. However, most (83%) perforations are being reported as Serious Events, despite being "anticipated" as the most important complication of colonoscopy.

The rate of colon perforations during colonoscopies reported in PA-PSRS (0.039-0.047%) is low compared to the rates reported in the literature. However, the *number* of perforations in the PA-PSRS database is high. In the literature that we reviewed, the largest number of perforations was 77, which occurred in a random sample of 5% of Medicare beneficiaries 65 years old or older in the Surveillance, Epidemiology, and End Results (SEER) program.

Because of the number of reports and the morbidity of colon perforations, the Pennsylvania Patient Safety Authority Board of Directors has decided to undertake a focused objective cooperative analysis of perforations during colonoscopy as a special safety improvement project. The initial objective of this special initiative is to reduce the number of perforations during colonoscopies to at least less than 60 within a single year.

Facilities are encouraged to volunteer their commitment and full participation in this special safety improvement project in the following ways:

- The PA-PSRS team is looking for physicians and nurses of all specialties who do colonoscopy and who are interested in volunteering to provide their expertise and experience to this project.
- PA-PSRS will be soliciting detailed information from facilities in follow-up to reports of perforations during colonoscopies. Hopefully, facilities will understand the importance of gathering in-depth information on this complication; the burden will be small for any single facility, and the benefit large.

The PA-PSRS team is looking for volunteer providers and facilities to provide comparable information in order to identify the risk factors for perforation by understanding which patient and procedure factors are not only commonly found with perforations, but more commonly found with perforations than with safe, uncomplicated procedures, it will be necessary to collect similar information on an equivalent-sized set of safely done procedures. The risk of perforation of the colon during colonoscopy can be reduced by:

- Identifying patient and procedural factors that could be modified to reduce the risk of perforation,
- Informing providers about these controllable risk factors, and
- Helping facilities implement programs to systematically control those risk factors during colonoscopies to minimize the risk of perforation.

The Authority will be able to identify controllable risk factors for perforation during colonoscopy, develop an educational program to inform Pennsylvania providers about these controllable risk factors, and assist them in developing system improvements to eliminate avoidable risks of perforation during colonoscopy.

# Update on Color-Coded Patient Wristbands

Volume 3, Supplement 1—August 2006

In December 2005, the Pennsylvania Patient Safety Reporting System (PA-PSRS) identified risks associated with using color-coded patient wristbands to communicate clinical information. In a PA-PSRS survey while nearly four out of five respondents' facilities use color-coded patient wristbands; there is little consistency among facilities in

the meanings associated with different colors. The lack of consistency in wristband meanings and how they are applied presents problems when patients are transferred among facilities and when patients are cared for by clinicians who work in multiple facilities.

In one case, a patient was nearly not resuscitated during cardiopulmonary arrest because she was incorrectly designated as “DNR” with a colored wristband by a nurse who worked in multiple facilities and was confused about the meanings of different colors. The lack of consistency in wristband meanings and how they are applied presents problems when patients are transferred among facilities and when patients are cared for by clinicians who work in multiple facilities.

Since the release of the December 2005 Advisory, a group of healthcare organizations in northeastern and central Pennsylvania started a grassroots effort to meet the challenge of making this practice safer. Facilities participating in “The Colors of Safety Task Force” implemented and standardized a number of safe practices across their facilities. The Colors of Safety Task Force started when Allied Services Rehabilitation Hospital (ASRH) in Scranton contacted the acute care hospitals that refer patients to them and those to which they transfer patients to see whether they could standardize this practice on a regional basis. Associate Vice President at ASRH and Chair of the Task Force, Bonnie Haluska says the process has worked because healthcare providers saw a patient safety issue that could only be resolved through cooperation.

News of their effort spread by word of mouth and sparked the interest of facilities in central and western Pennsylvania and even from other states. The Patient Safety Authority was also contacted by other states and national patient safety organizations. Because there is no evidence either for or against the effectiveness of color codes to communicate clinical information, PA-PSRS does not advocate that healthcare facilities begin this practice. However, facilities that do use these wristbands may wish to follow the model created by the Colors of Safety Task Force.

Highlights of some of the safe practices include:

- Limiting the spectrum of color-coded wristbands and standardizing the meanings associated with each color.
- Purchasing wristbands with preprinted, embossed text, rather than relying solely on color to communicate the meaning.
- Avoiding handwriting on the band except in emergent cases and allowing only nurses to apply or remove wristbands not family or friends.
- Labels or stickers used in the medical record to communicate the same risk factors as colored wristbands will use corresponding colors and text.
- Educating patients and their families on the risks associated with community bands and on the meanings of the colored wristbands applied in the healthcare setting.

The Task Force has made available on the Patient Safety Authority’s website [www.psa.state.pa.us](http://www.psa.state.pa.us) an Implementation Manual which includes:

- A detailed policy on color-coded patient wristbands and an implementation guide outlining requirements, specific actions and responsible parties.
- A refusal of consent form for patients who refuse to remove community wristbands or to wear wristbands applied by the healthcare facility.
- A form that provides an alternative means of communicating alerts for patients who cannot or will not wear wristbands applied by the healthcare facility.

- A curriculum for educating healthcare facility staff about the change in policy and procedure, and a competency checklist.
- Detailed procurement information for purchasing wristbands, as well as matching Kardex labels, that comply with the standardized policy.
- A poster that can be used to reinforce the relationships between the color-coded wristbands and their meanings.

The Pennsylvania healthcare facilities participating in the Colors of Safety Task Force have “banded together” to address these risks and have provided a roadmap for other facilities to follow.

## Bed Entrapment

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PA-PSRS has received over 100 reports of hospital bedrail entrapment since June 2004. In the past, healthcare workers considered bedrails a useful device to prevent patient falls from bed. Now, bedrails are recognized as a hazard that can result in death or serious injury.

Entrapment involves a patient who is caught, trapped, or entangled in the hospital bed system which includes the spaces in or around the bedrail, hospital bed mattress, or hospital bed frame. Entrapped body parts associated with risk for severe injury include the head, neck, and chest. The Food and Drug Administration (FDA) and the Hospital Bed Safety Workgroup (HBSW) have produced guidance documents that healthcare facilities and manufacturers can use as references to reduce entrapment risks.

PA-PSRS reported about 4% of the entrapment reports were classified as Serious Events, and about 50% of the Incidents indicated some type of injury. The remaining reports indicated either that no injury occurred or no injury was specified. The majority of entrapments resulted in either no harm or minor injuries (i.e., abrasions, skin tears, lacerations, bruises/redness, indentations, pain/discomfort); however, all reports indicated that healthcare workers needed to extricate the patient to prevent greater harm. Sixty-eight percent of the entrapped patients were 70 years of age or older. However, the ages of entrapped patients reported ranged from 10 months to 99 years old. Therefore, all ages may be at risk of entrapment, particularly if other risk factors are present. Entrapment of the head and chest (associated with potential for serious injury) occurred in 9% of the reports. The most common entrapped body parts were lower extremities (25%) and upper extremities (11%). Nine percent of reports involved entrapment of more than one body part, while another 3.5% involved the hip/pelvis. The remaining 3.5% indicated that the body/torso was entrapped.

Bedrails are beneficial in many circumstances, they can remind a patient not to get out of bed, or a patient can use them while repositioning or turning while in bed. Rails can be used as hand-holds to assist the patient while getting in or out of bed. They also define the sides of an unfamiliar bed and may provide the patient with a sense of security and comfort. Rails are also useful for preventing rolling out of bed which reduces the risk of falling from a bed or litter during transport. Raised bedrails may increase patient agitation and enhance feelings of isolation and restriction/imprisonment, thereby negatively affecting self esteem. All these collective benefits must be weighed against the risks of using bedrails.

Bedrail entrapments commonly occur in frail, elderly patient populations. Mentally or behaviorally impaired persons may be at risk, including those with agitation, delirium, hypoxia, confusion, dementia, and memory problems. Those with uncontrolled body movements may find themselves in an entrapment situation from which they cannot independently extricate themselves. Patients taking sedative or psychoactive drugs may not be aware of entrapment as it occurs. And those patients with acute urinary retention of fecal impaction are at risk for entrapment when attempting to go to the bathroom by getting out of bed with rails raised. Also, patients with sleeping problems or those who are fall risk may get entrapped in the bed system while attempting to get out of bed unassisted.

In older bed systems, the original design may not have accounted for the risk of patient entrapment. For example, replacement mattresses may be undersized and not fit as snugly as the initial mattresses. When a patient moves to

one side of some types of air mattresses that side compresses while the center of the mattress rises. The resulting “slide” allows the patient to move from the mattress to the bedrail. Such compression can also result in a wider space between the rail and the mattress, thus increasing entrapment risk. Another contributing factor that occurs is when the side rails no longer lock into the raised position, patient movement may cause a partially raised bedrail to dislocate onto a patient’s neck or extremity. Additional equipment-related entrapment risks include: bedrails with winged lower edges, improper match of bed frame with bedrails, loose bedrails, improper installation of the bed system, wide spaces between the bars in the rails, holders/supports that remain when the bedrail is removed.

Some simple risk reduction strategies include:

- Approach—Conduct a risk-benefit analysis and make bedrail decisions on a case-by-case basis.
- Assessment—Get input from the interdisciplinary healthcare team and the patient, family, and/or patient’s legal guardian. The assessment should also involve consideration of appropriate equipment.
- Awareness—Include staff, patients, families, physicians/prescribers, as well as materials managers, healthcare engineering professionals, long-term care ombudsmen, and representatives of legislative and regulatory agencies.
- Action—Strategies include ongoing care plans and treatment programs to help mitigate the risk of entrapment.

Mechanisms used to help reduce entrapment by accommodating patients’ needs and providing alternatives include:

- Anticipating and providing pain relief and calming interventions on a timely basis
- Providing distractions (e.g., television, music, food/fluids) to reduce agitation/restlessness
- Accommodating and incorporating patients’ preferred bedtime habits/routines into evening care
- Restricting the use of physical restraints on patients while in bed
- Lowering one or more bedrail sections
- Adhering to a toileting schedule that is customized to patient needs

If bedrails must be used, addressing the following equipment issues may reduce entrapment risk:

- When feasible, replacing beds with others that have lesser entrapment risk
- Using bolsters or spacers of firm foam blocks to fill gaps and provide an inlay to prevent patients from falling between the mattress and bedrails
- Replacing/modifying bedrails with gaps greater than 4½ inches or removing/lowering them altogether
- Applying bedrail covers, rigid plastic covers, clear pads, or netting to cover gaps in rails
- Using mattresses with raised/hard foam edges to reduce compression at mattress edges and to provide a sensory perimeter at the bed edges

Reducing the risk of entrapment also includes maintaining, reviewing, and taking corrective actions based on report review and the following documentation:

- Individualized patient care plans
- Bed system maintenance records
- Policies and procedures that specify risk factors and interventions to prevent entrapment
- Safety checklists for patients at high risk for entrapment
- Failure mode and effects analyses and root cause analyses

# Healthcare Industry Representatives

Volume 3, Number 3—March 2006

Healthcare industry representatives (HCIRs) can help physicians, nurses, and technicians in the OR stay current on rapidly changing surgical technology. They also serve as technical support to help OR staff cope with the proliferation of new products, increasingly complex instrumentation, sophisticated equipment, and new procedures. HCIRs may be more familiar with their own devices, systems, or procedures than the physician or healthcare team and can enhance safe product use through verbal assistance if necessary.

However, as shown in a number of reports to PA-PSRS, HCIRs can also be inappropriately involved in the healthcare setting in several ways:

- A surgeon may inappropriately rely upon the expertise of an HCIR, rather than directly acquiring the training/skills necessary to use a technology.
- An HCIR may deviate from established professional standards of conduct (for example, invasion of privacy).
- The surgical team may rely on the HCIR's incorrect advice rather than reviewing manufacturer's documents about the technology.
- The HCIR may become inappropriately involved as a member of or replacement for a member of the surgical team.

While the law may provide that a physician may use assistants, HCIRs are not considered appropriate assistants, as they lack facility credentialing. Therefore, an HCIR operating surgical equipment during a procedure may be considered practicing medicine without a license. Healthcare equipment and supply companies frequently have policies prohibiting their HCIRs from touching patients or instruments in contact with patients, helping nurses, or participating in extraneous conversations in the OR. Risks can be reduced and patient safety enhanced by written policies and procedures that clearly define the role of HCIRs in the facility, how their presence is authorized, what they are and are not allowed to do, and how their activities are monitored. The patient has the right to refuse the HCIRs presence and the use of the new product for the particular procedure.

The education and experience of HCIR's vary considerably from company to company. One company may have a certification program requiring an HCIR to successfully complete several hundred hours of laboratory and classroom instruction as a condition of employment. In contrast, another company may simply distribute written guidelines that inform an HCIR of simple OR protocols such as wearing surgical masks, donning OR attire, covering hair and shoes, and not touching tables with sterile materials. Basic education for HCIRs includes: a baccalaureate degree with basic science courses in human anatomy and physiology, biology, chemistry, and physics. In addition, the HCIR must know the medical system, device, or procedure. This can be shown by proof of experience in the OR with that product or proof of being successfully supervised by an experienced HCIR through a mentorship program.

Ultimately, the healthcare facility is responsible for an HCIR's conduct while they are in the facility. Proof of education, training, and competency can all be procured prior to the HCIR entering the OR, and an HCIR may be prohibited from entering the OR without successful completion of this facility-defined credentialing process. A facility-defined approval process in advance of HCIRs entering the OR/surgical suite allows department managers and staff to prepare for HCIR visits. Such preparations may include obtaining patient consent, providing an adequate work space for the HCIR and equipment, confirming that documentation of HCIR competencies exists. As part of the HCIR approval process, Surgical Services may require letters of reference. Moreover, a standard protocol can include a requirement for all HCIRs, sales calls/visitors or observers in the OR to make an advance appointment with facility leadership to facilitate procedure preparations. If a physician repeatedly brings in HCIRs without following authorization/credentialing policies, Surgical Services could refer the issue to the medical staff executive process for resolution. Some facilities institute an annual process of reapproval of HCIRs to help ensure competencies when HCIRs return to the facility to train a second generation of personnel on a given product. There is no requirement that HCIRs be allowed in the OR. Admission to the operating room is a privilege, not a right.

HCIRs must be familiar with OR standards and polices addressing:

- The concept of a sterile field
- Handwashing
- Protection from bloodborne pathogens
- OR traffic patterns
- Infection control practices
- Fire and electrical safety (including use of fire extinguishers and fire alarms, location of fire exits, overhead call codes)
- Patient rights and confidentiality including HIPAA compliance
- Appropriate conduct in the OR environment
- Other applicable protocols such as authorization for product use, patient consent, business procedures and the role of various staff.

A comprehensive policy encourages consistency in how HCIRs are approved and function within the facility/OR suite. Healthcare workers will have the protection and support of the policy to act upon policy deviations, use the chain of command, protect patient safety and privacy, and institute corrections if necessary. A clear policy allows patients and healthcare providers to receive the benefit of the HCIR's technical expertise while reducing the risks.

## **Skin Tears**

**Volume 3, Number 3—September 2006**

Skin tears are a painful but preventable problem for older patients. When the dermis separates from the epidermis, a partial thickness wound occurs, often causing a flap above the exposed dermis. This common problem has been reported to PA-PSRS 2,807 times—accounting for 2% of all reports from hospitals—during the first twelve months of mandatory reporting. These skin traumas are not serious enough to extend the hospital stay but are painful, unsightly injuries for the patient. Skin tear dressing changes are time consuming and painful.

Reports describing skin tears in the PA-PSRS database were reviewed for demographic information, location or department where the event occurred, event type, and other variables. The majority (62%) of reports involving skin tears were categorized as Skin Integrity events. However, nearly one-third (32%) were categorized as fall events, in which the skin tear was a result of falling or actions taken to prevent a fall. Patients aged 65 and older account for 88.2% of all skin tear reports, though they account for only 31.2% of patient days. The largest proportion of skin tears (41.3%) were reported in the 75-84 age cohort, which only accounts for 18.1% of patient days. Reports of skin tears were more commonly associated with male (51.7%) than female (48.3%) patients. This is contrary to the literature, which suggests that elderly women are at greater risk.

Gender-specific differences have been reported in the literature. Decreased hormone levels in women are implicated in skin changes pre-disposing to skin tears. The incidence of skin tears increases for females as they age, but this is not true for males, according to Malone. The PA-PSRS data found the opposite—that men were associated with more reports of skin tears than women—for all age groups but the 0-4 year cohort. Skin tears are most frequently reported from general Med/Surg units, which account for 33.2% of reported cases. This is consistent with the fact that Med/Surg units are responsible for the largest number of patient days in a facility and deliver care to a cross-section of patients for numerous conditions, especially those that require a protracted stay, as with the debilitated elderly patient.

The upper extremities were mentioned as the site of injury more frequently than other body parts, consistent with the literature. Reports involving skin tears do not always identify the location on the patient's body, but among those that do, the forearm was discussed most frequently (425) followed by arm (415) and hand (308). The lower extremity or leg was referenced 215 times. The head, face, and neck were sometimes reported as sustaining injury, with the forehead more frequently referred to than other locations on the head.

The hospital bed (792) is referenced more than any other equipment or furnishing followed by chair (174) and wheelchair (144). Bedrails and wheelchairs are mentioned in the literature as contributing to skin tears. Inspection of surfaces with padding of bedrails and edges of equipment and furnishings is suggested as a precautionary measure to prevent skin tears. Intravenous catheters (164) are discussed with skin tears more than any other tube or drain. Radiographic procedures (107) are the most frequently talked about procedure.

The literature discusses transfers and positioning as a time of high risk for the patient with fragile skin. Proper lifting, turning, positioning and transferring techniques are urged to prevent skin tears. Dressing changes and procedures involving tape removal were also frequently cited.

Risk factors for Skin Tear Characteristics include:

- Malnourishment
- Sensory changes/loss
  - Hearing
  - Sensation
  - Vision
- History of Skin Tears
- Immobility
- Ambulating independently
- Dry skin/hydration
- Agitation or restlessness

Caution is especially important when applying or removing tape from an at-risk patient for skin tears. The recurrent use and removal of adhesive tape and adhesive backed dressings in acute care sets the stage for skin injuries. One hundred seventy eight PA-PSRS reports mention tape or tape removal in relation to a skin tear. When a patient has thin, friable skin, the smallest amount of paper tape is preferred. A common misconception is that paper tape will not damage the skin, which has been proven otherwise by the reports in the database.

When tape use is unavoidable, as with securing an endotracheal tube or closing the patient's eyes, consider foam tape which provides a gentle bond to the skin. Skin sealant (skin prep) and adhesive remover are not recommended to be used near eyes. To facilitate tape removal, apply careful counter-pressure to the skin near the adhesive dressing as the tape is slowly rolled off.

In the acute care setting, awareness of a patient's risk for skin tears and implementing preventive measures involve:

- Choosing the right products for care
- Managing the environment defensively:
  - Reducing friction and shearing
  - Using a draw sheet
  - Padding bed rails and equipment edges
- Using paper tape and skin prep
- Removing tape with adhesive remover wipe and gently rolling off tape
- Educating ancillary staff, patients and families in measures to reduce skin tear risk.

The John A. Hartford Foundation Institute for Geriatric Nursing guideline "Preventing Pressure Ulcers and Skin Tears" summarizes treatment recommendations:

- “Gently clean the skin tear with normal saline.
- Let the area air dry or pat dry carefully.
- Approximate the skin tear flap.
- Apply petroleum-based ointment, steri-strips or a moist non-adherent wound dressing.
- Consider putting an arrow to indicate the direction of the skin tear on the dressing to prevent any further injury during dressing removal.
- Assess the size of the skin tear and consider a wound tracing.
- Document assessment and treatment findings.”

## Errors with Epinephrine

Volume 3, Number 3—September 2006

PA-PSRS has received numerous reports of accidental administration of concentrated epinephrine: a high alert drug. While not more prone to error than other drugs, epinephrine does pose greater risk of serious patient harm and death when used in error. The majority of the errors involving epinephrine can be traced to two problems: 1) expressing the concentration as a ratio strength rather than a metric per volume concentration, and 2) confusion between epinephrine and ephedrine.

Reports submitted to PA-PSRS describe clinicians administering undiluted epinephrine intravenously instead of a less concentrated solution, when this occurs the result to the patient is dramatic and life-threatening.

One such event occurred in a 16-year-old boy who was brought into the emergency department with priapism and died due to an epinephrine overdose. A urologist ordered epinephrine, but he thought that the 1:1,000 ratio on the epinephrine 1 mg/mL label meant that the epinephrine had already been “prediluted” with 1,000 mL of fluid. The patient received 4 mL of 1:1,000 undiluted epinephrine injected into his penis.

These overdose errors are caused, in part, by how drug concentrations are presented. The contents of most injectable medications are given as their mass concentration (mg or mcg per mL). Only a few drugs have concentrations expressed as a ratio or percentage. These expressions are error-prone because: 1) practitioners, even physicians and emergency medicine residents, may not recognize or understand the difference between dose concentrations, such as 1:1,000 or 1 mg/mL and 1:10,000 or 0.1 mg/mL) and 2) it is easy to confuse numbers in the thousands because there are so many zeros (i.e., 1,000 looks like 10,000). An inappropriate dose or life-threatening delay in treatment is quite possible, especially if these drugs are prescribed in mg (which requires prior knowledge of ratio or percent concentrations and calculations) or mL (which is a problem if multiple concentrations exist).

Another cause of errors involving epinephrine is confusion between epinephrine and ephedrine. These drug names look similar, and their use as vasopressors or vasoconstrictors makes storage near each other likely. Both products also may be packaged alike in 1 mL ampuls or vials. In another case reported to PA-PSRS, a patient in the post anesthesia care unit (PACU) was prescribed ephedrine. However, the nurse inadvertently chose and administered epinephrine IV push. An ECG was performed, and the patient required a longer stay and further monitoring in PACU.

Several of the emergency medications with concentrations expressed in ratios or percentages do not fall under FDA labeling standards. Until United States Pharmacopeia (USP) eliminates the use of ratio expressions on labels and changes the nomenclature to prevent confusion between epinephrine and ephedrine, the following preventive strategies may be helpful:

- Do not expect all healthcare practitioners to be familiar with percent or ratio expressions of concentrations, or to be adept at calculating doses for drugs with concentrations expressed in this manner.
- Use prefilled syringes, and limit storage of concentrated epinephrine to crash carts (except in the ED and OR) to reduce the risk of dilution errors or administration of the wrong product.
- Post a dose conversion chart reflecting available concentrations on emergency carts and in other areas where these medications may be prepared. Mention the potential for confusion with emergency drugs dosed in ratio or percent concentrations alone.
- Use “tall man” lettering to help differentiate EPInephrine from ePHEDrine, and avoid storing the two drugs side-by-side.

## Other Articles

Following is a list of all articles published in the *Patient Safety Advisory* in 2006. These and previous articles are available on the Patient Safety Authority website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

### **Vol. 3, No. 4—December 2006**

Remain Steadfast in Patient Safety Efforts  
 Bone Cement Implantation Syndrome  
 Perforations of the Colon during Colonoscopy  
 Oxygen-Enriched Environments Increase the Fire Risk from Alcohol-Based Hand Sanitizers  
 Purple Glove Syndrome  
 Keeping an Eye on Toxic Anterior Segment Syndrome  
 I’m Stuck and I Can’t Get Out! Hospital Bed Entrapment  
 Confirming Feeding Tube Placement: Old Habits Die Hard  
 Let’s Stop the Bleeding: Preventing Errors with Heparin Therapy

### **Vol. 3, No. 3—September 2006**

Patient Safety Authority Receives 2006 Eisenberg Award  
 Skin Tears: The Clinical Challenge  
 “Sandbags” May Not Be What You Think  
 Looking Beyond the Obvious Causes of Error  
 Delays in the OR: Stress Between “Running Two Rooms” and “Time Outs”  
 Getting Doctors to Report Medical Errors  
 Let’s Stop this “Epi”demic!-Preventing Errors with Epinephrine  
 Foiled Again! Risk from Transdermal Patches in MRI Procedures  
 What the “L” is the Dose?  
 Pressure Ulcers: A Look at Reports to PA-PSRS  
 Rethinking the Routine: Aspiration of Oral Contrast Solution with Bowel Obstruction

### **Vol. 3, Sup. 1—August 2006 Supplementary Advisory**

Update on Use of Color-Coded Patient Wristband Color-Coded Wristband Toolkit

### **Vol. 3, No. 2—June 2006**

Implementing Change Through PA-PSRS  
 Improving the Safety of Telephone or Verbal Orders  
 Abbreviation “Gotchas”  
 Mishaps Involving In-Line or Closed System Suction Catheters  
 Non-Radiopaque Sponges in the Operating Room: How One Department Can Affect Another  
 Hydrofluoric Acid Exposure—A Double Whammy That’s Not Just Skin Deep  
 Threat of Cornea Transplant Contamination  
 Demerol: Is It the Best Analgesic?  
 hydrOXYzene and hydrALazine Mix-Ups  
 Patient Safety in Mental Health: Reports from Behavioral Health Hospitals

**Vol. 3, No. 1—March 2006**

Responding to Adverse Events

Who Administers Propofol in Your Organization?

Letters to the Editor

American College of Surgeons Advocates Blunt Needles for Fascial Closures

The Changing Faces of Unit-Dose Tylenol Packets

Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks

Bioburden on Surgical Instruments

New Guidance on Preventing Anesthesia Awareness

Glacial Acetic Acid: Doing More Harm than Good?

Mix-up between Skin Prep Solution and Adhesive Remover

Electrosurgery Safety Issues

Hold on to These Orders

# **Education, Outreach and Collaboration**

## **Education and Outreach**

As noted earlier, the Board established several goals for the outlying years, including educational initiatives that promote the development of a “culture of safety” within individual facilities as well as specific clinical practices designed to prevent patient harm. In particular, they elected to target three groups for these outreach and promotion efforts: patient safety officers and risk managers; clinicians representing the spectrum of healthcare professionals from physicians and nurses to pharmacists, laboratory workers and technicians; and healthcare executives, with a special focus on CEOs and trustees.

### **Outreach to Facilities and Providers**

Authority staff participated in numerous hospital-based educational programs throughout the year by making presentations to clinical staff about patient safety. Most audiences included physicians, nurses, pharmacists, other healthcare workers and administrators. These presentations and follow up question-and-answer sessions provide an important opportunity to educate providers and managers about the importance of patient safety and the lessons learned from Pennsylvania’s mandatory reporting program. In most cases, attendance at these lectures qualifies participants for continuing education credits.

### **Professional Organizations**

Staff from the Authority was also invited to speak during regional and statewide conferences held by various Pennsylvania professional organizations. These conferences included meetings sponsored by the Hospital and Healthsystem Association of Pennsylvania, Quality Insights of Pennsylvania, the Allied Association Information and Resources Network (A2IRNET) and the Pennsylvania Pharmacists Association. In these cases, as in other meetings in which the Authority participated, the audience included representatives of various health professions, such as nursing, pharmacy, risk management and infection control. The Authority also spoke at a Medical Risk Management Seminar sponsored by the Erie County Medical Society and a local Erie law firm about the importance of patient safety and open disclosure. The Authority also participated in a panel discussion entitled “What’s New in Patient Safety: State Agencies Take Action” for the 19<sup>th</sup> Annual Conference of the National Academy for State Health Policy (NASHP) held in Pittsburgh.

### **PA-PSRS System Training and New User CD Available**

In December, the Authority sponsored a new user training session for the approximate 18 qualifying abortion facilities and providers. The training session was well attended with approximately 20 persons in attendance from 11 facilities. In May and June 2007, PA-PSRS will offer new user training for all Pennsylvania healthcare facilities. The Authority recognizes the need for new user training annually due to employee turnover, new facilities reporting and new employees assisting in reporting. For those who cannot attend the new user training sessions, a New User CD is available through the Authority’s website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

### **Root Cause Analysis Training**

In May 2006, the Authority sponsored an intensive, two-day seminar on Root Cause Analysis. This hands-on workshop was facilitated by a faculty headed by Dr. James Bagian, an internationally recognized safety expert, from Bagian Biomedical Consulting Firm. The curriculum was based on investigation practices that have been successful in the fields of aviation, spaceflight and medicine. The event was well attended with 81 people from 34 facilities— 20 acute care hospitals, eight ambulatory surgical facilities, three behavioral health facilities and three long-term acute care rehabilitation hospitals. An electronic survey was done following the course with overwhelmingly positive responses. For example, 100% rated the instructors as excellent or good in 4 out of 5 categories, and 98% as excellent or good in the 5<sup>th</sup> category; 100% said the training prepared them to participate in an RCA investigation; over 90% said that training prepared them to lead an RCA team; and 82% said the training prepared them to train others on RCA in their facility. Written comments included the following:

- “Ordinarily, selecting ‘excellent’ for all questions decreases the reliability of the survey response. However, in this situation, I feel strongly that the entire conference was, well, excellent. It was a valuable learning opportunity. Great job!”
- “I’ve been attending educational programs for more years than I care to count and this is the first time I enjoyed the ENTIRE program. We are scheduling meetings to review the program so we can prepare to educate facilitators to assist with the process. We have been doing RCA’s for several years. Your program will make this process smoother.”
- “I thought the team of speakers was excellent. I also like the fact that the staff of PA-PSRS sat at our tables during lunch and dinner and talked to us about concerns we had from our facilities. I learned so much and thought the seminar was excellent.”
- “I found this workshop informative and well-presented. I look forward to future educational offerings of the PSA.”

### **Failure Mode and Effects Analysis (FMEA) Workshop**

In 2006, the Authority began preparations to offer a two-day workshop on Failure Mode and Effects Analysis (FMEA) for all PA-PSRS users. Three regional sessions will be held in May and June 2007 in Pittsburgh, Gettysburg and Bethlehem. FMEA is a systematic methodology to proactively identify and evaluate all possible sources of failure in a clinical process and develop focused mitigation strategies to prevent harm. This hands-on workshop will allow teams from participating healthcare facilities to learn together and serve as a core resource to their institutions.

### **PSO Discussion Groups: Insight for Future Projects**

From late 2006 to early 2007, the Authority conducted three regional group discussions with Patient Safety Officers (PSOs) from healthcare facilities throughout Pennsylvania. The purpose of these meetings was to gain insight into how PA-PSRS can best help PSOs improve patient safety and to receive feedback on the current and future direction of PA-PSRS. Approximately 26 PSOs attended the sessions held in Pittsburgh, Central Pennsylvania and Philadelphia.

Participating facilities were asked the following questions during the two-hour meetings: What is the role of the PSO at your facility?; What more could the Authority/PA-PSRS do to help PSOs be more effective?; and How do we know we are making a difference in improving patient safety?

Some of the suggestions PSOs gave the Authority to help them include:

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

Facilities made very positive comments regarding the work of the Authority and PA-PSRS to date. Many attributed their patient safety progress to the Authority and provisions of Act 13. Some of the beneficial changes they or others have undertaken to improve patient safety include:

- After reading published information on the risk of bed entrapment, a technician on a unit in a PSO’s facility took the initiative to assess all beds on the unit. In due course, the beds were updated or changed to reflect the recommendations in the recently published information. “I was just so pleased that that came from a tech,” the PSO said.
- After learning of the risks of using color-coded patient wristbands to communicate patient information from a supplementary issue of the Patient Safety Advisory, a PSO’s facility conducted a failure mode and effects analysis (FMEA) project to determine whether the identified risks were present at their facility. Subsequently, they joined a task force to implement and standardize safe practices for this issue.
- Staff on the behavioral health unit at one PSO’s facility reported problems with patient falls. The task force found that carpeting in the hallway contributed to depth perception problems for certain patients; the carpeting was removed. In addition, the task force discovered that some patient falls were resulting from “sticky floors.” The tacky floors were traced to certain cleaning solutions used by environmental staff; the environmental staff was told of the problem and different cleaning solutions were recommended for use, reducing the unit’s fall rate.
- In another PSO’s facility, misinterpretation of labeling reportedly contributed to a medication error. A patient presented to the emergency department with prescription medications that had been filled by the pharmacy of a department store chain. Pharmacies under this chain labeled medications according to a specific system of numbers; however, at the time, the numbers appeared on the labels in the same location that a majority of pharmacies communicated dosage information. A misinterpretation of the label information resulted in an overdose to the patient. Following the overdose, the PSO’s facility contacted the Institute for Safe Medication Practices (ISMP), which contacted the pharmacy to discuss its labeling practices.

The discussion groups provided the Authority with a vast amount of useful information, particularly in regard to how the educational projects we are embarking upon can most benefit the facilities and their patient safety goals. More importantly, the discussion groups provide a way for PA-PSRS healthcare facilities to stay engaged in the growth of the Authority from a data collector to an educational resource. Their “buy-in” of the PA-PSRS system and what the data has to offer remains an integral part of what makes the information so valuable. In turn, facilities can build “cultures of safety” within their institutions by making *all* of their employees part of the process and achieving the “buy-in” necessary for them to participate in improving patient safety.

For the complete discussion group report, *A Conversation with Patient Safety Officers*, go to the Authority’s website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

### **Workgroup on Pharmacy Computer System Safety**

In December 2006, the Authority announced the Workgroup on Pharmacy Computer System Safety, a statewide online collaborative to help hospitals test the safety of their systems based on a model that the Institute for Safe Medication Practices (ISMP), an Authority subcontractor, has used nationally. Thirty-two hospitals participated in the collaborative. For the test, patient safety officers were provided with a set of unsafe medication orders which, when entered into their pharmacy system, should trigger alerts to the practitioner. The PSO worked with the Director of Pharmacy to complete the test, and the PSO submitted the results online through a web-based form. Participating facilities received a report at the end of the survey that gave their facility’s results along with the de-identified statewide results. The aggregate results were presented at the Patient Safety Authority board meeting held in March during 2007 National Patient Safety Week and are available on the Authority’s website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

## **Collaboration**

Since its founding, the Authority has worked collaboratively with many organizations, both within state government and outside, to promote patient safety. In addition, agencies in other states, the federal government, and national educational and research organizations continue to express interest in the Authority’s activities. Much of this interest is due to Pennsylvania’s unique status as the first and only state to require the reporting of both adverse events and near-misses. The PA-PSRS system is also widely recognized by other states and national health policy

experts for the volume of reports submitted into the database and the quality and usefulness of research published in the *Patient Safety Advisories*.

### **Department of Health**

Under Act 13, the Department of Health receives all reports of Serious Events, and the Authority remains committed to assuring that PA-PSRS meets the Department's regulatory and licensing responsibilities. In addition, in developing PA-PSRS, the Authority expanded the system's capacity to include the submission of what Act 13 defines as "Infrastructure Failure" reports to the Department of Health, even though those reports fall outside the scope of the Authority's responsibility. Throughout the year, Authority staff met regularly with staff from the Department of Health to evaluate the PA-PSRS system and assess how effectively it is meeting the needs of that agency. The Authority will work with the Department of Health and its surveyors to coordinate policy that affects patient safety in Pennsylvania's healthcare facilities.

### **Governor's Office of Healthcare Reform (GOHCR)**

The Authority has partnered with the Governor's Office of Healthcare Reform (GOHCR) to help support Governor Ed Rendell's ambitious healthcare initiative "Prescription for Pennsylvania." The Authority will work with the Pennsylvania Healthcare Cost Containment Council (PHC4) to educate Pennsylvania's healthcare facilities on how to fight hospital-acquired infections (HAI).

In the summer of 2006, the Authority, the Governor's Office of Healthcare Reform (GOHCR), representatives from several cabinet-level offices, the governor's office, and HAP met with David Marx, CEO of Outcome Engineering and proponent of a "Just Culture." The meeting was to introduce policy makers to the basic concepts of "just culture." In the fall, the administration asked for a follow-up meeting with a core group of stakeholders (including PSA Board Chair Ana Pujols-McKee) to ascertain interest in and a commitment to the development of a just culture community in Pennsylvania. The end result of the meetings is that the group gave the green light to proceed with a schedule of monthly meetings beginning in January to develop an implementation plan for the summer. The group would like to start training both healthcare regulators and providers beginning in the fall.

### **State Board of Medicine**

Previously, at the request of the State Board of Medicine within the Department of State, Authority staff met with the State Board, along with a larger audience of physicians, to inform them about the activities and findings of the Patient Safety Authority. In addition, the State Board of Medicine published another column by the Authority Administrator in the State Board's *Newsletter* describing the activities of the Patient Safety Authority and how physicians can benefit from the clinical lessons learned from Pennsylvania's mandatory reporting system.

### **Professional Associations**

The Authority has partnered with the Pennsylvania Medical Society to offer Continuing Medical Education (CME) credits to physicians for articles published in the *Patient Safety Advisory* through a link on the Society's website. A similar partnership exists with Pennsylvania Physicians for the Protection of Specialty Care (3PSC). These initiatives are consistent with the Authority's focus on promoting education and training while enabling physicians to meet Act 13 requirements for patient safety-related continuing education credits.

The Authority also gave a lecture to the University of Pittsburgh Medical Center (UPMC) School of Nursing Graduate Program on Health Policy. One of the Authority's future objectives is to do more educational initiatives geared towards educating the next generation of healthcare providers.

The Authority joined with the Hospital and Healthsystem Association of Pennsylvania (HAP) to cosponsor the 2006 Patient Safety Symposium in March to mark National Patient Safety Week. This well-attended, statewide educational conference was targeted toward patient safety officers, risk managers, physician- and nurse-managers, senior administrators, infection control officers, pharmacists and other clinicians. In 2007, the Authority co-sponsored the event and PA-PSRS staff conducted a breakout session at the symposium entitled "Effective Error Reporting and Analysis through PA-PSRS." The Authority also held a public board meeting at the symposium so that all attendees could see first-hand how the board operates. Presentations were given by PA-PSRS staff regarding results of the Workgroup on Pharmacy Computer System Safety and the discussion groups held earlier in the year with patient safety officers and other high level management staff.

## **Statewide and National Patient Safety Initiatives**

In 2006, the Authority continued to reach out to statewide and national organizations to further improve patient safety. Just as facilities are asked to work together to improve patient safety, the Authority believes it is important for statewide and national organizations to work together as well.

### **Hospital and Healthsystem Association of Pennsylvania (HAP)**

The Authority is currently working with the Hospital and Healthsystem Association of Pennsylvania (HAP) to further its patient safety initiative of engaging hospital boards of trustees in the patient safety effort to form “cultures of safety.” The concept of a “culture of safety” or “just culture” involves finding out why something happened and finding ways to fix it as opposed to simply finding out who made the error. The Authority sent a brochure to all hospital CEOs in September 2006 to introduce them to the work and goals of the Authority and PA-PSRS. The brochure was well received and the Authority received several additional requests for the information.

### **Health Care Improvement Foundation (HCIF) of the Delaware Valley Healthcare Council**

Generated from conversation with PRHI, it was suggested that the Authority work with the Health Care Improvement Foundation (HCIF) on some patient safety initiatives. The Authority and HCIF are currently in discussions regarding HCIF receiving de-identified data from the Authority on various topics from hospitals in Southeastern Pennsylvania. The information will allow HCIF to prioritize patient safety initiatives based upon what areas need the most improvement according to the data.

### **Institute of Healthcare Improvement (IHI) 100,000/5 Million Lives Campaign**

The Authority continued its support as a Pennsylvania node of the “100,000 Lives Campaign”, a national initiative developed by the Institute of Healthcare Improvement (IHI). The program encourages healthcare institutions to implement at least one of six proven healthcare protocols to prevent avoidable death. The 100,000 Lives Campaign has estimated 122,300 lives saved by participating hospitals; over 3,100 hospitals enrolled nationwide and 60 percent or better participation in the six campaign interventions.

In 2006, IHI expanded its campaign by going after harm in healthcare facilities. The “5 Million Lives Campaign” asks participating hospitals to prevent five million incidents of medical harm over the next two years. Along with continuing the six interventions from the 100,000 Lives Campaign, the new campaign adds new interventions targeted at harm. They include: preventing pressure ulcers; reducing Methicillin-Resistant Staphylococcus aureus (MRSA) infection; preventing harm from high-alert medications; reducing surgical complications; delivering reliable, evidence-based care for congestive heart failure; and getting hospital Boards of Trustees to support patient safety as a primary goal. Partners in the Pennsylvania Node include the Hospital and Healthsystem Association of Pennsylvania (HAP), VHA Pennsylvania, VHA East Coast, Hospital Council of Western Pennsylvania, Quality Insights of Pennsylvania and the Health Care Improvement Foundation of the Delaware Valley Healthcare Council, in addition to the Patient Safety Authority. Approximately 140 Pennsylvania hospitals are enrolled and participate in the “5 Million Lives Campaign.”

In 2006, the Authority met with representatives of the IHI campaign and HAP to discuss possible initiatives in helping facilities reach their goals in reducing harm. The Authority will provide data to help facilities prevent high-alert medication errors and also work with HAP to find hospital board “champions” of patient safety to serve as role models for other Pennsylvania hospitals.

### **Pennsylvania General Assembly**

The Authority recognizes the important role the Pennsylvania General Assembly plays in helping improve patient safety. The obvious role is in crafting legislation, such as Act 13, that subsequently created the Authority. However, another role, just as important, is helping patient safety organizations raise public awareness on important patient safety issues. In 2006, the Authority distributed informational pieces designed to educate the public about the importance of participating in their own health care. The first piece, a Speak Up™ brochure, developed by the Joint Commission gave the public advice on how to fully participate in their healthcare. Legislators from across the state joined health care facilities and organizations in spreading the word about the importance of participating in discussions about your healthcare treatment. The Authority also developed a consumer page on its website with a list of links to guide consumers to state and national organizations that have a primary focus on patient safety. The legislature was also instrumental in making their constituencies aware of the patient safety consumer information.

Finally, the Authority developed a “Who We Are” brochure that contained several real-life case studies based on PA-PSRS reports. The piece, geared toward the consumer, introduced the Authority and its work to the public-at-large for a better understanding of what we do. The legislature received several copies of the brochure for distribution in their district offices. A member of the Patient Safety Authority Board of Directors also spoke at a public hearing held in June 2006 by the House of Representatives. The hearing gave the Authority an opportunity to discuss with lawmakers the progress made by the Authority since its inception and insight into what objectives lie ahead for further patient safety improvements.

### **Pennsylvania Healthcare Cost Containment Council (PHC4)**

Through an ambitious healthcare agenda set forth by the Governor’s Office of Healthcare Reform, the Authority is meeting with the Pennsylvania Healthcare Cost Containment Council (PHC4) to discuss educational infection reduction initiatives to help combat the infection rates in Pennsylvania healthcare facilities. Further opening the lines of communication between the two agencies, Patient Safety Authority Chair, Dr. Ana Pujols-McKee, has recently been asked to serve as a councilmember of PHC4.

### **Pennsylvania Patient Safety Forum**

The Authority was a founding member of the Patient Safety Forum, a partnership of several dozen public and private sector entities, facilitated by the Pennsylvania Medical Society. This statewide collaborative provides a vehicle for organizations and individuals to discuss issues related to patient safety and initiate programs that enhance the safety of patients in Pennsylvania.

### **Pennsylvania eHealth Initiative**

The Authority was also a founding member of the PA eHealth Initiative, a collaborative statewide effort of several dozen organizations committed to promoting the development and adoption of electronic health records within the Commonwealth. This is consistent with the federal government’s plan to improve the country’s health IT infrastructure within the next ten years. The Initiative includes stakeholders representing healthcare organizations, professional associations, information technology businesses, insurers and other payers, government agencies and individual providers, among others.

### **Pittsburgh Regional Healthcare Initiative (PRHI)**

The Authority staff met with representatives from the Pittsburgh Regional Healthcare Initiative and a business consultant/professor at Carnegie Mellon University to discuss possible partnership activities. The discussion generated many possible opportunities to work together that include helping Pennsylvania healthcare facilities reduce infections. The Authority also participated in a panel discussion with PRHI entitled “What’s New in Patient Safety: State Agencies Take Action” for the 19<sup>th</sup> Annual Conference of the National Academy for State Health Policy (NASHP) held in Pittsburgh.

### **U.S. Pharmacopoeia (USP) and University HealthSystem Consortium (UHC)**

The PA-PSRS clinical staff is working with the U.S. Pharmacopoeia (USP) and University HealthSystem Consortium (UHC) on a research project related to the use of Heparin. The project’s objective is to identify types of problems reported to patient safety reporting systems involving heparin use in the acute-care hospital environment and to suggest strategies for reducing the risk to patients. Quantitative analysis of frequency and severity will be used to identify the most significant types of events and develop risk mitigation strategies. In the aggregate, the Authority, USP and UHC constitute a large data resource of adverse events and near misses from hospitals throughout the United States.

### **Reporting in Other States**

Healthcare administrators and policy makers in other states continue to look at Pennsylvania’s legislation and patient safety initiatives as their states evaluate steps they can take to improve patient safety within their healthcare systems. In 2006, the New York Department of Health, including the senior patient safety manager who oversees the NYPORTS (New York Patient Occurrence Reporting and Tracking System) reporting system, met with Authority staff to discuss PA-PSRS and Pennsylvania’s patient safety initiatives. The Authority was also contacted or visited by staff from other states, including Alabama, Florida, Hawaii, Illinois, Indiana, Maryland, New Jersey, Ohio, Oregon, Vermont and Washington as well as representatives from the Swiss federal government, Norwegian Health Ministry and the United Kingdom.

The RAND Corporation released a report, “A Review of State-Level Adverse Medical Event Reporting Practices: Toward National Standards,” which was prepared under contract for the federal Agency for Healthcare Research and Quality (AHRQ). The report focuses on existing state reporting systems and appears to be designed to provide AHRQ with options that can be replicated, adapted or copied verbatim should that agency move forward with a national reporting system. RAND was very interested in what we are doing in Pennsylvania. To quote from the report, “The PA-PSRS system is perhaps the most extensive reporting system in the United States. This comprehensive database could yield substantial amounts of information. . .PA-PSRS personnel will also have substantial expertise and experience in analyzing patient safety information that could be shared nationally.”

### **Speaking to National Patient Safety Organizations**

Throughout the year, Authority staff was invited to participate in various meetings and work groups held by such groups as the National Quality Forum, the National Patient Safety Foundation and the National Academy for State Health Policy. In addition to making presentations to these groups about the lessons learned through the PA-PSRS system, Authority staff also participated in educational seminars sponsored by the Robert Wood Johnson Foundation, Association for Professionals in Infection Control and Epidemiology (APIC), the Allied Association Information and Resources Network (A2IRNET) and the Pennsylvania Pharmacists Association.

Authority staff also met with policy makers and senior managers of various national groups to develop partnerships and discuss opportunities to promote the sharing of patient safety data and research findings. These included representatives from the federal Agency for Healthcare Research and Quality (AHRQ), University HealthSystem Consortium (UHC), U.S. Pharmacopoeia (USP) and the Institute for Healthcare Improvement (IHI).

In addition, because AHRQ has been charged by the U.S. Secretary of Health and Human Services to take the lead on implementing the patient safety reporting requirements of the federal Patient Safety and Quality Improvement Act (PSQIA) of 2005, Authority staff continue to meet with officials of that agency, at their request, to explain the technical and practical components of the PA-PSRS system. More information about the PSQIA can be found in “Federal Legislation” on page 71.

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## **Other Items**

### **Patient Safety Legislation and Recommendations for Statutory or Regulatory Change**

#### ***Federal Legislation***

On June 29, 2005, the President signed into law the Patient Safety and Quality Improvement Act (PSQIA) of 2005 (P.L. 109-41). The goal of this federal legislation is to improve patient safety and reduce the occurrence of events that adversely affect patient safety. An integral component of the law is the establishment of so-called "Patient Safety Organizations" throughout the country through which healthcare organizations will be able to voluntarily submit reports of adverse events. This information will be considered privileged and confidential and, in the aggregate, will be available to researchers for analysis of regional and national trends.

Federal agencies, most notably AHRQ, have been charged with defining the requirements and protocols for implementing the PSQIA statute. Concurrently, several non-governmental agencies, most notably NQF, are working to finalize common definitions and taxonomies related to the reporting of medical errors. Their conclusions and recommendations will likely have a significant impact on the final requirements and regulations of the PSQIA. To the extent possible, Authority staff is participating in these discussions by sharing Pennsylvania's experience with developing and implementing a reporting and analysis system with officials from these organizations.

#### ***Pennsylvania Legislation***

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

Also in 2006, the House introduced Resolution 550 calling for the Department of Health to study, review and make recommendations relating to standardizing color-coded patient wristbands. The resolution called for DOH to submit its findings and conclusions of the study no later than July 31, 2006. The resolution was never adopted and thus a study wasn't completed.

Previously, the House and the Senate unanimously passed House Bill 2041, which became Act 88 of 2005 when it was signed into law by the governor on December 22, 2005. Among its provisions is language that specifically defines the Authority as "an independent agency" under a Board of Directors "which shall have the sole power...to employ staff, including an executive director, legal counsel, consultants or any other staff deemed necessary...." The legislation also confirmed that Authority staff would be eligible for employee benefits provided to other Commonwealth employees. The Authority is moving forward with implementing these new provisions.

Act 88 also designated the Authority as "the sole public entity eligible to be certified as a Patient Safety Organization (PSO)" as defined in the federal law. Until AHRQ releases specific details about PSQIA, it is premature to predict how this designation might impact the day-to-day activities of the Patient Safety Authority. However, the Authority anticipates that a confidential federal reporting system will enhance patient safety and quality outcomes within Pennsylvania's healthcare institutions.

#### ***Recommendations for Change***

Act 13 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 recommendations for statutory or regulatory change. The Board has recently completed a strategic planning process. Two objectives on which the Board has decided are: 1) to issue formal recommendations that provide guidance to facilities about how

to reduce adverse events, and 2) to improve the consistency among facilities about the types of events that should be reported under Act 13. Achieving these objectives may involve recommendations for statutory or regulatory change.

## **Anonymous Reports**

Act 13 includes an important provision that permits individual healthcare workers to submit what Act 13 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 requires facilities to make Anonymous Report forms available to healthcare workers. The Authority also makes those forms available on the PA-PSRS website, which is accessible without a password. The reporting form is a simple, one page questionnaire.

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.

Act 13 requires that the Annual Report include the number of Anonymous Reports filed and reviews conducted by the Authority.

The Authority received no Anonymous Reports in 2006 that complied with Act 13 requirements.

## **Referrals to Licensure Boards**

Act 13 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 2006. 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 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 December 31, 2006, 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: Gilbertsville (Montgomery County)  
Pharmacist appointed by the Governor: Gary A. Merica, R.Ph.  
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 requires the Board of Directors to meet at least quarterly. During 2006, the Board met frequently. Representatives of healthcare, consumer and other stakeholder groups, including the General Assembly, have attended and spoken at many public meetings. Following are the dates of all public meetings held by the Authority during 2006:

January 10, 2006  
February 6, 2006  
March 14, 2006  
April 11, 2006  
June 13, 2006  
August 8, 2006  
September 12, 2006  
November 14, 2006  
December 12, 2006

Minutes of the public meetings are available on the Authority's website at [www.psa.state.pa.us](http://www.psa.state.pa.us) or through PA PowerPort, Keyword: Patient Safety

## **Fiscal Statements and Contracts**

Act 13 establishes the Patient Safety Trust Fund as a separate account in the State Treasury. Under Act 13, funds in the Patient Safety Trust Fund are administered by 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.

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 and ambulatory surgical 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 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 analytical tools that provide immediate, real-time feedback to facilities about their own adverse event and near-miss reports and activities. In 2006, a report was added that aggregates reports into National Patient Safety Goal categories. Facilities can use these tools for their internal patient safety and quality improvement programs. In addition, the Authority publishes the 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 provided world class root cause analysis training at greatly reduced cost to facilities by underwriting a program by noted safety expert, Dr. James Bagian. By directly offering clinical guidance and feedback 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 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. However, in all subsequent years, the Authority has recommended a partial assessment of \$2.5 million each year because that reduced amount has been adequate for ongoing operations, including numerous new programs, of the Patient Safety Authority. This partial assessment reduces the cost to Pennsylvania’s healthcare facilities.

Act 13 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 <sup>1</sup>
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 <sup>2</sup>
2005-06	450 <sup>3</sup>	\$ 2,499,906	\$ 2,500,149

<sup>1</sup>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.

<sup>2</sup>Total assessments received are greater than assessments made because some funds received were late payments for the previous year’s assessment.

<sup>3</sup>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 differences in the dates chosen to calculate the number of facilities for these two different purposes.

The following table summarizes Authority expenditures during 2006. Almost all expenditures included in Object Code 300 (Operating Costs) are associated with the contracts that are identified in the next section.

Actual Expenditures for 2006

Major Object Code	Amount
100: Personnel	\$ 267,913
300: Operating	\$ 2,805,250
400: Fixed Assets	\$ 0
TOTAL	\$ 3,073,163

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

During calendar year 2006, 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 # 4500304559 dated March 2, 2006  
(Software – VLA WINDOWS SRVR STD 2003 R2 ENG)  
Contract Amount: \$576.16  
Amount Expended in 2006: \$576.16

ASAP Software  
PO #4500323774 dated May 4, 2006  
(Software – GALAZY PREMIER SUPP- PSA share of cost .6%)  
Contract Amount: \$3,156.12  
Amount Expended in 2006: \$18.94

ASAP Software  
PO #4500329549 dated May 22, 2006  
(Software – PA DFM DISKNET PRO ENT- PSA share of cost .6%)  
Contract Amount: \$27,104.03  
Amount Expended in 2006: \$162.62

Computer Aid Inc.  
PO # 4500251055 dated September 1, 2005  
(Staff Augmentation for Senior Consultant 9/1/05 – 8/31/06)  
Contract Amount: \$263,125.00  
Amount Expended in 2006: \$194,750.00

Computer Aid Inc.  
PO # 4500351099 dated September 1, 2006  
(Staff Augmentation for Senior Consultant 9/1/06 – 4/11/07)  
Contract Amount: \$160,750.00  
Amount Expended in 2006: \$57,031.25

Department of State  
MOU #4000005306 July 1, 2003  
(Ongoing Memorandum of Understanding for support services in the areas of fiscal management, human resources and procurement/contracting)  
Contract Amount for each year: \$15,000.00  
Amount Expended in 2006: \$15,000.00

D S Water LP  
PO \$4500228150 dated July 1, 2005  
(Water delivery and cooler rental – Expired 6/30/06)  
Contract Amount: \$139.60  
Amount Expended in 2006: \$57.35

D S Water LP  
PO \$4500228150 dated July 1, 2006  
(Water delivery and cooler rental)  
Contract Amount: \$41.25  
Amount Expended in 2006: \$17.64

ECRI  
FC # 4000005348 dated September 19, 2003  
(Five-year contract for technical and clinical assistance in developing, implementing and maintaining a statewide reporting system as required under Act 13).

Contract Amount for FY2005-06 - FY2006-07: \$5,719,358.76  
Amount Expended in 2006: \$2,067,631.90

EPLUS Technology Inc  
PO4500328404 dated May 18, 2006  
(4800 Series Transfer Kit/Image Fuser Kit)  
Contract Amount: \$395.78  
Amount Expended in 2006: \$395.78

EPLUS Technology Inc  
PO4500338092 dated June 22, 2006  
(CISCO Secure ACS-PSA share of costs .6%)  
Contract Amount: \$17,759.82  
Amount Expended in 2006: \$81.35

EPLUS Technology Inc  
PO4500367937 dated October 10, 2006  
(CISCO Secure ACS-PSA share of costs .6%)  
Contract Amount: \$20,920.34  
Amount Expended in 2006: \$100.32

IBM Corporation  
PO4500304520 dated March 1, 2006  
(IBM xSeries Server)  
Contract Amount: \$4,432.72  
Amount Expended in 2006: \$4,432.72

McKissock and Hoffman, PC  
FC #4000006774 dated July 19, 2004  
(For legal counsel)  
Contract Amount for FY2005-06: \$200,000.00  
Amount Expended in 2006: \$15,650.78

OCE Imagistics  
PO4500279271 dated February 1, 2006  
(Copier Lease – Service Period 2/1/06-1/31/09)  
Contract Amount: \$8,958.24  
Amount Expended in 2006: \$1,645.26

OCE Imagistics  
PO4500325603 dated May 10, 2006  
(Staples for IM2520 Copier)  
Contract Amount: \$167.20  
Amount Expended in 2006: \$167.20

OES Inc  
PO4500257465 dated September 9, 2005  
(Consulting Services – Service Period 9/9/05-6/3/07)  
Contract Amount: \$22,000.00  
Amount Expended in 2006: \$7,905.00

PRK MOR Inc  
FC # 4900000796 dated January 5, 2004  
(Parking Lease)  
Contract Amount: \$2,660.00  
Amount Expended in 2006: \$ 2,660.00

RICOH Corp  
PO # 4500020782 dated December 19, 2002  
(Copier Lease –3Yr Contract; Contract expired December 31, 2005)  
Contract Amount for FY2004-05 –FY2005-06: \$8,999.64  
Amount Expended in 2006: \$249.99

The Hospital Health System  
PO #4500304671 dated March 7, 2006  
(Co-Sponsor Annual Patient Safety Symposium)  
Contract Amount: \$6,000.00  
Amount Expended in 2006: \$6,000.00

United Parcel Service  
PO #4500229389 dated July 1, 2005  
(Ground Delivery-Multiple Agencies Expired 6/30/06)  
Contract Amount: \$57,985.00  
Amount Expended in 2006: \$649.50

United Parcel Service  
PO #4500334325 dated July 1, 2006  
(Ground Delivery-Multiple Agencies Expires 6/30/07)  
Contract Amount: \$61,337.00  
Amount Expended in 2006: \$323.20

Veritas Software Global  
PO #4500304671 dated March 3, 2006  
(Software-VER B/U EXEC 10D WIN SVR CPS MLP)  
Contract Amount: \$7,479.50  
Amount Expended in 2006: \$7,479.50

York Stenographic Services, Inc.  
PO # 4500228937 dated July 1, 2005  
(Stenographic services)  
Contract Amount: \$8,213.83  
Amount Expended in 2006: \$4,052.36

York Stenographic Services, Inc.  
PO # 4500359985 dated September 13, 2006  
(Stenographic services)  
Contract Amount: \$4,565.75  
Amount Expended in 2006: \$1,522.59

The following Balance Sheet reflects the status of the Patient Safety Trust Fund as of December 31, 2006.

Patient Safety Trust Fund Balance Sheet (Unaudited)  
As of December 31, 2006

<b>ASSETS</b>	
Cash	\$ 0.00
Cash in Transit	(3,052.01)
Short Term Investments @ Market (Pool 98)	3,401,512.34
<b>TOTAL ASSETS</b>	<b>\$ 3,398,460.33</b>
<b>LIABILITIES AND FUND BALANCE</b>	
<b>Liabilities:</b>	
Accounts Payable and Accrued Liabilities	\$ 21,337.59
Invoices Payable	21,323.60
Accrued Payables Goods Receipt	18,842.11
<b>TOTAL LIABILITIES</b>	<b>\$ 61,503.30</b>
<b>Fund Balance:</b>	
Reserved for Encumbrances	\$ 3,042,080.84
Total Reserved	3,042,080.84
Unreserved – Undesignated	294,876.19
<b>TOTAL FUND BALANCE</b>	<b>\$ 3,336,957.03</b>
<b>TOTAL LIABILITIES AND FUND BALANCE</b>	<b>\$ 3,398,460.33</b>

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



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