



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

An Independent Agency of the Commonwealth of Pennsylvania

# 2005 Annual Report

April 28, 2006



# Letter from the Board Vice-Chair



An Independent Agency of the Commonwealth of Pennsylvania

April 28, 2006

Dear Fellow Pennsylvanians:

The Patient Safety Authority continues working to help reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.

During 2005, the Authority collected almost 170,000 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, identifying trends and recommending steps that hospitals and individual providers can take to help prevent future medical errors. Their findings were published in the Authority's *Patient Safety Advisory*, which in 2005 carried more than 60 scholarly articles on specific events reported through PA-PSRS. Pennsylvania citizens can be proud that this important quarterly journal serves as a clinical resource to the healthcare community, disseminating information about actual events and sharing best practices on healthcare delivery, patient outcomes and quality improvement.

Pennsylvania continues to gain national attention because of the Commonwealth's innovative approach to patient safety. We remain the only state to require the reporting of both adverse events and near-misses, and information contained in the Patient Safety Advisories is widely disseminated around the country and frequently cited by healthcare providers and publications.

As a member of the Authority's Board of Directors and acting chair, I know that this group represents diverse interests and professions. But, I also know that we share a common vision of promoting patient safety and while there is certainly more work to do, we also recognize how much we've accomplished in the short time since this agency was established. Not surprisingly, much of the credit goes to the Authority staff and we thank them for their hard work, diligence and ongoing commitment to the field of patient safety.

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

Lorina Marshall-Blake  
Vice Chair  
Board of Directors



An Independent Agency of the Commonwealth of Pennsylvania

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

*“Pennsylvania is to be commended for developing and implementing its new patient safety reporting system. By following the recommendations outlined in the Institute of Medicine’s 1999 report, Pennsylvania has taken steps that should not only improve patient safety in their state, but result in lessons for other states interested in setting up similar systems.”*

Marge Keyes  
U.S. Agency for Healthcare Research and Quality

*“Having analyzed state patient safety reporting systems, I believe Pennsylvania’s approach through PA-PSRS is innovative in including both adverse events and near misses, and in its capacity for analysis. The reporting system should prove to be useful in identifying best practices that have the potential to improve patient safety.”*

Jill Rosenthal  
National Academy for State Health Policy

*“I think we’re going to see in the Pennsylvania model a way to use mandatory reporting in a positive way that will make a difference.”*

Lucian Leape, MD  
Harvard University

*“Researchers also noted that Pennsylvania has been a leader in patient safety since the passage of the state’s Medical Care Availability and Reduction of Error Act...[which] established many new initiatives including the formation of a Patient Safety Authority to collect and analyze serious events and incidents....”*

National Report Card on the State of Emergency Medicine  
American College of Emergency Physicians (ACEP)

*[The Authority is the] first state agency in our country to review patient care performance issues and suggest procedural changes toward long-term improvements....The Pennsylvania Medical Society commends the comprehensive and outstanding work accomplished by the ...Authority during its first three years of operation. We anticipate equally successful patient-focused achievements by the Authority in the future.”*

Mark A. Piasio, MD  
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 and birthing centers. 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.

During 2005, the Patient Safety Authority turned its focus from the implementation of the Pennsylvania Patient Safety Reporting System (PA-PSRS) to expanding its research and educational outreach activities that promote its goal of reducing and eliminating medical errors. While much of the Authority’s effort in 2004 was dedicated to the development and implementation of PA-PSRS, efforts in 2005 were related to fine-tuning and enhancing PA-PSRS, analyzing the data received through the reporting system, disseminating information and best practices learned through that analysis, and increasing patient safety educational activities for healthcare professionals.

## PA-PSRS Research Promotes Change in Pennsylvania Facilities

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. More than 60 scholarly articles about specific events submitted through PA-PSRS were published in 2005. The *Advisory* is distributed electronically throughout the Commonwealth and around the country. It is also accessible on the Authority website.

Through survey conducted by the Authority in the fall of 2005, Patient Safety Officers confirmed the *Advisories* were a valuable resource. Nearly 75% of hospital respondents said they had implemented changes in their facility’s practices as a result of information from the *Advisory*.

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

- Raised awareness statewide and nationally of the risks associated with using color-coded wristbands when a patient nearly died in a Pennsylvania hospital due to confusion caused by the color of the wristband. The Authority is working with several other states and national health policymakers to try to resolve this issue.
- Focused attention on *Clostridium Difficile*, a potentially fatal bacterial infection found in both healthcare settings and the community at-large. Because the article contained clinical treatment and prevention protocols, the Authority targeted special mailings to get the information in the hands of as many hospital administrators, infection control managers, patient safety officers, physicians, nurses and other healthcare workers as possible.
- Demonstrated real-life cases where patients or loved ones spoke up and helped prevent medical errors while they were in the hospital. In these examples, having a family member act as an advocate helped prevent medical errors that could have resulted in patient harm.
- Identified the importance of discharge instructions when patients are released following medical procedures at ambulatory surgical facilities. The article focused on incidents where patients required hospital-level care within hours or days of treatment and contained important tips for both healthcare workers and patients/families on ways they can reduce the chance of post-discharge complications.

Because the Authority's research findings are disseminated widely through the *Patient Safety Advisories*, the "lessons learned" benefit not only Pennsylvania-based healthcare providers and facilities, but also healthcare professionals throughout the country and abroad. As Francis V. Dono, DO, medical director for an eight-hospital health system in a nearby state, wrote:

*The Patient Safety Advisory has been an outstanding resource for me and our health system. The articles are timely and address the important aspects of patient safety. As Medical Director of Patient Safety and Quality at OhioHealth, I share the Advisory with senior leadership, patient safety councils and medical staff leadership, including the house staff. The "lessons learned" are excellent examples for our staff. More states should embark upon this safety journey.*

## **The Authority Increased Education and Outreach Efforts to Promote a "Culture of Safety"**

Following implementation of the reporting system, and with report collection and analysis ongoing, the Authority has embarked on new education and outreach initiatives to improve patient safety in Pennsylvania's healthcare facilities.

Patient safety remains a concern for both healthcare professionals and the general public. In a Fall 2005 statewide survey of adult Pennsylvania residents sponsored by the Authority and conducted by the Penn State Center for Survey Research, more than half of respondents said that they were "very" or "somewhat" worried about the safety of their medical care, and one-third of respondents reported that they or a family member had been personally involved in a preventable medical error. Only 23% of those who experienced a medical error said the healthcare worker involved had disclosed the error to them. These findings validate the need for the Authority to promote patient safety through education and training programs for healthcare professionals and administrators.

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; and facilitated access to continuing education credits for physicians and other healthcare professionals.

The Patient Safety Authority Board plans to continue and expand its focus on educational programs by sponsoring an intensive two-day seminar on Root Cause Analysis. The seminar will help facilities get to the "root causes" of events that happen in their facilities, allowing them to learn from those events and prevent them from happening again.

The Authority believes 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.

Results from the Patient Safety Authority's Fall 2005 survey suggest that Act 13 and the Patient Safety Authority have helped to promote a culture of safety in Pennsylvania hospitals and Ambulatory Surgical Facilities. More than 80% of the Patient Safety Officers responding to the survey credited Act 13 with improving the culture of safety within their facilities. Equally important, almost 70% 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 goals in 2005 for the future that include promoting a "culture of safety" within individual healthcare facilities. 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.

## Improving the PA-PSRS System to Facilitate Reporting

Consistent with its core mission, the Authority collected and analyzed data submitted by Pennsylvania's 440 hospitals, ambulatory surgical facilities and birthing centers. These facilities submitted 169,072 reports of Serious Events (actual adverse events) and Incidents (often called near-misses) through PA-PSRS in 2005, with approximately 96% of the events classified as Incidents.

Monthly report volume in 2005 showed an increase of almost 26% over 2004. Analysts attribute this increase to improved adherence by healthcare facilities to Pennsylvania's mandatory reporting requirements, rather than to an increase in the number of actual events that occurred. Also, as Incidents increased at a greater rate than Serious Events, PA-PSRS analysts attribute this to an increased acknowledgement by healthcare workers that a near-miss had occurred.

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

A few examples of these enhancements include:

1. Providing PSA funding and staff time in order to facilitate an electronic interface to PA-PSRS for those facilities with existing electronic reporting systems, which will allow them to submit reports only once while still meeting their obligations under Act 13.
2. Augmenting the reporting system with a 6,000-item list of drug names to reduce input errors when submitting reports of medication errors and adverse drug reactions.
3. Offering PA-PSRS basic training for all new Patient Safety Officers and others who are assigned to input event reports to ensure they understand how to use the system.

The Authority also 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.

## Patterns and Trends in PA-PSRS Reports

When reporting an event to PA-PSRS, a facility uses a classification system or "taxonomy" to characterize the occurrence they are reporting. 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?" 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 2005 by their Event Type.

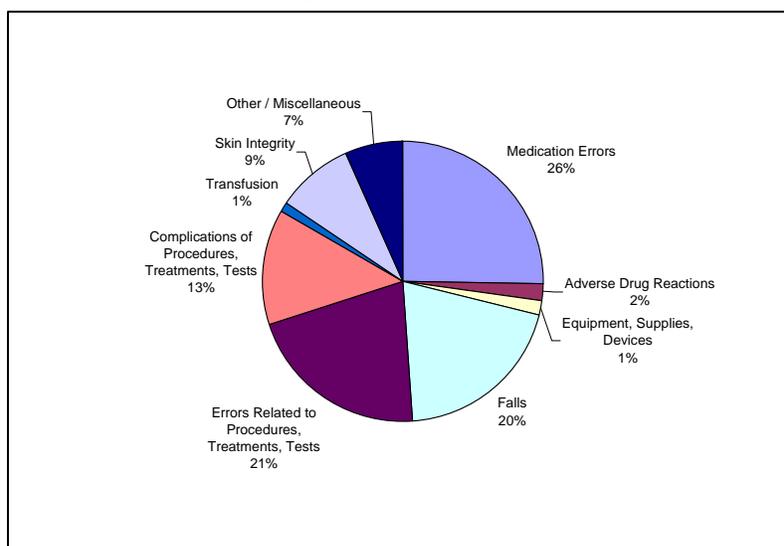


Figure 1. Distribution of Reports by Event Type (2005)

Other highlights of data submitted through PA-PSRS during calendar year 2005 are:

- 440 hospitals, birthing centers and ambulatory surgical facilities were subject to Act 13 reporting requirements. They submitted 169,072 reports of Serious Events and Incidents through PA-PSRS, an increase of 26% over 2004.
- Ninety-six percent of all reports were Incidents, in which the patient was not harmed; 4% of all reports were Serious Events, which indicates that the patient received some level of harm, ranging from minor, temporary harm to death.
- Reports from hospitals accounted for 98.8% of all reports submitted.
- When evaluated regionally, the largest numbers 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 counties submitted the largest number of reports. This does not necessarily suggest that facilities in that region were less safe than facilities elsewhere in the Commonwealth, but that those facilities may be more aggressive in identifying reportable events. This interpretation is supported by the observation that the difference in the number of reports submitted from the Northcentral counties involves Incidents, not Serious Events.
- Other regional variations are apparent with reports related to healthcare-associated infections (HAIs). The largest number of these reports comes from Southwestern Pennsylvania, where facilities submitted nine HAI-related reports per 10,000 patient days, a much higher volume than represented by other regions of the state. This volume can be attributed to a major regional initiative in the Southwest, sponsored by the Pittsburgh Regional Healthcare Initiative, to reduce incidence of HAIs within area hospitals.
- Statewide, the most frequently reported events in hospitals involved Medication Errors and Falls. However, Complications and Errors from procedures, treatments or tests represented the most frequently reported events from ambulatory surgical facilities and birthing centers.
- While patient Falls accounted for 21% of all reports, they only accounted for 4% of all Serious Events.
- Complications related to procedures, treatments or tests accounted for 38% of all Serious Events, up from 31% in 2004.
- 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 2005, 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.
- Medication Errors accounted for 25% of all reports (unchanged from 2004), but they represented only 1% of all Serious Events. That means that, in almost 99% of the cases, no patient was harmed by a medication error. Although most medication errors involve adults, medication errors involving children and adolescents were more likely to result in patient harm.

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

## Introduction and Acknowledgments

Much of the current interest in patient safety is a response to the publication by the Institute of Medicine (IOM) of its seminal report, *To Err Is Human*, at the end of 1999. That report generated considerable attention by the public, the media, healthcare providers, government officials and policy makers. Of significance to Pennsylvanians, the General Assembly enacted Act 13 of 2002 in no small measure in response to the IOM report, establishing and charging the Patient Safety Authority with taking steps to reduce medical errors and improve patient outcomes.

During 2005, many of the individuals and organizations who were propelled toward patient safety activities as a result of the IOM report took the opportunity to look back over the intervening five years to ask the obvious question: Are we safer today than we were before the IOM report was released?

There was a spate of articles on this topic in newspapers, scholarly publications and popular periodicals; academicians and policy makers appeared on television news and interview shows; and it seemed that at least one keynote address at every national meeting devoted to health, health policy and public affairs was devoted to evaluating the progress the health industry had made to improve patient safety over the previous five years.

The conclusions reached by most national scholars did not suggest much progress, but these same scholars also acknowledged that the healthcare industry had taken several initial steps that would hopefully generate ongoing quality improvement and patient safety initiatives. Among those steps was: 1) the recognition that most adverse events are the result of “systems” problems, not individual failings, and 2) acknowledgement that the public—specifically patients and their families—deserve meaningful answers to questions they ask when they or a loved one is the victim of an unexpected adverse event or medical error.

That has been the focus of the Patient Safety Authority—not to record numbers *per se*, but to look at the lessons that can be learned from an event and to implement appropriate protocols to avoid future mistakes. To that end, the work our staff performs on a daily basis is meant to support full and open disclosure of adverse events by healthcare providers, promote individual and institutional accountability, and facilitate a healthcare environment that encourages learning and quality improvement. As administrator of this program, I believe we have taken some of those initial steps to improve patient care, and I hope that the information included in this report will demonstrate some of these accomplishments.

The Authority is fortunate to have a dedicated staff engaged in the PA-PSRS project and the other work of this agency. To the extent that I can thank them, I want to mention some of these individuals by name. First, Mike Doering serves as PA-PSRS project manager, ably overseeing a myriad of technical, programmatic and administrative activities related to the program. His counterpart at ECRI, Bill Marella, plays an equally important role in ongoing program maintenance and development. Bill, too, is largely responsible for much of this Annual Report. Dr. John Clarke, PA-PSRS clinical director and editor of the *Patient Safety Advisory*, provides direction and valuable insight through his experiences both as a clinician and an authority on data collection and analysis.

Other members of the PA-PSRS team whom I want to mention by name include the following: at ECRI: Art Augustine, Courtney Bowman, Monica Davis, Ed Finley, John Hall, Jan Johnston, Evelyn Kuserk, Miranda Minetti and Ronni Solomon; at ISMP: Hedy Cohen, Mike Cohen, Michael Gaunt, Matt Grissinger and Allen Vaida; and at EDS: John Cacchiani, Tom Ignudo, Ben Kramer, Rich Marquette, Max Oligane, Carly Piatt, Badal Sanghvi and Holly Weaver. To each of you, a hearty and deeply felt “thank you” for a job well done.

Alan B.K. Rabinowitz  
Administrator  
Patient Safety Authority

## 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.

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.

Recently, the conversation about creating a “culture of safety” has expanded to include renewed emphasis on accountability among both individual providers and institutions. Dr. Lucian Leape, physician and Harvard professor who is considered the “father” of patient safety, published several articles in the past year on the moral imperative for physicians to be open, honest and accountable for their actions.<sup>1</sup> In a similar approach, David Marx, an attorney and engineer with experience in aviation and healthcare safety, widely champions the development of what he calls a “just culture” where both providers and regulators agree on a common approach to unanticipated events by balancing full disclosure and accountability with regulatory restraint.

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NOTE: There are numerous state and national organizations whose primary focus is patient safety. They include advocacy groups, healthcare and provider associations, federal agencies, foundations and partnerships. Their websites provide useful information, other resources and additional linkages related to patient safety. You can access many of these organizations through the Authority’s website ([www.psa.state.pa.us](http://www.psa.state.pa.us)) under Links.

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<sup>1</sup> See, in particular, L. Leape, “Ethical Issues in Patient Safety” *Thoracic Surgery Clinics*. 2005 Nov;15(4): 493-501.

# Activities During 2005

## Background

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 and birthing centers. 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 and ambulatory surgical facilities—currently totaling more than 450 facilities—must report what the Act defines as “Serious Events” (actual adverse events) and “Incidents” (so-called “near-misses”).<sup>2</sup> 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 what are called “Anonymous Reports” if they believe that healthcare facilities are not acting appropriately in response to a Serious Event within the facility.

Statewide mandatory reporting went into effect in June 2004, making Pennsylvania the first state in the nation to require the reporting of both actual adverse events and near-misses. By the end of 2005, Pennsylvania healthcare facilities had submitted nearly 240,000 reports of Serious Events and Incidents through PA-PSRS, with average monthly reports over 13,000.

## Program Administration

Having developed and implemented an electronic reporting system during the previous year, in 2005 the Authority focused on other initiatives to improve patient care and enhance patient safety for the citizens of Pennsylvania.

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“This is an excellent, well administered program.”

From a Patient Safety Officer  
in Somerset County

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The Authority’s Board of Directors held nine public meetings throughout the year, including one in suburban Philadelphia. The Board intends to hold at least one meeting each year in a location outside of Harrisburg. This

will allow interested stakeholders and individual citizens an opportunity to observe official Board activity and to speak to the Board, if they choose, prior to any Board vote or during the public comment period included on each meeting’s agenda.

Early in the year, the Board also held several strategic planning sessions during which members focused on clarifying the agency’s mission, identifying short-term and long-term goals and establishing priorities for the coming

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<sup>2</sup> While Act 13 charges the Authority with the responsibility for collecting information about Serious Events and Incidents, it does not charge the Authority with the responsibility for collecting information about medical errors, nor does it define the phrase “medical errors.” However, the Act establishes as one of its goals the reduction and elimination of “medical errors by identifying problems and implementing solutions that promote patient safety.”

year. The Board created a number of committees to facilitate the Board’s policy development, including committees dedicated to Long-Range Planning, Legislative Affairs, Budget and Education.

As part of policy and budgetary planning, the Board established several goals to be implemented over the coming years: 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 specific professional groups of healthcare workers and executives; and expanding the utility of the PA-PSRS reporting system for individual facilities and health systems by facilitating front-line report submission.

In March, 2005, Dr. Robert Muscalus, Pennsylvania’s Physician General and *ex officio* Board Chair, resigned from Commonwealth service. Dr. Muscalus had been involved in patient safety activities for several years prior to the enactment of Act 13, and he was actively engaged in helping to establish the Patient Safety Authority following the passage of the enabling legislation. Since his resignation, the Board vice-chair, Lorina Marshall-Blake, has served as acting chair.

The Authority conducted two important surveys during the year to gauge the impact of patient safety initiatives on both healthcare professionals and the general public. In one survey, the Authority questioned senior managers in Pennsylvania-based healthcare facilities about how Act 13 and the work of the Authority were affecting the delivery of care. In the other survey, professional staff from Penn State University interviewed a sampling of ordinary citizens about whether they or family members had been personally involved in a medical error. The findings of these two surveys provide valuable information for future Authority activities while providing benchmarks for ongoing research. Details about the surveys and their findings are included in “Public Perception about Patient Safety” on page 18 and “Impact of Act 13 on Patient Safety: Making a Difference” on page 15.

During the last half of the year, the Board devoted considerable attention to clarifying the Authority’s organizational structure. Although language in Act 13 of 2002 defined the Patient Safety Authority as a “body corporate and politic,” for the previous three years there was disagreement among government officials and policy makers about whether the Authority was actually an independent agency. This affected the day-to-day administrative and management operations of the Authority and, on occasion, the Authority’s interactions with other agencies and organizations. It also led to the termination of the Authority’s legal counsel in October 2005 without the Authority’s knowledge or consent.

In December, the legislature unanimously passed and the Governor signed House Bill 2041 into law. The measure, which became Act 88 of 2005, included language that specifically recognized the Authority as an independent state agency, with the sole power to employ staff, including legal counsel. It contained other provisions affecting the Authority as well. See page 13 for more detailed information about this and other legislation impacting patient safety in Pennsylvania.

## Sharing Lessons Learned

Healthcare facilities submitted nearly 170,000 reports of Serious Events and Incidents during 2005, each of which underwent varying levels of expert review by the PA-PSRS clinical staff. Under the direction of Dr. John Clarke, a trauma surgeon and data expert who serves as PA-PSRS clinical director, this staff includes analysts with experience in the fields of nursing,

patient safety, pharmacy, risk management, product engineering and law, among others. As trained researchers, they identify and evaluate trends, unusual occurrences, levels of harm, patterns of frequency and other

variables. Their research is informed by evidence from the medical literature in order to provide meaningful clinical guidance based on best practices and other standards of care.

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“The Patient Safety Advisory has been an outstanding resource for me and our health system. The ‘lessons learned’ are excellent examples for our staff.”

Francis V. Dono, DO  
Medical Director of Patient Safety and Quality  
OhioHealth

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The results of this research can be found in the *Patient Safety Advisory*, a quarterly publication based on actual reports submitted through the PA-PSRS system. Each *Advisory* includes numerous articles that contain a description and analysis of the events detailed in the reports, whether or not they resulted in patient harm. More important, each article contains clinical guidance and best practices that providers and facility managers can adopt to improve patient care in their facility and prevent a reoccurrence of a similar event. In response to a survey, more than 96% of responding facility staff said the *Advisory* is useful, relevant, readable and of good quality. In 2005, the Authority published four quarterly and two supplementary issues of the *Advisory*, comprising nearly 60 articles. Titles of some of those articles are shown in Figure 2.

- When Patients Speak-Collaboration in Patient Safety
- Unlabeled Basins, Bowls, and Cups in Surgery
- Focusing on Eye Surgery
- Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use
- Forgotten But Not Gone: Tourniquets Left on Patients
- Sequential Compression Devices and Patient Falls
- Unanticipated Care After Discharge from Ambulatory Surgery
- Color-Coded Patient Wristbands Create Unnecessary Risk

Figure 2. Selected Topics from the PA-PSRS Patient Safety Advisory in 2005

The Authority distributes the *Advisory* to patient safety officers and senior managers in all Pennsylvania hospitals, birthing centers and ambulatory surgical facilities, and to several thousand other clinicians throughout the state and elsewhere. Electronic copies are also included in many list-serves and discussion groups devoted to patient safety. The Authority has an open subscription and reprinting policy and encourages recipients to distribute the articles to their peers and co-workers throughout their organizations.

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 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 the American Organization of Nurse Executives and the American Association of Critical-Care Nursing. Clinical staff also published an article in the *American Journal of Surgery*.

## 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, participating in “Grand Rounds” or making other 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 were 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, Pennsylvania Medical Society, Pennsylvania Osteopathic Medical Society and Pennsylvania Society for Health System Pharmacists. 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 partnered with the Pennsylvania Trial Lawyers Association to offer a seminar on the state's mandatory patient safety reporting requirements.

## **PA-PSRS System Training**

The Authority sponsored three training sessions for new PA-PSRS users toward the end of the year. More than 110 personnel from 76 hospitals and ambulatory surgical facilities participated in these educational seminars, which were similar to the 19 training sessions the Authority held prior to the introduction of statewide mandatory reporting. These seminars, which were held in three different regions of the state, were specifically directed at new employees or facility patient safety staff who had not been previously trained on PA-PSRS. The high attendance validated the need for continued general training on use of the PA-PSRS system and the underlying foundations of patient safety upon which the reporting system is built.

## **Root Cause Analysis Training**

The Authority is sponsoring an intensive, two-day seminar on Root Cause Analysis. This hands-on workshop, which is being facilitated by a faculty headed by Dr. James Bagian, an internationally recognized safety expert, will be held in May 2006. The curriculum is based on investigation practices that have been successful in the fields of aviation, spaceflight and medicine, and the course is being given in response to previously expressed interest by hospital managers, clinicians and patient safety officers.

## **Statewide Conferences**

Consistent with the Board's focus on educational programs, the Authority is evaluating opportunities to educate clinicians and managers on patient safety efforts, and is developing appropriate curricula targeted at individual professions and job functions. As noted later in the section on "Collaboration with Other Agencies," the Authority became a cosponsor of the 2006 Patient Safety Symposium. Although the actual symposium took place on a date beyond the scope of this annual report, it is worth noting that almost 400 clinicians and managers from Pennsylvania hospitals participated in this event, providing an important educational opportunity in the area of patient safety.

## **Collaborating with Other Organizations**

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 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 that 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.

Senior staff from the Department also met with the Authority Board to discuss the impact of mandatory adverse event reporting on Pennsylvania's healthcare industry. Both the Department's Deputy Secretary for Quality

Assurance and Chief Counsel spoke to the Board on several occasions. They also provided background on the Department's newly proposed hospital regulations, which include numerous references to patient safety issues.

### **State Board of Medicine**

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 the audience about the activities and findings of the Patient Safety Authority. Like many similar presentations, this presentation qualified for Continuing Medical Education credits for those in attendance. In addition, the State Board of Medicine published a 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 as a result of Pennsylvania's mandatory reporting system.

### **Professional Associations**

The Authority is partnering 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.

Toward the end of 2005, the Authority joined with the Hospital and Healthsystem Association of Pennsylvania (HAP) to become a cosponsor of the 2006 Patient Safety Symposium scheduled for March 2006. 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. The Authority also elected to underwrite the keynote address given by David Marx, an engineer, attorney and principal of Outcome-Engineering of Plano, Texas, who developed the concept of "just culture," an innovative approach to uniting providers and regulators in a common effort to promote disclosure and accountability within a culture of learning.

### **Statewide Organizations**

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.

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.

To facilitate the adoption of clinical protocols to improve patient safety, the Authority joined with several other statewide healthcare organizations in becoming a Pennsylvania "Node" in support of the "100,000 Lives Campaign," a national initiative developed by the Institute for Healthcare Improvement (IHI). This program encourages healthcare institutions to implement at least one of six proven healthcare protocols to prevent avoidable death. 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. More than 120 Pennsylvania hospitals are enrolled in the "100,000 Lives Campaign."

### **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. Early in the year, the Oklahoma Joint Legislative Task Force on Patient Safety invited Authority staff to address a

public hearing on Pennsylvania's patient safety initiatives. The Authority was also contacted or visited by staff from other states, including Florida, Hawaii, Illinois, Maryland, New Jersey, Ohio and Oregon, as well as representatives from the Swiss federal government.

### **National Patient Safety Organizations**

Throughout the year, Authority staff were 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 American Osteopathic Association, American Society for Health Risk Management, the Betsy Lehman Center for Patient Safety of the Massachusetts Department of Public Health and the annual Quantros Patient Safety Conference, among other entities. Most, if not all, of these seminars qualified for continuing education credits for various health professional groups.

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) and U.S. Pharmacopeia.

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 recently enacted federal Patient Safety and Quality Improvement Act (PSQIA) of 2005, Authority staff have met 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 13.

### **Improving the PA-PSRS System**

As of December 31, 2005, 440 facilities were subject to Act 13's reporting requirements. This number fluctuates because of facility closures and mergers, and because new facilities, primarily ambulatory surgical facilities, are opened. During the year 2005, facilities submitted a total of 169,072 reports of adverse events and near-misses through the Pennsylvania Patient Safety Reporting System (PA-PSRS). See the section titled "The Reporting System" (page 23) for detailed analysis of this data.

The Authority introduced several new releases of the PA-PSRS software during the year that included more than 150 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 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.

Also related to the FDA, the PA-PSRS system is now able to generate a preprinted form that facilities can submit to the FDA if they are participating in the FDA's medical error reporting system. 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 redundant reporting.

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.

Many facilities have continued to use their existing incident-reporting systems in addition to PA-PSRS. This results in duplicate reporting and inefficient use of staff time. In response to requests from facilities, the Authority initiated

and completed a pilot program to assess the feasibility and practicality of developing an “interface” between those existing internal reporting systems and PA-PSRS. The test phase proved successful, and the Authority is making interface capacity available to all interested facilities and 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 will require considerable staffing and resource commitment by both the Authority and individual institutions, building an interface will enhance hospital efficiency, decrease redundancy and duplicate reporting, save facility staff time and resources, and promote patient safety at the point of care.

## Involving Patients in Their Care

Although the primary work of the Authority is focused specifically on healthcare facilities—for example, under Act 13 only facilities can submit reports through PA-PSRS—it is obvious that *patients* are at the center of all patient safety activities. The Authority is committed to keeping individual citizens, the consumers of healthcare, informed about initiatives that can impact their healthcare and steps they can take to assure they receive quality care.

There are many opportunities for patients and their loved ones to become involved in their healthcare, from making decisions about treatment protocols to assuring that providers are adhering to safe practices such as hand washing and verifying medications before administering them. Some articles in the *Patient Safety Advisories* have cited examples of how a patient or a family member has actually impacted healthcare delivery. While involvement by a patient or loved one can have a positive affect, the research also identifies situations where patient involvement can result in actual or potential harm.

The Authority’s goal is to keep patients informed about all of these issues so they can ask the right questions and make the right choices. The Authority’s research findings, especially the *Patient Safety Advisories*, are accessible on the agency’s website, and staff publicize that information among as wide an audience as possible. In addition, the website contains useful information about organizations, meetings, publications and other resources that are specifically directed to patients, including consumer- advocacy groups that work on behalf of patients and their families. Recently, the Authority expanded its webpage and published a consumer brochure that includes helpful hints about steps individuals can take to ensure safe care for themselves and their loved ones. Although this brochure was not released until early 2006, it warrants reference in this report.

## Patient Safety Legislation

### 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 effect 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 are 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

Also during 2005, 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.

## Impact of Act 13 on Patient Safety: Making a Difference

While the Authority is frequently—but incorrectly—perceived only as a data collection organization, the true function of the Authority is educational. Its mission is to prevent and reduce incidents of medical errors and other events that can or do result in patient harm. Given the high volume of reporting over the past 18 months, it is reasonable to conclude that the data collection efforts have been successful, but the important question is whether the Authority is making a difference in the delivery of healthcare.

### Culture of Safety

In the field of patient safety, we talk about a “culture of safety” to describe an environment that encourages full and open disclosure of medical errors, near-misses, and other actual or potential unanticipated adverse events. A culture of safety also promotes open communication, teamwork, and patient-focused care. In a recent survey of Patient Safety Officers, over 80% of respondents indicated that the culture of safety had improved in their facility since the implementation of Act 13. Almost 70% stated that the PA-PSRS system had improved their ability to monitor patient safety.

The PA-PSRS system contains built-in analytical tools that can generate reports and statistical charts for analysis and trending. A majority of respondents indicated that they use these reports to support the activities of their facility’s patient safety committees and risk and quality managers. Many also use the analytical tools to generate reports for trustees and senior officers. The Authority encourages Patient Safety Officers to use the reports for just these purposes. While the survey responses are based on self-assessment by Patient Safety Officers, these numbers validate our expectation that use of the PA-PSRS system can “make a difference” in patient care and safety.

### Collaborating with Facilities to Improve Patient Safety

In 2005, PA-PSRS staff initiated nearly 130 contacts with facility Patient Safety Officers to follow up on reports they had submitted to PA-PSRS. Sometimes staff initiates contact to provide the facility with feedback or other information that may be relevant to the Serious Event or Incident they reported. In other cases, staff want to learn more about the

event so that they can share one facility’s “lessons learned” with other facilities through the *Patient Safety Advisories*.

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“The Patient Safety Authority has been a great resource for patient safety....It’s clearly worth the effort, based on what we receive back for our effort.”

From a Patient Safety Officer  
in Northampton County

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On the whole, these contacts are quite positive. Patient Safety Officers genuinely appreciate that the reports they submit are being reviewed by clinical experts, and they are happy to see the knowledge they gained “the hard way” being shared with other institutions. Most Patient Safety Officers are happy to provide additional information about an event they reported, including in many cases the actions they have taken to ensure that similar events don’t happen in the future.

For example, a *Supplementary Advisory* published in April 2005 was based on several reports submitted by the same hospital over a short period, all concerning segments of catheters that sheared off and migrated through several patients’ circulatory systems. The hospital responded to this series of reports quickly, identifying the pattern and investigating to find the cause. In addition to submitting reports to PA-PSRS describing these events, this hospital’s Patient Safety Officer worked with PA-PSRS staff to describe the problem in sufficient detail for an *Advisory* article—even sending us pictures of the related equipment and reviewing the line drawings we developed to illustrate the problem.

As a result of these contacts, Patient Safety Officers frequently provide information or materials to supplement their reports to PA-PSRS. Where a Serious Event or Incident has prompted a change in a facility's clinical practices, the Patient Safety Officer will sometimes send us their revised Standard Operating Procedures (SOPs) to inform our analysis. When we develop an article for the *Advisory* based on the reports of a single institution, we typically offer their Patient Safety Officer an opportunity to review the article before publication and get useful feedback this way.

We often receive e-mail from Patient Safety Officers in response to specific *Advisory* articles. For instance, in the December 2005 *Advisory* we published two letters to the editor. One of these letters was from a pharmacist from a Pennsylvania hospital who was responding to our article "Problems Associated with Automated Dispensing Cabinets" (September 2005). The other was from the Patient Safety Officer of another facility, responding to our article about the risk of overdoses from patient-controlled analgesia "PCA by Proxy—An Overdose of Care" (June 2005), in which she described steps her facility had taken to educate patients and their families about how to use PCA safely.

Respondents to the 2005 PA-PSRS Users' Survey also indicated their commitment to working with PA-PSRS staff on a variety of issues. For example, nearly half of Patient Safety Officers responding to the survey said they would be willing to serve as expert reviewers of *Advisory* articles. Nearly one-third would be willing to collaborate on a workgroup of their peers to find solutions to particular patient safety problems. Over 20% would be willing to share their own experiences solving a patient safety problem in an *Advisory* article or during a training seminar. About 17% said they knew of a "physician champion" in their facility who could help garner support for patient safety initiatives either in their own facility or elsewhere.

## Promoting Change through the *Patient Safety Advisories*

The Authority also strives to improve patient care through the research and analysis published in each *Patient Safety Advisory*.

More than half (56%) of all Patient Safety Officers, and 75% of Patient Safety Officers representing hospitals, participating in the 2005 Users' Survey stated that they had made changes in their facilities based on articles in the *Patient Safety Advisories* (see page 47). This is a substantial increase over the one-third of respondents to our

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"I distributed [the *Advisory*] to our nursing and pharmacy staffs. Within 24 hours, a nurse identified an identical issue that was 'caught' before reaching the patient."

From a Patient Safety Officer at a hospital in Southcentral Pennsylvania

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December 2004 survey who said an *Advisory* article had prompted them to make changes. Examples of changes Patient Safety Officers are instituting in hospitals and ambulatory facilities as a result of *Advisory* articles include:

- Reducing the number of color-coded patient wristbands in use in their facility and purchasing wristbands with embossed text (e.g., "allergy") on the wristbands to avoid confusion.
- Minimizing the risk of alcohol-based fires by using towels to catch alcohol runoff in the operating room and eliminating use of alcohol-based hair products by patients.
- Adding to their list of prohibited abbreviations based on potentially confusing abbreviations identified in the *Advisory*.
- Holding an educational program for clinical staff on how to minimize the risk of anesthesia awareness and respond to it when it occurs.
- Educating surgeons about and getting their buy-in for a pre-operative "time out" before surgery, in which the patient's identity and other critical elements of the procedure are reviewed.

- Changing the color of tourniquets used throughout the facility so they are clearly differentiated from the patient’s skin color, reducing the likelihood that they will be left on the patient longer than intended.

We asked survey participants to identify the types of individuals within their facility to whom they distribute *Advisory* articles. Overall, *Advisory* content is widely distributed throughout PA healthcare facilities. Ninety-seven percent (97%) of Patient Safety Officers responding to the survey report distributing the *Advisory* to other staff in their healthcare facility. More than one-third of facilities (34%) distribute *Advisory* content to all staff, and among ASFs/BCs, 53% do so.

Because *Advisory* articles are the Authority’s primary instrument to disseminate patient safety information and lessons learned to clinicians, the Authority staff is working to encourage broader distribution of the *Advisories*, especially among physicians and pharmacists. Staff are also exploring ways to make it easier for Patient Safety Officers to redistribute and adapt content from the *Advisory* and use that information in internal educational programs.

Two articles published in 2005 demonstrate how these publications can help improve quality of care.

The June 2005 *Patient Safety Advisory* contained an article entitled “Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use.” This timely article describes the etiology of *C. Difficile*, a potentially life-threatening bacterial infection. The article also contains valuable clinical guidance about precautions healthcare workers can take to reduce the spread of this deadly bacterium and treatment protocols for individuals already diagnosed with *C. Difficile*. Because of the public and clinical interest in healthcare-associated infections, the Authority reprinted the article as a stand-alone publication to facilitate distribution and make the information more accessible. The Authority also targeted mailings to hospital managers, administrators and patient safety officers in an attempt to put the information in the hands of the appropriate staff, specifically physicians, nurses and healthcare workers involved in infection control.

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“Advisories are distributed to our patient safety steering committee monthly and are VERY helpful.”

From a Patient Safety Officer at a Philadelphia teaching hospital

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A second article, “Use of Color-Coded Patient Wristbands Creates Unnecessary Risk,” also demonstrates how the Authority can “make a difference.” This article

was published as a *Supplementary Advisory* in December 2005. While the use of color-coded patient wristbands to convey medical information practice is widespread, there are no common definitions among healthcare facilities for the meanings associated with different colors. Confusion about the meaning of these color-coded wristbands nearly led to failure to resuscitate a patient in cardiac arrest (see page 58 for more detail). In order to determine the prevalence of this practice throughout Pennsylvania, PA-PSRS conducted a voluntary survey in which nearly a third of all the Patient Safety Officers in the state participated, sharing information about how their facilities used these wristbands. Almost immediately upon its publication, the *Advisory* article garnered attention from Pennsylvania healthcare organizations and policy makers, as well as from nationally recognized patient safety experts and in postings on several web-based “bulletin boards” and discussion groups. A Resolution was introduced in the Pennsylvania House of Representatives related to the use of color-coded wristbands<sup>3</sup>, and legislatures in other states are considering various bills and proposals.

Because of the relevance of these and other research findings, the Authority hopes that the *Advisories* will have a positive impact on the delivery of healthcare in the Commonwealth. When queried, more than half of all of Patient Safety Officers in Pennsylvania stated that they had made changes within their facilities as a result of information contained in *Advisory* articles. This is a positive indication that, although there is as lot more to do, the Patient Safety Authority has been able to make a difference in healthcare for the citizens of Pennsylvania.

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<sup>3</sup> House Resolution No. 550, 2006. [www.legis.state.pa.us/WU01/LI/BI/BT/2005/0/HR0550P3405.HTM](http://www.legis.state.pa.us/WU01/LI/BI/BT/2005/0/HR0550P3405.HTM)

# Public Perceptions about Patient Safety in Pennsylvania

The Pennsylvania Patient Safety Authority (PSA) participated in a statewide survey of Pennsylvania adults to measure the public's attitudes and opinions about a number of government and social policy issues, including patient safety. For its part, the Authority tried to determine how patient safety has impacted individual Pennsylvanians by assessing their personal experiences with medical errors. The survey was conducted by the Penn State Center for Survey Research. Highlights appear in Figure 3.

Survey participants were randomly selected, and surveys were conducted by telephone with 859 Pennsylvanians age 18 or older between October 7 and December 17, 2005. The results reported here are appropriately weighted by demographic and geographic characteristics to ensure a representative sample. The sampling error for the poll is  $\pm 3.4$  percentage points.

## Importance of Patient Safety

Survey participants were asked an open-ended question: "What do you think is the most important problems facing Pennsylvania today?" Health care/Malpractice insurance issues were the fifth most frequently cited problem, behind taxes, education, and unemployment, but ahead of the economy, crime, and fuel prices.

Another question in the survey also shed some light on the public's sense of the importance of healthcare, specifically in terms of its safety. Participants were asked how worried they were about a series of topics, including healthcare safety, food safety, water and air quality, a burglary in their home, a terrorist strike where they live, and being injured in a car crash.

Nearly 53% of respondents reported that they were very or somewhat worried about the safety of the medical care they and their family receive (see Table 1). By this measure, healthcare safety ranked third in concern, after "being injured in a car crash" and "the quality of air you and your family breathe," slightly ahead of food safety and water quality.

These results are consistent with the findings of a national survey conducted in November 2004 by the Kaiser Family Foundation (KFF), Agency for Healthcare Research and Quality (AHRQ), and the Harvard School of Public Health (HSPH).<sup>4</sup> The National Survey on Consumers' Experiences with Patient Safety and Quality Information also found that concern over healthcare safety was lower than concern over air quality, but higher than water quality and food safety. In this survey, 48% of respondents reported that they were very or somewhat worried about the medical care they and their family receive.

- Healthcare/malpractice insurance issues were considered more significant problems than the economy, crime, and fuel prices.
- Pennsylvanians were more worried about the safety of their family's medical care than about the safety of their food and water, a burglary in their home, or a terrorist strike where they live.
- About one-third of respondents felt patient safety had improved in the past five years, while the majority felt it had stayed the same.
- One-third of respondents reported that they or someone in their family had been personally involved in a preventable medical error.
- Three out of four respondents reporting involvement in a medical error said that they were not informed by the doctor or healthcare worker involved.

Figure 3. Survey Highlights

<sup>4</sup> Kaiser Family Foundation (KFF), Agency for Healthcare Research and Quality (AHRQ), and the Harvard School of Public Health (HSPH). *National Survey on Consumers' Experiences with Patient Safety and Quality Information*, November 2004; 4. Available from Internet: [www.kff.org/kaiserpolls/upload/National-Survey-on-Consumers-Experiences-With-Patient-Safety-and-Quality-Information-Survey-Summary-and-Chartpack.pdf](http://www.kff.org/kaiserpolls/upload/National-Survey-on-Consumers-Experiences-With-Patient-Safety-and-Quality-Information-Survey-Summary-and-Chartpack.pdf).

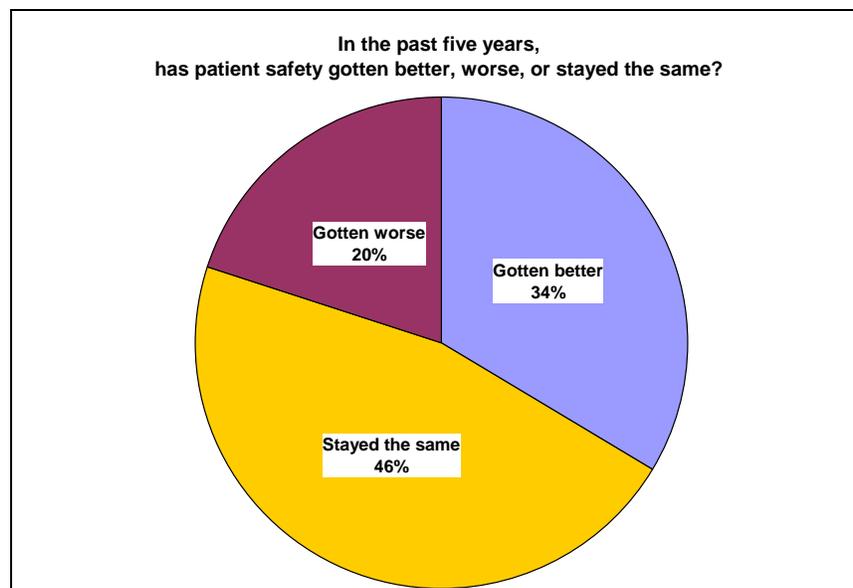
**Table 1. Level of Concern Over Healthcare Safety, Relative to Other Sources of Risk**

Rank (by % Very Worried or Somewhat Worried)	Are you very worried, somewhat worried, not too worried, or not worried at all about:	Very Worried or Somewhat Worried	Not Too Worried or Not Worried At All
1st	...being injured in a car crash?	61.3%	38.4%
2nd	...the quality of the air you and your family breathe?	60.7%	39.1%
3rd	...the safety of the medical care you and your family receive?	52.9%	46.9%
4th	...the safety of the food you and your family eat?	50.4%	49.6%
5th	...the quality of the water you and your family drink?	48.7%	51.1%
6th	...about a burglary in your home?	42.6%	57.3%
7th	...a terrorist strike where you live?	34.7%	65.2%

## Progress in Patient Safety

The survey asked respondents whether patient safety had gotten better, gotten worse or stayed the same over the last five years (see Figure 4). While many (46%) felt it had stayed the same, about one-third felt it had gotten better, while only one in five felt it had gotten worse.

In contrast, in the 1997 National Patient Safety Foundation (NPSF) Public Opinion of Patient Safety Issues survey, respondents were evenly split into thirds among the three categories.<sup>5</sup> In our survey, approximately 13% fewer people said patient safety had gotten worse, and they instead responded that it had stayed the same. Differences between the two surveys' results may reflect changes in public attitudes about the improvement in the safety of care, differences in attitude between the population in Pennsylvania and the nation as a whole, or both.



**Figure 4. Perceptions of Change in Patient Safety**

<sup>5</sup> National Patient Safety Foundation (NPSF). *Public Opinion of Patient Safety Issues*, September, 1997; 14. Available from Internet: [www.npsf.org/download/1997survey.pdf](http://www.npsf.org/download/1997survey.pdf).

## Personal Experiences with Medical Errors

### *Involvement in a Medical Error*

About one-third of survey respondents report that they or a family member was personally involved in a situation where a preventable medical error was made (see Figure 5). This finding is consistent with the November 2004 KFF/AHRQ/HSPH National Survey on Consumers' Experiences with Patient Safety and Quality Information, which also found one-third of respondents answering affirmatively.<sup>6</sup> This suggests that Pennsylvanians experience preventable medical errors at about the same rate as the general US population.

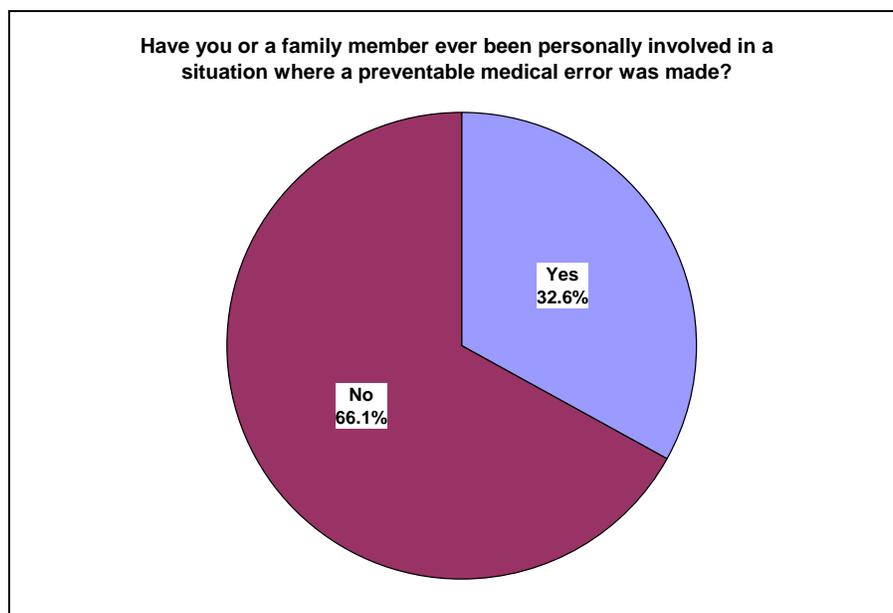


Figure 5. Personal Involvement in Medical Errors

Older surveys found slightly higher rates of personal involvement with medical errors. The KFF/HSPH survey *Medical Errors: Practicing Physician and Public Views*, conducted in December 2002, found that 42% of respondents reported involvement with a preventable medical error in their or their family's care.<sup>7</sup> The NPSF 1997 survey, which asked, "Have you, a close friend, or a relative ever been involved in a situation where a medical mistake was made?" also found 42% of respondents answering affirmatively.<sup>8</sup> We asked individuals who reported involvement in a medical error how long ago the error occurred. Seventeen percent (17%) reported that the medical error had occurred within the last year (see Figure 6).

<sup>6</sup> Kaiser Family Foundation, Agency for Healthcare Research and Quality, and the Harvard School of Public Health, *supra* note 1:38.

<sup>7</sup> Kaiser Family Foundation (KFF) and the Harvard School of Public Health (HSPH). *Medical Errors: Practicing Physician and Public Views* December, 2002; 4. Available from Internet: [www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14100](http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14100)

<sup>8</sup> National Patient Safety Foundation, *supra* note 2:34.

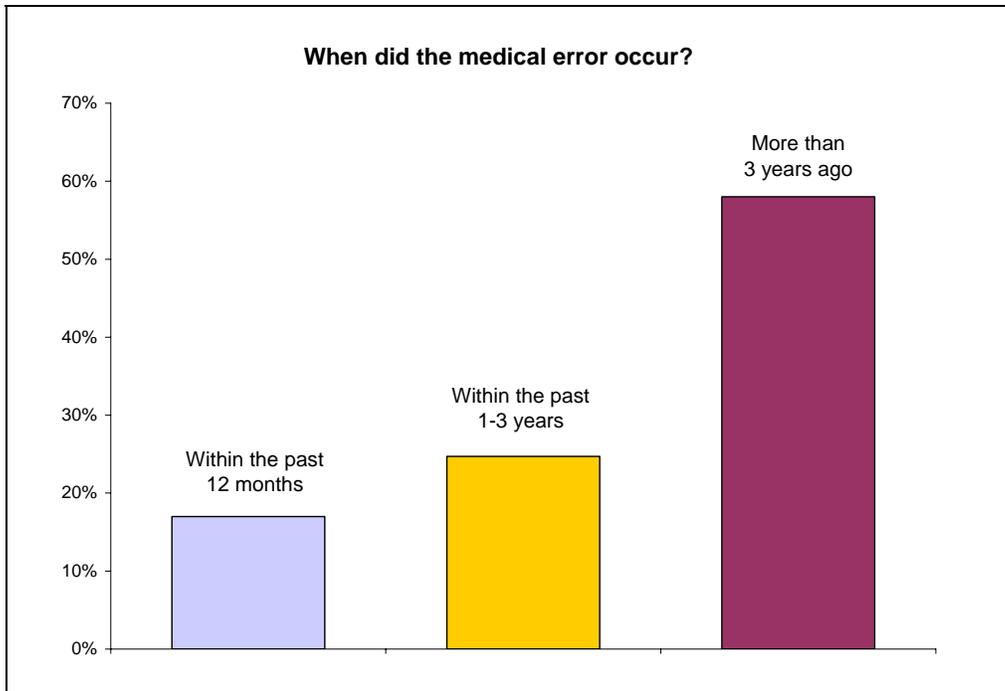


Figure 6. How Recently a Medical Error Occurred

### ***After a Medical Error***

Respondents who had experienced a medical error were asked a series of Yes/No questions about things that might have happened after the error was discovered. More than three out of four said that additional tests were required after the discovery of the error (see Figure 7). Three out of five said their hospital stay was extended. Half reported changing their doctor or hospital, and half said that additional surgery was needed.

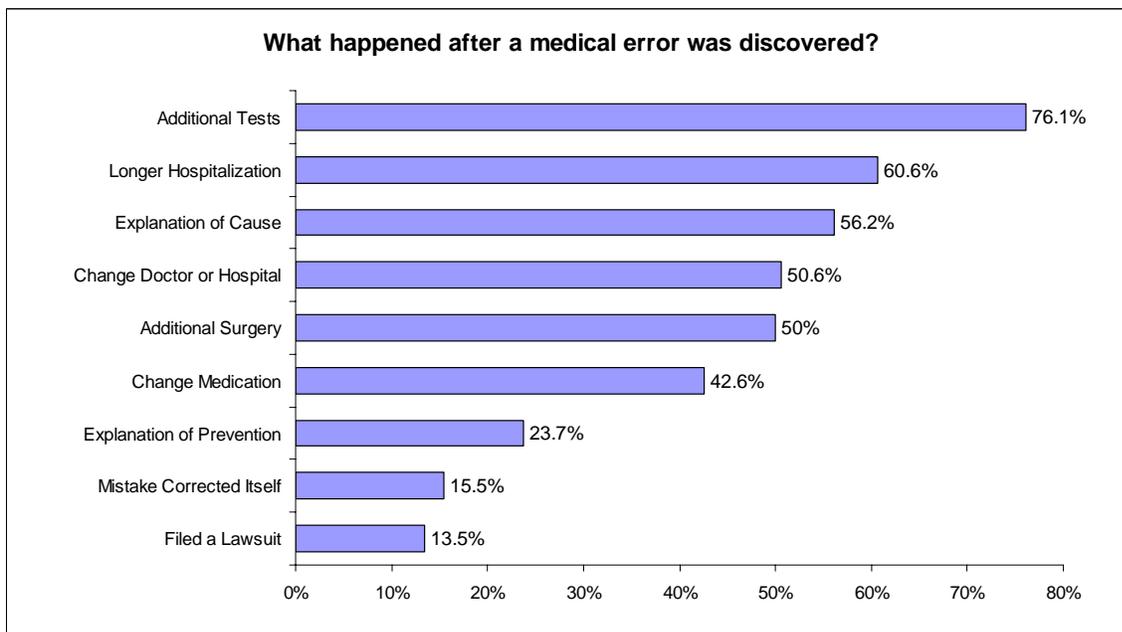


Figure 7. Reported Sequelae of Medical Errors

## Disclosure of Medical Errors

Three out of four respondents reporting involvement in a medical error say that the health professional involved in the error did not tell them about it (see Figure 8), while only 23% felt the professional involved disclosed the error. This figure is slightly lower than in recent national surveys, in which 28-30% of respondents felt they had been told of the error.<sup>9,10</sup>

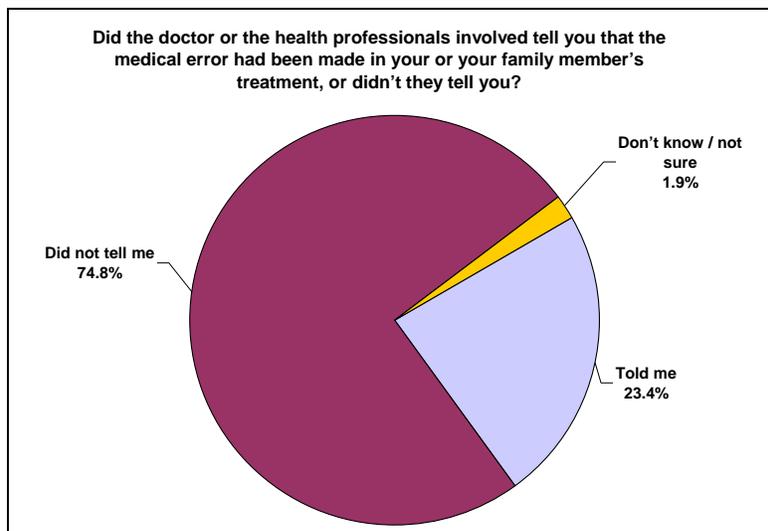


Figure 8. Disclosure of Medical Error by Health Professional Involved

This finding suggests there is still much room for improvement in terms of disclosing medical errors to patients or their families and in health professionals' understanding of patients' perceptions of what may constitute an error.

<sup>9</sup> Kaiser Family Foundation, Agency for Healthcare Research and Quality, and the Harvard School of Public Health, *supra* note 1:41.

<sup>10</sup> Kaiser Family Foundation (KFF) and the Harvard School of Public Health (HSPH), *supra* note 4:8.

# 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>11</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 62.)

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“I really like the reporting. The software is extremely easy to use. I was concerned about the amount of work and having yet another committee to sit on, but I find that our patient safety committee really makes us a better facility.”

From a Patient Safety Officer  
at an endoscopy center

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.

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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

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<sup>11</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.

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, more than half (56%) of all responding facilities and nearly 75% of respondents from hospitals indicated that they have implemented improvements within their facilities as a result of information contained in the *Advisories*.

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 47). 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.

## ***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.

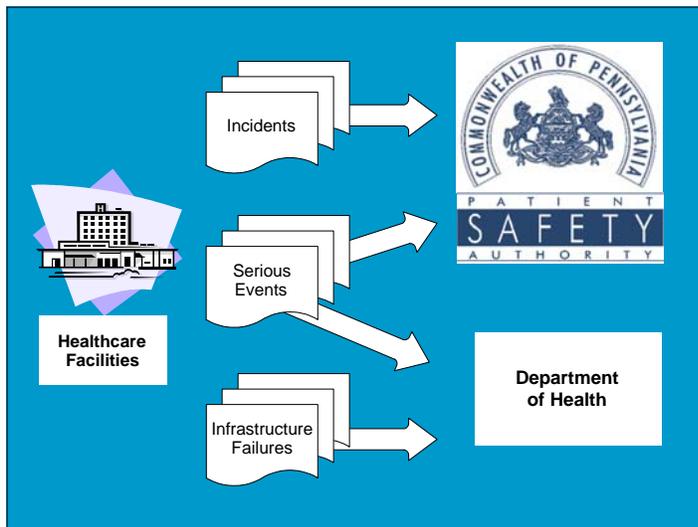
Even if the data were adjusted for volume, patient factors, and all other factors but safety and quality, PA-PSRS data would still be an inaccurate "report card" for individual healthcare facilities. For example, if Facility A has substantially more reports than a similar facility (Facility B), this 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, one incorrect medication out of a total of 50 administered doses is much different than one incorrect medication 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, 2005, and December 31, 2005.
- 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.



**Figure 9. Submission of PA-PSRS Reports**

Readers are advised to be cautious about 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.

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

## Definitions

Act 13 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 9, 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 three types of facilities to submit reports of Serious Events, Incidents, and Infrastructure Failures to PA-PSRS:

- **Hospital**—The Health Care Facilities Act (35 P.S. §448.802a) defines a hospital as “an institution having an organized medical staff established for the purpose of providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for the care of persons who are injured, disabled, pregnant, diseased, sick or mentally ill, or rehabilitative services for the rehabilitation of persons who are injured, disabled, pregnant, diseased, sick or mentally ill. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific medical specialties, but not facilities caring exclusively for the mentally ill.” For the purposes of this report, at the end of 2005, there were 241 Hospitals in the Commonwealth of Pennsylvania.
- **Ambulatory Surgical Facility**—The Health Care Facilities Act defines an Ambulatory Surgical Facility as “a facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. Ambulatory surgical facility does not include individual or group practice offices or private physicians or dentists, unless such offices have a distinct part used solely for outpatient treatment on a regular and organized basis. Outpatient surgical treatment means surgical treatment to patients who do not require hospitalization but who require constant medical supervision following the surgical procedure performed.” For the purposes of this report, at the end of 2005, there were 194 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 2005, there were five Birthing Centers in the Commonwealth of Pennsylvania.

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>12</sup>

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 5.

- **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.

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<sup>12</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.

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

Information collected through PA-PSRS throughout 2005 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 440 facilities providing acute medical care in the state (as of December 31, 2005) under the requirements of Act 13 of 2002, the Mcare Act.

The following data analysis summarizes over 161,000 accounts of Incidents without any indication of patient harm and over 7,500 Serious Events.

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 does not mean a patient was harmed. The vast majority of reports were not associated with harm to patients. Based on the reports, 96% of problems were caught by healthcare providers before harm could occur or were not serious enough to produce harm. These Incidents were submitted to identify situations in which unsafe actions might occur, but before they cause any harm.
- Not all Serious Events were due to unsafe actions. Serious Events must be reported whether or not an unsafe action has occurred. 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 necessarily mean bad care.
- One wants to see a reduction in Serious Events, whether or not they are the result of unsafe actions. The number of Incidents that are reported is not nearly as important as the number of Serious Events. 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.

*(Continued on next page)*

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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 number of Serious Events, a high number 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.”
- Although the classification of accounts into event types provides some general descriptive value, many narrative descriptions could be classified under a variety of event types. For instance, failure of an intravenous pump to prevent free flow of a medication infusion may be classified as a device failure or an overdose of medication.
- 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.

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 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 Department of Health and the Bureau of Professional and Occupational Affairs in the Department of State have the responsibility of asking if a provider is safe. 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.

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

# Report Volume

## Reports by Month and Submission Type

Between January 1, 2005, and December 31, 2005, Pennsylvania facilities submitted 169,072 reports to PA-PSRS. Table 2 shows the distribution of submitted reports by month for calendar year 2005.

Table 2. Reports Submitted to PA-PSRS in 2005, by Month

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Serious Events	603	622	687	559	606	661	607	697	649	661	578	574	7,504
Incidents	13,135	12,876	14,518	12,254	12,892	13,316	11,965	15,717	12,940	13,614	14,051	14,290	161,568
Total	13,738	13,498	15,205	12,813	13,498	13,977	12,572	16,414	13,589	14,275	14,629	14,864	169,072

Approximately 4.4% of submitted reports were Serious Events, while 95.6% were Incidents. On average, PA-PSRS received 14,089 reports per month. The number of Serious Event reports in 2005 averaged 625 per month, a 6% increase over 2004 report submission levels. The number of Incident reports in 2005 averaged 13,464 per month, an increase of about 26% over the average monthly volume in 2004.

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

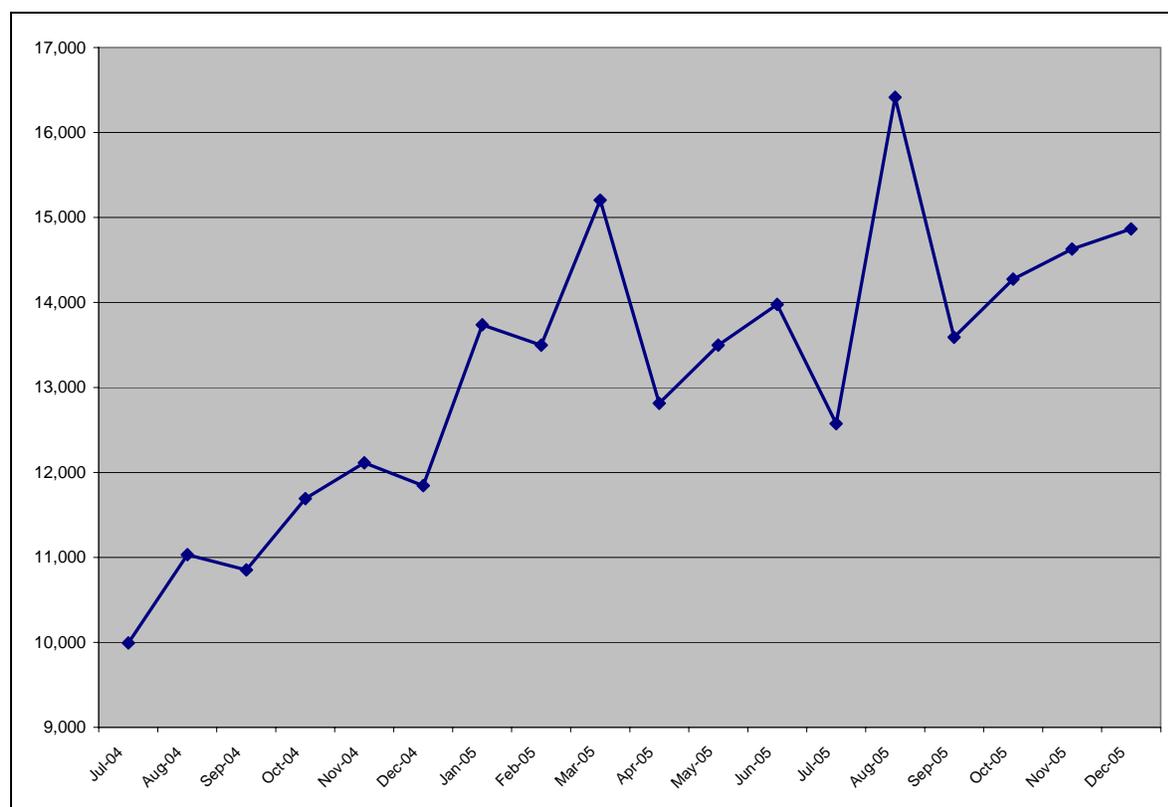


Figure 10. Number of Reports Submitted Each Month since Inception of PA-PSRS (Jul 2004-Dec 2005)

Figure 11 bears out this proposition. Depicting the volume of Serious Events and Incidents submitted each month shows that the increase in the volume of reports is attributable mostly to increased reporting of Incidents. That the volume of Serious Event reports remains relatively stable over this period—a period of increasing admissions

volume and patient days of care—lends support to the notion that Pennsylvania facilities continue to improve their ability to recognize and submit reports of near misses.

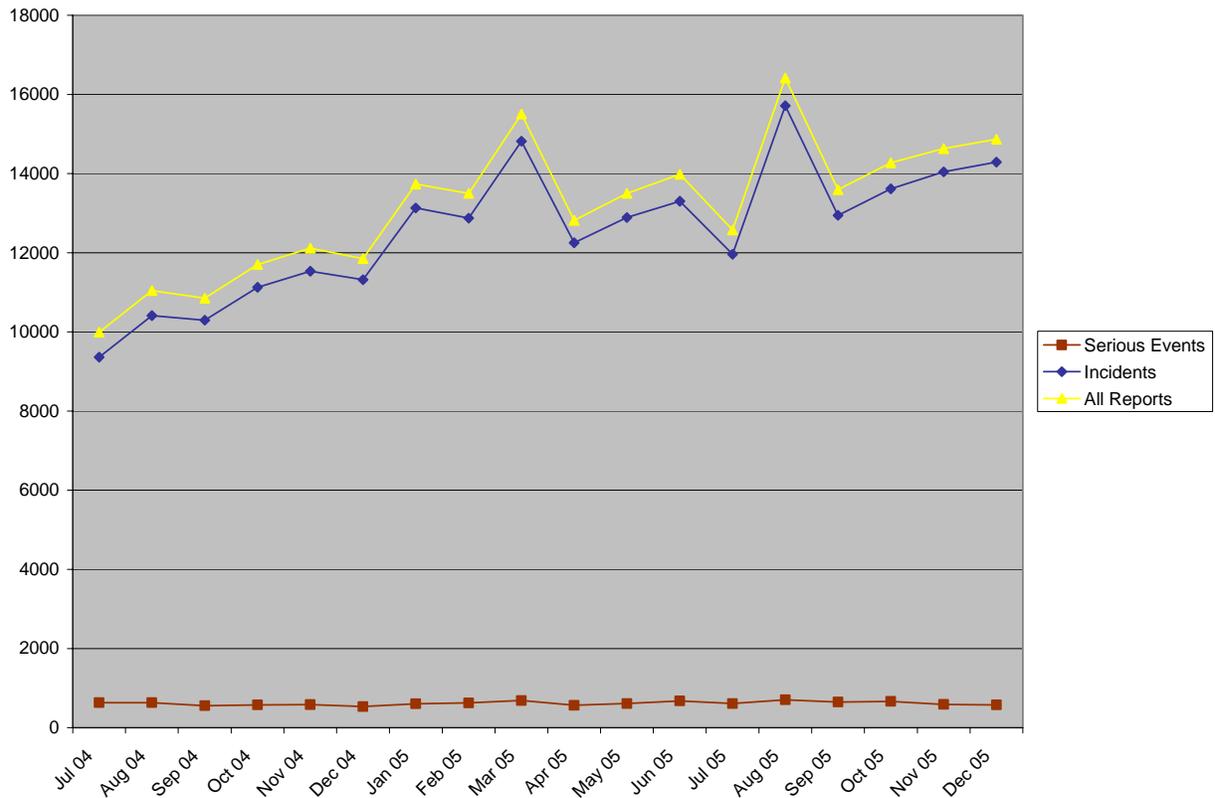


Figure 11. Monthly Report Volume by Report Type (Jul 2004-Dec 2005)

### Reports by Facility Type

As shown on Table 3, the vast majority of reports (98.8%) submitted to PA-PSRS were submitted by hospitals. More detailed information on reports from different facility types appears on Table 3.

Table 3. Reports to PA-PSRS by Facility Type

Facility Type	Hospitals	Ambulatory Surgical Facilities/ Birthing Centers	All
Number of Reports Submitted	166,998	2,074	169,072
Number of Facilities Active for year ending Dec. 31, 2005	241	199	440

## Reports by Region and Submission Type

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 not particularly surprising. One expects more reports to be submitted in regions with larger populations and greater numbers of healthcare facilities. Consistent with this expectation, the regions with the largest number of reports (Southeast and Southwest) were those with the Commonwealth’s two largest population centers: Philadelphia and Pittsburgh, respectively.

Figure 12. Pennsylvania Public Health Regions

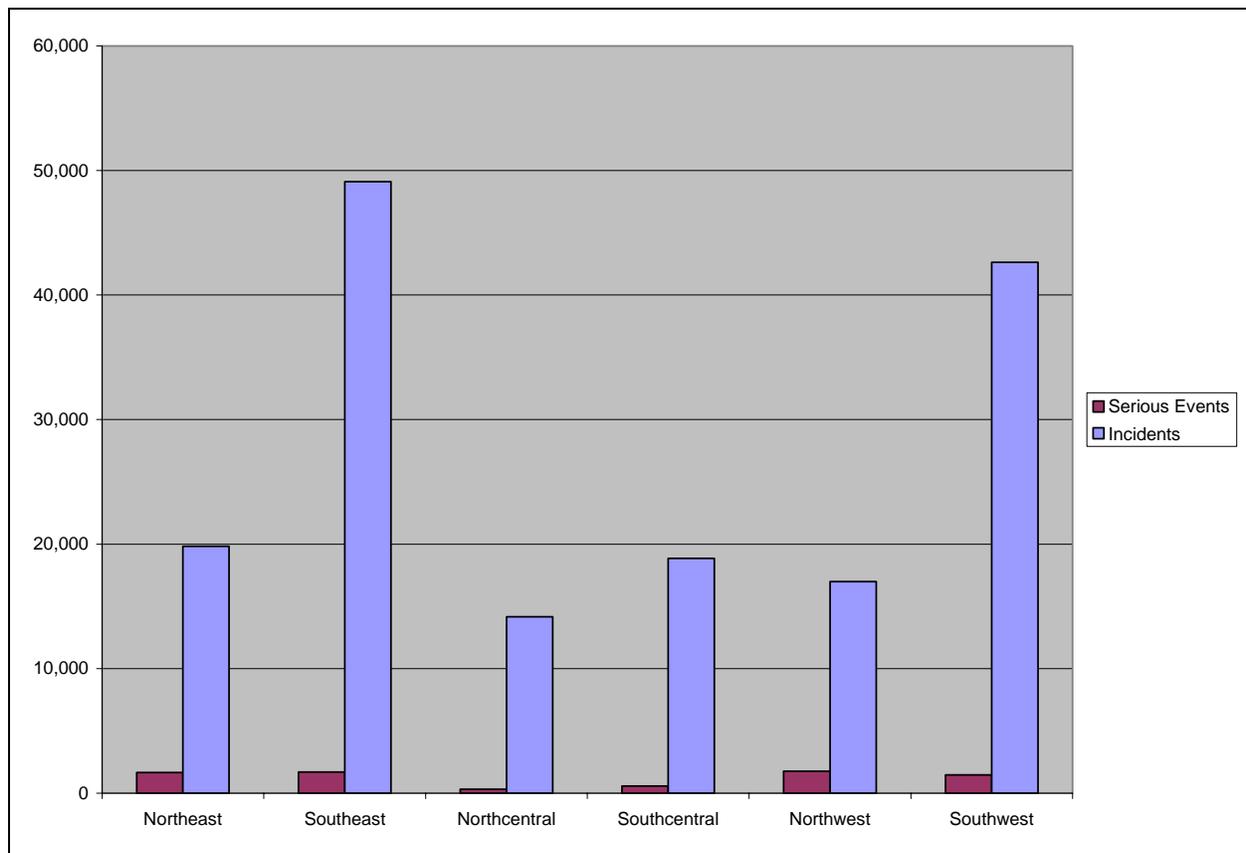


Figure 13. Number of Serious Event and Incident Reports by Region (2005)

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>13</sup> This figure shows that, after accounting for the

<sup>13</sup> Patient days are a commonly used measure of healthcare utilization or volume. A patient day is defined as one calendar day of healthcare provided to a hospital inpatient. Patient days for each region were calculated based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council ([www.phc4.org](http://www.phc4.org)). In each region, the number of reports submitted by hospitals from January through December 2005 was divided by the estimated number of patient days in 2005. Since only partial data were available for 2005, we estimated 2005 patient days through time series decomposition using data from January 1999 through March 2005.

differences in the volume of healthcare provided in each region, facilities in the Northcentral region reported a significantly greater proportion of Incidents (97.8% of their reports) than the statewide average (95.6%).

As evident in Figure 14, the number of reports per patient day in the Northcentral region was considerably higher than in other regions. This does not necessarily suggest that facilities in the Northcentral region were less safe than those in other regions. It may mean that the healthcare providers in these facilities were better at identifying and reporting potential patient safety issues. This interpretation is suggested by the fact that the increased volume of reports from this region consisted of Incidents (i.e., indicating that patients were not harmed), and that the number of Serious Event reports was consistent with other regions. Program staff will continue to evaluate trends related to geographical variation across the state.

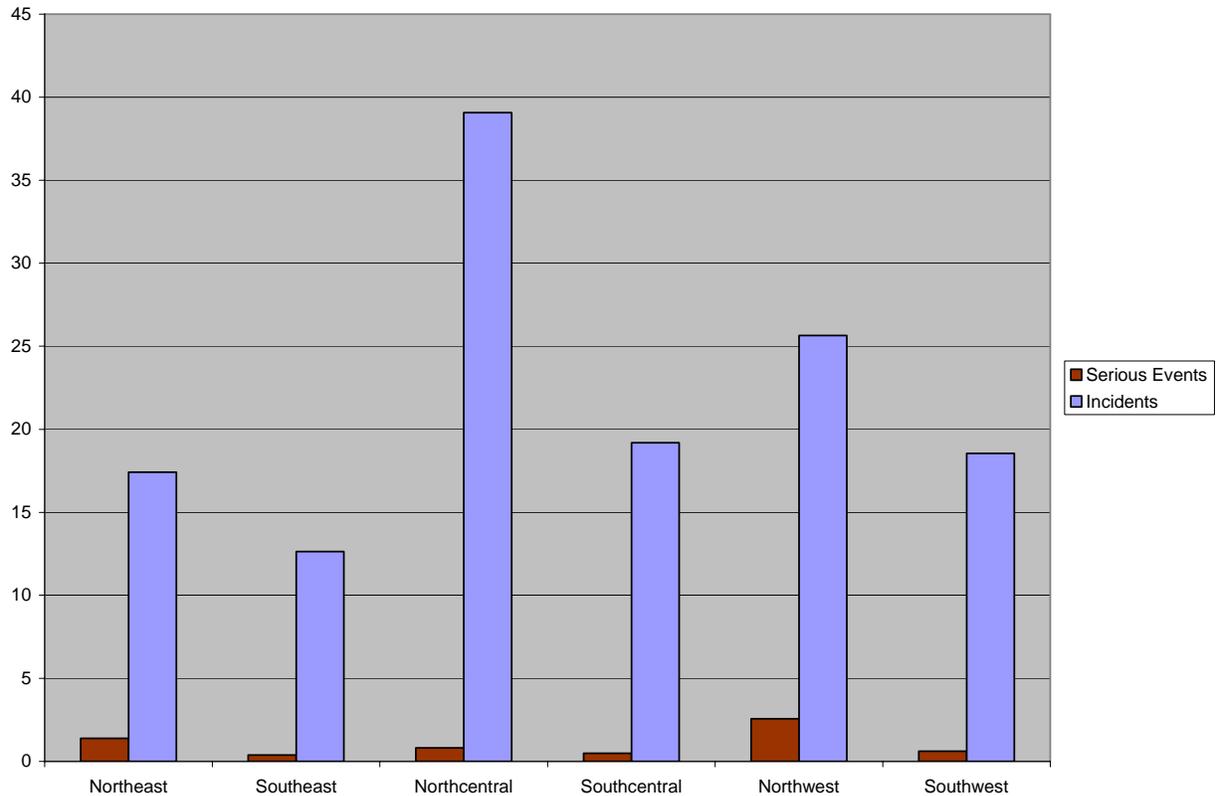


Figure 14. Reports from Hospitals per 1,000 Patient Days by Region (2005)

Overall, report volume in 2005 increased 26% over 2004 levels. In terms of reports from hospitals per 1,000 patient days, report volume increased 11%. This means that even after we adjust for the increased volume of care provided, there is still a substantial increase in reporting volume. Figure 15, showing the number of reports from hospitals per 1,000 patient days in 2004 and 2005, demonstrates that this increased report volume is not isolated to one or two regions of the Commonwealth. Rather, it is occurring statewide.

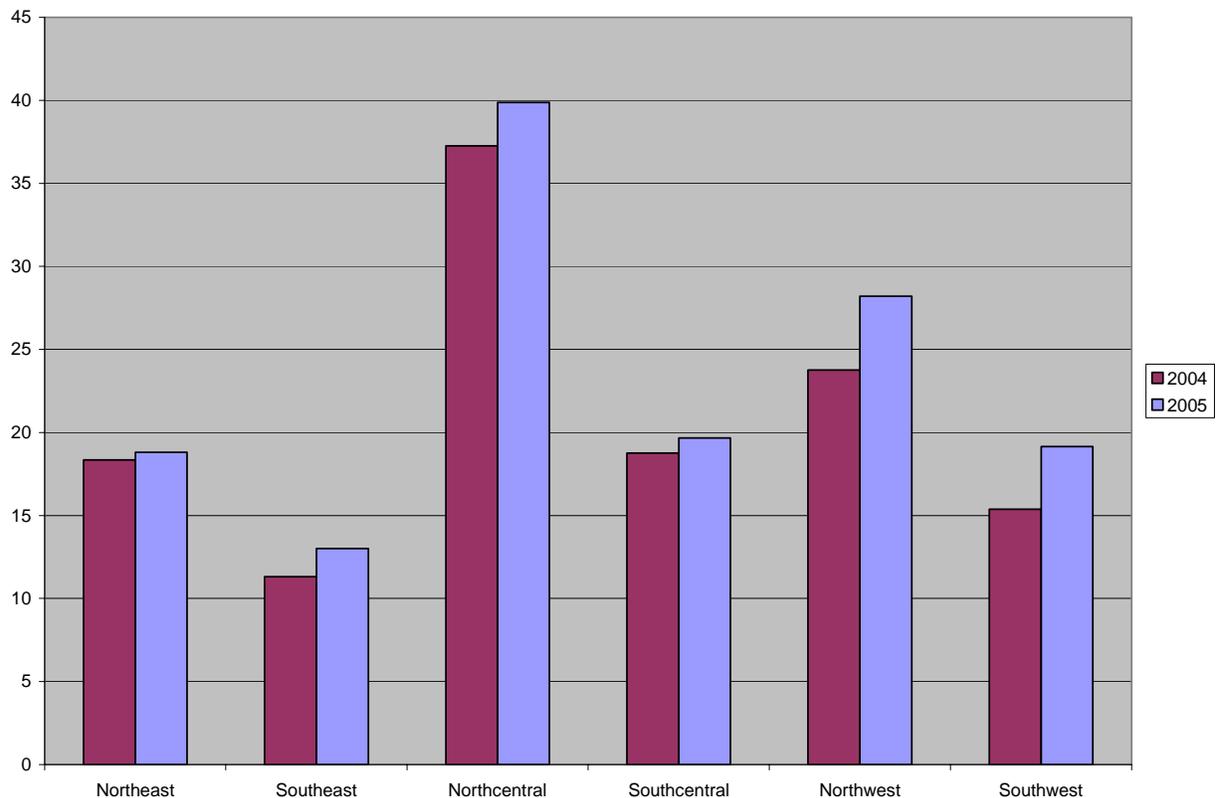


Figure 15. Reports from Hospitals per 1,000 Patient Days by Region (2004 vs. 2005)

Table 4 shows the number of reports per 1,000 patient days by Event Type and region. Again, it is evident that facilities in the Northcentral region report at a higher rate than average, particularly with regard to medication errors, where they report at more than four times the statewide average rate. These facilities also report proportionally more errors related to procedures/treatments/tests, where they report at more than twice the statewide average rate. The above-average reporting from this region most likely reflects above-average compliance with reporting requirements, since the difference appears in their reports of Incidents and not Serious Events.

Table 4. Reports from Hospitals per 1,000 Patient Days Event Type by Region (2005)

Event Type	Northeast	Southeast	Northcentral	Southcentral	Northwest	Southwest	Statewide
Medication Errors	5.1	3.1	18.5	6.2	6.5	3.3	4.6
Adverse Drug Reactions	0.4	0.2	0.7	0.3	0.8	0.5	0.4
Equipment / Supplies / Devices	0.3	0.2	0.6	0.4	0.4	0.3	0.3
Falls	3.2	3.3	4.4	3.6	4.3	4.2	3.6
Errors Related to Procedure / Treatment / Test	4.1	2.9	8.8	4.3	6.0	3.6	3.8
Complications of Procedure / Treatment / Test	1.9	1.3	4.0	1.8	5.6	3.6	2.4
Transfusions	0.1	0.2	0.2	0.3	0.3	0.1	0.2
Skin Integrity	3.0	0.8	1.5	1.2	1.5	2.5	1.6
Other / Miscellaneous	0.7	1.1	1.2	1.5	2.7	1.1	1.2
Total	18.8	13.0	39.9	19.7	28.2	19.2	18.1

Analyzing regional variations in reporting sometimes highlights interesting patterns in the data. For example, refer to the section on Healthcare Associated Infections (see page 44).

## 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 5 presents the number of reports received in 2005 by patient gender and age cohort.

Table 5. Reports Submitted by Age Cohort and Gender (2005)

Age Cohort	Female		Male		All Patients		% Patients Female
	No.	%	No.	%	No.	%	
0 to 4	3,009	3.3%	4,029	5.2%	7,038	4.2%	42.8%
5 to 14	1,433	1.6%	1,856	2.4%	3,289	1.9%	43.6%
15 to 24	4,328	4.7%	2,739	3.5%	7,067	4.2%	61.2%
25 to 34	5,597	6.1%	3,053	3.9%	8,650	5.1%	64.7%
35 to 44	7,066	7.7%	5,294	6.8%	12,360	7.3%	57.2%
45 to 54	9,244	10.1%	9,322	12.0%	18,566	11.0%	49.8%
55 to 64	11,348	12.4%	11,362	14.6%	22,710	13.4%	50.0%
65 to 74	14,814	16.2%	14,519	18.7%	29,333	17.3%	50.5%
75 to 84	21,859	23.9%	18,166	23.4%	40,025	23.7%	54.6%
85+	12,591	13.8%	7,443	9.6%	20,034	11.8%	62.8%
Total	91,289	100.0%	77,783	100.0%	169,072	100.0%	54.0%

## Patient Gender

Of the 169,072 reports submitted in 2005, 91,289 (54%) involved female patients, and 77,783 (46%) involved male patients. This pattern is consistent with our observations in 2004. During childbearing years women are more likely than men to have encounters with the healthcare system, and because women have a longer life expectancy than men, there are simply more women in the general population in the older age cohorts.

The proportion of reports classified as Serious Events differed slightly according to the patient's gender, with 4.7% of reports involving female patients classified as Serious Events, compared to 4.1% for reports involving males.

Table 6 shows the distribution of reports by patient gender and event type. Many of the same patterns observed in 2004 are evident this year as well. The proportion of reports involving female patients was significantly higher among reports of Adverse Drug Reactions, Complications, and Transfusion-related reports, and significantly lower among reports of Equipment-related events and Falls.

Table 6. Reports Submitted by Gender and Event Type (2005)

Event Type	Female		Male		All Patients		Ratio of Reports Involving Female Versus Male Patients
	No.	%	No.	%	No.	% of Total	
Medication Errors	23,267	54.9%	19,104	45.1%	42,371	25.1%	H
Adverse Drug Reactions	2,148	64.0%	1,210	36.0%	3,358	2.0%	H
Equipment / Supplies / Devices	1,295	50.8%	1,252	49.2%	2,547	1.5%	L
Falls	16,665	49.5%	16,989	50.5%	33,654	19.9%	L
Errors Related to Procedures / Treatments / Tests	19,557	54.9%	16,046	45.1%	35,603	21.1%	H
Complications of Procedures / Treatments / Tests	13,019	56.5%	10,038	43.5%	23,057	13.6%	H
Transfusion	928	56.8%	706	43.2%	1,634	1.0%	H
Skin Integrity	8,291	54.9%	6,824	45.1%	15,115	8.9%	H
Other / Miscellaneous	6,119	52.2%	5,614	47.8%	11,733	6.9%	L
Total	91,289	54.0%	77,783	46.0%	169,072	100.0%	

H=significantly higher than overall coverage of 54%; L=significantly lower than overall average of 54%.

## 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% of all reports to PA-PSRS in 2005. Also shown on this figure is the proportion of hospital inpatient admissions as reported by the Pennsylvania Healthcare Cost Containment Council (PHC4).<sup>14</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.

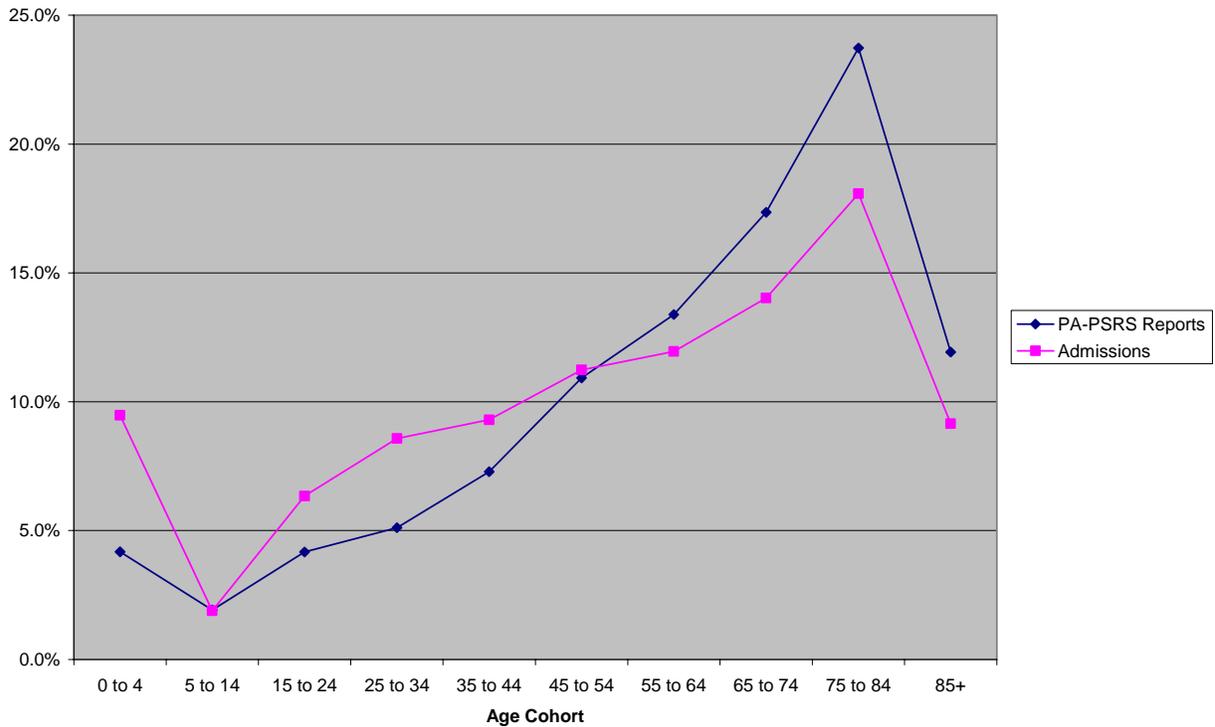


Figure 16. Proportion of Hospital Reports to PA-PSRS by Age Cohort (2005)

Where age does seem to play a role is in the likelihood that an occurrence will be classified as a Serious Event. Figure 17 shows the percentage of reports in each age cohort that were considered Serious Events. This percentage generally increases with age. While the overall percentage of reports considered Serious Events was 4.4%, younger patients in reports to PA-PSRS were more likely to be involved in reports of Incidents, and older patients were more likely to be involved in Serious Events. There are a number of possible explanations for this finding. Older patients may be more likely than younger ones to be harmed by the same occurrence. For example, a fall that might result in a fracture in an elderly patient may result in little injury to an adolescent. Older patients may also interact with the healthcare system for more serious illnesses that require more complex interventions. When admitted to a hospital, older patients typically remain in the hospital longer than younger patients, which may also increase the chances that one will experience a Serious Event.

<sup>14</sup> Based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council ([www.phc4.org](http://www.phc4.org)). Estimates were based on statewide inpatient hospital data from the third quarter 2004 through second quarter 2005.

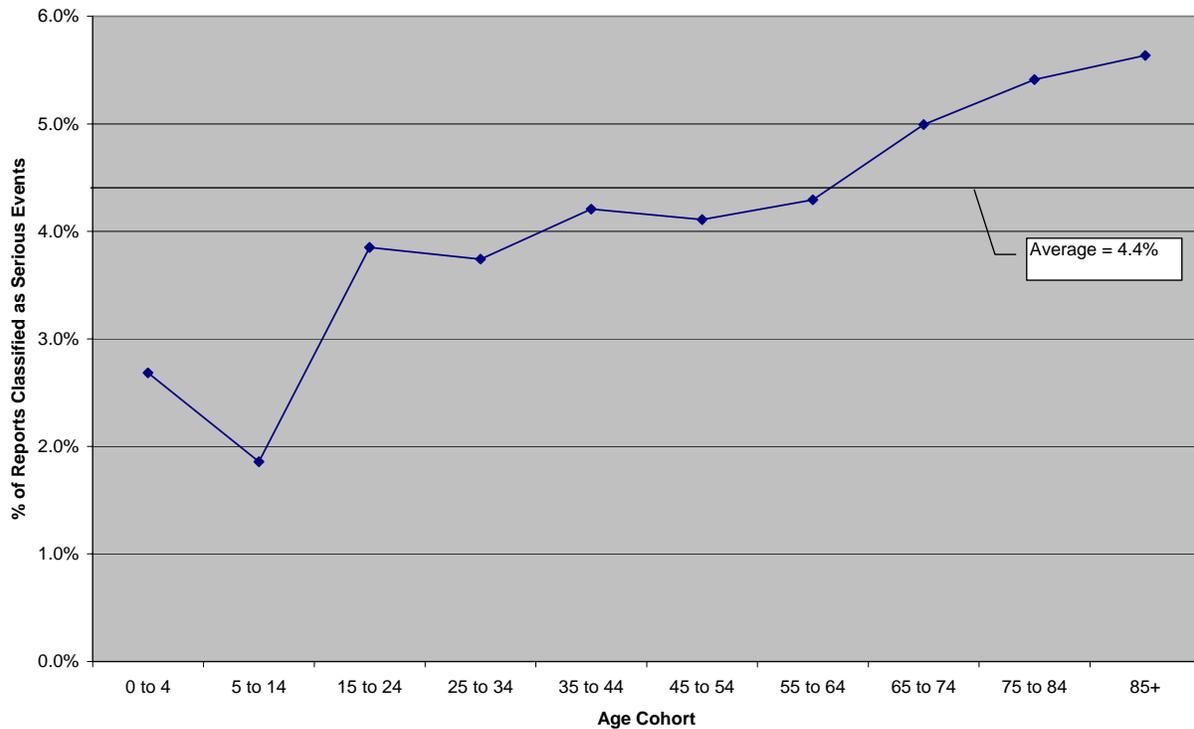


Figure 17. Proportion of Reports Classified as Serious Events by Age Cohort (2005)

### **Elderly Patients**

In the Authority's 2004 Annual Report, we identified several patterns of interest in reports involving elderly patients. These patterns have remained consistent through 2005. For example, in 2004, more than half of all reports (51.2%) involved patients 65 and older. In 2005, this figure rose slightly to 53%. Elderly patients accounted for 64% of Falls in 2004. This figure was unchanged in 2005. Elderly patients accounted for 72% of reports related to Skin Integrity. This figure rose to 73% in 2005.

### **Perinatal Patients**

In 2005, PA-PSRS received 2,885 reports involving perinatal patients (defined as those aged 30 days or younger), compared to 1,453 during the last seven months of 2004. Reports related to perinatal patients were more likely to be Errors or Complications of Procedures, Treatments, or Tests than reports related to the general population. These categories represented about two-thirds of the reports in this population, compared with about 35% in the general population. This doesn't 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.

Compared to 2004, the proportion of reports in this population involving Errors Related to Procedures, Treatments, or Tests has risen. These reports represented only about 23% of reports in this population in 2004, compared to one-third in 2005. Conversely, the proportion involving Complications of Procedures, Treatments, and Tests has dropped from about 45% in 2004 to about one-third in 2005. The proportion of reports about Medication Errors, which constitutes a large proportion of the reports in all age groups, among perinatal patients rose somewhat from 19% in 2004 to 22% in 2005.

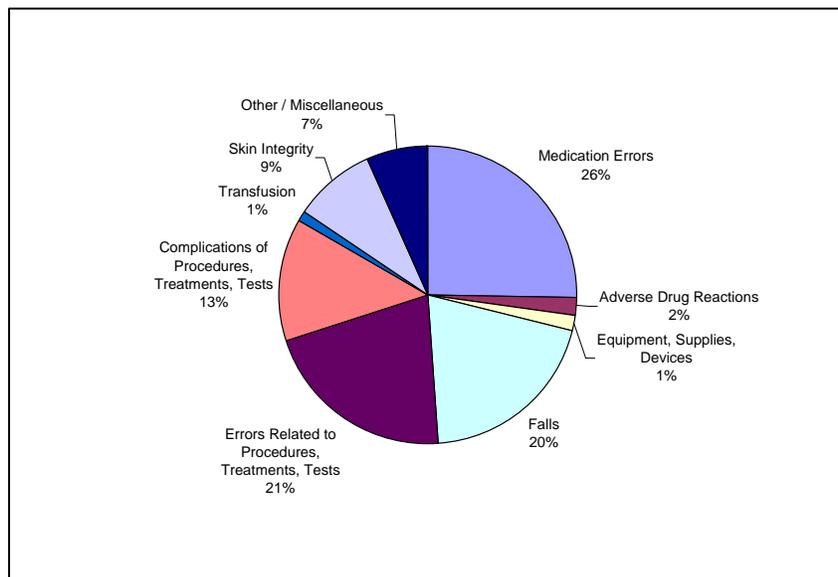
### **Children and Adolescents**

PA-PSRS received 12,170 reports involving children and adolescents (i.e., aged 21 and younger) in 2005, compared to 6,466 in 2004. Errors Related to Procedures, Treatments, and Tests were the most commonly submitted type of report in this population. These accounted for 28% of reports in this population, up from 23% in 2004. These were followed by reports of Medication Errors (25%, up from 22% in 2004) and Complications of Procedures, Treatments, and Tests (19%, down from 27% in 2004).

# Patterns and Trends in Reports to PA-PSRS

## Reports by Event Type

When reporting an event to PA-PSRS, a facility uses a classification system or “taxonomy” to characterize the occurrence they are reporting. 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

Figure 18. Percentage of Reports by Event Type

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

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

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

Figure 18 shows the percentage of reports submitted under each top-level Event Type. The most frequently reported occurrences were Medication Errors (25%) and Falls (20%). These two Event Types account for 45% of all reports submitted. While Medication Errors were the Event Type most frequently reported to PA-PSRS, they were not the ones most frequently associated with Serious Events.

Table 7 shows the proportion of reports classified as Serious Events or Incidents. The largest number of Serious Event reports was under the Event Type category Complications of Procedures, Treatments, Tests, followed by the category for Skin Integrity. These Event Types accounted for 38% and 20% 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 Medication Errors (1%).

Table 7. Reports by Event Type and Submission Type

Event Type	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Medication Errors	299	1%	42,072	99%	42,371	25%	L
Adverse Drug Reactions (not a medication error)	281	8%	3,077	92%	3,358	2%	H
Equipment / Supplies / Devices	68	3%	2,479	97%	2,547	2%	L
Falls	1,294	4%	32,360	96%	33,654	20%	
Errors Related to Procedure / Treatment / Test	656	2%	34,947	98%	35,603	21%	L
Complications of Procedure / Treatment / Test	2,822	12%	20,235	88%	23,057	14%	H
Transfusions	34	2%	1,600	98%	1,634	1%	L
Skin Integrity	1,502	10%	13,613	90%	15,115	9%	H
Other / Miscellaneous	548	5%	11,185	95%	11,733	7%	
Total	7,504	4%	161,568	96%	169,072	100%	

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

Because the vast majority of reports submitted to PA-PSRS were submitted by hospitals, the distribution of all reports by Event Type closely mirrors the distribution by Event Type in hospitals. However, the Event Types most frequently reported by hospitals were different from those reported by Ambulatory Surgical Facilities and Birthing Centers (see Table 8).

Table 8. 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	42,306	25%	99.85%	65	3%	0.15%	L
Adverse Drug Reactions (not a medication error)	3,285	2%	97.83%	73	4%	2.17%	H
Equipment / Supplies / Devices	2,490	1%	97.76%	57	3%	2.24%	H
Falls	33,597	20%	99.83%	57	3%	0.17%	L
Errors Related to Procedure / Treatment / Test	35,190	21%	98.84%	413	20%	1.16%	
Complications of Procedure / Treatment / Test	22,287	13%	96.66%	770	37%	3.34%	H
Transfusions	1,634	1%	100%	0	0%	0.00%	L
Skin Integrity	15,005	9%	99.27%	110	5%	0.73%	L
Other / Miscellaneous	11,204	7%	95.49%	529	26%	4.51%	H
Total	166,998	100%	98.77%	2,074	100%	1.23%	

H=significantly higher than overall average of 1.23%; L=significantly lower than overall average of 1.23%.

While reports of Medication Errors and Falls combined accounted for 45% of all reports submitted by hospitals, these categories accounted for only 6% of reports from Ambulatory Surgical Facilities and Birthing Centers. Well over half (57%) of reports from these latter facilities involved Complications or Errors Related to Procedures/Treatments/Tests. This difference is not surprising, because these facilities provide specialized services of a more limited scope and generally treat a healthier patient population than do hospitals.

## 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, while some differences may exist, the proportion of reports in each event type are remarkably consistent across hospitals of different size. Hospitals with fewer than 100 beds reported proportionally fewer Errors Related to Procedures/Treatments/Tests than larger hospitals. Hospitals in the 50-99 bed range submitted proportionally fewer reports related to Skin Integrity, 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 sized hospitals are similar.

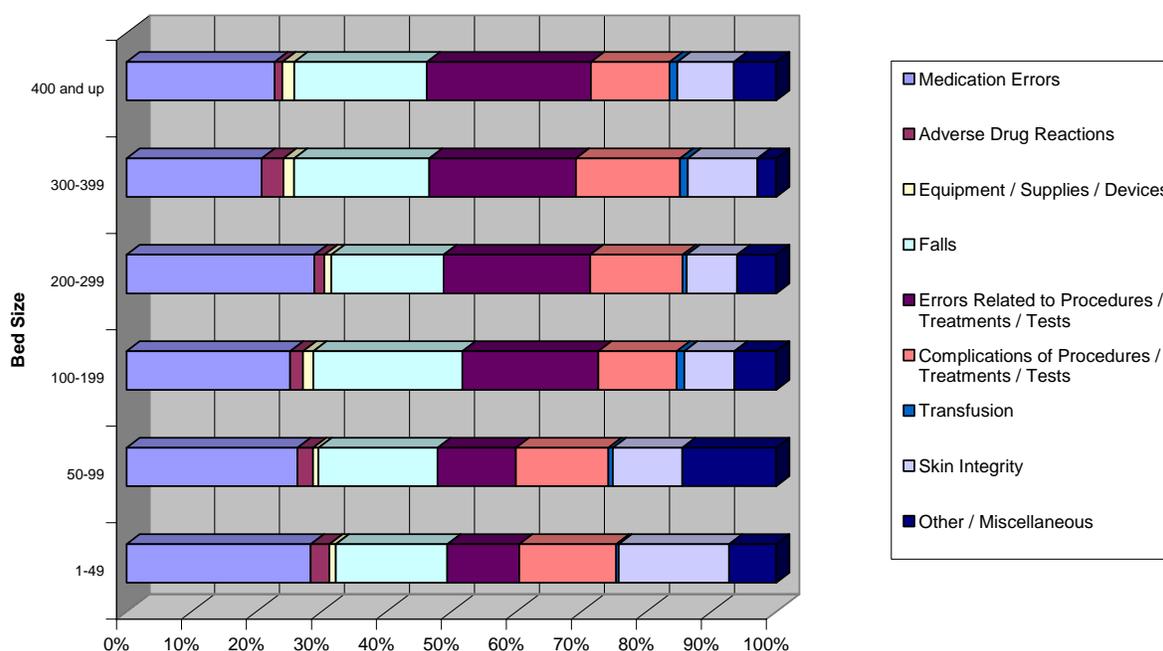


Figure 19. Reports from Hospitals by Event Type and Facility Size (2005)

## 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>15</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 10% 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 86% of all reports)

<sup>15</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, would be an event that did not reach the patient.

- Event, Harm—An event that reached the patient and caused temporary or permanent harm (4%)
- Event, Death—An event occurred that resulted in or contributed to death (0.3%)

Table 9 shows the reports received during 2005 categorized by the level of harm (as described above) and by Event Type. For the most part, the reports at each level of harm follow a similar distribution by Event Type as they do in the database as a whole. There are exceptions to this, however. For example, while complications comprise 14% of reports overall in 2005, they comprise 36% of the reports of events involving harm and 61% 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 25% of reports in 2005, they only comprise 4% of events involving harm and 2% of events contributing to or resulting in death. Reports of falls, skin integrity problems, and errors related to procedures/treatments/tests were also associated with harm or death at a frequency lower than their representation in the database as a whole.

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

Event Type	Unsafe Conditions		Event, No Harm		Event, Harm		Event, Death		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Medication Error	3,584	21%	38,488	27%	288	4%	11	2%	42,371	25%
Adverse Drug Reaction	200	1%	2,877	2%	273	4%	8	2%	3,358	2%
Equipment / Supplies / Devices	359	2%	2,120	1%	66	1%	2	0%	2,547	2%
Fall	571	3%	31,789	22%	1,278	18%	16	4%	33,654	20%
Error Related to Procedure / Treatment / Test	4,073	24%	30,874	21%	639	9%	17	4%	35,603	21%
Complication of Procedure / Treatment / Test	2,659	16%	17,576	12%	2,545	36%	277	61%	23,057	14%
Transfusion	212	1%	1,388	1%	31	0%	3	1%	1,634	1%
Skin Integrity	1,962	12%	11,651	8%	1,501	21%	1	0%	15,115	9%
Other / Miscellaneous	3,217	19%	7,968	6%	430	6%	118	26%	11,733	7%
Total	16,837	100%	144,731	100%	7,051	100%	453	100%	169,072	100%

To emphasize figures shown above, only 4% of all reports submitted involve harm to the patient, ranging from a simple laceration to a life-threatening situation and death. Figure 20 illustrates that the vast majority of reports do not result in Patient Harm.

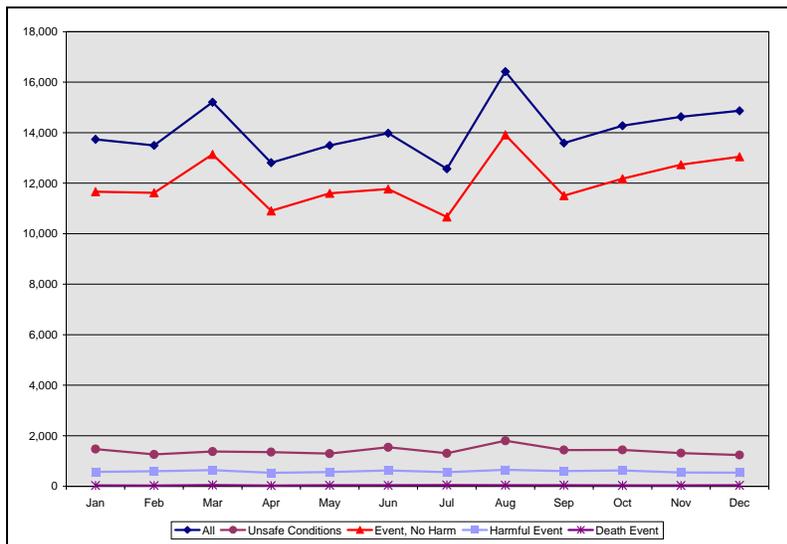


Figure 20. Reports by Level of Harm by Month (2005)

## Reports Involving Patient Death

In 2005, PA-PSRS received 453 reports of events that may have contributed to or resulted in the patient's death, compared to 207 reports received during the last seven months of 2004. These reports account for a quarter of one percent of all submitted reports. In terms of particular event types (see Table 10), although 14% of all reports in 2005 were attributed to Complications of Procedures/Treatments/Tests, 61% of all reports involving the patient's death were of that event type. Of those reports involving death associated with complications, the majority describe patients who died following surgery or another invasive procedure (50%) or patients who suffered cardiopulmonary arrest outside the ICU setting (22%). A further 10% involved maternal or neonatal injury associated with childbirth, and 9% were associated with healthcare-associated infections.

Table 10. Reports Involving the Patient's Death, by Event Type (2005)

Event Type	No.	%
Medication Error	11	2.4%
Adverse Drug Reaction	8	1.8%
Equipment / Supplies / Devices	2	0.4%
Falls	16	3.5%
Errors Related to Procedures / Treatments / Tests	17	3.8%
Complications of Procedures / Treatments / Tests	277	61.1%
Transfusion	3	0.7%
Skin Integrity	1	0.2%
Other / Miscellaneous	118	26.0%
Total	453	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 among these reports. Many of these reports involve patients who were found unresponsive, who went into respiratory arrest and resuscitation efforts failed, or who were admitted to the hospital and died of their disease.

Not all of these patient deaths were preventable, and they need not necessarily involve an error on the part of a healthcare provider to be reportable under Act 13. For example, one report describes a patient who fell from bed and sustained a head injury. The patient's bed exit alarm sounded, with clinicians responding to the alarm quickly. The patient had a bruise to the right temple and showed other signs of head trauma. A CT scan of the head showed subdural bleeding, which requires urgent treatment to prevent further injury. However, because of the patient's other health conditions, the family designated the patient "Do Not Resuscitate," opting for no treatment. The patient subsequently died. All indications in the report are that clinicians reacted quickly to the patient's fall and provided appropriate care in response to it.

In other cases, in which human error clearly played a significant role in the patient's death, it is usually easy to see evidence that medical errors typically have multiple causes. Rarely is a single individual at fault. For example, in a case of a fatal medication overdose, a nurse programmed an infusion of total parenteral nutrition (TPN) to run at 625 mg/hr, instead of the prescribed 62.5 mg/hr. The nurse inadvertently omitted the decimal point when programming the infusion pump. The error was not discovered until the patient became short of breath. Though the patient was treated for elevated potassium and glucose (both results of the overdose), the patient coded that day and died. While it would be easy to blame the nurse for this tragic mistake, upon further investigation, the facility identified another cause: the infusion pump did not alarm or warn the nurse that the TPN dose entered was outside the normal range. The facility made several changes in response to this event. First, they sought to eliminate the use of decimal points on TPN orders and instituted a practice of pharmacy "rounding" orders for adult TPN that continued to use decimal

places. They also reviewed their inventory of infusion pumps and programmed them with a warning to prevent this type of occurrence from happening again.

Every unanticipated patient death warrants investigation. When a facility identifies any Serious Event (including an unanticipated death), it is required to provide the patient or their family with written notice. Further, in addition to being reviewed by PA-PSRS staff, these reports were also submitted to the Department of Health, consistent with the Department’s regulatory role overseeing healthcare facilities.

### **Reports by Location/Department (Hospitals Only)**

When submitting a report to PA-PSRS, a healthcare facility must identify where in the facility the event occurred. Currently there are over 150 defined locations, or “care areas” from which a facility may select. As shown in Figure 21, among hospitals, General Medical/Surgical Units were cited most frequently as the location of the event, generating about one quarter (25.3%) of all reports submitted in 2005. Other types of units mentioned most frequently in submitted reports were Intermediate Units (9.1%), Ancillary Departments (8.3%), and Surgical Services (8%).

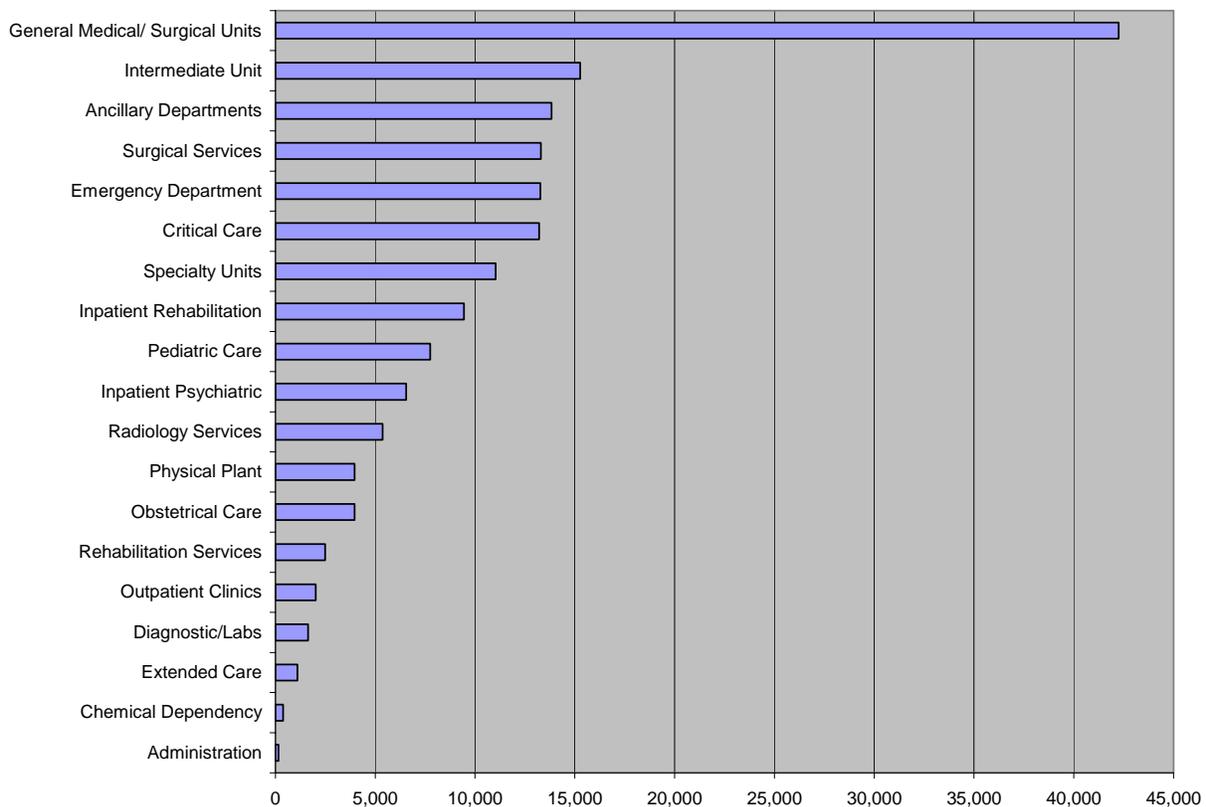


Figure 21. Reports by Location/Department (Hospitals Only)

Recording where in the facility an event occurred allows Patient Safety Officers to track patterns or trends in their own facility. For example, if significantly more reports of a certain type of event came from one general medical/surgical unit than another, and both units were caring for comparable numbers of patients with comparable health status, the Patient Safety Officer might be able to identify things the one unit could learn from the other to reduce those types of occurrences.

The PA-PSRS system facilitates this type of analysis by providing the Patient Safety Officer with graphical tools and reports they can use to identify these types of patterns.

# 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 22, Patient Characteristics (27%) and Team Factors (26%) were the groups of contributing factors cited most often in reports submitted in 2005.

“Lack of patient compliance/adherence” was the most frequently cited patient-related factor in the reports, and this factor was closely related to the Event Types of Falls and Complications of Procedures/Treatments/Tests. 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 when ambulating.

The specific Team Factor mentioned most frequently was “Communication problem between providers.” Communication was viewed as problematic most often in conjunction with reports of Medication Errors and Errors in Procedures/Treatments/Tests. These two Event Types accounted for more than three out of four of all reports mentioning provider communication as a contributing factor. Problems with provider communications encompasses a wide range of issues, including confusing or incomplete orders, verbal orders that are misinterpreted, illegible handwriting, and many others.

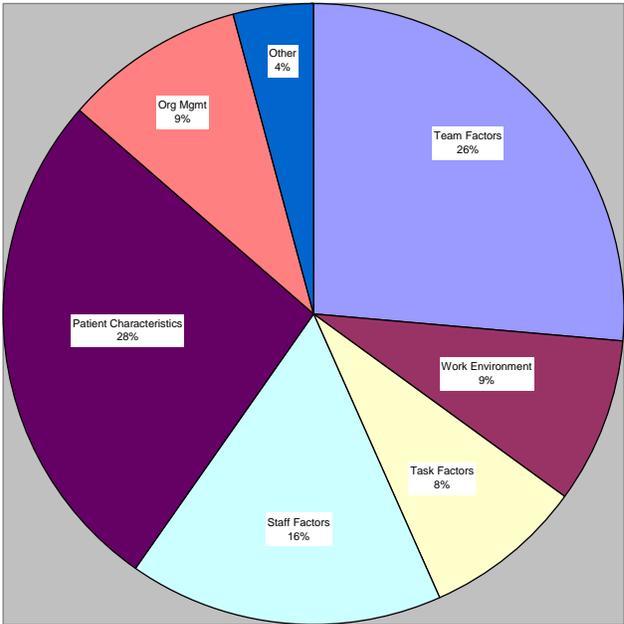


Figure 22. Contributing Factors Cited in Reports to PA-PSRS, by Category (2005)

Not surprisingly, staff communication was also the most frequently cited “root cause” among reports submitted to PA-PSRS in 2005—mentioned in 25% of reports that contained this information. Other frequently cited root causes include orientation and training of staff, patient physical assessment, and patient observation procedures. With the exception of this last category, the other three are also the three most commonly cited root causes of Sentinel Events reported to the Joint Commission on Accreditation of Healthcare Organization (JCAHO).<sup>16</sup>

## Healthcare-Associated Infections

Healthcare-associated infections (HAIs)<sup>17</sup> have garnered significant attention in Pennsylvania and in the nation this year. In 2004, Pennsylvania became the first state to mandate hospital reporting of selected types of HAIs, resulting in a July 2005 report from the Pennsylvania Healthcare Cost Containment Council (PHC4) that identified 11,668 HAIs reported in 2004 from 173 general acute care hospitals.<sup>18</sup>

In 2005, Pennsylvania hospitals submitted 3,268 reports of HAI through PA-PSRS, about 3.5 reports for every 10,000 patient days of care provided statewide (see Table 11). This figure likely understates the actual number of HAIs that occurred in Pennsylvania in 2005.

Table 11. Hospital Reports of Healthcare Associated Infections, by Region (2005)

Type of Infection	Northeast	Southeast	Northcentral	Southcentral	Northwest	Southwest	Statewide
Intravascular catheter infection	89	22	6	7	21	217	362
Wound or surgical site infection	129	25	29	22	58	462	725
Nosocomial pneumonia	51	6	6	13	28	223	327
Sepsis within 48 hrs of admission	71	5	1	13	6	39	135
Antibiotic-associated diarrhea	109	36	13	49	102	980	1289
Antibiotic resistant organism	147	42	4	16	38	100	347
Urinary tract infection	0	11	9	3	21	23	67
Other Nosocomial Infection	1	2	1	0	2	10	16
<b>Total</b>	<b>597</b>	<b>149</b>	<b>69</b>	<b>123</b>	<b>276</b>	<b>2,054</b>	<b>3,268</b>
Patient Days 2005 (Est.)	1,119,369	3,856,083	360,705	966,828	658,842	2,285,983	9,247,810
Reported Infections per 10,000 Patient Days	5.3	0.4	1.9	1.3	4.2	9.0	3.5

In contrast to the number of HAI reports in PA-PSRS, cases of HAIs reported to PHC4 in 2004 were equivalent to 15 cases per 10,000 patient days. A national estimate of the number of HAIs occurring annually in the United States is 98 per 10,000 patient days.<sup>19</sup>

Clearly, PA-PSRS is not capturing reports of all cases of HAI that occur in Pennsylvania, nor does Act 13 require this. While disease surveillance systems such as the National Nosocomial Infections Surveillance System of the

<sup>16</sup> Joint Commission on Accreditation of Healthcare Organizations. Sentinel event statistics, root causes of sentinel events (all categories; 1994-2005). Available from Internet: [www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/root+causes+of+sentinel+event.htm](http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/root+causes+of+sentinel+event.htm). Accessed 20 Feb 2006.

<sup>17</sup> In the 2004 Annual Report, we used the term “nosocomial infection” to describe infections that were inadvertently caused by or associated with clinical care. While the terms are used more or less synonymously, we are adopting the term “healthcare associated infections (HAI),” which is the current term of art among infection control practitioners.

<sup>18</sup> Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired infections in Pennsylvania. PHC4 Research Briefs. Issue 5; Jul 2005. Available from Internet: [www.phc4.org/reports/researchbriefs/071205/default.htm](http://www.phc4.org/reports/researchbriefs/071205/default.htm). Accessed 14 Feb 2005.

<sup>19</sup> Burke JP. Infection control—a problem for patient safety. *N Engl J Med*. 13 Feb 2003. 348(7):651-6.

Centers for Disease Control and Prevention (CDC) attempt to measure the incidence and/or prevalence of selected diseases, PA-PSRS operates under legislatively mandated definitions of reportable events. For an HAI—or any adverse event or “near miss”—to be reported to PA-PSRS, it must first be deemed by the healthcare institution involved to meet the statutory definition of a Serious Event or Incident.

The definitions for Serious Event and Incident both incorporate the notion of an “unanticipated injury” (see page 25). Healthcare workers might perceive many HAIs as anticipated due to the patient’s age, comorbid conditions, length of stay in the hospital, and other factors that may place the patient at higher risk relative to a healthy individual. If a patient contracts an infection, and the infection is considered *anticipated*, the facility’s Patient Safety Officer may consider the case not reportable. Facilities are also not likely to report HAIs that were contracted in the community or in another healthcare setting (e.g., nursing home).

Table 11 shows that there is substantial variation in report volume by region, even after adjusting for regional differences in the volume of care provided. We attribute this variation in report volume primarily to variations in facilities’ interpretation of Act 13 reporting requirements rather than to variation in the number of HAIs that occur in each region.

The largest number of HAI reports was submitted in the Southwestern region, with 9 reports per 10,000 patient days. We attribute this to heightened vigilance and a greater willingness to report to PA-PSRS in the Pittsburgh area, which has been home to the Pittsburgh Regional Healthcare Initiative (PRHI), a regional collaborative that has focused on reducing HAIs for several years. The fact that this region accounts for more than 75% of all reports of antibiotic-associated diarrhea supports this interpretation.

The public is rightfully concerned about the potential dangers associated with healthcare-associated infections. However, as a learning rather than a regulatory organization, the Authority is focused more on the lessons that can be learned from the reports than on the actual number of reports submitted through PA-PSRS. Many hospitals around the state are actively engaged in specific initiatives designed to prevent and reduce the spread of HAIs. Some of these are facility-specific, but several of them are part of regional or national collaboratives. For example:

- The **Pittsburgh Regional Healthcare Initiative (PRHI)** reduced healthcare associated bloodstream infections associated with intravenous catheters by 63%—from 4.3 down to 1.6 infections per 1,000 patient days at risk. Hospitals participating in the initiative achieved this goal through a variety of means including workflow redesign, involving front-line caregivers in immediate examination of mishaps, checklists for prevention of infections, staff training, and providing hospital units with feedback on their infection rates and adherence to preventive practices.
- In 2005, the **Delaware Valley Healthcare Council (DVHC)** launched its Partnership for Patient Care, a three-year initiative to promote evidence-based best practices in an effort to improve patient safety. In its first year, this collaborative is taking a regional approach to analyzing the potential mechanisms of failure that can lead to: urinary tract infection from urinary catheters, surgical site infection, and central line infections.
- Pennsylvania healthcare organizations have formed a statewide “Node” of the Institute for Healthcare Improvement’s **“100,000 Lives Campaign.”** This campaign is intended, as its name suggests, to save 100,000 lives a year by encouraging adoption of best practices in six key areas where the evidence is strong that improvement is achievable. Three of these areas focus on reducing HAIs by preventing: surgical site infections, central line infections, and ventilator-associated pneumonia.
- The **Patient Safety Forum**, a new statewide collaborative of many stakeholder groups, is targeting a reduction in incidents of MRSA (methicillin resistant staphylococcus aureus) infections, with an emphasis on engaging physicians in this initiative. This will further facilitate the collaboration of physicians, nurses, other practitioners, patient safety officers, infection control managers and hospital administrators in a way that cuts across traditionally compartmentalized job functions.

Infection control has long been a major concern of healthcare, and hospitals have routinely employed one or more infection control practitioners whose responsibility is to monitor, report on, and reduce the occurrence of HAIs. As a result of Act 13, hospitals in Pennsylvania are required to designate a Patient Safety Officer, who has the responsibility for submitting reports to PA-PSRS. Although it is anecdotal evidence, in our conversations with Patient Safety Officers, we have developed the impression that the functions of infection control and patient safety reporting are compartmentalized, and many institutions view HAIs through the traditional lens of infection control without recognizing HAIs as a patient safety problem as well. However, this view is beginning to change, as evidenced by some of the initiatives outlined above and the adoption of a “culture of safety” mindset within individual institutions.

PA-PSRS has published articles in the *Patient Safety Advisory* related to HAIs that provide feedback on steps healthcare institutions can take to reduce the incidence of infection. For example, the article “Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use” (June 2005) identified a pattern of deaths associated with *C. diff* after prophylactic antibiotic use in conjunction with relatively routine surgical procedures (see page 51). An upcoming *Advisory* article will address problems of inadequate cleaning and sterilization of surgical equipment following use. Because of the importance of reducing incidence of healthcare-associated infections, the Authority will continue to monitor trends in this area.

## Patient Safety Issues Identified through PA-PSRS 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 2005, the Authority published four quarterly issues of the *Advisory* and two supplements, comprising nearly 60 articles. Following are summaries of selected articles published during 2005.

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**"I use your Advisories for in-services and updates to the clinical staff. Very informative. Thank you."**

From the Patient Safety Officer at an ambulatory surgery center in Northwest Pennsylvania

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### When Patients Speak—Collaboration in Patient Safety

Volume 2, Number 1—March 2005

The patient is one of the most important allies in reducing medical errors.<sup>20</sup> Research indicates that when patients actively participate in their overall healthcare management, medical errors are reduced.<sup>21,22</sup> Though improving patient safety historically has not included the patient's perspective, patients can play a key role in promoting their own safety.<sup>23</sup> Some of the ways in which patients can help their clinicians in this respect include:

- Identifying side effects or adverse events quickly so that appropriate action can be taken.
- Ensuring that treatment is given, monitored, and complied with.
- Choosing an experienced, safe practitioner.
- Deciding upon a strategy for management or treatment of health problems.
- Helping to achieve an accurate diagnosis or analysis of a health-related issue.<sup>23</sup>

Reports submitted to PA-PSRS indicate that patients and family members who speak up about patient care issues have not only identified medical errors but also prevented errors and injuries. For example:

- A nurse was providing education to a patient and spouse prior to flushing a catheter. When the nurse mentioned Heparin, the spouse spoke up and said that the patient was allergic to Heparin. The nurse reviewed the chart and found no Heparin allergy documented. The allergy was documented on the patient's transfer record but had not been transcribed onto the chart. New orders were obtained for flushing this patient's catheter using saline only.
- A patient's husband approached nursing staff asking if "that band is still supposed to be tied so tight around her arm." When the patient's IV had been started two hours earlier, a nurse forgot to remove the tourniquet.
- The patient's son picked up his father who was discharged from the hospital. While en route home, he noticed that his father still had IV access in place. The son telephoned the hospital, and arrangements were made for removal of the IV access.

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<sup>20</sup> Meyer GS, Arnheim L. The power of two: improving patient safety through better physician-patient communication. *Family Practice Management* [online]. 2002 Jul/Aug [cited 2005 Jan 13]. Available from Internet: [www.aafp.org/fmp/20020700/47thep](http://www.aafp.org/fmp/20020700/47thep).

<sup>21</sup> Awe C, Lin SJ. A patient empowerment model to prevent medication errors. *J Med Syst* 2003 Dec;27(6):503-17.

<sup>22</sup> Cohen M. Causes of medication errors. In: Cohen M, ed. *Medication errors*. Washington (DC): American Pharmaceutical Association; 1999.

<sup>23</sup> Vincent CA, Coulter A. Patient safety: what about the patient? *Quality & Safety in Health Care* 2002;11:76-80.

## Opportunities for Improvement

In most instances, PA-PSRS reports indicate that when patients speak up, clinicians listen and take appropriate action. However, sometimes an error still occurs despite the opportunity for recovery provided by a patient's attentiveness and communication. Opportunities for improvement identified through PA-PSRS reports include:

- The need to explain diagnoses or treatments to patients without using jargon.
- Being attentive to patients when they question the need for or appropriateness of a test or procedure.
- Respecting information provided by patients, but seeking independent verification before acting on it.
- Using techniques to improve patient-clinician communication.

Studies of physician communication indicate that physicians redirect and interrupt a patient's initial descriptions of their concerns after an average of only 18 to 23 seconds.<sup>24,25</sup> This discourages patients from providing complete histories and can result in missed opportunities to gather important information. The order in which patients discuss their problems does not necessarily relate to their clinical importance.<sup>24</sup> Assuming that the chief complaint is the first complaint mentioned by the patient may be inaccurate.

Increasingly, improving communication skills have become a component of medical school curricula.<sup>26,27,28,29</sup> Common concepts in communication skills programs for clinicians include opening discussions by inviting/welcoming the patient's participation.<sup>20,29,30</sup> No question is considered too unreasonable, and no information is too trivial to share.<sup>20</sup> Active listening is used to gather information, balancing the use of both open and closed questions.<sup>29,30,31</sup> Discussion is encouraged without interruption or premature closure.<sup>32</sup> Nonverbal indications, as well as how the information is spoken, are identified<sup>31</sup> that might suggest what the patient is experiencing—emotions, conflicts, concerns. This allows a fuller understanding of the patient's perspective.<sup>29</sup>

Other skills include reflecting back to the patient by summarizing information that the patient has shared and requesting/accepting corrections and clarifications from the patient. One concept is "Don't just do something, stand there!"—pausing several seconds may allow the patient to feel understood and that the information imparted is being respected and taken seriously.<sup>31</sup> Finally, clinicians can check with the patient repeatedly for any additional concerns.<sup>24</sup> The University of Colorado School of Medicine incorporates these techniques into the concepts of "Invite, Listen, Summarize."<sup>32</sup>

## Unlabeled Basins, Bowls, and Cups in Surgery

Volume 2, Number 1—March 2005

Using unlabeled basins, bowls, and cups in the operating room (OR) can cause surgical staff to use the wrong drug or solution on a patient. One report described an occurrence in an operating room (OR) where Monsel's solution (20% ferric subsulfate) and Lugol's solution (potassium iodide) were both on the surgical field. The surgeon, wanting to use the Lugol's solution, removed the Monsel's bowl off the field without asking the scrub nurse to identify the solution. In another report highlighting a dangerous situation, three unlabeled basins that contained water, saline, and renografin solutions were found on a sterile back table in the OR.

<sup>24</sup> Silverman J, Draper J. Identifying the agenda in consultation. *Br J Gen Pract* 1995 Jan;45(390):52-3.

<sup>25</sup> Marvel MK, Epstein RM, Flowers K, et al. Soliciting the patient's agenda. *JAMA* 1999 Jan 20;281(3):283-7.

<sup>26</sup> Sharf BF. Teaching patients to speak up: past and future trends. *Patient Education and Counseling* 1988;11:95-108.

<sup>27</sup> Ellner A, Hoey A, Frisch L. Speak up! *BMJ* 2003 Aug 9;327:303-4.

<sup>28</sup> Laine C, Davidoff F. Patient-centered medicine: a professional evolution. *JAMA* 1996;275:152-6.

<sup>29</sup> Haq C, Steele DJ, Marchand L, et al. Integrating the art and science of medical practice: innovations in teaching medical communication skills. *Jam Med* 2004 Jan Suppl;36:543-50.

<sup>30</sup> Boyle D, Dwinnell B, Platt F. Invite, listen, and summarize: a patient-centered communication technique. *Acad Med* 2005 Jan;80(1):29-32.

<sup>31</sup> Coulehan JL, Platt FW, Egener B, et al. "Let me see if I have this right..." words that help build empathy. *Ann Intern Med* 2001;135:221-7.

<sup>32</sup> Silverman J, Draper J. Identifying the agenda in consultation. *Br J Gen Pract* 1995 Jan;45(390):52-3.

Several reports outside of PA-PSRS that gained national attention illustrate the hazards of this practice. In one case, a 37-year old male patient was severely burned when his physician mistakenly applied TBQ (a cationic germicidal detergent with a pH of 13) instead of vinegar for a wart removal. In another case, a patient was accidentally injected with hydrogen peroxide instead of lidocaine for local anesthesia. During the surgical procedure, hydrogen peroxide was drawn into a syringe from an unlabeled basin instead of the intended lidocaine, which was also in an unlabeled cup. Even in radiology, unlabeled products can lead to tragic outcomes. A patient was accidentally injected with lidocaine 2% instead of contrast media [Omnipaque (iohexol)] during angiography. The patient suffered a grand mal seizure but recovered.<sup>33</sup>

A report from *Hospital Pharmacy* in 1989 described the case of a patient who died during a surgical procedure to remove a cancerous eye. In this case, an unlabeled specimen cup was filled with glutaraldehyde to preserve the patient's enucleated eye, but was mistaken as spinal fluid. The fluid had been removed to reduce pressure because the malignancy had spread to the brain. The spinal fluid was in an identical unlabeled cup. Near the end of the procedure, an anesthesiologist accidentally injected the glutaraldehyde intrathecally, believing it was the patient's spinal fluid.<sup>34</sup>

Findings from the 2004 *ISMP Medication Safety Self Assessment*<sup>®</sup> for hospitals, gathered from more than 1,600 hospitals across the country, show that less than half (41%) of the hospitals always label containers (including syringes, basins, or other vessels used to store drugs) on the sterile field, even when just one product or solution is present. Eighteen percent do not label medications and solutions on the sterile field at all, and another 41% apply labels inconsistently. Although this represents an improvement from the 2000 findings (25% reported full labeling; 24% reported no labeling), surprisingly, this rather basic safety measure is not widely implemented in most hospitals.<sup>35</sup>

Following are examples of safe practices, some of which are mentioned in the Association of PeriOperative Registered Nurses (AORN) Guidance Statement: Safe Medication Practices in the Perioperative Practice Settings:<sup>36</sup>

- Making labeling easy by purchasing sterile markers, blank labels, and preprinted labels that can be opened onto the sterile field during all procedures. To minimize staff time, prepare surgical packs in advance with sterile markers, blank labels, and preprinted labels for all anticipated medications and solutions that will be needed for the case.
- Using labels on all medications, syringes, medicine cups basins, or other containers of solutions as well as chemicals, reagents on and off the sterile field, even if there is only one medication or solution involved.
- Using tall man lettering on labels to differentiate similar-sounding drug names (e.g., HYDRomorphone) or highlighting/circling the distinguishing information on the label.
- When possible, purchasing skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or other solutions.
- Individually verifying each medication and completing its preparation for administration, delivery to the sterile field, and labeling on the field before another medication is prepared.
- Verifying with the physician any medication on the physician's preference list before delivery to the sterile field, labeling, and/or administration.

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<sup>33</sup> ISMP. Medication Safety Alert! 18 June 1997. (2), 12.

<sup>34</sup> Cohen MR. Medication Error Reports. *Hospital Pharmacy*.1989;24(7).549.

<sup>35</sup> ISMP. Medication Safety Alert! 12 December 2004. (9), 24.

<sup>36</sup> Association of periOperative Registered Nurses (AORN). AORN Guidance Statement: Safe Medication Practices in Perioperative Practice Settings [online]. 2004. [Cited 22 Feb 2005.] Available on Internet: [www.aorn.org/about/positions/pdf/7f-safemeds-2004.pdf](http://www.aorn.org/about/positions/pdf/7f-safemeds-2004.pdf)

- Having the scrub person and circulating nurse concurrently verify all medications/solutions visually and verbally by reading the product name, strength, and dosage from the labels. If there is no scrub person, the circulating nurse could verify the medication/solution with the licensed professional performing the procedure.
- When passing a medication to the licensed professional performing the procedure, visually and verbally verifying the medication, strength, and dose by reading the medication label aloud.
- Keeping all original medication/solution containers in the room for reference until the procedure is concluded.
- At shift change or relief for breaks, having entering and exiting personnel concurrently note and verify all medications and their labels on the sterile field.
- Not making assumptions about what is in an unlabeled basin, bowl, cup or syringe.
- Discarding any unlabeled medication/solution found and considering the occurrence as a near miss.
- Performing regular safety rounds in areas that routinely have basins, bowls, cups, etc., to observe labeling procedures, promote consistency, and inquire about barriers to change.

## Focusing on Eye Surgery

Volume 2, Number 1—March 2005

PA-PSRS has received several reports in which the wrong intraocular lens (IOL) was implanted in the patient's eye. Half of the reports indicate that the patient returned to the operating room for implantation of the correct lens. In one case, the patient was satisfied with the level of correction obtained even with the incorrect lens. One report refers to the physician's selection of the incorrect lens from a cart.

The magnitude of the problem is evident from a review of a decade of claims. The Ophthalmic Mutual Insurance Company reviewed 168 claims which occurred from 1987 to 1997. Cataract procedures represented 33% of all closed claims during this period, and IOL cases were the largest group in the sample.<sup>37</sup> Causative factors identified with implanting the wrong IOL include:

- Use of an outdated IOL formula for the patient.
- Incorrect biometry or keratotomy readings.
- Mistakes in entering data into an IOL calculation program.
- Incorrect IOL labeling or packaging.
- Mistakes in providing the IOL during surgery.<sup>38</sup>

Different formulas can be used to determine the correct IOL, and each formula includes a variable known as a "lens constant." A widely used formula uses the "A-constant," which is dependent on the "specifics of the IOL design" and, as required by the US Food and Drug Administration, is printed on the IOL packaging by the manufacturer.<sup>39,40</sup> This A-constant is used in a string of interconnected calculations to determine the best lens for each patient. A quick

<sup>37</sup> Brick DC. Risk management lessons from a review of 168 cataract surgery claims. OMIC Publication Archives, Digest, [online]. Summer 1997, 1-9. [Cited 21 Feb 2005] Available from Internet: [www.omic.com/resources/risk\\_man/deskref/clinical/41.cfm](http://www.omic.com/resources/risk_man/deskref/clinical/41.cfm).

<sup>38</sup> American Association of Ophthalmologists. Minimizing wrong IOL placement, patient safety bulletin number 2 [online]. [Cited 10 Nov 2004.] Available from Internet: [www.aao.org/aao/education/library/safety/iol.cfm](http://www.aao.org/aao/education/library/safety/iol.cfm).

<sup>39</sup> Schwiegerling J. Optics of intraocular lenses. Clinical Optics [online]. [Cited 11 Mar 2005.] Available from Internet: [www.opthalmic.hyperguides.com/tutorials/clinical/optics\\_lenses/tutorial.asp](http://www.opthalmic.hyperguides.com/tutorials/clinical/optics_lenses/tutorial.asp)

<sup>40</sup> Wallace B. Refractive cataract surgery. Clinical Optics [online]. [Cited 11 Mar 2005.] Available from Internet: [www.opthalmic.hyperguides.com/tutorials/cateracts/refractive\\_cataract/tutorial.asp](http://www.opthalmic.hyperguides.com/tutorials/cateracts/refractive_cataract/tutorial.asp)

review of five companies' products revealed A-constants ranging from 114.2 to 119, with different A-constants for the same lens diopter.

When a facility changes vendors or lens manufacturers, it would be helpful to notify all ophthalmologists so the calculations can be adjusted accordingly. Ideally, the surgeon would select the lens prior to entering the operating room and note the change in vendor. However, this is often a delegated responsibility, and surgeons may unknowingly implant a different manufacturer's lens, not recognizing that a formula change is necessary because of differences in the A-constant between different manufacturers' products.<sup>41</sup>

The complete article in the March 2005 Advisory also reprints, with permission, suggestions for IOL verification in the operating room advocated by the American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals.

Among these are:

- Having the ophthalmic history and exam and the form that contains keratometry and axial length, primary and alternate lens/es for each patient, available in the operating room.
- Having the surgeon/assistant surgeon select the primary and alternate IOL/s before the start of the case. The surgeon verifies the IOL number, diopter, optic, A constant, and length against the appropriate form or documentation and/or patient medical record.
- When the surgeon requests the IOL, the circulating nurse shows the IOL box to the surgeon and verbally states the IOL model number and lens power and the surgeon acknowledges the communication.<sup>38</sup>

## **Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use**

**Volume 2, Number 2—June 2005**

*Clostridium difficile* (C. diff) is a bacterium in the Clostridia family, which also includes *C. perfringens* (gas gangrene), *C. tetani* (tetanus), and *C. botulinum* (botulism). Clinically, "C. diff" refers to an overgrowth of *C. difficile* in the colon which can manifest as diarrhea, sometimes profound, colitis, or toxic megacolon, sometimes complicated by dehydration, colonic perforation, and/or death. The overgrowth of *C. diff* in the colon usually results from alterations in the normal colonic flora associated with use of antibiotics.

*C. diff* is documented in almost half the reports submitted to PA-PSRS under the Event Type code "Nosocomial infection: antibiotic-associated diarrhea." Of greatest concern is the number of reports involving patient deaths in which *C. diff* is mentioned as a major contributing factor. At the time this article was published (about one year after mandatory reporting began) PA-PSRS has received 15 such reports to date. By late February 2006, this figure rose to 20. Diagnoses identified among the cases presented in June 2005 include sepsis/septic shock, toxic megacolon, colitis, diarrhea, and abdominal pain. Most patients in these reports (86%) were age 70 or older.

Several reports indicate that patients treated with antibiotics prophylactically for an elective surgical procedure developed symptoms of *C. diff* infection in the community after discharge. They failed to return to the healthcare system until their disease had progressed significantly. From the patient's perspective, the relatively routine nature of the surgery in several cases (e.g., knee replacement, repair of a hip or ankle fracture, hysterectomy) may have obscured the connection between the gastrointestinal symptoms of *C. diff* infection and their recent treatment.

The message for the healthcare community is to avoid complacency about the risk of *C. diff* infection and to help patients to understand when they need to return to the healthcare system for additional treatment, especially for diarrhea complicating antibiotic use. The risks of surgical complications may overshadow the risks of prophylactic antibiotics not only in the minds of patients and their families but also among healthcare workers.

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<sup>41</sup> Gordon A. Telephone Conversation with: Monica Davis. 2005 March 4.

Strategies for preventing this complication include:

- Following guidelines from the Centers for Disease Control and Prevention (CDC) on handwashing.
- Isolating patients who culture positive for *C. diff* to avoid transmission to others.
- Using personal protective equipment when caring for patients who culture positive, particularly during continence care.
- Thorough cleaning with disinfectants that are effective on *C. diff* spores.
- Prudent antibiotic use.
- Educating healthcare workers, patients, and families about the symptoms of *C. diff*, with emphasis on what types of symptoms to report to a physician.

The original article also included information on treating *C. diff* infections when they occur.

## **Forgotten But Not Gone: Tourniquets Left on Patients**

**Volume 2, Number 2—June 2005**

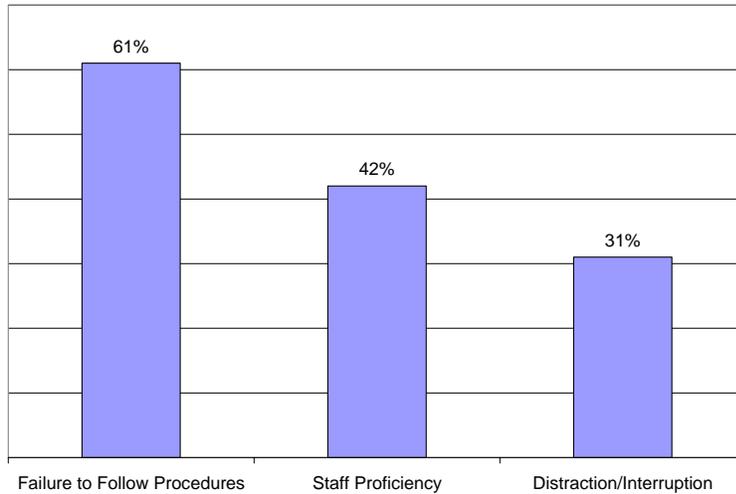
Since the implementation of PA-PSRS in June 2004 through May 2005, Pennsylvania healthcare facilities submitted more than 125 reports of tourniquets being left on patients' extremities. While few of the reports submitted to PA-PSRS were considered Serious Events, this problem has the potential to cause significant circulatory, neurological, vascular, and muscular damage.

The longer a tourniquet is left in place, the greater the chance of significant injury. In only 5% of the reports submitted to PA-PSRS was the tourniquet discovered within 30 minutes of application. Two-thirds were left on patients for up to two hours. The remaining third were left in place from two to 18 hours. In approximately half of the reports, the tourniquet was being used in conjunction with starting an IV line, while in the other half it was used for drawing a blood specimen for laboratory tests.

Many of the reports indicate that the cause of the error was related to failure to follow procedures or individual clinicians' proficiency. However, multiple reports were submitted by more than 60 hospitals, suggesting that this is a systemic problem that could benefit from system-wide solutions. Of the 36 reports that identified any contributing factors, 61% cite staff failure to follow procedures, 42% cite staff proficiency, and 31% cite distractions and interruptions (see Figure 23). Other contributing factors cited in the reports included: inexperienced staff, communication problems between providers, change of service, cross-coverage situation, lack of patient compliance, and lack of patient understanding.

The majority of facilities' recommendations for improvement involved individual counseling, discussion, or education, and referral to the department perceived as causing the occurrence. At least 17% of reports indicated that no system improvement issues were identified.

Despite this focus on the individual, environmental and task-related factors contributed to many of these occurrences. Several reports indicated that the presence of the tourniquet was hidden. For example, a tan-colored tourniquet may blend in with light skin tones, making it difficult to see. In ORs/Special Procedure areas, a surgical drape may cover an extremity in which an IV was started and a tourniquet was inadvertently left in place. In a critical care area, a tourniquet was discovered under an automatic blood pressure cuff. In a morbidly obese patient, a tourniquet may sink into fatty tissue/skin folds and may not be visible once applied.



**Figure 23. Factors Cited in Reports of Forgotten Tourniquets.** Among those reports citing any contributing factors, the percentage of reports citing these factors is shown. The most commonly cited factors suggest a narrow focus on the individual healthcare worker, rather than a broader focus on more systematic solutions.

While most reports focused upon the individual healthcare worker/department perceived as causing the occurrence, at least one Pennsylvania facility recognized that color might contribute to tourniquets being left on patients. In an effort to make their tourniquets more visible, the facility changed the color of its tourniquets from tan to royal blue, increasing their visual contrast with all skin tones.

Other strategies for reducing the incidence of this problem, some of which were identified by Root Cause Analysis teams within the Veterans Administration in a recent review,<sup>2</sup> include:

- Loosening tourniquets during any interruption in the blood draw process, when blood begins to flow into a vacuum tube or after the IV catheter is advanced, or before needle withdrawal.
- Having two healthcare workers sign the IV flow sheet to verify tourniquet removal after IV insertion.
- Controlling/reconciling the number of tourniquets used via checklists. Having a second healthcare worker verify that the number of tourniquets and IV kits used are equal/accounted for.
- When entering and leaving a unit, the phlebotomist reconciling a list of patients for venipunctures with the number of tourniquets in the venipuncture tray.
- For ambulatory patients, considering a separate location on the unit for specimen/blood draws. This may reduce distractions or interruptions.
- Standardizing blood draw/IV start schedules across departments so they do not coincide with periods of increased activity.
- Using long tourniquets so the ends of applied tourniquets are more visible.
- Being aware of patient nonverbal cues. Patient agitation/fussiness may be a symptom of discomfort associated with prolonged tourniquet use.
- Routinely incorporating into patient assessments an evaluation for the presence of tourniquets (even in verbal, oriented patients).
- Involving the patient/family in the care by instructing/developing a brochure<sup>3,4</sup> concerning phlebotomy/IV starts including:

- The concept that a tourniquet is usually left on for a few minutes.
- To tell healthcare workers if a tourniquet remains on for a longer period.
- That laboratory test results may be altered if a specimen is drawn from an extremity on which a tourniquet is applied for longer than 2-3 minutes.

A combination of strategies going across healthcare disciplines and departments, as well as patient involvement, may help to address the systems-related issues involved with forgotten tourniquets.

## Complexity of Insulin Therapy

Volume 2, Number 2—June 2005

With the rising prevalence of diabetes in recent years has come a corresponding increase in the use of insulin. Though it is often the most effective treatment for this chronic disease, data derived from scientific research and adverse event reporting systems such as PA-PSRS show that errors related to insulin are frequent and often cause significant patient harm. In fact, nearly 16% of all medication errors classified as Serious Events in PA-PSRS involved the use of insulin. A 1998 Institute for Safe Medication Practices (ISMP) study found that 11% of serious medication errors involve insulin misadministration.<sup>42</sup>

Insulin therapy has always required thoughtful management; however, over the last decade, the release of new insulin formulations, insulin delivery devices, and blood glucose monitors has made this process increasingly complex.<sup>43</sup> There are now close to a dozen different types of insulins manufactured by several companies, many with names or packages that look or sound alike.<sup>44</sup>

Humalog – Humulin R
Humulin N – Humulin R
Humulin R – Humulin 70/30
Humulin 70/30 – Humalog 75/25
Humalog 75/25 – Humalog
Lente Insulin – Lantus
Novolog – Novolog Mix 70/30
Novolog Mix 70/30 – Humulin 70/30
Novolin 70/30 – Novolog Mix 70/30

It should not be surprising that 12.8% of the medication error reports involving insulin have been classified as “wrong drug” errors. For instance, organizations have reported errors related to confusion between **LENTE** (insulin zinc suspension) and **LANTUS** (insulin, glargine) and **HUMULIN** (insulin, human) and **HUMALOG**. Figure 24 lists insulin product names that Pennsylvania facilities have reported as being confused with one another.

Figure 24. Examples of Insulin Products Reported to PA-PSRS as “Wrong Drug” Errors.

Insulin is a “high alert” drug that is prescribed, dispensed, and administered via error-prone processes and to patients who often are at risk for an adverse outcome if an error occurs. With such complexity, it is not surprising that errors with insulin are frequent and characteristically harmful to patients. As such, this medication warrants special handling.

The following strategies may help to reduce the incidence of insulin-related errors:

- **Obtaining an accurate history** of insulin therapy from patients upon admission and following up with questions to detect possible confusion between the many look- and sound-alike insulin products. Whenever possible, encourage patients or families to bring in the insulin for validation.
- **Communicating prescriptions clearly** using the entire product name and writing out the word “units.” (Overdoses have occurred when the abbreviation “U” has been misinterpreted as a “0” [zero] or a “4.”)

<sup>42</sup> Cohen MR, et al. Survey of hospital systems and common serious medication errors. *J Healthc Risk Manag.* 1998;18(1):16-27.

<sup>43</sup> ISMP. Medication Safety Alert! Acute Care Edition. 17 Apr 2002;(7)8.

<sup>44</sup> ISMP. Medication Safety Alert! Community/Ambulatory Care Edition. Jan 2004;(3)1.

- **Discouraging the use of verbal orders.** If they are used, reading back the spelling of the product name to avoid confusion with sound-alike insulin products. Considering the patient’s usual times for meals and specifying a clear relationship between insulin administration and the meals.
- **Storing insulin safely.** In the refrigerator, segregating vials (e.g., with storage bins) that may have look-alike names or packaging, or using other means (e.g., stickers, labels, enhancement with pen or marker) to call attention to important information that could be missed.
- **Building alerts into pharmacy and prescriber order entry systems to warn about the potential for error.** For example, using bold print or upper case lettering in order entry screens to clearly differentiate drug names that are similar and dangerous if confused (e.g., HumALOG vs. HumULIN, NovoLOG vs NovoLIN). In addition, emphasizing the word “Mix” along with the name of the insulin product mixture (e.g., Novolog **\*\*Mix\*\*** 70/30).
- **Performing an independent double check** of all doses before dispensing and administering insulin. Building the double check into daily work processes so it can be accomplished without disruption. In pharmacies, the original order could be compared with both the product to be dispensed and the computer-generated label before reaching the patient.
- **Providing staff with ongoing education** about insulin products, delivery devices, and monitoring devices. Consider providing staff with a chart that lists all insulin products used in your organization. Include: generic and brand names; onset, peak, and duration of action; time of administration in relationship to meals; and special precautions (e.g., measuring the proper dose, mixing instructions, more frequent patient glucose monitoring). Posting the charts in areas where insulin is prescribed, stored, and administered.

## ICU Reports More Likely to be Reported as Serious Events

Volume 2, Number 3—September 2005

Patients in intensive care units (ICUs) may be more likely than non-ICU patients to be injured by adverse events. The procedures performed on critically ill patients and the quantity and type of drugs used in their care may also increase their risk relative to non-ICU patients.<sup>45</sup>

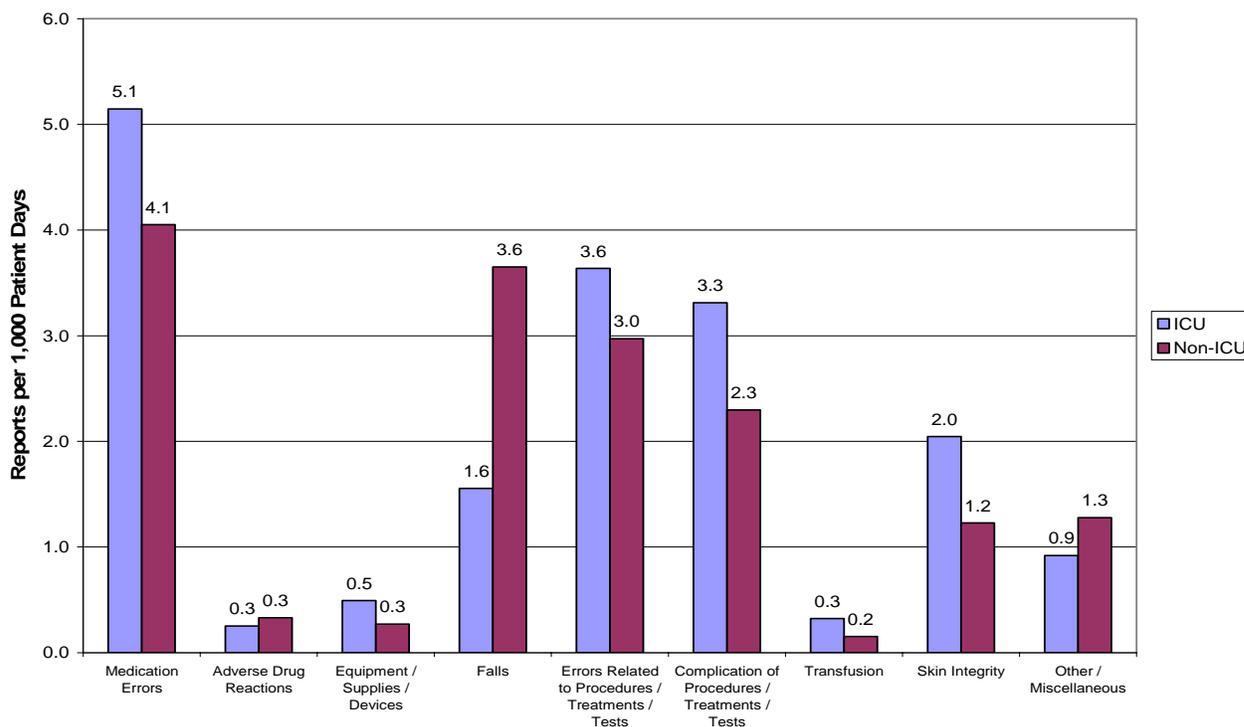
An analysis of reports submitted to PA-PSRS supports the hypothesis that ICU patients may have an increased risk of injury from adverse events. Among reports from hospitals, reports involving the ICU were about 20% more likely to be considered Serious Events than those that did not involve the ICU. Reports of Adverse Drug Reactions were 2.4 times as likely to be identified as Serious Events if they involved the ICU. Reports of Medication Errors and Complications of Procedures, Treatments, and Tests were 88% and 19% more likely to be Serious Events, respectively.

During the first year of mandatory reporting, Pennsylvania hospitals submitted 11,959 reports identified as occurring in the ICU (or 17.7 reports per 1,000 ICU patient days<sup>46</sup>). Of those reports, 5.4% were Serious Events, a significantly greater proportion than that from non-ICU areas. Reports involving the ICU accounted for 8.5% of all reports submitted by hospitals. Figure 25 presents the number of reports from ICU and non-ICU areas by Event Type in terms of the number of patient days.

<sup>45</sup> Cullen DJ, Sweitzer BJ, Bates DW, et al. Preventable adverse drug events in hospitalized patients: a comparative study of intensive care units and general care units. *Crit Care Med.* 1997 Aug;25(8):1289-97.

<sup>46</sup> Based on data from: Pennsylvania Department of Health, Bureau of Health Statistics and Research. Hospital and ambulatory surgery center data, standard output reports 2003-2004, Report 2A, Inpatient hospital unit data by facility and county. Reporting period: July 1, 2003, through June 30, 2004. Accessed 15 Aug 2005. Available online at [www.health.state.pa.us](http://www.health.state.pa.us).

Figure 25. Reports per 1,000 Patient Days by Event Type and ICU Involvement (Based on Reports Submitted by Hospitals from 6/7/04 through 6/6/05)



## Sequential Compression Devices and Patient Falls

Volume 2, Number 3—September 2005

At least 40 reports have been submitted to PA-PSRS in which patients fell while wearing sequential compression devices (SCDs). SCDs are considered to be a safe, noninvasive, and effective method of preventing deep vein thrombosis in post-surgical patients<sup>47</sup> and in patients who are immobile for extended periods.<sup>48</sup>

SCD units comprise an electric air compression pump and tubing that transfers the air from the pump to three-chambered pneumatic sleeves, which are placed over a patient's leg. These chambers inflate in a cycle, applying pressure in a sequential fashion, starting from the ankle/foot to the calf or thigh.<sup>48</sup> This results in a wavelike, milking motion that stimulates muscle activity<sup>49</sup> in the immobile patient, thus promoting venous blood flow and preventing thrombosis.<sup>47</sup>

While multiple studies demonstrate the benefits of SCDs,<sup>50</sup> reports submitted to PA-PSRS indicate that SCDs may increase the risk of harm when patients fall. Reports of falls in patients with SCDs were more than three times as likely to be reported as Serious Events compared to reports of falls in which SCDs were not mentioned.

The proportion of Serious Events reported in patients who fell while wearing SCDs was 15% (compared to 4.7% in all reports of falls<sup>51</sup>). Further, 23% of those occurrences categorized as Incidents had minor injuries requiring such

<sup>47</sup> Daly S, ed. *Nursing procedures*. Springhouse (PA): Springhouse Corporation; 1996:184-7.

<sup>48</sup> ECRI. Circulatory assist units, intermittent; sequential; stockings; compressing; pneumatic. *Healthcare Product Comparison System* 2004 Jul:1-44.

<sup>49</sup> Markel DC, Morris GD. Effect of external sequential compression devices on femoral venous blood flow. *J South Orthop Assoc* 2002 Nov 15;11(1):2-8.

<sup>50</sup> Kleinbart J, Williams MV, Rask K. Prevention of venous thromboembolism. Chapter 31. In: *Making health care safer: a critical analysis of patient safety practices*. Agency for Healthcare Research and Quality Pub No. 01-E058; 2001:333-48.

interventions as application of a dressing, ice, cleaning of a wound, limb elevation, or application of a topical medication.

The patterns in these reports provide clues to risk reduction strategies that may promote a safer environment when patients require SCDs. The following tips may be applicable to patients wearing intermittent pressure devices, as well:

- Regularly assessing patients for the need for SCDs. If a patient is mobile, SCDs may no longer be required. Timely discontinuation of SCDs when medically appropriate may help to prevent falls.
- Providing patient and family education concerning the reason for SCDs, how long they are to be applied, and calling for assistance so that the sleeves can be removed prior to leaving bed. Such education could be provided pre-operatively and when SCDs are applied.
- Automatically instituting fall prevention protocols on all patients wearing SCDs regardless of age, including a toileting schedule, rapid response to call bells, and regular re-orientation.
- Assisting with patients' toileting needs—particularly on night shift.
- Considering the feasibility of SCD units that have an audible disconnect/low pressure alarm or using bed/chair exit alarms so that healthcare providers can hear and quickly respond to patients wearing SCDs that are attempting to ambulate.
- One manufacturer has developed a miniature SCD that not only operates via line current but can also be powered by battery for up to four hours. The battery pack is worn during ambulation.<sup>2</sup> Such devices may reduce patient falls caused by getting tangled or tripping on tubes connected to an SCD unit hooked on the bed.
- Determining the proper size of the compression sleeves for each patient by using a measuring tape.<sup>47</sup> This may help prevent the compression sleeves from slipping out of place because of poor fit.

These measures may enhance the benefits of sequential compression device use while, at the same time, reducing the risk of patient harm.

## **Unanticipated Care After Discharge from Ambulatory Surgery**

**Volume 2, Number 4—December 2005**

Of the reports submitted to PA-PSRS in which patients required hospital-level care within hours or days of treatment at an ambulatory surgical facility (ASF), approximately 12% suggest that activities at discharge and during post-discharge follow-up may have been contributing factors. In a random sample of 100 of these cases, nine required hospital admission and three were treated in the emergency department.

Unlike postoperative discharge from a hospital, ASF discharge occurs within hours of the surgical procedure; therefore, an abbreviated time is available to perform patient assessment and provide discharge instructions. During this observation period, heightened sensitivity on the part of the clinician helps to identify and address any physiologic changes from the patient's preoperative state that would deem discharge unsafe. Additionally, the instructions given to the patient or caregiver—including information regarding how and when to contact the physician or when to seek emergent care—help to ensure a safe postoperative period.

PA-PSRS reports indicate that patients seek post-discharge medical intervention for a variety of reasons, but bleeding and pain are mentioned most frequently. A few reports also describe complaints of nausea/vomiting or urinary retention. In several reports, delays in seeking medical attention have occurred. Timely access to care may be related to the patient's compliance with discharge instructions, their understanding of postoperative expectations, or to their convenient access to care.

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<sup>51</sup> Based on an analysis of all reports of falls received through August 18, 2005. Relative risk ratio was 3.18 (95% CI: 1.52-6.66).

Ambulatory surgical facilities can improve patient safety by verifying that their discharge protocols address the following elements:

- Providing the patient/caregiver with well-defined, objective criteria for seeking follow-up care or physician contact.
- Discussing pain management expectations, trade-offs, and alternatives with the patient.
- Addressing incisional bleeding, dressings, pressure dressings and when to contact the physician for further intervention.
- Reviewing preoperative medications and postoperative resumption of medications, with special attention to anticoagulants.
- Reinforcing the risks related to specific instructions, such as driving within 24 hours postoperatively or lacking a supportive caregiver.
- Using a comprehensive discharge checklist.

This Advisory article was covered by the *Harrisburg Patriot News* and *Outpatient Surgery*. The U.S. Food and Drug Administration's Medical Device Surveillance Network (MedSun) has also expressed interest in reprinting this article in its own newsletter.

## **Color-Coded Patient Wristbands Create Unnecessary Risk**

**Volume 2, Supplement 2—December 14, 2005**

A Pennsylvania hospital reported to PA-PSRS an event in which clinicians nearly failed to rescue a patient who had a cardiopulmonary arrest because the patient had been incorrectly designated as “DNR” (do not resuscitate). A nurse had incorrectly placed a yellow wristband on the patient. In this hospital, the color yellow signified that the patient should not be resuscitated. In a nearby hospital, in which this nurse also worked, yellow signified “restricted extremity,” meaning that this arm is not to be used for drawing blood or obtaining IV access. Fortunately, in this case, another clinician identified the mistake, and the patient was resuscitated. However, this “near miss” highlights a potential source of error and an opportunity to improve patient safety by re-evaluating the use of color-coded wristbands.

To assess the scope of the problem, PA-PSRS surveyed the Patient Safety Officers of all Pennsylvania hospitals and ambulatory surgical facilities (ASFs). The 139 survey respondents represented one-third of these healthcare facilities. Highlights of the survey's findings include:

- Color-coded wristbands are widely used, with nearly four out of five (78%) survey respondents' facilities use patient wristbands to communicate clinical information other than the patient's identity. Of those that do, nearly all (98%) report that color is significant (i.e., used to communicate the meaning) on some or all wristbands.
- While color-coded wristband use appears more prevalent among hospitals, with nearly 87% reporting that they use them, wristband color-coding is also common among ASFs (67%).
- Some facilities report using as many as five color-coded wristbands, in addition to the patient identification (ID) band.
- There is wide variation among facilities on the types of clinical information they communicate via color-coded wristbands, and among those that use this method of communication, there is little consistency in the colors used to communicate specific clinical information.

PA-PSRS advised facilities of a number of steps they can take to reduce the risk of confusion from these color-coded wristbands, for those facilities that use them. These steps include:

- Limiting the number of different color wristbands in use and standardizing the meanings of specific colors among healthcare facilities.
- Using brief, pre-printed or embossed text on wristbands to provide clarification to clinicians. This can minimize misperception of colors in dimly lit patient rooms and alleviate confusion for color-blind caregivers. Text may also help reinforce the color-coding system for new clinicians.
- Explaining to patients and/or their families the purpose of all wristbands as they are put on, providing an opportunity for them to identify errors. This also reinforces a facility's commitment to promoting a culture of safety by encouraging patients and their families to participate in efforts to prevent errors.
- Removing colored wristbands that patients may be wearing when they present to the facility.
- Periodically reconfirming with the patient or family the meaning of wristbands that have been applied and correcting errors immediately.
- Making wristband verification part of the nursing assessment during shift changes.

This Supplementary Advisory generated considerable attention within Pennsylvania and around the country. The *Pittsburgh Post-Gazette* published an article based on this *Advisory* on December 15, 2005, and it was abstracted in a number of electronic newsletters including *Physicians News Digest*, *OR Manager*, and *Infection Control Today*, and others. It was featured on the home page of Patient Safety Net ([www.psnet.ahrq.gov](http://www.psnet.ahrq.gov)), a prominent web site sponsored by the Agency for Healthcare Research and Quality, and it generated considerable discussion on the National Patient Safety Foundation's LISTSERV. The Hawaii Patient Safety Task Force was promoted to contact the Authority and requested a copy of the survey instrument we used in Pennsylvania, which they intend to use to gauge the related practices of their member institutions.

The Pennsylvania House of Representatives also responded to the *Advisory*, initiating House Resolution 550 during the 2006 session.<sup>52</sup> If passed by the full House, this Resolution directs the Department of Health "to study, review and make recommendations relating to the imposition of Statewide standards for uniformity in the use by health care providers of color-coded patient wristbands."

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<sup>52</sup>General Assembly of Pennsylvania, House of Representatives. HR 550, PN 3405. January 25, 2006. Available: [www.legis.state.pa.us/WU01/LI/BI/BT/2005/0/HR0550P3405.HTM](http://www.legis.state.pa.us/WU01/LI/BI/BT/2005/0/HR0550P3405.HTM)

Following is a list of all articles published in the *Patient Safety Advisory* in 2005. These and previous articles are available on the Patient Safety Authority website at [www.psa.state.pa.us](http://www.psa.state.pa.us).

**March 2005 (Vol. 2, No. 1)**

When Patients Speak—Collaboration in Patient Safety  
Patient Safety Authority Recommends Two Patient Discount Programs  
“Give 40 of K” (You Know What I Mean, Don’t You?)  
Risk of Arrhythmia During Activation of Electrohydraulic Lithotripter  
Multiple Messages and Multiple Tasks  
Dangers Associated with Unlabeled Basins, Bowls, and Cups  
Focusing on Eye Surgery  
Mismatching Medical Devices and Accessories  
Ask the Analyst: Securing Tracheal Tubes  
Topical Anesthetic-Induced Methemoglobinemia  
Abbreviations: A Shortcut to Medication Errors  
Changing the Culture of Seclusion and Restraint  
The Need for Surgical Preparation

**April 21, 2005 (Vol. 2, Sup. 1)**

Convenience at a Cost: Changing Catheters over a Wire; Oxygen Flow Selector

**June 2005 (Vol. 2, No. 2)**

Clostridium Difficile: A Sometimes Fatal Complication of Antibiotic Use  
Emerging Strain of Clostridium Difficile  
PA-PSRS Pointers: Avoiding Betadine Burns  
The Five Rights: Not the Gold Standard for Safe Medication Practices  
PA-PSRS Pointers: Watch Out for that Dermabond  
A Different Mindset: One Facility’s Experience with the Anonymous Report Process  
Setting Your Own “Standards” of Care  
Risk of Fire from Alcohol-Based Solutions  
Poor Labeling of Respiratory Therapy Medications Can Impact Patient Safety  
Tips from PA Facilities: Enforcing the Time Out and Preventing Retained Foreign Bodies  
Spotted Again: Insulin/TB Syringe Confusion  
Forgotten But Not Gone: Tourniquets Left on Patients  
Unintended Lacerations or Punctures During Surgery  
PCA by Proxy—An Overdose of Care  
Skin Integrity Issues Associated with Pulse Oximetry  
Limitations of Pulse Oximetry  
Complexity of Insulin Therapy

**September 2005 (Vol. 2, No. 3)**

Why Near-Miss Reporting Matters  
Lost Surgical Specimens, Lost Opportunities  
Expecting the Unexpected: Ambulatory Surgical Facilities and Unanticipated Care  
Continuity of Oxygen Therapy During Intrahospital Transport  
Is CT a High-Risk Area for Patient Transport?  
PT—How Many Meanings?  
Unexpected Risk from a Beneficial Device: Sequential Compression Devices and Patient Falls  
SCD Misconnection Could be Fatal  
Upcoming PSA Public Meeting in Southeastern Pennsylvania  
ICU Reports More Likely to be Reported as Serious Events  
Patient Receives Shock During Defibrillator Operational Check  
Update on Alcohol-Based Surgical Prep Solutions  
Problems Associated with Automated Dispensing Cabinets  
Anesthesia Awareness

**December 14, 2005 (Vol. 2, Sup. 2)**

Color-Coded Patient Wristbands Create Unnecessary Risk

**December 2005 (Vol. 2, No. 4)**

Developing a Culture of Patient Safety

Unanticipated Care After Discharge from Ambulatory Surgical Facilities

Stress Management in Response to Practice Errors: Critical Events in Professional Practice

Brevity is the Soul of Wit, But Not of Safety

The Beers Criteria: Screening for Potentially Inappropriate Medications in the Elderly

From the Mouths of Babes: Healthcare Supplies and Environment Pose Dangers to Children

Emergency Department Management of the Suicidal Patient

The Highly Reliable Operating Team

Continuous Care Throughout Patient Transfer

Workarounds: A Sign of Opportunity Knocking

Clear Liquids May Place Patients at Risk

## Compliance with Act 13 Reporting Requirements

Because of the high volume of reports submitted through PA-PSRS each month, it can reasonably be assumed that Pennsylvania’s healthcare facilities are complying with Act 13’s reporting requirements. National patient safety advocates, clinicians and academicians have been impressed with the size of the PA-PSRS database, and more than one patient safety expert has cited PA-PSRS statistics as an indication that mandatory reporting, especially of near-misses, might in fact be a positive force for quality improvement rather than an impediment.

Nevertheless, it has been apparent to the PA-PSRS analytical staff that there are inconsistencies in when and how facilities submit reports. For example, we know from direct conversations with Patient Safety Officers and other institutional executives, as well as from queries to the PA-PSRS Help Desk, that facilities have different understanding of the meaning of the terms “Serious Event” and “Incident” as defined in Act 13. Clinicians and facility managers also frequently ask for clarification of the word “unanticipated” or the phrase “compromise patient safety.” [While Act 13 specifically defines “Serious Event” and “Incident,” it does not define these other words or phrases. See “Definitions” on Page 25.] In response to this confusion, the Authority tries to provide ongoing guidance to facilities to help them comply with Pennsylvania’s reporting requirements.

While enforcement of Act 13’s reporting requirements falls outside the Authority’s scope of responsibilities, the Authority recognizes the need to monitor how facilities are complying with the law. In October 2005, the Authority Board directed staff to identify the average number of reports submitted by different types of facilities, in order to screen for facilities that were potentially not complying with Act 13’s reporting requirements.

Staff calculated an average number of reports per-bed-per-month (PBPM) for facilities based on approximately 14 months’ worth of PA-PSRS data and based on facility size data from the 2004 PSA assessment (see Table 12). Facilities for which bed size data were not available were excluded from this analysis.

Table 12. Average Frequency of Reporting to PA-PSRS, by Facility Type

Variable	Hospitals	ASFs/Birthing Centers
Number of Facilities Included	238	154
Average # of Beds (Range)	184 (6-1,557)	3.06 (1-13)
Average # of Days in System (Range)*	464.8 (167-467)	462.7 (375-467)
Average Serious Events PBPM (Range)	0.01 (<0.01-0.19)	0.10 (<0.01-0.80)
Average Incidents PBPM (Range)	0.25 (<0.01-1.72)	0.19 (<0.01-2.83)
Average Total Reports PBPM (Range)	0.26 (<0.01-1.76)	0.29 (<0.01-2.83)

\*Some facilities, mostly ASFs, were only recently opened and have been entered into the system since they were licensed. Because they are small facilities they may not have experienced a reportable event up to this time.

To calculate reporting volume a slightly different way, on average, both hospitals and ambulatory surgical facilities submit about one report per bed every four to five months. Given the vast differences between hospitals and ASFs, it is somewhat surprising that reporting frequencies are so similar when one adjusts for facility size. On a same-size basis, ASFs do seem to report more Serious Events than do hospitals.

We used this information to identify 49 facilities that had submitted a lower volume of reports than we would have anticipated, based on the following criteria:

- Hospitals that had not reported any Serious Events or Incidents within the past three months.
- Ambulatory Surgery Centers and Birthing Centers that had not reported any Serious Events or Incidents in the past year.
- Facilities that had never submitted a Serious Event or Incident.

The hospitals that fell into this group included seven facilities. Five of these were behavioral health facilities (primarily engaged in substance abuse treatment), one was a small rehabilitation hospital, and one was a narrowly focused specialty hospital that performed procedures only once a week. The remaining 35 facilities were ASFs or birthing centers that are, by definition, low-volume facilities.

We contacted these facilities to determine why they were not reporting at the expected volume. The majority (63%) stated that they had not experienced any reportable events, citing such explanatory factors as low patient volume and that they deal with relatively healthy patient populations. A small group of staff (14%) reported being unfamiliar with Act 13 and its reporting requirements, primarily because they were new to their position, and 8% cited technical problems with the system (e.g., lost passwords).

The Authority and PA-PSRS staff took several steps to correct these deficiencies, including:

- Taking the opportunity of the phone contact described above to educate the facility about the reporting requirements and to address any technical problems identified.
- Holding three training sessions across the state to educate new Patient Safety Officers in the use of the reporting system.
- Developing articles in the *Advisory* to appeal specifically to types of facilities that believe they don't encounter reportable events, in order to demonstrate what other facilities like theirs are reporting.

Of the 49 facilities contacted, 11 submitted at least one report within the next few weeks. In addition, one facility was operating under a parent facility's license and, therefore, was not expected to report separately. Eight of the facilities contacted sent a representative to a PA-PSRS training session held later in the year in order to educate their staffs about the mandatory reporting system.

There are other ways to monitor compliance with Act 13 requirements. For example, when a Patient Safety Officer submits a report to PA-PSRS, he or she often does not have sufficient information to answer all the questions asked on the report submission form. If the facility conducts a thorough investigation into the underlying causes of a Serious Event, this analysis can take weeks and sometimes even months. In these cases, in answering questions about so-called "contributing factors" or in conducting a formal "Root Cause Analysis," the Patient Safety Officer would likely check a box on the report form labeled "To Be Determined" (TBD). The PA-PSRS system allows a facility up to 90 days to amend or update a report.

It is to a facility's advantage to answer all the questions on a Serious Event report submission form because those answers will provide important information to prevent a future occurrence of a similar event. However, in September 2005, the Authority's Board of Directors asked staff to investigate whether facilities were following up on reports to PA-PSRS by looking into the number of Serious Event reports that had questions answered as "TBD" beyond the 90-day window. The Board also directed staff to look into whether reports with questions answered as TBD were concentrated in certain facilities.

To investigate these issues, staff identified a set of Serious Event reports filed over the course of a three month period where all the reports had passed the 90-day amendment period. These reports, which numbered 1,737, were all the Serious Events submitted between 12/1/04 and 2/28/05.

Staff applied two analytical methods, the Gini coefficient and the Lorenz curve, to evaluate these reports. Among their findings were that about 92 (5.3%) of these Serious Event reports had at least one question answered as TBD after the 90-day amendment period had expired. This relatively low number indicates that facilities are correctly using the TBD option. Furthermore, failure to amend reports to answer questions marked "TBD" was not clustered in particular facilities. If it had been, this would have suggested that a few facilities were using the TBD option as an alternative to conducting internal investigations into the causes associated with a Serious Event. However, this was not the case.

Because recognizing and reporting an adverse event or near-miss is a central component of the development of a culture of safety, it is essential that all healthcare facilities submit reports of Serious Events and Incidents as required by Act 13. The Authority will continue to evaluate facility reporting frequency, advising facilities of their statutory requirements and working to encourage their full compliance.

## 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.

The Authority 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 three Anonymous Reports in 2005 that complied with Act 13 requirements. As required, in each case the Authority’s clinical staff reviewed the allegations made within the Anonymous Report, asked for and evaluated a written response from the facility, and conducted a follow-up review of records and held discussions with healthcare workers who had a personal knowledge of the event. The review team then prepared a summary and evaluation of each event. The team subsequently delivered a formal recommendation to the Authority Board about what Board action, if any, the team felt was appropriate.

In two of the incidents associated with Anonymous Reports in 2005, the Board concurred with the team’s recommendation that the event under review did not warrant referral to the Department of Health for failure to report a Serious Event, and the cases were closed. However, in the third incident, the investigation team concluded that the incident represented a Serious Event. Following a review, the Board confirmed the recommendation of the investigation team and the Authority notified the facility involved that they should submit a Serious Event report for the event in question. The facility complied with the recommendation in a timely fashion. To clarify the time sequence, please note that, although the Anonymous Report was submitted in 2005, the investigation and subsequent Board review did not take place until early 2006.

## 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 2005. 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.

At the end of 2004, the Authority began to assess various programs that might be appropriate for recommendation as a patient safety discount program. Staff from the National Patient Safety Foundation (NPSF) made a presentation on NPSF's "Stand Up for Patient Safety" program. This initiative encourages hospital senior managers to consider patient safety as a top priority for their facilities. By providing practical solutions and sharing best practices to minimize error and reduce risk, the program uses performance improvement to support patient safety initiatives within individual healthcare institutions. Much of the program's success is through integrating patient safety into a hospital's culture by involving facility administrators, trustees, clinical staff and patients in the effort.

At the start of 2005, the Authority Board voted to recommend this program as a program to be considered by the Departments of Health and Insurance for eligibility for the patient safety discount according to the protocols defined within Act 13.

At the time they voted to recommend the "Stand Up for Patient Safety" program, the Board also voted to recommend the "100,000 Lives Campaign," developed by the Institute for Healthcare Improvement, for the patient safety discount program. This is a national effort that encourages healthcare institutions to implement at least one of six proven healthcare protocols to prevent avoidable deaths. These healthcare improvement interventions are: Prevention of Ventilator-Associated Pneumonia; Prevention of Central Line-Associated Bloodstream Infections; Prevention of Surgical Site Infections; Prevention of Adverse Drug Events; Improved Care for Acute Myocardial Infarction; and Introduction of Rapid Response Teams.

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

## Board of Directors and Public Meetings

Members of the Board of Directors are appointed by the Governor and the General Assembly, according to certain occupational or residence requirements. Current members, as of April 17, 2006, include:

The Physician General, who serves as Chair: Vacant  
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)  
Physician appointed by the Governor: Nathan J. Zuckerman, MD  
Residence: Langhorne (Bucks County)  
Nurse appointed by the Governor: Joan M. Garzarelli, RN, MSN  
Residence: Gilbertsville (Montgomery County)  
Pharmacist appointed by the Governor: Gary A. Merica, RPh  
Residence: Red Lion (York County)  
Hospital employee appointed by the Governor: Roosevelt Hairston, Esq.  
Residence: Malvern (Chester County)  
Health care worker appointed by the Governor: Anita Fuhrman, RN, BS  
Residence: Lebanon (Lebanon County)  
Non-health care worker appointed by the Governor: Lorina L. Marshall-Blake  
Residence: Philadelphia (Philadelphia County)

Act 13 requires the Board of Directors to meet at least quarterly. During 2005, the Board met frequently to oversee the implementation of the PA-PSRS reporting system and to assess and develop future patient safety educational and advocacy activities. 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 2005:

February 7, 2005  
March 7, 2005  
April 4, 2005  
May 2, 2005  
June 6, 2005  
July 11, 2005  
September 12, 2005  
October 11, 2005  
November 7, 2005

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

Act 13 establishes the Patient Safety Trust Fund as a separate account in the State Treasury. Under Act 13, funds in the 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 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. 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. 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	- 0 - <sup>4</sup>

<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.

<sup>4</sup>At the start of the 2005-06 fiscal year, the Authority conveyed its recommendation to the Department of Health that the Department assess facilities at a partial (i.e., 50%) rate. The Department issued assessment letters to facilities in the second half of the fiscal year. At the time of preparing this Annual Report, no funds for FY2005-06 had been received or transferred to the Patient Safety Trust Fund.

The following table summarizes Authority expenditures during 2005. 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 2005

Major Object Code	Amount
100: Personnel	\$ 235,198
300: Operating	\$ 2,480,829
400: Fixed Assets	- 0 -
TOTAL	\$ 2,716,027

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 2005, 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 # 4500201808 dated February 14, 2005  
(Software – Adobe Acrobat)  
Contract Amount: \$151.63  
Amount Expended in 2005: \$151.63

ASAP Software  
PO #4500231552 dated June 2, 2005  
(Software – FTP PRO V9 w/Service)  
Contract Amount: \$1,879.08  
Amount Expended in 2005: \$1,879.08

Computer Aid Inc.  
PO # 4500251055 dated September 1, 2005  
(IT Staff Augmentation for Senior Consultant/Project Management  
9/1/05 – 8/31/06)  
Contract Amount: \$219,250.00  
Amount Expended in 2005: \$21,093.75

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: \$10,000.00  
Amount Expended in 2005: \$10,000.00

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 FY2004-05 - FY2005-06: \$4,721,781.87  
Amount Expended in 2005: \$2,067,631.90

Information Services Group, Inc. (ISG)  
PO # 4500070789 dated August 14, 2003  
(One-year initial contract plus a one-year extension, dated February 6, 2004, for services related to  
project management – Contract Expired June 30, 2005)  
Contract Amount for FY2004-05: \$357,882.50  
Amount Expended in 2005: \$165,243.78

McKissock and Hoffman, PC  
FC #4000006774 dated July 19, 2004  
(For legal counsel)  
Contract Amount for FY2004-05 – FY2005-06: \$272,119.93  
Amount Expended in 2005: \$82,090.77

Organizational Effectiveness Services, Inc (OES)  
PO#4500257465 dated September 9, 2005  
(IT Staff Augmentation: Consulting Service)  
Contract Amount for FY2005-2006: \$11,000  
Amount Expended in 2005: \$2,145.00

Websurveyor  
Purchased October 27, 2004  
(Survey and communications distribution software)  
Amount for FY2004-2005: \$2,500.00  
Amount Expended in 2005: \$2,500.00

York Stenographic Services, Inc.  
PO # 4500171489 dated October 13, 2004  
(Stenographic services)  
Contract Amount: \$5,330.45  
Amount Expended in 2005: \$5,330.45

York Stenographic Services, Inc.  
PO # 4500228937 dated May 23, 2005  
(Stenographic services)  
Contract Amount: \$5,076.25  
Amount Expended in 2005: \$2,004.74

Following is the Balance Sheet reflecting the status of the Patient Safety Trust Fund as of December 31, 2005.

Patient Safety Trust Fund Balance Sheet (Unaudited)  
As of December 31, 2005

<b>ASSETS</b>	
Cash	\$ 0.00
Cash in Transit	(18,520.92)
Short Term Investments @ Market (Pool 98)	3,636,481.04
<b>TOTAL ASSETS</b>	<b>\$ 3,617,960.12</b>
<b>LIABILITIES AND FUND BALANCE</b>	
<b>Liabilities:</b>	
Accounts Payable and Accrued Liabilities	\$ 9.58
Invoices Payable	149.01
Accrued Payables Goods Receipt	20,195.28
<b>TOTAL LIABILITIES</b>	<b>\$ 20,353.87</b>
<b>Fund Balance:</b>	
Reserved for Encumbrances	\$ 3,069,394.87
Total Reserved	3,069,394.87
Unreserved – Undesignated	528,212.11
<b>TOTAL FUND BALANCE</b>	<b>\$ 3,597,606.25</b>
<b>TOTAL LIABILITIES AND FUND BALANCE</b>	<b>\$ 3,617,960.12</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.

## Recommendations for Statutory or Regulatory 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. However, the Board's attention is actively focused on enhancing the utility of Act 13 by providing guidance to facilities on the meaning and interpretation of the language in the Act, particularly on helping facilities clarify what is, and is not, reportable under the definitions of Serious Event, Incident and the word "unanticipated." It is the Board's opinion that it would be premature to amend or revise Act 13 definitions at this time.





An Independent Agency of the Commonwealth of Pennsylvania

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