



2004 Annual Report

April 29, 2005

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Letter from the Board Vice-Chair



An Independent Agency of the Commonwealth of Pennsylvania

April 29, 2005

Dear Fellow Pennsylvanian:

Last year was an important year for the Patient Safety Authority.

During 2004, we initiated mandatory reporting of adverse events and near-misses, making Pennsylvania the first state in the country to require the reporting of both kinds of events.

We assembled a team of clinicians to analyze those reports, identify trends and recommend steps that hospitals can take to help prevent future medical errors.

We began the publication of *Patient Safety Advisories*, to disseminate information and best practices on healthcare delivery, patient outcomes and quality improvement.

And we took the first steps toward helping healthcare institutions reduce costs associated with their medical malpractice liability insurance premiums.

These significant accomplishments have earned national recognition, and Pennsylvanians can be proud of these initial steps to reduce medical errors and enhance patient safety.

The Authority's Board of Directors represents divergent interests and a variety of professions, but as a group we remain focused on our shared vision of promoting patient safety. There is a great deal more work to do if we are to truly make healthcare safer for the men, women and children of the Commonwealth. But we are committed to meeting this challenge.

It is my privilege to be serving as acting Board chair at this time, and I am pleased to submit the Annual Report for 2004 for your review.

A handwritten signature in black ink, reading 'Lorina Marshall-Blake'. The signature is written in a cursive style and is positioned to the left of a vertical red line.

Lorina Marshall-Blake
Vice Chair
Board of Directors



An Independent Agency of the Commonwealth of Pennsylvania

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“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

“Pennsylvania [is implementing] new patient safety initiatives that are seen as among the most progressive in the nation.”

Philadelphia Inquirer
June 1, 2004

Recipient of 2004 Healthcare IT Innovator Award from *Healthcare Informatics* magazine (September 2004 issue)

Published by Mc-Graw Hill Companies

“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

“Pennsylvania’s health care providers and patients are fortunate to have their safeguards championed by the Patient Safety Authority....By implementing the Pennsylvania Patient Safety Reporting System, the Authority has begun to assist health care systems in successfully identifying and correcting their shortcomings....[P]atients and health care providers are benefiting from the efforts of this pioneering group.”

William W. Lander, MD
President
Pennsylvania Medical Society

“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

Executive Summary

During 2004, the Authority finalized the development and implementation of the Pennsylvania Patient Safety Reporting System (PA-PSRS), a confidential, web-based data collection and analysis system for Serious Events (often called adverse medical events) and Incidents (often called near-misses).

Consistent with Act 13 of 2002 (the “Mcare” Act), the Authority initiated statewide mandatory reporting among all hospitals, birthing centers and ambulatory surgical facilities in June 2004, making Pennsylvania the first state in the nation to require the reporting of both near-misses and actual adverse events. As of December 31, 2004, there were 427 healthcare facilities subject to PA-PSRS reporting requirements, and through the end of the calendar year they submitted 70,851 reports of Serious Events and Incidents. All reports are de-identified, and they do not include any patient or provider names.

The PA-PSRS program includes a professional team of clinical analysts that reviews, prioritizes and analyzes all Serious Event and Incident reports. Their role is to identify and advise facilities of situations of immediate jeopardy and to identify trends or system improvements that can be implemented to improve patient safety.

During 2004, the Authority initiated the publication of *Patient Safety Advisories*, quarterly journals detailing clinical analysis of reports submitted through PA-PSRS. *Advisory* articles are directed primarily to healthcare professionals and facility administrators, and provide clinical guidance, supplemented by a scholarly search of medical literature, about process improvements facilities can adopt to improve patient safety and reduce potential patient harm. *Patient Safety Advisories* are distributed electronically throughout the Commonwealth and around the country and are accessible on the Authority website.

The Authority is funded through the Patient Safety Trust Fund, a separate account in the State Treasury funded through assessments on facilities subject to Act 13 reporting requirements. Although Act 13 permits a total facility assessment of \$5 million in any one year, plus an increase for cost of living adjustment, for the second year in a row the Authority requested a partial assessment of 50%, reducing the potential financial burden on Pennsylvania’s healthcare facilities.

Toward the end of 2004, the Authority initiated steps toward implementing the Patient Safety Discount provision of Act 13. Under this provision, facilities may be eligible for a reduction in their medical liability malpractice insurance premiums if they comply with certain protocols defined under the Act. In this regard, the Authority recommended two specific programs which may help facilities comply with this legislative option.

Also during 2004, the Authority continued to garner attention from other states and numerous federal government agencies, national healthcare organizations and patient safety advocacy groups and foundations. *Healthcare Informatics*, a monthly magazine, website and weekly e-newsletter published by the McGraw-Hill Companies, recognized the Authority by presenting

the Board chair with a 2004 Healthcare IT Innovator Award for the development and implementation of the PA-PSRS system.

Highlights of data submitted through PA-PSRS during calendar year 2004 are:

- 427 hospitals, birthing centers and ambulatory surgical facilities are subject to Act 13 reporting requirements. They submitted 70,851 reports of Serious Events and Incidents through PA-PSRS.
- 95% of all reports were Incidents, in which the patient was not harmed; 5% 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 98.7% of all reports submitted.
- In hospitals, the most frequently reported events involved medication errors and falls. However, complications and errors from procedures, treatments or tests represent the most frequently reported events from ambulatory surgical facilities and birthing centers.
- Falls accounted for 21% of all reports. However, 6% of all Serious Events involved patient falls.
- Complications related to procedures, treatments or tests accounted for 31% of all Serious Events.
- In 2004, 207 Serious Events reported a patient death, representing 0.3% of all reports and 5.5% of all Serious Events. In some cases, the death was the result of the patient's underlying clinical condition. In other cases, the death was a result of a "systems" issue, a series of events involving multiple, complex processes. In a few cases, the reports indicate that the facility penalized or sanctioned a provider—for example, by revoking medical privileges at the facility.
- Patients over age 65 are especially vulnerable to adverse events and near-misses. While those patients represent 41.2% of all inpatient hospitalizations, patients over age 65 were involved in 51.2% of all reports submitted to PA-PSRS from hospitals and represented 59% of all Serious Events. Falls were the most commonly reported occurrence among older patients, accounting for 64% of all patient falls. Older patients were also more likely to suffer from pressure sores, bruises and other skin-related conditions.
- Medication Errors accounted for 25% of all reports, 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 or adolescents were more likely to result in patient harm.
- Reports submitted to PA-PSRS validate steps that patients and their families can take to reduce their chance of being harmed. For example, patients or their loved ones should keep an up-to-date written personal health record that includes their medical condition

and medications. They should also ask as many questions as necessary to understand the purpose of any procedure, test or medication prescribed for them, and they should advise their doctor or nurse whenever something “doesn’t feel right.”

- The Authority provides direct feedback to facilities through regularly published *Patient Safety Advisories*. More than 30% of all hospitals responding to a survey indicated that they have implemented patient safety protocols as a result of specific articles in the *Advisories*.

More information about the Authority and access to *Patient Safety Advisories* is available on the Authority’s website, www.psa.state.pa.us.

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.

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 under Links.

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 420 facilities—must report what the Act defines as “Serious Events” (actual adverse events) and “Incidents” (so-called “near-misses”).¹ 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 December, facilities had submitted more than 70,000 reports of Serious Events and Incidents through PA-PSRS, with average monthly reports totaling as high as 12,000.

¹ 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.” See also page 4, “What Is Patient Safety?”

Activities During 2004

Activities during 2004 can be divided into two six-month periods. During the first half of the year, the Authority continued the development and testing of the PA-PSRS system and initiated mandatory reporting by rolling out the system statewide among more than 420 healthcare facilities. More detailed information about the PA-PSRS system itself is included in the section “The Reporting System” (see page 9).

Twenty-two healthcare facilities, representing large health systems, academic medical centers, community hospitals, ambulatory surgical facilities and rural hospitals from around the state, volunteered to participate in a test phase of the newly developed PA-PSRS reporting system. The test phase began at the end of 2003 and continued through June 2004.

During this phase, the test facilities evaluated the system’s information technology infrastructure as well as the accuracy and ease of use of the clinical components. They also provided valuable feedback on the system and made numerous suggestions for improvements prior to live implementation in June. In addition, during this timeframe, the Authority expanded the system’s capacity not only to collect patient safety data but to provide sophisticated analysis of the reports submitted. These tools have become integral to the system’s utility and provide valuable feedback to the facilities that submit reports through PA-PSRS.

Because Act 13 requires that the Department of Health receive certain reports through the PA-PSRS system, during the first half of 2004 the Authority worked closely with that agency to assure that their requirements were appropriately met. At the Department’s request, the Authority also helped to develop an interface to accommodate the transfer of data to the Department’s existing computer system. 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. The Authority offered to develop the Infrastructure Failure software in order to reduce the administrative burden on facilities by providing a non-redundant system for the submission of all Act 13 reports through a single portal and creating a unified reporting tool for the agencies involved.

During the first quarter of 2004, the Authority issued the first of what would become quarterly *Patient Safety Advisories*, scholarly publications based on data actually submitted through the PA-PSRS system. Release of the initial *Advisory* coincided with Patient Safety Awareness Week, a national observance facilitated by the National Patient Safety Foundation. Articles contained in *Advisories* provide valuable feedback to facilities about actual or potential patient harm and steps they can take to avoid future adverse events. More information about the *Advisories* is in the section “Patient Safety Advisories” (see page 45).

In preparation for the statewide rollout of mandatory reporting in June, the Authority conducted a series of all-day training sessions around the Commonwealth. In all, staff conducted 19 small group sessions, in 11 different locations over a nine-week period, which provided guidance on the underlying philosophy of patient safety and hands-on training on specific reporting and analytical applications of the PA-PSRS system. Nearly three-quarters of all facilities subject to

Act 13 reporting requirements, and almost 90% of all hospitals, participated in these voluntary training programs. In addition, staff from the Department of Health participated in each training session to provide guidance and answer questions about their regulatory responsibilities.

In May, the Authority published notice in the Pennsylvania *Bulletin* announcing the dates when mandatory reporting of Serious Events and Incidents would go into effect. Notice was published jointly with the Department of Health, because Act 13 required that certain other reporting requirements involving the Department of Health would be discontinued when the Authority initiated mandatory reporting.

During the second half of the year, the Authority introduced mandatory reporting in three phases, each based on a specific geographic region of the state. Phase-in was over a three week period, and as of June 28, all hospitals, birthing centers and ambulatory surgical facilities were required to submit reports through the PA-PSRS system, making Pennsylvania the first state in the nation to require the reporting of both actual adverse events and near-misses.

Because of Pennsylvania's position in the forefront of efforts to promote patient safety, considerable public attention was focused on the PA-PSRS system, both within the state and from outside. Just prior to the start of mandatory reporting, the *Philadelphia Inquirer* wrote in a June 1, 2004, editorial that "Pennsylvania [is implementing] new patient safety initiatives that are seen as among the most progressive in the nation."

By the end of July, one month after the start of mandatory reporting, almost 10,000 reports of Serious Events and Incidents had been submitted through PA-PSRS. Staff concluded that PA-PSRS was working effectively and that Pennsylvania's healthcare institutions had embraced the concept of mandatory state-based reporting. In retrospect, staff attributes this level of compliance to the confidential nature of Act 13 requirements and the utility of the PA-PSRS system itself. Staff also attributed facility compliance to the comprehensive instruction provided during the 19 training sessions held around the state. This was corroborated by the results of two user surveys, one conducted at the conclusion of each training session and the other conducted in November 2004, five months after statewide mandatory reporting was implemented.

In September, *Healthcare Informatics*, a monthly magazine, website and weekly e-newsletter published by The McGraw-Hill Companies, recognized the Authority by presenting the chair of the Board of Directors with a 2004 Healthcare IT Innovator Award for the development and implementation of Pennsylvania's Patient Safety Reporting System. This national recognition of the PA-PSRS system provided significant credibility to Pennsylvania's approach to promoting patient safety.

Other states and national organizations closely monitored PA-PSRS activities. At their request, Authority staff met with numerous state and federal government officials, legislators, and representatives of hospital and physician groups. There has been considerable interest in the reporting system itself and in the analysis of the submitted data. The Authority staff continues to share information about the Pennsylvania system with patient safety advocates and researchers.

By the end of the year, PA-PSRS had collected detailed information on more than 70,000 reports of Serious Events and Incidents, creating a significant database for the study of adverse events and their prevention. Few other medical error reporting systems in the country can equal the volume and depth of information contained within PA-PSRS, and the resulting *Patient Safety Advisories* provide valuable scholarship to healthcare providers throughout Pennsylvania and around the country.

During a visit to Pennsylvania in December, Dr. Lucian Leape, noted Harvard physician considered by many as the “father of patient safety,” made the following comment: “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.”

The Reporting System

The Pennsylvania Patient Safety Reporting System (PA-PSRS) is a secure, web-based system that permits healthcare facilities to submit reports of what Act 13 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.² 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 49.)

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. Additional information about the implementation and roll-out of mandatory reporting across the state can be found in the section “Activities During 2004” (see page 6).

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

² 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.

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 reviews 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 systems improvements that can be implemented to improve patient safety.

As a result of this comprehensive analysis, the Authority issues *Patient Safety Advisories* based on data submitted through PA-PSRS, supplemented by a scholarly search of the medical and clinical literature. *Advisory* articles are directed primarily to healthcare professionals for use by both clinical and administrative staffs. The Authority encourages these providers to use the articles as learning tools for patient safety and continuous quality improvement. In a recent survey, one-third of all responding 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 45). In addition, all copies of the *Advisory* are accessible on the Authority website, 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. Managers can use these reports for their internal quality improvement and patient safety activities. 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.

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.

The foundation of the PA-PSRS system is “Patient Safety Net,” a web-based patient safety reporting system developed and maintained by the University HealthSystem Consortium (UHC), an association of academic health centers around the country. ECRI entered into a licensing agreement to adapt this system to meet Pennsylvania-specific requirements. The resulting PA-PSRS system is fully owned by the Patient Safety Authority.

Data Submitted to PA-PSRS

Introduction

Interpreting the 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 June 7, 2004 (the date mandatory reporting began), and December 31, 2004. The data have not been adjusted to estimate anticipated annual report volume.
- 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 the phased implementation of PA-PSRS, in which facilities in different geographic regions began mandatory reporting at different times.

- The data are not adjusted to account for healthcare facility openings, closings, or changes of ownership.

As the PA-PSRS program evolves, the Patient Safety Authority is interested in exploring how data from PA-PSRS might either support or benefit from the patient safety activities of other reporting programs both at the state and national levels. For example, the National Quality Forum is currently developing a taxonomy for patient safety reporting that may enable systems like PA-PSRS to match Pennsylvania’s data with data from similar reporting systems. The Authority is also reviewing healthcare quality measures (such as the Patient Safety Indicators published by the Agency for Healthcare Research and Quality [AHRQ]) that may be useful in monitoring patient safety improvements in the Commonwealth.

However, 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.

Two issues remain problematic for facilities submitting reports through PA-PSRS: the meaning of the word “unanticipated” in the Act 13 definitions of Serious Events and Incidents (see Definitions on page 14), and use of the Event Type category “Other.”

Unanticipated Injuries

Many facilities have expressed to the Authority their difficulty in determining whether certain types of occurrences are reportable under Act 13, and this difficulty is particularly acute in relation to complications. In particular, facilities have difficulty determining whether complications were “anticipated.” The Act 13 definitions for both Serious Events and Incidents hinge, in part, on whether the patient did or could have experienced an “unanticipated injury.” This is not always an easy question to answer.

A related issue is that some reports submitted as Incidents would appear, based on the nature of the Event Type subcategory, to be Serious Events. For example, one might question how development of sepsis could be anything other than a Serious Event, since such infections are often lethal. It appears that when facilities are unsure whether something should be reported—because they cannot reliably determine whether the injury was unanticipated for any particular patient—they may err on the side of reporting but are reluctant to classify such occurrences as Serious Events.

It appears that individual facilities have taken different approaches to determining whether occurrences are reportable and when they constitute a Serious Event. The Authority recognizes

the need to provide clarity on this issue and intends to provide guidance to facilities on this subject. The PA-PSRS clinical staff is working with the Authority to clarify these issues and improve the consistency of reporting.

Use of the Category “Other”

When facilities have difficulty classifying a report by an Event Type category, they often choose the category “Other.” In some groups of reports, the use of the “Other” category is extensive. For example, nearly 17% of reports of patient falls were categorized as “Other,” when the available categories did not seem appropriate to the facility entering the report. The Authority is committed to continuous process improvement for the PA-PSRS system and intends to address this issue through additional guidance to facilities on consistency in report classification and through refinements of the reporting system itself.

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.

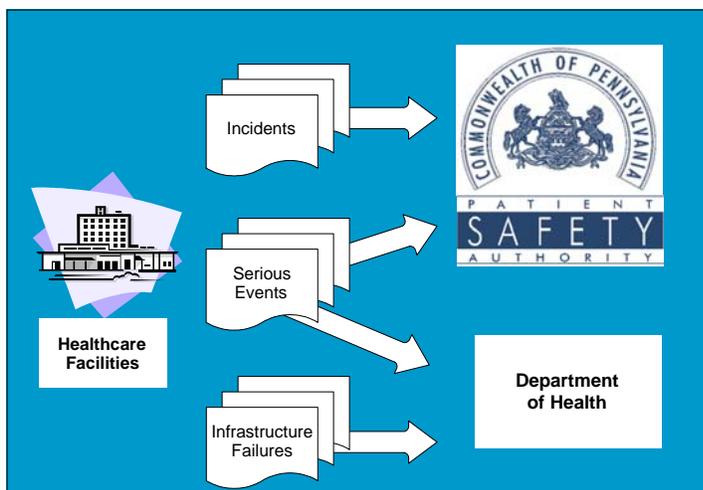


Figure 1. Submission of PA-PSRS Reports

As shown in Figure 1, 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 2004, there were 249 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 2004, there were 173 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 2004, there were five Birthing Centers in the Commonwealth of Pennsylvania.

Other pertinent definitions used in this report include the following:

- **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).³

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 4.

- **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.

³ 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

The first year's experience of collecting information through PA-PSRS 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 427 facilities providing acute medical care in the state beginning in June of 2004 under the requirements of Act 13 of 2002, the Mcare Act.

The following data analysis summarizes over 67,000 accounts of Incidents without any indication of patient harm and over 3,000 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, these current and potential consumers of healthcare 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, 95% 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 would 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. As an example, a patient had a ruptured aortic aneurysm, received an emergency operation (which has a 50% mortality rate), died, and was reported to PA-PSRS. 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 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 June 7, 2004, and December 31, 2004, Pennsylvania facilities submitted 70,851 reports to PA-PSRS. Table 1 shows the distribution of submitted reports by month for calendar year 2004.

Table 1. Reports Submitted to PA-PSRS in 2004, by Month

	June	July	August	September	October	November	December	Total
Serious Events	266	623	626	553	567	578	534	3,747
Incidents	3,050	9,370	10,405	10,299	11,126	11,538	11,316	67,104
Total	3,316	9,993	11,031	10,852	11,693	12,116	11,850	70,851

Please note that not all facilities were required to report to PA-PSRS for the entire month of June. PA-PSRS was implemented on a rolling schedule, with different regions coming online at different periods throughout that month.

Approximately 5% of submitted reports were Serious Events, while 95% were Incidents. On average, PA-PSRS received 11,261 reports per month, with a slight increase of 3% each month. The number of Serious Event reports averaged 587 per month with a slight decrease of 3% per month. The number of Incident reports averaged 10,674 per month, with an increase of about 4% each month.⁴

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 2. 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 3) is not particularly surprising.

Figure 2. Pennsylvania Public Health Regions

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.

⁴ Based on a regression analysis of the average number of reports per month between July and December 2004.

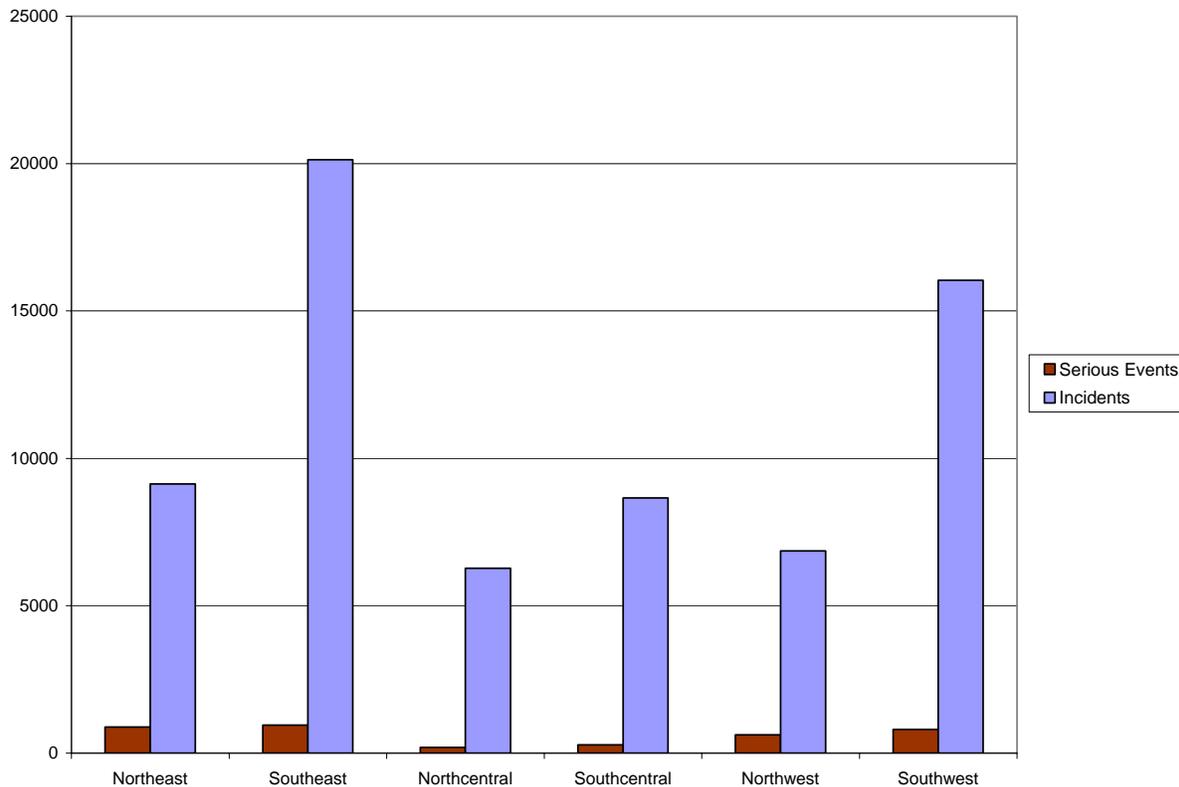


Figure 3. Number of Serious Event and Incident Reports by Region

Adjusting the report volume for a measure of healthcare utilization paints a different picture. Figure 4 shows, by region, the number of reports from hospitals per 1,000 patient days.⁵ This figure shows that, after accounting for the differences in the volume of healthcare provided in each region, facilities in the Northcentral region reported a significantly greater proportion of Incidents (97% of their reports) than the statewide average (95%).

As evident in Figure 4, 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.

⁵ Patient days are a commonly used measure of healthcare utilization or volume. A patient day is defined as one calendar day of healthcare provided to a hospital inpatient. Patient days for each region were calculated based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.phc4.org). In each region, the number of reports submitted by hospitals from July through December 2004 was divided by the number of patient days reported during the third and fourth quarters of 2003. While partial data is available for 2004, we chose to use the most recent third- and fourth-quarter data available to account for any seasonal fluctuations in utilization.

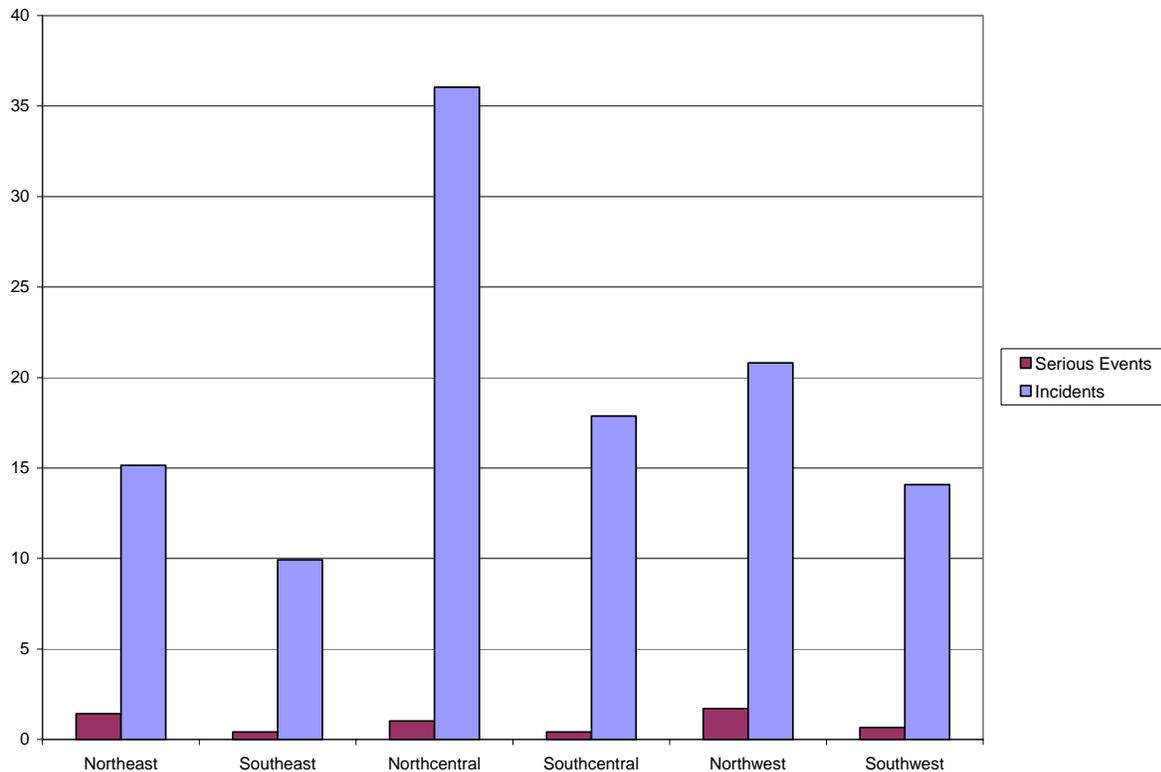


Figure 4. Reports from Hospitals per 1,000 Patient Days by Region (July through December 2004)

Reports by Facility Type

As shown on Table 2, the vast majority of reports (98.7%) submitted to PA-PSRS were submitted by hospitals. More detailed information appears on Table 4.

Table 2. Reports to PA-PSRS by Facility Type

Facility Type	Hospitals	Ambulatory Surgical Facilities/ Birthing Centers	All
Number of Reports Submitted	69,926	925	70,851
Number of Facilities as of Dec. 31, 2004	249	178	427

Patterns in Reports to PA-PSRS

Reports by Event Type

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

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

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

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

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

The complete Event Type dictionary is a three-level, hierarchical taxonomy with 198 distinct Event Types. This Event Type dictionary is one way PA-PSRS classifies and looks for patterns and trends in submitted reports.

Figure 5 shows the percentage of reports submitted under each top-level Event Type. The most frequently reported occurrences were Medication Errors (25%) and Falls (21%). These two Event Types account for 46% 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.

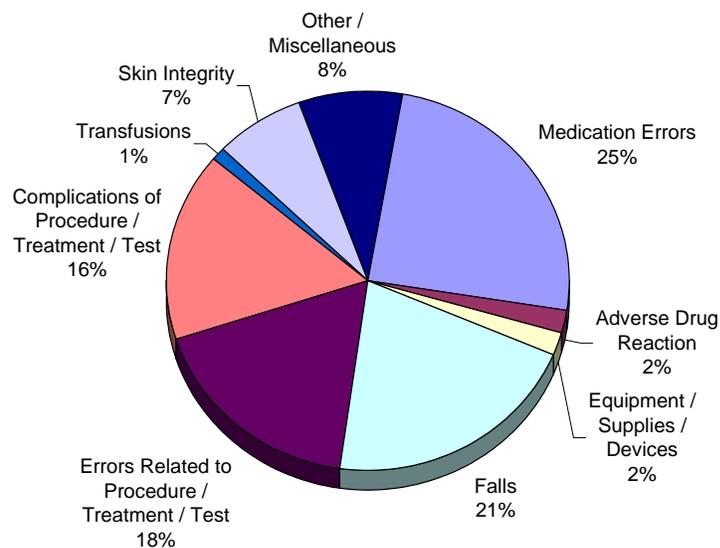


Figure 5. Percentage of Reports by Event Type

As shown in Table 3 below, the largest number of Serious Event reports was under the Event Type category Complications of Procedures, Treatments, Tests, followed by the category for Falls. These Event Types accounted for 31% and 22% of all Serious Event reports, respectively. Relative to the overall average of 5% of reports indicating harm, harm was significantly less likely to be reported under Medication Errors (1%).

Table 3. 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	198	1%	17,301	99%	17,499	25%	L
Adverse Drug Reactions (not a medication error)	109	8%	1,269	92%	1,378	2%	H
Equipment / Supplies / Devices	56	4%	1,386	96%	1,442	2%	L
Falls	820	6%	13,949	94%	14,769	21%	
Errors Related to Procedure / Treatment / Test	326	3%	12,294	97%	12,620	18%	L
Complications of Procedure / Treatment / Test	1,147	10%	10,277	90%	11,424	16%	H
Transfusions	30	4%	751	96%	781	1%	
Skin Integrity	778	16%	4,225	84%	5,003	7%	H
Other / Miscellaneous	283	5%	5,652	95%	5,935	8%	
Total	3,747	5%	67,104	95%	70,851	100%	

H=significantly higher than overall average of 5%; L=significantly lower than overall average of 5%.

Because the vast majority of reports submitted to PA-PSRS were submitted by hospitals, the distribution of all reports by Event Type closely mirrored the distribution by Event Type in hospitals. However, the Event Types most frequently reported by hospitals were different from those reported by Ambulatory Surgical Facilities and Birthing Centers (see Table 4).

Table 4. 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	17,473	25%	99.85%	26	3%	0.15%	L
Adverse Drug Reactions (not a medication error)	1,329	2%	96.44%	49	5%	3.56%	H
Equipment / Supplies / Devices	1,393	2%	96.60%	49	5%	3.40%	H
Falls	14,743	21%	99.82%	26	3%	0.18%	L
Errors related to Procedure / Treatment / Test	12,436	18%	98.54%	184	20%	1.46%	
Complications of Procedure / Treatment / Test	11,071	16%	96.91%	353	38%	3.09%	H
Transfusions	779	1%	99.74%	2	0%	0.26%	L
Skin Integrity	4,977	7%	99.48%	26	3%	0.52%	L
Other / Miscellaneous	5,725	8%	96.46%	210	23%	3.54%	H
Total	69,926	100%	98.69%	925	100%	1.31%	

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

While reports of Medication Errors and Falls combined accounted for 46% of all reports submitted by hospitals, these categories accounted for only 6% of reports from Ambulatory Surgical Facilities and Birthing Centers. Well over half (58%) of reports from these facilities involved Complications of Procedures, Treatments, or Tests or Errors Related to Procedures, Treatments, or 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.

Medication Errors

PA-PSRS received 17,499 reports of Medication Errors in 2004, accounting for 25% of all reports in the database and 5% of the reports of Serious Events. The vast majority (98.9%) of reports involving Medication Errors were classified as Incidents, in which no harm came to the patient, while 1.1% were classified as Serious Events.

As shown in Table 5, the most frequently reported type of Medication Errors was in the category Dose Omission. Though these reports accounted for nearly 28% of all reports of Medication Errors, they were rarely associated with reports of Serious Events. The types of Medication Errors most frequently associated with reports of Serious Events were: Wrong Dose (Overdose), Wrong Drug, and Extra Dose. These three categories accounted for 51.5% of all reports of Serious Events involving Medication Errors.

Table 5. Medication Error Reports by Event Subtype and Report Classification

Type of Medication Error Report	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Dose Omission	12	0.2%	4,820	99.8%	4,832	27.6%	L
Wrong Drug	32	1.7%	1,833	98.3%	1,865	10.7%	
Wrong Dose (Overdose)	55	3.5%	1,523	96.5%	1,578	9.0%	H
Extra Dose	15	1.1%	1,380	98.9%	1,395	8.0%	
Wrong Dose (Underdose)	2	0.2%	950	99.8%	952	5.4%	L
Medication List Incorrect	1	0.1%	932	99.9%	933	5.3%	L
Wrong Time	4	0.4%	904	99.6%	908	5.2%	
Prescription/Refill Delayed	1	0.1%	700	99.9%	701	4.0%	L
Wrong Patient	12	1.8%	658	98.2%	670	3.8%	
Wrong Rate (IV)	9	1.9%	460	98.1%	469	2.7%	
Wrong Route	5	1.3%	374	98.7%	379	2.2%	
Wrong Strength/Concentration	6	1.7%	341	98.3%	347	2.0%	
Unauthorized Drug	5	1.5%	334	98.5%	339	1.9%	
Wrong Dosage Form	1	0.5%	195	99.5%	196	1.1%	
Monitoring Error/Documented Allergy	8	4.4%	172	95.6%	180	1.0%	H
Wrong Duration	2	1.4%	138	98.6%	140	0.8%	
Monitoring Error/Clinical (Lab Value, Vital Sign)	2	1.7%	114	98.3%	116	0.7%	
Wrong Technique	2	3.2%	60	96.8%	62	0.4%	
Inadequate Pain Management	1	2.4%	40	97.6%	41	0.2%	

Type of Medication Error Report	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Monitoring Error/Drug-Drug Interaction	2	8.0%	23	92.0%	25	0.1%	H
Monitoring Error/Drug-Disease Interaction	1	9.1%	10	90.9%	11	0.1%	H
Monitoring Error/Deteriorated Drug/Biologic	0	0.0%	6	100.0%	6	0.0%	
Other Monitoring Error	3	5.5%	52	94.5%	55	0.3%	H
Other Medication Error	17	1.3%	1,282	98.7%	1,299	7.4%	
Total	198	1.1%	17,301	98.9%	17,499	100.0%	

H=significantly higher than overall average of 1.1%; L=significantly lower than overall average of 1.1%.

PA-PSRS has addressed issues of drug overdoses in several *Advisory* articles. For example, the September 2004 *PA-PSRS Patient Safety Advisory* offered facilities strategies to reduce the risk of overdose from multiple transdermal patches, and in October 2004 PA-PSRS issued a *Supplementary Advisory* on insulin overdoses caused by confusion between two different types of syringes. PA-PSRS also provided guidance on reducing the risk of “wrong drug” errors in December 2004, focusing on errors related to look-alike or sound-alike drug names (e.g., alprazolam and lorazepam) and confusing drug name suffixes.

Facilities submitting reports of Medication Errors to PA-PSRS are asked to identify at what stage(s) in the medication process the event occurred. Figure 6 illustrates that while many Medication Errors occur at the point of administration, a substantial portion of reports involve other stages in the medication process.

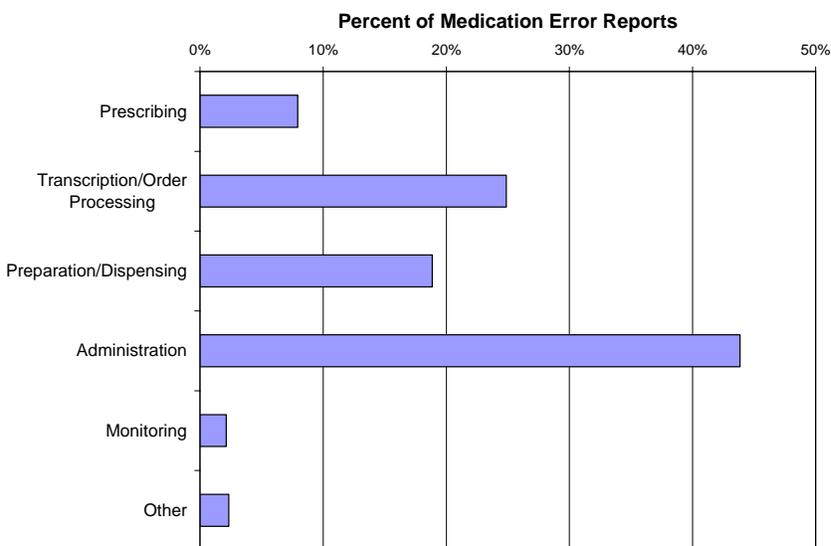


Figure 6. Stages in the Medication Process Cited in Reports to PA-PSRS

What this diagram illustrates is that medication errors do not happen solely at the point of care, such as when a patient receives the wrong drug. Giving a patient any medication is a process that involves many steps and many different people. When a patient experiences a medication error, one should not assume the problem rests with the person who administered the drug to the

patient. The entire medication process must be examined to find the root cause of the problem and implement safeguards that improve the safety of the entire system.

Falls

PA-PSRS received 14,769 reports of patient falls, 5.6% of which were reported as Serious Events (see Table 6). Not surprisingly, the most frequently reported types of falls were those occurring while the patient was ambulating; these accounted for about 23% of all reports of falls. Falls (out of bed) while lying in bed and falls while toileting were also frequently reported. Combined, these three categories accounted for over 57% of all reports of patient falls, and they account for over 62% of falls reported as Serious Events. (Most reports of falls categorized as “other” represent cases in which the patient was found on the floor of their room and clinicians did not witness the actions that precipitated the fall.)

Table 6. Reports of Falls by Report Classification

Type of Fall	Serious Events		Incidents		Total	Percent of Total
	No.	%	No.	%		
While ambulating	221	6.6%	3,131	93.4%	3,352	22.7%
While lying in bed	152	5.7%	2,504	94.3%	2,656	18.0%
While toileting	137	5.6%	2,330	94.4%	2,467	16.7%
Sitting in chair	64	4.6%	1,329	95.4%	1,393	9.4%
Sitting at side of bed	41	3.9%	1,001	96.1%	1,042	7.1%
Transferring	29	3.9%	722	96.1%	751	5.1%
During assisted sit	2	0.8%	255	99.2%	257	1.7%
In hallways of facility	24	14.9%	137	85.1%	161	1.1%
In exam room	9	7.3%	115	92.7%	124	0.8%
On grounds of facility	12	15.0%	68	85.0%	80	0.5%
Other / Unknown	129	5.2%	2,357	94.8%	2,486	16.8%
Total	820	5.6%	13,949	94.4%	14,769	100.0%

Steps facilities take to reduce the risk of patient falls, which were evident in many reports to PA-PSRS, include highlighting the patient’s fall risk to clinical staff, increased monitoring, instructing the patient to call for assistance before getting out of bed, using bed exit alarms to alert staff when patients leave the bed unattended, and using bedrails and other restraints when necessary.

PA-PSRS has provided guidance on fall reduction in several issues of the *PA-PSRS Patient Safety Advisory*. For example, our first *Advisory* in March 2004 addressed techniques for reducing patient falls involving wheelchairs. The September 2004 *Advisory* presented information on the use of bed exit alarms and also highlighted Internet resources for fall prevention programs. A brief article on the role of medications related to fall risk and injury from falls also appeared in the December 2004 *Advisory*.

Errors and Complications of Procedures, Treatments, or Tests

This section analyzes reports submitted under two Event Type categories: Errors Related to Procedures, Treatments, or Tests and Complications of Procedures, Treatments, or Tests. These

Event Types are combined for the purposes of this analysis because they cover similar domains of medical care. PA-PSRS received 24,044 reports under these Event Type categories. Of these, 6% were Serious Events, while 94% were Incidents.

Because these domains are so broad and the subcategories of these Event Types are so heterogeneous, it is challenging to summarize these reports both comprehensively and succinctly. To illustrate this point, under these two broad headings are 110 distinct Event Type subcategories. Broad generalizations about so many types of patient safety occurrences run the risk of being simplistic.

Therefore, this section will highlight selected groups of reports under these categories. Beyond those problems highlighted below, see also the section titled “Patient Identification” on page 39, which crosses several subcategories of Event Types related to Errors in Procedures, Treatments, or Tests. The section “Perinatal Patients” on page 34 also complications associated with maternity and childbirth.

Errors and Complications in Surgical Procedures

PA-PSRS received 5,122 reports of errors and complications related specifically to surgical procedures. These accounted for 21.3% of all reports under the Event Type categories: Errors Related to and Complications of Procedures, Treatments, or Tests. Of all reports of surgery-related errors and complications, 16.2% were reported as Serious Events, while 83.8% were reported as Incidents.

The most frequently cited category of complications related to surgery (excluding the category “Other”)⁶ were:

- Unplanned return to the Operating Room.
- Unplanned transfer to the Intensive Care Unit.
- Removal of a tube or other medical device by the patient.

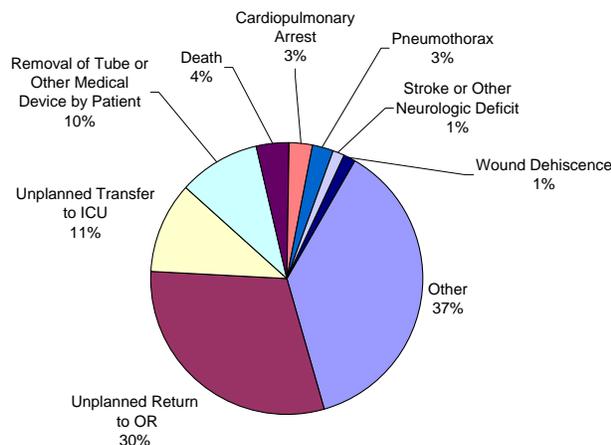


Figure 7. Reports of Complications Related to Surgery

These categories represent 50.8% of all reports of surgery-related complications. Figure 7 illustrates the distribution of surgical complications.

⁶ The reports categorized as “Other” in Figure 7 include several Event Type subcategories that were reported with frequencies less than one percent, as well as complications that may not be represented by a specific subcategory in the taxonomy but which the facility felt was reportable.

The most frequently reported errors related to surgery were: procedure cancellations, procedure delays, and problems related to obtaining patients’ informed consent. These categories accounted for 38.8% of reported errors related to surgery.

However, the most frequently reported surgery-related Serious Events were in the category: unintended laceration or puncture, with 121 of 218 reports (55.5%) involving harm. This single category accounted for 53.8% of all reports of Serious Events related to surgical errors. The organ most frequently associated with these reports was the colon, and most of these occurred with colonoscopy. The organ next most frequently associated with these types of injuries was the bladder, and most of these occurred with hysterectomy. Most of these injuries were repaired during the same surgical encounter. The PA-PSRS staff plans to address several of these issues in an upcoming *Advisory*.

Retained Foreign Objects

One group of surgical-related errors, coded under several Event Type categories in PA-PSRS, relates to what are called “retained foreign objects.” These include surgical sponges or medical instruments that are left inside patients during surgery. This type of event is rare but has been estimated to occur in one out of every 1,000 to 1,500 operations in the abdomen.⁷

Table 7 presents the number of Serious Events and Incidents reported to PA-PSRS related to retained instruments. While the vast majority of these reports (97.6%) were reported as Incidents (for example, describing successful reconciliation of incorrect counts, retrieval of items as the result of implemented procedures, verification that the missing item was not in the patient), there were 20 reports submitted as Serious Events in which a foreign object was left in the patient.⁸

Table 7. Reports of Incorrect Counts and Retained Foreign Objects

Event Type	Serious Events		Incidents		Total	
	No.	%	No.	%	No.	% of Total
Count Incorrect – Needles	1	0.3%	331	99.7%	332	40.6%
Count Incorrect – Sponges	3	2.7%	109	97.3%	112	13.7%
Count Incorrect – Equipment	0	0.0%	227	100%	227	27.8%
Count Incomplete/Not Performed	0	0.0%	96	100%	96	11.7%
Foreign Body in Patient	16	31.4%	35	68.6%	51	6.2%
Total	20	2.4%	798	97.6%	818	100%

The issue of retained foreign objects is potentially very serious, since these types of events can have serious consequences to patients when they occur. However, as the table above illustrates, the vast majority of cases reported to PA-PSRS (97.6%) were submitted as Incidents, in which the patient was not harmed. In most of these cases, the surgical team identified a potentially retained foreign object and removed it during the same surgical procedure (i.e., before closing

⁷ Gawande AA, Studdert DM, Orav EJ, et al. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003;348:229-35. Citing: Hyslop JW, Maull KI. Natural history of the retained surgical sponge. *South Med J* 1982;75:657-60; and Jason RS, Chisolm A, Lubetsky HW. Retained surgical sponge simulating a pancreatic mass. *J Natl Med Assoc* 1979;71:501-3.

⁸The four reports of “Count Incorrect” that were reported as Serious Events concerned retained instruments that required an additional procedure for removal.

the incision). In others, tiny instruments or fragments of instruments that break during a procedure were left in the patient knowingly because retrieving them could cause harm.

Surgical teams use a variety of techniques to help avoid this type of event. One standard technique involves counting each item used during surgery at several different points during a procedure. If the number of items counted at the end of the procedure is different than the number at the beginning, a retained foreign object is suspected, and the surgical team implements procedures to locate it before closing the incision. These procedures include manual exploration of the operative site as well as x-rays or other imaging to locate any missing items. Rarely, despite these measures, foreign objects are left in the patient following surgery.

PA-PSRS addressed this issue in a June 2004 *Advisory* article, “Use of X-rays for Incorrect Needle Counts,” which presented information from two studies about when potentially retained surgical needles may be too small to show up on an X-ray. PA-PSRS staff are continuing to track the issue of retained foreign objects and anticipate sharing additional lessons learned from the reports submitted by facilities in future *Advisories*.

Laboratory Tests

PA-PSRS received 4,890 reports of problems related to laboratory testing, the vast majority of which (99.5%) were reported as Incidents in which the patient was not harmed. Serious Events accounted for 0.5% of these reports.

The most commonly reported occurrences in this category were:

- Mislabeled specimens (22%)
- Test ordered but not performed (18%)
- Result missing or delayed (13%)

The Event Type in this category most likely to result in a Serious Event was having the wrong result reported on a laboratory test. Five percent (5%) of these reports were classified as Serious Events, compared to 0.5% for this group as a whole.

Problems with laboratory tests are a significant component of the broader problem of patient identification. PA-PSRS first addressed this issue in the June 2004 *Advisory* and will be revisiting it in the future. Please refer to the section “Patient Identification” on page 39 for a more detailed discussion.

Radiology/Imaging

A total of 1,502 reports were submitted describing problems with radiology/imaging tests. Of these, 98.1% were reported as Incidents, compared to 1.9% Serious Events. The most commonly reported categories included:

- Imaging studies being ordered but not performed (13%)
- Reports of imaging study results being unavailable or delayed (10%)
- Delay in scheduling an imaging study (9%)

However, the category in this group that stands out is “Incorrect reading.” Of the 69 reports submitted under this category, 19% were Serious Events, compared to 1.9% for Radiology/Imaging Problems overall. Most of these Serious Events involved patients whose disease or condition was not identified on the initial reading of the imaging study, and several of them cite communications problems between healthcare providers as contributing to the problem.

One case in particular highlights the need for patients to speak up when something “doesn’t seem right.” A patient who went to the hospital with abdominal pain had an ultrasound that was read as positive for gall stones. However, this patient informed the physician that he had previously had his gall bladder removed. PA-PSRS reported on similar cases in the December 2004 *Advisory*. However, because the patients in those cases were cognitively impaired, they could not alert their physicians to the incorrect ultrasound results and received unnecessary surgeries. The PA-PSRS staff is planning a more in-depth analysis of other problems in radiology and imaging.

Anesthesia

A total of 279 reports were submitted related to complications from anesthesia during a surgery or other invasive procedure. Reports of Serious Events represented 19.4% of these reports, compared to 80.6% reported as Incidents.

As shown in Table 8, the most commonly reported occurrences in named categories were intubation trauma and use of reversal agents, while the category most likely to result in a Serious Event was aspiration.

Table 8. Reports of Complications Related to Anesthesia

Event Type	Serious Events		Incidents		Total	
	No.	%	No.	%	No.	% of Total
Death	2	100.0%	0	0.0%	2	0.7%
Cardiopulmonary arrest	4	30.8%	9	69.2%	13	4.7%
Aspiration	9	45.0%	11	55.0%	20	7.2%
Intubation trauma	7	15.2%	39	84.8%	46	16.5%
Use of reversal agents	5	11.4%	39	88.6%	44	15.8%
Other anesthesia complication	27	17.5%	127	82.5%	154	55.2%
Total	54	19.4%	225	80.6%	279	100.0%

A large number of reports (over 55%) were classified as “Other Anesthesia Complication.” Reports in this heterogeneous group are reviewed individually by a clinical analyst on the PA-PSRS team. A minority of these reports describe significant patient safety issues, which program staff intends to address in an upcoming *Patient Safety Advisory*. In particular, PA-PSRS has received a number of reports of anesthesia awareness and will be providing guidance on this issue.

Nosocomial Infections

PA-PSRS received 747 reports classified as nosocomial—or “healthcare acquired”—infections. Serious Events accounted for 10.7% of these reports, while Incidents accounted for 89.3%. As

shown in Table 9, the most commonly reported nosocomial infections were from antibiotic-associated diarrhea (39.2%) and infections of wounds or surgical sites (22.2%), but the vast majority of these reports were Incidents. However, reports of patients developing sepsis (a systemic infection of the blood) shortly after admission were most likely to be classified as a Serious Event.

Table 9. Reports of Nosocomial Infections

Event Type	Serious Events		Incidents		Total	
	No.	%	No.	%	No.	% of Total
Intravascular catheter infection	12	15.2%	67	84.8%	79	10.6%
Wound or surgical site infection	38	22.9%	128	77.1%	166	22.2%
Nosocomial pneumonia	9	9.3%	88	90.7%	97	13.0%
Sepsis within 48 hours of admission	7	24.1%	22	75.9%	29	3.9%
Antibiotic-associated diarrhea	10	3.4%	283	96.6%	293	39.2%
Antibiotic resistant organism	4	4.8%	79	95.2%	83	11.1%
Total	80	10.7%	667	89.3%	747	100.0%

One pattern that has emerged in the PA-PSRS clinical team’s analysis of these reports is that a number of deaths have occurred associated with *Clostridium Difficile*, a particular infectious organism. This infection can result from antibiotics administered either therapeutically for infections or prophylactically to prevent infection in patients undergoing surgery. This issue will be addressed in an upcoming *Advisory*.

Other aspects of this table deserve comment. Based on data from other reporting systems, it appears that not all nosocomial infections that occurred in Act 13-covered healthcare facilities during 2004 were reported to PA-PSRS. One would expect the number of such reports to PA-PSRS to be greater than the number shown above, and PA-PSRS staff will work with facilities to encourage increased reporting of these infections. One explanation may be the way facilities interpret the word “unanticipated” in the definitions of Serious Events and Incidents. (See related discussion on page 6.)

While the same injury may be unanticipated for one patient, it may be anticipated for another. For example, a surgical site infection in a patient having drainage of an intra-abdominal abscess may be anticipated, while an infection in a patient who underwent a simple elective surgery as an outpatient may be considered unanticipated.

Event Types Associated with Death

Tragically, in 2004, PA-PSRS received 207 reports of events classified as having contributed to or resulted in the patient’s death. As shown in Table 10, these reports account for 0.3% of all reports submitted and 5.5% of all reports of Serious Events.

It is important to emphasize that while medical care was associated with these deaths, the definition of Serious Event does not require that the death involved a medical error in order to be reportable. For example, a patient death from a previously unknown medication allergy would be reportable, even though it does not involve an error.

The majority of these reports (58%) were classified under Event Type: Complications of Procedures, Treatments, or Tests. This Event Type was significantly more prevalent among reports of deaths than among all Serious Events or among all event reports. In contrast, Falls and Skin Integrity problems were significantly less prevalent among reports involving death. Of these 120 reports of complications, nearly 57% were complications of surgeries or other invasive procedures.

Table 10. Reports Indicating Patient Death by Event Type

Event Type	Deaths		All Serious Events		Total of All Reports (Serious Events and Incidents)		Proportion of Deaths vs. Serious Events	Proportion of Deaths vs. Total Reports
	No. Reports Indicating Death	Percent of Deaths	No.	Percent of Serious Events	No.	Percent of Total		
Medication Errors	6	2.9%	198	5.3%	17,499	25%		L
Adverse Drug Reactions (not a medication error)	3	1.4%	109	2.9%	1,378	2%		
Equipment / Supplies / Devices	4	1.9%	56	1.5%	1,442	2%		
Falls	8	3.9%	820	21.9%	14,769	21%	L	L
Errors Related to Procedure / Treatment / Test	13	6.3%	326	8.7%	12,620	18%		L
Complications of Procedure / Treatment / Test	120	58.0%	1,147	30.6%	11,424	16%	H	H
Transfusions	1	0.5%	30	0.8%	781	1%		
Skin Integrity	0	0.0%	778	20.8%	5,003	7%	L	L
Other / Miscellaneous	52	25.1%	283	7.6%	5,935	8%	H	H
Total	207	100.0%	3,747	100.0%	70,851	100%		

H=significantly higher than overall averages; L=significantly lower than overall averages.

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. In these cases, healthcare facilities have a number of investigational techniques at their disposal to find ways of preventing similar events from occurring in the future. These preventive measures were evident in the following examples of reports submitted to PA-PSRS:

A patient experiencing ventricular tachycardia (a potentially lethal rapid heartbeat) required emergency defibrillation, in which the heart is electrically shocked to restore a normal cardiac rhythm. The clinician had difficulty locating an important piece of equipment on the “crash cart” and had to use a similar but suboptimal item. The attempted resuscitation was unsuccessful, and the patient died. It is not clear whether the equipment substitution contributed to the patient’s death, but the item the clinician was looking for was later found on the equipment cart after all. In order to prevent similar problems from happening again, this hospital standardized the placement of devices and supplies on all cardiac emergency equipment carts, so that clinicians will not have to search for critical items during future emergencies.

A critically ill patient with multiple diseases, including an inability to swallow, required a feeding tube to be inserted through the nose and through the throat into the stomach. One risk of this procedure is that the feeding tube will accidentally be misplaced into a lung rather than into the stomach. To prevent this, an X-ray is taken after the tube is inserted to make sure it is placed in the stomach as intended. In this case, a physician interpreted the X-ray as indicating the tube was placed properly, and feeding was then initiated. Unfortunately, this interpretation was incorrect, and the tube was in fact in a lung. Though the feeding was promptly stopped, the patient's condition was complicated by this occurrence. In response, this hospital reviewed its procedures and practices for insertion and management of feeding tubes and instituted a new policy that required a radiologist (a doctor who specializes in medical imaging) to review X-rays for placement of all feeding tubes before feeding is initiated.

In reports associated with death, some reports demonstrate that some facilities have taken aggressive action against clinical staff when warranted. For example, in a report describing a patient with a life-threatening condition, a lengthy delay in treatment likely contributed to the patient's death. The facility stated that they were taking disciplinary action against the surgeon who accepted this patient as a transfer from another facility. In another report, a trauma patient suffered an unintended injury during insertion of a chest tube due to a surgical error. Following a thorough "root cause analysis" and internal peer review of this event, the facility revoked the surgeon's privileges for that clinical service.

The PA-PSRS clinical team's analysis indicates that in some reports involving a patient death, the death was likely due to the patient's clinical condition. For example, a number of reports described patients taken emergently to the hospital with ruptured aortic aneurysms. Even when such patients are rapidly diagnosed and treatment is initiated immediately, once an aortic aneurysm ruptures, the prognosis is not good. Death can occur within minutes from massive internal bleeding. Other reports concerned patients who were admitted with multiple serious illnesses, where their deaths were not unexpected. Many of the reports discussed in this section fall into this category. While such occurrences were not necessarily reportable under Act 13, facilities that did report them erred on the side of disclosure, and the Authority interprets this as evidence of these facilities' diligent efforts to comply with the reporting provisions of the Act and to use these reports as a learning opportunity.

The Authority will continue analyzing these reports and sharing "lessons learned" both from the PA-PSRS staff's analysis and from the recommendations for systems improvement identified by the healthcare facilities where these events occurred. This is the primary role of PA-PSRS: to communicate the lessons learned by a few facilities to many others through the *PA-PSRS Patient Safety Advisory*.

Special Populations

Healthcare researchers frequently study how characteristics of certain patient populations may influence their experiences with the healthcare system. Often, one group of patients may encounter differences in some aspects of their care when compared to other groups or to the

population as a whole. Sometimes these differences are associated with the demographic characteristics of the patients themselves.

In the interest of maintaining the anonymity of patients and healthcare workers involved in Serious Events and Incidents, PA-PSRS collects minimal demographic information. Information about patient characteristics is generally limited to age and gender. However, one can sometimes infer information about patient characteristics based on the type of occurrence a patient experienced, the type of unit where an occurrence happened, or what kinds of medical procedures a patient had.

This information allows us to identify differences in the relative frequency of certain types of Serious Events and Incidents reported among selected patient populations. These differences, which are described in the following subsections, enable us to focus our efforts on patient safety concerns that may be unique or more prevalent among these subpopulations.

Perinatal Patients

Events involving perinatal patients include Serious Events and Incidents involving either a mother or child during and around the period of birth. To identify reports involving this patient population, PA-PSRS staff identified reports involving patients whose age was less than 30 days as well as event types specifically associated with pregnancy and childbirth.

As shown in Table 11 below, PA-PSRS has received 1,453 reports concerning the perinatal patient population. These represent 2.1% of the reports submitted in 2004.

Table 11. Reports Involving Patients During the Perinatal Period

Event Type	Serious Events		Incidents		Total	% of Total	Proportion of Serious Events Among Perinatal Patients Versus All Patients	Proportion of All Reports Among Perinatal Patients Versus All Patients
	No.	%	No.	%				
Medication Errors	6	2.2%	273	97.8%	279	19.2%		L
Adverse Drug Reactions (not a medication error)	0	0.0%	2	100.0%	2	0.1%		L
Equipment / Supplies / Devices	2	4.7%	41	95.3%	43	3.0%		H
Falls	0	0.0%	6	100.0%	6	0.4%	L	L
Errors Related to Procedure / Treatment / Test	8	2.4%	328	97.6%	336	23.1%		H
Complications of Procedure / Treatment / Test	82	12.6%	567	87.4%	649	44.7%	H	H
Transfusions	0	0.0%	14	100.0%	14	1.0%		
Skin Integrity	4	12.5%	28	87.5%	32	2.2%	L	L
Other / Miscellaneous	7	7.6%	85	92.4%	92	6.3%		L
Total	109	7.5%	1,344	92.5%	1,453	100.0%		

H=significantly higher than overall averages; L=significantly lower than overall averages (reported in Table 2).

Complications of Procedures, Treatments, or Tests comprised a significantly larger percentage of reports among this population relative to the total patient population. Whereas this Event Type accounted for only 16% of reports overall, they accounted for nearly 45% of the reports concerning perinatal patients. Equipment/Supply/Device problems were also significantly more

common, although not as likely to be reported as Serious Events. Reports of Falls, Skin Integrity problems, and medication problems were significantly less common among this group compared to the general patient population represented in the database.

The most commonly reported complications among perinatal patients include:

- IV site complications (such as phlebitis, bruising, and infiltration), which account for 7% of reports involving perinatal patients, significantly higher than the 4% average among patients of all ages.
- Birth injury or trauma (such as shoulder dystocia or bruises/abrasions during delivery).
- Unplanned transfers to a neonatal intensive care unit.

Together, these three categories of events accounted for nearly 40% of the reports of complications in this patient population.

The *PA-PSRS Patient Safety Advisory* has included articles on topics relevant to perinatal patients. For example, the December 2004 *Advisory* included an article on fetal lacerations associated with Cesarean sections. PA-PSRS staff will continue monitoring trends associated with adverse events and near misses in this patient population.

Children and Adolescents

PA-PSRS received 6,466 reports in 2004 involving children and adolescent patients. While 5.4% of reports concerning adult patients were reported as Serious Events, only 3.9% of reports involving younger patients were classified this way, which is significantly lower. Table 12 below presents the distribution of reports by Event Type among children and adolescents compared to older patients.

While Medication Errors were the most frequently reported occurrence in the adult population, Complications of Procedures, Treatments, or Tests represented the largest category of reports for the child and adolescent population as well as the largest category of Serious Event reports in both populations. Complications accounted for approximately 42% of all Serious Events in younger patients, a significantly higher proportion than the 30% for adults.

Although reports of Medication Errors were significantly less likely to involve children and adolescents than adults, when they occurred they were significantly more likely to be reported as Serious Events, suggesting that the medication problems that did occur may be more likely to involve patient harm. Program staff is investigating potential causes that may suggest risk reduction strategies.

Table 12. Reports Involving Children and Adolescents Compared with Older Patients, by Event Type

Event Type	Patients Aged 0-21						Patients Aged Over 21						Proportion of Serious Events in Pediatric Patients Versus All Patients	Proportion of All Reports in Pediatric Patients Versus All Patients
	Serious Events		Incidents		Total		Serious Events		Incidents		Total			
	No.	%	No.	%	No.	% of Total	No.	%	No.	%	No.	% of Total		
Medication Errors	33	2.3%	1,387	97.7%	1,420	22.0%	165	1.0%	15,914	99.0%	16,079	25.0%	H	L
Adverse Drug Reactions (not a medication error)	7	6.9%	95	93.1%	102	1.6%	102	8.0%	1,174	92.0%	1,276	2.0%		
Equipment / Supplies / Devices	7	4.4%	152	95.6%	159	2.5%	49	3.8%	1,234	96.2%	1,283	2.0%		
Falls	13	2.6%	487	97.4%	500	7.7%	807	5.7%	13,462	94.3%	14,269	22.2%	L	L
Errors Related to Procedure / Treatment / Test	30	2.1%	1,429	97.9%	1,459	22.6%	296	2.7%	10,865	97.3%	11,161	17.3%		L
Complications of Procedure / Treatment / Test	107	6.0%	1,667	94.0%	1,774	27.4%	1,040	10.8%	8,610	89.2%	9,650	15.0%	H	H
Transfusions	2	3.6%	54	96.4%	56	0.9%	28	3.9%	697	96.1%	725	1.1%		
Skin Integrity	18	9.0%	183	91.0%	201	3.1%	760	15.8%	4,042	84.2%	4,802	7.5%	L	L
Other / Miscellaneous	37	4.7%	758	95.3%	795	12.3%	246	4.8%	4,894	95.2%	5,140	8.0%	H	H
Total	254	3.9%	6,212	96.1%	6,466	100.0%	3,493	5.4%	60,892	94.6%	64,385	100.0%		

H=significantly higher than overall averages; L=significantly lower than overall averages.

As might be expected, reports of Falls and Skin Integrity problems were relatively less frequent among younger patients, and those that were reported were less likely to result in significant harm to the patient.

Women

Approximately 55% of reports submitted to PA-PSRS in 2004 from hospitals involve female patients. This is not unusual, considering that female patients account for almost 58% of hospitalizations.⁹ In some age groups, the proportion of PA-PSRS reports involving women reaches 65%. These groups are during childbearing years and in the last years of life, when significantly more women than men are in the healthcare system.

As shown in Figure 8 below, among reports submitted to PA-PSRS by hospitals, the proportion of reports involving women tracks the proportion of hospital visits by women reasonably well.¹⁰

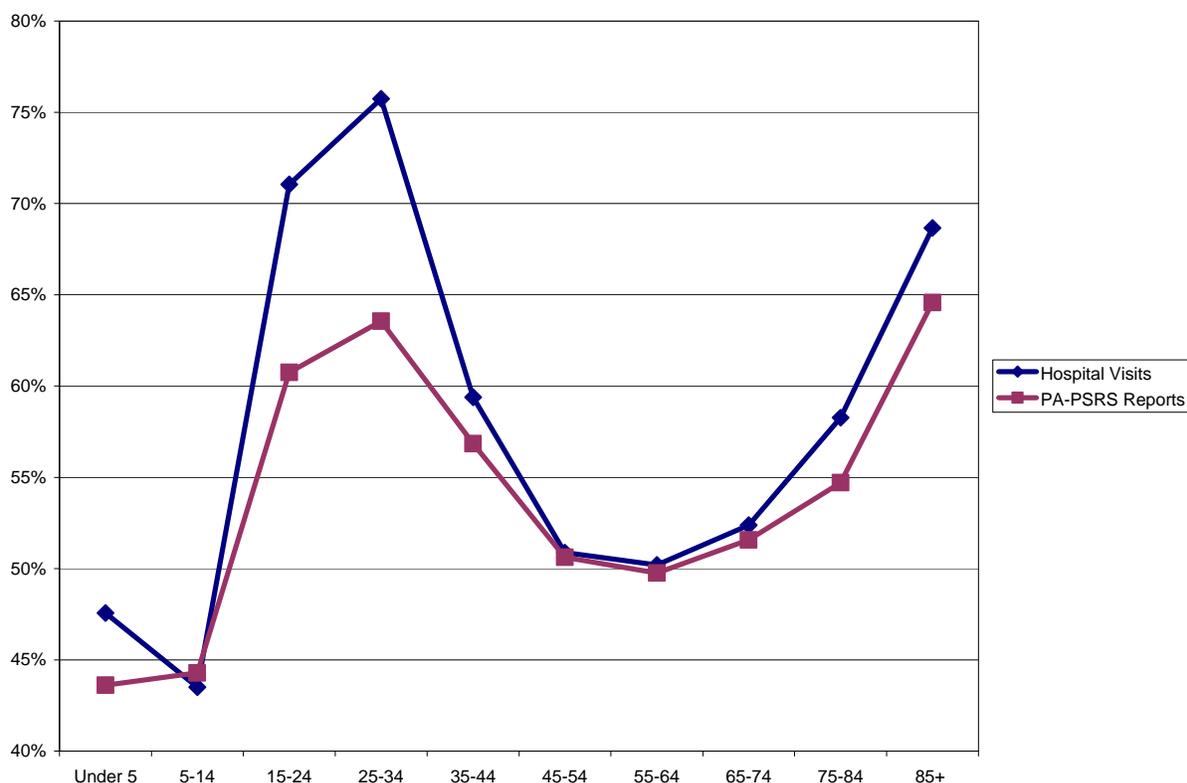


Figure 8. Percentage of Reports from Hospitals Involving Female Patients, by Age Cohort

⁹ Based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.phc4.org). Estimates were based on statewide inpatient hospital data from the third and fourth quarters of 2003. Cases where patient age is unknown or invalid were excluded by PHC4.

¹⁰ Based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.phc4.org). Estimates for hospital visits were based on statewide inpatient hospital data from the third and fourth quarters of 2003. Cases where patient age is unknown or invalid were excluded from PHC4 data. Cases where the patient age is over 105 were excluded from PA-PSRS data.

When analyzing the distribution of reports to PA-PSRS by patient gender and Event Type (see Table 13), the proportion of reports involving women was significantly greater for Adverse Drug Reactions and Medication Errors, as well as Complications of Procedures, Treatments, or Tests (see the section “Perinatal Patients” on page 34), but less for Falls. In particular, reports of Adverse Drug Reactions were 1.9 times as likely to involve female patients as male patients.

Table 13. PA-PSRS Reports by Gender and Event Type, All Facilities

Event Type	Female		Male		Total	Percent of Total	Ratio of Reports Involving Female Versus Male Patients
	No.	%	No.	%			
Medication Errors	9,758	55.8%	7,741	44.2%	17,499	24.7%	H
Adverse Drug Reactions (not a medication error)	896	65.0%	482	35.0%	1,378	1.9%	H
Equipment / Supplies / Devices	775	53.7%	667	46.3%	1,442	2.0%	
Falls	7,435	50.3%	7,334	49.7%	14,769	20.8%	L
Errors Related to Procedure / Treatment / Test	6,938	55.0%	5,682	45.0%	12,620	17.8%	
Complications of Procedure / Treatment / Test	6,470	56.6%	4,954	43.4%	11,424	16.1%	H
Transfusions	441	56.5%	340	43.5%	781	1.1%	
Skin Integrity	2,766	55.3%	2,237	44.7%	5,003	7.1%	
Other / Miscellaneous	3,155	53.2%	2,780	46.8%	5,935	8.4%	
Total	38,634	54.5%	32,217	45.5%	70,851	100.0%	

H=significantly higher than overall average of 54.5%; L=significantly lower than overall average of 54.5%.

At present, the causes and the potential significance of these patterns are unclear. Program staff will continue examining the role of gender as a potential risk factor in categories of reports submitted to PA-PSRS.

Elderly

Elderly patients are generally considered to be a vulnerable population with respect to health status, and this was reflected in the reports submitted to PA-PSRS. More than half of all reports submitted to PA-PSRS by hospitals in 2004 (51.2%) involved patients aged 65 or older. However, these patients accounted for only 41.2% of inpatient hospitalizations.¹¹ Patients in this age group were involved in 59% of all Serious Events reported in 2004.

As shown in Table 14, Falls were the most frequently reported occurrence among the elderly, and reports involving these patients accounted for 64% of all reports of patient falls, significantly more than in younger patients. Elderly patients were also significantly more likely to be involved in reports of problems associated with Skin Integrity, such as pressure sores, bruises, and skin tears.

¹¹ Based on publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.phc4.org). Estimates were based on statewide inpatient hospital data from the third and fourth quarters of 2003. Cases where patient age is unknown or invalid were excluded.

Table 14. Reports Involving Elderly Patients by Event Type, All Facilities

Event Type	Patients Aged 65 and Older		Patients Aged 0-64		Total		Ratio of Reports Involving Elderly Versus Nonelderly Patients
	No.	%	No.	%	No.	%	
Medication Errors	9,174	52%	8,325	48%	17,499	25%	H
Adverse Drug Reactions (not a medication error)	541	39%	837	61%	1,378	2%	L
Equipment / Supplies / Devices	604	42%	838	58%	1,442	2%	L
Falls	9,513	64%	5,256	36%	14,769	21%	H
Errors Related to Procedure / Treatment / Test	5,649	45%	6,971	55%	12,620	18%	L
Complications of Procedure / Treatment / Test	4,531	40%	6,893	60%	11,424	16%	L
Transfusions	458	59%	323	41%	781	1%	H
Skin Integrity	3,620	72%	1,383	28%	5,003	7%	H
Other / Miscellaneous	2,193	37%	3,742	63%	5,935	8%	L
Total	36,283	51%	34,568	49%	70,851	100%	

H=significantly higher than overall average of 51%; L=significantly lower than overall average of 51%.

Approximately 72% of reports of Skin Integrity problems involve patients aged 65 and older, a topic that will be addressed in an upcoming *Advisory*. Of these, more than half (51%) were reports of pressure sores. Transfusion problems were infrequent, but were significantly more commonly reported in the elderly, as were, to a lesser extent, Medication Errors. Reports of Errors and Complications related to Procedures, Treatments, and Tests, Equipment/Supplies/Devices, and Adverse Drug Reactions were significantly less likely to involve elderly patients than non-elderly patients.

Patient Safety Trends

Patient Identification

Ensuring positive identification of patients is critical in all healthcare settings. Sometimes patient misidentification can be a causative factor in many types of events, including medication administration, invasive procedures, transfusions, injections, phlebotomy, pathology specimen preparation, and provision of emergency medical services. Reports to PA-PSRS suggest that Pennsylvania facilities are not immune from the risks of patient misidentification.

In 2004, PA-PSRS received a number of reports in which patient identification was or may have been a contributing factor (see Table 15). While the percentage of these reports associated with harm (1.5%) was significantly lower than the average among all reports, the volume of reports demonstrates that patient identification can be a

Articles about “time outs” prior to surgical procedures (in which clinical staff double-check the patient’s identity, the procedure being performed, and the surgical site) resulted in one ambulatory surgery facility developing a time out verification checklist upon which every step of the time out process is documented. Another facility has implemented an “extended” time out, which includes not only the standard identification of the patient, procedure, site, and position, but also a review of the patient’s allergies and co-morbid conditions and a check to ensure that all equipment to be used in the procedure is functioning properly.

significant issue, and reported problems of wrong site/wrong side surgery were significantly more likely to involve patient harm.

Table 15. Reports Potentially Involving Patient Identification Problems

Event Type	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Medication Errors							
Wrong Patient	12	1.8%	658	98.2%	670	21%	L
Errors Related to Procedure / Treatment / Test							
<i>Surgery/Invasive Procedure Problem</i>							
Wrong Procedure	2	18.2%	9	81.8%	11	0%	
Wrong Patient	1	4.2%	23	95.8%	24	1%	
ID Missing/Incorrect	0	0.0%	152	100.0%	152	5%	L
Wrong Site	9	37.5%	15	62.5%	24	1%	H
Wrong Side (Left versus Right)	10	28.6%	25	71.4%	35	1%	H
<i>Laboratory Test Problem</i>							
Wrong Patient	2	0.7%	276	99.3%	278	9%	L
Wrong Result	10	4.7%	203	95.3%	213	7%	
Mislabeled Specimen	0	0.0%	1,053	100.0%	1,053	33%	L
Specimen Label Incomplete/Missing	0	0.0%	383	100.0%	383	12%	L
<i>Radiology/Imaging Test Problem</i>							
Wrong Procedure	1	0.8%	124	99.2%	125	4%	L
Wrong Patient	0	0.0%	131	100.0%	131	4%	L
Wrong Site	0	0.0%	27	100.0%	27	1%	
Wrong Side (Left versus Right)	1	3.2%	30	96.8%	31	1%	
Transfusion							
Wrong Patient Requested	0	0.0%	11	100.0%	11	0%	
Wrong Patient Transfused	0	0.0%	4	100.0%	4	0%	
Patient Identification: Total	48	1.5%	3,124	98.5%	3,172	100%	L
Total of All Reports	3,747	5.3%	67,104	94.7%	70,851		

H=significantly higher than overall average of 5%; L=significantly lower than overall average of 5%.

Healthcare facilities use a variety of methods to correctly identify patients and to catch identification errors when they occur, many of which were discussed when PA-PSRS first addressed this topic in the June 2004 issue of the *PA-PSRS Patient Safety Advisory*.¹² Some of these methods include:

- Applying wristbands or other visible forms of identification to each patient; defining processes for immediately fixing any wristband errors; correcting wristband errors prior

¹² Pennsylvania Patient Safety Reporting System. Patient identification. *PA-PSRS Patient Safety Advisory*. 2004 Jun;1(2):8-10.

to beginning a procedure; and reapplying a wristband as soon as possible following removal (such as during surgery).

- Using multiple independent forms of identification (such as a name and birthdate) to verify a patient’s identity prior to beginning a procedure, such as surgery or administering medication.
- Having independent double checks by two different nurses before giving high alert medications or blood products.
- Performing a “time out” prior to invasive procedures, which involves the entire clinical team confirming the patient’s identity, the procedure being performed, the procedure site, and other key information prior to beginning the procedure.
- Involving patients in the identification process, for example, by asking patients to state their name prior to giving medications, or asking them to state the procedure being performed and the procedure site.
- Using information technology, such as computerized physician order entry systems, electronic medical records, bar coding technology, and others to help ensure that procedures are performed and medications are administered to the right patients.

High Alert Medications

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

PA-PSRS highlighted the risks associated with high alert medications and provided risk minimization strategies—which many healthcare facilities have implemented—in the September 2004 *PA-PSRS Patient Safety Advisory*.¹³

Among reports of medication errors submitted to PA-PSRS, approximately one out of four involves one or more high alert medications. The most frequently cited high alert drugs in reports to PA-PSRS are pain management medications, insulin products, and anticoagulents such as heparin and warfarin (Coumadin®). Sixty-five percent of medication-related Serious Events involved high alert medications.

Strategies to safeguard the medication process (from prescribing through administration) where high alert medications are involved may include: limiting access to these medications; using auxiliary labels and automated alerts; standardizing the ordering, preparation, and administration of these products; and employing automated or independent double checks when necessary.

¹³ Pennsylvania Patient Safety Reporting System. Focus on high alert medications. *PA-PSRS Patient Safety Advisory*. 2004 Sep;1(3):6.

Drugs Associated with Falls

Approximately 21% of all reports of patient falls submitted to PA-PSRS indicate that the patient was receiving one or more drugs which can contribute to the risk of falling or which can increase the risk of injury when a fall occurs. Figure 9 (first developed for the December 2004 *PA-PSRS Patient Safety Advisory*) shows the percentage of these reports citing selected drug classes.¹⁴ Forty-three percent (43%) of these reports involved patients who were receiving drugs in more than one class. The percentages of patients who received these drugs, but did not experience a fall, is not known.

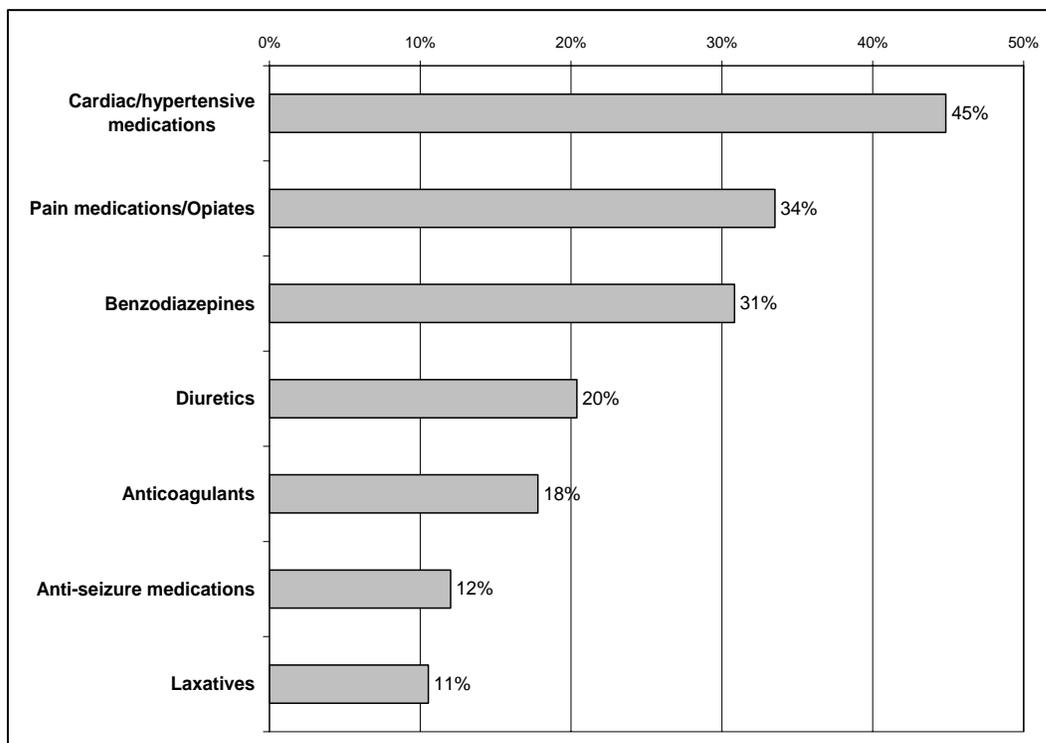


Figure 9. Drugs Identified in Reports of Patient Falls

Healthcare facilities routinely assess patients for whether or not they are at risk for falling, and they institute fall precautions for those patients determined to be at risk. Many facilities include in this assessment whether the patient is receiving any drugs that could influence the patient's fall risk or the severity of injury should a fall occur.

¹⁴ Pennsylvania Patient Safety Reporting System. Medications contributing to fall risk. *PA-PSRS Patient Safety Advisory*. 2004 Dec;1(4):6.

Insulin Overdoses from Syringe Confusion

PA-PSRS received several reports describing errors in which tuberculin (TB) syringes were used in place of insulin syringes, resulting in patients receiving more insulin than was prescribed. One reason for the error may have been the resemblance in packaging of the TB syringe and the insulin syringe. The TB syringe is packaged in a white wrapper with black and orange print with an orange plunger tip—the same color used for many years on insulin syringes.

PA-PSRS published a *Supplementary Advisory* on this issue,¹⁵ which contained the following strategies to help limit the potential for this type of error:

- Informing staff that are responsible for ordering and restocking syringes of the potential for error with these products. Pharmacies that supply these products to other facilities (physician offices, clinics, long-term care facilities) could notify the appropriate staff members at those sites to raise awareness about the potential for error.
- Storing insulin syringes separately from all other syringes and switching to TB syringes with 26-gauge (brown) or 27-gauge (gray) needles so that orange-colored syringe caps will appear only on insulin syringes. If no alternative exists and the syringes must be stored near each other, consider placing a prominent warning on the storage container for each syringe.
- Evaluating whether TB syringes are needed in patient care units. Except in pediatric units, the syringes often are used primarily for skin tests or small subcutaneous doses that could be dispensed by the pharmacy.
- Exploring alternate suppliers for TB syringes made by manufacturers who have made changes to the labeling of their packaging to differentiate them from insulin syringes.
- Printing insulin order sheets on orange paper to reinforce the use of the color orange as a color code for insulin-related products.

In response to the Supplemental Advisory on similar packaging of insulin and tuberculin syringes, many facilities have taken measures to avoid confusion that could result in patients receiving an incorrect dose of medication. Some facilities have changed vendors to obtain syringes with different packaging or with different color-coded needle caps. Other facilities have segregated these syringes in the workplace.

For example, in one facility, tuberculin syringes are used only for employee health while insulin syringes are used in patient care areas. Other facilities have developed processes in which the Pharmacy Department labels and dispenses a tuberculin syringe to a patient care area only upon an order for a specific patient. These syringes are secured in the patient medication drawer until used. Other facilities have segregated tuberculin syringes by placing them in their automated medication dispensing cabinets or in a locked box or cabinet separated from insulin syringes.

Many Pennsylvania facilities have told us they are implementing these suggestions. In a recent survey of Patient Safety Officers from around the state, approximately 30 facilities cited this

¹⁵ Pennsylvania Patient Safety Reporting System. Overdoses caused by confusion between insulin and tuberculin syringes. *PA-PSRS Patient Safety Advisory*. 2004 Oct 28;1(S1).

Advisory article as promoting them to make changes in their facilities to prevent this type of error.

A Patient Safety Officer from Southcentral Pennsylvania wrote to us: “Just wanted to thank you for the *Supplementary Advisory* on TB and insulin syringes. I distributed this to our nursing and pharmacy staffs. Within 24 hours, a nurse identified an identical issue that was ‘caught’ before reaching the patient. Thank you!” Several facilities from around the Commonwealth contacted us to share their own strategies for dealing with this hazard, which were published in the next issue of the *PA-PSRS Patient Safety Advisory*, so other organizations could benefit from this knowledge.

Fetal Lacerations Associated with Cesarean Section

PA-PSRS has received a number of reports of a complication during delivery that may be prevented or substantially reduced: fetal lacerations associated with Cesarean section (C-section). PA-PSRS addressed this topic in the December 2004 issue of the *PA-PSRS Patient Safety Advisory*.¹⁶

While most reported lacerations have been superficial, some have required suturing and/or plastic surgery intervention. This type of occurrence has been reported by at least 20 facilities, ranging from university medical centers to small community hospitals. Consistent with the clinical literature, approximately 70% of the lacerations occurred on the face, head, and ear. Approximately 20% occurred below the waist (buttocks, leg, ankle), while 10% were on the back. Emergency C-sections were documented in 20% of the reports.

Risk factors associated with increased risk for neonatal laceration identified in the literature include: ruptured membranes prior to C-section, low transverse uterine incision, active labor, emergent/urgent C-section, and inexperience of the surgeon or resident.

PA-PSRS identified several interventions reported in the clinical literature that may reduce the risk of this injury, including blunt entry into the uterine cavity, use of blunt instrumentation, moving the uterine wall away from the fetus prior to incision, and removing abdominal wall retractors prior to delivery.

¹⁶ Pennsylvania Patient Safety Reporting System. Fetal lacerations associated with Cesarean section. *PA-PSRS Patient Safety Advisory*. 2004 Dec;1(4):9-10.

Patient Safety Advisories

Pennsylvania healthcare facilities have submitted tens of thousands of reports to PA-PSRS since the system became operational in June 2004. Since that time the clinical staff of the PA-PSRS program have been reviewing those reports and identifying opportunities for improving patient safety by taking “lessons learned” at some facilities and sharing that knowledge with healthcare organizations throughout the state.

One of the ways PA-PSRS helps to improve patient safety in the Commonwealth is by analyzing submitted reports and sharing that analysis with healthcare facilities throughout Pennsylvania. The Authority accomplishes this through periodic publication of the PA-PSRS Patient Safety *Advisory* (see Figure 10), which is issued quarterly, with *Supplementary Advisories* published as needed.



Figure 10. PA-PSRS Patient Safety *Advisory*

The *PA-PSRS Patient Safety Advisory* is widely distributed via e-mail and the Internet. It is publicly available at the Authority’s website. Visit www.psa.state.pa.us, and click on “Advisories” in the left-hand navigation menu. Specifically, the *Advisories* are distributed via e-mail and the Internet to Patient Safety Officers in Pennsylvania healthcare facilities, who redistribute them to staff in their organizations. The *Advisories* are also sent to many other individuals both within Pennsylvania and the United States, as well as internationally.

The *Advisories* are developed by clinicians and healthcare researchers from ECRI and ISMP under contract to the Authority. Both organizations have international reputations in patient safety, and both happen to be headquartered in Pennsylvania. Their staffs include physicians, nurses, risk managers, pharmacists, biomedical engineers, and others who are skilled in analyzing healthcare adverse event reports. This same staff is responsible for developing the *PA-PSRS Patient Safety Advisory*, and their analysis is based on patterns and trends in reports submitted by Pennsylvania facilities and on available evidence from the clinical literature about how to prevent adverse events.

Copies of the four quarterly *Advisories* and the one *Supplementary Advisory* issued in 2004 are included in Volume 2 (Attachments) of this report.

Following is a complete list of articles published in the *PA-PSRS Patient Safety Advisory* in 2004.

March 2004 (Vol. 1, No. 1)

Potentially Dangerous Abbreviation in Surgery
The Story Behind Falls
Falls Associated with Wheelchairs
MRI Hidden Risks

June 2004 (Vol. 1, No. 2)

Hidden Sources of Latex in Healthcare Products
Use of Multidose Medication Vials and Latex Allergy
Use of X-rays for Incorrect Needle Counts
Problems Related to Informed Consent
Patient Identification

September 2004 (Vol. 1, No. 3)

Extravasation of Radiologic Contrast
Focus on High Alert Medications
Use of Checklists in Complex Environments
Electrosurgical Units and the Risk of Surgical Fires
Risk of Overdose from Multiple Transdermal Patches
Two Takes on the "Time Out"
Bed Exit Alarms to Reduce Fall Risk
Web Resources for Fall Prevention Programs

October 2004 (Vol. 1, Sup. 1)

Overdose Caused by Confusion Between Insulin & Tuberculin Syringes

December 2004 (Vol. 1, No. 4)

The Role of Empowerment in Patient Safety
Risk of Unnecessary Gall Bladder Surgery
Snip-It Safety
Follow-up on Previous *Advisory* Articles
 Insulin and Tuberculin Syringe Confusion
 "Time Out"
Medication Errors Linked to Drug Name Confusion
Fetal Lacerations Associated with Cesarean Section
Early Discharge from the ED
A Rare but Potentially Fatal Complication of Colonoscopy
Venous Air Emboli and Automatic Contrast Media Injectors
A Word about Air Detection Devices
Drug Name Suffix Confusion is a Common Source of Errors
Understanding the Benchmarking Process

Improving Patient Safety: Feedback from Facilities

Reports of Serious Events and Incidents to PA-PSRS are just one component of patient safety. The Authority continues to emphasize that quality improvement is everyone's responsibility, from facility administrators and trustees, to physicians, nurses, pharmacists, allied health practitioners and other healthcare workers. Patients, too, as well as their families and loved ones, have an important role to play in promoting safety and reducing potential harm.

While the PA-PSRS clinical staff monitors and investigates trends in patient safety at the statewide level, the PA-PSRS website also provides useful analytical tools to individual facilities that allow them to track and evaluate occurrences and patterns in their own facilities. For example, they can monitor the types of events occurring in different areas of their facility, identify patterns in the frequency or severity of different types of events occurring throughout their facility, and look for patterns in a particular type of event (e.g., Medication Errors).

In a recent survey of Patient Safety Officers, the Authority learned that many facilities use these analytical tools for risk and quality management, trend analysis, and Patient Safety Committee meetings. Many others use the tools to prepare reports for their senior management and trustees. While the "lessons learned" highlighted below present selected examples of the work performed by the PA-PSRS clinical staff, the Patient Safety Officers in each healthcare institution are also actively using the PA-PSRS reporting system to monitor progress in improving safety at their own facilities.

This report has highlighted some of the ways facilities have responded to selected patient safety issues discussed in the *PA-PSRS Patient Safety Advisories*. Following are some other changes Patient Safety Officers have told us they are making to improve patient safety:

- *The article concerning the risk of fires in the operating room (Sep. 2004) has prompted at least one facility to provide mandatory training to surgeons about how to prevent such occurrences. The focus is upon electrosurgical unit safety and methods to reduce oxygen pooling in areas where there is a source of ignition.*
- *The article on hidden risks of magnetic resonance imaging (MRI) (Mar. 2004) spurred another facility to revise its MRI screening and assessment worksheet to include implantable devices, which might malfunction in the magnetic field.*
- *Several facilities responded to the PA-PSRS article on extravasation (Sep. 2004), in which materials such as contrast media or dye used in medical imaging infuse into the tissue rather than into the circulatory system. Healthcare facilities report modifying their imaging policies, procedures, and checklists to capture more comprehensive patient histories and to provide more effective interventions for the prevention and treatment of extravasation.*

- *The article concerning hidden sources of latex (Sep. 2004) has provoked thought and action. Some facilities have developed multidisciplinary committees to assess for latex in products currently in use and to evaluate latex-free products. Some facilities are considering the feasibility of going latex-free. Other facilities' purchasing departments are now governed by a policy of preference for latex-free products if there is a choice. At least one facility has converted to using only latex-free stethoscopes and blood pressure cuffs.*
- *A facility has used the article on the risks associated with multiple transdermal patches (Sep. 2004) as a foundation for developing a format to track application and removal of such patches to prevent overdosing.*

As process changes are occurring, feedback from facilities indicates several common threads. First, education is key to helping healthcare workers understand why change is necessary to improve patient safety. This is being accomplished by “in service” and other training sessions and through broad distribution of materials, such as *PA-PSRS Patient Safety Advisory* articles. A second approach is to have multidisciplinary committees evaluate and implement changes that encourage “buy in” from all employees, including physicians, to the new processes. A third component is monitoring by senior administrators to ensure competencies and compliance with these changes.

Patient Safety Officers also say that implementing one change seems to result in many “spin offs” that also improve patient safety. For example, as one facility was evaluating its use of tuberculin and insulin syringes, it found other syringes with similar packaging. This was resolved by purchasing other types of syringes from another vendor.

This is an encouraging sign that promoting patient safety and encouraging a “culture of safety” is taking root in Pennsylvania’s healthcare facilities. While most efforts to promote patient safety are taken one step at a time, the Authority is hopeful that PA-PSRS will facilitate important quality improvement initiatives.

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 Authority 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. During 2004, the Authority received several Anonymous Report forms, but they did not all comply with the Act 13 Anonymous Report requirements. For example, one report form described an event that occurred prior to the implementation of mandatory reporting. Another report form did not comply with section 308 (a) of Act 13.

The Authority received one Anonymous Report in late 2004 that complied with Act 13 requirements. Follow-up and a subsequent investigation by the Authority took place during the first quarter of 2005. Although this activity occurred during a time period not included in this Annual Report, it is important to provide information about the investigation of this Anonymous Report, the ensuing clinical review and the Board’s deliberations.

In conducting its own review of the Anonymous Report, the facility concluded that a Serious Event had occurred, and the facility submitted a Serious Event report through PA-PSRS for this adverse event. The Authority’s own investigation, which was conducted by clinicians and an attorney, concurred with the facility’s conclusion. Upon review, the Authority Board accepted the results of its staff’s investigation and voted not to refer the facility to the Department of Health for failure to report.

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 2004. 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. During the December 2004 public meeting, 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.

Although the Authority Board did not vote to recommend this program until the start of 2005, following the period covered by this Annual Report, this is an important program that warrants inclusion in this section.

Relatedly, it is also important to note that, 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.

The Authority is hopeful that hospitals and other facilities throughout the Commonwealth will 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 27, 2005, 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)

The following persons, although no longer Board members, served on the Board during some period of 2004:

Mary Ann Dailey, RN
Patricia Clancy Kienle, RPh
Howard F. Messer, Esq.
Robert S. Muscalus, DO
Danae Powers, MD

Act 13 requires the Board of Directors to meet at least quarterly. During 2004, the Board met frequently to oversee the development and 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 2004:

February 2, 2004
March 1, 2004
April 5, 2004
May 3, 2004
August 2, 2004
October 4, 2004
December 6, 2004

Minutes of the public meetings are available on the Authority's website at 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.

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 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 of the Patient Safety Authority. This partial assessment provides considerable financial relief to Pennsylvania's healthcare facilities, which are already financially stressed.

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*
2002-03	356	\$ 4,999,922	\$ 4,663,000
2003-04	377	\$ 2,562,938	\$ 2,542,316
2004-05	414**	\$ 2,500,159	- 0 -***
TOTAL			\$ 7,205,316***

*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.

**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.

***At the start of the 2004-05 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 FY2004-05 had been received or transferred to the Patient Safety Trust Fund.

The following table summarizes Authority expenditures during 2004. 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 2004

Major Object Code	Amount
100: Personnel	\$ 247,538
300: Operating	\$ 2,567,383
400: Fixed Assets	\$ 27,390
TOTAL	\$ 2,842,311

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 2004, 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 # 4500163140 dated September 10, 2004
(For software)
Contract Amount: \$907.00
Amount Expended in 2004: \$907.00

Dell Marketing LP
PO # 4500102527 dated January 5, 2004
(For database, web servers & tape drive)
Contract Amount: \$40,318.70
Amount Expended in 2004: \$40,318.70

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 2004: \$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 FY2003-04 and FY2004-05: \$4,296,550.00
Amount Expended in 2004: \$2,154,095.55

EIKI International, Inc
PO # 4500131592 dated May 4, 2004
(Audio/visual equipment)
Contract Amount: \$2,293.00
Amount Expended in 2004: \$2,293.00

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 Amount for FY2003-04 and FY2004-05: \$451,826.00
Amount Expended in 2004: \$194,017.00

McKissock and Hoffman, PC
FC #4000006774, dated July 19, 2004
(For legal counsel)
Contract Amount: \$100,000.00
Amount Expended in 2004: \$57,569.07

Veritas Software
PO #4500099800 dated December 18, 2003
(For software)
Contract Amount: \$6,837.00
Amount Expended in 2004: \$6,837.00

York Stenographic Services, Inc.
PO #4500171489 dated October 13, 2004
(Stenographic services)
Contract Amount: \$4,843.25
Amount Expended in 2004: \$395.65

York Stenographic Services, Inc.
PO #4500057185 dated June 13, 2003
(Stenographic services)
Contract Amount: \$6,081.31
Amount Expended in 2004: \$2,261.06

Following is the Balance Sheet reflecting the status of the Patient Safety Trust Fund as of December 31, 2004.

Patient Safety Trust Fund Balance Sheet (Unaudited)
As of December 31, 2004

ASSETS	
Cash	\$ 0.00
Cash in Transit	(1,918.47)
Short Term Investments @ Market (Pool 98)	3,730,594.80
TOTAL ASSETS	\$ 3,728,676.33
LIABILITIES AND FUND BALANCE	
Liabilities:	
Accounts Payable and Accrued Liabilities	\$ 537.44
Invoices Payable	30,195.79
Accrued Payables Goods Receipt	4,170.08
TOTAL LIABILITIES	\$ 34,903.31
Fund Balance:	
Reserved for Encumbrances	\$ 2,017,993.79
Total Reserved	2,017,993.79
Unreserved – Undesignated	1,675,779.23
TOTAL FUND BALANCE	\$ 3,693,773.02
TOTAL LIABILITIES AND FUND BALANCE	\$ 3,728,676.33

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. Because mandatory statewide reporting through PA-PSRS has only been in effect for less than a year, the Authority is unable to make specific recommendations at this time. However, the Authority Board recognizes the importance of identifying issues that may warrant recommendations for future change.

Specifically, the Board is reviewing the effectiveness of provisions related to Anonymous Reports. The Board recognizes that, during 2004, very few Anonymous Reports were submitted, and only one met the statutory requirements. As mandatory reporting of adverse events and near-misses moves into its second year, the Authority will monitor the use of Anonymous Reports as an effective tool to assure compliance with Act 13 reporting requirements. The Board will assess whether other provisions for anonymous reporting might be appropriate, such as a hotline, a concept that has been proposed in several pieces of legislation.

In addition, the Board is continuing its discussions on ways to enhance “whistleblower” protections for healthcare workers covered under the Act. The Board recognizes that creating a “culture of safety” within healthcare institutions depends on developing a system of full and open disclosure that, while requiring accountability, does not assign blame or punishment for unintentional acts. In that regard, the Board supports the concept of enhancing whistleblower protection for healthcare workers.

ACKNOWLEDGMENTS

Several people played key roles in the development and implementation of the PA-PSRS system during 2004. Their efforts contributed significantly to the accomplishments detailed within this Annual Report. First, Mike Doering, PA-PSRS Project Manager, helped guide the project through complex systems development and implementation. Our attorneys at McKissock and Hoffman not only offered ongoing legal counsel, but Joan Plump, in particular, applied finely-tuned editing skills dating back to her days as an English major to the review of both clinical and more general documents, including this report. Badal Sanghvi, project manager at EDS, was instrumental in developing the PA-PSRS software and infrastructure. He and his enthusiastic staff spearheaded this complex project in a timely manner, despite frequently changing business requirements, but always with consummate respect for their customer. For the most part, the quality and integrity of the final IT product speaks for their efforts. Likewise, Dr. John Clarke, PA-PSRS Clinical Director at ECRI, and the extremely competent team of clinicians and data analysts from both ECRI and ISMP helped shape a data collection and analysis system that is garnering national recognition. They, too, are largely responsible for the *Patient Safety Advisories* and for the scholarship and analyses contained within this document. I especially want to acknowledge contributions made by William Marella, PA-PSRS data analyst at ECRI. Bill has been part of this project since its inception, helping to conceptualize the PA-PSRS system from its earliest iteration to its current form. Among many other activities, he is largely responsible for writing and formatting much of the Annual Report. Many thanks.

Alan B. K. Rabinowitz
Administrator
Patient Safety Authority

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