

April 29, 2008



PENNSYLVANIA PATIENT SAFETY AUTHORITY

2007 ANNUAL REPORT



PATIENT
SAFETY
AUTHORITY

An Independent Agency of the Commonwealth of Pennsylvania

Letter from the Board Chair



April 29, 2008

Dear Fellow Pennsylvanians:

In 2007, the Pennsylvania Patient Safety Authority kept its mission in focus by continuing its work to help reduce and eliminate medical errors by providing guidance to over 500 of Pennsylvania's healthcare facilities.

This year we developed a strategic plan to document the Authority's vision and to help others understand our goals. These initiatives will enable us to collaborate more with others as we work together to educate our hospital CEOs and administrators, reduce hospital and nursing home infections, enable Patient Safety Officers to communicate better to solve problems and offer facilities a liaison to help them reach their individual patient safety goals.

In July, legislation signed into law as Act 52 gave the Authority the opportunity to work with the Department of Health and other healthcare organizations to reduce infections in hospitals and nursing homes. The Authority established a Healthcare-Associated Infection Advisory Panel comprising Pennsylvania's most dedicated and accomplished infection control experts to help develop reporting requirements. The implementation has been a challenging process for all involved, but the significant steps taken in 2007 have begun the journey to reduce and eliminate healthcare-associated infections.

Throughout the implementation, the Authority continued to educate healthcare facilities with the *Patient Safety Advisory* and educational toolkits about preventing wrong-site surgery, medication errors and complications with hip surgery. Some articles were accompanied by a consumer tips sheet for the public to learn from as well. With an archive of over 140 scholarly articles healthcare professionals statewide, nationally and even internationally have used the *Advisory* and additional resources for healthcare guidance.

As chair of the Pennsylvania Patient Safety Authority's Board of Directors, I am pleased with what we have been able to accomplish to date, but I recognize the volume of work and effort that must continue for the Authority to achieve the goals outlined in its 2007 Strategic Plan. With my fellow board members and dedicated staff of the Authority I look forward to reaching those goals for improved patient safety that will reduce medical errors and ultimately save lives.

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

Ana Pujols-McKee, M.D.
Chair
Board of Directors



An independent agency of the Commonwealth of Pennsylvania

Board of Directors

Ana Pujols-McKee, MD
Anita Fuhrman, RN, BS
Joan M. Garzarelli, RN, MSN
William F. Goodrich, Esq.
Roosevelt Hairston, Esq.
Lorina L. Marshall-Blake
Gary A. Merica, R.Ph.
Clifford Rieders, Esq.
Stanton Smullens, MD
Marshall W. Webster, MD

* * *

Michael Doering, Executive Director
Laurene Baker, Director of Communications
Sharon Hutton, Administrative Assistant
Barbara J. Holland, Esq., Legal Counsel

* * *

Office Location

539 Forum Building
Harrisburg, PA 17120

Mailing Address

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

Phone: 717-346-0469

Fax: 717-346-1090

Email: patientsafetyauthority@state.pa.us

Website: www.psa.state.pa.us

Table of Contents

EXECUTIVE SUMMARY	1
A SUCCESSFUL BEGINNING — A PLAN TO ACHIEVE	1
REDUCING INFECTIONS THROUGH ACT 52	2
DATA COLLECTION — PATTERNS AND TRENDS IN REPORTS	2
PROVIDING GUIDANCE	4
EDUCATION, OUTREACH AND COLLABORATION	6
<i>Education and Training</i>	6
<i>Consumer Tips Sheets Involve Patients</i>	7
<i>Anonymous Report Brochure</i>	8
INTRODUCTION	9
BACKGROUND	10
WHAT IS PATIENT SAFETY?	10
THE PATIENT SAFETY AUTHORITY’S STRATEGIC PLAN	13
<i>Initiative A: Educate Executive Management and Boards of Trustees</i>	13
<i>Initiative B: Infection Awareness and Reduction</i>	13
<i>Initiative C: Patient Safety Knowledge Exchange (PasSKEy)</i>	14
<i>Initiative D: Improve Reporting Consistency and Recommendations</i>	14
<i>Initiative E: Increase Effectiveness through Extended Presence</i>	14
<i>Initiative F: Governor’s Office of Healthcare Reform (GOHCR) Collaboration</i>	14
<i>Initiative G: Data Collaboration</i>	14
<i>Initiative H: Patient Safety Methods Training</i>	15
<i>Initiative I: Nursing Home Data Analysis</i>	15
<i>Initiative J: PA-PSRS System Enhancements</i>	15
<i>Initiative K: Maintain Success of Patient Safety Advisory</i>	15
HEALTHCARE-ASSOCIATED INFECTIONS	17
BACKGROUND	17
<i>Key Provisions of Act 52</i>	17
<i>Patient Safety Authority Duties</i>	18
<i>Patient Safety Authority Accomplishments through December 2007</i>	18
<i>Future Goals and Tasks</i>	20
<i>Summary of Healthcare-Associated Infections Reported through PA-PSRS</i>	21
DATA COLLECTION AND ANALYSIS	23
THE REPORTING SYSTEM	23
<i>Introduction</i>	23
<i>Interpreting PA-PSRS Data</i>	24
<i>Definitions</i>	25
REPORT VOLUME	27
<i>Reports by Month and Submission Type</i>	27
<i>Reports by Region and Submission Type</i>	29
<i>Reports by Facility Type</i>	31
<i>Variation in Report Volume</i>	31
PATIENT DEMOGRAPHICS	33
<i>Patient Gender</i>	33
<i>Patient Age</i>	34
<i>Patients Most at Risk by Age</i>	35
PATTERNS IN REPORTS THROUGH PA-PSRS	35
<i>Reports by Event Type</i>	35
<i>Reports from Hospitals by Event Type and Facility Size</i>	39
<i>Reports by Level of Patient Harm</i>	41
<i>Reports Involving the Patient’s Death</i>	42
<i>Reports by Location/Department (Hospitals Only)</i>	43
<i>Contributing Factors and Root Causes Cited in Reports</i>	44

PATIENT SAFETY AUTHORITY GUIDANCE	47
PREVENTING WRONG-SITE SURGERY.....	47
COMPLICATIONS OF RETROBULBAR BLOCKS	50
AIRWAY FIRES DURING SURGERY	51
CONTRAST-INDUCED NEPHROPATHY—CAN THIS IATROGENIC COMPLICATION OF IODINATED CONTRAST BE PREVENTED?	53
FENTANYL TRANSDERMAL SYSTEM: TAKING ANOTHER LOOK.....	54
STRATEGIES TO MINIMIZE VASCULAR COMPLICATIONS FOLLOWING A CARDIAC CATHETERIZATION	55
DRUG LABELING AND PACKAGING — LOOKING BEYOND WHAT MEETS THE EYE	56
OBSTRUCTIVE SLEEP APNEA MAY BLOCK THE PATH TO A POSITIVE POSTOPERATIVE OUTCOME	58
DILIGENCE AND DESIGN IN BEHAVIORAL HEALTH IMPACT PATIENT SAFETY	59
SHOULD PATIENTS BE ACCOMPANIED WHEN DISCHARGED FROM AMBULATORY SURGERY?.....	60
PROMPT IDENTIFICATION AND EFFECTIVE COMMUNICATION OF STATUS MAY REDUCE MRSA INFECTIONS.....	61
SMART INFUSION PUMP TECHNOLOGY: DON’T BYPASS THE SAFETY CATCHES	62
EDUCATION, OUTREACH AND COLLABORATION	65
EDUCATION AND OUTREACH.....	65
COLLABORATING WITH OTHER ORGANIZATIONS	66
THE AUTHORITY’S ANNUAL SURVEY OF PATIENT SAFETY OFFICERS	69
HEALTHCARE-ASSOCIATED INFECTIONS	69
PATIENT SAFETY ADVISORY	70
FUTURE ENHANCEMENTS OF THE PATIENT SAFETY AUTHORITY.....	71
THE PATIENT SAFETY AUTHORITY: DRIVING CHANGE	71
OTHER ITEMS.....	73
PATIENT SAFETY LEGISLATION	73
<i>Federal Legislation</i>	73
<i>Pennsylvania Legislation</i>	73
RECOMMENDATIONS FOR STATUTORY OR REGULATORY CHANGE	73
ANONYMOUS REPORTS	73
REFERRALS TO LICENSURE BOARDS	74
PATIENT SAFETY DISCOUNT PROGRAM.....	74
BOARD OF DIRECTORS AND PUBLIC MEETINGS	75
FISCAL STATEMENTS AND CONTRACTS.....	77

What Pennsylvania Facilities Are Saying About the Patient Safety Authority

I find the Patient Safety Authority's Advisories very helpful in our quest to proactively enhance patient safety at Holy Spirit Hospital. We use "lessons learned" by other entities and change, if necessary, our processes to prevent the likelihood of a similar event from occurring. One example of the use of an Advisory is the color-coded armbands initiative. Holy Spirit Hospital conducted a FMEA and made changes to our own practices to decrease the likelihood of a caregiver misunderstanding the meaning of the color of an armband and potentially causing harm to a patient. We made our internal changes and "banded together" with other PA hospitals to enhance the safety of patients within our Commonwealth. We have captured national attention and have taken and continue to take steps to develop a national standard for color-coded wristbands. The strength of one isolated event in the state, which did not cause harm, is making a national difference for all patients in the nation. I believe anyone would agree the Authority's Advisories have served Patient Safety Officers and others well beyond our expectations!

Francesca J. Charney, RN, BS, MSHA, CPHRM, CPSO
Director of Risk Management/ Patient Safety Officer
Holy Spirit Health System

The Patient Safety Authority of the Commonwealth has, since its inception, labored to create a learning community across the state which embraces all those who directly or indirectly affect care at our patient's bedside. Abington Memorial Hospital was most fortunate to have visionary and engaged trustees who believed in and supported our patient safety work and with whom we transparently share our outcomes. The Patient Safety Authority's Advisories such as that on Wrong-site surgery have enlightened all of us from boardroom to bedside. Healthcare is fundamentally a human enterprise and human beings will always make mistakes. Our goal is to eliminate harm and we are pleased to regard the PSA as our partner as we seek to eliminate medically-related harm in the Commonwealth.

John J. Kelly, MD, FACP
Chief of Staff
Abington Memorial Hospital

I, as Patient Safety Officer, for Clearfield Hospital, applaud the efforts of the Patient Safety Authority. The transparency of sharing of Incidents has provided an excellent avenue for institutions to improve their processes. We are grateful to the Authority for regularly providing us with Patient Safety Advisories. We have used that information to improve the care to our patients, such as our assessment of sleep apnea, improved administration of transdermal medications, and the safe use of Phenergan, as several examples. Your articles are shared with hospital staff and have heightened awareness of MRI hazards and drug labeling, just two more examples of Advisory utilization. We encourage you to continue your exemplary efforts to improve patient safety.

James P. Davidson, MD
Patient Safety Officer
Clearfield Hospital

The Authority has been a tremendous help to me personally as a Patient Safety Officer, providing valuable resources to assist me in educating my staff about the root causes of patient safety events and the proven efforts to prevent them. What a plus to have the Authority here in PA! Our institution has access to, not only its written resources (i.e., the Advisory), but also access to its local Board Chair, Dr. Ana McKee, who has visited our institution and spoken to our board. This valuable experience allowed our board members to hear first hand about the Authority and to receive confirmation that they are on the right track. In the oncology setting, infection control and prevention has always been a priority at Fox Chase Cancer Center. Now with the increase in attention given to this topic on the national, regional, and local levels, efforts to build the business case for any initiatives for reducing and eliminating infections in healthcare facilities are strengthened. Partnering with the Authority to gain access to local benchmarks through the CDC's NHSN program will hopefully prove to be beneficial.

Delinda Pendleton
Director Quality/Risk Management & Infection
Hospital of Fox Chase Cancer Center

[This page intentionally left blank]

Executive Summary

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

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

A Successful Beginning — A Plan to Achieve

Since its inception, the Patient Safety Authority has primarily been focused on development and implementation of the Pennsylvania Patient Safety Reporting System (PA-PSRS), review and analysis of reports submitted through PA-PSRS, and the distribution of guidance primarily through the *Patient Safety Advisory*. The Patient Safety Authority made tremendous strides in fulfilling its mission and in the short time of its existence, has been recognized as a leader in patient safety data collection, analysis and guidance.

In 2007, the Patient Safety Authority Board determined that the Authority should do more to advance patient safety in Pennsylvania. The Board embarked on a strategic planning exercise. They listened to stakeholders, experts and staff. The outcome of this exercise is a strategic plan that the Board believes will guide the Authority’s activities for the next several years.

The Strategic Plan organizes the Authority’s objectives and priorities into a series of initiatives. These initiatives will be implemented over several years and will be allocated appropriate funding. The 11 initiatives follow:

- Initiative A: Educate Executive Management and Boards of Trustees
- Initiative B: Infection Awareness and Reduction
- Initiative C: Patient Safety Knowledge Exchange (PasSKEy)
- Initiative D: Improve Reporting Consistency and Recommendations
- Initiative E: Increase Effectiveness through Extended Presence
- Initiative F: Governor’s Office of Healthcare Reform (GOHCR) Collaboration
- Initiative G: Data Collaboration
- Initiative H: Patient Safety Methods Training
- Initiative I: Nursing Home Data Analysis
- Initiative J: PA-PSRS System Enhancements
- Initiative K: Maintain Success of Patient Safety Advisory

Implementing the strategic plan initiatives has been a priority in the second half of 2007. For example, The Authority is working with the Hospital and HealthSystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) to develop/adopt a curriculum for Pennsylvania’s CEOs and boards of trustees to understand their role in patient safety. Nursing home data and HAI prevention initiatives are being addressed through the implementation of Act 52. The Authority also met with several Patient Safety Officers throughout the year to present ideas and obtain feedback. These efforts support another strategic plan initiative regarding development of the Pennsylvania Knowledge Exchange (PasSKEy). This electronic confidential forum would allow Patient Safety Officers to discuss problems and share written solutions in their facilities freely with one another to improve patient safety. Also geared toward helping facilities improve patient safety, the Authority plans to hire Patient Safety Liaisons to go into facilities and help them implement better system processes. The PSLs would also obtain valuable feedback from the facilities to learn how the Authority can help them further. The Authority will also hire a Director of Education Programs. For more information on the Authority’s Strategic Plan, go to page 13 of this annual report.

Reducing Infections through Act 52

In July, Act 52 of 2007 gave the Authority responsibilities related to the prevention of healthcare-associated infections (HAI) in Pennsylvania. Specifically, the Act calls for the Authority to work with the Department of Health and the Pennsylvania Healthcare Cost Containment Council to collect infection data through the Centers for Disease Control and Prevention reporting system. To eliminate duplicate reporting, the Authority modified the CDC system to satisfy the reporting requirements for hospitals. Hospitals began reporting through NHSN on February 14, 2008.

The Act also requires the Authority to collect HAI reports from the approximately 800 Pennsylvania nursing homes. The Authority is working with the Department of Health to identify what information will be collected and the collection systems and processes. It is anticipated that the nursing homes will be reporting infections by the end of 2008. The Authority has also been charged with analyzing the infection data for Act 13 facilities and nursing homes and making the *Patient Safety Advisories* available to all.

In accordance with Act 52, the Authority established a panel of HAI experts to provide guidance for the effort to combat infections in Pennsylvania's hospitals and nursing homes. While developed and managed by the Authority, the Advisory panel is available to counsel all state agencies with responsibilities related to Act 52. More information about Act 52 and the Advisory Panel can be found on page 17.

Data Collection — Patterns and Trends in Reports

Collecting and analyzing reports of Serious Events and Incidents are vital components to the Authority's educational initiatives. The reports are submitted through the Pennsylvania Patient Safety Reporting System, known as PA-PSRS.

The data was submitted by Pennsylvania's 511 hospitals, ambulatory surgical facilities, birthing centers and certain abortion facilities. These facilities submitted 211,983 reports; 7,277 were classified as Serious Events (adverse events with patient harm) and 204,706 classified as Incidents (near misses and events that reached the patient but did not cause harm) into PA-PSRS in 2007. Almost 97% of the events in 2007 were classified as Incidents. The Authority believes that robust submission of Incident reports generally indicates a positive culture of safety within a facility that reflects open communication and attention to patient safety efforts. In Figure 1, report volume in 2007 showed an increase of 16,151 reports over 2006, with an increase in both Incidents (8%) and Serious Events (5%).

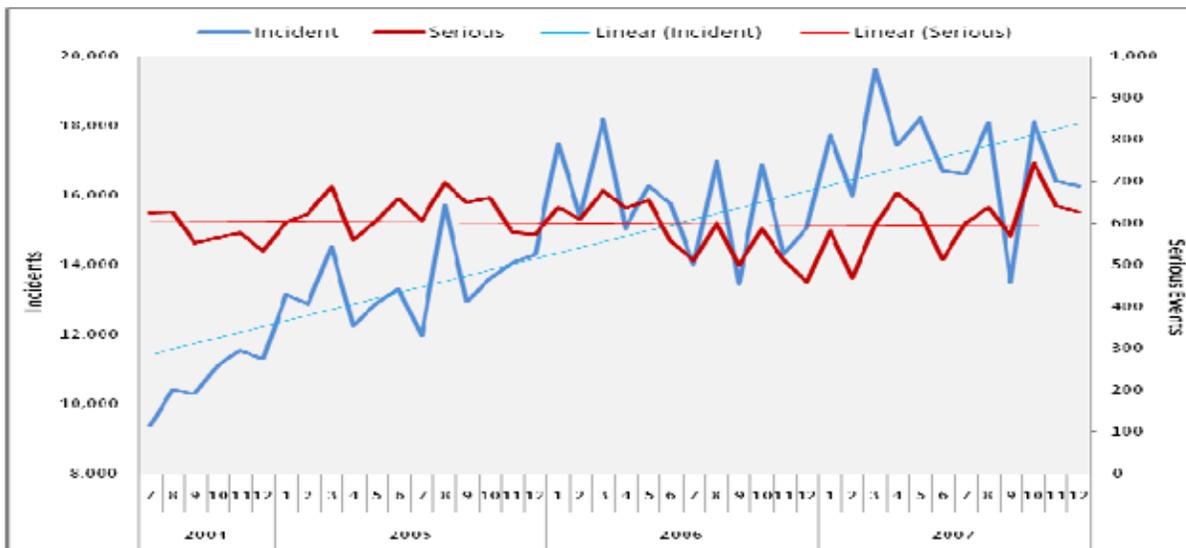


Figure 1. Number of Serious Event and Incident Reports since Inception of PA-PSRS

When reporting an event to the Authority, a facility uses a classification system or “taxonomy” to characterize the occurrence they are reporting. A facility classifies a report by identifying what PA-PSRS defines as the “Event Type.” The Event Type essentially answers the most basic question about an occurrence: “What happened?” While there is considerable detail within the taxonomy, at its most basic level, the PA-PSRS classification contains nine Event Types.

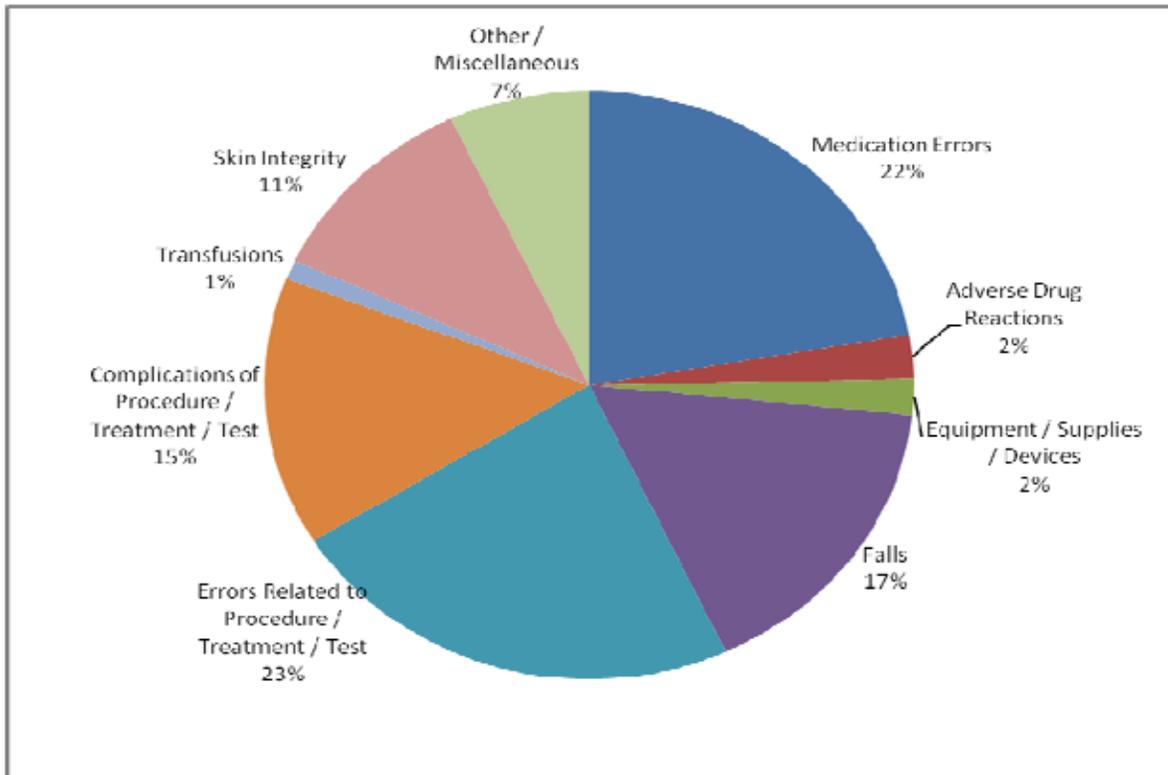


Figure 2. Percentage of Reports Submitted by Event Type (2007)

Other highlights of data submitted through PA-PSRS during the calendar year 2007 are:

- 512 hospitals, ambulatory surgical facilities and birthing centers were subject to Act 13 reporting requirements. They submitted 211,983 reports of Serious Events and Incidents through PA-PSRS, an increase of 16,151 reports or 13% from 2006.
- Almost ninety-seven (96.6) percent of all reports were Incidents, in which the patient was not harmed; approximately 3.4% of all reports were Serious Events, which indicates that the patient received some level of harm, ranging from minor, temporary harm to death. Incident reports increased 8% over last year. Serious Event reports increased 5%.
- Reports from hospitals accounted for 98.7% of all reports submitted.
- Women patients were more involved in reports (54.4%) than men (45.6%). Women are more likely to use the healthcare system during childbearing years. They also have a longer life expectancy than men and therefore are using the health system more.
- Adverse Drug Reactions for women were 63%, while for men they were 37%.
- Children and adolescent (aged 21 and younger) reports increased by 3.3% in 2007.
- Patient Falls accounted for 17% of all reports, a decrease from 21% in 2006.
- While Complications related to Procedures, Treatments or Tests accounted for just 15% of overall reports, they accounted for 44% of reports in which a patient was harmed and 59% of all reports of events resulting in or contributing to a patient’s death.
- Elderly reports have maintained a consistent pattern. More than half of all reports (52.7%) involve elderly (age 65 and over) patients, down slightly from 2006 (53.1%). Elderly patients accounted for

61.2% of Falls in 2007, a drop from 2006 (62.4%). Elderly patients accounted for 73.1% of reports related to Skin Integrity in 2006, this figure increased slightly in 2007 to (73.5%).

- Medication Errors accounted for 22% of all reports (slight decrease from 2006), and they represented only 1% of all Serious Events. Although most Medication Errors involve adults, Medication Errors involving children and adolescents were more likely to result in patient harm.

The complete data section can be found on page 23 of the annual report.

Variation in Report Volume

The volume of reports, after adjusting for volume of care delivered in different facilities, submitted to PA-PSRS varies significantly by facility. Table 1 shows the range of report volumes from hospitals by quartile. A small number of hospitals submitted no reports in 2007. Differences among hospital types does not explain the variations. Hospitals of all sizes, specialty and location fall into each of the quadrants shown below.

Table 1. Reports from Hospitals per 1,000 Patient Days, Quartiles (2007)

Quartile	Reports per 1,000 Patient Days
Fourth (Top 25%)	36.1 to 301.7
Third	20.9 to 36.0
Second	7.9 to 20.8
First (Lowest 25%)	0.0 to 7.8

The Authority believes the disparate reporting rates are due to several factors including differences in Act 13 interpretations, facility case mix, varying levels of facility cultures of safety, and potential over-reporting and under-reporting. The Authority will take steps to balance the reporting rates and has included this effort in the Strategic Plan. These steps will include discussions with the Department of Health to clarify Act 13 definitions and a special project aimed at determining the characteristics of high-reporting facilities. Appropriate educational efforts will follow these activities. (Additional discussion of this issue is provided on page 23.)

Providing Guidance

The Authority’s professional staff of clinical analysts reviews and analyzes all Serious Event and Incident reports. Their research, strengthened by extensive literature review, is published in the *Patient Safety Advisory*, a quarterly publication directed primarily to healthcare professionals and facility administrators. *Advisory* articles provide clinical guidance about process improvements facilities can adopt to improve patient safety and reduce potential patient harm. To date, more than 140 scholarly articles about specific events submitted through PA-PSRS have been published.

In 2007, through legislation signed into law as Act 52, the Authority was charged with collecting and analyzing healthcare-associated infection (HAI) reports from Pennsylvania’s nursing homes as well as hospitals under Act 13. The Act also calls for the Authority to offer healthcare-associated infection prevention guidance through *Advisory* articles and educate nursing homes and other healthcare facilities.

In a 2007 annual survey, 96% of responding hospitals and ambulatory surgical facilities found information in the *Patient Safety Advisories* useful and relevant, which may explain why the *Advisories’* reach extends beyond Pennsylvania’s borders. Many states from across the country have requested information and resources from the *Advisories* and many subscribe to the Authority’s mailing list to receive them regularly. If you would like to subscribe to the Patient Safety Authority’s *Advisory* go to www.psa.state.pa.us and click on *Advisories*.

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

- Raised awareness of frequent near miss and actual events of wrong-site surgery in Pennsylvania, while acknowledging that it is a national problem as well. Site visits with volunteer facilities helped us to

focus on procedures and behaviors that may reduce the risk of wrong-site surgery. Continued follow up will occur to maintain awareness of wrong-site surgery risks and to develop additional guidance.

- Highlighted the frequency of reports related to methicillin-resistant *Staphylococcus aureus* (MRSA), including 14 deaths. In 90% of the cases, a MRSA screening was not noted as having been done when the patient was admitted to the facility. In about 13% of reports where MRSA was found upon admission, the information about the infection was not communicated to other healthcare workers. Consumer tips for how the patient can help protect themselves against MRSA were included with this *Advisory* and have been distributed through other means.
- Assessed volunteer users of electronic pharmacy systems in Pennsylvania. The study raised awareness that the pharmacy computer systems were not detecting all unsafe drug orders. The Authority encouraged all Pennsylvania facilities to test their systems to ensure all potentially harmful medication errors are caught.
- Focused attention on the increased risks of anesthesia complications for patients with obstructive sleep apnea (OSA). A common sleep disorder that causes recurrent episodes of complete and partial airway collapse during sleep, resulting in the failure to breathe properly. Approximately 80-90% of patients with OSA are undiagnosed, but incorporating OSA into pre-surgical screening gives clinicians an opportunity to take steps to reduce anesthesia complications for these patients. Over 250 reports show OSA as a contributing factor for anesthesia complications. About 20% are considered Serious Events, including three deaths.
- Continued focus on frequency of medication errors highlighting unclear and confusing labeling and packaging, as well as look-alike or sound-alike drug names as potential causes. The Authority offered guidance on how to minimize the risk by using technology such as bar coding and automated dispensing technology; requiring staff to double check the dose before administering; and monitoring patients closely before discharge.

The Authority's research findings are disseminated widely through the *Patient Safety Advisories*. The importance of distributing the *Advisories* to all appropriate healthcare facility staff cannot be emphasized enough so that the facility can benefit fully from the "lessons learned." Several of Pennsylvania's Patient Safety Officers have commented on the usefulness of *Patient Safety Advisories*, and understand the importance of sharing the information with staff. Examples appear below.

The PSA has provided our organization with valuable information through their Advisory publications. They are widely distributed and used throughout our Health System. The Authority has also done a great deal to advance consistency in reporting of information, as well as insight into the frequency of safety Incidents and Serious Events as a whole. With the open discussion at our Patient Safety Committee meetings, many topics once "hidden" are now seeing the light of day. I believe we are a more well-informed organization - with heightened awareness of the events affecting us in our delivery of healthcare.

*Joan Silver, BSW, RN, MS, CPHQ
Vice President, Organizational Quality
Pinnacle Health System*

The Patient Safety Authority has greatly elevated our awareness of patient safety in our hospital. The Patient Safety Advisories, in particular, are a useful resource tool. The information is disseminated to the appropriate department managers and process improvements have been implemented as a result of the Authorities recommendations. We continue to strive to make safety a priority every day in everything we do at Reading Hospital.

*Roseann Castanaro
Risk Manager/Patient Safety Officer
Reading Hospital & Medical Center*

We have found the Patient Safety Advisories beneficial and we share them with the management staff and the physicians (Patient Safety Committee) to share the knowledge gleaned from the Advisories. Statewide trends are beneficial - seeing value come from our work is beneficial, we just don't enter data - we see feedback as a result of all facilities participating.

*Diane Cooper
Patient Safety Officer
Monongahela Valley Hospital*

The value of the Authority and PA-PSRS allows our facility to keep its fingers on the pulse of patient safety. The Advisories are keeping pace with current topics, and in many areas, striving to serve as a proactive source from retrospective data analysis. The ability to review the PA-PSRS data assists our facility to implement effective changes efficiently.

*Gene Mushak
Patient Safety Officer
Allied Services Rehabilitation Hospital*

“The Patient Safety Advisories are a valuable educational tool. When received, they are shared with members of our Patient Safety Committee, management staff, medical staff and employees who provide direct care to our patients. We have made the Patient Safety Advisory website available to our employees via our Intranet.”

*Brenda Rusnak
Patient Safety Officer
Jefferson Regional Medical Center*

I use the PSA for in-service and [distribute] Advisories to all staff for review. I recently used the Advisory on early identification of MRSA to support a capital equipment request for rapid turn-a-round culture lab equipment. This particular Advisory summed the need up concisely and was very helpful in supporting our request.

*Jo Evans, RN, BSN
Director Quality/Risk Management
Heart of Lancaster Regional Medical Center*

Education, Outreach and Collaboration

Education and Training

FMEA Training

In May and June 2007, the Authority offered a two-day workshop on Failure Mode and Effects Analysis (FMEA) for all PA-PSRS users and other attendees. The hands-on workshop allowed Patient Safety Officers to mitigate potential risks and develop control strategies where risk is present within their own healthcare facility.

PA-PSRS System Training

In May, a new user training session was held in conjunction with the FMEA training in Gettysburg and in December a webinar was offered for the first time with attendance at full capacity. The Authority also offers online training at www.psa.state.pa.us.

Wrong-Site Surgery Study

In June, the Authority held a press conference raising the awareness of wrong-site surgery, not only in Pennsylvania, but nationally as well. In September, the Authority visited several facilities to study why some facilities were better than others at preventing wrong-site surgeries. The wrong-site surgery study will continue as more information is obtained from facilities. For the complete *Patient Safety Advisory* article on the study and follow up go to the June 2007 and December 2007 *Patient Safety Advisories* at www.psa.state.pa.us.

Patient Safety Advisory Toolkits

The Authority also developed an educational toolkit with each *Advisory* as an additional resource for facilities to improve patient safety. The toolkits have covered topics such as preventing wrong-site surgery, decreasing the risk of medication errors in verbal orders, reducing the likelihood of skin tears and increasing hospital bed safety.

Outreach to Facilities and Providers

Authority staff and board members participated in numerous hospital-based educational programs throughout the year by making presentations to clinical staff about patient safety. Most audiences included physicians, nurses, pharmacists, other healthcare workers and administrators.

PSA Pharmacy Survey Project

In January 2007, 32 PA-PSRS facilities engaged in a statewide field test of hospital pharmacy systems. The study raised awareness that the pharmacy computer systems were not detecting all unsafe drug orders. Participating facilities received a report at the end of the survey that gave their facility's results along with the de-identified statewide results. The aggregate results were published in the March 2007 *Supplemental Patient Safety Advisory* and presented at the Patient Safety Authority board meeting held in March during 2007 National Patient Safety Week.

Colonoscopy Perforation Project

The Authority continued its study on the frequency of routine colonoscopy perforations and the risks associated with them. This study aims to answer questions about the rate at which colonoscopy-associated perforations occur, the risk factors for colonoscopy-associated perforation, and best practices for controlling modifiable risk factors. The Authority's PA-PSRS clinical director is working with a physician work group to determine the answers to these questions through data submitted to the Authority.

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

The Authority has provided the Health Care Improvement Foundation (HCIF) with de-identified data on wrong-site surgery and patient falls from hospitals in Southeastern Pennsylvania. The information will allow HCIF to prioritize patient safety initiatives based upon these areas that need improvement.

Consumer Tips Sheets Involve Patients

Although the primary work of the Authority is focused specifically on healthcare facilities it is obvious that *patients* are at the center of all patient safety activities. The Authority is committed to providing individual citizens, the consumers of healthcare, with information that can impact their healthcare and steps they can take to assure they receive quality care.

In 2007, the Patient Safety Authority developed and distributed consumer tips sheets with selected *Advisory* articles. These tips provide patients with more knowledge about specific healthcare topics. They include: medication errors, wrong-site surgery, color-coded wristbands, falls, MRSA, the risks for sleep apnea patients and the importance of knowing your medical history. There are many opportunities for patients and their loved ones to become involved in their healthcare, from making decisions about treatment protocols to assuring that providers are adhering to safe practices such as hand washing and verifying medications before administering them. The consumer tips sheets are another educational tool the Authority uses to reach out to the facilities and their patients. The Authority also continued to distribute the Speak Up™ brochure developed by the Joint Commission to give patients the information they need to "speak up" and ask their healthcare providers questions so they can be active participants in their healthcare.

To access the consumer tips sheets or other consumer-related information go to www.psa.state.pa.us and click on "Tips for Consumers."

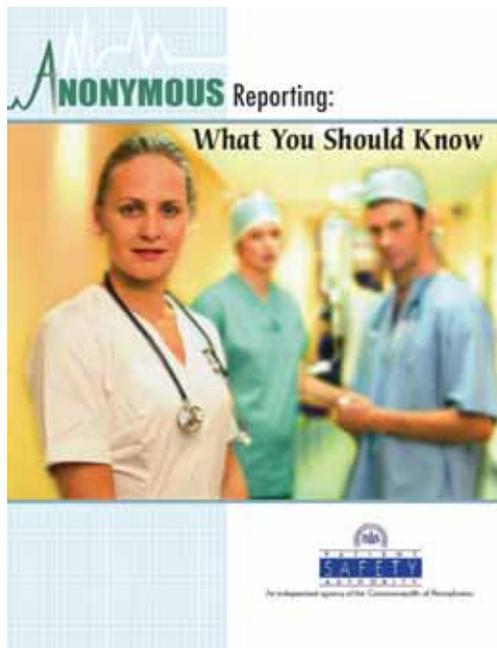
Anonymous Report Brochure

The Authority received only one Anonymous Report in 2007. The Anonymous Report is an important vehicle for comprehensive event reporting. In order to promote the Anonymous Report alternative, the Authority developed an Anonymous Report brochure this year for Patient Safety Officers to display prominently in their facilities for staff to access. The form is for healthcare workers to complete if they feel a patient in their facility suffered an unanticipated injury involving the clinical care of a patient. However, the healthcare worker's first obligation is to report the event internally according to their facility's patient safety plan. If the healthcare worker is not satisfied with the manner in which the report was handled by the facility, then they are asked to consider filing an Anonymous Report with the Patient Safety Authority. A report form is provided in the brochure.

It is a goal of the Authority's that these matters are handled properly within the healthcare facility so that Anonymous Reports are not necessary. Every healthcare worker should feel empowered to speak if he or she feels a patient has not been cared for properly. Healthcare management and supervisors should communicate openly with their staff so that staff feels their concerns are heard and dealt with accordingly.

The Authority believes open communication among hospital staff and patients is an integral component for a successful culture of safety in any facility.

For the complete annual report, more information about the Authority and access to issues of the *Patient Safety Advisory*, go to the Authority's website, www.psa.state.pa.us.



Introduction

The Pennsylvania Patient Safety Authority has grown since its inception in March 2003. Throughout the stages of reporting which began in December 2003, we have developed a relationship with the 500-plus healthcare facilities that submit reports to us through the Pennsylvania Patient Safety Reporting System (PA-PSRS). Their reports have given us the information needed to generate interest from around the world.

As the number of reports increases, the Authority has expanded its reach with other healthcare organizations to work more efficiently and use the data to its fullest. Collaborations in 2007 have enabled the Authority to strengthen relationships and build upon its quest to improve patient safety.

Some of the collaborations include a study on the frequency of perforated colons during a routine colonoscopy and the risk factors involved. In another, the Authority is working with the Health Care Improvement Foundation (HCIF) to reduce wrong-site surgeries and falls. The Authority also collaborated with the National Academy for State Health Policy (NASHP) to bring states together nationwide who have reporting systems or are developing them to improve patient safety. From the event, the Authority established contacts for more projects with other states that have reporting systems to share data and develop programs for continued healthcare guidance.

A significant collaborative involved the Governor's Office of Healthcare Reform, the Department of Health and the Pennsylvania Healthcare Cost Containment Council. The charge for all was to implement provisions in Act 52 of 2007 to reduce and eliminate healthcare-associated infections in Act 13 hospitals as well as in Pennsylvania nursing homes. The Authority established an infection control panel of experts from around the state to help develop the reporting requirements. Hospitals and other facilities under Act 13 are reporting infections according to the Act. Implementation continues for the approximately 800 nursing homes in Pennsylvania.

In May 2007, the Authority released its Strategic Plan with initiatives to: educate CEOs and boards of trustees in healthcare facilities, create a forum for Patient Safety Officers to communicate with one another about patient safety issues, improve reporting consistency and make recommendations, increase the Authority's effectiveness through patient safety liaisons and offer more educational patient safety programs through conferences and school curriculums. A majority of the initiatives are well underway. Expect more layers to be added to each initiative as they fully develop.

Since I began working for the Authority, I have seen it grow from an agency learning the ropes in reporting to an agency that is helping others develop their own reporting systems. While our focus remains the same—to reduce and eliminate medical errors—our initiatives continue to grow in fulfilling that mission. I look forward to the challenges that lie ahead that will be overcome to improve patient safety for patients and their families.

Michael C. Doering
Executive Director
Pennsylvania Patient Safety Authority

Background

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

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

Under Act 13, all hospitals, birthing centers, ambulatory surgical facilities and certain abortion facilities—currently totaling more than 500 facilities—must report what the Act defines as “Serious Events” and “Incidents” (Serious Events and Incidents are defined on page 25). In turn, the Authority analyzes and evaluates those reports so it can learn from the data reported in order to advise facilities and provide guidance 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 and only state in the nation to require the reporting of both adverse events and near misses (categorized in Pennsylvania as Serious Events and Incidents). By the end of 2007, Pennsylvania healthcare facilities had submitted a total of over 600,000 reports of Serious Events and Incidents through PA-PSRS, with average monthly reports over 17,000 in 2007.

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.”

Kate Flynn, FACHE, President of the Health Care Improvement Foundation of the Delaware Valley Healthcare Council has worked with the Authority to focus on specific issues in southeastern Pennsylvania healthcare facilities. She describes the efforts made by facilities to improve patient safety.

"Hospitals and healthcare providers across the Commonwealth have been dedicated to patient safety for more than a decade, even before the Institute of Medicine published its 1999 landmark report, *To Err is Human*. More and more, data has become an important tool in building a safer healthcare system. The business adage ‘What gets measured, gets managed’ applies as much to patient safety improvements as it does to any other serious

management challenge. Without data, how does an organization know the starting point? How do they choose what problem to focus on first? How do they know if efforts have resulted in improvement?

“The data system supported by the Pennsylvania Patient Safety Authority helps healthcare organizations apply the discipline of measurement to their practices of care and healing. In southeast Pennsylvania, hospitals are using this data to help implement improved practices in infection prevention, medication errors, and other safety issues ... working together to provide the safest, most effective healthcare possible.”

It is important to recognize that not every Serious 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 a Serious Event, it should not be considered an error *per se*.

The goal of patient safety is to reduce the likelihood of any 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 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.

[This page intentionally left blank]

The Patient Safety Authority's Strategic Plan

The Authority has enjoyed many successes in its first few years of operation. PA-PSRS is one of the largest repositories of patient safety event data in the world. Articles in the *Patient Safety Advisory* have had an impact on the operations of the reporting facilities. The Authority has garnered the respect of the reporting facilities and is seen as having an impact on patient safety. In recognition of its efforts, the Authority received the national 2006 John M. Eisenberg award for patient safety and quality. The Eisenberg Award, presented jointly by The National Quality Forum (NQF) and The Joint Commission, recognizes major achievements of individuals and organizations in improving patient safety and quality.

Through 2006 and into 2007, the Authority had been primarily focused on the development and implementation of the PA-PSRS (Pennsylvania Patient Safety Reporting System), data collection, analysis and guidance provided through the *Patient Safety Advisory*. The Authority Board wanted to build on these successes and have a greater impact on patient safety in Pennsylvania over the next several years. Input was solicited from primary stakeholders and national patient safety experts. The Authority received valuable feedback from Pennsylvania healthcare facilities, government entities, patient safety organizations, healthcare membership organizations and national patient safety organizations. Based on this information, the Authority developed a set of objectives and initiatives that have been incorporated into a comprehensive strategic plan that addresses the patient safety needs of Pennsylvania's healthcare community to better protect patients.

It is important to note, the initiatives incorporated in the Strategic Plan will not replace the current activities of the Authority: data collection, data analysis and providing guidance through the *Patient Safety Advisory*. They will build upon these successful activities to increase the Authority's role and presence in Pennsylvania patient safety. However, the Board believes the Authority could have a significantly greater impact on patient safety in Pennsylvania by branching out beyond past activities. Therefore, education, training, collaboration and communication are featured more prominently in the new initiatives.

The Strategic Plan was approved in May 2007. The plan provides direction to Authority efforts through the following initiatives.

Initiative A: Educate Executive Management and Boards of Trustees

Real change stands a better chance if driven from the top down through the organization. The purpose of this initiative is to engage facility boards and executive management in discussions of patient safety. The program will increase the profile of patient safety and raise the priority of patient safety at the board level. Responding to this initiative, in fall 2007, the Authority began collaboration with the Hospital and HealthSystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) to begin adoption of a curriculum for educating Pennsylvania hospitals' executive management and boards of trustees.

Initiative B: Infection Awareness and Reduction

In July, Act 52 of 2007 charged the Authority with collecting infection data from nursing homes as well as continuing the collection of infection data from Act 13 hospitals. Act 52 also required the Authority to establish a Healthcare-Associated Infection Advisory Panel to assist in the implementation. Working with the Governor's Office of Healthcare Reform (GOHCR), the Department of Health (DOH) and the Pennsylvania Healthcare Cost Containment Council (PHC4) the Authority recognizes the importance of reducing infections in Pennsylvania's healthcare facilities. Significant steps have been taken to achieve this important initiative.

Initiative C: Patient Safety Knowledge Exchange (PasSKEy)

The Patient Safety Knowledge Exchange would provide an electronic confidential forum for the exchange of information, ideas, and solutions within the facility patient safety community. In November, the Authority held a meeting with Patient Safety Officers throughout the state to discuss the PasSKEy initiative. The PSOs' enthusiasm for the project confirmed the need for the forum to further open communication lines for improved patient safety.

Initiative D: Improve Reporting Consistency and Recommendations

Different interpretations of Act 13 terms and definitions, facility structure and organization, and varying facility cultures of safety have led to disparate levels of reporting in Pennsylvania facilities. While the Authority has provided some guidance regarding what is reportable, there continues to be wide variations in reporting rates. Patient safety officers and other stakeholders have asked for clarification. Through this initiative, the Authority will address these issues by working with the Department of Health to provide clarifying guidance. We will also undertake a project to determine the attributes that characterize high-reporting facilities. Appropriate education efforts will follow these activities.

Initiative E: Increase Effectiveness through Extended Presence

In focus group sessions held in early 2007, Patient Safety Officers asked for more interaction from the Authority. This initiative would establish the Patient Safety Liaison (PSL). Steps are being taken to develop a pilot program and enable the Authority to hire PSLs in 2008. The PSL would promote patient safety activities within a designated region. Activities will include working regionally and individually with facilities to strengthen their system processes through educational tools provided by the Authority. In addition, the PSL will work with regional patient safety entities to promote collaboration with the Authority.

Initiative F: Governor's Office of Healthcare Reform (GOHCR) Collaboration

As mentioned, the Governor's Office of Healthcare Reform and the Authority are working together by implementing several initiatives identified in the Governor's healthcare reform plan, "Prescription for Pennsylvania." These activities include infection education and analyzing nursing home events. Working with GOHCR and other health-related agencies in the Commonwealth increases the efficiency and reach of patient safety initiatives.

Initiative G: Data Collaboration

In 2007, the Authority collaborated with several healthcare entities and interested parties to further utilize the rich repository of information contained in the over 650,000 reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS). In one activity, the Authority worked with the Health Care Improvement Foundation (HCIF) to pinpoint specific areas of desired improvement, including patient falls and wrong-site surgery. Also, a study on the frequency of colonoscopy perforations is being conducted to determine specific risk factors. The Authority also worked with the Institute for Healthcare Improvement (IHI) promoting its 5 million lives campaign. Data was provided to the regional IHI node on pressure ulcers, adverse drug events, high alert medications, central line infections and ventilator-associated pneumonia (VAP). The Authority will continue to seek additional ways to use PA-PSRS data to support patient safety improvement activities.

Initiative H: Patient Safety Methods Training

This initiative is an expansion of current Authority activities. The Authority has provided root cause analysis training and as part of this initiative, gave Failure Mode and Effects Analysis (FEMA) training in May. The training provided further encouragement for healthcare staff to re-examine current processes for any potential risks. Through this initiative the Authority is also identifying additional education and training courses with a specific focus on medical and nursing schools. In May, Dr. Robert Wright, chairman of the board of directors for the Northeast Pennsylvania Medical Education Development Consortium attended the Authority's board meeting to discuss the Authority's participation in developing a patient safety curriculum for the proposed medical college in Northeast Pennsylvania.

Initiative I: Nursing Home Data Analysis

Act 52 requires the Authority to collect and analyze infection data received from Pennsylvania's nursing homes. The Authority is working with the Department of Health and the HAI Advisory panel to develop reporting requirements and methods. The Authority will provide guidance similar to that given to hospitals through *Patient Safety Advisories*. The nursing home guidance will focus on infections and any other related topic derived from hospital data that can also help improve nursing home care.

Initiative J: PA-PSRS System Enhancements

Since PA-PSRS reporting began in June 2004, approximately 300 system enhancements have been implemented. In 2007, the Authority tried to limit enhancements because as PA-PSRS becomes more complex, any change has significantly more impact.

Simple enhancements will continue to be made under the current data collection and analysis contract. Also, the Authority will continue to assist facilities with conversion to all-electronic submission of Incidents through the PA-PSRS Interface. Approximately 35% of Incidents are submitted through the interface. The Authority will continue to support interface use by the reporting facilities.

PA-PSRS provides all facilities with access to their own data. However, Patient Safety Officers have asked that the analytical reports available to them be evaluated for efficiency and effectiveness. In response, the Authority held an analytical report focus group meeting to determine potential solutions. The Authority intends to modify the analytical report capabilities in 2008-2009.

Initiative K: Maintain Success of Patient Safety Advisory

The *Patient Safety Advisory* has been the Authority's signature product. It is one of the primary reasons the Authority was awarded the John M. Eisenberg Award for patient safety in 2006. In 2007, the *Advisory* was enhanced through the use of companion toolkits and availability of single articles on the Authority's website. Patient Safety Officers have also reported a significant number of changes made in their facilities due to the *Advisory* articles. The continued success of the *Advisory* is important for the credibility of the Authority and to continue facility improvements. The Authority will continue to focus on increasing targeted distribution of *Advisory* articles within facilities.

[This page intentionally left blank]

Healthcare-Associated Infections

Act 52 of 2007 — The Health Care-Associated Infection and Prevention Act of 2007

Background

The Centers for Disease Control and Prevention (CDC) estimates that healthcare-associated infections (HAIs) affect two million patients a year in the United States, accounting for an estimated 90,000 deaths and adding \$4.5 to \$5.7 billion in healthcare costs.¹ According to a report for 2004 by the Pennsylvania Health Care Cost Containment Council (PHC4), acute care hospitals in Pennsylvania reported 11,668 healthcare-associated infections, resulting in 1,793 patient deaths, \$2 billion in additional hospital charges, and 205,000 additional hospital days.²

Legislation aimed at reducing the incidence of HAIs was introduced in June 2007 as Senate Bill 968. On July 20, 2007, Governor Ed Rendell, as part of his “Prescription for Pennsylvania” plan, signed Senate Bill 968 into legislation creating Act 52 of 2007. This Act amends the Medical Care Availability and Reduction of Error (MCARE) Act 13 of 2002 by adding a new chapter addressing the reduction and prevention of healthcare-associated infections. This measure was adopted to continue the momentum of activities currently underway in Pennsylvania healthcare facilities, ensuring that the necessary protocols are in place to further prevent HAIs.

Key Provisions of Act 52

The Act requires a number of changes in healthcare facilities related to patient safety and quality of care. Act 52 of 2007 also defines duties for the Patient Safety Authority (the Authority), the Department of Health (DOH) and the Pennsylvania Health Care Cost Containment Council (PHC4) related to HAI prevention. The key provisions of the Act include:

- Requires that all healthcare facilities, including hospitals, nursing homes and ambulatory surgery centers develop and implement internal infection control plans to improve the health and safety of patients and healthcare workers. The deadline for plan submission to DOH was December 31, 2007.
- Requires that hospitals culture and screen all nursing home admissions for multi-drug resistant organisms (MDROs), including methicillin-resistant *Staphylococcus aureus* (MRSA).
- Requires hospitals to report HAIs electronically to the CDC’s National Healthcare Safety Network (NHSN), and to confer rights for data access by the Authority, DOH and PHC4. The deadline for the start of reporting into NHSN was February 14, 2008.
- Defines all HAIs as Serious Events under Act 13, which makes them reportable to the Authority and DOH and creates a requirement to provide patients or their representatives with a written Serious Event notice related to the HAI. All infections defined by the current CDC/NHSN manual – patient safety component protocol are reportable.
- Charges the Authority and DOH with establishing uniform definitions for identifying and reporting infections in nursing homes.
- Requires DOH to develop a methodology for determining and assessing the rate of HAIs in Pennsylvania.
- Requires DOH to develop benchmarks in consultation with the Authority and PHC4 by 2010.
- Requires that insurers and the Medical Assistance Program reimburse the facilities for the cost of routine cultures and screenings performed in accordance with their infection control plan.
- Provides for incentive payments to healthcare facilities that achieve a reduction in HAIs based on benchmarks developed in consultation with the Authority.

¹ McKibben L, Horan T, Tokars J, et al. Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee. *Am J Infect Control* 2005; 33:217-226.

² Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired infections in Pennsylvania. *PHC4 Research Briefs* 2005; 5:1-4.

- Charges DOH with development of an HAI public awareness campaign.
- Directs DOH to determine the feasibility of establishing population-specific active surveillance programs, such as for correctional facilities.
- Defines surcharges for nursing homes, quality improvement incentive payments for hospitals and nursing homes and penalties for failure to comply.

Patient Safety Authority Duties

Act 52 charges the Authority with taking steps to reduce and eliminate healthcare-associated infections. In addition to existing responsibilities, the duties of the Authority are expanded by the requirements of Act 52 as set forth below. Act 52 requires that hospitals and nursing homes report all CDC/NHSN-defined healthcare-associated infections as Serious Events. These reports are subject to the same regulations and patient notification requirements as set forth in Act 13.

A summary of the Authority's additional duties under Act 52 includes:

- Appoint an advisory panel of healthcare-associated infection control experts to advise the Authority and other agencies on Act 52 implementation.
- Establish, based on CDC definitions, uniform definitions using nationally recognized standards for the identification and reporting of healthcare-associated infections by nursing homes.
- Publish notices in the Pennsylvania Bulletin stating the uniform reporting requirements established for hospitals and nursing homes and the effective dates for the commencement of required reporting.
- Solicit public comment prior to publishing final notices, the Authority shall solicit public comments for at least 30 days after publication in the Pennsylvania Bulletin and respond to such.
- Issue *Patient Safety Advisories* to healthcare facilities as stipulated in Section 304 of Act 13.
- Include a separate chapter for providing information about healthcare-associated infections in the annual report.
- Create and conduct training programs for facilities about the prevention and control of HAIs. The Authority may work with DOH and other organizations to fulfill this requirement.
- Assist DOH in developing a methodology for determining and assessing the rate of HAIs in Pennsylvania.

Patient Safety Authority Accomplishments through December 2007

In September 2007 the Authority's Board of Directors approved a 15-member panel of infection control experts to provide guidance and clinical expertise for the implementation of Act 52. Members of the panel are listed in Figure 3.

Figure 3. Members of the HAI Advisory Panel (December 2007)

Erick J. Bergquist, MD, PhD

Medical Director for Epidemiology
Indiana Regional Medical Center

Dorothy Borton, RN, BSN, CIC

Infection Control Practitioner
Albert Einstein Healthcare Network

Patrick J. Brennan, MD

Chief Medical Officer and Senior Vice President
University of Pennsylvania Health System
Professor of Medicine

Kenneth Brubaker, MD

Director of Geriatric Program
Willow Valley Retirement Community

Susan E. Coffin, MD, MPH

Medical Director, Department of Infection Prevention
and Control
The Children's Hospital of Philadelphia

Joan M. Delovich, BSN, MS

Director of Nursing
Troy Community Hospital

Daniel Haimowitz, MD, FACP, CMD

Medical Director of Geriatric Program
Attleboro Retirement Campus

Kathleen Hess, RN, MS

Director of Nursing
Regional Staff Development Coordinator
HCR Manor-Care

Sharon L. Jacobs, RN, MS, CIC

Manager, Infection Prevention and Control
St. Clair Memorial Hospital
President, APIC-Three Rivers/Pittsburgh Chapter

Emily McCracken, MPH

Hospital Epidemiologist and Director of Infection
Control
Hamot Health System

S. Candy Mulholland, RN, MSN

Infection Control Coordinator
Kane Nursing Homes

Carlene A. Muto, MD, MS

Medical Director Department of Hospital Epidemiology
and Infection Control
University of Pittsburgh Medical Center

Stephen Ostroff, MD

Bureau Director
Bureau of Epidemiology
Pennsylvania Department of Health

Abby Weand, RN

HAI Project Leader
Pennsylvania Health Care Cost Containment Council
(PHC4)

Linda Winston, MSN, CIC

Infection Control Officer
Altoona Regional Health System

The first meeting of the HAI Advisory Panel was in October 2007. Items discussed included: clarification of reportable infections, the Authority's goal for collection of process information related to best practices, collection of data for the purpose of analyzing infection reports, avoidance of duplicate reporting, requirement for facilities to modify and utilize several custom fields in NHSN, coding of infection reports as per DOH requirements and DOH enforcement/audit plans. A subcommittee of six panel members was formed to address nursing home requirements. A follow up conference call was held in November to finalize facts for publishing a hospital reporting requirement notice in the Pennsylvania Bulletin.

During the fourth quarter of 2007, the Authority added to its contract staff an Infection Control/Patient Safety Analyst. The role of the analyst is to assist and support the Authority with Act 52 tasks and duties.

During the fourth quarter of 2007, the Authority, in conjunction with DOH and with the advice of the HAI Advisory Committee, developed a draft notice of hospital reporting requirements under Act 52. An important component of these requirements is that the Authority avoided the potential requirement for duplicate reporting in both NHSN and PA-PSRS. By allowing facilities to incorporate into their NHSN reporting the Authority's required reporting elements, we have reduced the resource burden on the facilities while still ensuring that meaningful data will be collected on HAIs.

The draft notice was published in the PA Bulletin December 22, 2007, followed by a 30-day public comment period. At the end of 2007 the Authority was in the process of analyzing the public comments.

The Authority has provided support to hospitals in meeting the new reporting requirements, including several training opportunities for facilities. The Authority, along with DOH, has participated in audio conferences organized by the Hospital and Healthsystem Association of Pennsylvania (HAP). The Authority and DOH also attended a meeting of the Hospital Council of Western Pennsylvania to discuss Act 52 reporting requirements. The Infection Control/Patient Safety Analyst has developed detailed instructions for customizing the NHSN reporting system to meet the Authority's requirements, and the Authority has provided one-on-one technical assistance as needed through the PA-PSRS Help Desk.

The Authority, in conjunction with DOH and the HAI Advisory Panel Long-Term Care subcommittee, has begun work on identifying infections that will become reportable in nursing homes. This work will be performed primarily in 2008.

Future Goals and Tasks

The Authority's goals for 2008 include full implementation of hospital reporting requirements under Act 52 and beginning to track infections reported through NHSN by individual hospitals. The Authority will also establish nursing home reporting requirements in 2008 and begin implementation of reporting in this care setting. Some other tasks are as follows:

- The analyst will conduct ongoing reviews of incoming infection-related reports to identify patterns, trends, potential system lessons, as well as determine whether immediate follow-up is required with reporting facilities. Follow up will be conducted in the form of an *Advisory* which will be written by the analyst.
- The analyst will review aggregate data to determine the need for infection-related *Advisories* or recommendations to facilities.
- The analyst will continue to participate in patient safety review meetings and anonymous report review meetings.
- The analyst will develop and deliver infection-related educational programs for healthcare professionals and other healthcare workers.
- The analyst will provide consultation services to DOH for the purpose of adopting and implementing evidence-based protocols and safe practices as defined by Act 52.

- Issue *Advisory* articles that provide clinical guidance for process improvement to be adopted by facilities. This includes ongoing encouragement of the facilities to adopt best practices
- Identify and prioritize HAI education and training plans with HAI Advisory Panel

Additional tasks will be addressed on an as needed basis.

Summary of Healthcare-Associated Infections Reported through PA-PSRS

The Authority received 6,266 reports related to infection control for 2007, reflecting a 16.5% increase in reported cases from 2006 (see Table 2). Reports were submitted most frequently related to wound/surgical site infections (21.6%), urinary tract infections (19.2%), and antibiotic-associated diarrhea (18.7%). The predominant care areas for HAIs were the critical care and medical/surgical units. Surgical site infections were also reported in the surgical services area.

Table 2. Reports Related to Healthcare-Associated Infections (2007)

Infection Type	Predominant Units/Services	Reports by Unit	Percentage by Unit	Number of Reports	Percentage of Total
Intravascular Catheter Infections	Critical Care Units	108	28.9%	374	5.97%
	Medical/Surgical Units	103	27.5%		
Wound/Surgical Site Infections	Critical Care Units	112	8.3%	1351	21.56%
	Medical/Surgical Units	369	27.3%		
	Surgical Services	497	36.8%		
Pneumonia	Critical Care Units	215	36.8%	584	9.32%
	Medical/Surgical Units	174	29.8%		
Sepsis 48 hours Post Admit	Critical Care Units	181	34.0%	532	8.49%
	Medical/Surgical Units	133	25.0%		
Antibiotic Associated Diarrhea	Critical Care Units	150	12.8%	1172	18.70%
	Medical/Surgical Units	530	45.2%		
Antibiotic Resistant Organism	Critical Care Units	121	22.9%	529	8.44%
	Medical/Surgical Units	215	40.6%		
Urinary Tract Infection	Critical Care Units	158	13.1%	1202	19.18%
	Medical/Surgical Units	399	33.2%		
Other Infections	Critical Care Units	119	22.8%	522	8.33%
	Medical/Surgical Units	177	33.9%		

Of the 6,266 reports, 5,917 were reported as Incidents and 349 were reported as Serious Events. Since the inception of PA-PSRS, many cases of HAIs that occurred in healthcare facilities were not reported or were reported as Incidents because practitioners felt they did not meet the criteria for a Serious Event as defined in Act 13. To be a Serious Event, an event must involve an unanticipated injury to the patient. However, many clinicians considered many HAIs to be anticipated. This uncertainty has been clarified through Act 52 of 2007, which makes all infections reportable to CDC's NHSN Serious Events. Incidents related to infection control problems (in which patients could have become infected but did not) will continue to be collected through PA-PSRS.

The Authority published two infection control-related articles in 2007 through the *Patient Safety Advisory*:

- “A Query on Clostridium Difficile” (March 2007) addressed CDC recommendations regarding the use of soap and water versus alcohol-based sanitizing agents for preventing transmission of *C. diff.*
- “Prompt Identification and Effective Communication of Status May Reduce MRSA Infections” (December 2007) addressed failure modes identified in reports to PA-PSRS related to MRSA prevention, such as failure to perform MRSA screening and failure to communicate a patient’s MRSA-positive status to caregivers.

We will be publishing additional articles on infection-control topics in upcoming issues of the *Advisory*.

Data Collection and Analysis

The Reporting System

Introduction

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

As defined by Act 13, PA-PSRS is a facility-based reporting system.³ 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 73.)

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

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

Among questions are those related to demographic information, such as a patient’s age and gender, the location within a facility where the event took place, the type of event and the level of patient harm, if any. In addition, the report collects considerable detail about “contributing factors,” details related to staffing, the workplace environment and 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 Authority’s clinical team initiates its analysis. This team includes professionals with degrees and experience in medicine, nursing, law, pharmacy, health administration, risk management, product engineering and statistical analysis, among other fields. In addition, through our contract staff, the Authority has access to a large pool of subject matter experts in virtually every medical specialty.

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

As a result of this comprehensive analysis, the Authority issues *Patient Safety Advisories* based on data submitted through PA-PSRS, supplemented by a scholarly search of the medical and clinical literature. *Advisory* articles are directed primarily to healthcare professionals for use by both clinical and administrative staffs. The Authority encourages these providers to use the articles as learning tools for patient safety and continuous quality improvement. In a recent survey, a majority (68%) of all responding facilities and 81% of respondents

³ 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.

from hospitals indicated that they have implemented improvements within their facilities as a result of information contained in this year's *Advisories*. The 180 Patient Safety Officers responding to the 2007 survey cited 471 process or system changes they had made as a result of *Advisory* articles.

Primary distribution of the *Advisories* is through electronic emails, enabling the Authority to circulate the *Advisories* to thousands of individual healthcare providers, hospitals and government and healthcare organizations around the world, including national patient safety and quality improvement organizations. As a result, the Authority is able to generate considerable interest in Pennsylvania's approach to promoting patient safety and in the lessons learned through the PA-PSRS system.

More information about the *Patient Safety Advisories* and the data collected through PA-PSRS is in the section "*Patient Safety Advisories*" (see page 70). 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. Many reports can also be exported to other software programs for inclusion in facility publications or in reports and presentations to trustees and senior management. In addition, facility personnel have the ability to export all, or any portion, of their facility's data. Managers can use this information for their internal quality improvement and patient safety activities.

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

PA-PSRS was developed under contract with ECRI Institute, a Pennsylvania-based independent, non-profit health services research agency, in partnership with EDS, a leading international, information technology firm, and the Institute for Safe Medication Practices (ISMP), also a Pennsylvania-based, non-profit health research organization.

Interpreting PA-PSRS Data

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

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

Numbers by themselves do not provide complete answers. For example, the number of incorrect medications administered is not meaningful without knowing the total number (known as the "denominator") of all medications administered. In other words, ten incorrect medications out of a total of 50 administered doses are much different than ten incorrect medications out of 10,000 administered doses.

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

- Data presented in this report include only reports of Serious Events and Incidents. While PA-PSRS also collects reports of Infrastructure Failures, these reports are submitted only to the Department of Health. The Authority does not receive reports of Infrastructure Failures.
- Unless otherwise noted, data presented in this report are based on reports submitted to PA-PSRS between January 1, 2007, and December 31, 2007.

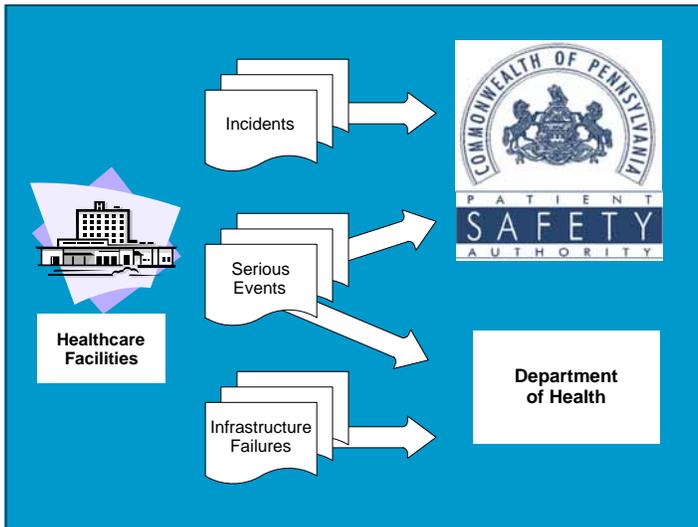


Figure 4. Submission of PA-PSRS Reports

- Unless specifically noted, numbers of reports in different categories are actual “raw numbers” and have not been adjusted for any facility- or patient-related factors that may influence differences in report volume among different facilities.
- The data are not adjusted to account for healthcare facility openings, closings or changes of ownership.

Caution is advised when comparing data contained in this report with data published by other patient safety reporting systems. The PA-PSRS program was developed within the context of Act 13, which has its own unique definitions for what is and what is not reportable to PA-PSRS. It also uses a specific list of Event Types that may be different

than the lists used by other systems. Most important, PA-PSRS is the only mandatory program collecting data on “near misses”—events which did not harm patients.

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

Definitions

Act 13 requires healthcare facilities to submit reports of the following three kinds of occurrences:

- **Serious Event**—An adverse event resulting in patient harm. The legal definition, from Act 13, reads: “An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare 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 healthcare 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.

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

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

- **Hospital**—The Health Care Facilities Act (35 P.S. §448.802a) defines a hospital as “an institution having an organized medical staff established for the purpose of providing to 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 2007, there were 243 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 2007, there were 246 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 2007, there were five birthing centers in the Commonwealth of Pennsylvania.
- **Abortion Facility**— Act 30 of 2006 extended the reporting requirements in Act 13 to abortion facilities that perform more than 100 procedures per year. For the purposes of this report, at the end of 2007, there were eighteen qualifying abortion facilities in the Commonwealth of Pennsylvania.

Other pertinent definitions used in this report include:

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

The failure of a planned action to be completed as intended (i.e., error of execution), and the use of a wrong plan to achieve an aim (i.e., error of planning). It also includes failure of an unplanned action that should have been completed (omission).⁴

⁴ Institute of Standards for Patient Safety. Patient safety: Achieving a new standard for care. Washington DC: National Academies Medicine, Committee on Data Press; 2004.

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

While PA-PSRS does include reports of events that result from errors, the program’s focus is on the broader scope of actual and potential adverse events. See the related discussion in “What Is Patient Safety?” on page 10.

- **Patient Safety Officer**—Act 13 requires each healthcare facility to designate a single individual to serve as that facility’s Patient Safety Officer. Under Act 13, 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.

Report Volume

Reports by Month and Submission Type

Between January 1, 2007, and December 31, 2007, Pennsylvania facilities submitted 211,983 reports to the Authority through PA-PSRS, bringing the number of reports submitted since the program’s inception to 647,738. Table 3 shows the distribution of submitted reports by month for calendar year 2007.

Table 3. Reports Submitted through PA-PSRS in 2007, by Month

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Serious Events	582	469	597	672	625	511	600	638	569	745	642	626	7,277
Incidents	17,744	15,999	19,625	17,424	18,229	16,695	16,599	18,100	13,480	18,122	16,412	16,278	204,706
Total	18,326	16,468	20,222	18,096	18,854	17,206	17,199	18,738	14,049	18,867	17,054	16,904	211,983

Approximately 3.4% of submitted reports were Serious Events, while 96.6% were Incidents. On average, the Authority received 17,665 reports per month, an increase of 8% over the 2006 average. The number of Incident reports averaged 17,059 per month, an increase of 8% compared to the previous year. The number of Serious Event reports averaged 606 per month, which represents a 5% increase from 2006.

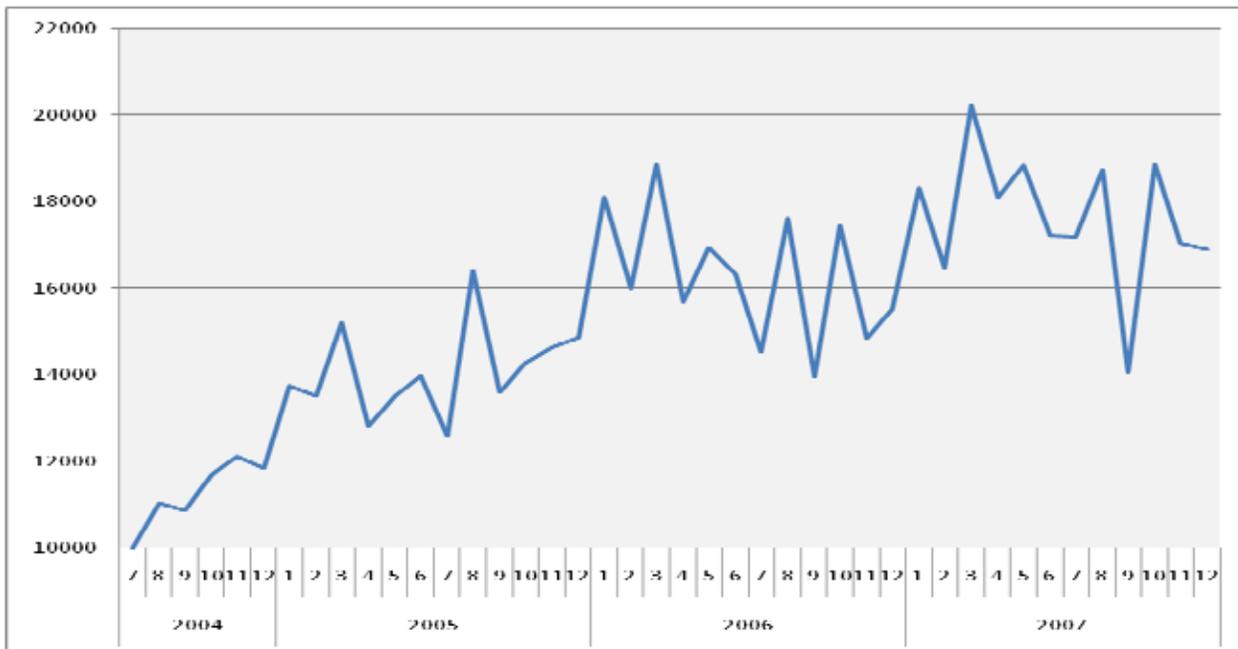


Figure 5. Number of Submitted Reports since Inception of PA-PSRS, by Month

Figure 5 demonstrates that the overall volume of reports submitted to the Authority through PA-PSRS each month has generally climbed since inception. We interpret this rise not as an increase in the number of reportable events occurring, but rather as continuously improving vigilance on the part of Pennsylvania healthcare facilities in recognizing and reporting Serious Events and Incidents. The number of reports submitted in March 2007, exceeded 20,000, the most in a single month since the inception of the program.

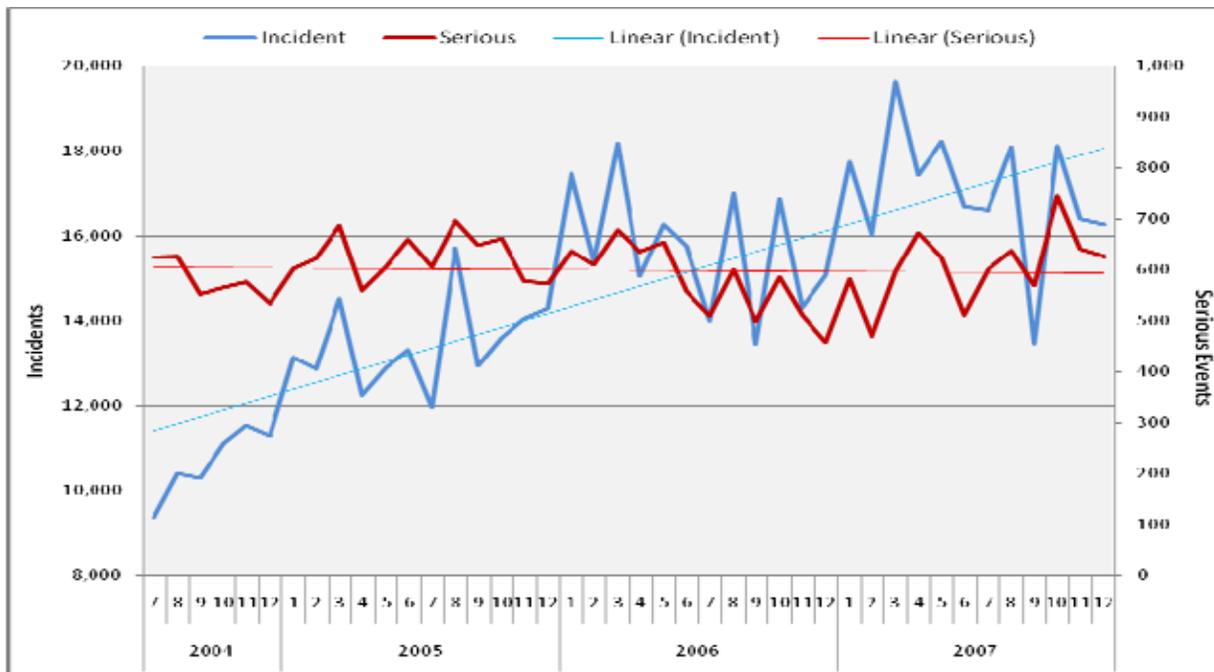


Figure 6. Number of Serious Event and Incident Reports since Inception of PA-PSRS

Figure 6 supports the proposition of improved vigilance, despite a reversal in the final six months of 2007. Depicting the volume of Serious Events and Incidents on a relative scale shows that the increase in the volume of reports is generally attributable to increased reporting of Incidents. The notable exception is the second half of 2007, which shows an increase attributable to several facilities that substantially increased submissions of Serious Events during this period. The second half of 2007 also saw a significant increase in reporting of HAIs as Serious Events. These two factors had a net effect of a rise in the percentage of Serious Events. Figure 7 also demonstrates the relation between Incidents and Serious Events over the past three years.

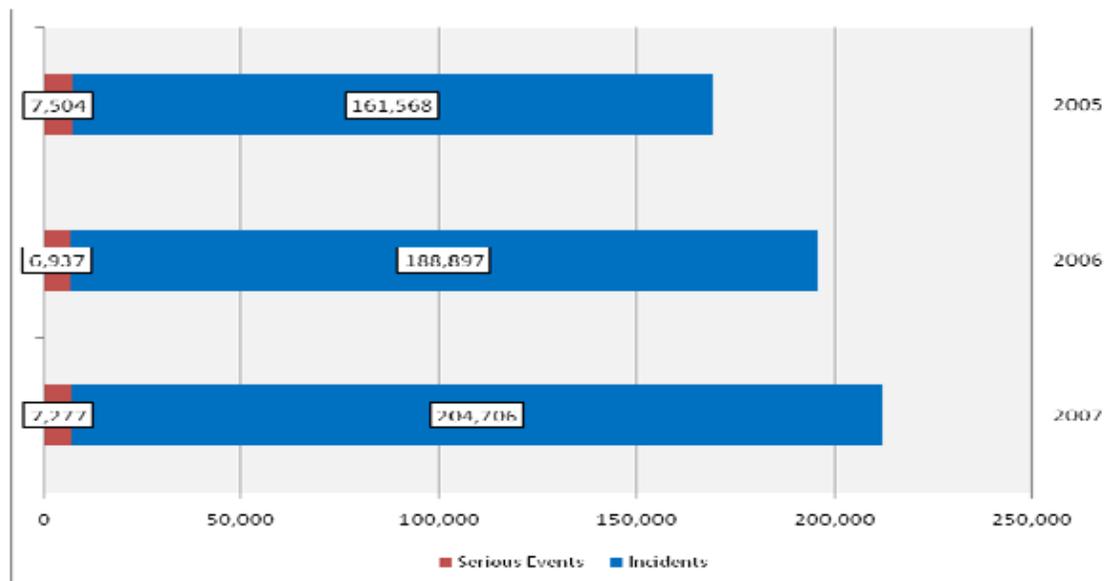


Figure 7. Comparison by Year of Serious Events and Incident Reports of PA-PSRS (2005-2007)

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 8. This breakdown is based on the Department of Health’s Public Health Districts.



The variation in the number of reports submitted through PA-PSRS by geographic region (see Figure 9) is not particularly surprising. One expects more reports to be submitted in regions with larger populations and greater numbers of healthcare facilities. Consistent with this expectation, the regions with the largest number of reports (Southeast and Southwest) were those with the Commonwealth’s two largest population centers: Philadelphia and Pittsburgh, respectively.

Figure 8. Pennsylvania Public Health Regions

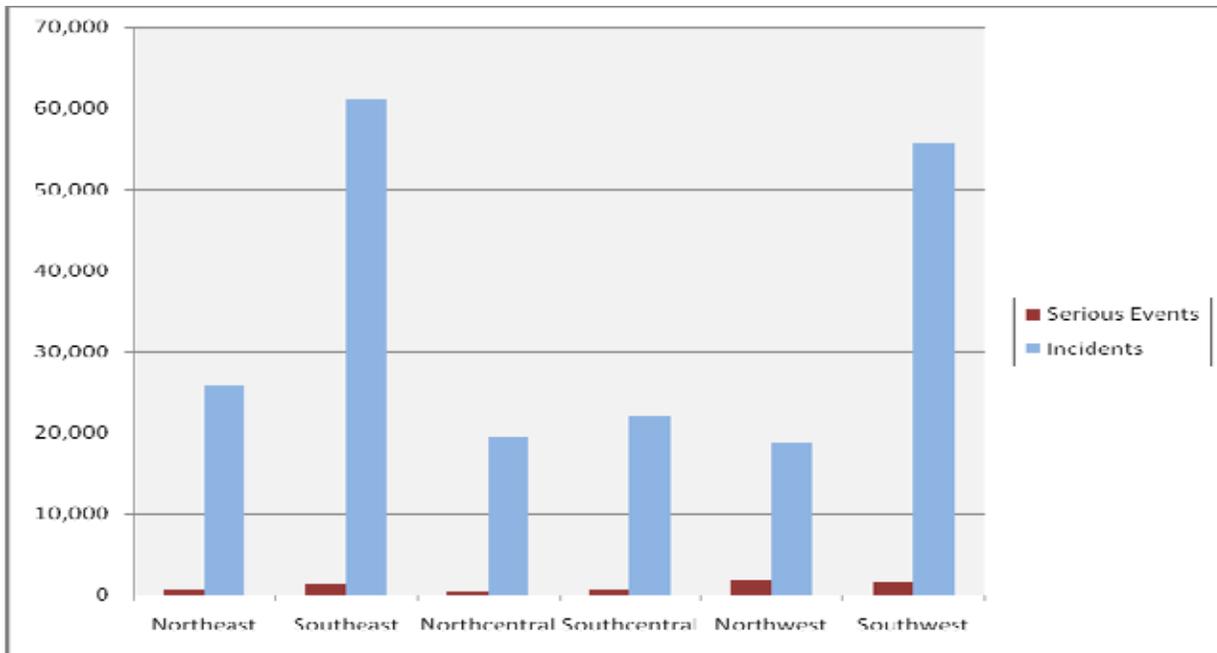


Figure 9. Number of Serious Event and Incident Reports from Hospitals by Region (2007)

Adjusting the report volume for a measure of healthcare utilization paints a different picture. Figure 10 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 (98.2% of their reports) than the statewide average (96.9%).

As evident in Figure 10, 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

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 January through December 2007 was divided by the number of patient days estimated for 2007. Since only partial data is available for 2007, we chose to use estimated figures for the year using seasonal decomposition to account for any seasonal fluctuations in utilization.

Further, data provided by PHC4 is based on patient home region, not necessarily the region of the facility in which the patient was treated. Inter-regional treatment accounts for 14.8% of admissions, based on calculations performed on a sample of 10% of Pennsylvania counties.

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

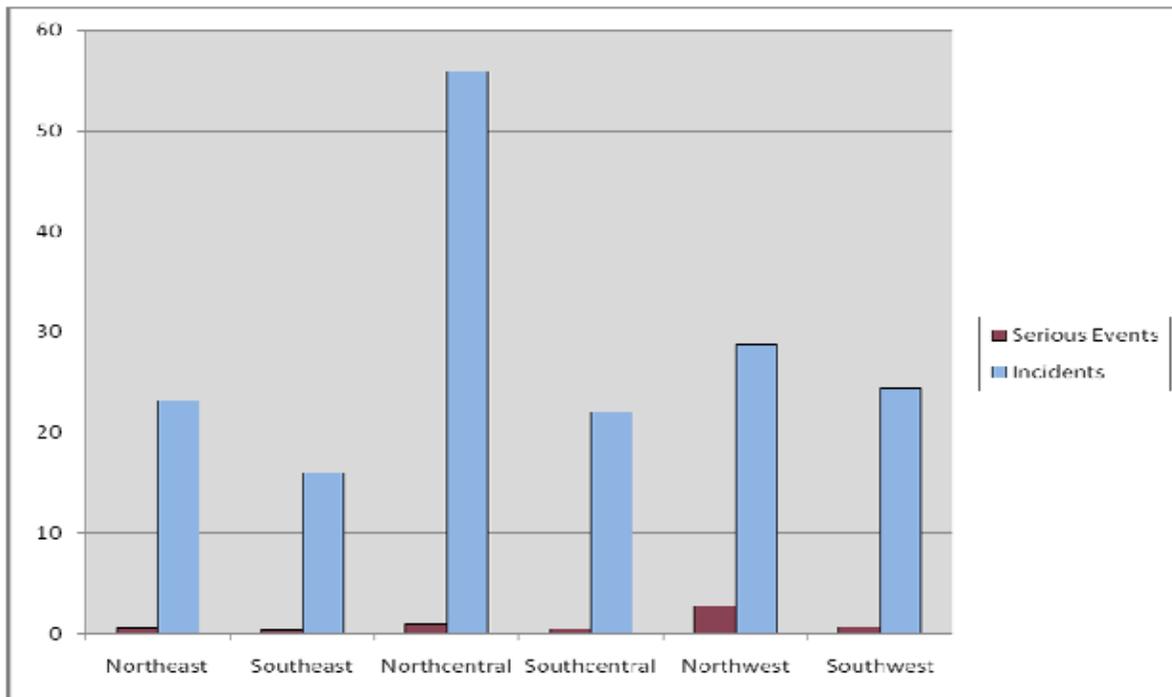


Figure 10. Reports from Hospitals per 1,000 Estimated Patient Days by Region (2007)

Comparing year to year, there is an observable increase across the regions of hospital reports per 1,000 patient days, as seen in Figure 11. The lone exception is a slight decrease in the Southcentral Region from 2005 to 2006, where reporting declined 1.5%. There was an average increase per region of 3.5 hospital reports per 1,000 patient days from 2006 to 2007.

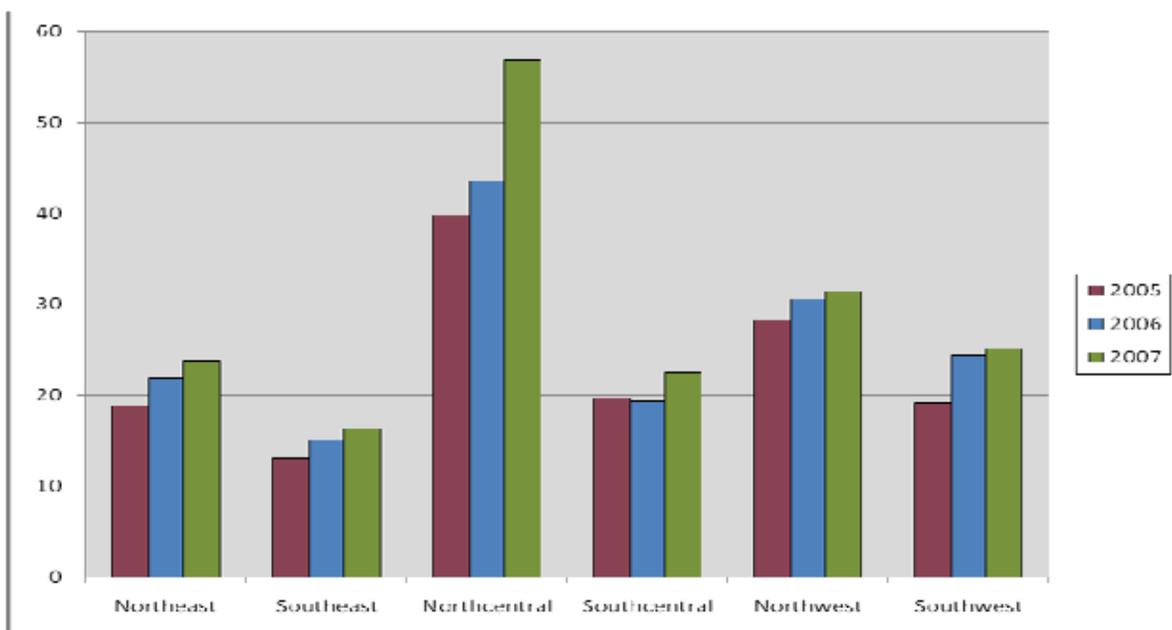


Figure 11. Reports from Hospitals per 1,000 Patient Days by Region (2005 through 2007)

Reports by Facility Type

As shown in Table 4, the vast majority of reports (98.7%) submitted through PA-PSRS were submitted by hospitals. More detailed information appears in Table 5.

Table 4. Reports through PA-PSRS by Facility Type

Facility Type	Hospitals	Ambulatory Surgical Facilities	Birthing Centers/Abortion Facilities	All
Number of Reports Submitted	209,285	2,627	71	211,983
Number of Facilities Active for year ending Dec. 31, 2007	243	246	23	512

Table 5 demonstrates a consistent reporting rate among non-hospital facilities (ASFs/BCs/ABFs) compared to hospitals from year to year. A slight decrease in the percentage of reports submitted from non-hospitals, despite the addition of abortion facilities to the group, is attributable to continued increased reporting from the hospitals rather than decreased reporting from non-hospitals. The number of reports from all facilities continues to rise.

Table 5. Reports by Facility Type since Inception of PA-PSRS

Year	Hospitals		Ambulatory Surgical Facilities/ Birthing Centers/Abortion Facilities		All Facilities Total
	No.	% of Facility Type	No.	% of Facility Type	
2004*	69,926	98.69%	925	1.31%	70,851
2005	166,998	98.77%	2,074	1.23%	169,072
2006	193,262	98.69%	2,570	1.31%	195,832
2007	209,285	98.73%	2,698	1.27%	211,983
Total	430,186	98.72%	5,569	1.28%	647,738

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

Variation in Report Volume

One challenge the Authority faces is the variation in the number of reports submitted by different healthcare facilities. As shown in Figure 12, even after adjusting for differences in the volume of care delivered in different hospitals, there are substantial differences in the number of reports submitted by each facility.

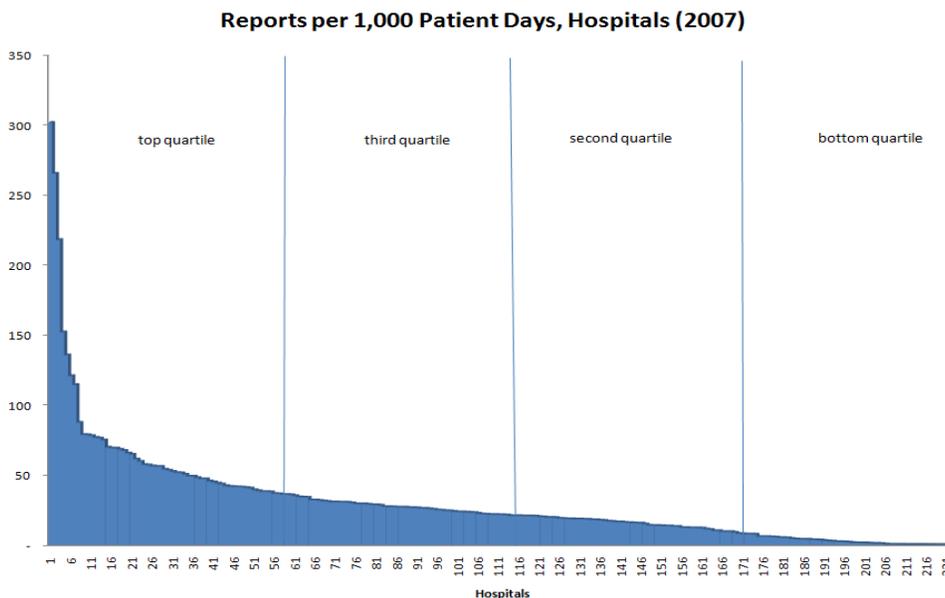


Figure 12. Hospital Report Volume (2007)

While the majority of hospitals report between 5.0 and 60 Serious Event and Incident reports per 1,000 patient days, there are groups at either end that report more or less frequently. Table 6 shows the range of report volumes from hospitals by quartile. A small number of hospitals submitted no reports in 2007.

Table 6. Reports from Hospitals per 1,000 Patient Days, Quartiles (2007)

Quartile	Reports per 1,000 Patient Days
Fourth (Top 25%)	36.1 to 301.7
Third	20.9 to 36.0
Second	7.9 to 20.8
First (Lowest 25%)	0.0 to 7.8

Differences among types of hospitals do not explain the variation in reporting rates. For example, while one large, urban, teaching hospital reports over 5 Serious Events per 1,000 patient days, another similar hospital reports only 0.08. Two 100-200 bed rehabilitation hospitals report 7.9 versus 0.2 Serious Events per 1,000 patient days. We see similar disparities in other types of specialty hospitals.

There are many potential explanations for this disparity:

- Act 13 includes several ambiguous terms that define what should be reported (e.g. ‘unanticipated’). Hospitals differ in their interpretations of these terms
- Some facilities may have more evolved cultures of safety that encourage higher levels of Incident reporting
- Reportable events might be missed and not reported
- Some facilities have implemented more systems that more effectively identify Serious Events and Incidents
- Facilities have different rates of Serious Events and Incidents due to their overall case mix
- Some facilities may over-report to ensure they are not missing any reportable events
- Facilities may have different rates of safety

These potential reasons have to do with the occurrence of patient safety events and of reporting the events. At this time, the Authority cannot define the amount of disparity caused by each potential explanation. The Authority is concerned with the reporting variation for several reasons. Balanced reporting would provide the Authority with additional reports which may provide a clearer picture of patient safety issues and trends in Pennsylvania. It creates the potential for failing to notify patients or their families when a Serious Event has occurred. It also leaves healthcare facilities open to financial penalties from the Department of Health for failure to report a reportable Serious Event. Patient Safety Officers themselves have asked the Authority for additional guidance about whether certain types of events are reportable, and facilities have expressed concern about conflicting advice they have received from different Department of Health surveyors.

In July 2006, the Authority released a Program Memorandum that explained how staff from PA-PSRS would evaluate events described in Anonymous Reports. This Memorandum provided interpretations of the Act 13 requirements, decision rules, and case examples for determining when an occurrence met the definition of a Serious Event. Some facilities use this algorithm for their internal deliberations when deciding whether an occurrence is reportable. However, this approach has not adequately reduced the reporting variation we continue to see in PA-PSRS. The Authority has also provided guidance that the inclusion of a potential mishap on the patient consent form should not be construed as grounds for stating the event was unanticipated.

Reducing this variation is an important initiative the Authority adopted in its 2007 Strategic Plan (see page 13). To accomplish this goal, the Authority will take the following actions:

- We will work with the Department of Health to explore both organizations’ interpretations of Act 13 requirements, with the goal of providing interpretive guidance that can be used by facility Patient Safety Committees and Department of Health surveyors.

- We are working with healthcare facilities in the Delaware Valley through the Health Care Improvement Foundation to improve reporting consistency for selected types of events.
- We will provide guidance to healthcare providers on disclosure of adverse events to patients and their families and on their reporting volume in comparison with similar facilities.
- We will perform a comparative analysis of healthcare facilities that are high- and low-volume reporters in an effort to determine how high-volume reporters are able to encourage a greater level of reporting. We will distribute our findings through the Pennsylvania *Patient Safety Advisory*.

Patient Demographics

PA-PSRS collects few demographic details about patients because the Authority is not authorized to collect individually identifying information. In general, most reports include only information on patient gender and age. Table 7 presents the number of reports received in 2007 by patient gender and age cohort.

Table 7. Reports Submitted by Age Cohort and Gender (2007)

Age	Female		Male		All Patients		% Patients
Cohort	No.	%	No.	%	No.	%	Female
0 - 4	3,326	2.9%	4,326	4.5%	7,652	3.6%	43.5%
5-14	1,406	1.2%	1,713	1.8%	3,119	1.5%	45.1%
15-24	5,706	5.0%	3,389	3.5%	9,095	4.3%	62.7%
25-34	7,143	6.2%	3,734	3.9%	10,877	5.1%	65.7%
35-44	8,662	7.5%	6,206	6.4%	14,868	7.0%	58.3%
45-54	12,380	10.7%	11,998	12.4%	24,378	11.5%	50.8%
55-64	14,718	12.8%	15,560	16.1%	30,278	14.3%	48.6%
65-74	18,459	16.0%	18,043	18.7%	36,502	17.2%	50.6%
75-84	26,448	22.9%	21,674	22.4%	48,122	22.7%	55.0%
85+	17,016	14.8%	10,076	10.4%	27,092	12.8%	62.8%
Total	115,264	100.0%	96,719	100.0%	211,983	100.0%	54.4%

Patient Gender

Of the 211,983 reports submitted in 2007, 115,264 (54.4%) involved female patients, and 96,719 (45.6%) involved male patients. This pattern is consistent with our observations since 2004. During childbearing years women are more likely than men to have encounters with the healthcare system, and because women have a longer life expectancy than men, there are simply more women in the general population in the older age cohorts.

The proportion of reports classified as Serious Events differed slightly according to the patient's gender, with 3.5% of reports involving female patients classified as Serious Events, compared to 3.3% for reports involving males. Using the chi-square test for significance, we find this difference statistically significant beyond the 99% level of confidence.

Table 8 shows the distribution of reports by patient gender and Event Type. Many of the same patterns observed in 2006 are evident this year as well. The proportion of reports involving female patients was significantly higher among reports of Adverse Drug Reactions and significantly lower among reports of Equipment-related events, Falls and Skin Integrity issues.

Table 8. Reports Submitted by Gender and Event Type (2007)

Event Type	Female		Male		All Patients		Ratio of Reports Involving Female to Male Patients
	No.	%	No.	%	No.	% of Total	
Medication Errors	26,498	55.8%	20,994	44.2%	47,492	22.4%	H
Adverse Drug Reactions	3,195	63.3%	1,856	36.7%	5,051	2.4%	H
Equipment / Supplies / Devices	1,620	51.3%	1,540	48.7%	3,160	1.5%	L
Falls	17,623	50.3%	17,410	49.7%	35,033	16.5%	L
Errors Related to Procedure / Treatment / Test	27,150	55.3%	21,908	44.7%	49,058	23.1%	H
Complications of Procedure / Treatment / Test	17,394	55.4%	14,023	44.6%	31,417	14.8%	H
Transfusions	1,287	55.7%	1,023	44.3%	2,310	1.1%	
Skin Integrity	12,497	53.0%	11,070	47.0%	23,567	11.1%	L
Other / Miscellaneous	8,000	53.7%	6,895	46.3%	14,895	7.0%	
Total	115,264	54.4%	96,719	45.6%	211,983	100.0%	

H=significantly higher than overall average of 54.4%; L=significantly lower than overall average of 54.4%.

Patient Age

Figure 13 shows the proportion of reports through PA-PSRS, from hospitals only, by gender and by patient age cohort. As noted above, this chart also illustrates that women are more likely than men to have encounters with the healthcare system during childbearing years. Patients aged 65 and older account for 52.9% of all reports from hospitals through PA-PSRS in 2007. Also shown on this figure is the proportion of hospital inpatient admissions as reported by the Pennsylvania Health Care Cost Containment Council (PHC4).⁶ However, this chart does not suggest that older patients are necessarily more likely than younger patients to be involved in a Serious Event or Incident. Rather, older patients' larger representation in the database simply reflects their larger representation in the healthcare system.

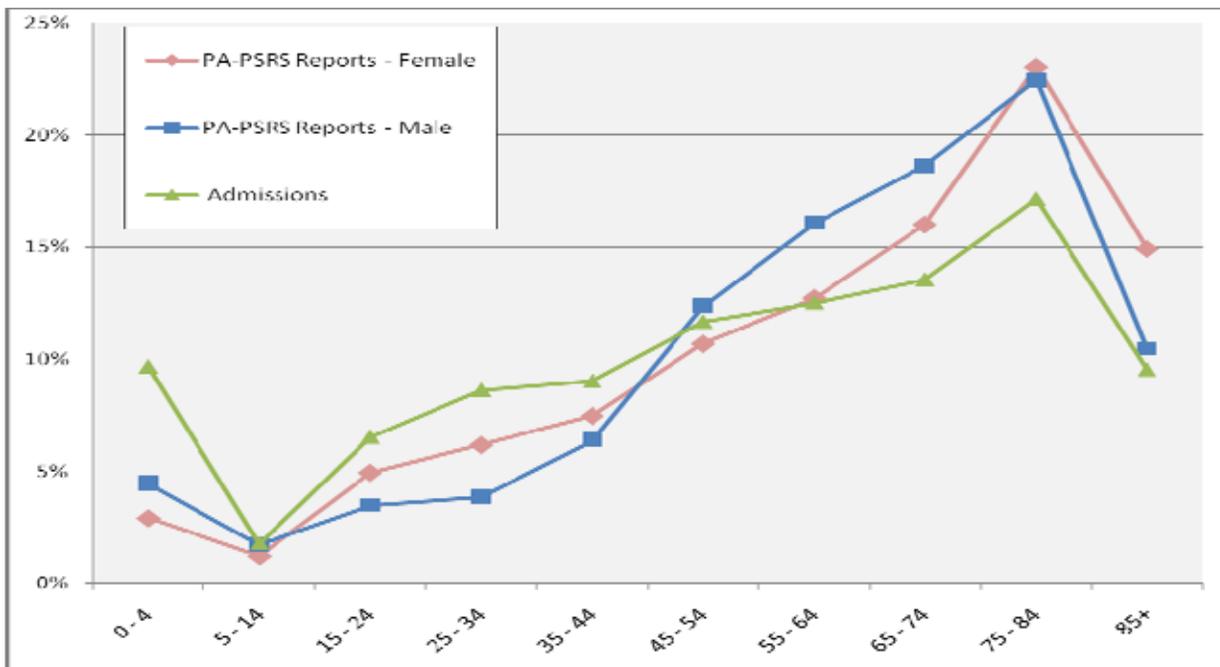


Figure 13. Proportion of Hospital Reports through PA-PSRS by Gender and Age Cohort (2007)

⁶ Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council (www.PHC4.org). Estimates were based on statewide inpatient data from the third quarter 2006 through second quarter 2007.

Patients Most at Risk by Age

Elderly Patients

In the Authority's previous annual reports, we identified several patterns of interest in reports involving elderly patients (65 and older). These patterns have remained consistent through 2007. For example, in 2006, more than half of all reports (53.1%) involved patients 65 and older. In 2007, this figure dropped only slightly to 52.7%. Elderly patients accounted for 64% of Falls in 2004 and 2005. This figure fell slightly to 62.4% in 2006 and further in 2007 to 61.2%. Elderly patients accounted for 73.1% of reports related to Skin Integrity in 2006; this figure increased slightly to 73.5%.

Perinatal Patients

There were 5,857 reports involving perinatal patients (those aged 20 days or younger), an increase of 10% from 2006, which is much greater than the 4.9% increase in all submitted reports. However, 4.0% of perinatal reports were classified as Serious Events, only slightly higher than the overall percentage of 3.4%.

Just as last year, two thirds (67.9%) of reports for these patients were related to Errors or Complications of Procedures, Treatments or Tests. This does not necessarily mean that these patients are more likely to experience errors or complications. Rather, they may not be as prone to other types of events (e.g., Falls, problems with Skin Integrity) as older patients.

About a fifth (20.1%) of reports involving perinatal patients was related to Medication Errors. This compares to 21% in 2006, 22% in 2005 and 19% in 2004.

Children and Adolescents

There were 3.3% more reports submitted through PA-PSRS in 2007 involving children and adolescents (i.e., aged 21 and younger) than in 2006. As was the case last year, Errors Related to Procedures, Treatments and Tests were the most commonly submitted type of report, accounting for 30.5% of the reports of this population. However, this represents moderation from last years' report share for this Event Type in this population. Errors comprised 35.3% of this population's reports in 2006, a significant increase from 28% of this population's reports in 2005 and 23% in 2004.

Patterns in Reports through PA-PSRS

Reports by Event Type

When reporting an event through 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 212 distinct Event Types. This Event Type dictionary is one way PA-PSRS classifies and looks for patterns and trends in submitted reports.

Figure 14 shows the percentage of reports submitted under each top-level Event Type. The most frequently reported occurrences were Errors related to Procedure/Treatment/Test (23%) and Medication Errors (22%). These two Event Types account for 45% of all reports submitted. While Errors related to Procedures/Treatments/Tests was the Event Type most frequently reported through PA-PSRS, they were not the ones most frequently associated with Serious Events.

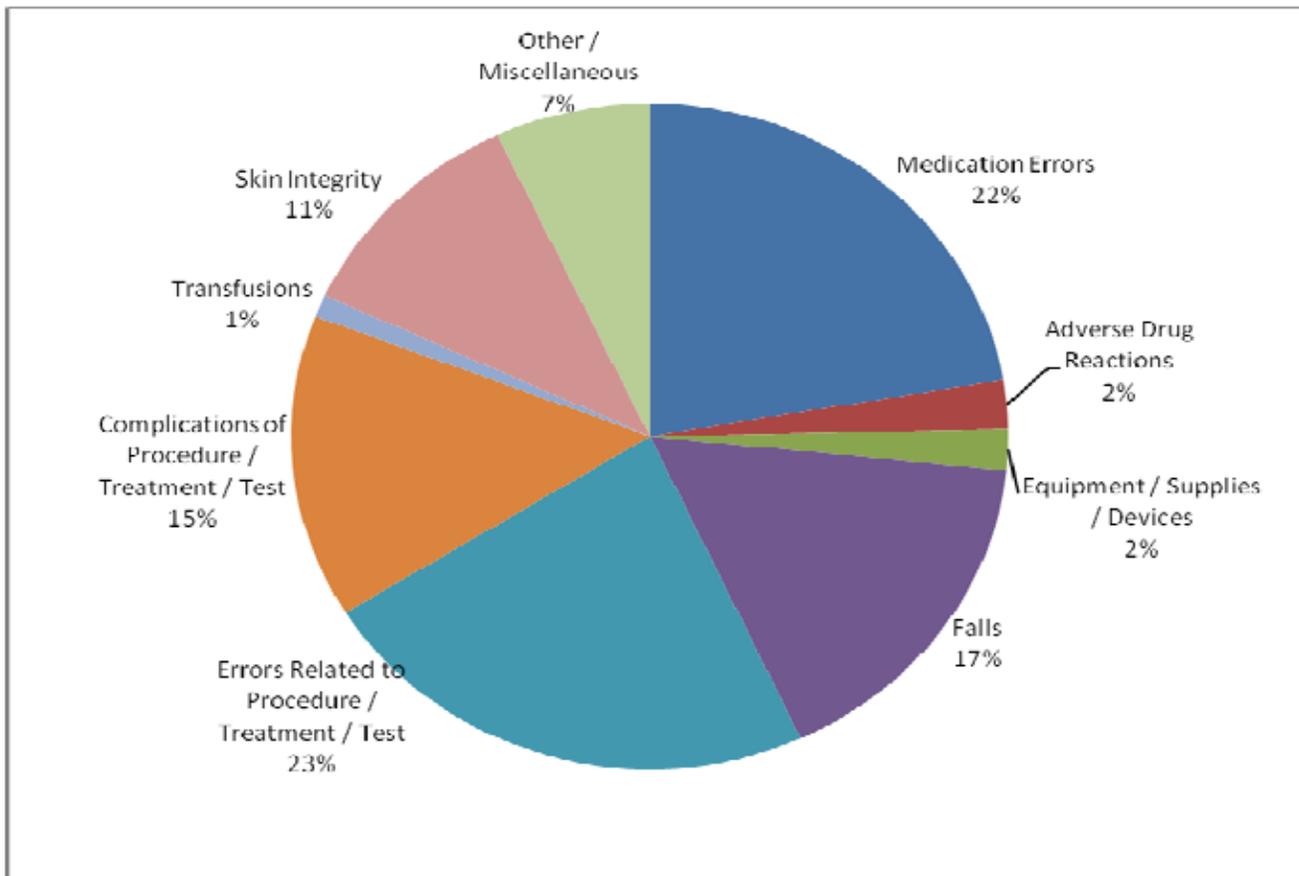


Figure 14. Percentage of Reports by Event Type (2007)

As shown in Table 9 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 45% and 17% of all Serious Event reports, respectively. Relative to the overall average of 3.4% of reports indicating harm, harm was significantly less likely to be reported under Medication Errors, Equipment/Supplies/Devices, Errors related to Procedure/Treatment/Test, and Transfusions.

Table 9. Reports by Event Type and Submission Type for 2007

Event Type	Serious Events		Incidents		Total	Percent of Total	Ratio of Serious Events to Incidents
	No.	%	No.	%			
Medication Errors	262	0.6%	47,230	99.4%	47,492	22.4%	L
Adverse Drug Reactions (not a medication error)	258	5.1%	4,793	94.9%	5,051	2.4%	H
Equipment / Supplies / Devices	62	2.0%	3,098	98.0%	3,160	1.5%	L
Falls	1,240	3.5%	33,793	96.5%	35,033	16.5%	
Errors Related to Procedure / Treatment / Test	596	1.2%	48,461	98.8%	49,057	23.1%	L
Complications of Procedure / Treatment / Test	3,283	10.5%	28,133	89.5%	31,416	14.8%	H
Transfusions	20	0.9%	2,290	99.1%	2,310	1.1%	L
Skin Integrity	750	3.2%	22,817	96.8%	23,567	11.1%	
Other / Miscellaneous	806	5.4%	14,091	94.6%	14,897	7.0%	H
Total	7,277	3.4%	204,706	96.6%	211,983	100%	

H=significantly higher than overall average of 3.4%; L=significantly lower than overall average of 3.4%.

Figure 15 illustrates the change in the number of Serious Event reports by Event Type over time. In most categories the reports of Serious Events declined slightly or remained steady. One notable exception is an increase in Serious Events classified as Complications of Procedures/Treatments/Tests. We attribute this increase to improved reporting compliance, particularly of HAIs. Another exception is a significant decline in Skin Integrity reports. A single high-volume reporting facility concluded that they were over-reporting pressure ulcers after reviewing a June 2006 *Patient Safety Advisory* article on the topic. This facility submitted 96% fewer Serious Events of Pressure Ulcers from the first five months of 2006 to the next five, accounting for an overall decrease of 10% of all Serious Events statewide in that time. Figure 15 clearly demonstrates that the largest decline in Serious Events from 2005 to 2007 occurred in Skin Integrity, the Event Type in which Pressure Ulcers are submitted.

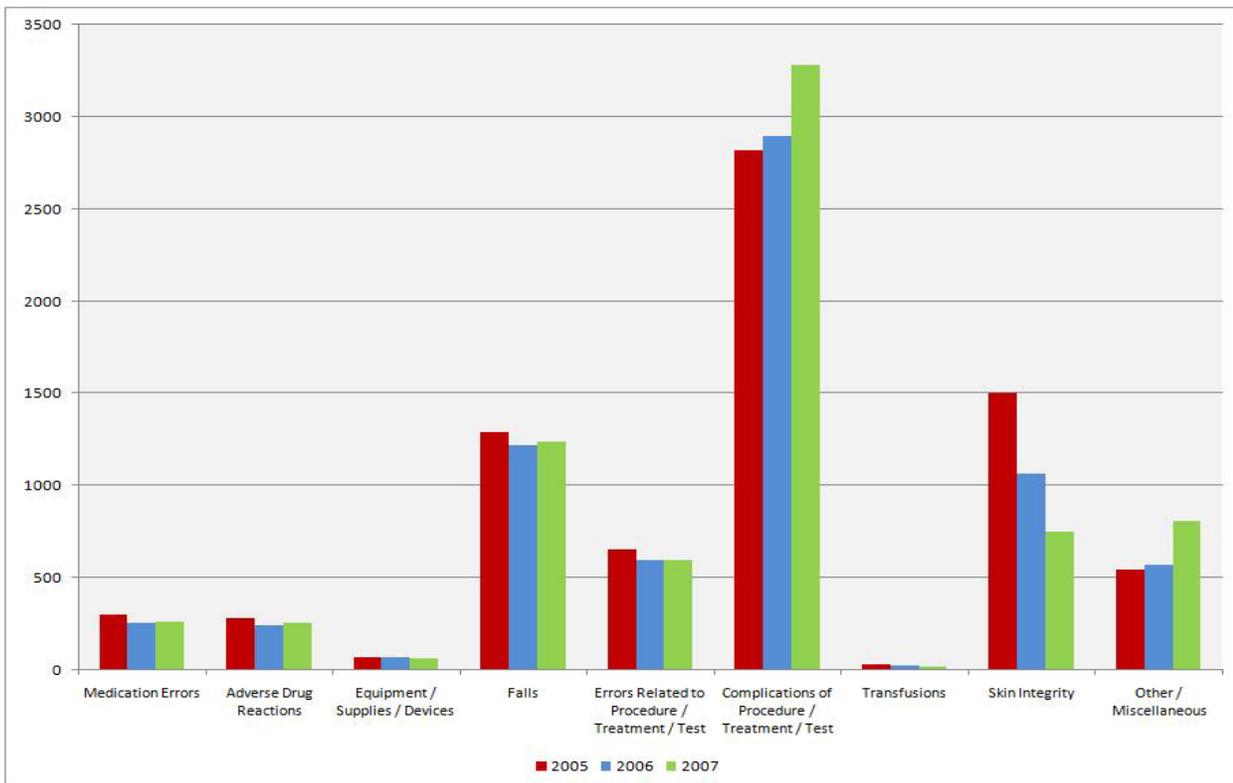


Figure 15. Reports Classified as Serious Events by Event Type (2005-2007)

Although somewhat consistent by percentage within each year since inception, Table 10 demonstrates that submissions of certain Event Types are increasing in greater proportions. While the Event Type distribution of reports submitted in 2007 is similar to 2006, the rise in report submissions of Adverse Drug Reactions was four times the overall report increase of 8%. Meanwhile, submissions of Skin Integrity, Transfusions and Other/Miscellaneous increased at a rate well above the overall percentage.

Table 10. Reports by Event Type by Year

Event Type	2005		2006		2007		% Increase from 2006 to 2007
	No.	% of Reports	No.	% of Reports	No.	% of Reports	
Medication Errors	42,371	25%	44,539	23%	47,492	22%	7%
Adverse Drug Reactions (not a medication error)	3,358	2%	3,834	2%	5,051	2%	32%
Equipment / Supplies / Devices	2,547	2%	3,155	2%	3,160	1%	0%
Falls	33,654	20%	33,882	17%	35,033	17%	3%
Errors Related to Procedure / Treatment / Test	35,603	21%	47,459	24%	49,057	23%	3%
Complications of Procedure / Treatment / Test	23,057	14%	27,910	14%	31,416	15%	13%
Transfusions	1,634	1%	1,936	1%	2,310	1%	19%
Skin Integrity	15,115	9%	20,945	11%	23,567	11%	13%
Other / Miscellaneous	11,733	7%	12,172	6%	14,897	7%	22%
Total	169,072	100%	195,832	100%	211,983	100%	8%

Because the vast majority of reports submitted through PA-PSRS were submitted by hospitals, the distribution of all reports by Event Type closely mirrored the distribution by Event Type in hospitals. However, the Event Types most frequently reported by hospitals were different from those most frequently reported by ambulatory surgical facilities, abortion facilities and birthing centers (see Table 11).

Table 11. Reports by Event Type and Facility Type

Event Type	Hospitals			Ambulatory Surgical Facilities/Birthing Centers/Abortion Facilities			Proportion of Reports from ASFs/BCs/ABFs versus Hospitals
	No.	% of Reports	% of Event Type	No.	% of Reports	% of Event Type	
Medication Errors	47,381	23%	99.77%	111	4%	0.23%	L
Adverse Drug Reactions (not a medication error)	4,976	2%	98.52%	75	3%	1.48%	
Equipment / Supplies / Devices	3,096	1%	97.97%	64	2%	2.03%	H
Falls	34,940	17%	99.73%	93	3%	0.27%	L
Errors related to Procedure / Treatment / Test	48,631	23%	99.13%	426	16%	0.87%	L
Complications of Procedure / Treatment / Test	30,437	15%	96.88%	979	36%	3.12%	H
Transfusions	2,309	1%	100%	1	0%	0.04%	L
Skin Integrity	23,477	11%	99.62%	90	3%	0.38%	L
Other / Miscellaneous	14,038	7%	94.23%	859	32%	5.77%	H
Total	209,285	100%	98.73%	2,698	100%	1.27%	

H=significantly higher than overall average of 1.27%; L=significantly lower than overall average of 1.27%.

While reports of Medication Errors and Falls combined accounted for 40% of all reports submitted by hospitals, these categories accounted for only 7% of reports from ambulatory surgical facilities, abortion facilities and birthing centers. Over half (52%) of reports from these facilities involved Complications of or Errors Related to Procedures/Treatments/Tests. This difference is not surprising because these facilities provide specialized services of a more limited scope and generally treat a healthier patient population than do hospitals.

Reports from Hospitals by Event Type and Facility Size

There is clearly a fundamental difference between hospitals and other types of facilities in terms of the types of reports they submit, as shown in Table 11 above. One might also expect a substantial difference in the volume of reports submitted among hospitals of varying sizes. For example, one might expect the reports from a large tertiary care hospital with a teaching program to be fundamentally different from the reports submitted by a 150-bed community hospital.

As shown in Figure 16, larger facilities submitted over a third of all reports through PA-PSRS in 2007 and the rate of reports per bed (4.7 reports per bed) was slightly lower than average for hospitals of all sizes (4.8 reports per bed). The group of hospitals with the fewest beds had the highest submission rate after adjusting for differences in facility size. Note that there is not necessarily a relationship between the submission rate and safety. It may mean that the healthcare providers in these facilities were better at identifying and reporting potential patient safety issues.

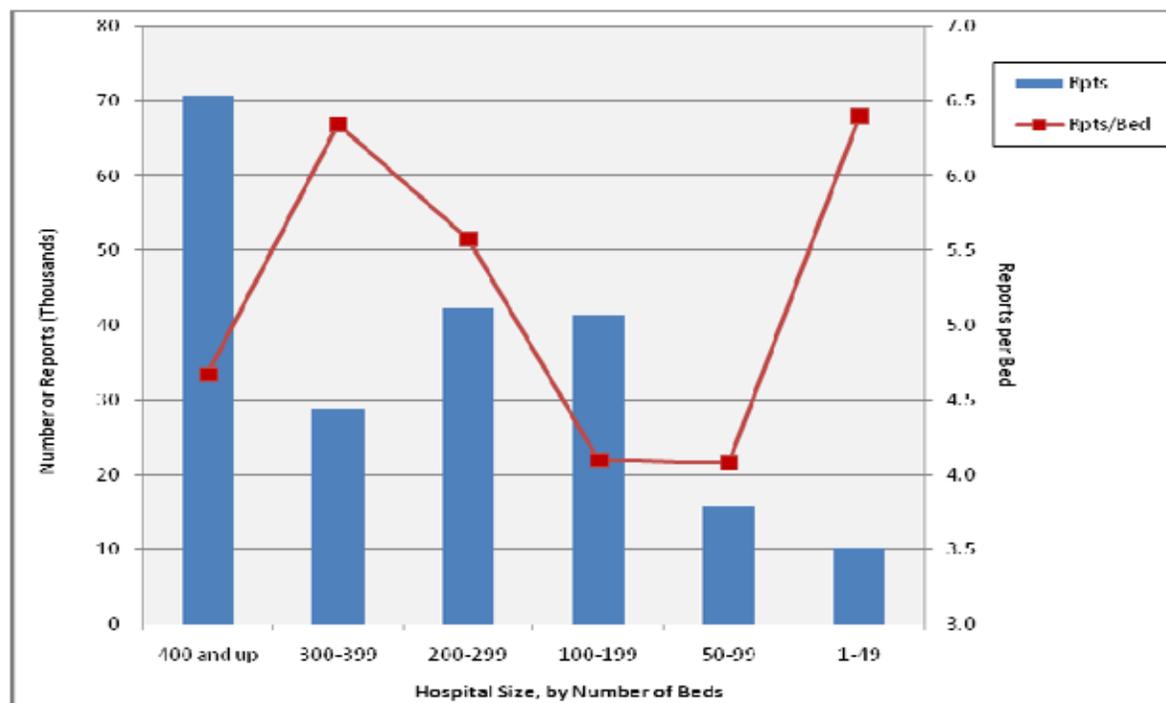


Figure 16. Number of Reports and Reports per Bed by Facility Size, Hospitals Only (2007)

The proportion of reports in each Event Type is somewhat consistent across hospitals of different sizes (Figure 17). Hospitals with fewer than 100 beds reported proportionally fewer Errors Related to Procedures/Treatments/Tests than larger hospitals. Those hospitals also submitted proportionally fewer reports related to Transfusions, and they were more likely to categorize their reports as “Other”. In addition, the hospitals with 400 or more beds submitted proportionally fewer reports of Medication Errors than the smaller hospitals. Aside from these few distinctions, the proportions of reports in each category from different size hospitals are similar.

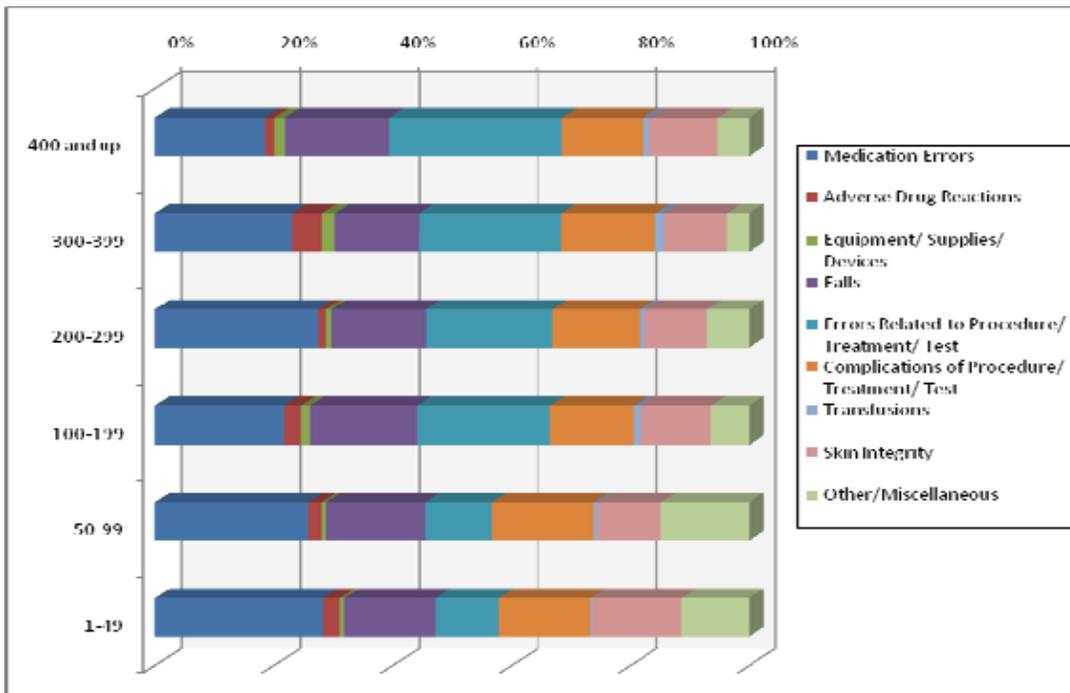


Figure 17. Reports from Hospitals by Facility Size and Event Type (2007)

When looking at Figure 17, a lower-volume Event Type such as reports related to Equipment/Supplies/Devices can be easily overlooked. Looking at the data in another way, Figure 18 plainly reveals that more than 40% of equipment-related reports come from the largest hospitals. One can also see a similar proportion of Falls were submitted by hospitals with 400 or more beds, hospitals with 200 to 399 and hospitals with less than 200 beds.

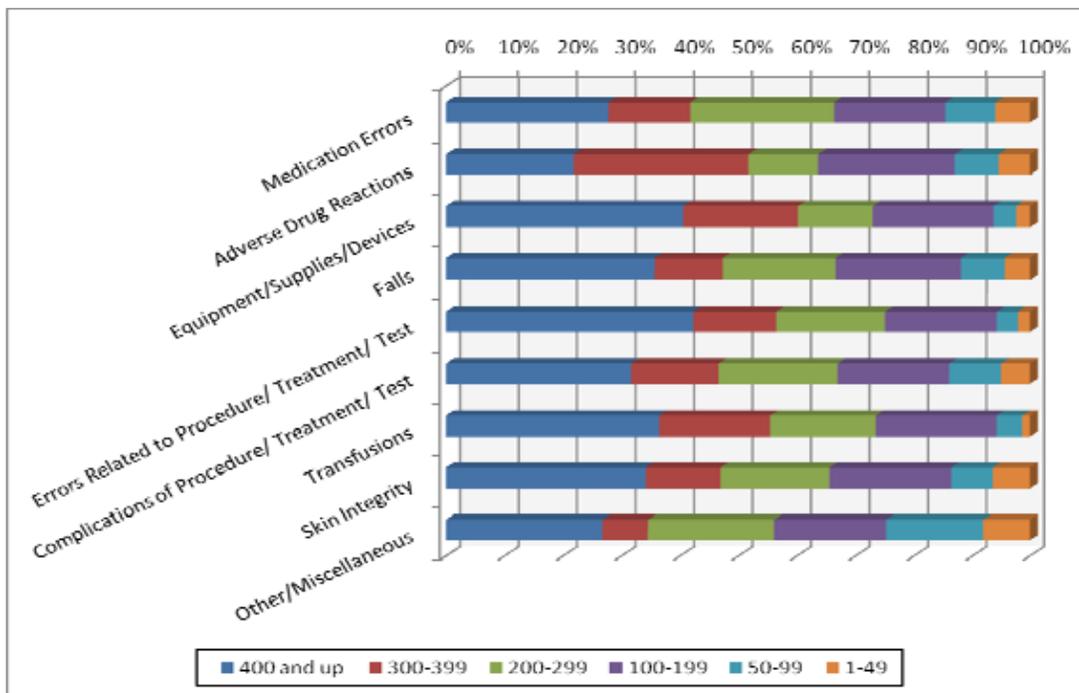


Figure 18. Reports from Hospitals by Event Type and Facility Size (2007)

Reports by Level of Patient Harm

For every report submitted through PA-PSRS, the healthcare facility applies a 10-item scale to measure whether an event “reached” the patient and, if so, how much harm it caused.⁷ This scale ranges from “unsafe conditions” (e.g., look-alike medications stored next to one another) to the death of the patient and can be summarized as follows:

- Unsafe Conditions—Circumstances that could lead to an adverse event (accounting for 9% of all reports)
- Event, No Harm—An event that either did not reach the patient or did reach the patient but did not cause harm (often called a “near miss,” accounting for 88% of all reports)
- Event, Harm—An event that reached the patient and caused temporary or permanent harm (3%)
- Event, Death—An event occurred that resulted in or contributed to death (0.2%)

Table 12 shows the reports received during 2007 categorized by the level of harm (as described above) and by Event Type. For the most part, the reports at each level of harm follow a similar distribution by Event Type as they do in the database as a whole. There are exceptions to this, however. For example, while Complications comprise 15% of reports overall in 2007, they comprise 44% of the reports of events involving harm and 59% of all reports of events resulting in or contributing to the patient’s death.

At the other end of the spectrum, while Medication Errors comprise 22% of reports in 2007, they only comprise 4% of events involving harm and 2% of events contributing to or resulting in death. Reports of Errors Related to Procedures/Treatments/Tests were also associated with harm or death at a frequency lower than their representation in the database as a whole.

Approximately 9% of reports in 2007 were classified as Unsafe Conditions, meaning that there was an observed situation in which some harm was a possibility if corrective action was not taken. As shown in Table 12, the Event Types in which Unsafe Conditions were most often reported were Error related to Procedures/Treatments/Tests (29%), Skin Integrity (21%) and Other/Miscellaneous (20%).

Table 12. Reports by Event Type and Level of Patient Harm (2007)

Event Type	Unsafe Conditions		Event, No Harm		Harmful Event		Death Event		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Medication error	1,662	9%	45,568	24%	255	4%	7	2%	47,492	22%
Adverse Drug Reaction	114	1%	4,679	3%	253	4%	5	1%	5,051	2%
Equipment / Supplies / Devices	466	3%	2,632	1%	59	1%	3	1%	3,160	1%
Fall	462	3%	33,331	18%	1,226	18%	14	4%	35,033	17%
Error related to Procedure / Treatment / Test	5,349	29%	43,112	23%	577	8%	19	5%	49,057	23%
Complication of Procedure / Treatment / Test	2,385	13%	25,748	14%	3,070	44%	213	58%	31,416	15%
Transfusion	336	2%	1,954	1%	20	0%	-	0%	2,310	1%
Skin Integrity	3,806	21%	19,011	10%	750	11%	-	0%	23,567	11%
Other / Miscellaneous	3,569	20%	10,522	6%	702	10%	104	28%	14,897	7%
Total (Σ and % of all levels)	18,149	9%	186,557	88%	6,912	3.26%	365	0.17%	211,983	100%

Approximately, 3.4% of all reports submitted involve harm to the patient, ranging from a simple laceration to a life-threatening situation and death. A subset of reports called Death Events can be isolated from other reported events. Death Events, as the term implies, are reports of events classified as having contributed to or resulted in

⁷ For example, an event in which a phlebotomist goes to draw blood from the wrong patient but catches the error by checking the patient’s wristband, would be an event that did not reach the patient.

the patient's death. These account for only less than a fifth of one percent of all submitted reports (0.17 %). In looking at particular Event Types, although 15% of all reports for the year were attributed to Complications of Procedures/Treatments /Tests, 58% of all Death Events were of that Event Type.

Figure 19 illustrates that the vast majority of reports do not result in patient harm.

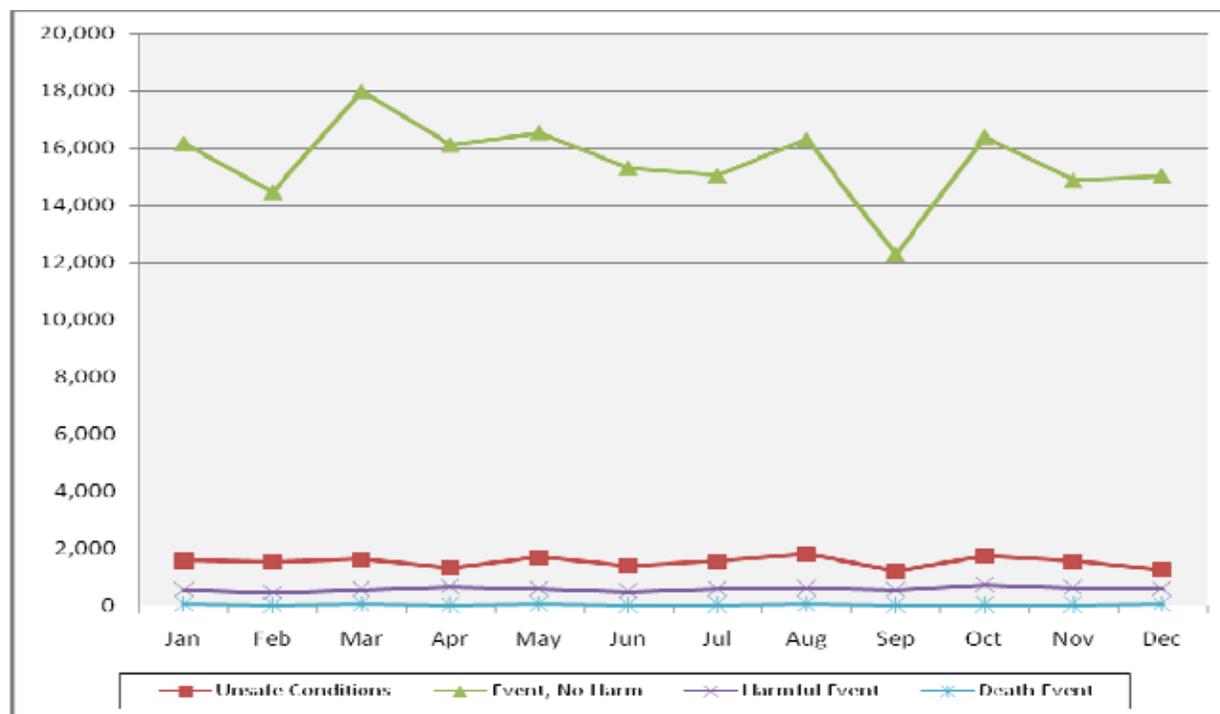


Figure 19. Reports by Level of Harm by Month (2007)

Reports Involving the Patient's Death

In 2007, PA-PSRS received 365 reports of events that may have contributed to or resulted in the patient's death. Not all of these patient deaths were preventable, and they need not necessarily involve an error on the part of a healthcare provider to be reportable under Act 13.

Reports involving the patient's death account for less than a fifth of one percent of all submitted reports. In terms of particular Event Types, although 15% of all reports in 2007 were attributed to Complications of Procedures/Treatments/Tests, about 59% of all reports involving the patient's death were of that Event Type. Of these reports involving death associated with complications, the majority describe patients who died following surgery or another invasive procedure (46%) or patients who suffered cardiopulmonary arrest outside the ICU setting (16%). A further 11% were associated with healthcare-associated infections, and 9% involved maternal or neonatal injury associated with childbirth.

Table 13. Reports Involving the Patient's Death, by Event Type (2007)

Event Type	No.	%
Medication error	7	1.9%
Adverse Drug Reaction	5	1.4%
Equipment / Supplies / Devices	3	0.8%
Fall	14	3.8%
Error related to Procedure / Treatment / Test	19	5.2%
Complication of Procedure / Treatment / Test	214	58.6%
Transfusion	-	0.0%
Skin Integrity	-	0.0%
Other / Miscellaneous	103	28.2%
Total	365	100%

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

Reports by Location/Department (Hospitals Only)

PA-PSRS has 155 designated Care Areas for hospitals. These are the locations or departments of the hospital in which a patient receives care or is exposed to in the process of receiving care. As we see in Figure 20, the Care Areas that are considered General Medical/Surgical Units were cited as the location for the greatest number of all reports submitted in 2007, generating almost a quarter (24.3%) of the total. Other hospital departments with higher report rates are Critical Care (17.6%), Intermediate Units (9.6%), Ancillary Departments (9.4%), and Surgical Services (8.5%).

Examples of Care Areas by Department:

- General Medical/Surgical Units
 - General Medicine Ward
 - Medical/Surgical/Oncology Unit
- Critical Care
 - Emergency Department
 - Burn Unit
 - Medical/Surgical ICU
- Intermediate Unit
 - Telemetry
 - Cardiac Intermediate Unit
 - Respiratory Intermediate Unit

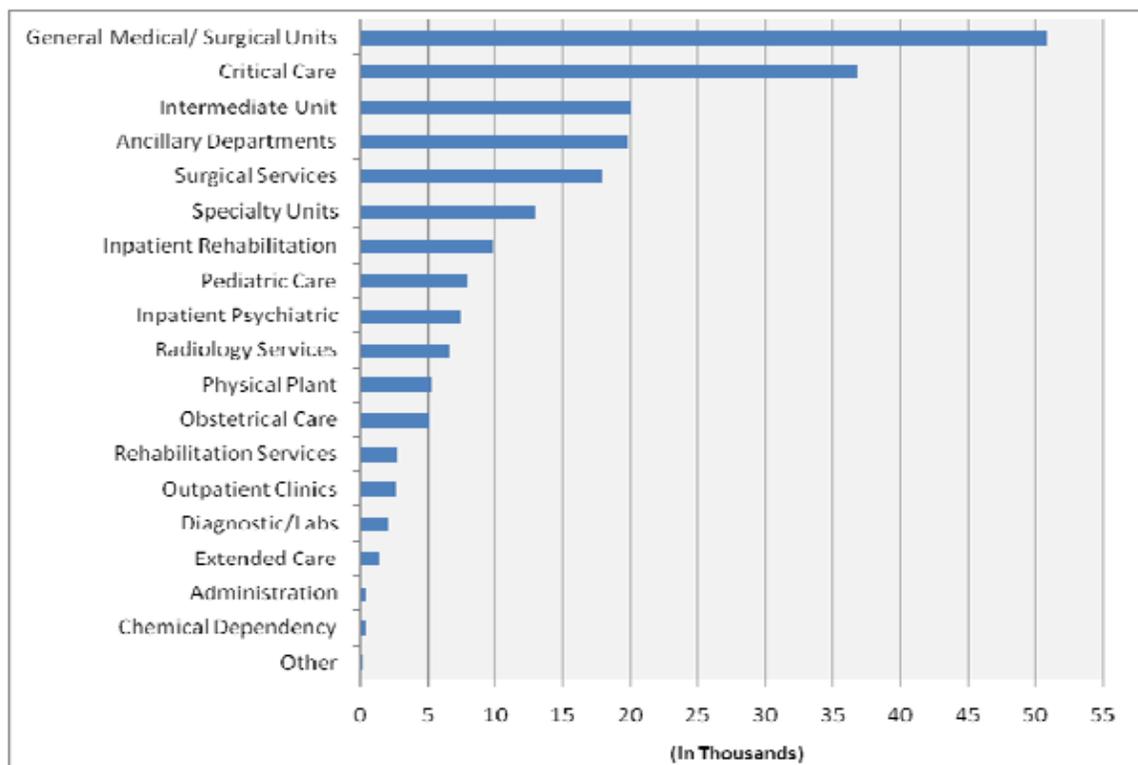


Figure 20. Reports by Location/Department (Hospitals Only, 2007)

Contributing Factors and Root Causes Cited in Reports

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

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

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

As shown in Figure 21, Team Factors (25%) and Patient Characteristics (24%) were the groups of contributing factors cited most often in reports submitted in 2007. This was also the case in 2006 (frequency of 24% each) and in 2005, although the frequency was at a higher rate (26% and 28%, respectively).

“Communication problem between providers” was the most frequently cited Team Factor in these reports, as it has been for the previous two years. Communication was viewed as problematic most often in conjunction with reports of Medication Errors and Errors in Procedures/Treatments/Tests. These two Event Types accounted for about 63% of all reports mentioning provider communication as a contributing factor. Problems with provider communication encompasses a wide range of issues, including confusing or incomplete orders, verbal order that are misinterpreted, illegible handwriting and many others.

As in 2005 and 2006, “Lack of patient compliance/adherence” was the most frequently mentioned patient-related factor and was most associated with Event Types of Falls. This Event Type accounted for more than three out of every five reports that mentioned this factor. Patient adherence to instructions can influence a patient’s likelihood of falling, if, for example, the patient does not request nursing assistance for toileting or does not use assistive devices while ambulating.

Another frequently mentioned Contributing Factor is “Issue related to proficiency” as a Staff Factor. Nine of 10 reports citing this factor were Errors in Procedures/Treatments/Tests and Medication Errors. Proficiency issues arise in the healthcare setting when a laboratory specimen is mislabeled or not labeled, the wrong test is ordered for a patient, the patient receives a wrong dose of medication or given the wrong drug altogether.

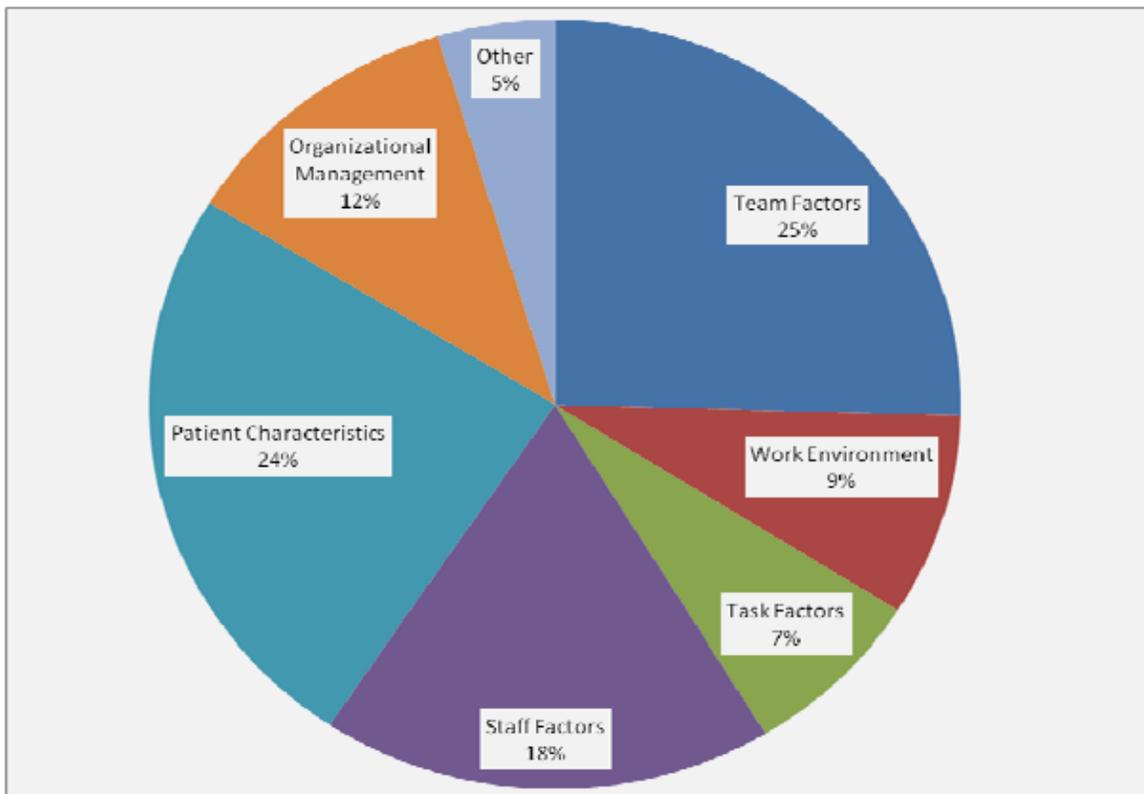


Figure 21. Leading Contributing Factors by Category (2007)

As in last year’s annual report, communication was the most frequently cited “root cause” in reports submitted in 2007, which is often associated with common medical errors.⁸ Other frequently mentioned root causes include orientation and training of staff, patient physical assessment and patient observation procedures. With the exception of patient observation procedures, these are four of the most commonly cited root causes of Sentinel Events reported to the Joint Commission (formally known as JCAHO).⁹

⁸ Sutcliffe KM, Lewton E, Rosenthal MM. Communication failures: an insidious contributor to medical mishaps. [Acad Med](#). 2004 Feb;79(2):186-94.

⁹ The Joint Commission. Sentinel event statistics, root causes of sentinel events (all categories; 1994-2005).

[This page intentionally left blank]

Patient Safety Authority Guidance

The primary way the Patient Safety Authority communicates with healthcare facilities about the significant trends identified in PA-PSRS reports is through the *Patient Safety Advisory*, a quarterly research publication with periodic supplements. The *Advisory* is widely distributed via email and is also available online at the Authority's web site (www.psa.state.pa.us). Since the first *Advisory* was issued in March 2004, the Authority has published over 140 articles on a variety of clinical issues. In 2007, the Authority published four quarterly issues of the *Advisory* and two supplements, comprising more than 40 articles. Educational toolkits are an additional resource for the facilities to use for patient safety improvements. Some of the topics for toolkits include: Preventing Wrong-Site Surgery, Verbal Orders; Express Breast Milk; Contrast-Induced Nephropathy; Hospital Bed Safety; Skin Tears; and Color-Coded Wristbands. Following are summaries of selected articles published during 2007. Refer to the original articles for more detail and for sources from the clinical literature.

Preventing Wrong-Site Surgery

**Volume 4, Number 2—June 2007 and
Volume 4, Number 4—December 2007**

Wrong-site surgery, though rare, may have devastating consequences to both the patient and the healthcare team when it does occur. Because wrong-site surgery is preventable, the National Quality Forum (NQF) has listed it as one of its serious reportable events (colloquially called “never events”), and the Joint Commission requires the reporting of wrong-site surgery as a sentinel event. Only Pennsylvania requires reporting of near-miss events that do not harm the patient, and these provide insight into the causes and potential recovery mechanisms for this chronic problem.

Since its inception in June 2004 through December 2006, 427 reports were submitted to PA-PSRS that reflected some aspect of wrong-site surgery. More than 40% of these errors actually reached the patient, and nearly 20% involved completion of a wrong-site procedure. The actual incidence of wrong-site surgery is unknown. PA-PSRS reports indicate few anatomic structures were spared the potential for wrong-site surgery, and no surgical specialty was immune from error. Contributing factors involved in wrong-site surgery reported to PA-PSRS included the following: actions of the surgeon in the OR, not completing a proper time out, anesthesia interventions prior to a time out, not verifying consents or site markings, inaccurate consents/diagnostic reports/images, and patient positioning.

In reports to PA-PSRS, wrong-site surgeries frequently occurred despite site verifications with the patient, marking the site and apparently proper time outs. Near-miss reports indicated the following factors that prevented wrong-site surgery from occurring: surgeons and nurses verifying consent/ medical record, surgeons and nurses conducting verification procedures in the preoperative holding area, patients providing correct information, and circulating nurses providing correct information. Ensuring the correct surgical site involves a series of processes involving many healthcare personnel in multiple locations. Such complexity makes operative site verification prone to error.

In July 2003, the Joint Commission implemented the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ to prevent these occurrences. Elements of the protocol include a standardized approach for:

- Verifying the patient's identity
- Marking the surgical site and requiring patients or a legally designated representative to be involved in the marking procedure
- Using a preoperative site verification checklist
- Confirming the availability of appropriate documents and studies before the start of the procedure
- Taking a brief time out immediately before skin incision, in which all members of the surgical team actively communicate and provide verbal verification of patient's identity, surgical site, surgical

- procedure, administration of preoperative medications, and presence of appropriate medical records, imaging studies, and equipment
- Monitoring compliance with protocol recommendations

Though the Joint Commission universal protocol has wide acceptance, there is great variability in the ways facilities interpret the protocol. We wanted to understand the variations in how the Universal Protocol was interpreted and implemented. In particular, we wanted to appreciate how variations might be related to the risk of wrong-site surgery.

Site Visits

The Authority staff visited six hospitals we knew were committed to patient safety despite their experiences with wrong-site surgery. Four hospitals had reported more than one wrong-site surgery per year per 400 beds, and the other two had no wrong-site surgeries over a three year period but were otherwise good reporters from the OR. Our Authority team, consisting of the clinical director and two nurse analysts, spent a day at each of the six hospitals and also an ambulatory surgical facility (ASF) attached to one of the hospitals.

In general, we noted considerable variation in the implementation of the Joint Commission Universal Protocol and with the facilities' own policies. We identified the following issues related to wrong-site surgery events. Errors usually result from one of two problems: misinformation or misperception. In both our retrospective analysis and our observations, we noted that wrong-site surgery errors were associated with the failure to identify incorrect information in the documents related to surgery, such as the schedule, consent, and surgeon's history and physical examination (H&P), before the operation. Misperception can result from right/left confusion and from confirmation bias, the tendency to confirm a mental impression despite the physical facts. In our retrospective analysis, incorrect information was frequently conveyed when scheduling a procedure, sometimes included on the consent, and occasionally present in the H&P.

Prospective Review

The Authority's analytical team began in-depth queries of wrong-site surgery reports in August 2007. Our preliminary data has produced useful information about the differences between near-miss events and actual wrong-site surgery events in operating rooms (ORs) and ASFs. As of December 16, 2007, we have received the results of 16 completed in-depth queries about near-miss events and 6 about actual wrong-site surgery events from cooperating facilities. The compliance rate with our request for detailed information within 30 days of the event has been 56%.

Two-thirds of the near-miss events (8 of 12) had errors in the information communicated to the OR from the surgeon's office staff when scheduling the case. One of the six actual wrong-site surgery events had scheduling errors, a significant difference. This is consistent with the previous observations on our retrospective review that most scheduling errors are detected and corrected during the preoperative verification and reconciliation process.

All of the near-miss reports indicated the use of a checklist to document the verification and reconciliation process. A checklist was used in only four of the six wrong-site surgery events, again a statistically significant difference. This suggests that the checklist may be valuable in detecting inconsistencies in the documents before they lead to wrong-site surgery.

The surgeon responded to a specific concern that a member of the OR team voiced about possible wrong-site surgery in all 11 replies about near-miss events, but only in 1 of 4 replies about wrong-site surgery events. This statistically significant difference suggests that reluctance to either express or acknowledge concerns may contribute to a situation becoming a wrong-site surgery rather than a near miss.

We are optimistic that the ongoing cooperation of facilities in providing in-depth information about wrong-site surgery events and near misses will reveal more clues about processes that are successful in preventing wrong-site surgery.

Risk Reduction Strategies

The strategies presented here are based on our site visits, in-depth queries of wrong-site surgery, and a comprehensive literature review. The following strategies may contribute to system reliability, resulting in fewer site verification errors and adverse events.

Scheduling

Many initial wrong-site errors start with information received from the outpatient/office/clinic when scheduling a surgical procedure. This information is carried through with the patient's documents resulting in an incorrect OR schedule. The following approaches may reduce errors in scheduling:

- Designate a person responsible for OR scheduling
- Use a standardized form/computer entry
- Document the entire procedure and other procedures, if applicable
- Document site, level, digit, and side/laterality
- Document specific information on implants/implant systems/ and or special equipment
- Do not use abbreviations
- Verify information received from the physicians' office by read-back, fax, or e-mail

Consent

Consent is obtained at the time the procedure is scheduled and contains the following information: patient's first and last name, date of birth, medical record number or other patient identifier, name and description of surgical procedure with appropriate site, level, digit, and side/ laterality. Additionally, the signatures and date of the patient or healthcare agent, physician, and witness are completed. Consider having the consent available for verification prior to the patient's arrival for the surgical procedure.

Preoperative verification

Verification of documents and relevant imaging studies is a critical step in preventing wrong-site surgery. Prior to the patient's arrival to the facility assign a designated person to compare all the following documents: OR schedule, consent, H&P, surgeon's office documents and any pertinent imaging studies to determine if any inconsistencies exist. A standardized checklist will facilitate this process. Next, verification occurs when the patient arrives at the facility on the day of surgery. Patient involvement occurs during consenting, verification, site marking, and while the patient is fully awake and not sedated. Any discrepancies in either the patient's understanding of the procedure or the documents listed below are resolved by the operating surgeon.

- Use two patient identifiers to determine correct person; ask open ended questions (i.e., what is your name? What procedure are you here for today?)
- Inform patients they will be asked to verbally identify the surgical site several times before surgery.
- Provide a patient brochure describing the correct-site surgery protocol
- Perform two independent verification of the following: procedure including site/side or vertebral level, OR schedule, consent, H&P, and surgeon's office documents
- Verify implants and any special equipment is available
- Verify imaging studies when applicable are available for viewing in the OR room.

Marking the Operative Site

Site marking is done after reconciliation of all documents and before the patient is sedated. The use of a marker that is sufficiently permanent to remain visible after the skin is prepped should be used. The site marking occurs prior to the patient moving into the operating room. The site marking encompasses following elements:

- The mark is legible
- The mark is unambiguous
- The mark is at or near the incision site
- The mark is observable after prepping, draping, positioning, and repositioning
- The mark is visible during the time out
- The surgeon or designee marks only the correct site with initials or "yes."
- The mark should be made before any interventions are done, including anesthetic blocks.

Time out

A time out occurs with all relevant documents examined while the patient is in the operating room. Surgical team members stop all work and actively participate with verbal acknowledgement of the time out. OR team members are empowered to any express concerns regarding the procedure and surgeons are encouraged to acknowledge any concerns. Elements of an effective time out include:

- Conducting the time out just prior to the incision
- Conducting the time out after the patient is prepped and draped
- Conducting the time out after patient is repositioned, when applicable
- Verifying the vertebral level, when applicable, with intraoperative images
- Verifying the site by radiologist, when applicable.

Conclusion

Based on our retrospective analyses, observations, and in-depth queries, we believe that the opportunities for wrong-site surgery are minimized when all salient information is in agreement. For elective surgery, reconciliation of all the important information, such as the OR schedule, the consent, the H&P, and definitive diagnostic studies, can occur before the day of surgery.

We also believe that confusion is minimized when all members of the OR team assume a personal responsibility to have firsthand knowledge that the correct patient is getting the correct procedure at the correct location. The mark on the operative site is the patient's voice, continuing to speak after sedation or induction of anesthesia.

We have concluded that the time out is commonly perceived as the opportunity to make sure that the correct procedure was being done on the correct patient. It is not; it is the *final* opportunity of many that began when the patient was scheduled for surgery. Many steps of preparing the patient for an operation and performing an operation can lead down the path of wrong-site surgery. Preventing wrong-site surgery may require attention at every step of the process, not just the three advocated by the Universal Protocol.

To read the complete articles from PA-PSRS published in 2007, visit the Authority's web site at www.psa.state.pa.us. Articles on wrong site surgery published this year include:

- "Insight into Preventing Wrong-Site Surgery" (*PA-PSRS Pat Saf Advis* 2007 Dec; 4[4]).
- "Three 'Never Complications of Surgery' Are Hardly That" (*PA-PSRS Pat Saf Advis* 2007 Sep; 4[3]).
- "Doing the 'Right' Things to Correct Wrong-Site Surgery" (*PA-PSRS Pat Saf Advis* 2007 Jun; 4[2]).

Complications of Retrobulbar Blocks

Volume 4, Number 1—March 2007

A retrobulbar block is an anesthetic technique used for intraocular surgery. Many practitioners are abandoning this technique and using topical anesthetics. A 2003 survey of physician members of the American Society of Cataract and Refractive Surgeons in the United States revealed that the use of topical anesthesia has increased from 8% in 1995 to 61% in 2003. Nonetheless, the survey also indicates that retrobulbar blocks remain an anesthetic technique used in 20% of ocular surgeries.

A retrobulbar block involves injecting anesthetic into a muscle group behind the globe (eyeball). Four muscles are attached around the outer radius or "equator" of the globe and come together at a point posterior to the eyeball to comprise the retrobulbar "cone." Injecting a local anesthetic into the cone provides anesthesia and akinesia (loss of the power of voluntary movement) of the globe and the extraocular muscles. There are structures within the retrobulbar cone that may be at risk during retrobulbar injection, including the optic nerve, and many veins and arteries of the orbit. The goal of retrobulbar anesthesia is to direct the tip of a needle under the globe and into the retrobulbar cone, a blind technique. Complications of retrobulbar blocks include chemosis (edema or swelling), bruising, retrobulbar hemorrhage, globe penetration and perforation, optic nerve damage

and atrophy, extraocular muscle malfunction and injury, brain stem anesthesia, globe ischemia, and complications of cranial nerve VII.

Since the inception of the PA-PSRS program in June 2004, two types of complications are evident in the PA-PSRS data: (1) three reports of central nervous system spread of anesthesia resulting in respiratory arrest, caused by inadvertent injection of anesthetic into an artery, and (2) over two dozen reports of retrobulbar hemorrhage, caused by needle penetration of venous or arterial vessels in the orbit.

The article presents risk reduction strategies that can help achieve safe and successful retrobulbar blocks:

- Education and competencies
 - Ensuring knowledge of anatomy of the globe, orbit and other ocular-related structures
 - Having training and checking competencies in performing the technique
- Patient condition
 - Evaluating the globe for pathological abnormalities
 - In severely hypertensive patients, consider postponing surgery until blood pressure is under control
- Technique
 - Using a small gauge needle
 - Inserting the needle when the eye is in primary gaze
 - Placing the needle tangential to the globe
 - Inserting the needle into a relatively avascular area
 - Aspirating before injecting the local anesthetic agent, to check for blood
 - Consider repositioning the needle if resistance occurs during injection
 - Analgesia/sedation
 - Considering other anesthesia modalities that may have fewer complications

The March 2007 *Patient Safety Advisory* also includes a listing of resources concerning anesthesia alternatives for cataract surgery, for complete *Advisory* go to www.psa.state.pa.us.

Airway Fires during Surgery

Volume 4, Number 4—March 2007

The Authority received three reports describing airway fires during electrosurgery or electrocautery surgical procedures. Of the three reports, one patient experienced minor redness in the airway. The other two patients did not experience injury. Airway surgeries often involve ignition sources to cut or coagulate tissue. Examples of ignition sources during airway surgery include, but are not limited to, electrosurgical, electrocautery, laser units and bronchoscope lights.

The risk of airway fires becomes more prominent when these ignition sources are used in an oxygen-enriched atmosphere (i.e., atmospheres containing more than 23% oxygen), which is common during airway surgery or nitrous oxide, an anesthetic gas, which can also support combustion. Both gases reduce the amount of energy (e.g., current, heat, friction) needed to ignite flammable substances. Flammable substances present in the airway during airway surgeries include tracheal tubes, catheters and surgical sponges.

Ways to minimize airway fires during electrosurgery include:

- Establishing protocols for when electrosurgery will be removed from the surgical field.
- Not using electrosurgical units to cut tracheal rings and enter the airway.
- Using only commercially available insulated probes when needed to prevent mouth burns during procedures such as tonsillectomies use only commercially available insulated probes.
- Scavenging around the surgical site with separate suction to catch leaking oxygen and nitrous oxide.

- Soaking gauze or sponges used with uncuffed tracheal tubes to minimize gas leakage into the oropharynx, and to keep them wet.

The delivery of laser energy may present a more serious airway fire risk than electrosurgery. Laser energy is delivered as a collimated, coherent, monochromatic, directed beam of electromagnetic radiation to cut, coagulate and vaporize tissue.

Ways to minimize airway fires during laser surgery include the following:

- Limit the laser output to the lowest clinically acceptable power density and pulse duration.
- Place the laser in standby mode when not in use.
- Allow the laser to be activated only by the person wielding it to minimize inadvertent activation.
- Deactivate the laser and place it on standby mode before removing it from the surgical site.
- During lower-airway surgery, keep the laser fiber tip in view and make sure it is clear of the end of the bronchoscope or tracheal tube before laser emission.
- Use appropriate laser-resistant tracheal tubes during upper-airway surgery.

Under general anesthesia, a patient is mechanically ventilated and lacks sensation; as such, hot gases can be forced deep into the lungs, causing extensive damage or death. Immediate action is required by the surgical team to reduce the extent of the damage. The guidance below can help clinicians develop a procedure for extinguishing airway fires. (Note, perform steps one and two rapidly and simultaneously.) Such a procedure should be reviewed prior to each surgical intubation.

Ways to fight airway fires include the following:

1. Stop the gas flow

Disconnecting the breathing circuit is the quickest way to stop the gas flow. By removing the source of oxygen and nitrous oxide from the airway, the fire's intensity is significantly reduced and may self-extinguish.

2. Remove the tube using a obturator or similar instrument if necessary, and use other means to maintain airway patency

To minimize thermal and chemical damage to the airway, quickly remove the tracheal tube from the patient. The intense heat from the O₂-fed fire will remain in the mass of the tube and can still harm the patient even if the fire is out; the fire can reignite if oxygen flow is restored. Additionally, remove cuff-protective devices or any segments of burned tube that may remain smoldering in the airway.

3. Extinguish the fire

A smoldering or glowing tube can ignite surgical drapes or gowns. OR personnel other than the anesthesiologist should extinguish the tube with water or saline in a basin or sink, or with a wet towel. Be wary of using any flammable liquids (e.g., alcohol) that may be near or in the surgical field to extinguish the fire. Liquids in the OR should be clearly labeled to avoid mix-ups. (For more information on labeling liquids see the article "Dangers Associated with Unlabeled Basins, Bowls, and Cups" in the March 2005 *Patient Safety Advisory*.) Save the tube and other relevant materials for later examination.

4. Care for the patient

Reestablish the airway and resume ventilation with air until absolutely nothing is burning in the throat; then switch to 100% oxygen. Some smoke and gases from the tracheal tube fire can cause chemical burns or toxic reactions. Examine the airway for the extent of damage and treat the patient accordingly. A rigid bronchoscope and forceps should be readily available during all tracheal surgery. Procedures such as lavage and suction to remove soot and particles in the airway, excision of burned tissue and melted material, or a tracheostomy may be necessary.

Airway Fires during Surgery

Airway surgeries that involve ignition sources to cut or coagulate tissue (e.g., electro-surgical units, lasers) pose a significant and sometimes deadly risk of fire. Hazards exist when these ignition sources are used in the oxygen-enriched atmospheres (i.e., more than 23% O₂) that are commonly present in the airway during surgery.

Ways to Minimize Airway Fires during Electrosurgery

During Tracheostomy

- Establish protocols to address when electro-surgery will be removed from the surgical field because of risk of fire. For instance, some hospitals remove the electro-surgical unit when the tracheostomy tube is put on the surgical field.
- Do not use electro-surgical units to cut tracheal rings and enter the airway. Instead, use a "cold" scalpel to avoid the risk of fire.

In the Oropharynx

- Use only commercially available insulated probes. Do not use red rubber catheters as sheaths. The heat from the active electrode will ignite rubber even in air.
- Scavenge around the surgical site with separate suction to catch leaking O₂ and nitrous oxide.
- Soak gauze or sponges used with uncuffed tracheal tubes to minimize gas leakage into the oropharynx, and keep them wet.

Ways to Minimize Airway Fires during Laser Surgery

- Use appropriate laser-resistant tracheal tubes during upper-airway surgery.
- Properly cleave and strip the laser fiber before use and as needed during surgery.
- Place the laser in standby mode when not in use.
- Allow the laser to be activated only by the person wielding it to minimize inadvertent activation.
- Deactivate the laser and place it in standby mode before removing it from the surgical site.
- During lower-airway surgery, keep the laser fiber tip in view and make sure it is clear of the end of the bronchoscope or tracheal tube before laser emission.



Image provided courtesy of ECHO Institute.

Ways to Fight Airway Fires

1a) Stop the Gas Flow*

Disconnecting the breathing circuit is the quickest way to stop the gas flow.

1b) Remove the Tube from the Patient*

Maintain the airway.

2) Extinguish the Fire

Operating room personnel other than the anesthesiologist should extinguish the removed tube and other smoldering materials. Remove segments of burned tube that may remain in the airway.

3) Care for the Patient

Reestablish the airway and resume ventilating with air until certain that nothing is left burning in the airway; then switch to 100% O₂.

* These steps should be done as quickly and simultaneously as possible.



For more information visit:
www.psa.state.pa.us

This poster was adapted from "Airway Fires during Surgery"
PA-PSRS Patient Safety Advisory
March 2007, Vol. 4, No.1.
© 2007 Pennsylvania Patient Safety Authority



Figure 22. Guidance to Minimize Airway Fires During Surgery

The Authority developed a poster (see Figure 22) to accompany this article as guidance in helping facilities implement safe practices to minimize airway fires during surgery. The poster summarizes ways to minimize airway fires during electrosurgery and laser surgery, and ways to fight airway fires should they occur. The airway fires poster can be found on the Patient Safety Authority web site at www.psa.state.pa.us. For the complete article, go to the March 2007 *Patient Safety Advisory* also on the Authority's website.

Contrast-Induced Nephropathy—Can This Iatrogenic Complication of Iodinated Contrast be Prevented? Volume 4, Supplement 1—March 2007

Iodinated contrast material used in diagnostic imaging is associated with many types of adverse reactions. The *Patient Safety Advisory* article focused on one potentially serious complication, contrast-induced nephropathy (CIN), an important cause of hospital-acquired renal failure. Patients who develop CIN have more complications, a worse prognosis, more serious long-term outcomes and prolonged hospital stays, which result

in increased medical costs. An increasing number of procedures utilizing contrast and the wider use of contrast media in seriously ill patients have increased the number of patients at risk for CIN. In healthy patients with normal kidney function, the changes produced in the kidney by contrast media are usually of no consequence. However, patients with certain risk factors may develop CIN in response to intravascular administration of contrast media. There are numerous risk factors for CIN. A number of risk factors presented in the *Advisory* include; pre-existing impairment of renal function, diabetes mellitus associated with renal insufficiency, use of nephrotoxic drugs, administration of high-osmolar contrast media, intravascular volume depletion, multiple myeloma, advanced age, sepsis, debilitating conditions, and patients with underlying risk factors undergoing certain procedures and patients with multiple risk factors.

Since June 2004, at least 70 reports have been submitted to the Authority that involve occurrences that reflect system/process issues related to renal function and contrast media. About 10% of the reports are categorized as Serious Events, compared to 4% of reports submitted overall. Five percent of the reports indicated that the patient required dialysis after a contrast-related procedure. PA-PSRS reports reveal patterns of errors. Some examples include failure to check laboratory tests prior to contrast-related procedures, performing contrast-related procedures on patients with pre-existing risk factors, performing contrast-related procedures on the wrong patient, and relying on the wrong patients laboratory studies prior to performing a contrast-related procedure. There is no treatment to reverse or ameliorate CIN once it occurs. To date, there is no single therapeutic intervention that has been conclusively proven effective to prevent CIN. The following risk reduction strategies may reduce the incidence of CIN:

- Risk identification by laboratory testing and patient history/questionnaires
- Risk scoring to predict the risk of CIN
- Risk-benefit analysis to determine if a contrast-related study is essential
- Consideration of alternative diagnostic procedures
- Optimization of renal function prior to contrast –related testing
- Hydration, especially in patients with pre-existing CIN risk factors
- Discontinuing nephrotoxic drugs in the periprocedure period when medically feasible
- Using the lowest volume/dose of contrast
- Premedication regimens

The decision to administer iodinated contrast is based upon clinical judgment about the clinical status of the patient, knowledge of the risks and effective prophylactic measures, and the expected benefits of the procedure. The Authority's PA-PSRS program developed a toolkit in conjunction with this article, to help facilities implement these risk reduction strategies. The toolkit includes: an informational video on CIN; an algorithm to identify risk factors for CIN; and a poster including the algorithm, premedication regimen information and reference tables. The toolkit is available on the Patient Safety Authority website at www.psa.state.pa.us. The complete article of the March 2007 *Supplementary Advisory* can also be found on the Authority's website.

Fentanyl Transdermal System: Taking Another Look

Volume 4, Number 2—June 2007

Fentanyl transdermal system provides many benefits for management of moderate to severe chronic pain, but this medication can be very dangerous. Errors involving these patches have a heightened risk of significant patient harm. Fentanyl is considered a high-alert medication, which means that, while not necessarily more prone to Medication Errors, an error carries greater risk of patient harm or death.

Use of fentanyl transdermal system is indicated in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a total daily dose at least equivalent to a transdermal system dose of 25 mcg/hr. Fentanyl transdermal system is contraindicated in patients who are opioid-naïve, patients who are in acute pain, patients who require opioid analgesia for a short period of time and in patients who suffer only mild pain. It is contraindicated in the management of intermittent or postoperative pain, including use after

outpatient or day surgeries. Fentanyl transdermal system depresses the respiratory centers, depresses cough reflex and constricts the pupils.

Reports submitted through PA-PSRS and national reporting programs demonstrate problems that have resulted in patient harm. These problems include multiple fentanyl transdermal patches inadvertently placed; concomitant use of transdermal patches with patient-controlled analgesia; inappropriate prescription, particularly with the opioid-naïve population; potential patient abuse of the patch; and lack of patient education, especially regarding administration and storage and disposal.

There are a number of strategies that can assist in the safe use of fentanyl transdermal patches, including the following:

- Prescribe fentanyl patches only for chronic pain and for those patients who are already tolerant to opioid therapy of comparable potency.
- Make sure the dose, dosing interval, and titration prescribed are appropriate for the patient and his or her age and condition.
- Require a pharmacist review when the route or technique of medication is changed.
- Update medication history forms to include prompts for information about transdermal patches.
- Assess patient's skin to check if patient is wearing any patch in the ED, upon admission, during routine assessments and at any change in the level of care.
- Improve methods of documentation and communication about patch location. List patch location and removal on the medication administration record (MAR).
- In facilities with computerized MARs, program patch information into the pharmacy computer system so that these entries automatically appear on the MAR.
- In medication administration policies, include safe medication practices that contain information about transdermal patch application.
- Conduct ongoing education and annual staff competencies on the safe administration of fentanyl transdermal patches.
- Be alert for signs of possible drug-seeking behaviors with these patches.
- Review with the patient the 22 patient information points listed in the product's package insert.
- Supply patients with clear and specific verbal and written directions about the patch usage, and caution patients to follow directions exactly.
- Educate patients to store patches and all other medications in a safe place out of the reach of children.
- Educate patients about the proper disposal of used patches.
- Teach patients to avoid exposure to direct heat sources (e.g., heating pads, saunas, hot tubs, heated water beds) while using the patches, because contact may increase fentanyl absorption.
- Provide a dosing calendar so patients can keep track of the location and time of patch application at home.
- Emphasize the need to remove old patches prior to the application of a new patch.

For the complete June 2007 *Patient Safety Advisory* article on fentanyl transdermal patches go to the Authority's website at www.psa.state.pa.us.

Strategies to Minimize Vascular Complications following a Cardiac Catheterization

Volume 4, Number 2—June 2007

Cardiac catheterization is considered the gold standard for the diagnosis, evaluation and treatment of cardiac diseases. This invasive procedure is not free of complications, even though one goal following cardiac catheterization is to reduce vascular complications. Almost half of reports concerning cardiac catheterization were classified as complications of the procedure and many were vascular complications associated with the

access site, bleeding, hematoma formation, retroperitoneal bleed, pseudoaneurysm and arteriovenous fistula (A-V) formation. The most often stated causes of the problem were medication errors, inconsistencies in patient assessments, unrecognized changes in patient condition, sheath removal and lack of appropriate interventions when complications occurred.

Risk factors that influence vascular complications include patient characteristics, interventional cardiologist technique, medications used during the catheterization, use of manual and/or mechanical compression at the access site, use of closure devices and nursing care.

Among the strategies that may help to minimize Incidents of vascular complications following a cardiac catheterization presented in the *Advisory* article include:

1. Identify individual patient risk factors that may increase the risk of vascular complications which include age, gender, weight, presence of peripheral vascular disease, hypertension, renal failure, low platelet count and hematocrit levels, congestive heart failure, chronic obstructive pulmonary disease and coagulopathies.
2. Employ techniques that can impact vascular complications which include careful entry into the artery, use of smaller sheaths, avoidance of venous sheath whenever possible, early sheath removal, use of low dose heparin and minimize procedure time.
3. Employ safe use of medications pre and post catheterization to prevent thrombosis of the target vessel while promoting hemostasis of the vascular access site.
4. Maintain hemostasis at the access site after cardiac catheterization to reduce complications, increase patient comfort and safety, and decrease hospital stay. While current data is insufficient to construct universal guidelines to minimize complications and patient discomfort, the methods currently used to obtain hemostasis post catheterization include manual or mechanical compression of the site and/or deployment of a vascular closure device (VCD). Refer to the *Advisory* article for the specific VCDs that were discussed.
5. Provide comprehensive education for nurses who care for patients undergoing cardiac catheterization through educational modules, simulation labs, competency skills list and annual competency performance assessment.

Front line nurses caring for patients before, during and after cardiac catheterization play a key role in the prevention of complications. The *Advisory* article includes a number of nursing care elements facilities can incorporate into nursing protocols and practice.

With the increasing number of cardiac catheterizations performed, evolving technology, and advances in pharmaceutical therapy comes an increased risk of vascular complications. The strategies described in this article can be incorporated into the daily practice of cardiologists and nurses caring for these patients.

For the complete June 2007 *Patient Safety Advisory* article click on *Advisories* at www.psa.state.pa.us.

Drug Labeling and Packaging — Looking Beyond What Meets the Eye

Volume 4, Number 3—September 2007

Ambiguous and confusing packaging and labeling as well as look-alike or sound-alike drug names significantly contribute to medication errors. Errors may occur when important information is printed in an inconspicuous place on the label, presented in an ambiguous manner or overshadowed by less important information. The printing on the label may also be less than optimal in size, boldness or contrast. Ornate graphics, emphasized corporate names or logos may distract from the primary purpose of the label: to permit the user (pharmacist, nurse, physician or patient) to identify the name(s), dosage form and strength of the product. Complicating the situation is that healthcare practitioners often read labels under less-than-ideal conditions (e.g., in a patient's room at night when lights are dimmed, during emergency situations).

There are many factors related to a medication's label or package design that can contribute to errors. Some of these factors as seen in PA-PSRS data include readability of labels and packaging, expression of the drug's strength or concentration, use of color and lack of contrast.

For example, the wording that appears on bags of infusion solutions (i.e., solutions commonly used to provide hydration) is cluttered with irrelevant information, causing further confusion to the practitioners using the product. (See Figure 23)



Figure 23. Similar labeling of hydration solutions has led to many errors reported to the Authority. (Liter bags of Dextrose 5% and Sodium Chloride 0.45% with Potassium Chloride 20 mEq on the left and Sodium Chloride 0.9% with Potassium Chloride 20 mEq on the right)

Image provided courtesy of ISMP.

Sources of confusion in drug labels include:

- Readability of Labels and Packaging
- Expression of the Drug's Strength or Concentration
- Use of Color
- Lack of Contrast

Risk Reduction Strategies

It is not enough to caution healthcare providers to be more careful because it is human nature to identify items by color, shape, type font, symbols used and other such characteristics. To help minimize errors related to nomenclature, labeling and packaging, consider the following strategies:

Performing a Failure Mode and Effects Analysis (FMEA)

Before adding a medication to your organization's inventory, consider gathering an appropriate interdisciplinary team to perform a FMEA (Failure Mode and Effects Analysis) to determine potential pitfalls with that medication. It may be necessary to include an evaluation of the look-alike potential of product containers as well as possible areas of storage throughout the organization, not just in the pharmacy.

Reviewing Reports from External Sources

Regularly reviewing professional literature may help to identify error-prone drug products.

Purchasing from Different Vendors

To reduce similarities and prevent errors, consider purchasing one product of an identified look-alike pair from a different vendor.

Segregating and Labeling

Consider separating and/or clearly differentiating products that are similar.

Building Alerts

Building alerts into computer systems may help to remind practitioners about problematic products in your organization.

For the complete September 2007 *Patient Safety Advisory* article on labeling on packaging medication errors go to *Advisories* at www.psa.state.pa.us.

Obstructive Sleep Apnea (OSA) May Block the Path to a Positive Postoperative Outcome

Volume 4, Number 3—September 2007

Obstructive sleep apnea (OSA) is a common sleep disorder characterized by recurrent episodes of complete and partial airway collapse during sleep, resulting in apnea or hypoapnea. Approximately 80-90% of OSA is undiagnosed. Patients with known or suspected OSA are at increased risk for life-threatening cardiopulmonary complications. The inherent problem of airway management during administration of general anesthesia and the large patient population with undiagnosed OSA increases the risk of developing complications postoperatively.

The Authority has received more than 250 reports since June 2004 in which OSA is specified as a contributing factor. Approximately 20% of reports were classified as Serious Events associated with patient harm, including three deaths. Sleep apnea was present in the medical history in approximately 50% of reports. Types of Incidents among the reports included the following: extended length of stay in the postanesthesia care unit (PACU), postoperative reintubation, transfer to a higher level of care, postoperative transfer from ambulatory care centers to acute care for further treatment, and need for reversal agents following narcotic administration. These findings reflect similar complications cited in the literature. Anesthesia providers need to consider risks factors for OSA and the perioperative management of potential problems in each patient.

Identification of patients at risk, preoperative assessment, intraoperative management, and post operative care are critical elements in optimizing patient care and safety. Preoperative evaluation is a fundamental component in reducing risk of complications for OSA patients and includes use of a screening tool, review of the medical history, and performing a physical examination to identify undiagnosed OSA.

Intraoperative care focuses on airway management, choice of anesthetic, patient monitoring, and nominal use of sedatives and opioids. Patients with OSA are at increased risk for difficult tracheal intubation. Techniques for optimal intubation include: placing the patient in the sniffing position (i.e., head extension with cervical flexion introduced), inserting an oropharyngeal airway, and using a fiberoptic bronchoscope. Additionally, OSA patients are susceptible to the respiratory depressant effects of sedatives, opioids, and inhaled anesthetics. Guidelines to consider when administering medications include: avoiding the use of sedatives and opioids, reducing doses and titrating slowly when administering sedatives and opioids, and administering local anesthesia whenever possible.

Postoperative care is the pivotal time to implement interventions to reduce complications, especially within the first 24 hours. Postoperative risk reduction strategies focus on monitoring patients for an obstructed airway so that early detection may lead to prompt treatment. Other risk reduction strategies include: positioning the patient in a lateral or semi-upright position, **not supine**; extubating the patient when fully awake; using CPAP and/or supplemental oxygen after extubation to maintain oximetry above 90%; monitor the patient's pulse oximetry continuously; obtaining arterial blood gas (ABG) for pulse oximetry less than 90%; and limiting the use of tranquilizers and narcotics whenever possible.

For the complete article on Obstructive Sleep Apnea go to the September 2007 *Patient Safety Advisory* at www.psa.state.pa.us.

Diligence and Design in Behavioral Health Impact Patient Safety

Volume 4, Number 3—September 2007

Behavioral health facilities are potentially dangerous places for both patients and staff when patients are looking for the opportunity to inflict harm. Reports submitted to the Authority indicate that patients continue to harm themselves in behavioral health facilities by using structures and objects common to the behavioral health environment, particularly in patient rooms.

Traditionally, behavioral health facilities have focused on access control and surveillance technologies such as fences, locks, key controls, doors and windows, alarm systems, and closed-circuit television systems, but these tools may be limited in their ability to address a vital issue to the behavioral health environment. This limited focus may miss cues and clues, affording patients the opportunity to construct weapons from or otherwise harm themselves with objects found in their environment.

Since 2004, the Authority has received more than 1,900 reports through PA-PSRS related to behavioral health issues, including suicide, self harm, violent behavior, and possession of items not permitted in the behavioral health environment that may contribute to harm. Of the five suicides reported through PA-PSRS, four were by strangulation using belts, cords and clothing. The fifth death resulted from an overdose with contraband medication that the patient had hidden.

Visit the Patient Safety Authority Web site (<http://www.psa.state.pa.us>) to view an interactive graphic of the objects or structures in patients' rooms that have contributed to patient harm. The graphic (see below) is also available in a printer-friendly format.



To view the graphic, click on “[Advisories and Related Resources](#)” in the left-hand column of the Authority’s home page. Then, click on “[Resources Associated with Patient Safety Articles](#).” The interactive graphic is located under the heading “Other Resources.” Be sure to review the accompanying descriptive text for system compatibility and user instructions.

The reports further demonstrate the resourcefulness of patients determined to harm themselves despite efforts to the contrary. There have been more than 400 reports of patients harming themselves with objects found in the behavioral health environment. More than 30 of these reports were related to attempted suicide by strangulation with common objects such as clothing, belts, bed linens and shoelaces. About 50% of the more than 400 reports indicated that patients lacerated or punctured themselves with items such as pens, pencils, paper clips, razor blades and kitchen items.

Although no environment of care can be totally safe and free of risk, facilities can reduce the environmental risk factors that have the potential to cause patient harm by comprehensive planning of facility design. This article addresses existing guidance for the adult behavioral healthcare unit that is applicable when designing a new building, renovating space or maintaining an existing behavioral healthcare program.

Alternative risk reduction strategies for behavioral health facilities to consider include:

- Provide a safe environmental design which includes but may not be limited to physical structure, windows, glass, electrical cords and outlets, bathrooms, and furniture and miscellaneous items.
- Provide education to clinical and non-clinical staff which includes how annual competencies relate to the hidden risks of the environment and the behavioral characteristics of the population.

Figure 24. Interactive Behavioral Health Room Graphic. This online graphic, which can be used as an educational tool, illustrates the problems reported to PA-PSRS related to items patients have used to harm themselves or others. By scrolling over the objects in the room, the user learns about reports from Pennsylvania facilities related to those items.

- Frequent patient assessment and reassessment to identify patients at risk for inflicting harm to themselves or others and include an inventory of patient's personal items, based on the observational assessment of the individual patient.
- Offer family members education about the details of patient safety issues, available community resources and information related to environmental hazards that may indicate potential for harm to the patient and/or others.

In addition, reports have identified patient rooms as especially vulnerable areas for patient harm because the extended periods of time that patients spend in their rooms provide ample opportunity for self-harm. For further education, the Authority's PA-PSRS program has developed an interactive illustration of the objects or structures in patients' rooms that have contributed to self-harm (see Figure 24). To view or download it, go to www.psa.state.pa.us. The entire September 2007 *Patient Safety Advisory* article on reducing the risk in behavioral health facilities can also be found on the Authority's website under *Advisories*.

Should Patients be Accompanied When Discharged from Ambulatory Surgery?

Volume 4, Number 3-September 2007

The Authority was asked by a Pennsylvania healthcare facility to address the issue of whether or not ambulatory surgical patients must have escorts who can accompany them home following the procedure. Hospital patients are discharged home when they fulfill discharge criteria; however, ambulatory surgical patients may not regain their pre-operative physiological state prior to discharge.

Studies have identified that ambulatory surgical patients may experience significant cognitive and psychomotor impairment after various types of anesthesia, including sleepiness and impaired driving skills. While groggy, patients may injure themselves or others and may be unable to obtain help if postsurgical complications arise. Other complications following ambulatory surgery may include postoperative bleeding, difficulties with postoperative pain management and lack of compliance with discharge instructions. The Authority reports have revealed some of the adverse outcomes patients experience following discharge from ambulatory surgical facilities (ASFs). Approximately 12% of the reports in which patients required hospital-level care within hours or days of treatment at an (ASF) suggest that activities at discharge and during post-discharge follow-up may have contributed to the events.

State regulatory bodies, accrediting organizations, and professional medical and nursing societies specify that ambulatory surgical patients have a responsible person accompany them home because of significant cognitive and psychomotor impairment after anesthesia and sedation. A responsible person must be physically and mentally able to make decisions for the patient's welfare if necessary. Moreover, the responsible person must understand requirements for post-anesthetic care and intend to comply with these requirements. A responsible person can ensure that the patient arrives home safely and assist in the event of postoperative complications. Discharge instructions can be reviewed with the patient and a responsible adult before discharge. The September 2007 *Patient Safety Advisory* presents a number of risk reduction strategies to ensure safe discharge of patients from ASFs:

- Conduct a staff meeting and develop action plans to ensure safe discharge for all patients.
- Compile a list of resources to call upon when transportation problems arise, such as community and volunteer groups, van services, homeless shelters and patient medical escort services.
- Some hospitals offer a "hotel bed where patients can pay a fee to stay in a hospital setting overnight without nursing care but with easy access to emergency assistance. Nursing homes or assisted living facilities may provide a supervised environment for such patients on a temporary basis.
- Offer home health visits or hire a nursing agency to help allow the patient to go home safely.
- If medically feasible, consider performing minor procedures with local or no anesthesia if transportation or a responsible person is not available to the patient.

The *Advisory* also identified additional ways ASFs can enhance the safety of patients, including development of protocols regarding escorts, education of healthcare workers about the protocol and monitoring of compliance with the protocol. ASFs may also provide patient education about the necessity for escorts along with pre-operative instructions.

Prompt Identification and Effective Communication of Status May Reduce MRSA Infections

Volume 4, Number 4—December 2007

More than 1,700 reports related to Methicillin resistant *Staphylococcus aureus* (MRSA), including 14 deaths, have been submitted to the Authority since its inception through October 2007. Less than 10% of MRSA reports indicated the facility performed a MRSA screening upon a patient's admission. Approximately 13% of reports submitted through PA-PSRS indicated that a patient's MRSA status, either an infection or colonization, was not communicated to healthcare workers. Failure to adequately identify and/or communicate patients' MRSA status can perpetuate infection and transmission to other patients and healthcare workers.

Healthcare-associated infections (HAIs) including multidrug-resistant organisms (MDROs), such as MRSA, remain a major cause of morbidity, mortality, increased hospital length of stay and increased healthcare costs. Although there is variation in the reporting of MRSA incidence and prevalence, a recent study by the Centers for Disease Control and Prevention (CDC) conducted at nine U.S. sites from July 2004 through December 2005 indicated there were 8,987 observed cases of invasive MRSA. Based on 2004 data, the Pennsylvania Health Care Cost Containment Council reported 13,722 hospitalized patients had a MRSA-related infection. A comparison of patients without a MRSA infection revealed that patients with a MRSA infection were four times more likely to die, and on average, patients with MRSA had an increased length of hospital stay.

Elimination of MRSA from healthcare facilities is a complex process that requires a comprehensive infection control program. Obtaining leadership support is essential for the success of infection control programs. A comprehensive program aimed at reducing MRSA includes the following: screening patients for colonization and infection, strict adherence to isolation precautions for colonized and or infected patients, implementation of hand hygiene protocols, and improvement in the decontamination of medical equipment and the healthcare environment.

Success in reducing MRSA starts with an active surveillance system—an ongoing, comprehensive method of measuring health statuses, outcomes, and related processes of care, and analyzing data within a healthcare facility to assist in reducing HAIs. The system incorporates screening and culturing patients on admission for MRSA.

Strict adherence to isolation precautions is an essential component to reduce MRSA. Contact isolation is intended to prevent the transmission of infectious agents, which are spread by direct or indirect contact with the patient or the patient's environment. Facilities may consider the following strategies for implementation of isolation precautions:

- Provide adequate supplies for isolation in all patient care areas
- Include consistent documentation in the medical record of isolation precautions
- Assign designated staff to post appropriate signage for contact isolation outside patient rooms
- Discuss isolation status for MRSA during hand-off communication
- Educate and train healthcare workers to ensure policies and procedures for contact isolation are understood and practiced
- Provide patients, family members and visitors with pamphlets educating them about proper hand hygiene, use of gown and gloves and care of equipment
- Conduct ongoing audits to determine effectiveness of methods implemented

Hand hygiene may be the single most important measure for controlling the transmission of MDROs. Despite the evidence supporting hand washing as a key element in reducing transmission of HAIs, healthcare workers' adherence to hand hygiene practices is unacceptably low. The average compliance is estimated at less than 50% in acute care facilities.

Improvement in the decontamination of medical equipment and the healthcare environment is the final component of a comprehensive program. Multiple studies have demonstrated that equipment carried by healthcare workers and items transported from patient to patient can become contaminated.

Another area of concern is the environment, in particular, the patient's bed and surrounding surfaces. The cleaning and disinfecting of all patient care items, especially those closest to the patient may reduce the spread of MRSA.

The incidence of MRSA infections continues to increase among hospitalized, at-risk patients. Analysis of the Authority reports identified that screening procedures are not consistently performed, and that even when facilities identify MRSA-positive patients, failure to communicate patients' MRSA statuses is common. Limiting the risk of MRSA transmission involves the development of a comprehensive infection control program.

For the complete MRSA article go to the December 2007 *Patient Safety Advisory* on the Authority's website at www.psa.state.pa.us.

Smart Infusion Pump Technology: Don't Bypass the Safety Catches

Volume 4, Number 4—December 2007

A new technology, commonly referred to as "smart" infusion pumps, is beginning to play a role in reducing the risk of administering IV medications. There are several roles of a smart pump including the ability to store "rules" (i.e., hospital-defined dosing limits) in a drug library, and to apply those rules during pump programming to warn clinicians about potentially unsafe drug therapy. In addition, these pumps allow organizations to enter various drug infusion protocols into a drug library with predefined upper and lower limits stored in pump.

Unfortunately, errors may still occur when using this technology. Numerous reports sent through PA-PSRS include examples of errors associated with the use of smart infusion pumps. Some of the examples include similar types of errors that may occur with the use of general infusion pumps.

Examples include:

- Giving medications at the wrong rate when IV lines are switched between separate pumps or dual-chambered pumps.
- Giving medications at the wrong dose when inaccurate patient weights are used to calculate or program weight-based doses.
- Selecting the wrong drug in the pump's library.
- Using the wrong unit of measure (e.g., mg/hr instead of mg/min).
- Over-riding smart pump alerts intended to warn caregivers about unsafe orders.

Safe Practice Strategies

It is not enough to purchase smart pumps, program the library to enable the technology, distribute the pumps, educate users and hope that the dose-checking feature will always be used. Organizations may consider some of the following steps if they are considering purchasing and implementing smart infusion pumps in the near future:

- Just like other forms of technology, a readiness assessment is essential with particular attention to the organizational culture when planning for the use of this technology.
- Establish a multidisciplinary team to determine best practices including IV-related policies and procedures, and standardized concentrations, dosing units (e.g., mcg/min versus mcg/kg/min), and drug nomenclature.
- Determine dosage limits for infusions and bolus doses on the basis of current policy and practice, the literature and consensus among the group. Also decide which dose limits require a hard stop versus a soft stop.
- Develop unit-based dosage limits (e.g., for adult ICU, adult general care, pediatric ICU, pediatric general care, labor and delivery and anesthesia) and procedures for nurses to follow when a drug is not in the software library or a nonstandard concentration must be used.
- Analyze pump logs, evaluate all overrides and make necessary adjustments to the drug library.
- Monitor and measure compliance with the technology to identify and remove any barriers to the safe and appropriate use of these pumps.

Healthcare clinicians should not view the dose-checking feature of smart pumps as an option that can be turned on or off. The alerts that arise from the system should not be allowed to be bypassed without serious consideration. For every error like those described above, there are many more that have been prevented because smart pump technology has been employed. There is little doubt that smart pumps can save lives if implemented properly AND used.

For the complete article on smart infusion pumps go the December 2007 *Patient Safety Advisory* at www.psa.state.pa.us.

[This page intentionally left blank]

Education, Outreach and Collaboration

Education and Outreach

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

Outreach to Facilities and Providers

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

Professional Organizations

Staff from the Authority was also invited to speak to various other groups throughout the Commonwealth. These include presentations to: the Pennsylvania Department of Insurance, Central Pennsylvania Association for Healthcare Quality (CPAHQ), HCPro, the Pennsylvania Association of Nurse Anesthetists, the National Academy for State Healthcare Policy (NASHP), the United Kingdom National Patient Safety Agency (NPSA) audit meeting, the USP-AHRQ meeting on national reporting systems and the Department of Public Welfare’s Bureau of Communicable Diseases staff.

PA-PSRS System Training

In May, a new user training session was held in conjunction with the FMEA training in Gettysburg and in December a webinar was offered for the first time with attendance at full capacity. The Authority recognizes the need for new user training annually due to employee turnover, new facilities reporting and new employees assisting in reporting. For those who cannot attend the new user training sessions held each year, user training is available for PSOs online through the PA-PSRS website at www.psa.state.pa.us.

Failure Mode and Effects Analysis (FMEA) Workshop

In May and June 2007, the Authority offered a two-day workshop on Failure Mode and Effects Analysis (FMEA) for all PA-PSRS users and other attendees. Three regional sessions were held in Pittsburgh, Gettysburg and Bethlehem. The program covered the steps involved in carrying out a proactive risk assessment using the FMEA methodology. In addition, methods were discussed for choosing an appropriate topic for evaluation. The hands-on workshop allowed Patient Safety Officers to mitigate potential risks and develop control strategies where risk is present within their own healthcare facility. Breakout sessions were included and facilitated by staff from the Authority. Program CME certification courses were approved for continuing education credits by Temple University School of Medicine and the Pennsylvania Patient Safety Authority.

PSA Pharmacy Survey Project

In January 2007, 32 PA-PSRS facilities engaged in a statewide field test of hospital pharmacy systems based upon a model that the Institute for Safe Medication Practices (ISMP), a PSA sub-contractor, has used nationally. For the test, Patient Safety Officers were provided with a set of test orders which, when entered into their pharmacy system, triggered alerts to the practitioner. The PSO was required to work with the Director of Pharmacy to complete the test, and the PSO submitted the results online through a web-based survey form. Participating facilities received a report at the end of the survey that gave their facility’s results along with the

de-identified statewide results. The aggregate results were presented at the Patient Safety Authority board meeting held in March during 2007 National Patient Safety Week.

Colonoscopy Perforation Project

The Authority continued its study on the frequency of routine colonoscopy perforations and the risks associated with them. We will attempt to answer the following key questions in the study. "At what rate does colonoscopy-associated perforation occur?" "What are the risk factors for colonoscopy-associated perforation?" "What are the best practices for controlling modifiable risk factors?" The Authority's PA-PSRS clinical director will work with a physician work group to try to determine the answers to these questions through data submitted to the Authority.

Collaborating with Other Organizations

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

Department of Health

The Authority has worked closely with the Department of Health to ensure implementation of Act 52 of 2007 goes as smoothly as possible. Throughout the year, meetings with the department have continued focusing on the implementation, but also to discuss various topics regarding facilities and PA-PSRS. The Authority recognizes the roles of each agency are different, but also understands the importance of communicating on a regular basis to ensure facilities are given the most accurate information, particularly in regard to Act 52 requirements. A member of the Department of Health sits on the Authority's Healthcare-associated Infection Advisory Panel.

Governor's Office of Healthcare Reform (GOHCR)

Congruent with Act 52 responsibilities, the Authority has partnered with the Governor's Office of Healthcare Reform (GOHCR) to help move the initiatives of Governor Ed Rendell's ambitious healthcare initiative "Prescription for Pennsylvania."

State Board of Medicine

Previously, at the request of the State Board of Medicine within the Department of State, Authority staff met with the State Board, along with a larger audience of physicians, to inform them about the activities and findings of the Patient Safety Authority. In addition, the State Board of Medicine published another column by the Authority's Executive Director and Clinical Director in the State Board's *Newsletter* about the importance of communication within the healthcare community, particularly in regard to physicians and hospital staff.

Pennsylvania Medical Society

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

Hospital and Healthsystem Association of Pennsylvania (HAP)

For the third year, the Authority joined with the Hospital and Healthsystem Association of Pennsylvania (HAP) to become a co-sponsor of the 2008 Patient Safety Symposium in April. This well-attended, statewide educational conference was targeted toward Patient Safety Officers, risk managers, physician- and nurse-managers, senior administrators, infection control officers, pharmacists and other clinicians. In 2007, the Authority held its board meeting at the event with Patient Safety Officers in attendance.

The Authority is also working with the Hospital and Healthsystem Association of Pennsylvania (HAP) to further its patient safety initiative of engaging hospital boards of trustees and improving patient safety by educating them about the importance of learning from events that are happening in the facility.

The Authority and HAP are also working to formalize a standard for color-coded patient wristbands. The model proposed by the “Color of Safety Task Force” and featured in the August 2006 *Patient Safety Advisory* is the foundation of discussions. Healthcare professionals from across the state will continue to meet to finalize the protocol that facilities will be asked to adopt. The Authority has also met with several surrounding states to ensure all states are on the same page in regard to the color standardization.

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

The Authority has provided the Health Care Improvement Foundation (HCIF) with de-identified data on wrong-site surgery and patient falls from hospitals in Southeastern Pennsylvania. The information will allow HCIF to prioritize patient safety initiatives based upon these areas that need improvement.

National Academy for State Health Policy (NASHP) Learning Exchange

Healthcare administrators and policy makers in other states continue to look at Pennsylvania’s legislation and patient safety initiatives as their states evaluate steps they can take to improve patient safety within their healthcare systems. In 2007, the Authority sponsored and participated in the Pennsylvania Patient Safety Learning Exchange: Helping States Improve and Integrate Patient Safety Initiatives. Three presentations were given by the Authority that include: “Building a Case for Change: The Power of Meaningful Data;” “Translating Data into Practice: Creating Meaningful Change;” and “Creating the State Infrastructure: Strategies for Success.” The two-day conference held in Harrisburg gave the Authority and other states with reporting systems or those interested in developing one a chance to get together and discuss the challenges we all face in collecting and using the data to its fullest potential.

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

The Authority continued its support as a Pennsylvania node of the “100,000 Lives Campaign”, a national initiative developed by the Institute of Healthcare Improvement (IHI). In 2006, IHI expanded its campaign by going after harm in healthcare facilities. The “5 Million Lives Campaign” asks participating hospitals to prevent five million incidents of medical harm over the next two years. In 2007, the Authority met with representatives of the IHI campaign and HAP to discuss possible initiatives in helping facilities reach their goals in reducing harm. The Authority will provide data to help facilities prevent high-alert medication errors, adverse drug events, central line infections, pressure ulcers, ventilator-associated pneumonia (VAP) and methicillin-resistant *Staphylococcus aureus* (MRSA).

Pennsylvania General Assembly

The Authority recognizes the important role the Pennsylvania General Assembly plays in helping improve patient safety. The obvious role is in crafting legislation, such as Act 13 that subsequently created the Authority. However, another role, just as important, is helping patient safety organizations raise public awareness on important patient safety issues. In 2007, the Authority distributed informational pieces designed to educate the public about the importance of participating in their own healthcare. When appropriate, the Authority develops a consumer tips sheet for legislators to distribute to their constituents. To date, consumer tips sheets have been distributed on topics such as: medication errors, falls, wrong-site surgery, MRSA, color-coded wristbands, sleep apnea risks, and the importance of knowing your medical history. Another piece, the Speak Up™ brochure, developed by the Joint Commission gives the public advice on how to fully participate in their healthcare.

Legislators from across the state joined healthcare facilities and organizations in spreading the word about the importance of participating in discussions about your healthcare treatment. The Authority also continues the consumer page on its website with a list of links to guide consumers to state and national organizations that have a primary focus on patient safety. The Authority's executive director also spoke at a public hearing held in June 2007 by the Pennsylvania Senate Public Health and Welfare Committee. The hearing gave the Authority an opportunity to discuss with lawmakers the progress made by the Authority since its inception and insight into what objectives lie ahead for further patient safety improvements, particularly in regard to infections.

Pennsylvania Health Care Cost Containment Council (PHC4)

The Authority met regularly with the Pennsylvania Health Care Cost Containment Council (PHC4) to discuss the implementation of Act 52 and initiatives to help combat the infection rates in Pennsylvania healthcare facilities. A member of PHC4 also sits on the Authority's Healthcare-Associated Infection Advisory Panel.

Pennsylvania Patient Safety Forum

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

Pennsylvania eHealth Initiative

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

University HealthSystems Consortium (UHC) and U.S. Pharmacopoeia (USP)

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

The Authority's Annual Survey of Patient Safety Officers

In November 2007, the Authority invited the registered Patient Safety Officers (PSOs) in the Commonwealth to participate in an online survey. The intent of the survey was to solicit their opinions on topics such as their view and handling of healthcare associated-infections (HAIs) in regard to Pennsylvania Act 52 legislation, along with feedback regarding the Pennsylvania Patient Safety Reporting System (PA-PSRS) and its role in their facilities. Responses were collected over a 14-day period. Of the 494 invitees, PSOs from 103 hospitals (HSPs), 74 ambulatory surgery facilities (ASFs), two abortion facilities (ABFs) and one birthing center (BC) responded, resulting in a 36% response rate. For purposes of data analysis, the abortion facility and the birthing center were grouped with the ASFs when comparing responses from different types of facilities.

Healthcare-Associated Infections

Act 52 was signed into law in July 2007 to help reduce and eliminate healthcare-associated infections (HAIs) in Pennsylvania. PSOs from hospitals were asked questions regarding the challenges their facilities face regarding HAI. PSOs felt the most challenged by the control of antibiotic-resistant organisms and measuring hand hygiene compliance, followed by mandated public reporting and tracking of infections across their entire hospital (see Figure 25).

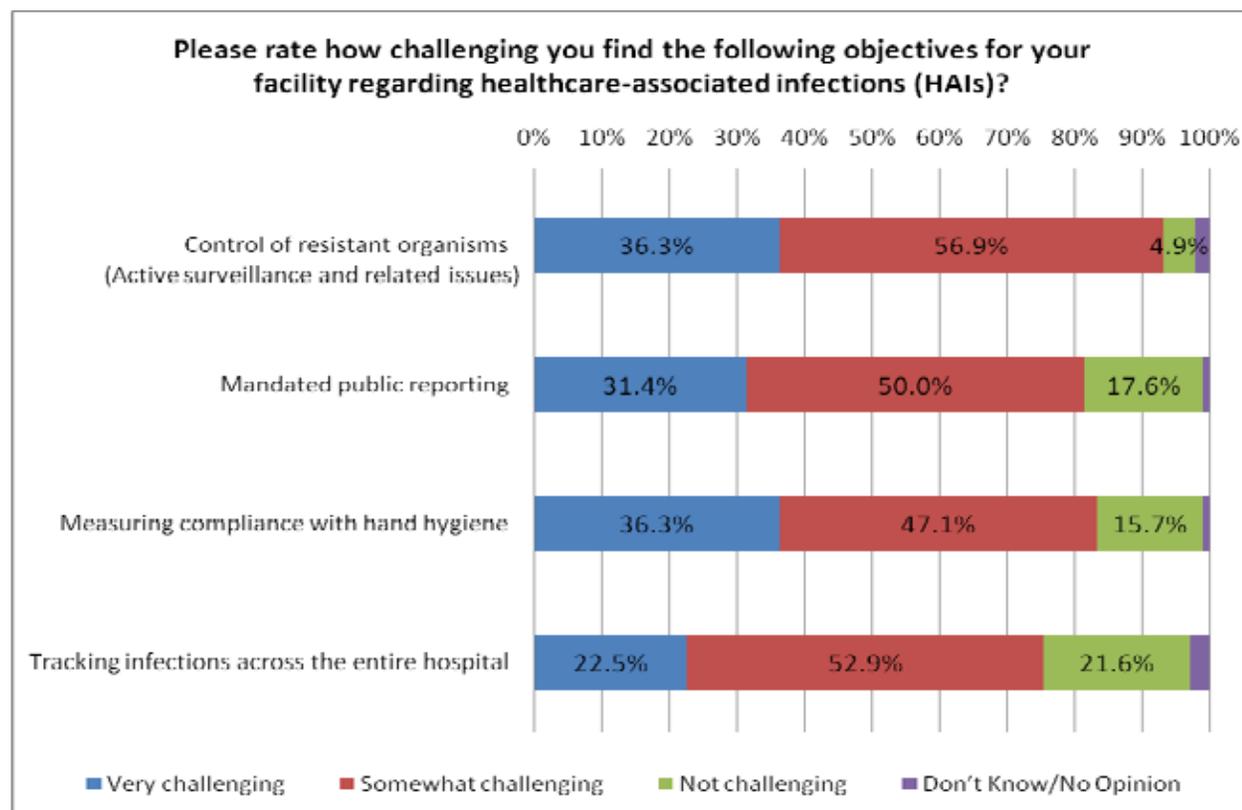


Figure 25. PSOs' Rating of Challenge of HAI Objectives

We asked PSOs to rate the significance of several barriers to infection prevention (see Figure 26). Funding/budget constraints and staffing were the most significant. It is interesting to note that while most PSOs felt that lack of support from their administration was not a major barrier in meeting their infection prevention challenges, funding and staffing constraints were. Since budgets and staffing levels are two key management levers, this may suggest that hospital leaders are committed to the goal of infection prevention but have not yet allocated sufficient resources to this problem.

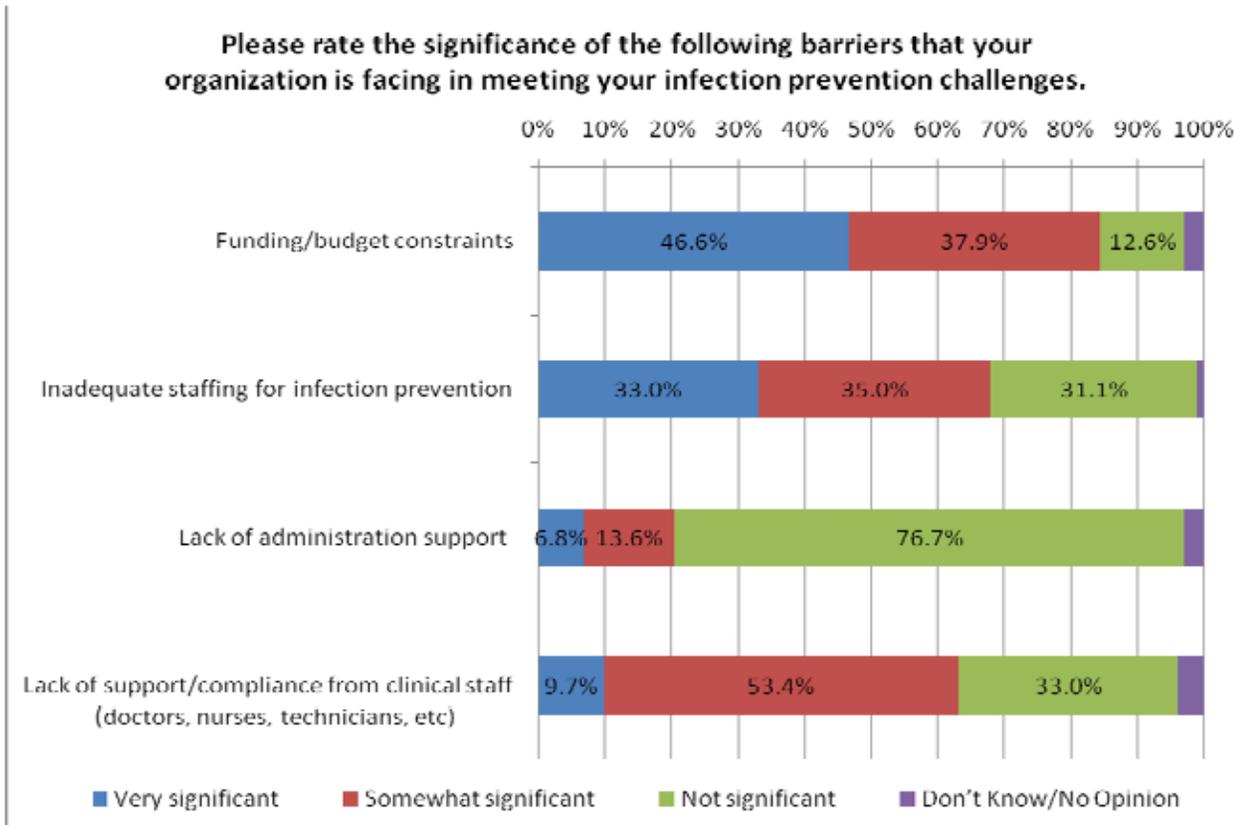


Figure 26. PSOs' Rating of Barriers Faced in Meeting Infection Prevention Challenges

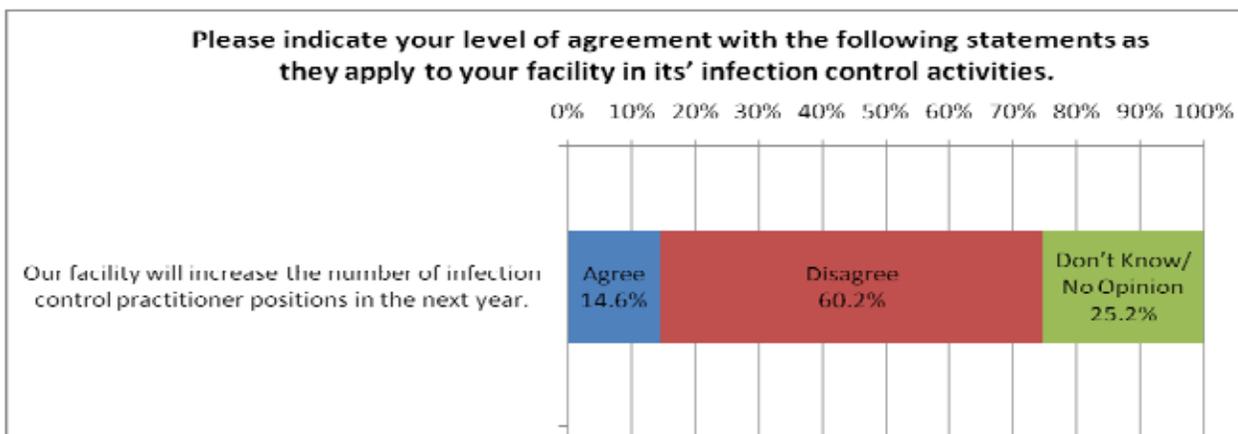


Figure 27. PSOs' Plans for Infection Control Staffing

Most PSOs do not expect their facilities to add additional infection control prevention positions in the next year, though a small percentage (14.6%) do expect to increase the number of infection control practitioners in their hospitals next year. This corresponds to the previous figure that shows facilities face barriers for funding and staffing for infection prevention.

Patient Safety Advisory

The *Patient Safety Advisory* is viewed by PSOs as being of good scientific quality and educational value (Figure 28). As in previous surveys, PSOs collectively gave the *Advisory* high marks on usefulness (96%), relevance (95%) and readability (97%).

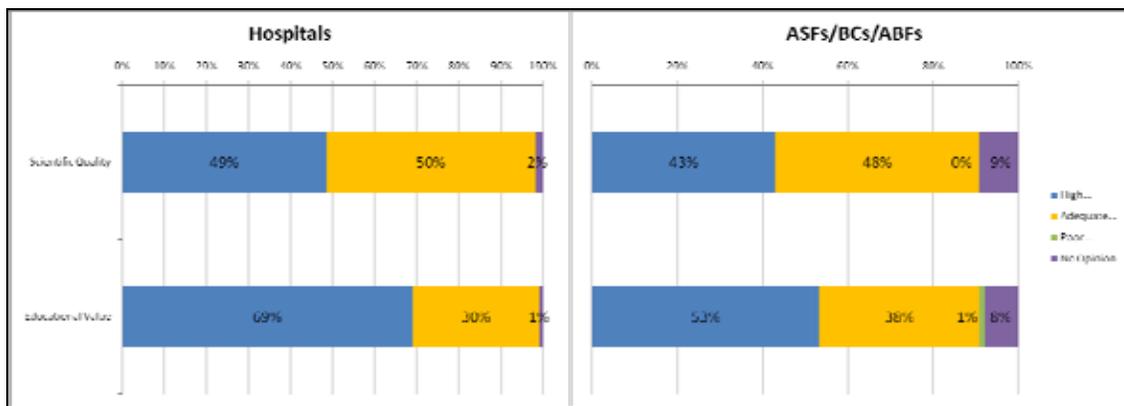


Figure 28. Comparison of PSO views of Patient Safety Advisory Quality

In the year since the last survey, the Patient Safety Authority has broadened its *Advisory*-related content by providing toolkits and other educational resources based on articles from the *Patient Safety Advisory*. PSOs were asked whether these new resources were used by their facility and 52% of them responded that they had. The most used resource among the list was the “Airway Fires during Surgery” poster. To see all the toolkits and educational resources, visit the Authority’s website at www.psa.state.pa.us.

Future Enhancements of the Patient Safety Authority

One initiative of the Patient Safety Authority is to increase the effectiveness of its work by establishing regional Patient Safety Liaisons (PSLs) who would interact more directly with reporting facilities. PSOs were asked to rate their likelihood of using the anticipated services of the PSLs. The services with the highest favorable responses were to utilize the PSLs for training on the PA-PSRS system and other patient safety fundamentals and to speak to front-line practitioners about clinical topics addressed in the *Advisory* (see Figure 29).

Another initiative of the Patient Safety Authority is to create the Patient Safety Knowledge Exchange (PasSKEy), an electronic forum for the confidential exchange of information, ideas and solutions among Patient Safety Officers. Again, PSOs were asked to rate how likely they would participate in the selected PasSKEy activities. Almost 75% responded that they would ask for guidance on a patient safety topic at their facility, while more than half were willing to share de-identified policies or procedures from their facilities and would propose group discussions on common topics of interest related to patient safety.

The Patient Safety Authority: Driving Change

The *Patient Safety Advisory* may be driving change more than previous years. Among PSOs participating in the survey, 68% report making or planning to make changes based on an *Advisory* article, compared with 63% who responded to the same question last year. This suggests that the Authority continues to achieve one of its’ original objectives of helping healthcare facilities across the state learn from adverse events and near misses that occur in other facilities. In fact, one PSO provided this comment:

“Articles help emphasize the issues and make staff realize the importance of reporting.”

This result is likely due in part to *Advisory* articles’ inclusion of specific suggestions for improvement. The 180 participants of the survey reported making 471 changes in their facilities as a result of specific *Advisory* articles from 2007, as seen in Figure 29. PSOs from hospitals (103) cited 364 changes, while PSOs from ASFs/BCs/ABFs (77) cited 107.

Examples of the kinds of improvements facilities made include:

- Introducing an ongoing campaign to prevent wrong patient, wrong procedure and wrong site surgeries.
- Implementing heparin protocols hospital-wide, reducing strength options of heparin to avoid errors.

- Reviewing storage of look-alike and sound-alike medications, as well as the use of tall man lettering to identify at-risk medications and posting lists of medications that are often mistaken.
- Changing methods of documenting placement and removal of fentanyl patches and other transdermal patches.
- Developing a feeding tube placement policy to insure that all care givers are using the same technique uniformly throughout the organization.
- Adopting a policy that required patients to come to ambulatory surgery with a responsible person who can escort them home and monitor them after the procedure.
- Performing sleep apnea/morbid obesity screening and sleep apnea scoring.
- Reassessing room configuration, reviewing suicide policy and heightening staff awareness for behavioral health patients.

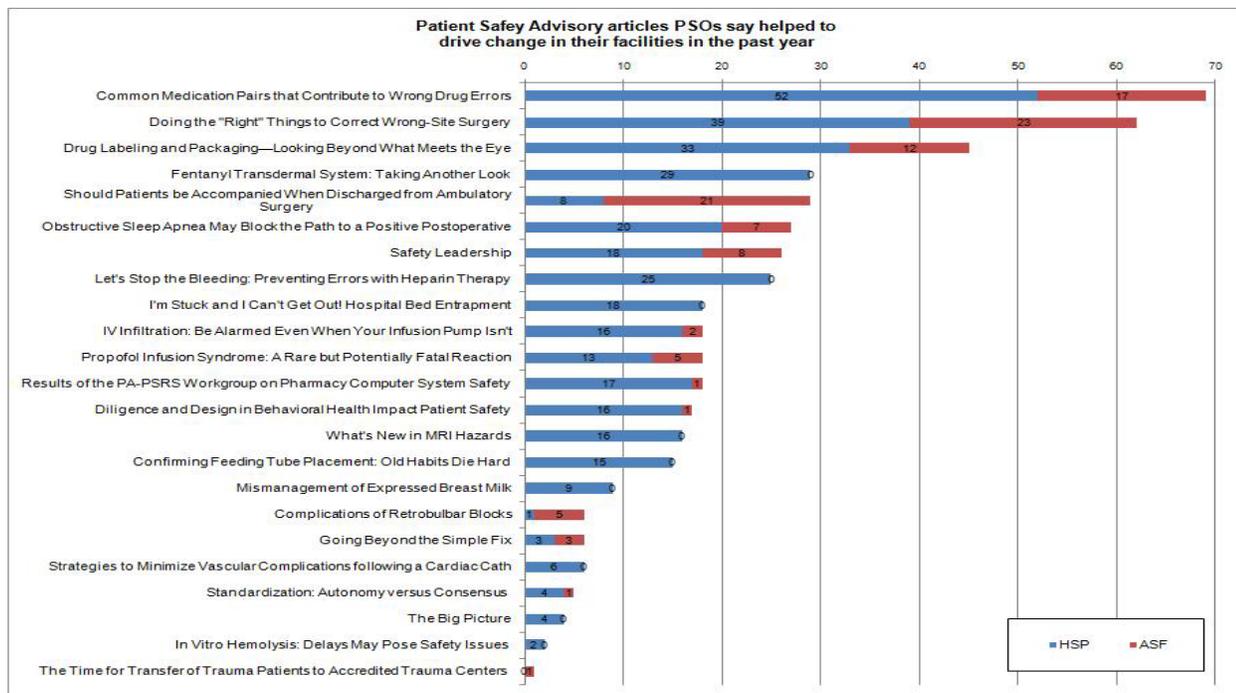


Figure 29. Patient Safety Advisory Articles Cited by PSOs as Prompting Them to Make Changes in 2007

Additional comments from PSOs regarding the Authority:

“I am particularly impressed by the pleasant helpful staff. We are a very low risk surgery center. Thank goodness we don't need much guidance, but when we do the staff has solved our issue with a great attitude. Thanks for your devotion to patient safety!”

“I think you offer a great service. The Advisories are very useful.”

“Overall, this is a very good organization. I think it is appropriate to report Incidents in this manner.”

“I find the articles informative- helpful as PSO and RM. Often they will spur a recheck of our process to ensure that the error identified could not happen here---the same way we use Sentinel Event Alert information.”

Other Items

Patient Safety Legislation

Federal Legislation

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

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

Pennsylvania Legislation

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

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

Recommendations for Statutory or Regulatory Change

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

Anonymous Reports

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

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

Healthcare workers are able to submit an Anonymous Report according to the protocols established through the PA-PSRS system. Persons completing the form do not need to identify themselves, and the Authority assigns professional clinical staff to conduct any subsequent investigations. The Authority developed the brochure “Anonymous Reporting: What Your Should Know,” which was distributed to all Pennsylvania healthcare facilities (see page 8). The Authority encourages healthcare workers to submit Anonymous Reports when they believe their facility is not responding appropriately to Serious Events.

Act 13 requires that the Annual Report include the number of Anonymous Reports filed and reviews conducted by the Authority. The Authority received one Anonymous Report in 2007 that complied with Act 13 requirements.

Referrals to Licensure Boards

Act 13 requires the Authority to identify the number of referrals to licensure boards for failure to submit reports under the Act’s reporting requirements. No such situations were identified during 2007. However, it is important to note that the Patient Safety Authority is unlikely to receive information related to a referral to a licensure board. That information is more appropriately referred to the Department of Health or will be reported directly by a facility to a specific licensing board.

Patient Safety Discount Program

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

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

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

Board of Directors and Public Meetings

Members of the Board of Directors are appointed by the Governor and the General Assembly, according to certain occupational or residence requirements. Current members, as of April, 2008 include:

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

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

January 9, 2007
March 5, 2007
April 10, 2007
July 10, 2007
September 11, 2007
October 9, 2007
November 13, 2007
December 11, 2007

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

[This page intentionally left blank]

Fiscal Statements and Contracts

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

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

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

In this regard, in designing PA-PSRS, the Authority included within the system a variety of integral and analytical tools that provide immediate, real-time feedback to facilities about their own adverse event and near-miss reports and activities and a report that aggregates reports into National Patient Safety Goal categories. Facilities can use these tools for their internal patient safety and quality improvement programs. The Authority also publishes the Patient Safety Advisory, a scholarly journal issued quarterly that includes detailed analysis and identification of trends of reports submitted through PA-PSRS. Finally, the Authority has provided regional root cause analysis, failure mode effect and analysis, and other training for free or at a greatly reduced cost to facilities. By directly offering clinical guidance and feedback to providers about actual events that occurred in Pennsylvania, the Authority provides a valuable “return on investment” to the healthcare industry that funds this program.

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

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

Facility Assessments

Fiscal Year	Number of facilities assessed by DOH	Total value of assessments	Total assessments received by DOH ¹
2002-03	356	\$ 4,999,922	\$ 4,663,000
2003-04	377	\$ 2,562,938	\$ 2,542,316
2004-05	414	\$ 2,500,159	\$ 2,508,787 ²
2005-06	450 ³	\$ 2,499,906	\$ 2,500,149
2006-07	270	\$2,500,034	\$2,500,034

¹Amounts 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.

²Total Assessments received are greater than assessments made because some funds received were late payments for the previous year's assessment.

³The number of facilities assessed by the Department of Health differs from the number of Act 13 facilities cited elsewhere in this report due to differences in the dates chosen to calculate the number of facilities for these two different purposes.

The following table summarizes Authority expenditures during 2007. 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 2007

Major Object Code	Amount
100: Personnel	\$ 259,923
300: Operating	\$ 3,504,134
400: Fixed Assets	\$ 0
TOTAL	\$ 3,764,057

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

During the calendar year 2007, 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# PO #4500386477 dated December 13, 2006
 (1 year service agreement-WS_FTP User License)
 Contract Amount: \$398.38
 Amount Expended in 2007: \$398.38

ASAP Software
 PO #4300051875 dated November 13,2007
 (1 year service agreement-WS_FTP User License)
 Contract Amount: \$409.75
 Amount Expended in 2007: \$00.00

ASAP Software
 PO#4300055878 dated December 4, 2007
 (One time purchase - Microsoft Office Project Professional 2003)
 Contract Amount: \$537.04
 Amount Expended in 2007: \$00.00

Computer Aid Inc.
 PO #4500351099 dated September 1, 2006
 (Staff augmentation for Senior Consultant 9/1/06-4/11/08)
 Contract Amount: \$412,457.56
 Amount Expended in 2007: \$231,734.52

Computer Aid Inc.
 PO #4300021201 dated June 27, 2007
 (Staff augmentation for Program Manager 7/1/07-4/11/08)
 Contract Amount: \$126,060.00
 Amount Expended in 2007: \$41,415.00

Computer Aid Inc.
PO #4300054585 dated December 4, 2007
(Staff augmentation for RFP 12/01/07-12/31/07)
Contract Amount: \$23,905.70
Amount Expended in 2007: \$00.00

DS Waters of America.
PO #4500381185 dated October 1, 2006
(Water cooler rental/water 10/1/06-6/30/07)
Contract Amount: \$65.00
Amount Expended in 2007: \$55.60

DS Waters of America.
PO #4300019334 dated March 23, 2006
(Water cooler rental/water 7/1/07-6/30/08)
Contract Amount: \$306.00
Amount Expended in 2007: \$24.45

EPLUS Technology Inc.
PO #4500367937 dated October 2, 2006
(Network Security (CISCO)-1 year service agreement)
Contract Amount: \$100.32
Amount Expended in 2007: \$100.32

EPLUS Technology Inc.
PO #4300052151 dated November 14, 2007
HP Fuser Kit – One time purchase
Contract Amount: \$222.13
Amount Expended in 2007: \$222.13

ECRI
FC# 4000005348 dated September 19, 2003
(Five-year contract for technical and clinical assistance in developing and implementing a statewide reporting system as required under ACT 13)
Contract Amount for \$13,409,170 over 5 years,
Expended FY 2006 \$2,609,105.80 – FY 2007 \$515,348.77
Amount Expended in 2007: \$3,124,454.57

Oce Imagisitics Inc
PO #4500279371 dated February 1, 2006
(2/1/06-1/31/09 contract for Photocopier maintenance).
Contract Amount for FY 2006-07 \$1,474.62 – FY 2007-08 \$2,005.39
Amount Expended in 2007: \$3,480.01

OES, Inc.
PO #4500257465 dated September 9, 2005
(9/9/05-6/30/07 contract for Consulting Services).
Contract Amount \$19,195.00
Amount Expended in 2007: \$2,475.00

PRK MOR, Inc
FC #4900000796 dated January 21, 2004
(Parking at the Forum Place – Yearly commitments).
Contract Amount \$2,880.00
Amount Expended in 2007: \$2,880.00

United Parcel Service Inc.
 PO #4500334325 dated July 1, 2006
 (Overnight/ground deliveries – 7/1/06-6/30/07)
 Contract Amount \$560.46
 Amount Expended in 2007: \$379.45

United Parcel Service Inc.
 PO #4300019512 dated July 1, 2007
 (Overnight/ground deliveries – 7/1/07-6/30/08)
 Contract Amount \$1,225.00
 Amount Expended in 2007: \$91.41

York Stenographic Services, Inc.
 PO #4500359985 dated September 13,2006
 (Court Reporting Services – 9/13/06-6/30/07)
 Contract Amount \$4,344.40
 Amount Expended in 2007: \$2,816.60

York Stenographic Services, Inc.
 PO #4300019945 dated June 20, 2007
 (Court Reporting Services – 7/13/07-12/31/07)
 Contract Amount \$12,679.40
 Amount Expended in 2007: \$2198.73

The following Balance Sheet reflects the status of the Patient Safety Trust Fund as of December 31, 2007.

Patient Safety Trust Fund Balance Sheet (Unaudited)
As of December 31, 2007

ASSETS	
Cash	\$ 0.00
Cash in Transit	(2,999.86)
Short Term Investments @ Market (Pool98)	2,769,340.43
TOTAL ASSETS	\$ 2,766,340.57
LIABILITIES AND FUND BALANCE	
Liabilities:	
Accounts Payable and Accrued Liabilities	\$ 2,364.04
Invoices Payable	515,430.64
Accrued Payables Goods Receipt	69,962.70
TOTAL LIABILITIES	\$ 587,757.38
Fund Balance:	
Reserved for Encumbrances	\$ 3,025,161.71
Unreserved - Undesignated	(846,578.52)
TOTAL FUND BALANCE	\$ 2,178,583.19
TOTAL LIABILITIES AND FUND BALANCE	\$ 2,766,340.57

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



Phone | 717-346-0469

Fax | 717-346-1090

E-mail | patientsafetyauthority@state.pa.us

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

Office Location

**539 Forum Building
Harrisburg , PA 17120**

Mailing Address

**P.O. Box 8410
Harrisburg, PA 17105-8410**