P A Patient Safety Authority

Safe healthcare for all patients

2016

Pennsylvania Patient Safety Authority Annual Report

April 28, 2017



Letter from the Board Chair

Dear Fellow Pennsylvanians:

The year 2016 proved to be a year of continuing improvement and transformation for the Pennsylvania Patient Safety Authority. Diligent efforts continued around data collection and analysis, patient safety information dissemination, education and outreach, and collaborative partnerships. In addition, the agency embraced new leadership, employed innovative strategies, and developed its 2017–2020 strategic plan, which includes expanded outreach to patients and other sectors.

Pennsylvania healthcare facilities continued efforts to identify and report patient safety events. Acute healthcare facilities reported 255,714 events, a 7% increase over 2015. The Authority continues to observe an increase in the percentage of events reported as Incidents (events that do not harm the patient) rather than Serious Events (events that harm the patient). Further, the Authority received 218 reports of events that may have contributed to or resulted in a patient's death, a 13.8% decrease from 2015. Notably in 2016, the Authority observed positive signs associated with efforts to standardize reporting implemented during 2015. With regard to nursing homes reporting healthcare-associated infections (HAIs), 2016 was the second calendar year for reporting using revised criteria. Nursing homes reported 27,544 HAI events, a 13% decrease from 2015.

In March 2016, the Authority bid farewell to Michael C. Doering, MBA, former executive director. We wish Mike well in his retirement, and appreciate his nine years of executive leadership that saw implementation of the patient safety liaison (PSL) program, HAI reporting, and other milestones in data analysis, publication, collaboration, and education and outreach initiatives.

Following Mike's retirement, the Board of Directors welcomed Regina Hoffman, MBA, BSN, RN, CPPS, as executive director. Regina joined the Authority in 2012, most recently served as director of the PSL program, and possesses relevant and fresh perspective about the agency's future. Under Regina's leadership to date, the Authority has

invoked innovation strategies that foster ideas and concepts to address longstanding and emerging patient safety topics. In the Authority's focus on innovation, it looks to strengthen existing services provided to healthcare facilities and cultivate new viewpoints when facilities seek to address patient safety concerns.

In 2016, staff and directors developed the Authority's third strategic plan. The 2017–2020 plan concentrates on four strategic pathways to focus on (1) improving diagnosis, (2) the patient, (3) long-term care, and (4) evaluating the reporting system. While foundational efforts have and will remain the priority, expanding outreach and education to patients and other sectors will prove beneficial for all patients.

In its past, present, and future, the Authority has been and projects to be effective and relevant in analyzing reports about patient safety events and disseminating, educating, and collaborating about strategies to reduce patient harm. Through 2016, the Authority's Pennsylvania Patient Safety Advisory has provided more than 540 patient-safetyfocused articles, associated with nearly 50 educational toolkits, as well as credited with more than 4,650 process improvements by healthcare facilities. In 2016 alone, the Authority's PSLs, infection prevention analysts, and patient safety analysts educated nearly 10,500 attendees of Authority patient safety programs and presentations. And success through 2016 in the Authority's collaborative improvement projects on targeted interventions in healthcare facilities has led to additional programs with Authority partners.

As chair of the Board of Directors, I look forward to our continuing work and new initiatives with Pennsylvania healthcare facilities and in the Authority's vision of safe healthcare for all patients.

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

Rachel Levine, MD

Physician General, Commonwealth of Pennsylvania

Chair, Board of Directors

Pennsylvania Patient Safety Authority

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Pennsylvania Patient Safety Authority

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Executive Summary

The Pennsylvania Patient Safety Authority recognizes the significant strides in patient safety improvement made by Pennsylvania healthcare facilities, as well as the important work that remains. In 2016, the Authority published a study of the effectiveness of data collection, data analysis, information dissemination, and statewide collaborative learning by the Authority and its partners to reduce healthcare-associated patient harm in the Commonwealth. In the five measures selected for analysis, these core patient safety efforts led to an estimated 2,600 lives saved and \$147 million saved since 2004.

The Authority, an independent state agency established under the Medical Care Availability and Reduction of Error (MCARE) Act¹ of 2002, collects and analyzes data reported through its Pennsylvania Patient Safety Reporting System (PA-PSRS) and then provides strategies and lessons learned to healthcare facilities to improve safety and help prevent patient harm.

Under the MCARE Act, healthcare facilities must report Serious Events (events that harm the patient) and Incidents or "near misses" (events that do not harm the patient) to the Authority. Facilities must notify patients or their families when a Serious Event has occurred. The Pennsylvania Department of Health also receives Serious Event reports for its regulatory role.

The Authority initiated statewide mandatory reporting in June 2004. All reports are confidential and non-discoverable. In 2007, MCARE was amended (Act No. 2007-52: Reduction and Prevention of Health Care-Associated Infection and Long-Term Care Nursing Facilities²) for nursing homes to report healthcare-associated infections (HAIs) as Serious Events to the Authority.

This executive summary highlights the Authority's 2016 activities; specific details are included in the corresponding sections of the overall annual report.



View Infographic online at www.patientsafetyauthority.org.

A change in leadership occurred in 2016, as former executive director Michael C. Doering retired. The Board of Directors named Regina M. Hoffman executive director in March 2016. The board and staff engaged in the Authority's third strategic planning process, in which participants developed a mission statement, vision, and four strategic pathways of focus on (1) improving diagnosis, (2) the patient, (3) long-term care, and (4) evaluating the reporting system. It is important to address these pathways while continuing the foundational efforts of data collection and analysis, information dissemination, education, and collaborative learning.

The aforementioned analysis about the value of patient safety improvement efforts in Pennsylvania also discusses the decrease in high-harm events (i.e., Serious Events that result in permanent harm, near death, or death), a trend that continues in events reported during 2016. Acute

MISSION

Improve the quality of healthcare in Pennsylvania by collecting and analyzing patient safety information, developing solutions to patient safety issues, and sharing this information through education and collaboration.

VISION

Safe healthcare for all patients

healthcare facilities reported 255,714 events, with an increasing percentage of events reported as Incidents (n = 248,166), rather than Serious Events (n = 7,548). This brings the total number of events reported (2004 through 2016) to 2.76 million. The reporting category, Error related to Procedure/Treatment/Test, continues to be the most common category of Incident reports, and Complication of Procedure/Treatment/Test the most common category of Serious Events. Of Serious Events, facilities reported 218 events that may have contributed to or resulted in a patient's death, a 13.8% decrease from 2015 as well as an overall decrease from 2005 through 2016.

Staff and board members, as well as participants from other agencies and organizations in the Commonwealth, engaged in efforts to improve consistency in acute health-care facility event reporting with standards effected in April 2015. In 2016, the Authority observed positive indicators associated with these standardization efforts, including improvement in Serious Event reporting, a near doubling of events reported under the new and revised event types and subtypes, and continued participation by reporting facilities in education about standardization principles.

Nursing homes reported 27,544 HAI events in 2016, a 13% decrease from the previous year. The year 2016 represents the second full year of data since revised reporting criteria was implemented in 2014. Some highlights of 2016 event data include that catheter-associated urinary tract infections (CAUTIs) continue to be the predominant urinary tract infection by pooled infection rate, gastrointestinal infection reports decreased (statistically significant) compared with such reports in 2015, and reports of influenza in Pennsylvania align with nationally reported data.

Events reported by Pennsylvania healthcare facilities, requests for information from Pennsylvania healthcare providers, and review of the medical and patient safety literature prompts analysis of the aggregate event reports. This leads to dissemination of analysis and guidance through the Authority's journal, the Pennsylvania Patient Safety Advisory. From the first issue in March 2004 through December 2016, the Advisory has provided nearly 540 safety-focused articles and nearly 50 associated "toolkits" of assessment tools and education, available at www. patientsafetyauthority.org. To date, Pennsylvania healthcare facilities credit the Advisory with contributing to more than 4,650 structure and process improvements. Topics addressed during 2016 include surgical procedures, medication-related events, infection prevention, maternity, leadership, patient/family involvement, and teamwork.

Of the Authority's website traffic in 2016 (n = 1,563,044 hits) Advisory articles and toolkits comprised the majority, with 753,893 and 145,548 hits, respectively.

Staff—including patient safety liaisons (PSLs), patient safety analysts, infection prevention analysts, and physicians—as well as patient safety and subject matter experts, use the Authority's analysis, disseminated information, and additional research to educate healthcare providers about patient safety strategies. In 2016, educational programs were associated with education of nearly 4,000 participants onsite at healthcare facilities, nearly 1,800 through regional/other presentations, nearly 4,000 through webinars, and nearly 800 through the Authority's online education system. The Authority further enhanced its PSL outreach to reporting facilities with "Keystones" (i.e., targeted, topical outreach to facilities accompanied by consultative tools and resources).

In its work to reduce HAIs, the Authority's infection prevention staff educated participants during activities mentioned above. Staff researched and published educational and assessment tools (e.g., accompanying Advisory articles) to address reported HAI events; in feedback, hospital and nursing home representatives reported that these tools were highly useful in increasing staff knowledge and identifying specific areas of focus for prevention efforts. Furthermore, staff continued work with the Pennsylvania Department of Health, the Hospital and Healthsystem Association of Pennsylvania (HAP), and local health departments to help Pennsylvania acute healthcare facilities prepare for episodic biological threats by providing consultation associated with site visits.

The Authority has long recognized the value of collaborative learning and continued its focus on such improvement efforts in 2016. Staff concluded work with HAP on Hospital Engagement Network (HEN) 2.0 immersion projects, addressing falls with harm and adverse drug events, as well as HAIs. Success in HEN 2.0 and during previous contracts led to the Authority again working with HAP, which was awarded a primary federal contract for the Hospital Improvement Innovation Network (HIIN) in September 2016. The Authority is leading HIIN projects addressing adverse drug events, falls, and culture of safety. The Authority is also co-leading a HIIN project with the Health Care Improvement Foundation to reduce emergency department radiologic diagnostic errors.

Finally, healthcare facilities again had the opportunity to showcase commitment to patient safety and reward the people involved through the annual "I Am Patient Safety" contest. The Authority recognized 14 individuals or groups from nominations from Pennsylvania facilities, all of whom are featured in this annual report.

The Authority recognizes that Pennsylvania healthcare facilities bear financial responsibility for costs associated with complying with mandatory reporting requirements. The Authority focuses on two fiscal goals: (1) to be prudent in the use of moneys contributed by the healthcare industry, and (2) to assure that healthcare facilities paying for PA-PSRS receive direct benefits from the system and Authority programs. The Authority's FY 2016–2017 budget totals

Notes

- Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No. 13, Cl. 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/ucons-Check.cfm?yr=2002&sessInd=0&act=13.
- Medical Care Availability and Reduction of Error (MCARE)
 Act Reduction and Prevention of Health Care-Associated Infection and Long-Term Care Nursing Facilities
 Act of July 20, 2007, P.L. 331, No. 52, Cl. 40. http://
 www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.
 cfm?yr=2007&sessInd=0&act=52.

\$8.5 million, with approximately \$7.2 million funding expenditures other than for HAI programs.

The Authority remains strongly committed to its foundational patient safety efforts, as evidenced by its continued attention to and enhancement of its data collection and analysis, information dissemination, education efforts, and collaborative learning outputs. Innovation is key to ongoing success, a critical concept for both the Authority's foundational efforts and its forthcoming strategic pathways to enhance patient safety for all patients in the Commonwealth.

Strategic Plan

During 2016, the Pennsylvania Patient Safety Authority Board of Directors and staff engaged in a third strategic planning process. A contracted facilitator conducted research and stakeholder interviews. Research included summaries of current thinking in the field, the issue of patient safety in nonacute-care settings, and an overview of state adverse-event reporting systems.

Using a creative problem-solving process, the Authority conducted a daylong strategic planning meeting in September 2016. The board and staff members participated in activities to develop a mission statement, vision, and strategic pathways. A strategic plan was drafted with the assistance of Authority board members and a representative from the HAI Advisory Panel. The Authority developed key strategic pathways to enhance its foundational work

under the Medical Care Availability and Reduction of Error (MCARE) Act.¹

The Authority continues to be committed to its key programs. However, the Authority also believes that expanding its outreach to patients and other sectors will enhance patient safety for all patients in the Commonwealth. Providing education to patients will help them become informed and engaged participants in their healthcare. Expanding education and outreach to sectors that are part of the circle of care will help healthcare facilities achieve their patient safety goals for the populations they serve.

More information about the Authority's 2017–2020 strategic plan is shown in the figure below.

Note

 Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No 13 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck. cfm?yr=2002&sessInd=0&act=13

Strategic Plan 2017-2020

VISION Safe healthcare for all patients

FOCUS ON IMPROVING DIAGNOSIS

Analyze internal and external data to identify trends

Update PA-PSRS to improve data capture

Lead an ED radiology collaborative

Expand educational offerings

Include focus on ambulatory clinics and practices

FOCUS ON THE PATIENT

Expand inclusion of patient perspective

Identify key topics

Educate patients on safe healthcare

Improve awareness of and access to resources

FOCUS ON LONG-TERM CARE

Identify key topics

Expand educational offerings

Lead an infection prevention collaborative

FOCUS ON EVALUATING THE REPORTING SYSTEM

Evaluate scope of patient safety events captured via PA-PSRS

Identify opportunities to improve data capture

We will continue to provide these foundational services to support our current and future work

Pennsylvania Patient Safety Reporting System (PA-PSRS)

Toolkits

Data analysis

Advisories/ recommendations Facility contact and consultation

Patient Safety Liaisons & Infection Preventionists

Online and live education

Website

Collaborative learning



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Definitions

Pennsylvania healthcare facilities are required to submit reports on the following four kinds of occurrences:

- 1. **Serious Event.** An adverse event resulting in patient harm. The legal definition from the Medical Care Availability and Reduction of Error (MCARE) Act:¹ "An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident."
- 2. **Incident.** A "near miss," in which the patient was not harmed. The legal definition from the MCARE Act:¹ "An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event."
- 3. **Infrastructure Failure.** A potential patient safety issue associated with the physical plant of a healthcare facility, the availability of clinical services, or criminal activity. The legal definition from the MCARE Act: "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 submitted only to the state Department of Health and, therefore, are not addressed in this report.
- 4. Other. The U.S. Centers for Medicare and Medicaid Services (CMS) requires hospitals to report to the Department any death of patients in restraints or in seclusion or in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints). Deaths in which the restraints or seclusion are suspected of or confirmed as having played a role in the death should be reported as Serious Events. Other deaths in which the restraint or seclusion use was incidental or not suspected should be reported under this "Other" category.

Reports of Serious Events and Incidents are submitted to the Pennsylvania Patient Safety Authority for the purposes of learning how the healthcare system can be made safer in Pennsylvania. Reports of Serious Events and Infrastructure Failures are submitted to the Department so it can fulfill its role as a regulator of Pennsylvania healthcare facilities.

The MCARE Act requires the following types of facilities to submit reports of Serious Events, Incidents, and Infrastructure Failures to the Authority through the Pennsylvania Patient Safety Reporting System (PA-PSRS):

Hospitals. The Health Care Facilities Act² 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 rehabilitation 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 this report, at the end of 2016, the Commonwealth of Pennsylvania had 238 qualifying hospitals.

Ambulatory surgical facilities. The Health Care Facilities Act² 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 of 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 this report, at the end of 2016, the Commonwealth of Pennsylvania had 309 qualifying ambulatory surgical facilities.

Birthing centers. The Health Care Facilities Act² defines a birthing center as "a facility not part of a hospital which provides maternity care to childbearing families not requiring hospitalization. A birth[ing] center provides a home-like atmosphere for maternity care, including

prenatal labor delivery and postpartum care related to medically uncomplicated pregnancies." For this report, at the end of 2016, the Commonwealth of Pennsylvania had six qualifying birthing centers.

Abortion facilities. Act 30 of 2006³ extended the reporting requirements in the MCARE Act to abortion facilities that perform more than 100 procedures per year. For this report, at the end of 2016, the Commonwealth of Pennsylvania had 19 qualifying abortion facilities.

Nursing homes. Act 52 of 2007⁴ revised the MCARE Act to require nursing homes to report healthcare-associated infections (HAIs) to the Authority. Specifically, the act states that "the occurrence of a health care-associated infection in a health care facility shall be deemed a serious event as defined in section 302." Reporting from these facilities began in June 2009. For this report, at the end of 2016, the Commonwealth of Pennsylvania had 703 qualifying nursing homes. See the **Healthcare-Associated Infections** section of this report for data received from nursing homes.

Other pertinent definitions used in this report are as follows:

Medical error. This term is commonly used when discussing patient safety, but it is not defined in the MCARE Act. The word "error" appears in PA-PSRS and in this report. For example, one category of reports discussed is "medication errors." The Institute of Medicine's Committee on Data Standards for Patient Safety defines an error as the "failure of a planned action to be completed as intended (i.e., error of execution) or 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)."⁵

Within the MCARE Act, the term "medical error" is used in section 102: "Every effort must be made to reduce and 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."

Adverse event. This term also appears in this report, although it is not defined in the MCARE Act. The Institute of Medicine Committee on Data Standards for Patient Safety defines an adverse event as follows: "An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient." The Authority considers this term to be broader than "medical error," because some adverse

events may result from clinical care without necessarily involving an error.

Although PA-PSRS includes reports of events that result from errors, the Authority's focus is on the broader scope of actual and potential adverse events—not only those that result from errors.

Patient safety officer. The MCARE Act requires each medical facility to designate a single individual to serve as that facility's patient safety officer. Under the MCARE Act, the patient safety officer is responsible for submitting reports to the Authority. The MCARE Act also assigns other responsibilities to the patient safety officer.

Patient safety liaison. The patient safety liaison (PSL) is a unique resource to Pennsylvania MCARE facilities. Serving as the face of the Authority, the PSL provides education and consultation to MCARE facilities and ensures that facilities are aware of the resources available to them through the Authority, such as educational toolkits, presentations, and webinars. The program has eight PSLs located regionally throughout Pennsylvania.

Analyst. The patient safety analyst (analyst) is a member of the Authority team of clinical professionals with degrees and experience in medicine, nursing, pharmacy, health administration, risk management, product engineering, and statistical analysis. The analyst reviews, aggregates, and investigates reports submitted through PA-PSRS. One example of an analyst is an infection prevention (IP) analyst, who tracks and trends reported HAIs. The IPs work closely with other agencies and groups (the Department, Association for Professionals in Infection Control and Epidemiology [APIC]) to address HAI topics in Pennsylvania.

Reporting standardization. Twenty-eight guiding principles went into effect on April 1, 2015, to improve consistency in event reporting through PA-PSRS. The guidance was developed to help provide consistent standards to acute healthcare facilities in Pennsylvania in determining whether occurrences within facilities meet the statutory definitions of Serious Events, Incidents, and Infrastructure Failures as defined in section 302 of the MCARE Act.⁶ The Authority, the Department, and healthcare facility staff have worked together toward a shared understanding of the requirements. The reporting guidelines were identified based on frequently asked questions (FAQs), controversies, and inconsistencies that were evident in the data collected by the Authority and the Department.

Notes

- Medical Care Availability and Reduction of Error (MCARE)
 Act of March 20, 2002, P.L. 154, No 13 40. Available:
 http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2002&sessInd=0&act=13.
- Health Care Facilities Act of Jul. 19, 1979, P.L. 130, No. 48, Cl. 35 § 448.802a. Available: http://www.legis.state.pa.us/WU01/LI/LI/US/PDF/1979/0/0048..PDF.
- Medical Care Availability And Reduction Of Error (MCARE)
 Act Extending Patient Safety Standards To Certain Abortion Facilities Act of May 1, 2006, P.L. 103, No.30 Cl.
 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2006&sessInd=0&act=30.
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 Act Reduction and Prevention of Health Care-Associated
 Infection and Long-Term Care Nursing Facilities Act
 of July 20, 2007, P.L. 331, No.52, Cl. 40. Available:
 http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2007&sessInd=0&act=52.

- Institute of Medicine Committee on Quality of Health Care in America. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): National Academy Press; 1999 Nov. 223 p. Also available: http://www.nationalacademies.org/hmd/ Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx.
- Final guidance for acute healthcare facility determinations of reporting requirements under the Medical Care Availability and Reduction of Error (MCARE) Act, 44 Pa. Bull. 6178 (2014 Sep 27). Also available: http://www.pabulletin.com/secure/data/vol44/44-39/2041.html.

Overview of Data Reported through PA-PSRS

Introduction

During 2016, more than a quarter million events were reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), with an increasing percentage of reports submitted as Incidents, rather than Serious Events. The category Error related to Procedure/ Treatment/ Test continues to be the most common category of Incident reports, and Complication of Procedure/ Treatment/ Test the most common category of Serious Events.

In 2016, the Pennsylvania Patient Safety Authority published an analysis based on clinical outcomes and economic estimates for patient-safety measures in which concentrated improvement efforts have occurred. Measures chosen for analysis included falls with harm, central line-associated bloodstream infection, catheter-associated urinary tract infection, wrong-site surgery, and high harm events. The intent was to estimate the value of data aggregation (e.g., through PA-PSRS), analysis, dissemination, and statewide collaborative learning to reduce healthcare-associated patient harm in the Commonwealth during reporting periods of 11 to 12 years (e.g., inception of PA-PSRS reporting in 2004 through 2015). The Authority

estimated that more than 2,600 lives and more than \$147 million were saved.

The analysis also discusses the decrease in high harm events numbers overall, including the following:

Given that the number of medical interactions is increasing, a plausible hypothesis for this decline in high harm events is that as improvements are realized in patient safety, the number and severity of harmful adverse events is decreasing. The Authority has seen an increase in the number of Incident (non-harm) events reported through PA-PSRS, and this is consistent with this hypothesis that there is a shift to earlier detection and reporting of events with fewer events reaching the patient and causing serious harm.¹

As noted, this decline of high harm events continues to be evident through the 2016 reporting period, as well as the increasing percentage of reports describing Incidents. This annual report section explains the PA-PSRS reporting process and focuses on reported event data and evident reporting trends.

Pennsylvania Patient Safety Reporting System (PA-PSRS)

PA-PSRS is a secure, web-based system that permits medical facilities to submit reports of "Serious Events" and "Incidents" involving patients, as defined by the Medical Care Availability and Reduction of Error (MCARE) Act.² Statewide mandatory reporting through PA-PSRS went into effect June 28, 2004. All information submitted through PA-PSRS is confidential, and no information about individual facilities is made public. The Department of Health can issue sanctions and penalties, including fines and forfeiture of license, to healthcare facilities that fail to comply.

As defined by the MCARE Act, PA-PSRS is a facility-based reporting system. Other complaint systems are available for individual citizens. Citizens can file complaints related

to hospitals and ambulatory surgical facilities by calling the Department of Health at 1-800-254-5164. The website to file complaints is http://www.health.pa.gov/facilities/Consumers/Complaints/Pages/default.aspx. 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.

Facilities submit event reports through a process identified in each facilities' own patient safety plans, as required by the MCARE Act. However, the MCARE Act provides for one exception to this facility-based reporting requirement: a healthcare worker who feels that his or her facility has not complied with the MCARE Act reporting requirements

may submit an Anonymous Report directly to the Authority (see Anonymous Reports).

Facility users can access PA-PSRS by means of a computer with Internet access and minimal, self-directed online training.* Patient safety liaisons assigned to each acute healthcare facility provide additional guidance, and an on-call Help Desk is available during business hours.

To report an event, facility users respond to 22 core questions (e.g., check boxes, free-text narratives); the system directs to follow-up questions, based on the answers to previous questions. The process is similar for nursing homes, which began reporting healthcare-associated infections (HAIs) in June 2009, with the system posing 18 core and follow-up questions, depending on the type of infection reported.†

Facility users provide 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. Patient and healthcare provider names are not solicited. Additionally, the report collects considerable detail about "contributing factors," such as staffing, the workplace environment and management, the impact of health information technology (HIT), and clinical protocols. Users are also asked to identify the root causes of Serious Events and to suggest procedures that can be implemented to prevent a reoccurrence.

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

Analysis, Resources, and Feedback

The Authority team that analyzes reports includes professionals with degrees and experience in medicine, nursing, pharmacy, health administration, risk and quality management, product engineering, and statistical analysis. Additionally, through its contract staff, the Authority has access to a large pool of subject matter experts in virtually every medical specialty.

Based on this comprehensive analysis and augmented by review of healthcare literature and interviews with experts, the Authority develops and publishes articles and additional resources through the *Pennsylvania Patient Safety Advisory*. The *Advisory* articles are directed primarily to healthcare professionals, for use by both clinical and administrative staff to improve processes and outcomes. The articles are often supplemented by toolkits, many of which are interactive, that may be used to clarify and standardize reporting practices as well as to assess and improve patient care practices at the organizational, microsystem, or

individual patient-care level. More information about the Advisory and the data collected through PA-PSRS is covered in The *Pennsylvania Patient Safety Advisory* section. Additionally, all issues of the *Advisory* are accessible on the Authority's website at www.patientsafetyauthority.org.

The Authority has also developed analytical tools within PA-PSRS that are available to reporting facilities. These tools provide patient safety professionals, quality improvement specialists, and risk managers with detailed reports analyzing data related to their specific facilities in a timely manner. Many reports can be exported to other software programs for inclusion in facility publications or reports and presentations to trustees and senior management. Additionally, facility personnel have the ability to export all, or any portion, of their own facility's data. Managers can use this information for their internal quality improvement and patient safety activities.

Interpreting PA-PSRS Data

Many factors influence the number of reports submitted by any particular facility, of which each facility's safety and

quality are just two. Additional factors that affect reporting include facility size, case volume, services provided,

^{*} Available to PA-PSRS users only; contact the Help Desk for more details.

[†] HAIs from nursing homes are addressed under Healthcare-Associated Infections.

patient case mix, severity of illness, understanding of what occurrences are reportable, and success in detecting reportable occurrences.

The following factors should be considered when reviewing PA-PSRS data:

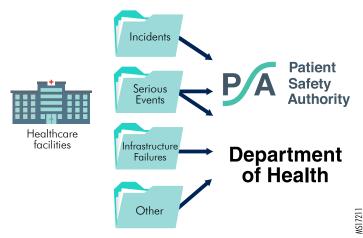
- Data presented in this report include only reports of Serious Events and Incidents. Although PA-PSRS also collects reports of Infrastructure Failures and reports that fall outside of these categorizations (Other), these reports are submitted only to the Pennsylvania Department of Health. The Authority does not receive reports of Infrastructure Failures or Other (Figure 1).
- Unless specifically noted, data presented in this report are based on reports submitted through PA-PSRS between January 1, 2016, and December 31, 2016. Data from acute-care facilities are presented in this section. HAI data from nursing homes are presented in Healthcare-Associated Infections.
- 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.
- Unless specifically noted, historic data and trend span the years 2005 through 2016. These years are the twelve full calendar years of PA-PSRS data collection.
- The data are not adjusted to account for medical 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. PA-PSRS was developed within the context of the MCARE Act, which has its own unique definitions for what is and what is not reportable through PA-PSRS.² PA-PSRS also uses a specific taxonomy of event types that may be different from the lists used by other systems. PA-PSRS was the first mandatory state program collecting data on

"near misses"—unsafe conditions and events that did not harm patients.³ After more than a dozen years of data collection, it is widely considered the most comprehensive program of this type in the United States.

Many factors influence differences between data obtained from different facilities. The most valuable comparisons 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.

Figure 1. Submission of PA-PSRS Reports



Finally, overarching explanations of why certain event types predominate in aggregate data are complex, especially because each event type may relate to numerous and diverse clinical situations. The Authority identifies and approaches themes from the annual report and specific topics from the event reports (i.e., that have the potential for generalizable learning and improvement to patient safety) based on their frequency, severity, interest to clinicians, or other relevance. Subsequently, the Authority develops information and opportunities for improvement, and disseminates said information to healthcare facilities in Pennsylvania and other consumers through its *Advisory*, education and collaboration focuses, and other outreach activities (see the respective sections of this report for specific examples).

Report Volume

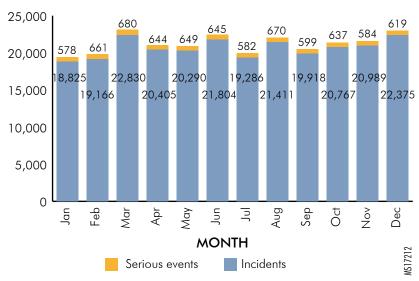
Reports by Month and Submission Type

Between January 1 and December 31, 2016, Pennsylvania acute care facilities submitted 255,714 reports through PA-PSRS, bringing the total number of reports submitted since the program's inception to 2,765,059. Figure 2 shows the distribution of submitted reports by month for calendar year 2016. For the year, 7,548 Serious Events and 248,166 Incidents were reported.

Of reports submitted in 2016, 3% were Serious Events, while 97% were Incidents. In 2016, the Authority received an average of 21,310 reports per month. This total breaks down to an average of 20,681 Incident reports and 629 Serious Event reports per month.

Figure 2. Number of Reports Submitted through PA-PSRS in 2016, Acute-Care Facilities

NUMBER OF REPORTS



Reports by Facility Type

As shown in Table 1, the total number of reports submitted through PA-PSRS in 2016 surpassed a quarter million. The vast majority of all reports (87.5%) were submitted by hospitals. Among acute-level facilities (non-nursing homes),

the predominance of reports from hospitals is even more pronounced (96.9%). Nursing homes submitted 9.7% of the overall total number of reports in 2016.

Table 1. Reports through PA-PSRS by Facility Type (2016)

| FACILITY TYPE | HOSPITALS | AMBULATORY SURGICAL FACILITIES | BIRTHING CENTERS/ ABORTION FACILITIES | ALL ACUTE LEVEL FACILITIES | NURSING HOMES (HAI ONLY) | ALL FACILITIES REPORTING VIA PA-PSRS |
|---|-----------|--------------------------------------|--|----------------------------------|--------------------------------|--------------------------------------|
| Number of reports submitted | 247,763 | 7,672 | 279 | 255,714 | 27,544 | 283,258 |
| Number of facilities active as of December 31, 2016 | 238 | 308 | 25 | 571 | 703 | 1,274 |

Figure 3. Number and Percentages of Reports by Acute Facility Types, 2005 through 2016 NUMBER OF SUBMITTED REPORTS Ambulatory facilities Hospitals 300,000 3.1% 2.1% 2.5% 2.9% 250,000 2.2% 1.7% 2.1% 1.6% 1.4% 1.3% 1.3% 96.99 200,000 1.2% 98.3% 98.49 98.6% 150,000 98.7 100,000 98.8% 50,000 0 2011 2013 2014 2016 2005 2006 2007 2008 2009 2010 2012 2015 YEAR NUMBER OF SUBMITTED REPORTS BY AMBULATORY FACILITIES 2,500 ■ Common cause variation Special cause variation 1,977.8 2,000 .804.7 1,500 1,631.6 1,000 Upper control limit 500 ower control limit 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | YEAR (BY QUARTER) **RANGE** 250 Upper control limit 212.6 200 150 100 50 0 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | YEAR (BY QUARTER) NUMBER OF SUBMITTED **REPORTS BY HOSPITALS** 80,000 70,000 Upper control limit 56,808.3 60,000 50,000 52,289.0 40,000 30,000 37,554.8 Lower control limit 20,000 10,000 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 YEAR (BY QUARTER) **RANGE** Upper control limit 11,823.6 12,000 10,000 8,000 6,000 4,000 2,000 0 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 2016 MS17279 YEAR (BY QUARTER)

Note: Control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

Control Charts Evaluate Process Stability over Time

How does one know whether variation in data from a process or system is expected or erratic? Control charts are used as a way to visually monitor a process for stability. When a process is stable, or in control, some variation is expected and is referred to as common cause variation. When the process is unstable, the chart will show out-of-range fluctuation, known as special cause or population.

Control charts contain these key elements:

- A line chart of data measuring the process over time.
- A center line (CL) calculated as the average or median of the data.
- An upper control limit (UCL) line calculated at 3 sigma above the center line.
- A lower control limit (LCL) line calculated at 3 sigma below the center line

Throughout this report, the individual moving range (IMR) control chart is used to evaluate stability of a single process using variable data (number of reports, rate per 1,000 patient days). One should evaluate the range (bottom) chart first. If it is "out of control," so is the process. If the range chart looks okay, then evaluate the X (top) chart.

Where appropriate, trend charts are used. The CL, UCL, and LCL are sloped at the same angle to portray the incline or decline of the respective data. This allows for evaluation of the trend against normal expectations of increase and decrease.

Note

 KnowWare International, Inc. What is a Control Chart? [online] [cited 2017 Mar 20] https://www.qimacros.com/control-chart/ The remainder of this data section will focus on acute-care facilities; data from nursing homes are presented in Health-care-Associated Infections.

Figure 3 shows the increasing percentage of report submissions from nonhospital acute-level facilities—ambulatory surgical facilities, birthing centers, and abortion facilities (ASFs/BCs/ABFs)—compared with hospital reports from 2005 to 2016. The figure contains trended control charts of quarterly report submissions from both ambulatory facilities and hospitals. Although both groups experienced increased reporting in general, the percentage from ambulatory facilities is increasing more quickly, by comparison. Notice that both reporting patterns appear to be stable, exhibiting common cause variation from quarter to quarter.

Report Submission Trends

The trend line superimposed over the number of monthly reports in Figure 4 indicates that the volume of reports is growing at a modest rate and that reporting has had a stable increase in recent years.

Figure 4. Number of Submitted Reports, Monthly, 2005 through 2016

NUMBER OF REPORTS

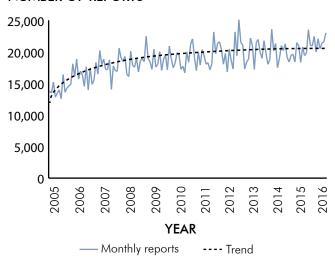
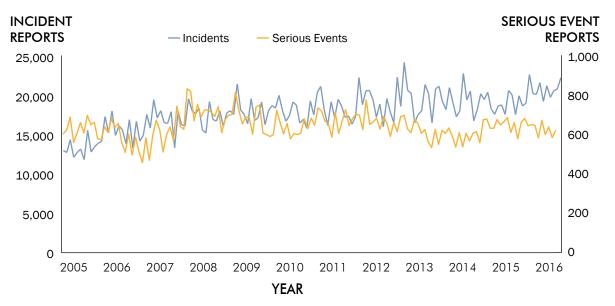
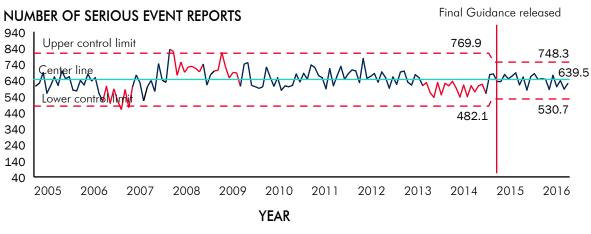


Figure 5 supports the proposition of improved reporting. Depicting the volume of Serious Events and Incidents on a relative scale (24:1) shows that the volume of Serious Events has increased somewhat over the long term, but not as sharply as the volume of Incidents. However, new published guidance* that clarified interpretations of the Serious Event definition and its component terms may have been temporally

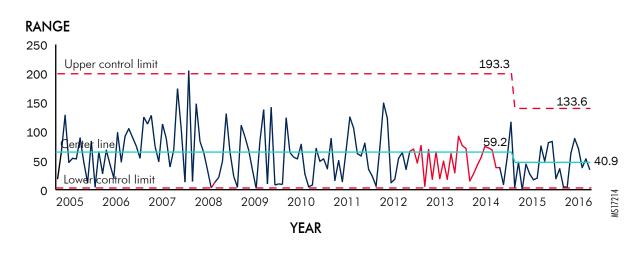
^{*} http://www.pabulletin.com/secure/data/vol44/44-39/2041.html

Figure 5. Number of Serious Event and Incident Reports and Trend of Serious Reports, Monthly, 2005 through 2016





Common cause variation



Special cause variation

Note: Control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

associated with reporting of these events. The two control charts in Figure 5 have an adjustment for when the final guidance was issued in April 2015—the process change point was noted and the variability recalculated. They sug-

gest that the timing of the guidance was associated with decreased variability (possibly greater standardization) in the number of Serious Events reported.

Reports by Event Type

When reporting an event through PA-PSRS, a facility uses a classification taxonomy to characterize the occurrence being reported. At the outset, a facility classifies a report by identifying what PA-PSRS defines as the "event type." An event type dictionary is one way the Authority classifies and analysts look for patterns and trends in submitted reports. The top-level event type essentially answers the most basic question about an occurrence: "What type of event happened?" The complete event-type dictionary is a three-level, hierarchical taxonomy with 222 distinct event types.

These categories are further broken down into secondand 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

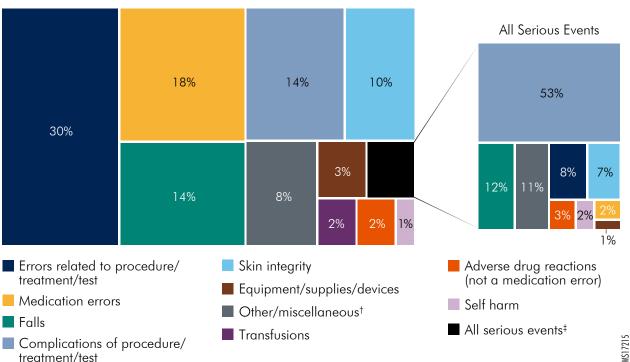


Figure 6. Comparison of Event Types by Percentage* of Total Reports Submitted, 2016

Event types are coordinated by color between Incidents (97%) and Serious Events (3%). At left, values are a percentage of total Incidents submitted. At right, values are percentage of total Serious Events submitted. Due to rounding, percentages may appear greater or less than 100%.

[†] This is not a single category of completely unclassified reports but rather a category that includes specific subcategories that did not logically fit under other existing top-level headings. Examples of subcategories under Other/Miscellaneous include Inappropriate Discharge, Other Unexpected Death, and Electric Shock to the Patient.

[‡] Serious Events represent 3% of overall 2016 PA-PSRS submissions. Transfusions, not pictured under Serious Events, represent less than 1% of the total Serious Events.

Figure 6 shows the percentage of reports submitted from acute-level facilities under each top-level event type in 2016. The most frequently reported occurrences were Errors Related to Procedure/ Treatment/ Test (29%) and Medication Errors (18%). These two event types account for about 47% of all reports submitted. Although Errors Related to Procedure/ Treatment/ Test was the event type most frequently reported through PA-PSRS, it was not the event type most frequently associated with patient harm.

Also shown in Figure 6 is a graphic comparison of the percentage of submissions as Serious Events and Incidents by event type. The event type Complications of Procedure/Treatment/ Test accounted for more than half (53%) of the Serious Events submitted in 2016. This event type historically constitutes the largest percentage of Serious Events. For example, in calendar years 2014 and 2015, the percentage of Serious Events from this event type were 53% and 54%, respectively.

Analysis reveals that the number of the event type Errors Related to Procedure/ Treatment/ Test increased 21%, compared to 2015. This category's increase equates to 76.2% of the total report submission increase in 2016. Table 2 shows several subtypes within that category accounting for the predominant increases by percentage. As noted previously, the Authority identifies and approaches apparent themes from the annual report and other analysis sources for subsequent education and prevention strategies to healthcare facilities. More in-depth analysis of these distributions may provide input in forthcoming education, if warranted.

This increase in Errors Related to Procedure/ Treatment/ Test was offset by decreases in overall Skin Integrity reports (-19.1%) and the Other/Other sub-event type reports (-14.5%). The standardization effort, which included the addition of several new reporting subtypes may have contributed to the decrease in the number reports submitted in the Other/Other subtype—for example, patients returning to the emergency department after discharge, surgical

Reports by Level of Patient Harm

For every report submitted through PA-PSRS, the associated healthcare facility applies a 10-item scale to measure whether an event "reached" the patient and, if so, how

Table 2. Highest Percentage Increases among Report Submissions by Event Subtype, 2016

| ERRORS RELATED TO PROCEDURE/ TREATMENT/TEST | CHANGE IN NUMBER OF REPORTS IN 2016 VS. 2015 | CHANGE (%) |
|--|---|---------------|
| Laboratory test problem/ Specimen quality problem | 6,160 | 83.9 |
| Laboratory test problem/ Other | 2,048 | 34.9 |
| Referral/Consult problem/ Delay in service | 939 | 46.2 |
| Surgery or invasive procedure problem/Procedure cancelled or not performed | 571 | 20.3 |

Table 3. Annual Decrease of Reports by Event Subtype, 2016

| DECREASING EVENT TYPES | CHANGE IN NUMBER OF REPORTS IN 2016 VS. 2015 | CHANGE (%) |
|--|---|---------------|
| Skin integrity/Pressure ulcers/ Admitted from other facility | -4,644 | -51.6 |
| Other/Other | -2,518 | -14.5 |
| Skin integrity/ Pressure ulcers/ New ulcer <24 hours after admission | -850 | -68.0 |
| Skin integrity/Other | -561 | -14.8 |

procedure complications, and orthopedic-related events. A decrease in Pressure Injury reports may also reflect the effect of standardization and clarifications made in the Final Guidance document.* Further information about the Standardization effort can be found in Reporting Standardization.

Table 3 lists several event subtypes that realized decreases.

much harm it caused.[†] This scale⁴ ranges from "unsafe conditions" (e.g., look-alike medications stored next to one another) to the death of the patient.

^{*} http://www.pabulletin.com/secure/data/vol44/44-39/2041.html

[†] For example, an event in which a phlebotomist prepares 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.

Figure 7 shows the reports received during 2016 categorized by the level of harm (as described above). 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 (e.g., Harm score C is generally the most frequently submitted harm score for each event type). However, as seen in recent years, not all event types adhere to the distribution shown in Figure 7. For example, while the event type Complication of Procedure/ Treatment / Test comprise 14.8% of reports overall in 2016, as previously noted, it comprises 53.0% of the reports of events involving harm, including those resulting in or contributing to the patient's death. Complication event examples include the following:

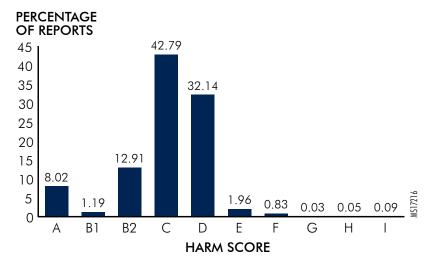
• Complication following surgery or invasive procedure/ Pneumothorax reports—57.1% involved harm

- Anesthesia Event/ Aspiration reports—54.2% involved harm
- Complication following surgery or invasive procedure/ Unplanned return to operating room—48.0% reports involved harm

These findings, similar to other data trends identified by Authority staff, will be queued and investigated further. If warranted, these data distributions may be addressed in forthcoming education.

At the other end of the spectrum, although the event type Medication Errors comprises 17.9% of reports in 2016, it comprises only 2.3% of reports involving harm and 0.9% of reports of events contributing to or resulting in death.

Figure 7. PA-PSRS Harm Scale for Acute-Level Facilities, 2016



| HARM LEVEL | HARM SCORE | DEFINITION |
|---------------------------------|--------------|--|
| Unsafe Condition | A | Circumstance that could lead to an adverse event |
| Event, No Harm | B1, B2, C, D | Often called a "near miss," an event that either did not reach the patient or did reach the patient but did not cause harm |
| Event, Harm, excluding Death | E, F, G, H | An event that reached the patient and caused temporary or permanent harm |
| Event, Death | I | An event that resulted in or contributed to death |

Note: Percentage of Harm Scores given to second decimal to illustrate low percentages of higher harm.

Reports of the event type Error Related to Procedure/ Treatment/ Test were also associated with harm or death at a frequency lower than their representation in the database as a whole. Although 7.4% of events resulted in patient harm, no deaths were associated with reports related to Skin Integrity.

The designation "Harm Score A" is intended to identify "unsafe conditions," meaning that there was an observed situation, or hazard, in which some harm was a possibility if corrective action was not taken. Unsafe conditions were cited in 8% of the reports submitted in 2016. As shown in Figure 8, and consistent with previous annual analysis, the event type in which unsafe conditions were most often reported was Error Related to Procedure/ Treatment/ Test (40%).

The event type in which unsafe conditions were least frequently reported by percentage was Adverse Drug Reactions. Of all reports of the Adverse Drug Reactions event type, 0.3% were reported as unsafe conditions.

Reports with harm scores of G, H, and I are deemed high harm events because they are associated with permanent harm or death. With the exception of high harm events in 2015, the number of high harm events has decreased annually since 2005, both in number and as a percentage of Serious Events, as shown in Figure 9. Although the overall number of high harm events is trending downward, the rate of decrease slows in the last eight quarters.

Figure 8. Reports by Event Type and Level of Patient Harm, 2016

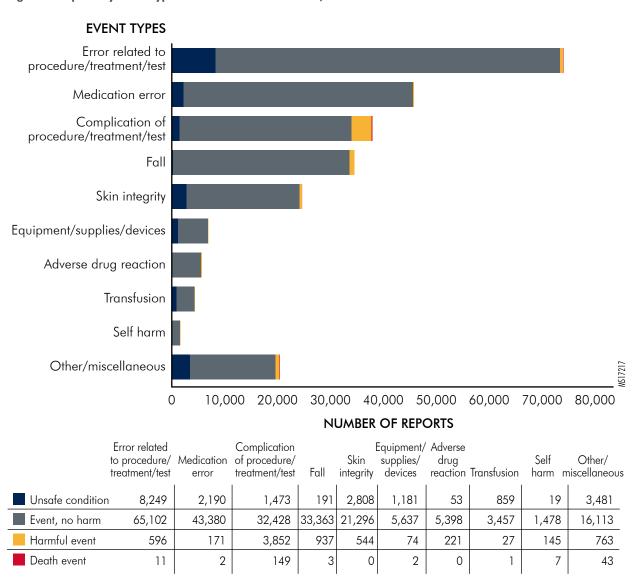
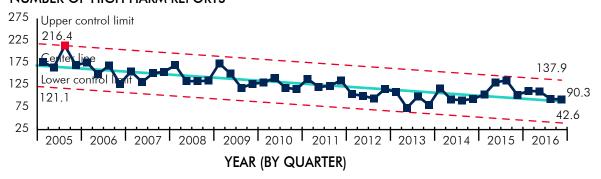


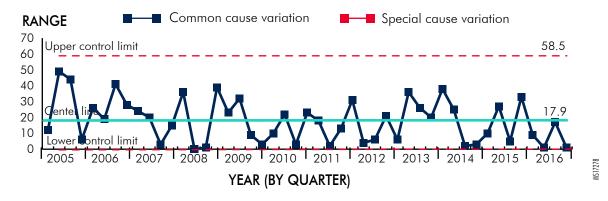
Figure 9. Number, Percentage, and Trends of High Harm Events Reported by Acute-Level Facilities through PA-PSRS by Year, 2005-2016





NUMBER OF HIGH HARM REPORTS





^{*} Percent of Serious Events

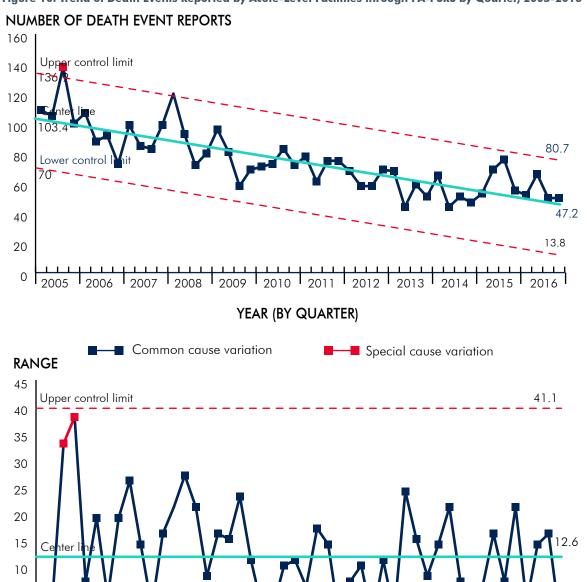
Note: Control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

Reports Involving the Patient's Death

Reports involving events that may have contributed to or resulted in the patient's death (harm score I) account for fewer than 0.09% (i.e., about one tenth of one percent) of all submitted reports. In 2016, the Authority received 218 reports of events that had a harm score of I, a 13.8% decrease from 2015.

This decrease follows the general trend of the decreasing number of harm score I reports, as seen in Figure 10, over the twelve-year period starting in 2005. The total for 2016 is second fewest for a full year of reporting in PA-PSRS history. The majority of reports involving a patient's death are associated with the event type Complications of Procedure/ Treatment/ Test.

Figure 10. Trend of Death Events Reported by Acute-Level Facilities through PA-PSRS by Quarter, 2005-2016



Note: Control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

2010

YEAR (BY QUARTER)

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2013 2014

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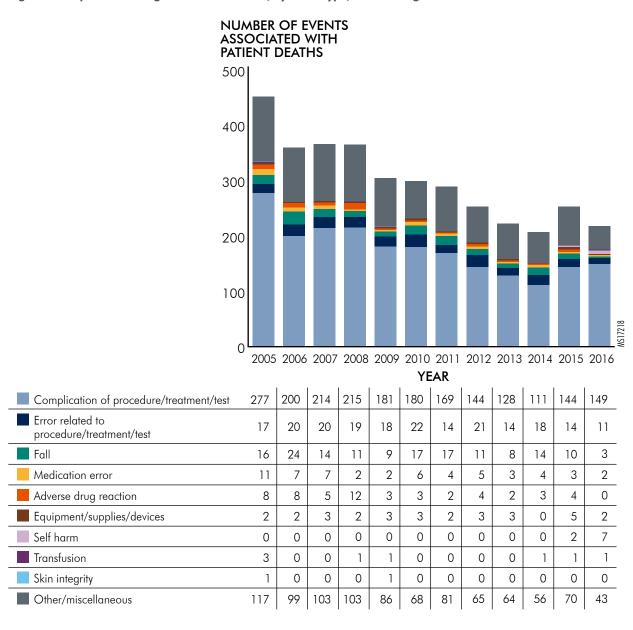
T 2009

5

In terms of particular event types, although 14.8% of all reports in 2016 were attributed to Complication of Procedure/ Treatment/ Test, 68.3% of all reports involving patient death were of that event type (Figure 11). Of the reports involving death associated with complications, the majority describe patients who died after surgery or

another invasive procedure (56.4%), with the next highest percentages reported as patients who suffered cardiopulmonary arrest outside the intensive care unit (ICU) setting (14.1%) and neonatal complications (7.4%).

Figure 11. Reports Involving the Patient's Death, by Event Type, 2005 through 2016



Notes: Event types listed in ascending order by total. Self-harm added as event type in 2015.

Patient Demographics

PA-PSRS collects few demographic details about patients because the Authority is not authorized to collect individually identifying information. As a result, patient disparity data are limited to gender and age. Figure 12 shows report submissions by age and gender.

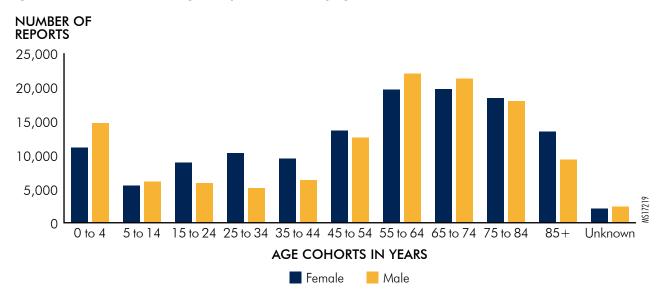


Figure 12. Number and Percentage of Reports Submitted by Age Cohort and Gender, 2016

Patient Gender

Of the 255,714 reports submitted in 2016, 132,144 (51.7%) involved female patients, and 123,570 (48.3%) involved male patients. This proportion by gender is in line with the Authority's reported trends since 2004 and with evidence in the medical literature. According to Nowatzki and Grant, 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 more women in the general population in the older age cohorts.⁵

The proportion of reports classified as Serious Events differed slightly according to the patient's gender, with 3.1%

of reports involving female patients classified as Serious Events, compared to 2.8% for reports involving males.

Figure 13 shows the distribution of reports by patient gender and event type. Many of the patterns observed in 2015⁶ are evident this year as well. Among these observed patterns, the proportion of reports involving female patients was greater than 60% among reports of Adverse Drug Reactions and Self Harm. The three event types involving a greater proportion of male patients in 2016 included equipment issues, falls, and skin integrity reports.

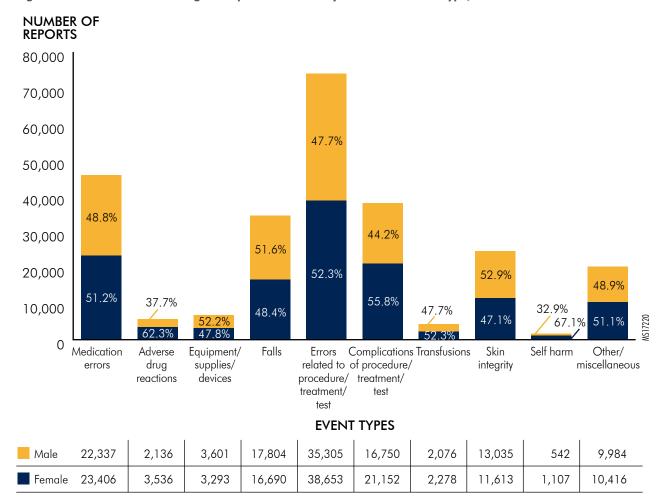


Figure 13. Number and Percentage of Reports Submitted by Gender and Event Type, 2016

Patient Age

Figure 14 shows the proportion of events reported through PA-PSRS, from hospitals only, by gender and by patient age cohort. As discussed above, this figure reflects that women are more likely as are men to have encounters with the healthcare system during childbearing years. Patients age 65 or older account for 41.0% of all reports from hospitals through PA-PSRS in 2016.

Also shown on this figure is the proportion of hospital inpatient admissions as reported by the Pennsylvania Health Care Cost Containment Council (PHC4).* Reports through PA-PSRS roughly track admissions by age cohort. Older patients' representation among PA-PSRS reports (41.0% of reports) merely reflects greater representation in the healthcare system in terms of number of admissions and patient days. The PHC4 data show that patients age 65 and older make up 39.8% of the admissions to hospitals in 2015.

The fact that patient age and gender in reports submitted through PA-PSRS track so closely to distribution of age and gender in the hospitalized population speaks to the overall generalizability of the data healthcare facilities submitted to the Authority.

^{*} Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council (www.PHC4.org). Estimates based on statewide inpatient data from 2015.

Patients in High and Low Age Cohorts

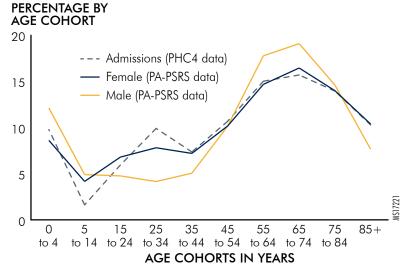
Elderly Patients

In the Authority's previous annual reports, several patterns of interest were identified with respect to reports involving elderly hospital patients (age 65 or older). For example, fewer than 50% of reported Falls have involved elderly patients since 2014 (Figure 15).

In another area of interest, elderly hospital patients accounted for 73.2% of Skin Integrity reports, including

pressure injuries, in 2005. This figure declined steadily to 64.6% in 2016. The decline in the submission of reports of pressure injuries may reflect the effect of standardization and exclusions in reporting as outlined in the Final Guidance document.* See the Reporting Standardization section for more details about previous and ongoing efforts.

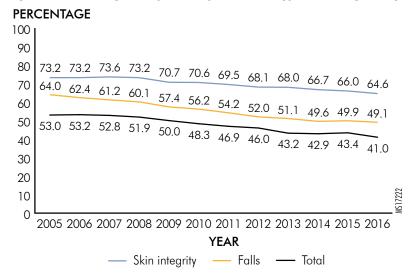
Figure 14. Proportion of Hospital Reports Submitted by Gender and Age Cohort, 2016*



^{*} Based upon publicly available data from the website of the Pennsylvania Health Care Cost Containment Council (www.PHC4.org). Estimates based on statewide inpatient data from 2015.

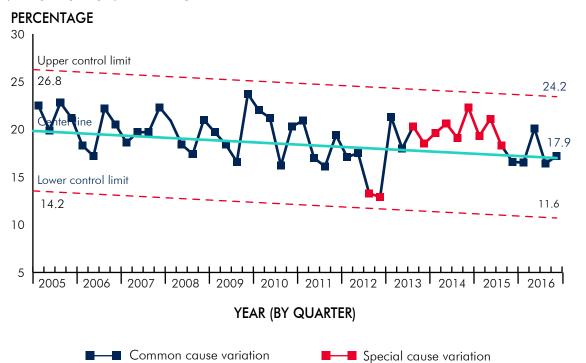
PA-PSRS, Pennsylvania Patient Safety Reporting System; PHC4, Pennsylvania Health Care Cost Containment Council.

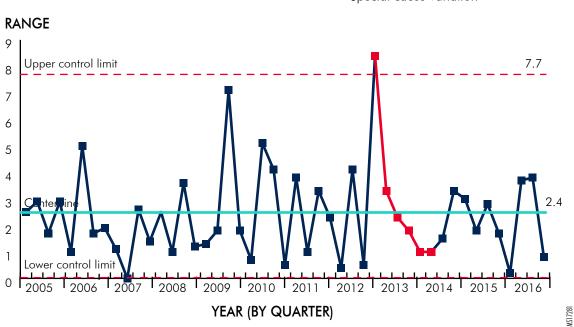
Figure 15. Percentage of Reports of Specific Event Types Involving Elderly Hospital Patients (age 65 or older)



^{*} Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act. 44 Pa.B. 6178, September 27, 2014. Available online: http://www.pabulletin.com/secure/data/vol44/44-39/2041.html

Figure 16. Percentage of Medication Errors among All Event Types Involving Perinatal Hospital Patients (20 days or younger), 2005 through 2016





Note: Control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

Perinatal Patients

In all, 8,551 reports involved perinatal hospital patients (those aged 20 days or younger), an increase of 879 reports (10.3%) from 2015. Less than 2% (1.36%) of perinatal reports were classified as Serious Events, noticeably lower than the overall Serious Event percentage of 3.0% for 2016.

About two thirds (66.4%) of reports for perinatal patients were related to events of Error or Complication of Procedure/ Treatment/ Test. Because of specialized needs based on age and size, these patients are proportionally more likely to experience errors or complications compared with other event types associated with older patient age groups.

About one fifth (19.9%) of reports involving perinatal patients were related to Medication Errors. There is a slight but consistent decline in the percentage of reports involving Medication Errors since 2005 for this age cohort (Figure 16). Complication of Procedure, Treatment and Test accounted for 73.3% of the Serious Events in this age group, which is somewhat higher than for this event type in 2015 (61.2%). Four out of five of these complications are neonatal complications, such as birth injury or trauma (n = 35), other (n = 15), unplanned transfer to the neonatal intensive care unit (NICU; n = 7) and neonatal death (n = 6).

Children and Adolescents

A total of 46,656 reports submitted through PA-PSRS in 2016 involved children and adolescents (i.e., patients younger than 21 years). This number is higher this year because of normal variation in reporting. The top two report types were Error Related to Procedure/ Treatment/

Test, accounting for 35% of the reports of this population, and Medication Errors, at 28.8%. However, the event type Complication of Procedure/ Treatment/ Test made up 55.4% of the 540 Serious Events for this age group. Table 4 lists the three largest event subtypes by percentage in this age group.

Table 4. Top Three Complication of Procedure/ Test/ Treatment Subtypes, by Percentage of Serious Events among Children and Adolescents, 2016

| COMPLICATIONS OF PROCEDURES/TREATMENTS/TESTS (ALL SERIOUS EVENTS FOR CHILDREN AND ADOLESCENTS) | SERIOUS EVENTS (NO.) | SERIOUS EVENTS (%) |
|--|----------------------|--------------------|
| Complications of Procedures/Treatments/Tests | 299 | 55.4 |
| Complication following surgery or invasive procedure/Unplanned return to operating room | 74 | 13.7 |
| Complication following surgery or invasive procedure/Other | 59 | 10.9 |
| Neonatal complication/Birth injury or trauma | 35 | 6.5 |

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 illustrated in Figure 17, the care areas designated as Critical Care Areas and General Medical/Surgical Units were cited as the locations for the greatest number of overall reports submitted in 2016, each generating nearly one fifth of the total. Other hospital departments with high report rates were Pediatric Care, Surgical Services, and Intermediate Unit.

Although most hospital reports were submitted from the Critical Care and General Medical/ Surgical areas, the greatest number of Serious Events came from Surgical Services, accounting for nearly one third of Serious Events from hospitals. However, the care areas with highest proportion of Serious Events per submitted report were the Diagnostic/Labs Care Group and Surgical Services (Table 5).



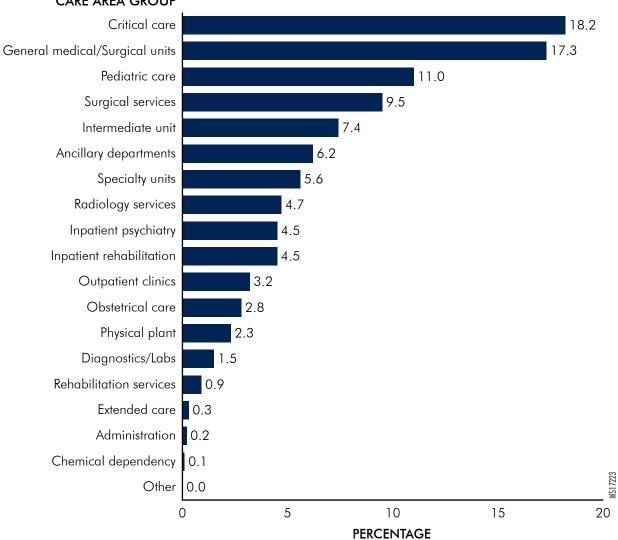


Table 5. Number and Percentage of Serious Events among all Serious Events and of Submitted Reports, by Care Area Location (Hospitals Only), 2016

| LOCATION | SERIOUS EVENTS | TOTAL | SERIOUS EVENTS BY GROUP (%) | SERIOUS EVENTS (% OF TOTAL) |
|-----------------------|----------------|---------|--------------------------------|--------------------------------|
| Diagnostic/Labs | 299 | 3,686 | 8.1 | 5.1 |
| Surgical services | 1,873 | 23,506 | 8.0 | 32.0 |
| Inpatient psychiatric | 380 | 11,066 | 3.4 | 6.5 |
| Obstetrical care | 228 | 6,959 | 3.3 | 3.9 |
| Physical plant | 147 | 5,577 | 2.6 | 2.5 |
| 14 other care groups | 2,922 | 196,969 | 1.5 | 50.0 |

Reports by Region and Submission Type

For this report, the Pennsylvania Patient Safety Authority Board of Directors has adopted a geographic breakdown of the Commonwealth into six regions, as shown in Figure 18. 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 (Figure 19) may be explained by noting proportion of reporting patterns; for example, more reports may be submitted in regions with larger populations and greater numbers of healthcare facilities. Consistent with this statement, the regions with the greatest number of reports (Southeast and Southwest) were those with the Commonwealth's two largest population centers: Philadelphia and Pittsburgh, respectively. The Authority will continue to look for trends and closely monitor the data within these regions.

Adjusting the report volume for a measure of healthcare utilization paints a different picture. Figure 20 shows, by

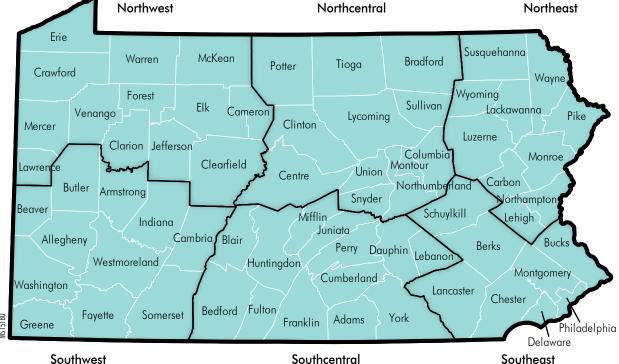
Figure 18. Regions of the Commonwealth

region, the number of reports from hospitals per 1,000 patient days.* This figure shows that, after accounting for the differences in the volume of healthcare provided by hospitals in each region, those in the Northwest and Southcentral regions reported the highest number of Incidents per 1,000 patient days.

Figure 21 shows that the Northcentral and Northeast regions submitted the greatest proportion of Serious Events, comprising 4.9% and 3.4% of their event reports, respectively, as compared to the statewide pooled mean of 2.6%. Conversely, the Southeast and Southwest regions submitted the highest proportion of Incidents comprising 98.2% and 98.0% of their event reports, respectively.

Many factors contribute to reporting variation. The Authority continues to provide education about reporting, to refine the reporting criteria when appropriate, and to examine variance. It would be speculative to consider facilities in any of the regions as less or more safe than





Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council (www.PHC4.org). Estimates based on statewide inpatient data from 2015.

those in other regions based solely on this data. It may mean that the healthcare providers in certain facilities or regions were better at identifying and reporting potential patient safety issues. The Authority does not risk adjust for factors (e.g., severity of illness). The Authority will further review this variation in the coming year.

Figure 22 shows that the Southwest region has the largest number of reports submitted per hospital.

Further analysis reveals that regional reporting by hospitals varies by event type. For instance, the hospitals in the

Southeast region submitted 46.9% of all Medication Errors submitted in 2016. Meanwhile, the region accounted for 19.9% of all Other/Miscellaneous reports, as compared to the region's 34.3% overall share of the Commonwealth's reports.

Another example of variability in reporting is found in the Northwest region; hospitals of that region submitted 14.8% of all its reports as Other/Miscellaneous reports, the highest percentage of the state.

Figure 19. Number of Serious Event and Incident Reports from Hospitals by Region, 2016

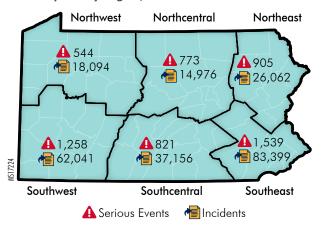


Figure 20. Reports from Hospitals* per 1,000 Estimated Patient Days by Region, 2016

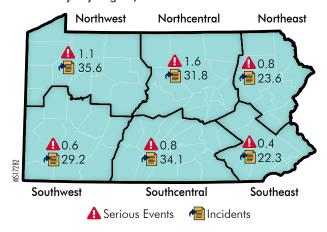


Figure 21. Percentage of Incident and Serious Event Reports from Hospitals by Region, 2016

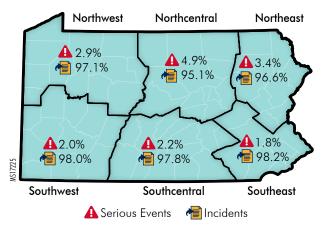
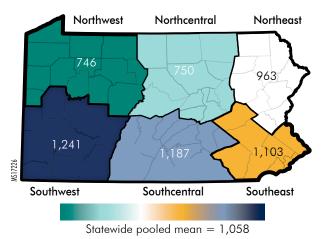


Figure 22. Pooled Mean of Reports Submitted Per Hospital by Region, 2016



^{*} Based upon publicly available data from the website of the Pennsylvania Health Care Containment Council (www.PHC4.org). Estimates based on statewide inpatient data from 2015.

Figure 23 shows the percentage of each event type submitted by regional hospitals. Figures 24 through 29 isolate each region, comparing the overall submission

percentage against the percentage of submissions by event type.

Figure 23. Percentage of Reports Submitted by Hospitals per Event Type by Region, 2016

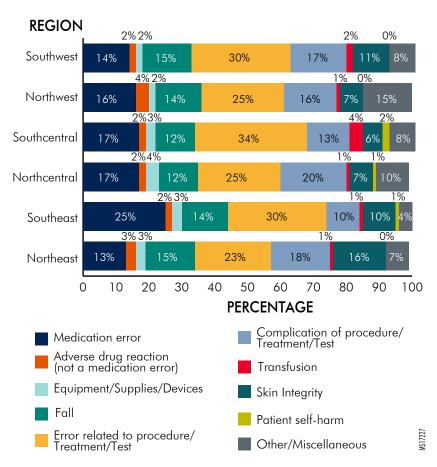


Figure 24. Reports Submitted by Hospitals per Event Type by Northeast Region, 2016

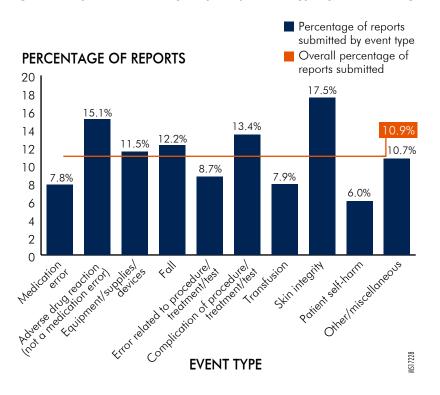


Figure 25. Reports Submitted by Hospitals per Event Type by Southeast Region, 2016

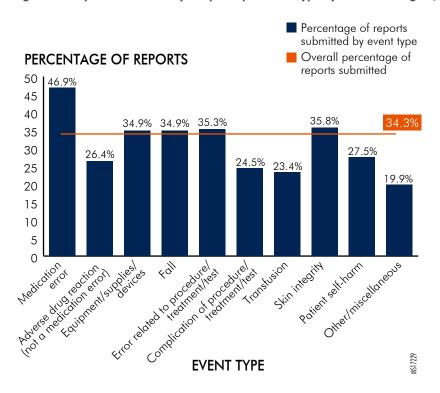


Figure 26. Reports Submitted by Hospitals per Event Type by Northcentral Region, 2016

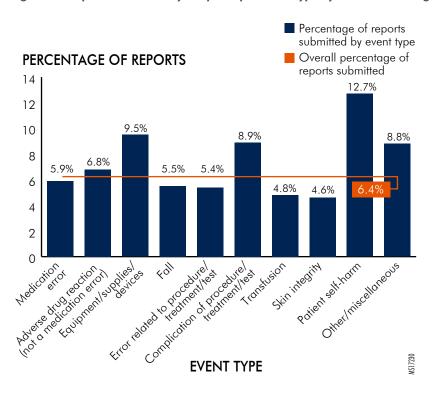


Figure 27. Reports Submitted by Hospitals per Event Type by Southcentral Region, 2016

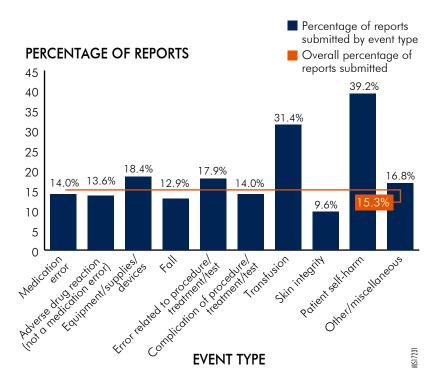


Figure 28. Reports Submitted by Hospitals per Event Type by Northwest Region, 2016

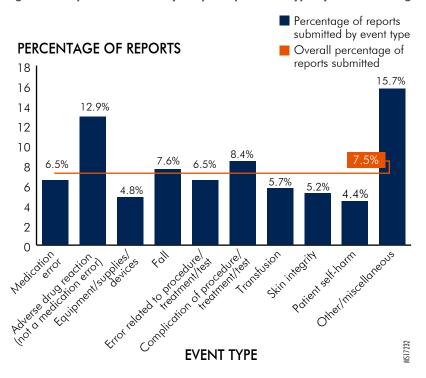
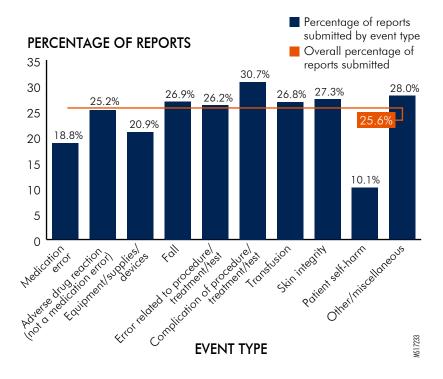


Figure 29. Reports Submitted by Hospitals per Event Type by Southwest Region, 2016



Conclusion

The data presented in this section suggest that healthcare facilities in the Commonwealth continue to make progress in their efforts to identify and report patient safety events. The average monthly number of events submitted through PA-PSRS by Pennsylvania acute-level healthcare facilities increased 7% in 2016 over 2015. The increased reporting of Incidents may suggest earlier recognition and proactive mitigation of hazards with fewer events reaching the patient and causing serious harm. The number of Serious Events related to death continues to be a low and decreasing proportion of submitted reports. As the

Authority completes its twelfth calendar year of collecting, analyzing, and providing information about medical errors and patient harm, the data trends noted reflect positively on the efforts made by healthcare institutions in the Commonwealth. As noted previously, the Authority estimated that more than 2,600 lives and more than \$147 million were saved since 2005. The encouraging trends noted above are starting points. The Authority looks forward to learning whether these observations and trends are repeatable.

Notes

- Magee MC, Marella WM, Newstadt HM, Clarke JR, Doering MC. The value of improving patient safety in Pennsylvania. Pa Patient Saf Advis. 2016 Dec;13(4):125-36. Also available: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2016/Dec;13(4)/Pages/125.aspx.
- Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No. 13, Cl. 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/ucons-Check.cfm?yr=2002&sessInd=0&act=13.
- Levinson DR. Adverse events in hospitals: state reporting systems. Washington (DC): Office of Inspector General (OIG), Department of Health and Human Services; 2008 Dec. 37 p. Also available: http://oig.hhs.gov/oei/reports/ oei-06-07-00471.pdf.

- 4. NCC MERP index for categorizing medication errors. National Coordinating Council for Medication Error Reporting and Prevention; 2001 Feb. 1 p. Also available: http://www.nccmerp.org/types-medication-errors.
- Nowatzki N, Grant KR. Sex is not enough: the need for gender-based analysis in health research. Health Care Women Int. 2011 Apr;32(4):263-77. Also available: http://dx.doi.org/10.1080/07399332.2010.519838. PMID: 21409661

Reporting Standardization: Guidance for Acute Healthcare Reporting

Introduction

Twenty-eight guiding principles went into effect on April 1, 2015, to improve consistency in event reporting through the Pennsylvania Patient Safety Reporting System (PA-PSRS). The Pennsylvania Patient Safety Authority (Authority) and the Pennsylvania Department of Health (Department) jointly developed the "Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act." This guidance document provides consistent standards to acute healthcare facilities in Pennsylvania in

determining whether occurrences within facilities meet the statutory definitions of Serious Events, Incidents, or Infrastructure Failures as defined in section 302 of the MCARE Act.² The Authority, the Department, and healthcare facility staff have worked together toward a shared understanding of these requirements. The reporting guidelines were identified based on frequently asked questions (FAQs), controversies, and inconsistencies that were evident in the data collected by the Authority and the Department.

Education

An online education program was developed and made available concurrent with the April 1, 2015, release of the Final Guidance to ensure that all Authority, Department, and healthcare-facility staff had a common understanding of the principles.

The Authority's outreach to disseminate and educate people about the new reporting standards continued in 2016 with more than 6,600 education modules completed by 809 (i.e., 80%) of registered online learners.

Assessing the Impact of Reporting Standardization

A set of performance measures was identified to assess the impact standardization had on reporting practices. In 2016, the Authority was encouraged to see that the indicators it felt were important continued to move in the desired direction. For example:

- An improvement in Serious Event reporting has been noted since the new standards went into effect in April 2015.
- The number of reports submitted under the new and revised event types and subtypes that promote more consistent reporting have nearly doubled over the total submitted in 2015 (see Table).
- Healthcare facilities continued to participate in education for the standardization principles. By

- the end of December 2016, 80% of registered online learners completed all required modules.
- Analysis of events reported as related to health information technology revealed that more than half involve medication errors.

The principles continue to have good acceptance among healthcare providers, as evidenced by the improvement in the volume and quality of the reports submitted.

Table. Number of Events Submitted under the New Event Type and Subtypes

| REPORTS | Q1 | Q2 | Q3 | Q4 | TOTAL |
|---------|-------|-------|-------|-----------|-------|
| 2015 | N/A | 683 | 1,323 | 1,443 | 3,469 |
| 2016 | 1,629 | 1,495 | 1,704 | 1,948 | 6,776 |

Note: As reported to the Pennsylvania Patient Safety Authority, April 2015 through December 2016.

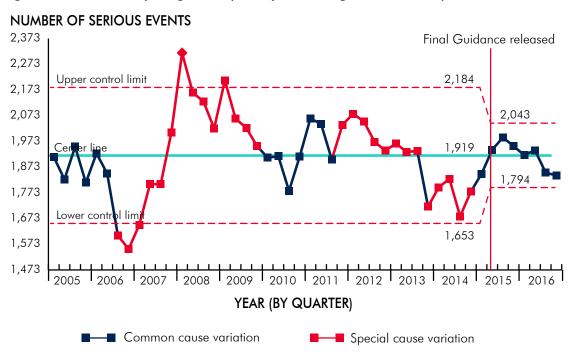
N/A: Not applicable.

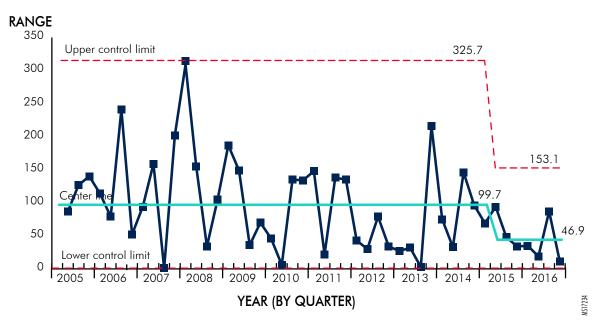
Serious Events

The guidance clarified interpretations of the Serious Event definition and its component terms. The number of Serious Event reports from acute healthcare facilities in Pennsylvania in 2016 increased by 6.7% over 2014. The Authority believes standardization contributed to this increase

(see Overview of Data Reported through PA-PSRS, Figure 5). Standardizing Serious Event reporting was intended to improve the accuracy of event reporting; the number of Serious Event reports increased in 2015 after standardization, and 2016 numbers appear to remain consistent with

Figure 1. Serious Event Reporting Pattern (January 2005 through December 2016)



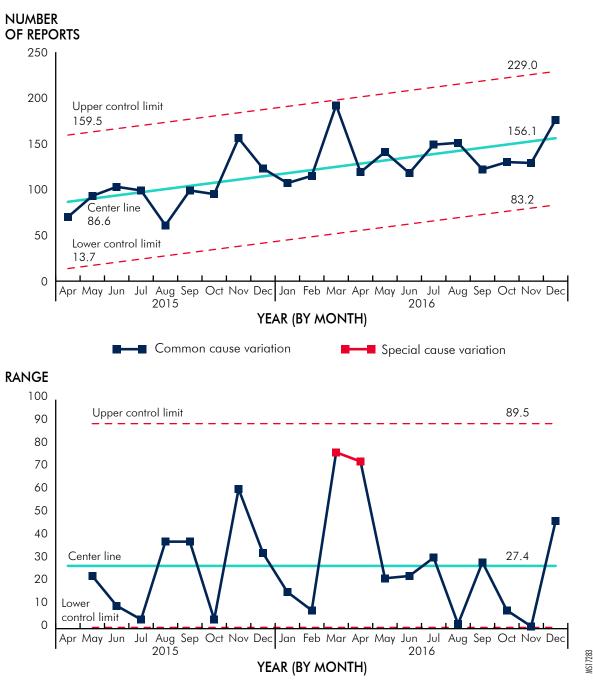


Note: As reported to the Pennsylvania Patient Safety Authority; control charts generated using QlMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

patterns after standardization. The monthly mean number of Serious Event reports submitted by acute healthcare facilities before standardization (i.e., 2014 through March 2015) was 595 and increased to 640 after implementation (i.e., April 2015 through December 2016). The control chart shown in Figure 1 shows the change in

the Serious Event reporting pattern. Before standardization went into effect in April 2015, the number of reports trended downward. However, this trend changed when the guidance was implemented with a noted reduction in the reporting pattern variation through 2016.

Figure 2. New Event Type "Patient Self-Harm" Reporting Pattern (April 2015 through December 2016)



Note: As reported to the Pennsylvania Patient Safety Authority; control charts generated using QlMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.gimacros.com/pdf/qiuser.pdf).

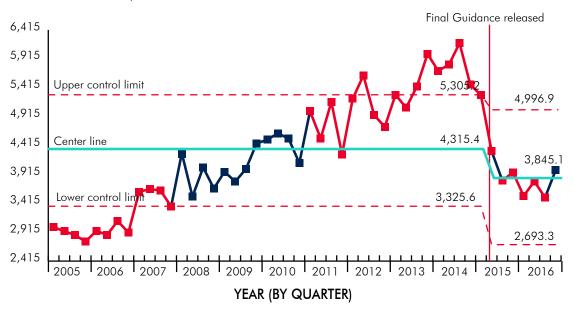
New Event Type and Subtypes

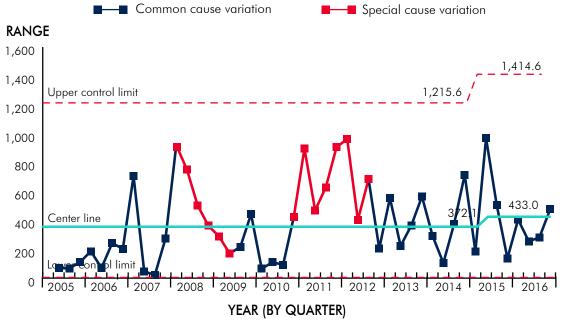
New and revised event types and subtypes were created in PA-PSRS to help facilities standardize and improve reporting accuracy. The PA-PSRS new event type, Patient Self-Harm and other new subtypes, appear under Complications of Procedure/Treatment/Test and Other/Miscellaneous. In

2016, facilities submitted more than 6,700 Serious Events and Incidents using the new event type and subtypes (see Table), a 95.3% increase over the total number of events submitted in these categories in 2015.

Figure 3. Event Type "Other/Miscellaneous" Reporting Pattern (January 2005 through December 2016)

NUMBER OF OTHER/MISCELLANEOUS REPORTS





Note: As reported to the Pennsylvania Patient Safety Authority; control charts generated using QIMacros® 2016 (KnowWare International, Inc., Denver, CO), based on Six Sigma principles and Healthcare IHI rules (information available at https://www.qimacros.com/pdf/qiuser.pdf).

Complications of Procedure/Treatment/Test

As a part of the standardization effort, new and revised event subtypes were created in the Complication of Procedure, Treatment, or Test event type. "Patient in 302 process eloped – with injury" was a new addition under Emergency Department (302 process is involuntary commitment into a mental health institute for emergency

psychiatric evaluation). "Use of reversal agents (Not neuromuscular blockers)" in the subtype Anesthesia Event was revised. With the addition of these new event subtypes, the total number of Serious Events reported increased 7.2% as compared with Serious Events reporting in 2014. See Overview of Data Reported through PA-PSRS.

Patient Self-Harm

Pennsylvania healthcare facilities continued to submit event reports using the patient self-harm event type and subtypes. Figure 2 illustrates a steady increase in the number of reports submitted through this event type since it was introduced in April 2015. The implementation of this category allowed for specific reporting of these events,

and the rise in the number of reports may be attributable to improved awareness (e.g., online education) of the event type by PA-PSRS users. The Authority will continue to evaluate events reported and offer solutions to mitigate harmful patient outcomes. See Overview of Data Reported through PA-PSRS.

Other/Miscellaneous

The number of new reports submitted by facilities using the event type "Other/Miscellaneous" continued to decline, as expected with the development of new subtypes. The control chart shown in Figure 3 shows the change in the "Other/Miscellaneous" reporting pattern over time. With the development of the new subtypes, the number of events reported using this event type has trended downward since April 2015, with a noted reduction in the reporting pattern variation through 2016.

In 2016, the number of events reported as subtype "Other" in this category fell by 36% and 14.5% as compared with reporting in 2014 and 2015, respectively, suggesting that reporters used more specific categories to report events and resulting in an overall improvement in the specificity of the reports submitted. The greatest increase in the number of events reported using new event types and subtypes was submitted through the new event subtype, Unanticipated Transfer to Higher Level of Care. More than 5,000 events were submitted using this subtype with Intrafacility Transfer comprising nearly 70% of the reported events.

Health Information Technology

Healthcare organizations have rapidly adopted electronic health records (EHRs) over the past few years as information systems increasingly become interoperable, and the Authority has seen an increase in events that are related to health information technology (HIT) as a causative or contributing factor. However, HIT may also help prevent other types of safety problems that are not necessarily HIT-related. To identify events in which HIT may have played a role, several questions were added through PA-PSRS to help identify such events and the systems involved.

The HIT measure represents the aggregate number of events submitted with "yes" responses to the question,

"Did HIT cause or contribute to this event?" Figure 4 shows the progression in the number of affirmative responses to this question from April 2015 through December 2016. The majority of these HIT-related events involve Medication Errors (54.6%) and Errors in Procedures/Treatments/Tests (32.3%).

After collecting and analyzing events associated with medication errors in which HIT caused or contributed to reportable events, the Authority will publish a *Pennsylvania Patient Safety Advisory* analysis about this topic in 2017.

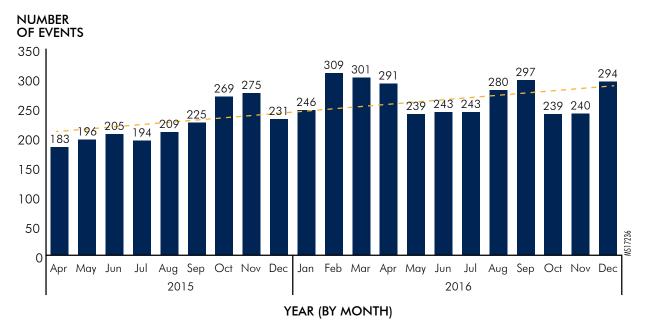


Figure 4. Events Related to Health Information Technology (April 2015 through December 2016)

Note: As reported to the Pennsylvania Patient Safety Authority.

Infrastructure Failures and Other

Infrastructure Failures and specific "Other" events related to restraints and seclusion are reportable to the Department and are beyond the scope of this report.

Facilities with Low Report Volume

The events reported through PA-PSRS inform the analyses published in the *Pennsylvania Patient Safety Advisory*, and they are the basis for the educational programs and collaborative forums that allow healthcare organizations throughout the state to learn from one another. The Authority consistently monitors and notifies those facilities that: (1) submit a low volume of reports as compared with the volume of reports from like facility types or (2) do not submit any reports through PA-PSRS. A goal of standardization is to increase the number and precision of reports received through PA-PSRS from all facility types.

Figure 5 shows the annual number of hospital and ambulatory surgical facilities with low report volumes.

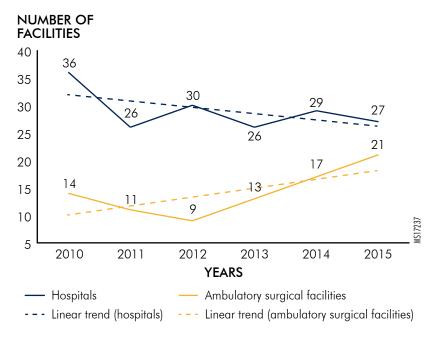
Hospitals identified with low report volumes meet any of the following criteria:

- No Serious Events submitted through PA-PSRS for one year
- No Incidents submitted through PA-PSRS for one year
- Reporting of Serious Events, Incidents, or total reports per 1,000 patient days is less than 10% of the mean of their hospital type (e.g., acute, behavioral, children's facilities)

Ambulatory surgical facilities identified with low report volumes meet any of the following criteria:

- No reports submitted through PA-PSRS for one year (4+ rooms) or two years (<4 rooms), AND
- There are no extenuating circumstances identified by the facility's patient safety liaison
- Facilities of unknown room size will be treated as having fewer than 4 rooms

Figure 5. Number of Facilities with Low Report Volumes



Note: As reported to the Pennsylvania Patient Safety Authority.

Failure to report as required by the MCARE Act is a violation of the Health Care Facilities Act.² In addition to any penalty that may be imposed under the Health Care Facilities Act, a medical facility that fails to report a Serious Event or an Infrastructure Failure may be subject to an administrative penalty of \$1,000 per day imposed by the Department. The Authority actively monitors facilities with low report volumes and notifies senior leaders in writing.

Evidenced by the number of facilities identified as reporting low event volumes, the Authority established the first patient safety liaison Keystone project, The Keys to Reporting, in 2016 to help facilities identify opportunities to improve and evaluate common barriers to reporting. The patient safety liaisons also offer education to facilities and health-care providers at their request. See Educational Programs for more information.

Pressure Injury Reporting Standardization

To help acute healthcare facilities determine whether occurrences of pressure injuries meet the statutory definitions of Incidents or Serious Events as defined in the MCARE Act, the Authority staff and its Board of Directors identified pressure injury reporting as the next priority for standardization. A multi-disciplinary work group with backgrounds in medicine (including wound care), nursing (including Wound, Ostomy, and Continence nurses), administration and facility operations, regulation, patient safety and healthcare quality, and a patient representative developed recommendations for pressure injury reporting.

These guidance recommendations were intended to provide consistent and clear standards for the MCARE Act's reporting requirements for pressure injuries so that the

Authority, the Department, and healthcare facility staff have a shared understanding of the requirements. The subjects of these requirements were identified based on inconsistencies that were evident in the data collected by the Authority and the Department.

The drafted guidance document was published in the *Pennsylvania Bulletin* 46 Pa.B. 6198 on October 1, 2016, for public comment through October 31, 2016. The Authority, the Department, and the other members of the work group reviewed 15 public comments and will make selected changes to the document in response to those comments. A final guidance document will be issued to guide interpretations about whether occurrences of pressure injuries meet the statutory definitions of Incidents or Serious Events as

defined under the MCARE Act and will include the agencies' response to the correspondence received. Assuming the Authority's Board of Directors and the Secretary of the Department approve the final guidance document in

2017, the agencies will need to modify PA-PSRS to support implementation of these standards and develop an education program for staff of both agencies as well as affected healthcare facilities.

Notes

- Final guidance for acute healthcare facility determinations of reporting requirements under the Medical Care Availability and Reduction of Error (MCARE) Act, 44 Pa. Bull. 6178 (2014 Sep 27). Also available: http://www.pabulletin.com/secure/data/vol44/44-39/2041.html.
- Medical Care Availability and Reduction of Error (MCARE)
 Act of March 20, 2002, P.L. 154, No 13 40. Available:
 http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2002&sessInd=0&act=13.

Healthcare-Associated Infections

Introduction

Healthcare-associated infections (HAIs) continue to be an important public health challenge. HAIs are infections patients develop while receiving treatment for other conditions and can occur in any healthcare setting. The Centers for Disease Control and Prevention (CDC) estimates 1 in 25 hospitalized patients will develop an HAI during their care. Research by Columbia University estimates 1.6 million to 3.8 million HAIs occur among nursing home residents in the United States annually. These infections are associated with significant morbidity and mortality and increased healthcare costs. According to CDC, pneumonia, gastrointestinal illness such as Clostridium difficile or norovirus infections, urinary tract infections, primary bloodstream infections, and surgical site infections are the most common HAIs.

Working toward the elimination of HAI is a priority for the Authority because many of these infections are preventable. The Medical Care Availability and Reduction of Error (MCARE) Act was amended (Act 52)⁴ in 2007 to encompass HAI prevention, and it mandates HAI reporting for hospitals and nursing homes. Pennsylvania hospitals report infections through CDC's National Healthcare Surveillance Network (NHSN) and Pennsylvania nursing homes report infections through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

The Authority uses knowledge gained through analysis of HAI reports to detect infection trends and develop new strategies to prevent HAIs. HAI data from CDC's NHSN are also analyzed by the Department of Health for hospital trends. The HAI Advisory Panel provides advice and guid-

ance to both the Authority and Department on activities to prevent HAIs. The Authority's infection prevention analysts use data from HAI reports to prioritize prevention activities. The Authority also partners with local, state, and national organizations to reduce HAIs.

The Authority sponsors in-depth educational offerings tailored to meet the needs of the audience, covering topics including sepsis, scabies, pneumonia, and environment of care issues. Multiple modalities are used to present the education, including webinars, *Pennsylvania Patient Safety Advisory* articles, toolkits, presentations at conferences and symposiums, and on-site facility consultations and presentations.

The Centers for Medicare and Medicaid Services (CMS) released new regulations for long-term care in October 2016. Key elements of these regulations include the establishment of a formal infection prevention and control program with a comprehensive facility assessment and a designated infection prevention and control officer to oversee the program; development of an antibiotic stewardship program with involvement of a pharmacist to oversee antibiotic use; standardization of information provided during care transitions; and food and nutrition services to comply with applicable federal, state, and local laws, regulations, and codes. The Authority's infection prevention analysts are an available resource, providing guidance to help facilities meet the requirements of these regulations.

This section summarizes the Authority's HAI activities in 2016.

Education and Outreach Programs

In 2016, the Authority's infection prevention analysts provided education to about 5,600 healthcare workers. The infection prevention analysts presented information at healthcare facilities, on statewide webinars, for our

national and state partners, in a grade school district annual event, and for each of the Authority's ambulatory surgical facilities' symposia. An overview of this education is shown in the following graphic.

Infection Prevention Education and Outreach Programs

Webinars*: 981 attendees

Antibiotic Stewardship
Central Line-Associated
Bloodstream Infections
Improving Isolation Awareness
PA-PSRS Analytics
Urinary Tract Infections

"Tips from the Toolbox"

- Early Detection of Sepsis in Long-Term Care
- Preventing Non-Ventilator Healthcare Acquired Pneumonia
- Scabies

Schools: 150 students and teachers

Hempfield Area School District's "3rd Annual STEAM Academy" — Science, Technology, Engineering, Arts, and Math skills

Facility Education: 386 attendees

Clostridium difficile Influenza Pneumonias and Antimicrobial Therapy Safe Injection Practices Zika



ASF Symposia: 155 attendees

Topic:

"Environmental Hygiene in Ambulatory Surgery Facilities"

State and National Presentations:
3,200 attendees through
national partners
813 attendees through
state partners

Professional Organizations:

Association for Professionals in Infection Control and Epidemiology Central Pennsylvania Association for Healthcare Quality

Pennsylvania Association of Directors of Nursing Administration

Pennsylvania Coalition of Affiliated Healthcare & Living Communities

Pennsylvania Health Care Association

*Attendees located in PA, DE, NJ, WV, and LA.

I will use the Patient Safety Authority resources more frequently.

Most of the program was new information that I can put into practice.

I learned we have a good system; just need to keep people informed, educated, and accountable.

You just helped me put a new spin on an old issue.

Thank you for all you do to help;
I feel more connected to the
infection control community.

Innovation

The Authority's infection prevention analysts attended innovation training provided by the Authority in 2016. This training provided knowledge of the creative problemsolving framework for the analysts to use in their work with education, the *Advisory*, PA-PSRS nursing home data, resources, and the Authority's HAI Advisory Panel (see lightbulb).

Infection Prevention and Control Annual Survey

In the fall, the Authority distributed an infection prevention and control–specific survey to hospital and nursing home infection prevention analysts, as a subset of an annual survey. It was intended to elicit information about the effectiveness of the Authority's guidance and educational programs and to capture critical information about facilities' infection prevention and control practices. The responses inform and help the Authority prioritize future research, education, and collaboration programs.

The top five infection prevention and control areas of interest for hospitals are (in order of importance): hand hygiene, C. difficile infection, surveillance for HAI, antibiotic stewardship, and environmental infection control. Nursing homes listed the top five infection prevention and control topics of interest as urinary tract infection (UTI), antibiotic stewardship, pneumonia, surveillance for HAI, and influenza.

Infection prevention HAI Advisory Panel Think Big Success Support Facility consults Brainstorming Ideas Innovation Teamwork Education Efficient Plan Sharing Strategy Tools Goals Resources Inspiring Statewide Research Leading Creative Analysis

As a result of reading one or more of the 2016 infection prevention and control Advisory articles, hospitals and nursing homes made 117 changes to policies, systems, education, collaboration, and communication. The

following graphic shows samples of changes initiated by Pennsylvania healthcare facilities as a result of reading a specific infection control *Advisory* article.

Advisory: Early Detection of Sepsis in Pennsylvania's Long-Term Care Residents

- Added to QAPI initiative
- Staff educated on early warning signs
- Sepsis protocol pilot to MEC for input

Advisory: Strategies to Turn the Tide against Inappriopriate Antibiotic Utilization

- Developed formulas for appropriate antibiotic choices
- Instituted a recheck of antibiotics and culture results
- Antibiotic use tracked and evaluated at QAPI meetings

Advisory: A Conceptual Framework for Improving Isolation Awareness in Pennsylvania Acute Care Hospitals

- Standardized network isolation practices across multiple hospitals
- Increased observations (use) of PPE, and made isolation compliance a PI measure
- Reevaluated signage system and patient/visitor education



HEALTHCARE FACILITY
CHANGES AS A
RESULT OF READING
PENNSYLVANIA PATIENT
SAFETY ADVISORY
ARTICLES

Advisory: Scabies - Strategies for Management and Control

- Changed environmental cleaning process
- New tracking forms provide better (case) information
- Revamped policy on scabies infestation management

Advisory: Data Snapshot: Clostridium Difficile Infections in Long-Term Care Facilities

- Reinforced C. diff contact precaution practices
- Implemented new environmental cleaning products and schedules
- Improved QA and ongoing review and early identification process

517095

C. diff, Clostridium difficile infection; MEC, medical executive committee; PI, performance improvement; PPE, personal protective equipment; QA, quality assurance; QAPI, Quality assurance and performance improvement.

Survey respondents who indicated that they used one or more of the Authority tools gave the majority of the tools high scores for their usefulness in increasing staff knowledge about infection prevention and control, identifying specific areas in which to direct infection control resources and helping infection prevention analysts perform their job. Most impressive was the response from multiple respondents that a decrease in HAIs in their respective facilities was attributed to use of one or more of the Authority tools. Figure 1 shows how the facilities scored the usefulness of 11 tools in decreasing HAIs. All of the tools are accompanied by an *Advisory* article.

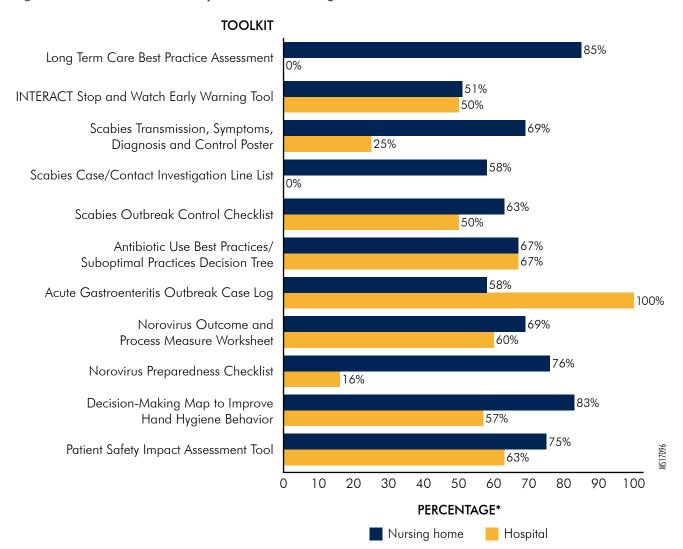


Figure 1. The Usefulness of Authority Toolkits in Decreasing HAI Rates

Healthcare-Associated Infection Advisory Panel

In response to the requirements of Act 52 of 2007,⁴ the Authority's board of directors approved a panel of infection control experts to help implement the Act. The role of the HAI Advisory panel is to provide advice and guidance to the Authority and other state agencies, such as Pennsylvania Department of Health, in implementing the HAI legislation.

The Advisory panel met in June 2016 to review CDC changes to UTI criteria and to discuss potential changes to PA-PSRS and overall guidance from the panel. The panel suggested aligning UTI reporting in PA-PSRS with national

criteria, adding notes to the PA-PSRS user manual with the UTI criteria changes, and providing facilities with the updated information through a program memorandum.

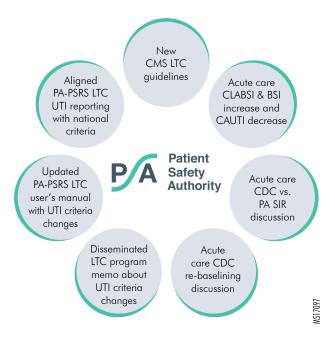
The panel met in December 2016 to discuss an increase in central line–associated bloodstream infections and bloodstream infections (CLABSIs/BSIs), a decrease in catheter-associated urinary tract infections (CAUTI), new baseline HAI rates from CDC, CDC's standardized infection ratio (SIR) method versus Pennsylvania's SIR method, and the new CMS long-term care guidelines. The Department, which currently calculates Pennsylvania's baseline

^{*} Among survey respondents who used one or more Authority tools, percentage who found tool useful.

HAI rates, provided an overview of CDC's revised hospital baseline calculations. Feedback from the panel of experts provided guidance to the Department to facilitate alignment with CDC criteria for hospital data.

The HAI Advisory panel continues to meet to discuss HAI-related topics. A new HAI Advisory panel member was added and was to begin participating in activities in 2017. See Figure 2.

Figure 2. HAI Advisory Panel Activities



BSI, Bloodstream infection; CAUTI, catheter-associated urinary tract infection; CDC, Centers for Disease Control and Prevention; CLABSI, central line-associated bloodstream infection; CMS, Centers for Medicare and Medicaid Services; LTC, long-term care; LTCF, long-term care facility; PA-PSRS, Pennsylvania Patient Safety Reporting System; PA, Pennsylvania; SIR, standardized infection ratio; UTI, urinary tract infection.

Emergency Preparedness

The Authority, the Department, the Hospital and Health-system Association of Pennsylvania (HAP), and local health departments have worked together over the past two years to help Pennsylvania acute-care facilities prepare for episodic biological threats by providing consultation before and during site visits. The Authority provides infection prevention and control expertise for the following:

- Employee health
- Patient safety and holistic care
- System design
- Workflow management

- Equipment evaluation
- Personal protective equipment use
- Suggestions for simulation and practice drills

Although these activities fall under the auspices of Ebola disease preparedness and build on CDC's Rapid Ebola Preparedness team visits, the Authority has supported and worked with Pennsylvania facilities on emergency preparedness since 2014. The Authority looks forward to continuing the partnerships with the Department, HAP, local health departments, and the acute-care facilities that have been designated as biologic hazard preparedness treatment centers or that continue to strive for that status.

Nursing Home Data Analysis

The year 2016 was the second full calendar year of data from nursing homes reported through PA-PSRS using the revised McGeer criteria. Authority analysts grouped several infection classifications into specific care areas because this practice helps nursing homes concentrate their surveillance, resources, and prevalence investigations. Individual facilities can access reports about their own HAI occurrences in specific patient care areas in the PA-PSRS nursing home HAI analytics tab. In 2016, Pennsylvania nursing homes reported 27,544 HAI events through PA-PSRS, a 13% decrease from the 31,672 submitted in 2015.

In previous reports, analysts have provided figures and tables depicting trends of nursing home HAI in Pennsylvania. Because 2016 represents the second calendar year

of data based on the McGeer criteria, comparison in this report of two data points would have no statistical significance in terms of realizing or predicting trends. The 2017 annual report will make possible testing of these data for trends, because three calendar years will be avaliable for statistical analysis.

However, comparison of lower respiratory tract infection (LRTI) events is provided (in subsequent sections) by month and year because they are affected by seasonal variability and the influence of community disease pressure on the nursing home. A year-to-year comparison of device-related bloodstream infections is also provided to draw attention to the observation by Authority analysts that the number of reports increased in most months.

Analysis Method

Of the 703 facilities active as of December 31, 2016, basic validation criteria were met by 678 (96.4%) facilities, spanning five care areas.*

The Authority excluded 25 facilities for analysis based on the following (where relevant, comparisons to exclusions in 2015 are provided):

- Resident days were not entered for every month of 2016; 8 nursing homes were excluded, compared with 17 in 2015.
- Nursing homes had a month during which occupancy was above 100% or below 50%. Occupancy is calculated by dividing the number of resident days by the number of beds listed for each facility. The

quotient is then divided by the number of days in each month. In the 2016 data, 16 nursing homes were excluded, compared to 21 in 2015.

- No nursing homes were excluded at the unit level for reporting infections without accompanying resident days in 2016 data.
- One nursing home was excluded from analysis for CAUTIs in 2016 data because CAUTIs were reported without accompanying catheter days.
- No nursing homes were excluded from analysis for CLABSIs in 2016 data for reporting CLABSIs without accompanying central-line days.

Urinary Tract Infection

Table 1 shows 2016 UTIs by care area and in aggregate total. CAUTI overall has the greatest rates of the UTI category, followed by symptomatic urinary tract infection (SUTI), then both of the asymptomatic bacteremic urinary tract infection (ABUTI) types.

^{*} The following sections and associated tables and graphs include breakdowns by care area where applicable.

Care areas are defined in the PA-PSRS Training Manual and Users' Guide. Nursing Home Event Reporting.⁷

CAUTI

Ventilator-dependent units seem to have significantly lower CAUTI rates as compared with other units. Dementia and mixed units appear to have the highest rates of CAUTI (Figure 3). The dementia units have a very low rate of device use, signaling that it may be difficult to lower their CAUTI rate further unless novel care practices are developed to address prevention. The skilled nursing/short-term rehabilitation (SN/STR) units have the highest

device use rate. Compared with 2015 data, SN/STR units experienced a decrease in CAUTI, albeit not statistically significant:

- 2015: rate 0.85 (95% confidence interval [CI], 0.77 to 0.93)
- 2016: rate 0.82 (95% CI, 0.74 to 0.91)

SUTI

SUTI (Figure 4) remains low overall; however, it is most prevalent in mixed and SN/STR units.

ABUTI

Both C types are depicted as having pooled rates of zero. ABUTI signals the transformation of an asymptomatic UTI into a bloodstream infection, essentially sepsis or at least bacteriemia. ABUTI should remain a focus from a

prevention standpoint in all environments regardless of rate interpretation because of its potential for lifetheatening consequences.

Respiratory Tract Infection

Pneumonia continues to be the predominant infection type in all care areas (Table 2). The rates of other lower respi-

ratory tract infection (LRTI) types remain fairly consistent throughout the months, with the exception of influenza.

Influenza

The incidence of influenza in January 2016 as compared to January 2015 was lower in terms of LRTI rates (Figure 5), probably because of the influence of annual and seasonal variability. The rate of influenza has a temporal association with the rate of pneumonia within this population of patients. CDC FluView data (Figures 6 and 7) show the national impact of influenza by week. When data in these figures is combined to equate to calendar year 2016, in terms of trends, the resulting national laboratory data is similar epidemiologically with Pennsylvania event reports through PA-PSRS in 2016 (Figure 8).

This similarity in statewide and national influenza trends reinforces the need for continued preventative measures that protect residents in a nursing home facility from

Gastrointestinal Infection

Gastrointestinal infections in 2016 were primarily C. difficile and norovirus (Table 3). There were few reports of bacterial gastrointestinal infections.

influenza when the incidence in the community is unusually large. For example, nursing homes may consider screening visitors for respiratory illness before or during a visit, then provide just-in-time education about respiratory etiquette, mask use, and hand hygiene.

Other interventions nursing homes may wish to consider include placing signage and providing materials such as masks, hand sanitizer, and tissues at entrances, which could help protect residents from illness and heighten awareness of visitors about their impact on the health of residents. Resident education and their use of respiratory etiquette, as well as appropriate use of isolation, could be areas of focus.

C. difficile

The rate of *C. difficile* infection was highest in the ventilator dependent units, which may be related to the fact that the ventilator dependent units also experienced a higher rate of pneumonia as compared with other unit types (Table 2). According to Chmielewska and co-authors, "One of the most common gastrointestinal infections after the antibiotic treatment of community or nosocomial pneumonia is caused by the anaerobic spore *Clostridium difficile*." Given the higher acuity and nature of the constellation of patients on ventilator dependent units and their susceptibility to respiratory infection, these units may be prime areas of focus for antibiotic stewardship programs for the prevention of *C. difficile* infection.

A statistically significant decrease in the confidence interval in gastrointestinal total infections occurred between 2015 and 2016:

- 2015 rate per 1,000 resident days: 0.15 (95% CI, 0.15 to 0.16)
- 2016 rate per 1,000 resident days: 0.12 (95% CI, 0.12 to 0.13)
- This reduction is likely atributed to a reduction in the rate of norovirus with a positive laboratory result as well as norovirus by Kaplan criteria. Analysis of this difference is impossible without national trend data in order to identify external pressure and seasonality.⁹

Norovirus

CDC's "U.S. Trends of Norovirus-associated Outcomes Figures" webpage was last reviewed on June 24, 2016, and last updated on October 30, 2013.9 To aid Pennsylvania nursing homes, Figure 9 provides seasonal trends to help nursing homes prepare for norovirus in the coming year associated with timing and expected duration of

external pressure. A norovirus outbreak is defined as three or more cases of norovirus defined within a three-day period. ¹⁰ Further, Figure 9 shows the number of reports from nursing homes that did or did not meet the norovirus outbreak definition.

Skin and Soft Tissue Infection

Cellulitis, soft tissue, or wound infection remain constant throughout the defined care areas, which is consistent with the 2015 annual report. The incidence of both scabies and conjunctivitis is present in all care areas. Units for ventilator-dependent patients seem to experience more conjunctivitis in general. The Authority encourages staff

in ventilator dependent units, as well as others, to assess infection-control practices, such as hand hygiene and isolation practices, and to conduct root-cause analysis when scabies or conjunctivitis cases occur, to build knowledge and prevention strategies. See Table 4 for 2016 events.

Central Line-Associated Blood Stream Infection

CLABSI is split into three separate categories: dialysis lines, temporary lines, and permanent lines. The definition for each line type is available in Figure 11.

A rate table is not included in this analysis because the pooled rates by care area for 2016 remain at 0.0. CLABSI is measured as a rate per 1,000 central line days. 11 In circumstances in which CLABSI rates are very low, even zero, there may still be infections happening. For example, Pronovost and co-authors noted that, after their intervention aimed at CLABSI reduction, "within 3 months after implementation the median infection rate was 0." 12 That is

to say, the median rate per 1,000 central line days was 0, not that there were no infections occurring.

Pennsylvania nursing homes reported more CLABSI events in 2016 than in 2015 (Figures 10 and 11). Because only two years of data are available for analysis, there are too few data points to predict whether this will become an ongoing trend. According to the literature, mortality rates because of CLABSI are between 12% and 25% and costs are between \$3,700 and \$36,000 per occurrence. 13,14 CLABSI should remain a focus for all care areas that house residents with central lines regardless of zero or

very low-pooled rates of infection. The Authority encourages facilities to assess practices related to the care and maintenance of central lines and adhere to accepted clini-

cal standards. Facilities could also engage dialysis centers in conversations about care and maintenance of dialysis lines, to coordinate care and maintenance.

Conclusion

The analytics presented herein related to HAI are no longer static yearly reports. Upon login to PA-PSRS, nursing homes can access facility-specific data as well as statewide and peer group data through the "Analytical Data Tools Menu"; the data are updated daily. The Authority

encourages individual facilities to use the analytics within PA-PSRS to lead continuous performance improvement interventions at the facility level.

See following pages for data tables and figures.

Note: Table rows indicating totals show the number of nursing homes reporting for the given type of infection with each unit name. This is not to be confused with the sum of the unit types for that infection. There may be overlap of unit types reporting at any given facility.

Table 1. Urinary Tract Infections, Pooled Mean Rates, by Subcategory and Care Unit, 2016

| UNIT NAME (N) | NUMBER OF | RESIDENT DAYS | CATHETER DAYS | DEVICE UTILIZATION RATE* | POOLED INFECTION RATE (95% CI)†.‡ |
|--|-----------------------|----------------------|--------------------|--------------------------------|-----------------------------------|
| | | | | removed within | the past 2 calendar days |
| at the facility | _ | | - | | |
| Dementia unit (25) | 33 | 2,293,538 | 37,318 | 0.016 | 0.88 (0.58 - 1.19) |
| Mixed unit (118) | 335 | 7,739,418 | 372,521 | 0.048 | 0.9 (0.8 - 1) |
| Nursing unit (107) | 281 | 8,426,415 | 355,114 | 0.042 | 0.79 (0.70 - 0.88) |
| SN/STR unit (157) | 392 | 9,109,775 | 475,261 | 0.052 | 0.82 (0.74 - 0.91) |
| Vent unit (7) | 30 | 173,405 | 43,885 | 0.253 | 0.68 (0.44 - 0.93) |
| Total (356) | 1,071 | 27,742,551 | 1,284,099 | 0.046 | 0.83 (0.78 - 0.88) |
| Device-Related ABUT | l—Catheter in place v | without localizing u | rinary signs or sy | mptoms | |
| Dementia unit (1) | 1 | 2,293,538 | 37,318 | 0.016 | 0.03 (0 - 0.08) |
| Mixed unit (10) | 10 | 7,739,418 | 372,521 | 0.048 | 0.03 (0.01 - 0.04) |
| Nursing unit (7) | 10 | 8,426,415 | 355,114 | 0.042 | 0.03 (0.01 - 0.05) |
| SN/STR unit (18) | 23 | 9,109,775 | 475,261 | 0.052 | 0.05 (0.03 - 0.07) |
| Vent unit (2) | 3 | 173,405 | 43,885 | 0.253 | 0.07 (0 - 0.15) |
| Total (37) | 47 | 27,742,551 | 1,284,099 | 0.046 | 0.04 (0.03 - 0.05) |
| SUTI—Catheter not pr | esent or catheter re | noved for more tha | n 2 calendar day | s within the facili | ty with localizing urinary |
| signs or symptoms | | | | | |
| Dementia unit (84) | 230 | 2,293,538 | NA | NA | 0.1 (0.09 - 0.11) |
| Mixed unit (160) | 1,328 | 7,739,418 | NA | NA | 0.17 (0.16 - 0.18) |
| Nursing unit (181) | 1,215 | 8,426,415 | NA | NA | 0.14 (0.14 - 0.15) |
| SN/STR unit (252) | 1,649 | 9,109,775 | NA | NA | 0.18 (0.17 - 0.19) |
| Vent unit (7) | 12 | 173,405 | NA | NA | 0.07 (0.03 - 0.11) |
| Total (491) | 4,434 | 27,742,551 | NA | NA | 0.16 (0.16 - 0.16) |
| ABUTI—Catheter not urinary signs or symp | • | | nan 2 calendar da | ys within the fac | ility without localizing |
| Dementia unit (5) | 9 | 2,293,538 | NA | NA | 0 (0 - 0.01) |
| Mixed unit (31) | 41 | 7,739,418 | NA | NA | 0.01 (0 - 0.01) |
| Nursing unit (26) | 39 | 8,426,415 | NA | NA | 0 (0 - 0.01) |
| SN/STR unit (39) | 70 | 9,109,775 | NA | NA | 0.01 (0.01 - 0.01) |
| Vent unit (2) | 2 | 173,405 | NA | NA | 0.01 (0 - 0.03) |
| Total (93) | 161 | 27,742,551 | NA | NA | 0.01 (0 - 0.01) |

Note: As reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2016

ABUTI, Asymptomatic bacteremic urinary tract infection; CI, confidence interval; CAUTI, catheter-associated urinary tract infection; NA, not applicable; SN/STR, skilled nursing/short-term rehabilitation; SUTI, symptomatic urinary tract infection; vent, ventilator-dependent.

^{*} Device utilization rate (DUR): number of urinary catheter days \div number of resident days

 $^{^{\}dagger}$ Basic urinary tract infection (UTI) rate calculation: number of UTI \div number of resident days \times 1,000

 $^{^{\}ddagger}$ CAUTI rate calculation: number of CAUTI \div number of catheter days imes 1,000

Figure 3. CAUTI Rates, by Care Unit and Month, 2016

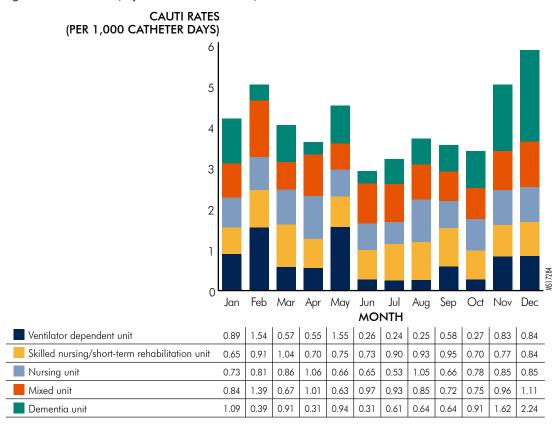


Figure 4. SUTI Rates, by Care Unit and Month, 2016

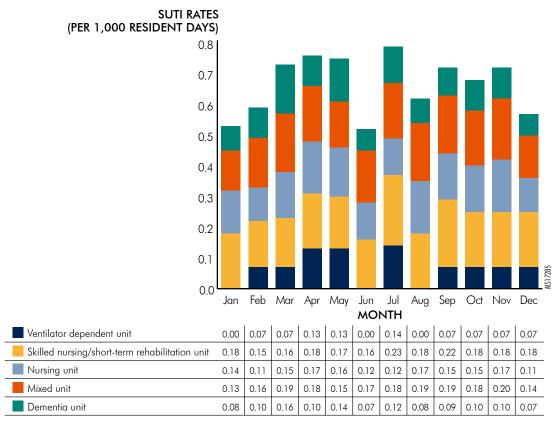


Table 2. Respiratory Tract Infections, Pooled Mean Rates, by Subcategory and Care Unit, 2016

| UNIT NAME (N) | NUMBER OF INFECTIONS | RESIDENT DAYS | POOLED INFECTION RATE (95% CI)* |
|---|---|----------------------------|----------------------------------|
| Influenza—The resident h | nas tested positive for influenza | | |
| Dementia unit (18) | 55 | 2,293,538 | 0.02 (0.02 - 0.03) |
| Mixed unit (40) | 131 | 7,739,418 | 0.02 (0.01 - 0.02) |
| Nursing unit (45) | 135 | 8,426,415 | 0.02 (0.01 - 0.02) |
| SN/STR unit (62) | 168 | 9,109,775 | 0.02 (0.02 - 0.02) |
| Vent unit (1) | 4 | 173,405 | 0.02 (0 - 0.05) |
| Total (81) | 493 | 27,742,551 | 0.02 (0.02 - 0.02) |
| | e resident has fever, influenza is suspe | ected. Testing for influen | za is negative or not performed, |
| , , | n, but no other overt signs | 0.000.500 | 0.40 0.01 |
| Dementia unit (9) | 10 | 2,293,538 | 0 (0 - 0.01) |
| Mixed unit (13) | 32 | 7,739,418 | 0 (0 - 0.01) |
| Nursing unit (17) | 34 | 8,426,415 | 0 (0 - 0.01) |
| SN/STR unit (29) | 37 | 9,109,775 | 0 (0 - 0.01) |
| Vent unit (0) | 0 | 173,405 | 0 (0 - 0) |
| Total (137) | 113 | 27,742,551 | 0 (0 - 0) |
| Lower respiratory tract in without fever; or no chest | fection—Chest radiograph is negative radiograph performed | for pneumonia or a new | infiltrate and the resident is |
| Dementia unit (81) | 233 | 2,293,538 | 0.1 (0.09 - 0.11) |
| Mixed unit (137) | 823 | 7,739,418 | 0.11 (0.1 - 0.11) |
| Nursing unit (152) | 718 | 8,426,415 | 0.09 (0.08 - 0.09) |
| SN/STR unit (198) | 1,132 | 9,109,775 | 0.12 (0.12 - 0.13) |
| Vent unit (9) | 28 | 173,405 | 0.16 (0.1 - 0.22) |
| Total (426) | 2,934 | 27,742,551 | 0.11 (0.1 - 0.11) |
| Pneumonia—Resident's c | hest radiograph is positive for pneumo | onia or a new infiltrate | |
| Dementia unit (120) | 377 | 2,293,538 | 0.16 (0.15 - 0.18) |
| Mixed unit (186) | 1,548 | 7,739,418 | 0.2 (0.19 - 0.21) |
| Nursing unit (206) | 1,451 | 8,426,415 | 0.17 (0.16 - 0.18) |
| SN/STR unit (283) | 1,958 | 9,109,775 | 0.21 (0.21 - 0.22) |
| Vent unit (9) | 99 | 173,405 | 0.57 (0.46 - 0.68) |
| Total (198) | 5,433 | 27,742,551 | 0.2 (0.19 - 0.2) |
| Total Respiratory Tract Inf | fections | | |
| Dementia unit (136) | 675 | 2,293,538 | 0.29 (0.27 - 0.32) |
| Mixed unit (194) | 2,534 | 7,739,418 | 0.33 (0.31 - 0.34) |
| Nursing unit (217) | 2,338 | 8,426,415 | 0.28 (0.27 - 0.29) |
| SN/STR unit (303) | 3,295 | 9,109,775 | 0.36 (0.35 - 0.37) |
| Vent unit (11) | 131 | 173,405 | 0.76 (0.63 - 0.88) |
| Total (577) | 8,973 | 27,742,551 | 0.32 (0.32 - 0.33) |

Note: As reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2016

CI, Confidence interval; SN/STR, skilled nursing/short-term rehabilitation; vent, ventilator dependent.

^{*} Rate calculation: number of infections \div number of resident days \times 1,000

Figure 5. Lower Respiratory Tract Infection (LRTI) Rates, by Criteria Definition and Month, 2015 versus 2016

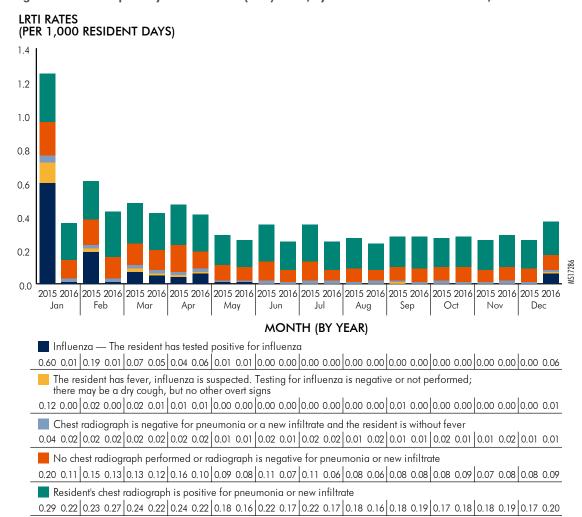
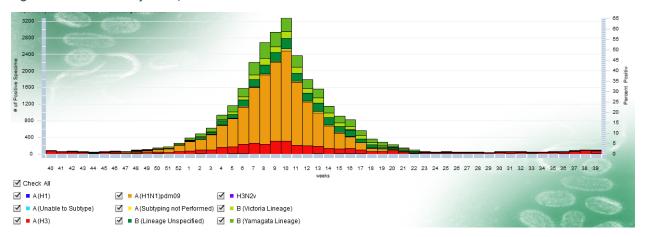
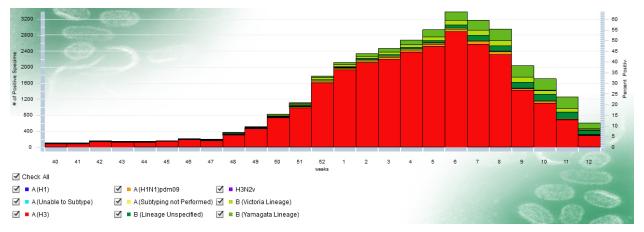


Figure 6. CDC FluView by Week, 2015-2016



Source: From Centers for Disease Control and Prevention. Influenza positive tests reported to CDC by US public health laboratories, national summary, 2015–2016, week ending Oct 01, 2016 [online]. [cited 2017 Mar 26]. https://gis.cdc.gov/grasp/fluview/fluportaldashboard.html

Figure 7. CDC FluView by week, 2016-2017



Source: From Centers for Disease Control and Prevention. Influenza positive tests reported to CDC by US public health laboratories, national summary, 2016–2017, week ending Mar 18, 2017 [online]. [cited 2017 Mar 26]. https://gis.cdc.gov/grasp/fluview/fluportaldashboard.html

Figure 8. Influenza Reports, by Care Unit and Month, 2016

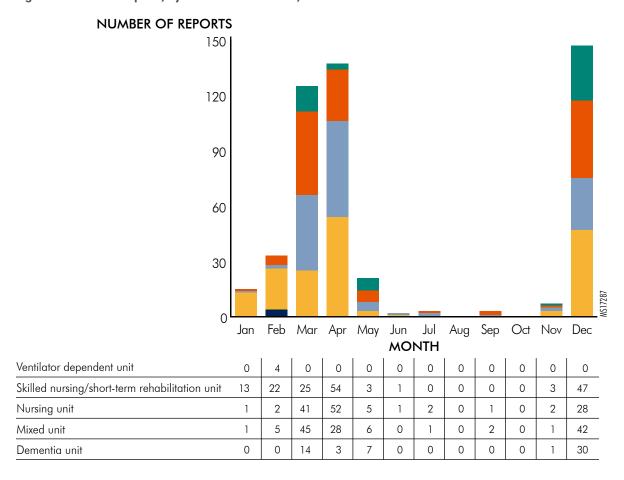


Table 3. Gastrointestinal Infections, Pooled Mean Rates, by Subcategory and Care Unit, 2016

| UNIT NAME (N) | NUMBER OF INFECTIONS | RESIDENT DAYS | POOLED INFECTION RATE (95% CI)* |
|--|------------------------------|---------------------------------|---|
| toxin-producing C. diffici | | = | difficile toxin A or B, or a esting, or Pseudomembranous colitis |
| Dementia unit (32) | 53 | 2,293,538 | 0.02 (0.02 - 0.03) |
| Mixed unit (160) | 548 | 7,739,418 | 0.07 (0.06 - 0.08) |
| Nursing unit (150) | 447 | 8,426,415 | 0.05 (0.05 - 0.06) |
| SN/STR unit (250) | 1,074 | 9,109,775 | 0.12 (0.11 - 0.12) |
| Vent unit (11) | 43 | 173,405 | 0.25 (0.17 - 0.32) |
| Total (480) | 2,165 | 27,742,551 | 0.08 (0.07 - 0.08) |
| Norovirus—The resident | has diarrhea and/or vomitin | g and laboratory results are po | sitive for Norovirus |
| Dementia unit (1) | 1 | 2,293,538 | O (O - O) |
| Mixed unit (7) | 15 | 7,739,418 | O (O - O) |
| Nursing unit (4) | 4 | 8,426,415 | O (O - O) |
| SN/STR unit (13) | 21 | 9,109,775 | 0 (0 - 0) |
| Vent unit (0) | 0 | 173,405 | O (O - O) |
| Total (22) | 41 | 27,742,551 | 0 (0 - 0) |
| Bacterial gastroenteritis- bacteriologic pathogen | —The resident has diarrhea o | and/or vomiting and laboratory | results are positive for a |
| Dementia unit (1) | 1 | 2,293,538 | 0 (0 - 0) |
| Mixed unit (6) | 7 | 7,739,418 | 0 (0 - 0) |
| Nursing unit (5) | 5 | 8,426,415 | 0 (0 - 0) |
| SN/STR unit (7) | 8 | 9,109,775 | O (O - O) |
| Vent unit (0) | 0 | 173,405 | O (O - O) |
| Total (19) | 21 | 27,742,551 | 0 (0 - 0) |
| Kaplan—Norovirus is sus results are negative | pected based on Kaplan crit | eria; the resident has diarrhea | and/or vomiting and C. difficile |
| Dementia unit (17) | 137 | 2,293,538 | 0.06 (0.05 - 0.07) |
| Mixed unit (20) | 294 | 7,739,418 | 0.04 (0.03 - 0.04) |
| Nursing unit (25) | 325 | 8,426,415 | 0.04 (0.03 - 0.04) |
| SN/STR unit (30) | 417 | 9,109,775 | 0.05 (0.04 - 0.05) |
| Vent unit (0) | 0 | 173,405 | O (O - O) |
| Total (67) | 1,173 | 27,742,551 | 0.04 (0.04 - 0.04) |
| Total Gastrointestinal Inf | ections Reported | | |
| Dementia unit (32) | 192 | 2,293,538 | 0.08 (0.07 - 0.1) |
| Mixed unit (160) | 864 | 7,739,418 | 0.11 (0.1 - 0.12) |
| Nursing unit (150) | 781 | 8,426,415 | 0.09 (0.09 - 0.1) |
| SN/STR unit (250) | 1,520 | 9,109,775 | 0.17 (0.16 - 0.18) |
| Vent unit (11) | 43 | 173,405 | 0.25 (0.17 - 0.32) |
| Total (504) | 3,400 | 27,742,551 | 0.12 (0.12 - 0.13) |

Note: As reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2016

CI, Confidence interval; SN/STR, skilled nursing/short-term rehabilitation; vent, ventilator dependent.

^{*} Rate calculation: number of infections \div number of resident days \times 1,000

Figure 9. Norovirus Outbreaks by Month, 2016

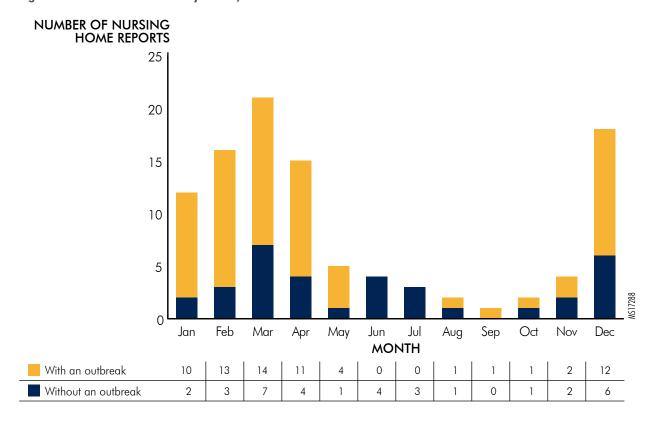


Table 4. Skin and Soft Tissue Infections, Pooled Mean Rates, by Subcategory and Care Unit, 2016

| UNIT NAME (N) | NUMBER OF INFECTIONS | RESIDENT DAYS | POOLED INFECTION RATE (95% CI)* |
|---------------------------------|----------------------|---------------|---------------------------------|
| Cellulitis, soft tissue, or wou | nd infection | | |
| Dementia unit (103) | 317 | 2,293,538 | 0.14 (0.12 - 0.15) |
| Mixed unit (183) | 1,597 | 7,739,418 | 0.21 (0.2 - 0.22) |
| Nursing unit (206) | 1,609 | 8,426,415 | 0.19 (0.18 - 0.2) |
| SN/STR unit (277) | 1,769 | 9,109,775 | 0.19 (0.19 - 0.2) |
| Vent unit (11) | 56 | 173,405 | 0.32 (0.24 - 0.41) |
| Total (546) | 5,348 | 27,742,551 | 0.19 (0.19 - 0.2) |
| Conjunctivitis | | | |
| Dementia unit (101) | 365 | 2,293,538 | 0.16 (0.14 - 0.18) |
| Mixed unit (150) | 1,004 | 7,739,418 | 0.13 (0.12 - 0.14) |
| Nursing unit (177) | 1,099 | 8,426,415 | 0.13 (0.12 - 0.14) |
| SN/STR unit (200) | 975 | 9,109,775 | 0.11 (0.1 - 0.11) |
| Vent unit (9) | 28 | 173,405 | 0.16 (0.1 - 0.22) |
| Total (455) | 3,471 | 27,742,551 | 0.13 (0.12 - 0.13) |
| Scabies | | | |
| Dementia unit (14) | 36 | 2,293,538 | 0.02 (0.01 - 0.02) |
| Mixed unit (27) | 42 | 7,739,418 | 0.01 (0 - 0.01) |
| Nursing unit (19) | 44 | 8,426,415 | 0.01 (0 - 0.01) |
| SN/STR unit (41) | 98 | 9,109,775 | 0.01 (0.01 - 0.01) |
| Vent unit (0) | 0 | 173,405 | O (O - O) |
| Total (91) | 220 | 27,742,551 | 0.01 (0.01 - 0.01) |
| Total Skin and Soft Tissue In | fections | | |
| Dementia unit (140) | 718 | 2,293,538 | 0.31 (0.29 - 0.34) |
| Mixed unit (205) | 2,643 | 7,739,418 | 0.34 (0.33 - 0.35) |
| Nursing unit (221) | 2,752 | 8,426,415 | 0.33 (0.31 - 0.34) |
| SN/STR unit (309) | 2,842 | 9,109,775 | 0.31 (0.3 - 0.32) |
| Vent unit (12) | 84 | 173,405 | 0.48 (0.38 - 0.59) |
| Total (589) | 9,039 | 27,742,551 | 0.33 (0.32 - 0.33) |

Note: As reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) in 2016

CI, Confidence interval; SN/STR, skilled nursing/short-term rehabilitation; vent, ventilator dependent.

^{*} Rate calculation: number of infections \div number of resident days \times 1,000

Figure 10. Device-Related Bloodstream Infections, by Care Unit

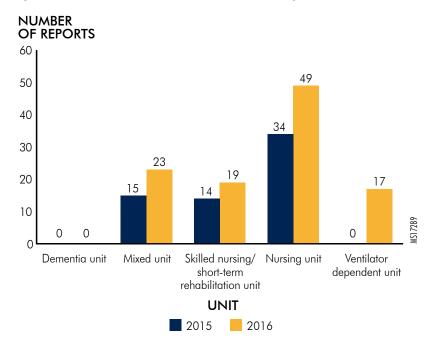
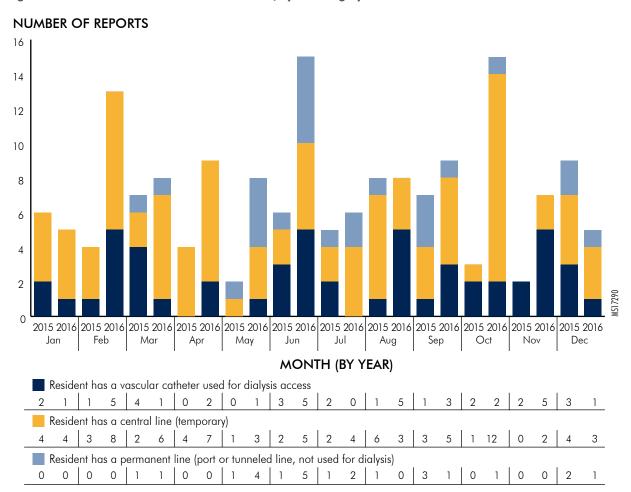


Figure 11. Device-Related Bloodstream Infections, by Subcategory



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The Pennsylvania Patient Safety Advisory

Through its Pennsylvania Patient Safety Advisory, the Pennsylvania Patient Safety Authority continues to help improve patient safety in Pennsylvania. From the first issue in March 2004 through December 2016, the Advisory has provided nearly 540 safety-focused articles. Patient safety events—including "good catches" and unsafe conditions—reported by Pennsylvania healthcare facilities, requests for information from Pennsylvania healthcare providers, and review of the medical and patient safety literature prompts analysis of the aggregate event data; specific examples from 2016 include the following:

- A select set of patient safety measures—falls with harm, central line—associated bloodstream infections, catheter-associated urinary tract infections, wrong-site surgeries, and high harm events—was analyzed to demonstrate patient safety improvements associated with the combined efforts of Pennsylvania healthcare facilities, statewide quality improvement entities, and the Authority. The Authority estimates that through 2015, for these five measures alone, more than 2,600 lives and more than \$147 million were saved.¹
- Although rarely reported to the Authority in Pennsylvania, incorrect-end colostomy formation using the distal bowl limb can potentially result in serious harm to patients or even death.²
- In a Pennsylvania event associated with a "good catch," a healthcare worker noted that pads for an automated external defibrillator (AED) were incompatible with the accompanying AED. Beyond just ensuring that all of the parts fit together correctly on this particular AED, this person went further, and checked on the other similar devices throughout the facility.³
- Analysts estimate that an average of 1.7 newborn misidentification events occur daily in Pennsylvania, affecting 4.6 newborns per 1,000 births.⁴
- Through November 2015, Pennsylvania nursing homes reported 484 cases of scabies and

- 37 outbreaks; hospital inpatient, emergency, and outpatient settings reported 110 events associated with scabies.⁵
- In an analysis of the most recent 10 years of events reported in Pennsylvania, analysts identified a 66.4% reduction in the number of opioid wrongdrug events reported, and a 79.4% reduction in the number of wrong-drug events involving mix-ups between morphine and HYDROmorphone.⁶
- Healthcare personnel are responsible for removing the tourniquet after intravenous insertion, phlebotomy, and anesthesia blocks are complete. An online video provides suggestions to help healthcare providers overcome persistent challenges in ensuring tourniquet removal (https://youtu.be/fsc6chuPBkc).⁷

Overall, in responses collected through annual surveys conducted since 2005, Commonwealth facilities credit the Advisory with contributing to more than 4,650 structure and process improvements; the Authority assumes these numbers represent just the tip of the iceberg. Supporting education and improvement endeavors constitute the primary objective of the Advisory, as follows:

"The Pennsylvania Patient Safety Advisory provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare-delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and problems in which urgent communication of information could have a significant impact on patient outcomes."

By introducing video presentations and heat map graphics, staff continued to enhance the readability and presentation of information during 2016. A graphic display of scabies transmission, symptoms, diagnosis,

and control was a highlight. Articles consistently identified and analyzed problems and challenges, presented narrative stories, and offered strategies and solutions. The Advisory also featured several articles addressing modern concepts and processes in patient safety and care delivery, such as using simulation to improve care, appreciating the essential human element in technology-driven care processes, and promoting the value of lessons learned through "good catches," which stimulated system-wide

improvements. Finally, as noted in Educational Programs, Advisory-based, concise webinars allowed participants to interact with analysts and explore the principles of patient safety and methods to implement improvements.

The following pages illustrate the depth and breadth of the Authority's Advisory in 2016, as well as during its 13-volume history, and its demonstrated value in the healthcare community.

Notes

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2016 Articles

Surgery

Incorrect-End Colostomies Preoperative Screening: Collaboration

Ophthalmology Process Assessment

Wrong-Site Surgery: Updates

Infection Prevention

Clostridium difficile Infections

Early Detection of Sepsis

Infection Control and CAUTIs

Nursing Homes Reduce CAUTIs Scabies



Scabies Transmission, Symptoms, Diagnosis, and Control

Patient and Family Involvement

Health Literacy

Identifying Patients with Dementia

Wrong-Site Surgery: Patient Engagement

Medication **Drua** Interactions

Incorrect Patient Weights Medication Errors involving Students Prescribing Errors **Opioids**



Computerized Prescriber Order Entry (CPOE) System Evaluation



Can Simulation in situ Improve Patient Safety?

Maternity

Newborn Identification Maternal Serious Events Postpartum Hemorrhage

Leadership

Checklists Healthcare: Complex, Adaptive, Evolving I Am Patient Safety Awards Innovation is Key Saves, System Improvements, and Safety II

Value of Improving Patient Safety

Teamwork

Blood Transfusions

Forgotten Tourniquets

Intraosseous Lines

Isolation Awareness

Missed Respiratory Therapy

That Pesky Human Factor



Tourniquet Removal and Discard Process

Content is grouped according to predominant patient safety foci. For more information by areas of focus, see "Patient Safety Focus" at http://patientsafetyauthority.org.

Scope

540+ articles

published in 64 issues and supplements since March 2004



49 toolkits

available, including myriad tools (2016 emphasized)









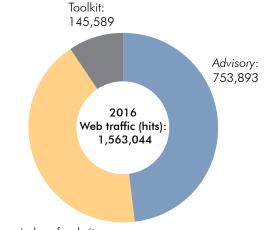






irus Anticoagulatio PREVENTING WRONG-SITE SURGERY ionia Diagnostic Error SCABIES **HEALTH LITERACY** ıza (Flu) Newborn Injuries PRESCRIBING ERRORS Blood Tra

On the Web



Remainder of website: (e.g., homepage, search, webinar recordings, press releases) 663,562

2016 Advisory Hits: Top Articles per Issue

March

Medication Errors Involving Healthcare Students

Family Members Advocate for Improved Identification of Patients with Dementia in the Acute Care Setting

June

Newborns Pose Unique Identification Challenges

Health Literacy and Patient Safety Events

September

Prescribing Errors that Cause Harm

Early Detection of Sepsis in Pennsylvania's Long-Term Care Residents

December

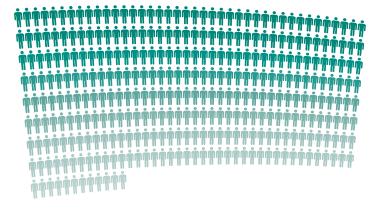
Update on Wrong-Site Surgery: Reports from Ambulatory Surgical Facilities

Analysis of Reported Drug Interactions: A Recipe for Harm to Patients

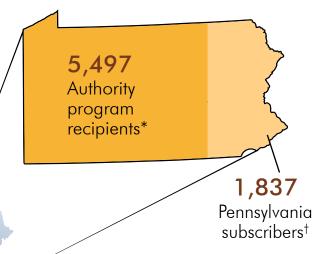
1,000 1,500 2,000 2,500 3,000

Note: Hits as of December 31, 2016. Articles published earlier have had more time to garner hits.

Readership



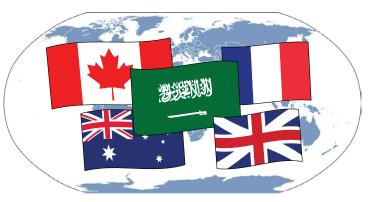
332 new subscribers in 2016



3,107 subscribers in the United States

Subscribers in 49 states, as well as Washington, DC, and Puerto Rico

Subscribers in 45 countries 3,276 subscribers worldwide (top five, other than U.S. emphasized)



^{*} Recipients include reporting system users from acute healthcare facilities and nursing homes, as well as board and panel members in Pennsylvania. These recipients are not included in the total numbers of PA/U.S./worldwide subscribers indicated above.

[†] Subscriber numbers reported through 2016 exclude any subscribers with email addresses that indicated lack of receipt (i.e., "bounced") during 2016.

Value

4,650+ documented* changes in Pennsylvania acutecare facilities and nursing homes directly attributed to *Advisory* articles since 2005

2016 Ratings of the Advisory



Annual Survey Respondents

The tracking forms are more helpful than what we were using. I was able to provide better and more useful information to staff.

We now ensure that someone, patient or significant other, has a complete understanding of post-op discharge instructions.

We have developed an antibiotic stewardship program—to be rolled out next week.

We have patients' height and weight taken in preoperative area so it is accurate on H&P for procedure date.

We are in the process of changing our electronic medical record and will incorporate your points

12,320+Advisory-based CME credits,
2006 through 2016[†]

Through 2016, the media or medical literature attributed or mentioned

Authority-associated content in more than

850 instances, including nearly

450 references to Advisory articles.

^{*}According to Authority user surveys (internal reports): acute-care facilities (2005-2016) and nursing homes (2009-2016).

[†] The Authority applies select articles for CME credit through the Pennsylvania Medical Society (http://www.pamedsoc.org).

Educational Programs

Educating healthcare providers about risk and mitigation strategies is key to improving patient safety. Without knowledge and understanding of events, creating meaningful improvement is difficult. The Authority's statewide perspective of events allows a unique insight into the challenges healthcare providers face and a unique opportunity to use this information to develop programs specific to these challenges.

Authority staff—including patient safety liaisons (PSLs), patient safety analysts, infection prevention analysts, and physicians—in conjunction with outside patient safety and subject matter experts conduct these educational

programs. Education is offered through various means so that individuals can participate in ways that are most convenient for them. Educational programs can be provided on-site at an individual facility's request, in large regional meetings with opportunities to network with peers, on live webinars that can be accessed from any computer while allowing for interaction with the presenters, or by means of online education that can be done at anytime from anywhere. Eighty-three individual patient safety officers were educated via in-person just-in-time training, and 144 education sessions were held on-site at the request of facilities.



2016 Education Programs

Webinars: 3,964 attendees

Newborn Safety
Errors involving
Healthcare Students
Improving Isolation Awareness
Behavioral Patients in the
Acute Care Setting
Safety-I and Safety-II
Scabies

That Pesky Human Factor

Other (professional organizations and schools):

1,164 attendees

Board's Role

Don't Gamble on Patient Safety

From Reporting to Prevention

Nurse Leaders

Dementia

Human Factors

Moving Patient Safety Forward

In-Person: 3,957 attendees

Health Literacy Clostridium difficile Falls

Distractions in the Operating Room Failure Modes and Effects Analysis

From Reporting to Prevention

Root Cause Analysis

Just Culture

Medication Safety

Culture of Safety

Wrong-Site Surgery Safe Injection Practices

Regional: 612 attendees

Ambulatory Surgery
Just Culture
Health Literacy
10 Things Every
Patient Safety Officer

Should Know

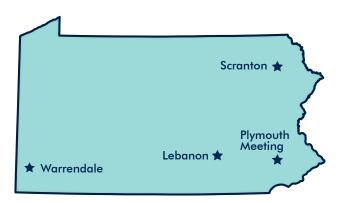
Online learning management system (LMS) and continuing medical eduction (CME):

783 attendees

Final Guidance for Reporting
Alarm Management
Health Information Technology
Pressure Ulcers
Hand Hygiene

Teamwork

ASF SYMPOSIA 2016



Annual symposia held to meet the specific requests and educational needs of Ambulatory Surgical Facilities

TOPICS

- On Becoming a QAPI Cat: Improving Quality
- Active Shooter Workplace Violence
- Wrong-Site Surgery
- Environmental Hygiene



strongly agree that they would recommend this program to a friend



327 hours of CME were awarded for Authority programs through our partnership with UPMC.

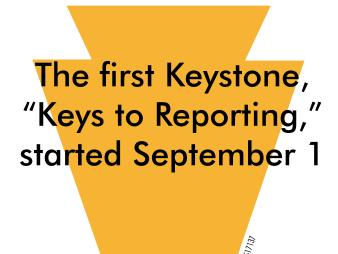


MS17131

Patient Safety Liaison (PSL) Program

The PSL program continues to be a unique program available to Pennsylvania hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities. The PSLs serve as a resource to these facilities for reporting under the Medical Care Availability and Reduction of Error Act, patient safety education, patient safety consultative services, and for ensuring facilities are knowledgeable about Authority resources. The PSL team consists of eight professionals who bring a wide range of skills and experience in patient safety to these facilities.

In 2016, the PSL program underwent some redesign, with a focus on creating a more cohesive team with shared vision and goals and additional resources for facilities. Periodically, the PSLs will roll out a new "Keystone." Each keystone will have a specific topic focus with consultative tools and resources to support facilities in those areas.





730
In-person visits

730
Consultations

317 Educational programs
26 On-site consultations

Collaborative Strategies to Improve Patient Safety

Unity is strength...when there is teamwork and collaboration, wonderful things can be achieved. —Mattie Stepanek

The Pennsylvania Patient Safety Authority has formed strategic partnerships with organizations and facilities in the Commonwealth, collaborating to improve patient safety. All collaborations use evidence-based best practices and provide education, tools, resources, and opportunities for facility networking and sharing. The Authority evaluates grant and other funding and partnership opportunities to support collaborative efforts.

The Authority partnered with the Hospital and Healthsystem Association of Pennsylvania (HAP) at the end of 2015 and 2016 to work on the second Hospital Engagement Network (HEN) contract* and begin work on the Hospital Improvement Innovation Network (HIIN) contract.† The Authority will continue the success of previous HEN contracts with the HIIN contract, which began on September 28, 2016. Following is a summary of the collaborative and partnership activities.

Hospital and Healthsystem Association of Pennsylvania Hospital Engagement Network*

On September 24, 2015, HAP was awarded the primary federal contract for Pennsylvania's Hospital Engagement Network 2.0 (HAP PA-HEN 2.0). The Authority partnered with HAP and other Pennsylvania healthcare organizations to work with Pennsylvania hospitals to reduce healthcareacquired conditions. The contract ended on September 23, 2016.

The goals of the national Partnership for Patients (PfP) Hospital Engagement Network (HEN) 2.0 were as follows:

- Reduce all-cause preventable inpatient harm by 40%.
- Reduce 30-day all-cause readmissions by 20%.

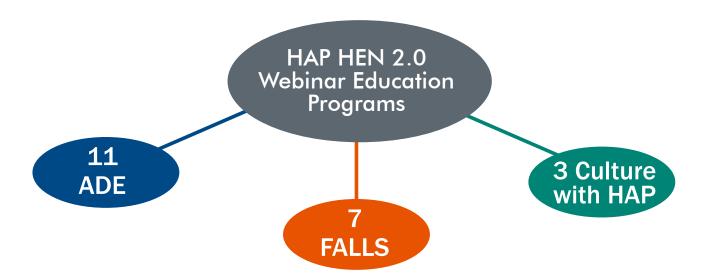
The Authority continued to build on the success of first HAP PA-HEN by continuing to manage the HEN 2.0 immersion projects, comprising Falls with Harm Reduction project (Falls) and the Preventing Harmful Adverse Drug Events Related to Anticoagulants, Insulin, and Opioids project (ADE). The Authority also co-led a culture of safety program in partnership with HAP and supported HAP with the PA-HEN 2.0 Healthcare Associated Infections (HAI) projects. The Authority provided support by providing access to PassKey, a secure, collaborative site that allowed each project to communicate and share information with participants.

The main HAP PA-HEN 2.0 project activities for 2016 are shown on "Building on Success: HEN 2.0 Collaboration."

^{*} The analyses upon which this publication is based were performed under Contract Number HHSM- 500-2015-00300C, entitled, "Partnership for Patients Hospital Engagement 2.0 Contract."

[†] The analyses upon which this publication is based were performed under Contract Number HHSM-500-2016-00066C, entitled, "Partnership for Patients Hospital Improvement Innovation Network Contract, sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services."

Building on Success: HEN 2.0* Collaboration





Anticoagulants tools: http://patientsafetyauthority.org/Educational-Tools/PatientSafetyTools/ams/Pages/Home.aspx
Insulin tools: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/insulin/Pages/home.aspx
Opioids tools: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/opioids/Pages/home.aspx



Falls tools: http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/falls/Pages/home.aspx

ADE, Preventing Harmful Adverse Drug Events Related to Anticoagulants, Insulin, and Opioids project; Falls, Falls with Harm Reduction project; COS, culture of safety; HAP, Hospital and Healthsystem Association of Pennsylvania; HEN 2.0, Partnership for Patients Hospital Engagement 2.0 Contract.

^{*} The analyses upon which this publication is based were performed under Contract Number HHSM- 500-2015-00300C, entitled, "Partnership for Patients Hospital Engagement 2.0 Contract."

Preventing Harmful Adverse Drug Events Related to Anticoagulants, Insulin, and Opioids

The Authority partnered with HAP PA-HEN 2.0* to reduce adverse drug events related to anticoagulants, insulin, and opioids. The Authority's analysis of adverse drug events found the following:

- Over an 18-month period ending in 2009, Pennsylvania healthcare facilities submitted 2,685 medication error reports to the Authority involving the use of insulin. More than 52% of the reported events led to situations in which a patient may have or actually received the wrong dose of insulin (e.g., dose omissions, wrong dose/overdosage, wrong dose/underdosage, extra dose, wrong rate errors), which could lead to difficulties in glycemic control.
- Analysts reviewed medication error reports submitted from July 2013 through June 2014 involving oral anticoagulants. Of the 831 errors related to oral anticoagulants analyzed, the most common event types were drug omissions (32.5%, n = 270), other (18.5%, n = 154), and extra doses (11.7%, n = 97).²
- As a part of the first HAP adverse drug event collaboration, a 45-item organization assessment tool was developed to assess the safety of opioid practices in hospitals. Findings from the assessment revealed many opportunities to improve medication safety and established a baseline of current practices regarding opioid use that can be used to evaluate ongoing improvement.³
- In the same project, an 11-question opioid knowledge assessment tool was developed to assess

practitioners' current knowledge about the use of opioids. More than 1,700 individual practitioners completed the assessment. It has identified numerous, basic knowledge gaps by practitioners, which will hopefully spur organizations to address these gaps and assess staff knowledge about other high-alert medications.⁴

The goals of HAP PA-HEN 2.0 were to reduce adverse drug events related to anticoagulants, insulin, and opioids by 40%, help hospitals assess their practices, provide education on these adverse drug event topics, and help hospitals improve their discharge education process for anticoagulants and insulin. The outcome measures for the immersion project are shown in the Table.

Fourteen hospitals focused on the immersion project. The Collaborative for Effective Prescription Opioid Policies (CEPOP) recognized the work being done by the ADE team through its CEPOP Salutes award (http://cepoponline.org/resource/cepop-salutes-webinar-august-2016/). This award recognizes HENs for their efforts to combat prescription opioid misuse, abuse, and diversion, beginning with pain management in the inpatient setting.

The ADE project provided hospitals educational webinars, the use of PassKey, one-on-one coaching calls, and multiple hospital coaching calls. The ADE project offered 11 educational webinars that were made available to all HAP PA-HEN 2.0 hospitals. Although this contract has ended, the work to preventing adverse drug events related to anticoagulants, insulin, and opioids will continue with HIIN.

Prevention of Falls with Harm

The Authority partnered with HAP to reduce falls with harm, which was the second most reported Serious Event in Pennsylvania in 2015. Falls can have a serious impact on a person's ability to function, as well as their life expectancy. In 2015, Pennsylvania facilities reported 34,004 falls events through the Pennsylvania Patient Safety Reporting System (PA-PSRS). Of these falls events, 947 had harm sufficient to be classified as a Serious Event. The category Falls with Harm continues to represent a significant patient safety challenge for hospitals. The goal of the HAP PA-

HEN 2.0 Falls project was to reduce the number of falls with harm by 40% from the 2010 baseline.

Thirty-four hospitals participated in the falls project: 28 acute-care hospitals, 2 behavioral health hospitals, 3 rehabilitation hospitals, and 1 skilled nursing and rehabilitation unit. Of these, 23 hospitals had participated in the first HEN falls project, and 11 were new enrollees for HEN 2.0.

^{*} The analyses upon which this publication is based were performed under Contract Number HHSM- 500-2015-00300C, entitled, "Partnership for Patients Hospital Engagement 2.0 Contract."

Table. HEN 2.0* Outcome and Process Measures for Anticoagulants, Insulin, Opioids, and Falls Projects

| | IMMERSION PROJECT | | HEN-WIDE |
|-----------------|---|---|---|
| PROJECT TYPE | OUTCOME MEASURES | PROCESS MEASURES | OUTCOME MEASURE |
| Anticoagulant | INRs >5 per the number of inpatients prescribed warfarin therapy | Patients discharged on an anticoagulant receiving drug-specific information education per patients discharged on these medications | Aggregate anticoagulant serious events |
| Insulin | Blood sugars <50 mg/dL per total number of patients receiving insulin | Patients discharged on an insulin receiving drug-specific information education per patients discharged on these medications | Aggregate insulin serious events |
| Opioid | Naloxone use to reverse adverse effects from opioids per total number of patients receiv- ing opioids The number of rapid response team calls related to opioids per the total number of rapid response calls | Patients discharged on an opioid receiving drug-specific information education per patients discharged on these medications | Aggregate opioid serious events |
| Falls with harm | Falls with harm per 1,000 patient days (using PA definitions) | The percentage of patients identified at risk who had a prevention protocol in place before the fall with harm The percentage of patients who were assessed for risk prior to experiencing a fall with harm | Falls with harm per 1,000 patient days (using PA definitions) |

HEN, Hospital Engagement Network; INR, international normalized ratio; PA, Pennsylvania Safety Authority's standardization project.

Hospitals used the Pennsylvania standardized definition of falls and falls with harm to ensure consistency in reporting. The Falls project offered educational webinars, coaching calls, hospital visits, in-person regional meetings, a collaborative website, and falls preventions tools (see Building on Success: HEN 2.0 Collaboration for links to tools) as resources for the participants.

The Falls project offered immersion hospitals a model to follow using the acronym FALLS.

This helped to guide the hospital project teams in developing and improving their falls-prevention programs. Hospitals that participated in this project were required to

complete the self-assessment survey and action plan. The evidence-based self-assessment tool was developed in the first HEN contract and revised for HEN 2.0. The other tools were optional and provided additional resources to the hospitals for monitoring their falls programs. The Authority also offered hospital visits to provide feedback to the falls team, assist with data analysis and assessment, help with action plan development and monitoring, and identify opportunities to collaborate with other hospitals. During the HAP PA-HEN 2.0 falls project, 26 hospitals participated in hospital visits.

^{*} The analyses upon which this publication is based were performed under Contract Number HHSM-500-2015-00300C, entitled, "Partnership for Patients Hospital Engagement 2.0 Contract."

The falls project provided hospitals seven educational webinars and coaching calls that were made available to all the HAP PA-HEN 2.0* hospitals. Although this contract has ended, the work to prevent falls with harm will continue with the HIIN subcontract (see Table).



Hospital and Healthsystem Association of Pennsylvania Hospital Improvement Innovation Network[†]

On September 28, 2016, HAP was awarded one of the 16 primary federal contracts for HIIN. The Authority has formed partnerships with HAP and other Pennsylvania healthcare organizations to work with Pennsylvania hospitals to reduce healthcare-acquired conditions.

The goals of the HIIN are to achieve the following:

- A 20% decrease in overall patient harm.
- A 12% reduction in 30-day readmissions as a population-based measure from 2014 baseline.

The Authority's success in previous partnerships with HAP has led to the leadership of the Authority on the adverse drug events, prevention of falls with harm, and culture of safety projects. The Authority is also leading a project with the Health Care Improvement Foundation to reduce emergency department radiologic diagnostic errors. The Authority issued a press release in November 2016 that can be found on the Authority's website: http://patientsafetyauthority.org/NewsAndInformation/PressReleases/Pages/pr_November_10_2016_Final.aspx.

Experts Work to Prevent Wrong-Site Anesthesia Nerve Blocks in Pennsylvania

Wrong-site local and regional anesthesia nerve blocks represent a significant portion of wrong-site operating room procedures. Between July 1, 2004, and December 31, 2016, wrong-site nerve blocks performed by anesthesiologists and surgeons comprised 25.9% of all wrong-site procedures reported through PA-PSRS. Given that only a fraction of patients who are vulnerable to wrong-site surgery receive anesthesia in the form of blocks, the proportion of wrong-site anesthesia blocks is notable.

The Authority has partnered with the Pennsylvania Society of Anesthesiologists for the following:

- To evaluate current practices for preventing wrongsite/side blocks, through interviews with expert panel members and stakeholders including anesthesiologists, surgeons, nurses, and patient representatives.
- To conduct a systematic literature review that will be used as a knowledge base for developing a guidance document.
- To draft and disseminate guidance and resource document(s) to address wrong-site/side regional anesthesia block prevention for physicians, nurses, and healthcare facilities.

^{*} The analyses upon which this publication is based were performed under Contract Number HHSM- 500-2015-00300C, entitled, "Partnership for Patients Hospital Engagement 2.0 Contract."

[†] The analyses upon which this publication is based were performed under Contract Number HHSM-500-2016-00066C, entitled, "Partnership for Patients Hospital Improvement Innovation Network Contract, sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services."

Collaborative Feedback

Annual Survey Collaborative Results

The Authority seeks feedback from facilities each year through an annual survey. Some of the questions in the survey help the Authority learn about topics that facilities are interested in for collaboration. A summary of the results is shown in the following infographic:

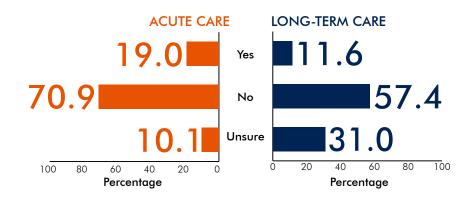
And the results are...

Percentage of facilities that responded by facility type





Is your facility currently participating in any collaborative projects? -



Acute Care Topic Interests:

Infection prevention (overall)

Simulation to improve patient safety

Standardizing emergency codes

Long-Term Care Topic Interests:

Preventing urinary tract infections

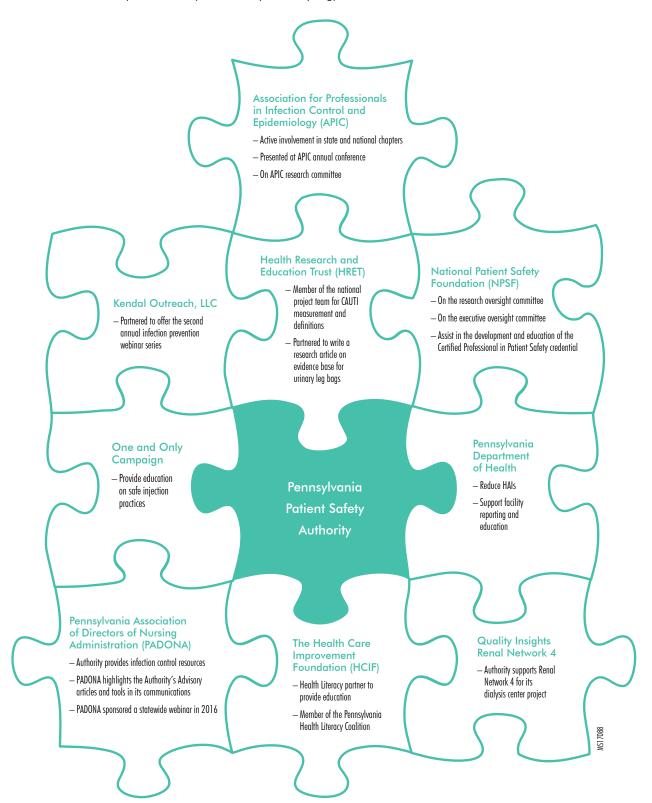
Antibiotic stewardship

Modifying risk factors for respiratory tract infections

21/00/

Partnerships

The Authority's partnerships help provide important relationships that complement, enhance, and expand the knowledge of the Authority. The graphic below provides information on our partnerships in 2016 (an interactive version is available online with this annual report at www.patientsafetyauthority.org).



Notes

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- Grissinger M. Results of the opioid knowledge assessment from the PA hospital engagement network adverse drug event collaboration. Pa Patient Saf Advis. 2013
 Mar;10(1):27-33. Also available: http://patientsafety authority.org/ADVISORIES/AdvisoryLibrary/2013/Mar;10(1)/Pages/19.aspx.
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AM patient safety



The Authority Celebrates Pennsylvania Healthcare Providers for Outstanding Patient Safety Efforts



Regina Hoffman, MBA, BSN, RN, CPPS Executive Director Pennsylvania Patient Safety Authority

Introduction

The Pennsylvania Patient Safety Authority held its annual I Am Patient Safety contest to recognize individuals and groups taking action to positively impact patient safety. The contest provides an opportunity to showcase the great work being done in Pennsylvania healthcare facilities and reward the people involved. We received more nominations this year than ever before. As one of the judges, I personally read all 184 submissions and was impressed by the evident level of dedication and resulting impact on patient safety.

The judging panel, composed of an Authority board member, executive and management staff, and a patient community member, evaluated submissions using the following criteria: the person or group demonstrated (1) a discernible impact on patient safety for one or many patients, (2) a commitment to patient safety, (3) a strong patient safety culture present in the facility, and (4) initiative. Winners were awarded with a plaque, certificate, and recognition pin from the Authority. Their photos and patient safety efforts were highlighted on posters that could be displayed within their facilities. Winners and healthcare

facility representatives were also invited to attend the March 2017 Authority Board of Directors meeting and a luncheon to meet Authority board members and staff. I want to thank everyone who participated in the contest. It is always a challenge to narrow such an impressive group of nominations down to just a handful of winners.

The next round of nominations begins May 1, 2017. Please take the time to acknowledge the patient safety stars in your facilities by nominating them for this contest. The Authority board members and staff appreciate the time you have taken to tell us about your colleagues' efforts to improve patient safety in Pennsylvania.

Thank you, again, to all who participated in the I Am Patient Safety contest. Please join me in congratulating the winners for their commitment to patient safety.

The individuals and groups recognized for the I Am Patient Safety contest and their achievements are grouped by name of facility.¹



Scan this code with your mobile device's QR reader to view videos about winners on the Authority's Facebook page.

¹ Any included numbers and/or results were provided for publication by the recognized healthcare facilities. The Pennsylvania Patient Safety Authority has not independently verified, and bears no responsibility or liability for, these numbers and/or results.

Trisha Patel, PharmD, BCPS, BCCCP Critical Care and Infectious Disease Pharmacist Cancer Treatment Centers of America® at Eastern Regional Medical Center

A patient with cancer was ill with signs and symptoms that suggested a urinary tract infection. Trisha Patel, a critical care and infectious disease pharmacist, went beyond her standard inpatient duties to review the outpatient's urine test results. Trisha, who works to ensure that patients are on the right antibiotics for their particular disease, noticed the patient was infected with a harmful, multidrug-resistant bacterium. She called the infectious disease consultant and the patient was admitted to the hospital to receive necessary intravenous (IV) antibiotics.

Trisha's attention to detail and quick identification of the bacteria prevented the patient from developing a worsening infection.

Melissa Hewitt, Clinical Nurse Manager, Registered Nurse, Certified Neonatal Intensive Care Nursing, MSN Arlene Stonelake, Registered Nurse, Certified Meghan Mahoney, Registered Nurse, Certified Labor & Delivery Department Einstein Medical Center Montgomery

A manufacturer changed the packaging of a medication for IV treatment, and the new bag looked very much like another medication. As nurses in the Labor & Delivery department, Melissa Hewitt, clinical nurse manager; Arlene Stonelake, registered nurse; and Meghan Mahoney, registered nurse worried that the wrong medication could be given to patients. After trying numerous solutions, the group and hospital pharmacy changed procedures so that instead of using two sizes of IV bags, the medication with the new packaging is prepared only in a 500 mL bag, the department's only bag of that size.

The team's persistence led to a safer process for distinguishing IV medications.

Rose Hall, RT (R) (CT), and her team in the CT Scan Department Einstein Medical Center Philadelphia

Although important in evaluating patients, computed tomography (CT) scans increase patient exposure to

dangerous radiation. Rose Hall, supervisor of the CT Scan Department, and her team made it their priority to reduce the amount of radiation used in scans. They worked with radiologists to implement new protocols, and new scanning technology was introduced.

Because of these changes, the image quality of CT scans improved and average radiation exposure was cut in half. Einstein ranked in the top 17th percentile of participating providers in the American College of Radiology Dose Index Registry.

Andrew Klee, Infection Control Practitioner The Healthcare Acquired Infections Team Guthrie Robert Packer Hospital

Good hand hygiene is important in protecting patients from healthcare-acquired infections (HAIs) that healthcare workers can unintentionally spread. The HAI Team, under infection preventionist Andrew Klee, convinced the hospital to install an electronic hand-hygiene monitoring system. Any employee who routinely enters patient rooms wears a monitoring badge, and handwashing compliance is posted for all to see. The team also collaborated with the Environmental Services Department to use an ultraviolet-light robot to disinfect operating and intensive care unit rooms.

The results were favorable—the oncology unit saw a threefold decrease in patients infected in the hospital with the harmful bacterium *Clostridium difficile*.

Paul Karlin, DO, Medical Director of Critical Care Unit (CCU) and Division Chief for Pulmonary Medicine Jeanes Hospital

Jeanes Hospital performs case reviews for each patient death, to improve patient safety and quality of care. Dr. Karlin performs the lion's share of these case reviews. He looks to improve clinical care, foster respect and communication among providers, provide patient dignity, and enhance family-member relations. He is frank about opportunities for improvement but does not place blame.

His efforts, as architect of a new departmental structure and captain of the ship, have prompted physician and staff education, policy and process revisions, and practice changes that support better patient outcomes.

The Pain Center of OSS Health OSS Health

A large team of nurses in a pain-management procedure center needed to consult about cases while still maintaining patients' privacy. To achieve this, the center implemented among the staff use of two-way wireless communications, with devices that have a microphone and a single earpiece.

Recently, a patient in the procedure room fainted while being helped from the procedure table to a wheelchair. The procedure room nurse used her wireless device to call for assistance. Multiple staff members responded. Thanks to the wireless system, the post-op nurses were also aware of the situation and notified the family and gathered the supplies needed to properly care for the patient.

Wannetta Love, Registered Nurse, CCRN Intensive Care Unit Phoenixville Hospital

As a registered nurse in the intensive care unit (ICU), Wannetta (Neadie) Love observed two patients who each had an endotracheal tube. One patient had a facial pressure injury associated with the endotracheal tube, while the other patient did not. She investigated and found that the unaffected patient had been transferred from another facility that used a special holder to reduce pressure-injury development. Love championed the use of these holders.

Because of her efforts, the hospital decided to purchase the pressure-reduction devices, which are now used in the ICU. No facial pressure injuries have occurred since.

Erin Madden, Patient Care Assistant - Nursing 4S PCT Phoenixville Hospital

As a patient care assistant, Erin Madden was helping a patient into bed. She had made sure the bed's wheels were locked, but during the patient's transfer, the bed shifted away. Fortunately, the patient did not fall. The bed was repaired. But Erin remained concerned and raised the issue during one of the unit's daily safety huddles. The concern was relayed to hospital leadership. It was discovered that even with wheels locked, nearly 60% of the beds on the unit were unstable.

This finding led to a hospital-wide assessment and repair of the wheel locks on all beds in the facility, lessening patients' risk of falling.

Ashley Hartzell, Registered Nurse
Babette Rudick, Registered Nurse
Lisa Swenson, BSN, RN, ONC
Jacqueline Brown, Medical Assistant
Tina Frank, MHS, BSN, RN
Teresa Diez, Certified Registered Nurse Practitioner
Surgery Optimization Clinic
PinnacleHealth System

A surgery optimization clinic was established by Tina Frank, MHS, BSN, RN, with the help of her team Teresa Diez, CRNP; Lisa Swenson, BSN, RN, ONC; Ashley Hartzell, RN; Babette Rudick, RN; and Jacqueline Brown, MA. They collaborate with healthcare providers inside and outside the hospital to coordinate care, looking at "the whole person" through one-on-one education and support before surgery. These programs include screenings related to pain, smoking, sleep apnea and alcohol use, weight management and dietary practices, and "prehabilitation" to improve mobility.

Endoscopy Department and Infection Prevention and Control Staff

PinnacleHealth System

Recently, gastrointestinal professionals were shocked to learn that nationally, an antibiotic-resistant organism was being spread to patients through endoscopes that were contaminated, even after proper cleaning (the scopes have crevices that shelter bacteria). The PinnacleHealth endoscopy leadership, the endoscopy team, and the infection control department devised a plan to mitigate the risk to patients. The endoscopy team embraced the new disinfecting process, even though it takes more time.

After reorientation and education, the Endoscopy Department staff process endoscopes beyond professional standards.

Renu Joshi, MD, Medical Director, Endocrinology Endocrinology Team NP Inpatient Endocrinology Service PinnacleHealth System

When patients with diabetes are hospitalized, controlling their blood glucose levels is difficult. Hospital workers may not have expertise in managing glucose levels. Additionally, the patient is seen by multiple practitioners—each treatment can affect a patient's blood glucose levels. As medical director for endocrinology, Dr. Joshi heads a Diabetes Clinical Initiative and championed the creation of a Nurse Practitioner Inpatient Endocrinology Service. This multidisciplinary service improves knowledge among nonspecialist staff and provides education, advice, and support to clinical staff, patients, and families.

Because of this program, diabetic patients' hospital stays are shorter and they have fewer surgical-site infections than before.

Donna Miller, Nurse Manager
Jessica Radicke, Administrative Charge
Registered Nurse
Marissa McMeen, Infection Control Practitioner
Bone Marrow Transplant Unit
Thomas Jefferson University Hospital

Concerned about the number of central line—associated bloodstream infections (CLABSIs) in the Bone Marrow Transplant Unit, Donna Miller, nurse manager; Jessica Radicke, administrative charge registered nurse; and Marissa McMeen, infection control practitioner made positive changes. Protocols were altered to limit who could change central-line dressings, and staffing was adjusted to cover this task. They introduced a medical manikin so nurses could practice and demonstrate accessing the central line. Senior leadership recognized and celebrated the team's success.

Since the action plan was implemented, the unit experienced just one CLABSI in 15 months.

Quality Based Improvement Resident Teams
Department of Surgery
Thomas Jefferson University Hospital

Recognizing the importance of quality and safety education, surgical residents at Thomas Jefferson University
Hospital established the Quality Based Improvement
Resident Teams (QBIRT) initiative. Under QBIRT, residents have researched, developed, and launched programs to reduce harm and improve the quality of care for surgical patients. They have led projects that have resulted in reducing surgical site infections and catheter-associated urinary tract infections and safer insertion of feeding tubes. With one hospital-wide QBIRT initiative, residents analyzed data and created a "risk score" to help predict postoperative respiratory failure in an effort to intervene earlier and prevent these complications.

Through advanced analytics, best practice implementation, team integration, and innovation, the residents of QBIRT have made a significant difference in patient care and surgical outcomes.

ICU Service Partners Infectious Disease Practitioners UPMC Susquehanna's Williamsport Regional Medical Center

A team of intensive care service partners, infectious disease practitioners, and a professional development specialist analyzed every CLABSI in the ICU. They aimed to reduce CLABSIs. The expectation was set that staff would wear a mask and use a sterile drape whenever accessing a central line (to give medications or draw blood). The professional development specialist conducts competency checks and infectious disease practitioners monitor compliance with infection-control practices.

After achieving 572 days without a CLABSI, these partners continue with the goal of zero CLABSI for patients in the ICU.

Recommendations to the Department of Health

The Medical Care Availability and Reduction of Error (MCARE) Act calls upon the Authority to suggest recommendations for statutory or regulatory changes that may help improve patient safety in the Commonwealth. In 2016, the Board had no formal recommendations for

statutory or regulatory changes. However, the Authority continues to work in partnership with the Department of Health to standardize reporting requirements. Please see Reporting Standardization: Guidance for Acute Healthcare Reporting.

Anonymous Reports

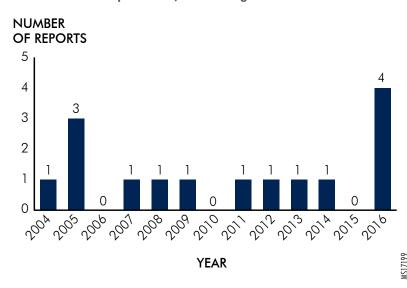
The Medical Care Availability and Reduction of Error (MCARE) Act includes an important provision that permits individual healthcare workers to submit what the act defines as an "anonymous report." Under this provision, a healthcare worker who has complied with section 308(a) of the act may file an anonymous report regarding a Serious Event. The MCARE Act requires facilities to make the anonymous report form available to healthcare workers.

The form is available on the Pennsylvania Patient Safety Authority's website and through the Pennsylvania Patient Safety Reporting System. The reporting form is a simple, one-page questionnaire. To ensure healthcare workers are aware of the option to submit an anonymous report, the Authority developed an anonymous report pamphlet. It includes an anonymous report form with guidelines for filing a report. The Authority's patient safety liaisons also

review the anonymous-report process with new patient safety officers as part of their educational and onboarding programs. See Educational Programs for more information. Individuals completing the form do not need to identify themselves, and the Authority assigns professional clinical staff to conduct any subsequent investigations. The Authority encourages healthcare workers to submit anonymous reports when they believe their facility is not appropriately reporting or responding to a Serious Event.

The MCARE Act requires that the annual report include the number of anonymous reports filed and reviews conducted by the Authority. In 2016, the Authority received four anonymous reports that complied with MCARE Act requirements. The Authority has received 15 anonymous reports since reporting began in 2004 (see Figure).

Figure. Anonymous Reports Received by the Authority that Complied with MCARE Act Requirements, 2004 through 2016



Note

 Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No 13 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck. cfm?yr=2002&sessInd=0&act=13.

Referrals to Licensure Boards

The Medical Care Availability and Reduction of Error (MCARE) Act requires the Pennsylvania Patient Safety Authority to identify the number of referrals to licensure boards for failure to submit reports under the Act's reporting requirements. MCARE specifies that it is the medical facility's responsibility to notify the licensee's

licensing board of failure to report. No such situations were reported to the Authority during 2016. However, the Authority is unlikely to receive information related to a referral to a licensure board because Pennsylvania Patient Safety Reporting System (PA-PSRS) reports do not include the names of individual licensed practitioners.

Note

Medical Care Availability and Reduction of Error (MCARE)
 Act of March 20, 2002, P.L. 154, No 13 40. Available:
 http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2002&sessInd=0&act=13.

Fiscal Statements and Contracts

The Medical Care Availability and Reduction of Error (MCARE) Act¹ establishes the Patient Safety Trust Fund as a separate account in the Pennsylvania Treasury. Under the MCARE Act, the Pennsylvania Patient Safety Authority determines how those funds are used to effectuate the patient safety provisions of the Act and administers funds in the Patient Safety Trust Fund. Funds come primarily from assessment surcharges made by the Department of Health on certain medical facilities.

The Authority recognizes that Pennsylvania hospitals, birthing centers, ambulatory surgical facilities, abortion facilities, and nursing homes bear financial responsibility for costs associated with complying with mandatory reporting requirements. Accordingly, the Authority has focused on two fiscal goals: (1) to be prudent in the use of moneys contributed by the healthcare industry, and (2) to assure that healthcare facilities paying for the Pennsylvania Patient Safety Reporting System (PA-PSRS) receive direct benefits from the system and from Authority programs in return. Pursuant to Section 304(A)(4) of the MCARE Act, as a general rule, the Authority is authorized to receive funds from any source consistent with the Authority's purposes under the Act. Consistent with this mandate, the Authority at times contracts with and receives funding from other healthcare-related entities to reduce medical errors and promote patient safety in the Commonwealth. These contracts in 2016 are described in the section, "Contracts under which the Authority Received Revenue in 2016 as a Contractor," which lists contracts with the Hospital and Healthsystem Association of Pennsylvania (HAP) and the Health Care Improvement Foundation (HCIF).

In this regard, within the design of PA-PSRS, the Authority included a variety of integral and analytical tools that provide immediate, real-time feedback to facilities

on their own adverse event and near-miss reports and activities. The Authority recently provided nursing homes with an infection analytic system within PA-PSRS. Facilities can use these tools for their internal patient safety and quality improvement programs. In 2016, the Authority began working on the PA-PSRS Application Modernization (AMOD). The AMOD project entails a complete redesign of the PA-PSRS application with a planned release to the facilities in 2018. Also in 2016, the Authority's SAS Visual Analytics Reporting System was named a national finalist in the Emerging & Innovative Technologies category of the National Association of State Chief Information Officers (NASCIO) 2016 State IT Recognition Awards.

The Authority provides numerous training and education programs, including programs related to reporting, investigating, and analyzing events, risk assessment, and patient safety topic-specific education. The Authority also publishes the Pennsylvania Patient Safety Advisory. a scholarly journal issued quarterly that includes detailed analysis and identification of trends of reports submitted through PA-PSRS. All these programs are offered at no additional cost to the facilities. As identified elsewhere in this annual report, the Authority expanded its services by organizing and supporting research collaborations with reporting facilities and other patient-safety-centric organizations. The Authority also provides continuing medical education and patient safety curriculum development. By directly offering clinical guidance, feedback, and educational programs to providers about actual events that occur in Pennsylvania, the Authority provides measurable value back to the healthcare industry that contributes to funding this program.

Funding Received from Hospitals, Ambulatory Surgical Facilities, Birthing Centers, and Abortion Facilities

The MCARE Act¹ set an initial limit of \$5 million on the total aggregate assessment on acute-care facilities for any one year beginning in 2002, plus an annual increase based on the consumer price index (CPI) for each subsequent year. For fiscal year 2016–2017, the maximum allowable acute-care assessment is \$7,097,85, against the Authority Board's approved aggregate acute-care assessment of \$6,675,000.

On December 13, 2016, the Authority Board authorized a recommendation to the Department of Health that the FY 2016–2017 acute-care assessment surcharges should total \$6.675 million. This amount is a \$175,000, or 2.7%, increase over the FY 2015–2016 acute-care assessment and is 6.0% less than the maximum annual

amount that could have been assessed for the year pursuant to Section 305(d) of the MCARE Act. Beginning in 2015, the Authority Board authorized the use of the Northeast Medical Professional Services CPI to calculate annual adjustments to maximum assessments.

At the time of this acute-care assessment recommendation, the Patient Safety Authority Board considered several points, including the following:

 The Patient Safety Authority's FY 2016–2017 budget totals about \$8.5 million, with approximately \$7.2 million funding expenditures other than for healthcare-associated infection (HAI).

Table 1. Acute Care Facility Assessments A

| FISCAL YEAR | NUMBER OF FACILITIES ASSESSED BY DEPARTMENT OF HEALTH | APPROVED ASSESSMENTS | TOTAL ASSESSMENTS RECEIVED BY DEPARTMENT OF HEALTH B |
|----------------------|---|-------------------------|--|
| 2002-03 | 356 | \$5,000,000 | \$4,663,000 |
| 2003-04 | 377 | \$2,500,000 | \$2,542,316 |
| 2004-05 | 414 | \$2,500,000 | \$2,508,787 ^c |
| 2005-06 | 450 | \$2,500,000 | \$2,500,149 |
| 2006-07 | 453 | \$2,500,000 | \$2,500,034 |
| 2007-08 | 526 | \$5,400,000 | \$5,391,583 |
| 2008-09 | 524 | \$4,000,000 | \$3,972,677 |
| 2009-10 | 519 | \$5,000,000 | \$4,989,781 |
| 2010-11 | 542 | \$5,000,000 | \$4,981,443 |
| 2011-12 | 550 | \$5,100,000 | \$5,063,723 |
| 2012-13 | 545 | \$5,500,000 | \$5,504,549 |
| 2013-14 | 556 | \$5,500,000 | \$5,492,002 |
| 2014-15 | 564 | \$6,200,000 | \$6,209,459 |
| 2015-16 | 569 | \$6,500,000 | \$6,494,845 |
| 2016-17 ^D | | \$6,675,000 | |
| | | | \$68.814.348 |

A The number of facilities assessed by the Department of Health differs from the number of the Medical Care Availability and Reduction of Error (MCARE) Act's facilities cited elsewhere in this report because of differences in the dates chosen to calculate the number of facilities for these two different purposes.

^B Amounts assessed and amounts received differ because a few facilities may have closed in the interim or are in bankruptcy. In a few cases, the Department of Health has pursued action to enforce facility compliance with the MCARE Act's assessment requirement

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

^D 2016-17 missing figures were unavailable at the time of publication and will appear in next year's annual report.

- The Patient Safety Authority's FY 2016–2017 budget increased by \$249,000, or 3.0%, from the previous fiscal year budget.
- The FY 2016–2017 acute-care assessment of \$6.675 million has increased by \$1.675 million from the Authority's initial acute-care assessment in FY 2002–2003 of \$5.0 million, a 2.39% per year average increase.
- Since the Authority's FY 2007–2008 acute-care assessment of \$5.4 million, the acute-care assess-

ment has increased by an average of 2.62% per year.

Also considered in authorizing this increase were staff and program growth, significant increases in Commonwealth of Pennsylvania mandated burdened benefit rates, and projected contract revenue in FY 2016–2017.

Table 1 shows the number of acute-care facilities assessed, approved assessments, and assessments received for each fiscal year.

Funding Received from Nursing Homes

Act 52² of the MCARE Act allows the Department of Health to assess Pennsylvania nursing homes up to an aggregate amount of \$1 million per year for any one year beginning in 2008, plus an annual increase based on the CPI for each subsequent year. In 2008, following the Authority's suggestion, the Department assessed 725 nursing home facilities a total of \$1,000,000 and transferred \$1,000,782 to the Patient Safety Trust Fund for FY 2008–2009. This money could be spent only on activities related to HAI and implementation and maintenance of Chapter 4 of the MCARE Act. For FY 2016–2017, the Act 52 maximum allowable assessment is \$1,145,915, against the Authority Board's approved aggregate assessment of \$1,110,000.

On December 13, 2016, the Authority Board authorized a recommendation to the Department that the FY 2016–2017 nursing home assessment surcharges should total \$1.11 million. This amount is \$20,000 more than the previous year's assessment and is approximately 3.1% below the maximum assessment permitted under Act 52, based on annual CPI adjustments. Beginning in 2015, the Authority Board authorized the use of the Northeast Medical Professional Services CPI to calculate annual adjustments to maximum assessments.

Table 2 shows the number nursing homes assessed, approved assessments, and assessments received for each fiscal year.

Table 2. Nursing Home Assessments

| FISCAL YEAR | NUMBER OF FACILITIES ASSESSED BY DEPARTMENT OF HEALTH | APPROVED ASSESSMENTS | TOTAL ASSESSMENTS RECEIVED BY DEPARTMENT OF HEALTH |
|-------------|---|-------------------------|--|
| 2008-09 | 725 | \$1,000,000 | \$1,000,782 |
| 2009-10 | 711 | \$800,000 | \$799,382 |
| 2010-11 | 707 | \$800,000 | \$799,829 |
| 2011-12 | 707 | \$800,000 | \$804,473 ^A |
| 2012-13 | 711 | \$900,000 | \$913,315 [^] |
| 2013-14 | 698 | \$1,000,000 | \$998,751 |
| 2014-15 | 703 | \$1,050,000 | \$1,049,842 |
| 2015-16 | 702 | \$1,080,000 | \$1,079,505 |
| 2016-17 в | | \$1,080,000 | |
| | | | \$7,445,879 |

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

^B FY 2016-2017 missing figures were unavailable at the time of publication and will appear in the next year's annual report.

Annual Expenditures

During calendar year 2016, the Authority spent about \$7.833 million and received contract and service related receipts of \$546,000, resulting in net expenditures of \$7.286 million (Table 3).

Table 3. Expenditures for Calendar Year 2016

| CONTROL LEVEL | AMOUNT |
|---------------------------|-------------|
| 61: Personnel | \$2,494,304 |
| 63: Operating | \$5,338,706 |
| Contract Revenue Receipts | -\$546,399 |
| Net expenditures | \$7,286,611 |

Patient Safety Authority Contracts

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

ECRI Institute, FC # 4000018888

Four-year, nine-month contract for program administration, clinical analysis, training and data collection, and reporting infrastructure services.

October 1, 2014, through June 30, 2019

Total contract amount: \$24,227,233

over 4 years and 9 months

Amount invoiced for 2014

(October through December): \$1,135,983.79

Amount invoiced for 2015

(January through December): \$4,824,833.20

Amount invoiced for 2016

\$4,946,827.23 (January through November):

(December 2016 invoice estimated and unaudited)

IKON Office Solutions, PO # 4500712922

Ricoh B&W copier lease

August 1, 2013, to June 30, 2017 @ \$202.62/month

12-month lease expense

(Jan-Dec) paid in 2016: \$2,431.44 During calendar year 2016, the Authority received services under the following contracts (FC, funds commitment; PO, purchase order).

XEROX Corp., PO # 4500734462

Xerox color copier lease

October 1, 2013, to August 31, 2017 @ \$398.39/ month with no overage charge

12-month lease expense (Jan-Dec)

\$4,780.68 paid in 2016:

DELL Marketing LP, PO # 4300446203

SAS Visual Analytics software maintenance

Valid from March 31, 2016 - March 31, 2017

Amount expended in 2016: \$11,909.78

Happy Cog, Philadelphia, PA (Purchasing Card)

Logo design contract (completed)

Amount expended in 2016: \$10,000.00

Contract Value: \$10,000.00 Contracts under which the Authority Received Revenue in 2016 as a Contractor:

HCIF (Health Care Improvement Foundation) Agreements 1 (Completed) & 2 (Ongoing) -**Health Literacy Projects**

HCIF 1 Total Receipts in 2016: \$27,198.02

HCIF 2 Total Receipts in 2016: \$1,198.99

HAP/CMS subcontract agreement – HAP-PA Hospital Engagement Network (HEN 2.0), Completed in 2016

Total Receipts in 2016: \$518,002.00

Notes

- 1. Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No 13 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck. cfm?yr=2002&sessInd=0&act=13.
- 2. Medical Care Availability and Reduction of Error (MCARE) Act - Reduction and Prevention of Health Care-Associated Infection and Long-Term Care Nursing Facilities Act of July 20, 2007, P.L. 331, No. 52, Cl.40. http:// www.legis.state.pa.us/cfdocs/legis/li/uconsCheck. cfm?yr=2007&sessInd=0&act=52.

Patient Safety Authority Balance Sheet

Table 4, Balance Sheet, reflects the status of the Patient Safety Trust Fund as of December 31, 2016.

Table 4. Patient Safety Trust Fund Balance Sheet (Unaudited), as of December 31, 2016

ASSETS

| 33,803 |
|---------|
| 32,604 |
| \$1,199 |
| |

LIABILITIES AND FUND BALANCE

Liabilities

| Total Liabilities | \$427,045 |
|--|-----------|
| Invoices payable | \$420,070 |
| Accounts payable and accrued liabilities | \$6,975 |

Fund Balance

| Restricted | \$5,206,758 |
|------------------------------------|-------------|
| Total Fund Balance | \$5,206,758 |
| Total Liabilities and Fund Balance | \$5,633,803 |

Source: Comptroller Operations, Commonwealth Bureau of Accounting and Financial Management

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. As of December 31, 2016, members included:

Physician appointed by the Governor who serves as Chair: Rachel Levine, MD, Physician General

Residence: Middletown (Dauphin County)

Appointee of the President pro tempore of the Senate: Daniel Glunk, MD, MHCDS

Residence: Williamsport (Lycoming 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, Vice Chair

Residence: Philadelphia (Philadelphia County)

Appointee of the Minority Leader of the House: Eric Weitz, Esq.

Residence: Philadelphia (Philadelphia County)

Pharmacist appointed by the Governor: Arleen G. Kessler, PharmD, MBA, RPh

Residence: Williamsport (Lycoming County)

Hospital employee appointed by the Governor: Radheshyam Agrawal, MD

Residence: Pittsburgh (Allegheny County)

Healthcare worker appointed by the Governor: Jan Boswinkel, MD

Residence: Havertown (Delaware County)

Non-healthcare worker appointed by the Governor: Mary Ellen Mannix, MRPE

Residence: Wayne (Delaware County)

Note

1. Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002, P.L. 154, No. 13, Cl. 40. Available: http://www.legis.state.pa.us/cfdocs/legis/li/ucons-Check.cfm?yr=2002&sessInd=0&act=13.

Physician appointed by the Governor: John Bulger, DO, MBA

Residence: Danville (Montour County)

The Medical Care Availability and Reduction of Error (MCARE) Act requires the board of directors to meet at least quarterly. During 2016, the board met frequently to assess and develop future patient safety educational and advocacy activities, including developing standards for more consistent reporting. 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 2016:

- January 26, 2016
- March 8, 2016
- April 26, 2016
- June 7, 2016 (cancelled)
- July 26, 2016
- September 13, 2016
- October 25, 2016
- December 13, 2016

Summary minutes of the public meetings are available on the Authority's website at http://www.patientsafetyauthority.org.

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