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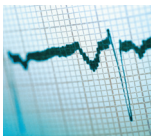

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OBJECTIVE

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.

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Manuscripts consistent with the objectives of the *Pennsylvania Patient Safety Advisory* are welcome. For information and guidance about submission and instructions for authors, please contact the editor.

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Aligning Behavioral Health Management of Patient Aggression with State and National Initiatives

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ABSTRACT

In 1997, Pennsylvania introduced a program to reduce the use of restraints and seclusion in state behavioral health hospitals. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. Between January 1, 2012, and August 31, 2013, coercive interventions (i.e., restraints and seclusion) were the most frequently identified interventions used to manage patient-to-patient aggression in behavioral health patient aggression-related event reports submitted through the Pennsylvania Patient Safety Reporting System. Analysts, interested by this finding, explored how patient aggression is managed in two behavioral health hospitals that have incorporated the philosophy and principles of the Pennsylvania Recovery and Resiliency program to inform the management of patient aggression using noncoercive techniques. The Recovery and Resiliency program promotes trauma-informed care and the Sanctuary Model to address patient issues and build a restraint-free environment. (Pa Patient Saf Advis 2015 Jun;12[2]:49-53.)

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INTRODUCTION

*It is 3 p.m. on the adult behavioral health unit when inpatient Joe starts to appear agitated about another patient, Bob. Suddenly, Joe punches a wall. A peer tells Joe to make a good choice and please stop hitting the wall and encourages him to ask staff for help.**

Patient aggression is an anticipated behavior in acute care inpatient behavioral healthcare settings. Aggressive patients can direct their aggression toward themselves, staff, or other patients. In Pennsylvania, patient-to-patient aggression in behavioral health hospitals and acute care inpatient behavioral health units was the leading type of inpatient aggression event reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS).[1] Coercive interventions, such as restraint and seclusion, were the most frequently described responses to patient-to-patient aggression events for pediatric and adult patients when interventions were identified. In the geriatric population, coercive interventions and interventions that were not specifically identified in the literature as noncoercive or coercive (e.g., patient distracted or redirected) were described with equal frequency. See the Figure.

Based on the Pennsylvania Patient Safety Authority's findings that coercive interventions were most frequently reported, the analysts were interested to learn more about how behavioral health hospitals within Pennsylvania address patient aggression; approaches from two facilities are presented. For a description of the data query and analysis of interventions, see "Patient Aggression Management Strategy Analyses."

Patient-to-patient aggression can present as a verbal confrontation between patients that escalates to a physical confrontation or can begin, without warning, as a physical confrontation between patients.

Staff who engage with patients involved in aggression-related altercations often have opportunities to diffuse the situation, calm the patients down, and help the patients deal with their anger or frustration in a nonviolent way. The following PA-PSRS event narrative† illustrates this issue:

> *A patient grabbed another patient's [neck] and started punching that patient [in the face]. Staff immediately responded and separated the patients.*

Patient aggression is a complex issue that arises from a mix of patient risk factors, such as history of violence, and environmental risk factors, such as lack of structured activity or frequent use of temporary staff.[2] Interventions—classified as noncoercive or coercive—have the potential to defuse patient aggression. Use of noncoercive interventions, such as de-escalation techniques, is the preferred method to manage patient aggression whenever possible because it promotes patient engagement and preserves dignity.[2-8] Coercive measures (i.e., restraints and seclusion) may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.[4,9,10]

In 1997, a program was introduced by Charles Curie, then Pennsylvania deputy secretary of mental health and substance abuse services, to reduce seclusion and restraint use in state behavioral health hospitals. The basis of the program was tied to his philosophy that "most [state hospital] patients are already the victims of trauma. There is no need to reinforce that trauma."[11]

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* Patient names and circumstances are fictitious and used for example purposes only.

† The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality. None of these event narratives came from Philhaven or Southwood Psychiatric Hospital.

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In the following year, the *Hartford Courant* published a series of reports about patient deaths associated with the use of restraints in patients needing psychiatric care[12] In the initial *Hartford Courant* report, where ages could be identified, "more than 26 percent of [deaths involved] children—nearly twice the proportion they constitute in mental health institutions."[12] A follow-up review conducted six years later showed patient deaths caused by restraints were still occurring.[13]

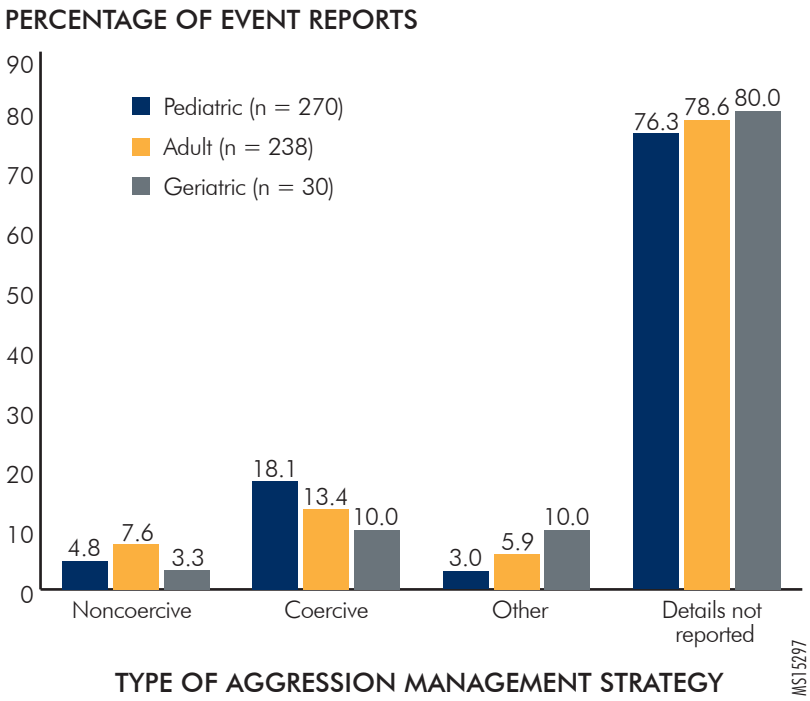
In 2006, the Pennsylvania Department of Human Services, formerly the Department of Public Welfare, urged providers of child residential care to move toward reducing or eliminating the use of restraints. A kickoff event, Alternatives to Coercive Techniques, and 12 other forums were held across the state, addressing organizational change, leadership, de-escalation, incident debriefing, data collection, and youth and family involvement. The forums were designed to help providers understand the vision for building a restraint-free system and gain their support for creating organizational change by introducing the trauma-informed care (TIC) philosophy using the Sanctuary Model.[14,15]

As a result of the forums and recommendations, the Sanctuary Model was brought to Pennsylvania. "Preliminary data from implementation of the Sanctuary Model in other states showed positive results, including a decrease in the use of restraints, less staff turnover, and better outcomes for children and youth."[15]

TWO BEHAVIORAL HEALTH FACILITY APPROACHES

Two behavioral health organizations, Philhaven and Southwood Psychiatric Hospital, discussed their organizational philosophies and approaches to managing patient aggression with the analysts.

Figure. Patient-to-Patient Aggression Interventions Reported through the Pennsylvania Patient Safety Reporting System January 2012 through August 2013



Philhaven is a multisite behavioral health organization serving patients of all ages in the Lancaster, Lebanon, York, and Harrisburg areas. Analysts met with Heidi McMullan, RN, MSN, chief nursing officer; Brent Swope, director of milieu and behavior management training program; and others at the Mt. Gretna facility and were given a tour of the facility.

Southwood Psychiatric Hospital, located in the southwest region of Pennsylvania, is a private for-profit children's behavioral hospital that is part of Acadia Healthcare, a national behavioral healthcare corporation. The director of nursing at Southwood Psychiatric Hospital, Kim Owens, DrPH, RN, and the analysts held a conference call to discuss her organization's philosophy and approach to managing patient aggression. Analysts found similarities in the facilities' philosophies and programs.

Organizational Culture

Both organizations have a culture that fosters a proactive approach to prevent and address patient aggression while helping patients learn more effective ways to manage their emotional challenges. Philhaven attributes the adoption and maintenance of its proactive approach to a stable long-term commitment in senior leadership, including a medical director who began working at Philhaven as a psychiatrist in the 1980s, succession planning for future leadership personnel, education and training of staff, and board support.

Leadership commitment to proactively address one of the potential consequences of patient aggression, property damage, is evident in an example provided by Ms. McMullan, who said, "Leadership recognizes that patient aggression is a potential aspect of a psychiatric patient's mental

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PATIENT AGGRESSION MANAGEMENT STRATEGY ANALYSES

Analysts used the 538 Pennsylvania Patient Safety Reporting System patient-to-patient aggression event reports identified in a previous *Pennsylvania Patient Safety Advisory* article.[1] Analysts also used the previously identified age categories—pediatric (i.e., age 18 or younger), adult (i.e., age 19 to 64), and geriatric (i.e., age 65 or older)—to analyze the type of strategies used to manage patient-to-patient aggression. The categorization of aggression-related management strategies was based on a taxonomy identified by Davison: noncoercive, coercive, and strategies not clearly explained in the event reports (e.g., separated, pulled apart, staff intervened).[2]

A detailed analysis of intervention strategies used by behavioral healthcare providers was performed to identify trends in the event reports. Analysts discovered that the majority (more than 75%) of the event reports did not identify specific intervention strategies used to manage patient-to-patient aggression. In the event reports in which intervention strategies were identified, coercive interventions (i.e., restraints and seclusion) were the most frequently reported. Several population-specific analyses were performed: harm score and intervention type by patient population, aggressor or victim status by patient population, and combination of intervention strategies used during an event (e.g., coercive alone, coercive and noncoercive) by patient population. These analyses, however, resulted in extremely small numbers that limited conclusions about the patient aggression management strategies behavioral health hospitals implement and were subsequently excluded from further study.

Notes

1. Gardner LA, Magee MC. Patient-to-patient aggression in the inpatient behavioral health setting. Pa Patient Saf Advis [online] 2014 Sep [cited 2015 Apr 30]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Sep;11(3)/Pages/115.aspx
2. Davison SE. The management of violence in general psychiatry. *Adv Psychiatr Treat* 2005;11:362-70.

illness and when designing the facility for safety, takes into account the potential for property damage."[16] Philhaven's organization-wide effort to change its philosophy to reduce restraint use, initiated by leadership in the early 2000s, is now a fundamental part of its organizational culture and day-to-day operations.

Southwood Psychiatric Hospital's organizational philosophy uses a similar proactive approach to preventing and addressing patient aggression. Southwood Psychiatric Hospital attributes the adoption and maintenance of its proactive approach to recruitment and retention of the right staff, beginning with a robust orientation program. Dr. Owens stated, "New hires, including myself, are screened for their approach toward managing patient aggression. Staff are put through a rigorous orientation prior to working with the patients." Anticipating the potential for aggressive situations and planning for them proactively provides leadership, physicians, and frontline staff with the necessary tools to reduce the occurrence and mitigate the consequences of patient aggression.

Southwood Psychiatric Hospital, like Philhaven, is data-driven in using key performance indicators and participating in national benchmarking. For example, both organizations participate in the Joint Commission's Hospital-Based Inpatient Psychiatric Services measure set. The physical restraint use rates for June 2013 through July 2014 for these two organizations are lower than national and state average rates for the same time period. Philhaven's and Southwood Psychiatric Hospital's overall rates of physical restraint use per 1,000 patient-hours were 0.0869[17] and 0.0923,[18] respectively, compared with the national average rate of 0.5226 and state average rate of 0.3303.[17,18]

Theoretical Foundation: Trauma-Informed Care

TIC is a nationwide movement and part of a larger statewide initiative, the Pennsylvania Recovery and Resiliency program, managed by the Pennsylvania Office of Mental Health and Substance Abuse Services.[15] Dr. Owens stated that the recovery and resiliency movement in behavioral health started "years ago [2006]" and represents a change from what mental health services did "*to* you [the behavioral health patient]" to what they do "*with* you" and involves the patients' families.[15,19]

TIC is a theoretical framework that is identified as "a program, organization, or system that is trauma-informed [and]:

1. Realizes the widespread impact of trauma and understands potential paths for recovery;
2. Recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system;
3. Responds by fully integrating knowledge about trauma into policies, procedures, and practices; and
4. Seeks to actively resist re-traumatization."[20]

Philhaven and Southwood Psychiatric Hospital have adopted these principles to transform their cultures of restraint use.

The American Psychiatric Nurses Association position statement identifies the "growing awareness that inpatient treatment must be shaped by the principles of trauma-informed care and the recovery movement and that these philosophies will create a collaborative spirit that is essential to restrain reduction and elimination efforts."[21]

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Sanctuary Model

The Sanctuary Model, introduced in 2006 as part of the implementation of the TIC philosophy in Pennsylvania, represents a "theory-based, trauma-informed, evidence-supported, whole culture approach . . . to teach individuals and organizations the necessary skills for creating and sustaining nonviolent lives and nonviolent systems and to keep believing in the unexplored possibilities of peace."[14] The Sanctuary Model, a part of the Pennsylvania Recovery and Resiliency program, focuses on training staff consistently to build relationships with patients and among staff.[14] Philhaven's residential program is a certified sanctuary program.[22]

Therapeutic Crisis Intervention

Philhaven and Southwood Psychiatric Hospital have adopted the Therapeutic Crisis Intervention program, originally developed for child and youth populations, to educate staff on how to prevent and manage a crisis[23] and to align with the TIC model. Philhaven adapted and implemented this program for all inpatient units, regardless of patient age. According to Mr. Swope, "Staff are trained on the Therapeutic Crisis Intervention model to reduce behavioral crises, support patients and staff in the day-to-day management of patients, and help patients learn new behavioral health management skills."[24] Upon hire, new employees are required to attend and successfully complete an initial 24 hours of training in Therapeutic Crisis Intervention. Training is then provided on a quarterly basis, during which staff are exposed to additional role-play and simulations of behavioral events.

At Southwood Psychiatric Hospital, staff receive a two-and-a-half day initial training in Therapeutic Crisis Intervention that focuses on de-escalation and attend a four-hour refresher course annually.[19] This training also includes role-play and simulation.

The Importance of Milieu

Both organizations stressed the importance of milieu in the management of aggression. The "milieu" includes the surroundings and environment of patients and staff.[25] As depicted in the scenario in the introduction, unit culture in the form of positive peer interaction and proactive staff response to aggression is an important aspect of the milieus both facilities try to foster.

At Philhaven, the milieu includes the physical structure, patient and unit routines, and patient relationships with staff. The physical building at Philhaven has a lot of natural light, wide hallways, and many private rooms. Every patient is assigned a staff member who is their primary contact for purposes of encouragement, goals review, and general support. Staff are constantly reminded about tailoring de-escalation techniques to fit the client's needs or character, as illustrated in the following PA-PSRS event narrative:

> *Patient was punched in the face when arguing with a female peer on the unit. No injury apparent. Patient followed verbal redirection and went to [her] room to calm down.*

At Southwood Psychiatric Hospital, milieu management includes the following: (1) creating and maintaining a calm and safe environment, (2) encouraging positive interactions between staff and patients, and (3) addressing the environmental elements outside of group therapy, such as unit routines. Dr. Owens related that staff "gauge activities that are appropriate for the patients. Keeping children in smaller groups and reducing stimuli and clutter can help manage agitation and aggression. For example, some children need help with brushing their teeth, getting a shower, or making their bed; clear prompts are provided by staff about completing these activities, and these prompts help address impulsive issues."[24]

Southwood Psychiatric Hospital employs the principles of normalizing the environment. This concept supports physical healthcare delivery by focusing on holistic design and promoting socialization by integrating public and private spaces in a secure manner.[26] When caring for children, both organizations provide information and education for parents.

CONCLUSION

State and national trends emphasizing noncoercive strategies in the management of patient aggression in the behavioral health setting began two decades ago with the intention of reducing the use of restraints and seclusion. Operationalizing organizational changes to effect noncoercive patient care strategies requires a long-term commitment that starts with leadership.

In Pennsylvania, Philhaven and Southwood Psychiatric Hospital have aligned their philosophical and operational approaches to noncoercive management of patient aggression with state and national initiatives. Both facilities continually evaluate the effectiveness of their approaches and adapt as circumstances dictate, achieving overall restraint use rates that are lower than state and national averages.

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NOTES

1. Gardner LA, Magee MC. Patient-to-patient aggression in the inpatient behavioral health setting. Pa Patient Saf Advis [online] 2014 Sep [cited 2015 Mar 5]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Sep;11(3)/Pages/115.aspx
2. Davison SE. The management of violence in general psychiatry. *Adv Psychiatr Treat* 2005;11:362-70.
3. Macpherson R, Dix R, Morgan S. A growing evidence base for management guidelines: revisiting . . . guidelines for the management of acutely disturbed psychiatric patients. *Adv Psychiatr Treat* 2005;11:404-15.
4. Centers for Medicare and Medicaid. Medicare and Medicaid programs; hospital Conditions of Participation: patients' rights [final rule]. *Fed Regist* 2006 Dec 8;71(236):71378-428.
5. Dean AJ, Duke SG, George M, et al. Behavioral management leads to reduction in aggression in a child and adolescent psychiatric inpatient unit. *J Am Acad Child Adolesc Psychiatry* 2007 Jun;46(6):711-20.
6. Richmond JS, Berlin JS, Fishkind AB, et al. Verbal de-escalation of the agitated patient: consensus statement of the American Association for Emergency Psychiatry Project BETA de-escalation workgroup. *West J Emerg Med* 2012 Feb;13(1):17-25.
7. Price O, Baker J. Key components of de-escalation techniques: a thematic synthesis. *Int J Ment Health Nurs* 2012 Aug;21(4):310-9.
8. Center for Mental Health Services. Substance Abuse and Mental Health Services Administration. Roadmap to seclusion and restraint free mental health services [online]. DHHS Pub. No. (SMA) 05-4055. 2005 [cited 2015 Mar 5]. http://www.asca.net/system/assets/attachments/2661/Roadmap_Seclusion.pdf?1301083296
9. 55 Pa. Code §§ 13.1-13.9. Also available at http://www.pacode.com/secure/data/055/chapter13/chap13toc.html
10. Pennsylvania Department of Public Welfare. The use of seclusion and restraint in mental health facilities and programs [online]. 2002 Apr 8 [cited 2015 Mar 05]. http://www.pccyfs.org/dpw_ocyfs/Seclusion-Restraint/2006/OMHSAS_Bulletin_02-01(Apr2002).pdf
11. Pennsylvania Department of Public Welfare. Pennsylvania seclusion and restraints reduction initiative [online]. 2000 [cited 2015 Mar 11]. http://www.power2u.org/downloads/Pennsylvania_S&R_Initiative.pdf
12. Module 1: the personal experience of seclusion and restraint [online]. In: Center for Mental Health Services. Substance Abuse and Mental Health Services Administration. Roadmap to seclusion and restraint free mental health services. 2005 [cited 2015 Mar 9]. http://store.samhsa.gov/shin/content//SMA06-4055/SMA06-4055-B.pdf
13. Altimari D. Many restraint deaths unreported [online]. Hartford Courant 2006 Oct 14 [cited 2015 Mar 9]. http://articles.courant.com/2006-10-14/news/0610140661_1_inspector-general-psychiatric-hospitals-deaths
14. An integrated theory: what is the Sanctuary Model? [online]. [cited 2015 Mar 12]. http://www.sanctuaryweb.com/TheSanctuaryModel.aspx
15. Pennsylvania Recovery and Resiliency. Trauma-informed care for children [online]. [cited 2015 Mar 13]. http://parecovery.org/services_trauma_informed_care.shtml
16. McMullan, Heidi (Chief Nursing Officer, Philhaven). Interview with: Lea Anne Gardner and Mary C. Magee. 2015 Feb 24.
17. Joint Commission. Quality report—hospital: Philhaven. National quality improvement goals: hospital-based psychiatric services—reporting period: July 2013 – June 2014 [online]. [cited 2015 Mar 31]. http://www.qualitycheck.org/QualityReport.aspx?hcoid=3112&x=nqigQtr&program=Hospital&mst=Hospital-Based Inpatient Psychiatric Services&msrId=66
18. Joint Commission. Quality report—hospital: Southwood Psychiatric Hospital. National quality improvement goals: hospital-based psychiatric services—reporting period: July 2013 – June 2014 [online]. [cited 2015 Mar 31]. http://www.qualitycheck.org/QualityReport.aspx?hcoid=1048&x=nqigQtr&program=Hospital&mst=Hospital-Based Inpatient Psychiatric Services&msrId=66
19. Owens, Kim (Director of Nursing, Southwood Psychiatric Hospital). Interview with: Lea Anne Gardner and Mary C. Magee. 2015 Feb 27.
20. Substance Abuse and Mental Health Services Administration. Trauma-informed care and alternatives to seclusion and restraint [online]. [cited 2015 Mar 9]. http://www.samhsa.gov/nctic/trauma-interventions
21. American Psychiatric Nurses Association. APNA position statement on the use of seclusion and restraint [online]. Revised 2014 [cited 2015 April 28]. http://www.apna.org/i4a/pages/index.cfm?pageid=3728
22. Sanctuary network: programs that are adopting the Sanctuary Model [online]. [cited 2015 Mar 12]. http://www.sanctuaryweb.com/TheSanctuaryModel/ComponentsoftheSanctuaryModel/SanctuaryNetwork.aspx
23. Cornell University Residential Child Care Project. Therapeutic crisis intervention system: information bulletin [online]. 2010 [cited 2015 Mar 9]. http://rccp.cornell.edu/assets/TCI6_SYSTEM_BULLETIN.pdf
24. Swope, Brent (Director of Milieu and Behavior Management Training Program, Philhaven). Interview with: Lea Anne Gardner and Mary C. Magee. 2015 Mar 12.
25. *Dorland's Illustrated Medical Dictionary*. 30th ed. Philadelphia: Saunders; 2003, s.v. "milieu."
26. Muirhead K, Treece MA. Normalizing the patient environment [online]. Behav Healthc 2006 Feb 1 [cited 2015 Mar 12]. http://www.behavioral.net/article/normalizing-patient-environment

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Oral Anticoagulants: A Review of Common Errors and Risk Reduction Strategies

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ABSTRACT

Oral anticoagulants, a class of high-alert medications, are widely used in the United States for varying indications, including treatment after deep-vein thrombosis or pulmonary embolism as well as prevention of stroke in valvular and non-valvular-related atrial fibrillation. Analysts reviewed medication error reports submitted from July 2013 through June 2014 through the Pennsylvania Patient Safety Reporting System (PA-PSRS) involving four oral anticoagulants: warfarin, apixaban, rivaroxaban, and dabigatran. Of the 831 errors related to oral anticoagulants analyzed from PA-PSRS, the most common event types were drug omissions (32.5%, n = 270), other (18.5%, n = 154), and extra doses (11.7%, n = 97). Medication errors categorized as "other" involved problems related to prescribing, wrong dose, wrong patient, and inaccurate medication lists. Risk reduction strategies include establishing functional hard-stop drug alerts during order entry, establishing an anticoagulant management service program, and providing continuous education for staff on anticoagulant use. (Pa Patient Saf Advis 2015 Jun;12[2]:54-61.)

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INTRODUCTION

Oral anticoagulants have been identified as one of the most commonly implicated drug classes in adverse drug events.[1,2] In fact, anticoagulants and cardiovascular agents, when compared with other medications, are more likely to cause potentially preventable adverse events that result in or prolong hospital stays.[3,4]

The Institute for Safe Medication Practices (ISMP) considers oral anticoagulants high-alert medications, as they bear a heightened risk of harm if used in error.[5] ISMP has written on risks associated with the use of anticoagulants, such as duplicate or concurrent therapy, accidental stoppage of therapy, dosing errors during transition of care, and monitoring problems.[6] The National Quality Forum (NQF) endorsed two warfarin-related measures from the Centers for Medicare and Medicaid Services to help identify problems and prevent adverse events.[7] Newer oral anticoagulants do not have as long a track record of data, including event reports; however, proactive efforts, targeted education, and error mitigation efforts should be encouraged to prevent errors.[8] Furthermore, the Joint Commission continues to designate careful oral anticoagulant use as part of the National Patient Safety Goals.[9]

In a retrospective, hospital-specific, five-year study by Piazza et al., the investigators found that 48.8% (n = 226) of all adverse drug events involved anticoagulant-related medication errors.[10] In the study, the 30-day mortality rate was increased in the 11% of patients who experienced an anticoagulant-associated adverse drug event. Retrospective studies on emergency hospitalizations for adverse drug events in older Americans implicated warfarin (Coumadin®) as the leading (33.3%) medication contributing to hospitalization.[11] It is important to note that at that time, warfarin was the only available oral anticoagulant, so future data will likely include newer agents.

Prior to 2010, warfarin was the only approved oral anticoagulant agent. Since then, several new oral anticoagulants, also referred to as target-specific anticoagulants, have been introduced into the market. Among them are apixaban (Eliquis®), dabigatran (Pradaxa®), and rivaroxaban (Xarelto®). Another agent, edoxaban (Savaysa®), received final US Food and Drug Administration (FDA) approval in January 2015.

Not all oral anticoagulants are approved and labeled for use for all of the same indications. Warfarin, a vitamin K antagonist, works by altering the clotting mechanism via protein C and S as well as factors II, VII, IX and X.[12] Target-specific oral anticoagulants, except dabigatran, work by inhibiting platelet activation and fibrin clot formation via selective and reversible inhibition of both free and clot-bound factor Xa.[13,14] Dabigatran works by reversibly inhibiting both free and fibrin-bound thrombin, resulting in reduced thrombin-mediated platelet aggregation.[15]

Unlike warfarin, target-specific oral anticoagulants cannot be monitored using international normalized ratio (INR) or other blood tests and do not require dietary modifications.[16] Although all target-specific anticoagulants are shown to be safe and effective for the indications for which they are approved, data in elderly patients or those with chronic illness is limited.[16] Also, many prescribers are still not quite versant on how to deal with target-specific oral anticoagulants in cases of trauma, surgery, and sudden emergencies requiring conversion from oral to intravenous anticoagulants such as heparin or argatroban.[17] Anticoagulants need to be monitored closely to avoid serious adverse effects (e.g., bleeding, thrombosis) that may result from inappropriate use.[16] Unlike warfarin, which can be reversed with phytonadione (vitamin K), there is still no FDA-approved antidote for the newer agents.

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Time needed for oral anticoagulant agents to reach full therapeutic effect also varies. Warfarin does not reach full therapeutic effect until five days after treatment initiation. The target-specific oral anticoagulants can reach full effect in less than 24 hours. Both warfarin and the target-specific oral agents have significant drug-drug interactions that should not be overlooked. Warfarin's dosing and monitoring is also complicated by consumption of foods containing vitamin K, such as spinach and kale.[12] Also, target-specific anticoagulants are highly protein-bound, making it quite difficult to remove them with dialysis.[13-15]

METHODS

Analysts queried the Pennsylvania Patient Safety Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) database for medication error reports involving each of the approved oral anticoagulant products. Specifically, the "medication prescribed" and "medication administered" fields in medication error event reports were queried by the brand and nonproprietary names of the approved oral anticoagulants apixaban, dabigatran, rivaroxaban, and warfarin. Categorization of the reports by harm score was adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Medication Errors.[18]

RESULTS

Pennsylvania healthcare facilities submitted 831 medication error reports associated with oral anticoagulants to the Authority from July 2013 through June 2014. The highest number of errors were reported as drug omissions (32.5%, n = 270), "other" (18.5%, n = 154), and extra doses (11.7%, n = 97) (see the Table). Approximately 2.5% (n = 21) of the events reported as "other" did not include enough detail to determine what occurred or factors contributing to the event. While the analysts were unable to separately categorize these reports, these errors remained in the analysis to be categorized based on harm score and demographics such as patient age, medication involved, and patient care area. Medical-surgical units were identified as having the highest incidence of errors at 24.1% (n = 200), followed by telemetry 9.9% (n = 82) and then rehabilitation units 9.4% (n = 78).

Of the oral anticoagulants, warfarin was predominantly reported (81.5%, n = 677), followed by rivaroxaban (11.9%, n = 99), dabigatran (3.6%, n = 30), and apixaban (2.2%, n =18). Of the reported errors, 78.7% (n = 654) involved adults age 60 or older. Over a third of the medication errors (34.4%, n = 286) involved adults age 80 or older, whose risk of adverse drug events is increased because of declining liver and renal function, greater propensity for drug interactions due to polypharmacy, and other comorbidities.

After categorization of reports by harm score using the NCC MERP index,[18] it was noted that nearly a third of the cases (29.4%, n = 244) were reported as having a harm score of D to F. This means that not only did the error reach the patient, but it also required, at minimum, intervention to prevent harm as well as further monitoring of the patient. A large number of events (44.0%, n = 366), grouped as having a harm score of C, reached the patient but did not cause

Table. Number of Oral-Anticoagulant-Related Medication Errors, by Event Type, Reported to the Pennsylvania Patient Safety Authority, July 2013 through June 2014 (N = 831)

EVENT TYPE	n	%
Dose omission	270	32.5
Other (specify)	154	18.5
Extra dose	97	11.7
Wrong dose/overdosage	50	6.0
Monitoring error: clinical (lab value, vital sign)	46	5.5
Wrong time	40	4.8
Unauthorized drug	34	4.1
Wrong dose/underdosage	28	3.4
Wrong patient	23	2.8
Medication list incorrect	22	2.6
Prescription/refill delayed	20	2.4
Wrong drug	14	1.7
Monitoring error: drug-drug interaction	8	1.0
Wrong duration	5	0.6
Wrong strength/concentration	5	0.6
Wrong technique	5	0.6
Monitoring error: other (specify)	5	0.6
Wrong dosage form	2	0.2
Wrong route	1	0.1
Monitoring error: drug-disease interaction	1	0.1
Monitoring error: deteriorated drug/biologic	1	0.1

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harm. Additionally, 1.8% (n = 15) of the reported events contributed to temporary harm to the patient (harm score E). There were no reports categorized as harm score G to I.

It should be noted that warfarin has been the mainstay of anticoagulant therapy for decades, while the other oral anticoagulants have been introduced over the past few years. Therefore, throughout this analysis, it was expected that the number of events involving warfarin would be greater than the number of events involving newer anticoagulants.

ANALYSIS

Dose Omissions

An omission of an anticoagulant, especially if that omission occurs for multiple doses, places the patient at risk of a thromboembolic event. Based on the analysis of event descriptions, the reasons for dose omissions involving anticoagulants varied, and different sources of the origin of the errors were identified, ranging across the medication-use continuum from breakdowns in prescribing to not administering an anticoagulant. Errors of omission (n= 270) resulted from medications not being ordered (35.9%, n = 97), orders not being administered (31.5%, n = 85), and orders being processed incorrectly (27.8%, n = 75).

It is worth noting that a small number (1.5%, n = 4) of patients did not receive their medications because the pharmacy could not provide them. These four cases involved target-specific anticoagulants. As with many newer medications, which lack generic equivalents, it is possible that these agents were not included in the hospital formulary.

In the analysis, 88.5% (n = 239) of dose omissions involved warfarin. It is common practice for institutions to order warfarin on a daily basis as a "one time" dose after evaluating the patient's INR for that day. This is unlike the administration of other oral anticoagulants, which are independent of INR results and can be prescribed with a fixed dosing schedule. In the example below, an oral anticoagulant dose was missed after the procedures, but it is unclear who was supposed to write the order. Note that the details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

> *Upon assessment of patient, it was noted that warfarin daily order was to be obtained for an INR of 1.9 (target INR goal = 2 – 3), but the dose was missed the previous day. Upon review of the chart to determine the dose the patient received the previous day, it was noted that following the TEE [transesophageal echocardiogram] and cardioversion, no warfarin was ordered.*

Problems have also been reported in which medication orders are temporarily "held" for scheduled tests or procedures but are not restarted as intended once the procedure is completed.[19] Most hospitals have established standard times for the administration of oral anticoagulants, which primarily affects warfarin, as the dose depends on receiving and responding to INR results. Unfortunately, if transfer or movement of patients occurs during the standard administration times, breakdowns in communication among members of the healthcare team might lead to dose omissions.

In 6.7% (n = 18) of reported omission-related events, doses were omitted during transitions of care. In most instances, one provider expected another provider to order the medication. In other cases, a patient was transferred from one unit to another without receiving a scheduled dose for the day or arrived in another care location and providers in the receiving care area were not aware of the omission, as shown in the following example.

> *Upon reviewing the most current warfarin doses, it was noted that there was no warfarin ordered or given for one day. Reviewed the initial postoperative orders, which indicated "medicine" [medical service] was to dose. Hospitalist consulted and will be following the case.*

Nurses play an important role in the medication-use process to ensure that the correct medication and appropriate dose are administered to the patient. However, breakdowns in medication administration processes can include forgetting to call for orders, signing off on lab results and not notifying the prescriber to place an order, and not ensuring that the patient actually takes the medication, such as leaving the medication with the patient to self-administer without supervision. In some cases it was unclear whether the ordered medications were received from the pharmacy or why they were not given to the patient if they were supplied, as shown in the following examples.

> *Patient [presented] to the ED [emergency department] complaining of dizziness, blackouts, and one-sided body pain from waist down into leg. Past medical history of DVT [deep-vein thrombosis]. Warfarin and Lovenox® (enoxaparin) ordered but not given. Error discovered by staff after patient was discharged from the ED. Patient called and asked to return to the ED for medication. Patient did return and received both warfarin and Lovenox. No immediate harm to patient.*

> *The patient has an order to receive rivaroxaban 20 mg PO [by mouth] daily. During the daily cart exchange, one dose was remaining in the patient's drawer. A review of the MAR [medication administration record] showed the previous dose was signed off as given. No apparent harm to patient noted. Patient and physician notified.*

Drug omissions also originated during order processing. Errors occurred when written orders either were not faxed or

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scanned to the pharmacy or were written with parameters such as pending laboratory results but laboratory tests were scheduled for the next day. Another issue included situations when orders were scanned after the hospital's standard administration times and the dose was scheduled to start the next day. Hospitals that use standardized times may risk a dose omission if the system defaults to the next standardized time and no alert is presented to the pharmacist during order entry. The following examples highlight multiple opportunities for a dose being missed.

> *Physician notified me that she placed an order for warfarin 4 mg PO every night at 1930. The patient did not receive dose that night because the medication time for evening is 1800 and the system automatically scheduled the first dose at 1800 on the next day. The patient's first dose was delayed 24 hours.*

> *Pharmacy overlooked profiling time. Patient was ordered a one-time warfarin dose. Patient did not have an INR drawn; order was placed as conditional and pharmacy requested INR result be called to pharmacy. INR was not entered or drawn until the morning. Warfarin dose was missed. Pharmacist did not follow up when INR results were not called. No adverse outcome reported due to omission.*

Extra-Dose Errors

When patients receive extra doses of anticoagulants, they are placed at an increased risk for bleeding events. As previously stated, nearly 12% (n = 97) of the reports involved extra doses of anticoagulants. In the following example, the error stemmed from not holding an order of warfarin after an elevated INR. Care should be exercised, as hold orders without specific instructions on when to resume or who restarts them, may lead to dose omissions after the INR stabilizes.

> *Patient was admitted for acute DVT of the left lower extremity and was receiving daily warfarin. Due to elevated INR results earlier in the day, patient's daily dose of warfarin was to be held in the evening. This was not done, and warfarin was given. The INR the next morning was elevated to 8.5, and 3 units of FFP [fresh frozen plasma] were ordered and administered to the patient. An additional unit of FFP was given the next day. The patient did not experience any active bleeding during this time.*

Extra doses were also administered when an order to discontinue an existing anticoagulant was missed, as in the following example.

> *Patient admitted for pulmonary embolism and placed on heparin protocol. The resident ordered rivaroxaban 15 mg by mouth BID [twice daily] to start that evening. At about 1800, I instructed the evening shift nurse to stop heparin drips right before rivaroxaban was given. The next day, the medical resident indicated that the heparin drips had been continued by the nurse until the following morning. Patient received both rivaroxaban and heparin for several hours, which placed her at an increased risk of bleeding.*

Unfortunately, a break in care that results from a change in clinicians may lead to unintended extra-dose errors. While shift change is an opportunity to communicate the patient's clinical status to the next practitioner, completing a thorough review of the each patient's MAR may not be plausible. In addition, though not always evident, patient preferences might also conflict with the hospital's preferred times for medication administration. If daily oral anticoagulant status is not properly communicated (i.e., given versus not given) or if clinicians do not thoroughly review the patient's MAR, errors can happen, as shown in this example.

> *An order was placed for 10 mg of warfarin to be given at night, which the patient received in the morning. At 2100, a resident rounded on the patient and noted that there was no order for warfarin and placed another order for a one-time dose of 10 mg of warfarin. The patient received the medication. His INR rose to 7. The patient was monitored without any bleed. He also received 10 mg of PO vitamin K, with INR decreased to 1.9 on the day of discharge.*

Error Type "Other"

Analysis of events submitted as "other" (n = 154) revealed similar errors that could have been classified as more specific event types, such as errors related to prescribing, wrong dose, wrong patient, inaccurate medication list, or omission errors. Prescribing errors (29.2%, n = 45) comprised the largest subcategory, followed by incomplete medication list (13.0%, n = 20). During prescribing, errors primarily involved duplication of therapy.

Patients receiving oral anticoagulants either at the time of admission or after admission would not need additional prophylaxis medications for DVT, unless there was a break in therapy. In the following example, a prescriber ordered a target-specific oral anticoagulant but did not discontinue subcutaneous heparin for DVT prophylaxis.

> *The patient was receiving heparin 5,000 units [subcutaneously] every 8 hours for DVT prophylaxis. Later in the day, apixaban 5 mg BID was also prescribed. The heparin was not discontinued. Therefore, the patient received subcutaneous heparin while receiving therapeutic anticoagulation with apixaban.*

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When starting warfarin therapy, it takes several days for the INR to reach the target or therapeutic goal ranges. As a result, practitioners follow "warfarin bridging" practices. This method of giving an oral anticoagulant together with heparin is used to ensure the patient stays anticoagulated enough to avoid clot growth or re-thrombosis as the INR level rises to a therapeutic level. Medication error reports, such as the following example, revealed problems with prescribers ordering multiple anticoagulants including both oral and injection formulations.

> *Physician wrote orders for dabigatran, subcutaneous Lovenox, and warfarin. The medications were not administered, and all orders were discontinued by the physician except for the Lovenox.*

Warfarin and target-specific oral anticoagulant agents ordered concurrently, as in the following example, also reflects a duplication of therapy.

> *The patient was on rivaroxaban 15 mg PO BID for treatment of PE [pulmonary embolism]. Five days later, warfarin 10 mg by mouth one dose was ordered and profiled. The warfarin was given that evening. The additional prescription was noted by the clinical pharmacist the next day. The attending physician and nurse were notified, and the warfarin was stopped. The patient was discharged and continued on rivaroxaban anticoagulation only.*

As previously noted, incomplete medication lists were the second most common source of error identified in the "other" reports. Unfortunately, incomplete medication lists continue to be a problem, particularly during transitions of care, when a patient is admitted to the hospital, transferred from one care area to another, or discharged from the hospital. The Joint Commission's National Patient Safety Goal 03.06.01 states that organizations have to "maintain and communicate accurate patient medication information."[9] When all (N = 831) oral anticoagulant medication errors are considered, the rate of incomplete medication lists is approximately 5.2% (n = 43).

RISK REDUCTION STRATEGIES

Organizations and healthcare facilities can strive to identify system-based causes of errors involving oral anticoagulant agents and implement effective types of risk reduction strategies to prevent harm to patients. Education relies heavily on individual performance. System-based improvements such as constraints and standardization are more effective.[20,21] Consider the strategies described below, which are based on a review of current literature, events submitted to the Authority, and observations from ISMP.

Constraints

- Oral anticoagulants are sometimes involved in complex drug regimens, with risks for drug interactions or duplications. A pharmacist's review of each medication order prior to dispensing could help with verifying the drug and dose against therapeutic indication.[6]
- Functional drug alerts, such as hard stops, that prevent a provider from ordering two anticoagulants at a time without giving a reason may prevent duplication of therapy.[6]
- Verbal orders can be misinterpreted, misunderstood, or not transcribed correctly.[22] Organizations can strive to eliminate the use of verbal orders unless in emergency situations. If verbal orders have to be used, consider a "read back" method, such that the nurse first documents the order in writing (or electronically) and then reads it back to the prescriber, versus a "repeat back" method, in which there may be a gap, and potentially interruptions, before order entry is completed.

Standardization

Prescribing

- The dose of some of the target-specific agents requires adjustment based upon patient characteristics (e.g., renal function, body weight). Therefore it is important to standardize the baseline information, such as weight in kilograms and serum creatinine function, needed during the ordering of oral anticoagulants.[6] Also, having a standardized process for updating computer systems and healthcare records is important. Displaying the current calculated creatinine clearance during electronic prescribing is helpful to prevent errors.[6,23,24]
- Elderly patients may require lower starting doses for oral anticoagulants, depending on the agent ordered, because of reduced renal function or, in some instances, lower body weight.[6]
- Dose omissions that were seen often were in part a result of orders that were held and not reinstated. Establishing a standard process and following a strategy for handling "hold" orders is vital. Having an active order or reminder listing the drug, route, and frequency, with clear annotation on the records to ensure that a dose is prescribed each day according to lab values in both the pharmacy and MARs, may help minimize omissions.[19,25]
- Organizations are encouraged to establish anticoagulation management service (AMS) programs for dosing and monitoring, as well as for teaching patients about their therapy.[26-28] The first step in developing AMS programs is to assess current practices associated with anticoagulation safety. The self-

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assessment process allows facilities to identify ways in which to provide safer care while improving patient outcomes.[28] The Authority has accessible resources to help organizations interested in establishing an AMS program as well as an anticoagulant organization assessment (available at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/ams/Pages/Home.aspx).[29] AMS programs help to centralize care of the patient and provide agreed-upon interdisciplinary treatment and monitoring guidelines.

- Standard protocols for rapid or emergency reversal of anticoagulation and expected restarting of anticoagulants can be useful tools for use in institutions. The effects of some reversal agents such as phytonadione continue for up to a week; therefore, use of national guidelines for guidance on restarting anticoagulation if indicated may be helpful.[6]
- The Joint Commission addresses incomplete and "blanket" orders, even in electronic prescribing, such as "resume all meds," and recommends they not be used.[30] Standardized processes for the medication reconciliation process during handoffs or at any transition of care can help ensure appropriate anticoagulant ordering takes place.
- "NOAC" has been used in medical literature as an abbreviation for the target-specific, or "novel," oral anticoagulants. Unfortunately, this abbreviation has been misunderstood as "no anticoagulation" and may contribute to unintended discontinuation of the medication, leading to dose omissions.[31] ISMP recommends the abbreviation be prohibited, as it is prone to error and misinterpretation.

Dispensing and Administration

- Administration of warfarin at a standard time allows for a thorough review of daily laboratory results and any necessary dose adjustments before administration; however, coordination of laboratory data and dose administration is important.[6]
- Most organizations will only stock one medication per therapeutic class to streamline costs by reducing inventory and carrying costs. However, due to the uniqueness of each of the newer oral agents, this might not be the best strategy for these medications. If only a limited selection of medications is added to the formulary, define policies and procedures for therapeutic substitution or ways to approve use of a patient's own medication to avoid missed doses.[8]

Redundancies

- Strategically placed independent double checks—such as a pharmacist check of stock medications for units and of automated dispensing cabinets (ADCs) before leaving the pharmacy or a nurse verification of a dose for new starts as well as one-time orders for anticoagulants—may avoid anticoagulant-related errors.[6]
- Clinical decision support in computerized order entry and pharmacy information systems may help avert dosing errors and duplication of orders by firing alerts to users.[29]
- Bar-code scanning during stock replenishment of ADCs may reduce stocking errors.[32] In addition, bar-code scanning during administration may help ensure the correct drug and dose is administered.[33]

Therapeutic Monitoring

- When an oral anticoagulant is indicated, baseline lab test results such as renal function tests need to be available in two hours or less to help guide therapy.[6]
- Process control charts can be used to display trends in INR values for patients and to assist with dosing oral anticoagulants, especially warfarin.[6]

Education and Information

Staff Education

- Annual competence assessments for clinicians who prescribe, dispense, or administer oral anticoagulants help to ensure clinicians understand different oral anticoagulant medications and their uses in therapy.[6]
- When a new anticoagulant is added to the organization's formulary, notify staff using tools like newsletters and in-services. Studies show that even with continuous offerings for educational programs on therapeutic agents, healthcare professionals find it difficult to keep completely up to date through independent effort. Therefore, providing relevant and reliable information may be helpful.[34]
- When a new oral anticoagulant is added to the organization's formulary, ensure underlying protocols, including oral anticoagulant reversal protocols, are up to date. Organizations may consider proactively developing protocols even if the product is not on formulary in anticipation of a patient being admitted on a target-specific anticoagulant.
- Combining oral anticoagulants with oral antiplatelet agents such as clopidogrel, although potentially useful in some situations, increases bleeding risk, and expertise in therapy management is critical.[35]

Patient Education

- Patient counseling and education provides an opportunity to empower patients to recognize, intercept, and prevent errors. At the onset

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of therapy and prior to discharge, provide education to patients who are on anticoagulants. Some of the oral anticoagulants have complex dosing and the potential for serious drug-drug interactions, so it is extremely important for a patient to understand how to take the medication.[16,36] Remind patients that the risks of anticoagulants include bleeding but that there are also risks of clotting from the underlying condition due to inadequate anticoagulation when doses are missed.[16] Tools exist, such as ISMP's patient counseling sheets, which can be shared with patients to help prevent errors with warfarin.[36]

- The patient's ability to afford and purchase oral anticoagulant agents can impact adherence to therapy. Consider involving case management services prior to discharge to prevent situations in which a patient is forced to omit a dose for financial or other reasons.
- Hospitals providing discharge process education also noted it was better for the patient and the hospital team to not delay discharge education until the day of discharge. Organizations are encouraged to plan teaching a couple of days prior to discharge to ensure the care team has adequate time to review and make suggestions for the patient's therapy without being rushed. In addition, this provides the patient with an opportunity to review and ask questions prior to discharge.[37]

Monitoring of Adverse Drug Events

- When errors happen, investigating and sharing them with other clinicians raises awareness on issues surrounding oral anticoagulants.
- Prior potential, near-miss, and harmful event reports may help facilities identify possible errors and areas for improvement.
- Defined adverse drug event triggers such as INR greater than 6, sudden decline in renal function, bleeding, or hypercoagulability may help monitor patients and identify the potential or actual onset of new adverse drug events.[38] Administration of reversal agents such as vitamin K1 and protamine are additional triggers that can be used to identify adverse events during chart review processes.[37]

CONCLUSION

Oral anticoagulants are considered high-alert medications because, when used in error (e.g., dose omission, inappropriate administration), there is a heightened risk of causing significant patient harm (i.e., failure to prevent life-threatening thrombosis, contribution to life-threatening bleeding). While the approval of new oral anticoagulants has provided clinicians and patients with more therapeutic options, the target-specific agents have varied indications and mechanisms of action, and this complexity introduces more opportunities for errors. The errors noted in this article reflect errors that can happen during any stage of therapy, from prescribing through administration. Extra precautions and risk reduction strategies provided in this analysis may help hospitals minimize the occurrence of oral-anticoagulant-related adverse events.

NOTES

1. Office of Inspector General (OIG). US Department of Health and Human Services. Adverse events in hospitals: national incidence among Medicare beneficiaries [online]. Report no. OEI-06-09-00090. 2010 Nov [cited 2015 Apr 10]. http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf
2. Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006 Oct 18;296(15):1858-66.
3. Davidsen F, Haghfelt T, Gram LF, et al. Adverse drug reactions and drug non-compliance as primary causes of admission to a cardiology department. *Eur J Clin Pharmacol* 1988;34(1):83-6.
4. Bordet R, Gautier S, Le Louet H, et al. Analysis of the direct cost of adverse drug reactions in hospitalised patients. *Eur J Clin Pharmacol* 2001 Mar;56(12):935-41.
5. Institute for Safe Medication Practices. ISMP list of high-alert medications in acute care settings [online]. 2014 [cited 2014 Dec 15]. http://www.ismp.org/Tools/institutionalhighAlert.asp
6. Institute for Safe Medication Practices. High-alert medication feature: anticoagulant safety takes center stage in 2007. [online]. ISMP Med Saf Alert Acute Care 2007 Jan 11 [cited 2014 Dec 15]. http://www.ismp.org/Newsletters/acutecare/articles/20070111.asp
7. National Quality Forum. Patient safety measures [online]. 2014 [cited 2014 Dec 15]. http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73701
8. Dunn SP, Kazmi H. New oral anticoagulants: implications for health systems [online]. Pharmacy Times 2013 Jul 22 [cited 2014 Dec 15]. http://www.pharmacytimes.com/publications/health-system-edition/2013/July2013/New-Oral-Anticoagulants-Implications-for-Health-Systems
9. Joint Commission. National Patient Safety Goals effective January 1, 2015 [online]. 2015 Jan 1 [cited 2015 Jan 2]. http://www.jointcommission.org/assets/1/6/2015_NPSG_HAP.pdf
10. Piazza G, Nguyen TN, Cios D, et al. Anticoagulation-associated adverse drug events. *Am J Med* 2011 Dec;124(12):1136-42.

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11. Budnitz DS, Lovegrove MC, Shehab N, et al. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med* 2011 Nov 24;365(21):2002-12.
12. Bristol-Myers Squibb. Coumadin® (warfarin sodium) [prescribing information online]. 2011 Oct [cited 2014 Dec 15]. http://packageinserts.bms.com/pi/pi_coumadin.pdf
13. Janssen Pharmaceuticals, Inc. Xarelto® (rivaroxaban) prescribing information [online]. 2014 Sep [cited 2014 Dec 15]. http://www.xareltohcp.com/sites/default/files/pdf/xarelto_0.pdf
14. Bristol-Meyers Squibb. Eliquis® (apixaban) [prescribing information online]. 2014 Aug [cited 2014 Dec 15]. http://packageinserts.bms.com/pi/pi_eliquis.pdf
15. Boehringer Ingelheim Pharmaceuticals, Inc. Pradaxa® (dabigatran etexilate mesylate) [prescribing information online]. 2014 Sep [cited 2014 Dec 15]. http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing%20Information/PIs/Pradaxa/Pradaxa.pdf
16. New oral anticoagulants for acute venous thromboembolism. *Med Lett Drugs Ther* 2014 Jan 6;56(1433):3-4.
17. Darves B. No antidote: reversal strategies for newer anticoagulants [online]. 2013 May [cited 2014 Dec 15]. http://www.todayshospitalist.com/index.php?b=articles_read&cnt=1671
18. National Coordinating Council for Medication Error Reporting and Prevention. NCC MERP index for categorizing medication errors [online]. 2001 Feb [cited 2014 Dec 15]. http://www.nccmerp.org/medErrorCatIndex.html
19. Hold on to these orders. PA PSRS Patient Saf Advis [online] 2006 Mar [cited 2014 Dec 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Mar3%281%29/documents/33.pdf
20. Cohen MR, Smetzer JL, Tuohy NR, et al. High-alert medications: safeguarding against errors. Chapter 14. In: Cohen MR, ed. *Medication errors*. 2nd ed. Washington (DC): American Pharmacists Association; 2007.
21. Institute for Safe Medication Practices. Medication error prevention "toolbox." *ISMP Med Saf Alert Acute Care* 1999 Jun 2;4(11):1.
22. Cohen MR. Preventing prescribing orders. Chapter 9. In: Cohen MR, ed. *Medication errors*. 2nd ed. Washington (DC): American Pharmacists Association; 2007:190-2.
23. Galanter WL, Didomenico RJ, Polikaitis A. A trial of automated decision support alerts for contraindicated medications using computerized physician order entry. *J Am Med Inform Assoc* 2005 May-Jun;12(3):269-74.
24. Michaels AD, Spinler SA, Leeper B, et al. Medication errors in acute cardiovascular and stroke patients: a scientific statement from the American Heart Association. *Circulation* 2010 Apr 13;121(14):1664-82.
25. Cohen MR. Preventing prescribing orders. Chapter 9. In: Cohen MR, ed. *Medication errors*. 2nd ed. Washington (DC): American Pharmacists Association; 2007:187.
26. Streiff MB, Kraus PS, Pronovost P. Penny-wise, pound-foolish? Highmark Medicare Services' proposal for anticoagulation clinic reimbursement. *Ann Pharmacother* 2010 Apr;44(4):733-6.
27. Ansell J, Hirsh J, Hylek E, et al. Pharmacology and management of the vitamin K antagonists. *Chest* 2008 Jun;133 (6 Suppl):160S-198S.
28. Anticoagulation management service: safer care, maximizing outcomes. Pa Patient Saf Advis [online] 2008 Sep [cited 2014 Dec 15]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/81.aspx
29. Pennsylvania Patient Safety Authority. Pennsylvania Hospital Engagement Network: organization assessment of safe anticoagulant practices [online]. 2014 [cited 2015 Jan 7]. http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/ams/Documents/assessment.pdf
30. Joint Commission. Standard MM.04.01.01. In: *Comprehensive accreditation manual for hospitals*. Update 2. Oakbrook Terrace (IL): Joint Commission Resources; 2015 Jan.
31. Institute for Safe Medication Practices. Use of "NoAC" abbreviation. *ISMP Med Saf Alert Acute Care* 2013 Dec 12;18(25):2-3.
32. Institute for Safe Medication Practices. Guidance on the interdisciplinary safe use of automated dispensing cabinets [online]. 2008 [cited 2015 Apr 9]. http://www.ismp.org/tools/guidelines/ADC/ADC_Guidelines_Final.pdf
33. Medication errors occurring with the use of bar-code administration technology. Pa Patient Saf Advis [online] 2008 Dec [cited 2015 Apr 9]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Dec5(4)/documents/122.pdf
34. Routledge PA, O'Mahony MS, Woodhouse KW. Adverse drug reactions in elderly patients. *Br J Clin Pharmacol* 2004 Feb;57(2):121-6.
35. Holmes DR Jr, Kereiakes DJ, Kleiman NS, et al. Combining antiplatelet and anticoagulant therapies. *J Am Coll Cardiol* 2009 Jul 7;54(2):95-109.
36. Institute for Safe Medication Practices. Medication safety tools [online]. 2014 [cited 2014 Dec 15]. http://www.consumermedsafety.org/tools-and-resources/medication-safety-tools-and-resources
37. Martin ES 3rd, Overstreet RL, Jackson-Khalil LR, et al. Implementation of a specialized pharmacy team to monitor high-risk medications during discharge. *Am J Health Syst Pharm* 2013 Jan 1;70(1):18-21.
38. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care* 2003 Jun;12(3):194-200.

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Delivering the Right Diet to the Right Patient Every Time

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ABSTRACT

Pennsylvania Patient Safety Authority analysts identified 285 events involving dietary errors submitted January 2009 through June 2014. Meals delivered to patients who were allergic to a food item on the tray were identified as the most frequently reported type of event (n = 181), with serious harm reported in eight events. Other types of events included patients receiving the wrong diet (n = 50), meals meant for other patients (n = 43), and meals delivered to patients who were not to receive any food by mouth (e.g., preoperative patients) (n = 11). Review of the published literature and interviews conducted by analysts of clinical dietitians and dietary directors in Pennsylvania hospitals suggests strategies to prevent dietary errors and patient harm by standardizing practices, such as matching food allergies with dietary ingredients, and by using communication tools, such as whiteboards or diet wheels. (Pa Patient Saf Advis 2015 Jun;12[2]:62-70.)

INTRODUCTION

Delivering the right diet to the right patient at the right time is a carefully orchestrated team effort in the acute care setting.[1] The medical staff prescribe the diet, and the nursing and dietary staff ensure that patients receive meals that are tailored to specific health conditions and designed to support continued recovery and health. During routine review of Pennsylvania Patient Safety Reporting System (PA-PSRS) reports, analysts noted several events involving patients who received incorrect diets, resulting in harm.

Published information identified from a literature search indicated that food allergies are a large and growing public health problem in the United States.[2] Studies have estimated that the prevalence of food allergies in the US adult population may be nearly 4%.[2] Analysis of PA-PSRS data revealed the types of foods reported by patients with allergies and how this compares with food allergen prevalence in the United States.

Other information reported in the literature and interviews conducted by analysts of dietary personnel in Pennsylvania hospitals suggests strategies to prevent dietary errors and patient harm by standardizing practices, such as matching food allergies with dietary ingredients, and by using communication tools, such as whiteboards or diet wheels.

METHODS

Analysts queried the PA-PSRS database for reports submitted January 2009 through June 2014 of events involving patients who had experienced a dietary error related to oral feedings. Terms such as "allergy," "tray," "wrong," "NPO" (nothing by mouth), and "diet" were used to identify reports, which were then analyzed individually to identify only those reports that described dietary events. Analysts determined the reason for the dietary error by reviewing the event report narratives and categorized the events into one of four predominant classifications: allergy to a food item on the tray, receiving the wrong diet, meals meant for other patients, and meals delivered to patients who were not to receive any food by mouth. Event reports were analyzed according to event type and harm score.

Narratives from event reports involving food allergies were also reviewed to identify the types of foods involved in allergic reactions and to compare these foods with the eight major food allergens in the United States—milk, egg, peanuts, tree nuts, soy, wheat, fish, and crustacean shellfish.[1]

Analysts conducted a review of the literature, as well as an Internet search, to identify allergy statistics, best practices, and risk reduction strategies for dietary issues in healthcare facilities. Interviews with clinical dietitians and dietary directors were also conducted to identify best practices and resources developed specifically for dietary departments to reduce the risk of patient harm in healthcare facilities.

RESULTS

Analysts identified 285 dietary events submitted through PA-PSRS. The majority of dietary events (n = 181, 63.5%) involved patients who received a tray containing a food item to which the patient was allergic; more than three-quarters of these allergies (n = 141, 77.9%) were both known and documented in the medical record prior to the event (see Figure 1). In 8 (4.4%) of the 181 events in which patients with a known food allergy ingested the identified food, serious harm occurred, resulting in emergency administration of epinephrine or other medications, transfer to a higher level of care, and/or intubation.

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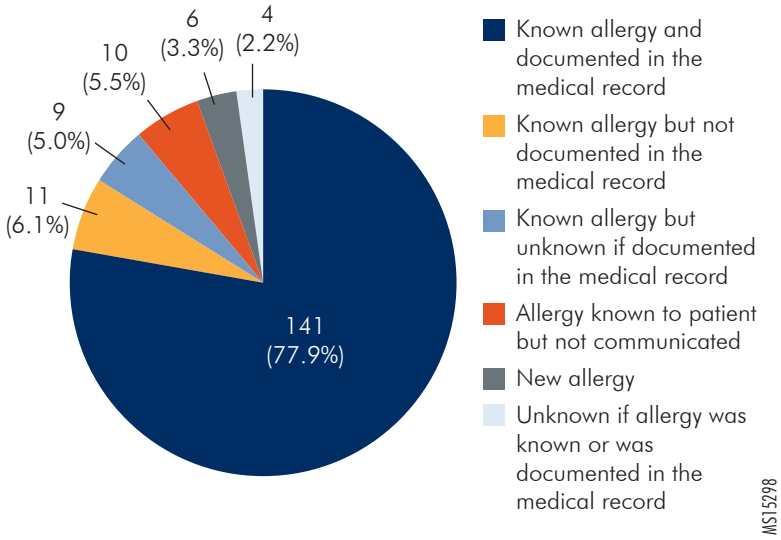
Figure 1. Allergy-Related Dietary Events Submitted to the Pennsylvania Patient Safety Authority January 2009 through June 2014 (N = 181)



Other dietary events involved patients receiving the wrong diet (n = 50 of 285, 17.5%), patients receiving a tray meant for another patient (n = 43 of 285, 15.1%), and patients who were supposed to have a status of NPO who received a food tray (n = 11 of 285, 3.9%).

Types of Dietary Events

Food allergy. The following are examples of events reported to the Pennsylvania Patient Safety Authority involving dietary allergy errors without injury:*

> *The nurse ordered apple juice for patient, not realizing that the patient was allergic to apples. After discovering error, nurse then called dietary to inform them of patient's allergy to both apples and carrots. When patient's meal arrived, tray contained a dish of carrots and carrots in the salad. After talking to the patient, the nurse learned the patient had received apple juice and applesauce the prior day.*

> *Patient has documented allergy to seafood. Was given a house tray for lunch, which had main course of fish. Personal caregiver brought issue to nursing's attention. The caregiver states patient "only had one bite" of food. Upon review of chart, allergy to "sea water" was documented under "medication," with comment saying patient has allergy to seafood, not sea water. Kitchen informed of allergy. Allergy information changed in computer. Tray was discarded and new tray was ordered. No allergic reactions noted.*

> *The patient's breakfast tray had a packet of peanut butter on it. Patient was alert, did not touch the peanut butter. Patient has a history of severe allergic reaction to peanut butter and beans. Documented under allergies, and dietary made aware.*

Examples of allergy events with injury are as follows:

> *The patient entered via emergency department. Allergy to seafood documented in [emergency department] record. Patient was admitted to [unit], seafood allergy not documented in [electronic medical] record. Patient received fish on food tray during admission and suffered anaphylactic reaction requiring multiple IV [intravenous] medications, IM [intramuscular] epinephrine, and [intensive care] observation. The patient's condition improved and returned back to baseline. No residual effects. Seafood allergy was updated in [electronic medical record], and allergy band placed on patient's wrist. Both nurse and physician were reeducated and counseled regarding completion of the nursing assessment, as well as confirming patient's allergies and entering them in the patient's electronic record.*

> *The patient received a fruit cup on food tray that contained pineapples. The patient is allergic to pineapples. This was documented in the electronic medical record; however, it was noted as a drug not food. So the pineapple allergy was not transferred to the [dietary] department. The patient did eat the fruit except for the pineapple. The patient experienced an allergic reaction requiring intubation and transfer to the critical care unit. The patient was extubated and has since been discharged.*

> *Patient [is] allergic to fish. Allergy listed during admission only as drug allergy but not food allergy. Patient slightly less alert related to treatment and did not realize he was eating fish received on dinner tray. Patient with immediate allergic response to fish was given medication and transferred to ICU [intensive care unit] for upper airway edema and required intubation.*

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

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Wrong diet. Examples of patients who received a different diet than was ordered, such as a diabetic, low-salt, or thickened diet, are as follows:

> *The patient is on a pureed-thin liquid diet. Received a regular tray and ate the meal when it is to be pureed. Meal consisted of chicken, cornbread, and fruit cup.*

> *The patient was given [food supplement A] with her lunch–[food supplement B] had been ordered. Patient's blood sugar was 354 [that night]. Food services apparently placed wrong supplement on meal tray.*

> *The patient received wrong diet on lunch tray. Patient is ordered a dysphagia diet [for patients with difficulty swallowing] with nectar-thick liquids and received a whole chicken breast and a piece of white bread on tray.*

Wrong tray. Examples of patients who received a tray meant for another patient are as follows:

> *[Dietary] hostess gave patient wrong food tray with another patient's name on it. The food order was correct in the computer system and labeled correctly but given to the wrong patient. Physician notified. No harm to patient.*

> *Patient on clear liquids due to acute GI [gastrointestinal] bleed. Given dinner tray of another patient who was on a cardiac 2 gm sodium diet. Patient and family stated no one asked [the patient's] name. Patient ate some of the food from the wrong dinner tray.*

> *Patient's diet is listed in computer orders as gluten-free (patient has gluten allergy); however, patient's lunch tray [dietary slip] listed diet as regular house diet. Dietary contacted immediately to inform and correct. There are two patients on unit with the same last name, and the other patient received the gluten-free diet instead. Patient consumed entirety of lunch tray contents, which did include items containing gluten. Attending physician informed, and nutritionist in to see patient regarding the event.*

NPO. Examples of patients who received trays despite NPO orders are as follows:

> *Staff put verbal order for soft diet on wrong patient chart for patient who was to be NPO. Patient was given a soft diet. Patient aware [of NPO status] and informed the dietician. Nurse manager made aware of event and will discuss with staff that took verbal order.*

> *Patient came in with PEG [percutaneous endoscopic gastrostomy] tube. As per transfer record, patient was on NPO and tube feed. Dietary staff came up and brought a tray. The order was put in wrong and was clarified right away by the attending doctor.*

> *Patient ordered NPO. Written on whiteboard in patient's room. Dietary gave patient breakfast tray and patient ate wrong patient's tray.*

Types of Food Allergies

Foods most commonly reported to the Authority as food allergens were very similar to the eight major food allergens that account for 90% of all food-related allergic reactions in the United States.[2,3] Fruit, dairy, egg, and fish were the most frequently reported food allergens; and 10 major food allergens accounted for nearly 90% of the food-related allergic reactions in dietary events reported in Pennsylvania hospitals (see Figure 2).

DISCUSSION

Healthcare facility workers are challenged with meeting the dietary needs of their patients. From the moment a patient arrives in the facility until the patient leaves, medical staff, nursing, and dietary workers coordinate efforts for patients with specific dietary needs caused by food allergies, medical conditions such as diabetes or dysphagia, and food interactions with medications such as anticoagulants.[1]

Patients' dietary needs may not remain static throughout their hospitalization. As a result of medical status changes, patients may be transferred from a medical-surgical unit to a specialized unit (such as intensive care), prepped for a surgical procedure (including an NPO order), or moved within a unit because of a change in behavior. Transfers, treatments, and tests may necessitate changes to a patient's diet order or may change the location of the patient at any time of the day, which may result in the patient receiving the wrong diet or tray.[1] Errors may occur at many points in this multistep workflow; see "How a Diet Error Can Occur" for more information.

Limited Guidelines

Hospital practices. Limited guidance has been published to aid healthcare institutions in the reduction of dietary errors. Most literary resources focus primarily on food allergy prevalence and reactions in the pediatric and adult populations,[2] best practices to improve patient satisfaction,[4] use of computer software that aids in nutrition care management,[5] and strategies to improve food service quality.[6]

One hospital developed guidelines based on the "service delivery innovation profile" featured on the Agency for Healthcare Research and Quality website.[7] After experiencing many events of the wrong food being delivered and often consumed by patients on a 58-bed medical-surgical floor, a Tennessee hospital developed a "diet wheel" tool to decrease the number of dietary errors. The diet wheel was hung on the patient's door and allowed the nursing staff to "dial" to the type of diet ordered for the patient (e.g., renal, full liquid, low fat, low sodium, NPO),

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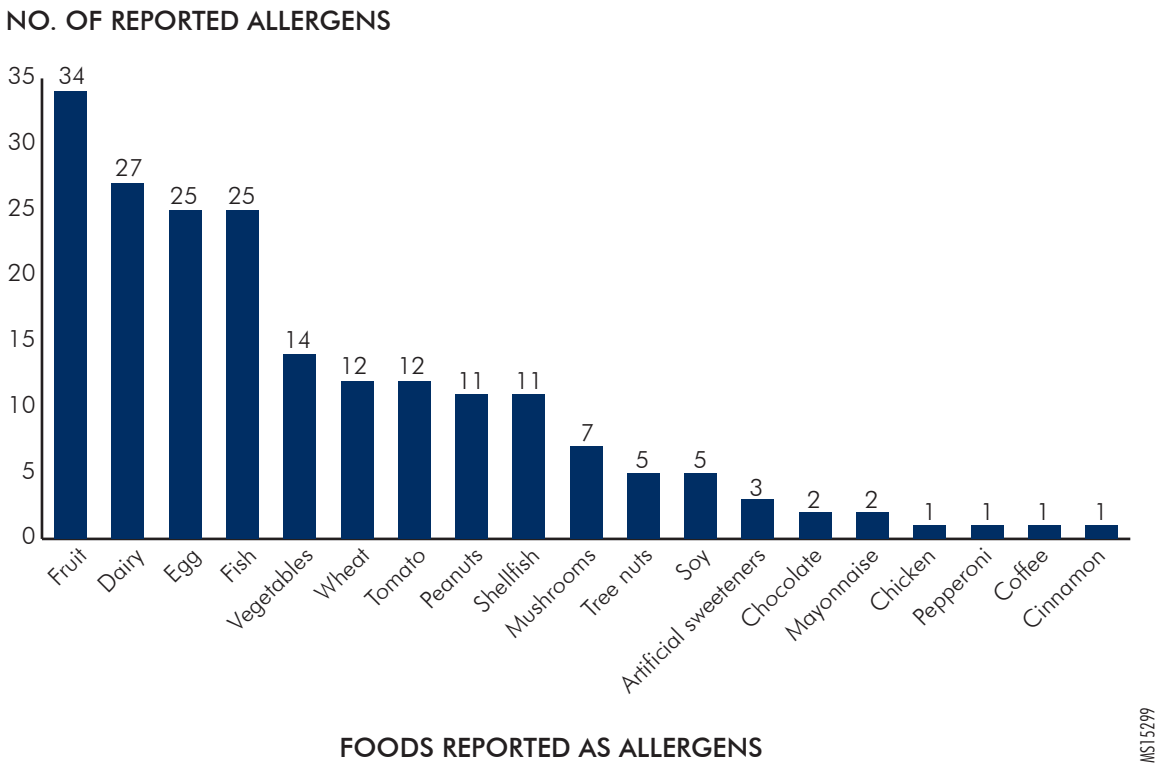
Figure 2. Foods Reported as Allergens in Events Submitted to the Pennsylvania Patient Safety Authority January 2009 through June 2014 (N = 199)



providing a visual cue for the dietary staff when delivering a food tray to the patient's room.

After using the diet wheel for a period of time, nurses reported they rarely observed instances in which a patient consumed a different diet than that ordered by the physician, and there were fewer interruptions of nurses to clarify a diet order. Nursing staff expressed satisfaction with the results of the program.[7]

Other visual cues used by hospitals include patient whiteboards that serve as a communication tool among hospital providers and as a mechanism to encourage patient and family engagement,[8] as well as stickers on medical records and color-coded allergy wristbands that alert medical staff of the patient allergy or specialized diet.[9]

Previous work by the Authority has discussed the value of standardizing the colors and meanings of wristbands, as well as providing information and resources about best practices. To access the Authority's resources on color-coded wristbands, see http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/wristbands/Pages/home.aspx.

Caution may be warranted if food and medical allergies are documented in different parts of an electronic or written health record. Interfaces between dietary documentation and the medical documentation may be helpful.

Guidelines from regulating and accreditation entities. Governmental and nongovernmental accrediting organizations and regulatory bodies such as the Pennsylvania Department of Health,[10] the Joint Commission,[11] and the Centers for Medicare and Medicaid Services (CMS)[12] offer guiding principles for dietetic services in their regulations and interpretative guidelines for hospitals.

Information typically includes general guidance for organization and staffing, equipment, food storage, education programs, infection control, and nutritional aspects of patient care. The guidelines do not specifically address how to ensure the right diet or tray is delivered to the right

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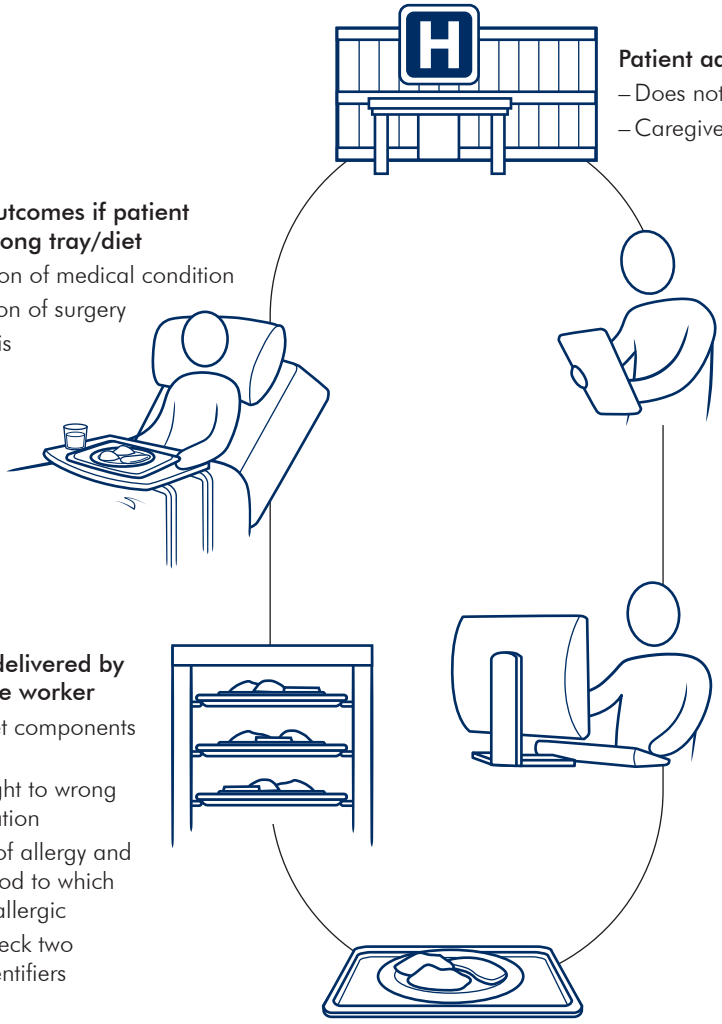
How a Diet Error Can Occur



Patient admission/ongoing care
- Does not/cannot give accurate history
- Caregiver unavailable to give history

Medical staff/designee orders diet
- Does not check patient's food allergy and medical history
- Orders wrong diet
- Enters order on wrong patient chart
- Fails to review recommendations of other healthcare professionals

Nursing manages diet order
- Places allergy in wrong section on patient chart
- Fails to use two patient identifiers when serving tray
- Orders wrong diet
- Enters order on wrong patient chart
- Gives patient food before receiving order
- Delays sending new diet information to food service department

Food service department fills order
- Sends standard tray before receiving patient's menu
- Fails to access patient's diet information and apply it to the menu on meal tray
- Fails to remove restricted food item before tray leaves kitchen
- Substitutes ingredients not listed in standardized recipe

Meal tray delivered by food service worker
- Wrong diet components dispensed
- Tray brought to wrong room/location
- Unaware of allergy and delivers food to which patient is allergic
- Fails to check two patient identifiers

Potential outcomes if patient receives wrong tray/diet
- Exacerbation of medical condition
- Cancellation of surgery
- Anaphylaxis
- Aspiration

Note: As reported in events submitted to the Pennsylvania Patient Safety Authority from January 2009 through June 2014.

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patient. The Pennsylvania Department of Health states that "conferences should be held regularly within the dietary services department at all levels of responsibility, to disseminate information, interpret policy, solve problems, and develop procedures and program plans."[10]

The Joint Commission does not have a separate chapter on dietary guidance; rather, it recommends dietary compliance in their chapters on leadership, provisions of care, and record of care.[11] For example, in the chapter on record of care, provisions call for the medical record to contain any allergies to food.

CMS calls for a system for diet ordering and patient tray delivery.[12] Other provisions call for menus to meet the special needs of the patients, screening criteria to identify patients at nutritional risk, review of patient records to verify the diet orders are provided as prescribed, and review of competencies for administrative and technical personnel in their assigned duties. A 2014 CMS ruling allows qualified dietitians or nutritional professionals to order a patient diet. See "CMS Rules on Therapeutic Diet Orders" for information about diet orders in Pennsylvania.

CMS RULES ON THERAPEUTIC DIET ORDERS

The Centers for Medicare and Medicaid Services (CMS) announced a rule in 2014 regarding hospital diet orders, stating that patient diets must be ordered by a practitioner responsible for the care of the patient or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with state law governing dietitians and nutrition professionals.[1]

Pennsylvania is 1 of 16 states that has significant statutory or regulatory impediments that presently preclude registered dietitian nutritionists (RDNs) from ordering patient diets, according to Meg Rowe, MS, RD, LDN, FAND, consumer protection and licensure chair, Pennsylvania Academy of Nutrition and Dietetics.[2]

Allowing registered dietitians the ability to order patient diets would create efficient and effective practices for RDNs to perform at the height of their competencies, according to Rowe. The provision of nutrition care to patients would be streamlined, resulting in more timely nutrition intervention for the patients and, ultimately, improvement of patient care and safety, she said.

To be implemented in Pennsylvania, the rule needs approval by the Pennsylvania Department of Health and the Pennsylvania State Board of Nursing, and then each hospital and its medical staff must approve privileges for qualified dietitians and nutrition professionals to order diets. Rowe and the CMS task force of the Pennsylvania Academy of Nutrition and Dietetics are working with professional groups such as the Hospital and Healthsystem Association of Pennsylvania, the Pennsylvania State Board of Nursing, the Pennsylvania Osteopathic Medical Association, and the Pennsylvania Medical Society to obtain privileges for RDNs to be able to order patient diets independently, consistent with the CMS recommendation.[1,2]

Notes

1. Centers for Medicare and Medicaid Services. Revised guidance related to new & revised regulations for hospitals, ambulatory surgical centers (ASCs), rural health clinics (RHCs) and federally qualified health centers (FQHCs) [letter online]. Ref: S&C: 15-22-Hospital/ASC/RHC/FQHC. 2015 Jan 30 [cited 2015 Apr 30]. http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-22.pdf
2. Rowe, Meg (Consumer Protection and Licensure Chair, PA Academy of Nutrition and Dietetics). Conversation with: Pennsylvania Patient Safety Authority. 2015 Mar 5.

Food Allergies

Food allergy is a growing public health concern in the United States. Between 1997 and 2011, there was a reported 50% increase in allergies among children.[1-3] As many as 15 million people have food allergies—9 million adults (i.e., 4% of all adults) and 6 million children (i.e., 8% of all children), with a greater prevalence in younger children. Food allergies appear to be more common in boys than in girls.[1-3]

The Centers for Disease Control and Prevention reported that food allergies result in more than 300,000 ambulatory care visits a year among children under the age of 18. Most allergic reactions result from foods that were thought to be safe. Some allergic reactions can be attributed to a product mislabeling or cross-contact during food preparation.[1-3]

Following ingestion of a food allergen, a person with food allergies can experience a range of reactions, including a severe, life-threatening allergic reaction called anaphylaxis. Symptoms of allergic reactions can include tingling or itchy sensations; external edema; flushed skin, rash, or hives; abdominal cramps, emesis, or diarrhea; and coughing, stridor, or wheezing. Anaphylaxis may progress to bronchospasm, hypotension, upper airway obstruction, shock, cardiac arrest, or death.[1-3] Healthcare providers may be less familiar with the gastrointestinal manifestations of anaphylaxis, such as emesis or diarrhea, which may precede hypotension and shock, as compared with respiratory manifestations.[13]

Depending on the severity of the allergic reaction, treatments can range from the use of antihistamines or injection of epinephrine or other medications to transfer to a higher level of care or intubation. Strict avoidance of the allergy-causing food is the only way to avoid a reaction.

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Eating away from home can pose a significant risk to people affected by food allergies, as close to half of fatal food allergy reactions are triggered by food consumed outside the home.[1-3]

Reading ingredient labels is a primary method to avoid allergens. Since hospitalized patients do not have this opportunity, they are dependent on healthcare workers to identify and inform the appropriate network of individuals about their food allergies and to provide safe food choices.[1-3]

RISK REDUCTION STRATEGIES

In the absence of abundant literature and clinical guidelines specific to reducing dietary events in the acute care setting, the Authority reached out to clinical dietitians and dietary directors in Pennsylvania hospitals for their expert opinions.[14-18]

In a conversation with the Authority, Jennifer Ross, director of nutrition services, Abington Health, highlighted several strategies to make sure patients are not served foods to which they have a known allergy.[18] She said Abington Health compares information about a patient's allergies with food ingredient information.

Using a food service interface integrated with the main hospital's electronic health system, dietary orders are automatically updated in real time with patient allergies, admission and discharge information, and transfers. Not all food allergies are entered into the interface, she said, and some must be entered manually. Any allergy that is not addressed using the interface is posted on a report and reviewed at safety meetings twice a day.

All menus and tray tickets for patients with allergies are marked with a prominent red slash, Ross said. "This tells each staff member to use the safety tool STAR so they can stop, think, act, and review," she said. "Trays with these slashes also require an independent second check and sign-off, usually done by a manager or supervisor. It must be someone who has not participated in assembling the tray in order to get fresh eyes."

The following strategies are suggested for healthcare facilities seeking to improve the quality of dietary care for patients.

Hospital Personnel

- Education is the first line of defense. Provide continuing education and training about food allergies and special diets, as well as the proper way to answer patients' questions and concerns, to all staff, including healthcare providers (such as nurses and dietitians) and allied health professionals (such as food service personnel).[1,14-18]
- Create a written procedure for handling food allergies and special diets for all staff members to follow.[1-3] Consider the following questions when creating a policy:[1]
  - ☐ Who will be responsible for identifying the allergic patient's dietary needs or special diets?
  - ☐ How will dietary information be disseminated to the rest of the medical staff, to the food service staff, and to the patients' visitors?
  - ☐ What is the hospital's policy to address the questions of the patient who has a food allergy or other dietary restriction?
  - ☐ When would a patient be referred to a dietitian to address the patient's food allergies or special diets?
  - ☐ What does the food service staff need to know to avoid cross-contact with allergen-containing foods?
- Develop a staff team of physicians, nurses, dietitians, food service personnel, and unit secretaries to coordinate the continuum of processes that impact patients with food allergies or other dietary needs.[1]
- Examine a sample of medical records to review where personnel are recording patients' food allergies. Consider listing all allergies (e.g., medication, food, latex) in the same place.[1]
- Use communication tools such as diet wheels, whiteboards, stickers for the menu or medical record, or informational wristbands.[7-9]
- Eliminate foods from the hospital that are known to cause interactions with certain medications, such as grapefruit or cranberry juice.[1]

Food Services

- Make sure tray servers consistently check at least two patient identifiers (such as patient name and date of birth).[14-18]
- Ensure cooks/chefs use only the ingredients listed on a recipe and do not make substitutions.[16]
- Place the patient's diet information on the tray to alert kitchen staff assembling or checking the meal tray that the patient has a food allergy or has a special diet. Staff can then remove the restricted food item before the tray leaves the kitchen.[18]
- Meet in a huddle daily or more often to review the daily census, food substitutions, and other circumstances that could affect the daily operations of the department.[18, 19] Include kitchen staff, registered dietitian nutritionists, retail staff (workers who are generally not involved with patient care), and the management team. See "Dietary Safety Huddles" for an example of a dietary safety huddle agenda.
- Provide nutrition consultation, and consider the following when meeting with a patient with a food allergy or special diet:[1]
  - ☐ Be understanding, listen carefully, and answer questions thoughtfully.

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- ☐ Determine if further patient education is needed, and arrange for follow-up.

- Listen carefully to food service complaints. Stay focused on getting all the facts and follow up, as appropriate.[1] Review patient satisfaction surveys for patient safety concerns.[4]
- Interface the food service department dietary orders with the main hospital's electronic health system so that dietary orders can be automatically updated in real time with patient allergies, admission and discharge information, and transfer information. This also reduces the number of personnel who must manually process the dietary order.[5]
- Review how a wrong tray or diet was delivered to a patient, and consider steps to prevent this from happening again.[1]

DIETARY SAFETY HUDDLES

A typical agenda at Abington Health includes discussion of the following:

- Number of days since the hospital's last serious safety event
- Hospital census
- Eating census for next meal
- Staffing (e.g., absentees, training, changes to workflows)
- Equipment and supplies (e.g., equipment repairs, supplies on order)
- Food shortages or substitutions
- What's working well (e.g., staff share a good-patient experience; staff appreciate a coworker who went above and beyond)
- Patients with food allergies who are at "high risk" or any patients with special needs or attention
- Patient satisfaction reports and comments
- Hospital-wide daily check-in (anything of particular note is communicated)
- Rewarding "good catches" when staff prevent a patient from receiving the wrong diet order
- Other announcements or questions

Source: Ross, Jennifer (Director of Nutrition Services, Abington Health). E-mail to: Pennsylvania Patient Safety Authority. 2015 Apr 4.

CONCLUSION

Delivering the right diet to the right patient at the right time is a complicated process in the acute care setting; multiple hospital departments and services must communicate, cooperate, and function as a coordinated team. A dietary error can occur at any point in the dietary process, from order entry through tray delivery. The most frequent type of dietary event reported through PA-PSRS submitted from January 2009 through June 2014 involved providing a patient a tray that contained a food item to which that patient was allergic; eight of these events resulted in serious harm. As food allergies are a growing public health problem in the United States, hospitals may need to create a safe haven for patients with food allergies.

NOTES

1. Food Allergy and Anaphylaxis Network. Food allergy training guide for hospital and food service staff [online]. 2006 [cited 2015 Mar 4]. http://www.foodallergy.org/document.doc?id=149
2. Food Allergy Research & Education. Food allergy facts and statistics for the U.S. [online]. [cited 2015 Mar 4]. http://www.foodallergy.org/document.doc?id=194
3. US Food and Drug Administration. Food allergies: what you need to know [online]. 2010 Jun [cited 2015 Mar 4]. http://seafood.oregonstate.edu/.pdf%20Links/Food%20Facts%20-%20Food%20Allergies.pdf
4. Massachusetts General Hospital. Results of the patient satisfaction survey over the last four years [online]. [cited 2015 Mar 8]. http://www.mghpcs.org/pcs/magnet/documents/evidence/Re_designation_Docs/RD_5_Patient_Satisfaction.pdf
5. CBORD Group, Inc. Foodservice Suite [online]. [cited 2015 Mar 8]. https://hcl.cbord.com/products/product.asp?id=20
6. Kim K, Kim M, Lee KE. Assessment of foodservice quality and identification of improvement strategies using hospital foodservice quality model. *Nutr Res Pract* 2010 Apr;4(2):163-172.
7. Agency for Healthcare Research and Quality. Hospital posts appropriate diet for patient on room door, reducing diet-related mistakes and nursing interruptions [online]. [cited 2015 Mar 4]. https://innovations.ahrq.gov/profiles/hospital-posts-appropriate-diet-patient-room-door-reducing-diet-related-mistakes-and
8. Sehgal NL, Green A, Vidyarthi AR, et al. Patient whiteboards as a communication tool in the hospital setting: a survey of practices and recommendations. *J Hosp Med* 2010 Apr;5(4):234-9.
9. Use of color-coded patient wristbands creates unnecessary risk. PA PSRS Patient Saf Advis [online] 2005 Dec 2 [cited 2015 Mar 4]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/dec14_2(suppl2)/Pages/dec14;2(suppl2).aspx

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10. 28 Pa. Code §§ 111.1-111.27. Also available at http://www.pacode.com/secure/data/028/chapter111/chap111toc.html
11. Joint Commission. Joint Commission E-dition [online]. [cited 2015 Mar 6]. http://www.jcrinc.com/e-dition
12. Centers for Medicare and Medicaid Services (CMS). Appendix A—survey protocol, regulations and interpretive guidelines for hospitals [online]. In: CMS. State operations manual. 2015 Apr 1 [cited 2015 Apr 1]. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_a_hospitals.pdf
13. Kim H, Fischer D. Anaphylaxis. *Allergy Asthma Clin Immunol* 2011 Nov 10; 7 Suppl 1;S6.
14. Werner, Annette (Clinical Nutrition Manager, Doylestown Hospital); Strogis, Ellen (Patient Service Manager, Doylestown Hospital). Conversation with: Pennsylvania Patient Safety Authority. 2014 Aug 8.
15. Ignatz, Colleen (Clinical Nutrition Team Leader, Jefferson Hospital); Hampton, Kristen (Director of Nutrition Services, Jefferson Hospital). Conversation with: Pennsylvania Patient Safety Authority. 2014 Oct 30.
16. Kipe, Margaret (Director, Nutrition Services, Reading Health System). Conversation with: Pennsylvania Patient Safety Authority. 2015 Feb 12.
17. Shepps, Amy (Clinical Nutrition Manager, Pinnacle Health System). Conversation with: Pennsylvania Patient Safety Authority. 2015 Feb 18.
18. Ross, Jennifer (Director of Nutrition Services, Abington Health). Conversation with: Pennsylvania Patient Safety Authority. 2014 Oct 30.
19. Ross, Jennifer (Director of Nutrition Services, Abington Health). E-mail to: Pennsylvania Patient Safety Authority. 2015 Apr 4.

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Antibiotic Stewardship in Hospitals and Long-Term Care Facilities: Building an Effective Program

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ABSTRACT

Inappropriate antibiotic use, which includes prescribing drugs that are unnecessary, no longer necessary, or incorrectly dosed or using broad-spectrum agents when narrow-spectrum agents are appropriate for susceptible bacteria, is a national patient safety and public health concern. This practice perpetuates and exacerbates antibiotic resistance and contributes to conditions such as Clostridium difficile*–associated diarrhea, as well as adverse drug effects and increased morbidity and mortality. According to the Centers for Disease Control and Prevention, as much as 50% of all antibiotics prescribed in acute care hospitals in the United States are unnecessary or inappropriate. In long-term care facilities, 49% to 62% of prescriptions are estimated to meet appropriate diagnostic criteria. Control of multidrug-resistant organisms in healthcare facilities requires attention to judicious antibiotic use through adoption of an antibiotic stewardship program. Results of Pennsylvania Patient Safety Authority surveys of Pennsylvania acute care hospitals and long-term care facilities include opportunities for improvement in all facets of antibiotic stewardship and indicate facility interest in learning more about antibiotic stewardship and participating in a statewide or regional collaboration to support antibiotic stewardship programs. This article outlines strategies for identifying existing gaps in antibiotic stewardship programs and presents strategies for instituting or enhancing antibiotic stewardship programs in acute and long-term care facilities. (Pa Patient Saf Advis 2015 Jun;12[2]:71-8.)*

INTRODUCTION

Antibiotics have transformed the practice of medicine, combating life-threatening bacterial diseases, reducing morbidity, and saving lives.[1] However, inappropriate antibiotic use is a national patient safety and public health concern, as this practice perpetuates and exacerbates antibiotic resistance and contributes to conditions such as *Clostridium difficile*–associated diarrhea.[1] Inappropriate antibiotic use includes prescribing drugs that are unnecessary, no longer necessary, or incorrectly dosed, as well as using broad-spectrum agents when narrow-spectrum agents are appropriate for susceptible bacteria.[1]

A Centers for Disease Control and Prevention (CDC) 2014 *Vital Signs* report found that 20% to 50% of all antibiotics prescribed in acute care hospitals in the United States are unnecessary or inappropriate.[2] Poor communication when patients transfer facilities—for example, from a long-term care facility (LTCF) to a hospital—can result in antibiotic misuse.[3] Few studies have examined the percentage of inappropriate use of antibiotics in LTCFs; however, estimates of appropriate antibiotic use in LTCFs range from 49% to 62%.[4] For example, a 2001 study found that just 49% of prescriptions in LTCFs met appropriate diagnostic criteria.[5]

The Problem of Antibiotic Resistance

The ability of bacteria to resist the effects of antibiotics is perhaps the single most important infectious-disease threat.[4] Infections with resistant organisms are difficult to treat and require costly and potentially toxic alternatives. According to CDC, "Every year, more than two million people in the United States get infections that are resistant to antibiotics, and at least 23,000 people die as a result."[6] In addition, *C. difficile* infections, which can be very difficult to treat and also life-threatening, cause about 250,000 hospitalizations and at least 14,000 deaths annually in the United States.[4] Inappropriate antibiotic use can adversely affect the health of patients who are not even exposed to antibiotics due to the potential for the spread of resistant organisms.[1]

Frequent use of antibiotics in LTCF settings has led to resistant florae, and the proximity and contact between residents and healthcare workers facilitates the spread of these organisms.[7] In 2013, CDC highlighted the need to improve antibiotic use as one of four key strategies required to address the problem of antibiotic resistance in the United States.[8] Control of multidrug-resistant organisms in healthcare facilities requires attention to judicious antibiotic use through adoption of an antibiotic stewardship program.[1,9]

What Is Antibiotic Stewardship?

The Society for Healthcare Epidemiology of America defines antibiotic stewardship as "coordinated interventions designed to improve and measure the appropriate use of antimicrobial agents by promoting the selection of the optimal antimicrobial drug regimen including dosing, duration of therapy, and route of administration."[10] Why implement an antibiotic stewardship program? Effective stewardship programs promote improved patient outcomes by doing the following:

- Reducing treatment failures, lengths of stay, morbidity, and mortality
- Increasing infection cures and the frequency of appropriate, cost-effective prescribing for therapy and prophylaxis

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Table. Antibiotic Stewardship Survey Results for Hospitals and Long-Term Care Facilities

	HOSPITALS (N = 12)				LONG-TERM CARE FACILITIES (N = 12)			
CDC DOMAIN AND CORE ELEMENTS*	YES	PLAN	NO	DON'T KNOW	YES	PLAN	NO	DON'T KNOW
LEADERSHIP DOMAIN								
Communicates formal statements supporting monitoring and improved use of antibiotics	9	2	1	0	5	0	7	0
Includes stewardship tasks in job descriptions and performance reviews	4	2	6	0	3	0	9	0
Supports training and education	9	1	2	0	8	0	4	0
ACCOUNTABILITY DOMAIN								
Identifies a physician leader for stewardship program activities and outcomes	12	0	0	0	8	0	4	0
EXPERTISE/SUPPORT DOMAIN								
Identifies a pharmacist to colead the program	12	0	0	0	5	0	7	0
Includes physician support	12	0	0	0	7	0	5	0
Includes nursing support	5	1	3	3	8	0	4	0
Includes department head support	3	0	5	4	3	0	9	0
Includes epidemiologist support	8	0	2	2	3	0	9	0
Includes staff support for quality assurance and performance improvement	6	0	3	3	5	0	7	0
Includes laboratory staff support	9	0	2	1	3	0	9	0
Includes information technology support	7	0	3	2	2	0	10	0
ACTION DOMAIN								
Developed and implemented policies and procedures to document dose, duration, and indication of antibiotics	6	2	4	0	5	1	5	1
Developed facility-specific treatment recommendations	10	0	2	0	4	0	7	1
Uses an antibiotic time-out after 48 hours	5	1	5	1	5	0	6	1
Developed site-specific treatment recommendations (e.g., for urinary tract infections)	8	0	3	1	4	0	7	1
Implements infection-specific interventions	9	0	2	1	4	0	7	1
Implements syndrome-specific interventions	5	1	5	1	2	0	9	1
Implements pharmacy-specific interventions	10	1	1	0	4	0	7	1
Implements preauthorization for specific antibiotics	7	0	5	0	1	0	10	1
Changes intravenous to oral antibiotic therapy automatically in appropriate situations	8	0	4	0	5	0	7	0
Implements dose adjustments in cases of organ dysfunction	10	0	1	1	5	0	7	0

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Table. Antibiotic Stewardship Survey Results for Hospitals and Long-Term Care Facilities (continued)

CDC DOMAIN AND CORE ELEMENTS*	HOSPITALS (N = 12)				LONG-TERM CARE FACILITIES (N = 12)			
	YES	PLAN	NO	DON'T KNOW	YES	PLAN	NO	DON'T KNOW
ACTION DOMAIN (continued)								
Implements dose optimization for treatment of organisms with reduced susceptibility	11	0	1	0	4	0	5	3
Implements automatic alerts when therapy may be duplicative	9	0	2	1	4	0	7	1
Implements time-sensitive automatic-stop orders	5	1	4	2	4	0	6	2
TRACKING AND REPORTING DOMAIN								
Uses periodic assessment of appropriate antibiotic use (retrospective chart review)	11	0	0	1	8	0	4	0
Provides feedback to stewardship program members	9	2	0	1	8	0	4	0
Uses provider feedback	8	3	0	1	5	0	7	0
Documents program monitoring and feedback	8	2	0	2	4	1	6	1
Measures antibiotic use in days of therapy	4	2	5	1	4	0	7	1
Measures antibiotic use in defined daily dose	3	3	4	2	3	1	7	1
Tracks clinical outcomes to measure the impact of interventions	3	2	5	2	4	0	8	0
Tracks time to proper treatment if empiric therapy was started	5	3	0	4	6	0	6	0
Tracks adverse reactions to antibiotics	7	2	1	2	9	0	3	0
Reports resistance trends in facility antibiotics	10	1	0	1	7	0	4	1
Distributes a yearly antibiogram	10	0	1	1	2	1	8	1
Measures the cost of antibiotics	11	0	0	1	3	0	7	2
EDUCATION DOMAIN								
Provides education to clinicians and other relevant staff on antibiotic prescribing	9	1	2	0	8	0	4	0
BARRIERS DOMAIN								
Lack of funding	9	NA	0	3	8	NA	3	1
Lack of education	4	NA	5	3	8	NA	4	0
Lack of administrative support	5	NA	4	3	4	NA	8	0
Lack of time	7	NA	2	3	8	NA	4	0
Lack of information technology support	4	NA	5	3	4	NA	8	0
Provider opposition	4	NA	5	3	4	NA	8	0

Note: Responses of "yes" and "plan" are categorized as positive responses.
* Adapted from: Centers for Disease Control and Prevention (CDC). *Core elements of hospital antibiotic stewardship programs*. Atlanta: US Department of Health and Human Services; 2014. Also available at http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf

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(continued from page 71)

- Reducing adverse effects of antibiotics, the incidence of *C. difficile*–associated diarrhea, and antibiotic resistance
- Improving pathogen susceptibility profiles

CMS regulations require antibiotic review as part of infection control programs in hospitals and LTCFs.[11,12] In conjunction with other infectious diseases and infection control societies, CDC describes the core elements of an antibiotic stewardship program as follows: (1) leadership support, (2) accountability, (3) drug expertise and key support for the stewardship program, (4) action to support optimal antibiotic use, (5) tracking and reporting antibiotic prescribing, use, and resistance, and (6) education.[1]

METHODS

Antibiotic stewardship practices in Pennsylvania acute care hospitals and LTCFs were analyzed based on responses from two sources: (1) the 2014 Annual Pennsylvania Hospital and Long-Term Care Facility User Survey and (2) the 2015 Antibiotic Stewardship Questionnaire of Implementation of Antibiotic Stewardship Practices.

2014 Annual User Survey

In the fall of 2014, as part of the Pennsylvania Patient Safety Authority annual survey, acute care hospitals and LTCFs statewide were queried about interest in and implementation of antibiotic stewardship programs.

2015 Antibiotic Stewardship Questionnaire

Over the first quarter of 2015, analysts queried a convenience sample of 12 Pennsylvania hospitals and 12 LTCFs that indicated that their facility has an antibiotic stewardship program in place. The purpose of conducting these questionnaires was to determine if stewardship practices were consistent with the best practices outlined in the CDC core elements of antibiotic stewardship program. The questionnaire was conducted using a combination of telephone, in-person, and e-mail communication. Responses of "yes" or "plan to implement" were identified as "positive" responses. See the Table.

RESULTS

2014 Annual User Survey

Of 172 hospital survey respondents, 77.3% (n = 133) indicated interest in learning more about antibiotic stewardship. Responses to the 2014 LTCF survey showed that 36.6% (n = 64 of 175) of the respondents had an antibiotic stewardship program in place. Analysis of survey responses also showed that 46.5% (n = 59 of 127) of LTCF respondents that were interested in participating in a statewide or regional collaboration were specifically interested in an antibiotic stewardship collaboration.

2015 Antibiotic Stewardship Questionnaire

Analysis of questionnaire responses from the 12 hospitals and the 12 LTCFs contacted showed that compared with the hospital respondents, fewer LTCFs had implemented all core elements of an antibiotic stewardship program in all six domains. See Figure 1.

Leadership support. Analysis of hospital responses to the three leadership questions revealed 75% (27 of 36) positive and plan-in-progress responses for implementation of the elements of leadership support, compared with 44% (16 of 36) for the LTCFs. Both the hospitals and LTCFs surveyed identified that the greatest opportunity for leadership improvement was in incorporating stewardship-related tasks in job descriptions and performance reviews. The LTCFs also identified an opportunity to improve formal leadership communication supporting improved use of antibiotics.

Physician leader responsible for program outcomes. Analysis of hospital responses to the one accountability question revealed 100% (12 of 12) positive and plan-in-progress responses for identification of a physician leader accountable for stewardship activities, compared with 67% (8 of 12) for the LTCFs.

Drug expertise and key support for the stewardship program. Analysis of hospital responses to the eight key support questions revealed 66% (63 of 96) positive and plan-in-progress responses for identification of key experts to support the stewardship program, compared with 38% (36 of 96) for the LTCFs. The hospitals identified that the greatest opportunity for improvement in key support for stewardship was involving quality improvement staff and department heads in working to improve antibiotic use. The LTCFs identified that the greatest opportunity for improvement was multidisciplinary support from the quality assurance and process improvement (QAPI) and the information technology departments.

Actions to support optimal antibiotic use. Analysis of hospital responses to the 13 specific questions on actions to improve antibiotic prescribing indicated 70% (109 of 156) positive and plan-in-progress responses for this domain, compared with 33% (52 of 156) for the LTCFs. The hospitals' greatest opportunities for improvement included 48-hour antibiotic time-outs and time-sensitive automatic-stop orders. The LTCFs' greatest opportunities for improvement were in implementing specific infection treatment and pharmacy interventions.

Tracking and reporting antibiotic prescribing, use, and resistance. Analysis of hospital responses to the 12 questions on how antibiotic prescribing, use, and

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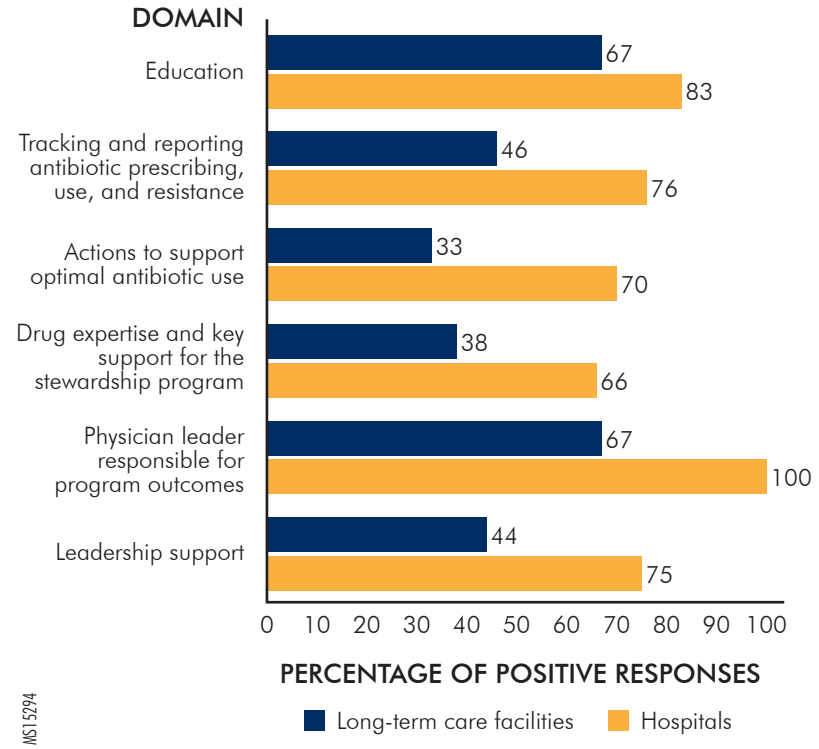
Figure 1. Positive Responses Regarding Implementation of Core Antibiotic Stewardship Elements, by Domain



Note: **Based on responses from 12 hospitals and 12 long-term care facilities to the Pennsylvania Patient Safety Authority's antibiotic stewardship questionnaire conducted in March 2015. The questionnaire is based on the Centers for Disease Control and Prevention's core elements of hospital antibiotic stewardship programs.* The data above reflects the percentage of positive and plan-in-progress responses to core element questions within the six domains of antibiotic stewardship: education (1 question); tracking and reporting antibiotic prescribing, use, and resistance (12 questions); actions to support optimal antibiotic use (13 questions); drug expertise and key support for the stewardship program (8 questions); physician leader responsible for program outcomes (1 question); and leadership support (3 questions).**

* Centers for Disease Control and Prevention (CDC). *Core elements of hospital antibiotic stewardship programs.* Atlanta: US Department of Health and Human Services; 2014.

resistance is tracked and monitored revealed 76% (109 of 144) positive and plan-in-progress responses to implementation of specific tracking and reporting stewardship actions, compared with 46% (66 of 144) for the LTCFs. Both the hospitals and the LTCFs identified that the greatest opportunity for improvement was tracking clinical outcomes to measure the impact of interventions. LTCFs also identified distribution of a yearly antibiogram, tracking clinical outcomes, and measuring the cost of antibiotic use as opportunities for improvement.

Education. Analysis of hospital responses to the one education question revealed 83% (10 of 12) positive and plan-in-progress responses to providing education on antibiotic prescribing, compared with 67% (8 of 12) for LTCFs.

Barriers to antibiotic stewardship. Analysis of responses to the six barrier questions found that both hospitals and LTCFs reported lack of funding and lack of time to be their most common challenges. LTCFs also noted lack of education as a barrier. See Figure 2.

STRATEGIES TO ASSESS KEY COMPONENTS OF A STEWARDSHIP PROGRAM

Successful stewardship process measures involve implementing a systematic assessment of the core elements of a stewardship program and periodic assessment of the treatment of infections.[5,13] Initial steps to this approach begin with using a standardized assessment to measure the level of integration of stewardship best practices and administrative support for the program. Detecting the gaps in current practice, support, accountability, monitoring, and resources enables both hospitals and LTCFs to define specific targets for intervention and to take action to close performance gaps.

Hospital Assessment

The CDC *Core Elements of Hospital Antibiotic Stewardship Programs* is accompanied by a checklist to help healthcare facilities assess integration of the core elements into their antibiotic stewardship programs.[11] The CDC checklist can be found online at http://www.cdc.gov/getsmart/healthcare/pdfs/checklist.pdf. The core elements of the CDC stewardship program, as well as actions to support optimal antibiotic use, include the following:[1,11]

Leadership support. Distribute a formal written statement of support, dedicated personnel, and financial and information technology resources to improve antibiotic prescribing.

Accountability. Appoint a physician leader responsible for program outcomes.

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Drug expertise. Appoint a pharmacist responsible for improving antibiotic use.

Key support. Work with clinical, infection prevention, quality improvement, laboratory, and information technology leaders to improve antibiotic use in the facility. Base written policies to support optimal antibiotic prescribing on national guidelines and facility antibiograms, and require prescribers to document dose, duration, and indication for antibiotics.

Broad interventions to support optimal antibiotic use. Complete an "antibiotic time-out" (a review of appropriateness of antibiotics within 48 hours after initial orders), and establish preauthorization processes for specific antibiotic agents and prospective case review of antibiotic orders by a physician or pharmacist.

Pharmacy-driven strategies to support optimal antibiotic use. Implement automatic changes from intravenous to oral therapy, dose adjustments for organ dysfunction, therapeutic drug monitoring, and dose optimization for highly drug-resistant bacteria. Additional pharmacy interventions include instituting automatic alerts for simultaneous use of multiple agents with overlapping activity and time-sensitive stop orders.

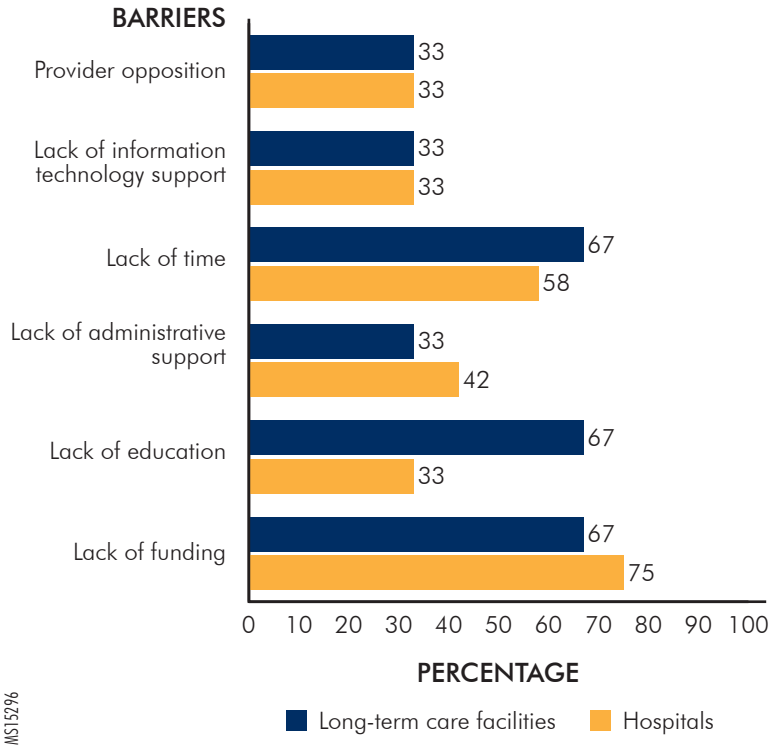
Diagnosis and infection-specific strategies to support optimal antibiotic use. Implement specific interventions to improve prescribing for specific conditions, such as pneumonia, urinary tract infections, and skin and soft-tissue infections. These syndromic management interventions also include empiric coverage for methicillin-resistant *Staphylococcus aureus*, treatment guidelines for *C. difficile* infections, and tailoring treatment for culture-proven invasive infection.

Tracking antibiotic prescribing, use, and resistance. Measure the impact of strategies to improve antibiotic use, including monitoring antibiotic prescribing and adherence to the documentation policy and treatment recommendations, tracking incidence of *C. difficile* infections, and producing an antibiogram. Monitoring antibiotic use also includes tracking days of individual antibiotic therapy, the number of grams of antibiotic used daily, and the cost of antibiotics used.

Reporting information. Share antibiograms and facility-specific and personalized antibiotic-use reports with prescribers.

Regular educational updates. Provide a foundation of knowledge about prescribing, resistance, and infectious-disease management to influence prescribing behavior. Education is most effective when accompanied by implementation of strategies and feedback of process and outcome measures.

Figure 2. Barriers to Implementation of Antibiotic Stewardship Activities



Note:* Based on responses from 12 hospitals and 12 long-term care facilities to the Pennsylvania Patient Safety Authority's antibiotic stewardship questionnaire conducted in March 2015. The questionnaire is based on the Centers for Disease Control and Prevention's core elements of hospital antibiotic stewardship programs.

* Centers for Disease Control and Prevention (CDC). *Core elements of hospital antibiotic stewardship programs*. Atlanta: US Department of Health and Human Services; 2014.

LTCF Assessment

Results of the convenience sample suggest that LTCFs may face greater challenges than hospitals. Clearly there are differences between acute and long-term care settings. Nursing home administrators and medical directors need to know what to do to effect change. Because the resources and expertise in LTCFs can vary, a stepwise approach to stewardship

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may be appropriate to control antibiotic overuse and resistance.

The CMS regulatory requirements for LTCFs note that antibiotic review should be part of the infection control program.[10] How does an LTCF judge if any of these core elements are appropriate in long-term care, and what kind of data can an LTCF collect and measure that will show success? A variety of approaches from the CDC core measures for hospitals may be appropriate for antibiotic stewardship programs in LTCFs. Assess antibiotic appropriateness and identify gaps in practice by focusing on the following steps:[5]

- Apply accurate diagnostic criteria.
- Prescribe the recommended agent for indication.
- Document indications and planned duration of therapy.
- Obtain cultures and relevant tests prior to treatment.
- Modify antibiotic choices appropriate to microbiologic findings.
- Ensure that treatment is compliant with facility policy on documentation of dose, duration, indication, antibiotic time-outs, and therapy reassessment.

The use of antibiotic stewardship program interventions should generally be targeted to institutional needs and resource availability:[5]

- Passive monitoring of antibiotic resistance is accomplished by reviewing lab results, facility antibiograms, and usage patterns, such as antibiotics orders, route of administration, therapy based on cultures, and antibiotics ordered by phone.
- Front-end approaches influence the initial choice of an antibiotic, such as having an institutional formulary, developing infection-specific treatment algorithms, or using antibiotic order forms requiring prescriber justification and preauthorization for select antibiotics.
- Back-end approaches involve activities such as regular feedback to prescribers and individual prescriber case reviews of the appropriateness of antibiotic use.
- Multifaceted education, such as small-group interactive sessions, videos, written materials, outreach visits, and one-to-one interviews with physicians, has been found to reduce antibiotic prescriptions for urinary tract infections when combined with a diagnostic and treatment algorithm.[5,14]

Antibiotic stewardship is ideally an area for QAPI activities in the LTCF setting. An effective, involved medical director acting as champion would also be critical for the program's success.

CONCLUSION

The growing problems of antibiotic resistance and *C. difficile* infection, as well as antibiotic treatment failures, increased lengths of stay, increased morbidity and mortality, and adverse effects of antibiotic therapy, can be minimized by programs dedicated to improving antibiotic prescribing. Antibiotic utilization can be enhanced by implementation of key elements of an effective antibiotic stewardship program.

Antibiotic stewardship programs help to ensure optimal treatment for patients with infections in both hospitals and LTCFs and may enhance the length of time antibiotics in current use remain effective. The first step in developing an effective antibiotic stewardship program is to conduct a standardized assessment to identify practice gaps and potential areas for improvement. Guidance on implementation of specific strategies for addressing practice gaps and opportunities for improvement will be presented in future *Pennsylvania Patient Safety Advisory* articles.

NOTES

1. Centers for Disease Control and Prevention (CDC). *Core elements of hospital antibiotic stewardship programs*. Atlanta: US Department of Health and Human Services; 2014. Also available at http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf
2. Centers for Disease Control and Prevention. Making health care safer: antibiotic Rx in hospitals: proceed with caution [online]. Vital Signs 2014 Mar [cited 2015 Mar 31]. http://www.cdc.gov/vitalsigns/antibiotic-prescribing-practices/index.html
3. Centers for Disease Control and Prevention. Antibiotic use in nursing homes [online]. 2013 Nov [cited 2015 Mar 31]. http://www.cdc.gov/getsmart/healthcare/learn-from-others/factsheets/nursing-homes.html
4. US Department of Health and Human Services (HHS). Long-term care facilities [online]. Chapter 8. In: US HHS. National action plan to prevent health care-associated infections: road map to elimination. 2013 Apr [cited 2015 Mar 31]. http://www.health.gov/hcq/pdfs/hai-action-plan-ltcf.pdf
5. Loeb, M, Simor AE, Landry L, et al. Antibiotic use in Ontario facilities that provide chronic care. *J Gen Intern Med* 2001 Jun;16(6):376-83.
6. Centers for Disease Control and Prevention. Antibiotic resistance: urgent health threat jeopardizing modern medicine [online]. 2015 Feb 20 [cited 2015 Mar 31]. http://blogs.cdc.gov/safehealthcare/2015/02/20/antibiotic-resistance-health-threat-jeopardizing-modern-medicine

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7. Smith PW, Watkins K, Miller H, et al. Antibiotic stewardship programs in long-term care facilities. *Ann Longterm Care* 2011 Apr 12;19(4):20-5.
8. Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013 [online]. [cited 2015 Mar 31]. http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf
9. Siegel JD, Rinehart E, Jackson M, et al. Management of multidrug-resistant organisms in healthcare settings, 2006 [online]. 2007 Dec [cited 2015 Mar 31]. http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf
10. Society for Healthcare Epidemiology of America, Infectious Diseases Society of America, Pediatric Infectious Diseases Society. Policy statement on antimicrobial stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society (PIDS) [online]. 2012 Apr [cited 2015 Mar 31]. http://www.shea-online.org/View/smid/428/ArticleID/141.aspx
11. Centers for Medicare and Medicaid Services. Hospital infection control worksheet [online]. [cited 2015 Mar 31]. http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf
12. Centers for Medicare and Medicaid Services. Revisions to appendix PP—"Interpretive Guidelines for Long-Term Care Facilities," Tag F441" [transmittal 55 online]. 2009 Dec 2 [cited 2015 Mar 31]. http://www.cms.hhs.gov/transmittals/downloads/R55SOMA.pdf
13. Centers for Disease Control and Prevention. Checklist for core elements of hospital antibiotic stewardship programs [online]. [cited 2015 Mar 31]. http://www.cdc.gov/getsmart/healthcare/pdfs/checklist.pdf
14. Loeb M, Brazil K, Lohfeld L, et al. Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infection in residents of nursing homes: cluster randomized controlled trial. *BMJ* 2005 Sep 24;331(7518):669.

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Snapshot: Quarterly Update on Wrong-Site Surgery

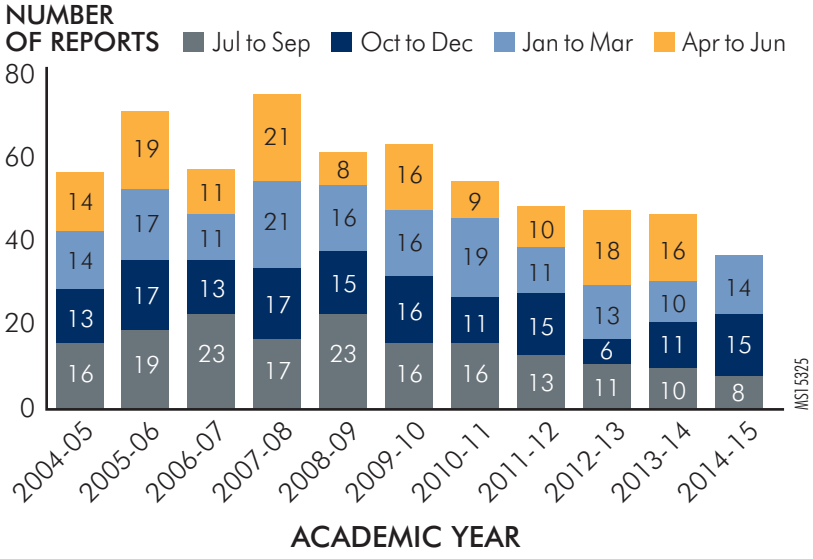
There were 14 reports of wrong-site surgery in Pennsylvania operating rooms (ORs) during the first quarter of 2015. This number represents a continued regression in the 2014-2015 academic year despite progress in the first quarter of the academic year (see the Figure). Half of the reported events involved injections or spinal procedures (50%, n = 7): two wrong-side paravertebral pain blocks, one intra-articular pain injection, one wrong-side preoperative regional block by an anesthesia provider, one unconsented local anesthetic injection by a surgeon despite a formal time-out, and two wrong-level spinal procedures. The most common types of all 625 wrong-site OR procedures reported to the Pennsylvania Patient Safety Authority since July 2004 have been anesthetic blocks by anesthesiologists and surgeons (n = 172), wrong-level spinal procedures (n = 77), and pain management procedures (n = 71)—the persistent top three types of wrong-site operating suite procedures.

Confirmation bias and misperception in the OR are repetitive problems, as illustrated by the following report:*

> *A surgical arthroscopy of the left ankle was scheduled. The patient was taken to the operating room. Incorrect right leg had tourniquet applied and injected with 5 mL of 1% lidocaine and 5 mL of 0.25% Marcaine™ when circulator realized incorrect site/side injected. Correct left ankle was then injected and surgery completed.*

Although monitoring the more than 600 wrong-site surgical events reported since July 2004 has allowed Authority analysts to trend and research common event types that led to wrong-site surgery and to issue 21 evidence-based best practices (see "Principles for Reliable Performance of Correct-Site Surgery" at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/principles.aspx), the Authority receives equally valuable reports that showcase near-miss or good catch events.

Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year



Scan this code with your mobile device's QR reader to access the Authority's toolkit on this topic.

* The details of the Pennsylvania Patient Safety Reporting System event narratives in this article have been modified to preserve confidentiality.

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An example of a reported good catch reflects staff empowerment to "stop the line" when a concern for patient safety and the potential for a wrong-site event is recognized. The following deidentified report is an example of staff assertiveness to ensure that best practices are maintained for surgical site marking:

> *Surgeon marked top of patient's left knee instead of patient's left foot. Patient using chlorhexidine wipes preoperatively, and surgeon did not want to wait to mark correct site. Site marking removed by nursing staff, and surgeon was informed to re-mark the correct site.*

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Self-Assessment: Wrong-Site Orthopedic Operations on the Extremities

LEARNING OBJECTIVES

- Identify high-risk areas of the body prone to wrong-site procedures.
- Recall ways the surgical mark can help prevent wrong-site surgery.
- Recognize when two time-outs would be indicated for an orthopedic operation on the extremity in the OR.
- Select ways of verbally confirming information that are high-risk and low-risk for wrong-site surgery.

SELF-ASSESSMENT QUESTIONS

The following questions refer to the experience in Pennsylvania, from July 2004 through June 2013, of wrong-site operating room (OR) procedures on the extremities, typically done by orthopedic surgeons (Clarke JR. Wrong-site orthopedic operations on the extremities: the Pennsylvania experience. Pa Patient Saf Advis [online] 2015 Mar [cited 2015 May 19]. http://patientsafetyauthority.org/ADVISORIES/Advisory Library/2015/mar;12(1)/Pages/19.aspx).

The questions may be useful for internal education and assessment. You may use the following examples or come up with your own questions.

1. In Pennsylvania, in the nine years between July 2004 and June 2013, wrong-site orthopedic operations were performed on all extremity parts *except*:
   a. The foot
   b. The knee
   c. The shoulder
   d. The hand
2. Which of the following errors is most commonly involved in wrong-site hand procedures?
   a. Operating on the wrong patient
   b. Operating on the wrong hand
   c. Doing the wrong procedure at the correct location
   d. Doing a carpal tunnel release instead of the intended trigger finger release
3. Which of the following errors is most commonly involved in wrong-site knee procedures?
   a. Operating on the wrong patient
   b. Operating on the wrong knee
   c. Doing the wrong procedure on the correct knee
   d. Injecting anesthesia into the wrong knee joint as a prelude to the operation
4. Which of the following errors is most commonly associated with injecting anesthesia into the wrong knee as a prelude to the operation?
   a. Not marking the operative site
   b. Putting the tourniquet on the wrong leg
   c. Draping the wrong leg
   d. Not doing a time-out before the injection
5. There is no need to mark the site for an open repair of a fracture.
   a. True
   b. False
6. Which of the following interventions is most effective for preventing wrong-site hand surgery?
   a. Ensuring the accuracy of the information when scheduling the procedure
   b. Having the patient point to the correct site of operation before being prepped and draped
   c. Marking the site as close to the incision as possible and referencing it during the time-out
   d. Fully stating the procedure and site during the time-out

(continued on page 82)

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(continued from page 81)

Question 7 refers to the following scenario:

The patient was interviewed in the holding area preoperatively and verbally stated the correct limb and procedure in agreement with the consent. The correct knee was marked. After the patient was taken to the OR, the circulating nurse asked the patient, "Left knee, correct?" Patient answered, "Right." The resident put a tourniquet cuff on right knee. The surgeon injected the right knee while prepping. The circulating nurse asked to do a time-out. During the time-out, it was noted that the consent was for the left knee and the right knee had been prepared and injected with 1% lidocaine.

7. Which of the following statements is most likely true:
    a. The circulating nurse made the best effort possible to elicit confirmatory information, but the patient gave incorrect information in response.
    b. The members of the OR team were aware of the site mark during their preparation of the patient in the OR.
    c. A separate time-out is not indicated under the Universal Protocol for an injection of local anesthetic in the knee prior to an arthroscopy.
    d. The site mark was referenced in the prepped and draped field during the time-out.
    e. An injection of local anesthetic in the wrong knee prior to an arthroscopy meets the definition of a wrong-site procedure.

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"What Goes Wrong" (Safety-I) and "What Goes Right" (Safety-II)

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In our efforts to optimize the safety of healthcare, is preventing "things that go wrong" a sufficient strategy?

Many, if not all, healthcare safety programs focus on understanding what went wrong when an adverse event affects a patient. In seeking to prevent the possible recurrence of adverse events, there has been a cultural movement away from a "name, shame, and blame" process[1] and toward a search for multiple underlying contributory causes.[2] Investigative processes such as root-cause analysis (RCA) are intended to retrospectively identify—and potentially provide an opportunity to mitigate—conditions or circumstances that may have contributed to an adverse event. Exploration of a comprehensive list of contributing causes is an important part of the RCA process, and a variety of methods, such as Ishikawa's Fishbone or the 5 Whys, have been advocated.[3] The RCA process appeals to our understandable desire to "tame risk and uncertainty."[4] RCA meetings typically involve multiple diverse stakeholders; participation creates "an opportunity for improved communication in the workplace through organized sense making."[4]

Hollnagel and others label this approach as "Safety-I"—a reactive approach to understanding what factors may have contributed to an undesired outcome.[5] Typically, infrequent events that involve the greatest harm receive the most attention. There is a complementary approach, "Safety-II," which additionally seeks to understand "what goes right," including what goes right during ordinary healthcare delivery.[5] Proactive attention is paid to understanding how healthcare that works is actually accomplished.

Safety-II focuses on trying to anticipate developments and events. The Safety-II perspective explores what goes right to make sure that as much as possible will go right in the complex, sometimes unpredictable environment of healthcare delivery.[5] For example, in addition to analyzing what goes wrong in patient care units with high rates of certain events (e.g., falls, infections), Safety-II also looks at the many more events that turn out right to understand what makes for successful work. Additionally, it may also be worthwhile to evaluate patient care units that have low rates of undesired events. What do they do that might be different? Have they eliminated hazardous processes or materials, or implemented design controls (such as engineering controls based on human factors principles) or administrative controls that have resulted in improvements?[6]

Simulation is one resource that can be used to improve our understanding of both what goes wrong and what goes right. A simulation scenario can re-create common or uncommon healthcare situations; participants from multiple disciplines respond and collaborate to manage a simulated patient together. A simulation can also show how people adjust their performance to the conditions, resources, and demands of healthcare delivery. In addition to providing practice to improve the teamwork and probably the sense making of the healthcare providers, during the subsequent debriefing or guided reflection, participants can articulate and reinforce helpful activities as well as identify opportunities for improvement. These improvements may involve actions, equipment, processes, or other aspects of the patient care process. Although many simulations are based on real events, the simulation itself does not include direct risk or adverse outcomes for real patients.[7] Skilled facilitation helps participants reflect on the patient care process in a constructive and supportive manner.

Hollnagel and others suggest that humans, rather than being liabilities or hazards, are necessary resources that provide system flexibility and resilience.[5] Many organizations understand the value of rewarding "good catches" by healthcare providers, support services personnel, or other organizational staff. The Pennsylvania Patient Safety Authority recognizes individuals and groups within Pennsylvania healthcare facilities

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who have demonstrated a personal commitment to patient safety, including acknowledgment during the annual I Am Patient Safety campaign (see http://patientsafetyauthority.org/NewsAndInformation/PressReleases/2015/Pages/pr_March_5_2015.aspx).

Beyond celebrations, there may also be lessons to be learned from studying frequent events in which there was a "good catch," just as lessons may be learned by studying events in which undesired outcomes occur. Safety-I and Safety-II are complementary; both perspectives can add to our understanding of how to improve the safety of healthcare delivery.

NOTES

1. Tevlin R, Doherty E, Traynor O. Improving disclosure and management of medical error - an opportunity to transform the surgeons of tomorrow. *Surgeon* 2013 Dec;11(6):338-43.
2. Dew JR. In search of the root cause. *Qual Prog* 1991 Mar;24(3):97-102.
3. Karl R, Karl MC. Adverse events: root causes and latent factors. *Surg Clin North Am* 2012 Feb;92(1):89-100.
4. Cassin BR, Barach PR. Making sense of root cause analysis investigations of surgery-related adverse events. *Surg Clin North Am* 2012 Feb;92(1):101-15.
5. Hollnagel E, Wears R, Braithwaite J. From Safety-I to Safety-II: a white paper [online]. 2015 [cited 2015 Apr 25]. http://resilienthealthcare.net/onewebmedia/WhitePaperFinal.pdf
6. Card AJ, Ward J, Clarkson PJ. Successful risk assessment may not always lead to successful risk control: A systematic literature review of risk control after root cause analysis. *J Healthc Risk Manag* 2012;31(3):6-12.
7. Deutsch ES. Simulation in otolaryngology: smart dummies and more. *Otolaryngol Head Neck Surg* 2011 Dec;145(6):899-903.

LETTER TO THE EDITOR: WORKING TO REDUCE DISTRACTIONS IN THE OPERATING ROOM

We read with great interest the article "Distractions in the Operating Room" in the June 2014 edition of the *Pennsylvania Patient Safety Advisory*. Here in Australia, we have been working on a project to reduce noise and distractions while promoting situational awareness and directed focus in our operating theatres. Our initial research led us to conclude that the airline industry had made outstanding advancements in flight safety with the development of the "sterile cockpit" concept. It was from this work in aviation that we adopted the term "Below Ten Thousand" for use in the operating room environment. As described in your article, we identified critical times during operative procedures that were in essence our "Below Ten Thousand" moments and that required quiet and directed focus to the task at hand. These critical times are induction/intubation, surgical counts, completion of the surgical safety checklist, and extubation.

"Below Ten Thousand" is a phrase that surgical team members can use to promote situational awareness during times of heightened procedural complexity or to signal that distractions are recognized to be hampering the performance of an individual. When used by surgeons, "Below Ten Thousand" simply and effectively communicates to the team that the surgeon is performing a complicated task and needs everyone in the "cockpit" to be on high alert and focused. We chose the phrase "Below Ten Thousand" because it was iconic, safe, nonconfrontational, easily communicated, and would not arouse concern in a conscious patient that the team was compromised by the noise and/or the distractions around them.

We are excited and encouraged that despite the large gulf of land and water that divides our nations, we can draw similar conclusions about the importance of eliminating distractions in the operating room and are promoting similar safety protocols.

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Editor's Note

Thank you for contacting the Pennsylvania Patient Safety Authority and sharing information on the very important work you have been doing in Australia. It is so wonderful to know that the patient safety work we have been charged to perform in our state is reaching an audience around the world. We applaud you for raising awareness of this important issue and for your innovative efforts to address patient safety within your operating theatres.

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PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (MCARE) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's website at http://www.patientsafetyauthority.org.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for more than 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures, and drug technology.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community, including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.