Pennsylvania Patient Safety Advisory

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See the Action Agenda (/ADVISORIES/Pages/201806_actionagenda.aspx) for this issue.

Reviews & Analyses

Surgical Fires: Decreasing Incidence Relies on Continued Prevention Efforts
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx)
In Pennsylvania, there has been a statistically significant reduction in the patient risk of surgical fires since 2004. Although on the decline, surgical fires remain a serious patient safety hazard.

Identifying Patient Harm from Direct Oral Anticoagulants
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_DOACs.aspx)
Employing standard protocols to guide therapy, reviewing baseline patient information, including patient weight (in metric units) and laboratory test results such as renal and liver function, and considering the therapeutic indication can aid selection of an appropriate anticoagulant medication for patients.

Focus on Infection Prevention

Combat Norovirus Infections in Long-Term Care Facilities
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_NorovirusUpdate.aspx)
Long-term care facilities continue to experience annual norovirus outbreaks. Facilities are encouraged to implement strategies to control initial norovirus cases before they result in an outbreak next season.

Other Features

Safety Stories: Luer Lock
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SafetyStories.aspx)
This vignette presents a brief, timely highlight of a luer lock event reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

Safety Stories: Telemetry
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SafetyStories_Telemetry.aspx)
This vignette presents a brief, timely highlight of a telemetry event reported through PA-PSRS that may provide a learning opportunity for facilities.

Empowering Patients and Agents to Help Prevent Errors with Living Wills, DNRs, and POLSTs
(http://patientsafety.pa.gov/ADVISORIES/Pages/201806_DNR.aspx)
Factors that interfere with the ability of patients to communicate their medical care wishes are complex, particularly if care decisions must be made emergently or if patients have chronic or temporary cognitive impairments.
Surgical Fires: Decreasing Incidence Relies on Continued Prevention Efforts

Authors
Mark E. Bruley, CCE, FACCE
Vice President Emeritus, Accident and Forensic Investigation, ECRI Institute
Editorial Advisory Board, Pennsylvania Patient Safety Advisory

Theresa V. Arnold, DPM
Manager, Clinical Analysis
Pennsylvania Patient Safety Authority

Edward Finley, BS
Data Analyst
Pennsylvania Patient Safety Authority

Ellen S. Deutsch, MD, MS, FACS, FAAP, CPPS
Medical Director
Pennsylvania Patient Safety Authority

Jonathan R. Treadwell, PhD
Senior Associate Director, ECRI Institute

Corresponding Author
Ellen S. Deutsch

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx
Fires on the operating field, although preventable and declining in number, continue to be a hazard to patients and providers. The Pennsylvania Patient Safety Authority has updated its 2012 analysis of surgical fires reported through the Pennsylvania Patient Safety Reporting System. Using the same analytical criteria, analysts identified reports of fires submitted over the subsequent five years that occurred in the operating room (OR) on the sterile operating field and involved flaming combustion resulting from a combination of heat, oxygen, and fuel. Twenty-eight events that met the analysts’ definition of fires on the operating field were reported from July 2011 through June 2016, equating to 5.6 fires per year in Pennsylvania. That incidence is down from the 10 fires per year found in the 2012 analysis and represents a 44.0% reduction since 2011. Since 2004, the rate of surgical fires varied from 0.83 per 100,000 OR procedures in the academic year 2005 (AY2005; July 2004 through June 2005) to 0.24 per 100,000 OR procedures in AY2016. This represents a statistically significant (p < 0.001) reduction in the patient risk of surgical fires of 71% since 2004. In this updated analysis, one-half of the reported events indicated some degree of harm to the patient. The operative sites of the head, neck, and upper chest constituted about two-thirds of the locations that were mentioned; oxygen-enriched atmospheres continue to be a major contributing factor to these incidents. Surgical fires with devastating consequences remain a significant risk. Facilities should consider using the Fire Risk Assessment Score and adhere to the recommendations of the American Society of Anesthesiologists Task Force on Operating Room Fires, the Anesthesia Patient Safety Foundation, and those of ECRI Institute.
Introduction

Surgical fires are rare events that should never happen, but do, despite established preventive measures and continuing educational initiatives. Devastating patient injuries including death have been reported. Surgical fires are dangerous not only to the patient, but to operating room (OR) team members, as well. In 2012, the Pennsylvania Patient Safety Authority published an analysis of surgical fires reported through its database for the primary purpose of determining whether surgical fires continued to be a problem, as identified by the Joint Commission or had responded to advisories on prevention, such as those promulgated by the American Society of Anesthesiologists, the Anesthesia Patient Safety Foundation, and ECRI Institute. This updated analysis of events reported through the Authority's database sought to determine whether the incidence of surgical fires changed in the years after the 2012 publication.

Methods

For this updated analysis, a panel of patient safety analysts identified surgical fires reported to the Authority between July 1, 2011, and June 30, 2016. Using the same analytical criteria as in the prior study, 937 potential reports of interest were identified using the following key terms: fire, flam*, ignit*, extinguish*, burn*, spark*, singe*, singi*, ignit*, dous*, smok* and flash. Reports were excluded during the search if they contained the following terms: brush burn, flashing, eye burn, inflammatory debris, c/o burn, candle burn, cigar, betadine, outlet, be flashed, denies*burn, match, autoclave, cool, evapor, iodine, chemical, cig*rette, tape burn, smoker, flash ster, stapl, sparkle, and did not fire. The wildcard (*) allows variations (e.g., flam* could include flame, flames, flaming, or flamed).

A report was classified as a surgical fire if it—

• Occurred on the operating field or in the patient's airway, and

• Caused combustion of surgical or anatomic substance

The operating field is defined as the surgical operative site within the drape/towel fenestration and includes the sterile field surrounding and above the drapes.

The analysts reviewed each narrative and excluded 909 reports based on the following circumstances:

• Heat-related injuries caused by direct contact with a heat source, such as electrosurgical active electrodes (e.g., Bovie units), lasers, fiberoptic light cord, surgical lights, hot water, hot instruments

• Normal arcing from electrosurgical active electrodes between tip and tissue without secondary ignition of a substance

• Arcing or ignition of the insulation of electrosurgical active electrodes without secondary ignition of a substance

• Reports of smoke without evidence of combustion

• Heat-related melting without evidence of combustion

• Fires off the operating field (e.g., equipment fires not in direct contact with the patient)

• Fires as a cause of the patient's presenting medical condition (e.g., the patient was burned in a house fire or industrial accident, and was then admitted for treatment)
To calculate the rates at which fires occurred, analysts obtained the number of patients undergoing OR procedures and the number of procedures done in Pennsylvania hospital ORs and ambulatory surgical facilities from the Pennsylvania Health Care Cost Containment Council (PHC4).* As with the methodology for the previous publication, "2 patients undergoing an OR procedure" could include two unique patients having one procedure each, or one patient having two procedures, typically on separate days, during this period. Reliable numbers of patients undergoing OR procedures were available from July 1, 2004, through June 30, 2016. It is possible for one patient to have more than one OR procedure at a time. Reliable numbers of OR procedures were available from July 1, 2007 (when a change in reporting processes became effective), through June 30, 2016. Using the same methodology as in the 2012 publication, the rate of fires per surgical patient and the rate of fires per OR procedure were calculated by academic year (e.g., AY2005 includes data from July 2004 through June 2005), and the results from both studies were aggregated.

For statistical analysis of the trend in surgical fires in Pennsylvania, analysts fit the data to an exponential decay model using the nl command in Stata (StataCorp LLC, College Station, TX). This curvilinear model is more realistic than a linear model, because the decay model makes it impossible for the rates to go below zero.

The analysts also recognized the vulnerability of any statistical regression to the data at the endpoints (AY 2005 and AY2016), because outliers at those points could produce misleading results. To address this vulnerability, the analysts performed a sensitivity analysis by doing a second nonlinear regression after removing the two years at the ends. If this latter analysis were also significant, this would give confidence that the original model was not being driven by the endpoints.

* The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens regardless of ability to pay. PHC4 has provided data to this entity in an effort to further PHC4’s mission of educating the public and containing health care costs in Pennsylvania.

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This analysis was not prepared by PHC4. This analysis was done by the Pennsylvania Patient Safety Authority. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

**Results**

The following numbers were found in the five years from July 1, 2011, through June 30, 2016:

- 28 reports met the analysts' definition of fires on the operating field
- 9,213,796 patients were reported to have undergone OR procedures
- 9,486,042 OR procedures were performed
The Figure shows the rate of surgical fires per 100,000 patients from AY2005 through AY2016. The data and the plot clearly suggest a reduction over time. This was confirmed by our statistical model of exponential decay. The reduction was statistically significant ($p < 0.001$). The model equation was $y = 0.927957 \times \exp(-0.11203 \times x)$ where $y$ is the rate of fires per 100,000 patients and $x$ is the time period, by AY.

The plot suggests a relatively high rate in AY2005 but also a relatively low rate in AY2016, and these two endpoints could be very influential in the model. After removing these endpoints, a second analysis demonstrated that the downward trend was still statistically significant ($p = 0.021$, with a model equation of $y = 0.8017 \times \exp(-0.0845 \times x)$). Thus, the statistical significance of the original analysis was not driven by the endpoints.

The model suggests a 71% decrease in the patient risk of surgical fires from AY2005 through AY2016, from a rate of 0.83 to 0.24 fires per 100,000 OR procedures; or from 1 fire per 120,500 OR procedures to 1 per 416,700 OR procedures. The analysts also note that in AY2005, there was about one surgical fire per month in Pennsylvania, and, if the downward trend continues, the rate will be only one surgical fire per year in AY2032 (as extrapolated from the exponential model based on AY2005 to AY2016).

Analysts also performed analyses using the number of OR procedures for the denominator instead of numbers of surgical patients; the results were nearly identical. The Figure and Table 1 present only the data based upon the number of surgical patients.

Table 1. Rates of Fires per 100,000 Patients Undergoing Operating Room Procedures

<table>
<thead>
<tr>
<th>Academic Year*</th>
<th>Number of Surgical Fires†</th>
<th>Number of Patients‡</th>
<th>Rate of Surgical Fires per 100,000 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>14</td>
<td>1,549,082</td>
<td>0.90</td>
</tr>
</tbody>
</table>

Note: Academic years are for the 12 months ended June 30 of each year.

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx
Patient harm was reported in 15 reports (54%) and no harm to patients or staff was reported in the remaining 13 (46%) of the 28 reports.

The source of ignition was identified in 26 reports: an electrosurgical unit (e.g., "Bovie") in 22 reports (79% of 28 reports), a battery-powered cautery unit in two reports (7%), and a laser in two reports (7%). Two reports did not mention the ignition source.

The role of oxygen was mentioned in 14 reports (50%). Nitrous oxide was not mentioned as an oxidizing agent in any reports.

The materials that caught fire are listed in Table 2 along with the number of reports related to that burned material. Multiple materials were noted in some reports.

Table 2. Materials, Medications, and Ointments that Caught Fire

<table>
<thead>
<tr>
<th>Item</th>
<th>Number of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair, eyebrows, or beard</td>
<td>7</td>
</tr>
<tr>
<td>Sponge</td>
<td>6</td>
</tr>
<tr>
<td>Drape or towel</td>
<td>5</td>
</tr>
<tr>
<td>Eyelashes only</td>
<td>4</td>
</tr>
<tr>
<td>Flammable skin-barrier ointment</td>
<td>3</td>
</tr>
<tr>
<td>Alcohol-based skin prep</td>
<td>2</td>
</tr>
<tr>
<td>Endotracheal tube or bronchoscope</td>
<td>2</td>
</tr>
</tbody>
</table>
Adhesive 1
Bone cement 1
Electrosurgical active cable 1
Glove 1
Petroleum ether 1

Note: As reported to the Pennsylvania Patient Safety Authority, July 2011 through June 2016.

The location of the fire was noted in 25 reports, with 4 noting more than one site. Sites on the surface of the patient's body were mentioned in 14 reports, internal sites were mentioned in 6 reports, bone cement in 1 report, a fire on a nurse's hands in 1 report, and there were 2 reports of fires on the drapes where the location was unspecified (see Table 3). Of the surface and internal patient sites mentioned, 18 were located in the head or neck areas.

Table 3. Location of Surgical Fires as Reported to the Pennsylvania Patient Safety Authority

<table>
<thead>
<tr>
<th>Anatomic Location</th>
<th>Number of Mentions</th>
</tr>
</thead>
<tbody>
<tr>
<td>External</td>
<td></td>
</tr>
<tr>
<td>Scalp (temporal region)</td>
<td>3</td>
</tr>
<tr>
<td>Face (n = 13)</td>
<td>4</td>
</tr>
<tr>
<td>Face and chin</td>
<td></td>
</tr>
<tr>
<td>Eyelid</td>
<td>4</td>
</tr>
<tr>
<td>Eyebrow</td>
<td>2</td>
</tr>
<tr>
<td>Eyelashes</td>
<td>3</td>
</tr>
<tr>
<td>Neck (n = 2)</td>
<td>1</td>
</tr>
<tr>
<td>Neck</td>
<td></td>
</tr>
<tr>
<td>Tracheal stoma</td>
<td>1</td>
</tr>
<tr>
<td>Chest</td>
<td>2</td>
</tr>
<tr>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Oropharynx</td>
<td>1</td>
</tr>
<tr>
<td>Trachea</td>
<td>2</td>
</tr>
<tr>
<td>Chest cavity (surgical sponges)</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Knee incision (bone cement)</td>
<td>1</td>
</tr>
<tr>
<td>Nurse's hand</td>
<td>1</td>
</tr>
<tr>
<td>On drapes (unspecified)</td>
<td>2</td>
</tr>
<tr>
<td>Location not given</td>
<td>3</td>
</tr>
</tbody>
</table>

Methods to extinguish fires, when mentioned, primarily involved rapidly removing the burning material, turning off delivered oxygen, and/or dowsing the burning area with sterile water or saline.

Discussion
Analysis indicates a statistically significant decrease in the rate of surgical fires per 100,000 patients from AY2005 through AY2016. The authors believe that this encouraging decline has been due to Authority efforts aligned with recent initiatives by a variety of medical professional societies and healthcare organizations.4-9

The principal factor contributing to surgical fires has historically been the use of open oxygen supplied at 100% concentration from an anesthesia machine or wall oxygen outlet to a disposable mask or nasal cannula on the face during surgery of the head, neck, and upper chest with monitored anesthesia care. Fires in 20 of the 28 relevant reports (80%) in this study were located in these areas, although only 7 of the reports noted open oxygen delivery (e.g., via nasal cannula or mask). Three events involved oxygen enrichment from oxygen leaking from an exposed lung during a thoracotomy.

Other studies have indicated that oxygen-enriched atmospheres contribute to about 70% of surgical fires.7 With 50% of the 28 reports in this analysis involving oxygen enrichment, clinical review of the need to use open oxygen is still indicated on an individual patient basis. Recommendations for such individual patient review are readily available.5-7,9,10

Response to a Surgical Fire

Surgical fires are preventable, but if a fire occurs, the surgeon and other surgical team members can immediately remove burning materials from the patient and extinguish the fire with an aqueous solution or a wet sponge or towel. Burning materials that have been removed from the patient can then be extinguished by other team members, if needed, with an aqueous solution, or in extreme cases, with a carbon dioxide fire extinguisher. A summary of actions to extinguish fires burning either on the patient or in the airway is available from ECRI Institute.11

Prevention of Surgical Fires

Three elements are necessary for a fire: a heat source, oxygen, and a fuel. The surgeon is usually in control of the heat source, most commonly an electrosurgical unit, and can remove it from the field. The anesthesia professional is usually in control of the supplemental oxygen source and can minimize the oxidizer component of the fire triangle. The scrub technician can help ensure meticulous application of alcohol-containing skin prepping solutions and confirm that they are dry before the application of surgical towels and drapes.

More prudent than a coordinated team response to a surgical fire specifically would be to avoid the risk, such as by not incising the oxygen-filled trachea with an electrosurgical unit in the first place.7 A coordinated approach to surgical fire prevention and response, plus effective perioperative communication by the surgical team, is important to eliminate fire hazards and to minimize the time until a fire is extinguished.4-7,9-14

On a broader scale for prevention, the Christiana Care Health System in Wilmington, Delaware, has developed a concise Fire Risk Assessment Score to identify operations at increased risks for surgical fires.9 The score assesses the presence of three elements.

Christiana Fire Risk Assessment Score (one point each):

- Surgery above the xiphoid
- Open oxygen source
- Available ignition source (e.g., electrosurgery, laser, fiberoptic light cord)

A score of 3 points indicates a high risk for a surgical fire. A score of 2 indicates a low risk with potential for conversion to high risk. A score of 1 indicates low risk. The Fire Risk Assessment Score can easily be included in either the WHO Surgical Safety Checklist preoperative briefing or the Universal Protocol time-out.

6/25/2018

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx
When an operation is assessed as being at high risk for a surgical fire, risk mitigation can decrease the risk. ECRI Institute has summarized mitigation strategies related to surgery of the head, face, neck, and upper chest, and for oropharyngeal procedures, bronchoscopic surgery, and tracheostomy.\textsuperscript{10}

The American Society of Anesthesiologists Task Force on Operating Room Fires and the Anesthesia Patient Safety Foundation have determined that the most important practice for managing the risk of a surgical fire is to minimize the use of supplemental oxygen to the level needed for adequate arterial oxygen saturation and to minimize the free flow of supplemental oxygen through a controlled airway, such as an endotracheal tube or laryngeal mask.\textsuperscript{5,6}

There are defined exceptions where supplemental oxygen delivery may be required via an open source on the face, such as when a patient needs to speak during the surgery. For such cases, starting with an administered concentration of oxygen at 30% and using occlusive draping techniques can minimize the risks of dangerously high concentrations of oxygen being trapped under the drapes.\textsuperscript{7,10}

Electrosurgical active electrodes should be activated only when the tip is visible to the surgeon and should be holstered or removed from the sterile field when not in active use. Bipolar electrodes could also be used in conditions of high oxygen concentration at the target tissue.\textsuperscript{7,10}

Moistening sponges before use can minimize the risk of setting a sponge on fire. A dry sponge can be ignited easily, especially in the presence of an oxygen-enriched atmosphere, whereas a moist sponge resists ignition.\textsuperscript{5-7,10} Water or saline for dousing a fire should also be available on the surgical field. A 5-pound carbon dioxide fire extinguisher should be available in the OR.\textsuperscript{5-7,10,12}

The decreasing incidence of surgical fires in Pennsylvania hospital ORs and ambulatory surgical facilities should be considered within the context of other initiatives to prevent surgical fires, which include the following:

- 2003: Joint Commission Sentinel Event Alert on Preventing Surgical Fires\textsuperscript{4}
- 2005 (extended through 2009): Joint Commission Patient Safety Goal for Ambulatory Surgery \textsuperscript{15}
- 2006: Christiana Care Health System "Surgical Fire Risk Assessment"\textsuperscript{59}
- 2006 and 2014: Association of periOperative Registered Nurses (AORN) "Fire Safety Tool Kit"\textsuperscript{16}
- 2009: ECRI Institute's comprehensive "New Clinical Guide to Surgical Fire Prevention"\textsuperscript{7}
- 2010: Anesthesia Patient Safety Foundation fire safety video\textsuperscript{6}
- 2012 to 2013: American Society of Anesthesiologists "Practice Advisory for the Prevention and Management of Operating Room Fires"\textsuperscript{55}
- 2011 to 2015: U.S. Food and Drug Administration "Preventing Surgical Fires Initiative"\textsuperscript{8}

Limitations of this study include potential variability in the completeness of reporting, despite the requirements of Pennsylvania's Medical Care and Reduction of Error (MCARE) Act of 2002. The identification and interpretation of reports are based on the content of free-text narratives, which include nonstandardized content. As with the 2012 analysis, surgical fires without harm may have been reported as infrastructure failures.

Recommendations in this article for prevention of surgical fires are not intended as standards, guidelines, or absolute requirements. Adoption, modification, or rejection of the recommendations may be considered based on clinical assessment of individual patient needs; and recommendations are not presented with the intent of replacing local institutional policies.
The sensitivity of surgical, anesthesia, and OR nursing staff members to surgical fire hazards has waned since the use of flammable anesthetic agents ceased in the late 1970s. However, it is encouraging that during the past 10 to 15 years, there has been a resurgence in awareness of this continuing risk, as well as increased understanding of the need for a team approach to surgical fire prevention.

**Conclusion**

Although on the decline, surgical fires remain a significant patient safety hazard. As can be observed from the Pennsylvania event reports, most fires are associated with the use of electrosurgical active electrodes around the head and neck in the presence of supplemental oxygen flow. OR personnel should consider the use of a Fire Risk Assessment Score process and adhere to the recommendations of the Anesthesia Patient Safety Foundation and the American Society of Anesthesiologists Task Force on Operating Room Fires in their ongoing efforts to prevent surgical fires.

A summary list of resources for surgical fire prevention and education is provided after the notes.

**Acknowledgments**

We appreciate the thoughtful editing support from Julia Barndt and Eloise DeHaan.

**Notes**


2. Yardley IE, Donaldson LJ. Surgical fires, a clear and present danger. Surgeon. 2010 Apr;8(2):87-92. Also available: [http://dx.doi.org/10.1016/j.surge.2010.01.005](http://dx.doi.org/10.1016/j.surge.2010.01.005). PMID: 20303889


Supplemental Material

Resources for Surgical Fire Prevention and Education

Anesthesia Patient Safety Foundation (APSF). Free educational video and Supplemental Information (released April 2010). The 18-minute video is available online (as well as a free DVD) at www.apsf.org/resources_video.php


Christiana Hospital. Surgical fire risk assessment tools: www.christianacare.org/FireRiskAssessment

ECRI Institute. Free surgical fire prevention educational posters having the most current recommendations, a large bibliography, and recommendations on appropriate fire extinguishers for the OR and other references. www.ecri.org/surgical_fires


SurgicalFire.org. An online resource for information on surgical fires from the family of an affected patient. www.surgicalfire.org

U.S. Food and Drug Administration (FDA). Preventing Surgical Fires Initiative. Begun in Oct 2011, the initiative brought together numerous stakeholders in surgical fire prevention and education. Since 2015, the FDA initiative leadership has been taken over by The Joint Commission and The Council on Surgical and Perioperative Safety. www.cspsteam.org/7-fire-safety/
Identifying Patient Harm from Direct Oral Anticoagulants

Abstract

Direct oral anticoagulants (DOACs), a newer class of oral anticoagulants, have been promoted as a safer and more effective option than warfarin. A query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events involving DOACs that occurred from January 2011 through August 2017 revealed 1,811 reported events, including 265 that resulted in patient harm. The data from these reports were categorized into two groups: harmful events (i.e., adverse drug events) (14.6%, n = 265) and medication errors without harm (85.4%, n = 1,546). Hemorrhage was the most frequently reported adverse event (70.2%, n = 186 of 265). Almost 40% (38.5%, n = 102 of 265) of harmful events occurred to patients who were 80 years or older. Duplicate therapy (33.3%, n = 515 of 1,546) was the most frequently reported type of error without harm. Employing standard protocols to guide therapy, reviewing baseline patient information, including patient weight (in metric units) and laboratory test results such as renal and liver function, and considering the therapeutic indication can aid selection of an appropriate anticoagulant medication for patients.
About 2.6 million people have atrial fibrillation in the United States, and that number is expected to rise to 12 million by the year 2050. Anticoagulants are routinely used in these patients to help prevent and treat thromboemboli related to this arrhythmia. Direct oral anticoagulants (DOACs)—including apixaban (Eliquis®), dabigatran (Pradaxa®), edoxaban (Savaysa™), and rivaroxaban (Xarelto®)—have grown to a combined 42% share of the U.S. oral anticoagulation market since the release of dabigatran in late 2010. In 2015, rivaroxaban was the most widely prescribed DOAC, accounting for 29% of all ambulatory anticoagulant orders.

Additionally, apixaban, dabigatran, and rivaroxaban have gained approval for postoperative deep vein thrombosis (DVT) prophylaxis for knee and hip replacements, indications for which warfarin (Coumadin®) had previously been the primary medication of choice. Before the development of the first DOAC, dabigatran, warfarin had been the primary oral anticoagulant and heparin was the most used injectable anticoagulant.

Warfarin pharmacokinetics make achieving desired effects complicated because it has a highly variable rate of elimination, slow onset of action, and a long half-life. Warfarin works as a vitamin K antagonist, interacting within many different points along the coagulation pathway, specifically affecting factors II, VII, IX, and X. These issues with warfarin increase the difficulty of ensuring the patient has a safe and therapeutic dose. Even at therapeutic doses, all anticoagulants have the risk of causing a spontaneous hemorrhage, and even mild trauma can lead to severe complications from a resulting hemorrhage.

Effective and safe use of warfarin also requires detailed patient assessment, regular monitoring, and the potential for frequent, patient-specific dose adjustments to minimize the high risk of hemorrhage. It has been estimated that a patient on warfarin has a 15% to 20% annual risk of developing a hemorrhage and a 1% to 3% chance of having a severe hemorrhage. Additionally, warfarin has a large number of drug-drug interactions along with varied efficacy related to the patient's dietary intake of foods rich in vitamin K. One study shows that even adherent patients whose warfarin dosage is stable are within their therapeutic range only about 55% of the time.

It is not surprising that a new class of oral medications was seen as a leap forward for anticoagulant therapy. DOACs have a fixed, indication-based dosing; short half-life; and quick onset of action. Additionally, as the drug-class name implies, they work "directly" on a single pathway, inhibiting either factor Xa (apixaban, betrixaban [Bevyxxa®], edoxaban, rivaroxaban) or thrombin (dabigatran). Although enoxaparin (Lovenox®) and fondaparinux (Arixtra®) also selectively inhibit factor Xa, they are available only in injectable formulations, which is not preferred for long-term outpatient treatment.

Data from both the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) shows that oral anticoagulants continue to be one of the leading causes of hemorrhages and account for about 17.6% of all emergency department (ED) visits.

Pennsylvania Patient Safety Authority analysts reviewed errors associated with the use of DOACs distinct from warfarin. Analysts sought to characterize the types of events that occurred with these medications, identify contributing factors, and describe system-based risk reduction strategies.

**Methods**

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events related specifically to DOACs that occurred from January 2011 through August 2017. Portions of each DOAC's proprietary and nonproprietary name, to account for possible misspellings, were used to search applicable drug name and event data from both the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) shows that oral anticoagulants continue to be one of the leading causes of hemorrhages and account for about 17.6% of all emergency department (ED) visits.

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description fields. The query resulted in 2,610 reports. Of these, 799 reports were excluded for lack of relevance, most frequently because the anticoagulant mentioned within the report did not contribute to the event (e.g., a DOAC was prescribed after an event occurred). The final detailed analysis yielded 1,811 event reports.

Analysts categorized the events using a number of criteria, including whether or not the event resulted in patient harm. Questions used by analysts to categorize events included:

- Did the patient require medical intervention or was medical treatment sought or required?
  - Did the event result in harm to the patient?
    - What type of harm occurred to the patient?
  - Did the report specify that the patient had a hemorrhage?
    - In what area of the body did the hemorrhage occur?
- Was the adverse event due to a medication error?
- Was an antidote or blood product given to mitigate the adverse effect of a DOAC?
- Was the DOAC treatment regimen changed (e.g., to a different anticoagulant)?
- Did the use of a DOAC result in procedure cancellations or complications?
- Did a patient require a transfer to a higher level of care or an extended hospitalization?

Reports that were determined to involve harm were labeled as adverse drug events (ADEs) and required the report to specifically mention that a patient experienced an untoward effect from a DOAC (e.g., hemorrhage). ADEs can include events that are considered preventable (i.e., medication errors) or unpreventable (i.e., adverse drug reactions). DOAC errors without harm, for this portion of the analysis, consist of preventable events that could have or did result in an error but did not cause harm to the patient.

Events were considered to involve "improper bridging" when a DOAC was intentionally used concomitantly with warfarin until the therapeutic international normalized ratio (INR) goal was reached. These reports are excluded from the event type therapeutic duplication because the report details were specific enough for analysts to determine that the duplication was intentionally chosen as a bridging treatment.

Reports were also analyzed based on the patient age, medication name, event type, event description, and nodes of the medication use process as provided by the reporting facility. Analysts completed the medication-name field in reports in which a medication-name data field was left blank or incomplete but the name was provided in the event description.

**Results**

Of the 1,811 reports, 14.6% (n = 265) were considered ADEs and 85.4% (n = 1,546) were medication errors without harm. Three DOACs were identified in the submitted reports (Table). There were no reports involving edoxaban or betrixaban. As use of DOACs in clinical practice has increased, so too has the number of reports involving these agents submitted to the Authority (Figure 1).
Table. Direct Oral Anticoagulants Involved in Reported Events (N = 1,811)

<table>
<thead>
<tr>
<th>Drug</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban</td>
<td>922 (50.9)</td>
</tr>
<tr>
<td>Apixaban</td>
<td>544 (30.0)</td>
</tr>
<tr>
<td>Dabigatran</td>
<td>345 (19.1)</td>
</tr>
</tbody>
</table>

Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 2011 through August 2017.

Adverse Drug Events

The average age of a patient who experienced harm was 74.5 years. Breakdown by decade of life shows an increase in the number of adverse events over each decade of life until the over-90 group (Figure 2). Analysis of adverse events by gender shows that 135 of 265 events (50.9%) involved females compared with 130 (49.1%) males.
Analysts identified that 14.6% (n = 265 of 1,811) of the events described some type of patient harm. This included 2 reports of patient death, 10 reports of embolic stroke, 5 reports of hemorrhagic stroke, and 1 case of Stevens-Johnson syndrome. The two deaths reported were due to hemorrhages—one gastrointestinal (GI) and the other pulmonary. Both reports resulting in a death also stated that the patients had received a non-DOAC anticoagulant before switching to rivaroxaban. The reported data was insufficient to determine whether improper selection or management of anticoagulation medications contributed to the deaths. Following are the two reports of patient death:

The patient had an RRT [rapid response team] [call]. [Two days later] a mid-line was placed and the patient was noted to have post-procedure bleeding. The patient received 2 units of packed red blood cells. The patient was receiving enoxaparin [for five days] [followed by] rivaroxaban on [the day of the mid-line insertion]. The patient coded and was found to have a massive GI bleed. The patient, despite reversal of [the anticoagulants] and having his intravascular volume repleted, expired the next night.

Patient was taken off Coumadin [warfarin] and placed on Xarelto [rivaroxaban]. The patient developed a hematoma secondary to Xarelto most likely, and this showed up on CT [computerized tomography] scan of the chest and CT scan of the thorax—large left retroperitoneal bleed. Shortly after he was transferred to ICU [intensive care unit], he went into respiratory failure. Shortly after, the patient expired.

The most common type of outcome reported was hemorrhage, at 84.2% (n = 223 of 265). The remaining types were allergic reaction 4.5% (n = 12), embolism 3.8% (n = 10), abnormal lab value 3.4% (n = 9), gastritis 1.9% (n = 5), and other 2.3% (n = 6). Rivaroxaban was associated with the largest percentage of ADEs (44.9%, n = 119), followed by apixaban (37.0%, n = 98) and dabigatran (18.1%, n = 48).

Analysts found that 88.3% (n = 234 of 265) of reports noted that patients required medical treatment when an adverse event occurred. One-third (33.8%, n = 234) of the events requiring medical treatment resulted in administration of an antidote or blood transfusion to treat the hemorrhage.
Prescribers in 31.7% (n = 84 of 265) of ADEs discontinued the suspect drug and initiated a new treatment plan. The patient's DOAC dose was either held or reduced in 16.2% (n = 43) of adverse events. Analysts were unable to determine the status of the medication order in 46.8% (n = 124) of the adverse event reports.

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

### Anatomic Site of Hemorrhage

More than three-quarters of the reports involving hemorrhage (83.4%, n = 186 of 223) identified the site where bleeding occurred. GI tract was the most common hemorrhage location (48.9%, n = 91 of 186). Upper GI tract (31.2%, n = 58) was more commonly reported than lower GI tract (17.7%, n = 33). Other anatomic hemorrhage sites included urinary (12.4%, n = 23), surgical (10.8%, n = 20), cerebral (8.6%, n = 16), nasal (5.9%, n = 11), multiple sites (2.7%, n = 5), and other (10.8%, n = 20). Additionally, 11 reports noted a required transfer of the patient to a higher level of care within the hospital or to a different facility. Following is an example of event resulting in a hemorrhage, reported through PA-PSRS:

A 63 y/o female patient was admitted pre-op on Plavix® [clopidogrel] and Coumadin. After the patient's right hip arthroplasty, the patient was prescribed CeleBREX® [celecoxib], Xarelto, Coumadin, and Plavix. The patient took the medications [for four days]. GI [team] was consulted on [the second post-operative day] due to anemia and hematemesis. GI [team] said that her anemia was likely multifactorial and possibly due to taking multiple anticoagulants together.

### Preventable Adverse Drug Events

Preventable errors were identified in 21.5% of the event reports involving harm (n = 57 of 265) (Figure 3). Analysts categorized these events into six types of errors: therapeutic duplication, wrong dose, improper bridging, restarted anticoagulation treatment too soon, drug-drug interaction, and wrong duration of therapy. Therapeutic duplication (54.4%, n = 31 of 57) and wrong dose (24.6%, n = 14) were the most common types of errors. Following are examples of preventable adverse drug events reported through PA-PSRS:

A 78-year-old patient had hip surgery in the fall and has not been as mobile since. She has recently started ambulating. She presented to the ED [emergency department] with left lower extremity swelling and pain. She was diagnosed with a DVT. The ED physician wrote for Lovenox [enoxaparin] 130 mg subcutaneously and decided to admit the patient to the hospital. The inpatient physician came to see the patient and prescribed Xarelto 15 mg 2 hours after the Lovenox was administered. The patient had a significant gastrointestinal bleed 24 hours after the duplicate therapy was administered. The patient went into shock and was transferred to the ICU. The patient was given factor IX, fresh frozen plasma, and packed red blood cells.
Patients who were improperly bridged accounted for 8.8% (n = 5 of 57) of the reports involving preventable errors. These five patients had an average age of 86.8 years, with one requiring a transfer to the ICU. Following are examples of inappropriate bridging events reported through PA-PSRS:

87 y/o male patient received warfarin. Dabigatran was started as a "bridge to Coumadin therapy." Patient transferred to ICU. Patient developed bilateral nasal bleeding. Received vitamin K, fresh frozen plasma, and packed RBCs. The aPTT [activated partial thromboplastin time] result was elevated.

92 y/o female patient admitted with hydropneumothorax. Had been taking apixaban 2.5 mg bid [twice a day] at home, and this was resumed [on the fourth day of the admission]. [Four days later] she was also started on warfarin 5 mg with plan to continue apixaban x 3 doses as bridge. [The next day the patient] was noted to have hematuria, INR = 1.6. Apixaban was discontinued and warfarin was continued. INR [the next day] was 1.7 with no additional bleeding documented.

89 y/o female patient was discharged in October after admission for atrial fibrillation. She had been on a cardiac heparin protocol during admission and PTT [partial thromboplastin time] was 45 in the morning prior to discharge. She was [started on] warfarin [a day] prior to discharge. No INR was drawn. Discharge instruction for this admission listed warfarin 4 mg daily. Patient was given Pradaxa [dabigatran] 150 mg prior to discharge with samples of Pradaxa to take home. The Pradaxa was not listed on the discharge instructions. Patient was admitted again to critical care for lower GI bleeding. Admissions paperwork noted patient being bridged with Pradaxa. INR on admission was 2.27 and vitamin k 2 mg was given IV. Hemoglobin was 11.0 prior to discharge and was 9.3 when readmitted.

**DOAC Errors without Harm**

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**Figure 3. Types of Preventable Adverse Drug Events Involving Direct Oral Anticoagulants (N = 57)**

<table>
<thead>
<tr>
<th>TYPE OF EVENT</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic duplication</td>
<td>31 (54.4%)</td>
</tr>
<tr>
<td>Wrong dose</td>
<td>14 (24.6%)</td>
</tr>
<tr>
<td>Improper bridging</td>
<td>5 (8.8%)</td>
</tr>
<tr>
<td>Restarted treatment too soon</td>
<td>4 (7.0%)</td>
</tr>
<tr>
<td>Drug-drug interaction</td>
<td>2 (3.5%)</td>
</tr>
<tr>
<td>Wrong duration of therapy</td>
<td>1 (1.8%)</td>
</tr>
</tbody>
</table>

*Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 2011 through August 2017.*
DOAC errors without harm were categorized into nine specific types of events. The three most common types of events accounted for 66.6% (n = 1,030 of 1,546) of all errors without harm (Figure 4). These three categories were therapeutic duplication, dose omission, and wrong dose. As Figure 5 shows, the medications most commonly involved in DOAC duplicate therapy events without harm were heparin (56.1%, n = 289 of 515); enoxaparin (29.9%, n = 154), and warfarin (8.0%, n = 41). Of the 289 instances when heparin was given, 101 reports were identified as heparin infusions. Following are examples of errors without harm reported through PA-PSRS:

53 y/o male patient in OR [operating room] for hip replacement, on Eliquis [apixaban] at home - this was entered to continue home therapy here. Then the orthopedic resident entered an order for rivaroxaban. One problem - physician did not recognize duplicate drugs, two - computer does not screen for duplicates when item is entered as non-formulary.

Pharmacist reported 67 y/o female post-TEE [transesophageal echocardiography] orders written to discontinue Coumadin & start Eliquis when INR less than 2. Coumadin regimen not removed from profile. Error noted two days later when order for Coumadin received. Pharmacist called MD to clarify med orders. New orders to discontinue Coumadin & start Eliquis.

93 y/o male had orders written for digoxin and Xarelto, doses missed, never entered into medication administration system. IV ordered was entered into system but was not started. Med errors found upon review of chart orders.

According to medication reconciliation history, it was documented that patient was taking rivaroxaban 20 mg bid for DVT. For patient with good renal function, it is dosed 15 mg bid for 21 days and then 20 mg daily. Pharmacist verified the dose and patient received 20 mg on [two consecutive days]. Patient told us during rounds that he was taking rivaroxaban starter pack (15 mg bid for 21 days and 20 mg daily). Pharmacist should have identified the medication reconciliation error. Patient was not harmed.
Figure 4. Types of Preventable Events without Harm Involving Direct Oral Anticoagulants (N = 1,546)

<table>
<thead>
<tr>
<th>TYPE OF EVENT</th>
<th>NUMBER OF REPORTS</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicate therapy</td>
<td>515 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>Dose omission</td>
<td>263 (17.0%)</td>
<td>(16.3%)</td>
</tr>
<tr>
<td>Wrong dose</td>
<td>252 (16.3%)</td>
<td>(7.6%)</td>
</tr>
<tr>
<td>Procedure cancellation</td>
<td>121 (7.6%)</td>
<td>(7.7%)</td>
</tr>
<tr>
<td>Other</td>
<td>119 (7.7%)</td>
<td>(3.8%)</td>
</tr>
<tr>
<td>Wrong drug</td>
<td>89 (5.7%)</td>
<td>(3.4%)</td>
</tr>
<tr>
<td>Extra dose</td>
<td>59 (3.8%)</td>
<td>(3.3%)</td>
</tr>
<tr>
<td>Medication error</td>
<td>52 (3.3%)</td>
<td>(1.6%)</td>
</tr>
<tr>
<td>Hold error</td>
<td>51 (3.3%)</td>
<td>(3.3%)</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>25 (1.6%)</td>
<td></td>
</tr>
</tbody>
</table>

*Includes events in which the medication was held for too long, not held long enough, or not held.

Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 2011 through August 2017.
Procedure Cancelations and Complications

Outpatient procedure cancelations and complications due to patients either holding or not holding their DOAC were noted in 7.6% (n = 137 of 1,811) of reports. In 88.3% (n = 121 of 137) of those reports, the procedure was canceled when the DOAC had not been held. These events were caught by facility staff when conducting medication reviews during a pre-operative assessment.

Reports show that patient harm occurred in 16 events. Stroke or stroke-like symptoms were noted in 75.0% (n = 12 of 16) of the reports when the medication was held prior to the procedure. Two reports indicated stroke-like symptoms were identified prior to the patients' procedures. The remaining 10 patients were identified with stroke-like symptoms or with having an embolic event after their procedure. Clinician documentation of the error reports suggested that holding the patient's anticoagulant medication contributed to development of a postoperative embolic stroke or a DVT/PE (pulmonary embolism). One-quarter (25%, n = 4) of events resulted in patients developing a postoperative hemorrhage from not holding their anticoagulant medication. Following are examples of procedure cancellations or complications reported through PA-PSRS:

70 y/o female on postoperative day 2 was identified to have a possible CVA [cerebrovascular accident] due to impaired speech, expressive aphasia, and facial droop. Patient was transferred to [a different facility]. The patient had a CT scan, which revealed a double clot. IR [interventional radiology] initiated the procedure for mechanical thrombectomy. The patient spontaneously opened one occlusion. Physician regarded the event most likely cardioembolic, secondary to being off her Eliquis for her atrial fibrillation for the procedure. Pt made a full recovery.

Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 2011 through August 2017.
81 y/o male 2 day post nephrolithotomy procedure unable to resume Xarelto because of bleeding, developed slurred speech and left-sided weakness. CT of the brain showed stroke and patient was transferred to tertiary care facility.

Patient underwent an UGI [upper gastrointestinal endoscopy] and colonoscopy for a history of abdominal pain, diarrhea, and weight loss. She was on Pradaxa for atrial fibrillation, which was stopped prior to the procedure. In the recovery area, she suddenly developed aphasia and confusion. A CT showed a stroke. She was admitted to the hospital.

Discussion

Therapeutic duplication was involved in more than half of preventable DOAC events associated with patient harm. Using two antithrombotic medications at the same time can increase the risk of patient harm even after administration of only a few doses. Heparin was involved in more than half of all therapeutic duplications. The high number of DOAC and heparin events could be influenced by limited understanding from prescribers and other healthcare professionals on how to prescribe, monitor, administer, and convert to or from these newer anticoagulants. Decision support systems should be designed properly to catch therapeutic duplication errors.

DOAC usage has increased every year since their release.1 One reason is the benefit of not requiring INR-based dosing. Another is that DOACs have fewer drug-food and drug-drug interactions than warfarin.6,11,12 However, clinicians prescribing DOACs must still see the patient regularly. Instead of reviewing the INR results for warfarin dose titration changes to keep a patient safely anticoagulated, as is done with warfarin therapy, clinicians need to conduct a clinical review and ensure laboratory monitoring is up to date to ensure liver and kidney functions have not changed. Especially within the geriatric population, these steps are vital to ensure the DOAC is still the appropriate anticoagulant and the dose does not require adjustment for a patient’s change in status.

The patient’s age appeared to be a predominant risk factor within these reports. As patients age, they become more susceptible to harm when medication errors occur. Unfortunately, there is not strong clinical data to guide DOAC dosing in patients older than 75 years of age. Most of the pivotal DOAC clinical trials excluded patients who were older than 74 years.13 Reports submitted to the Authority showed that 38.6% of patient harm occurred in patients 80 years of age or older.

CDC estimates that the U.S. population has about a 2% chance of developing atrial fibrillation before the age of 65, and this risk increases to about 9% after age 65.8,14 Additionally, the risk of thrombosis (DVT or PE) for someone under 45 is 1:10,000, which gradually increases with each decade of life to about 6:1,000 by the age of 80.7,15 Currently, apixaban is the only DOAC with specific dosing recommendations for the geriatric population.2

Because DOACs are used to treat diseases that impact adult and elderly patients, prescribers should be cognizant of the patient’s age along with any additional comorbidities that can increase the risk of a hemorrhage. Patients 80 or older have the highest risk of a major hemorrhage within the first 90 days of starting a DOAC, so it is highly recommended that additional clinical reviews and laboratory monitoring is completed during the first 90 days of therapy.12,16 All the trials used for DOAC approvals excluded patients with a creatinine clearance (CrCl) less than 25 –30 mL/min for VTE studies or a CrCl less than 30 mL/min for nonvalvular atrial fibrillation (NVAF) studies.16

Use of dabigatran, especially, can be challenging because its renal dosing was never studied and, as a prodrug, it requires proper liver function for conversion to its active metabolite and proper renal function for elimination. Apixaban and edoxaban have been shown to be safer for the elderly population, but if kidney function is enhanced (CrCl greater than 95 mL/min) there is a risk of decreased edoxaban efficacy.17 It is important that an evaluation of the patient’s liver and renal function be conducted before and during treatment to assess which DOAC is best for a patient.

6/25/2018

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_DOACs.aspx
Limitations

In-depth analysis by the Authority of events involving DOACs is limited by the information reported by facilities through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete. The reporting cultures and patterns in each facility, and their interpretations of what occurrences are reportable, can lead to reporting variations. Although the narrative fields of the reports help analysts discern what happened during the event, they often do not contain details describing how the event deviated from the standard operation or which factors contributed to the event.

The changing availability of the various DOACs over time limits the ability to make direct comparisons between DOACs or to determine whether one DOAC appears be safer than another. For example, there were no reports involving edoxaban or betrixaban, presumably because of their later approval and more limited market share.

Risk Reduction Strategies

Organizations and healthcare facilities can strive to identify system-based causes of errors involving oral anticoagulant agents and implement risk reduction strategies to prevent harm to patients. Providing education is commonly recommended to prevent errors, but this strategy, while important, is less reliable because it is heavily influenced by individual performance. System-based improvements such as constraints and standardization are more effective and produce results with less variability.\textsuperscript{18,19} Consider the strategies described below, which are based on a review of current literature, events submitted to the Authority, and observations from the Institute for Safe Medication Practices (ISMP).

Clinical Patient Information

- When an oral anticoagulant is indicated, before initiating therapy, collect and make readily available baseline patient information including patient weight (in metric units) and laboratory test results such as renal and liver function.\textsuperscript{2,6,12,19-23}
- When a patient is admitted on oral anticoagulation medications, including DOACs, include the indication and how long the patient has been on the medication(s) in the medication reconciliation note.\textsuperscript{24}

Drug Information

- Employ and optimize clinical decision support and approved, standardized order sets in computerized order entry and pharmacy information systems to help providers make the best treatment selection. Avert dosing errors, treatment duplication, and laboratory value interactions by firing alerts to users.\textsuperscript{18,19}
- 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.\textsuperscript{19,25}
- Ensure anticoagulation clinical decision support and protocols, including oral anticoagulant reversal protocols, are up to date. Consider proactively developing protocols even if the product is not on the organization’s formulary, in anticipation of a patient being admitted on a DOAC or a patient being admitted due to an adverse event with a nonformulary medication.\textsuperscript{19}
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 the therapeutic indication.\textsuperscript{19,23,26}

**Communication of Drug Orders and Other Drug Information**

- Establish a process for changing anticoagulants with particular focus on preventing additional and missed doses. Having only one active order with clear annotation of when one medication should be stopped and the other is to be started in both computer systems and medication administration records (MARs) may help minimize errors.\textsuperscript{19,24,27}

- Establish a standard process for bridging anticoagulants during the perioperative period. Use protocols to guide therapy and reduce the risk of the improper selection of agents when initiating or changing anticoagulant therapy, including transitions from injectable products to a DOAC.\textsuperscript{28-30} Design protocols to protect against unnecessary bridging when starting a DOAC.

- Establish standard protocols for rapid or emergency reversal of anticoagulation and when to restart anticoagulant therapy.\textsuperscript{9,19}

**Staff Competency and Education**

- Annual competency assessments for clinicians who prescribe, dispense, or administer oral anticoagulants help to ensure clinicians understand different oral anticoagulant medications, differences in dosing regimens, and their indications.\textsuperscript{19,23}

- When a new anticoagulant is added to the organization's formulary, notify staff using tools such as 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 at the time that it is needed for patient care may be helpful.\textsuperscript{19,31}

**Patient Education**

- Patient counseling and education provides an opportunity to empower patients to recognize, intercept, and prevent errors. At the onset of therapy and prior to discharge, provide education to patients who are on anticoagulants. Remind patients that the risks of anticoagulants include hemorrhaging but that there are also risks of clotting from their underlying condition due to inadequate anticoagulation when doses are missed.\textsuperscript{19,32}

**Quality Processes and Risk Management**

- Define patient symptoms and condition changes, such as sudden decline in renal function, hemorrhaging, or hypercoagulability, that correlate to an ADE. Using decision support to monitor these triggers can help identify the potential or actual onset of new ADEs.\textsuperscript{19,33}

- When errors happen, investigate and share results with other clinicians to raise awareness about issues surrounding oral anticoagulants.\textsuperscript{19,27}

- Sharing success stories as well as potential, near-miss, and harmful event reports may help facilities identify possible errors and areas for improvement.\textsuperscript{19,27}
Conclusion

For every seven DOAC medication errors, you can expect one to result in patient harm. While safer than warfarin, DOACs should not be thought of as risk-free anticoagulants. Similar to published data for warfarin, analysts found hemorrhages were the most common adverse event involving DOACs noted in reports submitted to the Authority. Also, the patient’s age appeared to be a predominant risk factor: reports submitted to the Authority showed that 38.6% of patient harm occurred in patients 80 years of age or older. Finally, additional effort is needed to address therapeutic duplication errors, because this was the most commonly reported event category regardless of whether harm occurred.

Notes


8. Baker WL, Cios DA, Sander SD, Coleman CI. Meta-analysis to assess the quality of warfarin control in atrial fibrillation patients in the United States. J Manag Care Pharm. 2009 Apr;15(3):244-52. Also available:


29. Spyropoulos AC, Al-Badri A, Sherwood MW, Douketis JD. Periprocedural management of patients receiving a vitamin K antagonist or a direct oral anticoagulant requiring an elective procedure or surgery. J Thromb

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_DOACs.aspx


Combat Norovirus Infections in Long-Term Care Facilities

Authors
Sharon Bradley, RN, CIC
Senior Infection Prevention Analyst

Edward Finley, BS
Data Analyst

Pennsylvania Patient Safety Authority

Corresponding Author
Sharon Bradley

Abstract

New Criteria, Same Norovirus Concerns

New criteria allow more accurate distinction between norovirus and other causes of gastroenteritis.

Norovirus is responsible for 41.3% of gastroenteritis events in Pennsylvania long-term care facilities.*

* Events as reported to the Pennsylvania Patient Safety Authority July 2016 through June 2017.
http://patientsafety.pa.gov/ADVISORIES/Pages/201806_NorovirusUpdate.aspx
Norovirus causes up to 21 million cases of acute gastroenteritis and about 800 deaths annually in the United States. Older adults in long-term care (LTC) facilities are particularly at risk. The Pennsylvania Patient Safety Authority analyzed norovirus cases reported by LTC facilities during the three most recent norovirus seasons. Reports to the Authority showed that norovirus events comprised more than 40% of all gastrointestinal infections. The norovirus outbreak rate varied by region within the state, but with the exception of the Northcentral region in academic year 2016, all regions reported infections in each of the three years studied. In the timeframe analyzed, Pennsylvania LTC facilities reported an increased number of norovirus events from November through March—the typical norovirus season. This shows that norovirus infection control continues to be problematic in Pennsylvania LTC facilities, indicating a need to implement improved prevention and control strategies.

**Introduction**

According to the Centers for Disease Control and Prevention (CDC), norovirus causes up to 21 million cases of acute gastroenteritis and results in about 800 deaths annually in the United States. Older adults in long-term care (LTC) facilities are particularly at risk. In a recent study, CDC found that among nursing home patients in three states, hospitalization and death rates increased by 10% during norovirus outbreaks. Also, the risk for hospitalization and death among patients 90 years of age or older increased by 20% to 30% during norovirus outbreaks.\(^1\)\(^2\)

In LTC settings, most outbreaks are caused by person-to-person transmission, because of the high levels of personal contact in close spaces. Also, the hygiene of some residents, such as those who are physically or mentally impaired, may be inadequate.\(^3\) From an administrative viewpoint, norovirus outbreaks in healthcare facilities often result in significant financial and operational burdens.\(^4\) In 2010, the Pennsylvania Patient Safety Authority published an article about controlling the annual threat of norovirus gastroenteritis outbreaks, accompanied by a toolkit.\(^4\) Available data was limited at the time because norovirus infection was not reported in Pennsylvania as a distinct subcategory of gastrointestinal (GI) infections.

In April 2014, in accord with changes to national standards,\(^5\) the Authority revised the LTC criteria for identifying and reporting gastroenteritis. The revision included a new gastroenteritis subcategory that allows detailed surveillance and reporting of norovirus cases separate from other causes of gastroenteritis within the Pennsylvania Patient Safety Reporting System (PA-PSRS).

This first report since the standards were revised takes a fresh look at the incidence of norovirus gastroenteritis in Pennsylvania LTC facilities. The new criterion allows analysis of the number of cases and outbreaks of norovirus as a subset of overall GI infections.

**Methods**

Authority analysts queried the PA-PSRS database for GI infection reports for the three most recent academic years (AYs), AY2015 through AY2017 (July 2014 through June 2017). Analysts compared the proportion of norovirus events to other causes of GI infections by year and month, as reported to the Authority, and the number of outbreaks by year and month by regions (based on the Pennsylvania Department of Health’s Public Health Districts).

A norovirus outbreak as defined by CDC is an occurrence of two or more similar illnesses characterized by staff and/or residents having vomiting and/or diarrhea within 48 hours, resulting from a common exposure that is either suspected or laboratory-confirmed to be caused by norovirus.\(^6\)\(^,7\)
Rates calculated for analytic comparisons used incidence per 1,000 resident days, as reported through PA-PSRS.

**Results**

**Event Seasonality**

Of the 11,532 records of GI infections returned, 4,761 (41.3%) were categorized as norovirus events, compared with 6,682 (57.9%) classified as *Clostridium difficile* infection, 81 (0.7%) classified as other bacteriologic GI pathogens, and 8 (0.1%) classified as *Pseudomembranous colitis*. Figure 1 shows the percentages of types of infections over the three years. For two-thirds of the months analyzed in this time period, *C. difficile* was the GI infection reported most often through PA-PSRS. However, norovirus events comprised the majority of GI infections for 12 of 36 months in three clusters of consecutive months concurrent with what is commonly considered the norovirus season (Figure 2). These three clusters accounted for 87.5% of all norovirus reports over the three-year period. Also of note are the seasonal spikes of monthly norovirus rates as compared to relatively stable monthly rates of other GI infections (Figure 3).

**Figure 1. Percentage of GI Infection Reports by Type, Academic Years 2015 through 2017**

<table>
<thead>
<tr>
<th>GI Infection</th>
<th>AY2015</th>
<th>AY2016</th>
<th>AY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium difficile</em></td>
<td>52.3%</td>
<td>69.4%</td>
<td>55.1%</td>
</tr>
<tr>
<td>Pseudomembranous colitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norovirus</td>
<td>47.2%</td>
<td>29.8%</td>
<td>44.1%</td>
</tr>
<tr>
<td>Other bacteriologic GI pathogen</td>
<td>0.5%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System by long-term care facilities. Academic years are for the 12 months ended June 30 of each year. Totals may not equal 100% because of rounding. AY, Academic year; *C. difficile*, *Clostridium difficile*; GI, gastrointestinal.
Figure 2. Number of Norovirus Infection Reports, Academic Years 2015 through 2017

NUMBER OF NOROVIRUS INFECTION REPORTS

Note: Academic years are for 12 months ended June 30 of each year. Data reported through the Pennsylvania Patient Safety Reporting System by long-term care facilities. AY, Academic year.

Figure 3. Norovirus versus Other Gastrointestinal Infection Rates for Academic Years 2015 through 2017

NOROVIRUS AND GI INFECTION RATE (1,000 RESIDENT DAYS)

Note: Academic years are for the 12 months ended June 30 of each year. Data reported through the Pennsylvania Patient Safety Reporting System by long-term care facilities. AY, Academic year; GI, gastrointestinal.

Events by Pennsylvania Region
The timing and magnitude of event clusters varied among facilities, as shown when grouped by Pennsylvania region (Figure 4). Each region had different monthly peaks, demonstrating that although events are seasonal, variability exists by region. Table 1 shows peak norovirus periods and rates for the Authority's six state regions.

**Figure 4. Norovirus Infection Rates by Region and Month for Academic Years 2015 through 2017**

**Note:** Rates calculated from norovirus event and resident days as reported through the Pennsylvania Patient Safety Reporting System by long-term care facilities; the size of the bubble is proportional to the rate represented. Academic years are for the 12 months ended June 30 of each year. *AY*, Academic year.

**Table 1. Regional Peak Outbreak Rates, by Region, Academic Years 2015 through 2017**

<table>
<thead>
<tr>
<th>Region</th>
<th>Peak Month and AY</th>
<th>Peak Rate*</th>
<th>Average Rate, AY15–AY17*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northcentral</td>
<td>January 2014</td>
<td>0.37</td>
<td>0.03</td>
</tr>
<tr>
<td>Northeast</td>
<td>April 2015</td>
<td>0.44</td>
<td>0.07</td>
</tr>
<tr>
<td>Northwest</td>
<td>March 2016</td>
<td>0.51</td>
<td>0.07</td>
</tr>
<tr>
<td>Southcentral</td>
<td>January 2016</td>
<td>0.67</td>
<td>0.08</td>
</tr>
<tr>
<td>Southeast</td>
<td>February 2016</td>
<td>0.25</td>
<td>0.06</td>
</tr>
<tr>
<td>Southwest</td>
<td>March 2014</td>
<td>0.18</td>
<td>0.04</td>
</tr>
</tbody>
</table>

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_NorovirusUpdate.aspx
Outbreaks

Of 222 LTC facilities reporting norovirus, 183 (82.4%) had norovirus clusters that met CDC’s definition of an outbreak. These 364 outbreaks encompassed 4,564 (of 4,761, 95.9%) of the reported norovirus events in this period (Table 2). The longest outbreak was reported over the course of 27 days and included 138 cases. The most concentrated outbreak included 86 cases reported over two days. Eighty-three LTC facilities (37.4%) had multiple outbreaks; 37 (16.7%) had three or more outbreaks over the three-year period.

Table 2. Norovirus Outbreaks and Cases in Long-Term Care Facilities with Outbreaks, Academic Years 2015 through 2017 (n = 183)

<table>
<thead>
<tr>
<th>Outbreaks*</th>
<th>Number of Cases Associated with Outbreaks</th>
<th>Percentage of Cases Associated with Outbreaks (N = 4,761 Norovirus Events)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum</td>
<td>16</td>
<td>184</td>
</tr>
<tr>
<td>Minimum</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mean</td>
<td>1.99</td>
<td>24.94</td>
</tr>
<tr>
<td>Median</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>364</td>
<td>4,564</td>
</tr>
</tbody>
</table>

Note: Academic years are for the 12 months ended June 30 of each year.

* From facilities determined to have at least one outbreak.

Discussion

Analysis revealed that norovirus infections comprise 4,761 (41.3%) of gastroenteritis events in LTC facilities in Pennsylvania, with most events occurring during the winter. No substantial decline was evident in norovirus events reported through PA-PSRS in the three most recent norovirus seasons.

This suggests that prevention and control of norovirus gastroenteritis outbreaks continues to be problematic in Pennsylvania LTC facilities.

The symptoms of vomiting and diarrhea are self-limiting and, for most people, resolve within a few days, but these symptoms can be deadly for the older population. There is currently no U.S. Food and Drug Administration approved vaccine or cure for norovirus. Recent advances enabling development of human norovirus in the laboratory setting show potential to contribute to vaccine research and targeted treatment methods.
Authority findings are consistent with CDC data demonstrating that norovirus infections are most common in winter but can occur at any time during the year. According to the CDC, from August 1, 2017, through February 12, 2018, there were 775 norovirus outbreaks reported by nine participating states. During the same period in the previous year, 770 norovirus outbreaks were reported to the CDC by these states. The number of outbreaks reported to the CDC in the 2017-2018 norovirus season to date is above the range reported during the same period over the previous seven years.9

Healthcare facilities may be unprepared to manage large numbers of infected residents. Unchecked norovirus outbreaks can be prolonged, sometimes lasting months. Costs include indirect and direct costs related to staff call-outs, sick leave, and overtime, as well as the costs of additional healthcare cleaning expenses and supplies, such as linens, commodes, bleach, sanitizers, mops, gloves, and gowns. Healthcare facilities may experience financial losses when temporarily closing units or buildings until the outbreak can be controlled or otherwise runs its course.

When new strains of the virus are circulating, norovirus infections can increase by 50%.10 According to 2013 research by Green, "Since 2002, new GII.4 variants have emerged every 2 to 3 years resulting in epidemics."11 Cannon research shows that "between September 2013 and August 2016 . . . GII.4 Sydney viruses caused 58% of outbreaks."9 Of the seven main genotypes, four of which infect humans, 49% of the confirmed norovirus outbreaks submitted to CDC from September 1, 2017, through May 31, 2018, were genogroup GII.P16-GII.4 Sydney.12 This comparison of genetic sequencing data with existing sequences contributes to continued efforts to identify trends in norovirus disease outbreaks and preventive measures.13

The best method to control norovirus is to have a preseason plan in place, in which all members of the multidisciplinary team are clear about their roles in prevention, control, and quality improvement measures. The Authority offers a free, online Patient Safety Topic about norovirus. Implemented by a facility's team prior to norovirus season, these tools enable effective preparation, including strategies to prevent widespread outbreak and evaluation of the effectiveness of process and outcome measures. The updated Norovirus Patient Safety Topic includes a concise slide presentation with "train the trainer" notes for staff education.

**Pennsylvania Patient Safety Authority Norovirus Preseason Preparedness and Outbreak Control Toolkit**

**Controlling the Annual Threat of Norovirus Gastroenteritis Outbreaks**

This Pennsylvania Patient Safety Advisory article presents evidence-based strategies to modify risk factors for outbreaks, including how to prepare for norovirus season, ensure basic outbreak control measures, use enhanced precautions, and conduct leadership and post-outbreak activities.

http://patientsafety.pa.gov/ADVISORIES/Pages/201012_141.aspx (/ADVISORIES/Pages/201012_141.aspx)

**Norovirus Prevention and Response Recorded Webinar**

Designing a Norovirus Prevention and Rapid Response Program: An Evidence-Based Approach.

https://www.youtube.com/watch?v=ud3S9b3zJRA&t=4s (https://www.youtube.com/watch?v=ud3S9b3zJRA&t=4s)

**Norovirus Preparedness Checklist**

This sample checklist is designed to help facilities assess facility-specific preparedness plan activities, basic precautions, enhanced precautions, and outcome and process measures.

http://patientsafety.pa.gov/pst/Pages/Norovirus/checklist.aspx (/pst/Pages/Norovirus/checklist.aspx)

**Acute Gastroenteritis Outbreaks Case Log**

http://patientsafety.pa.gov/ADVISORIES/Pages/201806_NorovirusUpdate.aspx
Facilities can use this sample log to determine common factors about acute gastroenteritis outbreaks and collect information in a timely, reliable, and organized fashion. http://patientsafety.pa.gov/pst/Pages/Norovirus/log.aspx

**Norovirus Preparedness: Outcome and Process Measures Worksheet**

This sample worksheet can be used for documenting facility-specific process and outcome measures associated with norovirus. http://patientsafety.pa.gov/pst/Pages/Norovirus/measures.aspx

**Norovirus Preparedness and Control Video**

Norovirus preparedness and controlling the annual threat of a norovirus outbreak. https://www.youtube.com/watch?v=2979jsf0SNc&t=40s

**Train the Trainer PowerPoint Slides—NEW!**

This short training program for clinicians is accompanied by train-the-trainer notes. http://patientsafety.pa.gov/pst/Pages/Norovirus/training.aspx

**Stop the Spread of Norovirus Poster (for Clinicians)**

Norovirus is a highly contagious virus and the principal cause of worldwide acute gastroenteritis epidemics in all age groups. This poster can help ensure healthcare facilities and their staff are better equipped to respond to norovirus. http://patientsafety.pa.gov/pst/Pages/Norovirus/norovirus_clinicians.aspx

**Stop the Spread of Norovirus Poster (for Patients)**

Norovirus is a highly contagious gastrointestinal infection, also referred to as the "stomach flu." This poster can help patients protect themselves. http://patientsafety.pa.gov/pst/Pages/Norovirus/norovirus_patients.aspx

**Conclusion**

LTC facilities continue to struggle with annual norovirus outbreaks, despite the existence of accessible state and national resources for prevention and control of this very contagious viral infection. Considering the severe contagiousness and annual onset of norovirus, healthcare facilities are encouraged to implement strategies to help their multidisciplinary teams control initial norovirus cases before they result in an outbreak next season. The Authority encourages LTC facilities to access the Authority Patient Safety Topic on norovirus, which houses all the tools, and select a multidisciplinary team to implement the accompanying strategies to develop a strong preseason prevention and control program.

**Notes**


Safety Stories
This vignette presents a brief, timely highlight of an event reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

The Luer Lock That Wouldn't

Event*

Facility staff found that the Luer lock connection on a medical device did not stay engaged. Staff removed all stock from service and notified the manufacturer. Facility resumed use of the previously utilized product, and provided samples of both products to the manufacturer.

Opportunity

When possible, facilities are urged to consider an engineering solution in preference to staff training as a method to manage a problematic mechanical system.

* The details of the PA-PSRS event narrative in this article have been modified to preserve confidentiality.
Safety Stories
This safety story presents a brief, timely highlight of an event reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

Telemetry

Event*

Staff in a remote monitoring location identified a patient emergency. Attempts to reach nursing staff in the patient's unit by telephone were not immediately fruitful. Staff ran from the remote monitoring unit to the patient's unit to alert staff.

Opportunity

To prepare for circumstances in which staff in remote monitoring locations recognize that a patient's health may be in imminent danger, but in-person assessment of the patient's condition cannot be accomplished in a timely manner, facilities are encouraged to develop back-up processes. These could include protocols to alert rapid response or resuscitation teams.

* The details of the PA-PSRS event narrative in this article have been modified to preserve confidentiality.
Empowering Patients and Agents to Help Prevent Errors with Living Wills, DNRs, and POLSTs

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

Ferdinando L. Mirarchi, D.O., FAAEM, FACEP*
Medical Director
Department of Emergency Medicine, UPMC Hamot
Chief Medical & Scientific Officer of the Institute on HealthCare Directives
Founder of MIDEO™ (My Informed Decision on VidEO)

Corresponding Author
Regina M. Hoffman

* Dr. Mirarchi is an owner of Video Directives, LLC. Ms. Hoffman and the Editor have no financial relationship with products or services discussed in this editorial.

From the Executive Director's Desk

An unconscious patient shows up with the words "DO NOT RESUSCITATE" tattooed across his chest and goes into cardiac arrest. What do you do?

Does a little attorney sitting on your shoulder say you must resuscitate this patient because a tattoo across the chest has no legal standing? Does your own internal ethical compass tell you not to? Surely, someone who has gone to such lengths to communicate this message must mean it, right?

This real-life story engaged a doctor and myself (a nurse) on social media late one evening as the national debate around this actual event ensued. We have each written a section of this commentary.

We represent an entire healthcare community that is faced with making these critical decisions when time is of the essence. We are also forced to live with those decisions when we find out later that we had incorrect information. It is no more comforting to know a person's last moments were spent receiving medical interventions that they did not want than knowing a person was not resuscitated who wished to live.
In 2016, acute healthcare facilities in the Commonwealth reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) nearly 100 events involving the code status or treatment level of patients. Twenty-nine patients were resuscitated against their wishes. Two patients were not treated when their wishes indicated they should have been. The remaining cases represent near misses that could have affected the patient, but were resolved before harm occurred.

The Pennsylvania Patient Safety Authority is unable to verify whether the do not resuscitate (DNR) orders or physician orders for life-sustaining treatment (POLST) were appropriate, correctly created, or verified prior to these patient safety events occurring in real time.

Examples include the following:

* Failed to initiate cardiopulmonary resuscitation (CPR) or call a code. Advance directive stated patient wanted CPR.

  CPR was initiated as per electronic record stated “CPR assess needed,” so it needed to be treated as full code until otherwise ordered. RN showed code team the POLST copy and during the code, one of the ED MDs called family who stated to stop interventions at that time. Patient had already had compressions done and an attempt at starting a central line until patient and family wishes were clarified.

  Patient in ventricular fibrillation (V-fib). RN entered the patient room to find the patient unresponsive and without a pulse. A DNR bracelet was not visualized on the patient so a code was initiated along with CPR. DNR order was found and the code and CPR was immediately stopped.

* Details of PA-PRSR event narratives in this article have been deidentified to preserve confidentiality.

A Physician’s Perspective

This is yet another example of major communication failures within the larger healthcare system—failures about which patients are aware. Given the expanse of knowledge and technological capacity available to us as medical professionals, a patient should never feel the need to result to such extremes as permanently marking their body to prevent an error in over-treatment from occurring. This unfortunate situation reveals the reality of a nationwide patient safety concern related to medical errors that involve living wills and DNR and POLST orders.

Interpretation complications have caused medical errors of both over-treatment and under-treatment. Over-treatment against the patient's wishes costs the system an enormous sum of money and uses precious healthcare resources. Under-treatment results in patients not receiving aggressive treatment, resulting in injury or even premature death.

Systems must vigilantly look for these errors; if you do not look for them, you will not see them occurring. To be advocates for patient safety, we must empower patients and agents at points of entry into healthcare settings, where errors often start.

The first process error is creation of an inaccurate code status related to provider misunderstanding of patient wishes and documents. From a body of research called TRIAD (The Realistic Interpretation of Advance Directives), we know that living wills are misinterpreted nationally as DNR orders at an alarming occurrence rate of 80%. This same research reveals that DNR orders are also misinterpreted as end-of-life care orders or do not treat orders.

In the next process, two common questions are asked of patients or agents on behalf of patients after they enter a healthcare setting:

1. "Do you have a living will?"
2. "How do you want to be treated in the event of cardiac arrest?"

The first question has been propagated as a Condition of Medicare Participation, which began with the passage of the Patient Self Determination Act of 1990. The second question is meant with good intentions but is often presented in such a way that it produces a dichotomous answer of "Yes" or "No." The reality is that the answer can often be "it depends." Healthcare systems are not created to allow the "it depends" option. Nevertheless, the answer to the cardiac arrest question should be that it depends. It depends on the condition from which the patient is suffering and whether that condition might benefit from cardiopulmonary resuscitation (CPR) and advanced cardiac life support (ACLS). Note, too, that CPR differs from ACLS; the latter often includes CPR.

The third process in this critically ill versus end-of-life spectrum is the use of the POLST and its rapid deployment nationally. Across the country, systems have changed their code-status order generation to mirror what is documented on the state-approved POLST form. This has resulted in many providers trying to interpret living will documents and create code status designations. The POLST is not the same as a living will and can also be misinterpreted, resulting in both over-treatment and under-treatment medical errors.

Recently, my practice of medicine has evolved to combine evidence-based practices with patient safety initiatives, culminating in the creation of "patient-to-clinician videos." I consider this a best practice of advance care planning. I use this approach and technology to medically evaluate patients for acute end-of-life risk, risk related to interpretation errors, and risk of POLST outside of its specified indications.

The evidence-based research from the TRIAD VIII study confirms this is a best practice to prevent medical errors related to misinterpretation of documents. TRIAD VIII also confirms we can prevent the medical errors related to under-use of resuscitation (causing harm and potentially death) as well as over-use (causing harm, not allowing natural death, and wasting expensive medical resources). My medical practice further educates and trains my patients to carry documentation of their advance-directive videos with them and present this information at points of entry into the healthcare system to prevent the first error of inaccurate code-status order creation. Several companies offer video-documentation products, with varying degrees of scripting and other guidance.

If we empower patients and agents with processes to ensure their informed consent, these same patients and agents can be empowered with the answers to address these crucial initial questions. These answers at healthcare points of entry can prevent the first medical error of incorrect code-status order generation and produce enormous patient safety benefits that will be advantageous to patients and providers as well as the healthcare facilities and financial payment systems.

Additional Resources

These commentaries touch on two related aspects of advance directives and medical decision-making. One part of this process involves providing information and support to help patients articulate informed decisions about their own end-of-life care. The other part of this process is communicating the patient's current desires to healthcare providers in a comprehensive, infallible manner.

Factors that interfere with the ability of patients to communicate their medical care wishes are complex, particularly if care decisions must be made emergently or if patients have chronic or temporary cognitive impairments. These situations are frustrating for patients and their families and challenging for providers. They have been difficult to resolve because they involve nuanced medico-legal, ethical, and logistical considerations. To explore these factors in greater depth, the following resources may be useful:
• Discussion of the ethical dilemmas posed by the tattooed patient mentioned above is available online:
  http://dx.doi.org/10.1056/NEJMc1713344

• Discussion of additional factors that influence the effectiveness of do not resuscitate (DNR) decisions is available online:
  http://dx.doi.org/10.1007/s11606-011-1632-x

• Principles approved by the American College of Emergency Physicians are available online:
  https://www.acep.org/Clinical-Practice-Management/Ethical-Issues-of-Resuscitation/

• In response to a question about whether the "Pennsylvania Orders for Life-Sustaining Treatment" (POLST) form must be used, regulatory clarifications published by the Commonwealth of Pennsylvania Department of Human Services state that "Out of hospital DNRs and any document accepted by the home's local EMS [emergency medical services] responders would also be acceptable":

• A discussion of legal considerations and list of registries, including those that offer video recording, is available from the American Bar Association Commission on Law and Aging's *Bifocal* journal.

• A discussion of living wills and DNR orders published in the *Pennsylvania Patient Safety Advisory* in 2008 is online:
  http://patientsafety.pa.gov/ADVISORIES/Pages/200812_111.aspx

**Notes**


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