Reviews & Analyses

Adapting Verification Processes for Preventing Wrong Radiology Events
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_WrongSiteRadiology.aspx)
Developing and implementing verification processes specific to the medical-imaging care continuum is essential to reduce the risk of harm from wrong radiology events.

The Breakup: Errors when Altering Oral Solid Dosage Forms
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_AlteringDosage.aspx)
These errors may disproportionately impact vulnerable patient populations with dysphagia in acute care, rehabilitation, and long-term care facilities.

Speaking Up for Safety—It's Not Simple
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_SpeakingUpforSafety.aspx)
To evaluate engagement of Pennsylvania patients in common safety practices, the Pennsylvania Patient Safety Authority developed a poll, which was administered in 2006, 2013, and most recently, 2018. Reported engagement varied among the safety practices in 2018, but the ranking of the safety practices by positive inclination remained relatively consistent.

Focus on Infection Prevention

A Second Breadth: Hospital-Acquired Pneumonia in Pennsylvania, Nonventilated versus Ventilated Patients
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_NVHAP.aspx)
Recent analysis finds not only that nonventilator hospital-acquired pneumonia continues to be as lethal as ventilator-associated pneumonia, but that it demonstrates higher incidence and is more costly as a whole.

Other Features

Safety Stories: A Weighty Problem (http://patientsafety.pa.gov/ADVISORIES/Pages/201809_SafetyStories_Weight.aspx)
This vignette presents a brief, timely highlight of a patient weight event reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

Safety Stories: Site Marks (http://patientsafety.pa.gov/ADVISORIES/Pages/201809_SafetyStories_SiteMarks.aspx)
This vignette presents a brief, timely highlight of surgical site marking events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

Principles for Reliable Performance of Correct-Site Nerve Blocks
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_NerveBlockPrinciples.aspx)
An initiative between the Pennsylvania Patient Safety Authority and the Pennsylvania Society of Anesthesiologists assesses the frequency of wrong-site nerve blocks and presents Pennsylvania anesthesia providers and healthcare facilities with practices to prevent them.

A New Pairing: Root Cause and Success Analysis
(http://patientsafety.pa.gov/ADVISORIES/Pages/201809_Commentary.aspx)
Root cause analysis is commonly used in attempts to improve the safety of healthcare delivery, but a variation—success analysis—may also be useful.
Adapting Verification Processes to Prevent Wrong Radiology Events

Author
Cynthia Field, BSN, RN, NE-BC, CPHQ
Senior Patient Safety Analyst
Pennsylvania Patient Safety Authority

Abstract

Wrong radiology studies can expose patients to risks of harm, from unnecessary radiation exposure or contrast doses to delays in diagnosis or treatment. The Pennsylvania Department of Health reported that more than 16 million radiology studies were performed by Pennsylvania hospitals in 2016. This high frequency of studies and the complexities of the medical-imaging care continuum put patients at risk for wrong patient, wrong procedure, wrong site, wrong side events. The Pennsylvania Patient Safety Authority analyzed wrong radiology events reported from July 2016 through June 2017. Analysts identified 993 wrong radiology events, including near misses (i.e., events that

http://patientsafety.pa.gov/ADVISORIES/Pages/201809_WrongSiteRadiology.aspx
The events occurred across the imaging process, from the initial step of ordering through performing the study to the final step of communicating results. Errors involved system failures related to identifying patients and ordering and verifying procedures, including study type, body site, and laterality. Contributing factors cited in event-report details included increased workload, miscommunication, complexities related to healthcare technologies, and studies performed outside of radiology departments. Developing and implementing verification processes specific to the medical-imaging care continuum is essential to reduce the risk of harm from wrong radiology events.

Introduction

The Pennsylvania Patient Safety Authority received a request from a Pennsylvania healthcare facility for an analysis of wrong radiology safety events (e.g., wrong patient, wrong procedure, wrong site, wrong side events) reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS). The request cited a previous Pennsylvania Patient Safety Advisory article (http://patientsafety.pa.gov/ADVISORIES/Pages/201106_63.aspx) that identified 652 radiology/imaging events reported through PA-PSRS in calendar year 2009 (CY2009).

Analysts queried the PA-PSRS database for recent reports of wrong radiology events using criteria similar to that used to analyze the 2009 data. Analysts' review of the PA-PSRS data identified almost 1,000 wrong radiology imaging events reported during a 12-month period. This article will provide an analysis of wrong radiology events submitted through PA-PSRS in academic year 2017 (AY2017; July 2016 through June 2017).

The current analysis classified the events' stage, based on where along the medical-imaging care continuum the events occurred, and contributing factors associated with the events. This analysis highlights the need for harm-prevention strategies specific to radiology procedures, for which typical procedural time-out processes are challenging to implement because of a team structure that is often distributed across physical locations and time.

Methods

Analysts queried the PA-PSRS database for radiology events reported by Pennsylvania healthcare facilities from July 1, 2016, through June 30, 2017, and identified 1,700 events that mentioned radiology or interventional radiology errors. Of the 1,700 events, structured data-field analysis identified 630 wrong radiology events based on event type and subtype categories (e.g., wrong patient, wrong procedure, wrong site, wrong side). Review of free-text event details in the remaining events identified 363 additional reports of wrong events, for a total of 993 wrong radiology events.

Wrong Radiology Event Type

The query was expanded for this analysis compared to the CY2009 analysis, with criteria for the wrong radiology events defined as follows:

Wrong Patient

- Study ordered and/or performed on the wrong patient
- Wrong patient record selected (e.g., study performed using the wrong patient record, study results documented in the wrong patient record)
- Wrong patient transported to radiology/imaging department
Wrong patient scheduled for a study

Wrong Procedure

- Wrong study protocol performed—that is, specific protocols or study series based on patient diagnosis and/or physician preference (e.g., dissection protocol, scan protocol for atrial fibrillation ablation, navigation protocol) performed incorrectly

- Wrong study performed (e.g., computerized tomography [CT] versus magnetic resonance imaging [MRI], barium study versus video barium study, weight-bearing versus non-weight-bearing, three-view versus five-view studies)

- Incorrect contrast used

- Study completed with contrast versus without contrast

- Unnecessary study performed (e.g., unintended duplicate studies, old study orders that were completed in error, earlier orders placed and not cancelled until after the study's completion)

Wrong Site

- Study ordered and/or performed on an incorrect body part or location, (e.g., head versus chest, lumbar versus cervical spine, first versus fourth finger)

Wrong Side

- Study ordered and/or performed on the wrong side (e.g., left versus right, left or right versus bilateral)

- Incorrect laterality identified on images using lead x-ray markers

- Laterality incorrectly identified in study reports

Wrong Time

- Study not performed at the time specified in the order or based on the imaging protocol
  - Study ordered to be done after a procedure but done before the procedure occurred (e.g., chest tube removal, central line or endotracheal tube placement, surgery)
  - Study ordered to be performed after specific patient preparation completed and the study was delayed because the patient was not appropriately prepared or the study was done before the appropriate preparation was completed (e.g., patient fasting, MRI screening, fluid hydration)

- Study ordered STAT (emergently) that was delayed

- Delayed reading of the study

- Delayed communication of critical findings

- Delayed performance or completion of the study due to insufficient resources (e.g., time, personnel, supplies, medication)
Analysts excluded reports of injury from devices or equipment (e.g., bumping the patient's head, skin tears). Also excluded were reports of the following patient issues: changes in patient status (e.g., fainting, dizziness, anxiety, chest pain, seizures), allergic reaction or adverse events from contrast, pregnancy screening issues, and intravenous infiltration or extravasation of contrast. Finally, reports of technical issues with images (e.g., lost, overexposed) and contrast issues (e.g., syringe loaded incorrectly) also were excluded.

Events of wrong-result reporting that addressed incorrect patient identification, laterality, or site (e.g., right side was imaged but resulted as left side) were included; however, resulting errors related to diagnostic error were excluded.

Similar to stages of an Imaging Care Cycle described by Jones, the stages for this article have been classified as follows:

- Preprocedure (study ordering, requesting, scheduling)
- Procedure (patient registering, imaging, processing)
- Postprocedure (image resulting and communication of results)

The total number of inpatient, and outpatient radiology procedures was obtained from the Pennsylvania Department of Health, Division of Health Informatics' annual hospital questionnaire.

**Results**

Analysis of the data identified 993 wrong radiology events reported in AY2017. Figure 1 shows the number of the reports identified in the CY2009 data analysis (n = 652) and the AY2017 data analysis (n = 993).
In the current analysis, more than half of the wrong radiology errors (51.2%, n = 508 of 993) were reports of wrong-patient and wrong-side events. The most common wrong imaging events involved radiography studies (44.5%, n = 442) and CT scans (24.5%, n = 243). Figure 2 shows PA-PSR events from AY2017 by the type of wrong event and radiologic study involved.

* Data reported through the Pennsylvania Patient Safety Reporting System.
* The database query was expanded for AY2017 to include wrong-time events because this category had a significant number of events with patient outcomes similar to other wrong radiology events.

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* Data reported through the Pennsylvania Patient Safety Reporting System, July 1, 2016, through June 30, 2017.
Although AY2017 PA-PASR data indicates a higher incidence of radiography and CT errors than for other types of imaging studies, this does not represent a higher event rate because Pennsylvania Department of Health reporting of CY2016 imaging data identifies diagnostic x-rays and CT scans as the two most common types of radiologic procedures performed at Pennsylvania facilities.\(^3\)

The total number of inpatient, and outpatient procedures as reported by Pennsylvania hospitals for CY2016 to the Pennsylvania Department of Health Division of Health Informatics' annual hospital questionnaire are as follows:\(^4\)

- Diagnostic x-ray 9,337,684
- CT scan 3,521,923
- Ultrasound 2,519,280
- MRI exam 1,052,614
- Diagnostic and therapeutic nuclear medicine use 351,255

Of the 993 wrong-site radiology events, 646 (65.1%) reached the patient (i.e., the study was initiated or completed before the error was identified). An additional 328 events (33.0%) were reported as near misses (i.e., a circumstance that might have caused harm but did not reach the patient due to chance alone or active recovery efforts by caregivers\(^5\)). The remaining 19 (1.9%) event reports contained insufficient detail to determine whether the error reached the patient.

The 993 wrong radiology events included 85 reports of studies completed at the wrong time, an event type that was not included in the 2009 data analysis.

**Medical-Imaging Care Continuum: Preprocedure, Procedure, Postprocedure**

Analysis of wrong-site radiology events reported through PA-PSRS identified that errors occurred at single or multiple points along the stages of the medical-imaging care continuum.

Identifying the occurrence points along the continuum helps to determine areas of focus for prevention strategies. Over half of the events occurred during the procedure stage, and the three most common events types occurring during the procedure stage were wrong patient, 30.5% (n = 174 of 571); wrong side, 23.5% (n = 134); and wrong site, 21.9% (n = 125).

Figure 3 shows examples of event details from the PA-PSRS database as they occurred along the medical-imaging care continuum.
Figure 3. Wrong Radiology Events Along the Medical Imaging Care Continuum

Preprocedure 38.3% (n = 367 of 993)

CRNP ordered CT chest w/contrast - indication was R/O PE. Order needed to be changed to CTA for PE.

Patient arrived with a STAT script but study ordered as routine. Script was for left hand but right hand was ordered. Orders corrected.

MD is not in the system, so an order cannot be entered through EMR health, instead order goes to a scheduler to be transcribed and scheduled. MD ordered a pelvic ultrasound but the order was transcribed as an ultrasound of the abdomen, which does not include the bladder.

Scheduling

Ordering

Paper Prescription

Electronic

Phone or Fax

The PA wrote an order on the wrong infant. The error was found after the x-ray was done so the patient received an x-ray she didn't need.

Pt ordered CT of head with NO contrast as a telephone order. RN entered incorrect order, entered as CTA with contrast. Pt had BUN of 29. MD notified of error and ordered IV fluids to decrease risk of kidney injury.

Patient on ventilator arrived to radiology via EMS. Wrong imaging was scheduled by the nursing home. US unable to do the procedure. Patient transported to the ED per radiologist.

Procedure 57.5% (n = 571 of 993)

Both father and son have the same month and day for their birthday. Registration accidently ordered a chest x-ray on the father but was actually for the son. This was a near miss as the problem was caught by the technologist when checking the name and date of birth before the x-ray was performed.

Wrong pt was taken from CT scan to radiology for x-rays. Did not double check the ID band and request. Pt was unable to communicate due to his medical condition. Exam was done before realizing we had the wrong pt.

When the patient came into radiology, she was coughing. I did not look closely at the order. I started performing a chest x-ray when I realized she was actually ordered for an x-ray of the knee. Her mother was notified of the mistake.

Imaging

Registering

Script had read x-ray of the right foot, registration ordered the x-ray of the left foot. One view of the left foot was x-rayed before the error was caught.

The patient was brought into the room and the father verified the patients ID and that it was the right foot and ankle to be imaged. The father took off the patient's sock and shoe. The imaging was started and I realized the wrong side had been x-rayed.

A patient came to the emergency department with a brain bleed. He had a history of diabetes and hypertension. A CT of pelvis and abdomen w/contrast was done but not ordered for him. He developed renal failure requiring dialysis treatments X 3 and monitoring in the ICU for 6 days.

Postprocedure 2.0% (n = 19 of 993)

X-ray report sent to orthopedics and found that the interpretation appeared to be wrong: ankle vs. shoulder.

MRI of the right thigh performed but read as left thigh.

Patient had chest x-ray completed and results faxed with the patient name and correct exam but had results of a Doppler study done on another patient. The image report on the electronic chart is correct.

Resulting

Communicating Results

RN from PICU notified radiology regarding portable chest x-ray performed on her patient. Stated that the report reflects an ETT, but his patient does not have an ETT in place. Appears that the radiologist dictated the report on the wrong patient.

Script transcribed over the phone from an external provider. Code provided has several options under the ICD-10 code. No descriptive words on the script, scheduler chose the incorrect descriptive under the code and the report went to physician with incorrect diagnosis.

Note: The details of the Pennsylvania Patient Safety Reporting System (PA-PSRS) event narratives in this figure have been modified to preserve confidentiality. Data reported through PA-PSRS, July 1, 2016, through June 30, 2017.

BUN, blood urea nitrogen level; CRNP, certified registered nurse practitioner; CT, computed tomography; CTA, computed tomography angiography; ED, emergency department; EMR, electronic medical record; EMS, emergency medical services; ETT, endotracheal tube; ICU, intensive care unit; ID, identification; IV, intravenous; MRI, magnetic resonance imaging; PA, physician assistant; PICU, pediatric intensive care unit; Pt patient; R/O PE, rule out for pulmonary embolism; US, ultrasound.

*Discussion of insufficient event narrative details, Pennsylvania Patient Safety Authority analysts were unable to classify 36 of the 983 events by stage. Stage classification was limited by the use of variables and undefined terms to describe radiology processes in the event narratives.
Contributing factors cited in the radiology event report details included the following:

- Increased workload
- Limited resources (e.g., personnel, contrast media)
- Miscommunication between healthcare providers
- Patient or family miscommunication (e.g., patient incorrectly identified the extremity to be imaged, patient was unable to communicate their identity due to altered mental status, patient misunderstood the study to be done because of a language barrier)
- Health information technologies (e.g., platforms that don't interface, selection of wrong patient in the electronic record, selection of incorrect study for indication)
- Studies performed outside of the radiology department (e.g., events related to completing portable x-rays on the wrong patient because a patient moved to a different room)

Limitations

The wrong-radiology event data analysis is limited by the information reported through PA-PSRS: The number of reports, type of events, and narrative details analyzed for this article depend on individual facility reporting practices. The increased numbers of wrong radiology events reported in this analysis may also be attributed to the expanded AY2017 database query.

The ability to accurately calculate a rate of event occurrence is limited by differences in report years: AY2017 PA-PSRS event data versus CY2016 Pennsylvania Department of Health annual hospital questionnaire data.

Discussion

Most strategies in the literature intended to prevent wrong-site radiology events focus on interventional radiology (IR) procedures, which often involve teams of radiology staff with roles specific to the IR location and procedures. Literature review found fewer articles addressing strategies for preventing wrong-site radiology events outside of the IR suite.¹ ² ³ ⁴ ⁵ ⁶

Analysis of the PA-PSRS data highlights the complexity of radiology imaging involving nonstandard "procedural" teams—for example, a radiology team consisting of a bedside nurse assisting a radiology technologist performing an x-ray study with a portable machine. Lack of standardized team roles and time-out processes may contribute to the occurrence of wrong radiology events and may lead healthcare providers to incorrectly perceive a low risk of patient harm associated with radiology imaging.
Although free-text event narratives often stated no or little harm to patient, the consequences of repeated exposure to radiation, the potential side effects due to an incorrect contrast or isotope, or a delay in availability of the correct imaging study can negatively impact the patient. Perception of low patient harm may also be due to the lack of immediacy of harm, because outcomes of harm in these circumstances may not present until months or years after the wrong radiology event.

**Risk of Harm from Exposure to Radiation**

In many of the reported events, patients were exposed to unnecessary and/or additional radiation (i.e., patients did not need the imaging study or patients had incorrect imaging studies performed and needed more imaging to complete the correct study). Although research has shown there is not a specific cancer-causing dose of radiation exposure, scientific evidence supports the theory that repeated exposure to radiation increases the risk of cancer. The American Cancer Society states on its website, "Most scientists and regulatory agencies agree that even small doses of gamma and x-radiation increase cancer risk. In general, the risk of cancer from radiation exposure increases as the dose of radiation increases." Similarly, the BEIR VII Phase 2 (2006) Consensus Study Report found there was "a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans." Based on these findings, the risk of cancer could be higher for patients who undergo imaging studies that are frequently repeated and studies that have higher doses of radiation, such as CT scans, fluoroscopy, and nuclear medicine studies. Linet and co-authors estimate that the average effective dose for a single CT scan of the head would be equivalent to the effective dose of 150 chest x-ray studies. Unnecessary radiation exposure from an added or repeated CT scan would have greater impact than a single additional x-ray study.

**Risk of Harm from Administration of Contrast Agents**

Incorrect or unintentionally administered contrast agents increase risk of renal failure in patients who have been inadequately screened for impaired renal function and/or have not had proper preprocedure preparation, such as discontinuation of contraindicated medications (e.g., metformin), completion of laboratory testing, and administration of premedication regimens or isotonic crystalloid fluids (e.g., normal saline).

Receiving unintended or incorrect contrast also exposes patients to the unnecessary risks of adverse reactions and contrast-media extravasation associated with contrast administration. Reports of events of ordered contrast not given and reports of contrast given unintentionally often resulted in repeating the procedure, which also puts the patient at risk for harm associated with increased radiation exposure.

**Risk of Harm from Delay of Radiology Procedure**

Wrong radiology events may contribute to delayed or missed diagnosis, which can lead to harm from delay of care or from the initiation of incorrect interventions.

**Risk Reduction Strategies**

Physicians, radiology technologists, nurses, inpatient transporters, and other healthcare providers involved in radiology imaging procedures need processes that improve patient safety, minimize impact to workflow, and are user friendly. The authors of the Advisory article, "Applying the Universal Protocol to Improve Patient Safety in Radiology Services," suggested implementing safety processes and checklists for radiology imaging that include elements of verification similar to those in the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.
A review of the literature found articles describing use of verification processes and checklists for imaging studies that are similar to those used in surgery. For example, Rubio and Hogan found that implementing a brief two-person verification approach significantly decreased wrong-patient and wrong-study radiology events.\footnote{Rubio and Hogan found that implementing a brief two-person verification approach significantly decreased wrong-patient and wrong-study radiology events.}{16}

A presentation at the Radiological Society of North America 2015 annual meeting reported that a hospital in the Generations and Northern Manhattan Network of Bronx, New York, implemented a "Radiology Exam Verification and Time Out" process. This time-out by the radiology technologist and another healthcare provider occurs at the location of the study (e.g., radiology area, neonatal unit, emergency department) and includes a two-person verification of patient identifiers, procedure to be performed, site, laterality, site marking, contrast (orders and expiration date if applicable) and pregnancy screening. Both the technologist and witness initial each item of verification then sign an acknowledgement that all the steps of verification were completed.\footnote{A presentation at the Radiological Society of North America 2015 annual meeting reported that a hospital in the Generations and Northern Manhattan Network of Bronx, New York, implemented a "Radiology Exam Verification and Time Out" process. This time-out by the radiology technologist and another healthcare provider occurs at the location of the study (e.g., radiology area, neonatal unit, emergency department) and includes a two-person verification of patient identifiers, procedure to be performed, site, laterality, site marking, contrast (orders and expiration date if applicable) and pregnancy screening. Both the technologist and witness initial each item of verification then sign an acknowledgement that all the steps of verification were completed.}{17}

Einstein Healthcare Network of Philadelphia, Pennsylvania, has developed a clinical decision support process for ordering CT scans. The tiered approach uses two different platforms, an evidenced-based algorithm embedded in the electronic medical record (EMR) to help clinicians decide whether a CT scan is indicated and a clinical decision support imaging tool which advises whether or not an ordered scan is appropriate. The utilization of these platforms standardizes advanced radiologic procedure clinician ordering, with the intent to decrease exposure to unnecessary radiation and improve workflow, which could significantly decrease wrong-procedure errors.\footnote{Einstein Healthcare Network of Philadelphia, Pennsylvania, has developed a clinical decision support process for ordering CT scans. The tiered approach uses two different platforms, an evidenced-based algorithm embedded in the electronic medical record (EMR) to help clinicians decide whether a CT scan is indicated and a clinical decision support imaging tool which advises whether or not an ordered scan is appropriate. The utilization of these platforms standardizes advanced radiologic procedure clinician ordering, with the intent to decrease exposure to unnecessary radiation and improve workflow, which could significantly decrease wrong-procedure errors.}{18}

As in the analysis of 2009 data, this current analysis found that the errors were caused by process failures (e.g., incorrect order or requisition entry, failure to confirm patient identity) which occurred at any point of patient interaction or care during the continuum stages. Strategies to decrease the risk for wrong radiology events should include developing verification processes specific to the radiology services environment, resources, and medical-imaging care continuum. Creating a culture of safety, which encourages reporting and sharing of radiology safety events by staff (including near miss events), provides opportunities to learn about and reduce risk of harm to patients. Analysis by radiology staff of wrong radiology events and where they occur along the facility's medical-imaging care continuum can identify areas of vulnerability and points along the continuum where implementing a verification process might decrease the risk of wrong radiology events.\footnote{As in the analysis of 2009 data, this current analysis found that the errors were caused by process failures (e.g., incorrect order or requisition entry, failure to confirm patient identity) which occurred at any point of patient interaction or care during the continuum stages. Strategies to decrease the risk for wrong radiology events should include developing verification processes specific to the radiology services environment, resources, and medical-imaging care continuum. Creating a culture of safety, which encourages reporting and sharing of radiology safety events by staff (including near miss events), provides opportunities to learn about and reduce risk of harm to patients. Analysis by radiology staff of wrong radiology events and where they occur along the facility's medical-imaging care continuum can identify areas of vulnerability and points along the continuum where implementing a verification process might decrease the risk of wrong radiology events.}{2}

Verification processes should include confirmation that all sources of information relevant to the planned imaging agree, including the written order or prescription, the electronic order, the documentation or electronic record, and the patient or parent report. Every detail (patient identifiers; procedure to be completed, including laterality and site; reason for the procedure) from each source should agree. Any discrepancies should be resolved before the procedure is initiated.\footnote{Verification processes should include confirmation that all sources of information relevant to the planned imaging agree, including the written order or prescription, the electronic order, the documentation or electronic record, and the patient or parent report. Every detail (patient identifiers; procedure to be completed, including laterality and site; reason for the procedure) from each source should agree. Any discrepancies should be resolved before the procedure is initiated.}{19}

A link to Authority resources for radiology imaging verification, an example of the Generations and Northern Manhattan Network's "Radiology Exam Verification and Time Out" form, and other guidance materials are provided in Supplemental Material.

**Conclusion**

Wrong radiology events can occur during any process and stage of the medical-imaging care continuum. Addressing system issues and implementing verification processes along the continuum can prevent harm from wrong radiology events. Verification of patient identification, correct imaging, and preprocedure preparation should occur at multiple points along the continuum, and processes need to address the specific challenges of completing time-outs in the radiology imaging setting.

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http://patientsafety.pa.gov/ADVISORIES/Pages/201809_WrongSiteRadiology.aspx
Using verification processes and checklists in the diagnostic radiology setting has been reported as an effective strategy for reducing wrong-site events. A key concept for any radiology verification process is verifying patient and procedure details at every point along the medical-imaging care continuum. If the patient’s identity cannot be verified or if information conflicts in the source documents, radiology teams are encouraged to stop the process and seek clarification before proceeding with any imaging study.

Notes


Supplemental Material

- Applying the Universal Protocol to Improve Patient Safety in Radiology Services (/ADVISORIES/Pages/201106_63.aspx)
- Example: Radiology Exam Verification and Time Out (/pst/Pages/Radiology_Universal_Protocol/checklist.aspx) from Generations + Northern Manhattan Network Lincoln Medical and Mental Health Center
The Breakup: Errors when Altering Oral Solid Dosage Forms

Authors
Viktoriya Ingram, PharmD, FISMP
Medication Safety Analyst

Michael J. Gaunt, PharmD
Sr. Medication Safety Analyst

Matthew Grissinger, RPh, FISMP, FASCP
Manager, Medication Safety Analysis

Pennsylvania Patient Safety Authority

Abstract

Altering oral solid dosage forms of medications may be required to meet patient-specific doses, help patients who have swallowing issues, or facilitate administration via enteral feeding tubes. However, this step increases the risk of errors and adverse events. Analysts identified 621 events involving altered solid dosage forms of medications in reports submitted to the Pennsylvania Patient Safety Authority, which occurred from January 2006 through September 2017. Nearly three-quarters (73.9%, n = 459) of events were associated with splitting tablets, while crushing tablets (24.3%, n = 151) and opening capsules (1.8%, n = 11) accounted for the remainder. Almost 90% (87.1%; n = 541) of events reached patients, and 28.2% (n = 175) involved high-alert medications. Overdose and extra dose represented the most commonly reported event types associated with splitting medications (71.5%, n = 328 of 459). More than half of events involved older patients (65 years or older; 56.0%, n = 348 of 621), which is consistent with the higher incidence of dysphagia in this population. Potential risk reduction strategies include using technology to provide patient information (e.g., limitations in swallowing) and drug information to providers, limiting oral dosage form alterations to cases in which commercial alternatives are unavailable, dispensing medications in patient-specific doses to minimize preparation on patient care units, and implementing procedures to handle dosage-form alterations and administration via feeding tubes.

Introduction

Although medications commercially available in oral solid dosage forms are suitable for most patients, there are populations and circumstances that require splitting tablets, crushing tablets, or opening capsules. For example, pediatric and geriatric populations may require dosage strengths that are not commercially available. Variable dosing during dose titration or tapering to prevent withdrawal symptoms may also result in the need to split tablets (e.g., for older patients, a 50 mg tablet must be split to administer trazodone 25 mg initially or as a last dose when tapering
antidepressant therapy). Further, tablets are sometimes split to avoid delays in drug administration while awaiting pharmacy delivery. In addition, pharmacies may not carry all of the commercially available strengths for all products.\textsuperscript{1-3} There may be times when patients receive medications through a feeding tube or are unable to swallow whole tablets but liquid medication formulations are unavailable.\textsuperscript{2}

Inappropriately altering tablets and capsules can result in treatment failure and patient harm. For example, altering enteric-coated (e.g., delayed-release) tablets can result in local irritation, loss of drug stability, and failure of proper absorption. Altering film- and sugar-coated tablets can result in medication instability and unacceptable taste. Some extended-release capsules can be opened, as long as the pellets inside are not damaged, while others should never be opened, to prevent changes in pharmacokinetics and bioavailability.\textsuperscript{2,4-6} Altering hazardous drugs (e.g., chemotherapy, drugs posing a risk of reproductive or developmental harm) raises concerns of occupational health and safety for the healthcare provider.\textsuperscript{7,8} Relying on personal or coworker experience rather than consulting a pharmacist or administration guidelines, if available, contributes to nonstandard practices and increases the risk of improper medication preparation and administration and drug incompatibilities when administered with enteral feedings.\textsuperscript{2,4,5,9-12}

Risks with splitting oral solid dosage forms include missed or misinterpreted administration instructions (e.g., give “1/2”) and dose deviations, which may be especially dangerous with drugs that have narrow therapeutic indexes.\textsuperscript{2,13,14} (Narrow therapeutic index drugs, such as warfarin and levothyroxine, are medications for which small differences in dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that result in persistent or significant disability or incapacity or are even life threatening.\textsuperscript{15})

In 2016, the U.S. Food and Drug Administration (FDA) reported significant dose variations when tablets are split.\textsuperscript{16,17} The Veterans Administration National Center for Patient Safety (VA NCPS) looked at reports of splitting medications and found that patients frequently forgot to split tablets, which resulted in overdose and adverse drug events, or healthcare providers chose the wrong formulation for splitting (e.g., extended release).\textsuperscript{18} High-alert medications, drugs that bear a heightened risk of causing significant patient harm when used in error,\textsuperscript{19} were involved in about one-quarter of events, and about half of those cases mentioned medications that had commercially available strengths that could have been used without alteration.\textsuperscript{18}

In addition to inappropriate manipulation of oral solid dosage forms at the point of administration, prescribers and pharmacists have less ability to prevent medication errors when patient information (e.g., presence of a feeding tube) is not readily available and medications are not matched to the patient’s conditions.\textsuperscript{2,13,16} In a retrospective chart review, Li et al. found that, among patients for whom pharmacists were not informed that they were receiving their medications via feeding tubes, 43% received one or more medications that should not be crushed.\textsuperscript{20} Dysphagia, or difficulty swallowing, a common disorder in older patients, is frequently unidentified.\textsuperscript{21-23} With aging populations on the rise, the need to identify and address swallowing issues in medication administration becomes increasingly important.\textsuperscript{21,24,25}

This article will review medication errors and other events associated with altered oral solid dosage forms, identify the reasons the events took place, encourage the use of best practices when oral dosage forms need to be altered, and propose risk reduction strategies.

\textbf{Methods}
Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events reported as medication errors and adverse drug reactions in which the free-text data fields (e.g., event description) included variations of and wildcards for the following keywords: open, crush, break, split, cut, pill, tablet, capsule, half, and ½. In addition, analysts queried a convenience sample from the database for all event types in which an analyst had previously identified the event as an alteration of oral solid dosage forms. The search was limited to events that occurred from January 2006 through September 2017.

The search returned 987 events. A total of 366 events were excluded because they described ——

- Nondrug events (e.g., crush injury).
- Events with other dosage forms (e.g., injectables, patches).
- Events not involving dosage-form modifications (e.g., two tablets instead of one).
- Other unrelated events (e.g., fragmented pills found in an automated dispensing cabinet [ADC]).

Six hundred twenty-one events involved alteration of oral solid dosage forms, meeting the inclusion criteria, and were included in the final analysis.

The medications involved in the reports were provided by the reporting facilities and were standardized by an analyst to generic names specifying modified-release dosage forms (i.e., delayed release, extended release), if applicable. When a medication-name data field was blank, but the name was provided in the event description, an analyst adjusted the medication name field for data analysis. The reporting facility provided the harm scores,26 which are adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) harm index27, as well as facility type, patient care area, patient age, node of medication-use process, event type, event description, and whether students or new nurses were involved.

Reports were categorized into type of dosage form alteration (i.e., crushing, splitting, opening) and routes of administration (i.e., enteral feeding tube, oral) based on analysis of the event description. Event reports were then categorized into two types: dosage forms that can be altered and dosage forms that should not be altered.

The appropriateness of each medication alteration and commercial availability of alternative medication strengths and formulations were evaluated using the web-based electronic drug information resources DailyMed (U.S. National Library of Medicine, Bethesda, MD)28 and Lexicomp® Online (Wolters Kluwer Clinical Drug Information, Inc., Hudson, OH)29 as well as the Institute for Safe Medication Practices' (ISMP) Oral Dosage Forms That Should Not Be Crushed 2016 list.30 When reports specified that the medication should not be crushed but analysts could not find any supporting references, the medication was categorized as "OK to crush" (e.g., raNITIIdine).

Analysts identified reports involving high-alert medications based on ISMP's lists of high-alert medications in acute care and long-term care settings.19,31 Analysts identified reports involving hazardous medications based on the list provided by the National Institute for Occupational Safety and Health (NIOSH)7 and Lexicomp® Online.29 Analysts identified risk factors and potential prevention strategies based on event descriptions and event recommendations provided by the reporters.

Results
According to reporter-assigned harm scores, 87.1% (n = 541 of 621) of events reached the patient (harm scores C through I; Figure 1). Fewer than 1% (0.6%, n = 4) of the events were marked by reporters as causing patient harm (harm scores E through I). However, there were 14 reports categorized with harm score C or D that described apparent patient harm in the event description. When combined, 2.9% (n = 18) of the reported events were associated with patient harm. Ten reports indicated patients received four times the prescribed dose. One report mentioned that a patient received a 10-fold overdose. Following is the example, reported through PA-PSRS:*: 

*Patient to receive clonidine 30 mcg stat. Attending physician entered order for clonidine 30 mcg suspension, via oral gastric tube every 8 hours, STAT. In product selection area, chose [100 mcg] tablet form. Pharmacist saw order sentence specifying suspension, but dispensed [3] tablets since that was the product selected in the order. When med dispensed on unit, label on bag read: clonidine 30 mcg = 0.3 tabs. All 3 doses for the day were in the bag. Nurse crushed/diluted all 3 tabs and gave them. Error was realized promptly, and the OG [orogastric] tube was aspirated. MD aware. No further interventions or harm. No bp [blood pressure] or VS [vital signs] changes. Per MD, dose given (300 mcg) is within daily limits.

Figure 1. Harm Scores for Events Involving Alteration of Solid Oral Dosage Forms (N = 621)

<table>
<thead>
<tr>
<th>Incident</th>
<th>Serious Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (1.3%)</td>
<td>4 (0.6%)</td>
</tr>
<tr>
<td>B1 (0.2%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>B2 (11.4%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>C (55.6%)</td>
<td>192 (30.9%)</td>
</tr>
<tr>
<td>D (0.6%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>E (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>F (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>G (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>H (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>I (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

Note: Data reported through the Pennsylvania Patient Safety Reporting System; events occurred January 2006 through September 2017.

The top facility types identified in event reports were acute care hospitals (75.0%, n = 466 of 621), rehabilitation hospitals (11.9%, n = 74), and long-term acute care hospitals (LTAC; 7.4%, n = 46). Figure 2 shows the most commonly reported patient-care areas, representing 68.0% (n = 422 of 621) of events. More than half of events involved older patients (65 years or older; 56.0%, n = 348), while a minority (4.8%, n = 30) involved pediatric patients (younger than 18 years).
High-alert medications, including opioids, hypoglycemic agents, and anticoagulants, were involved in 28.2% (n = 175 of 621) of events. Almost 5% (4.7%, n = 29) of events involved a narrow therapeutic index drug. Hazardous medications were involved in 11.6% (n = 72) of events. Nearly three quarters (73.9%, n = 459) of the events involved splitting of medications. The remainder of the reports involved either crushing a medication (24.3%, n = 151) or opening a capsule (1.8%, n = 11).

Four hundred thirty (69.2%) reports specified that errors took place during the administration node. Students and new nurses were involved in a small number of events (4.2%, n = 26 of 621).

Patients and family members helped identify or prevent errors in five reports (0.8%). However, patients also contributed to a small number of events. Nineteen reports (3.1%) specified a patient as the one altering the solid dosage form. Following is an example of such an event reported through PA-PSRS:

*Patient reported to be chewing phenytoin extended-release capsules. Pharmacy made aware. Geriatrics and trauma made aware. Phenytoin free level drawn and medication changed to liquid form.*
In two cases, nurses altered OxyCONTIN® (oxyCODONE extended release) per patient’s request. Following is an example of such an event reported through PA-PSRS:

Apparently told nurse she crushes her OxyCONTIN for administration as an outpatient. Nurse administered crushed tablet. Patient developed a change in mental status and was given Narcan® [naloxone] X 3.

Splitting Medications

A majority (73.9%, n = 459 of 621) of the events were related to splitting or failure to split medications. Figure 3 shows the medications commonly involved in these events. Overdose and extra dose represented the most commonly reported event types associated with splitting medications (71.5%, n = 328 of 459; Figure 4). Analysts identified that patients were harmed in 1.1% (n = 5 of 459) of reports. High-alert medications were involved in 26.1% (n = 120 of 459) of the reports, almost half (43.3%, n = 52 of 120) of which were long-acting opioids.

Commercially available products and strengths could have been used without alteration in 31.6% (n = 145 of 459) of the events. Misinterpreting or missing directions to administer ½ tablet was specified in 10.7% (n = 49) of reports and involved all stages of the medication-use process, including medication reconciliation, prescribing, transcribing, and administration stages.

Following are examples of events involving splitting of medications reported through PA-PSRS:

Digoxin entered incorrectly into [electronic health record] and confirmed as correct. 0.125 mg 1/2 tablet ordered. 0.125 – 1 1/2 tabs entered. The patient received 3x ordered dose for one dose.

Order read glipiZIDE 2.5 mg 1/2 tab. Nurse dispensed 1/2 tablet of a 2.5 mg tablet = 1.25 mg. This order should have been clarified when written. Physician meant 1/2 tablet of a 5 mg tablet = 2.5 mg. order was clarified one hour post med administration.
Figure 3. Ten Most Common Medications Associated with Events Involving Splitting of Solid Oral Dosage Forms (N = 459)*

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CionazePAM</td>
<td>28 (6.1%)</td>
</tr>
<tr>
<td>Metoprolol tartrate</td>
<td>23 (5.0%)</td>
</tr>
<tr>
<td>OxyCODONE extended release†</td>
<td>20 (4.4%)</td>
</tr>
<tr>
<td>Metoprolol, not specified</td>
<td>18 (3.9%)</td>
</tr>
<tr>
<td>ALPRAZolam</td>
<td>17 (3.7%)</td>
</tr>
<tr>
<td>LORazepam</td>
<td>14 (3.1%)</td>
</tr>
<tr>
<td>Metoprolol succinate</td>
<td>11 (2.4%)</td>
</tr>
<tr>
<td>Morphine extended release†</td>
<td>11 (2.4%)</td>
</tr>
<tr>
<td>OxyCODONE†</td>
<td>11 (2.4%)</td>
</tr>
<tr>
<td>Sotalol</td>
<td>11 (2.4%)</td>
</tr>
</tbody>
</table>

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System; events occurred January 2006 through September 2017.

* Percentages in the figure are based on N = 459 medication-associated events involving splitting of solid oral dosage forms. The number of events (n = 164 of 459) represented in the figure corresponds to the 10 most commonly reported medications.

† A high-alert medication.
A majority (80.6%, n = 370 of 459) of the events related to splitting medications involved oral dosage forms that can be split but were not when dispensing or administering the patient's specific dose. Almost one in five (17.6%, n = 65 of 370) reports specifically stated that a medication was not dispensed in a split form. In other event descriptions, it was unclear why medications were not available in a patient-specific dose, although a few reported that whole tablets from a supply of previous (discontinued) doses were used. Reporters described in 12.7% (n = 47 of 370) of the events that errors occurred despite use of a barcode medication administration (BCMA) system. In these events, reporters documented the following as factors contributing to practitioners administering more medication (e.g., a whole tablet, two halves of a tablet) than prescribed:

- Medication administration takes place before barcode scanning.
- Practitioners are not looking at the computer screen when a product is scanned.
- Barcode scanners malfunction.

Note: Data reported through the Pennsylvania Patient Safety Reporting System, events occurred January 2006 through September 2017.
Practitioners misunderstand the system warnings.

There is pressure to multitask.

Distractions occur.

A few events involved medications that can be split, but selection of an inappropriate tablet strength precluded dividing tablets accurately, as seen in the following example:

*Patient was ordered warfarin 1.25 mg PO q PM [by mouth, once every night]. When medication was verified in [the pharmacy computer system], the order defaulted to a warfarin 2 mg tablet. [For five days] multiple nurses vended warfarin 2 mg tablets from the automated dispensing machine. In order to achieve the 1.25 mg dose from a 2 mg tablet, 0.63 tab would need to be administered. All doses were charted as given on the MAR [medication administration record] as 1.25 mg. The pharmacy was not contacted by the nursing staff to make any adjustments to the order to obtain the appropriate tablet size (2.5 mg) that could be split in half to achieve the ordered 1.25 mg dose. The patient's INR [international normalized ratio] subsequently rose to a peak of 6.1 [most common target INR ranges, depending on diagnosis, are 2 to 3 and 2.5 to 3.5] and he required PO vitamin K.*

Among these 370 reports, prescribed dosage strengths were commercially available in more than one-quarter of cases (26.5%, n = 98).

**Do Not Split**

Almost one in five events (19.4%, n = 89 of 459) involved medications that should not be split. A few reported events involved the accidental selection of an extended-release product instead of an immediate-release dosage form. Following are examples of errors with medications that should not be split:

*Patient ordered MS Contin® [morphine sulfate extended release] 7.5 mg BID [twice a day]. Pharmacy closed. Nurse did override on med [medication] cabinet. 7.5 mg not available. Nurse took 15 mg and cut it in half and administered it. It was an extended-release tablet. Pt required IV naloxone after becoming unarousable. Vitals OK.*

*Cardizem CD® [diltiazem] 120 mg was ordered for patient and Pharmacy order was for Cardizem CD 240 mg 1/2 capsule. Patient received several doses before RN contacted the pharmacy concerning splitting a capsule. Medication order was corrected.*

For medications that should not be split, high-alert medications were involved in 53.9% (n = 48 of 89) of the reports. Almost half (49.4%, n = 44) of reports of medications that should not be split involved long-acting opioids. Some events, such as the one below, describe the pharmacy entering orders for half tablets for medications that should not be split:

*Pharmacy profiled 100 mg oxyCONTIN as 2½ tabs of 40 mg tablets. Staff administered split oxyCONTIN tab to patient.*

Among these 89 reports, prescribed dosage strengths were commercially available in more than one-half (52.8%, n = 47) of cases.

**Crushing Medications**

About one-quarter (24.3%, n = 151 of 621) of the overall events were related to crushing medications. Most (90.1%, n = 136 of 151) of these involved medications that should not be crushed. The drugs involved in 50.7% (n = 69 of 136) of medication events in which crushing is contraindicated are listed in Figure 5. Alternative, commercially available products could have been used in the majority (72.8%, n = 99 of 136) of these cases.

Patients were harmed in 8.6% (n = 13 of 151) of reports. Among all events related to crushing medications, almost one in three (31.1%, n = 47 of 151) involved high-alert medications, and a majority of these were long-acting opioids (n = 42). Following are examples of events related to medication crushing reported through PA-PSRS:

The Breakup: Errors when Altering Oral Solid Dosage Forms | Advisory

http://patientsafety.pa.gov/ADVISORIES/Pages/201809_AlteringDosage.aspx
OxyCONTIN crushed for oral administration by nurse. Medication is a sustained release med and should not have been crushed. Patient refused medication. Nurse stated she did not know that medication could not be crushed.

Nurse accidently crushed sustained release OxyCONTIN pill with her other meds. No ill effects to patient. Daughter aware.

Figure 5. Five Most Common Medications That Should Not Be Crushed But Were (N = 136)*

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OxyCODONE extended release†</td>
<td>21 (15.4%)</td>
</tr>
<tr>
<td>Morphine extended release†</td>
<td>17 (12.5%)</td>
</tr>
<tr>
<td>Metoprolol succinate</td>
<td>15 (11.0%)</td>
</tr>
<tr>
<td>NIFEdipine extended release</td>
<td>8 (5.9%)</td>
</tr>
<tr>
<td>Isosorbide mononitrate extended release</td>
<td>8 (5.9%)</td>
</tr>
</tbody>
</table>

Note: Data reported through the Pennsylvania Patient Safety Reporting System; events occurred January 2006 through September 2017.

* Percentages in the figure are based on N = 136. The number of events (n = 69 of 136) represented in the figure corresponds to the five most common medications that should not be crushed but were.

† A high-alert medication.

Opening Capsules

Events involving opening of capsules to administer the medications were reported the least frequently (1.8%, n = 11 of 621). Most (90.9%, n = 10 of 11) of these involved medication capsules that should not be opened, such as dabigatran and tamsulosin. Commercially available alternatives existed in 27.3% (n = 3 of 11) of the cases. None of the events were associated with harm, but one reporter expressed occupational-hazard concerns with an order for tacrolimus that required opening capsules on the unit.

Enteral Feeding Tube Administration

One hundred thirteen (18.2% of 621) events specifically mentioned an alteration of a solid oral dosage form for administration via an enteral feeding tube. Medications that should not be crushed were involved in 90.3% (n = 102 of 113) of these cases. Although reporters described orders specifying enteral tube administration in the majority of
these cases, 28.3% (n = 32 of 113) of the reports indicated that the prescriber's order directed oral (by mouth) administration. Four cases involved patients in whom enteral tubes were recently placed, but the ordered by-mouth medications were not reviewed for appropriateness of administration via the new route. Following is an example of an error involving an enteral feeding tube reported through PA-PSRS:

*Patient admitted with GI [gastrointestinal] bleed, has nasoduodenal tube, was ordered NIFEdipine extended release and [isosorbidemononitrate] to be given oral, nurse crushed both pills and administered through nasoduodenal tube, shortly thereafter, the patient became hypotensive and lethargic, requiring intubation and resuscitation, the patient is stable in the intensive care unit.*

Analysis of reports also revealed one case of administering crushed oral medication intravenously while training new staff. Following is the example, reported through PA-PSRS:

*Tablet crushed and dissolved in sterile water by preceptor and new staff person. Medication administered via central line instead of gastric tube accidentally.*

One report described crushing and administering multiple medications via a feeding tube. Following is the example, reported through PA-PSRS:

*Medications spurted out of syringe while giving medications via PEG [percutaneous endoscopic gastrostomy] tube. Since medications were crushed, unsure of which medications patient received and which ones were omitted.*

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

**Discussion**

Data analysis revealed errors with splitting and crushing tablets as well as opening capsules reached patients in 87.1% of reports. Some of the events involved high-alert medications, particularly long-acting opioids, and revealed underutilization of commercially available products that do not require alteration (e.g., oral liquids) or can be altered safely. The prominence of events involving older patients and patients in rehabilitation units is consistent with the higher incidence of dysphagia in this population.33

Analysts found that 56.0% of the events involved older adult patients predominantly in acute care, rehabilitation, and LTAC hospitals. Literature suggests that older adults in different healthcare settings are more likely to require dosage-form alteration. This is especially important to remember because in the face of a growing aging population that is more likely to have comorbidities, multiple medications, and be particularly sensitive to toxicities, especially when narrow therapeutic index or high-alert medications are used.21,24,25 ISMP cautions that lack of or inaccurate patient information—including patient age, presence of an enteral feeding tube, and swallowing issues (e.g., dysphagia, dementia, aspiration risk, Parkinson's disease)—increases risk of errors.34

ISMP also cautions that not using commercially available strengths and dosage forms that require no manipulation increases the risk of errors.4,5,34 Data analysis indicated that commercially available dosage strengths and formulations could have been used without alteration in almost one-third (31.6%) of events involving splitting medications. Commercially available products that require no manipulation or can be altered safely could have been used in the majority (72.8%) of events involving crushing medications and in more than one-quarter (27.3%) of events involving the opening of capsules.
The process of identifying dosage forms that should not be altered should not rely on healthcare practitioner knowledge or memory.\textsuperscript{10,12} Hazardous, narrow therapeutic index, and high-alert medications were involved in events. High-alert medications were inappropriately altered in more than one-quarter (28.2\%) of cases, including events involving long-acting opioids that can lead to central nervous system (CNS) and respiratory depression. Some reports specifically noted that electronic systems did not warn the user about the risk of altering dosage forms when prescribing, verifying orders in the pharmacy computer system, accessing the MAR, or retrieving medications from an ADC.

Data also showed that even medication names indicating extended release (e.g., NIFEdipine extended release) failed to alert practitioners that the medication should not be crushed. Bassett et al. described the case of a 69-year-old man whose NIFEdipine extended-release 90 mg tablet was crushed and administered through a duodenal tube, resulting in blood pressure 65/44 mm Hg, pulse 80 beats/minute in a ventrically paced rhythm, and a decreased level of consciousness, requiring pharmacological interventions.\textsuperscript{35} The risk is even higher with medication names that do not signal that a drug should not be altered (e.g., OxyCONTIN, MS Contin, Kadian\textsuperscript{®}, Pradaxa\textsuperscript{®}).\textsuperscript{4-6,36}

The markings on tablets can also cause confusion about whether a medication should be split. In March 2013, FDA provided guidance to industry that new modified-release products for which the control of drug release can be compromised by tablet splitting should not have a scoring feature;\textsuperscript{17} however, there are some older medications that should not be split or crushed but still are scored. In these cases, manufacturers use a scoring feature as part of their tablet identification and imprint system. However, this introduces risk of misinterpretation and inappropriate splitting of the tablet. For example, KlonoPIN 0.5 mg tablets are scored, but the manufacturer states that tablets should be swallowed whole.\textsuperscript{37,38} Also, some scored medications can be split but not crushed (e.g., metoprolol succinate).\textsuperscript{39,40}

Healthcare practitioners and patients are sometimes faced with information from the manufacturer's product information and the literature that conflicts about whether a product can be altered. In the case of Cymbalta\textsuperscript{®} (DULoxetine), the manufacturer specifies that capsules should be swallowed whole,\textsuperscript{41} and FDA states that adverse effects have been reported when patients opened Cymbalta capsules.\textsuperscript{42} However, other drug-information resources specify that the medication has been found to be stable for up to two hours after sprinkling the contents of capsule on applesauce or in apple juice, if care is taken to not crush the pellets or damage the enteric coating.\textsuperscript{43}

Also, the same medication may be manufactured by different companies that provide different directions for altering the dosage form. For example, most dilTIAZem extended-release products specify that the capsules should not be opened, chewed, or crushed, but this drug under the brand names Taztia XT\textsuperscript{®} and Tiazac\textsuperscript{®} extended release specifies that capsules may be opened.\textsuperscript{44-46}

When it comes to safe handling of medications, NIOSH provides information on antineoplastic and other hazardous drugs.\textsuperscript{7} Information about handling hazardous drugs may prove even more important with increasing use of oral chemotherapy drugs. Data analysis showed that hazardous medications in NIOSH groups 1, 2, and 3 were involved in 11.6\% of events mentioning an alteration of oral solid dosage forms reported through PA-PSRS. Most reporters neither stated concerns about altering hazardous drugs nor mentioned the use of healthcare-provider personal protection measures. This may indicate that these types of employee concerns or potential harm are not captured through PA-PSRS. It may also indicate that staff do not identify certain drugs as hazardous or realize the safety risks of altering them.

### Splitting Tablets

Splitting medications was found to be involved in almost three-quarters of the reported events and was most likely to result in extra doses and overdoses. The VA NCPS and VA Patient Safety Centers of Inquiry (VA PSCI) evaluated potential medication problems caused by tablet splitting using their Patient Safety Information System database. They
found a similar risk (66% of adverse pill-splitting events involved patients receiving too high a dose) with this type of oral solid dosage form alteration. The VA analysis also found that the prescribed doses had been commercially available in a form that did not require tablet splitting in more than one-half (51%) of their reported events. Similarly, PA-PSRS data showed that forgetting to split a dose was a common contributing factor to errors and that commercially available alternatives that do not require alteration could have been used in many cases.

Although not explicitly described in the data, the splitting of tablets in place of using commercially available strengths could be associated with pharmacies not carrying certain dosage strengths or use of nonformulary drugs. Some reports indicated that staff remove medications (not patient-specific doses) from night cabinets when a pharmacy is closed or use whole tablets left from a prior dose supply. Because evaluating ADC and night cabinet inventory for adjustment of medication quantity is recommended, these data raise the question of whether evaluating prescribing trends might help identify the actual strengths used.

When medications require splitting, information may not be clearly presented and communicated to all healthcare providers throughout the medication use process. Some reporters expressed concern with unclear dosing information on medication orders when strength and ½ tablet directions run together (e.g., does "glipiZIDE 2.5 mg ½ tablet" mean a dose of 2.5 mg or 1.25 mg?). Directions can also be missed if they are placed in the free-text comments or special-instruction fields by prescribers when ordering a medication.

Misinterpretation and miscommunication of doses was observed with medication reconciliation (e.g., patients did not specify that they took only half of a reported tablet strength) and transcribing by a nurse or pharmacist (e.g., half of a tablet was entered as 0.5, ½, 1.5, 1 ½, or 1-2; half tablet was not entered in the order; half tablet did not display on the MAR or ADC screens). Some reports specified that ½ tablet directions were missed or forgotten during administration. Some staff accidentally administered the second half of a tablet or split a tablet in half again. These data support prior voiced concerns regarding communicating information about splitting medications.

Concerns with narrow therapeutic index drugs involved in errors have also been expressed, especially because an FDA study revealed that there is significant dose variation with tablet splitting. With narrow therapeutic index medications, even small changes in dose and blood concentrations may lead to serious therapeutic failures or adverse drug events. Accidental extra doses and overdoses increase this risk.

ISMP warns that risk can be introduced when a pharmacy fails to dispense patient-specific doses. All the reported events associated with splitting medications required splitting for a patient-specific dose. Almost a fifth of the reports identified the pharmacy's dispensing of whole tablets as a contributing factor to errors. Some also reported a failure of pharmacy labels to specify that a tablet should be split. Reporters described that errors occurred despite BCMA systems in place, highlighting the fact that technology may be unreliable in catching these types of errors.

A few events also indicated concerns with dispensing whole tablets or capsules with label directions to split them unevenly. Some of these included high-alert or narrow therapeutic index drugs, such as the warfarin order, which would have required the nurse to cut tablets to a 0.63-tablet dose.

**Crushing Tablets and Opening Capsules**

Early identification and communication of a patient's swallowing issue is important. Healthcare practitioners may not always be aware that patients are altering oral solid dosage forms. A survey by Pergolizzi at el. revealed that 80% of patients with chronic pain and dysphagia have never been asked about their ability to swallow medications and 65% did not know that altering dosage forms can result in adverse events and ineffective pain management. Similarly, ISMP received a report of an 83-year old patient dying after chewing his Cardizem CD (dilTIAZem extended release) capsules.
Data submitted through PA-PSRS indicates that patient-initiated dose alterations were not always readily identified. For example, healthcare practitioners did not identify patients who chewed extended-release medications. In other cases, nurses, without first consulting with prescribers or pharmacists, crushed OxyCONTIN (oxyCODONE extended release) based on the patient's report of doing so at home.

Crushing and combining medications for oral administration is another area limited by scant data and guidance. In November 2017, the Centers for Medicare and Medicaid Services (CMS) released a revised version of Appendix PP (Guidance for Surveyors for LTC [Long Term Care] Facilities) in its State Operations Manual. The revision states that best practice is to crush each medication separately and administer each medication separately with food. However, the agency acknowledges that separating crushed medications may not be appropriate for all patients and facilities should implement person-centered approaches for medication administration and ensure appropriate clinicians are consulted for any concerns.

**Enteral Feeding Tube Administration**

Analysts identified a gap in identifying and communicating the presence of a feeding tube among healthcare providers. For example, the oral route of administration was listed in some medication orders for patients with feeding tubes, which can increase the risk that pharmacists dispense unsuitable medications. Lack of guidance on appropriate administration of medications was also mentioned. Similarly, Li et al. found that pharmacists are concerned that they do not always have easy access to information on the actual route of administration for a specific patient and may fail to add "do not crush" directions in order to populate electronic health records and ADC screens.

To address these communication gaps, Li et al. describe a process that optimizes patient safety and improves patient and drug information sharing by using an organization-wide medication review service for patients with feeding tubes. A 600-bed hospital used a publicly available list of medications that should not be crushed to identify medications on the facility's formulary. They then examined their health information technology (IT) platform and ADC systems to make sure they included "do not crush" comments on applicable products. The organization also created an automatic medication substitution list. Additionally, they collaborated with the IT group to create a system that notifies the pharmacist (a generated electronic task list) about patients who have an inserted enteral tube, prompting review of medications and substitutions.

**Limitations**

The Authority's analysis of medication errors involving oral solid dosage form alteration is impacted by limitations in the process of reporting information within facilities and through PA-PSRS. The retrieval of reports from the PA-PSRS database is limited by the process of identifying relevant reports, including the use of convenience sampling during ongoing event review.

**Risk Reduction Strategies**

Organizations and healthcare facilities can strive to identify system-based causes of errors involving the alteration of oral solid dosage forms, keeping in mind that these errors do not occur only during medication administration. Event descriptions support the literature findings that errors involving dosage form alteration originate in all stages of the medication use process, including prescribing and dispensing. These alteration errors involve a number of key elements of medication use system, such as patient and drug information; communication; drug labeling and packaging; drug storage, stock, standardization, and distribution; environmental factors; staff competency and education; patient education; and quality processes and risk management.
Several reports described implementation of lower-leverage risk reduction strategies,\textsuperscript{34} such as double checking by the same person, concentrating on the task at hand, or educating staff. Only two reporters described higher-leverage strategies, such as building in additional redundancies with pharmacist involvement and optimizing use of technology. Educating patients and staff, including students and new employees, is a necessary component of a safety plan but relies on human vigilance to prevent errors. Layering multiple high- and low-leverage strategies is important to reduce the risk of error (Figure 6).

Figure 6. Rank Order of Error Reduction Strategies

HIGH LEVERAGE

- Fail safes and forcing functions
- Constraints
- Automation and computerization
- Standardization and protocols
- Checklists, independent double-check systems, and other redundancies
- Rules and policies
- Education and information
- Suggestions to be more careful or vigilant

LOW LEVERAGE


Note: Items at the top of the list, such as forcing functions, constraints, and automation, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system yet rely in some part on human vigilance and memory. Items at the bottom, such as education, are tools that are important but focus on individual performance and therefore are weaker and ineffective when used alone.

Manufacturers and FDA also have a role in preventing errors. Maintaining up-to-date drug information depends on both groups working together to ensure official prescribing information is updated when new information on altering the dosage form of a drug is available. Timely distribution of updated information to drug-information providers and healthcare practitioners can help them implement or adjust electronic warnings and employ other risk reduction strategies.

To prevent errors, consider the following strategies, based on events reported to the Authority, current guidelines and

http://patientsafety.pa.gov/ADVISORIES/Pages/201809_AlteringDosage.aspx
literature, and observations from ISMP.

**General Strategies**

- Limit altering oral solid dosage forms to cases in which commercially available alternatives are unavailable, especially for high-alert and narrow therapeutic index drugs.\(^3\)\(^-\)\(^5\)\(^,\)\(^34\)

- Do not accept blanket orders to crush or split all medications.\(^2\)

- Remove discontinued dosage forms and strengths from patient care areas.

- Develop guidelines and implement procedures for handling crushing, splitting, and opening of formulary and nonformulary oral solid dosage forms.\(^2\)

- Review the organization’s formulary and identify medications and dosage forms that should not be altered.\(^1\)\(^,\)\(^2\)\(^,\)\(^20\)

  Consider developing a substitution list for identified medications (e.g., for oral and enteral feeding administration).\(^20\)

- Collaborate with the IT department and system vendors, as follows:
  - Identify ways of alerting practitioners during prescribing, transcribing, verifying, dispensing, and administering (e.g., clinical decision support with order entry, ADC screen, MAR) to medications that should not be altered.
  - Take into consideration the risk of “alert fatigue” when reviewing options.\(^2\)\(^,\)\(^18\)\(^,\)\(^20\)\(^,\)\(^47\)
  - Develop procedures to prevent medication errors during downtimes and technological malfunctions.

- Identify hazardous medications and implement procedures for safe handling (e.g., preparing in the pharmacy under controlled conditions, handling on patient-care units using NIOSH or other resources).\(^7\)\(^,\)\(^8\)

- Avoid storing hazardous medications in ADCs.\(^47\)

- Optimize use of profiled ADCs to prevent removal of wrong dosage forms or strengths.\(^47\)\(^,\)\(^48\)

- Use barcode scanning to confirm that the medication selected for distribution to the ADC and placed in the ADC matches the medication listed on ADC fill report.\(^47\)

- Minimize distractions during order entry, medication dispensing, ADC stocking, and drug administration.\(^47\)\(^,\)\(^52\)

- Increase patient monitoring when switching dosage forms.

- Provide training and periodic competency review for prescribers, pharmacists, nurses, new staff, and students regarding procedures for safe alteration of oral solid dosage forms (i.e., opening of capsules, splitting and crushing of tablets). This should include information on effective use of technology (e.g., computerized prescriber order entry [CPOE] with clinical decision support, pharmacy order entry, electronic MAR, ADC, BCMA).\(^2\)\(^,\)\(^18\)\(^,\)\(^20\)

- Educate staff to consult pharmacy with all medication-related questions.\(^1\)\(^-\)\(^3\)

- During inpatient stays, educate patients on their medication therapy, including medications that should not be altered.\(^2\)\(^,\)\(^23\)

- At discharge, provide patients with written and verbal instructions for altering dosage forms and for which medications should not be altered.
Provide directions on how to accurately split a tablet as well as use and clean a tablet splitter.

Provide instructions on discontinued dosage forms and strengths for medications that may still remain at home.

Use the "teach back" method to ensure understanding.2,3,18,34

- When a new medication is added to the formulary, perform a proactive risk assessment to evaluate potential risk factors associated with altering of the dosage form and implement risk reduction strategies (e.g., availability of commonly used dosage strengths and alternatives, adding "do not crush" comment).

- Routinely review internal and external error reports related to altering oral solid dosage forms to identify error-prone conditions and implement risk reduction strategies. Ensure staff participating in medication use processes receive this information.11

- Ensure sufficient multidisciplinary staffing for evaluation, revision, and implementation of procedures as well as staff education.

- Incorporate prompts or questions into the medication reconciliation process to ask patients whether they split or alter any medication at home for dosing or to facilitate administration.

### Splitting Tablets

- Consider analyzing prescribing trends for commonly used doses (including tablet-splitting) and stock ADC and night cabinets with commercially available options whenever possible.47

- For cases in which commercial strengths are unavailable, develop a standardized process for orders to provide explicit directions for tablet splitting (e.g., trazodone 50 mg, give half of a tablet [25 mg]) and ensure they appear on medication labels.1,3,18

- Perform a proactive risk assessment to ensure doses other than whole tablets are clearly displayed on CPOE, pharmacy, and ADC screens; printed and electronic MARs; and medication labels.

- When splitting is required and appropriate, provide patient-specific doses to patient care units by splitting tablets in the pharmacy.1,3,34,53

- If tablet splitting is necessary on a patient care unit, provide clear instructions on medication labels and the MAR.1,2 Educate nurses to prepare one medication at a time.

- Optimize use of BCMA technology to provide warnings about dosing. Ensure nurses receive initial and ongoing education about the alerting mechanism, what the scanner warnings and sounds indicate, and what to do when scanners malfunction.

### Crushing Tablets and Opening Capsules

- Implement a procedure that identifies patients with swallowing issues on admission and with changes in condition (e.g., changing to a soft or pureed diet).2,23 Collaborate with the IT department and system vendors to identify ways of readily and clearly communicating this information to prescribers and pharmacists.

- Whenever possible, provide ready-to-use doses to minimize mixing, dilution, opening, and crushing medications on patient care units. Provide clear directions if preparation on patient care units is required.2,34,53
- Separately prepare and administer extended- and delayed-release capsules that can be opened. Educate patients not to chew contents of these dosage forms.

**Enteral Feeding Tube Administration**

- Implement a procedure to promptly communicate information about a patient's current or newly inserted feeding tube to better enable pharmacists to conduct a thorough review of the patient's medications, including compatibility of the medications with administration via a feeding tube.\(^2,20\)

- Implement procedures for administering medications through enteral tubes. Include information to guide selection of appropriate dosage forms, preparations of drugs, and administration of each drug separately as recommended by the American Society for Parenteral and Enteral Nutrition (ASPEN) and CMS.\(^9,10\)

- Provide warnings to avoid use of parenteral syringes for enteral administration.\(^4,5,11\)

- Avoid using modified-release dosage forms when administering medications via feeding tubes.\(^4,5\)

**Conclusion**

Oral solid dosage forms include narrow therapeutic index, hazardous, and high-alert medications, such as long-acting opioids. Opening capsules as well as splitting and crushing tablets that should not be altered can lead to medication errors, increasing the risk of adverse events, such as CNS and respiratory depression. These errors may disproportionately impact vulnerable patient populations with dysphagia in acute care, rehabilitation, and long-term care facilities.

Nearly 9 out of 10 (87.1%) reported events in which pills were split or crushed or capsules were opened reached patients. Of note, nearly three-quarters of reported events associated with splitting medications involved overdose and extra dose. To reduce the risk of errors, healthcare practitioners need up-to-date information on patient swallowing difficulties and the presence of feeding tubes, as well as effective strategies to prevent dangerous drug alterations, including maximizing use of commercially available dosage strengths and formulations. Organizations can implement system-based risk reduction strategies to minimize the occurrence of these medication errors.

**Notes**


2. Crushing or splitting the wrong tablet can be a deadly error. ISMP Long-Term Care Advise-ERR. 2017 Apr;5(4):1-4.

3. Tablet splitting: Do it only if you "half" to, and then do it safely. ISMP Med Saf Alert Acute Care. 2006 May 18;11(10):1-2.


44. Actavis Pharma, Inc. Label: TAZTIA.

45. Valeant Pharmaceuticals North America LLC. Label: TIAZAC EXTENDED RELEASE.


51. ASCP received emerging details from CMS. Alexandria (VA): American Society of Consultant Pharmacists (ASCP); 2017 Nov. 2 p. Also available: http://update.nyshfa.org/attachment/1230/mm17-98.pdf?g_download=1


Patient education, engagement, and empowerment have been at the core of many organizations’ efforts to make healthcare safer. To measure and focus such efforts, the Pennsylvania Patient Safety Authority developed a patient poll about basic safety practices, such as asking about healthcare worker handwashing. The poll was administered in 2006, 2013, and, most recently, February through April 2018. Results from 2018 remain consistent with the previous two iterations: high reported likelihood to ask questions to gain understanding and low reported likelihood to question
potential safety breaches. In 2018, 96% of patients reported positive inclination towards asking for a fuller explanation, and just 33% reported positive inclination towards asking a healthcare worker if they washed their hands. This gap represents an opportunity for future safety work in Pennsylvania and beyond.

Introduction

Empowering patients to be advocates for patient safety has been a focus of countless educational campaigns and interventions. From regulatory bodies to grassroots advocacy groups, international agencies to hospitals, patient empowerment has become a principal component of mission statements, strategic plans, and calls to action. The Pennsylvania Patient Safety Authority is one such organization, established in 2002 by the Medical Care Availability and Reduction of Error Act (known as MCARE). The Authority joins organizations such as the Agency for Healthcare Research and Quality, Joint Commission, and the Centers for Medicare and Medicaid Services in promoting patient engagement in safe healthcare through education, access to resources, and incorporation of the patient voice.

To evaluate engagement of Pennsylvania patients in common safety practices, the Pennsylvania Patient Safety Authority developed a poll, which was administered in 2006, 2013, and most recently, February through April 2018. Analysis of the poll results will inform future patient safety efforts in Pennsylvania and beyond.

Methods

The Center for Survey Research, Penn State Harrisburg conducted a random telephone poll of 606 adults in Pennsylvania from February 19, 2018, through April 19, 2018. Similar to the previous polls, interviews consisted of basic demographic questions and the following questions measuring engagement in select patient safety practices:

In regard to your healthcare, how likely are you to—

1. ask a healthcare worker if they have washed their hands?
2. ask a healthcare worker to confirm your identity before performing a procedure?
3. seek a second opinion regarding an important healthcare decision?
4. ask a healthcare worker to explain more fully something they just said that you don't understand?

How often do you engage in the following practices related to your healthcare?

5. Check that you received the right drug and strength before leaving the pharmacy.
6. Take a list of all the medications you are currently taking when going to the doctor.
7. Call your doctor when you have a medical test ordered, but no one calls you with the results.

If you were a patient in a hospital, how likely are you to—

8. question the reason for a procedure before it is performed?
9. question medications or pills if you don't recognize them and never took this medication in the past?
10. refuse care, such as x-ray or drawing blood, that you were not told about by your doctor or nurse?
Three new questions, focused on patient-provider communication, were added to the 2018 poll, and will be addressed in a future Advisory article.

The sample included both landline and cell phone numbers generated using a random-digit-dial sampling procedure to ensure equal probability of selection. An additional randomized respondent selection technique was used on landline calls to ensure equal probability of selection for all adults within each sampled household. Given the portability of mobile devices, all cell phone calls were screened to ensure participant residence in Pennsylvania. The 606 completed interviews consisted of 25% landline numbers and 75% cell phone numbers. The overall survey cooperation rate, adjusted for frame overlap, was 71.6%. The margin of error for the poll at a 95% confidence interval is plus or minus four percentage points.

**Figure 1. Sampling Statistics**

![Sampling Diagram]


* Cooperation rate calculated by the Center for Survey Research, Penn State Harrisburg using the American Association of Publication Opinion Research’s Cooperation Rate 3 (COOP 3) formula, which divides the number of completed interviews by the sum of the number of completed interviews, the number of partially completed interviews, and the number of respondents who refused to participate.

To ensure the poll results were representative, the data were weighted as a function of respondent age and gender using Pennsylvania population estimates collected by the U.S. Census Bureau on July 1, 2016. The analysis that follows uses this weighted data.

Differences in patient engagement were evaluated using results of the 2018, 2013, and 2006 polls. Statistical measures included the Goodman and Kruskal gamma (for the association between two ordinal variables), chi-squared test for independence (for the association between two categorical variables), and the Wilson score method without continuity correction (for the computation of confidence interval around a single-group proportion). For select analyses, a two-level response variable was used by collapsing the categories “very likely” with “likely” and “always” with “often.” Similarly, “somewhat likely” and “not likely at all” were collapsed as were “sometimes” and “never.”

In the 2018 poll, the response choice “does not apply to me” was added to the three questions measuring perceived frequency of engagement in select safety practices (i.e., checking prescriptions, bringing a medication list, and calling about test results); analysis of these three questions was therefore limited to 2018 only.

Analysts conducted a review of the literature on patient engagement in safety to provide context to the poll results.
Results

Table 1 shows the weighted respondent demographics for the 2018 poll.

Table 1. Weighted Demographic Distribution of 606 Survey Participants in the 2018 Penn State Poll*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>293</td>
<td>48.4</td>
</tr>
<tr>
<td>Female</td>
<td>313</td>
<td>51.6</td>
</tr>
<tr>
<td><strong>Age category</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 through 34 years</td>
<td>172</td>
<td>28.3</td>
</tr>
<tr>
<td>35 through 64 years</td>
<td>301</td>
<td>49.7</td>
</tr>
<tr>
<td>65 years of age or older</td>
<td>133</td>
<td>22.0</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White alone</td>
<td>504</td>
<td>86.0</td>
</tr>
<tr>
<td>Black, African American alone</td>
<td>36</td>
<td>6.1</td>
</tr>
<tr>
<td>Some other race (includes 2 or more races)</td>
<td>47</td>
<td>7.9</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school diploma/GED or less</td>
<td>142</td>
<td>23.5</td>
</tr>
<tr>
<td>Some college (includes two-year degree, technical degree, associate's degree)</td>
<td>227</td>
<td>37.6</td>
</tr>
<tr>
<td>College degree (four-year college graduate)</td>
<td>116</td>
<td>19.3</td>
</tr>
<tr>
<td>Graduate work</td>
<td>118</td>
<td>19.6</td>
</tr>
<tr>
<td><strong>Household income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $30,000</td>
<td>100</td>
<td>19.9</td>
</tr>
<tr>
<td>$30,000 to $59,999</td>
<td>140</td>
<td>28.1</td>
</tr>
<tr>
<td>$60,000 to $99,999</td>
<td>129</td>
<td>25.9</td>
</tr>
<tr>
<td>$100,000 or more</td>
<td>130</td>
<td>26.1</td>
</tr>
</tbody>
</table>
### Region (Counties)

<table>
<thead>
<tr>
<th>Region</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northwest</td>
<td>62</td>
<td>10.3</td>
</tr>
<tr>
<td>Northcentral</td>
<td>29</td>
<td>4.8</td>
</tr>
<tr>
<td>Northeast</td>
<td>70</td>
<td>11.6</td>
</tr>
<tr>
<td>Southwest</td>
<td>122</td>
<td>20.1</td>
</tr>
<tr>
<td>Southcentral</td>
<td>101</td>
<td>16.6</td>
</tr>
<tr>
<td>Southeast</td>
<td>222</td>
<td>36.6</td>
</tr>
</tbody>
</table>

### County density

<table>
<thead>
<tr>
<th>Density</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban</td>
<td>423</td>
<td>69.7</td>
</tr>
<tr>
<td>Rural</td>
<td>183</td>
<td>30.3</td>
</tr>
</tbody>
</table>


* Respondent numbers may not total 606 because of rounding, as well as the exclusion of “don't know” and “declined to answer” responses.

Figure 2 shows the results of the 2018 poll.
The relationships between demographic variables and respondents’ engagement in the 10 safety practices are displayed in Table 2. Gender accounted for statistical differences in the highest number of safety practices, with females being more likely than males to engage in five practices (i.e., healthcare worker handwashing, patient identification, fuller explanation, medication list, questioning procedures).

Table 2. Relationship Between Demographic Variables and Respondents' Likelihood of Engaging in Safety Practices

<table>
<thead>
<tr>
<th>Safety Practice Topic</th>
<th>Gender</th>
<th>Age</th>
<th>Race</th>
<th>Education</th>
<th>Income</th>
<th>Region</th>
<th>County Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare worker handwashing</td>
<td>Females more likely (p = 0.003)</td>
<td>n.s.</td>
<td>Blacks, African Americans alone, more likely than whites (p = 0.002)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>NC more likely than SC (p = 0.003)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Patient identification</td>
<td>Females more likely (p = 0.002)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Second opinion</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>NC more likely than SC (p = 0.045)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Fuller explanation</td>
<td>Females more likely (p = 0.029)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Check prescriptions</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Medication list</td>
<td>Females more likely (p = 0.041)</td>
<td>Older more likely (p = 0.001)</td>
<td>Blacks, African Americans alone, less likely than whites (p = 0.003) or than Other (p = 0.004)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>Rural more likely than urban (p = 0.033)</td>
</tr>
<tr>
<td>Test results</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Question procedures</td>
<td>Females more likely (p = 0.028)</td>
<td>n.s.</td>
<td>Higher education more likely (p = 0.043)</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Question medications</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
<tr>
<td>Refuse care</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
Note: The Goodman and Kruskal gamma was used to measure the association between poll results and the demographic variables gender, age, education, income, and county density. The chi-squared test for independence was used to measure the association between poll results (represented as two-level response variables) and the demographic variables race and region.


NC, Northcentral; n.s., not statistically significant (p ≥ 0.05); SC, Southcentral.

Figure 3 shows respondents’ positive inclination toward the safety practices in the three iterations of the poll.
Comparing the poll results from 2006 to 2018, statistically significant improvements were observed in the likelihood of patients asking about healthcare-worker handwashing and patient identification. Comparing the poll results from 2013 to 2018, statistically significant declines were observed in the likelihood of engagement in healthcare-worker handwashing and questioning procedures.

**Discussion**

As was observed in the previous two polls, reported engagement varied among the 10 safety practices in 2018, but...
the ranking of the safety practices by positive inclination remained relatively consistent.

Respondents reported being most inclined toward asking for a fuller explanation, questioning medications, and questioning procedures. More than 80% of respondents reported being positively inclined to engage in each of these three safety practices, which also ranked highest in the 2006 and 2013 polls. These safety practices all relate to health literacy and seeking understanding rather than pointing out safety breaches. This propensity towards asking clarifying questions rather than challenging or "actively" participating in care (e.g., helping with site marking) has been a consistent theme in the literature.12-15

The safety practice respondents reported being least inclined toward in the 2018 poll was asking about healthcare worker handwashing; just one in three respondents reported being positively inclined. This safety practice also ranked lowest in the 2006 and 2013 polls. Despite widespread publicity this fundamental safety practice has received, social and personal barriers—such as not wanting to damage the patient-provider relationship or be labeled as "difficult"—may prevail. These barriers may also affect the other consistently low-ranking safety practices: asking about patient identification and refusing care.

The ubiquity of alcohol-based hand rub could also make asking a healthcare worker if he or she has washed their hands obsolete; for example, patients can see staff use the dispenser or continue to cleanse their hands as they enter the room. After-the-fact patient surveys and more novel safety hotlines and patient-led patient safety reporting systems may augment this reluctance to speak up at the point of care but, unfortunately, not mitigate potential harm that has already occurred.16,17

Respondents' willingness to engage in many of the practices declined from 2013 to 2018. This lack of improvement in the poll results was unexpected, but the positive gains since 2006 were nonetheless encouraging. Extrinsic factors such as politics, culture, technology, and social media could all influence these trends. The evolution of healthcare delivery may make some of the safety practices in this poll no longer reflective of reality, such as the availability of patient portals to access medication lists and test results or use of barcode scanners for patient identification. The impact of newer phenomena, such as the electronic documentation burden and virtual healthcare, will be interesting to evaluate in the future. Regardless of the way healthcare is delivered, the fundamental principles of handwashing, patient identification, and health literacy appear to be timeless and thus worthy of continued promotion.

**Limitations**

The ambiguous wording of some poll questions creates the possibility that interpretation differed among respondents. The theoretical nature of the poll questions and the social desirability of certain responses might have caused respondents to misrepresent how they would actually behave if faced with the scenario described.

**Conclusion**

The results of the 2018 Pennsylvania patient poll align with that of the 2006 and 2013 iterations: high reported engagement in practices to seek understanding and low reported engagement in practices that question potential safety breaches. Asking about healthcare worker handwashing remains the most significant opportunity for awareness, empowerment, and innovation.
Acknowledgments

Jonathan R. Treadwell, PhD, senior associate director, ECRI Institute–Penn Medicine Evidence-based Practice Center, consulted on statistical testing for this article.

Notes


**Supplemental Material**

The Pennsylvania Patient Safety Authority maintains a repository of Safety Tips for Patients (/PATIENTSCONSUMERS/Pages/PatientConsumerTips.aspx) to help inform and empower patients and their loved ones.

The Authority also sponsors a Patient Voice Council (/PATIENTSCONSUMERS/Pages/Home.aspx) to infuse the perspective of patients into its efforts to improve patient safety. Individuals interested in participating may inquire online.
A Second Breadth: Hospital-Acquired Pneumonia in Pennsylvania, Nonventilated versus Ventilated Patients

Authors
James Davis, MSN, RN, CIC, CCRN, HEM, FAPIC
Senior Infection Prevention Analyst

Edward Finley, BS
Data Analyst

Pennsylvania Patient Safety Authority

Corresponding Author
James Davis

Abstract

Research published in 2012 by Pennsylvania Patient Safety Authority analysts determined that nonventilator hospital-acquired pneumonia (NV-HAP) affected more people than ventilator-associated pneumonia (VAP) and was as lethal as, and more costly than, VAP. This article updates the Authority's original data set, using the same methods and outcome measures. Analysts queried the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for complete nosocomial pneumonia data sets from January 1, 2013, through December 31, 2016, inclusive of the total inpatient population for Pennsylvania acute-care facilities. Data sets from the Authority's original data (from January 1, 2009, through December 31, 2012) are included for comparison. The analysis found not only that NV-HAP continues to be as lethal as VAP but that it demonstrates higher incidence and is more costly as a whole.

Introduction

Research published in 2012 by the Pennsylvania Patient Safety Authority determined that nonventilator hospital-acquired pneumonia (NV-HAP) affected more people than ventilator-associated pneumonia (VAP) and was as lethal as and wholly more costly than VAP. Furthermore, the incidence of NV-HAP was on the rise in patients in conventional wards and was likely to be underreported.¹

Since the original Authority work identifying and defining the impact of NV-HAP on Pennsylvania residents and healthcare facilities was published, U.S. researchers interested in furthering the body of knowledge for NV-HAP have focused on the condition. Subsequent publications have validated the Authority's original findings and identified new areas of impact.
Examples of NV-HAP research findings include the following:

- Hospital-acquired pneumonia (HAP) accounts for about 21.8% of the burden of all hospital-associated infections meeting criteria of the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN). Of these HAP cases, 60.9% can be attributed to NV-HAP, and 39.1% can be attributed to VAP.\(^2\)

- Mortality attributed to NV-HAP ranges from 13.1% to 30%.\(^1,6\)

- Additional length of stay associated with NV-HAP ranges from 4.0 to 15.9 days.\(^6\)

- Estimated NV-HAP acute-care treatment costs range from $28,008 to $40,000 per case.\(^1,2,6,7\)

This article updates the Authority's original data set, using the same methods and outcome measures. The authors include prevention strategies proposed by other investigators that complement the Authority's original targeted interventions.

**Methods**

Pennsylvania state law (Act 52 of 2007) requires that all acute-care healthcare-associated infections be reported through NHSN. Analysts queried NHSN for complete nosocomial pneumonia data sets from January 1, 2013, through December 31, 2016, inclusive of the total inpatient population for Pennsylvania acute-care facilities. Data sets from January 1, 2009, through December 31, 2012, are included for comparison. The original data set was expanded to include 2012\(^1\) to provide equal time-series sets and to address changes to NHSN's VAP definition that occurred in January 2013.\(^8\)

Analysts also extracted data for patients with nosocomial pneumonia who died during that period. The NHSN field "Died" was used to aggregate the number of patients with pneumonia who died, regardless of responses found in the "Contributed to death" field. Of those cases of NV-HAP and VAP, the number of patients who died was also extracted. Time-series data was aggregated into yearly subtotals.

Besides comparing NV-HAP versus VAP incidence and mortality, estimated costs of NV-HAP versus VAP cases are compared. The baseline estimated average cost per NV-HAP case (in 2010 dollars) is $28,008.\(^9\) The estimated average cost per VAP case is $37,442.\(^9\) Authority analysts accounted for inflation, adjusting yearly values to accurately present financial impact.\(^10\) Another outcome, distribution of NV-HAP cases by NHSN unit type, is based on aggregate data expressed in rate per 1,000 patient-days for January 1, 2013, through December 31, 2016.

**Results**

Table 1 shows the number of NV-HAP and VAP cases for 2009 through 2016 from NHSN. Although NV-HAP is as lethal as VAP, NV-HAP demonstrates higher incidence.

The table also includes the percentages of patients with NV-HAP and VAP who died. The difference in mortality percentages for patients with NV-HAP and VAP are not statistically significant; see Figure 1.
### Table 1. Pennsylvania Nosocomial Pneumonia Incidence and Number of Patients with NV-HAP or VAP Who Died

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of NV-HAP Patients</th>
<th>Number of NV-HAP Patients Who Died</th>
<th>Percentage of Patients with NV-HAP Who Died (Confidence Interval)</th>
<th>Number of VAP Patients</th>
<th>Number of VAP Patients Who Died</th>
<th>Percentage of Patients with VAP Who Died (Confidence Limit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>1,848</td>
<td>366</td>
<td>19.81 (17.78–21.83)</td>
<td>737</td>
<td>144</td>
<td>19.54 (16.35–22.73)</td>
</tr>
<tr>
<td>2011</td>
<td>1,780</td>
<td>318</td>
<td>17.87 (15.9–19.83)</td>
<td>643</td>
<td>127</td>
<td>19.75 (16.32–23.19)</td>
</tr>
<tr>
<td>2013</td>
<td>1,528</td>
<td>285</td>
<td>18.65 (16.49–20.82)</td>
<td>767</td>
<td>160</td>
<td>20.86 (17.63–24.09)</td>
</tr>
<tr>
<td>2014</td>
<td>1,419</td>
<td>256</td>
<td>18.04 (15.83–20.25)</td>
<td>901</td>
<td>199</td>
<td>22.09 (19.02–25.16)</td>
</tr>
<tr>
<td>2015</td>
<td>1,427</td>
<td>277</td>
<td>19.41 (17.13–21.7)</td>
<td>912</td>
<td>218</td>
<td>23.90 (20.73–27.08)</td>
</tr>
<tr>
<td>2016</td>
<td>1,380</td>
<td>280</td>
<td>20.29 (17.91–22.67)</td>
<td>980</td>
<td>221</td>
<td>22.55 (19.58–25.52)</td>
</tr>
</tbody>
</table>

**Note:** Data as reported to the National Healthcare Safety Network (NHSN). The NHSN field “Died” was used to aggregate the number of patients with NV-HAP or VAP who died regardless of responses found in the “Contributed to death” field.

NV-HAP, Nonventilator hospital-acquired pneumonia; VAP, ventilator-associated pneumonia.

---

### Table 2. Estimated Total Yearly Cost of NV-HAP and VAP Cases in Pennsylvania

<table>
<thead>
<tr>
<th>Year</th>
<th>NV-HAP Cases</th>
<th>Total Cost for NV-HAP Cases*</th>
<th>VAP Cases</th>
<th>Total Cost for VAP Cases*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,977</td>
<td>$53,955,118</td>
<td>922</td>
<td>$33,638,285</td>
</tr>
</tbody>
</table>

**Note:** Data as reported to the National Healthcare Safety Network (NHSN). The NHSN field “Died” was used to aggregate the number of patients with pneumonia who died, regardless of responses found in the “Contributed to death” field.

NV-HAP, nonventilator hospital-acquired pneumonia; VAP, ventilator-associated pneumonia.

---

Table 2 compares the estimated total costs for NV-HAP and VAP cases. NV-HAP wholly is more costly than VAP.

---

Figure 1. Percentage of Patients Who Died with Pneumonia Who Died

**PERCENTAGE OF PATIENTS WITH PNEUMONIA WHO DIED**

<table>
<thead>
<tr>
<th>Year</th>
<th>NV-HAP</th>
<th>VAP</th>
<th>Upper confidence interval</th>
<th>Lower confidence interval</th>
<th>Rate (percentage of patients with pneumonia who died)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td></td>
<td></td>
<td>18.41</td>
<td>17.68</td>
<td>19.81 (17.78–21.83)</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td>19.81</td>
<td>19.54</td>
<td>18.95 (16.83–21.07)</td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td></td>
<td>17.87</td>
<td>17.65</td>
<td>19.61 (15.98–23.25)</td>
</tr>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td>18.04</td>
<td>18.65</td>
<td>19.41 (17.13–21.7)</td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td>18.65</td>
<td>18.04</td>
<td>20.86 (17.63–24.09)</td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
<td>18.04</td>
<td>22.09</td>
<td>19.41 (17.13–21.7)</td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
<td>23.90</td>
<td>22.55</td>
<td>22.09 (19.02–25.16)</td>
</tr>
<tr>
<td>2016</td>
<td></td>
<td></td>
<td>22.55</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Data as reported to the National Healthcare Safety Network (NHSN). The NHSN field “Died” was used to aggregate the number of patients with pneumonia who died, regardless of responses found in the “Contributed to death” field.

NV-HAP, nonventilator hospital-acquired pneumonia; VAP, ventilator-associated pneumonia.
<table>
<thead>
<tr>
<th>Year</th>
<th>NV-HAP Cases</th>
<th>Patient-Days</th>
<th>Pooled Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>1,848</td>
<td>$51,758,784</td>
<td>737</td>
</tr>
<tr>
<td>2011</td>
<td>1,780</td>
<td>$50,667,789</td>
<td>643</td>
</tr>
<tr>
<td>2012</td>
<td>1,620</td>
<td>$47,462,290</td>
<td>571</td>
</tr>
<tr>
<td>2013</td>
<td>1,528</td>
<td>$45,480,874</td>
<td>767</td>
</tr>
<tr>
<td>2014</td>
<td>1,419</td>
<td>$42,903,380</td>
<td>901</td>
</tr>
<tr>
<td>2015</td>
<td>1,427</td>
<td>$43,106,716</td>
<td>912</td>
</tr>
<tr>
<td>2016</td>
<td>1,380</td>
<td>$42,259,340</td>
<td>980</td>
</tr>
</tbody>
</table>

**Note:** Cases identified in the National Healthcare Safety Network (NHSN) database.

The estimated average cost per NV-HAP case is $28,008. The estimated average cost per VAP case is $37,442.

NV-HAP, nonventilator hospital-acquired pneumonia; VAP, ventilator-associated pneumonia.


Table 3 shows the distribution of NV-HAP cases by NHSN unit type for years 2013 through 2016. This data is intended to identify and prioritize high-risk patient populations, to facilitate effective deployment of infection-prevention efforts and resources.

**Table 3. Distribution of NV-HAP Cases, Pooled Mean per 1,000 Patient-Days (Based on Aggregate Data for Pennsylvania, 2013 through 2016)**

<table>
<thead>
<tr>
<th>Unit*</th>
<th>Facilities</th>
<th>NV-HAP Cases</th>
<th>Patient-Days</th>
<th>Pooled Mean†‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute/Critical Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>12</td>
<td>625</td>
<td>892,396</td>
<td>0.700</td>
</tr>
<tr>
<td>Surgery</td>
<td>11</td>
<td>477</td>
<td>908,216</td>
<td>0.525</td>
</tr>
<tr>
<td>Oncology medical/surgical</td>
<td>2</td>
<td>40</td>
<td>76,697</td>
<td>0.522</td>
</tr>
<tr>
<td>Neurosurgical</td>
<td>9</td>
<td>304</td>
<td>720,303</td>
<td>0.422</td>
</tr>
<tr>
<td>Medical</td>
<td>24</td>
<td>775</td>
<td>2,028,708</td>
<td>0.382</td>
</tr>
<tr>
<td>Cardiothoracic</td>
<td>30</td>
<td>562</td>
<td>1,550,793</td>
<td>0.362</td>
</tr>
<tr>
<td>Long-term acute care</td>
<td>3</td>
<td>50</td>
<td>189,497</td>
<td>0.264</td>
</tr>
<tr>
<td>Medical/surgical</td>
<td>117</td>
<td>1,883</td>
<td>7,212,260</td>
<td>0.261</td>
</tr>
<tr>
<td>Cardiac</td>
<td>19</td>
<td>222</td>
<td>963,748</td>
<td>0.230</td>
</tr>
<tr>
<td>Prenatal</td>
<td>1</td>
<td>2</td>
<td>11,566</td>
<td>0.173</td>
</tr>
<tr>
<td>Neurologic</td>
<td>4</td>
<td>18</td>
<td>106,348</td>
<td>0.169</td>
</tr>
<tr>
<td>Ward</td>
<td>Total</td>
<td>Admissions</td>
<td>Encounters</td>
<td>CMI</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
<td>------------</td>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>Burn</td>
<td>4</td>
<td>27</td>
<td>194,824</td>
<td>0.139</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2</td>
<td>6</td>
<td>59,180</td>
<td>0.101</td>
</tr>
<tr>
<td>Medical/surgical pediatric</td>
<td>5</td>
<td>36</td>
<td>693,549</td>
<td>0.052</td>
</tr>
<tr>
<td>Nursery</td>
<td>19</td>
<td>75</td>
<td>1,800,203</td>
<td>0.042</td>
</tr>
<tr>
<td>Step-down nursery</td>
<td>9</td>
<td>35</td>
<td>1,077,720</td>
<td>0.032</td>
</tr>
<tr>
<td>Cardiothoracic pediatric</td>
<td>3</td>
<td>9</td>
<td>331,409</td>
<td>0.027</td>
</tr>
<tr>
<td>Medical pediatric</td>
<td>0</td>
<td>0</td>
<td>25,322</td>
<td>0.000</td>
</tr>
<tr>
<td>Surgery pediatric</td>
<td>0</td>
<td>0</td>
<td>10,484</td>
<td>0.000</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>10</td>
<td>85,764</td>
<td>0.117</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>6</td>
<td>61</td>
<td>698,634</td>
<td>0.087</td>
</tr>
<tr>
<td>Neurosurgical</td>
<td>3</td>
<td>24</td>
<td>452,944</td>
<td>0.053</td>
</tr>
<tr>
<td>Medical</td>
<td>53</td>
<td>612</td>
<td>11,976,937</td>
<td>0.051</td>
</tr>
<tr>
<td>Surgical</td>
<td>38</td>
<td>331</td>
<td>6,433,864</td>
<td>0.051</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>1</td>
<td>5</td>
<td>103,484</td>
<td>0.048</td>
</tr>
<tr>
<td>Medical/surgical</td>
<td>122</td>
<td>1,285</td>
<td>29,471,925</td>
<td>0.044</td>
</tr>
<tr>
<td>Telemetry</td>
<td>24</td>
<td>118</td>
<td>2,824,988</td>
<td>0.042</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>41</td>
<td>129</td>
<td>3,982,174</td>
<td>0.032</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>24</td>
<td>84</td>
<td>2,909,777</td>
<td>0.029</td>
</tr>
<tr>
<td>Gynecology</td>
<td>2</td>
<td>4</td>
<td>140,379</td>
<td>0.028</td>
</tr>
<tr>
<td>Neurologic</td>
<td>7</td>
<td>17</td>
<td>682,517</td>
<td>0.025</td>
</tr>
<tr>
<td>Gerontology</td>
<td>1</td>
<td>1</td>
<td>77,734</td>
<td>0.013</td>
</tr>
<tr>
<td>Behavioral</td>
<td>40</td>
<td>116</td>
<td>10,670,565</td>
<td>0.011</td>
</tr>
<tr>
<td>Surgical pediatric</td>
<td>1</td>
<td>1</td>
<td>115,905</td>
<td>0.009</td>
</tr>
<tr>
<td>Trauma orthopedic</td>
<td>1</td>
<td>3</td>
<td>334,186</td>
<td>0.009</td>
</tr>
<tr>
<td>Antenatal</td>
<td>1</td>
<td>1</td>
<td>117,704</td>
<td>0.008</td>
</tr>
<tr>
<td>Labor &amp; delivery</td>
<td>4</td>
<td>4</td>
<td>546,418</td>
<td>0.007</td>
</tr>
<tr>
<td>Medical pediatric</td>
<td>2</td>
<td>5</td>
<td>838,051</td>
<td>0.006</td>
</tr>
<tr>
<td>Labor &amp; delivery/postpartum</td>
<td>5</td>
<td>5</td>
<td>1,077,758</td>
<td>0.005</td>
</tr>
<tr>
<td>Rehabilitation pediatric</td>
<td>1</td>
<td>1</td>
<td>204,761</td>
<td>0.005</td>
</tr>
<tr>
<td>Behavioral health pediatric</td>
<td>1</td>
<td>1</td>
<td>261,356</td>
<td>0.004</td>
</tr>
<tr>
<td>Postpartum</td>
<td>10</td>
<td>11</td>
<td>2,740,931</td>
<td>0.004</td>
</tr>
<tr>
<td>Medical/surgical pediatric</td>
<td>4</td>
<td>5</td>
<td>1,530,652</td>
<td>0.003</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---</td>
<td>---</td>
<td>-----------</td>
<td>-------</td>
</tr>
<tr>
<td>Behavioral health adolescent</td>
<td>1</td>
<td>1</td>
<td>681,088</td>
<td>0.001</td>
</tr>
<tr>
<td>Nursery</td>
<td>1</td>
<td>2</td>
<td>1,908,707</td>
<td>0.001</td>
</tr>
<tr>
<td>Ear/nose/throat</td>
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<td>736</td>
<td>0.000</td>
</tr>
<tr>
<td>Orthopedic pediatric</td>
<td>0</td>
<td>0</td>
<td>113,178</td>
<td>0.000</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>0</td>
<td>0</td>
<td>31,926</td>
<td>0.000</td>
</tr>
<tr>
<td>Jail</td>
<td>0</td>
<td>0</td>
<td>155,176</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>Ward—Oncology</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Leukemia/lymphoma</td>
<td>2</td>
<td>14</td>
<td>110,550</td>
<td>0.127</td>
</tr>
<tr>
<td>Hematology/oncology</td>
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<td>343</td>
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<td>0.120</td>
</tr>
<tr>
<td>Hematopoietic stem cell transplant</td>
<td>2</td>
<td>37</td>
<td>317,854</td>
<td>0.116</td>
</tr>
<tr>
<td>Hematology/oncology pediatrics</td>
<td>0</td>
<td>0</td>
<td>551,696</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>Specialty Care Area</strong></td>
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<td></td>
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</tr>
<tr>
<td>Solid organ transplant pediatric</td>
<td>1</td>
<td>4</td>
<td>128,615</td>
<td>0.031</td>
</tr>
<tr>
<td>Long-term acute care pediatric</td>
<td>0</td>
<td>0</td>
<td>22,860</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>Step-down Unit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult</td>
<td>60</td>
<td>555</td>
<td>8,272,644</td>
<td>0.067</td>
</tr>
<tr>
<td>Pediatric</td>
<td>1</td>
<td>1</td>
<td>415,707</td>
<td>0.002</td>
</tr>
<tr>
<td>Nursery</td>
<td>0</td>
<td>0</td>
<td>71,542</td>
<td>0.000</td>
</tr>
<tr>
<td>Long-term acute care</td>
<td>22</td>
<td>184</td>
<td>3,867,389</td>
<td>0.048</td>
</tr>
</tbody>
</table>

**Note:** Data as reported to the National Healthcare Safety Network (NHSN).

NV-HAP, nonventilator hospital-acquired pneumonia.

* Units are based on NHSN classifications.

† Pooled mean = total cases / total patient-days x 1,000.

‡ Per 1,000 patient-days.

**Discussion**

Both NV-HAP and HAP continue to be problematic for acute-care patients in Pennsylvania. Many healthcare providers are unaware of the importance of good dental care in preventing both NV-HAP and HAP. Li and co-authors noted that "the teeth are the only nonshedding surfaces in the body, and bacterial levels can reach more than 10^{11} microorganisms per mg of dental plaque [biofilm]." The presence of subgingival biofilm serves as a continual and enormous bacterial load. Poor oral hygiene increases plaque load, increasing enzyme levels in saliva. As a
consequence of the plaque load, increased levels of oral proteolytic enzymes change the lining of the mouth, increasing attachment and colonization by exogenous and/or endogenous pathogenic bacteria. The oral cavity is a source as well as a reservoir for pathogenic bacteria in both planktonic and biofilm states.

Dental-biofilm removal is mainly accomplished by using dentifrice-containing compounds, such as detergents, abrasives, and antimicrobials, which require mechanical tooth brushing to be effective. Given the characteristics of dental biofilm, part of a comprehensive NV-HAP prevention program includes tooth and tongue brushing with toothpaste.

Other preventive measures include protecting the patient from macro and micro aspiration and strengthening host defenses to infection. Figure 2 provides selected interventions to prevent NV-HAP. Figure 3 provides the Hospital-Acquired Pneumonia Prevention Initiative (HAPPI) oral care protocol designed by researchers at Sutter Medical Center and California State University, Sacramento, and approved by the American Dental Association Board of Trustees in 2017. The HAPPI research developed a targeted oral-care protocol that specifies patient type, equipment, procedure, and frequency for oral care.
Figure 2. Selected Interventions to Prevent Nonventilator Hospital-Acquired Pneumonia

**Selected interventions to prevent colonization:**
- Provide information about optimal pulmonary state.
- Optimize functional reserve capacity.
- Strengthen patient’s resistance to atelectasis.
- Maintain patient’s resistance to infection:
  - Perform hand hygiene.
  - Institute a routine oral hygiene regimen.
  - Eliminate oral bacterial reservoirs.
  - Consult with a dental professional.
  - Protect oral epithelial cells and nasal passages by providing moisture and avoiding large-bore nasogastric tubes.
  - Avoid unnecessary antibiotics.
  - Avoid unnecessary stress ulcer prophylaxis (if necessary, consider a cytoprotective agent).
  - Consider chlorhexidine oral rinse or chlorhexidine bath for select patient populations.

**Selected interventions to prevent aspiration:**
- Teach techniques for optimizing cough and airway clearance.
- Avoid unnecessary medications that reduce level of consciousness.
- Maintain head of the bed at 30 degrees or greater unless contraindicated.
- Encourage ambulation.
- Provide subglottic suctioning.
- Consult with speech and/or swallowing professionals when appropriate.

**Holistic prevention strategies:**
- Administer vaccines and immunizations.
- Provide smoking cessation counseling.
- Institute environmental infection control measures.
- Encourage personal hygiene, including hand hygiene.
- Evaluate the patient’s risk for aspiration.
- Provide dementia screening.
- Assess the patient’s nutritional status.
- Encourage routine professional denial care.
For preventive interventions to be successful, they need to be performed at specified frequencies. In a large, multicenter, nationwide study, in regard to hospital care performed in the 24 hours before NV-HAP diagnosis, Baker and Quinn found evidence of limited compliance, as follows:\textsuperscript{14}

- Oral care ≥2 times was not documented for 58.6% of patients.

---

Reprinted with permission from Dian Baker, PhD, RN, California State University, Sacramento, School of Nursing, Folsom Hall - 7057 Folsom Blvd., Sacramento, CA 95819-6096; and Barbara Quinn, MS, RN. Integrated Quality Services, Sutter Medical Center 1262 25th Street, Sacramento, CA 95816.

AM, ante meridiem; morning; HS, hora somni, at bedtime; NPO, nil per os, nothing by mouth; PRN, pro re nata, as needed.

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For preventive interventions to be successful, they need to be performed at specified frequencies. In a large, multicenter, nationwide study, in regard to hospital care performed in the 24 hours before NV-HAP diagnosis, Baker and Quinn found evidence of limited compliance, as follows:\textsuperscript{14}

- Oral care ≥2 times was not documented for 58.6% of patients.
Most patients (64.5%) had documented head-of-bed elevation to 30 to 45 degrees, whereas 35.5% did not.

If permitted, 28.7% of patients were out of bed twice in a 24-hour period, and 55.4% were out of bed fewer than two times (15.9% were not allowed mobility intervention).

Incentive spirometry was not documented for 81.8%, nor were cough and deep breathing exercises (67.4%), in the 24-hour period before pneumonia diagnosis.

The poor performance of basic NV-HAP prevention methods is unfortunate and likely signals the need for improved workflows, systems, tools, and human resources to deliver the care that is needed to prevent the condition. The job of prevention should fall upon all care providers, not just nurses and patient care assistants. Perhaps enlisting respiratory therapists, speech and swallowing therapists, and dental professionals could help ensure prevention tasks are performed at appropriate intervals.

The dental professional's participation is of paramount importance. Adachi and co-authors correlated weekly dental cleaning by a hygienist with fewer cases of fever and fatal pneumonia in the nursing home setting. Similarly, Abe and co-authors noted a reduction in influenza infection in older patients because of weekly professional dental cleaning. Perhaps, for HAP prevention, the dental professional should play an active role in the hospital and other healthcare settings.

Limitations and Data Nuances

NHSN's VAP criteria-definition changes occurred in January 2013, which, unfortunately, renders impossible direct comparisons between VAP and NV-HAP for the time periods before and after the change. Analysts did not calculate for analysis the pooled mean for NHSN events for the time periods before or after the criteria change, because the totals would be incomparable.

Analysis by patient-days may underestimate the true rate of NV-HAP because this metric potentially lowers rates because of extensions of length of stay related to NV-HAP. Authority analysts did not have access to unit-level-specific admissions by location type for this analysis—hence, the use of patient-days by location type.

Comparison of Table 1 from this article with Table 1 from the original Authority article reveals few differences, likely due to institutional edits over time. Regardless, the outcomes are the same for this updated data compared with the original data.

Conclusion

Both NV-HAP and VAP continue to be problematic for acute-care patients in Pennsylvania. NV-HAP affects more patients, contributes to more deaths, and increases costs more than VAP. Focusing care on bacterial reservoirs and the oral portal of entry is the most realistic approach for preventing NV-HAP. Improving oral hygiene is essential in preventing NV-HAP (and VAP). Staff compliance with interventions, as noted herein, and helping all patients to get HAPPI care is likely to prevent extra lengths of stay, save money, and prevent premature deaths.

Notes


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

A Weighty Problem

Events*

Reviewing patient's profile and found her weight entered as 73 lb. Patient reweighed and weight is 73 kg [161 lb].

Weight of 8.8 kg written on the order sheet. Orders for medications for intubation based on weight of 8.8 kg. Actual weight is 4 kg [8.8 lb]. Patient's vital signs remained stable during intubation.

Patient weighed during preoperative assessment, weight charted as 13.2 kg. Pt to OR. During procedure, physician's assistant recalled patient weight as 6 kg at the last office visit. After procedure, patient weighed and weight documented at 6.2 kg. Weight was done in kg [during preoperative assessment]; family had requested weight in pounds and pound weight was documented as kg weight.

Opportunity

Errors involving documentation that confuse kilograms (kg) and pounds (lb) are particularly hazardous for pediatric patients—whose medications or other treatments are usually adjusted according to the patient's weight—but may also have consequences for adult patients.\(^1\) In the first case, the patient's weight was obtained in kilograms but incorrectly documented in pounds. In the second case, the patient's weight in pounds was incorrectly documented as kilograms and he received a medication overdose.

Because of the magnitude of the difference between weights in pounds and in kilograms (1 kg = 2.2 lb), the error is often identified by astute clinicians who recognize the difference between the documented weight and their knowledge of the individual patient. However, relying on clinician vigilance is an insufficient strategy.

The Pennsylvania Patient Safety Authority recently issued recommendations that all patients be weighed and those weights are both obtained and documented in metric units. The recommendations are available (https://www.pabulletin.com/secure/data/vol48/48-36/1430.html) through the Pennsylvania Bulletin.\(^2\)

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


Safety Stories: Site Marks
This vignette presents a brief, timely highlight of surgical site marking events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) that may provide a learning opportunity for facilities.

Site Marks

Events*

The physician assistant began to prep the patient for surgery. The surgeon observed through the OR [operating room] window that the site mark was not visible. The surgeon entered the OR and confirmed that the prep had been initiated on the wrong extremity. The correct site was verified. The prep, draping, time-out and procedure were completed on the correct extremity.

Operating room staff noticed that the patient's surgical site mark was on a dressing and not the patient's skin. When requested to mark the site, the surgeon berated the staff in front of the patient. The surgeon continued to make sarcastic remarks about site marking throughout the course of the procedure.

Surgeon marked the patient's arm instead of her shoulder, and the nurse requested that he re-mark the patient. When the patient arrived in the OR, she had multiple large marks covering her extremity. During the time-out, the surgeon asked if the site marking was sufficient.

Opportunity

OR procedures involve a cascade of choreographed events, and finely honed teams accomplish complex tasks following both implicit and explicit signals. Site marks provide a very direct signal that supports procedure verification before irreversible actions—such as incisions—occur. Site marks provide information not just for the surgeon or anesthesiologist (e.g., for a nerve block), but for the entire team, which is coordinating the equipment, supplies, and room set-up.

In the first event described above, the site mark provided important information to the surgeon, who is to be commended for alertness in recognizing the hazard even before entering the OR. Unfortunately, in the second and third events, the surgeons demonstrated disrespect by their actions and by their words; this disrespect is likely to impair team function throughout the course of the procedure.¹

Wrong-site perioperative procedures continue to occur about once a week in Pennsylvania,² and any member of the team might be the individual who recognizes and prevents a wrong-site procedure. The Authority offers a gap analysis tool (/pst/Pages/Wrong%20Site%20Surgery/gap_analysis.aspx) for OR personnel³ and a poster (/pst/Pages/Wrong%20Site%20Surgery/poster_avoid_wss.aspx) for patients and their families.⁴

Respectful teamwork helps all team members contribute to decreasing the incidence of these unwanted events.

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


Principles for Reliable Performance of Correct-Site Nerve Blocks

Editor's Note

The American Society of Regional Anesthesia and Pain Medicine's August 2018 newsletter, ASRA News, includes an article addressing principles to promote correct-site nerve blocks. The article, abstracted below, discusses a partnership initiative between the Pennsylvania Patient Safety Authority and the Pennsylvania Society of Anesthesiologists to assess the frequency of wrong-site nerve blocks and present Pennsylvania anesthesia providers and healthcare facilities with practices to prevent them.

Principles

Analysis of wrong-site procedure events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) from July 2004 through September 2017 found that wrong-site nerve blocks comprised nearly 26% of these events.* Beginning in 2015, the Authority and the Society partnered to address a perceived slower adoption of prevention practices by anesthesiologists in perioperative or pain services than that of surgical teams.

A systematic review of English-language world literature conducted by the partnership team identified five themes contributing to wrong-site nerve blocks: time pressure, personnel factors, site mark not visible, distraction, and inadequate communication. The partnership team used the literature review results, as well as interviews conducted of a task force of anesthesiologists, surgeons, nurses, and patient representatives from Pennsylvania healthcare facilities, to identify more than 60 prevention practices. Subsequent review and consensus sought from task force members about the practices resulted in 21 principles (/pst/Pages/Wrong%20Site%20Surgery/nerveblock_correctsite.aspx), which address process of care (n = 12) and healthcare facility structure and culture of safety (n = 9).

The partnership team notes that these principles are unique from previous recommendations of professional organizations. The principles were informed by actual events reported in Pennsylvania and perspectives of a multidisciplinary task force. Other factors of the principles include using data sources, such as patients, to verify the surgical site and considering the environment and culture associated with performance of nerve blocks. Anesthesiologists are encouraged to familiarize themselves with the principles and endeavor to integrate them in their healthcare facilities.

* According to an article in the March 2018 issue of the Pennsylvania Patient Safety Advisory (/ADVISORIES/Pages/201803_WSSUpdate.aspx), from July 2004 through September 2017, there were 779 wrong-site perioperative events, including wrong-site nerve blocks, reported through PA-PSRS.

9/20/2018
Source


Additional Resources

A complete list of Principles for Reliable Performance of Correct-Site Nerve Blocks (/pst/Pages/Wrong%20Site%20Surgery/nerveblock_correctsite.aspx) is available from the Authority website as part of a broad set of resources addressing the patient safety topic of wrong-site surgery (/pst/Pages/Wrong%20Site%20Surgery/hm.aspx).
Introduction

Root cause analysis (RCA) is commonly used in attempts to improve the safety of healthcare delivery, but a variation—success analysis—may also be useful. Traditional RCA is based in Safety-I principles: to improve safety, practitioners focus on serious events with undesired outcomes and attempt to identify what went wrong using investigative techniques. Success analysis, evolving from Safety-II principles, can be used to learn how success was achieved, reinforce correct decisions and actions, and learn how process modifications might contribute to greater improvements.

Limitations of RCAs

RCA has been lauded because it was one of the first tools available to healthcare that looked beyond proximate cause (e.g., the final act or omission) by a healthcare provider closest to or at the "sharp end" of an undesired patient outcome. However, the traditional RCA approach has important limitations.
RCA inquiry focuses primarily on determining where "errors" or failures may have occurred. The RCA may determine that factors at the "blunt" end, distal or far from actual patient care processes (e.g., staffing decisions, equipment purchases) contributed to a serious event; however, that analysis may still suggest that responsible people made incorrect decisions. Some hazards may be identified, or antecedent or contributing factors may become evident during the investigation. However, finer details and granularity, such as momentary distractions, plausibility of decision-making, and options available to the involved providers in the moment are often elusive. RCA variations such as apparent cause analysis, common cause analysis, and root cause analysis and action (RCA\(^2\)) generally follow similar principles of critical inquiry.

Health and illness are biologic processes, whereas the delivery of healthcare is a complex socio-technical system that requires human workers to coordinate the work on other humans. Because healthcare delivery is a human-made system, "the search for a human in the path of a failure is bound to succeed... The assumption that humans have failed therefore always vindicates itself."\(^{9}\)

An often-overlooked aspect of healthcare work is the overarching contribution of all the humans within the system to the vast majority of the care that is delivered safely and without incident. Understanding how "things go right" provides an untapped opportunity for mitigation of risk from less frequent incidents of harm and injury within a healthcare system.

### The Safety-II Approach

Safety-II principles, based in resilience engineering theory, find value in the exploration, replication, and amplification of events with desirable outcomes.\(^{10}\) These events include successful responses to extraordinary circumstances or, more often, everyday achievements and normal care.

Because the circumstances of patient care often include fluid, evolving elements, adaptability is necessary to attain success. Rather than seeking to constrain healthcare providers, their knowledge and skills are valued and the healthcare provider is afforded the flexibility to provide care in a way that maximizes the chance for success.\(^{1}\) RCAs are typically based in Safety-I principles aimed at preventing failure; success analysis can be based on Safety-II principles aimed at achieving success and safe healthcare. Safety-I and Safety-II principles can coexist and complement each other (Table).

<table>
<thead>
<tr>
<th>Safety-I</th>
<th>Safety-II</th>
</tr>
</thead>
<tbody>
<tr>
<td>What goes wrong</td>
<td>What goes right</td>
</tr>
<tr>
<td>Defined by failure</td>
<td>Defined by success</td>
</tr>
<tr>
<td>Humans are a problem</td>
<td>Humans are a resource</td>
</tr>
<tr>
<td>Achieved by limits and constraints</td>
<td>Achieved by adaptability</td>
</tr>
<tr>
<td>Inquiry tone is critical</td>
<td>Inquiry tone is appreciative</td>
</tr>
</tbody>
</table>

**Source:** Adapted from Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: a white paper. University of Southern Denmark; University of Florida; 2015. 43 p.
Success Analysis

Success analysis, while not yet codified, is based on principles of Safety-II and explores "what went well" or "what went right" during patient care events. In this context, the term events refers to patient care interactions (e.g., at the "sharp end"), or actions that occur even earlier in the healthcare delivery process, such as providing redundancy in staffing or structuring decision-making in a manner that allows input from all individuals with insight about the care being delivered (e.g., at the "blunt end"). A success analysis could be conducted in a manner similar to RCAs, with a focus on identifying actions and resources that contribute to success, with the same caveats about limitations.

For example, after identifying challenges in the provision of extracorporeal membrane oxygenation (ECMO), an organization that responded to a patient care crisis with successful emergency implementation of ECMO then conducted a success analysis. The event investigators found that provider capacity (e.g., availability because of margin in their workload) was a critical component of the ability to respond rapidly.

Two of the National Academy of Medicine's publications espouse a similar principle of learning from success. Improving Diagnosis in Healthcare states that organizations can "ensure that their evaluations generate much-needed evidence to identify successful interventions" and that "feedback entails informing an individual, team, or organization about its diagnostic performance, including its successes. . ." as well as near misses and diagnostic errors.11 Crossing the Quality Chasm states that "the 21st-century health care system means combining the many ways to generate and test ideas with ways to enhance the spread of 'good ideas' and impede the spread of 'not so good' ideas."12

Ideally, the serious events that serve to initiate RCAs are uncommon and unexpected. In contrast, implementing success analysis on a predictable schedule (as well as in conjunction with RCAs) may mitigate some logistical challenges. The regular occurrence of success analyses would help safety and risk personnel refine their understanding of healthcare delivery as a complex and dynamic socio-technical system, which would also provide an opportunity for more robust and realistic action plans and interventions. Success analysis also can help build team relationships as team members gain understanding of the ways each individual's actions contribute to safe care, perhaps in ways that were previously unrecognized.

Allowing Safety to Emerge

Of course, it is not that simple. Whether event explorations occur during RCAs or during success analyses, it will not be possible to identify all of the discrete causes and circumstances that contribute to success and failure. Pairing these approaches may provide the most holistic perspective of how "work is done" and what is needed to ensure the ratio of success to failure remains high for every patient. Success analysis focused on events that go well—both extraordinary and ordinary events—offers greater opportunities to support organizational resilience. To paraphrase a concept attributed to James Reason, "opportunities for patient harm are infinitely creative." So, too, are opportunities for safety. Success analysis, based in Safety-II principles, provides a change in focus that can help us understand and support systems that allow safety to emerge.

Notes


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