Reviews & Analyses

Near-Miss Event Analysis Enhances the Barcode Medication Administration Process (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_BCMA.aspx)
Pennsylvania healthcare facilities have increasingly reported events associated with barcode medication administration (BCMA). In collaboration with the Authority, a Pennsylvania health system used its “near misses” to improve its BCMA process.

Preparing for Unplanned Admissions to the NICU (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_NICU.aspx)
Both premature and term infants have experienced unplanned admissions to the NICU. In Pennsylvania, the most frequently reported conditions were respiratory distress, metabolic issues, prematurity, neonatal abstinence syndrome, and infection.

Medication Errors in Outpatient Hematology and Oncology Clinics (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_oncology.aspx)
Oncology care is provided in outpatient settings due to increased patient convenience and decreased cost; however, medication errors in this setting have not been fully explored.

Warming Blankets and Patient Harm (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_warmingdevices.aspx)
Hospitals seeking to prevent these adverse events can adopt risk reduction strategies consistent with perioperative guidelines for preventing and treating hypothermia and manufacturers’ guidelines for device use and preventative maintenance.

From the Database

Data Snapshot: Complications Linked to Iatrogenic Enteral Feeding Tube Misplacements (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_feedingtubes.aspx)
Analysis of these misplacements found more than half led to complications, including death. Pneumothorax was the most common outcome; complications of other misplacements included coiling, perforation, and placement in the wrong portion of the GI tract.

Other Features

Saves, System Improvements, and Safety-II (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_safetyII.aspx)
This recurring feature highlights successes of healthcare workers in keeping patients safe; in this instance, the application of process standardization.

Patient Safety: No Harm, No Foul? (http://patientsafety.pa.gov/ADVISORIES/Pages/201712_patientsafety.aspx)
The unusual breadth of patient safety event report collection in Pennsylvania offers important and unique opportunities to inform our collaborative efforts to make healthcare safer.
Near-Miss Event Analysis Enhances the Barcode Medication Administration Process

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Near-miss event reporting and analysis is an essential part of a robust patient safety program. Pennsylvania has seen an increase of more than 2,700% in reports of near-miss barcode medication administration (BCMA) events over twelve years, from January 2005 through December 2016. During the same period, events that reached the patient and caused harm (Serious Events) accounted for only 0.5% of reported BCMA-related events. Reporting, but more importantly, the analysis of near-miss events can lead to improvements in processes and reduce the potential for patient harm. Through a case study, the Pennsylvania Patient Safety Authority shares the story of how Blue Mountain Health System reduced its barcode-workflow events by 53% between 2014 and 2016. Through a collaborative effort with the Authority's analysts and patient safety liaison, the health system used near-miss event review and analysis to improve its BCMA process. The Authority shares best practice strategies for BCMA use in the context of near-miss event analysis.

Introduction

The Lighthouse of Patient Safety

Much as a lighthouse serves as a navigational aid that warns sailors of hazards and high-risk areas, near-miss event reporting and analysis can warn facilities about patient safety hazards and system weaknesses before patient harm occurs. For this article, a near miss has a Pennsylvania Patient Safety Reporting System (PA-PSRS) harm score of A, B1, or B2. A near miss represents unsafe conditions (i.e., circumstances that could cause an adverse event) or a circumstance that might have caused harm but did not reach the patient because of chance alone or active recovery efforts by caregivers.¹
Near-miss event reporting and analysis is common in industries such as aviation, nuclear energy, and chemical engineering.\textsuperscript{2-6} It identifies precursor situations and trends in order to prevent the occurrence of harmful and fatal events. The Institute of Medicine's 1999 report, \textit{To Err is Human: Building a Safer Health System}, advocated studying near misses "to detect system weaknesses before the occurrence of serious harm."\textsuperscript{9,10} Since then, the Pennsylvania Patient Safety Authority and others have promoted near-miss event reporting and analysis as part of a robust patient safety program.\textsuperscript{10-16} According to an article by Marella, "Near-miss reporting, trending, and data analysis provide an opportunity to take action before someone is injured."\textsuperscript{10} Further, "if your hospital collects only reports of adverse events and ignores near-misses, you are missing out on the most valuable source of data for identifying patient safety priorities and for measuring your progress on the problems you're trying to fix."\textsuperscript{10}

In a recently published article, the Authority profiled the Good Catch ratio, a calculation of the number of near-miss events to the number of Serious Events.\textsuperscript{16} One would expect several near-miss events for each Serious Event. Theoretically, a greater Good Catch ratio may signal a safety culture that values recognition and reporting of hazards before harm occurs.\textsuperscript{16} Merely reporting and counting events, however, is insufficient without analysis of the data. In the case of Blue Mountain Health System, its patient safety liaison (PSL) was cued by an analyst to multiple near-miss events that occurred within the health system and were categorized as an Other/Miscellaneous event type described as "MAK workflow" (Siemens Med Administration Check\textsuperscript{TM}). The analyst determined that these events were reported with relative consistency, on a monthly basis, over several months, and appeared to involve the medication administration process.

**Barcode Medication Administration**

With the advent and adoption of health information technology (Health IT), such as the electronic health record (EHR), pharmacy computer systems, automated dispensing cabinets, and barcode medication administration (BCMA) systems, complexities are believed to be better managed, albeit not free from workarounds or error.\textsuperscript{17-20} BCMA, an inventory control system, uses barcodes to help prevent medication-administration errors.\textsuperscript{21-23} The technology is designed to improve the likelihood that the right patient will receive the right medication in the right dose at the right time.\textsuperscript{22}

BCMA systems started with U.S. Department of Veterans Affairs (VA) hospitals in the late 1990s and were mostly stand-alone systems that did not integrate with other medication-management technologies.\textsuperscript{24,25} In 2004, the U.S. Food and Drug Administration (FDA) published its final rule on barcode labels, and manufacturers had until 2006 to comply with the medication-labeling standards.\textsuperscript{26}

Excluding specialty, federal, and VA hospitals, 86\% to 93\% of U.S. hospitals have adopted BCMA.\textsuperscript{27,28} In its most recent survey published in 2015, the American Society of Health-System Pharmacists reported that "significant increases [in the number of hospitals using BCMA] were seen in the last five years" and reported a more than 6,000\% increase in adoption of BCMA since its 2002 survey.\textsuperscript{28}

Blue Mountain Health System, located in northeastern Pennsylvania, includes Gnaden Huetten and Palmerton hospitals.\textsuperscript{29} In 2007, the health system's leadership committed to system-level organizational changes to become a high-reliability organization. The strategies included establishing a culture of safety that prioritized goals that would achieve the biggest impact on patient safety. High-risk functions and processes, such as medication management, were chosen as a high priority.\textsuperscript{30} Health system leadership identified BCMA improvement opportunities and engaged Authority staff to help improve aspects of the hospitals' BCMA process. Near-miss event review and analysis proved critical to understanding BCMA workflow at the health system and ultimately led to improvements in medication-administration safety.
Leaders at Blue Mountain Health System noticed a lack of internal near-miss event reporting prior to 2010 and modified their internal medication-error reports to capture contributing factors. Leadership's commitment to be "obsessed with failure" included focusing on identifying hazards and increasing near-miss event reporting. In 2012, the health system upgraded its automated dispensing cabinets to include barcode scan on medication removal for all inpatient nursing units and barcode scan on refill by pharmacy. The bedside barcode scanning application software provided the capability of running medication administration–related reports.

**Methods**

Authority analysts queried the PA-PSRS database for BCMA events occurring in Pennsylvania healthcare facilities from January 1, 2005, through December 31, 2016—a twelve-year period adequate to capture a sufficient number of events for analysis and spanning the progressive adoption of BCMA implementation in healthcare facilities.

The query included all facility types, event types, and care areas. The reporting facilities provided the following information regarding the event: event type, harm score, and event description. Analysts searched free-text data fields for the following key words and phrases, including their variations: barcode, BCMA, and MAK Workflow. The query yielded 2,220 events. Analysts manually reviewed all events. Included for analysis were events caught at the point of administering the medication to the patient and excluded were 841 events that were not medication barcode events, as well as 70 events that were not applicable (e.g., barcode description did not involve the medication administration node). This resulted in 1,309 events as the final sample for analysis. Preliminary analysis demonstrated a relatively large number of reports submitted during 2007; further analysis was conducted to identify whether one or multiple facilities contributed to this increase.

A simple percentage-change formula was used to calculate the percentage increase of PA-PSRS BCMA near-miss events from 2005 to 2016 and the percentage decrease of Blue Mountain Health System's barcode scanning events from 2014 to 2016.

**Good Catch Ratio**

The Good Catch ratio (good catch-to-Serious Event) was calculated by comparing the number of good catch reports (i.e., events submitted with harm scores, A, B1, or B2) to the number of Serious Event reports (i.e., harm scores E, F, G, H, or I), creating a proportion that can be expressed as x:1, or simply x.16

**Medication Management**

The medication management process is a series of interdisciplinary, complex tasks that can be divided into five to eight stages or nodes, from selecting a medication through monitoring medication effects on patients.31-34 For this analysis, analysts assigned each event to one or more of four applicable nodes:

- Prescribing
- Transcribing
- Dispensing
- Administering

**Literature Review**

http://patientsafety.pa.gov/ADVISORIES/Pages/201712_BCMA.aspx 12/20/2017
Analysts conducted a review of the literature and an internet search to obtain data and information on BCMA, barcode implementation, near-miss event reporting in healthcare and other industries, and workarounds. A medical librarian assisted with a search for published articles indexed between January 1, 2011, and December 13, 2016, in the Association for Computing Machinery, CINAHL, Embase, Google Scholar, Medline, PubMed, and Scopus databases. Search terms included the following: automatic data processing, barcodes, BCMA, hospital medication systems, implementation, installed, medication errors, workflow, safety management, hazards, and workarounds.

**Event Details* and Facility-Level Data**

The health system's co-authors analyzed data captured in the bedside barcode scanning software application for medication administration, and provided the facility-level data that represents the actual number of reports submitted to their quality improvement and patient safety committees.

The health system's director of pharmacy/medication safety officer reviewed and analyzed this report data and compiled the results according to the PA-PSRS harm score taxonomy.

**Blue Mountain Health System's Bedside Barcode**

To assess whether nursing staff was performing barcode scanning at the patients' bedsides, the team analyzed the bedside barcode scanning application system's data from the medication administration node that correlated with the right-patient/right-medication scanning step. After standardizing the medication management practices at both campuses, the health system team validated that the medication-management processes were improving.

* The details of the PA-PSRS event narratives in this article were modified and de-identified to preserve confidentiality. Unless otherwise noted, none of the event narratives came from Blue Mountain Health System reports.

**Results**

**Barcode Medication Administration Event Trend**

Figure 1 illustrates an increase in the number of BCMA events reported through PA-PSRS from 2005 through 2016. The increase in 2007 is attributable to a single facility (not a Blue Mountain Health System facility), which accounted for 86.5% (n = 270) of the 312 reports that year. The most recent trend began in 2012, and a spike in reporting occurred in 2015.
Nodes, Harm, and Near-Misses

BCMA events occurred during each node of the medication-management process; 9.9% (n = 130 of 1,309) of reports involved more than one node, and therefore, the following percentages will equate to more than 100%. The majority of events, 81.3% (n = 1,064) involved the administering node. The remaining events involved these nodes:

- Dispensing, 27% (n = 354)
- Prescribing, 1.6% (n = 21)
- Transcribing, 0.8% (n = 11)

Although all of the events in the sample were identified as BCMA events, 245 did not involve the administering node, as seen in the following example in which the dispensing node was involved and the error was caught during administration:

*The patient was ordered an extended release oral diabetes medication [and the] pharmacy sent [the immediate release version]. The error was caught in scanning the barcode.*

The majority of events, 65.5% (n = 857), reached the patient (harm scores C through I; Figure 2). However, only seven (0.5%) Serious Events occurred (i.e., resulted in patient harm; harm scores E through I). All of the patient harm events involved only the administering node.
Near-miss events accounted for 34.6% (n = 453) of the 1,309 BCMA events and 34.8% of the 1,302 Incidents, as seen in these examples attributed to successful barcode scanning:

The pharmacy dispensed the wrong dose of a [dopamine promoter] medication. The error was caught upon barcode scanning. The intended process functioned as designed. Pharmacy re-dispensed the medication and the patient received the correct dose.

The nurse scanned the barcode for the [antibiotic], and the system alerted to wrong medication. Nurse verified with pharmacy that the wrong medication was dispensed. The patient received the correct medication.

The Good Catch ratio for BCMA events in this study is 65:1. Interestingly, the Good Catch ratio for the subset of Blue Mountain Health System’s BCMA events is incalculable because no Serious Events were reported in this study period, compared with the 122 reported near misses.

Figure 3 illustrates a 2,725% increase in number of near-miss BCMA events reported through PA-PSRS from 2005 to 2016. The increased trend began in 2014 and a spike in reporting occurred in 2015. The percentage increase from the start of the trend (2014) is 105.5%.
The Blue Mountain Health System's bedside barcode scanning software application allowed for increased data capture and internal reporting capability. Using these reports, the health system noticed a 172.7% increase in overall medication-administration error reports (n = 77 in 2011 to n = 210 in 2012) at the first campus and a 36.4% increase (n = 77 in 2011 to n = 105 in 2012) at the second campus. In addition, the team determined that the proportion of near-miss event reports had increased more than 280% at both campuses, from 20.5% of total reports in 2011 to 78.6% in 2012.

Figure 4 illustrates Blue Mountain Health System's downward trend (improvement) in near-miss BCMA events. The overall improvement is 52.9% from January 2014 to December 2016.

* Data reported through the Pennsylvania Patient Safety Reporting System, January 1, 2005, through December 31, 2016.

http://patientsafety.pa.gov/ADVISORIES/Pages/201712_BCMA.aspx
Workflow and Workarounds

Failure to follow a policy or procedure or employing workarounds was identified in 40.3% (n = 527) of the BCMA events reported through PA-PSRS. Of those 527 events, 83.1% (n = 438) reached the patient but only 0.9% (n = 5) involved serious harm including death, as seen in these examples:

The nurse selected the wrong patient in the computer and administered the medication without checking the patient's ID. The patient was subsequently transferred to a higher level of care for more frequent monitoring.

An RN mistakenly administered an opioid at four times the ordered dose. The construct of the electronic order contained both the ordered dosage and the high-alert dose range. A second RN verified the higher dose with the administering RN before handing over two syringes. A syringe was scanned after the medication was administered. The patient later died.

Of BCMA events, 25.7% (n = 337) involved a problem related to equipment, including unreadable patient identification bracelets, uncharged scanners, missing or smudged barcode labels on medication, and lack of wireless connectivity. Fourteen of these equipment-related events also involved staff bypassing policy or procedure.

Blue Mountain Health System's Bedside Barcode

At the health system, the initial percentage of nurses using BCMA for patients at bedside on the inpatient units was 97.7%, which increased to 99.6% after one year. Initially 94.1% of the barcode errors occurred during the right-patient/right-medication step of the administration node; this increased to 97.5% after one year. Examples of the types of administration errors included missed doses, delays in medication administration, and wrong-patient scans, including what appeared to be intentional barcode scans of the wrong patient.

Discussion

The number of reports of overall BCMA events reported through PA-PSRS, specifically near-miss BCMA events, is trending higher. The sharp increase in reporting seen in 2007 is likely special cause variation and, as mentioned, is attributable to a single facility. The Authority reached out to the facility responsible for that increase, but as of press
time had not received a response. In comparing Figures 1 and 3, the majority of the 2007 reporting spike seen in Figure 1 is attributable to events with a harm score of C or D, meaning the "event reached the patient but did not cause harm or required monitoring to confirm that it resulted in no harm, and/or required intervention to prevent harm."\(^1\)

The 2015 spike in reporting seen in both figures is attributable, in part, to Blue Mountain Health System's event-identification initiative and reporting. Additionally in 2015, the Authority updated PA-PSRS to collect information regarding health IT–related contributions to events, as applicable.\(^36\)

The low number of Serious Events compared to Incidents is encouraging. Near-miss events are increasingly being identified and reported. Analysis of these "lighthouse" events can alert staff to patient safety hazards and system weaknesses and, similar to the work shared by the health system, can help identify opportunities to measure progress on existing initiatives and improve patient safety.

**Workflow and Workarounds**

A death was reported in which staff bypassed the BMCA procedure. Although the Authority cannot say for certain that this death could have been prevented, recognizing when and identifying why staff use workarounds or modify procedures to "get the work done" enables leaders to identify hazards and at-risk behavior and potentially redesign the work.\(^37\)

**Blue Mountain Health System and the Authority's Collaboration for Improvement**

Simultaneous to the health system's team's tracking and trending of the bedside barcode scanning reports, an Authority analyst detected and notified the Authority PSL of a pattern of "MAK workflow"–related near-miss reports submitted by the health system. The PSL was invited to observe the facility's BCMA workflow and identified system and process opportunities.

The health system's near-miss reporting results appeared to indicate an intentional barcode scan of the wrong patient. For example, patient A should have been scanned, but Patient B was scanned instead. The error report was generated because the nurse had the wrong patient on the bedside barcode scanning application computer screen. The barcode scanning report caught this discrepancy, and when the Authority's PSL observed medication-administration workflows, she found that nursing staff was not clearing the previous patient from the barcode scanning system before scanning the next patient, because staff found this procedure modification more efficient (fewer mouse clicks).

As is common with BCMA and other health information technologies, a given task may be performed multiple ways within the system; therefore, more opportunities exist for errors to occur.\(^17,18,22,34\) When the health system conducted a failure modes and effects analysis on failure points identified through the on-site observations, frontline staff identified challenges related to the system design of the BCMA workflow practices. The BCMA system allowed for variations in access to patient medication administration records and charting. This variation created increased risk of near-miss events associated with barcode scanning workflow, such as potential wrong-patient selections. Limitations of the system (e.g., lack of internet connectivity) led to staff employing workarounds that they believed were the safest alternatives, yet posed additional opportunities for error. For example, the health system noted certain patient rooms had greater numbers of barcode scanning events than others, which was associated with limited or no internet connectivity. Internet connectivity was expanded to include those areas.

In reviewing all of the 2015 barcode scanning events, the team found some correlation to specific users (i.e., nurses) and the number of events per user. The unit director conducted individual staff interviews and provided education. Staff development provided formal education on an *as needed* basis.
To understand the nurses’ barcode scanning workflow better, the team surveyed nursing staff about their scanning process, including whether they scan the medication or the patient first. The existing policy set an expectation that the patient is scanned first, then the medication. However, nurses would engage a workaround in certain circumstances (e.g., when the same medication was ordered for multiple patients [e.g., acetaminophen], nurses would first scan the medication). This workaround contributed to some of the wrong-patient scan totals. In addition to policy re-education, nursing directors affixed a STOP sign visual reminder to the mobile computers (Figure 5), which reinforced the proper scanning sequence. This reminder helped reduce the number of wrong-patient scan errors.

Figure 5. Stop Sign on Mobile Computer

Scan = Scan the patient, scan the medication  
Close = Close the screen to  
Advance = Advance to the  
Next = Next patient profile

The health system team continues to focus on all medication events as well as sustaining the progress made in the bedside barcode scanning workflow and wrong-patient-scan events. The health system hospitals are implementing a new EHR and plan to use the system's reporting capabilities to identify processes that need improvement and make those improvements.

Strategies for Success

Research supports near-miss event reporting and analysis with the successful implementation of BCMA. Highlights of best practices and strategies for success are featured below.

Prior to bringing on new processes/systems
• Promote event reporting. Collect and analyze all reports, and specifically near-misses, to help identify patient safety hazards and detect existing system weaknesses.8,13,16 Establish a baseline of performance before implementation to provide a means of comparison for like events during and after implementation.23,38

• Secure administrative support. Support from leadership and the creation of an implementation team are keys to successful implementation.17,21 Both help keep the project on track, and leaders can help remove road blocks. Blue Mountain Health System continued to dedicate resources well after the initial "go-live," which led to continued improvements.

• Communicate with and involve frontline staff. Facilities adopting medication management–related technologies, whether stand-alone or integrated, can consider the technologies' interconnectedness and functionality for the end user.18,21,34,37

• Evaluate current workflows, procedures, and processes. Understanding "work as done" will assist facility staff in selecting the appropriate product or service.23,34,37

• Conduct failure mode and effects analysis. Proactively assessing potential failures will inform team leaders and help them select and design successful implementation strategies.21,38,39

During the initial phases of implementation

Facility and team leadership can build upon the previous strategies with these enhancements:

• Conduct direct observations of staff workflows. Observing processes currently and soon after implementation allows team leaders to engage with patients and staff about the system and how it is working, compared to how it was imagined during planning, and determine necessary adaptations to workflow.18,34,37,38,40 These observations will afford leaders the opportunity to identify and manage equipment failures. Incorporate these observations into existing processes, such as Joint Commission's Tracers™.41,42

• Conduct simulation exercises. Simulating certain scenarios or key tasks can identify new or unforeseen tasks or steps that emerge during a new or revised process and allows staff to practice the redesigned or newly created procedures.43,44

• Analyze event reports. Encouraging reporting and analyzing events ensures staff have a venue to inform leadership about the processes and workflows and, as mentioned previously, ensures a means of comparison for like events.8,13,16,23,38

After implementation

• Perform root cause analyses. Exploring the root causes of factors that contribute to near misses and events that reach the patient, regardless of harm, helps workers understand whether and why (or why not) steps or tasks followed the plan, laying the ground work for solution identification.34

• Seek assistance from the Authority. Inviting Authority staff, such as the PSL, on-site to conduct observations allows for objective evaluation and feedback of part or all of the processes. Authority staff can help with PA-PSRS data analysis and the calculation of the Good Catch ratio.

Limitations
Some data presented here are from the PA-PSRS database. Despite mandatory reporting laws, the data are subject to the limitations of self-reporting, including the complexities of selecting the appropriate event type, harm level, and harm score. Over time, the Authority has collaborated with facilities, organizations, and the Department of Health to clarify definitions and reporting standards, which the Authority believes has helped standardize and facilitate reporting.

In-depth analysis by the Authority is limited by the information provided by the facility on the event report submitted through PA-PSRS, including the event descriptions. BCMA is not a structured data field in the PA-PSRS report; therefore, a keyword search of the event detail and other free-text data fields was applied. However, facilities may have submitted reports using different terminology.

**Conclusion**

Near-miss event analysis provides an organization the opportunity to uncover real and potential hazards in a process before an event reaches a patient and causes harm. Healthcare is catching up to other industries, such as aviation and nuclear energy, with regard to near-miss event reporting and analysis. Pennsylvania healthcare facilities can use their own aggregated PA-PSRS data as a resource to trend near-miss reporting. The Good Catch ratio may be a useful tool to assess BCMA reporting practices in addition to the overall near miss-to-Serious Event ratio.

As seen in the Blue Mountain Health System example, the facility and the Authority independently tracked and trended PA-PSRS reports and as a result, the Authority assisted the health system in improving aspects of its BCMA process. Pennsylvania facilities are strongly encouraged to reach out to the Authority for assistance.

Preventing patient harm is a healthcare priority, and the importance of near-miss event analysis to this end cannot be overstated. Near-miss analysis provides a valuable source of information about patient safety hazards and system weaknesses, identifies patient safety priorities, and measures progress on safety and quality-improvement initiatives. Using the lighthouse analogy, near-miss event reporting and analysis helps organizations keep patients safe as they navigate through the healthcare system.

**Acknowledgment**

The Blue Mountain Health System co-authors were willing to share their medication-administration quality improvement story for altruistic purposes in the hope that other facilities may learn from their journey. The Authority is grateful to Blue Mountain Health System employees for their transparency and willingness to co-author this article.

**Notes**


30. Patzek D. (Vice president of Nursing/Chief Nursing Officer, Blue Mountain Health System). Interview with Mary C. Magee. 2015 Feb 16.


44. Deutsch ES. Simulation can improve the healthcare systems we work within. Pa Patient Saf Advis. 2015 Dec;12(4):159-60. Also available: http://patientsafety.pa.gov/ADVISORIES/Pages/201512_159.aspx (/ADVISORIES/Pages/201512_159.aspx).
Preparing for Unplanned Admissions to the NICU

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Abstract

An admission to the neonatal intensive care unit (NICU) may be planned if problematic maternal or fetal conditions have been identified during the pregnancy. However, in other instances, an unplanned admission to the NICU may happen because of unexpected maternal, fetal, delivery, or post-delivery conditions. In the United States, the number of admissions to the NICU continues to rise, with most infants presenting as preterm, with a low birth weight or with a clinical condition requiring specialized care. In addition, in the past two decades, more information has become available on the unique risks and treatment needs for infants identified as late preterm (34 0/7 to 36 6/7 weeks' gestational age).

Providers in Pennsylvania asked the Pennsylvania Patient Safety Authority to review and report conditions and trends related to unplanned admissions to the NICU that have been identified from submitted reports. In response to this request, Pennsylvania Patient Safety Reporting System (PA-PSRS) data was analyzed at five-year intervals (2006, 2011, and 2016), which included 3,385 reports. Of these reports, 95.5% (n = 3,231) were submitted as Incidents that resulted in no patient harm. Analysis of PA-PSRS data revealed that both premature and term infants experienced unplanned admissions to the NICU. Admissions to the NICU generally increased during the reporting period, and a single event report may describe multiple associated conditions. The most frequently reported conditions related to an unplanned admission to the NICU were respiratory distress (29.5%), metabolic issues such as hypoglycemia and hyperbilirubinemia (16.2%), prematurity (9.5%), neonatal abstinence syndrome (NAS; 7.6%), and infection (6.1%).

Introduction

An unplanned admission to the neonatal intensive care unit (NICU) may happen because of unexpected maternal, delivery, or fetal conditions. Admissions to the NICU continue to rise in the United States, with 500,000 infants born annually as preterm, with low birth weight, or having a clinical condition that requires specialized care. Care in the NICU, which focuses on supporting organ development and providing necessary assessment and treatment by specially trained staff, has reduced newborn mortality and morbidity over the past 40 years. Providers in Pennsylvania asked the Pennsylvania Patient Safety Authority to review and report on conditions and trends resulting in an unplanned admission to the NICU identified from submitted reports.
Methods

Analyst queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events involving patients younger than 12 months of age reported for the years 2005 through 2016. The search criteria used to identify events involving an unplanned admission to the NICU included the "unplanned admission to the NICU" event subtype as well as events that contained the following key words in the narrative details: nicu, transfer, gest, premature, term, diabet, maternal, and mecon. Use of a wildcard character (*) ensured that the search yielded events containing multiple word forms (e.g., diabet* returns both diabetes and diabetic).

The analysis was limited to sampling full years at five-year intervals: the years 2006, 2011, and 2016. A manual review of these reports was completed and reports were included if the event type was "unplanned transfer to the NICU" or the narrative detail stated a transfer to the NICU, ICU, or higher level of care occurred. Further manual analysis was completed to identify the conditions associated with the unplanned admission to the NICU event, gestational age if noted, and trends over time. A single event could contain more than one condition associated with the unplanned admission to the NICU.

All reports that identified an event in which the NICU physician, resident, or nurse was summoned to a delivery or for a consultation that did not result in an unplanned admission to the NICU were excluded. Also excluded were reports that described situations in which the patient was admitted to the NICU postoperatively per surgical plan or in which the report category or narrative detail did not identify the NICU admission as unplanned.

Results

In years 2005 through 2016, healthcare facilities reported 18,085 events potentially involving an unplanned admission to the NICU to the Authority. The pre-manual review identified 4,780 reports of potential unplanned admissions to the NICU (2006, n = 659; 2011, n = 1,717; and 2016, n = 2,404).

A total of 1,395 events were excluded, leaving 3,385 reports for further analysis (2006, n = 430; 2011, n = 1,321; and 2016, n = 1,634). Of these reports, 3,231 (95.5%) were submitted as Incidents that resulted in no patient harm. The conditions associated with an unplanned admission to the NICU are shown in Figure 1. In addition, 248 reports included gestational age, and although the differences between the years are small, the age range most frequently having an unplanned admission to the NICU was late preterm. This information is summarized in Figure 2.
The following is a sample of respiratory complication events reported to the Authority.*
Infant Girl born via C-section at 39 weeks’ gestation. NICU staff at delivery. Upon rupture of membranes during the C-section there was very thick meconium in the fluid. Infant stimulated and bulb syringe for resuscitation after spontaneous crying. Infant retracting with intermittent grunting, had a copious amount of meconium stained secretions. Infant was deep suctioned for 6 cc of dark meconium stained fluid, which decreased the retractions. NICU was called back at 43 minutes of life because of retractions, worsening of grunting, and nasal flaring. NICU came back, gave continuous positive airway pressure (CPAP) for 1 minute. Pulse oximetry within normal limits. Stated more air was moving in lungs, but still diminished. NICU called at 70 min of life for respiratory status not improving. It was then decided infant would be transferred to NICU.

Patient was delivered via C-section at 26 5/7 weeks’ gestation. Complications of pregnancy included pre-eclampsia and intrauterine growth restriction. Patient was intubated after delivery due to respiratory failure. Patient self-extubated and converted to synchronized inspiratory positive airway pressure, with no re-intubation required.

The following is a sample of a hypoglycemia event reported to the Authority:

Infant born to insulin dependent gestational diabetic mother. Infant’s blood sugar upon birth was 33. Post breastfeed sugar was unchanged. Infant fed 18 mL Similac formula via bottle and his after-feed sugar was 34. NICU PA-C aware of infant blood sugars and axillary temp of 97.2°F, infant transferred to NICU for low blood sugars.

The following is a sample of a neonatal abstinence syndrome (NAS) event reported to the Authority:

36-week gestation infant delivered weighing 5 lb, 6 oz.; exhibiting signs of withdrawal. Oxycodone noted in mother’s toxicology screen. Infant transitioned to darkened nursery, swaddled, decreased stimuli in efforts to reduce withdrawal symptoms. Withdrawal symptoms continued. Infant transferred to NICU for management of NAS.

The following is a sample of an infection event reported to the Authority:

Newborn at 39 weeks and 1 day gestation. Baby had low temperature and upon recheck was lower. Nurse reported cloudy amniotic fluid in report. Provider suspects possible sepsis. Baby is being transferred to NICU.

The following is a sample of late preterm infant event reported to the Authority:

34-week preterm gestation in preterm labor. Infant born via C-section and developed respiratory distress and possible sepsis. Patient transferred to NICU.

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

**Discussion**

PA-PSRS data revealed that both preterm and term infants experienced unplanned admissions to the NICU. During the sampled dates between 2006 and 2016, the most common reasons for unplanned transfer to the NICU were respiratory distress, hypoglycemia, and prematurity. The number of reports of NAS, gastrointestinal/feeding issues and infection also increased over those dates.

Facilities that provide birthing services must be prepared to promptly recognize problems and intervene to reduce morbidity and complications. The NICU provides neonates with specially trained medical, nursing, and support staff along with advanced technology to monitor and treat the compromised infant. A multidisciplinary NICU team includes neonatologists, pediatricians, fellows, residents, registered nurses, nurse practitioners, respiratory therapists, occupational therapists, dieticians, lactation consultants, pharmacists, social workers, and chaplains.¹
Factors that can place an infant at increased risk of being admitted to the NICU can be related to the following maternal, delivery, or infant issues:\textsuperscript{1,2,5-11}:

**Maternal conditions:**

- Advanced maternal age
- Diabetes
- Hypertension
- Amniotic fluid problems
- Chorioamnionitis
- Drug and alcohol use
- Black/non-Hispanic mothers with private insurance

**Delivery conditions:**

- Fetal distress
- Breech delivery
- Meconium aspiration
- Nuchal cord
- Use of forceps
- Cesarean section (C-section) delivery
- Preterm labor and premature rupture of membranes (PTL/PPROM)

**Fetal conditions:**

- Young gestational age
- Low birth weight
- Birth defects
- Respiratory distress due to the following: respiratory distress syndrome, apnea, bronchopulmonary dysplasia, pneumonia, transient tachypnea of the newborn (TTNB), pneumothorax, pulmonary hemorrhage, pleural effusion, congenital or surgical anomalies; need for supplemental oxygen, CPAP, or mechanical ventilation requirement
- Cardiac: bradycardia, patent ductus arteriosus, tetralogy of Fallot, septal defects, coarctation of the aorta, transposition of the great arteries
- Infection: sepsis, necrotizing enterocolitis
- Seizures
- Hypoglycemia
- Asphyxia
• Intracranial hemorrhage, intra or periventricular hemorrhage
• Congenital anomalies
• Jaundice
• Temperature instability
• Other clinical conditions requiring increased monitoring and services at birth

**Respiratory System Conditions**

Respiratory conditions are the most common reason for admission to the NICU in both term and preterm infants, as noted in PA-PSRS data and the literature.\(^\text{12}\)

Lung immaturity can make the transition from intrauterine to extrauterine life difficult for a preterm or late preterm infant. Surfactant production starts at about 24 weeks' gestation and alveolar development, which allows the infant to expel lung fluid upon birth, begins at about 32 weeks' gestation. If the infant cannot clear this fluid, TTNB may develop.\(^\text{9}\) Lack of surfactant combined with alveolar immaturity can leave the infant unable to fully oxygenate, causing respiratory distress syndrome.\(^\text{9}\)

In addition, the term infant can also experience respiratory conditions such as meconium aspiration, pulmonary hypertension of the newborn, pleural effusion, surfactant protein deficiency, and alveolar capillary dysplasia.\(^\text{6,12}\) TTNB usually resolves by 72 hours in term infants.\(^\text{2}\)

Congenital and surgical anomalies such as pulmonary airway malformation, diaphragmatic hernia, lobar emphysema, choanal atresia, trachea-esophageal fistula, and pulmonary sequestration can cause respiratory problems. Nonrespiratory conditions such as heart failure, neuromuscular disorders, hypoxic ischemic encephalopathy, and metabolic acidosis can also lead to respiratory distress.\(^\text{6}\)

The NICU care team must be skilled at recognizing the signs of respiratory compromise to ensure that appropriate assessments, diagnosis, and management—including transfer to the NICU—are put in place promptly.\(^\text{6}\) Infants with respiratory distress may exhibit grunting, tachypnea, sternal retraction, and nasal flaring. Oxygen saturation may be reduced and the infant may become pale or cyanotic. Chest x-rays can help clinicians differentiate between respiratory distress syndrome and pneumonia. Other studies may be performed to see whether infection or a metabolic issue might be the underlying cause of the distress.\(^\text{6,8}\)

It might be necessary to prevent hypoxia through ventilatory support. Strategies to reduce lung injury, including less aggressive ventilation are more common now, as is administration of surfactant therapy. Less invasive methods of ventilation such as nasal synchronized intermittent mandatory ventilation is used with CPAP, offering a higher level of support.\(^\text{13}\) The utilization of surfactant therapy increased from 40% to 80% in infants born between 22 and 28 weeks' gestational age from 1993 to 2011.\(^\text{13}\) Stoll and co-authors performed a prospective study of these infants with birth weights of 401 to 1,500 g, born at 26 network centers between 1993 and 2012 and found that use of antenatal corticosteroids increased from 24% to 87% and C-section deliveries increased from 44% to 64% during the study period. Delivery room intubation of these neonates decreased from 80% to 65%.\(^\text{13}\)

Fetal distress during labor can cause meconium to pass into the amniotic fluid before the infant is delivered.\(^\text{6}\) When the infant inhales the meconium, mechanical obstruction of the airway, chemical pneumonitis, and infection can occur.\(^\text{6,8}\) Meconium aspiration syndrome (MAS) is mostly treated with supportive therapy until the lung inflammation resolves.\(^\text{6}\)

In March 2017, the American College of Obstetricians and Gynecologists (ACOG) published a committee opinion...
regarding management of the newborn with meconium-stained amniotic fluid. ACOG recommended the following:\(^\text{14}\):

*Infants with meconium-stained amniotic fluid, regardless of whether they are vigorous or not, should no longer routinely receive intrapartum suctioning. However, meconium-stained amniotic fluid is a condition that requires the notification and availability of an appropriately credentialed team with full resuscitation skills, including endotracheal intubation. Resuscitation for infants with meconium-stained fluid should follow the same principles as for those with clear fluid.*

Metabolic Conditions

Hypoglycemia was the second most common reason for an unplanned admission to the NICU per PA-PSRS data.

Certain conditions, such as maternal diabetes, maternal obesity, and fetal distress during labor and delivery may predispose the infant to hypoglycemia. Other risk factors include intrauterine growth restriction, infection, low Apgar score at 5 minutes, and infants who are large for gestational age.\(^\text{15}\) The late preterm infant is at risk for hypoglycemia due to smaller glycogen stores and an immature hepatic system.\(^\text{16}\) An infant with hypoglycemia may exhibit several clinical signs, including irritability, jitteriness, seizures, lethargy, floppiness, and difficulty with feeding.\(^\text{15}\)

The primary treatment for hypoglycemia is supporting feeding, especially breastfeeding. If blood glucose is less than 40 mg/dL, treatment with dextrose may be ordered, as well as considering transferring infant to the NICU. Monitoring serial blood glucose levels timed around feeding attempts is necessary until the infant’s condition has stabilized. Other systemic conditions that may influence glucose regulation may also be considered.\(^\text{15,17}\)

Hyperbilirubinemia was less commonly reported. Hyperbilirubinemia is present if the infant is unable to break down and eliminate bilirubin through the urine and stools. Infants with hyperbilirubinemia may exhibit jaundice, a yellow discoloration of the infant’s skin and sclera.\(^\text{9}\) A preterm infant (36 weeks’ gestational age) has six times the chance of having elevated serum bilirubin, compared with a term infant (40 weeks’ gestational age). Preterm and late preterm infants are at increased risk due to several factors such as poor feeding effort and lower levels of the uridine diphosphate glucuronyl transferase, a bilirubin-conjugating enzyme. In addition, preterm and late preterm infants pass meconium more slowly than their term counterparts, which delays clearance of bilirubin via the stool.\(^\text{16}\)

Failure to diagnosis and treat hyperbilirubinemia can lead to kernicterus, a severe neurological event. Total serum bilirubin (TSB) may peak at four days for a term infant, but the peak will be delayed in the preterm and late preterm infant.\(^\text{16}\) Treatment to clear the excess bilirubin includes supporting feeding so the infant stays hydrated, increases stool volume, and passes meconium and stool. Phototherapy may be used to provide photo-oxidation to help the liver break down the excess bilirubin in the blood.\(^\text{9}\)

Neonatal Abstinence Syndrome

NAS is present when infants exposed to prescription or illicit medications in utero exhibit symptoms of withdrawal.\(^\text{18,19}\) Current PA-PSRS data shows that in Pennsylvania between 2011 and 2016, the number of reports of unplanned admissions to the NICU due to NAS more than doubled, and this is consistent with PA-PSRS data previously reviewed.\(^\text{20}\)

The national incidence of NAS doubled between 2009 and 2012, and infants with NAS account for 4% of NICU admissions.\(^\text{21-23}\) Infants admitted to the NICU with NAS have an average length of stay of 40 to 50 days, especially when the infant requires pharmacologic treatment.\(^\text{24}\)

Infants with NAS can exhibit tremors, high-pitched crying, convulsions, tachypnea, difficulty with feeding, diarrhea, and other problems.\(^\text{19}\) Diagnosis assesses toxicology-screening results of maternal and infant urine and meconium and observations made using a selected tool, such as the Finnegan or Lipsitz scoring system.\(^\text{18}\) The Finnegan scoring system is most commonly used and rates four areas: central nervous system irritation, respiratory distress,
gastrointestinal (GI) distress, and vegetative symptoms. Assessment and scoring is begun within the first 24 hours of birth and continued every three to four hours, with a score of eight or more requiring increased monitoring and intervention.\textsuperscript{19}

Treatment for NAS can be both pharmacologic and nonpharmacologic. Medications are used for moderate to severe NAS. Morphine or methadone is used as first-line treatment.\textsuperscript{18,25,26} Phenobarbital or clonidine may be used, if needed, in conjunction with first line-medications.\textsuperscript{19,25,26}

Nonpharmacologic treatment includes breastfeeding support and other methods to encourage sucking.\textsuperscript{18,19} Other methods employed include providing a calm environment for the infant, such as swaddling the infant and keeping the room quiet and dark. Parental education should provide the parents with skills to maintain an environment to soothe the infant.\textsuperscript{18,19}

**Infection**

According to PA-PSRS data, reports of infection as a cause associated with an unplanned admission to the NICU increased 300\% over the past 10 years.

Infants are susceptible to infections as they transition to life outside the uterus, and preterm infants are four times as susceptible as term infants.\textsuperscript{8} The placental barrier provides protection from infection, and the maternal immune substances stored in the fetal tissue in the last few weeks of gestation provide the infant with passive immunity against many infections.\textsuperscript{10} Infection or sepsis can occur prenatally from the mother's blood or during labor if the infant ingests or aspirates infected amniotic fluid.\textsuperscript{8} Maternal conditions that put the infant at a higher risk for developing an infection include lack of prenatal care, substance use, maternal infections such as a urinary tract infection or chorioamnionitis, and premature rupture of membranes or preterm labor.\textsuperscript{2} Infection that progresses systemically to sepsis in the neonate is classified as early or late onset. Early-onset sepsis (EOS) typically occurs in the first three days of life, caused by maternal transfer either in utero or during delivery.\textsuperscript{8,27} Preterm infants are highly susceptible to EOS and pneumonia because preterm delivery has been associated with maternal bacterial pathogens, which are frequently gram-negative organisms such as group B streptococcus (GBS).\textsuperscript{2,27} Nationally, prophylactic maternal antibiotic use has decreased the incidence of EOS due to GBS.\textsuperscript{28} Mortality is high for very low birth weight infants (less than 1,500 g), and 20\% of deaths in this population are from sepsis.\textsuperscript{27}

Late-onset sepsis occurs after three days of life, is primarily nosocomial, and is frequently caused by a gram-positive pathogen.\textsuperscript{8,27} Bacterial infection can occur through sites such as the umbilical stump; mucous membranes of the eyes, ears, nose, and throat; and the respiratory, nervous, urinary, and GI systems.\textsuperscript{10} Late-onset sepsis is frequently a complication of very premature infants, with *Staphylococcus aureus* frequently being the dominant pathogen.\textsuperscript{28}

Recognizing infection can be challenging because symptoms of systemic infection can be nonspecific and may mimic symptoms of other health issues. Staff must be alert to subtle changes in the infant's clinical appearance and behavior.\textsuperscript{2} The infant may exhibit circulatory changes, such as cold, clammy, or mottled skin, with hypotension and either bradycardia or tachycardia. Respiratory clinical signs may include dyspnea, apnea or tachypnea, cyanosis, grunting, or retractions. Central nervous findings may include diminished or increased movement and tone. Feeding problems along with vomiting, diarrhea, abdominal distention, hepatomegaly, or blood in the stool may indicate infection.\textsuperscript{8}

In addition to ongoing physical assessment, laboratory studies including cultures of the blood, urine, and cerebral spinal fluid (CSF) are used to determine the focus of infection and the specific pathogen to be treated. Treatment for infection will include medication (based on the organism), maintenance of fluid and electrolyte balance, appropriate oxygenation, and continual monitoring.\textsuperscript{2} Factors that reduce the incidence of late-onset sepsis for infants in all
gestational ages include maintaining strict infection-prevention practices, hand hygiene, and skin care; encouraging human milk feeding; and employing good catheter insertion and care practices and discontinuing invasive devices when not needed.²

Necrotizing enterocolitis (NEC) is an inflammatory disease of the bowel resulting in ischemic changes to the bowel. It affects very low birth weight infants more frequently, with about 10% to 15% developing this condition and up to 50% of these infants requiring a surgical procedure. Mortality is high, with about 34% of infants who develop NEC dying of this condition and its associated complications. Infants with NEC have a higher incidence of bloodstream infections and neurological injuries.²,2⁹ The exact cause of NEC is unknown, but multiple risk factors such as prematurity and low birth weight put the infant at a higher risk.²

NEC is most commonly seen between 3 and 12 days of life. Clinically, the infant may exhibit GI symptoms such as abdominal distention, tenderness, decreased or absent bowel sounds, bilious emesis, blood in the stools, and difficulty feeding. Other clinical signs may include respiratory distress, lethargy, and hypotonia.²,2⁹ Abdominal x-rays along with laboratory studies (complete blood count [CBC], arterial blood gases, and blood cultures) help in diagnosing NEC. Severity of NEC is based on the stage: IA, IB, IIA, IIB, IIIA and IIIB.² Medical NEC (stage IA to IIIA) can be treated with medication and support of the infant's metabolic, respiratory, and cardiac systems. Stage IIIB is considered a surgical condition, treated with procedures such as peritoneal drainage to decompress the abdomen, potentially followed by laparoscopy, ostomy creation, and bowel resection to remove necrotic bowel.²,2⁹

**Late Preterm Infants**

Prematurity can predispose infants to significant problems during the transition to extrauterine life. Immature vital organs, such as the lungs, heart, GI tract, liver, and brain require support to ensure continued development.²,5,8 In the United States, about 500,000 infants are born annually preterm or with a low birth weight, and these infants comprise 70% to 90% of all infants admitted to the NICU.¹,²,3⁰ A time-trend analysis from 2007 through 2012 by Harrison and colleagues, across all U.S. live birth weights, found that during the study period, NICU admissions showed a relative increase of 23%. Also, as that five-year period unfolded, infants admitted to the NICU were increasingly larger and less premature.⁴

In the past two decades, attention has focused on the late preterm infant. In 2005, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) agreed that this group of infants should be clearly defined. "Near-term" was replaced by "late preterm" for infants between 34 0/7 and 36 6/7 weeks' gestational age.¹⁷,3¹-3³

Late preterm infants account for 75% of preterm deliveries and 9% of all overall deliveries in the United States.¹²,3² From 1990 to 2005, late-preterm-infant births increased by 24.5%.¹²,3¹ Many factors can contribute to the increase of late preterm births, which include increased monitoring in the prenatal period, inaccurate gestational age assessment, changes in infertility treatments, increased multiple pregnancies with early deliveries, and increased elective inductions and C-sections.¹²,3¹

The late preterm infant physically appears more like the term infant than the more premature infant. When late preterm infants were called "near-term," the impression was that they had similar risks of morbidity and mortality as their term counterparts, and their vulnerabilities may have been missed.¹⁷,3¹ Hospital protocol may dictate whether the late preterm infant receives care in the newborn nursery or in the NICU, and staff will need to be able to assess clinical issues and initiate transfer to a higher level of care. Discharge of late preterm infants may make them vulnerable for readmission if hospital policy allows these infants to be discharged early. Late preterm infants never
admitted to the NICU have an increased risk of being readmitted to the hospital after discharge when compared with term infants.\textsuperscript{12,17} Staff focus on appropriate discharge care planning and family support is necessary to avoid readmission.\textsuperscript{34}

Vulnerabilities of a late preterm infant are predictable, preventable, and manageable.\textsuperscript{17} Professional organizations such as the California Perinatal Quality Care Collaborative (CPQCC) and the National Perinatal Association have published toolkits and guidelines for the care and management of the late preterm infant\textsuperscript{6,35} and recommend that providers develop a plan of care to address these infants' vulnerabilities. Specific attention is recommended to reduce the risk of respiratory distress, hypothermia, sepsis, hypoglycemia, feeding difficulties, and hyperbilirubinemia while supporting breastfeeding and nutritional supplementation as needed.\textsuperscript{32}

Consider delaying discharge until at least 48 hours of age. Document overall stability for 24 hours before discharge, to include feeding competency and bilirubin level. Follow-up after discharge needs to occur promptly to ensure that the infant continues to thrive, is not experiencing signs of respiratory distress or hyperbilirubinemia, and has developed satisfactory feeding and elimination.\textsuperscript{9,17,35}

**Conclusion**

PA-PSRS data revealed the most frequently reported conditions associated with reports of an unplanned admission to the NICU were respiratory distress, prematurity, hypoglycemia, NAS, gastrointestinal/feeding issues, and infection. Understanding the potential risks that infants at different gestational ages may experience—which may result in an unplanned transfer to the NICU—and being prepared to provide the appropriate care for the infant experiencing distress are necessary for organizations that provide birthing services.

Admissions to the NICU continue to rise in the United States, with most infants presenting as preterm, with a low birth weight, or with a clinical condition requiring specialized care. PA-PSRS data reflects this national trend, with reports of unplanned admission to the NICU rising over a fifteen-year period. In addition, the late preterm infant has received more attention in the past two decades as more information has become available on their unique risks and treatment needs. Professional organizations have developed toolkits and guidelines specific to this subset of premature infants to ensure appropriate plans of care are initiated.

**Notes**


15. Wisconsin Association for Perinatal Care (WAPC). Caring for the late preterm infant. A sample care plan for late preterm infants (gestational age 34 0/7 wks to 36 6/7 wks). Madison (WI): Wisconsin Association for Perinatal Care (WAPC); 2013 Mar. 7 p. Also available:


Medication Errors in Outpatient Hematology and Oncology Clinics

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Abstract

Oncology care is increasingly provided in outpatient settings because of its increased patient convenience and decreased cost. Reported medication errors in this setting have not been fully explored and give cause for examination. A query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for reports from July 2015 through June 2017 in outpatient hematology and oncology clinics affiliated with hospitals or health systems revealed 1,015 reported medication errors. More than half (53.7%, n = 545) reached the patient. The most commonly reported event types included dose omissions (15.3%, n = 155) and wrong dose/over dosage (13.1%, n = 133). High-alert medications were reported in 55.5% (n = 563) of the events. Antineoplastic agents made up 94.3% (n = 531) of medication errors reported with high-alert medications. Due to the potential hazards associated with antineoplastic agents, special care is warranted to reduce the risk of errors associated with this class of medications. Error reduction strategies in outpatient hematology and oncology clinics begin with a risk assessment of medication use processes and focus on patient information, order communication, quality processes, and risk management.

Introduction
Errors may occur with any medication; however, chemotherapy presents unique dangers due to narrow therapeutic indices, potential toxicity even at therapeutic dosages, complex regimens, and a vulnerable cancer patient population. Experts estimate that there are more than 20 million visits for chemotherapy annually in the United States. Of these visits, the vast majority are in ambulatory settings where the chemotherapy is administered by nurses.

Despite this, few medication-error studies have been conducted in outpatient hematology and oncology clinics. Existing literature describes medication errors occurring in the inpatient setting on oncology units. Ford et al. characterized self-reported errors from nurses in a two-year prospective study in which nurses recorded 141 medication administration errors. Forty-one percent of these errors were nurse administration errors, 38% were nurse or pharmacy dispensing errors, and 21% were order writing and transcribing errors.

Pennsylvania Patient Safety Authority analysts reviewed medication errors associated with outpatient hematology and oncology clinics affiliated with hospitals or health systems. Analysts sought to characterize the types of medication-error events that occurred in this practice setting, identify contributing factors, and describe appropriate system-based risk reduction strategies.

**Methods**

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for medication error events that occurred from July 2015 through June 2017 and were categorized as occurring in outpatient hematology and oncology clinics affiliated with hospitals or health systems.

In PA-PSRS, outpatient care area types include "O/P" as part of the name. Analysts queried the care area type field for reports that included "O/P." The data was then filtered in Excel for care area types that indicated they were from oncology and hematology clinics.

Reports were analyzed based on the medication name, event type, event description, nodes of the medication use process, and harm score, adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index, as provided by the reporting facility. Analysts completed the medication-name field in reports in which a medication-name data field was left blank or incomplete but the name was provided in the event description. Reports related to both chemotherapy and non-chemotherapy medications (e.g., pre-medications, analgesics, and colony stimulating factors) were included in the analysis. Errors with an event type categorized as "Other" by the reporting facility were further evaluated to classify the event type. Analysts also examined all the reported event details for common contributing factors associated with reported events.

**Results**

The query yielded 1,015 event reports of potential or actual medication errors. More than one-half (53.7%, n = 545) of events reached the patient (PA-PSRS harm score C through I). More than forty-three percent (43.3%; n = 439) of events were reported as errors that were intercepted before reaching the patient (harm score B1 = 1.6% [n = 16] and B2 = 41.7% [n = 423]), and 3.1% (n = 31) of events were reported as circumstances or events that have the capacity to cause error (harm score A; Figure 1).
This analysis included reported events that involved antineoplastic medications in addition to other medication classes such as chemotherapy pre-medications. It is notable that most reported events were related to antineoplastic agents, which are high-alert medications. High-alert medications, or medications that pose an increased risk of patient harm when involved in medication errors, were reported in more than half (55.5%, n = 563) of reported events. The most commonly prescribed high-alert drug class was antineoplastic agents (94.3%, n = 531 of 563), followed by opioid analgesics (2.3%, n = 13 of 563), and anticoagulants (1.4%, n = 8 of 563). Fluorouracil, CARBOplatin, and PACLixel were the three most commonly reported antineoplastic agents (Figure 2). Overall, antineoplastic agents, colony stimulating factors (e.g., pegfilgrastim), and systemic corticosteroids (e.g., dexamethasone) were the most common medication classes involved in medication-error events (Figure 3).

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System, July 2015 through June 2017.

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**Figure 1. Harm Scores for Medication-Error Events Occurring in Outpatient Hematology and Oncology Clinics (N = 1,015)**

<table>
<thead>
<tr>
<th>Incident</th>
<th>Number of Reports</th>
<th>Harm Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>31 (3.1%)</td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td>16 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>423 (41.7%)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>376 (37.0%)</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>167 (16.5%)</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
- Reports of events that did not reach the patient (n = 470; 46.3%)
- Reports of events that reached the patient (n = 545; 53.7%)

**Figure 2. Common Antineoplastic Agents Involved in Medication-Error Events Occurring in Outpatient Hematology and Oncology Clinics (N = 531*)**

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System, July 2015 through June 2017.

* The sum of the reports is less than 1,015 because only a subset of the reports involved antineoplastic agents and only the top 10 antineoplastic agents are displayed (n = 407 of 531).
Medication errors occurred during every step of the medication use process (Figure 4). Errors most frequently involved the prescribing node followed by the administering node.
The most commonly reported event types were dose omissions, "Other," and wrong dose/over dosage. The medication classes associated with the five most commonly reported event types can be seen in Figure 5.

**Figure 4.** Common Medication Classes Involved at Each Node of the Medication Use Process for Medication-Error Events Occurring in Outpatient Hematology and Oncology Clinics (N = 1,019)*

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System, July 2015 through June 2017.

* Facilities may select zero, one, or multiple nodes for a given medication-error report.

The most commonly reported event types were dose omissions, "Other," and wrong dose/over dosage. The medication classes associated with the five most commonly reported event types can be seen in Figure 5.

**Figure 5.** Medication Classes Associated with Common Event Types* for Medication-Error Events Occurring in Outpatient Hematology and Oncology Clinics (N = 650 reports)

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System, July 2015 through June 2017.

* Event types are defined by Pennsylvania Patient Safety Reporting System taxonomy and are assigned to events by healthcare facilities at the time of report submission. Only the top five event types are displayed (n = 485 of 650).
Dose Omission

About three-fourths (74.2%, n = 115 of 155) of dose omission events were reported as reaching the patient, and one of these events (0.6%) resulted in patient harm. The dose omission event that resulted in patient harm involved an antineoplastic agent. Following is the dose-omission event that resulted in patient harm:

A patient received four cycles of EP (etoposide and CISplatin) over two months. The patient also previously underwent surgical resection at another hospital. It was determined that the patient probably should have received bleomycin in the initial treatment regimen.

The most commonly reported medication classes associated with dose omissions were antineoplastic agents (32.9%, n = 51 of 155), colony stimulating factors (25.8%, n = 40), and systemic corticosteroids (12.9%, n = 20). The most common medications associated with dose omissions were pegfilgrastim (20.6%, n = 32), dexamethasone (10.3%, n = 16), bevacizumab (5.2%, n = 8), fluorouracil (5.2%, n = 8), and denosumab (4.5%, n = 7). In addition to systemic corticosteroids, which are typically included as chemotherapy pre-medications, additional chemotherapy pre-medications such as antiemetic agents and combinations of antiemetic agents with alpha-adrenergic agonists, antihistamines, and anti-inflammatory agents made up 14.2% (n = 22) of dose omission events. Following are examples of dose-omission events reported through PA-PSRS:

Order sent to [infusion center] from the physician's office. Order written as Herceptin® [trastuzumab] 2 mg/kg (184 mg) in 250 mL NS [normal saline] IV [intravenously] over 30 minutes Cycle day 8 and day 15 Q 21 days. Order interpreted as "Administer Q 21 days" when intended dosing was Day 1, Day 8, and Day 15. Patient missed doses due Day 8 and Day 15. Oncologist notified and patient informed. Dosing schedule adjusted. Oncologist altered schedule for remaining chemo doses.

Zofran® [ondansetron] order was missed on day one and day two of chemotherapy. Chemotherapy order with multiple cross outs. Zofran order printed in small font and not in the same section as other pre-medications.

Wrong Dose/Over Dosage

The medication classes most commonly involved in wrong dose/over dosage events were antineoplastic agents (66.2%, n = 88 of 133) and systemic corticosteroids (4.5%, n = 6 of 133). The three most common antineoplastic agents involved in these events were CARBOplatin (15.9%; n = 14 of 88), bevacizumab (8.0%, n = 7 of 88), and rITUXimab (6.8%, n = 6 of 88). Most wrong dose/over dosage events were intercepted before reaching the patient (66.2%, n = 88 of 133).

Although none of the wrong dose/over dosage events resulted in patient harm, almost one-third (33.1%, n = 44 of 133) of these events reached the patient and 10.5% (n = 14 of 133) of these events reached the patient and required monitoring or intervention to preclude patient harm. In addition, 15.0% (n = 20 of 133) of wrong dose/over dosage events were at least in part due to patient information errors, particularly incorrect patient weight, height, body surface area (BSA), and serum creatinine level. Following are examples of wrong dose/over dosage events reported through PA-PSRS:

Female outpatient with diagnosis of metastatic breast cancer arrived at the [infusion center] for continuation of her chemotherapy regimen. Upon review of the orders by the pharmacist, it was noted that the doses of Perjeta® [pertuzumab] and Herceptin® [trastuzumab] were incorrect. The doses were too high as they were based off the loading doses the patient received on her previous visit. The pharmacist contacted the prescriber who changed the orders for both drugs to the appropriate doses. The patient received the correct doses of both chemotherapy drugs.
Pharmacist entering chemotherapy for future appointment noted that there was a 5 cm discrepancy of height from previous doses. All previous chemotherapy doses were calculated based on a height of 145 cm. Upcoming dose was calculated based on a height of 150 cm. This resulted in an increase of dose. Pharmacist confirmed with ordering office that the patient's height was 150 cm and that the previous height was incorrect. All previous doses were given at the lower dose.

Wrong Time

Wrong-time events comprised 7.8% (n = 79) of 1,015 reports. More than half of these events (64.6%; n = 51 of 79) reached the patient, with 11.4% (n = 9) of the events requiring monitoring or intervention to preclude patient harm. Antineoplastic agents were the only high-alert medication class involved in wrong-time events and were also the most common medication class associated with wrong-time errors (43.0%, n = 34). Other medication classes commonly associated with wrong-time events were colony stimulating factors (15.2%, n = 12), bisphosphonate derivatives (8.9%, n = 7), and antiinflammatory agents (7.6%, n = 6). Fluorouracil (17.6%, n = 6 of 34) and RITUXimab (11.8%, n = 4) were the two most common antineoplastic agents involved in wrong-time events. Analysts identified 30 (38.0%) of 79 reports that were attributable to schedule errors and 12 (15.2%) reports that were attributable to treatment delays. Following is an example of a wrong-time event reported through PA-PSRS:

Patient in the infusion center for 1st cycle of chemotherapy. Orders were written for Gemzar® (gemcitabine) IV x1 on day 1 and day 8. CARBOplatin IV x1 on day 8. Orders clearly state the days of administration. Patient received Gemzar as ordered but also received the CARBOplatin that was ordered for day 8 on day 1. This was missed by both nurses, who did independent double checks, and by the pharmacy, which profiled the medication and sent it up to the infusion center to administer. Spoke with nurse and she will make physician aware of event. Patient scheduled to come back the following week for day 8 Gemzar and Neulasta® [pegfilgrastim] on body injector. Error was caught by coding department who was coding the chart and questioned why CARBOplatin was given on day 1. No patient harm identified from this event.

Wrong Drug

Wrong-drug errors were identified in 7.8% (n = 79) of 1,015 reports. The medication classes most commonly involved in wrong-drug events included antineoplastic agents (43.0%, n = 34 of 79), colony stimulating factors (11.4%, n = 9), and systemic corticosteroids (10.1%, n = 8). PACLitaxel made up 14.7% (n = 5 of 34) of wrong-drug errors related to antineoplastic agents. DOCEtaxel and CISplatin were each cited in 8.8% (n = 3 of 34) wrong-drug error reports involving antineoplastic agents. Almost half of wrong-drug errors involved high-alert medications (46.8%, n = 37 of 79). Two of these high-alert medication events involved confusion between morphine and HYDROmorpheine while 33 events were related to antineoplastic agents. Analysts identified that 24.1% (n = 19 of 79) of the wrong-drug reports were attributable to name similarity. Six of these name pairs are included on the Institute for Safe Medication Practices Confused Drug Name List (Table). 

Table. Commonly Confused Drug Pairs

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Similar Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARBOplatin</td>
<td>CIplatin</td>
</tr>
<tr>
<td>inFLIXimab</td>
<td>rITUXimab</td>
</tr>
<tr>
<td>morphine</td>
<td>HYDROmorpheine</td>
</tr>
<tr>
<td>rOPINIRole</td>
<td>risperiDONE</td>
</tr>
<tr>
<td>SOLU-Medrol® (methylprednisolone sodium succinate)</td>
<td>Solu-CORTEF® (hydrocortisone sodium succinate)</td>
</tr>
<tr>
<td>Taxotere® (DOCEtaxel)</td>
<td>Taxol® (PACLitaxel)</td>
</tr>
</tbody>
</table>
Following are examples of wrong-drug events reported through PA-PSRS:

*Patient with an Hx [history] of adenocarcinoma of the left lung. Physician ordered medroxyPROGESTERone 40 mg for patient, this did not seem correct. I called physician and he said he meant to order methylPREDNISolone 40 mg. Physician corrected order.*

*Patient was originally ordered rITUXimab. Gemcitabine and oxaliplatin [were ordered for the following day]. A nurse indicated order OK, riTUXimab was processed, mixed, delivered, and administration initiated. Later, the order date for the gemcitabine/oxaliplatin was moved, and second nurse questioned administration of rITUXimab. On further investigation, it was determined that the patient should not have received rITUXimab.*

*Filgrastim (Neupogen®) 300 mcg subcutaneous ordered. Infusion nurse went to the automated dispensing cabinet to remove. There was no drug in refrigerator. Pharmacy dispensed Granix [bto-filgrastim] 300 mcg subcutaneous to infusion nurse. Upon infusion nurse scanning drug, she received the message "this drug cannot be given in this encounter." RN proceeded despite the message. Granix 300 mcg subcutaneous given. (Granix is an auto-substitute for Neupogen).*

*3 mg of morphine sulfate ordered, HYDROMorphone 3 mg given. Physician aware. Patient stable time of discharge.*

**Patient Information**

Analysts also identified trends involving patient information events, which included errors related to patient weight, height, serum creatinine, BSA, identity, current medication, and other missing or inaccurate patient information. These made up 8.5% of all reports (n = 86). Almost half of these events (45.3%, n = 39 of 86) resulted in dosing errors, including under- and overdosing events in which at least one antineoplastic agent was mentioned in 84.6% (n = 33 of 39). For example, there were dosing errors related to the use of old, outdated patient weights. The use of wrong-patient weights and heights or the wrong unit of measurement contributed to incorrect BSA calculations, which in turn may have contributed to dosing errors. In addition, the inappropriate use of ideal body weight or adjusted body weight may have also contributed to dosing errors. Wrong-patient identification was the second most common event type (27.9%, n = 24 of 86) in which patient information was a contributing factor. Following are examples of wrong-patient information events reported through PA-PSRS:

*In preparation for stem cell transplantation, patient had a 24-hour urine creatinine clearance measured. Patient completed this and brought sample to the lab for analysis. Lab automatically calculates corrected creatinine clearance based on calculations using patient height in cm and weight in kg. Laboratory inappropriately used height in inches instead of centimeters, which resulted in a significant overestimation of the actual urine creatinine clearance. This was discovered by patient's physician who identified the wrong value used in the equation and notified lab to correct. Could have resulted in chemotherapy overdose if not caught in advance.*

*Two patients present for different doses of Procrit® [epoetin alfa]): patient A 60,000 units, patient B 20,000 units. Patient name band and drug scanned, and warning was ignored. Patient was not positively identified, but answered to patient B's name. Patient A given 20,000 units and then an additional 40,000 units given to correct error. Patient B received correct dose.*

*Patient is 5 ft, 4.5 inches. It was written as such on the chart. Transferred to a later date as 54.5 inches. The patient received 2 cycles of etoposide and CARBOplatin at 54.5 rather than 64.5 inches.*

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

**Discussion**
Errors that occurred in outpatient hematology and oncology clinics affiliated with hospitals or health systems spanned six different harm scores,8 more than 40 different medication classes, and each of the nodes of the medication use process (i.e., prescribing, transcribing, dispensing, administering, and monitoring). Consistent with conclusions by Schwappach and Wernli,1 medication errors in administration accounted for many events, exceeded only by prescribing errors.

More than one-half of events (53.7%, n = 545 of 1,015) reached the patient in the current analysis of errors in outpatient hematology and oncology clinics. This is in contrast to the analysis by Lennes et al., in which 27.0% of reported chemotherapy errors (n = 89) reached the patient out of a total of 330 reported chemotherapy errors.12 The analysis by Lennes et al. differs from this PA-PSRS analysis in that chemotherapy-related safety events occurred over five years, 2010 through 2014, at Massachusetts General Hospital and its affiliate practices, whereas the current PA-PSRS analysis included any error that occurred in an outpatient oncology and hematology clinic, even errors unrelated to chemotherapy, and excluded events that occurred in inpatient practice settings. In addition, the PA-PSRS analysis included outpatient hematology and oncology clinics associated with multiple different hospitals and health systems in Pennsylvania. It is not clear why more errors reached patients in Pennsylvania outpatient hematology and oncology clinics than in the inpatient settings of Massachusetts General Hospital and its affiliate practices. One potential explanation is that while the PA-PSRS analysis included errors related to chemotherapy, analysts also captured ancillary medication errors and medication errors related to chemotherapy pre-medications. Further comparative research would be needed to assess the differences in errors between inpatient and outpatient oncology care settings.

Recognizing and addressing areas of vulnerability in the complex process of chemotherapy delivery is critical to maximizing safety. Analysts found that errors occurred most frequently during the prescribing and administering nodes, which might be attributable to the complexity of many chemotherapy regimens. Similarly, a retrospective observational study in the outpatient oncology setting reported a 20% prescribing error rate.13 These prescribing errors were incomplete orders mostly related to missing dosages, route of administration, infusion rate, or other prescription elements. In a priority-setting study, cancer-care clinicians ranked the prescribing node as the most vulnerable to medication safety threats.14 In another outpatient oncology setting, a retrospective record review of outpatient adult and pediatric visits identified administration node errors (56%) followed by the prescribing node errors (36%) as the most common.5

Errors that occurred during the administering node comprised nearly one-third of errors. These errors can present patient safety risks because there may be fewer opportunities for intervention built into the system during or after this stage of the medication use process. Schulmeister surveyed oncology nurses involved in chemotherapy administration in the United States about their personal experience with errors.15 Of the chemotherapy medication errors reported, 39% involved over- and underdosing, 21% involved schedule and timing errors, 18% involved wrong drugs, and 14% involved chemotherapy given to the wrong patient.15 Less common errors included infusion-rate errors, omission of drugs or hydration, and improper preparation of drugs. Ten percent of these errors required medical intervention and prolonged hospital stays. Even with barcode medication administration (BCMA) technology instituted to prevent administration errors, administration errors can go unnoticed and therefore also unreported.16

Antineoplastic agents, colony stimulating factors, and corticosteroids were most commonly involved in reported events regardless of the medication use node or event type. The most common event type was dose omissions. Omission of a colony stimulating factor could result in prolonged neutropenia, predispose patients to risk of infections, and delay future treatments.17 In addition, analysts found that chemotherapy pre-medications, which include systemic corticosteroids, were also involved in the dose omission events, which may adversely impact patient comfort and outcomes. Similarly, antineoplastic agents, colony stimulating factors, and bisphosphonate derivatives were commonly associated with wrong-time events, which may also adversely affect patient outcomes.
Wrong dose/over dosage and under dosage events were often associated with inaccurate or lack of patient information. Events were mostly attributed to problems with patient weight. A variety of problems were described in the event descriptions, which included outdated patient weight, wrong unit used for documenting the patient's weight (kilogram versus pound), mix-up between ideal and actual weight, and subsequent wrong BSA calculation. Such inadvertent dosing errors with high-alert medications, especially chemotherapy, may expose patients to increased toxicity or reduced probability of cure, or other effects. Current patient information, including patient's height, weight, BSA, laboratory values, cardiac function tests, and current medications are important to guide appropriate chemotherapy prescribing, and this information needs to be readily available throughout the medication use process so various checks can be implemented.

Some of the medication errors observed in this analysis may be prevented with safeguards such as electronic-based or paper-based chemotherapy order templates. Standardization and simplification of the chemotherapy order and dose calculation processes reduce the risk of medication errors. For example, many electronic order entry or computerized prescriber order entry (CPOE) systems are capable of automatic chemotherapy dosage calculations based on patient height, weight, and laboratory values in the patient's record; however, the usefulness of these systems are limited by the accuracy of the available patient information. For example, outdated patient weights or delayed laboratory results, as observed in events reported to the Authority, may result in incorrect dose calculations. This may be caused by up-to-date patient information that is not readily available at the time of prescribing, dispensing, preparing, and administering.

However, technology alone is insufficient to capture all discrepancies. Suzuki et al. found that despite the use of CPOE in Japan, use of a pharmacy documentation and intervention tool, in this case a paper-based tool, supported pharmacists in their review of chemotherapy orders and helped identify important interventions not caught by the CPOE system. The intervention tool included critical information needed for accurate chemotherapy verification, such as patient information, regimen cycle, antineoplastic drugs (including dose, route, and rate), pre-medications, and supportive drugs.

**Limitations**

The reports included in this analysis are from outpatient hematology and oncology clinics affiliated with hospitals or health systems, and the results of this study may not apply to other patient care settings. In-depth analysis by the Authority of medication error reports from outpatient hematology and oncology clinics is limited by the information reported through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete. Although the narrative fields of the reports help analysts discern what happened during the event, they may not contain details describing how the event deviated from the standard operation or which factors contributed to the event.

**Risk Reduction Strategies**

Efforts to prevent harm from medication errors in outpatient hematology and oncology clinics can focus on either reducing the occurrence of potential errors before they happen or mitigating the risk of adverse outcomes associated with errors that reach the patient. Consider the strategies listed below, which are based on events reported to the Authority, current literature, and observations from the Institute for Safe Medication Practices:

**Communicating Drug Orders and Other Drug Information**

- Use either electronic or paper chemotherapy templates to standardize chemotherapy orders.
• Require reference(s) of primary literature if ordering chemotherapy outside of the chemotherapy template.

• Define a process to immediately communicate, document, and explain rationale for order changes and clarifications to the patient's healthcare team, including updating orders previously entered or processed when patient information, such as patient weight and serum creatinine levels, change.\(^1\)

• Explicitly write or indicate specific days for chemotherapy drugs (e.g., write as "Day 1, 2, 3").\(^1\)

• Develop policies and procedures that guide healthcare practitioners to identify, verify, and document the current cycle and the day within the cycle of chemotherapy (e.g., cycle 3 of 6, day 3 of 5) against an established treatment protocol before each dose is administered.\(^1\)

• Include the patient-specific dose and the mg/kg, mg/m\(^2\), units/m\(^2\), or other dosing method used to calculate the patient-specific dose for all chemotherapy drug orders (e.g., for a 1.67 m\(^2\) patient: 240 mg/m\(^2\); dose = 400 mg).\(^1\)

• Create chemotherapy order sets that include appropriate pre- and post-chemotherapy medications (e.g., colony stimulating factors).\(^2\)

**Quality Processes and Risk Management**

• Implement a two-pharmacist independent double check of all chemotherapy orders prior to dispensing.

• Build hard stops that cannot be overridden, as appropriate, in computer systems for orders that exceed established maximum dose limits.\(^1\)

• Enable dose-error reduction software with soft stops and catastrophic or hard stops on electronic ordering systems and smart infusion pumps to intercept and prevent wrong dose/wrong infusion rate errors that can occur when programming pumps, calculating doses, or prescribing medications.\(^1\)

• When double checking prescribed chemotherapy doses, verify the patient's BSA using the patient's height and weight (in metric units) entered into the computer, and recalculate the actual dose (mg/m\(^2\) or mg/kg).\(^1\)

• Incorporate an independent double check of the prescriber's calculated dose for chemotherapy—according to the protocol or treatment plan—that considers the chemotherapy cycle before administering the drug.\(^1\)

• Ensure that independent double checks, whenever required by the organization's policy, are always performed and documented in the CPOE system and electronic health record.\(^2\)

• Institute a time-out immediately before administering the chemotherapy. During this time-out, two licensed healthcare practitioners independently double check the correct patient, compare the drug label to the order/medication administration record, verify the drug, diluent, dose, route, and rate, as well as pump settings, pump channel, and line attachment as applicable.\(^1\)

• Implement bar coding systems to verify drug selection prior to compounding and dispensing chemotherapy and treatment-related drugs (includes robotic dispensing) and at the point of care to verify chemotherapy and treatment-related drug selection prior to administering medications.\(^1\)

• Implement a chemotherapy error policy to direct healthcare practitioners to report and evaluate chemotherapy medication errors.

• Institute a system to review, learn from, and disseminate chemotherapy errors.
Patient Information

- Institute a structured process to collect and document, in a designated location, the patient's current (actual) height and weight in metric units.\(^1\)

- Evaluate pertinent monitoring parameters before and throughout chemotherapy, such as absolute neutrophil count (ANC) before and during each treatment cycle.\(^1\)

- Design policies and procedures as well as electronic order entry systems to prevent processing of chemotherapy orders before patient weight, height, updated laboratory test results, allergies, and associated reactions have been identified, documented, and reviewed.\(^1\)

- Ensure prescribers document on the order which "dosing weight" (i.e., actual, ideal, or adjusted body weight) will be used to calculate the dose of the chemotherapy.\(^1\)

- Develop an institution-specific weight and height policy that defines when changes in patient weight and height should trigger recalculating medication doses.

- Use a standard method defined by your organization to calculate ideal body weight or adjusted body weight (in metric units).\(^1\)

Patient Education

- Educate patients about their chemotherapy regimen, including the name of the agent(s) used, therapeutic indication, usual and actual doses, expected and possible adverse effects, methods for preventing or managing adverse effects, and when to follow up with their prescriber.\(^1\)

- Involve patients in error detection and prevention.\(^1,23,24\) Instruct patients on how they can protect themselves from medication errors. Inform patients of their right to ask questions and seek satisfactory answers.\(^1\)

- Implement a chemotherapy error policy to direct caregivers on what to do in the event of a chemotherapy error or overdose.

Conclusion

Of all the medication errors reported from hospital and health system–affiliated outpatient hematology and oncology clinics to the Authority from July 2015 through June 2017, the most common error types included dose omission, wrong dose/over dosage, wrong time, and wrong drug. For each of these event types, antineoplastic medications were the drugs most commonly involved. Despite the attention given to antineoplastic medications as high-alert medications and several published safe practice recommendations, preventable medication errors still occur.\(^1,21\)

Layers of risk reduction strategies that address the underlying causes of errors are needed to prevent errors and mitigate harm when an error reaches a patient. Although the number of reports with harm submitted to the Authority was small, organizations can use the data presented here to proactively evaluate the safety systems in place in their outpatient hematology and oncology clinics to minimize the risk for harm for their patients and to prevent similar errors from recurring.

Notes


Introduction

In August 2017, following news coverage of a pediatric patient's death associated with use of a warming blanket, the Pennsylvania Patient Safety Authority received inquiries about patient harm associated with these devices. In response, analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for reports of patient safety events involving warming blankets.

Methods

Analysts queried the PA-PSRS database for events containing the following terms: warming blanket, warmed air blanket, water blanket, circulating water, warming device, warmer, and Bair Hugger (including misspellings). The database was searched for event reports from the beginning of the PA-PSRS reporting program in July 2004 through August 2017. Analysts reviewed each of these events individually to identify event reports resulting in harm or potential harm associated with the use of warming blankets and exclude reports of warming blankets/devices mentioned incidentally.

For this article, the term "warming blanket" or "warming device" includes any powered devices (e.g., forced air warming blankets, circulating water blankets, resistive heating blankets) and excludes warmed blankets (i.e., blankets warmed in a heating cabinet).

Results

Pennsylvania hospitals reported 278 events from July 2004 through August 2017 resulting in harm or potential harm to patients associated with the use of warming blankets. Of these, 11 events (4%) were reported as Serious Events resulting in harm up to and including death. Preliminary review of all events revealed thermal injury to be the most frequently reported patient harm (36%; n = 100). Examples of patient harm or potential harm identified in event reports include hyperthermia, hypothermia, skin tears, and/or irritation from adhesives, and equipment problems.

The following are examples of events reported to PA-PSRS that describe each of these types of harms.*
Thermal Injuries

Patient put on warming blanket in the evening. An hour and a half later, the tubing to blanket was found disconnected and was reconnected. Skin checked every 30 minutes with temperature checks. Patient off blanket after five hours. Upon repositioning patient in the morning, patient found to have a large blister on the left medial aspect of shin.

When the patient was moved after appendectomy, it was discovered that the patient had been lying directly on top of the warming blanket. The patient's skin was very red and a small reddened area was noted on the right buttock. No blistering noted.

Hyperthermia

The adult patient, who is unresponsive and unable to orient at baseline, had a temperature of 94.5°F [34.7°C] in the morning and a forced-air warming blanket was placed. That evening, the patient was found to have temp of 106.1°F [41.2°C]. The warming blanket was removed and the patient was packed with ice. The patient remained unresponsive with shallow respirations and their temperature decreased through the evening, reaching 100.5°F [38.1°C] late that night, and 98.8°F [37.1°C] the following morning.

The patient's rectal temperature probe reading was 37.2°C [99.0°F]. The forced-air warming blanket settings were adjusted to maintain a temperature of 36-37°C [96.8-98.6°F]. The patient was noted to be tachycardic, with elevated blood pressure and reddened skin. The axillary temperature was found to be 39.5°C [103.1°F]. The rectal temperature probe cable connected to the monitor was then replaced and found to match the axillary temperature. Cable sent to biomedical engineering.

Hypothermia

At the end of the surgical procedure, it was discovered that the warming blanket [sic] had been set to 40° Fahrenheit instead of Celsius so the patient was being cooled instead of warmed during the case. The lowest temperature recorded during the case was 34.7°C. Patient was taken to the intensive care unit postoperatively.

The patient's temperature was reported to be 97.1°F [36.2°C] when last checked in the post-anesthesia care unit after the forced-air warming blanket was removed. When the patient reached the intensive care unit, rectal temperature was 95.4°F [35.2°C], and the patient was confused and lethargic. Another warming blanket was obtained and placed on patient with temperature and vital sign monitoring every 30 minutes. The patient's temperature returned to normal after two hours. In the future, patients should remain in the post-anesthesia care unit for 30 to 60 minutes after the warming blanket has been removed to confirm they are maintaining their core body temperature prior to transfer.

Skin Tears and/or Irritation from Adhesives

Upon removal of the warming blanket, a skin tear was noted across the patient's chest from the adhesive strip on the blanket.

During the preoperative time-out, the nurse reported that the patient had an allergy to adhesive and that it blistered the skin. During the procedure, the warming blanket adhesive was placed directly on the skin and adhesive bandages were used. The patient's skin became red, irritated, and developed blisters.

Equipment Problems

The surgical procedure was underway when an unusual smell was noted in the operating room. The nurse anesthetist identified sparks and smoke coming from the warming blanket. The device was removed from the room immediately. The heating source was not connected to the patient at the time, and the patient was not harmed.

The warming blanket was turned on during the surgical procedure and water was heard dripping on the floor. The warming blanket connections were checked and found to be correctly connected. The water was found to be dripping from blanket itself and presumed to be due to a hole in the blanket. The warming blanket and sheets against the patient's skin were wet and could not be removed during the procedure.
Discussion

Warming blankets apply heat to the body through convection (i.e., forced-air warmers or circulating water devices), or direct-contact thermal conduction (i.e., low voltage electrical current passed through a material that produces heat). These devices are most commonly used to warm patients in the perioperative setting, and forced-air warming is the most commonly used modality. Because of this, guidelines for warming-blanket use are included in protocols for preventing and treating hypothermia in the perioperative care setting. However, literature and guidelines for use of these devices in other care settings are lacking.

Patients with disordered central temperature control may be at greater risk of developing hyperthermia while being treated with warming devices.

Risk Reduction Strategies

The following risk reduction strategies can prevent patient harm associated with the use of warming blankets.

- Provide education to all clinicians caring for patients with hypothermia about clinical indications for, and proper use of warming blankets.
- Establish protocols for the use of warming blankets that are consistent with evidence-based guidelines and manufacturers' guidelines for device use.
- Ensure that all clinicians operating warming blankets are trained in their proper use, including interventions required to adequately monitor the patient and prevent harm.
- Consider using warming blankets only in clinical-care areas where body temperature and clinical condition can be monitored continuously (i.e., intensive care unit, operating room, postanesthesia care unit, emergency department).
- Closely monitor and carefully assess patients treated with warming blankets who are unable to communicate their comfort level.
- Use a consistent method and anatomical site to directly measure or estimate core body temperature in patients being treated with warming blankets every 15 to 30 minutes, or continuously when possible.
- Take steps to prevent thermal injury as specified in manufacturer's guidelines for device use. For example—
  - Place a sheet between the patient's skin and all-vinyl circulating water blankets
  - Ensure that the hose is always connected to the blanket when using forced-air warming devices
  - Do not position patients on top of direct-contact thermal conduction blankets that are designed to cover patients

Conclusion
Pennsylvania hospitals have reported patient safety events resulting in harm or potential harm to patients associated with the use of warming blankets. Hospitals seeking to prevent these adverse events are encouraged to adopt hospital-wide risk reduction strategies consistent with perioperative guidelines for preventing and treating hypothermia and manufacturers' guidelines for device use and preventative maintenance.

Notes


Data Snapshot: Complications Linked to Iatrogenic Enteral Feeding Tube Misplacements

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Introduction

Analysis of enteral feeding tube misplacements* over a six-year period found more than half led to complications, including death. The analysis was prompted by a request from the American Society for Parenteral and Enteral Nutrition (ASPEN), which was looking for current statistics about enteral feeding tube misplacements in Pennsylvania. Pennsylvania Patient Safety Advisory articles published in 2006 (/ADVISORIES/Pages/200612_23.aspx) and 2014 (/ADVISORIES/Pages/201406_78.aspx) contained reviews and analyses about misplacements and verification methods.

* Complications after enteral access device (EAD) placement can include misplacement, which is when the tip of the EAD is placed in an anatomical position not intended for the proper administration of enteral nutrition.

Methods

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify events that occurred over a six-year period between January 1, 2011, and December 31, 2016, using the following keywords and derivations: bronch*, covidien, dobhoff, esoph*, feeding, kangaroo, keofeed, lung, naso*, placement, pneumo, position, replace, small bore, thorax, and xray. The wildcard character (*) ensured that the search also yielded events containing other word forms (e.g., bronch* returns both bronchus and bronchial). Expanded criteria were used in the analysis of the data, compared with the criteria used for the 2014 publication (which reported data from January 2011 through October 2013). The additional criteria included adding naso* to the keyword search and included coiled feeding tubes in the analysis.

Analysts manually reviewed the resulting set of 2,125 event report narratives to identify reports describing misplaced feeding tubes. Excluded were reports in which an inadvertent dislodgement occurred during patient positioning or self-removal by the patient. Event reports were then grouped into related categories by event type, harm score, age, outcomes, and placement verification methods.
Results

Analysts identified 166 enteral feeding tubes misplacements occurring between January 2011 and December 2016 (Figure 1). Of the 166 misplacements, 16 additional events were identified from January 2011 through October 2013 using the expanded criteria, compared with data published in the 2014 review and analysis.

Figure 1. Number of iatrogenic Enteral Feeding Tube Misplacements by Year (N = 166)

Note: As reported to the Pennsylvania Patient Safety Authority and occurring between January 1, 2011, and December 31, 2016.

The identified events were submitted in five event type categories with 80.7% (n = 134 of 166) reported in the “complication of procedure/treatment/test” event type, followed by 15.7% (n = 26) reported in the “error related to procedure/treatment/test” event type. All reported events occurred in a hospital. Fifty-six percent (n = 93) were reported as Serious Events, with two (1.2%) resulting in death. The remaining reports (44.0%, n = 73) were of “no harm” or “unsafe conditions.”

Misplacement Types and Outcomes

Misplacements in the lungs occurred in 137 events (82.5%), resulting in a pneumothorax in 88 events (64.2%, 88 of 137). Perforation of the gastrointestinal tract and other body parts occurred in eight events. Other events included coiled feeding tube (n = 13), position unknown (n = 6), and wrong portion of the gastrointestinal tract (n = 2).

In the 2014 review and analysis, events reported to the Authority indicated an increase in the reported events of misplacement. Analysis of this information, including facility interviews, surmised that the increase might have been in part related to a change in feeding-tube brands that was not communicated to staff at various facilities. Therefore, it was suggested that staff should be consistently trained when introducing new brands of enteral feeding tubes. No reports after October 2013 contained event descriptions in which staff were described as being unfamiliar with the brand of feeding tube or any other common themes for the misplacements.

Misplacement Events

Examples of misplacement outcome events are as follows:*
**Pneumothorax**

Feeding tube placed. X-ray confirmation performed. Received call from radiology stated tube perforated lung, causing a pneumothorax.

**Misplaced in lung**

Placed a feeding tube. Placed accidentally in the left lower main bronchi. Tube taken out. Two x-rays showed no pneumothorax.

**Coiled**

Critical x-ray result called to floor. Feeding tube coiled. Recommended repositioning. Placement verified with air bolus. X-ray then performed.

**Perforation of the gastrointestinal tract**

Patient had nasogastric tube inserted. Difficulty passing it. X-ray showed tube perforated the esophagus.

**Position unknown**

Nasogastric tube placed in specialty care. Removed when x-ray revealed it to be out of position.

**Placed in wrong portion of gastrointestinal tract**

Infant’s tube was thought to be nasogastric but found to be nasoduodenal at fluoroscopy.

**Age**

Patients in the age range of 60 through 89 years were affected in most of the reported misplacements (68.7%, n = 114). The largest number of Serious Events (42.2%, n = 70), including one death, were reported for this age range. Newborns and infants (0-11 months) experienced 6.6% (n = 11) of the reported misplacements with 2.4% (n = 4) resulting in temporary harm. On average in the United States, patients age 0-17 years received 23.2% of the enteral nutrition (EN), while patients 65 years or older received 44.6% of the EN. See Figure 2.
Verification

Misplaced feeding tubes were radiographically verified in 81 of the event descriptions before feeding through the tube began (and so feeding was not started), and radiographs were misinterpreted in 16 of the misplacements. To verify tube location, the American Association of Critical Care Nurses Clinical Resources Task Force endorses measurement of pH aspirate at the bedside and radiographic confirmation, and does not recommend auscultation.5

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

Conclusion
Analysis of PA-PSRS data revealed development of a pneumothorax was the most common outcome of iatrogenic enteral feeding tube misplacement for patients 60 through 89 years old. Complications of other misplacements included coiling during placement, perforation, and placement in the wrong portion of the gastrointestinal tract. More than half of the events (56.0%) were reported as Serious Events, including two deaths. Almost half of the misplacements were discovered with a chest x-ray study, which is one of the recommended practices for verification.

Notes


Saves, System Improvements, and Safety-II

"Saves, System Improvements, and Safety-II" is an occasional feature in the Pennsylvania Patient Safety Advisory, highlighting successes of healthcare workers in keeping patients safe. The Safety-II approach assumes that everyday performance variability provides adaptations needed to respond to varying conditions and that humans are a resource for system flexibility and resilience.¹

**Standardization: a Double-Edged Sword**

The following events were reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS)* and illustrate how process standardization is not inherently good or bad. These contrasting event reports show that standardization can be a powerful tool, but must be applied thoughtfully.

- **A laboratory test was ordered because of concerns about contamination of a previous specimen. When the provider looked for the results in the computer, he saw that the test had been cancelled because the test was ordered too soon following the previous test; the automatic cancellation process was designed to prevent test duplication. The facility will review its test-duplication policies.**

- **A surgeon was performing an emergency procedure and requested the equipment tray. The tray did not contain specific items that she required. Investigation revealed that there are multiple versions of the equipment tray, which contain different instruments. The facility will standardize the equipment tray going forward.**

These juxtaposed examples demonstrate that the value and safety of standardization depend on circumstances. In one case, standardization—possibly intended to avoid unintentional duplication—interfered with clinically indicated patient-care processes. In the other case, lack of standardization resulted in process inefficiency that might have been avoidable. Thoughtful implementation of standardization includes consideration of the risks and benefits of standardization in specific contexts and acknowledgment that unanticipated circumstances or unintended consequences are possible.

Both facilities are to be commended for addressing these events with system-wide interventions.

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

**Notes**

Patient Safety: No Harm, No Foul?

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Introduction

As we work together to improve patient safety, should we focus on provider error or patient harm?

In 2006, the Pennsylvania Patient Safety Authority published a report of six intraoperative cardiac arrests (/ADVISORIES/Pages/200612_01b.aspx) that occurred during hip arthroplasties using bone cement to implant prostheses; five of those events were fatal. At that time, there were few similar reports in the literature, and what is now known as "bone cement implantation syndrome" was not well understood. Reporting these rare events through Pennsylvania's statewide reporting system allowed recognition of a pattern that might not have been evident at individual facilities. Considering the knowledge generally available at that time, providers may not have thought that there were any errors in these patient-care events, but they reported the events in compliance with Pennsylvania's reporting criteria of unanticipated patient harm and thereby contributed to enhancing future patient safety.

Pennsylvania's Proactive Perspective

Pennsylvania's leadership has been ahead of the curve in establishing a reporting system based on unanticipated patient harm, as well as in recognizing the value of aggregating and reporting healthcare safety data. Healthcare providers are required to submit Incident and Serious Event reports to the Authority through the Pennsylvania Patient Safety Reporting System (PA-PSRS), which allows healthcare safety data to be accumulated at a statewide level. The Authority analyzes PA-PSRS reports and publishes aggregate data and related information in the Pennsylvania Patient Safety Advisory. The Authority, established by the Medical Care Availability and Reduction of Error (MCARE) Act of 2002, fulfills its mission to improve the quality of healthcare in Pennsylvania by collecting and analyzing patient safety information, developing solutions to patient safety issues, and sharing this information through education and collaboration.

It is tempting to place the greatest value on analyzing reports that describe events in which patients were harmed, because these events are often heartbreaking for both patients (and families) and care providers. It is also tempting to look for any errors that may have contributed to the harm. Errors may involve slips, lapses, or mistakes, or they may involve not following policies, protocols, or generally accepted standards. Errors may be attributed to actions or...
decisions by direct care providers (at the "sharp end" of patient care), or they may be attributed to actions or decisions that occurred in other parts of the complex adaptive systems that are enmeshed in healthcare delivery, such as purchasing, training, staffing, or strategic planning decisions.

In our quest to provide the safest healthcare for Pennsylvanians, learning about events involving errors is important, but insufficient. The consequences of some errors may be unimportant. The consequences of other errors may be effectively mitigated to prevent harm, depending on complex interactions between recognition and reversibility of the error and the resilience of the patient, the providers, and the systems they work within. Conversely, we know that patients may be harmed even if no error occurred, as in the bone cement implantation syndrome events described earlier in this article. And we should not wait for harm to occur if we can identify unsafe conditions before they contribute to harm.

**Pennsylvania's Radical Approach**

In Pennsylvania, we are uniquely fortunate to benefit from a visionary perspective. PA-PSRS not only collects information about healthcare events in which patients were harmed, but also information about healthcare events in which harm could have occurred, but the event did not reach the patient (e.g., a "near miss"). Further, PA-PSRS collects reports about unsafe conditions, which might not yet affect a specific patient, but which are latent safety threats. Understanding these concepts helps care providers recognize, mitigate, and learn from hazardous conditions, even before patients are harmed. The construct of PA-PSRS may seem radical, but it has many benefits. Reporting without preconditions of harm or error should remove much of the defensiveness and even shame that may accompany and inhibit event reporting.

Although PA-PSRS is one of the earliest and broadest statewide acute-care patient safety event reporting systems in the country, many providers in Pennsylvania, including those in leadership positions, do not understand the following: how the Authority uses information from Serious Event and Incident reports for educational purposes; that (beyond the facility's internal reporting system) Incident reports are only seen by the Authority; and that the Authority and the Department of Health have different roles and responsibilities with respect to PA-PSRS data.

Online education about the value, importance, and obligation of reporting patient safety events in acute healthcare facilities in Pennsylvania is available at [http://ecrilearning.ecri.org/PAPSRS_Acute](http://ecrilearning.ecri.org/PAPSRS_Acute); select “2016_06 Pennsylvania Patient Safety Reporting.”

**Summary**

Collecting data based on patient outcomes has value. Limiting data collection and analysis to those events that involve provider error will reinforce negative constructs of patient safety, even if that is not the intention. Collecting data based on patient harm will bring us closer to the goal of safe patient care. Enlarging that perspective to include events in which hazards were recognized, harm was avoided, and patient care was improved will help us achieve the safest patient care. Submitting rich, informative details in PA-PSRS reports will help the Authority better illuminate hazards that are particularly serious, common, or otherwise of educational value to facilities and to share solutions from facilities and the literature. The unusual breadth of PA-PSRS data collection offers important and unique opportunities to inform our collaborative efforts to make healthcare safer.

**Notes**

http://patientsafety.pa.gov/ADVISORIES/Pages/201712_patientsafety.aspx


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