Quality & Safety

OFFICE OF HEALTH SYSTEMS MANAGEMENT

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IN THIS ISSUE

Medication Error Dashboard

Aggregate Report on Errors related to Medications, Pediatric Patients
NYPORTS, 2002-2011

Stage of process during which event originated

Purchasing/formulary	2
Storage	3
Prescribing	31
Transcribing	1
Preparing	11
Dispensing	5
Administering	22
Monitoring	3
Unknown	2
Total	**80**

Processes of Care (more than one process may be involved for a completed medication error)

Incorrect patient	1
Incorrect medication or substance	11
Incorrect dose, overdose	40
Incorrect dose, underdose	2
Incorrect dose, missed or omitted dose	2
Incorrect dose, extra dose	1
Incorrect route	4
Incorrect timing, given too early	**1**
Incorrect timing, given too late	4
Incorrect rate, given too quickly	10
Incorrect duration	2
Incorrect strength or concentration, too high	6
Incorrect preparation	8
Expired or deteriorated substance	1
Administration of known allergen	2
Administration of known contraindicated medication	3
Incorrect family or patient action	1
Insufficient monitoring following medication administration	6

Small Patients, Big Responsibilities: Medication Errors in Pediatric Patients

INTRODUCTION

A trip to the hospital can be a frightening experience for both children and their families. For parents, it means handing over the care of their child to others, and requires trust in both individual practitioners and in the hospital's safety system. Unfortunately, errors sometimes occur despite the best effort of hospitals and professionals. When a child experiences harm from a medical error, the hospital has the responsibility to identify the causes of the error and implement high leverage risk reduction strategies that will prevent the error from reoccurring. In addition, the health care system as a whole also needs to learn from the collective experience and guarantee proactive and continuous quality improvement activities to improve their patient's safety.

In New York state, medication errors resulting in patient death or serious injury that occur in hospitals are reported to the New York State Patient Occurrence and Reporting Tracking System (NYPORTS). Until July 2011, the NYPORTS system also received voluntary reports of medication errors that did not result in serious harm but which were investigated by the facility to identify opportunities for systematic improvements. The NYPORTS reports include a narrative of the event as well as the findings of the root cause analysis activities conducted by the facility. The department recently analyzed 80 medication error cases affecting patients 19 years of age and younger reported to NYPORTS in the ten year span from January 2002 to December 2011. Tragically, there were 17 deaths that were directly attributed to a medication error or for which a medication error may have contributed. Additionally, 41 children experienced injury that required increased monitoring or intervention to sustain life or restore function, such as advanced cardiac life support, intubation, rescue medications, or dialysis. Just over half of the reported occurrences involved children less than one year of age, which is consistent with the overall patterns of hospitalization for pediatric patients (newborns account for 56% of hospitalizations among patients age 19 and younger).

SHORT STORIES, LARGE LESSONS

This newsletter provides information on serious medication errors that have affected New York's children. A series of short narratives highlight: 1) circumstances surrounding the adverse events 2) contributing factors identified in Root Cause Analyses (RCAs) and 3) risk reduction strategies undertaken after an occurrence. For all occurrences that are discussed within the newsletter, we have also provided system improvement strategies and safeguards based

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Small Patients, Big Responsibilities *(continued)*

on the Institute of Safe Medication Practices (ISMP) 2011 Medication Safety Self Assessment for Hospitals (www.ismp.org/selfassessments/hospital/2011/). The Patient Safety Center collaborated with ISMP, the Hospital Association of New York State (HANYS) and the Greater New York Hospital Association (GNYHA) to promote the Self Assessment and provide hospitals with medication safety recommendations and tools. This collaboration was funded by Health Research Incorporated by a grant from the NYS Office of the Attorney General aimed at improving pharmaceutical safety practices in New York.

RECORDING WEIGHT: A 90-POUND TODDLER?

A toddler presented in the emergency department (ED) following a fall. The nurse asked the parents how much the child weighed, and they reported "42." The nurse entered "42"into the kilogram field of the computerized triage system. An ED resident calculated the dose of ketamine based on the recorded weight of 42 kilograms. After administration, the child's heart rate and respirations decreased and a code was called. The patient required oxygen, naloxone and multiple aerosol treatments. The child was admitted to the pediatric floor. Upon admission, a pediatric resident noted that a 90 pound toddler was unusual and the team realized the child weighed 42 pounds, not 42 kilograms. Since a pound is 2.2 times heavier than a kilogram, the dose of ketamine administered was 2.5 times higher than the correct weight based dose. The child was observed overnight, and subsequently recovered fully.

What went wrong

Unsurprisingly, the weight reported by the parents was in pounds, not kilograms. There were also several other reports to NYPORTS that followed a similar story: a young child in the emergency department and emergency department staff assuming the reported weight provided by parents is in kilograms. In this occurrence, hospital's triage system had separate fields for pounds and kilograms, and allowed for the entry of either pounds, or kilograms, or both. As part of the investigation of this event, the RCA team documented every instance where weight is recorded on patient charts, and discovered other opportunities for inconsistency in addition to that identified in the ED triage record.

What they did

As an immediate short term step, the hospital revised the computer system to give a warning if the weight is out of range for the patient's age, and to display weights recorded in pounds in red, which visually prompts the user that the weight is not in a standard form. Based on a recommendation from their nursing leadership, they followed up with a more effective long term solution by standardizing the process so patient's weights are only entered in kilograms – a step recommended by The Joint Commission and the ISMP. They also revised the ED sedation protocol to build in a double check: the practitioner administering the sedation medications must re-calculate the dose, including verifying the patient's weight.

ISMP Self Assessment

Item 25

All weights and heights are measured and documented in written and electronic systems in metric units (i.e., grams or kilograms for weight, centimeters for height).

VERBAL ORDERS: WHAT DID YOU SAY?

During an emergent procedure in the neonatal intensive care unit (NICU), an attending gave a verbal order for morphine sulfate – at a dose of "point one milligram per kilogram" (0.1mg/kg). The verbal order was not written down or read back. The nurse heard the verbal order as "one milligram per kilogram" (1 mg/kg). Consequently, the infant received 2.8 mg instead of 0.28 mg, a 10-fold overdose. The patient required several doses of naloxone. Afterwards, when the event was reviewed by staff caring for the infant, they described a "tense environment," with the attending asking for multiple things at the same time.

What went wrong

Effective communication can be a challenge in urgent situations. The RCA team investigating this event found it stemmed from not following the facility's write down and read back procedure for verbal orders. The facility's medication policy states a verbal order must be written down,

1 Note: minor changes were made in the narratives in this newsletter to protect confidentiality.

including the dosing formula (mg/kg) and the total calculated dose, and then read back to the prescriber with confirmation of the correctness of the order. (e.g. "You want to give point one milligram per kilogram of morphine sulfate for a dose of two point eight milligrams. Is that correct?") This was not done, and the RCA team felt it represented a missed opportunity to spot the error and prevent an adverse event. Errors related to verbal orders account for about 15% of the pediatric medication errors analyzed. While most of these were in emergent situations such as described above, several were in less urgent circumstances, and did not warrant the additional inherent risks associated with verbal orders. When errors involving verbal orders are investigated, RCA teams should address the appropriateness of the use of verbal orders in the given clinical situation and assure the policy for verbal orders is clear and unambiguous.

What they did

Pharmacy removed the morphine sulfate 5 mg/ML vials that were available in the NICU at the time of the event and replaced them with 1 mg/mL ampules, a more appropriate concentration for the neonatal population. The facility initiated interdisciplinary simulations of patient care emergencies to practice medication management, especially verbal order "write down and read back." They added morphine, fentanyl and naloxone to their patient-specific emergency medication reference sheets. This reference sheet is updated weekly and kept on the front of each medical record to provide the appropriate weight-based dose of high-risk medications that might be needed in an emergency. In order to improve communication, they initiated quarterly interdisciplinary patient care emergency drills, including practicing the management of medications and effective verbal orders.

ISMP Self Assessment

Item 70

When verbal or telephone orders must be taken, the practitioner receiving the order immediately transcribes the order and then reads it back to the prescriber for verification of telephone orders, or at a minimum, repeats it back for verification of verbal orders received during emergencies (e.g., codes) or during sterile procedures.

LOOK-ALIKE PACKAGING: WHICH ONE OF THESE THINGS IS NOT LIKE THE OTHER?

A child required intramuscular gentamicin. A pharmacist withdrew a vial of gentamicin from the stock bin, prepared and labeled the syringe, and sent it to the unit. Several hours later, while cleaning the work area, the pharmacist realized an adult concentration of gentamicin (80 mg/2 mL) had been used to prepare the injection instead of the pediatric formulation (20 mg/2 mL), resulting in a four-fold overdose. The patient was monitored and received extra hydration. Follow up testing revealed no permanent harm.

What went wrong

Hundreds of medication names and packaging either sound or look similar, often leading to confusion, if not actual error. The Joint Commission National Patient Safety Goals suggests evaluating the potential for look-alike

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Small Patients, Big Responsibilities *(continued)*

packaging as a source of errors. In this example, the adult and pediatric packages of gentamicin looked nearly identical and were stored next to one another in the pharmacy. The RCA team could not determine whether the pharmacist grabbed a vial from the adult bin, or if a vial of adult medication was erroneously stocked in the pediatric bin. Because the label affixed to the syringe by the pharmacy had the dose that was ordered, the nursing staff could not identify the medication error prior to administering the medication.

What they did

The hospital immediately segregated pediatric injectable medications in one region of the pharmacy. They eliminated gentamicin 80 mg/2 mL vials, substituting instead 80 mg/20 mL formulation. (Since gentamicin is administered to adults by IV infusion, there was no need to stock a concentrated dose.) They investigated the storage of pediatric injectable medications outside of the main pharmacy and made revisions in areas that contained floor stock of these meds. Finally, now when the pharmacy dispenses a syringe of pediatric medication or an IV bag, they attach the actual vial used to prepare the dose, so a nurse can verify the correct medication and perform an independent calculation of the dose.

ISMP Self Assessment

Item 80

Products with look-alike drug names and packaging that are known by the hospital staff to be problematic are segregated and not stored alphabetically, and a system clearly redirects staff to where the products have been relocated.

INADVERTENT SUBSTITUTION

It was a busy, hectic night shift. A febrile child was brought to the emergency department at 2a.m. by his parents. After triage, the resident discussed ordering antibiotics with the attending, and subsequently ordered intramuscular (IM) ampicillin and gentamicin. After the emergency department nurse questioned the IM route, the resident changed the order to intravenous (IV). The nurse placed a peripheral IV and administered the antibiotics as ordered. An hour later when reviewing the orders, the resident realized that the gentamicin dose that was ordered was based on the weight based dosing for cefotaxime, resulting in approximately 20x overdose. Subsequent testing revealed no damage to the child's kidneys or hearing.

What went wrong

The resident and attending discussed ordering ampicillin and cefotaxime, but the resident picked gentamicin in the computerized order entry (CPOE) instead of the intended cefotaxime. The facility's CPOE system has weight based dosing decision support for all pediatric medications, but the resident used the manual medication ordering pathway, bypassing this important safety system. The facility reported several other factors contributing to the error. In terms of the ordering process, the resident did not write down the antibiotics discussed with the attending, and the CPOE system did not prevent the resident from bypassing the weight based dosing. The nurse reconstituted the antibiotic and administered it without recalculating the dose or confirming it with another practitioner. When the order was retrieved from the CPOE, the nurse could not determine from the order that it was manually created rather than using the weight based ordering decision support. These actions, inactions and mistakes occurred during an unusually busy night in an ED which was overcrowded and understaffed. In this stressful situation, the communication between the resident and the nurse became confrontational when the nurse questioned the route, and this discord resulted in a breakdown in

communication that contributed to the error reaching the patient. This occurrence was one of several antibiotic overdoses among children reported to NYPORTS that had similar root causes related to using the incorrect weight based dosing formula. In particular, administration of gentamicin using weight based dosing for cefotaxime has been reported on multiple occasions in the past 10 years.

What they did

The facility made the use of the weight based decision support in the CPOE system mandatory for pediatric patients. The RCA team believed a higher leverage solution would have been to restrict the use of the manual ordering pathway for pediatric patients or by resident physicians, but this change was not possible in their system. The CPOE system was modified such that the order text automatically included the weight based dosing used, so that the nursing staff can verify the dose and the use of the weight based dosing decision support. They also made changes to their policies to add more check points in the process. Like verbal orders, resident's discussions with the attending physicians concerning treatment decisions can be subject to ineffective communication which would likely be enhanced by resident validation of orders with superiors. To this end, the hospital strengthened their policy to require that attending physicians sign-off on orders of high risk medications and antibiotics for pediatric patients that are written by residents. Pediatric doses of high risk antibiotics were removed from the ED stock, and the pharmacy will begin preparing patient specific IV antibiotics for pediatric patients. The facility recognized that the problematic interaction between the providers was due to stress caused by inadequate staffing, and committed to changing the staffing model for the ED.

ISMP Self Assessment

Item 9

A nurse, pharmacist, or prescriber verifies that any patient allergy information entered into the information technology system is clinically accurate, and that the names of allergens are spelled correctly and properly coded to allow for clinical decision support screening.

INFUSION PUMPS: FOLLOW THE TRAIL.

While in the process of hanging a new total parenteral nutrition (TPN) bag and tubing for a premature infant in the NICU, the nurse was interrupted by an emergent situation with another infant. Shortly after the emergent situation was over, the nurse was scheduled to go on break. Before leaving, she checked the pump settings with the covering nurse, but they did not trace the line from the bag through the pump to the patient. Later in the shift, the infant's respiratory monitor alarm sounded, and soon after the infant became bradycardic and apneic. The infant was intubated and successfully resuscitated. Arterial blood gases revealed metabolic acidosis. Upon investigation it was realized that the old TPN bag was still connected to the umbilical catheter with the infusion only controlled by a partially loosened free flow, resulting in infusion of the entire remaining solution.

What went wrong

"Smart pumps" have been a boon to patient safety, allowing for better systematic control of intravenous medication and fluid administration. These safety improvements are only realized if the safety systems – alarms and drug libraries, for example – built into the pumps are used correctly. The RCA team found the root cause of this event was human error during the changing the TPN line and set up of the pump. Changing the TPN line involves several steps including inserting the line into the bag, then inserting the TPN tubing into the pump, flushing the line with solution, and connecting the line to the catheter. In this case, the original TPN line was removed from the pump, leaving it connected directly to the catheter while the new line was installed. If she hadn't been interrupted, the nurse would have made the catheter connection after putting the new line into the pump. The staff didn't realize this step was missed until the infant's alarm sounded later in the shift. Additionally, it was determined that the nurse manually loosened the free flow prevention clamp on the old TPN bag in order to keep the line patent. This at-risk behavior by-passed the important safety features of the infusion pump and tubing. As with the previous example, distraction and a busy hectic environment contributed to the error. Inclement weather had necessitated the involved nurse, who normally worked the night shift, to report to work earlier than usual. Hanging new TPN bags and tubings was not part of her daily routine and lack of familiarity with the process contributed to delayed recognition of the error in set-up.

What they did

The facility changed their policy to require that NICU staff inform their covering nurse prior to initiating an IV line change, so that they are not be pulled away in the middle of the process. They also retrained all night shift nurses and instituted IV line change simulation exercises for all

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shifts. Finally, they added tracing the line from the bag to the catheter to the bedside hand-off procedure. Use of IV infusion pumps and tubing that prevent free flow when the pump is not properly set-up is a high leverage strategy to prevent errors, but this event shows that the process is not error proof. The federal Food and Drug Administration has acknowledged that continuous improvements are needed for infusion pump designs, and launched the Infusion Pump Improvement Initiative in 2010 to foster the development of safer, more effective infusion pumps (see http://www.fda.gov/medicaldevices/productsandmedicalprocedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm).

ISMP Self Assessment

Item 237

When an event involves staff who cut corners, breeched a policy, and/or did not follow a procedure, the conditions that led to these AT-RISK BEHAVIORS are investigated to uncover system-based incentives that encourage the behavior and/or system-based disincentives that discourage safe behaviors.

RECORDING DRUG ALLERGIES: IDK, NKA?

A young girl presented to the pediatric emergency department (PED) with suspected appendicitis. During triage, her parents reported she was allergic to penicillin. The allergy was recorded on the triage sheet, and an allergy alert band was place on her wrist. While ordering morphine to relieve her pain, the attending mistakenly wrote "NKA" (no known allergies) on the order sheet. The sheet was faxed to the pharmacy, where the pharmacy technician recorded "no known allergies" in the patient's electronic medical record (EMR). In the PED, penicillin IV was ordered and administered. Both the ordering physician and administering nurse noted the "NKA" on the morphine order sheet, but did not check the triage record. The pharmacy dispensed the penicillin because the previous order sheet had indicated "NKA." Because the operative team was assessing the patient, the nurse was hindered from checking the patient for an allergy wrist band prior to administering the drug. The patient experienced hives and shortness of breath, requiring treatment with antihistamine and epinephrine.

What went wrong

The RCA team got to the heart of the matter and noted the root causes of this event were knowledge deficits, ineffective communication, and a failure of leadership and culture. Although the facility had adopted a hospital wide EMR and CPOE system, the PED staff were not compliant in entering allergy information onto the system or in using the CPOE to place orders. They were, instead, still using a paper based system that the pharmacy accommodated by entering the allergy information from the faxed order sheets. The team also noted several other points in the medication use process where the policies and procedures were not followed by PED staff. RCA Teams often identify systems issues by applying the substitution rule: If three other practitioners with similar skills and knowledge would do the same in similar circumstances, then the error was due to a system failure. In this occurrence, the culture of the PED enabled lack of compliance to recording allergies in the EMR as well as other at-risk behavior, so this was an "accident waiting to happen."

ISMP Self Assessment

Item 132

With each new bag/bottle, or change in the rate of infusion of selected high-alert drugs and selected pediatric/neonatal parenteral solutions, one practitioner readies the solution for administration and a second practitioner and/or electronic technology (e.g., SMART INFUSION PUMP with dose checking capabilities, point-of-care bar-coding) independently verifies all of the following before starting the infusion: drug/solution, drug concentration, rate of infusion, patient, channel selection (for multiple channel pumps), and line attachment.

What they did

The facility immediately began to enforce the medication use policies and procedures in the PED, including requiring use of the EMR and CPOE. In collaboration with the pharmacy, the PED established a system of monitoring compliance by tracking input of allergy information and CPOE use via monthly reports. They also identified a need for nursing leadership specific to the PED, and recruited a nurse coordinator for this role.

ISMP Self Assessment

Item 42

COMPUTER ORDER ENTRY SYSTEMS perform dose range checks and warn practitioners about overdoses and underdoses for all high-alert drugs and for most other medications.

CONCLUSION

Even before their baby is born, the expectant parents spend hours assuring the baby's safety. They buy car seats. They read about the best cribs. They cover the electrical outlets and lock the cabinets where the cleaning fluids are kept. All these preparations are because children need adults to protect them. Similarly, safe medication use for children calls for safeguards above and beyond those in place for adult patients. In particular, pediatric patients are considered to be at higher risk of overdoses due to their small size and the need for weight based dosing, the more frequent need to compound or reconstitute their medications, the differing concentrations of pediatric medications compared to adult formulations, and so on. Pediatric patients may also be more susceptible to harm from medication errors due to their underdeveloped organ systems and small body weights. While some of the root causes related in this newsletter – look-alike drugs, ineffective communication of verbal orders, missing or inaccurate patient information – are not unique to pediatrics, sometimes the solutions must be: separate formularies, separate order sets, separate drug storage and preparation areas, etc. Both the ISMP Medication Safety Self Assessment and the Joint Commission Sentinel Event Alert, 'Preventing Pediatric Medication Errors http://www.jointcommission.org/assets/1/18/SEA_39.PDF, provide insight into the tools that will help us protect our smallest patients.

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