Changes in Routines Often Increase The Risk of Mishaps

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PROBLEM: To improve the safety of administering intravenous (IV) medications and to discontinue use of the “rule-of-six,” a pediatric hospital implemented a “smart” infusion pump syringe system (Medfusion 3500, PharmGuard software, Smiths Medical). (The rule-of-six is a shortcut that is used to calculate pediatric critical care drug infusions that are dosed in mcg/kg/minute; the formula is 6 x weight [kg] = the amount of drug in milligrams that should be added to 100 mL of solution.) Smart pumps use a hospital-defined drug library to alert practitioners if the pump is programmed to administer a medication at a potentially dangerous dose or rate of infusion.

To support the new technology, substantial changes that affect how IV medications are ordered, prepared, and administered are often required. In the pediatric hospital, the new system required a change to standard IV drug concentrations for continuous and intermittent infusions, allowing nurses to program the dose, rather than just the flow rate, into the pump.

Before they began to use the smart pumps, the pharmacy staff had prepared doses by drawing the needed volume of concentrated drug into a syringe, which was dispensed to the patient-care unit. The nurse diluted the dose in a volume-control ( burette chamber) set.

In the new system, which utilizes standard drug concentrations, the prescribed dose is prepared in the pharmacy from a diluted stock solution of the drug. Thus, the product is dispensed in a pharmacy-prepared, ready-to-use form in the standard concentration that matches the only set in the pump’s drug library. Although this new method held the promise of improved safety, many previously well-rehearsed routines had to be changed. The result: an unanticipated mishap about a week after the new process was implemented.

During morning rounds, a supplemental IV phosphate bolus had been prescribed for a critically ill 12-year-old child with a low phosphate level. Later that evening, the child’s phosphate level was extremely high. Despite aggressive therapy to correct the abnormal electrolyte level, the patient died the following day. It was then discovered that the child’s death was caused by an accidental overdose of phosphate.

A dose of 25 mmol of phosphate (as sodium phosphate) had been prescribed. The standard concentration for sodium phosphate, as listed in the pump’s drug library, was 0.15 mmol/mL. With this newly established standard concentration, therefore, a total volume of 167 mL was required for a 25-mmol dose. An admixture procedure in a pharmacy-compounding manual provided directions to make a stock supply of the standard concentration from which the 167 mL could be removed. The pharmacy technician did not realize that there was a new standard concentration for phosphate. He followed the former procedure of filling the order with the concentrated form of sodium phosphate taken directly from commercially available vials. The resulting product contained 167 mL of a 3-mmol/mL concentration of sodium phosphate (sodium phosphate dose = 501 mmol) rather than a 0.15 mmol/mL concentration (sodium phosphate dose = 25 mmol).

Although the technician had used several vials for compounding, when the pharmacist checked the final product, only one partially used vial was present. Thus, the pharmacist assumed that the correct concentration of the product had been made. The error was not detected, and the product was subsequently dispensed to the nursing unit.

From a nursing perspective, the nurse caring for the child could not have identified that the bottle actually contained a 20-fold overdose, because the product’s label read “sodium phosphate (0.15 mmol/mL), 25 mmol = 167 mLs.” This matched the prescriber’s ordered dose and the standard concentration programmed in the syringe pump. In addition, the label had the pharmacist’s initials in red ink, indicating that the product had been checked. Subsequently, the medication was administered to the patient.

An exceptional amount of work by the nurses, pharmacy staff, and medical staff members went into establishing standard concentrations and implementing the new smart pumps. To support the new process in the pharmacy, procedures were redesigned; standard concentrations were developed, line items in the pharmacy computer were created to support the new concentrations, and a compounding manual with new dilutions was disseminated. Pharmacy staff members were informed of the pending changes at the change-of-shift report, but this step proved to be insufficient. A memo has also been distributed to all staff members in the pediatric pharmacy division.

This process change had a tremendous impact on pharmacy workflow, staffing requirements, and space needed to adequately prepare and check IV medications. In retrospect, the magnitude of the change was underestimated, and the efforts to redesign the pharmacy process and prepare first-line pharmacy technicians and pharmacists were not adequate to prevent the serious system failure that occurred.

SAFE PRACTICE RECOMMENDATIONS: The suggestions that follow, provided by the Institute for Safe Medication Practices (ISMP), were derived from a root cause analysis of the accidental phosphate overdose.

1. Failure mode and effects analysis and pilot-testing. Whenever a well-rehearsed routine is changed, unanticipated mishaps can occur. To prevent serious failure, it is recommended that a root cause analysis of the mishap be conducted to identify the root cause and to prevent similar mishaps in the future. This is known as a failure mode and effects analysis (FMEA). The analysis should be performed on the new process and should include all potential failures, including human errors, process errors, and system errors. The analysis should also include a pilot-testing phase, where the new process is tested in a controlled environment before it is implemented in the real world. This will help to identify any potential problems that may not have been identified during the FMEA phase.

2. Change management. Change management is the process of managing changes in an organization. This includes planning, communicating, training, and supporting employees through the change process. In this case, the change management process should have included a change management plan that outlined the steps to be taken to implement the new process. This plan should have included a timeline for the implementation of the new process, training for employees, communication to employees, and support for employees during the change process.

3. Risk management. Risk management is the process of identifying, evaluating, and mitigating risks. In this case, risk management could have been used to identify potential risks associated with the new process. This would have included a risk assessment, which would have identified potential risks, and a risk management plan, which would have outlined the steps to be taken to mitigate these risks.

4. Process improvement. Process improvement is the process of identifying and improving processes to achieve better results. In this case, process improvement could have been used to identify and improve the processes associated with the new process. This would have included a process analysis, which would have identified the steps in the process, and a process improvement plan, which would have outlined the steps to be taken to improve the process.

5. Communication. Communication is the process of sharing information with others. In this case, communication could have been used to ensure that all employees were aware of the new process and the changes that were being made. This would have included training sessions, communication materials, and ongoing communication to employees.

6. Monitoring and evaluation. Monitoring and evaluation are the processes of monitoring the new process and evaluating its effectiveness. In this case, monitoring and evaluation could have been used to ensure that the new process was working as intended. This would have included regular monitoring of the process, as well as periodic evaluations to ensure that the process was achieving its goals.

7. Continuous improvement. Continuous improvement is the process of continually improving processes to achieve better results. In this case, continuous improvement could have been used to continually improve the new process. This would have included a continuous improvement plan, which would have outlined the steps to be taken to improve the process continuously.

8. Leadership. Leadership is the process of providing direction and guidance to others. In this case, leadership could have been used to provide direction and guidance to employees during the change process. This would have included providing clear direction, setting expectations, and providing support to employees.

9. Support and resources. Support and resources are the processes of providing support and resources to employees. In this case, support and resources could have been used to provide support and resources to employees during the change process. This would have included providing training materials, communication materials, and ongoing support to employees.

10. Training. Training is the process of providing employees with the skills and knowledge they need to perform their jobs. In this case, training could have been used to provide employees with the skills and knowledge they need to perform their jobs during the change process. This would have included providing training materials, training sessions, and ongoing support to employees.

11. Change management. Change management is the process of managing changes in an organization. In this case, change management could have been used to manage the change process. This would have included a change management plan, which would have outlined the steps to be taken to implement the new process, and a change management team, which would have been responsible for implementing the new process.

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pated new sources of errors are possible. Staff members, for example, sometimes resume previous habits or do not receive adequate communication about the change. Thus, it is crucial to conduct a failure mode and effects analysis (FMEA) before making permanent changes. This step can identify ways in which the new process might fail so that steps can be taken to mitigate any harm. Pilot-testing and simulations of the new process involving current staff members are also essential to identify potential errors during critical, error-prone steps, particularly when high-alert medications are involved. The FMEA, pilot-tests, or simulations can also help employees become familiar with the new process.

2. Communication and education. It is imperative that instruction about changes regarding all new processes be clearly stated. Ongoing communication is appropriate for large process changes; change-of-shift reports and memos are frequently inadequate. Ideally, after employees have been instructed in the new process, return demonstrations to verify their competency in performing new procedures should take place as well. It is also important to update all references, process guidelines, and other resources that might inadvertently continue to support the old process.

3. Preparation and checking processes. After the error involving the pediatric patient, the process for preparing and checking pharmacy IV products was redesigned as follows:
   a. A system to facilitate adequate checking was developed. The preparer now places into a single bin all source containers (e.g., commercial vials, labeled and checked dilution containers) used for product preparation as well as syringe plungers pulled back to indicate added volume.
   b. Preparation labels that include the exact admixture instructions, final concentration, and signatures, indicating that a pharmacist has verified the accuracy of the stock solution, have now been created for all IV dilutions.
   c. A preparation label is affixed to the dilution bottle, and a second copy of this label becomes part of a permanent record, helping to promote compliance with a cognitive independent double-check system. This step had not always been taken previously.

   Culture change. Another important consequence of the incident involving the child has been a culture change in the pharmacy. Before the event, no reliable mechanism had been available for staff members to voice their concerns about new work processes or for these concerns to be addressed. Since then, newly created support systems, such as the addition of a medication safety officer, operations manager, pediatric-trained pharmacy informatics specialist, as well as other resources, have helped the staff feel more empowered to express their safety concerns. The support systems have also created a mechanism to incorporate the staff’s suggestions for improvement. For example, during implementation of computerized physician order entry (CPOE) in pediatrics, first-line pharmacists have participated alongside leaders in CPOE development and testing and have introduced training and reference materials for the pharmacy staff.

   Staffing patterns and environment. Other root causes of the error have been addressed in the pediatric hospital at a higher level. The budget was adjusted to include the hiring of additional technicians and pharmacists, and the pediatric pharmacy is being completely redesigned and enlarged to support a safe and efficient workflow.

   A heightened index of suspicion. The ISMP recommends raising technicians’ awareness of a potential error if they find that more than three dosage containers are needed to prepare a single dose or compound a solution, as occurred in the pediatric situation. Bringing the need for multiple dosage containers to the attention of the pharmacist during the preparation of products can add another level of safety to the dispensing process.

The reports described in this column were received through the ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP Web site (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAILSAFE or via e-mail at ismpinfo@ismp.org.