A Mislabeled Event With Batched Drugs: The Unintended Consequences Of Practice Changes

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Problem: Any time a change is made in the structure or processes associated with a task, the risk of an unanticipated error is introduced—even if the changes are intended to reduce the risk of errors or improve the quality of outcomes. This is exactly what happened in a hospital pharmacy where two key changes had been made in response to external forces. The changes led to a series of errors while batching medications for administration by anesthesia providers.

First, the pharmacy had begun internal preparation of numerous intravenous (IV) products that had previously been compounded by an external compounding pharmacy. The change was made in response to the very public and deadly meningitis outbreak caused by contaminated products from the New England Compounding Center (NECC) in Massachusetts. This national event caused the hospital (and many other hospitals) to reassess whether IV products should be prepared internally or outsourced to compounding pharmacies.

The other significant change made by the hospital pharmacy was in response to the U.S. Pharmacopoeial Convention (USP) <797> standards. This resulted in modifications in how labels were applied to batched IV admixtures. The hospital had moved the labeling process from the laminar airflow workbench to outside the direct compounding area. In this case, the changes, along with several other contributing factors, led to a series of patients receiving a neuromuscular blocking agent IV instead of lidocaine.

Error: The pharmacy was preparing various medications in syringes for anesthesia use, including a neuromuscular blocking agent, propofol, and 1% lidocaine. The 1% lidocaine was used to lessen the burning sensation that accompanies propofol administration. A pharmacy staff member preparing batches of a neuromuscular blocking agent and lidocaine inadvertently switched the labels and mistakenly identified the syringes containing the neuromuscular blocking agent as lidocaine, and the syringes containing lidocaine as the neuromuscular blocking agent. Both batches included the same number of syringes, and the syringes all contained 5 mL of a clear solution, making detection of the error after the labeling mix-up nearly impossible.

Several surgical patients were given what was thought to be IV lidocaine during the administration of IV propofol, but they actually received the neuromuscular blocking agent instead. These patients demonstrated the usual signs and symptoms of neuromuscular blockade and required respiratory support via manual bagging or rapid intubation. Several patients experienced the paralyzing effects before sedation had been achieved and, thus, had recall of the terrifying event. Anesthesia staff suspected an error after discussing the adverse events their patients had experienced. The mix-up between the batched neuromuscular blocking agent and lidocaine syringes was then identified during pharmacy investigation of the adverse events.

Contributing Factors

During investigation of the error, several system issues and human factors that contributed to the events were identified.

Batched products not labeled immediately and separately. While it was pharmacy policy and practice to batch one product at a time in the laminar airflow workbench, pharmacy staff did not view the labeling of batched products as a process that should be conducted immediately after production and separately from other batched products. Attempting to comply with USP <797>, the hospital felt that the bioburden from the labels would be lessened by labeling the products outside the laminar airflow workbench. However, the labeling process did not occur immediately after each batch was completed and removed from the workbench. Thus, the propofol, lidocaine, and neuromuscular blocking agent syringes were all labeled outside the laminar airflow workbench along with other products that had been prepared during that time after the batching process had been completed.

Production pressure at the end of shift. A large volume of IV compounding previously accomplished at an external compounding pharmacy had moved into the hospital pharmacy, significantly increasing the burden and workload. At the time of the event, pharmacy staff reported working under considerable pressure to get the batches completed and dispensed before the end of the shift. Batching was typically scheduled during the last hour of the shift.

Safe Practice Recommendations

The hospital where this event occurred made numerous changes in the processes associated with the error. We have highlighted those changes and provided some additional recommendations below.

Review Batched Drugs

Regularly review all medications being batched or compounded to determine whether a less error-prone approach to providing the drug is available (e.g., dosage and dosage form available commercially, outsourcing). In this case, vial-to-syringe batching of lidocaine was found to be unnecessary because the drug is available in a ready-to-use form in small vials—pharmacy was simply removing the drug from the vial.

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Assess Batching Schedules

Conduct a time analysis to prioritize pharmacy work. Set batching and planned compounding schedules based on time and staff availability and on priority.

Provide a Visual Alert

Avoid using the same exact volume for any of the batched products prepared sequentially to help provide a visual alert of potential product mix-ups. While this intervention may not be possible in hospitals where many products are prepared in batches, it was possible in the hospital where the event occurred.

Limit the Number of Printed Labels

Provide the exact number of labels required for batched or compounded products. Instruct staff to suspect an error if there are too many or not enough labels during the labeling process. This intervention is similar to comparing the expected yield of a product (as documented in batching/compounding logs) with the actual yield and fully investigating any discrepancies. Also, print just one set of labels for batched products at a time. Do not print the next set of labels until the current batch of products has been labeled.

Employ Safe Labeling Practices

Labeling of batched or compounded products should occur immediately after each product has been completed and before preparation of the next drug or batch. (The use of an electronic pharmacy workflow manager may help promote separate labeling practices because new labels will not print until the process has been completed.) To limit the bioburden that paper can create when introduced into a clean area, the best practice recommendation for batched products is that label placement occurs outside the laminar airflow workbench or the direct compounding area. Thus, procedures should be established to ensure that the labels (and any other documentation and source containers) and the final batched products are kept together outside the laminar airflow workbench and that the products are labeled immediately after each specific batch has been completed.

Verify the Labels

If feasible, build an independent check by a pharmacist into the process to verify the labels for batched products before they are affixed to the products. This check does not replace order entry verification; it is an additional check before affixing the labels to batched products. No batched products should be left unlabeled and unattended while awaiting label verification by a pharmacist.

Identify Risk Points Before Batching or Compounding

Before batching or compounding products in the pharmacy, particularly those that have been previously provided by an external source (e.g., compounding pharmacy, commercial vendor), conduct a failure modes and effects analysis (FMEA) to identify risk points specific to the product’s prescribing, preparation, dispensing, and administration process, and take the steps necessary to reduce the risk of errors. (While the focus of the FMEA may be on a different method of preparing the drug, changes in the concentration of products, labeling, delivery, or administration methods may contribute to prescribing, dispensing, and administration errors. Thus, all phases of the medication-use process should be included in the FMEA.) Prospectively assure that available resources are appropriate for the increased production.

Keep the Index of Suspicion High

If a clinical outcome is not as expected, every practitioner who provided care to the patient should carefully consider the last few things he or she did for the patient to identify potential errors so that their effects can be mitigated to the greatest extent possible. A preoccupation with failure, rather than with success, is an attribute of highly reliable organizations and will help to quickly identify errors and implement interventions to mitigate patient harm.

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 website (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAIL-SAFE or via email at ismpinfo@ismp.org.