ISMP Medication Error Report Analysis

Mislabeled Event With Batched Drugs: Unintended Consequences of Practice Change

Morse Code Imprint

Multiple Barcodes Cause Confusion

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

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MISLABELING EVENT WITH BATCHED DRUGS: UNINTENDED CONSEQUENCES OF PRACTICE CHANGE

Any time a change is made in the structure or processes associated with a given 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 2 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 been previously compounded by an external compounding pharmacy. The change was made in response to the very public and deadly meningitis outbreak in late 2012 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 US Pharmacopeial 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.

The Error

The pharmacy was preparing various medications in syringes for anesthesia use, including a neuro-

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muscular 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 and human factors issues 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.

Addressing the Situation

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 (eg, 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.

Assess batching schedules. Conduct a time analysis to prioritize pharmacy work. Set batching and planned compounding schedules based on time and staff availability and 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. Although 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 into the process an independent check by a pharmacist 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 (eg, compounding pharmacy, commercial vendor), conduct a failure mode 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. (Although 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 medication use process should be included in the FMEA.) Prospectively ensure 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 they 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.

MORSE CODE IMPRINT

A pharmacist brought to our attention a generic mycophenolate mofetil capsule that did not have an imprinted alphanumeric code to help identify the product. All that appears are the 2 bars seen in Figure 1.

In the Code of Federal Regulations [CFR Part 206 (a)], it states that oral solid dosage forms must be "clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of a drug product and the manufacturer or distributor of the product." However, it also says, "Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself." The mark on the capsule seems to meet the requirements of the CFR. Still, without a company name on the capsule, it's hard to see how, particularly in an emergency, anyone would be able to easily identify this item by searching for an orange and blue capsule with 2 horizontal bars. The mark alone does not seem to meet the intention of the CFR that this product be identifiable.

We've notified the company (Accord Healthcare) and the US Food and Drug Administration (FDA) about our concerns.

MULTIPLE BARCODES CAUSE CONFUSION

As you have probably noticed, there are a number of medications with 2 or more barcodes printed on the package (see Figure 2). The presence of multiple barcodes on products is confusing to frontline staff. Typically, the barcode associated with the national

Figure 1. These mycophenolate mofetil capsules seem to be missing a proper ID code.

Figure 2. Products with more than one manufacturer barcode are confusing.

drug code (NDC) is intended for scanning during barcode medication administration (BCMA) workflow. But all too often, the manufacturer includes an additional barcode that is used in its production and quality control processes. When the clinician tries to scan one of these barcodes, it won't scan properly, leading to frustration. As a result, there have been instances where a practitioner has overridden the barcode system, leading to potential errors.

Although hospitals may try to make these additional barcodes function, the manufacturer changes the scanned values of these second barcodes from time to time, making this impractical. We have asked the FDA to discuss this problem internally with their barcode work group to see whether they can have manufacturers redeploy these barcodes elsewhere on the package, or at least clearly identify which barcode should be scanned during clinical use. ■