Another Tragic Parenteral Nutrition Compounding Error

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**Problem:** The Institute for Safe Medication Practices received a report about an infant who had been born prematurely, weighing less than 1 kg at birth but thriving at 6 weeks. His nutritional requirements were being supported with parenteral nutrition (PN). On the day of the event, the infant’s physician prescribed a total of 14.7 mEq of sodium chloride and 982 mg of calcium in the infant’s PN. The order was faxed to the pharmacy after midnight, at which time a pharmacy technician made an error when entering the order into the automated compounder machine’s software. Apparently, the technician accidentally entered the prescribed dose of calcium (“982” mg) into the mEq field for sodium. The technician then prepared the PN, which contained a total of 982 mEq of sodium, using an automated intravenous (IV) compounder. The technician affixed the printed label to the PN, which showed the erroneous sodium content.

Unfortunately, the error was not detected when a pharmacist checked the final product. Furthermore, a different label that listed the sodium content as 14.7 mEq, the originally prescribed amount, was applied directly over the label produced by the compounder software that had listed the actual amount of sodium (982 mEq) in the solution. Thus, the nurse who eventually started administration of the PN solution was unable to detect the error.

A few hours after the PN was started, routine lab studies showed that the infant’s sodium level was abnormally high. The infant’s physician assumed the study results were inaccurate and asked for the lab test to be redone. This was never accomplished before the infant experienced a cardiac arrest and died.

**Possible Causes of the Event**

News reports of the event did not indicate the vendor of the automated compounder and related order-entry software in use at the time of the error. However, according to *Pharmacy Purchasing & Products*, Baxa compounders and Abacus software are the most widely used in hospitals. Thus, we have evaluated how this event could have happened if the Abacus order-entry system had been used at the time of the error. This way, we can help a majority of our readers identify how this error could happen in their organizations. Abacus software is not interactive with the pharmacy order-entry system; screening for dose irregularities (and drug interactions, incompatibilities, etc.) does not occur. However, the software comes with two types of dose warnings:

1. **Baxa Only Warning Limits**, which are extremely high, catastrophic dose limits established and installed by Baxa personnel for typical products used to compound neonatal, pediatric, and adult PN. The entry of doses above these limits results in a hard-stop warning that cannot be bypassed. Any modifications to these limits must be requested through Baxa.

2. **Template Institutional Warning Limits**, which are suggested dose limits intended for organizations to review and modify as desired. These dose limits are designed as templates that the customer can use to establish more restrictive dose limits, as the Baxa Only Warning Limits are so high that a fatal dosing error could easily be entered into the system without issuing a warning.

The Baxa catastrophic dose limits are not distinctively weight-based. For example, all dose limits set for neonates are based on a 10-kg infant. However, the institutional warning templates provided with the software allow users to define and install more appropriate weight-based dose limits. The Abacus software can employ multiple sets of dose warning limits for adults, pediatric patients, and neonates, each associated with specific rules regarding how PN orders are processed and how the components of PN are calculated. Since the Abacus software can also be used for sterile preparations that are not directly infused (e.g., cardioplegia solutions, dialysates), users can create non-PN templates into which these orders can be entered. These non-PN templates do not employ the catastrophic dose limit warnings provided by the vendor.

In this event, the sodium dose of 982 mEq would have been entered into the Abacus software. The Baxa Only Warning Limit for sodium is set at 385 mEq for neonates. Thus, you would expect the system to warn the user with a hard stop after entering the 982 mEq dose. One possible scenario that would allow this entry to be made without a hard-stop dose warning is if the PN order had been entered into a non-PN patient-type template that the user had created without dose limits. Another possibility is if an adult application of the software was purposely used to enter the neonatal PN (the Abacus adult catastrophic sodium limit is 1,000 mEq). A final possibility is that a different vendor’s software system was used that did not employ catastrophic dose warnings or user-defined dose warnings with a hard stop.

**Safe Practice Recommendations:** If your organization prepares PN using an automated compounder and associated order-entry software, please consider the following recommendations to avoid potential harm to your patients. Most recommendations are also applicable in organizations that use automated compounder-associated software for PN calculations alone (not actual compounding) and/or prepare PN solutions manually.

**Compound PN orders during the day.** Policies that require pharmacists to compound PN during the day shift should be established and enforced to maximize the safety with which these solutions are prepared and dispensed. When using an IV compounding pharmacy to prepare PN solutions, the order should be transmitted to the pharmacy during the day so it continued on page 822
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can be checked by a hospital pharmacist with PN expertise before it is sent to be compounded. Pharmacy staff should be aware of patients who are receiving PN and should check if orders have not been received by the established time.

**Standardize the format of PN orders.** Synchronize the order and format of listing ingredients in PN order sets, the pharmacy computer system, the compounding software, and the PN label to help prevent errors caused by jumping back and forth.

**Maximize decision support.** Install, test, and maximize automated dose-limit warnings in the pharmacy computer system and automated compounding order-entry system, particularly for high-alert medications such as PN and its ingredients. If your PN software supports warning limits, fully implement them. Turning off warning limits is like driving without a seat belt. However, do not rely solely on the catastrophic dosing limits established by software vendors. Vendor-established dose limits, such as the Baxa Only Warning Limits, will still allow a potentially fatal dose to be entered into the software without issuing a warning. Organizations need to define more restrictive weight-based dosing limits applicable to their patient populations. These warnings should function as a hard stop without the ability to proceed until the dose has been checked via a peer review process. Organizations should also print all alerts encountered during the order-entry process so the person checking the order entry can view and respond to the alerts. Reinforce with all staff the importance of reacting to the alerts.

**Label products and use critical thinking skills.** Produce product labels and associated work labels used by pharmacy staff to compound solutions that include the actual dose/strength of the base solution and each additive, not just the volume amounts needed to prepare the products. Encourage technicians who compound products to focus not only on the volumes needed to prepare the solution but also on the dose of the additives and the concentration of the solutions. Apply easy-to-read labels that print from the compounding order-entry system to compounded products to ensure the label lists the actual contents. These labels should follow the format of the prescriber’s order.

**Carry out effective redundancies.** Several verification processes should occur in the pharmacy:

1. Before order entry into the automated compounding software to verify that the PN order is appropriate for the patient (e.g., based on weight, height, disease state, lab values)
2. After initial order entry into the automated compounding software to match it to the verified order
3. Before injecting any additives that must be added manually, and
4. Once the PN has been compounded

Verification of manual additives should include inspection of the actual vials and filled syringes prior to admixture (the “pullback” method is not recommended). Final verification of the compounded PN should include review of the original order, product label, and work label, as well as comparison of the expected weight/specific gravity with the actual weight/specific gravity. If different than expected or off by 3% or more, the product should be prepared again. If PN compounding is outsourced, a pharmacist should verify the appropriateness of the order before sending it to the pharmacy and verify that the product received matches the verified prescriber order. Before administering PN, nurses should also independently compare the label on the solution with the physician’s order.

**REFERENCES**