Pharmacist supervision is critical for proper preparation of CLINIMIX multi-chamber bags

CLINIMIX E is a parenteral nutrition multi-chamber bag with one chamber containing dextrose and calcium and the other chamber containing amino acids and electrolytes. A seal that separates the two chambers must be broken to mix the contents of both chambers together prior to dispensing/administration. Intravenous fat emulsion and additional electrolytes may be added as necessary in the pharmacy.

We received a report in which a physician ordered this product to be administered “if the patient does not eat at least 50% of breakfast.” Two pharmacists confirmed with the nurse that the patient had, in fact, eaten about 50% of breakfast. So, the product was not dispensed. However, the patient ate almost no lunch or dinner, so a decision was made to start Clinimix E.

After the pharmacy was closed, two charge nurses entered the pharmacy to retrieve a bag of Clinimix E—a practice allowed at this hospital. The next day, another nurse discovered that the container had been hung without breaking the seal between the chambers. Since the access port for the IV administration set on the Clinimix E bag leads into the chamber with electrolytes and amino acids, the patient received a concentrated dose of these products, including 30 mEq of potassium chloride, and no dextrose or calcium. Fortunately, the patient’s metabolic profile collected that morning revealed normal values of electrolytes, and the patient experienced no adverse effects.

ISMP has been steadfast in its opposition to allowing non-pharmacy staff access to the pharmacy after it is closed, primarily due to staff unfamiliarity with the many items in a typical hospital pharmacy’s inventory. Many state laws explicitly prohibit non-pharmacists from entering a pharmacy after it is closed. The Joint Commission is also openly opposed to this practice.

In hospitals without 24-hour pharmacy service, it is safest to provide access to a pre-approved formulary of medications via emergency kits, automated dispensing cabinets (ADCs), or other means chosen with safety in mind. The selection of drugs and processes for accessing them should be approved by a pharmacy and therapeutics committee. Nurses should seek assistance from an

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call pharmacist whenever there is a question about a medication.

Having pharmacists in a remote location review all orders before any medication is administered, except in an emergency, when a pharmacist is not on site is another option. However, a mechanism to transport or dispense medications only available in the pharmacy must be provided to avoid non-pharmacy personnel from entering the pharmacy for needed drugs.

Another strategy is to avoid starting the first infusion of parenteral nutrition when the pharmacy is closed. If the first infusion is prepared by the pharmacy, all subsequent solutions can be anticipated and dispensed by the pharmacy as needed. Parenteral nutrition is a non-urgent medication; the physician can always order 10% dextrose to infuse until the pharmacist can prepare and dispense the first infusion of parenteral nutrition.

Parenteral nutrition is one of the most complex sterile preparations to prepare, relying on a specific order of mixture as well as method of preparation to assure sterility, compatibility, and stability. Clinimix E, CLINIMIX (a similar product without electrolytes), and other FDA-approved, commercially available parenteral nutrition products may reduce the risk of errors associated with mixing these complex solutions. However, ISMP has published previous reports in which nurses or pharmacy staff have failed to activate or mix multi-chamber bags of parenteral nutrition solutions, antibiotics (e.g., ADD-Vantage), and other products that require manipulation by nurses prior to administration. Since the initial error cited above was reported to ISMP, we have received reports of three more instances of failing to mix Clinimix products prior to administration, all occurring at the same hospital.

The safest strategy is for pharmacy to dispense Clinimix products for each patient after proper mixing and labeling of the bag. The manufacturer of Clinimix products has documented in the prescribing information that, once removed from the overwrap, mixed or not, Clinimix solutions may be stored under refrigeration for up to 9 days. Information about storage at room temperature is not available.

If the product is available in its overwrap in ADCs or other areas outside the pharmacy, nurses should be taught to activate this product. Educational resources are freely available at: www.clinimix.com/popups/video.jsp. These resources illustrate the dual-chamber bag technology and offer step-by-step bag activation training. Some hospitals report that errors have been reduced by applying a noticeable auxiliary label to the overwrap, advising that the product must be activated prior to hanging (e.g., Mix Contents of Both Chambers Prior to Administration). We have also contacted Baxter to request more visible labeling regarding the need to mix the product before use.

**Report errors with parenteral or enteral nutrition to ISMP**

While parenteral nutrition and enteral nutrition are not traditionally thought of as medications, they are therapies that are prescribed, dispensed, and administered similar to medications. Administration also involves infusion devices that may be used in error. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) recommends that errors such as the one described above be reported to the ISMP Medication Errors Reporting Program (MERP), accessed at: https://www.ismp.org/orderForms/reporterrorsisolMP.asp. As with all reports received via the ISMP MERP, they will be forwarded, if appropriate, in confidence to FDA and the manufacturer. The reporter has the option of remaining anonymous and may direct us to contextually de-identify information in the report.
Adding drug to hanging IV bag poses many risks

Adding medications to IV solution bags or bottles that are already hanging is a risky practice. Besides obvious infection control and drug compatibility concerns, inadequate mixing is also a problem. Without proper mixing to ensure a uniform concentration of the drug in solution, patients might inadvertently be subjected to a bolus of the drug that sank (pooled) to the bottom of the bag instead of receiving an infusion over time.

An experiment conducted many years ago with potassium chloride concentrate injection, dyed blue with food coloring, easily demonstrated this problem. (In practice, concentrated potassium chloride should not be available on patient care units and should never be added to an IV bag already hanging.) Until the bag was removed from the IV pole and inverted vigorously several times, the blue-colored potassium chloride pooled near the bottom of the bag where the IV administration set was attached. The medical literature describes several cases of severe hyperkalemia and even death that occurred as a result of drug pooling when concentrated potassium chloride was added to hanging IV bags (Williams RHP. Potassium overdosage: a potential hazard of non-rigid parenteral fluid containers. Brit Med J. 1973;1:714-15; Lankton JW, Siler JN, Neigh JL. Hyperkalemia after administration of potassium from nonrigid parenteral-fluid containers. Anesthesiology. 1973; 39:660-61).

To cite another example, adding oxytocin (PITOCIN) to a hanging IV bag on a postpartum patient to control bleeding could lead to the delivery of more than the desired amount of oxytocin. Without proper testing, it is unknown whether other drugs are at similar risk of pooling when added to IV solutions, thus putting patients at risk of an overdose and potential harm.

Another problem with adding medications to a hanging IV solution is that it’s impossible without knowing exactly how much fluid remains in the bag to determine the actual concentration of the drug in the solution once it is added to the remaining fluid. The administration of medications in higher than recommended concentrations could lead to adverse drug effects. Further, the container would be mislabeled unless a new label was applied listing the drug, strength/concentration, and fluid volume.

Here’s what you can do: The safest practice is to avoid adding medications to hanging IV solutions, regardless of how much solution is left in the bag or bottle. If the patient’s physician prescribes new additives in the IV solution, hang an entirely new bag/bottle that has been prepared and dispensed by pharmacy.

**Special Announcement**

May 11 webinar, ISMP will present Beyond the 5 Rights: A Safety Bolus for Nursing Leadership. Learn where risk is “hidden” in your medication administration system, and discover the high-leverage error-reduction strategies that reduce the risk of errors. For details, visit: www.ismp.org/educational/webinars.asp.

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least 80% of the needs in neonatal patients. The list is now available on the ISMP website at: www.ismp.org/Tools/PediatricConcentrations. We urge all NICU staff to review the list and consider full adoption if possible. Your efforts can help reduce the risk of medication errors when treating our tiniest patients.

A different type of allergy problem. No one knows how it happened, but during a hospitalization, “vitamin D” was entered into the allergy field of a renal transplant patient’s medical record. The patient never reported adverse effects from the vitamin and, in fact, needed vitamin D and calcium to prevent bone loss that can lead to osteoporosis. During an emergency department (ED) visit a few years ago, she asked staff to remove the erroneous allergy information; she repeated the request during another ED visit when, again, someone mentioned the allergy to her. Most recently, despite promises to correct the problem, vitamin D was still listed as an allergy when she visited a new primary care physician in a hospital-owned practice. It turns out, medical personnel in clinical areas did not know how to correct the prior electronic medical records entry. However, the patient’s new physician said he would contact a programmer in the IT department who could make the correction. It is important for clinicians to understand procedures or whom to contact to correct electronic information, no matter what the practice setting, without jeopardizing the integrity and security of electronic information. This type of event and other errors or potential errors related to IT systems should be reported as a medication error via your hospitals medication error reporting process. This will help to improve the system by gaining the attention of the risk management/ patient safety department and hospital administration.

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The Institute for Safe Medication Practices (ISMP), in partnership with the Health Research & Educational Trust (HRET) and the American Hospital Association (AHA), has just launched the 2011 ISMP Medication Safety Self Assessment® for Hospitals. You can access the assessment at: http://www.ismp.org/selfassessments/default.asp.

The ISMP Medication Safety Self Assessment helps hospitals:

- Evaluate their medication safety practices
- Identify opportunities for improvement
- Compare their experiences over time with those of similar organizations.

Previous ISMP self assessments were conducted in 2000 and 2004. The 2011 self assessment will document progress during the last 5 years of intense national attention to medication safety and identify the impact of emerging challenges, including shrinking reimbursement systems and application of new technologies.

Join the growing body of hospitals that conduct the assessment and submit findings to the Institute for Safe Medication Practices!

To ensure anonymity, submission of self-assessment findings is accomplished through a secure, web-based portal at http://www.ismp.org/selfassessments/default.asp. A unique, random password for submitting responses will be provided to participants who sign on. Respondents who submit their findings to ISMP anonymously will receive weighted scores and will be able to compare their confidential results with aggregate results of similar organizations.