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USP Patient Safety CAPSLink™

PROVIDED BY THE USP CENTER FOR THE ADVANCEMENT OF PATIENT SAFETY

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This message has been sent to you as a service of the U.S. Pharmacopeia, Center for the Advancement of Patient Safety (CAPS). USP is a not-for-profit, non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. CAPS is a component of USP's Patient Safety public health program. The USP Center for the Advancement of Patient Safety was created to encourage medication error reporting, conduct data analysis and research, develop educational programs, and propose standards, recommendations, and guidelines that ultimately improve the safety and quality of patient care.

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Assessing the Safety of Parenteral Nutrition¹

Parenteral Nutrition (also referred to as “total parenteral nutrition”, “TPN”, or “hyperalimentation”) is indicated in patients who are unable to obtain adequate nutrients by oral or enteral routes. Parenteral solutions supply basic nutrients, including fluid, protein, carbohydrate, fat, minerals, trace elements, and vitamins intravenously. Parenteral nutrition (PN) is a potentially life-saving therapy, but can lead to patient harm if not appropriately prescribed, compounded, dispensed, and administered.

The interdisciplinary nature of PN therapy, the complexity of PN orders, and the variety of settings where patients may be treated (e.g., hospitals, long-term care, or at home) make PN therapy especially vulnerable to errors. Many health care facilities have performance improvement programs in place to monitor the appropriate use of PN, accuracy of PN orders, and metabolic and infectious complications. However, despite these improvement programs, errors continue to occur.

Data submitted to USP's two medication error reporting programs - MEDMARX and the Medication Errors Reporting (MER) program provide some insight as to the nature of PN complications, including the system breakdowns leading to adverse events. Errors involving PN resulted in patient harm (i.e., categories E-I*) approximately 4.4% of the time for reports submitted to MEDMARX. From 1998-2002, the average overall harm rate for error reports submitted to MEDMARX has been approximately 2.5% indicating that PN errors have a higher incidence of patient harm when compared to errors overall. Data collected from MER during the same time period revealed a harm rate of 18% for PN-related errors compared to 14% for errors overall. These findings underscore the heightened potential for harm when PN therapy is part of a patient's medication regimen.

Based on reports to MER, errors made in the dispensing phase involved problems with preparing the PN, using automated compounding devices, and labeling of the PN bag. Commonly reported causes for preparation errors include similar packaging and/or labeling of drug products resulting in drug mix-ups.

MER Case #1:

A PN order for an infant patient was to contain injectable calcium gluconate. After the PN was initiated, patient lab tests were run showing an increase in magnesium levels, but no increase in calcium levels. Subsequent investigation revealed that the pharmacy had erroneously used magnesium sulfate 50% (American Regent Labs) instead of calcium gluconate 10% (American Pharmaceutical Partners). Both products came in 10mL glass vials with purple and white label logos and purple snap-off vial caps. The similarities of the two products was cited as a key cause for this error. The infusion was discontinued and the child fully recovered.

MER Case #2:

The central supply department inadvertently delivered a case of Sterile Water for Irrigation instead of Sterile Water for Injection to the pharmacy. The automated compounding machine used by pharmacy to prepare PN's holds up to six bags of solution – one of the six bags is supposed to be Sterile Water for Injection. The night pharmacist was preparing PN's for the morning shift, did not notice a difference in the sterile water bag, and set up the automated compounder using the irrigation solution instead of the injection solution. Three patients received PN solutions containing the improper ingredient before the error was discovered. Both the Sterile Water for Irrigation (2,000 mL) and the Sterile Water for Injection (3,000 mL) have red writing imprinted on the bag.

System breakdowns also occur during the prescribing, transcribing, and administering of PN therapy. Analysis of 2,519 reports to MEDMARX from August 1998 through August 2003 revealed the following:

21% (n = 521) contained some issue related to an aspect of prescribing PN solutions:

- Incomplete order (e.g., no base solution ordered, omission of essential components like protein/dextrose/electrolytes, no total volume specified, no flow rate specified, failure to designate peripheral or central administration)
- Inaccurate or inappropriate order (e.g., order given for a central PN when patient only has a peripheral line, wrong strength of electrolytes ordered)
- Many dosage clarifications by pharmacy were needed
- Procedures and protocols related to prescribing/ordering PN's were not followed

36% (n = 912) contained some issue related to an aspect of administering PN:

- Administering PNs peripherally when the order instructed a central line infusion
- Hanging the PN on the wrong patient
- Incorrect programming of the iv pump causing the PN to infuse at the wrong rate
- Hanging PN bags out of sequence thereby causing the expiration and waste of those previously compounded

14% (n = 347) contained some issue related to an aspect of transcribing/documenting PN:

- Orders were addressographed with the wrong patient's name plate
- Orders were changed after the original order was sent to the pharmacy but the revised (i.e., "new") orders were never pulled from the chart
- Procedures and protocols related to prescribing/ordering PN's were not followed

MEDMARX Case #1:

A physician prescribed a PN for a neonate containing less than 1% protein while also containing both calcium and phosphorous electrolytes. Pharmacy notified the prescriber and informed him that the calculated protein was not high enough to prevent precipitation of the calcium phosphate, but the physician did not change the order. Precipitate formed in the solution shortly after the PN was hung. The infusion was stopped, the order was subsequently changed. The patient went unharmed, but precipitates of calcium phosphate are one of the most dangerous incompatibilities and have resulted in fatal embolisms.

MEDMARX Case #2:

A PN order was written for 1.7 liters over 24 hours. The physician later changed the volumes on the base ingredients but did not adjust the rate from what he prescribed on the original order. Consequently, the PN bag completely infused in less than 24 hours. A bag of Dextrose 10% was hung until a new bag of PN could be made.

MEDMARX Case #3:

A central hyperalimentation IV was administered through a peripheral line and ran for 42 hours before the error was discovered. The patient developed phlebitis at the IV site. Capillary blood glucose levels were not monitored and the patient's glucose level peaked at 331.

MEDMARX Case #4:

A PN infusion was ordered to infuse at 80 mL/hour but the IV pump was programmed for 802 mL/hour. The entire bag infused in only 2 hours and 45 minutes. The patient experienced muscle spasms and shortness of breath. A pulmonologist's evaluation concurred that the patient's adverse symptoms were the result of fluid overload and required the patient to undergo additional diuresis.

MEDMARX Case #5:

A patient had been receiving PN at home. Upon admission to the hospital, a PN order was copied incorrectly which led to an increase in the number of dextrose calories from 1,260 kcal/day to 2,130 kcal/day. The patient's blood sugar levels jumped to 416

requiring that the patient be placed on an insulin drip. The error was discovered by a dietitian after 3 days of incorrect PN infusions.

Suggestions to Improve the Safety of Parenteral Nutrition Therapy²

1. Create standardized order forms for both adult and pediatric PN therapy. Make sure that these forms are clear and understandable to all healthcare professionals who are typically involved with the patient's PN therapy (e.g., physician, dietitian, nurse, and pharmacist). All pre-printed, standardized forms should carry a unique form number and revision date associated with it. Forms should be periodically reviewed by the appropriate institutional committees. The form should also:
 - List all the PN components in the same format (e.g., amount per day) and in the same sequence as the PN bag label thereby facilitating the verification of the final compounded IV bag with the order in the pharmacy and at the bedside.
 - Avoid using a percent concentration when ordering the macronutrient (i.e., dextrose, protein, and fat) components
 - Avoid the use of all dangerous abbreviations and dose expressions (e.g., U for units or trailing zeros)
 - Indicate the administration route (central or peripheral access)
 - Capture patient height, dosing weight, allergies, and why PN is indicated
 - Indicate the rate of infusion
 - Provide contact information for the person writing the order as well as for available institutional resources (e.g., nutrition support service)
2. Review and validate the process of compounding PN solutions by pharmacy to ensure the proper additive sequencing of ingredients. When using automated compounding devices, request an additive compounding sequence from the manufacturer of the device along with the manufacturers of the nutrient products used by the institution.
3. Visually inspect each compounded PN formulation for signs of gross particulate contamination, particulate formation or phase separation. Perform either in-process or end-product testing on the compounded solutions to verify the accuracy of the final product prior to dispensing to the patient care area.
4. Establish policies and protocols that address the indications for intravascular catheter use, the insertion and maintenance of catheters, and infection control measures to prevent catheter-related infections.
5. Establish policies regarding the use of tubing sets, extension tubing, and filters and include guidelines on when sets should be changed, the use of aseptic technique, and universal precautions.
6. Visually inspect the iv bag for leaks, color changes, emulsion cracking, clarity, and

expiration dates prior to administration.

7. Verify the identity of the patient using at least two identifiers and the PN bag label prior to administration.
8. Establish policies and protocols regarding the safe and proper use of infusion pump devices and provide protection against “free-flow” (i.e., the rapid and un-regulated flow of iv fluid into the patient).
9. Monitor the patient to determine the efficacy of the therapy, to detect and prevent complications, and to evaluate and document changes in clinical conditions and outcomes.
10. Establish a policy and procedure that addresses the use of PN solutions prepared by an outside facility.

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1. Additional analysis on this topic was covered in a poster titled “Safety of Parenteral Nutrition: Where Can the System be Improved” presented by P.J. Schneider, J.M. Mirtallo, and J.P. Santell earlier this month at the 28th Annual Clinical Congress of A.S.P.E.N during Nutrition Week.
 2. Based on draft recommendations presented at the 28th Annual Clinical Congress of A.S.P.E.N during Nutrition Week, February 7-10, 2004. These draft guidelines are currently undergoing field review and are pending Board of Director approval. Publication of the comprehensive guidelines is expected within the next year.

* For complete error category definitions see www.nccmerp.org



1. JCAHO Updates

New Scoring System: JCAHO has established a new scoring system for the standards and the Elements of Performance (EPs) (i.e., the measurable part of the standard).

Standards are either compliant or not compliant; however, EPs can be scored as satisfactorily compliant (score of 2), partially compliant (score of 1) or insufficiently compliant (score of 0). [Click here to read more.](#)

Periodic Performance Review: A third option to the Periodic Performance Review (PPR) has recently been approved. The PPR assesses the organization performance in mid-cycle. Similar to Option 2, in Option 3, the mid-cycle survey would be performed but no written documentation or report of the survey would be left with the organization. [Click here to read more.](#)

New Online Resources: The Frequently Asked Questions section has been updated regarding

- Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. [Click here to read more.](#)
- Sentinel Event Statistics: [Click here to read more.](#)

2. Practitioners' Reporting News

Cases Submitted to USP's Medication Errors Reporting (MER) Program: [View cases](#)

submitted to the MER Program, including a mix up between Novolog® Mix 70/30, Novolin® 70/30, and Novolin® 70/30 InnoLet®; an abbreviation mix up involving "SSRI"; and the potential medication error that could occur with the Broselow® Tape dosing tool. [Click here to read more.](#)

Manufacturers Take Actions to Change Product Labeling & Packaging: View cases submitted to the USP Medication Errors Reporting (MER) Program that have initiated manufacturers to take some action in relation to the report. These changes may prevent or reduce medication errors from occurring. By reporting to national programs such as the MER Program, practitioners are providing a valuable service to the healthcare community. [Click here to read more.](#)

Similar Drug Names: Reports submitted to the MER Program regarding similar drug names where the brand names look alike/sound alike, brand and generic names look alike/sound alike, or generic names look alike/sound alike are highlighted. Some of the similarities reported by practitioners include: citalopram vs. escitalopram; dactinomycin vs. daptomycin; and lexapro vs. loxapine. [Click here to read more.](#)

Similar actual or potential errors can be submitted to the MER Program on-line at www.usp.org/patientSafety/reporting/mer.html or by calling 1-800-23-ERROR (1-800-233-7767) to request a reporting form.

3. FDA Updates

FDA Finalizes Rule Requiring Bar Codes on Drugs and Blood Products: On Feb. 25, 2004, FDA finalized a rule requiring bar codes to be included on the labels of drugs and biological products. At a minimum, each bar code for a drug will have to contain the drug's National Drug Code (NDC) number. Companies also may include information about lot number and product expiration dates. Most of the previously approved medicines and all blood and blood products will have to comply with the new requirements within two years while newly-approved medications will have to include bar codes within 60 days of their approval. [Click here to read more.](#)

Dosing Errors with Morphine Oral Solution: Serious dosing errors have occurred with Roxanol Morphine Sulfate Oral Solution made by Elan Pharmaceuticals. Reports indicate that serious overdoses occurred when the medication was prescribed in mg, but then administered in mL (e.g., 5 mg of morphine was ordered, but 5 mL was administered). Roxanol Concentrated Oral Solution contains 20 mg of morphine sulfate per mL. [Click here to read more.](#)

Recall of DURAGESIC Patches by Janssen Pharmaceutica: A Class I recall of DURAGESIC 75 mcg/hour with control number 0327192 (expiration October 2005) has been issued by Janssen Pharmaceutica and the FDA. There is a potential for the seals on these patches to breach on one edge that can allow the drug to leak from the patch resulting in an increased absorption of the opioid component, fentanyl. Conversely, if the hydrogel contents leak out of the patch, there may not be adequate medication to treat the patients' pain. [Click here to read more.](#)

Revised MedWatch Forms: FDA recently announced it has revised the forms for reporting adverse events involving single-use medical devices that have been reprocessed for reuse. The revised forms and instructions, for voluntary and mandatory reporting to MedWatch, are available at <http://www.fda.gov/medwatch/getforms.htm>. The new forms are effective

immediately, although the prior version of the forms can be used until Aug. 17. For more, see the Federal Register notice at [click here](#) and look under "Food and Drug Administration."

4. Benefits and Risks re: CPOE

Computerized prescriber order entry is peaking the interest of many healthcare organizations, but the price tag to implement such a system along with the complications that can arise from its use are creating some hesitancy in its widespread adoption. Some of the hospitals who have already taken the plunge claim the benefits have outweighed the risks. Here are the stories of three organizations that took the CPOE plunge. [Click here to read more.](#)

5. ISMP Questions Practice of Adding Lidocaine to Potassium Infusions

A report to the USP-ISMP Medication Errors Reporting (MER) program highlights several safety issues including the unclear labeling of Xylocaine that led to an excess of lidocaine in a potassium chloride admixture. The Institute for Safe Medication Practices questions whether the comfort supposedly provided by a small amount of anesthetic is worth the risk of dysrhythmia.

<http://www.ismp.org/MSAarticles/SafetyPrint.htm>

6. Pilot Safety Training Used to Teach Patient Safety

Vanderbilt University Medical Center conducts a patient safety class for its physicians, nurses, and other health care workers that includes a safety program used by pilots. The objective of this approach is to convey that when pilots are fatigued, communication isn't clear, teamwork breaks down and important procedures aren't followed — sometimes with disastrous results. [Click here to read more.](#)

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USP operates two complementary error reporting programs; the Medication Errors Reporting Program presented in cooperation with the Institute for Safe Medication Practices and MEDMARX. MEDMARXSM is an Internet-accessible, anonymous medication error reporting program and quality improvement tool used to track and trend medication errors.
For more information, visit www.usp.org

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