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**USP Patient Safety  
CAPSLink™**

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### USP Patient Safety CAPSLink™

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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USP Medication Error Analysis

#### Examining Intralipid Errors in the Neonatal Intensive Care Unit<sup>a</sup>

Intralipid nutrition is often an important component of the overall treatment plan for infants hospitalized in the NICU environment. Intralipids are fat emulsions of soybean triglycerides that are primarily composed of long chain fatty acids called triacylglycerols. They can provide neonates with the appropriate calories, essential fatty acids (EFA), and fat soluble vitamins that will lead to effective growth and development. Intralipid therapy is critical for those infants who, for whatever medical reason, are unable to effectively use their enteral organ system for proper nutritional intake. This therapy is of particular value in premature infants, who have low essential fatty acid stores, but yet who have a high metabolic and/or neurodevelopmental need.<sup>1,2</sup>

Medication errors that occur during the infusion of intralipid therapy often result in harm and further add to the list of complications that these already fragile patients experience. These complications can include such serious preventable adverse events as hypertension, fat embolism, respiratory distress, liver dysfunction, and other complex medical problems.<sup>3-8</sup> Medication errors involving intralipid therapy pose a serious risk of significant harm to newborn infants being cared for in neonatal intensive care units. In general, it has been reported that medication errors are common in children, with a documented incidence rate nearly three times of that associated in the adult population.<sup>9</sup> For neonatal patients, medication errors have been documented to occur in a range of 25% to 91% of all NICU admissions, and may be responsible for 17% of all pediatric errors.<sup>9,10</sup>

During the period of January 1, 2000 through December 31, 2005, 173 hospitals reported 7,329 NICU medication errors to MEDMARX. Of these, 266 (3.6%) reports involved intralipid medication errors from 55 (31.8%) hospitals. The hospitals, which reported were primarily general community facilities (~75%), and university hospitals (~23%).

### **Medication Use Nodes**

Medication errors related to intralipid therapy in neonatal patients were reported to occur in every node (phase) of the medication use system; however, vast majorities (93.2%) were documented to occur during the administration node. Prescribing node errors (2.3%) related predominantly to incorrect and/or incomplete medication orders for intralipids including a lack of specificity as to the total volume to be infused and the infusion rate. All other medication errors reported were equally distributed across the remaining medication use processes.

### **Types of Error**

There were 277 types of error selections as documented in Table 1. The leading type of error was improper dose/quantity (69.3%). Wrong administration technique (10.8%), omission errors (8.3%) and wrong time errors (4.3%) were also included in the top four most frequently reported types of errors. Wrong technique errors often involved improper programming of the infusion pump. Overall, the top four types of errors were documented in approximately 93% of all records.

**Table 1. Types of Neonatal Intralipid Medication Errors<sup>a</sup>**

Type of Error	n	%
Improper dose/quantity	192	69.3
Wrong administration technique	30	10.8
Omission error	23	8.3
Wrong time	12	4.3
Drug prepared incorrectly	3	1.1
Prescribing error	3	1.1
Wrong patient	3	1.1
Data not provided	2	0.7
Expired product	2	0.7
Wrong dosage form	2	0.7
A type not determined	1	0.4
Deteriorated product	1	0.4
Extra dose	1	0.4
Unauthorized/wrong drug	1	0.4
Wrong route	1	0.4
Total Selections	277	

a. Based on 266 records and 277 selections for the period 1/00-12/05.

### Causes of Neonatal Intralipid Medication Errors

The two leading causes of intralipid medication errors were performance deficit (26.8%) and improper use of the infusion pump (25.8%) (Table 2). These two causes often led to improper dosing (both over and under dosing). Almost one-third (29.3%) of the reported causes, included five different causes: procedure protocol not followed (10.4%); calculation error (5.9%); monitoring inadequate/lacking (4.7%); pump failure, malfunction (4.3%); and decimal point (4%).

**Table 2. Causes of Neonatal Intralipid Medication Errors<sup>a</sup>**

Cause of Error	n	%
Performance deficit	113	26.8
Pump, improper use	109	25.8

Procedure/protocol not followed	44	10.4
Calculation error	25	5.9
Monitoring inadequate/lacking	20	4.7
Pump, failure/malfunction	18	4.3
Decimal point	17	4.0
Communication	11	2.6
Knowledge deficit	10	2.4
Dispensing device involved	9	2.1
System safeguard(s)	6	1.4
Transcription inaccurate/omitted	6	1.4
Data not provided	5	1.2
Equipment design	5	1.2
Written order	4	0.9
Documentation	3	0.7
Incorrect medication activation	3	0.7
Workflow disruption	3	0.7
Reference material	2	0.5
Abbreviations	1	0.2
Dosage form confusion	1	0.2
Equipment (not pumps) failure/malfunction	1	0.2
Fax/scanner involved	1	0.2
Handwriting illegible/unclear	1	0.2
Labeling (your facility's)	1	0.2
Packaging/container design	1	0.2
Preprinted medication order form	1	0.2
Similar packaging/labeling	1	0.2

a. Based on 266 records associated with 422 selections for the period 1/00-12/05.

### **Level of Care Required Following Error**

The serious impact that medication errors have on both the patient and health-system is evidenced with prolonged hospitalizations and interventions that may be required in providing an acceptable level and scope of care that includes diagnosing, and treating any harmful sequelae caused by the error. Data on intralipid medication errors in neonates revealed that a total of 43 new drug therapies were either initiated or changed representing 21% of the 207 *Level of Care* selections documented by reporters. Additionally, 39 laboratory and one X-Ray or other diagnostic tests were required to be ordered for these infants, representing 20% of the 207 selections and 25 patient observations were either initiated or increased.

**Case Examples:**

- In one case involving the total volume of the infusion, a physician ordered intralipids to run at 0.2mL / hr for a total of 10 hours, but specified the total volume as 20 mL instead of 2 mL
- The pharmacy delivered an intralipid infusion at the wrong time, thus delaying the start of the infusion from 7:00 p.m. to 6:00 a.m.
- An order was written for intralipids to be administered at the rate of 0.5 mL per hour as well as total parenteral nutrition (TPN) therapy at the rate of 3.5 mL per hour. Because of incorrect programming of the infusion pumps, the rates for the intralipid and TPN infusions were switched. Subsequently the intralipid was infused completely in 7 hours thereby requiring additional laboratory tests to monitor the infant's triglyceride levels.
- Another infant received intralipid infusion too rapidly, leading to respiratory failure. The infusion pump programming error resulted in prolonged hospitalization, and the child to undergo mechanical ventilation and nitric oxide therapy.

**Recommendations to Prevent Medication Errors Related to the Prescribing, Dispensing and Administration of Intralipids to Neonates**

In an effort to prevent medication errors pertaining to the ordering, dispensing and administration of intralipids to neonates, the following procedural and policy safeguards should be considered as part of a comprehensive medication management plan in the neonatal intensive care unit environment:

1. Create a detailed workflow schematic of intralipid prescribing, dispensing and administration. Identify specific problem areas and develop targeted improvement strategies.
2. Standardize infusion pumps (brand and functionality) throughout the facility.
3. Ensure that policies and procedures are understandable and effectively communicated. Ensure procedures are uniformly practiced to minimize workflow variations.
4. Offer regular educational programs and in-services that target personnel on all shifts, especially those from the evening and night workforce.
5. Develop and implement checklists and/or mandatory double dose checking procedures, especially for those nurses and other personnel who are working a new lengthy schedule of days or nights, or who work the evening shifts.
6. Pay attention to and ensure adequate staff-to-patient ratios, especially in critical care areas like the NICU environment.
7. Adopt and implement IV pumps with enhanced logic ("smart pump") technology with standardized interdisciplinary policies and procedures approved through the hospital's Pharmacy and Therapeutics (P&T) or other appropriate Committee. Newer IV pumps should have enhanced clinical rules software with dosing limits and early warning alarm systems. Collaborate with the P&T Committee to develop policies that address intralipid rule sets that are location specific ensuring that the approved lipid infusion volume/rate are not greater than that of the total parenteral nutrition rate.

a. This story is an adaptation of an article published in the *Joint Commission Journal on Quality and Patient Safety*, February, 2007 Vol 33 No.2

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### **1. FDA Revises Its Processes for the Safety of Drugs after Initial Approval**

A study released by the FDA on September 30, 2006 that found many pharmaceutical manufacturers never completed a majority (nearly 75%) of post-marketing drug studies that they had promised would be done as a “condition of drug approval” by the FDA. The agency has made a commitment to make changes in the way it operates that will address the types of drug safety controversies that have plagued the FDA and manufacturers in recent years. For additional information see: <http://www.fda.gov/cder/drugSafety.htm>

### **2. Veterans Administration Chief Pharmacist Debunks VA Pharmacy Benefit Myths**

Michael Valentino, M.S., RPh, Chief Pharmacist for The Department of Veterans Affairs (VA) pharmacy system has begun a campaign to get the word out to all eligible veterans in an attempt to dispel rumors and myths about the VA pharmacy benefit. Among those myths recently reported is that VA's formulary only includes approximately 1,300 drugs, which is much less than a third of the approximately 4,300 drug products that are widely available through a majority of Medicare Part D drug plans. Mr. Valentino stated “The fact is, VA dispenses 4,778 drugs from the formulary.” For the full story [click here](#).

### **3. Many Seniors Do Not Follow Doctor's Orders**

As reported in the February 14, 2007 issue of the Patient Safety Monitor, a new study

shows that an estimated 40% of seniors (>age 65) frequently do not adhere to their physicians' orders due to the cost of the medication, questionable efficacy, or other reasons. The study appears in the January 2007 *Journal of General Internal Medicine*. Many of the seniors, who were surveyed, stated that the cost of the drug was often a factor in ceasing to take their prescribed medication. Others reported that they stopped taking their medication because they did not believe it was working, or were also concerned about side effects. To read an abstract of the published article, [click here](#).

#### **4. Significant Pharmacy Computer Alerts Go Unnoticed, ISMP Warns**

The Institute for Safe Medication Practices (ISMP) has issued a warning and strongly desires that hospital pharmacists better understand and recognize the potential for patient harm that could occur as a result of pharmacy interns and technicians to override important alerts when entering medication orders into a computerized system. For additional information: [click here](#)

#### **5. On-Line Patient Safety Educational Tools for Physician Practices**

As recently reported in the February 20, 2007 issue of Patient Safety and Quality Healthcare News, many physician practices may soon have new online resources and other computerized on-line tools help improve patient safety. The Health Research and Educational Trust (HRET), the Institute for Safe Medication Practices (ISMP) and the Medical Group Management Association (MGMA) recently were awarded a grant from The Commonwealth Fund to develop three educational, Web-based tools for physician practices specifically designed to improve patient safety. The tools, which are entitled Pathways for Patient Safety™, will increase awareness, knowledge and implementation of best practices to reduce the risk of patient harm in physician practices.

<http://www.psqh.com/enews/0207h.shtml>

#### **6. Federal Guidelines Issued For Proper Disposal of Prescription Drugs**

On February 20, 2007, The White House Office of National Drug Control Policy, the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) jointly issued new guidelines to encourage all Americans to dispose of their prescription drugs properly. The guidelines are entitled “WHAT EVERY AMERICAN CAN DO TO PREVENT MISUSE OF PRESCRIPTION DRUGS “, and are designed to reduce prescription drug diversion, while at the same time protecting the environment. Because of the significant increase in the trend of prescription drug abuse, the new guidelines focus on the lay public and the proper disposal of unused, unneeded, or expired prescription drugs.

<http://www.whitehousedrugpolicy.gov/news/press07/022007.html>

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#### **USP Medication Error Reporting Programs:**



**MEDMARX**®—USP's comprehensive, Internet-accessible, anonymous medication errors reporting program, and quality improvement tool. The program facilitates productive and efficient documentation, tracking, trending, and prevention of medication errors.



**Medication Errors Reporting (MER) Program**—presented in cooperation with the Institute for Safe Medication Practices, this nationwide program makes it possible for health professionals to report medication errors confidentially and anonymously to USP.

#### Other USP patient safety resources:

- [MEDMARX Annual Data Summary reports](#)—provides readers with a wealth of information on reported error events including patterns in the types, causes, and level of harm associated with medication errors.
- [Understanding and Preventing Medication Errors: A Resource for Healthcare Practitioners](#)—a CD toolkit with practical guidelines, forms, and templates to help healthcare facilities improve error-reduction initiatives.
- [Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success](#)—a book in which hospitals share stories about how they reduced medication errors and promoted safer patient care.
- Medication Safety Pocket Reference—a pocket-sized reference booklet containing listings of similar drug names and dangerous abbreviations that could cause medication errors. Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for item #3227702.
- Similar Drug Names Poster—a wall poster for easy reference listing look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. Posters are packaged in quantities of 1 (item # 3728251) 10 (item # 3728252) and 50 (item # 3728253). Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for the appropriate item number.

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