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USP Patient Safety CAPSLink™

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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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Insulin Errors: A Common Problem

Errors associated with insulin have been reported for many years yet, despite these reports, their common occurrence continues. Many hospitals use a 'sliding-scale' therapeutic approach whereby short-acting insulin is used, usually before meals, with the dose dependent on the level of blood glucose at the time of administration. If the blood glucose is normal, no insulin is given, but if it is elevated, insulin is given at a dose determined by a preset algorithm. Past studies question the benefits of the sliding scale approach, especially if used without a standing dose of intermediate-acting insulin. (Arch Intern Med 1997 Mar 10;157 (5): 545-52).

Analysis of data reported to USP's MEDMARXSM reporting program over a two year period (i.e., 2000 and 2001) uncovered a total of 4,764 insulin errors with approximately 6.6% (n = 320) of these causing harm to the patient. Historically, the average harm threshold for error reports submitted to MEDMARX has been approximately 2.8%, indicating that when an insulin product is involved, it may be twice as likely to result in **harm** (Categories E-I) (Table 1).

Table 1. Error Category Breakdown for Insulin Errors

ERROR CATEGORY	COUNT	PERCENT
A	252	5.3%
B	1,210	25.4%
C	1,815	38.1%
D	1,167	24.5%
E	288	6.0%
F	30	0.6%
G	1	0.02%
H	1	0.02%
I	0	0

Data from USP's MEDMARX program for years 2000, 2001

Omission errors (leading to hyperglycemia) and *Improper dose/quantity* (leading to hyper or hypoglycemia) were the two most frequently reported **Types** of error associated with insulin. (See Table 2).

Table 2.	Error Type	Count	Percent
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Omission error	1,461	33.9
Improper dose/ quantity	1,098	25.5
Unauthorized (i.e, wrong) drug	614	14.3
Prescribing error	363	8.4
Extra dose	357	8.3
Wrong time	357	8.3
Wrong patient	226	5.2
Wrong drug preparation	191	4.4
Wrong dosage form	53	1.2
Wrong route	43	1.0
Wrong administration technique	33	0.8

Data from USP's MEDMARX program for years 2000, 2001

In addition to the problems associated with the 'sliding scale' approach, causes of insulin errors are the result of multiple factors including the use of "U" for units being misread as a number, manufacturer's labeling, accessibility as floor stock, and non-standard compounded IV solutions and infusion rates. The numerous types of insulin products (i.e., approximately 23 different brands) further amplify the potential for errors to occur. Reports submitted to USP's MEDMARX and Medication Errors Reporting (MER) programs illustrate mix-ups between similarly named products (e.g., Humalog Mix 75/25[®] and Humulin 70/30[®] and Novolog Mix 70/30[®] and Novolin 70/30[®]).

Selected Insulin Error Reports:

Case #1: An order was written for sliding scale Regular Insulin "4U" when blood sugar is 240-300. The order was misinterpreted and 44 units were given. In addition, NPH insulin was given instead of Regular Insulin. The patient was given three cups of juice and transferred to ICU for close monitoring.

Case #2: A patient was receiving treatment within the dialysis unit at the hospital. Insulin was kept as floor stock within this unit and a dialysis technician inadvertently administered insulin instead of heparin. The patient suffered fatal neurological damage due to decreased glucose levels. A policy was implemented to remove Insulin from floor stock, use patient-specific labeling for all insulin doses, and keep all doses in a patient-specific bin. Insulin doses for ambulatory areas are now prepared by the pharmacy.

Case #3: A patient presented to the ER in a hyperglycemic state. An order for Novolin[®] Regular was written to be infused at 5 units per hour. Pharmacy prepared a 100units/100mL drip and sent it to the ER. The entire drip was infused within one hour (i.e., the patient received 100 units/hour versus the ordered 5 units/hour).

Case #4: A diabetic patient in ICU was receiving an i.v. of Regular Insulin 1unit/mL at a rate of 10 units/hour titrated per sliding scale. Upon changing to a new bag of insulin, the i.v. pump was reset manually to clear prior totals and to enter the new volume to be infused. Shortly after the new bag was hung, a nurse noticed that the infusion pump was incorrectly set at 150mL (i.e., 150 units) per hour. The infusion was stopped and the patient was given orange juice and closely monitored for the next three hours. If the total volume of the bag (100mL) had been infused at the rate of 150mL/hour, it would have taken only 40 minutes for the patient to receive 100 units of insulin potentially causing irreversible brain damage and/or death from cerebral edema and insulin shock.

Ideas to Improve Insulin Safety: USP's Safe Medication Use Data Analysis Work Group and Endocrinology Expert Committee are currently formulating recommendations for the safe use of insulin and have discussed the following ideas:

1. Not using long acting insulins in sliding scale protocols
2. Using only regular insulin for sliding scale protocols
3. Using only "Units" and not "U" in orders for insulin
4. Using preprinted ordering sheets for insulin use
5. Never using trailing zeros in orders for insulin
6. Always using a "double-check" system to inspect insulin preparations for correct dosage before administration to the patient
7. Using one standard concentration for all i.v. infusion preparations
8. Discarding the outer package/carton after opening

Additional ideas practitioners should consider:

1. Label all insulin vials (or individual syringes if pre-drawn by pharmacy) with a specific patient's name and ensure they are returned to the pharmacy upon the patient's discharge.
2. Minimize or eliminate, to the extent possible, insulin as a floor stock item. When floor stock is deemed necessary, make the Regular formulation the only form available.
3. Never use free-flow tubing for insulin infusions.
4. Standardize the type of programmable IV pumps used within the facility.
5. Use standard order forms that clearly spell out the key attributes (e.g. long vs. short acting, ability to mix with other insulins), standard drip concentration, and dosing protocols for each insulin product on formulary.
6. Insert warnings and/or cautionary statements/signs about common, problem-prone name confusions in storage locations and within computer systems.
7. Conduct in-services for medical, nursing, and pharmacy staff prior to the addition of a new insulin product to the facility's formulary.
8. Request that the P& T Committee undertake a critical evaluation of the commercially available insulin brands on the formulary to assess if a reduction in the number of different types is feasible.
9. Conduct a daily review of all insulin orders from the pharmacy computer

system.

10. Make insulin a particular target of review during routine nursing unit floor stock inspections.

Researchers at 60 sites nationwide are testing a new form of insulin that is inhaled rather than injected in an effort to eliminate the need for insulin injections. Practitioners should be alert to the possible new errors that may arise from this formulation.



1. JCAHO Updates

Joint Commission Resources and USP to Conduct Seminar on Reducing Medication Errors: USP's Center for the Advancement of Patient Safety (CAPS) in conjunction with Joint Commission Resources will conduct a one-day seminar titled - "*Transforming Data Collection and Analysis into Meaningful Information*". This interactive program will be offered on August 7 in Philadelphia and will teach participants methods to categorize error events by severity, determining thresholds to signal performance problems, and evaluate the impact of actions taken. This seminar is offered in conjunction with the program - *Executive Briefings on JCAHO's New Medication Management Standards* to be conducted on August 8. Significant savings in registration is offered when signing up for both programs. For more information and to register call JCR Customer Service Center toll free at 877-223-6866 or go on-line at [Click here for registration information.](#)

2004 Aggregation Decision Rules: JCAHO's Accreditation Committee approved the 2004 aggregation and decision rules that are used to score and determine accreditation decisions. These rules provide the framework for the new accreditation decision process for Shared Visions-New Pathways. [Click here to read more.](#)

2004 National Patient Safety Goals Announced: JCAHO recently announced the National Patient Safety Goals for 2004. All six of the 2003 Goals will continue to be in force plus one new Goal with two Requirements that focus on reducing the risk of health care-acquired infections. [Click here to read more.](#)

Changes for Random Unannounced Surveys: Beginning in January 2004, random unannounced surveys will cover organization-specific critical focus areas and the following four "fixed performance areas": staffing, infection control, medication management, and the National Patient Safety Goals relevant to the organization's care and services. Random unannounced surveys will cease in January 2006, when the accrediting group starts conducting all its surveys without announcing the dates of the upcoming visit. [Click here to read more.](#)

[Additional Performance Data Required in 2004](#): Accredited hospitals will be required to submit data on an additional set of core performance measures beginning in January 2004. Under the new requirement, data on three of the four currently available sets of core performance measures (acute myocardial infarction, heart failure, community acquired pneumonia, and pregnancy and related conditions) must be submitted. This change will align the JCAHO requirements with the core measures for the voluntary Quality initiative led by the AHA, Association of American Medical Colleges and Federation of American Hospitals. [Click here to read more](#).

2. FDA Alert on Temodar®

Serious medication errors have been reported to the FDA, some of them fatal, with the drug Temodar® (Temozolomide). USP has also received error reports with this product. Factors involved with the reported errors include misreading the label (the milligram strength and the number of capsules per bottle appear near each other on the label and the number of capsules can be misread as the strength in milligrams, and vice versa), and a dosing regimen that exceeded recommendations.

FDA recommends health professionals take the following steps: (1) circle or highlight the milligram strength on the label to distinguish it from the number of tablets or dispense Temodar in unit-dose form rather than from a multiple-dose bottle; (2) do not dispense more than a five day supply at one time; and (3) be sure to clarify all orders or prescriptions that are vague or unclear about the dosage or dosing instructions. The FDA is working with the manufacturer to change the labeling so that it's clearer. [Click here to read more](#).

3. Use of Technology in Preventing Errors

An article in the *New England Journal of Medicine* by David Bates and Atul Gawande titled "Improving Safety with Information Technology" discusses how such technology can help prevent errors and adverse events. The article also includes examples of these technologies and the barriers and directions for improvement. Dr. Bates is a member of USP's Safe Medication Use Expert Committee and Chair of USP's Project Team on Computerized Prescriber Order Entry (CPOE). [Click here to read more](#).

4. AHRQ WebM&M

The fifth issue of the [AHRQ WebM&M](#) online patient safety journal features a case of blood thinner mismanagement; a wristband mix-up that resulted in a patient nearly getting the wrong surgery; a child whose eye was mistakenly glued shut with a skin adhesive; and a woman whose adverse reaction to morphine was noticed only when she nearly stopped breathing. Cases from previous issues are still available under

"Past Issues" and "Archives." <http://webmm.ahrq.gov>

5. Patients Rate Hospitals

The California HealthCare Foundation (CHCF) and the California Institute for Health Systems Performance (CIHSP) recently launched a website that allows Californians to view how patients rated their care during hospitalization within the state. Using the Web site, consumers are able to compare hospital results by city, county, or zip code. Statewide, about 25% of hospitals received an above average rating for their overall performance. Eighteen percent were rated below average and 57% were rated average. www.calhospitals.org

6. Florida Law Mandates Legible Prescriptions

Effective since July 1, Florida physicians must comply with standards for writing prescriptions, including writing "legible" text or typing text, writing out months instead of using numbers, and noting quantities of drugs by both a numerical number and written text. Florida is only the second state in the nation to pass a legible-prescription law, but some experts say that other states may follow suit as concern over patient safety grows. The law specifies that illegible handwriting is that which cannot be understood by the pharmacists filling prescriptions.

In a related story... Tufts Health Plan intends to give 5,000 physicians hand-held BlackBerrys to write and transmit their prescriptions in an effort to reduce handwriting errors, lost orders, dangerous drug interactions for patients, and eventually healthcare costs. [Click here for Florida Story](#) and [Click here for Tufts story](#)

7. USP's Practitioners' Reporting News

[Ben Venue/Bedford Labs Changes Acetazolamide Labeling](#): In response to labeling similarity complaints, Ben Venue/Bedford Laboratories has changed the labeling of their acetazolamide 500 mg vials. Product name will utilize "Tall Man" letters. Two reports were submitted to the USP Medication Errors Reporting Program. http://www.usp.org/reporting/prnews/dsw_105.htm

[Atrovent® & Peanut Allergy](#): A report received through the USP Medication Errors Reporting Program describes a child's visit to a clinic for asthma symptoms. Connection between Atrovent Inhalation Aerosol and the patient's peanut allergy had not been realized. Genentech assures The Food Allergy & Anaphylaxis Network that a peanut allergy study using Xolair is in development. http://www.usp.org/reporting/prnews/dsw_104.htm

8. Senate HELP Committee Approves Patient Safety Bill

By a unanimous vote, the Senate Health, Education, Labor and Pensions (HELP) Committee recently approved patient safety legislation promoting the voluntary reporting of adverse medical events. The Patient Safety and Quality Improvement Act of 2003 (S. 720) would provide legal privilege and confidentiality protections for patient safety data and promote the development of voluntary national information technology standards. The legislation is intended to strike an important balance between protecting providers from litigation when reporting and protecting the rights of patients. [Click here to read more.](#)

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USP operates two complementary error reporting programs; the ***Medication Errors Reporting Program*** which operates in cooperation with the Institute for Safe Medication Practices and ***MEDMARX***™. MEDMARX 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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