Encouraging pharmacy involvement in pharmacovigilance; an international perspective.

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Medication errors and pharmacovigilance

Pharmacovigilance is defined as a system for monitoring the safety and effectiveness of medicines.

As part of the overall effort, analysis of medication errors represents a critical component.

Knowledge of the medication use system is required to understand root causes of medication errors, including medical product issues.
Medication errors are a public health issue.

Patient harm arises from both adverse drug reactions and medication errors.

Medication error reporting and learning must be part of international pharmacovigilance efforts.

Similar adverse outcomes arise from medication errors globally.
Medication errors and pharmacovigilance

Because of their knowledge of medication use systems, familiarity with regulated products, and ultimate responsibility for medication safety, pharmacists are ideal health professionals to assume roles in pharmacovigilance.

Such medication safety expertise must be incorporated into pharmacovigilance efforts in a collaborative way.

The main purpose is to share learning, identify unsafe conditions and support implementation of product and practice improvement strategies that serve to prevent patient harm.
Established to support and facilitate the transfer of information to benefit medication error prevention efforts in participating countries
The International Medication Safety Network (IMSN) is an international network of safe medication practice centres established with the aim of improving patient safety. This is achieved by operating medication error reporting programmes and producing guidance to minimise preventable harms from medicine use in practice. IMSN promotes safer medication practice to improve patient safety internationally.

About IMSN
WHO Initiative

- Support and strengthen consumer reporting of ADRs and adverse events
- Expand the role and scope of national pharmacovigilance centres to prevent medicine-related adverse events
- Promote better and broader use of existing pharmacovigilance data for patient safety
- Develop additional methods of pharmacovigilance to complement data from spontaneous reporting systems
IMSN – WHO
PV training – Morocco
National Medication Errors Reporting Program

Operated by the
Institute for Safe Medication Practices
www.ismp.org

ISMP is a federally certified patient safety organization (PSO)

Pennsylvania Patient Safety Reporting Program

An independent agency of the Commonwealth of Pennsylvania

MEDWATCH PARTNER
Incident reporting and analysis is an iterative loop

Intake & processing: acquiring data → Narrative reports → Primary analysis: understanding data

Input process → Analysis by experts → Database

Reporters → Industry & Practitioners → Publication of findings

Corrective action → Feedback; sharing new knowledge → Learning → Secondary analysis: looking for patterns
Medication Error Reporting System

- **Early warning system**
  - Issue nationwide hazard alerts and press releases

- **Learning**
  - Dissemination of information and tools

- **Change**
  - Product nomenclature, labeling, and packaging changes, device design, practice issues

- **Standards and Guidelines**
  - Advocates for national standards and guidelines
Error Reporting Programs

- Not just focused on quantitative data
- Learning is from qualitative information in the reports
- Allows national alerts after just a single report of a major safety issue
- Generally reaches audiences long before FDA, CDC, industry actions
- However, all too often, practitioners and organizations don’t act until it happens to them
15 Syrian children die after measles vaccinations

REUET - At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government airstrikes on a central city climbed to nearly 90, a heavy toll even by the vicious standards of the country's civil war, activists said.

The children, some just babies, all exhibited signs of "severe allergic shock" about an hour after they were given a second round of measles vaccinations in rebel provinces on Tuesday, with many suffocating to death as their bodies convulsed, said witness Abdullah Abu, who administered the vaccinations in a medical center in the town of Jarjanaz.
Two chamber vial used for medications with diluents

Lyophilized powder or vaccine component A

Liquid diluent or vaccine component B
The following information is intended for healthcare professionals only:

Instructions for use – Dual chamber syringe (See diagram overleaf)

VIATIM, Suspension and solution for suspension for injection in pre-filled syringe
Hepatitis A [inactivated, adsorbed] and Typhoid polysaccharide vaccine

1. Remove the tip-cap (A).
2. Attach needle and needle shield (B) to the syringe.
3. Screw the plunger (C) into the plunger stopper (Stopper 2).
4. Shake the syringe; then mix the vaccine components by slowly pushing the plunger, keeping the needle upwards. The vaccine in the lower chamber moves into the upper chamber by means of the by-pass channel.
5. Shake vigorously until a homogeneous suspension is achieved.
6. Holding the needle shield at the tip, remove by pulling upwards without twisting.
7. Proceed immediately with the injection. A vein test may be carried out by pulling slightly on the plunger. The stoppers may separate but ensure that Stopper 2 does not reach the by-pass channel in order to avoid any leakage of liquid. If a blood vessel has been penetrated, blood will be pulled back into the syringe.
Most accidental poisonings in children occur when medicine is not in its normal packaging.

A rapid increase in the number of children being treated for poisoning has been reported recently. While there is no single cause for this increase, many believe that it is due to a combination of factors, including increased use of household medicine cabinets and decreased awareness of the dangers of over-the-counter medications. This is a significant concern because many of these medicines contain ingredients that can be highly toxic if ingested by children.

In a recent study, researchers examined the safety of over-the-counter medicines used in children under the age of 6. They found that over-the-counter medicines were not as safe as they should be, with 11% containing ingredients that could be harmful to children. The study also found that over-the-counter medicines were not properly labeled, which can make it difficult for parents to identify the ingredients and potential hazards.

To address these concerns, the researchers recommend that over-the-counter medicines be reformulated to be safer for children. They also recommend that more effective labeling be used to help parents identify the ingredients and potential hazards. In addition, they recommend that parents be educated about the dangers of over-the-counter medicines and the importance of keeping them out of reach of children.

In conclusion, the use of over-the-counter medicines needs to be more closely regulated to ensure the safety of children. This will require a coordinated effort among government agencies, health care providers, and the public to identify and address the risks associated with over-the-counter medicines.

References:

Acute Care
ISMMP Medication Safety Alert!

VARIZIG dilution problems reported

An airline came to our attention recently regarding varialsix immune globulin (VARIZIG), indicated for prophylaxis and therapy against chickenpox in high-risk individuals, such as children and adults who are immunocompromised. The product is available as a kit (Figure 1) that contains a single-usage vial of diluent along with a 10 mL container of lyophilized (also known as international unit or IU) interferon that must be reconstituted with the diluent prior to use. The kit is intended for use in the United States and Canada.

Recently, a US hospital emergency department (ED) received 125 units of VARIZIG. However, a nurse mistakenly reconstituted the vial using only 25 units of diluent instead of the required 100 units. This resulted in a dose of 0.25 IU per mL instead of the intended 2 IU per mL. The mistake was discovered during the dilution process, and the nurse immediately notified the ED pharmacist.

The ED pharmacist contacted the manufacturer of the diluent to investigate the issue. The manufacturer confirmed that the diluent contained 100 units of diluent with 0.25 IU per mL, which is the correct concentration. The manufacturer also advised the ED that the diluent should be stored at 2-8°C (36-46°F) and that the diluent should be used within 24 hours of reconstitution.

The ED pharmacist recommended that the diluent be discarded and that a new vial be obtained. The nurse received the new vial and reconstituted it using the correct amount of diluent (100 units of diluent with 0.25 IU per mL). The nurse then administered the correct dose of 2 IU per mL to the patient.

The incident was reported to the manufacturer, who reviewed the production process and determined that the diluent was correctly formulated and packaged. The manufacturer also recommended that the diluent be stored at 2-8°C (36-46°F) and that it be used within 24 hours of reconstitution. The manufacturer further recommended that the diluent be visually inspected before use to ensure that it is correctly formulated and packaged.

In conclusion, this incident highlights the importance of careful reconstitution and storage of varialsix immune globulin (VARIZIG). Healthcare providers are encouraged to follow the manufacturer’s recommendations for storage and reconstitution to ensure the safety and effectiveness of the product.

References:

SafetYwires

Nasal infection injection site reactions: Common practice is not enough

Nasal infection injection site reactions are common, but common practice is not enough. Injection site reactions can be minimized by using the correct needle and syringe and by using proper technique. The needle should be inserted at a 90° angle to the skin and the syringe should be held firmly in place.

SafetYwires

Long-Term Care Advisor ERR

UGENT Health systems need to plan NOW for upcoming changes in enteral feeding device connectors

As we look to the future design changes coming soon in enteral feeding device connectors, it is important to ensure that the health care system is prepared. The new connectors will require changes in equipment and supplies, and it is important to plan ahead to ensure that the changes are implemented smoothly.

It is important to consider the following factors when planning for the new connectors:

- The need for new connectors on existing equipment
- The compatibility of new connectors with existing supplies
- The need for training on new connectors
- The need for new equipment and supplies

In conclusion, it is important to plan NOW for the upcoming changes in enteral feeding device connectors. This will require a coordinated effort among all health care providers to ensure that the changes are implemented smoothly and that patients are safe and well cared for.

References:
Proper disposal of fentaNYL patches is critical to prevent accidental exposure

On April 18, 2012, the U.S. Food and Drug Administration (FDA) alerted healthcare providers and consumers about the importance of proper storage, application, and disposal of transdermal fentaNYL (fentaNYL patch) to prevent dangerous, accidental pediatric exposure (www.fda.gov/Drugs/DrugSafety/ucm300747.htm). FDA noted 26 cases of accidental pediatric exposure during the past 15 years, including 10 that resulted in death and 12 that resulted in hospitalization. Sixteen events involved children 2 years old or younger. Incidents have occurred in the home but can also originate within a healthcare institution, where children may accompany adults who are visiting patients.

On the heels of a heartbreaking event recently reported to the ISMP National Medication Errors Reporting Program (ISMP MERP) by a grieving mother, this alert is intended to complement the recent FDA alert by focusing on safe disposal of fentaNYL patches in hospitals and long-term care facilities.

Last November, a 2-year-old boy, Blake (see photo in upper right corner), died after accidental exposure to a used fentaNYL patch hastily discarded in a long-term care facility. The family was visiting the boy’s great-grandmother at a nursing home. Two days after the visit he was found unconscious, in respiratory arrest, and was unable to be resuscitated. A medical examiner later found a small, white, 1 inch by ½ inch piece of what appeared to be tape in the boy’s throat. Later, a toxicology report came back indicating that a lethal dose of fentaNYL was in Blake’s system. The “tape” was sent to a laboratory for processing and turned out to be a used fentaNYL patch, with a high concentration of the potent opioid fentaNYL still remaining.

Blake’s parents spoke with authorities and related a history of the boy’s visit to the nursing home. County detectives and the state health department officials began an investigation. At the facility, authorities found that medication patches were not being disposed of properly. A used fentaNYL patch was seen on a bedside table and, according to the mother, patches had been disposed of in the trash pail in the boy’s great-grandmother’s room. Authorities also found used medication patches in other patient rooms on the floor, stuck to bed railings, and in other unsecured patient areas.

A theory emerging about the child’s death is that he may have run over a used fentaNYL patch on the floor of his great-grandmother’s room with his Tonka truck wheels. After the visit, he may have peeled off the patch and stuck it in his mouth. Used fentaNYL patches can still contain a large quantity of unabsorbed medicine after they are removed, so both new and used patches can be dangerous to children and pets.

The theory is quite feasible given that other children have been exposed to patches in a similar manner. In another case received through the ISMP MERP, a child sat on a used fentaNYL patch that had fallen off a family member, and it stuck to her thigh, causing drug-related symptoms. Another child continued on page 2—Fentanyl patches
ISMP Websites

www.ismp.org  www.asmsmo.org/  www.consumermedsafety.org
Look-alike products
Which Concentration to Select?

Nimbex® Injection (cisatracurium besylate)
Equivalent to 200 mg/20 mL (10 mg/mL) cisatracurium. For ICU use only.

Nimbex® Injection (cisatracurium besylate)
Equivalent to 20 mg/10 mL (2 mg/mL) cisatracurium. 0.9% benzyl alcohol (added as a preservative)
Opticlik Pen Device
Insulin safety for people who inject with a 'pen'

by Michael R. Cohen, R.Ph., M.S.

With millions of Americans suffering from diabetes, there’s been tremendous growth in the use of insulin. For convenience, many insulin-dependent diabetics carry their insulin in a prefilled syringe available from drug manufacturers. The device is called an insulin pen because it sort of looks like a pen and can be carried in your pocket. But it’s actually a sophisticated device designed for multiple injections of insulin until the cartridge within the pen needs to be replaced.

Unfortunately, not every insulin-dependent patient knows how to use their pen in the proper way and they sometimes place themselves at dangerous risk of complications. We received an interesting report from a certified diabetes educator/RN about a patient who suffered an insulin overdose by misreading the amount dialed. With some of the most popular insulin pens now in use, you have to turn a dose selector dial to set the pen to deliver the prescribed dose. The dose then appears in a little built-in window on the pen. Once you set the dose you inject the pen’s needle into your skin and push a button to release the dose. In the picture below you can see what that looks like where the insulin dose that has been dialed is 46 units.

In this actual case that happened when a new patient was giving herself Novolog insulin for the first time, the patient ultimately wound up in a hospital emergency room, unconscious and with a dangerously low blood sugar of just 20 mg/dL. A normal blood sugar would be above 70 to around 100. A blood sugar that low risks permanent brain injury if not caught in time.
FDA Center for Drug Evaluation and Research

• Office of Surveillance and Epidemiology
  • Office of Medication Error Prevention and Risk Management
  • Division of Medication Error Prevention and Analysis
Figure 1. Unapproved Morphine Sulfate Oral Solution 20 mg/mL previously marketed by Roxane.

Figure 2. Morphine Sulfate Oral Solution 20 mg/5 mL by Roxane.
Figure 1. Unapproved Morphine Sulfate Oral Solution 20 mg/mL previously marketed by Roxane.

Figure 2. Morphine Sulfate Oral Solution 20 mg/5 mL by Roxane.
Before

MORPHINE SULFATE
Oral Solution

20 mg/mL

ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT

SUGAR AND ALCOHOL FREE.

Rx only

Roxane Laboratories

After

MORPHINE SULFATE
Oral Solution

100 mg per 5 mL
(20 mg/mL)

ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT

PHARMACIST: Must dispense the enclosed Medication Guide to each patient.

Roxane Laboratories Inc. Sugar and Alcohol Free.

Boehringer Ingelheim

Rx only
FDA Medication Error Prevention Guidances

- Safety Considerations for Product Design to Minimize Medication Errors (December 2012)
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (April 2013)
- Best Practices in Developing Proprietary Names for Drugs (May 2014)
Forthcoming ISO standards to prevent healthcare catheter misconnections

- Enteral applications (feeding tubes and formula delivery systems)
- Breathing systems and driving gases applications (oxygen and ventilators)
- Urethral and urinary applications
- Limb cuff inflation applications
- Neuraxial applications (spinal and epidural catheters and infusions)
- Intravascular or hypodermic applications
ISMP Launches Targeted Medication Safety Best Practices for Hospitals

Deciding what to focus your safety efforts on during the next year? ISMP is encouraging adoption of consensus-based best practices on specific issues that continue to cause harmful errors despite repeated warnings.

For more information and a printable copy of the best practices, visit www.ismp.org.

The 2014-15 ISMP best practices address:
- VinCRISTine
- Oral methotrexate
- Patient weights in metric units
- Oral syringes
- Oral liquid dosing devices
- Glacial acetic acid

www.ismp.org
Examples of Continuing Medication Safety Issues

- Wrong-route errors
- Order communication errors
  - oral, written, CPOE
- Look-alike packaging
- Look-alike/sound-alike drug name confusion
- PCA-related errors
- IV compounding errors
- Vaccine errors
Causes of medication errors

- **Critical patient information missing?** (age, weight, allergies, lab values, pregnancy, patient identity, location, renal/liver impairment, diagnoses, etc.)

- **Critical drug information missing?** (outdated/absent references, inadequate computer screening, inaccessible pharmacist, uncontrolled drug formulary, etc.)

- **Miscommunication of drug order?** (illegible, ambiguous, incomplete, misheard, or misunderstood orders, intimidation/faulty interaction, etc.)

- **Drug name, label, packaging problem?** (look/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, etc.)

- **Drug storage or delivery problem?** (slow turn around time, inaccurate delivery, doses missing or expired, multiple concentrations, placed in wrong bin, etc.)
Causes of Medication Errors

- **Drug delivery device problem?** (poor device design, misprogramming, free-flow, mixed up lines, IV administration of oral syringe contents, etc.)

- **Environmental, staffing, or workflow problems?** (lighting, noise, clutter, interruptions, staffing deficiencies, workload, inefficient workflow, employee safety, etc.)

- **Lack of staff education?** (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)

- **Patient education problem?** (lack of “counseling,” noncompliance, not encouraged to ask questions, lack of investigating patient inquiries, etc.)

- **Lack of quality control or independent check systems?** (equipment quality control checks, independent checks for high alert drugs/high risk patient population drugs etc.)
Use of storytelling

- Powerful communication strategy
  - package experiences in an interesting way
  - share lessons learned
  - people remember information that evokes emotion, captures attention, involves personalization
  - people who remember stories also remember the rationale behind specific error-reduction strategies, thus improving compliance
Communicating low frequency, high harm events

### October-December 2013 ISMP Quarterly Action Agenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the October-December 2013 issues of the ISMP Medication Safety Alert have been prepared for an interdisciplinary committee to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, several recommendations to reduce the risk of errors, and the issue number to locate additional information as desired. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the ISMP's List of High-Avoid Medications (www.ismp.org/tools/high-alertmedications.pdf). The Action Agenda is also available for download in a Microsoft Word format (www.ismp.org/newsletters/subscription/articles/issue agendas/2013/Q4ActionAgendaFinal.pdf) that allows expansion of the columns in the Table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Many product-related problems can also be viewed in the ISMP Medication Safety Alert section of our website at: www.ismp.org. Continuing education credit is available for nurses at: www.ismp.org/Newsletters/nursece/ceactionagenda.asp.

<table>
<thead>
<tr>
<th>Issue No.</th>
<th>Problem</th>
<th>Recommendation</th>
<th>Organization Assessment</th>
<th>Action Required/Assignment</th>
<th>Data Completed</th>
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<td>(20)</td>
<td>More than 1,100 patients received less potent chemotherapy than intended. Large bags of chemotherapy had been prepared and divided into smaller doses for multiple patients. Overfill in the large bags was not considered when listing the concentration on the label because the compound pharmacy thought each large bag was to be used as a single dose, although the full dose in each bag was listed on the label, the actual concentration on the label was incorrect. There are several methods that can be used to prepare sterile products, each with specific means for managing the overfill volume to avoid confusion.</td>
<td>Choose the most appropriate method of preparing each medication infusion according to whether or not the volume/concentration is critical. Obtain a list of overfill amounts of commonly used products from vendors for reference as necessary. For continuous infusions related to effect, ensure standardization in the preparation process to order to avoid variations in concentration and incompatibilities with the dose delivered. For a single dose drug infusion, the most critical aspect of the process is ensuring that the entire contents in the container are administered; the label should include a reminder, “Inject entire contents for full dose.”</td>
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<td>(22)</td>
<td>As the use of U-500 insulin grows, so do the number of errors, mostly related to dosing confusion caused by not having a syringe with a U-500 scale. Healthcare providers and patients rely on syringes marked for U-100 insulin to measure U-500 insulin doses. This results in communicating the dose by the number of units that correspond to the U-100 syringe. Another source of confusion is name similarity since HUMULIN R is the name used for both U-100 insulin and U-500 insulin.</td>
<td>Until U-500 syringes or pens are available, use tuberculin syringes to measure doses by volume, using a dosing conversion chart available at: <a href="http://www.ismp.org/CS/Get-500">www.ismp.org/CS/Get-500</a>). Total doses should be expressed in both units and volume (i.e., 200 units [0.4 mL]). To minimize name confusion, ensure the strength is listed with each HUMULIN R insulin product during order entry. Separate U-100 insulin and U-500 insulin vials in storage areas.</td>
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<td>Catheter misconnections happen when tubing from one type of delivery system is connected to another delivery system that serves a different function. An international effort is underway to standardize the various types of connectors used in healthcare, making them incompatible with each other.</td>
<td>A phased-in approach to launch the new connectors, starting with enteral devices, will occur in 2014. Organizations should review the publication, Stay Connected, for Frequently Asked Questions (<a href="http://www.ismp.org/CS/Get-500">www.ismp.org/CS/Get-500</a>) and begin the initial steps to prepare for these changes.</td>
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### Initiative to eliminate tubing misconnections

**January 30, 2014**

**ISMP Medication Safety Alert**

**QAA 1**
Making error reporting work

- Capitalize on altruism
- No public disclosure of involved staff
- Personal response to reporters
- Feedback and changes communicated
- Non-critical of individuals – it’s the system
- Expert and credible analysis
- De-identified information forwarded to authorities
- Regulator and manufacturer advocacy
Data Elements

Possible causes

- Critical patient information missing?
- Critical drug information missing?
- Miscommunication of drug order?
- Drug name, label, packing problem?
- Drug storage or delivery problem?
- Drug delivery device problem?
- Environmental, staffing, or workflow problems.
- Lack of staff education?
- Lack of patient education?
- Lack of quality control or independent check systems?

(Assess-ERR™ [www.ismp.org/Tools/AssessERR.pdf])
**ASSESS-ERR™**

**Medication System Worksheet**

Patient MR# 
(if error reached patient)
Date of error: 
Date information obtained: 

Drug(s) involved in error:

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<th>Y/N</th>
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Did the patient require any of the following actions after the error that you would not have done if the event had not occurred?

- [ ] Testing
- [ ] Additional observation
- [ ] Gave antidote
- [ ] Care escalated (transferred, etc.)
- [ ] Additional LOS
- [ ] Other

Patient outcome:
Role of voluntary error reporting programs

- Programs should NOT have a regulatory role or even direct connection with regulators – examples Pa-PSRS; ISMP national MERP)

- Reporting inversely proportional to publicity generated for specific event types

- Reporter satisfaction/reward when actions communicated widely or changes visible; knowledge that others will benefit
How do you ensure representative reporting?

- Difficult with mandatory reporting
  - Hospital incident reporting
  - Serious reportable events
  - Allowance for “whistle blowers”

- Voluntary can be open to all (e.g., ISMP MERP) or closed (e.g., specialty such as blood or laboratory)
  - Practitioners (ismp.org)
  - Consumers (consumermedsafety.org)

- Specialty organizations
  - (ISMP has links to other organizations for reporting of diabetes medication incidents, nutrition-related incidents, others)
How are errors investigated?

May/may not be
- Mandatory reporting may be for data collection or public accountability vs. detail needed for action by reporting program
- Voluntary reporting allows free discussion with reporter
  - Materials such as photographs, screen prints, information from product manuals, etc. often retrievable
    - Note: IT vendors have sometimes prohibited such communications via signed agreement/contract
  - Expert analysis applied
  - Reporting agency gathers facts from external sources as required
  - More detailed reporting encouraged via responses communicated with individuals and constituency
How are results from analyses and investigations distributed?

- Direct communication with reporter/organization
- Published data analysis
- Anecdotal reports/story telling more possible with voluntary reporting
- Published in newsletters/journal articles; websites; media releases; news columns/blogs; social media; meetings with constituents; webcasts, etc.
- Multiple journal columns; Medscape;
- Communication with regulatory agencies, product vendors, accreditation agencies
- Communication with consumers
Public health benefits

- Minimal cost, little work for health-systems
- Manufacturers and regulatory agencies receive follow-up and improvement ideas
- Practice related reports are processed
- Data analysis and trending
- Practitioner education
- Useful in developing drug standards and drug information