The 2012 Landscape of I.V. Medication Safety: Processes, Tools, and Training

Presented as a Midday Symposium and Live Webcast at the 47th ASHP Midyear Clinical Meeting and Exhibition

Tuesday, December 4, 2012
Las Vegas, Nevada

Remind Me Tool

Planned and conducted by ASHP Advantage and supported by an educational grant from Hospira, Inc.

W E B C A S T I N F O R M A T I O N

What is a live webcast? A live webcast brings the presentation to you – at your work place or in your home. You view and hear the presentations in "real time" complete with slides and video of the speakers and have the opportunity to ask questions at the end of the activity. Continuing pharmacy education (CPE) credits earned through participation in webcasts qualify as **live CPE credit.** Please join the webcast at least 5 minutes before the scheduled start time for important activity announcements.

How do I register? Go to www.ashpadvantage.com/IV/medsafety/#webcast and click the **Register Now** button. You will receive an email confirmation with webcast connection information.

How do I process my CPE? After completion of this webcast, you will process your CPE online and print your statement of credit at http://ce.ashp.org. You will need the **Activity and Session Codes** that will be announced at the end of the webcast. Complete CPE processing instructions are available in this handout. If you have questions about processing CPE online, contact support@ashpadvantage.com.

What if I would like to arrange for my colleagues to participate in this webcast as a group? One person should register for the webcast and will receive the webcast linking instructions via email. Each participant processes his or her CPE statement online at the conclusion of the activity.

How do I ask a question of the presenters during the webcast?

Click the "Ask a Question" bubble icon  to type a question and your email. The speakers will answer as many questions as possible at the conclusion of the activity. Responses to technical questions will be sent to the email address you provided.

Why doesn't the presentation appear? If you're using a pop-up blocker, configure it to allow this site's pop-ups. You will need to change settings in your browser.

Why can't I hear audio? Check your volume controls and whether the device you are using has speakers. There are three areas you may find volume controls:

- Player volume: look for volume icon inside the player.
- Adjust the volume slider and confirm that mute is not selected.
- External speakers (optional): check whether the speakers have a volume control dial or knob that you can use to increase or decrease the volume level.

What if my video frame keeps freezing, progressing a bit, and then freezing again? Depending on the speed of your internet connection, there may not be enough bandwidth to accommodate the audio, slides, and live video. To alleviate this, either minimize or turn off the video by using the icons on your screen. You can also use the Classic Player version of the webcast tool to achieve better viewing.

What do I need to participate in the webcast?
For the best presentation viewing experience, we recommend a broadband internet or Wi-Fi connection and the following system requirements:

Microsoft® Windows®	Mac®	Linux
• Windows 2008, Windows 7, Windows Vista, Windows XP, Windows 2003 • Internet Explorer® 7.0 or later, Firefox® 3.6 or later or Google Chrome™ • Windows Media® Player 9.0 or later • Microsoft Silverlight® 5* • Broadband Internet connection	• Mac OS® X 10.4.8 or later • Safari® 2.0.4 or later or Firefox 3.6 or later • Microsoft Silverlight 5* • Broadband Internet connection	• SUSE Linux Enterprise Desktop 10, openS USE 11.0 or later, Ubuntu 8.04 or Fedora Core 9 • Firefox 2.0 or 3.0 depending on Linux operating system • Moonlight™ 1.0 • Microsoft Media Pack for Moonlight • Broadband Internet connection (256Kbps or more) • On-demand playback only

** If Silverlight is not detected on your computer when viewing a presentation, you will be automatically prompted to install the plug-in. Silverlight only needs to be installed once and will then be available for watching any other presentations.*

Classic Player Option
If you are unable to install Silverlight or your bandwidth speed is slower than required, another version of the webcast is available. The requirements are as follows:

Microsoft® Windows®	Mac®	Linux
• Microsoft® Windows 7, Windows Vista, Windows XP, Windows Server 2008 • Windows Server 2003 • Internet Explorer 6.0 SP1 or later, Firefox® 2.0 or later, or Google™ Chrome 1.0 • Windows Media® Player 9.0 or later • Broadband Internet connection (256Kbps or more)	• Mac OS X 10.4.8 or later • Safari™ 2.0.4 or later or Firefox 2.0 or later • Microsoft Silverlight 1.0 or later* • Broadband Internet connection (256Kbps or more)	• SUSE Linux Enterprise Desktop 10, openSUSE 11.0 or later, Ubuntu 8.04, or Fedora Core 9 • Firefox 2.0 or 3.0 depending on Linux operating system • Moonlight™ 1.0 • Microsoft Media Pack for Moonlight • Broadband Internet connection (256Kbps or more)

** If Silverlight is not detected on your computer when viewing a presentation, you will be automatically prompted to install the plug-in. Silverlight only needs to be installed once and will then be available for watching any other presentations.*

iPad	iPhone and iPod	Android	BlackBerry
• iOS 4.3 or later • Mobile Safari™ • Wi-Fi or cellular data connection (3G or higher)	• iPhone 4 or later • iPod 4th generation or later • iOS 4.3 or later • Mobile Safari • Mediasite Mobile app (free download available from the Apple® App Store) • Wi-Fi connection	• Android 4.0 or later • On-demand playback only • Wi-Fi or cellular data connection (3G or higher)	• BlackBerry OS 7.0 or later • On-demand playback only • Wi-Fi or cellular data connection (3G or higher)

A G E N D A

11:30 a.m. – 11:40 a.m.	**Welcome and Introductions** Rita Shane, Pharm.D., FASHP, FCSHP
11:40 a.m. – 12:15 p.m.	**The Evolution of I.V. Safety: What Improvements Have Been Made Since the 2008 Safety Summit?** Rita Shane, Pharm.D., FASHP, FCSHP
12:15 p.m. – 12:45 p.m.	**Meeting the Challenge of I.V. Safety** Luci A. Power, M.S., B.S.Pharm.
12:45 p.m. – 1:15 p.m.	**Back to Basics: Innovative Strategies for Teaching the Principles of Safe Medication Compounding** Steven R. Abel, Pharm.D., FASHP
1:15 p.m. – 1:30 p.m.	**Faculty Discussion and Audience Questions** All Faculty

F A C U L T Y

Rita Shane, Pharm.D., FASHP, FCSHP
Activity Chair
Director, Pharmacy Services
Cedars-Sinai Medical Center
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy
Los Angeles, California

Luci A. Power, M.S., B.S.Pharm.
Senior Pharmacy Consultant
Power Enterprises
San Francisco, California

Steven R. Abel, Pharm.D., FASHP
Associate Vice Provost for Faculty Affairs
Purdue University
West Lafayette, Indiana

D I S C L O S U R E S T A T E M E N T

In accordance with the Accreditation Council for Continuing Medical Education's Standards for Commercial Support and the Accreditation Council for Pharmacy Education's Guidelines for Standards for Commercial Support, ASHP Advantage requires that all individuals involved in the development of activity content disclose their relevant financial relationships. A person has a relevant financial relationship if the individual or his or her spouse/partner has a financial relationship (e.g., employee, consultant, research grant recipient, speakers bureau, or stockholder) in any amount occurring in the last 12 months with a commercial interest whose products or services may be discussed in the educational activity content over which the individual has control. The existence of these relationships is provided for the information of participants and should not be assumed to have an adverse impact on presentations.

All faculty and planners for ASHP Advantage education activities are qualified and selected by ASHP Advantage and required to disclose any relevant financial relationships with commercial interests. ASHP Advantage identifies and resolves conflicts of interest prior to an individual's participation in development of content for an educational activity.

The faculty and planners report the following relationships:

Rita Shane, Pharm.D., FASHP, FCSHP

Dr. Shane declares that she has no relationships pertinent to this activity.

Luci A. Power, M.S., B.S.Pharm.

Ms. Power declares that she serves on the scientific advisory board and as a consultant for Intelligent Hospital Systems, has a royalty agreement for ChemoPlus Training Kit with Covidien Chemo Protection, and is a stockholder and consultant with S.E.A. Medical Systems, Inc.

Steven R. Abel, Pharm.D., FASHP

Dr. Abel declares that he has no relationships pertinent to this activity.

Kristi N. Hofer, Pharm.D.

Dr. Hofer declares that she has no relationships pertinent to this activity.

ASHP staff has no relevant financial relationships to disclose.

ACTIVITY OVERVIEW

Safe use of i.v. medications in the hospital setting remains a challenge, especially in light of the increasing complexity of therapies, unprecedented medication shortages, evolving technologies to support sterile compounding, and lack of pharmacists with knowledge and skills in this specialized area. National efforts to improve the safety of i.v. medications continue to evolve. The compounding of i.v. medications also continues to present patient safety challenges. This educational activity will examine national efforts in improving i.v. medication safety, focusing on innovation in care and overcoming challenges and unintended consequences associated with complex workflow processes. In addition, faculty will present creative ideas for education that can be implemented to avoid errors and promote safety.

ACTIVITY OBJECTIVES

After attending this application-based educational activity, participants should be able to

- Summarize national efforts for improving i.v. medication safety.
- Apply strategies for minimizing risk of intravenous medication errors.
- Describe educational methods that can be used to train pharmacists about safe i.v. preparation.
- Describe human factors and workflow processes that impact i.v. safety.

Available soon at
www.ashpadvantage.com/IV/medsafety

A web-based activity based on today's live symposium is being developed. Encourage your pharmacist colleagues who were unable to attend today to look for this free on-demand educational activity in March 2013.

(Please note that individuals who claim CPE credit for the live symposium or webcast are ineligible to claim credit for the web-based activity)

CONTINUING EDUCATION ACCREDITATION

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 2.0 hour (0.2 CEUs) of continuing pharmacy education credit (ACPE activity #0204-0000-12-436-L05-P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education credit at the ASHP CE Center at **http://ce.ashp.org** following the activity.

Complete instructions for receiving your statement of continuing pharmacy education online are on the next page. Be sure to record the session code beginning with "A" announced during the activity.

New! PRACTICE REMINDER EMAIL

During this educational activity, we encourage you to jot down points about what YOU want to remember to do as a result of what you are learning.

- Use your smart device to link directly to the reminder tool and type in your ideas.
- Next month, we will send you an email as a reminder from YOURSELF about what YOU want to do after attending this activity.
- Do it more than once…multiple entries for this activity from the same email address will be combined into one email.
- If you do not have a smart device, go to the reminder tool on the activity website http://www.ashpadvantage.com/iv/medsafety/?remindme=1

Instructions for Processing CPE online at http://ce.ashp.org

The ASHP CE Center allows participants to obtain statements of continuing pharmacy education (CPE) conveniently and immediately using any computer with an internet connection. To obtain CPE statements for ASHP Advantage activities, please visit

http://ce.ashp.org

1. Select **Process Meeting CE** from bottom left. Log in to the ASHP CE Center using your e-mail address and password.
2. **If you have not logged in to the ASHP CE Center and are not a member of ASHP,** you will need to create a free account by clicking on **Register** at the bottom of the **Register as a New User** panel. Once logged in to the site, click on **Process Meeting CE.**
3. If this activity title does not appear in your meeting list, enter the 5-digit activity code in the box above the list and click submit. The **Activity and Session Codes** are announced at the end of the activity. Click **Submit** when prompted and then click on the **Start** link to the right of the activity title.
4. Enter the session code, which starts with the letter "A" and was announced during the activity, and select the number of hours equal to your participation in the activity. Participants should only claim credit for the amount of time they participate in an activity.
5. Click **Submit** to receive the attestation page.
6. Confirm your participation and click **Submit**.
7. Print and/or save your CE statement as appropriate.
8. Complete activity evaluation by selecting the **My Account** tab and continue to **My Transcript.**
9. Select the applicable year from the drop down menu and locate the activity.
10. Click **Complete Evaluation** under the **Status** column to be taken to the evaluation page.
11. Complete **all** evaluation questions and click **Finish.**

Date of Activity	Activity Code	Session Code (announced during the live activity)	CPE credit hours
December 4, 2012	12436	A12_____	2

NEED HELP? Contact ASHP Advantage at **support@ashpadvantage.com**.

Rita Shane, Pharm.D., FASHP, FCSHP
Director, Pharmacy Services
Cedars-Sinai Medical Center
Los Angeles, California
Assistant Dean, Clinical Pharmacy Services, School of Pharmacy
University of California, San Francisco

Rita Shane, Pharm.D., FASHP, FCSHP, is Director of Pharmacy Services at Cedars-Sinai Medical Center, a 950-bed acute, tertiary care, teaching institution in Los Angeles, California, and Assistant Dean, Clinical Pharmacy Services, at the University of California, San Francisco (UCSF), School of Pharmacy.

Dr. Shane has been recognized for her passion for the profession. Most recently, she received the 2012 Harvey A. K. Whitney Award. She is also the recipient of the 2007 California Society of Health-System Pharmacists (CSHP) Pharmacist of the Year Award and the 2007 Distinguished Service Award from the American Society of Health-System Pharmacists (ASHP) Section of Pharmacy Practice Managers. Dr. Shane was the 2005 recipient of the ASHP Distinguished Leadership Award and the 1995 recipient of the John Webb Visiting Professorship in Hospital Pharmacy for management excellence.

Dr. Shane is a co-investigator in two research studies in collaboration with the UCSF School of Pharmacy and approved by the California State Board of Pharmacy to demonstrate the safety and importance of allowing technicians to check technician-filled medication cassettes in hospitals. She also worked collaboratively with CSHP to author language in support of this regulatory change which was approved by the State of California effective in January 2007. Dr. Shane was co-investigator of a 2000 National Patient Safety Foundation Research Award to study the impact of dedicated medication nurses on the rate of medication administration errors in a randomized, controlled trial, the results of which were subsequently published in the *Archives of Internal Medicine*.

Dr. Shane recently served as the United States facilitator at the Global Conference on the Future of Hospital Pharmacy held during the 68th Congress of the International Pharmaceutical Federation and was responsible for reviewing the international literature on the subject of medication administration. She is an investigator in a multicenter study of medications errors recovered by emergency department pharmacists which was published in the *Annals of Emergency Medicine*. Throughout her career, Dr. Shane has participated on committees and task forces at the state and national level. She recently was a member of the American Hospital Association Committee on Health Professions and the National Quality Forum Patient Safety Advisory Committee. She is the ASHP representative to The Joint Commission Hospital Professional Technical Committee. She has presented at local, state, national, and international meetings and has published a number of papers in the pharmacy literature including one of the background papers for the recent ASHP Pharmacy Practice Model Summit.

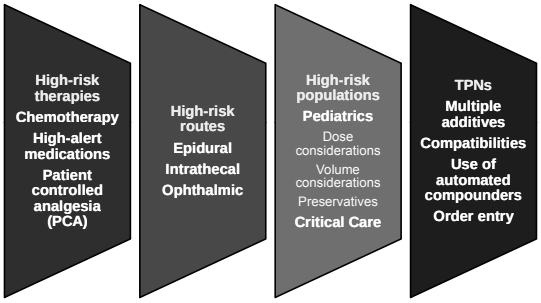
The Evolution of I.V. Safety: What Improvements Have Been Made Since the 2008 Safety Summit?

Rita Shane, Pharm.D., FASHP, FCSHP
Director, Pharmacy Services
Cedars-Sinai Medical Center, Los Angeles
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy

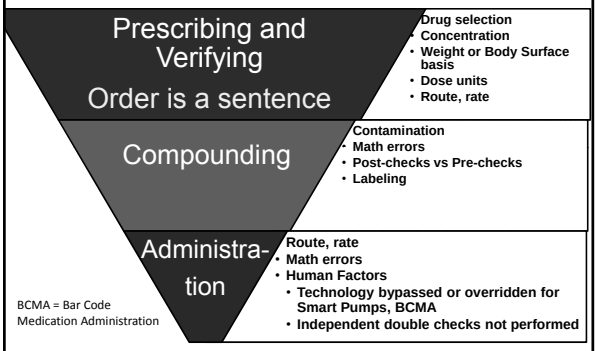
Learning Objectives

- Describe key recommendations from recent I.V. Safety Summits
- Identify types of errors associated with i.v. medication
- Identify challenges associated with emerging therapies given by the i.v. route
- Describe strategies for ensuring the safety of outsourced medications

I.V. Therapies are High-Risk



Sources of I.V. Errors



2008 ASHP I.V. Safety Summit

Formulary/Medication-Use Policy	• Standard concentrations • Processes for high alert meds • Use commercially available products • Comprehensive I.V. medication administration policies
Prescribing	• Standard I.V. med orders including diluents, concentrations • Standard dosing protocols for high alert & emergency meds
Storage	• Stock commercially available product for emergency use • Limit concentrations of I.V. meds on patient care units
Preparation/ Dispensing	• Dispense I.V. medications ready to administer • Standard processes for compounding, USP Chapter <797> • Competencies for staff
Administering	• Independent double checks • Standard processes: 2 patient identifiers, line labeling • Smart pumps

ASHP. *Am J Health-Syst Pharm*. 2008; 65:2367-79.

I.V. medication administration errors involve all of the following except:

A. Wrong route
B. Bypassing alerts on smart pumps
C. Lack of independent checks
D. Compounding

FDA and Compounding

- Medical Center Pharmacy v. Mukasey, 2008
  - The Fifth Circuit concluded that compounded drugs are "new drugs" ….within the meaning of the FDCA and therefore are subject to regulation by the FDA.
- Pushback from compounding pharmacies
- Universal requirements not implemented
- Distinction between compounding based on patient-specific prescription vs non-patient specific compounding in advance of prescription

U.S. FDA. Guidance, Compliance, and Regulatory Information. URL in Ref List.

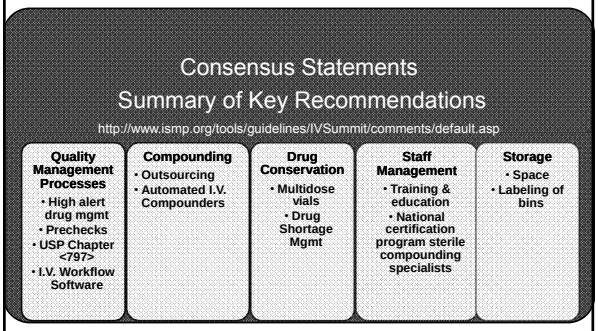
FDA and Compounding

- 2011 Contamination of TPN in Atlanta
  - Bacterial contamination - 6 deaths
- ISMP Calls for Greater FDA Guidance and Pharmacy Board Oversight of Sterile Compounding
  - All state boards of pharmacy should require compounding pharmacies to comply with USP Chapter <797> and survey these pharmacies
  - 17 states follow USP Chapter <797>
  - 200 adverse events involving sterile products over the past 2 decades (ISMP 10/18/12)

Meningitis Outbreak - New England Compounding Pharmacy October 2012

- Contaminated epidural methylprednisolone and potentially cardioplegia and other products
  - 344 cases of meningitis, stroke, or CNS infection; 25 deaths (as of 10/27/12; cdc.gov)
  - Product recall involving over 3000 line items
- FDA Inspection-Form 483 (fda.gov)
  - 83 vials with greenish black matter
  - Non-sterile powder used
  - Lapses in cleanroom processes
- Move by Congress to introduce legislation to enhance FDA authority related to compounding

2011 ISMP Sterile Preparation Compounding Safety Summit



Recommendations from recent I.V. Safety Summits include use of prechecks.

A. True
B. False

Current I.V. Compounding Landscape 2011 ASHP Survey

- USP Chapter <797> Compliant Cleanroom: 65.2%
- I.V. Robots: 2.5% (chemotherapy: 0.1%)
- Remote video supervisor of technicians: 3.6%
- Bar code verification during i.v. compounding: 11.9%
- Automated TPN Compounders: 20.4%
- Validation technology: not assessed
- Partial or complete outsourcing: 70.9%
  - PCA and epidural analgesia: 73.3%
  - Increased outsourcing due to drug shortages, limited concentrations of products, and to extend dating for sterile products

Pederson CA et al. *Am J Health-Syst Pharm*. 2012; 69:768-85.
ASHP. *Am J Health-Syst Pharm*. 2010; 67:757-65.

ASHP Guidelines on Outsourcing Sterile Compounding Services

- Request for proposal
- Site visit
  - Review of training materials
  - Review of personnel files
  - USP Chapter <797> compliance
  - Beyond-use dating references
  - Use of technology
  - Review of labels
  - Observation of practices
- Quarterly reports of quality assurance program
- Annual onsite evaluation
- Outsourcing Sterile Products Preparation-Contractor Assessment Tool

ASHP. *Am J Health-Syst Pharm*. 2010; 67:757-65.
ASHP Foundation. Outsourcing sterile products preparation: contractor assessment tool. URL in Ref List.

Strategies for safe outsourcing include all of the following except:

A. Routine site visits
B. Observation of compounding processes
C. Review of staff training records
D. Use of outsourcing for compounding in lieu of commercially available products

Current Technology Landscape and I.V. Safety: Prescribing and Administration

- CPOE: 34.2%
- Electronic MAR: 67.3%
- BCMA: 50.2%
- Smart infusion pumps: 67.9%

Advances:
- Commercially available pump library
- Smart Pump-Electronic Medical Record Integration
  - Requires wireless capability
  - Importance of 2-way integration
  - RN needs to scan one i.v. preparation at a time

Pedersen CA et al. *Am J Health-Syst Pharm*. 2012; 69:768-85.
Prusch AE et al. *Am J Health-Syst Pharm*. 2011; 68:835-42.

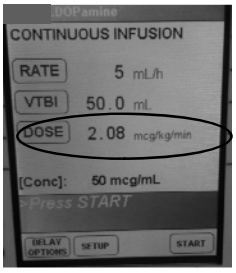
Sources of Risk

Smart Pumps in Pediatrics

- Weight-based dose entered: 20 units/kg/h
- Weight is 2kg but 20kg is entered in error
- Smart pump displays 20 units/kg/h
- Lack of continuous weight display
- Infusion rate of 400 units/h instead of 40 units/h
- Unintended consequence: correct weight-based rate, wrong weight → 10-fold error

Tourel J et al. *Am J Health-Syst Pharm*. 2012; 69:1628-9.

Pediatric Pump Display



Lack of I.V. Knowledge and Skills

- I.V. medication therapy is not an area of focus in pharmacy training[1]
  - Survey on sterile preparations in U.S. pharmacy schools: 13% of schools reported "adequate training in compounding sterile preparations"
- Evaluation of accuracy of compounding 2 simple solutions by pharmacy students[2]
  - Solution 1: only 54% of students prepared the medications within 10% of desired concentration; 46% had errors ranging from <75% to >200% of the desired concentration
  - Solution 2: 78% of students within 10% of the desired concentration; however, the range of concentration errors was greater (-89% to 269%).

Hellums M et al. *Am J Health-Syst Pharm*. 2007; 64:2267-74.
Kadi A et al. *Am J Pharm Educ*. 2005; 69:508-15.

I.V. Medication Administration Errors

- Prospective observational study of 107 nurses and 568 i.v. administrations
- 69.7% had at least one clinical error; 25.5% were serious
- 4 error types (wrong intravenous rate, mixture, volume, and drug incompatibility) accounted for 91.7% of errors.
- Wrong rate: 95 of 101 serious errors.
- Error rates and severity decreased with clinical experience.
  - Each year of experience, up to 6 years, reduced the risk of error by 10.9% and serious error by 18.5%.
- Administration by bolus was associated with a 312% increased risk of error

Westbrook JI et al. *BMJ Qual Saf.* 2011; 20:1027-34.

I.V. Therapy Innovation and Challenges

- Growth of parenteral biologics and other specialty pharmaceuticals for chronic diseases
  - Biologics for chronic disease: approx. 400 specialty medications across 25 therapeutic categories; primarily injectable medications
  - Patient's own I.V. therapy +/- infusion device
- Growth in intrathecal pain management and use of non-sterile powders
- Cellular immunotherapy for cancer and other diseases

Draft ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy

- Provides comprehensive guidelines across medication use system focusing on competency
- Overall chemotherapy error rate of 8.1 errors/100 clinic visits
  - 7.1% of adult clinic visits
  - 18.8% of pediatric clinic visits
  - Errors across all steps of medication use process; most common: administration (56%) and ordering (36%) errors
- CPOE for chemotherapy not widely adopted; can introduce new errors
- American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) guidelines

URL in Ref List.

Intrathecal Pain Management

- Drug delivery systems (pump and catheter) that deliver small quantities of analgesic intrathecally
- Indicated for chronic, intractable pain; severe spasticity
- Off-label use of medications: clonidine, ketamine
- Non-sterile powder used in compounding
- Safety issues
  - Infections, respiratory depression, neurologic injury, paralysis, inflammatory mass
  - Catheter complications: disconnection, fracture, leak, migration, kinks, granulomas

Chronic I.V. Therapies and Transitions of Care

- The "new" patient's own medication: patient's own injectable +/- infusion device
  - Biologics for chronic disease
  - Intrathecal analgesia
- Product integrity and liability
  - Stability
  - Sterility
  - Counterfeit
- Preparation considerations
  - Pharmacy staff competency in infusion devices and other drug delivery systems

Chronic I.V. Therapies and Transitions of Care

- Preparation considerations
  - Non-sterile powder compounding
  - Outsourcing considerations
- Administration considerations
  - Nursing knowledge of infusion device operation
  - Patient competency for self-administration
    - Nursing ability to assess patient competency-TJC requirement
- Patient's Own Infusion Device
  - Preventive maintenance
  - Infection control considerations
- Coordination of patient-specific medications and supplies across transitions of care

Immunotherapy

- Research advances in treatment of cancer and immune disorders
  - Biological response modifiers
  - Cancer vaccines
  - Gene therapy
  - Non-specific immunomodulating agents, e.g. BCG
- New competencies
  - Storage, Preparation, Dispensing, Monitoring
- Facility requirements

National Cancer Institute. Fact Sheet: Biological therapies for cancer. URL in Ref List.

Why Focusing on I.V. Medication Safety is an Imperative

- Sterile Compounding is a specialty area
- Safe use of i.v. medications requires knowledge and skills across the entire med-use process
- Technology and automation: need to balance benefits with unintended consequences
- Ensuring safety of outsourcing is essential
- Research advances will increase complexity
- Human factors are at the core of safe i.v. medication use

Luci A. Power, M.S., B.S.Pharm.
Senior Pharmacy Consultant
Power Enterprises
San Francisco, California

Luci A. Power, M.S., B.S.Pharm., is an independent lecturer and consultant on pharmacy intravenous (i.v.) and hazardous drug systems. Prior to this role, Ms. Power served in a variety of capacities at the University of California Medical Center in San Francisco Department of Pharmaceutical Services for over 25 years. She was Senior Pharmacist and Manager of I.V. Additive Services, where she was responsible for the compounding of inpatient i.v. therapy and developed chemotherapy and other hazardous drug compounding services for both inpatients and outpatients. As Senior Pharmacist and Manager of Parenteral Support Services, Ms. Power designed, implemented, and managed an off-campus, USP Chapter <797> -compliant compounding center producing TPN and batch i.v. doses for two campuses, as well as supporting the continuous renal replacement therapy (CRRT) service.

Ms. Power has been a member of the American Society of Health-System Pharmacists (ASHP) for over 30 years. She is a primary author of both the 1985 and 1990 ASHP Technical Assistance Bulletins on Handling Cytotoxic and Hazardous Drugs; lead author of the 2006 ASHP Guidelines on Handling Hazardous Drugs; and first author of the ASHP Safe Handling of Hazardous Drugs Video Training Program. Ms. Power is also a contributing author to the second and third editions of ASHP's text entitled, *Compounding Sterile Preparations*.

Ms. Power is an original member of the National Institute for Occupational Safety and Health (NIOSH) working group on hazardous drugs. As the group leader for the Work Practices small group, she was an author of the 2004 NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings.

Ms. Power has research interests in closed system transfer devices and has worked with i.v. robotics for the safe compounding of hazardous and non-hazardous drugs. She serves on several advisory boards for new technology to improve both patient and worker safety. She has presented numerous programs on hazardous drugs, i.v. therapy, USP Chapter <797>, i.v. robotics, and errors in drug therapy.

Meeting the Challenge of I.V. Safety

Luci A. Power, M.S., B.S.Pharm.
Senior Pharmacy Consultant
Power Enterprises
San Francisco, California

Learning Objectives

- Examine existing i.v. technology to determine which technologies best support i.v. staff and provide patient safety
- Review i.v. technology in terms of how it works and if it can be "worked around"
- List the deficiencies in some i.v. technology that may compromise product and patient safety

Back to Basics: I.V. Compounding

- We cannot improve i.v. safety if we don't accept the basics
  - Knowledge and skills are required in the I.V. Room
  - I.V. skills are NOT innate or intuitive
  - MONITORING is required in the I.V. room
  - There is no substitute for well-trained and experienced i.v. technicians and PHARMACISTS
  - Technology and automation are only TOOLS

What are the Compounding Challenges of I.V. Safety?

- Sterility
- Accuracy

What Meets the Challenges of I.V. Safety?

- People?
- Technology/automation?
- People using technology and automation?

What Meets the Challenges of I.V. Safety?

Well-trained staff properly using well-designed technology

MAGIC and myths!

- There are no magic rooms in the pharmacy!
- There are no magic boxes in the I.V. Room!
- There are no magicians in the I.V. Room!

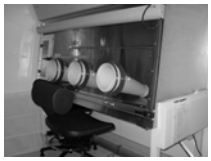
Myth: "Clean" Rooms

- The architects only determine "clean" by design
- Staff and work practices determine if it is "clean" in use

True or False?

As long as sterile preparations are compounded in an ISO 7 "Clean Room" they will ALWAYS be sterile.

What if I have a "magic" box in my clean room?



Photos courtesy of NuAire

True or False?

Challenges to the "magic" boxes

- Cleaning
- Maintenance
- Technique

Challenges to the "magic" boxes (also known as isolators)

- Gloves - pinholes and changing
- Sleeves - damage to gasket or material
- Cleaning - requires tools
  - What can't I reach?
  - Can I open the front?

The "magic" may be broken!

- Gloves must be changed frequently – not all damage is this obvious!
- Check for pinholes

- The sleeves and gaskets may also be damaged
- There may be pinholes in the sleeves

What about accuracy?

- What meets the challenge of accuracy?
- Technology?
- Automation?

What works?

What can be worked around?

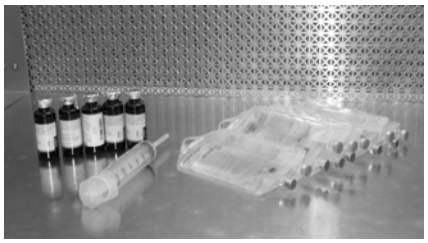
Case Study: Compounding Error

Six doses of 10mL IV cotrimoxazole in 100mL D5W are needed for BMT patients on a PCP prophylaxis regimen. There are a number of partial 30mL, amber multi-dose vials left over from earlier compounding. The compounder decides to use these vials for compounding the required doses.

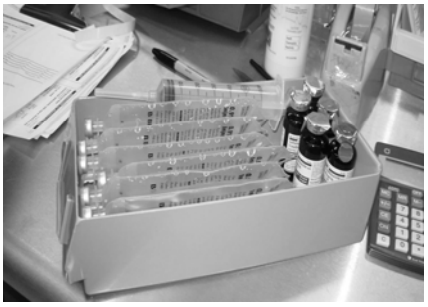
Challenges?

- Batching with open drug vials is a serious risk both for sterility and accuracy
- Shortages of drugs makes using open vials imperative
- Technology has gaps for batching and for using partial-filled vials

Manual compounding: This is in the "hood"



This is what is presented to be checked



This is the problem

Will technology solve the problem?

- Bar Code Verification in the Clean Room?
- I.V. Workflow Software?
- I.V. Robotics?
- Other?

Bar Code Verification for preparation in Clean Room?

- YES - IF EACH vial is scanned
- NO - IF ONE vial is scanned 5 times!

I.V. Workflow Software

DoseEdge™ - I.V. Soft® - ScriptPro Telepharmacy

- Interface with pharmacy system
- Barcode verification of drug vials
- Photo capture of vials, labels, etc.
- Remote checking based on photos

Considerations

Accuracy

- Barcode each vial or 1?
- Image captures ONLY what is photographed – 1 vial or 5 vials?
- Remote checker only sees images that are captured
- Dose is done before verified

Sterility

- Placement in PEC airflow
- Touch contamination
- Lapses in aseptic technique are not captured
- HD touch contamination and technique lapses

I.V. Workflow Software?

- Using multiple partial-filled vials is difficult for technology

- YES - IF compounder follows the rules
- NO – IF not
- Camera only records what is shown

Photo of DoseEdge™ courtesy of Baxter

I.V. Workflow Software?

- Image capture technology ONLY shows what is photographed
- Lapses in compounding technique are NOT captured
- Short-cuts and "work-arounds" are NOT captured

I.V. Robotics?

I.V. Robotics are most likely to avoid the error

- Barcode and image capture of all items
- Exact processes
- No "work arounds"
- Will only use robot-punctured partial vials
- Gravimetric methods
- Remote checker verifies all compounding steps

BUT …

- Robots are NOT "plug and play"
- Robots are Class II Medical Devices

Class II Medical Devices

- BOTH are Class II Medical Devices and BOTH use the FDA 510K process to get to market.
- The FDA does not "approve" Class II Medical Devices the same way it approves drugs.

Can robots make mistakes?

- YES - if given the wrong information
  - Drug databases must be accurate
  - Density input must be accurate
  - Calculation/concentration input must be accurate
- If errors in databases, MANY doses are affected

Other Technology – The "Final" Check?

- USP Chapter <797>, Boards of Pharmacy, and others are recommending end product testing for ACCURACY
- New technology allows testing in the I.V. Room
  - CDEX - Valimed G4
  - SEA Medical – IV Check

ValiMed G4

- The ValiMed G4 drug validation system identifies drug strengths and volume-by-weight in real-time, validating proper dose, diluents, and concentration of high-risk compounded medications and treatment solutions.
- This "catches" errors that may be missed with other technologies.

IV Check

- IV Check measures i.v. samples anywhere i.v. medications are prepared, and instantly reports the drug, dose, and diluent present to validate i.v. preparations.
- IV Check allows pharmacy technicians and pharmacists to verify the drug, concentration, and diluent of i.v. preparations during the compounding process to reduce the drug and time wasted in re-compounding wrong doses.

Poor Job Performance

- No one goes into the I.V. Room planning to make a mistake
  - Knowledge deficit
  - Inadequate training
  - Not enough time
  - Too many interruptions
  - Changing priorities

Human Factors are at the Core of Safe I.V. Medication Use

- Hire the smile and train the skill
  - Training those who compound, check, and administer i.v. medications is critical for patient and worker safety; and for safety for the immediate and surrounding environment
  - This would apply to bugs and drugs
  - Select workers who care, are reliable, and follow rules

Character and personal force are the only investments that are worth anything

Walt Whitman

Steven R. Abel, Pharm.D., FASHP
Associate Vice Provost for Faculty Affairs
Purdue University
West Lafayette, Indiana

Steven R. Abel, Pharm.D., FASHP, is Associate Vice Provost for Faculty Affairs, Purdue University, Associate Dean for Clinical Programs and Bucke Professor of Pharmacy Practice, Purdue University College of Pharmacy. He served as Head, Department of Pharmacy Practice, from 1996 to 2012. Dr. Abel received his Bachelor of Science in Pharmacy and Doctor of Pharmacy degrees from Purdue University, and he completed residency training at Mayo Medical Center. He completed an academic leadership fellowship through the Committee on Institutional Cooperation in 2007-2008 and an inaugural Purdue University Provost fellowship focused on faculty affairs in 2009-2010.

Dr. Abel is passionate about student education, leadership development, and mentorship. His research focuses on the development, implementation, and evaluation of progressive pharmacy services, student enhancement of pharmacy practice, patient safety, and interprofessional collaborative strategies to improve the medication use process in any setting. Dr. Abel developed the only fully immersive USP Chapter <797> -compliant virtual cleanroom, based on video game technology, used for student education.

Dr. Abel led the team that implemented international collaboration between the Purdue University College of Pharmacy, Indiana University School of Medicine, and Moi University in Eldoret, Kenya. Currently, two full-time faculty members sustain the most comprehensive international initiative associated within a college of pharmacy in the United States. He also specializes in ocular pharmacology. Dr. Abel has a history of active service in various pharmaceutical organizations, including the Indiana Pharmacists Alliance, American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Association of Colleges of Pharmacy, and International Pharmaceutical Federation.

Back to Basics: Innovative Strategies for Teaching the Principles of Safe Medication Compounding

Steven R. Abel, Pharm.D., FASHP
Associate Vice Provost for Faculty Affairs
Purdue University
West Lafayette, Indiana

Objective

- Describe educational methods that can be used to train pharmacists about safe i.v. preparation

Introduction to Purdue University College of Pharmacy

- Each class (P1 → P4) has ~160 students
- Current curriculum includes 2-credit hour Parenteral Products course
  - Spring semester of P3 year
  - Instruction on preparation of sterile i.v. admixtures
  - Emphasis on USP Chapter <797> regulations
  - I.V. Room environment requirements, including proper attire

The Problem

- Cleanroom training of pharmacy students occurs mainly in classroom
- Four laboratory sessions to practice "hands-on" exercises
  - Five individual tabletop hoods
  - Required to wear sterile gloves
  - Focus on product manipulation only
- Only 2 hospitals in the West Lafayette, IN area with i.v. cleanrooms

The Problem

- Student feedback showed lack of comfort when performing appropriate i.v. procedures
- Many students never step foot in a cleanroom prior to APPE rotations
- Many students are unfamiliar with hospital labeling and packaging
- Lack of physical space and funds to build a cleanroom on campus
- Cost to maintain a USP Chapter <797> compliant space as standards change

The Goal

- Develop an interactive environment which allows students to gain comfort and confidence with the layout and special procedures associated with an i.v. cleanroom as well as products
- Design cleanroom so it would be adaptable for various scenarios and changing standards as well as USP Chapter <797> compliant
- Make learning enjoyable

The Solution

- Proposal for "Development of Virtual Reality USP Chapter <797> Compliant Clean Room"
  - $70,000 educational innovation grant from Purdue University
- Partner with Envision Center for Data Perceptualization at Purdue to create a virtual cleanroom
  - Three computer technology students
  - The pharmacy students
  - Version one designed over the course of a year after visiting multiple Indiana cleanrooms
  - Validated as USP Chapter <797> compliant by member of coordinating committee

The Technology

- Multi-wall immersive environment which works on wall sized panels as well as a portable display system
- Equipment involved
  - 3-D glasses
  - Wireless controller for navigation (AKA joystick)
  - Head tracking device to adjust the view of the student

The Lab Session

- Learning Objectives
  - List USP Chapter <797> standards for a cleanroom
  - State the proper attire for a cleanroom
  - Describe the physical layout and basic cleanroom procedures
  - Identify safety issues within a cleanroom
  - Evaluate an actual intravenous medication order for accuracy
  - Select the appropriate product(s) for i.v. preparation
  - Generate recommendations for prescribers, as appropriate

The Lab Session

- Pre-assessment and proper attire
- Activities
  - Orientation to cleanroom environment
  - Safety issues
  - Medication order assessment
  - Product preparation
- Post-assessment

The Lab Session

- Virtual Cleanroom Exercise
  - Tour of the cleanroom
  - Review of environmental processes and procedures
  - Safety issues and product preparation

Anteroom	Chemotherapy Room	Clean Room
Trissel's Handbook	Spill on Floor	Drink in Refrigerator
ADD-vantage Bags	Vancomycin Bottle in Hood	Overflowing Sharps Container
Linezolid Vial	Cigarette in Hood	Cardboard Boxes
Large Volume IVF	Syringe Laying on Edge of Hood	Stock Bottle Blocking Syringe in Hood

The Lab Session

Ceftriaxone	Methylprednisolone
Diltiazem	Norepinephrine
Heparin	Potassium chloride
Meropenem	Tobramycin

The Lab Session

- ***Heparin 25,000 units in 100 mL, infuse over 1 hour***
- Did the physician write this order appropriately?
- Does this medication need to be reconstituted before dilution? If so, how?
- What is a normal concentration for this preparation following dilution?
- If there are multiple products/strengths available, which is the most appropriate? Why?

The Lab Session

- ***Heparin 25,000 units in 100 mL, infuse over 1 hour***
- How much active drug should be used and how is this quantified based on the chosen product?
- Which diluent is most appropriate for use with this medication? How much?
- Are there any infusion rate requirements for this medication? If so, what are they?
- Are there any special storage requirements for this product?

The Lab Session

- Results
  - 96% of students participated
  - 59% had no prior I.V. Room experience
  - 88% agreed or strongly agreed the lab met their expectations
- When resurveyed at end of the APPE experience, 92% of students who participated felt the virtual environment was helpful to their understanding prior to the real experience

The Lab Session

- Results

Statement	Pre-Assessment	Post-Assessment
Medication errors can significantly impact patient outcomes	96% A/SA	96% A/SA
The likelihood of a skilled pharmacist making an error is low	57% D/SD	64% D/SD
My potential for making an error upon entering practice is low	73% D/SD	73% D/SD

The Lab Session

- Results

Statement	Pre-Assessment	Post-Assessment
I perceive medication errors to be more significant after completing this lab	N/A	75% A/SA
My experience in the virtual clean room has enhanced my understanding of clean room procedures	N/A	88% A/SA
The problem assigned for this lab reinforced my understanding of order processing within the clean room setting	N/A	90% A/SA

The Lab Session

- Feedback
  - "…very hands-on and provided a realistic example of clean room standards and violations."
  - "I got a great appreciation of what a clean room actually is. I think in a real clean room I would be overwhelmed with things and wouldn't appreciate them as much."
  - "The 3-D technology is fun and… whenever you can get out of the classroom to learn is positive."

The Lab Session

- Feedback
  - "The virtual clean lab was a great experience, especially for students with little experience in the environment."
  - "Fun lab. It gave me a lot of perspective of what a cleanroom is like."
  - "Great exercise to have us interpret IV orders!"
  - "I think this is a good experience, [I] saw what a cleanroom looks like and also how to avoid errors that could occur during IV preparation."

The Virtual Cleanroom

- Time for a tour!
  - Anteroom
  - Chemo prep room
  - I.V. Room
  - What's wrong with this picture?
  - I.V. product preparation assignment

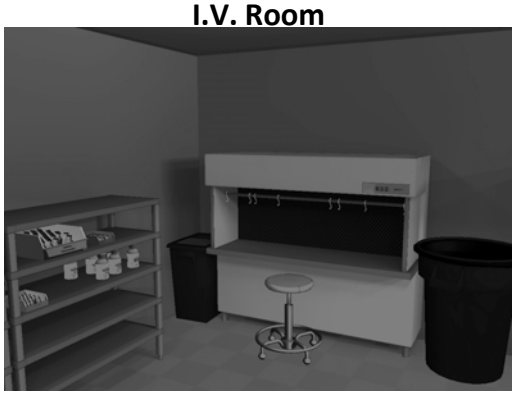
Anteroom

Anteroom

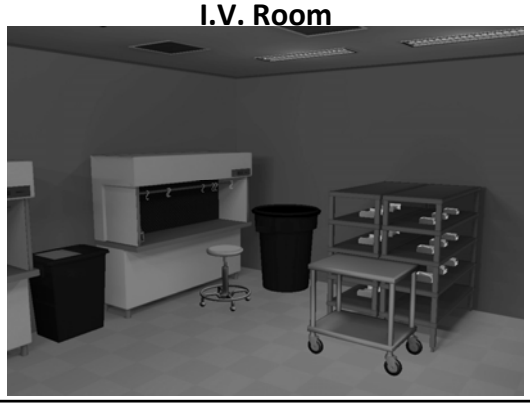
Anteroom

Chemo Room

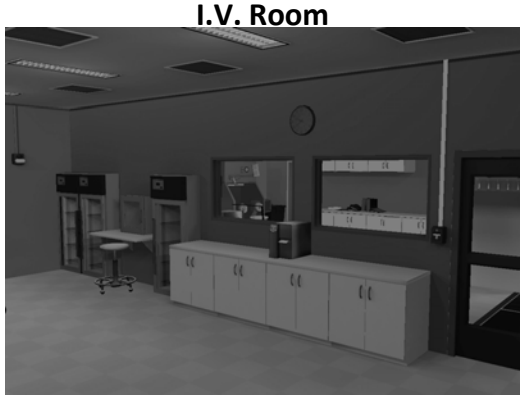
I.V. Room



I.V. Room

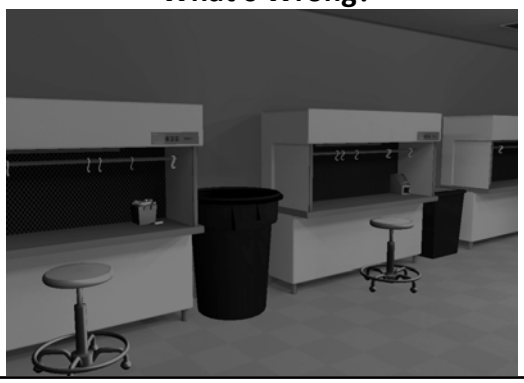


I.V. Room



What's Wrong?

What's Wrong?



I.V. Product Selection

I.V. Product Selection

Future Plans

- Continue to incorporate virtual clean room into training of P3 students
- Enhance virtual clean room experience for P2 students (prior to hospital IPPE)
- Session to be mandatory
- Enhance inventory and add compounding technology
- Enhance programming for use with interactive glove and other technology
- Develop laptop and web-based platform for supplemental instruction
- Virtual community pharmacy and ICU

Recommendations for Staff Training

- Mix the methods (didactic, simulation, hands-on)
- Make it practical
- Integrate accurate examples with those containing errors
- Do not stop the learning process if a gross error is occurring (exception: stepwise procedures)
- Incorporate common sense

Conclusion

- Unique solution developed for a complex problem
- Allowed students to gain hands-on training in a virtual environment modeled from actual cleanrooms throughout Indiana
  - Majority of students felt their confidence with and understanding of i.v. cleanrooms had improved as a result
- Progressive and effective way to provide an introduction to an i.v. cleanroom and its common components, aseptic procedures, USP Chapter <797> requirements, and medication safety

Conclusion

2012 Landscape of I.V. Medication Safety

- Human factors continue to be at the root of harmful events related to i.v. medications
- Expect significant changes in regulatory requirements for sterile compounding at national and state levels
- Training of pharmacy staff in sterile compounding is an imperative and needs to be integrated into pharmacy education and post-graduate training
- I.V. technology continues to evolve and safe use requires significant knowledge, skills, and diligence
- I.V. errors can occur at any step of the medication use process
- I.V. Medication Management should be considered as an area for specialty development

S E L E C T E D R E F E R E N C E S

American Society of Health-System Pharmacists. ASHP guidelines on outsourcing sterile compounding services. *Am J Health-Syst Pharm*. 2010; 67:757-65.

American Society of Health-System Pharmacists. Draft ASHP guidelines on preventing medication errors with chemotherapy and biotherapy. 2012. Available at: http://www.ashp.org/DocLibrary/BestPractices/DraftDocs/DraftGdlChemo.aspx. Accessed Oct 13, 2012.

American Society of Health-System Pharmacists. Proceedings of a summit on preventing patient harm and death from i.v. medication errors. *Am J Health-Syst Pharm*. 2008; 65:2367-79.

ASHP Foundation. Outsourcing sterile products preparation: contractor assessment tool. 2011. Available at: http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool. Accessed Oct 21, 2012.

Hellums M, Alverson SP, Monk-Tutor MR. Instruction on compounded sterile preparations at U.S. schools of pharmacy. *Am J Health Syst Pharm.* 2007; 64:2267-74.

Institute for Safe Medication Practices. Sterile preparation compounding safety summit proceedings. 2011. Available at: http://www.ismp.org/tools/guidelines/IVSummit/comments/default.asp. Accessed Oct 21, 2012.

Kadi A, Francioni-Proffit D, Hindle M et al. Evaluation of basic compounding skills of pharmacy students. *Am J Pharm Educ.* 2005; 69:508-15.

National Cancer Institute. Fact Sheet: Biological therapies for cancer. Available at: http://www.cancer.gov/cancertopics/factsheet/Therapy/biological. Accessed Oct 18, 2012.

Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration – 2011. *Am J Health-Syst Pharm*. 2012; 69:768-85.

Prusch AE, Suess TM, Paoletti RD et al. Integrating technology to improve medication administration. *Am J Health-System Pharm*. 2011; 68:835-42.

Tourel J, Delage E, Lebel D et al. Smart pump use in pediatric patients. *Am J Health-Syst Pharm*. 2012; 69:1628-9.

Westbrook JI, Rob MI, Woods A, Parry D. Errors in the administration of intravenous medications in hospital and the role of correct procedures and nurse experience. *BMJ Qual Saf.* 2011; 20:1027-34.

U.S. Food and Drug Administration. Guidance, Compliance, and Regulatory Information. Pharmacy Compounding. Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm134919.htm . Accessed Oct 12, 2012.

S E L F – A S S E S S M E N T Q U E S T I O N S

1. Requirements for compounding pharmacies have been developed by the FDA.
   a. True
   b. False

2. Why is focusing on intravenous (i.v.) medication safety essential?
   a. Errors can occur at each step of the medication use process.
   b. Pharmacists do not receive sufficient training in this area.
   c. Technology can introduce new sources of error.
   d. All of the above

3. Which of the following best meets the challenges of i.v. safety?
   a. Well-trained and experienced i.v. staff
   b. Technology designed for implementation in the i.v. room
   c. Well-designed technology properly used by well-trained staff
   d. All of the above

4. The use of compounding isolators, barcode verification, and i.v. workflow software in an ISO 7 i.v. clean room guarantee correct aseptic procedures are in use.
   a. True
   b. False

5. The virtual cleanroom setting can be used to teach
   a. Individualized (hands-on) sterile compounding technique.
   b. USP Chapter <797> standards.
   c. Product compatibility.
   d. Inventory management.

6. Which of the following is true?
   a. The virtual cleanroom environment did not support the education of pharmacy students.
   b. The virtual cleanroom environment emphasizes patient/medication safety issues.
   c. The virtual cleanroom environment is inconsistent with practice.
   d. The virtual cleanroom will be outdated with changes in USP Chapter <797>.

Answer Key

1. b
2. d
3. c
4. b
5. b
6. b