Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

Presented as a Midday Symposium at the 45th ASHP Midyear Clinical Meeting and Exhibition

Monday, December 6, 2010
Anaheim, California
Please be advised that this activity is being audio recorded for archival purposes and, in some cases, for repurposing of the content for enduring materials.
AGENDA

11:30 a.m. – 11:35 a.m.  Welcome and Introduction
Burnis D. Breland, Pharm.D., M.S., FASHP
Chair

11:35 a.m. – 12:05 p.m.  Intravenous Infusion Pumps: Planning for the Future to Reduce Medication Errors

12:05 p.m. – 12:40 p.m.  Case Study 1 – Smart Infusion Pumps: A Continuous Quality Improvement Approach to Improve Patient Safety
Burnis D. Breland, Pharm.D., M.S., FASHP

12:40 p.m. – 1:15 p.m.  Case Study 2 – A Step-Wise Approach to Developing an Intravenous Medication Delivery System to Prevent and Reduce Medication Errors in a Diverse Population
Kelly A. Michienzi, Pharm.D.

1:15 p.m. – 1:30 p.m.  Closing Remarks and Discussion
All Faculty

FACULTY

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Director of Pharmacy
The Medical Center, Inc.
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**Burnis D. Breland, Pharm.D., M.S., FASHP, Chair**

Dr. Breland declares that he serves as a speaker and consultant for Hospira.

**Kelly A. Michienzi, Pharm.D.**

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

**Richard D. Paoletti, M.B.A., B.S.Pharm.**

Mr. Paoletti declares that he has no relationships pertinent to this activity.

**Erika L. Thomas, M.B.A., B.S.Pharm.**

Ms. Thomas declares that she has no relationships pertinent to this activity.
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

ACTIVITY OVERVIEW

This symposium will provide a discussion of current issues related to the optimization of smart pump technology to improve patient safety in hospitals and components of health systems. An overview of the evolution of smart pumps and their functionality will be briefly discussed. Industry, regulatory, and other national efforts to improve the safety of these medical devices will be described including the FDA Infusion Pump Improvement Initiative. Two case studies will be presented to provide examples of how institutions have implemented and utilized smart pump technology to decrease medication errors and improve patient safety. Emphasis will be placed on strategies employed to achieve pump compliance and successful efforts to utilize data to improve the quality of the drug libraries. An automated audience response system (ARS) will be used for this activity to facilitate active learning and application of knowledge to practice.

ACTIVITY OBJECTIVES

At the conclusion of this knowledge-based educational activity, participants should be able to

- List and discuss three expected outcomes of the Food and Drug Administration (FDA) Infusion Pump Improvement Initiative.
- Describe three examples of human factors that impact patient safety in the utilization of smart pump technology and discuss strategies to address these challenges.
- Discuss the ability to drive appropriate therapeutic decision-making through the use of smart pump technology.
- Describe several examples of improvements to patient care resulting from the implementation and use of smart pump technology.
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 hours (0.2 CEUs) of continuing pharmacy education credit (ACPE activity #204-000-10-476-L05P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education credit at the ASHP Learning 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 six-digit session code announced during the activity.

Tell your colleagues!

So that this educational activity can be shared with a wider audience, an on-demand web-based version is being developed. Encourage your pharmacist colleagues who were unable to attend the Midyear to look for this free online continuing pharmacy education (CPE) activity beginning in March 2011.

Please note that individuals who claim CPE credit for the live symposium are ineligible to claim credit for the web-based activity.

Watch your email for details or visit http://www.ashpmedia.org/symposia/smartpumps in March.
Instructions for Processing CPE online at http://ce.ashp.org

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

http://ce.ashp.org

1. Log in to the ASHP Learning Center using your e-mail address and password.
   
   If you have not logged in to the new ASHP Learning Center (launched August 2008) and are not a member of ASHP, you will need to set up an account by clicking on “Become a user” and following the instructions.

2. Once logged in to the site, click on “Process Meeting CE.”

3. If you are a registered attendee at the ASHP Midyear Clinical Meeting, click on the start button to the right of ASHP Midyear Clinical Meeting 2010.

   If you are not registered to attend the ASHP Midyear Clinical Meeting, click on the start link to the right of the activity title. If this activity title does not appear in your meeting list, enter the 6-digit activity code in the box above the list and click submit. The activity code for this activity is 10476. Click register again when prompted. When you receive the “thank you for registering” message, click continue. This step will bring you back to your meeting list. Click on the start link to the right of the activity title. Do not click on “remove"or you will not be able to process CE for this activity.

4. Click on the click here link to view sessions associated with the day of the activity. This activity was held on Monday, December 6, 2010.

5. Enter the session code (e.g., A12345 and note that the letter is case sensitive) which was announced during the activity, and select the number of hours equal to your participation in the activity.

6. Click submit to receive the attestation page.

7. Confirm your participation and click submit.

8. New this year, complete the overall Midyear evaluation and click the “finish” button. You will then be able to view and print your transcript.

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NEED HELP? Contact ASHP Advantage at support@ashpadvantage.com.
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

Vice President of Operations – Pharmacy, Laboratory, and Diagnostic Imaging
Lancaster General Hospital
Lancaster, Pennsylvania

Richard D. Paoletti, M.B.A., B.S.Pharm. is Vice President of Operations – Pharmacy, Laboratory, and Diagnostic Imaging at Lancaster General Health in Lancaster, Pennsylvania. He is responsible for inpatient and outpatient operations of the Pharmacy, Laboratory and Radiology Departments for a health care system that includes a 638-bed hospital with a level II trauma center and an emergency department that experiences over 100,000 visits per year. Prior to this appointment, he served as Director of Pharmacy Services at Lancaster General where he was responsible for improving the safety and efficiency of medication administration systems, designing and implementing new inpatient and outpatient pharmacies with barcode and robotic dispensing technologies, and expanding the role of clinical pharmacy practice.

Before joining Lancaster General Health in 2004, he served in various hospital pharmacy roles for over twelve years at Crozer-Keystone Health System, a five-hospital system south of Philadelphia. He is a managing partner of Shrinksafe Systems, LLC, a company that he founded to create innovative pharmaceutical packaging to improve medication safety. Mr. Paoletti and his team were recognized with two American Society of Health-System Pharmacy (ASHP) Best Practices in Health-System Pharmacy Awards in 2005 and 2009. He was recently honored as a recipient of University of the Sciences in Philadelphia Young Alumnus Award.

Mr. Paoletti received his Bachelor of Science in pharmacy from the Philadelphia College of Pharmacy, and Master of Business Administration from the University of Delaware.
Learning Objectives

• List and discuss three expected outcomes of the Food and Drug Administration (FDA) Infusion Pump Improvement Initiative.
• Describe three examples of human factors that impact patient safety in the utilization of smart pump technology and discuss strategies to address these challenges.
• Discuss the ability to drive appropriate therapeutic decision-making through the use of smart pump technology.
• Describe several examples of improvements to patient care resulting from the implementation and use of smart pump technology.

Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

Does your practice site use intelligent infusion devices?
1. No
2. Yes, for less than 2 years
3. Yes, for longer than 2 years
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

If you do not currently use intelligent infusion devices, does your practice site have plans to implement?
1. Yes, within the next year.
2. Yes, in a year or longer.
3. No plans to implement.

Intravenous Infusion Pumps: Planning for the Future to Reduce Medication Errors

Vice President of Operations – Pharmacy, Laboratory, and Diagnostic Imaging
Lancaster General Hospital
Lancaster, Pennsylvania

Types of Infusion Pumps
- General Purpose Infusion Pumps
- Patient Controlled Analgesia (PCA)
- Elastomeric
- Ambulatory
- Syringe Infusers
- Insulin
- Enteral
Recent Rx Pump Challenges

- Smart Pump Library Development
- Positioned as Device Experts
- New Smart Pump Data Analysis
- USP 797 Compliance – Local Anesthetics
- Patient Own Infusion Pumps
- New High Alert! Therapies – Prostacyclins
- Operational Budget Reductions

Smart Pumps

- Standardized Infusion Library
- Dosing Limits
- Automatic Dose Calculation
- Data Capture

Smart Pump Challenges

- Pharmacy Resource / Pump Experience
- Standardization Requirements
- Education / Training Needs
- BIG Cultural Impact on Nursing
- Device Recalls
- Wireless Network Infrastructures
- New Data Analysis Requirements
- Persistent Silo Mentality
Observations

• Difficulty finding meds in library
  – Trade vs. generic
  – Look-alikes – CefTAZidime vs CefoTETAN
  – Wrong drug selected – dose, concentration
• VTBI / infuse over times different than order
• Wrong patient weights entered
• Ordered 55mcg/kg/min – entered at 55mL/hr
• Library not utilized for various medications

Manual Programming @ LG Health

VIDEO SHOWN HERE

Safety Issues - 2005 to 2009

• More than 56,000 ADE Reports to FDA
• More than 500 patient DEATHS
• 87 Device Recalls
  – 70 Class II
    • Temporary or medically reversible event
  – 17 Class I
    • Reasonable probability of significant event or death
Recommended Reading

Infusion Pump Improvement Initiative
April 2015
Center for Devices and Radiological Health
U.S. Food and Drug Administration

http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/UCM206189.pdf

Causes for Concern

• Software Defects
  – Key bounces, inappropriate alarms
• User Interface Issues
  – Unit of measurement issues (lb/kg errors)
• Mechanical &/or Electrical Failures
  – Broken components / casing
  – Premature battery failures
  – Sparks or fires

Infusion Pump Improvement Initiative

• New requirements for vendors
  – Risk assessments for pre-market clearance
  – Design validation testing in environment
  – Post-market reporting requirements
• Facilitate device improvements
  – In-house experts reviewing software code
  – Generic Infusion Pump Project (open-source)
• Increase user awareness
• Apply technology solutions…
• Use intelligent infusion devices with dose limiting software features enabled
• Promote collaboration among IT system vendors and health care providers…
• Encourage vendors to design…
  • for interoperability…
  • for fail-safe tubing connections…

Do your nurses use smart pumps with dose-limiting features enabled?

1. Yes, compliance less than 50%
2. Yes, compliance 51-74%
3. Yes, compliance greater than 75%
4. We do NOT use smart pumps

Have you engaged vendors in conversations regarding fail-safe tubing connections?

1. Yes
2. No
Have you built any automated data comparison of IV order and pump settings?

1. Yes, for reporting purposes only
2. Yes and it’s real-time
3. Yes, real-time & RPh responds to mismatches
4. No

Intermountain Health

Have you engaged your IT vendors in conversations regarding interoperability of infusion devices?

1. Yes
2. No
Infusion Pump Interoperability will be implemented at my site...

1. Already implemented
2. Within the next year
3. In 1-5 years
4. Hopefully before I retire
5. What is infusion pump interoperability?

IV Interoperability at LG Health
IV Interoperability at LG Health

VIDEO SHOWN HERE

Programming – 17 Steps to 7

<table>
<thead>
<tr>
<th>Manual Programming</th>
<th>IV Interoperability</th>
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</thead>
<tbody>
<tr>
<td>Scan patient</td>
<td>Select CCA</td>
</tr>
<tr>
<td>Scan medication and complete required fields</td>
<td>Scan medication and complete required fields</td>
</tr>
<tr>
<td>Manually document in eMAR/BCMA</td>
<td>Scan pump channel</td>
</tr>
<tr>
<td>Program pump:</td>
<td>Press start</td>
</tr>
<tr>
<td>Select CCA</td>
<td>Select &quot;Yes&quot; to confirm</td>
</tr>
<tr>
<td>Select line</td>
<td>Press ‘OK’ to document in eMAR/BCMA</td>
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<tr>
<td>Press drug list</td>
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<tr>
<td>Selecting the IV line</td>
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<td>Adding drug</td>
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<tr>
<td>Selecting the IV line</td>
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<tr>
<td>Adding dose</td>
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<tr>
<td>Selecting the IV line</td>
<td></td>
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<td></td>
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<tr>
<td>Adding volume to be infused</td>
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<td></td>
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<tr>
<td>Press start</td>
<td></td>
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<td>Select &quot;Yes&quot; to confirm</td>
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Manual vs. IV Interoperability

<table>
<thead>
<tr>
<th>Challenges of Manual Pump Programming</th>
<th>Advantages of IV Interoperability</th>
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<tbody>
<tr>
<td>Manual input process</td>
<td>Pump programming parameters (dose/rate, weight, volume to be infused) populated by order</td>
</tr>
<tr>
<td>User must opt into safety features</td>
<td>魔ryptically occurs; guarantees correct medication is selected</td>
</tr>
<tr>
<td>Complex workflow on limited real estate</td>
<td>Streamlined workflow</td>
</tr>
<tr>
<td>Nurse must focus on one IV task</td>
<td>Pump alert display on computer screen</td>
</tr>
<tr>
<td>Limited drug library size</td>
<td>Can program rate and volume to be infused off the order for medications NOT in the drug library</td>
</tr>
<tr>
<td>Pump settings are influenced by the user</td>
<td>Standardization is introduced; pump is programmed according to order</td>
</tr>
<tr>
<td>Disconnect between what occurs on the pump and medical record</td>
<td>Pump settings are documented in the medical record</td>
</tr>
<tr>
<td>Process totally owned by the nurse</td>
<td>Pump is populated with clinically appropriate, evidence-based, safe infusion rates as profiled by pharmacist</td>
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Smart Pump Warning in EMAR

Advantages

- Ensures correct medication
- Ensures infusion pump dose limit checking
- Auto-programs even if drug NOT in library
- Documentation – real-time, actual event
- Pharmacist oversight on rate adjustments
- Data – supports performance improvement
- Standardizes IV Workflow Process

So What’s the Problem???

- Intellectual Property
- Vendor Collaboration
  - Traditional competitors required to partner?
- Lack of Industry Standards
- Regulatory Concerns
  - Is the wireless network a medical device?
  - Is the EMR system a medical device?
  - Requirement for clinical research trials?
Hope for the future

- Clinicians will study hazards & develop mitigation
- Standards will be created
- Regulators / payers will promote change
- New models will emerge
- Hospitals will adopt
- Patient safety will improve

See page 22 for enlarged view
What's the future?

Collaboration is Required

- As we continue to integrate information systems, the team required will grow. New models of hospital & vendor relationships will emerge. In order to maximize success, companies will need to openly share standardized data.

Welcome to the information age…
AAMI / FDA Summit Priorities

Top 13 Priorities Generated by Participants of the AAMI / FDA Infusion Device Summit

October 5 and 6, 2010
Silver Spring, MD

Published in AAMI White Paper October 17, 2010

1. No process for collaborative failure analysis.
   a. Lack of safe space for infusion incident related disclosure/access to information about
      problems: Consider Patient Safety Organizations (PSO).

2. Incompatibility across devices and with systems: (e.g., inconsistent bar coding, wireless, power
   supplies, HIT systems: Consider variability of systems to a national director.) HIT and
   HIMS are working on this. Lack of shared products for bar code that support data transfer.

3. A high percentage of events: AAMI are due to use errors. Address issues related to high
   percentage of sentinel events due to use errors. Figure out how to develop & implement
   a failure analysis process that makes it easy for the user to do the right thing. Consideration: e.g.,
   reusable human factors, human factor vulnerability, human factors, automated identification
   (e.g., bar coding), value of all the steps involved.

4. Standardization technology used in the infusion related systems (patient and device) across the
   product and device, across the product and device, containers, etc.

5. Lack of knowledge/familiarity with the device, lack of effective training — from both
   manufacturers & facility.

6. Alarm management not effective.
   a. High number of false alarms. Can also lead to true alarms being ignored (e.g., air).
   b. Alarms difficult to prioritize.
   c. Unclear how to resolve.

7. Widespread evidence of patient confusion (e.g., home care) — design and use issues and differences
   among home, hospital and other environments. Products designed for the home environment
   may be used in hospital environments (and vice versa).

8. Inability to determine root cause of incidents due to difficulty accessing and analyzing
   incident data. Also applies to CD.

9. Poor system (incomplete, inadequate) for reporting aggregate state/national adverse event
   data: (e.g., MAUDE, PSO).
   a. Lack of standardization that supports data aggregation.

10. The numbers are not conveying the bigger picture in terms of volume of incidents involving
    pumps. “Close calls” and “near misses” and their root causes are not required to be reported.

11. Uploading/moving/maintaining drug libraries can be difficult.
   a. Lack of coordination between pump requirements and hospital capabilities.
   b. Need for secure on-site configuration management.
   c. Difficulty in managing the same drug used in multiple units in multiple ways.

12. Lack of formulation and standardization (e.g., standardization of concentrations and transparency
    (e.g., sharing between facilities) of drug libraries.

13. Difficulty in inventory management (e.g., containers, manifolds, catheters, transport) — dealing
    with the complexity of multiple inhalers, including nebulizers, inhalers, etc.

NOTE: The top 13 priorities above were reviewed by the AAMI Infusion Device Committee at its
meeting on October 17, 2010 in Silver Spring, MD. The committee identified specific recommendations
to address the above issues.

Also, the top 13 priorities, as listed above, are not necessarily arranged in order of
importance.

http://www.aami.org/meetings/infusion.summit/presentations/Top_13_priorities.pdf
SELF-ASSESSMENT QUESTIONS

1. Which of the following statements is true about SMART pumps?
   a. SMART pumps should be implemented without standardization of IV infusions.
   b. SMART pump implementations often correct all forms of IV medication errors.
   c. Data collection and analysis is an important function of SMART pump programs.
   d. No SMART pump device has ever been recalled from the market.

2. In 2008, a summit on preventing patient harm and death was convened by the American Society of Health-System Pharmacists; several strategies were outlined to improve intravenous medication administration, including appropriate utilization of intelligent infusion devices.
   a. True.
   b. False.

3. Real-time, actual infusion programming event documentation within an electronic medication record can be a benefit of infusion device interoperability initiatives.
   a. True.
   b. False.

Answers
1. c
2. a
3. a
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**Burnis D. Breland, Pharm.D., M.S., FASHP**  
Director of Pharmacy  
The Medical Center, Inc.  
Columbus Regional Healthcare System  
Columbus, Georgia

Burnis D. Breland, M.S., Pharm.D., FASHP, is Director of Pharmacy at Columbus Regional Healthcare System, Columbus, Georgia, and Affiliate Clinical Professor, Department of Pharmacy Practice at Auburn University. He serves as preceptor for the University of Georgia, Mercer University, and South University Schools of Pharmacy. Dr. Breland also serves as Director of the Pharmacy Residency Programs at Columbus Regional.

He currently serves as a member of the Board of Directors for the Safety Net Hospitals for Pharmaceutical Access (SNHPA) and the Advisory Board for the 340B Prime Vendor Program. Dr. Breland is also Chairman of the VHA Georgia Pharmacy Advisory Council, a member of the Pharmacy Executive Council of Novation, Inc., and has previously served as Chairman of the Novation Pharmacy Purchasing Council. He has held many positions in the American Society of Health-System Pharmacists (ASHP) including Chairman of the ASHP Practice Management Group, member and Chair of the Council of Professional Affairs, and nominee for the ASHP Board of Directors and Chairman of the ASHP House of Delegates. He has served as Delegate or Alternate Delegate to the ASHP House of Delegates for the State of Georgia for many years. Dr. Breland has also been involved with the Georgia Society of Health-System Pharmacists (GSHP) in various roles including President and Chair of the Board of Directors.

GSHP recognized Dr. Breland as Pharmacist of the Year in 1990 and again in 2002. He received the 2005 Innovative Pharmacy Practice award from the Georgia Pharmacy Association, the ASHP Best Practices Award in 2002, the John W. Webb Lecture Award from ASHP, and was recognized in 2008 as a Distinguished Alumnus of the University of Mississippi, School of Pharmacy.

Dr. Breland received his Bachelor of Science Degree in Pharmacy and Master of Science in Hospital Pharmacy from the University of Mississippi, Doctor of Pharmacy from the University of Tennessee in Memphis, and completed his ASHP Accredited Residency in Hospital Pharmacy at St. Luke’s Episcopal, Texas Children’s Hospital, Texas Heart Institute, Houston, Texas. Dr. Breland was recognized as a Fellow of ASHP in 1991.
Case Study 1:
Smart Infusion Pumps: A Continuous Quality Improvement Approach to Improve Patient Safety
Burnis D. Breland, M.S., Pharm.D., FASHP
Director of Pharmacy and Clinical Research
Columbus Regional Medical Center
Columbus, Georgia

The Medical Center, Inc.

- 413 bed non-profit, community teaching hospital (DSH)
- Trauma center, level II ED, level III NICU, critical care, oncology, neurosurgery

Intelligent Infusion (Smart Pumps)

- Advanced infusion technology
- Improves medication and medication administration safety
- Technology that impacts quality of care
- Valuable technology investment
- Pharmacy should be a strong advocate for implementation
Safety Functionality

- Drug library (drug safety limits), customizable by patient care area
- Wireless technology to accommodate real time reporting and library upgrades
- Network server manages data collection and enables reporting for CQI purposes
- Capable of integration with other information systems (pharmacy, medication administration, CPOE)

Successful Implementation

- Success depends upon:
  - device selection, planning & organizing, training, communication, investigation, installation, belief in and buy in, compliance, monitoring, and CQI

Planning and Implementation

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<tr>
<td>10/30/2010</td>
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The Drug Library

• What is it: a listing of drugs and fluids, descriptions (doses or concentrations), infusion rate or dosing rate limits.
• What are safety stops or limits:
  – Upper hard limit
  – Upper soft limit
  – Lower soft limit
  – Lower hard limit

Safety Stops

Adapting to Using Safety Software

• Determine how drugs are used
• Standardize administration practices, recognize and validate need for variations
• Incorporate institution policies (e.g., potassium infusion rates)
Drug Library Build

- Determine medication administration limits
- Extensive time commitment
- Remember therapeutics and safety
- Clinical review, validate, approve
- Pharmacy ownership of the library
  - Continued ownership

All of the following statements are true about the drug library except:

1. The library contains medications with safety stops to prevent infusions beyond safe limits.
2. Is downloaded to the infusion device.
3. Is developed and supplied by the vendor.
4. Can be revised to accommodate different but safe infusion practices in patient care areas.
5. May be improved through a CQI process using infusion data reports.

Preparation and Implementation

- Education and training
- Assignment of libraries
- Customization of libraries by patient care area or service area
- Communication, feedback, reeducation
- Avoid conflicting instructions
  - Pharmacy medication label instructions consistency with safety limits
    - e.g., phenytoin load 1000 mg/100 ml, message on label to infuse over 30 minutes would exceed LSL if set at 25 mg/min
Compliance

Driving Compliance

- Education and training
- Improvements
- Measuring and reporting
- Buy in and belief in
- Enforcement, accountability
- Real time feedback, "pump rounds"
- Routine monitoring and reporting
- Reinforcement
Continuous Quality Improvement Processes

• Routine data monitoring and analysis
• Data reports provide objective data on pump use (summaries and details)
• Library improvement (safety limits)
  – Primary purpose is to assure patient safety
  – Clinically safe and effective guidelines
  – Practical considerations (improve practitioner efficiency, reduce ineffective alerts)

Examples of Standard Reports

| Device Tracker | Includes data to efficiently manage the entire inventory of infusers. |
| Device Utilization | Information on the number of hours infusers have been in use. |
| Auto Programming History | Information about usage of auto programming functionality. |
| Unrelated Medication | Information about usage of auto programming requests resulting in Drug Inhaled or Other Drug in Infuser. |
| Hard Stop History | Summary of program errors, user-corrections, and edited the program. |
| Expiration Log | Information about the medications required for a specific infuser. |
| Device Status History | Identifies devices that have not communicated for specified time period. |
| Auto-Programs with Unmatched Medications | Information about auto-programming requests resulting in No Drug Selected or Other Drug on infuser. |
| Unmatched Medication Hard Stop Detail | Line-item detail of every program where user received an alert and edited the program. |
| Hard Stop Summary | Summary of programs where user received an alert and edited the program. |
| Device Status History | Identifies devices that have not communicated for specified time period. |
| User Change Analysis | Identifies changes in user interaction to monitor infusions and follow up on notifications not sent outside of limits. |
| Medication History | Information on the number of hours infusers have been in use. |
| Medication Program by Time of Day | Summary of infusions started during each hour of the day and whether a medication was selected. |
| Medication Program | Number of infusions started during each hour of the day and whether a medication was selected. |
| Medication Program by Area | Number of infusions started during each hour of the day and whether a medication was selected. |
| Medication Program by Time of Day | Number of infusions started during each hour of the day and whether a medication was selected. |
| Most Commonly Infused Medications | Includes the top 15 most commonly infused medications selected from the drug library. |
| Most Commonly Infused Medications | Includes the top 15 most commonly infused medications selected from the drug library. |
| Soft Override Attempts | Line-item detail of every program where user received an alert and chose to continue with entered value. |
| Soft Override Summary | Summary of data regarding soft limit attempts and responses to alerts for each mediation. |
| Soft Limit Alert Responses | Summary of user responses to soft limit attempts and responses to alerts for each medication. |
| Soft Limit Alert Responses | Summary of user responses to soft limit attempts and responses to alerts for each medication. |
| Software Download | Status of downloaded infuser software including version and last transfer status. |
| Total Program Activity | Programming activity, including total edits and overrides for the selected time period. |

Data Analysis

• Currently, most commonly used reports
  – Summary report of all infusions
  – Override report of attempts beyond the soft safety stops (summary and detail)
  – Program attempts beyond the hard stop safety stops (summary and detail)
• Opportunity reports
  – Real time infusion status
  – Medications infused (system-wide perspective on medication practices)
Using Reports in CQI

- Quality management approach, always strive to improve
- Reveals practice patterns
- Enables action
  - Education of staff
  - Corrective action, change in behavior
  - Changes to the safety limits
- Enables drill down by patient care area or medication

Ongoing CQI Through Data Analysis

- On-demand reporting capabilities
- Investigation of events, irregularities
- Discussion with users; understand the issues, questions or concerns
- Patient care area specific data
- Real time discussion and intervention
- Pump rounds

Pump Rounds

- Identify infusers with cautionary symbol indicating infusions without dosing limits
- Obtain input from users (why?)
  - Understand problems and issues from the front line staff
- Investigate overrides and edit variances
  - Opportunity to provide education
  - Opportunity to improve library
Library Upgrades

- **Frequency**
  - initially (quarterly or sooner)
  - less frequent thereafter (every six months)
- **New product additions**
- **Review administration practices**
  - adjust if necessary for practical purposes, but only if clinically safe
- **Pharmacy and Therapeutics Committee role**
- **Communication of changes**

Example of Library Changes

- **Heparin: (units per hour)**
  - Initially LH ---, LS 50, US 1500, UH 2500
  - Revised LH 500, LS 700, US 1500, UH 2500
  - Revised LH 400, LS 700, US 1500, UH 2500
- **Heparin High Dose: (units per hour)**
  - After four years
  - LH 1500, LS 2000, US 2500, UH 2900

Examples of Library Changes

- **Phenytoin: (mg/min)**
  - Load of 1000 mg/100 ml over 30 minutes
  - Initially: LH ---, LS ---, US 25, UH 50
  - Revised: LH ---, LS ---, US 40, UH 50
- **Amiodarone 450 mg/250 ml: (mg/min)**
  - Initially: LH ---, LS 0.5, US 1, UH 2
  - Revised: LH ---, LS 0.24, US 1, UH 2
- **Atracurium 250 mg/250 ml: (mcg/kg/min)**
  - Initially: LH ---, LS ---, US 9, UH 15
  - Revised: LH ---, LS ---, US 10, UH 15
Examples of Library Changes

- Propofol 1000 mg/100 ml: (mcg/kg/min)
  - Initially: LH ---, LS ---, US 75, UH ---
  - Revised: LH ---, LS ---, US 75, UH 250

- Nicardipine 20 mg/200 ml: (mg/hr)
  - Initially: LH ---, LS 1, US 9, UH 15
  - Revised: LH ---, LS 0.1, US 10, UH 15

- Norepinephrine 8 mg/250 ml: (mcg/min)
  - Initially: LH ---, LS 1, US 16, UH 30
  - Revised: LH ---, LS 1, US 20, UH 30

Analyzing Catches

- Heparin 25000 units/250 ml
  - LH limit (400 units/hr); set at 15; revised to 1000
- Pip/Tazo 3.375 g 4hr inf 3375mg/120ml
  - LH limit (34 ml/hr); set at 301; revised to 30
  - UH limit (34 ml/hr); set at 100; revised to 30
- Potas – KCl IVPB 100 ml 40 mEq/100 ml
  - UH limit (10 mEq/hr); set at 4041; revised to 10
- Potas – KPHos 30 mm 100 ml
  - UH limit (100 mEq/hr); set at 525; revised to 25
- Vancomycin 1500 mg/500 ml
  - LH limit (1 gram/hr); set at 8; revised to 0.8
  - UH limit (1 gram/hr); set at 1.52; revised to 0.75
- Doripenem 500mg 4 hr inf 500 mg/112ml
  - LH limit (32 ml/hr); set at 200; revised to 25
- Insulin 100 units/100 ml
  - UH limit (30 units/hr); set at 22; revised to 2
Critical Catch

- 62 y.o. male, transported via helicopter to ED
- Intubated during transport
- Seizure disorder, coagulopathy, acute renal failure, right lower lobe pneumonia
- Heparin 5000 unit load; infusion of 1100 units/hr; rule out pulmonary embolism
- Heparin 5000 units IVP; then pump set at “5”
- Nurse was thinking about 5000 load
- Lower hard safety limit set at 400 units/hr
- Pump caught error, nurse corrected rate

Critical Catch

- 73 y.o. male brought to ED via ambulance, presumptive diagnosis of stroke
- Intubated due to severe SOB and altered mental status
- Midazolam infusion ordered, 2 mg/hr
- On day two, ICU nurse set midazolam infusion at 32 mg/hr
- Nurse had in mind the amiodarone infusion she had just set at 33 ml/hr
- Midazolam UH limit of 10 mg/hr prevented the error

Library Review of Select Antimicrobial Agents
11-14-2008

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Lower Hard</th>
<th>Lower Soft</th>
<th>Upper Soft</th>
<th>Upper Hard</th>
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<tbody>
<tr>
<td>Doxycycline 100 mg/250 ml</td>
<td>63 ml/hr</td>
<td>75 ml/hr</td>
<td>150 ml/hr</td>
<td>200 ml/hr</td>
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<tr>
<td>Gentamicin ODD 100 ml</td>
<td>60 ml/hr</td>
<td>75 ml/hr</td>
<td>200 ml/hr</td>
<td>250 ml/hr</td>
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<tr>
<td>Gentamicin Conventional 50 ml</td>
<td>50 ml/hr</td>
<td>100 ml/hr</td>
<td>150 ml/hr</td>
<td>200 ml/hr</td>
</tr>
<tr>
<td>Meropenem 100 ml – 140 ml</td>
<td>33 ml/hr</td>
<td>40 ml/hr</td>
<td>280 ml/hr</td>
<td>300 ml/hr</td>
</tr>
<tr>
<td>Piperacillin/tazobactam 50 ml</td>
<td>12.5 ml/hr</td>
<td>20 ml/hr</td>
<td>120 ml/hr</td>
<td>125 ml/hr</td>
</tr>
<tr>
<td>Piperacillin/tazobactam 50 ml 2.25g and 3.375g</td>
<td>25 ml/hr</td>
<td>40 ml/hr</td>
<td>200 ml/hr</td>
<td>220 ml/hr</td>
</tr>
<tr>
<td>Linezolid 300 ml</td>
<td>125 ml/hr</td>
<td>150 ml/hr</td>
<td>300 ml/hr</td>
<td>500 ml/hr</td>
</tr>
</tbody>
</table>
Using Drug Administration Limits to Drive Therapeutic Outcomes

• Piperacillin/tazobactam*
  – 3.375 gm 4 hr inf:  26, 28 – 32, 34
  – 3.375 gm 30 min:  12.5, 20 – 120, 125
• Doripenem**
  – 500 mg 4 hr inf:  24, 26 – 30, 32
  – 500 mg 1 hr inf:  96, NL – NL, 114
• Prolonged infusions set with narrow infusion limits


Smart infusion pumps may be utilized to accomplish all of the following except:

1. Prevent administration of medications at unsafe doses or unsafe infusion rates.
2. Improve the standardization of medication infusion practices within the institution.
3. Aid in improving therapeutic outcomes by driving medication administration practices using narrow safety stops.
4. Alert users of medication doses in unusual ranges.
5. Enforce the formulary.

Sharing of Data

• Monthly (in person) report to nursing directors: present overall performance
• Periodically review edit variance reports by clinical area (patient care area or service)
• Explanation of data, discussion of catches
• Determination of educational needs
• Obtain feedback for individual practitioners
Future Reporting Needs

- Reports: auto-run and on demand
  - Condensed, Excel or PDF, custom designable, focused on events > 1 standard deviation from the mean
  - Measures and advises of opportunities to make safety limit changes due to frequency of overrides exceeding soft limits and within hard limits
  - Report advising of medications in CCA but not used; frequency report over user defined time period
  - Report that automatically notifies manager via e-mail or FAX real time of override within X% (user defined) of hard limit based on soft limit; real time reporting
  - Report of repeated override or edits in same area over time (same repeating error)
  - Report notification of variations in safety limits of same drug by CCA
  - Sent direct via e-mail to CCA manager/other

Conclusion

- Planning, education and training, implementation: a team effort
- Wireless technology is essential
- Importance of library build cannot be overemphasized - time consuming but worth the effort!
- Pharmacy must take responsibility for and own the library

Conclusion (continued)

- CQI process: early and continuous (ongoing)
- Analysis of data: understanding edits and overrides
- Sharing of information: timely feedback, pump rounds
- Enhance compliance: education, library refinement and auditing
  - Safe only if used
CQI with Intelligent Infusion Devices

- Medication safety is never enhanced by static behavior. We must continually review and seek to improve processes to prevent errors and reduce adverse drug events.
SELF–ASSESSMENT QUESTIONS

1. Intelligent infusion devices or smart pumps offer IV medication infusion safety improvements including all of the following EXCEPT

   a. Provide records of pump programming steps.
   b. Enables monitoring of medication infusion practices.
   c. No mechanism to infuse medications not listed in the pump library.

2. Standard CQI reports that may be useful in monitoring intelligent infusion devices include all the following EXCEPT

   a. Real time spectrophotometer analysis of medications being infused.
   b. Programming attempts beyond the hard safety limits.
   c. Overrides beyond the soft safety limits.

3. Smart infusion pumps may be used to accomplish all of the following EXCEPT

   a. Prevent administration of medications at unsafe doses or unsafe infusion rates.
   b. Improve the standardization of medication infusion practices within the institution.
   c. Alert users of medication doses in unusual ranges.
   d. Enforce the formulary.

Answers

1. c
2. a
3. d
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety
Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety

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Kelly A. Michienzi, Pharm.D. is Clinical Pharmacy Coordinator at Kaleida Health, Women and Children’s Hospital of Buffalo in New York where she primarily practices in neonatal and pediatric critical care. She currently serves as co-chair of the Pediatric Pharmacy and Therapeutics Subcommittee. She maintains the adult and pediatric drug library and the standard concentrations for Women and Children’s Hospital of Buffalo. Dr. Michienzi also precepts Lake Erie College of Osteopathic Medicine, and St. John Fisher College Wegmans School of Pharmacy IPPE and APPE pharmacy students, and Kaleida Health PGY-1, PGY1 pediatric, and PGY-2 critical care residents in addition to serving as Adjunct Clinical Instructor and Preceptor for the State University of New York at Buffalo School of Pharmacy and Pharmaceutical Sciences.

In 2009, Dr. Michienzi and the team at Women and Children’s Hospital of Buffalo were awarded the American Society of Health-Systems Pharmacists (ASHP) Research and Education Foundation Award for Excellence in Medication-Use Safety. Dr. Michienzi is a reviewer for the American Journal of Health-System Pharmacy (AJHP) and several books, including the ASHP Smart Pump Implementation Handbook. Dr. Michienzi is an active member of several professional organizations including the Society of Critical Care Medicine, American College of Clinical Pharmacy, and ASHP.

Dr. Michienzi received her Doctorate of Pharmacy from the State University of New York at Buffalo, School of Pharmacy and Pharmaceutical Sciences in Buffalo, New York. She completed an ASHP Accredited Pharmacy Practice Residency from Kaleida Health, Buffalo General Hospital in New York.
Case Study 2:
A Step-Wise Approach to Developing an Intravenous Medication Delivery System to Prevent and Reduce Medication Errors in a Diverse Population

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ISMP Guidelines for Safe Implementation and Use

• “Organizational resources must be considered”

• “The software also cannot replace independent double checks”

Drug library development

• Multidisciplinary team
  – Pharmacists
  – Nurses
    • Staff, educators, and managers
    • Transport team
  – Physicians
    • Department chairs
    • Physician pharmacologists
    • Anesthesiologists
  – Vendor consultants
  – Biomedical engineers
  – Information services & technology
Areas of Concern: Drug Library Compliance

- Why drug libraries are not used
  - Falsely low perceptions of risk
  - Failure to make timely corrections to DL for alerts that are not credible
  - Extra steps to use technology / time pressures
  - Clinical emergencies
  - Culture supporting at-risk behaviors including technology work arounds

ISMP Medication Safety Alert! Smart pumps are not smart on their own. April 19, 2007 Volume 12 Issue 8.

Increasing Drug Library Usage

- Listed most common drugs / indications first
- Front line follow up
- Timely drug library updates
- Make it easy to do right - hard to do wrong
- Publicizing “good catches”

Drug Library Compliance
October 2009 – October 2010

<table>
<thead>
<tr>
<th></th>
<th>Total Programs</th>
<th>Alerts</th>
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</thead>
<tbody>
<tr>
<td>No alert</td>
<td></td>
<td>52.7%</td>
</tr>
<tr>
<td>Code Rate Changes</td>
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<td>18.8%</td>
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<tr>
<td>Code Longevity</td>
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</tr>
<tr>
<td>Code Related</td>
<td></td>
<td>18.8%</td>
</tr>
<tr>
<td>Order Call</td>
<td></td>
<td>18.8%</td>
</tr>
<tr>
<td>VVM Exception</td>
<td></td>
<td>18.8%</td>
</tr>
<tr>
<td>VVM Call</td>
<td></td>
<td>18.8%</td>
</tr>
<tr>
<td>Total</td>
<td>52.7%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
Drug Library Development: Drug List

- Continuous Infusions
- Standard concentration list
- Stat log / fill list
- R.N. requests
- Sample libraries
- IV medication policy

- Intermittent Doses
  - Drug class
    - Antibiotics/antifungals
      - Exceptions
        - vancomycin
        - acyclovir
    - Aminoglycosides
    - Individual drugs

Areas of Concern

- How to represent diverse patient populations within the same unit
  - Creative naming
  - Creative ordering
- How do you engage anesthesiologists?

Customized Drug Naming

- Tall man lettering
- Drug indication
  - “Heparin-ECMO” and “Heparin-anticoagulation”
  - “Insulin” and “Insulin for Overdose” and “Insulin —OB”
  - “Vasopressin-Shock”, “Vasopressin-GI Bleed”, and “Vasopressin-DI”
  - “Norepinephrine” and “Norepinephrine ADULT”
Standard Concentrations

- Multiple concentrations per drug
- Drop-down menu listing concentrations
- Health-system wide vs. house-wide vs. unit specific concentrations
- Anesthesiologists

When it comes to standard concentrations, how much is too much?

1. 2 concentrations
2. 3 concentrations
3. 4 concentrations
4. All of the above

Know when to say when... know your unit, know your needs.

Standard Concentrations
Standard Concentrations

What is wrong with this picture?

1. Too many concentrations
2. Concentrations begin with the same number
3. Nothing. It’s for a NICU and we’re special!
4. 1 and 2

Standardizing Dosing Units

• Vasopressin – DI
  – milliUnits/kg/hr
• Vasopressin – Shock
  – Units/kg/min
• Vasopressin – Shock (milliUnits)
  – milliUnits/kg/min
• Vasopressin – Shock ADULT
  – Units/min
• Vasopressin GI Bleed
  – Units/kg/min
• Vasopressin GI Bleed (milliUnits)
  – milliUnits/kg/min
Additional Dosing Considerations

- Multiple dose checks per drug
  - Rate
  - Dose/kg
  - Total Dose
- mEq/kg/hr
  - KCl and other electrolytes
    - Also want max total dose

User feedback

- Simplify
  - Vasopressin
    - Three indications
    - Two concentrations
    - Two different dosing conventions
- Diversify
  - IV Fluids
    - Arterial line solution
    - Central line solution

Which of the following statements are included in the ISMP Guidelines?

1. Dispel any misperceptions that certain areas are unique and cannot standardize practices, procedures, or drug libraries.
2. Pediatric/NICU/Nursery drug concentrations may differ from adult care areas.
3. OR/PACU medications, concentrations, and specific doses may be administered that should never be used in other patient care areas.
4. All of the above.
Drug Library Development

• Avoid over exposure to overrides
• Mirror your library to your standard of care
• Nursing education
  – Max doses in pump allow for outliers
  – Soft limits encompass most patients
  – Gut check = double check
  – Drug library is not the safe dose check for nursing

Drug library development: Patient care areas

• Pump settings
  – Alarms
  – Lights/brightness
  – Pressure limits
• Patient care areas
  – Consider report abilities
• Code CCA
• Training CCA

Customizing Patient Care Areas

• NICU
  – grams
  – VTBI
  – no bolus
  – Max rate: 30 ml/hr
  – Max weight 10 kg
• PICU
  – Kg
  – Volume infused
  – Allow bolus off primary
  – Drug specific max rates
Patient Care Areas

Training Drug Library

Multi-campus Health Systems

- Same patient population at different campuses – same library limits
- Epinephrine
  - mcg/kg/min vs. mcg/min
  - “Epinephrine-ADULT” and “Epinephrine”
- Labetalol
  - mg/min vs. mg/kg/hr
Drug Library Changes

- OB library
  - Changed insulin to units/ hour (not units/kg/hr)
  - Consistency between sites for multi-campus health systems
- Reports
  - Programmed magnesium load: 50 grams
  - Intended load 4 grams / 50 ml bag
  - DL limits prevented the error
  - Importance of integration
    - Safety software alone isn’t enough; drug availability alone isn’t enough
    - PB for loading dose; larger volume diluted bag for maintenance infusion

Drug Library Development

- Know the pump weight
  - If pump weight changes, how does the drug delivery change
- Know how changes in other fields affect the dose
  - Time
  - Rate
  - VTBI

Drug Library Development

- Know what infusion errors occur at your site and why
  - TPN and intralipid rates flip flopped
  - Patient receives 24-hour intralipid dose in a few hours
  - Solution: make intralipids weight based with a daily max of 4g/kg/day
  - RN enters weight and rate in ml/hr
  - Dose is double checked in g/kg/day
- Importance of Integration
  - Staggered dispensing of TPN / intralipids in 2010
  - 2008: 16 reported attempts
  - 2010: 9 reported attempts
User Feedback

Concentration / ml vs. total drug / total volume

- Dopamine in PICU 1600 & 3200 mcg/ml in automated dispensing machine
- $800 \text{ mg} / 250 \text{ ml} = 3200 \text{ mcg/ml}$
- $800 \text{ mcg/ml}$ also in library for NICU transfers / ECMO
- Error: pick 800 mcg/ml instead of 3200 mcg/ml
- Delete 800 mcg/ml from PICU drug library
- RNs instructed to use NICU drug library for small patients

User Feedback

- Anesthesiologists
  - Concentrations
    - List of standards plus options for inputting total mg/ total ml
    - "vial in a bag"
  - Doses
    - Soft limits only
    - Hard limits
    - Alarm settings

Catches

- IVIG
  - Upper Hard Limit 0.08 ml/kg/min
  - Attempted infusion rate: 0.8 ml/kg/min
  - New pump, new drug library, new nurse, new fellow = pump must be wrong!
Critical Catches

- Insulin
  - Upper Hard Limit: 0.2 unit/kg/hr
  - Attempted programmed limit: 0.5 units/kg/hr
    - Reprogrammed correctly to 0.05 units/kg/hr
  - Attempted programmed limit: 7 units/kg/hr
    - Reprogrammed correctly to 0.1 unit/kg/hr

Critical Catches

- Heparin
  - Lower soft limit: 10 units/kg/hr
  - Programmed dose: 2.7 units/kg/hr
  - Reprogrammed dose: 18 unit/kg/hr
  - Not a wean
Critical Catches

- Remifentanil
  - Programmed limit 43 mcg/kg/min
  - Reprogrammed dose 0.3 mcg/kg/min

  4 inadvertently hit instead of the decimal

Critical Catches

- Epinephrine

- Attempted programmed dose
  30 mcg/kg/min

- Reprogrammed to 10mcg/kg/min

Changes Based on Reports

- Naloxone
  - Limits 0.2 – 2 mcg/kg/hr
    - Determined by references
  - Clinical experience fairly new to us
  - 2 incidents RN attempted to program rate instead of dose

  - Consider 2 entries to encompass wide dose range
Wireless Technology

- Real time data
- Potential inquires
  - Daily report of “No drug selected” entries
    - Drug not in library
    - Limits not appropriate
    - Concentration not appropriate
  - Hard limit alerts
  - High risk medication alerts
- Drug library push

How often should drug library updates occur?

1. Every month
2. Every 3 months
3. Every 6 months
4. Annually

Lessons Learned

- Anesthesia
  - Engage early and often
  - Pump cycling
  - Wireless
- Avoid Unilateral Decision Making
  - Barcodes changes
    - Purchasing Department
    - Drug shortages
- Contingency Planning
  - Who can make changes to the drug library
Lessons Learned

- Establish a process for Recalls / Alerts
  - Who is the primary contact for the vendor
    - Purchasing?
    - Pharmacy?
    - Quality?
    - Biomedical engineering?
    - Legal / risk?
    - All of the above?
  - Dissemination of Information

Clinical Pharmacists

- Data from reports for research
  - Drug use patterns by time of day
- Information about actual drug usage
  - Tachyphylaxis with cisatracurium
- Educational opportunities

Culture Change

- Nurses
  - Now ask for safety software
  - Want every drug in the library
  - Want tighter limits
- Reviewed reports retrospectively
  - Now want real time data
- Administration / QA
  - So much data available
    - QA
    - Research
SELF-ASSESSMENT QUESTIONS

1. Potential ways to increase compliance / use of the drug library include
   a. Avoid end user feedback in the development of the drug library.
   b. Use strictly alphabetical drug listing.
   c. List the most commonly used medications on the first screen.
   d. Do not include indications with drug names.

2. Pharmacy should develop the drug library independent of input from nursing and physician leadership.
   a. True
   b. False

3. To date, no published guidelines exist regarding smart pump implementation.
   a. True
   b. False

Answers
   1. c
   2. b
   3. b
Selected References


Current Considerations in the Optimization of Smart Pump Technology to Improve Patient Safety


