New and Uncommon Drugs

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48th Annual Meeting
Navigating the Oceans of Opportunity

Disclosure

☐ I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation

Objectives

☐ Explain new medications and unique dosage forms recently FDA approved
☐ Compare newer medications with existing similar agents regarding preparation, safety considerations and cost
☐ Discuss older and uncommon medications with significant preparation, safety or storage and handling requirements

Safety Stat

☐ “There is a one in 1,000,000 chance of a traveller being harmed while in an aircraft. In comparison, there is a one in 300 chance of a patient being harmed during health care.”

-World Health Organization Fast Facts

Medication Error Stats

☐ Of Preventable Medication Errors:
  ☐ 37% due to dosing issues
  ☐ 11% due to drug allergies or harmful drug interactions

☐ Due to the high volume of medications dispensed, approximately 100 undetected dispensing errors can occur each day

New Oral Anticoagulants

Apixaban (Eliquis®)
Approved: December 2012

Rivaroxaban (Xarelto®)
Approved: July 2011

Dabigatran (Pradaxa®)
Approved: October 2010
New Oral Anticoagulants

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>Apixaban</th>
<th>Rivaroxaban</th>
<th>Dabigatran</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce risk of stroke in NVAF patients</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Prevent DVT &amp; PE after hip or knee surgery</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
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<tr>
<td>Treat DVT &amp; PE</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Reduce risk of DVT &amp; PE recurrence in previously treated patients</td>
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<td>✔️</td>
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</tbody>
</table>

* When used for DVT treatment, therapy is started after 5-10 days of parenteral therapy

Kcentra®

Generic: Prothrombin Complex Concentrate (PCC)
Approved: May 2013

Kcentra®

Indication: Urgent reversal of coagulation factor deficiency caused by warfarin
- Acute major bleeding
- When urgent surgery or procedure is warranted

Dosing: 25units/kg to 50units/kg IV
- Dosing is INR dependent and based on factor IX activity

Pricing: $2.17/unit

Kcentra®

Supplied As:
- 500unit kit and 1,000unit kit

Kit contents
- Medication vial
- 20mL (500unit kit) OR 40mL (1,000unit kit) sterile water vial
- Mix2Vial filter transfer set
- Alcohol swab
Storage and Handling:

- **Un-reconstituted:**
  - Store between 36-77°F
  - Do not freeze
  - Store in the original carton protecting from light

- **Reconstituted:**
  - Store between 36-77°F: Use within 4 hours
  - Administer at room temperature
Kcentra®

- **Safety Opportunities:**
  - Confirm units for each box vs. required for the patient
  - Ensure education of staff in impacted areas
  - PCC terminology
    - Contains higher levels of factor VII and should not be confused with products that contain low levels
  - Boxed Warnings: Arterial and venous thromboembolic complications

Tranexamic Acid

- **Indication:**
  - Labeled: Reduction/prevention of hemorrhage and reduction of replacement therapy need in hemophilia patients post-tooth extraction
  - Unlabeled:
    - Trauma associated hemorrhage
    - Post-operative bleeding prevention in:
      - Cardiac surgery
      - Spinal surgery
      - Total knee replacement surgery
      - Transurethral prostatectomy
      - Blood loss reduction post-caesarean delivery

- **Comparison**

<table>
<thead>
<tr>
<th>Vitamin K dependent coagulation factors</th>
<th>Recombinant Factor VIII</th>
<th>Fresh Frozen Plasmas</th>
<th>Three-Factor Prothrombin Complex Concentrate</th>
<th>Four-Factor Prothrombin Complex Concentrate</th>
<th>Factor VIII Inhibitor Bypass Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>IX</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>VII</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>II</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>


- **Safety Opportunities:**
  - Confused drug name: Cyklokapron® vs. cycloSPORINE
  - Caution with variable dosing
  - Educate staff in affected departments
  - Administer NO faster than 100mg/min

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- **Dosing:** Variable standard and weight based

- **Supplied As:** 1000mg/10mL single dose vial

- **Pricing:** $70.43/1000mg vial

- **Preparation:**
  - May be administered via direct IV injection
  - Doses may be further diluted in 50-250mL

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  - Un-reconstituted: Room temperature
  - Reconstituted: Use the same day
  - Review package insert for generic products

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Activase®
Generic: Alteplase
Approved: June 1996

- **Indication:**
  - Thrombolytic used for:
    - Acute ischemic stroke
    - ST-elevation myocardial infarction
    - Acute pulmonary embolism (PE)

- **Dosing:** Slightly variable weight based

- **Pricing:**
  - $3,914.75/ 50mg vial
  - $7,829.50/ 100mg vial

Supplied As:
- 50mg kit
  - Medication vial
  - Sterile water for injection
- 100mg kit
  - Medication vial
  - Sterile water for injection
  - Transfer device

Activase®

Preparation:
- 50mg kit
- 100mg kit

Storage and Handling:
- Un-reconstituted: Room temperature (max 86° F) OR Refrigerated
- Reconstituted: Use within 8 hours

Safety Opportunities:
- Do NOT discard reconstituted unused vials
- High alert medication
- Ensure Nursing units have all tools needed
- Continually reeducated and reassess your process

Granix™
Generic: Tbo-filgrastim
Approved: August 2012
Granix™

- Indication: Reduction in duration of severe neutropenia when receiving some anticancer medications
- Dosing: 5mg/kg SubQ daily until absolute neutrophil count (ANC) reaches goal
- Supplied As: 300mcg/0.5mL and 480mcg/0.8mL prefilled syringes

Pricing:
- 300mcg: $286.80/syringe [filgrastim: $372.18]
- 480mcg: $459.00/syringe [filgrastim: $592.68]

Safety Opportunities:
- ISMP Safety alert May 8, 2014
- Commas instead of decimal points
- Ensure proper dating of unrefrigerated items
- Avoid shaking - DO NOT TUBE

Exparel®

- Indication: Reduction of post-operative pain by injection into the surgical site
- Dosing: Dependent on surgical site
- Supplied As: 1.3% (13.3mg/mL)
- 10mL and 20mL single dose vials
- Pricing: $342/20mL vial

Generic: Bupivacaine liposome injection suspension
Approved: November 2011

Name This Drug

- Bupivacaine liposome injection suspension
- Approved: November 2011
Exparel®

- **Preparation:**
  - 10mL vials require no further dilution
  - 20mL vials may be diluted with 10mL NORMAL SALINE

- **Storage and Handling:**
  - Refrigerated 36-46°F (do not freeze)
  - After removal from the refrigerator:
    - Unopened vials at 68-77°F for maximum of 30 days
    - Withdrawn medication or diluted vials use within 4 hours

Exparel®

- **Safety Opportunities:**
  - Confusion with conventional bupivacaine
  - Potential Harm:
    - Accidental systemic administration
      - Toxicity may manifest as cardiac anomalies and result in cardiac arrest
    - Separate sound-alike/look-alikes
    - Provide convenient labels
    - Educate and communicate
    - Stop the line

Vibativ®

- **Indication:**
  - Complicated skin & skin structure infections treatment
  - Hospital acquired & ventilator associated pneumonia treatment

- **Dosing:** 10mg/kg IV every 24 hours x 1-3 weeks

- **Supplied As:** 250mg and 750mg powder vials

- **Pricing:** $358/750mg vial

Preparation of Vibativ® for IV administration

<table>
<thead>
<tr>
<th><strong>Vibativ</strong> vial size</th>
<th><strong>Volume of reconstitution solution</strong> to add to vial</th>
<th><strong>Total volume of resultant reconstituted solution in vial</strong></th>
<th><strong>Resultant concentration of reconstituted vial</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>250 mg vial</td>
<td>15 mL</td>
<td>Approximately 17 mL</td>
<td>15 mg/mL</td>
</tr>
<tr>
<td>750 mg vial</td>
<td>45 mL</td>
<td>Approximately 50 mL</td>
<td>15 mg/mL</td>
</tr>
</tbody>
</table>

*50% Dextrose Injection, USP, Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP
**Vibativ®**

- **Storage and Handling:**
  - Un-reconstituted:
    - Refrigerated at 35-46°F in original package
  - Reconstituted:
    - Room temperature: Use within 12 hours
    - Refrigerated: Use within 7 days

- **Safety Opportunities:**
  - Confused drug name:
    - Telavancin vs. telithromycin
    - Vibativ vs. vibramycin
  - Apply appropriate dating labels

- **Boxed Warnings:**
  - Nephrotoxicity
  - Pregnancy contraindication

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**Teflaro®**

- **Indication:**
  - Treatment of acute skin and skin structure infection
  - Treatment of community acquired pneumonia

- **Dosing:** 600mg IV every 12 hours x 5-14 days
- **Supplied As:** 400mg and 600mg powder vials
- **Pricing:** $75.80/vial

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**Teflaro®**

- **Generic:** Ceftaroline
- **Approved:** November 2010

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**Teflaro®**

- **Storage and Handling:**
  - Un-reconstituted:
    - Refrigerated 36-46°F
  - Room temperature (not exceeding 77°F): Use within 7 days
  - Reconstituted:
    - Refrigerated: Use within 24 hours
    - Room temperature: Use within 6 hours

- **Safety Opportunities:**
  - Apply appropriate dating labels
Marqibo®
Generic: VinCRIStine liposomal injection
Approved: August 2012

Marqibo®
Indication: Treatment of Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) relapse after ≥2 antileukemic therapies

- Dosing: 2.25mg/m² IV every 7 days
- Supplied As: 5mg/31mL injection kit
- Pricing: $12,156.30/kit

Marqibo®
Preparation:
- Must have uninterrupted time (60-90 minutes)
- Follow hazardous medication preparation standards for your institution
- Follow detailed preparations instructions in the package insert

Storage and Handling:
- Un-reconstituted: refrigerated, do not freeze
- Reconstituted: stable for 12 hours at room temperature

Marqibo®
Safety Opportunities:
- High alert medication
- Boxed Warnings
  - Dosing is NOT interchangeable with other vinCRIStine products
  - Intravenous administration ONLY
  - Fatal if given by other routes
  - Dilute into piggybacks

Summary
- New products may provide cost saving opportunities to similar older products
- New medications may offer benefits over older similar products
- New products may come with unique indications or storage and handling requirements
- Old medications can sometimes re-invent themselves
- Don’t be afraid to stop the line
References


References