ESETT USE NEXT BOX

Erin Bengelink
Use Next Box – Study Drug Strata

Use Next Box color will correlate to study drug strata

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18 years</td>
<td>children = purple</td>
</tr>
<tr>
<td>18-65 years</td>
<td>young adults = yellow</td>
</tr>
<tr>
<td>&gt;65 years</td>
<td>older adults = gray</td>
</tr>
</tbody>
</table>
Contents

• Protocol Assist Device – iPod
• Study Drug Vial
• Broselow-like tape
• Dosing Chart
• Inclusion/Exclusion Criteria
• Instruction Card
• iPod charger
Study Drug Vial
Study Drug Vial

fosphenytoin 16.66 mg PE/ML, valproate 33.33 mg/ml, or levetiracetam 50mg/ml.
PE= phenytoin equivalent.
I.V. Solution in 0.9% sodium chloride injection.

Caution: New Drug - Limited by Federal Law to Investigational Use
Manufactured by University of California, Davis

This vial contains 100 mL.
IND Number: 119756
Length Based Weight Estimation

Colors match Broselow

Use only for Children
Length Based Weight Estimation

MEASURE FROM THIS END
Pocket Card

- Inclusion Criteria -
- Seizing for >5 minutes
- Continued/recurring now despite adequate benzo
- Last dose of benzos given >5 minutes ago
- Last dose of benzos given <30 minutes ago
- Age ≥ 2 years (and ≥ 7.5kg)

- Exclusion Criteria -
- Known pregnancy, severe metabolic/liver/renal disease
- Known allergy or contraindication to:
  - phenytoin (Dilantin), fosphenytoin (Cerebyx),
  - levetiracetam (Keppra), or valproic acid (Depakote)
- For this episode of status epilepticus already...
  - given intravenous 2nd line anticonvulsant or
  - non-benzo sedatives with anticonvulsant properties
    (propofol, etomidate, ketamine, etc) or
    - endotracheally intubated
- Status epilepticus thought to be caused by:
  - hypoglycemia < 50 mg/dL
  - hyperglycemia > 400 mg/dL
  - acute traumatic brain injury
  - cardiac arrest/post anoxia
- Prisoner
- Opt-out identification declining ESETT

Instructor HOTLINE: 1-855-ESETT-PI (373-8874)

<table>
<thead>
<tr>
<th>Estimated Weight (Kg)</th>
<th>Infusion Volume (total mL)</th>
<th>Rate (mL/min over 10 min)</th>
<th>Length Based Color (peds only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 7.4</td>
<td>Do Not Enroll</td>
<td></td>
<td>Grey</td>
</tr>
<tr>
<td>7.5 - 9.9</td>
<td>9</td>
<td>0.9</td>
<td>Pink</td>
</tr>
<tr>
<td>10 - 12.4</td>
<td>12</td>
<td>1.2</td>
<td>Red</td>
</tr>
<tr>
<td>12.5 - 14.9</td>
<td>15</td>
<td>1.5</td>
<td>Purple</td>
</tr>
<tr>
<td>15 - 19.9</td>
<td>18</td>
<td>1.8</td>
<td>Yellow</td>
</tr>
<tr>
<td>20 - 24.9</td>
<td>24</td>
<td>2.4</td>
<td>White</td>
</tr>
<tr>
<td>25 - 29.9</td>
<td>30</td>
<td>3.0</td>
<td>Blue</td>
</tr>
<tr>
<td>30 - 34.9</td>
<td>36</td>
<td>3.6</td>
<td>Orange</td>
</tr>
<tr>
<td>35 - 39.9</td>
<td>42</td>
<td>4.2</td>
<td>Green</td>
</tr>
<tr>
<td>40 - 49.9</td>
<td>48</td>
<td>4.8</td>
<td></td>
</tr>
<tr>
<td>50 - 59.9</td>
<td>60</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>60 - 69.9</td>
<td>72</td>
<td>7.2</td>
<td></td>
</tr>
<tr>
<td>70 - 74.9</td>
<td>84</td>
<td>8.4</td>
<td></td>
</tr>
<tr>
<td>≥75</td>
<td>90</td>
<td>9.0</td>
<td></td>
</tr>
</tbody>
</table>
Patient still seizing? Go to ESETT

1. IDENTIFY PATIENTS
   Look for patients who received enough benzos and are still seizing, who now need a second line anticonvulsant (fos-phenytoin, valproic acid or levetiracetam).
   Remember...adequate benzos given + still seizing = GO to ESETT!

2. GET THE ESETT BOX
   Correct color box for age.
   Review Exclusions on the Pocket Card
   Open Box, Turn On the iPod.

3. GO SPIKE VIAL & HANG FOR IV PUMP OR DRAW UP FOR SYRINGE PUMP
   Estimate Weight, prime the line, set the rate and volume (see dosing chart).
   - GO! Start Pump, touch GO on iPod, hang fluid to chase (if needed).
   - Very Low HR or BP? Give fluid, reduce rate.

4. STOP INFUSION AT 10 MINUTES
   (iPod will remind you. Take down infusion)
   Allow Drugs to Work for 10 Minutes
   Don't give other anticonvulsants until needed
   Say What You See When You See It... example "Convulsions stopped"
   Usually should NOT intubate.
   This is what we want 2nd line to do
   Still Convulsing after 10 min
   3rd Line (or preferred rescue)
   Not Convulsing? Continue to Watch

5. STUDY TEAM ARRIVES OR CONFIRM THEY ARE ON THE WAY
   Collect the box (or put in a safe place).
   Tell study team if rescue meds were given and if family is present.
   YAY...YOU DID IT!

Call for questions - 24/7 Real Time Help!
1-866-ESETT-PI (373-8874)
iPod Charger and Tether
Loading the Use Next Box

- WebDCU™ will specify which study drug vial should be placed in each box
- Once loaded in designated Use Next Box, confirmation will be required in WebDCU™
Storage

• Secured area
• Temperature controlled: 2-8 degrees C
• Easily accessible by clinical team
• Ongoing reminders to clinical team
• Back-up study drug vial stored in pharmacy
Subject Enrollment

- Treating team will use the matching Use Next Box based on the subject’s estimated weight
- Length based weight estimation tool
Restocking

• Enter randomization CRF in WebDCU™ within 8 hours
• Restock with back up vial*
• Charge iPod
• Reload length based weight estimation tool
• Reload iPod charger

*Nothing is entered into WebDCU™ for the back-up vial
Study Drug Replacement

- Enter randomization information into WebDCU™
- Next treatment assignment will be shipped
- Restock Use Next Box with back-up study drug vial
- New vial arrives, exchange with back-up vial
- Return back-up vial to pharmacy
Supplies and Contacts

• Need more boxes? Supplies? ESETT-Supplies@umich.edu

• ESETT Site Managers
  Arthi Ramakrishnan  Erin Bengelink
  arthrama@med.umich.edu  ezajaros@umich.edu
  734-936-2454  734-232-2137