Know the Predication on No Medication:
Managing Drug Shortages in EMS

- James Augustine, MD
What are the Safety Issues?

• The drugs are not there when patients need them, or in a form that is useful for the EMS provider (usually a paramedic)

• Safety for the provider:
  - Change in protocols
  - More training
  - More reading of packages
  - More need for documentation
Worsening Medication Shortages

• This is currently a problem at the manufacturer level
• Almost all injectable drug classes
• Non-compliance with regulatory standards and good manufacturing practices (GMPs)
• Recalls
• Regulatory issues (DEA vs. FDA)
• Issues with compounding pharmacies in some sites
Emergency Drug Shortage
February 2013

<table>
<thead>
<tr>
<th>Item #</th>
<th>NDC</th>
<th>Description</th>
<th>Shortage</th>
<th>Date Shortage Expected to be Reversed</th>
<th>Recovery Date</th>
<th>( RCD )</th>
<th>( RCMF )</th>
</tr>
</thead>
</table>

This Week
160 Preparations
56 Medicines
What are Opportunities?

- **Active Inventory Management**
- **Protocol Changes**
- **Packaging**
- **Point of Care Support and Education**
- **Incident Management Team and an Action Plan**

The 3 P’s
Where Fire EMS Leaders are going for Safety Info

American Society of Health-system Pharmacists: http://www.ashp.org/shortage
State Level EMS Mgt

- Cooperation/liaison with state boards of pharmacy, health, and medicine
- Flexibility in state law, rules and regulations related to personnel capabilities
- Agency oversight allowing emergency agencies and hospitals to share stocks
- Sharing of best practices, particularly related to safety
• Track Medication Budget
  - Look at expensive meds
  - Glucagon now about $160 a dose

• Overall medication list prices up 91% last year
Active Inventory Management

• Track Each Medication in Protocol
  - Know use of each medication, focus on meds on shortage list
  - Individual medicine plan
  - Work now to specify therapeutic alternatives
    • Check with State on any control issue
  - Keep medicines near expiration at site they are likely to be used
  - Reduce meds in box, keep more central
The Expired Medicine Issue

- Science says meds are effective beyond posted expiration date
- Especially if stored correctly (active inventory control management)
System Safety Opportunities

• Optimal use of supplies
• Expand Supply
• Don’t let any go to waste in community

EMS Office

Department of Health
Drug Shortage Safety Strategies – 3 P’s

- Community Meds (EpiPens)
- 1st Responders
- Protocol Changes

EMS

ALS Care

- Primary Drug Supply
- EMS Supervisor MedComm One
- Hospital Communication
- Hospital Supplies (Hazmat Meds)
- Point of Care Support
- Resupply

EMS Supervisor

MedComm One

Packaging

Safe Quality Emergency Care

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Support
Protocol Change: Each Medication with Alternatives

<table>
<thead>
<tr>
<th>Drug</th>
<th>Shortage Status</th>
<th>Where Carried</th>
<th>Therapeutic Substitution</th>
<th>Management Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>None</td>
<td></td>
<td>Ibuprofen</td>
<td>None needed</td>
</tr>
<tr>
<td>Adenosine</td>
<td>Some versions</td>
<td></td>
<td>Verapamil</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Albuterol</td>
<td>Inhalers</td>
<td></td>
<td>Levaibenol</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Some</td>
<td></td>
<td>Lidocaine</td>
<td>Substitute Lidocaine now, but issue an approval let</td>
</tr>
<tr>
<td>Aspirin</td>
<td>None</td>
<td></td>
<td>None</td>
<td>None needed</td>
</tr>
<tr>
<td>Ativan</td>
<td>Many</td>
<td></td>
<td>Midazolam, Valium</td>
<td>This is drug that needs refrig. Get state approval</td>
</tr>
<tr>
<td>Atropine</td>
<td>Many</td>
<td></td>
<td>None</td>
<td>Secure approval to tap hospital stocks</td>
</tr>
<tr>
<td>Calcium</td>
<td>Some versions</td>
<td></td>
<td>Other forms of calcium</td>
<td>Get state approval for all forms of calcium</td>
</tr>
<tr>
<td>Captopril</td>
<td>None</td>
<td></td>
<td>Lisinopril</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Cardizem</td>
<td>None</td>
<td></td>
<td>Verapamil</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Dextrose</td>
<td>Few</td>
<td></td>
<td>Different prep</td>
<td>Oral glucose</td>
</tr>
<tr>
<td>Dimenhydrinate</td>
<td>None</td>
<td></td>
<td>Diphenhydramine</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>Many</td>
<td></td>
<td>Dramaine, Vistaril</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Dopamine</td>
<td>Many</td>
<td></td>
<td>Dobutamine</td>
<td>None needed</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>Many, including</td>
<td></td>
<td>None</td>
<td>Establish hospital relationship, request they mix 1:10,000 vials</td>
</tr>
<tr>
<td></td>
<td>important 1:10,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Etomide</td>
<td>Many</td>
<td></td>
<td>Propofol (also short)</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Fentanyl, Dilaudid</td>
<td>Many</td>
<td></td>
<td>Morphine and each other</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Furesemide</td>
<td>None</td>
<td></td>
<td>Bumetanide</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Glucagon</td>
<td>Many</td>
<td></td>
<td>None</td>
<td>Very expensive. Substitute glucose or INR50</td>
</tr>
<tr>
<td>Glucose (oral)</td>
<td>None</td>
<td></td>
<td>None</td>
<td>None needed</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>Many</td>
<td></td>
<td>Droperidol</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Heparin</td>
<td>Few</td>
<td></td>
<td>Different version</td>
<td>None needed. Not an important EMS medicine</td>
</tr>
<tr>
<td>Hydroxocobalamin</td>
<td>None</td>
<td></td>
<td>Lilly Kt</td>
<td>Assure state approval</td>
</tr>
<tr>
<td>Ipratropium</td>
<td>None</td>
<td></td>
<td>Straight albuterol</td>
<td>None needed</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>None</td>
<td></td>
<td>None</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>None</td>
<td></td>
<td>Amiodarone</td>
<td>None needed</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Many</td>
<td></td>
<td>Different version</td>
<td>Establish hospital relationship</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>Some</td>
<td></td>
<td>Other beta-blockers</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Naloxone</td>
<td>Many</td>
<td></td>
<td>None</td>
<td>Establish hospital relationship</td>
</tr>
<tr>
<td>Nitroglycerine</td>
<td>None</td>
<td></td>
<td>None</td>
<td>Establish hospital relationship</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>Acute</td>
<td></td>
<td>Promethazine</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Promethazine</td>
<td>Many</td>
<td></td>
<td>Zofran, Compazine</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Sodium Bicarbonate</td>
<td>None</td>
<td></td>
<td>None</td>
<td>None needed</td>
</tr>
<tr>
<td>Solumedrol</td>
<td>Many</td>
<td></td>
<td>Desamethison, hydrocortisone</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Terbutaline</td>
<td>Many</td>
<td></td>
<td>Albuterol</td>
<td>None needed. Uncommon in EMS protocols</td>
</tr>
<tr>
<td>Thiamine</td>
<td>Few</td>
<td></td>
<td>None</td>
<td>None needed. Uncommon in EMS protocols</td>
</tr>
<tr>
<td>Valium</td>
<td>Many</td>
<td></td>
<td>Alivan, Midazolam</td>
<td>Get state approval</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>Few</td>
<td></td>
<td>Epinephrine</td>
<td>None needed. Uncommon in EMS protocols</td>
</tr>
</tbody>
</table>
Packaging for Safety

- Personnel must be confident on use of critical medicines
- Don’t discourage med use

Package for safety
## Packaging Changes
What will crews recognize easily

<table>
<thead>
<tr>
<th>Pain Medications</th>
<th>Morphine, Fentanyl, Hydromorphone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure Meds</td>
<td>Midazolam, Diazepam, Lorazepam</td>
</tr>
<tr>
<td>Nausea Meds</td>
<td>Ondansetron, Promethazine, Prochlorperazine, Droperidol</td>
</tr>
<tr>
<td>Sedatives</td>
<td>Ketamine, Etomidate, Propofol</td>
</tr>
</tbody>
</table>
Packaging for Safety

- Minimize changes in medicines
- Drugs in usable vials, carpjects and needleless forms
- Package in recognizable forms
- As medicines vary, put information right on the package
- Active inventory management
  - Less complexity for clinicians = More complexity and cost for logistics
Point of Care Support and Education

- At site of medicine acquisition
- In drug box
- On laptop computer
Point of Care for Clinical Providers

- Education
- Make the system error-resistant and ...
- Encourage error reporting
- Use IT help
Point of Care Education: Crew Notification

• Educational brochures, posters
• Email blasts
• Text messages
Incident Action Plan

- Create a management group
- Get resource persons together in-house
- Need state cooperation from EMS and pharmacy boards
- Initiate cooperation with other agencies and hospitals

Provider Satisfaction

Safety of Care

Finance and logistics

Shared drug sources: Right place, right time
Incident Management

Incident Command

Operations
Planning
Logistics
Finance

Public Information
Safety Officer
Liaisons
LEVEL 1 ADVISORY

Advisory and Preparatory Activities

Hospitals
Intel and Feedback on shortages
Design and approve agreements for sharing meds with each other and EMS

County EMS and Fire Agencies
Develop therapeutic equivalent list
Make appropriate protocol changes to allow substitutions
Using paramedic input design:
- Packaging solutions for safety
- Safety program
- Needed just in time educational programs

DOH
Assist in study of tracking program for typical and atypical meds
Study sources for atypical meds

Planning Team
Study legal and regulatory challenges and develop recommendations
Design medication tracking program and what elements of DOH program that can be applied
Create the process for declaring shortage and allowing compounding
Design a “no risk” safety reporting program
Study the central sourcing program
Publish “Drug Shortage Status Bulletin” for Command Team, state, local hospitals and providers
Develop LEVEL 3 elements and props

Finance
Budget projections on the impact of this program
Purchase Order process for timely and emergency acquisition, and designate a compounding pharmacy
Study reliable sourcing and pricing programs

LEVEL 2 MODERATE SHORTAGES

Medication shortages affect availability and patient care in emergency operations, with Life Threatening Risk

Trigger: When multiple therapeutic substitutions are being used, and multiple medicines are in shortage status at hospital and EMS sources

Hospitals approve agreements for sharing meds with each other and EMS

County EMS and Fire Agencies
Implement protocol changes to allow substitutions
Using paramedic input design initiate:
- Packaging solutions for safety
- Safety program
- Just in time educational programs
First stage of “Medication Command” utilization

DOH implements elements of tracking program for typical and atypical meds
Initiate sourcing for atypical meds

Planning Team
Implement needed legal and regulatory changes
Finalize state “releases”
Implement process for declaring shortage and start needed compounding program
Implement medication tracking program and elements of DOH program
Implement “no risk” safety reporting program
First stage implement central sourcing program
First stage of drug quality management program
Final design LEVEL 3 elements and props

Finance
Purchase Order process for timely and emergency acquisition

LEVEL 3 SEVERE SHORTAGES

Many medication shortages affect patient care, with Life Threatening Risks

Trigger: When many medicines are in therapeutic substitutions at hospital and EMS

Hospitals actively sharing meds with each other and EMS

County EMS and Fire Agencies
Implement protocol changes to allow substitutions
Full complement of packaging solutions for safety
Safety program
Just in time educational programs
Uniform use of “Medication Command” program with core group of designated personnel and distribution program

Make full use of DOH tracking program for typical and atypical meds
Implement program for use of atypical meds

Planning Team
Implement needed legal and regulatory changes
Declare shortage and fully utilize compounding program
Implement central medication sourcing program and elements of DOH program
Convert to drug quality management program doing active analysis of the “no risk” safety reporting program
Design the “all clear” criteria
Integrate Finance and timely emergency acquisition

Aftermath
Active medicine inventory management with overall less budget impact
Safer medicine packaging and “No Risk” rting
Expanded protocols and JIT education program
Safety Aftermath

- Active medicine inventory management with overall less budget impact
- Safer medicine packaging
- “No Risk” reporting
- Just in time educational process
Safety Summary

- Drug Shortage has Big Impact in Emergency Care
- Safety Impacts for Patients and Providers
- Credibility Impact for all leaders and suppliers
- Financial Impact
- Regulatory Challenge for all aspects of the system