Stockpiling Influenza Antiviral Drugs and Other Countermeasures

Biomedical Advanced Research and Development Authority (BARDA)

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Stockpiling Questions to Consider

• Why stockpile countermeasures?

• What countermeasures has HHS stockpiled for pandemic preparedness?

• What are considerations for stockpiling pandemic influenza countermeasures?
Why stockpile countermeasures for pandemic influenza?

• When we need a large quantity in a short period of time

• When it is or may become a scarce but necessary resource

• When a product has no commercial market/is not otherwise available
6.1.5. - Encourage and subsidize the development of State-based antiviral stockpiles to support response activities

6.1.6. - Ensure our national stockpile and stockpiles based in states and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics and general supply

6.1.7. - Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient antiviral medications and vaccine for front-line personnel and at-risk populations, including military personnel

6.1.9. - Establish domestic production capacity and stockpiles of countermeasures to ensure antiviral treatment for those who contract a pandemic strain of influenza
National Pandemic Influenza Antiviral Drug Program

• Target of 81 M stockpile of treatment courses between HHS and States

• Defined mix of oseltamivir and zanamivir

<table>
<thead>
<tr>
<th>Treatment Courses</th>
<th>Stockpile Type</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 M</td>
<td>HHS</td>
<td>“Quenching”</td>
</tr>
<tr>
<td>44 M</td>
<td>HHS</td>
<td>Treatment</td>
</tr>
<tr>
<td>31 M</td>
<td>State</td>
<td>Treatment</td>
</tr>
<tr>
<td>81 M</td>
<td>HHS &amp; State Combined</td>
<td></td>
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</tbody>
</table>

Development of Federal and State Influenza Antiviral Drug Stockpiles

- BARDA led and managed the State Stockpile Program to 100% participation
  - Achieved 84% of program goal for antiviral purchases
  - Collaborated with CDC to surpass goals outlined in the NSPI calling for sufficient antiviral drugs to treat 25% of the US population
  - Contracts signed with Roche, GSK and BioCryst for IV NAIs
    - IV peramivir (purchased for use under EUA)
    - HHS Critical Workforce stockpiles
## Current Antiviral Drug Stockpiles

<table>
<thead>
<tr>
<th>Antiviral Drugs (regimens)</th>
<th>Current SNS Inventory (regimens)</th>
<th>Deployed from SNS in H1N1 Domestic Response (regimens)</th>
<th>State Purchased (regimens)</th>
</tr>
</thead>
<tbody>
<tr>
<td>zanamivir</td>
<td>16.3 M</td>
<td>2.5 M</td>
<td>3.6 M</td>
</tr>
<tr>
<td>oseltamivir 75 mg</td>
<td>35.7 M</td>
<td>7.6 M</td>
<td>20.9 M</td>
</tr>
<tr>
<td>oseltamivir pediatric formulations (30 mg, 45 mg, suspension)</td>
<td>15.5 M</td>
<td>1.9M</td>
<td>1.2 M</td>
</tr>
<tr>
<td>Total</td>
<td><strong>67.5 M</strong></td>
<td><strong>12.0 M</strong></td>
<td><strong>25.7 M</strong></td>
</tr>
<tr>
<td>IV peramivir (Investigational)</td>
<td>9,071</td>
<td>2,129</td>
<td>NA</td>
</tr>
</tbody>
</table>
Other Countermeasures for Pandemic Preparedness

- Ventilators and associated equipment
- Antibiotics for secondary infections and intravenous fluids
- Personal Protective Equipment and infection control supplies
- Needles and syringes
Respirators and Masks to Support All Hazards Response

<table>
<thead>
<tr>
<th>RPD</th>
<th>SNS Inventory (March 2011)</th>
<th>Quantity Deployed in H1N1 Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95 Respirators (NIOSH)</td>
<td>12.4 M</td>
<td>27.8 M</td>
</tr>
<tr>
<td>N95 Respirators (NIOSH/FDA)</td>
<td>5.4 M</td>
<td>57.4 M</td>
</tr>
<tr>
<td>Surgical Masks</td>
<td>37.7 M</td>
<td>14 M</td>
</tr>
<tr>
<td>Total</td>
<td>55.5 M</td>
<td>99.2 M</td>
</tr>
</tbody>
</table>
Other Countermeasures for Pandemic Preparedness

Ancillary Supplies:

• 56 M kitted syringes
  — Needles, syringes, and alcohol swabs

• 10 M PFS needles (adults and pediatrics)

• 3M mixing syringes for adjuvanted vaccines
Considerations for Stockpiling

• Trade-offs and risk tolerance

• Costs - purchase, testing/maintenance and storage

• Vendor-managed inventories

• Shelf life extension

• Essential role of requirements setting
Conclusions

• BARDA, in collaboration with HHS partners, has developed a stockpile of countermeasures to support pandemic preparedness and response

• There are risks and benefits to stockpiling countermeasures

• Careful consideration must be given to align national needs with countermeasures attributes
Interfacing with BARDA

• **www.phe.gov**
  – Program description, information, news, announcements

• **www.medicalcountermeasures.gov**
  – Portal to BARDA
  – Register, request a meeting
  – Tech Watch

• **www.fedbizopps.gov**
  – Official announcements and detailed information about all government contract solicitations