Beyond the Last Mile: Monitoring and Assessing Medical Countermeasure Use in Response to Public Health Emergencies

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- Setting the Stage: Defining Terminologies and Sharing Stakeholder Perspectives
- Data Needs, Data Sources, and Collection Methodologies for Stakeholder Decision Making
- Considerations for Conducting Rapid Clinical Research on MCMs during a PHE
- Inspiring Collective Action: Perspectives from Federal Stakeholders and Reflections from Individual Workshop Participants
FDA’s MCM Roles

- Facilitating development of and access to safe and effective MCMs
- Legal mechanisms (e.g., EUA, IND, IDE, Expanded Access)
- Consumer protection
- Collaboration
- Monitoring MCM use for safety and effectiveness

www.fda.gov/medicalcountermeasures
There is a critical need for the U.S. Government (USG) to build and maintain a national capability to monitor and assess medical countermeasures (MCMs) after they are dispensed or administered in response to a chemical, biological, radiological, or nuclear threat or an emerging infectious disease.

https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm561377.htm
How is assessment different in a public health emergency?

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<th>PHE</th>
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<td><strong>Intent</strong> – respond and mitigate</td>
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<tr>
<td>Unplanned / Unexpected</td>
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<td>Uncontrolled or no data collection</td>
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<td>Undefined number of individuals</td>
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<td>Simultaneous administration / multiple products</td>
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<td>Requires rapid decision-making</td>
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<td>Little or no tracking / monitoring</td>
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<td>Lack of / limited clinical provider oversight</td>
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<td>Limited reporting and information dissemination</td>
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<th>TRADITIONAL R &amp; D</th>
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<td><strong>Intent</strong> – generalizable knowledge</td>
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<tr>
<td>Planned / Deliberate</td>
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<td>Well-controlled clinical trials</td>
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<td>Defined number of individuals</td>
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<td>Stepwise progression / single product administration</td>
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<td>Allows more time for decision-making</td>
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<td>Strict oversight and monitoring</td>
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<td>Principal investigator / clinical study staff interaction</td>
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<td>Informed consent/IRB</td>
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<td>Clearly defined reporting requirements and information sharing</td>
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www.fda.gov/medicalcountermeasures
Progress to Date

www.fda.gov/medicalcountermeasures

Image courtesy of BARDA
OCET M&A Projects in FY17 / FY18

NASEM Workshop: Building a National Capability to Monitor and Assess MCM Use in Response to PHEs
- A Stand Alone Workshop for stakeholders interested in MCM monitoring and assessment

U.S. Critical Illness and Injury Trials (USCIIT) Group / SCCM Discovery-PREP
- Streamlining Countermeasure Data Collection During Public Health Emergencies

FDA Sentinel Initiative
- Assess the Sentinel System’s capabilities to conduct MCM safety and effectiveness studies

FDA Real-Time Application for Portable Interactive Devices (RAPID) Platform
- Perform studies in real time to evaluate MCM safety & effectiveness during MCM events
USCIIT / Discovery-PREP

- Develop and pre-position protocols
- Use central IRB for expedited review of clinical protocols
- Develop eCRF for standardized data collection
- Create data dissemination plan to share key findings

www.fda.gov/medicalcountermeasures
Healthcare Professionals and consumers submit regular and emergency surveillance adverse event reports.

1. **Mobile Data Collection:**
   - Clinicians, reporters, and patients create general surveillance and emergency surveillance reports.

2. **Data Transferred to FDA:**
   - Data is submitted from mobile device and sent over Cellular network or WiFi to FDA GovCloud via web services.

3. **Perform Analytics:**
   - Utilize RAPID Dashboard, location-based data, and Empirica (signal detection) for analysis.

4. **Response Sent to Reporter:**
   - Within 24 hours a targeted response is sent via email containing links to multimedia files like images and podcasts.

5. **Obtain External Data:**
   - Data will be shared from external sources via web services (e.g., HL7 ICSR) and increase the effectiveness of analysis performed using RAPID analytical tools.

**Adverse Event Analytical Tools**
- RAPID AE Dashboard & Data
- Geovisualization
- RAPID Heatmap
- Empirica

**RAPID External Data (Future)**

**AWS GovCloud**
Patient Diagnosis Codes Present (Y/N)
- Yes
- No

Influenza IVDs Used (Y/N)
- Yes
- No

No MCM Dispensed
1. Death
2. In ICU receiving mechanical ventilation or ECMO
3. In ICU without mechanical ventilation or ECMO
4. Non-ICU hospitalization, requiring supplemental oxygen
5. Non-ICU hospitalization, not requiring supplemental oxygen
6. Discharge

MCM Dispensed (oseltamivir, zanamivir, peramivir)
1. Death
2. In ICU receiving mechanical ventilation or ECMO
3. In ICU without mechanical ventilation or ECMO
4. Non-ICU hospitalization, requiring supplemental oxygen
5. Non-ICU hospitalization, not requiring supplemental oxygen
6. Discharge
Coordination & Collaboration

NATIONAL INSTITUTES OF HEALTH
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CDC
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THE WHITE HOUSE
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U.S. DEPARTMENT OF HOMELAND SECURITY
U.S. DEPARTMENT OF CONGRESS
World Health Organization
International
DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA
Biotechnology Industry Organization
PARMA
Alliance for Biosecurity
Academia
Public
NGOs & Think Tanks
State & Local
Resources

• MCM Monitoring and Assessment (new page)
  – https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm561377.htm

• FDA Medical Countermeasures Initiative (MCMi)
  – https://www.fda.gov/medicalcountermeasures

  – https://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm

• PAHPRA (Public Law 113-5)

• MCM emergency use authorities (EUA, etc.)
THANK YOU!

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