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

Preparedness Summit
Atlanta, GA
April 26, 2017

Gregory Measer, JD
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
CBRN and EID Threats
FDA’s MCM Mission

- Facilitate the **development** of and **access** to safe and effective MCMs to counter high-priority chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats (e.g., Zika, Ebola, pandemic influenza)
FDA’s MCM Roles

• Facilitating development of MCMs; approving, licensing, clearing, and regulating MCMs

• Using legal mechanisms to prepare for and facilitate emergency use (e.g., EUAs, other emergency use authorities)

• Ensuring consumer protection against fraudulent claims; enforcing against misbranded and adulterated products

• Collaborating with government partners (e.g., HHS, NIH, CDC, DOD, State, tribal, local, and territorial (STLT) public health partners) for preparedness and response

• Monitoring MCM use for adverse events (e.g., MedWatch, VAERS) to ensure safety and efficacy of FDA-regulated products
Public Health Emergency Medical Countermeasures Enterprise

Key
- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

Acronyms
- PHEMCE: Public Health Emergency Medical Countermeasures Enterprise
- DHS: Department of Homeland Security
- DoD: Department of Defense
- USDA: U.S. Department of Agriculture
- VA: Department of Veterans Affairs
- HHS: Department of Health and Human Services
- ASPR: Assistant Secretary for Preparedness and Response
- BARDA: Biomedical Advanced Research & Development Authority
- CDC: Centers for Disease Control and Prevention
- FDA: Food and Drug Administration
- NIH: National Institutes of Health

www.fda.gov/medicalcountermeasures
External Stakeholders

- National Institutes of Health
- BARDA
- CDC
- Department of Homeland Security
- United States Congress

International

World Health Organization

NGOs & Think Tanks

CFR

AAAS

State & Local

State & Local

Academia

Public

Industry

PHEMCE
FDA Medical Product Assessment

VAERS
Vaccine Adverse Event Reporting System
A National Program for Monitoring Vaccine Safety

EvGen
Evidence Generation

Sentinel Initiative

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
http://mdic.org/cc/landscape/

NEST

BD4P

MDEpiNet

Innovation in Medical Evidence Development and Surveillance

MEDWATCH
Consumer Voluntary Reporting
(FORM FDA 3500B)

www.fda.gov/medicalcountermeasures
What Makes MCMs Different?

- MCMs pose a unique burden on data collection
  - Unapproved products made available for emergency use (e.g., via an Emergency Use Authorization)
  - Products approved under the Animal Rule with limited human data collected (yet still need to meet post-market requirements/commitments)
  - Approved products used for an unapproved indication during a PHE
  - Products dispensed/administered via non-traditional methods

- Emergency environment
  - Often the first time to collect effectiveness data in humans
  - Speed of distribution, dispensing, administration
  - Varied / uncertain geographic spread of event
  - Non-traditional locations
## Research During a PHE

### PUBLIC HEALTH EMERGENCY
- Intent – respond and mitigate
- Unplanned/unexpected
- Chaos or controlled chaos
- Large numbers of individuals
- Potential for simultaneous administration/multiple products
- Rapid decision making/response
- STLT and federal government actors/roles/authorities, with potential private/non-profit sector involvement
- Limited primary provider oversight/tracking of MCM use/monitoring of MCM adverse events and outcomes
- Limited reporting or information dissemination
- Potential for non-traditional locations (e.g., PODs, alternate care sites)
- Resource shortages (staff, space, supplies)

### TRADITIONAL MEDICAL PRODUCT R&D
- Intent – generalizable knowledge
- Planned/deliberate
- Well controlled clinical trials
- Smaller numbers of individuals
- Stepwise progression/single product
- Careful decision making/time
- Strict oversight and monitoring
  - Informed Consent/process
  - IRB Review and Approval
  - Adverse event reporting
- Traditional health care settings (e.g., hospitals with appropriate record keeping capabilities)
- Sufficient health care staffing
Establishing a Middle Lane

Limited or Anecdotal Collection of MCM Data During PHE

“Middle Lane” Centralized Coordination

Traditional Data Collection, Well Controlled Trials (e.g., RCTs)

“Middle Lane” to bridge the gap between limited or no data collection during a PHE and traditional Randomized Controlled Trial (RCT) data collection
Core Capabilities

1. Collect Data on MCMs
2. Manage, Analyze, and Interpret Data
3. Recommendations for MCM Use
4. Communication
5. Administrative/Budget Preparedness
So…what is being done about it?

Prepared for:
Food and Drug Administration,
Office of Counterterrorism and Emerging Threats
HHS Health Federally Funded Research and Development Center
Task Order No. #HHSF223201310225W

Adverse Events Monitoring and Analysis
Proof of Concept Final Technical Report

Version 1.2
August 19, 2015

Brief Report

Using a Handheld Device for Patient Data Collection: A Pilot for Medical Countermeasures Surveillance

ABSTRACT
Medical countermeasures (MCMs) are medical products used during public health emergencies. This study, conducted within the Mini-Sentinel Initiative, sought to develop the patient identification and matching processes necessary to assess safety outcomes for MCMs. A handheld device was used to collect identifying information (e.g., name, birthdate, and sex) from the drivers’ licenses of 421 individuals presenting for routine care at their primary care medical office. Overall, 374 individuals (88.8%) could be linked to their electronic health data using the driver’s license information. The device was also pilot-tested at a seasonal influenza immunization clinic: detailed vaccine information (e.g., lot number and manufacturer) was captured with a high degree of accuracy. This investigation demonstrated that a handheld device is a feasible means of collecting patient identity and medical product receipt data. This capacity should be useful for safety surveillance of MCMs, particularly when dispensed in settings outside the traditional health-care delivery system.

The Not-Too-Distant Future

- **Electronic Health Records**
  - 96% of non-federal acute care hospitals
  - ¾ of physicians

- **Data Collection and Analysis**
  - Apple, Google, IBM Watson, Intel

- **Federal Efforts**
  - Office of the National Coordinator for Health IT
  - Food and Drug Administration (Sentinel, NEST, RAPID)
  - Centers for Disease Control and Prevention
  - Biomedical Advanced Research & Development Authority (Clinical Studies Network; Analytical Decision Support)
  - National Institutes of Health (Public Health Emergency Research Review Board)
  - Department of Defense / Veterans Health Administration

...any many, many, many, many more.

www.fda.gov/medicalcountermeasures
Challenges (or Opportunities!)

- Data privacy and information sharing laws
- Institutional policies and data use agreements
- Human subjects protections
- Shift thinking beyond distribution and dispensing/administration
- Ownership of the components (and the data!)
- Sustainability and incentives

*Need more than just technology…need the infrastructure and coordination*
What’s Next?

• Why FDA? Why Here?
  – Ultimately, FDA is looked to for assurance that medical products are safe, effective, and appropriate for their intended use

• June 6-7, 2017 – NAS Workshop (Washington, DC)
  
  Building a National Capability to Monitor and Assess Medical Countermeasure Use in Response to Public Health Emergencies: A Stand Alone Workshop
  
  http://www.nationalacademies.org/hmd/Activities/PublicHealth/MedicalCounterMeasures/2017-JUNE-06.aspx
Discussion

“Data Collection”

“BIG Data”

“Monitoring & Assessment”

“Data Analysis”

“Safety”

“Communication”

www.fda.gov/medicalcountermeasures
THANK YOU!

Gregory Measer, JD
Gregory.Measer@fda.hhs.gov
301-796-2968

www.fda.gov/medicalcountermeasures
AskMCMi@fda.hhs.gov
@FDA_MCMi