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

Preparedness Summit

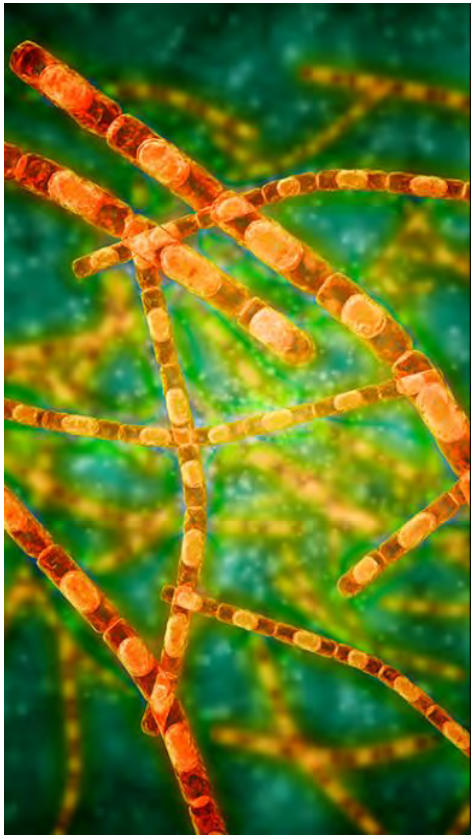
Atlanta, GA

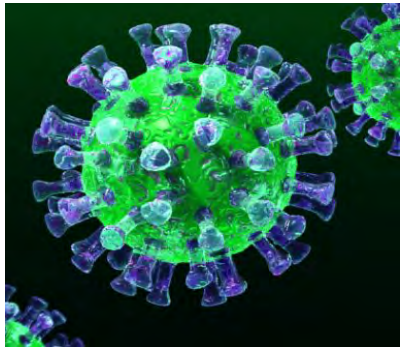
April 26, 2017

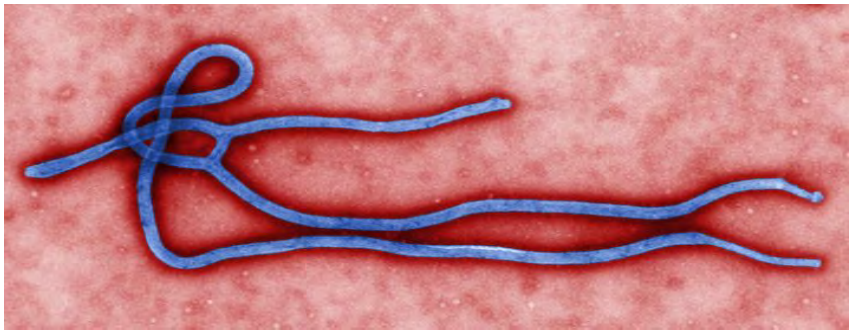
Gregory Measer, JD

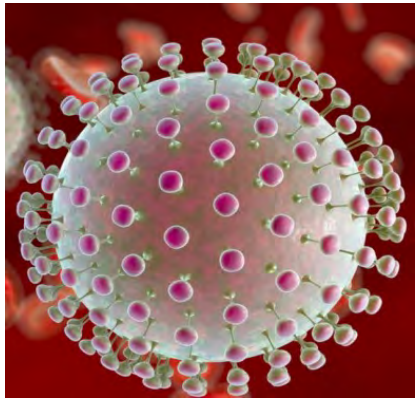
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration

CBRN and EID Threats

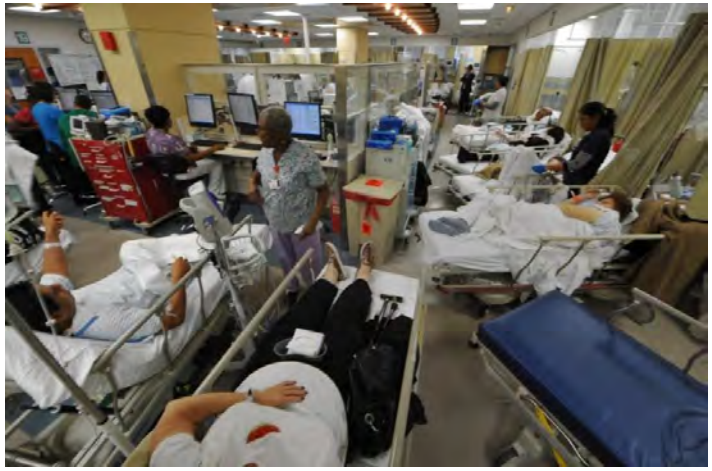








Public Health Emergencies



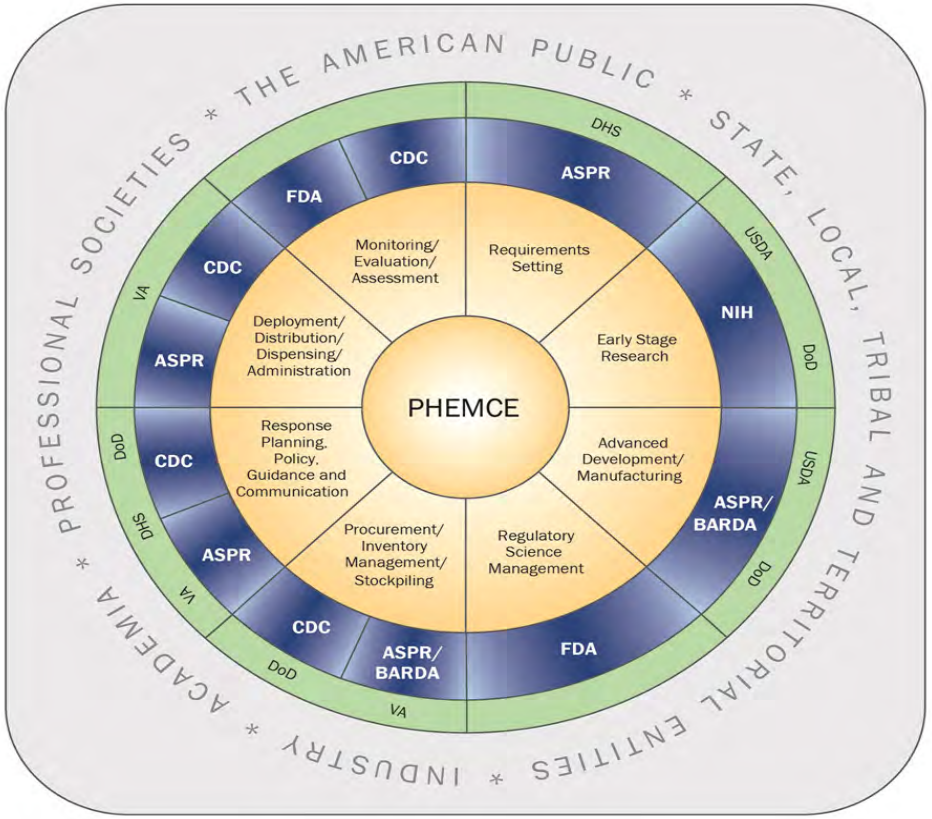
FDA's MCM Mission

- 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

External Stakeholders

FDA Medical Product Assessment

EvGen Evidence Generation

Sentinel Initiative

RAPID FDA

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

http://mdic.org/cc/landscape/

NEST

BD4P

Innovation in Medical Evidence Development and Surveillance

openFDA

FDA DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH Consumer Voluntary Reporting
(FORM FDA 3500B)

Form Approved: OMB No. 0910-0291
Expiration Date: 9/30/2018
(See PRA Statement below)

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

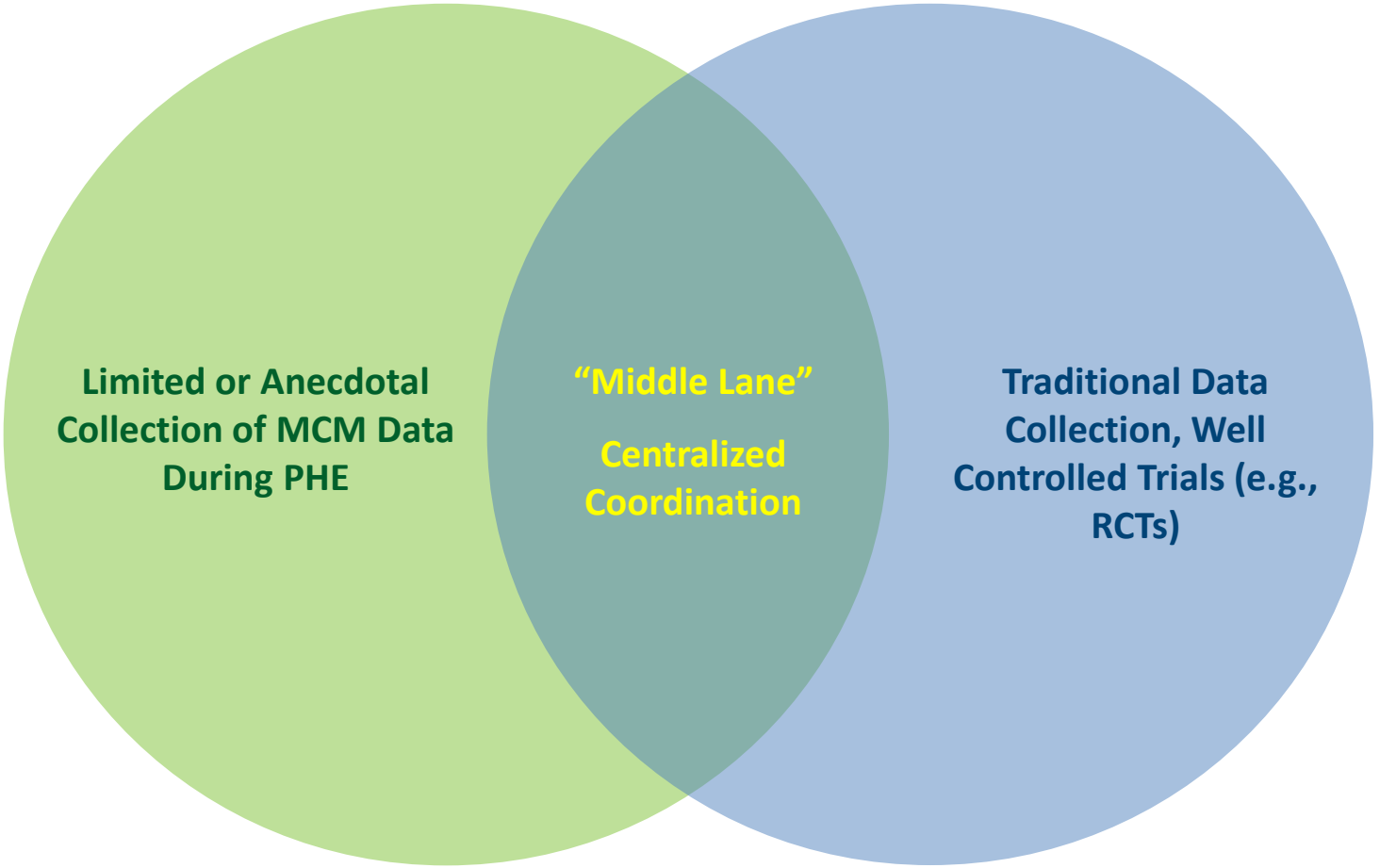
- Emergency environment
  - Often the first time to collect effectiveness data in humans
  - Speed of distribution, dispensing, administration
  - Varied / uncertain geographic spread of event
  - Non-traditional locations

Research During a PHE

PUBLIC HEALTH EMERGENCY	TRADITIONAL MEDICAL PRODUCT R&D

• 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)
	• 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



"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?

FDA

PUBLIC HEALTH EMERGENCY
PHEMCE
MEDICAL COUNTERMEASURES ENTERPRISE

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

DEPARTMENT OF VETERANS AFFAIRS
DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

RAPID FDA

Sentinel Initiative

BRIEF REPORT

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

MATTHEW F. DALEY, MD[a,b]
KRISTIN GODDARD, MPH[a]
MELISSA MCCLUNG, MSPH[c]
ARTHUR DAVIDSON, MD, MSPH[c]
GRETCHEN WEISS, MPH[d]
TED PALEN, MD, PHD, MSPH[a]
CARSIE NYIRENDA, MPH[a]
RICHARD PLATT, MD, MSc[e]
BROOKE COURTNEY, JD, MPH[f]
MARSHA E. REICHMAN, PHD[g]

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 driver's 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 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.

UNITED STATES CRITICAL ILLNESS AND INJURY
USCIITG
TRIALS GROUP

http://www.usciitg.org/

The National Academies of SCIENCES ENGINEERING MEDICINE

http://www.nationalacademies.org/

Daley MF, Goddard K, McClung M, et al. Using a Handheld Device for Patient Data Collection: A Pilot for Medical Countermeasures Surveillance. *Public Health Reports*. 2016;131(1):30-34.

www.fda.gov/medicalcountermeasures

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.

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
- Cost. Cost. Cost.
- Ownership of the components (and the data!)
- Sustainability and incentives

Need more than just technology…need the infrastructure and <u>coordination</u>

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"

"Reporting"

"Safety"

"Data *Analysis*"

"Communication"

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU!

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

www.fda.gov/medicalcountermeasures

AskMCMi@fda.hhs.gov

@FDA_MCMi