Public Health Emergency Response: Use of electronic health data

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Public Health Emergencies
Public Health Emergencies (PHEs)
Who is the PHEMCE?

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
Beyond the Last Mile: Monitoring and Assessment of PHE MCMs Post-Administration

To establish a comprehensive, government-wide coordinated capability to monitor and assess medical countermeasure (MCM) use through data collection and analysis during and after an emergency event to enable assessment and decision-making during both present and future public health responses.
Beyond the Last Mile: Monitoring and Assessment of PHE MCMs Post-Administration

To establish a comprehensive, government-wide coordinated capability to monitor and assess MCM use (safety, compliance, clinical benefit) through data collection and analysis during and after an emergency event to enable assessment and decision-making during both present and future public health responses.
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
First Steps

• Define needed dataset
• Develop simple protocol to collect needed dataset
• Send protocol to local IRBs for review
• Develop reliance agreements between local IRBs and a centralized IRB
• Pre-position IRB-approved protocol and exercise on a yearly basis

http://www.atworkmgt.nl/en/services-solutions/on-premise-implementation
2001 Amerithrax
US Critical Injury and Illness Trial Group
2016 Anthrax MCMs: Ph4 Protocols
Infrastructure for Data Exchange

Needs to be “in place the day before we need it”!
Many Moving Pieces

Primary care

First responder/EMS

Hospital-based Healthcare

EHRs and Apps

Wearables
Electronic Data Sources

Health information Exchange

- Urgent Care
- Primary Care
- Specialty Care
- Pharmacy
- Sentinel Initiative
- EvGen
- Points of Dispensing
- Community
- Public Health

www.fda.gov
Electronic Health Records

Structured data:
1. Drop-down menus
2. Standardized codes
   (e.g. NDC, SnowMed, LOINC)
3. Standardized formats
   (e.g. Radiology, MRI, CT)

Unstructured data:
1. Free text field
2. Diction field

eCase Report Forms

Paper format
Filing cabinets

Transformation
HL7, CDISC, JSON, etc

EHR Vendors

- Allscripts
- eClinicalWorks
- Healthland
- Cerner
- Epic
- McKesson
- Meditech
- Medsphere
- NextGen
- QuadraMed
- Sigmund Software

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