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

NASEM Biosecurity Luncheon

Washington, DC

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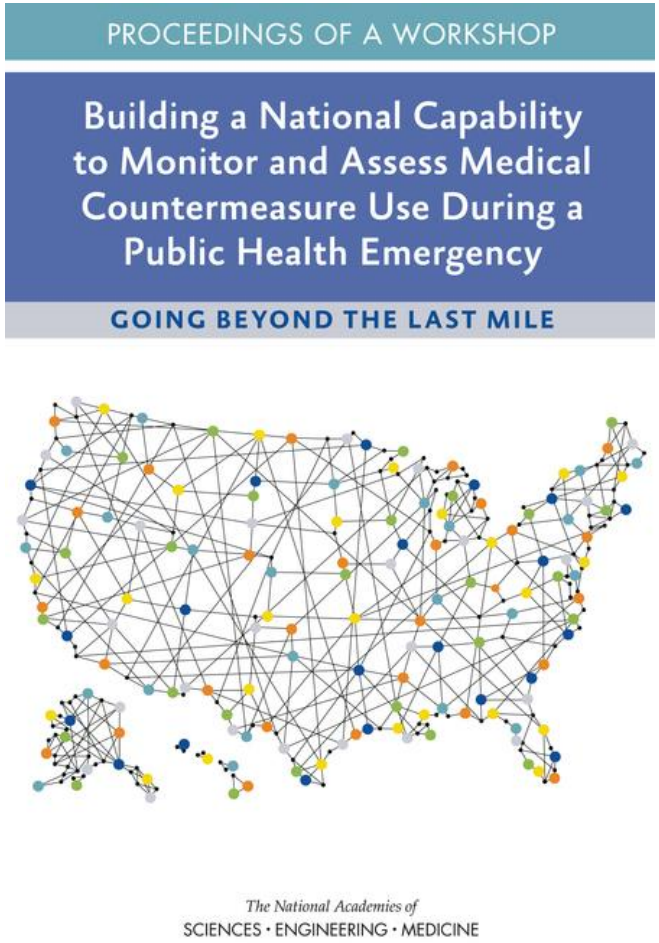
NASEM Workshop



June 6-7, 2017
Washington, DC

- 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

National Academies of Sciences, Engineering, and Medicine. 2017. Building a National Capability to Monitor and Assess Medical Countermeasure Use During a Public Health Emergency: Going Beyond the Last Mile: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/24912.

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**

Monitoring and Assessment (M&A)

The U.S. government has a limited capacity to rapidly collect and analyze public health emergency (PHE) medical countermeasure (MCM) safety and effectiveness data, especially during a PHE response.

…now what?

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?

PHE

- Intent – respond and mitigate
- Unplanned / Unexpected
- Uncontrolled or no data collection
- Undefined number of individuals
- Simultaneous administration / multiple products
- Requires rapid decision-making
- Little or no tracking / monitoring
- Lack of / limited clinical provider oversight
- Limited reporting and information dissemination

TRADITIONAL R & D

- Intent – generalizable knowledge
- Planned / Deliberate
- Well-controlled clinical trials
- Defined number of individuals
- Stepwise progression / single product administration
- Allows more time for decision-making
- Strict oversight and monitoring
- Principal investigator / clinical study staff interaction
- Informed consent/IRB
- Clearly defined reporting requirements and information sharing

Progress to Date

FDA

EvGen Evidence Generation

openFDA

PHEMCE

MDEpiNet

USCIITG

Sentinel Initiative

RAPID

The National Academies of SCIENCES ENGINEERING MEDICINE

Food and Drug Administration MEDWATCH

Innovation in Medical Evidence Development and Surveillance

BD4P

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

NEST

VAERS Vaccine Adverse Event Reporting System

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

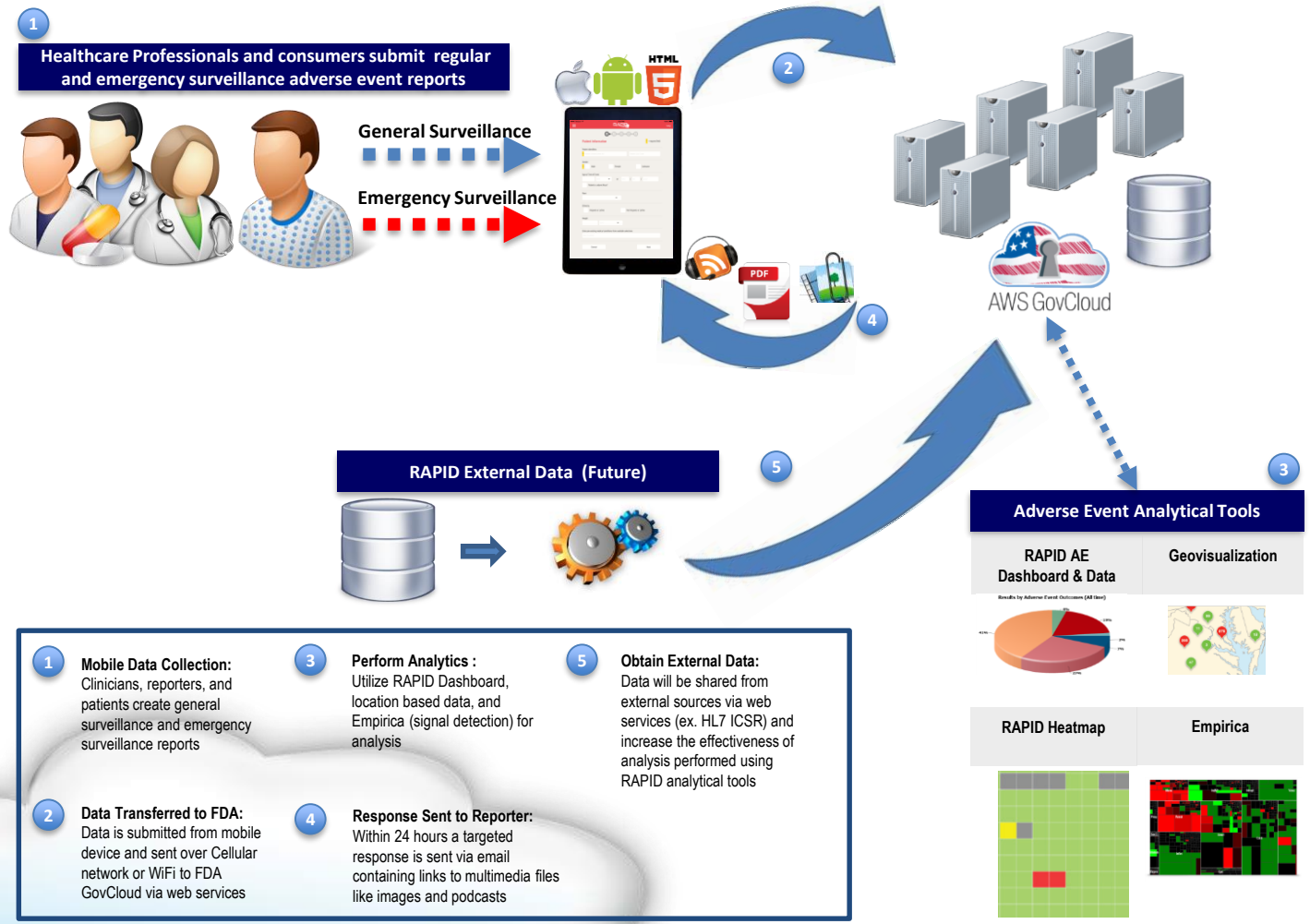
- Perform studies in real time to evaluate MCM safety & effectiveness during MCM events

USCIIT / Discovery-PREP

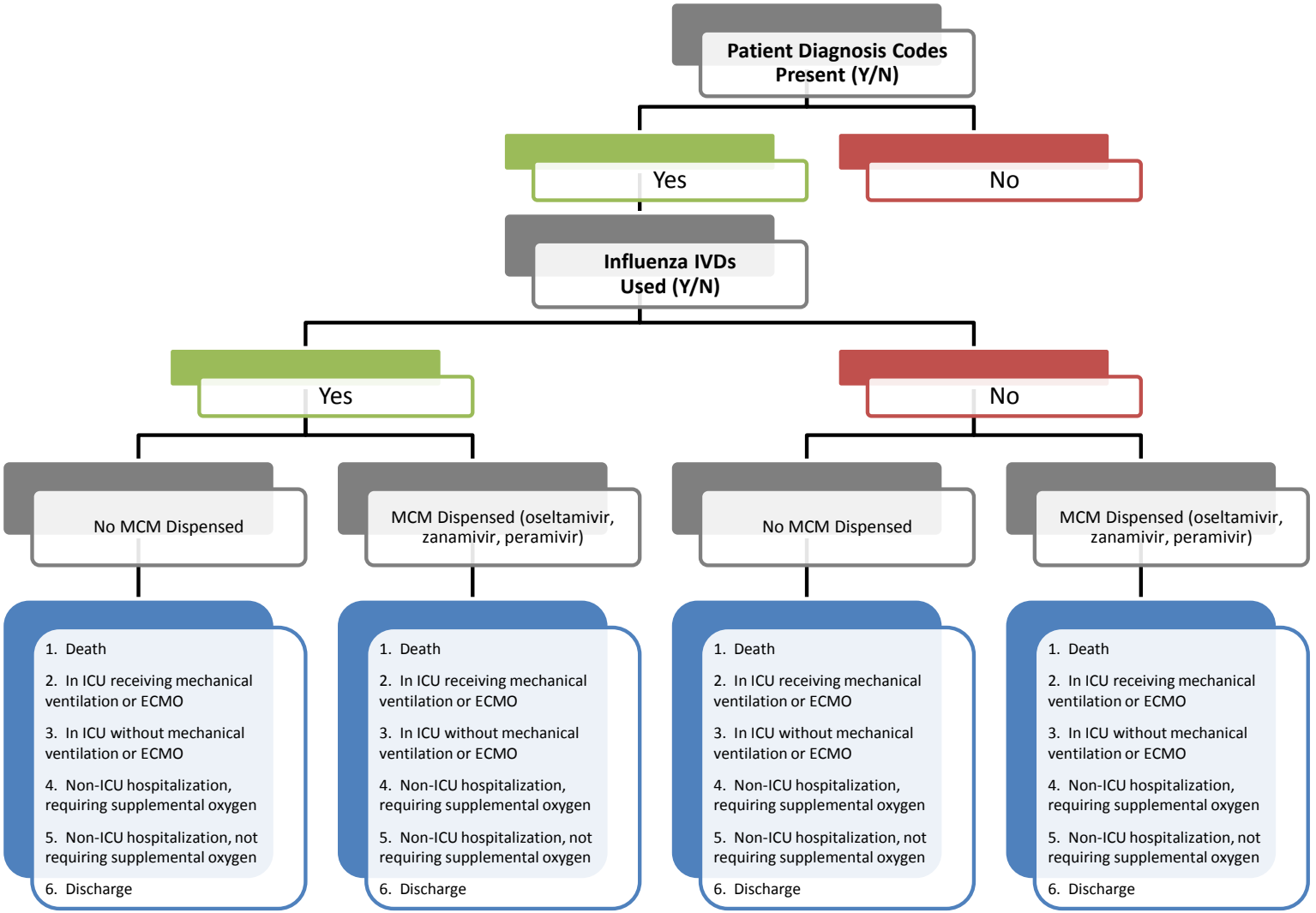
- Develop and pre-position protocols
- Use central IRB for expedited review of clinical protocols
- Develop eCRF for standardized data collection
- Create data dissemination plan to share key findings

DISCOVERY™
The Critical Care Research Network

FDA RAPID


1
Healthcare Professionals and consumers submit regular and emergency surveillance adverse event reports
General Surveillance
Emergency Surveillance
HTML
2
PDF
4
AWS GovCloud
3
Adverse Event Analytical Tools
RAPID AE Dashboard & Data
Geovisualization
RAPID Heatmap
Empirica
RAPID External Data (Future)
5
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 (ex. HL7 ICSR) and increase the effectiveness of analysis performed using RAPID analytical tools

FDA Sentinel Initiative



Coordination & Collaboration

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
- Emergency Use Authorization of Medical Products and Related Authorities – Jan. 2017 Guidance
  - https://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm
- PAHPRA (Public Law 113-5)
  - http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf
- MCM emergency use authorities (EUA, etc.)
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411432.htm

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU!

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