NIH Disaster Research Response (DR2) Project:
A Model for Overcoming the Challenges

Aubrey Miller, MD, MPH
CSTE National Disaster Epidemiology Workshop
May 13-14, 2015
Research Vital: Disasters & Emerging Threats

WTC Widespread Contamination
Study: 27,500 Responders*

- Asthma: 28%
- Sinusitis: 42%
- Lung Tests: 42%
- PTSD: 9%
- Panic: 8%
- Depression: 28%

Gulf Oil Spill April 2010

- Little known about long-term health effects!
- Hundreds of large (>700 tons) tanker oil spills in past 40 years
- Only 8 health studies & all but one was cross-sectional or very short term

Barrels of Oil (1 B = ~ 40 gallons)

1989 Exxon Valdez, USA          270,000
1993 MV Braer, UK              620,000
1996 Sea Empress, UK          525,000
1997 Nakhodka, Japan        >44,000
1999 Erika, France             146,000
2002 Prestige, Spain          460,000
2003 Tasman Spirit, Pakistan  270,000
2007 Hebei Spirit, South Korea  73,000
2010 Deepwater Horizon, USA  4,900,000

- Dispersant Use > 1.8 M gallons
Gulf Oil Spill: Rapid Public Health Responses

• Acute Symptom Surveillance
  – Sentinel hospitals, Workplace reports, Poison Control Centers

• Focused Surveys of Specific Populations
  – NIOSH worker investigations (Health Hazard Evaluations)
  – Community Assessment for Public Health Emergency Response (CASPER)
  – Community Surveys (e.g., LA Bucket Brigade)

• Acute responses NOT designed to understand longer-term physical and mental health or other consequences
Key Points

- **Longitudinal human health research is clearly indicated**
- Health studies should begin as soon as possible
- Mental health and psychosocial impacts must not be overlooked
- Sensitive populations need to be monitored
- External stakeholders must be part of the process
- Data and data systems should be developed to support wider research efforts
NIH Gulf Oil Spill: Research Responses

Intramural Research

GuLF STUDY
A health study for oil spill clean-up workers and volunteers

Deepwater Horizon Research Consortia:
Health Impacts & Community Resiliency

Extramural Research

Worker Training
Oil Spill Cleanup Initiative

Toxicology Research

Partnership
Need for Public Health Disaster Research

• **Is it safe?**
  - For whom, what, when, and where
  - Longer-term physical and mental health impacts

• **Did our strategies work?**
  - Protect the public for the long-term
  - Risk communications
  - Worker safety and health
  - Improved preparedness and recovery
Moving from Public Health Practice to Research

• Building on acute response platforms (surveillance, cross sectional)
  – Ad-hoc convenience based investigations to hypothesis driven research
  – Integrating into response activities effectively without impediment
  – Feedback to identify research priorities and opportunities

• Cohort Identification: high-risk groups, kids, elderly, EJ community

• Toxicity and Exposure Data: to understand health effects

Missed Opportunities for Key Questions!
- H1N1 Response- treatment research, IRB issues
- DWH Oil Spill - 9 months to start GuLF Study
- Hurricane Sandy- 11 months to fund extramural efforts
Starting research quickly to not lose critical Information!

- Enumerating research issues for whom, what, where?
- **Study Development** (who’s responsible / resources)
  - Secure funding
  - Protocols, questionnaires, equipment, data handling, specimen handling
  - Processes (e.g., IRB & Certificates of Confidentiality)
- **Study Implementation**
  - Integrating with emergency management, health authorities, etc
  - Community engagement and participation
  - Trained researchers, field support and logistics
NIH Disaster Research Response (DR2) Project

Started Aug. 2013 to help improve timely research capabilities

“Timely research is critical to prevent injury & illness and support recovery”
Lurie, Manolio, Patterson, Collins, Frieden. NEJM Mar 2013

DR2 Vision:

"A dynamic and interdisciplinary testbed of products, processes, & enhanced relationships that will improve our capabilities to perform timely health research in response to disasters & emerging threats”
NIH Disaster Research Response (DR2) Project

Project Started Aug. 2013 to help improve timely research capabilities

Objectives

1. Identification of important research questions and priorities
2. Improved access to data collection tools for researchers
3. Improved NIEHS & partner capability to quickly collect data
4. Trained researchers versed in disaster tools and issues
5. Integration into planning and emergency response systems
6. Research process including public health, academia, and impacted workers and communities
Identifying Research Priorities

• Improved use of Networks
  – NIH Environmental Health Sciences Network
  – NIH Disaster Interest Group & ASPR SPIRIT

• Exploring other models
  – DOI Science Support Group
  – National Academies of Science (Hurricane Sandy, Gulf Spill)
    • NEW ASPR, NIEHS, CDC effort:
      – Jointly funded NAS to pull together experts for disasters
      – Ebola Research Priorities Workshop (Nov. 3, 2014)*

Repository of Data Collection Tools
Surveys, Questionnaires, Protocols, Guidance, Forms

- **Tools** to help establish *early baselines and cohorts* for research
  - **Search:** NIEHS studies (e.g., DWH), literature searches, CDC, USCG, other
    - 450 research tools evaluated (rosters, epi-data, clinical forms, etc.)
    - 165 tools selected for initial inclusion in database

- **Broad categories** (eight to start)
- **Implementation guidance and forms** (e.g., consent forms, clinical testing)
- **Training and Exercise Materials**

- **Useful to researchers** *regardless of federal response*
  - e.g., local events, tornados, wildfires, factory explosions
NIH DR2 Tools - Data Collection Type

- Mental Health (e.g., PHQ, CES-D)
- Disaster-Specific (e.g., GULF STUDY)
- Toolkits and Other (e.g., PhenX, NIH)
- General Health (e.g., SF-36, CDC HRQOL)
- Occupational Health (e.g., DOD Pre- and Post-Deploy)
- Organ-Specific (e.g., CARAT, ISAAC)
- Environmental Exposure (e.g., CARTaGENE, NhEXAS)
- Social Support (e.g., Family Support Scale)

- Mental Health: 54
- Disaster-Specific: 25
- Toolkits and Other: 23
- General Health: 22
- Occupational Health: 16
- Organ-Specific: 13
- Environmental Exposure: 6
- Social Support: 6
NIH DR2 Tools - Compiling Metadata for Repository

- Short Description and # of Items
- Purpose and Uses
- Mode of Administration
- Time to Administer
- Population of Interest
- Existence of Validity Studies
- Languages/Reading Level
- Special Interviewer Training
- History of Use in the Disaster Setting
- Professional Admin Requirements
- Ease of Use in Disaster
- Availability

New Improvements under way:
- Tools: downloadable files (MS Word & EpilInfo) for paper or electronic entry
- Improved searching and sorting into categories
- Creation of Survey Builder functionality using EpilInfo
Refine Your Results

Data Collection on

- Environmental Exposure(s) (6)
- General Health (22)
- Mental Health (54)
- Occupational Health (16)
- Social Support (5)
- Specific Body Systems (13)
- Specific Disasters (25)
- N/A (22)

Publication Year

- Unknown (6)

Displaying records 1 - 6 of 6

Page 1 of 1

Results/Page: 10

Sort: Newest First

1. Appendix D: Recognition and Management of Mold-Related Illness Table B: Questions for Patients with Common Symptoms; Table C: Environmental Questionnaire; Table D: Current Symptoms

Source: National Institutes of Health, Disaster Research Response Project

Annotation: University of Connecticut Health Center, Division of Occupational and Environmental Medicine, Center for Indoor Environments and Health has mold questionnaires in Tables B, C, and D of Appendix D (page D-1) of "Guidance for Clinicians on the Recognition and Management of Health Effects related to Mold Exposure and Moisture Indoors." Questionnaires in the tables consist of a general health history, items pertaining to possible symptoms, work/residence settings and locations for the respondent, potential exposures, and diagnostic assessment. Table B: Questions for Patients with Common Symptoms is on page D-3. Table C: Environmental Questionnaire is on page D-4. Table D: Current Symptoms: History and Relationship to Home, Work, or School (For Patients in which a Potential Exposure to Mold Exists) is on page D-6.

Ease of Use in Disaster Setting: Moderate

Population: Residential/Workplace

Length: 50 questions

Administered by: Self Administered/Self Report

Language(s): English

URL: http://www.oecz.uche.edu/clinser/MOLD%20GUIDE.pdf

ID: 7815. From Disaster Lit, a database of the U.S. National Library of Medicine.

2. GEESI (Quick Environmental Exposure and Sensitivity Inventory)

Source: National Institutes of Health, Disaster Research Response Project

Annotation: This validated questionnaire, the Quick Environmental Exposure and Sensitivity Inventory, or GEESI, also known as the "TILT Test," helps researchers, doctors, and their patients identify individuals with multiple chemical intolerances. The GEESI was developed as a screening questionnaire for multiple chemical intolerances (MCI). The instrument has four scales: Symptom Severity, Chemical Intolerances, Other Intolerances, and Life Impact. It can be used to assess the onset of new or intensified symptoms following an event.
From your mobile device – DR2 is responsive to screen size

NIH Disaster Research Response (DR2)

Training & Exercises

NIH is collaborating on training activities to develop a network of trained, deployable "Research Responders." These activities support findings and gaps following many large disasters as described in the 2013 New England Journal of Medicine article, Research as a Part of Public Health Emergency Response. Relevant slides and videos from these activities will be housed in the DR2 tool database.

Activities

Coming soon! 2015 Houston Tabletop Exercise

2014 Los Angeles Tsunami Tabletop Exercise
Rapid Acquisition of Pre/Post Incident Disaster Data (RAPIDD) Protocol

- **Reduce the time it takes to initiate data collection**
  - Pre-reviewed by IRB *(NIEHS IRB provisional approval granted May 2015)*
  - Standardized methods using established instruments
  - Pre-positioned study documents, questionnaires, supplies, and staff

- **Initial Goal: Timely research of workers involved in a response**
  - Contact information for cohort development
  - Gather early survey information
  - Collect biospecimens and baseline medical tests (e.g., PFT)
    - **Core:** 29 questions ~ 5 mins
    - **Basic:** 89 questions ~ 10 mins
    - **Enhanced:** 184 questions ~ 20 mins
IRB Approval Before Initiating Study

- Specifics of the disaster submitted to IRB for approval before starting study
  - Research setting
  - Sample size
  - Accrual duration
  - Procedures
  - Questionnaires
  - Outcomes of interest

- Grantees developing similar protocols
- NIEHS IRB “best practices workshop” & leading NIH
- Discussions started with OMB to support process
NIEHS Rapid Response Data Collection Team
Support for National Research Capacity

- **Deployment of Intramural Clinical Program Assets** (support contract)
  - Technical Support (assistance with questionnaires etc.)
  - Field support for data and specimen collection for others
- **NIEHS Study Implementation**

Possible Biospecimens

- Metabolic, endocrine, stress, TM
- Metabolic, endocrine, stress
- Serum and clot
- Plasma and PCV
- Whole blood or Lymphs
- Trace metals
- RNA, DNA studies
- Metabolic, endocrine, stress, TM
- Endocrine, TM
DR2 Outreach, Implementation, and Integration with partners
Environmental Health Science (EHS) Network

What: working with our partners to...

- Help develop and prioritize DR2 concepts, tools, website, training materials
- Build off acute response “Public Health Practice” (surveillance, x-sectional surveys)
- Get timely environmental exposure and toxicology data to support health research

Who:

- **New EHS Network Workgroup**
  - NIEHS Training Program, Academic Centers, & Grantees input
- **Federal Partners (HHS Agencies and Others)**
- **Other Stakeholders**
  - Public Health, Responders, & Community (incl. “citizen science”)
Research Responder Training & Education

- **Training & Education** “those involved in research/data collection”
  1. National response plans and HHS mechanisms
  2. Training to use DR2 and other data collections tools, protocols, etc.
  3. Site/Situation Specific Health and Safety Issues

- **Training Exercises** on identified scenarios and issues

**Training Exercises**
- 2014 Los Angeles & 2015 Houston
- Participants: federal, state, local, academia and community, industry
- Evaluate State and partner research capabilities & DR2 Project concepts and training tools
- Discussion: integration, issues of concern
PHERRB

• DHHS established the **Public Health Emergency Research Review Board (PHERRB)** in 2012 to provide centralized, rigorous and expeditious human subject protections review of research studies addressing **public health emergencies (PHEs)**
  
  – PHEs include: natural disasters, biohazards including anthrax; chemical and radiological emergencies; oil spills; pandemic influenza or other infectious diseases; and other mass casualty events

• **National Institutes of Health (NIH)** designated to maintain **PHERRB infrastructure and functions**
  
  – Leverage expertise of NIH IRB members
  – Provide staff
  – Develop operating procedures
  – Maintain operations
  – OHSRP is the point of contact for PHERRB operations
THANK YOU!

CAPT Aubrey Miller, MD, MPH
miller.aubrey@nih.gov

e-mail the DR2 Staff at:
dr2@niehs.nih.gov

DR2 Project Webpage