NIH Disaster Research Response: Translating Lessons Into Action

PEPH Public Health Disaster Research Response

September 19, 2014
Events come in all shapes and sizes
Environmental Health a part of most!

- 9/11 and Anthrax
- Re-emerging H5N1
- Katrina, Rita, Wilma
- Ike, Gustav
- H1N1 Pandemic
- Haiti earthquake
- Deepwater Horizon
- Japan Earthquake Nuclear Event
- 2011 Tornadoes
- Irene
- Isaac
Widespread Contamination

Complex Mixed Exposures

Study: 27,500 Responders*

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

Limited Health Studies on Oil Spills

- 38 supertanker oil spills in past 50 years
- Only 8 studied for health effects, all but one cross-sectional or very short term

<table>
<thead>
<tr>
<th>Year</th>
<th>Location</th>
<th>Barrels of Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>Exxon Valdez, USA</td>
<td>270,000</td>
</tr>
<tr>
<td>1993</td>
<td>MV Braer, UK</td>
<td>620,000</td>
</tr>
<tr>
<td>1996</td>
<td>Sea Empress, UK</td>
<td>525,000</td>
</tr>
<tr>
<td>1997</td>
<td>Nakhodka, Japan</td>
<td>&gt;44,000</td>
</tr>
<tr>
<td>1999</td>
<td>Erika, France</td>
<td>146,000</td>
</tr>
<tr>
<td>2002</td>
<td>Prestige, Spain</td>
<td>460,000</td>
</tr>
<tr>
<td>2003</td>
<td>Tasman Spirit, Pakistan</td>
<td>270,000</td>
</tr>
<tr>
<td>2007</td>
<td>Hebei Spirit, South Korea</td>
<td>73,000</td>
</tr>
<tr>
<td>2010</td>
<td>Deepwater Horizon, USA</td>
<td>4,900,000</td>
</tr>
</tbody>
</table>

- Dispersant Use > 1.8 M gallons

**Exposure Assessment:**
- only 1 study had estimates of exposure (used surrogate measures e.g. distance from spill)
NIH Funded Gulf Oil Spill Research

Intramural Research

Deepwater Horizon Research Consortia:
Health Impacts & Community Resiliency

Extramural Research

Worker Training
Oil Spill Cleanup Initiative
GuLF STUDY (Gulf Long-term Follow-up Study)

- Prospective study of 32,762 adults involved in oil spill clean-up or support
  - Enrolled March 2011 to March 2013
    - Baseline telephone interview on clean-up jobs, symptoms, health
    - In-home clinical assessment and biospecimen collection – 11,210 from Gulf states
  - Followed 10 or more years
    - Telephone interview every 2-3 years
    - Subgroup with repeated mental health and resiliency assessments
    - Linkage to vital records and cancer registries
  - Comprehensive clinical exam (~4,000 from AL, LA) started 8/14
Deepwater Horizon Consortium

- 5-year $25.2 M program
- Four university/community partnerships
  - Tulane
  - LSU
  - Univ. of Florida
  - Univ. of Texas Medical Branch
- Steering group leadership
  - Includes GuLF STUDY
  - Input from NTP
- Distinct populations & foci
  - Women and children
  - Pregnant women
  - Cultural/ethnic minorities
  - Seafood safety
- Shared approaches
  - Seafood
  - Resiliency
  - Population studies
  - Community outreach and dissemination

Funding: NIEHS, NCI, NHLBI, NIMH, NIMHD, NINR, NCATS, OBSSR
Elk River WV Chemical Spill, Jan. 2014

Is it really safe? How can we prepare for the next one?

- ~10,000 gallons of 4 methylcyclohexane methanol (MCHM) + polyglycol ethers (PPH) leaked into Elk River
- No water for over 300,000 residents, affecting some for more than a week
- About 500 patients seen in response
- Missed opportunity to assess exposures and health impacts
- Currently: CDC looking at surveillance opportunities and NIEHS/NTP developing toxicology studies

Issue: No toxicology/health data >50,000 chemicals!

How can we get rapid toxicology information?
Disaster Environmental Health Research Issues

- Building on acute response platforms (surveillance, cross sectional studies)
- Ad-hoc, convenience based collection of health and env. data
- Missing Data: baseline and longitudinal data
- Exposure data not collected/measured to understand effects
- High risk groups: pregnancy, elderly, pre-existing illness
- Lack of toxicity / health data for exposures, especially mixtures
- Minimal community engagement
Disaster Research Response (DR2) Project Genesis

- National Biodefense Safety Board Recommendations (Apr, 2011)

- Sep. 2012 NIH/ASPR Federal Partners Meeting: Identified Areas of Concern
  Funding, IRB/OMB, Data collection tools, trained research workforce, infrastructure support, and community engagement

- Ongoing Lessons: research too slow and critical data is perishable!
  - H1N1 Response- treatment research, IRB issues
  - DWH Oil Spill- 9 months to start GuLF Study
  - Hurricane Sandy- 11 months to fund extramural efforts

“Timely research is critical to prevent injury & illness and support recovery”
Lurie, Manolio, Patterson, Collins, Frieden. NEJM Mar 2013:
Key components to ensure robust science response

<table>
<thead>
<tr>
<th>Components</th>
<th>Making it operational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rostered experts in research design, technology, and topical areas of concern</td>
<td>Identify and roster experts, including modelers; plan for ‘ready reserve’</td>
</tr>
<tr>
<td>“Science response” is part of core response plans</td>
<td>Amend planning documents; consider organizational structure and pre-scripted mission assignments for science</td>
</tr>
<tr>
<td>Identification of knowledge gaps and research questions</td>
<td>Prioritize, assess feasibility, and recommend which to pursue</td>
</tr>
<tr>
<td>Generic and scenario-specific templates and protocols</td>
<td>Pre-approval of core survey documents; pre-scripted clinical protocols and minimum data set</td>
</tr>
<tr>
<td>Rapid IRB review &amp; oversight mechanisms</td>
<td>Establish PHERRB, modify the Common Rule, grantees commit to faster review</td>
</tr>
<tr>
<td>Rapid funding</td>
<td>Implement administrative changes/mechanisms to enable</td>
</tr>
<tr>
<td>Registries and networks for studies</td>
<td>“Registry in a box”; add capabilities for baseline surveys &amp; specimen collection</td>
</tr>
<tr>
<td>Involvement of affected communities</td>
<td>Establish mechanisms to directly engage community to discuss concerns; share findings</td>
</tr>
</tbody>
</table>
NIH Disaster Research Response (DR2) Project
Project Started Aug. 2013 and is ongoing

Pilot project to help galvanize and accelerate needed infrastructure as part of a larger HHS Effort

Objectives
1. Central repository data collection tools & research protocols
2. NLM public website: “Disaster Research Responder”
3. Rapid Data Collection Capability: baseline epi., clinical, & biospecimens
4. Environmental Health Research Response Network (EHS Network)
5. Training intra/extramural disaster researchers
6. Share & Integrate: HHS/federal response & recovery frameworks
7. Toxicology Support information and testing
8. Environmental Data to go with human health information
Repository of Data Collection Tools
Surveys, Questionnaires, Protocols, Guidance, Forms

- **Tools** to help establish *early baselines & cohorts* for research
  - **Search:** NIEHS studies (e.g., DWH), literature searches, CDC, USCG, Others
    - 450 research tools evaluated (rosters, epi-data, clinical forms, etc.)
    - ~200 tools selected for initial inclusion in database
  - **Menu:** selectable categories and items (mold, respiratory, mental health)

- **Metadata**
  - Ease of use, length/time, differing languages, history of use and references

- **Implementation guidance & forms** (e.g., consent forms, clinical testing)

- **Pre-approval by NIEHS IRB & OMB** to the extent possible

- **Useful to researchers regardless of federal response**
  - e.g., local events, tornados, wildfires, factory explosions
Disaster Research Response Website
National Library of Medicine (NLM)

- Website to host the data collection tools repository (>160 currently available)
- Addition to Disaster Information Management Research Center
- Publically available information to support research response
  - Facilitates research in the absence of Federal Disaster Declarations
NIEHS Rapid Response Data Collection Team

- **Deployment of Intramural Clinical Program Assets** (support contract)
  - Baseline/early data collection, medical tests, & biospecimens
  - Cohort development, contact information, etc.
  - Data & specimens for use by NIH, CDC, academia, and others for longer-term research

- “Plug and Play” protocol with pre-existing IRB & OMB reviews

**New NIEHS IRB**: “Best Practices for Disaster Research”

**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
Env. Health Science (EHS) “Research Response Network”
National EHS "Network" for future threats and disasters

- **Who:**
  - Government agencies (federal, state, local)
  - Academia (NIEHS funded centers & grantees)
  - Community and Worker partnerships

- **What:** *“Working with our partners to...”*
  - Help develop and prioritize the DR2 tools, website, training materials
    - Continuous feedback loop to create useful products for the research community
  - Forum to evaluate & improve “research response” concepts & objectives
  - Improve synergy & participation among EHS community, incl. “citizen science”
  - Develop a U.S. network of trained EHS researchers to assist in disaster responses

**NEW ASPR, NIEHS, etc. Project:** *IOM to pull together experts for disasters*
Research Responder Training & Education

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

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

---

4/7 Port of Los Angeles Training Exercise
- USGS Tsunami Scenario
- 140 people involved: fed, state, academia and community
- Evaluate DR2 Project concepts and support
- Discussion: integration, issues of concern
NIEHS Disaster Research Response Looking Forward

1. **Data Tool Improvement**: build on DR2 Repository and NLM Website, Training

2. **RAPIDDD Protocol**: for health data collection (IRB & OMB approvals / issues)

3. **“EHS Network”**: weave together interested partners to collectively create this

4. **Exercises** to assess our strategies, tools/protocols, and training (e.g., IRB/PHERRB)

5. **Environmental data** collection to go with health data!
   - Explore role of new technologies, social media, and “citizen science” in research

6. **Toxicology information and data**
Disaster Research Response Workshop: June, 2014*

“Enabling Public Health Research During Disasters”

- Build a broader network
- Frame a national research agenda and action items
- Integrate research into existing response structures
- Identify critical research needs and priorities
- Identify obstacles and barriers to research
- Discuss structures and strategies needed for deployment
- Share ideas, innovations, technology to support research
- Explore data collection tools and sharing mechanisms

*IOM Report available by November 2014
THANK YOU!

QUESTIONS?

For more information contact: CAPT Aubrey Miller, MD, MPH
miller.aubrey@nih.gov

Or email the DR2 Staff at:
dr2@niehs.nih.gov

Project Webpage