NIH Disaster Research Response (DR2) Program: Improving Timely Environmental Health Research

CIHR Best Brains Exchange
Ottawa, Canada

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February 19, 2016

National Institutes of Health • U.S. Department of Health and Human Services
The National Institute of Environmental Health Sciences

• One of the National Institutes of Health, but located in Research Triangle Park, NC

• Wide variety of programs supporting our mission of environmental health:
  -- Intramural laboratories  -- Clinical research program
  -- Extramural funding programs  -- National Toxicology Program
  -- Disease Prevention  -- Public Health Focus
Each disaster presents new issues & uncertainties
Research is vital to inform the response, recovery, and future events
Health Impacts of World Trade Center (WTC) Attack

- Widespread contamination
- USGS identified complex, mixed exposures
- WTC Medical Monitoring program findings
  - Study of 27,500 Responders
    - Asthma 28%
    - Sinusitis 42%
    - Lung Tests 42%
    - PTSD 9%
    - Panic 8%
    - Depression 28%

Gulf Oil Spill April 2010
11 workers killed, 17 injured, 98 survivors

- **Exposures of Concern:**
  - Oil Components
    - Poly-aromatic hydrocarbons (PAHs)
    - Volatile organic chemicals (VOCs)
    - Heavy metals
  - Dispersants
  - Burning Particulate

- **Health Concerns:**
  - Skin
  - Lungs
  - Eating contaminated seafood
  - Mental health
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Ship Name</th>
<th>Weight</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

Barrels of Oil (1 B = ~ 40 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

Worker Training
Oil Spill Cleanup Initiative

Extramural Research

Deepwater Horizon Research Consortia:
Health Impacts & Community Resiliency

Toxicology Research

Partnership
Deep Water Horizon (DWH) Research Consortium

- Trans-NIH effort of university & community partnerships
- Population-based & lab research
- Studies designed together to assess health impacts on Gulf Coast communities
- Build capacity, train residents, further env. health literacy
Oil Spill Research Challenges

• **Study Populations: Workers and Volunteers**
  - Use of NIOSH roster & combining multiple lists (BP, national guard)

• **Study Development Process**
  - IRB, OMB, & Certificates of Confidentiality

• **Baseline Data for Comparison**
  - Available only for small fraction of cohort (e.g., Coast Guard)
    - Health information, biospecimens, relevant tests ??

• **Exposure Reconstruction**
  - Multiple databases that need to be integrated
  - Available data difficult to use to reconstruct exposures

• **Timeliness of Extramural Awards & Initiation of Studies**
Charleston, West Virginia: Elk River Chemical Spill

- Crude 4- methylcyclohexanemethanol (MCHM) plus other chemicals were released from a Freedom Industries facility
- Water use suspended for 300,000 people in nine counties
- >500 hospital visits: reported nausea, vomiting, rashes, lung & eye irritation
- Unknown health effects of released chemical
- Residents told to not drink, bathe, cook or wash with tap water due to uncertainty
Lingering Questions of Concern:

- Can MCHM affect development of an unborn child?
- Are there long-term effects?
- How reliable are the studies on MCHM used to identify a safe level?
- Chance of the spilled chemicals having surprising health effects?

>80,000 chemicals in the US have never been tested for their toxic effects on health & the environment
NTP Studies to Help Assess Various Uncertainties related to MCHM & other chemicals of interest

<table>
<thead>
<tr>
<th>Questions of Concern</th>
<th>Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Prenatal Toxicity</td>
<td>X</td>
</tr>
<tr>
<td>Mouse Dermal Irritation and Hypersensitivity</td>
<td>X X X X</td>
</tr>
<tr>
<td>5-Day Rat Toxicogenomic DNA Damage Assays</td>
<td>X X X X</td>
</tr>
<tr>
<td>Zebrafish Developmental Nematode Toxicity</td>
<td>X X X X</td>
</tr>
<tr>
<td>Immune Toxicity Studies</td>
<td>X X X X</td>
</tr>
<tr>
<td>High Throughput Screening</td>
<td>X X X X</td>
</tr>
<tr>
<td>Computer Modeling/Structure Activity (SAR) Analysis</td>
<td>X X X X</td>
</tr>
</tbody>
</table>

Can MCHM affect an unborn child?   X
Are there long-term effects?       X
Reliability of studies for safe level? X X X
Surprising toxicological effects? X X X

Guideline
Non-guideline
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

• **Who needs to be looked at?**: high-risk groups, kids, elderly, EJ community

• **What additional information do we need?**: 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
Need for Environmental & Occupational Health Data

• Is it safe?
  - For whom, what, when, and where?
  - Longer-term physical & mental health impacts?
  - Safety of homes, residences, work places

• Focal areas of research
  1. Environmental Exposures
  2. Health Risks and Effects
  3. Value of Interventions or Mitigation Strategies
  4. Ecosystem Effects
NIH Disaster Research Response (DR2) Program

Improving Disaster Responses, Reducing Health Impacts, and Preventing future harm through:

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
Efforts to Improve Timely Research in Four Areas

- **Research Issue Identification & Prioritization**
  - Examples:
    - NAS Rapid Workshops
    - DOI SSG
    - Gov’t & NGO Experts

- **Process Barriers**
  - Funding
  - IRB & OMB
  - Site Access

- **Infrastructure Barriers**
  - Data collection
  - Samples & Medical Tests
  - Logistics
  - Training

- **Relationships Coordination Engagement**
  - Integration into NRF
  - Research Networks
  - Community partners
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 (SSG)
  – National Academies of Science (Hurricane Sandy, Gulf Spill)

• **New: NAS Committee** to pull together experts for disasters
  – Ebola Research Priorities Workshop (Nov. 2014)*
  – Zika Virus Workshop (Feb. 2016)

DR2 Repository of Data Collection Tools
Surveys, Questionnaires, Protocols, Guidance, Forms

- 165 Tools to help start early baselines and identified research
- Implementation guidance, forms, training (e.g., consents, clinical testing)
- Available to all researchers regardless of event

8 categories initially

- 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 & EpiInfo) for paper or electronic entry
- Improved searching and sorting into categories
- Creation of Survey Builder functionality using EpiInfo
Refine Your Results

Data Collection on

- Environmental Exposure(s) (6)
- General Health (22)
- Mental Health (54)
- Occupational Health (16)
- Social Support (6)
- 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.oehc.uchc.edu/clinser/MOLD%20GUIDE.pdf](http://www.oehc.uchc.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.
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

  - Rapid Acquisition of Pre/Post Incident Data (RAPIDD)
    - Questionnaires
    - Biospecimen Collection
    - Medical Testing
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
## Questionnaire

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<tr>
<th>Questionnaire &amp; Brief Description</th>
<th># Questions</th>
<th>Estimated Time</th>
<th>Select?</th>
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<tr>
<td>Registry Basic Core Form</td>
<td>26</td>
<td>5 minutes</td>
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<tr>
<td>Registry Enhanced Core Form</td>
<td>36</td>
<td>10 Minutes</td>
<td>Yes ☐</td>
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<tr>
<td>Demographics and Sociological Factors</td>
<td>16</td>
<td>5 Minutes</td>
<td>Yes ☐</td>
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<tr>
<td>ERHMS/ATSDR Based Deployment Module</td>
<td>8</td>
<td>Unavailable</td>
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<tr>
<td>General Health</td>
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<td>ACE General Survey – Medical History Module F.</td>
<td>19</td>
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<td>ERHMS Basic Pre – Deployment Health Screening</td>
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<td>ACE General Survey - Acute Health Effects Module B</td>
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<td>Rand Medical Outcomes Study Short Form Survey 20</td>
<td>20</td>
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<td>Veterans Rand 12 Health Survey (VR-12)</td>
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<td>NHANES 2013 -2014 Physical activity/ Fitness Module</td>
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<td>Measures of Overall Psychological Well-Being</td>
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<tr>
<td>Kessler 6 (K6)</td>
<td>6</td>
<td>2-3 minutes</td>
<td>Yes ☐</td>
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<tr>
<td>Kessler 10 (K10)</td>
<td>10</td>
<td>5 Minutes</td>
<td>Yes ☐</td>
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<td>Measure(s) of Post-Traumatic Stress Disorder (PTSD),</td>
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<td>PTSD Self Rating Scale (PTSD-SRS)</td>
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<td>Unavailable</td>
<td>Yes ☐</td>
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<td>Primary Care PTSD Screen (PC-PTSD)</td>
<td>4</td>
<td>1-2 Minutes</td>
<td>Yes ☐</td>
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<tr>
<td>Impact of Event Scale Revised (IES-R)</td>
<td>22</td>
<td>10 Minutes</td>
<td>Yes ☐</td>
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<tr>
<td>Measure(s) of Anxiety and Depression</td>
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<td></td>
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<td>Zung Self Rated Depression Scale</td>
<td>20</td>
<td>10 Minutes</td>
<td>Yes ☐</td>
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<tr>
<td>Patient Health Questionnaire (PHQ)</td>
<td>11</td>
<td>5 Minutes</td>
<td>Yes ☐</td>
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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
IRBs & Ethical Conduct of Disaster-related Research

  – Provide IRB review of protocols that are conducted or supported by HHS and are multisite studies (e.g., H1N1)
  – Standard Operating Procedures approved August 2015

• NIEHS Office of Human Research Compliance
  – Provisional approval of NIEHS RAPIDDD Protocol
  – Focusing on ethical issues including vulnerability & informed consent
  – Workshop July 2016 at NIEHS
Developing Training Materials, Field Guides, Go Kits

Field Surveys

Medical Testing

Sample Collection Go Kits

Possible Biospecimens
DR2 Outreach, Implementation, & Integration with Partners
Environmental Health Science (EHS) Network

Vision: working with our partners to...

Create a national “network” for timely environmental health research

Who:

- **New EHS Network Workgroup**
  - NIEHS Training Program, Academic Centers, & Grantees

- **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 concepts & training tools
- Discussion: integration & issues of concern
Texas OneGulf
Disaster Research Response
Measuring Environmental Exposures..next steps

SCIENTIFIC AMERICAN

Bracelets Can Detect Chemical Exposures
The next wave of wrist wear might act as a fashionable archive of your exposure to everything from caffeine to pesticides

Wristbands are the accessory of choice for people promoting a cause. And the next wave of wrist wear might act as a fashionable archive of your chemical exposure.

Researchers at Oregon State University outfitted volunteers with slightly modified silicone bracelets and then tested them for 1,200 substances. They detected several dozen compounds — everything from caffeine and cigarette smoke to flame retardants and pesticides.

Slide Courtesy: Dr. Kim Anderson Oregon State Univ.
http://eprep.oregonstate.edu/
Discussion Items – Organizational Capacity

- What is your capacity to conduct timely health research after disasters?
  - Who & how are decisions made regarding involvement, support, etc.?
  - Who is available and ready to participate? Training? How fast?
  - How fast can protocols, consent forms, etc. be developed & approved?
  - Ability to implement research (e.g., operating procedures, surveys, baseline health evaluations, collect & store biospecimens)?
  - Plans for data management and communication of results?
  - Role of your IRB?
Discussion Items – Research Needs, Relationships, & Coordination

• Relationship & coordination with academia, government organizations, business, and community groups to implement health research?

• What processes are in place to identify research needs and priorities?
• Process for requesting support from the state, federal, others?
• How can you be integrated into disaster health research efforts to collect needed data or information?
• How can you coordinate with others to collect needed information?
• How would new and existing collaborations be made and continued?
Thank You!

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

DR2 Project Webpage
Lesson Learned From Disaster Research Responses

• Early & consistent community engagement critical for study development, participation, implementation, & communications

• Combining federal efforts with state, academic, & community partners builds local infrastructure and resilience for the future

• Must include mental health & health care considerations during all health assessments of impacted communities

• All efforts should be made to identify issues of concern, assess exposures, and understand health effects as fast as possible