Long-term Follow-up Study of Gulf Oil Spill Clean-up Workers

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Gulf Worker Study

A health study for oil spill clean-up workers and volunteers
Primary objectives

• Assess potential short- and long-term health effects associated with oil spill clean-up

• Create a resource for future collaborative research
  – Focused hypotheses
  – Specific subgroups
Previous oil spills

- 38 supertanker spills in past 50 years
- Only 8 studied for health effects
- With notable exceptions (e.g. Prestige, Spain 2002), research typically cross-sectional
- Deepwater Horizon disaster larger than any previously studied spill
Health outcomes of interest

- Based on scant research on previous spills
- Studies of other groups with exposure to compounds in oil, dispersants, heat, or disaster-related stress

<table>
<thead>
<tr>
<th>Health Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Respiratory</td>
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<tr>
<td>Cardiovascular</td>
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<tr>
<td>Hematologic</td>
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<tr>
<td>Mental Health</td>
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<tr>
<td>Cancer</td>
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<tr>
<td>Neurologic (function and peripheral neuropathy)</td>
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<tr>
<td>Liver</td>
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<tr>
<td>Immunologic</td>
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<tr>
<td>Renal</td>
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<tr>
<td>Dermatologic</td>
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<td>Reproductive</td>
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</table>
Study population

- Adults $\geq 18$ years
- Communicate in English, Vietnamese, Spanish
- **Exposed**: worked one or more days in any clean-up task – paid or volunteer
- **Unexposed**: completed training but did not work; other community members (friends, relatives) as needed
Identification of participants

- NIOSH roster
- Other lists
  - Petroleum Education Council (PEC) training list
  - Parish responders
  - BP contractor payroll
  - Vessels of Opportunity
  - Coast Guard
- Community input on protocol, study materials and recruitment (set the stage)
- Community outreach, media campaign
Study Design

- Approach 70,000 from master list
  - Maximize Gulf states
  - Maximize higher exposures
- Administer enrollment questionnaire - phone
  - Health, lifestyle, usual occupation, socioeconomic factors, demographics,
  - Clean-up activities, living accommodations, spill-related health effects
  - Stress, depression, anxiety, trauma, rashes, respiratory problems
- Expected response rate 70-75%

➢ Cohort of 50,000 workers and controls
Active and passive follow-up cohorts

- Identify 25,000 for active participation in long-term study – **Active Cohort**
  - All clean-up job categories (~20,000 exposed; 5,000 not exposed)
  - Oversample higher exposed and/or smaller job categories
  - Maximize or limit to 4 gulf states
  - Restrict to those with work experience within 9 months of study start

- Follow remainder via record linkage – **Passive Cohort**
Active Cohort - baseline

- Home visit
  - Additional questionnaires
    - Health, occupation, residence
  - Biospecimens
    - Blood, urine, toenail clippings and/or hair, saliva for DNA
  - Environmental samples
    - Household dust wipe, tap water
  - Physiologic and anthropometric measures
    - Height, weight, waist, blood pressure, lung function

- Report to participants body mass index and selected clinical measurements
Active Cohort – follow-up

• Annual newsletter
• Telephone questionnaires years 2 and 4
• Passive surveillance
  – Cancer registries, vital statistics, other record linkage
  – Poison control data, other syndromic surveillance data?
  – Electronic medical records?
Biomedical Surveillance Sub-cohort

• Protocols developed and carried out by researchers in the Gulf area; common protocol with some variation
• Select ~ 5,000 from active cohort
• Clinic based, mobile van, or in-home assessment – years 1 and 3
  – Biological and environmental samples
  – Comprehensive pulmonary function tests
  – Neurological/neurobehavioral testing
  – Mental health screening
  – Laboratory tests
    • Immunologic, liver, cytogenetics, DNA damage, renal, other
  – Subgroup studies (e.g. reproductive function)
## Data collection schedule

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Baseline</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Cohort</strong></td>
<td>EQ, BQ, BS, ES</td>
<td>N, U</td>
<td>FQ, N, U, L</td>
<td>N, U, L</td>
<td>FQ, N, U, L</td>
<td>N, U, L</td>
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<tr>
<td><strong>Biomedical Surveillance</strong></td>
<td>EQ, BQ, BS, ES</td>
<td>E, BS, ES, N, U</td>
<td>FQ, N, U, L</td>
<td>E, BS, ES, N, U, L</td>
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</tbody>
</table>

**Abbreviations:**
- EQ = enrollment qx
- BQ = baseline qx
- BS = biological samples
- ES = environmental samples
- N = newsletter
- U = contact update
- L = linkage
- FQ = follow-up qx
- E = exams

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**Source:** National Institute of Environmental Health Sciences

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**
National Institutes of Health
Informed consent

• Letter and brochure
• Telephone consent for Enrollment Questionnaire
• Written informed consent at home visit; additional consent for Biomedical Surveillance
  – Allow for add-on studies and data sharing
  – Address record linkage and long-term follow-up
  – Develop FAQs and consent summary document (one page)
• Certificate of Confidentiality
Participant remuneration

• No compensation to Passive Cohort

• Small non-coercive compensation for Active Cohort – for blood, urine, other sample collection

• Compensation schedule developed for components of Biomedical Surveillance protocol
Biospecimen collection

- Protocols from UK Biobank and Sister Study
  - Blood
    - Request fasting if feasible
    - Minimal field processing
    - Serum, clots, plasma, buffy coat/RBCs, whole blood, metal-free sample, RNA, cryopreserved whole blood or lymphocytes
    - Hematologic assays (CBC) on fresh sample for subset
  - Urine
    - Assess feasibility of first morning void
    - Dipstick urinalysis (protein, leukocytes, glucose, pH, other)
  - Hair and/or toenail clippings
  - Saliva for DNA
Biorepository

• EPL in RTP, NC
  – Long history of support for NTP
  – ≥ 10 years of support for NIEHS studies
  – Well-coordinated with other study contractors
    • Close proximity, frequent meetings
    • Use Bioserve database for sample tracking
  – Follow guidelines for best practices including rigorous quality control measures
Exposure reconstruction

• Evaluate data collected by OSHA, NIOSH, EPA, BP, CG, others

• Industrial Hygiene assessment - exposures by task, location, time
  – Consider PPE use, Hazard Evaluations
  – Draw on government, industry expertise
  – Include local experts

• Other data
  – Weather, GIS-based information (e.g. fishing area closings, occupational and residential proximity to crude oil, burning, waste sites)
  – Existing exposure measurements and experimental data

• Create job-exposure matrices and GIS based exposure measures
Enrollment period

• Phased roll-out
  – One area first 2-3 weeks
  – Mini-pilot for protocols and approaches

• Engagement of local community
  – Endorse study
  – Role model (join)
  – Spread the word
  – Facilitate recruitment of special populations
  – Employ local staff

• Enrollment and baseline data collection – 6-9 months
  – Start late October
  – Faster recruitment of most exposed
Communications, reports, referrals

- Comprehensive communication strategy developed
- Reports
  - Participants
  - Local communities and groups
  - Partner organizations
  - Larger scientific community
- Newsletters, website, e-communications, scientific publications, community meetings
- Community referral strategy developed in collaboration with local health departments and other groups
Data sharing

• Data sharing plan will be developed
  – Questionnaires and summary data posted on website
  – Privacy and rights of participants to be fully safeguarded
  – Clear procedures for requesting datasets and add-on studies
  – Controlled access process for sharing individual level data as consistent with informed consent
Oversight

• Scientific peer-review of protocol
  – NIEHS, IRB, IOM, other as required

• Study Advisory Board – subcommittee of NIEHS Board of Scientific Counselors
  – Include one or more members of BSC
  – Other experts
  – Community representatives

• Community Advisory Board

• Additional oversight by IOM and Federal panels
Limitations

- No systematic pre-exposure samples or health assessments
  - Little or no biomonitoring; some environmental sampling
- Enrolling after exposures ended
- No ideal unexposed comparison group
  - Unexposed community members otherwise similar, but also exposed to oil-spill stressors
  - Persons far from spill may differ from those nearby and add complexity and cost
  - Not a typical worker cohort; other workers not comparable
  - Inclusion of questions from national surveys (e.g. NHANES, BRFSS) may facilitate comparisons, but regional data may not be available
Limitations

- No quantitative exposure measures for chemicals with short half-life
  - Qualitative rankings
    - Most to least exposed
    - Exposed to crude oil, burning oil, weathered oil
    - Distance from spill or burning sites
  - Semi-quantitative job/task exposure matrices
- Some more persistent compounds may be quantified in biosamples (e.g. metals)
GuLF study investigators

• NIEHS
  – Dale Sandler
  – Lawrence Engel
  – Richard Kwok
  – Aaron Blair
  – Aubrey Miller

• Contractors (SRA)
  – Matthew Curry
  – David Brown
  – Rich Cohn