

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



Chronicle / Kurt Rogers



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

Respiratory

Liver

Cardiovascular

Immunologic

Hematologic

Renal

Mental Health

Dermatologic

Cancer

Reproductive

Neurologic (function and peripheral neuropathy)



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

Subgroup	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Passive Cohort	EQ	N, U	N, U, L	N, U, L	N, U, L	N, U, L
Active Cohort	EQ, BQ, BS, ES	N, U	FQ, N, U, L	N, U, L	FQ, N, U, L	N, U, L
Biomedical Surveillance	EQ, BQ, BS, ES	E, BS, ES, N, U	FQ, N, U, L	E, BS, ES, N, U, L	FQ, N, U, L	N, U, L

EQ = enrollment qx

N = newsletter

U = contact update

L = linkage

BQ = baseline qx

BS = biological samples

ES = environmental samples

E = exams

FQ = follow-up qx

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

