



GuLFSTUDY

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

National Children's Study Federal Advisory Committee
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- Explosion killed 11 workers; injured 17, 98 others survived
- 48 miles southeast of Louisiana coast ; 5000 feet of water

- **Crude Oil**
 - Polycyclic Aromatic Hydrocarbons (PAHs)
 - Volatile Organic Compounds (VOCs) (benzene, toluene, ethylbenzene, xylene, naphthalene)
 - Heavy Metals (arsenic, cadmium, lead, nickel, zinc)
- **Dispersants**
 - Detergents (sulfonic acid salts)
 - Solvents (2-butoxyethanol, propylene glycol)
 - Petroleum Distillates (paraffins, PAHs)
- **Burning**
 - PAHs, respirable particulates (PM), hydrogen sulfide, sulfur dioxide, dioxin
- **Other**
 - Heat Stress, Physical Hazards, Mental Health

- **Limited health studies**: about 40 supertanker spills last 50 yrs, only 8 studied
 - Exxon Valdez , USA 1989 (270,000 barrels)
 - MV Braer, UK 1993 (620,000 barrels)
 - Sea Empress, UK 1996 (525,000 barrels)
 - Nakhodka, Japan 1997 (>44,000 barrels)
 - Erika, France 1999 (146,000 barrels)
 - Prestige, Spain 2002 (460,000 barrels)
 - Tasman Spirit, Pakistan 2003 (270,000 barrels)
 - Hebei Spirit, South Korea 2007 (73,000 barrels)
 - **Deepwater Horizon, USA 2010 (~ 4.9M barrels)**
- **Designs**: typically cross-sectional designs without controls or follow-up
- **Exposure Assessment**: except for one study, none had quantitative measurements & used surrogate measures such as distance from spill
- **GOS Exposure Complexity**
 - Exposure measurements from various sources and methods.
 - Chemical mixtures: raw & weathered crude oil, dispersants, combustion by-products.

- **Health Concerns from Previous Studies of Oil Spills**
 - **Acute**
 - Dermal, Ocular, Respiratory
 - **Longer-term health effects**
 - Pulmonary abnormalities
 - Genotoxicity
 - Generalized anxiety, PTSD, depressive symptoms
- **GOS health findings through July 27th** (NIOSH Report August 13, 2010)
 - **Injuries and Illness through July 27th**
 - N=2130 (1136 injuries (53%) 994 illnesses (47%))
 - **For illnesses about 75% Onshore vs. Offshore**
 - 192 Heat stress
 - 171 Multiple Symptoms (more than one organ system with no specific underlying cause)
 - 127 Headache / Dizziness
 - 122 Gastrointestinal
 - 78 Dermatologic
 - 42 General Symptoms (malaise, fatigue, non-specified allergic reactions)
 - 28 Cardiovascular

Health Outcomes of Interest

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

Respiratory

Liver

Cardiovascular

Immunologic

Hematologic

Renal

Mental Health

Dermatologic

Cancer

Reproductive

Neurologic (function and peripheral neuropathy)

Primary Objectives

- Assess short-and long-term health effects associated with oil spill clean-up
- Create a resource for future collaborative research
 - Focused hypotheses
 - Specific subgroups

Scientific Hypotheses

- Controlling for other factors, exposure to oil-spill related chemicals etc. is associated with adverse health effects
 - There is a dose-response relationship between exposures and health effects (using qualitative and semi-quantitative measures)
 - Biomarkers of potentially adverse effects are associated with chemical exposures
- Workers from the gulf region will be at greater risk for mental health outcomes than workers & controls from other regions

Study Population

- Adults \geq 18 years
 - Workers (BP, Vessels, Shoreline Crews)
 - Volunteers
 - Federal State: Coast Guard, Fish & Wildlife, Others
- Communicate in English, Vietnamese, Spanish, others TBD
- Potential for exposure based on work history etc.
 - **Exposed** - worked one or more days in any clean-up task paid or volunteer
 - **Unexposed** - completed training but did not work; eligible but not deployed; other community members (friends, relatives) as needed

Study Design

- Approach ~75,000 from master list
 - Maximize Gulf states, higher exposures, complaints
 - Enrollment questionnaire (~ 30 minutes, phone or in-person)
 - Health, lifestyle, occupation, socioeconomic factors, demographics
 - Clean-up activities, living accommodations
 - Spill-related health effects (rashes, respiratory & neurologic symptoms)
 - Stress, depression, anxiety, perceived risk
- Cohort size 55,000 with 70% response rate

Cohort Follow-up (n~55,000)

- Recruit 27,000 for active participation in long-term clinical study – **Active Follow-up Sub-Cohort**
 - All clean-up job categories (~20,000 exposed)
 - Oversample higher exposed and/or smaller job categories
 - ~7,000 unexposed controls
 - 4,000 local; 2,000 non-local; 1,000 Federal
 - Maximize or limit to 5 gulf states
 - Follow remainder via record linkage (~28,000)
- ➔ Follow-up 10 or more years

Biospecimen Collection

- **Protocols from UK Biobank and Sister Study**
- Biomarkers of exposure: opportunity lost (except metals)
 - Benzene, PAH-hemoglobin adducts not available
- Biomarkers of effect: (based largely on worker studies & benzene effects)
 - Blood (fasting if feasible & minimal field processing)
 - DNA Changes (comet & micronuclease assays)
 - Serum, clots, plasma, buffy coat/RBCs, whole blood, metal-free sample, RNA, cryopreserved whole blood or lymphocytes
 - Saliva for DNA (if can't collect blood)
 - Hematologic assays (CBC) on fresh sample for subset
 - Urine (renal damage?)
 - Dipstick glucose & Urinalysis (protein, leukocytes, glucose, pH, other)
 - Hair and/or toenail clippings (for heavy metals)
- **Further analyses deferred pending exposure assessment, funding, etc.**

Biomedical Surveillance Sub-cohort (TBD)

Collaborations with researchers in the Gulf area;
common protocol with some variation

- Select ~ 5,000 from active follow-up sub-cohort
- More Extensive Clinical Assessment – (years 1 and 3)
 - Biological Samples
 - Comprehensive pulmonary function tests
 - Neurological/neurobehavioral testing
 - Mental health screening
 - Reproductive function
 - Laboratory tests
 - Environmental Samples

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 Sub-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



Data sharing

Comprehensive transparent data sharing plan modeled on recent studies, NIH guidelines

- Questionnaires, study documentation, data access protocol, and summary data on website
- Clear impartial procedures for accessing data and proposing add-on studies
- Controlled access process for sharing individual level data as consistent with informed consent
- Privacy and rights of participants fully safeguarded
 - Community and participant concerns addressed
 - Legal and ethical issues considered

Oversight

Peer-review of protocol

- NIEHS: blinded extramural review
- IRB, OMB
- Federal agencies, committees
- Public

Study Advisory Board

- Subcommittee of NIEHS Board of Scientific Counselors
 - Include one or more members of BSC
 - Other experts
 - Community representatives
 - Federal agency liaisons

Ongoing oversight by IOM and Federal panels



GuLF study investigators

NIEHS PIs

- Lawrence Engel, Ph.D.
- Richard Kwok, Ph.D.
- Dale Sandler, Ph.D.

Other NIEHS Investigators

- Aubrey Miller, M.D., M.P.H.
- Stephanie London, M.D., Dr.P.H.
- Christine Parks, Ph.D.

Consultants

- Aaron Blair, Ph.D.
- John Hankinson, Ph.D.
- Joseph (Chip) Hughes