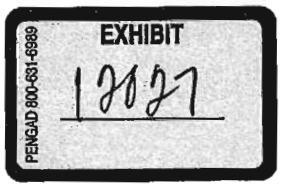

From: Heron, Richard
Sent: Mon Jul 05 06:52:47 2010
To: Flower, David; Martin, Alison (HSE); Tremmel, Fred J; Chau, May T; Dobbie, John M; O'Shea, Kevin J; Murray, Kate A; Saperstein, Mark
Cc: 'gkrieger@newfields.com'
Subject: Fw: HHE Expansion and Biomonitoring
Importance: Normal
Attachments: Heron.Proposal.2.docx

All
Please do not circulate but do comment.

I have managed to secure early release of significant funding from GRI.

This is to enable base-lines to be set.

As you can see below, I am also at a relatively good stage with CDC/NIOSH in helping them shape a programme which can be run (with funding) from their charitable foundation.

Gary is drafting our "criteria for use"

I welcome your comments before Wednesday if possible, later if not

Richard

Kind Regards,

Richard

Dr Richard JL Heron

Vice-President Health
BP International
Building B
Chertsey Road
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TW16 7LN

Mobile: +44(0)7920 586890
E-mail: Richard.Heron@uk.bp.com

Sent from my BlackBerry Wireless Handheld.

From: Howard, John (CDC/NIOSH/OD) <zkz1@cdc.gov>

To: Heron, Richard
Cc: Kitt, Margaret (CDC/NIOSH/OD) <ajy8@CDC.GOV>
Sent: Sun Jul 04 19:24:31 2010
Subject: RE: HHE Expansion and Biomonitoring

Richard:

Happy 4th of July from the colonies! Our thinking has not been stagnant during the hiatus. Attached is another draft—the 4th of July version—that reflects our recent thinking about how all the pieces we are doing fit together. I hope you like it. Happy to chat anytime. Safe travels!

Cheers!

JH

From: Heron, Richard [mailto:Richard.Heron@uk.bp.com]
Sent: Sunday, July 04, 2010 10:23 AM
To: Kitt, Margaret (CDC/NIOSH/OD)
Cc: Howard, John (CDC/NIOSH/OD)
Subject: RE: HHE Expansion and Biomonitoring

Margaret, John,

Hope you both managed a little time out this holiday weekend!

Some progress here on funding for base-line and basic science studies at least. Just had to switch PC's and most of my e-files not with me - Can you resend the original proposal you and John put together.

Wayne Carr will be making contact sometime this week to set up a call with you. I will be in Houston Monday evening thru Friday this week, which makes call timing a little more straightforward

Richard

From: Kitt, Margaret (CDC/NIOSH/OD) [mailto:ajy8@cdc.gov]
Sent: 02 July 2010 23:34
To: Heron, Richard
Cc: Howard, John (CDC/NIOSH/OD)

Subject: HHE Expansion and Biomonitoring

Hi Richard:

I just wanted to update you on NIOSH's plan to extend response worker exposure characterization and quantification by incorporating a feasibility study on biomonitoring as a part of the expanded HHE efforts BP has asked NIOSH to do. In light of air sampling yielding undetectable levels of toxins, or levels far below established limits, we are concerned about making sure the dermal route of exposure is well-characterized.

Also, as we heard from the IOM workshop last week, the topic of biomonitoring needs to be addressed. We have a group within our NIOSH Division of Applied Research and Technology that have expertise in biomonitoring. There is also another group at CDC/NCEH with expertise in this area. Both groups have been working with Dr. Bruce Bernard to develop a scientifically sound protocol to use as a path forward. In fact, NIOSH would like to have the IOM review this protocol and provide input. We certainly will share the protocol with you once the draft is completed.

The major areas addressed in the draft protocol include:

- Enrolling 50-75 workers exposed to oil and 50 controls.
- Quantifying body burden using urine testing of poly-aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs), and a metabolite of 2-butoxy-ethanol (used in Corexit 9527 discontinued almost 2 months ago); measure creatinine (to normalize urinary metabolite results) and cotinine (to help determine whether levels may be influenced by smoking or tobacco use):
  - o We would collect three urine samples: a pre-work shift, post-work shift on one work day and another post-workshift sample on another work day.
  - o We would have them complete a consent form
  - o Have them complete a short questionnaire, which would provide needed personal information and information on potential confounders, such as smoking history, 2nd hand smoke, other exposures to grilled foods and oils (lotions, tar shampoos, sunscreen, etc.).
- Measuring and comparing their urine levels pre- and post-work shift exposure, exposed and unexposed, and to previous studies of asphalt workers (exposed to PAHS) and petroleum workers, and general population results from the recent N-HANES study.
- Proposing that biomonitoring be conducted at the Plaquemines ICS (Venice Branch) in Venice, Louisiana.
- Our goal would be to determine whether the workers' body burden of these compound increased with exposure (within the limitations of confounders).
- The results will help determine if recommendations can be made to improve work practices, PPE efficacy, and safety procedures are needed.

We realize that implementation of the protocol presents a whole other level of logistical challenges. NIOSH will need the support of you and the rest of BP leadership to meet these implementation hurdles. Please let us know your thoughts.

Thank you and I hope your father-in-law's health has stabilized.

Margaret

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Deputy Director for Program
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Deepwater Horizon Response Health Assessment Proposal

4 July 2010: Draft 2

Introduction

Federal health agencies are engaged in a number of activities as a result of the Gulf of Mexico Oil Spill including: (1) disseminating information to decrease uncertainty about nature of short and longer term physical and psychological or behavioral health effects arising from the oil spill; (2) providing assistance to workers and residents experiencing physical and psychological or behavioral health effects associated with the oil spill; and (3) making recommendations aimed at preventing illness, injury and disability among responders and the community as a result of the oil spill.

At the Institute of Medicine (IOM) Workshop on 22-23 June 2010 on the Gulf of Mexico Oil Spill, it was clearly identified that a better understanding of potential long term health effects among response workers and community populations is needed. Prior to the IOM Workshop, CDC initiated actions to protect workers from harmful exposures *during* their response work, to identify health effects during response work, and began laying the groundwork for identifying health effects that may appear over the longer term. CDC has also engaged in activities to assess the human health and psychological needs among impacted residents. Since the IOM Workshop, CDC has refined its ongoing activities and developed plans for longer term studies of responders and the affected community.

I. Responder Health Studies

Determining health effects in Deepwater Horizon Response workers involves implementing a comprehensive plan *during* response activities that builds step-wise to the evaluation of longer term health effects in responders *following completion* of their individual response activities and at the conclusion of the oil spill cleanup activities in general.

Experience from disasters such as the World Trade Center and the Exxon-Valdez Oil spill indicates that six steps are critical to both successful protection of workers' health from harmful exposures *during* the response, and are critical to the evaluation of health effects *following* completion of response work (see Figure 1).

CDC is actively engaged in activities which implement the five of the six steps for assessment of short and longer term health studies: (1) establishment of a complete roster of response workers containing basis demographic information; (2) characterization and quantification of exposure through inhalational and dermal routes across all worker exposure categories ; (3) toxicological studies of crude oil, oil dispersants, and other potential toxic exposures, and psychological stressors that may play a role in producing short term and longer term adverse physiological and psychological health effects; (4) quantitative assessment of risk using exposure and toxicity data; and (5) health surveillance for physiological and psychological health effects by means of active worker health monitoring **during** the response and by means of competitively-awarded research grants whose purpose would be to identify any longer term

physiological and psychological health effects from response work utilizing findings from studies conducted **during** the response and collection of biological samples.

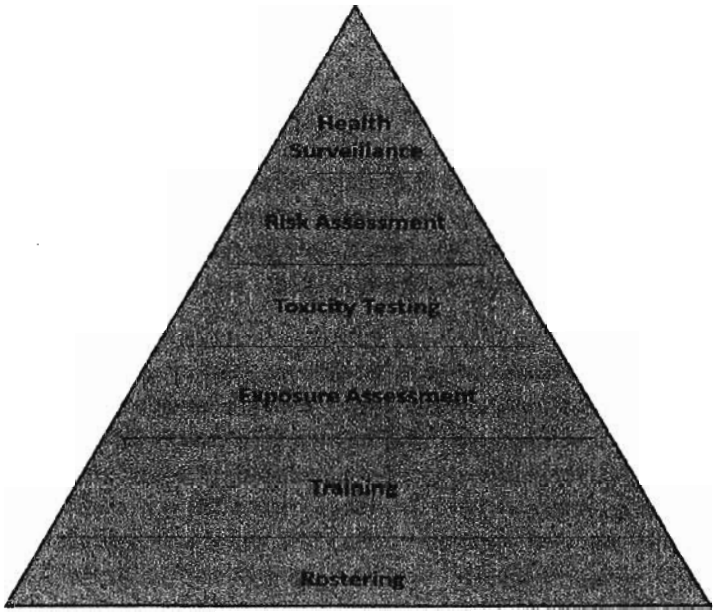

Figure 1: Stepwise elements for assessment of short and longer-term health effects in response workers

Step 1. Rostering

A key lesson learned from the WTC disaster in New York City in 2001 is the importance of having a roster of all workers responding to a large-scale, long-duration disaster. Currently, CDC/NIOSH is engaged in rostering Deepwater Horizon Response workers, creating an electronic database of responder demographic and job data, and analyzing the data to create a profile of a possible cohort for longer term health studies. For current rostering information, see http://www.cdc.gov/niosh/topics/oilspillresponse/workerroster.html

Step 2. Training

Effective exposure prevention depends on effective worker training. Currently, the Worker Education and Training Program (WETP) at NIH/NIEHS and at OSHA are ensuring that responder training is effective. See http://www.niehs.nih.gov/news/newsletter/2010/june/spotlight-spill.cfm and http://www.osha.gov/oilspills/Basic_Training_Fact_06_22_10.pdf .

Step 3. Exposure Assessment

Responders are exposed to heat, long hours, interrupted sleep, musculoskeletal injuries, lacerations and contusions, insect bites, physical safety hazards, and chemical constituents of crude oil and oil dispersants. See http://www.cdc.gov/niosh/topics/oilspillresponse/data.html

Environmental air sampling has been conducted on various categories of response workers by a number of different governmental (e.g., EPA, NOAA, OSHA, Coast Guard and CDC/NIOSH) and non-governmental entities (e.g., Center for Toxicology and Environmental Health). To date, air sampling has demonstrated undetectable levels, or levels far below established safe levels, for toxic chemical constituents of crude oil and oil dispersants. However, the potential for dermal exposure also exists.

Responder health surveillance for acute health effects has shown that some workers have reported eye, nose and throat irritation, headache, dizziness, nausea and allergic skin reactions. These symptoms may be indicators of exposure to the volatile components of crude oil or some may be a result of heat stress, fatigue and other exposures not related to crude oil/oil dispersant mixtures.

The NIOSH-OSHA Interim Guidance for Protecting Deepwater Horizon Response Workers and Volunteers http://www.cdc.gov/niosh/topics/oilspillresponse/protecting/provides recommendations for protection against lung and skin contact with crude oil/oil dispersant components. In addition, CDC/NIOSH is conducting a series of health hazard evaluations (HHEs) http://www.cdc.gov/niosh/topics/oilspillresponse/gulfspillhhe.html to characterize the exposure categories identified for responders and to quantify their exposures through air monitoring and through biological sampling. The six categories of workers are (1) source control workers; (2) workers involved in burning crude oil; (3) workers on vessels not involved in burning; (4) shoreline and marsh cleanup workers; (5) equipment and wildlife decontamination workers; and (6) waste stream management workers.

Biomonitoring and Collection of Biological Samples. Exposure assessment by means of biomedical sampling, or "biomonitoring," permits in theory a more complete exposure assessment because it represents the accumulated exposure from all routes of exposure (lung, skin and gastrointestinal). The possible use of biomonitoring in assessing exposure in response workers was introduced at the IOM Workshop. However, biomonitoring of chemical exposure has many limitations and its use must be carefully considered.

Biomonitoring across all worker exposure categories for the more volatile components of crude oil, such as polycyclic aromatic hydrocarbons (PAHs), like naphthalene and non-PAH chemicals such as short-chain alkanes, benzene and xylenes, is unlikely to yield useful exposure information as these evaporate within a day. Therefore, exposure to these volatile components would be likely to occur in the immediate area of the source. Workers not at the source are exposed to weathered crude oil which has higher concentrations of heavier molecular weight (4-5 rings) PAHs than fresh crude oil.

Biomonitoring is not recommended for epidemiological investigations of populations with suspected chemical exposures or for individual clinical investigation, but it may prove useful in carefully controlled and highly standardized research studies of workers with the greatest potential for exposure to crude oil such as source control workers or workers on vessels involved in burning. Even so, the short half-lives of PAH metabolites, with levels rising and falling within a 24 hour period, and the multiple confounding exposures from certain foods, contribute to significant within-day intra-subject variability.

Even though biomonitoring can be used to further understand exposures and to evaluate the effectiveness of worker protection strategies, its use in occupational settings during an active response has been limited. Biomonitoring of chemical exposure was done among New York City Firefighters responding to the World Trade Center disaster, but comparison of exposed and control groups indicated that levels of only a few of the more than 100 chemicals sampled in exposed firefighters, although statistically elevated, were generally low compared with reference values in the general population or workplace threshold levels.[1]

NCEH-ATSDR and CDC/NIOSH are collaborating on a feasibility study protocol of biomonitoring as part of the ongoing Deepwater Horizon Response suite of HHEs. Its application in an active response effort where workers with potentially the highest levels of exposures are working on vessels at the source or on vessels engaged in burning presents challenges. See Appendix A for brief description of limited biomonitoring study for feasibility.

A more detailed consideration of the role of biomonitoring may be a suitable subject for IOM input and discussion, including the collection of biomedical samples for subsequent biomarker studies, including genotoxicity studies.

Step 4. Toxicity Testing

Workers involved in the oil spill containment and cleanup efforts have reported upper and lower respiratory distress, headaches and dizziness. These symptoms suggest inhalation of crude oil constituents and oil dispersants aerosols may have health effects. Dermal exposure may also occur and be associated with local skin reactions and longer term systemic effects depending on the toxicity of oil and dispersant constituents. Studies are planned to determine the inhalational and dermal toxicity of constituents through computational toxicology, cell culture and assay and acute animal exposure studies. Genotoxicity studies are also being considered.

Step 5. Risk Assessment

Workers involved in various oil spill clean-up tasks may be exposed to toxic and carcinogenic compounds such as benzene, naphthalene, and selected PAHs. Using published data on exposure-response relationships CDC/NIOSH is currently engaged in projecting the magnitude of risks for workers conducting response tasks (in six exposure categories identified in HHEs). Using toxicity testing data and accumulating exposure data, NIOSH will give consideration to developing new, and evaluating, existing recommended exposure limits (RELs) for crude oil/oil dispersant constituents and revise them, if warranted.

Step 6. Health Surveillance

a. Symptom Surveys during Response

CDC/NIOSH field teams have administered and continue to administer health surveys to response workers in a representative sampling of off-shore and on-shore work sites. Health surveys are conducted in order to provide immediate assessment of need for changes in education and training, work practices or other controls, use of personal protective equipment, or medical monitoring and care. Health survey data may also be useful in planning or modifying exposure assessment activities.

During the administration of health surveys, field teams are able to provide information to workers and management representatives regarding potential occupational health concerns (such as heat stress and chemical exposures) and review first-aid or infirmary logs in locations where those are present. Data from individual surveys are evaluated on-site by the field teams; the collective data are being evaluated currently. In the future, these health survey data will be used in the design of health screening evaluations and longer term health studies.

b. Health Screening during Response Work or Following Response Work (at Exit)

A worker health survey of all rostered individuals in the near term—either during response work or at exit—will serve three purposes. First, an interview will provide for each individual a more detailed description of the job duties, work schedules, PPE use, and other measures of potential exposures which are needed to better characterize exposure potential by job duties and to identify subgroups for further follow-up. Second, the interview will provide a measure of acute symptoms and health problems experienced by workers so that changes in OSHA-NIOSH Interim Guidance and its recommendations can be made. Third, the interview will help direct specific design needs for possible studies of longer term health effects.

c. Health Surveillance and Longer Term Health Studies

Review of the world's literature on tanker oil spills, including the Exxon-Valdez Oil Spill, reveal scant studies of longer term health effects in oil spill clean-up workers or in the community (see Appendix B). Most studies are cross-sectional epidemiologic studies that have focused on acute health effects and psychological symptoms; others utilized *in vitro* or *in vivo* methods to determine cell-level health effects or focused on biological markers for genotoxicity and endocrine toxicity.

Longer term health effects have been studied, though, in petroleum refinery workers, but these workers may be exposed to carcinogens not found in crude oil. Petroleum refinery workers cohort studies have largely shown no significant increase in mortality,[ii, iii] but caution has been voiced that cohort studies "based on mortality data and not including an internal group as a control may be affected by several biases."[iv] Case control studies have also been done in petroleum refinery workers. For instance, one study showed an increased risk of esophageal adenocarcinoma among male offshore petroleum workers assumed to have had the most extensive contact with crude oil,[v] and another case control study of kidney cancer, following up

on the observation that male rats exposed to unleaded gasoline, demonstrated a dose-related increase in kidney cancer, did not show the same result in male refinery workers.[vi]

Aguilera et al[vii] recommends, considering the high frequency of environmental disasters arising from tanker oil spills, that protocols should be developed and include collection of biological samples during the response "in order to establish the levels of individual internal exposure effects at the acute and chronic level, especially those related to genotoxicity."[viii]

CDC plans to use the results from ongoing exposure assessment and health screening efforts described above to consider whether longer term health studies should be conducted, and if so, what study design will be most appropriate. The exposure results being collected now would inform the design of any longer term study, including identification of the health effects and subgroups that would be included.

Appendix A

Brief Description of a *Feasibility* Study of Biomonitoring during Deepwater Horizon Response

Aims: To determine whether workers' body burden of selected analytes increase with exposure (within the limitations of confounders). The expected results can be used to make recommendations to improve work practices, personal protective equipment efficacy, and to determine if biomonitoring can assist in the effort to more precisely characterize and quantify exposure assessment.

Enrollment: 75 workers who are at highest risk of exposure to crude oil/oil dispersant (source control workers) and 75 controls. Consideration may be given to enrolling active duty Coast Guard personnel working at the source.

Location: Biomonitoring to be conducted at the Plaquemines ICS (Venice Branch) in Venice, Louisiana.

Methods:

1. Completion of a short questionnaire, which would provide needed personal information and information on potential confounders, such as smoking history, 2nd hand smoke, other exposures to grilled foods, smoked foods, and oils (lotions, tar shampoos, sunscreen, etc.).

2. After enrollment and completion of a consent form, three urine samples will be collected: a pre-work shift, post-work shift on one work day and another sample 24 hours after a shift;

3. Measure creatinine (to normalize urinary metabolite results) and cotinine (to help determine whether levels may be influenced by smoking or chewing tobacco use or secondhand smoke).

4. Quantify body burden using urine testing of poly-aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs), and a metabolite of 2-butoxy-ethanol (used in Corexit 9527 [discontinued almost 2 months ago] and in currently used Corexit 9500 and 9500A).

5. Measure and compare worker urine levels pre- and post-work shift exposure, exposed and unexposed, and to previous studies of asphalt workers (exposed to PAHs) and petroleum workers, and general population results from the recent NHANES study.

Appendix B

Human Health Effects Studies from Selected Oil Tanker Spill Disasters

Previous reports have associated symptoms and other adverse health effects in clean-up workers and communities with spills of crude and fuel oil from tankers. These studies involve crude oil or refined petroleum products that may not be directly comparable to crude oil in the Deepwater Horizon event. Studies of eight tanker disasters are shown below. More detailed information is available in several recent reviews by Aguilera et al 2010[ix] and Rodriguez-Trigo et al 2007. [x]

Spill	Type of Oil	Health Effects	Author
Exxon Valdez (Alaska, 1989)	Crude	Worker comp claims (1811): sprains/strains (506), respiratory (264), cut/laceration (150) & contusion/crushing (144).	Gorman et al, 1991[xi]
		Alaskan Native and Euro-American residents found to have depressive symptoms. One year later, PTSD was associated with social disruption.	Palinkas et al, 1992[xii] and 2004[xiii]
MV Braer (Scotland, 1993)	Crude	Residents affected by the oil spill compared to a control community 95 km away. Subject had significantly more headache, throat irritation, and itchy eyes. Day 1 after the spill was the most frequent day for onset of symptoms; 97% resolved by day 7. Six months later, exposed residents more likely to report their health was poor or had deteriorated.	Campbell et al, 1993;[xiv] Campbell et al, 1994[xv]
Sea Empress (Wales, 1996)	Crude	Residents in exposed areas reported higher rates of physical and psychological symptoms than control areas.	Lyons et al, 1999[xvi]
Nakhodka (Japan, 1997)	Fuel C oil	Residents had low back pain and leg pain, headache, and symptoms of the eyes and throat despite low measured levels of exposure.	Morita et al, 1999[xvii]
Erika (France, 1999)	Heavy #6 Fuel Oil	Workers (1465) surveyed: backache (439), headache (317), skin irritation (230), eye irritation (126), difficulty breathing (98), nausea & vomiting (91).	Schvoerer et al, 2000[xviii]
Prestige (Spain, 2002)	Residual fuel oil ("bunker C oil")	Workers had headaches, itchy eyes, nausea, vomiting, dizziness, throat & respiratory problems. Risk factors for symptoms included working periods longer than 20 days in highly polluted areas, performing three or more activities, and having skin contact with fuel on head/neck or upper limbs. Receiving health and hygiene information prior to starting a clean-up activity was a protective factor.	Suarez et al, 2005[xix]
		Cleanup exposure caused increase in genotoxic damage.	Perez-Cadahia et al, 2006[xx]
		Workers (7000) had significantly higher rates of upper and lower respiratory tract symptoms, with a dose related increase based on number of days, number of hours worked per day and number of activities.	Zock et al, 2007[xxi]
Tasman Spirit (Pakistan, 2003)	Crude	Workers had acute decline in lung function measured by spirometry in 31 clean-up workers. More weeks of work was associated with greater losses of lung function. One year later, repeat spirometry among 20 workers showed function comparable with controls.	Meo et al, 2008;[xxii] Meo et al, 2009[xxiii]
Heibei Spirit (South Korea, 2007)	Crude	Workers had increased levels of VOC metabolites in urine. Resident of heavily/moderately oil-soaked areas had higher anxiety and depression. Both groups had increased headache, nausea, dizziness, sore throat, cough, skin rash, and sore eyes.	Lee et al, 2010[xxiv] Lee et al, 2010b[xxv]

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