Review of the Proposal for the Gulf Long-Term Follow-Up Study: Highlights from the September 2010 Workshop: Workshop Report

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Lynn Goldman, Abigail Mitchell, and Margie Patlak, Editors; Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill; Institute of Medicine

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Highlights from the September 2010 Workshop

Workshop Report

Lynn Goldman, Abigail Mitchell, and Margie Patlak, *Editors*

Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill

Board on Population Health and Public Health Practice

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Willing is not enough; we must do."
—Goethe

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COMMITTEE TO REVIEW THE FEDERAL RESPONSE TO THE HEALTH EFFECTS ASSOCIATED WITH THE GULF OF MEXICO OIL SPILL[1]

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[1] The report summarizes the views expressed by workshop participants, and while the committee is responsible for the overall quality and accuracy of the report as a record of what transpired at the workshop, the views contained in the report are not necessarily those of the committee.

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This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's (NRC's) Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Tomás Aragón, University of California, Berkeley
Rose Goldman, Harvard School of Public Health
David Hoel, Medical University of South Carolina
Maureen Lichtveld, Tulane University
David Tollerud, University of Louisville

Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the report before its release. The review of this report was overseen by **Stephen Fienberg,** Carnegie Mellon University and **Jonathan Samet,** University of Southern California. Appointed by the National Research Council and the Institute of Medicine, respectively, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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INTRODUCTION

On April 20, 2010, the Deepwater Horizon, a semisubmersible offshore drilling rig in the Gulf of Mexico, exploded. The well that the rig was drilling began to spew crude oil into the Gulf and continued to spew millions of liters of crude oil, until it was successfully capped in mid-July. This oil spill is unprecedented in its size, duration, and deep-water nature and in the use of dispersants and controlled burns in an attempt to ameliorate the spill. The potential for human health effects linked to exposure to the oil in the environment and to the dispersants and fumes from the controlled burns is of concern. Mental and behavioral health effects due to the temporary or permanent loss of livelihoods among the individuals in the fishing community and oil workers and uncertainty about the health of their environment and when they can return to work are also of concern.

Although studies of previous oil spills provide some basis for identifying and mitigating the human health effects of oil spills, the existing data are insufficient to provide a full understanding of and to be able to predict the overall impact of hazards from the Gulf of Mexico oil spill on the health of individuals—including workers, volunteers, residents, visitors, and special populations.[1] Many of the previous studies were designed to evaluate short-term health effects only and dealt with spills that were finite in volume and time (for example, the *Exxon Valdez* and *Prestige* spills in 1989 and 2002, respectively). Aiming to fill the gap in knowledge on the health effects of oil spills, as well as to assemble information that can be used for prevention of adverse health outcomes and interventions against such outcomes in any similar disasters in the future, the National Institute of Environmental Health Sciences (NIEHS) plans to conduct a study designed to investigate potential short- and long-term health effects among workers engaged in cleanup activities linked to the Gulf of Mexico oil spill. That study, the Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers (the GuLF study), aims not to study a few narrow hypotheses but, rather, aims to allow the investigation of a wide range of potential adverse health effects, including physical, psychological, and biological effects.

As part of its ongoing commitment to the U.S. Department of Health and Human Services (HHS) to provide periodic independent reviews of the federal response to the Gulf of Mexico oil spill as it relates to the surveillance and monitoring of acute and long-term physical and behavioral health effects, the Institute of Medicine (IOM) convened the Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill. As part of its work, the committee planned a workshop to bring together experts to review and make comments on the GuLF study protocol, which was published on the IOM website just before the conference.[2] This document highlights the presentations and discussions that occurred during the workshop, which was held on September 22, 2010, in Tampa, Florida. The workshop agenda can be found in the Appendix.

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[1] IOM (Institute of Medicine). 2010. *Assessing the Effects of the Gulf of Mexico Oil Spill on Human Health.* Washington, DC: The National Academies Press.

[2] The version of the GuLF study protocol that the workshop participants provided comments on can be accessed at http://iom.edu/~/media/Files/Activity%20Files/PublicHealth/FedResponseOilSpill/GuLF%20Study%20Protocol%20DRAFT%20to%20IOM%202010-09-17.pdf.

GuLF STUDY DESIGN

Dale Sandler, principal investigator of the GuLF study, gave a basic description of the study, noting that its primary objectives are to assess the short- and long-term health effects associated with the oil spill cleanup and to create a resource for future collaborative research on more focused hypotheses and specific subgroups. More detailed information about the GuLF study can be found on the NIEHS website.[3]

The study's main broad hypothesis is that exposure to the oil, dispersants, or combustibles given off by the burning of the oil, as well as disaster-related stress and working under excessive heat conditions, places workers at greater risk for developing mental or physical health problems. The study is open-ended, in that it is not assessing specific health outcomes, although investigations will be guided to some degree by the health complaints of others with similar exposures, such as those involved with previous oil spills.

The study population is proposed to consist of two groups:

- Exposed adults 18 years of age or older who worked for pay or on a volunteer basis for one or more days in any cleanup task and
- Unexposed adults who completed safety training but who did not perform cleanup work, and other community members, such as friends and relatives of the workers, if needed.

The study will have a nested design, such that a large anticipated cohort of workers (55,000, if the response rate is 70 percent) will receive a baseline phone questionnaire and will then be passively followed by linking them to cancer registries and vital statistics databases. A smaller subset of these workers will be actively studied by following up with detailed questionnaires and by collection of biological specimens and environmental samples and of physiological and anthropometric measures. A subset of these active participants will undergo biomedical surveillance done in collaboration with researchers in the Gulf area. Although the exact nature of the biomedical surveillance component of the study is still being worked out, these investigators will probably conduct comprehensive pulmonary function analyses, neurological and neurobehavioral testing, reproductive function evaluation, and mental health screening.

The GuLF study will have a community advisory board. GuLF study investigators have already implemented some initial outreach activities to a number of communities in the affected states. The investigators plan to engage the community refining the design and protocols and to work with the community to explain the rationale for collecting data. Community stakeholders will be involved at key study points, according to Dr. Sandler, who hopes to facilitate community involvement and ownership to foster trust and mutual understanding. The GuLF study team also hopes to create opportunities for community-directed research either by answering questions of concern or by fostering add-on or companion studies.

The GuLF study may be subject to numerous limitations that Dr. Sandler pointed out, including

- Limited availability of preexposure biological samples or health assessments,
- Limited availability of quantitative exposure measures,

[3] http://www.niehs.nih.gov/about/od/programs/gulfworkerstudy.cfm

- Likely low individual exposures, and
- For some cohort members, petrochemical and other exposures not due to their oil spill cleanup activities.

Dr. Sandler said that the study processes in the GuLF study, including data gathering, will be transparent and shared according to National Institutes of Health (NIH) guidelines. Sharing of individual-level data will be through a controlled-access process. Francis Collins, director of the NIH, suggested using the genome-wide association studies (GWAS) as a model for the GuLF study data access policies. He noted that GWAS data were stripped of all individual identifiers and that data access for GWAS was two tiered, such that the public had access to the study protocol and descriptive information, whereas investigators approved by a data access committee had controlled access to more detailed data.

Harvey Fineberg, president of the Institute of Medicine, noted the pathbreaking nature of the GuLF study. A study of this type has never been assembled in such a short time frame before, he said. Although it is uncertain whether the study will ultimately discover disease and health consequences, "what can be certain is that from methodology, the processes, and the manner in which you conduct this study, you have the opportunity to set new standards. You have an opportunity to engage with a community in a way that has never been quite accomplished."

A number of themes for improving the GuLF study emerged from the workshop discussions, although they do not reflect consensus among the workshop participants, as the workshop did not have the goal of reaching a consensus. The list of themes follows and each theme is expanded upon below.

- Making greater use of resources and expertise available both at the federal level and locally, including adding investigators from federal agencies other than NIH to the core research team;
- Providing more details in the protocol concerning the administration and coordination of the various components of the study and a plan for ensuring data sharing and quality;
- Validating exposure assumptions and assessments and collecting data on likely confounders;
- Choosing appropriate controls;
- Providing more specific, focused outcomes or concrete hypotheses that can be used to guide decisions about the data to be collected;
- Planning for enrollment lower than that predicted in the protocol and giving careful consideration of how to maximize the enrollment and retention of study participants;
- Fostering more collaboration with the community, with communications with all members of the community needing to be culturally sensitive and taking health literacy into account;
- Planning to ensure that the health referrals likely to be needed for the participants with immediate health concerns are adequate;
- Planning for the legal issues related to confidentiality likely to arise and the potential impact on participant enrollment; and
- Including more health outcomes such as additional psychosocial measurements and gathering of data from pregnant women affected by the oil spill.

TAPPING EXISTING RESOURCES

Several participants at the workshop pointed out existing resources that the NIEHS could be making greater use of in its study. These resources include the relevant expertise, tools, and data of other government agencies.[4] The Environmental Protection Agency (EPA) not only has thousands of water, sediment, and air samples collected from the oil spill site but also has unique exposure reconstruction tools that it is willing to share, according to Michele Colon from EPA. She indicated that the agency is eager to be involved in the GuLF study because it views worker health as an important sentinel for assessing environmental health consequences of the oil spill. The National Oceanic and Atmospheric Administration has also been heavily engaged in collecting water and air samples from the oil spill and has published its data on its website. The Food and Drug Administration (FDA) could aid with the food safety and exposure assessments, a few participants suggested. Several participants noted that the federal government is working to create a website integrating the environmental and food sampling data obtained through the efforts of various federal agencies.

According to Scott Deitchman of the Centers for Disease Control and Prevention (CDC), state public health agencies have established temporary state-based surveillance for health effects related to the oil spill. The CDC has collected and combined these state tracking data. This surveillance was recently discontinued when the number of reports of health effects diminished. No apparent trends in public health problems could be discerned from the data, but the agency continues to collect reports of health effects from its poison control center databases and U.S. Department of Veterans Affairs hospitals. In addition, the CDC will conduct by telephone a behavioral risk factor survey in four of the affected states over a 1- to 2-year period. This special behavioral risk factor survey will include a number of questions from the standard behavioral risk factor surveillance system questionnaire to enable the use of historic controls to analyze the data collected in this survey. Although such data can be shared with NIEHS, it may be difficult to make linkages because the data have been deidentified, Dr. Deitchman noted. He added that his agency has an extensive health communications network through its partners with state and local public health agencies and health care providers and can make this communications resource available to investigators in the GuLF study.

Responders to the oil spill included members of the U.S. Coast Guard. Erica Schwartz and Jennifer Rusiecki of the Coast Guard said that they could provide a roster of those responders. This roster, however, does not document the specific tasks that each Coast Guard worker did but, rather, indicates the general office to which each worker was assigned. However, the Coast Guard is currently gathering data from the survey that it administered to all of its responders upon demobilization. The responses to this survey contain more detailed information on the location of the response efforts, the missions performed, and self-reported exposures. This information can be linked to the data on its members that the Coast Guard routinely collects, as well as biospecimen samples in a serum repository. The annual personal health assessments of Coast Guard members who did not work on the Gulf oil spill could be used as data for a control population.

[4] Additional information about interagency efforts can be accessed at http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/FedResponseOilSpill/Interagency%20Meeting%20Summary%20GuLF.pdf.

James Spahr of the National Institute of Occupational Safety and Health (NIOSH) noted that his agency aims to make all information that it has collected on workers available and transparent. NIOSH has access to British Petroleum's (BP's) list of 55,000 response workers, including injury and illness data that the oil company collected. In addition, the agency continues to conduct animal-based toxicology studies on the effects of dispersants and combustible materials related to in situ burning of the oil.

Bernard Goldstein, a member of the IOM committee that hosted the workshop, pointed out that NIEHS, the National Toxicology Program, NIOSH, and EPA all have toxicology expertise that should be used to improve the understanding of the effects of some of the higher-molecular-weight crude oil and dispersant products, about which little is known and to which exposure is likely. David Tollerud of the University of Louisville stressed that NIEHS, EPA, the National Cancer Institute (NCI), and others have considerable experience in community outreach and subject retention and that that expertise should be tapped. He also recommended referencing and drawing upon the experiences of similarly large, ongoing cohort studies, such as the Nurses Health Study or the Normative Aging Study.

Princess Jackson of the Health Resources and Services Administration (HRSA) noted that her agency may be able to help provide linkages to the medical services that participants in the GuLF study may need. Her agency is currently exploring how it may be able to help in this regard, she said, but added that most HRSA community centers are distant from the areas affected by the Gulf of Mexico oil spill.

Teri Manolio of the NIH Office of Population Genomics noted that NIH may not have all the data critical to effectively conduct the GuLF study and that the investigators in that study will consult with multiple agencies to acquire that information. Aubrey Miller, a GuLF study coinvestigator, added that some effort will be made to unify the surveys of all the agencies and to make sure that their efforts are coordinated.

In his presentation, Robert Wallace of the University of Iowa suggested that the GuLF study make good use of archival data, including social indicators that can be mined from unemployment claims, data collected by community mental health centers, crime rate statistics, adult protective services calls, and abuse cases that may be detected from children's emergency room visits. He also suggested assessing environmental contaminant levels by use of the results of FDA seafood testing and air pollution monitoring. In addition, Dr. Wallace suggested taking advantage of ongoing cohort studies that may be taking place in the region, including NCI's Surveillance, Epidemiology, and End Results Program; the National Health Interview Study; the Bogalusa Heart Study; and the Health and Retirement Study. Maureen Lichtveld of Tulane University added that ongoing studies of a unique cohort of Vietnamese participants performed before and after Hurricane Katrina may be able to provide some useful data or resources.

Several participants stressed using community connections already established by health care workers and academic researchers in the affected areas. David Kalman of the University of Washington suggested engaging local scientists and potential users of the data collected in the GuLF study and providing transparent access to that information. Establish "lines of communication" with the local research community, he said. Dr. Lichtveld suggested engaging locally practicing health providers.

Dr. Goldstein summarized. He noted that successful completion of the study requires cooperation with local communities and community organizations and agencies, particularly

state and local health departments. Substantial academic expertise in the Gulf area exists and should be included in the study. Roberta Ness,[5] a member of the IOM committee, noted that virtually no one listed on the current team of investigators is a local academic or linked in some way to the local community, which is needed to build buy in and future capacity.

Those involved in designing the GuLF study noted that they have planned to partner with consortia of local academic researchers and community groups to address health issues that are not the focus of the GuLF study. NIH is currently developing a cross-institute effort to acquire funds for these consortia, Linda Birnbaum, director of NIEHS, said. "We are hopeful that there will be enough that we can form several consortia that can apply for five-year grants," she said. Dale Sandler added, "We've been researching the researchers" and assessing "who has the best chance of actually contributing something that we need to the study. Our plan all along has been to bring in more collaborators" to make up for the lack of expertise in-house. Such collaborators will either be incorporated into the study investigator team, be used as expert consultants, or be responsible for the add-on studies that will be done by the consortia. Francesca Dominici, a member of the IOM committee, suggested clarifying what scientific questions will be addressed by the NIEHS investigators and what questions will be addressed by the research consortia.

ADMINISTRATIVE AND DATA OVERSIGHT DETAILS

DeJuran Richardson of Lake Forest College suggested detailing in the protocol how the GuLF study will be administered, especially how the various components will be coordinated and how the data will be linked and managed. "Such details are extremely important and key to making sure that this quite large effort is kept on course," he said. Large studies with similar complexity that do not work well often do not pay attention to these administrative details.

He called for putting in place protocols for everyday management that ensure the timely feedback of information to those who can use it, so that adjustments to study operations can be made when needed. Plans also need to be put into place, he added, to ensure data compatibility, linkage, quality, and updating. David Tollerud also suggested developing a sustainability plan that will detail how the investigation will be sustained in the future.

Dale Sandler responded that regular meetings with contractors, steering committees, and advisory boards are planned; and Richard Kwok, a GuLF study coinvestigator, added that the GuLF study is also building on the administrative templates used in other similarly large and complex cohort studies. Dr. Sandler noted that BP contractors collected many data that they are willing to share, but that such data from different groups need to be assessed for comparability and that it is hard to put data into a common language. Also, some of the data that the BP contractors collected were not collected with the intent of being useful for research, she said.

EXPOSURE ASSESSMENT CHALLENGES

The workshop participants had much discussion about the difficulties in obtaining accurate and comprehensive exposure information on participants in the GuLF study, because many of those assessments will be made several months after the workers were exposed,

[5] Dr. Ness was unable to attend the workshop in person, but provided written comments.

hampering accurate recall and sampling efforts. As several participants pointed out, the immediate concerns of the public health officials who responded to the oil spill were protecting the workers and community members from contamination and not collecting the samples and information needed to ascertain exposure for a future research study, such as the GuLF study. In addition, many workers will have had multiple exposures during the oil spill, and the intensity of those exposures will vary over time, such that single exposure measurements may not be sufficient to fully assess total exposure.

"Exposure is oftentimes the Achilles heel of large-scale population studies, especially retrospective ones or ones that are being done in an emergent way," said David Kalman. "There are a lot of reasons to be concerned about exposure misclassification," he stressed.

Consequently, researchers should validate exposure assessments and pay attention to what approaches they use to deal with missing data, several participants suggested. Stephen Cole from the University of North Carolina, Chapel Hill, strongly stressed the importance of doing formal sensitivity analyses to test the validity of the exposure assumptions made in the study, especially since the study will not be randomized. Others suggested the usefulness of a data-monitoring committee.

Dr. Kalman suggested validating exposures by using multiple, overlapping exposure information on the study participants, including information from employers, the participants themselves, and the various groups doing exposure monitoring in the area, such as BP and the U.S. Coast Guard. "There is a ton of stuff. If it can in fact be brought to bear on this study in an ideal way, it will help a lot with the lack of real time measurement," Dr. Kalman said. He pointed out that because cleanup activities are ongoing, researchers can collect additional data that can be used to validate approaches to exposure evaluation. "This is a door of opportunity that is closing. So, if it were a tradeoff between getting it perfectly six months from now or getting it mostly right six weeks from now, I would vote for the later," Dr. Kalman said. Dr. Cole noted that multiple measures of exposure may be needed to adequately analyze the data, and Roberta Ness suggested that all relevant information that can be used to analyze exposure be collected, including food and water samples. Bernard Goldstein added that biological markers of exposure could be helpful after oil spills but that most do not persist long enough to be of value to the GuLF study at this late date.

David Cohen, a member of the IOM committee, suggested that key to assessing exposure accurately will be determinations of whether workers used the personal protective equipment that was given to them and whether they had additional personal hygiene habits that might have further limited their exposure.

Dr. Cole suggested considering in advance the types of data analyses that will need to be done and the likely confounders, as these will determine the study design and what data are collected. He also suggested doing partial random sampling to have a more powerful study.

Lawrence Engel, a coinvestigator of the GuLF study, responded that exposure assessments done in the GuLF study will include determining what cleanup tasks were done, whether there was dermal or other types of contact, and whether personal protective equipment was used while the study participants were doing those tasks. He added that plans have been made to do a sensitivity analysis of the exposure assumptions. Dr. Engel also recognized the potential problem with exposure misclassification but noted that there are legal limitations to the

data that they can collect from employers that may improve exposure classifications. He added that the investigators plan to validate the exposure data for a small subset of participants.

Dr. Engel said that the concerns about using an appropriate control group were valid and that the workers with the greatest exposure will be compared to the workers with the lowest exposure to help address bias issues to some degree. Limited data from NIOSH and other sources can also be used to assess how workers who opt to participate in the study differ from those who decline participation.

Lynn Goldman, chair of the IOM committee, noted that the longer that it takes to conduct exposure assessments, the less accurate those assessments will be and suggested starting the passive phase of the study as quickly as possible while figuring out the protocols for the active and biomedical components of the study. Doing the study in stages would make sure that the investigators gathering the passive information would still have that crucial window of opportunity that closes shortly after the exposure occurs.

SELECTING APPROPRIATE CONTROLS

Dale Sandler stated that the plan is to enroll 7,000 people who were unexposed to serve as a control group for the GuLF study. The investigators are "hoping to enroll non-exposed individuals, about 4,000 from the local community, 2,000 from further away, and then we have this special category of federal workers. We will include in our cohort federal workers, who may not come from the Gulf States," Dr. Sandler said. She acknowledged that "this is tricky to do." David Tollerud expressed concern that regarding the number of controls, "there's just not enough to do what you need to do."

Maureen Lichtveld agreed that exposure reconstruction "will make or break" the study, as a true baseline is no longer available; the study participants were exposed to multiple contaminants and had multiple exposure routes and exposure opportunities; and the exposure duration to each contaminant could have been brief, intermittent, or continual. This muddies the waters when distinguishing exposure between workers and controls and choosing an appropriate control group. She suggested that federal workers outside the Gulf coast are the least appropriate controls and that Gulf coast fishermen or workers outside affected areas would be the most relevant control populations. Several other participants also had concerns about the appropriateness of the proposed control groups.

Stephen Cole suggested structuring eligibility criteria to maximize the nonexposure comparability of participants. He also stressed the need to collect information on possible confounders, including those variables that are a common cause of dropout and cautioned against having a healthy worker selection effect. Roberta Ness added that it is likely that those who were trained but not selected to work on the cleanup are systematically different from those who were, and it may be difficult to figure out how they differ because such information was not necessarily recorded. She suggested using workers' friends as controls or using other BP or federal workers as an out-of-region control group. Roxane Cohen Silver of the University of California, Irvine, noted that one should not assume that the impact, especially the mental health impact, on those who were indirectly exposed, such as family members of the cleanup workers, was minimal.

PREDICTING OUTCOMES

Several participants suggested providing more specific, focused outcomes or concrete hypotheses that can be used to guide what data are collected. A study of this scale needs an open quality, but you also need to have testable questions related to health effects and put those out there to give people something concrete to think about, said David Kalman. Dr. Kalman also suggested that the study set benchmarks for data collection and interpretation of findings. Robert Wallace suggested using the literature as a guide to define likely primary outcomes in clear clinical and physiological terms and to define the terms for the secondary social and economic outcomes as needed. Bernard Goldstein added that the comprehensive approach to studying a wide variety of outcomes is necessary but will likely generate hypotheses rather than provide definitive outcomes.

PLANNING FOR LOWER ENROLLMENT

Many participants questioned the 70 percent enrollment figure given for the GuLF study, which they viewed as being overly optimistic, given that enrollment in the World Trade Center Registry was less than half that. In addition, many Gulf of Mexico oil spill cleanup workers have already moved to other areas and will be difficult to locate. The lack of trust of the government that many in the local community have after being disappointed in how the government responded to the Hurricane Katrina disaster will also impede enrollment. Although different government agencies were involved in response the hurricane, to many in the area, the government is a monolithic institution, some participants pointed out. Robert Wallace added that additional factors will impede enrollment, including other ongoing studies of health and economic effects, foreign national and undocumented worker status, general and health illiteracy, the existence of a mobile group of young males who traditionally have lower rates of participation in surveys, and legal claims related to BP or government programs.

Dr. Wallace suggested considering doing a formal pretest of recruitment with oil spill cleanup workers from the different cultural groups and communities affected and, if recruiting does not go well, considering the use of alternative sampling methods. He suggested planning for lower rates of enrollment, response, and retention. Roberta Ness added that it is critical to compare the population of interest to those who choose to participate in the GuLF study.

ENGAGING THE LOCAL COMMUNITY

Many participants had suggestions for engaging members of the local community, thereby building trust and making them more receptive to participating in the GuLF study and increasing the likelihood that those who do choose to participate respond adequately for the duration of the study. Admiral James Galloway, the HHS representative to the National Incident Command for the Deepwater Horizon oil spill, noted that he and his colleagues had several town meetings that both fishermen and academics attended. He found at these “dockside chats” significant interest in health evaluations mixed with skepticism of the government. Retention will be critical in the GuLF study, but that will be achieved only if researchers gain the trust of the participants, he said.

You need to bring communities in as leaders, not just as advisers, by carefully listening to their concerns and incorporating them into your study, Admiral Galloway said. He suggested ensuring that the community liaison be a person whom the community trusts to accurately represent it, planning discussions with potential participants at the appropriate education levels and "thoughtfully discussing what we need and what they need." He noted that the health issues that the members of the community have are often different from those of concern to the government. As Maureen Lichtveld pointed out, communities often expect services, not research. Others at the workshop noted this as well and pointed out that the main health concerns of those people affected by the oil spill tend to be whether the water is safe to drink and whether they can eat or sell the fish and seafood that they catch. Some participants suggested either making attempts to answer those questions with the research that is done in the GuLF study or partnering with other institutions that can assess this so participant concerns are addressed.

The people who have been affected by the oil spill "are the real experts," said Ruth Parker, a member of the IOM committee. "The more that we figure out how we put their voice at the table and partner with them," she said "the closer we will get to doing something that will really have meaning for everyone." Howard Osofsky of Louisiana State University concurred, adding that investigators need to listen to the concerns of stakeholders. Dale Sandler responded that members from the GuLF study have been having dockside chats with the cleanup workers, and she welcomes help in understanding what health concerns the community has. She added that the research consortia with which the study will be partnering will address those community concerns more directly.

Others stressed the importance of communicating clearly when talking to potential study participants and being explicit about what the GuLF study will not address. As Roxane Cohen Silver noted, researchers can acknowledge to the study participants the presence of ambiguity and uncertainty, as long as they do so honestly and believably. Several workshop participants suggested ensuring that the communication materials used in the study pass low-literacy requirements; be sensitive to cultural differences, such as how health concerns are viewed and reported; and be appropriately translated into Vietnamese and the other languages that the study participants speak and ensuring that those communication materials are pretested in focus groups. "Having a seat at the table doesn't mean I'm going to participate at all, if I'm not educated about what's going on," Dr. Lichtveld said. IOM committee member Nancy Kass added that a useful way of assessing whether participants fully understand what they are being told is to have them say in their own words what they think the study is about, why it is being done, and what is expected of them if they join.

Many participants also recommended the use of focus groups, as they can be valuable additions to a community advisory board (CAB) to obtain input on all aspects of the GuLF study design, including communication materials and the basic approach taken in the study. Dr. Lichtveld suggested that the CAB be repositioned as a community assistance board that takes a more active role in determining study design and operations. Involve participants early and often, because when you have an interactive relationship early on, problems will be solved early on, said DeJuran Richardson. Dr. Lichtveld added that you need to involve and collaborate with the public. The study hovers between involvement and collaboration, and it needs to be more collaborative. She suggested that the GuLF study investigators "be bold" and "elevate community engagement as a study objective."

Dr. Cohen Silver had several suggestions for improving community involvement in the GuLF study, including recognizing that "a one-size recruitment strategy might not fit all" and encouraging a sense of personal responsibility for participation among eligible respondents rather than focusing on the large numbers of study participants, which minimizes a sense of individual importance. One must communicate to the participant why that person's participation is crucial, she said, and provide incentives for that person's participation. Dr. Lichtveld commented that providing financial incentives for study participation is critical and that the currently proposed incentives and are not commensurate with current research practice. Moreover, incentives should be provided without being coercive both at the completion of each activity and at completion of the entire study. She also suggested providing honoraria to community representatives involved in the study. Another participant noted that the incentives used may need to vary according to the population to which they are offered.

Dr. Cohen Silver suggested being sensitive to study participant burden and minimizing the number of questions that they are asked, as well as how often those questions are asked. Have well-trained interviewers, she said, who are specifically trained to "convert" those who do not want to participate. Although it is important to provide opportunities for respondent to refuse to be in the study, she said that information about those refusal opportunities should be balanced with information on the importance of continuing participation. The consent form says a lot about how people can drop out and does not highlight the importance of staying in, Dr. Cohen Silver said. To improve retention, she stressed obtaining extensive recontact information during the initial contact and repeatedly thereafter.

In addition to partnering with community representatives, Dr. Cohen Silver suggested partnering with the media, as openness with the media breeds trust and trust is necessary for successful communication. The media, as well as schools, the workplace, primary care physicians, mental health agencies, and faith-based organizations, can help researchers educate the public about the importance and value of participating in the study and why "just telling your story" is so important, she added. Dr. Lichtveld also suggested including local media as an important stakeholder and supporting a Gulf coast-wide community network to synergize individual community organization efforts and facilitate frontline education and outreach.

Dr. Lichtveld and others also stressed the importance of communicating study results in a clear, concise, and timely manner. A plan for how results will be communicated to the participants, especially a plan for how results for household samples will be communicated, should be developed now rather than postponed until later, said Susan Santos, a member of the IOM committee.

Aubrey Miller responded that investigators from the GuLF study have been meeting with community representatives in the Gulf, who have been providing them with feedback on the cultural sensitivity of the study design and their specific concerns. Dale Sandler and Francis Collins noted that it is hard to assess which community representatives are the most appropriate ones to seek input from, as several often exist for specific communities in the Gulf. Howard Osofsky noted that after the Hurricane Katrina disaster, community members were somewhat disappointed with community representatives because they did not adequately advocate the needs of the community. Dr. Lichtveld added that there are a number of active community advocacy organizations, but the ones best able to adequately represent their communities when research is involved are those with assets that have been proven to be used by the community in the Hurricane Katrina or other disasters.

Dr. Osofsky added that more than one representative for each community may be needed, as young Vietnamese, for example, may not adequately speak for older Vietnamese. Detailing the job description of the community leader who will be advising researchers in the GuLF study will help direct researchers to appropriate community representatives, Dr. Lichtveld said. Another participant suggested having more focus groups rather than relying on community leaders, who may not represent the full scope of what the community wants.

Dr. Sandler said she hoped that the local research partners in the GuLF study will help with the selection of appropriate community representatives, and she also recognized the importance of having more focus groups for the study. Vicki Seyfert-Margolis, from the FDA, added that town hall meetings have served as important venues for the FDA to acquire feedback from the community.

Dr. Miller noted that investigators in the GuLF study have been acquiring feedback from worker representatives, worker health officers, and local public health officials as to what incentives are the most likely to work for the study participants. Stephen Cole suggested that the economic literature also be reviewed to discern the incentives most likely to be effective.

ESTABLISHING REFERRAL NETWORKS

As part of addressing community needs, the GuLF study should have a plan for dealing with the numerous health care referrals that participants are bound to need, as some will have significantly elevated blood pressure levels, uncontrolled asthma, and other immediate health concerns that investigators will detect in their evaluations, several participants stressed. David Cohen noted that participants "could die immediately from things you might discover during your evaluation," and asked "how do you ensure, how do you work with communities to make sure that the person can actually get care that may not be there?" Others are likely to have serious mental health problems also requiring a referral. Mark Farfel of the World Trade Center Registry suggested having stress management protocols in place for participants or family members with heightened distress.

Howard Osofsky suggested implementation of a referral plan that not only specifies which providers people should be referred to but also indicates appropriate follow-up for the referral, such as assessing whether people used the referrals and how successful they were. Aubrey Miller responded that being able to make adequate referrals is a major concern of GuLF study investigators and that they have been trying to build a referral network utilizing the local infrastructure. They may also have a local coordinator to do follow-ups and make certain that the referral system is working. Dr. Osofsky suggested doing some clinical resource mapping so that it is clear what resources, in addition to emergency hotlines, are available and where they can be found.

Nancy Kass suggested including funds for bolstering local health clinics as part of the study budget, including donating more mobile clinics to local public health facilities and funding a few more health care staff for them. She noted that being able to tell participants that services are in place to address some of the concerns that they articulate will have enormous value in terms of trust and study retention.

PLANNING FOR LEGAL ISSUES

The workshop participants extensively discussed the legal issues linked to patient confidentiality and the sharing of data, as these issues will influence, in part, how many people will be willing to enroll in the study, what data should be collected, and how data will be shared. The Health Insurance Portability and Accountability Act (HIPAA) and other legal constraints associated with patient consent forms can limit the sharing of participant data between government agencies, such as the Occupational Safety and Health Administration (OSHA) and NIH, as well as between BP and NIH, Dale Sandler pointed out. Often, to meet patient privacy concerns, the data in various databases are deidentified, making it difficult to link data from more than one database to the same participant. In addition, participants may be pressured by their lawyers to withhold information if they want to make a legal claim, investigators may be pressured by the courts to provide information that they have gathered, and states may require the mandatory reporting of any incriminating health information ascertained, such as that indicating domestic abuse.

Bernard Goldstein noted that long-term follow-up of individuals in communities affected by the *Exxon* V*aldez* oil spill was hampered by the actions of a federal judge who required the release of the information gathered from those individuals, despite a promise of confidentiality from the investigators. Lynn Goldman added that those data used in the reconstruction of exposure, such as height, weight, and when the person was working at a specific location, may enable an employer or others to identify a participant. Mai-Nhung Le, a member of the IOM committee, noted that confidentiality will be hard to maintain without oversampling of small homogeneous groups, such as the Vietnamese fishermen.

Larry Engel, a coinvestigator of the GuLF study, responded that, to the extent that they can, investigators of the GuLF study will have representative groups large enough so that people at the aggregate level will not be identifiable at the individual level. Teri Manolio added that the data will not be available to the public and that those who receive the data in the study will not attempt to identify participants or use the data against them. However, she added that investigators cannot promise that the data will never become public and can make clear to the participants only what protections they do have for the data.

Stephen Cole noted the tension that exists between the availability of data to scientists and the ability to identify individual participants. He stressed that this tension needs to be faced. He added that in GWAS deidentified data were eventually identified by two engineers. Dr. Manolio noted other, similar incidents in which patient confidentiality was breached. It is important to be upfront with people and when there are problems take every step possible, she said.

Dr. Manolio pointed out that the Privacy Act determines the way in which government can use data and share them, although the constraints on the sharing of data within agencies can be exempted during emergencies. It is still not clear whether individual-level data from OSHA and the U.S. Department of the Interior can be shared, she said.

Leslie Wolf of the Georgia State University College of Law stressed that litigation on the Gulf of Mexico oil spill will occur and said that there may be ways in which someone participating in the study will become involved in litigation that may not have anything to do with the study, but what is acquired in the study may be relevant. Think deliberately about what

information is being collected and why. Don't ask questions unless the answers are necessary, especially if it might create a situation where it becomes necessary to report the information for legal cases.

Ms. Wolf recommended using certificates of confidentiality that offer investigators protection from compelled disclosure but added that the certificate may not be enough. Certificates are given on a project basis, she said, and subprojects may not be included under their domain. Ms. Wolf stressed that a plan for how investigators should respond if they get a legal request for data that they have collected should be in place. "You really want a protocol that is maximally protective, and everybody at every level understands that," she said. She also noted that social media will be a useful tool to keep participants informed about the study but that it can be abused by those using social media to identify participants in the study. Ms. Wolf said that NIH is currently doing a study of the effectiveness and limitations of certificates of confidentiality and is beginning to form ideas of best practices in this regard. Ms. Wolf added, however, that NIH is only in the early stages of starting to accumulate evidence and make policies about this issue.

Dr. Goldstein summed up the discussion on legal issues by stating that a wide range of legal issues threaten the successful completion of the study, including the possibility that tort actions will result in significant limitations in confidentiality and enrollment of subjects. Francesca Dominici added comments on the importance of developing guidelines on how to protect personal information and formalize how the information will be collected and disclosed, as well as implementing a plan describing the type of information that is absolutely needed versus the type of information that is legally sensitive and that may not be necessary to collect.

ADDITIONAL HEALTH ENDPOINTS FOR STUDY

Some participants thought that the GuLF study neglected a few study areas, such as the effects of the oil spill on pregnant women and the spill's psychosocial effects. Twenty percent of the Gulf of Mexico oil spill cleanup workers were women, some of whom might have been pregnant. This provides an unprecedented opportunity to gather information on the health effects of an oil spill on pregnancy outcomes, but the study does not plan to include any pregnant workers until the postpartum period, noted Roberta Ness.

Lawrence Engel responded that assessing such health effects is not feasible, given the time constraints of the study and its main objective of assessing the health characteristics of the cohort as a whole. He suggested that attempts will be made to involve other researchers to address this important issue, however. Dale Sandler added that the gathering of information on reproductive health is an opportunity for creating partnerships.

Maureen Lichtveld suggested that more psychosocial measures be collected from the study participants and that mental health be more explicitly listed as a potential health risk, especially because studies of other disasters have shown mental and behavioral health issues to be major outcomes. A few participants added that it would be helpful to assess such mental health outcomes in subpopulations, such as those at higher risk for developing mental health complications because of previous traumas and underlying depression.

FINAL REMARKS

The workshop participants made numerous suggestions on how to improve the GuLF study while at the same time recognizing the time, legal, and resource limitations that may impede those improvements from being made. Many participants stated that the GuLF study will be pathbreaking. As future disasters of this type and magnitude will occur, it is important that the lessons learned from designing this study be useful for future studies, said Bernard Goldstein. However, he added that it will be challenging to overcome all the current limitations of the study. Quoting a letter that Abigail Adams wrote to her son John Quincy Adams in 1780, Francis Collins noted, "It is not in the still calm of life, or in the repose of a pacific station, that great characters are formed. The habits of a vigorous mind are formed in contending with difficulties."

APPENDIX

Workshop Agenda
A Workshop to Obtain Input on the Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers

Hosted by the Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill

September 22, 2010

Snowy Egret
Grand Hyatt Tampa Bay Hotel
2900 Bayport Drive
Tampa, FL 33607

8:00 a.m. **Opening Remarks**
Harvey V. Fineberg, president, Institute of Medicine

8:10 a.m. **Remarks**
Francis Collins, director, National Institutes of Health

8:30 a.m. **Welcome, Introductions, and Overview of Workshop**
Lynn R. Goldman, committee chair and dean, George Washington University School of Public Health and Health Services

8:40 a.m. **Overview of NIH Gulf Long-Term Follow-Up of Cleanup Workers Study**
Dale Sandler, chief, Epidemiology Branch, National Institute of Environmental Health Sciences

9:40 a.m. **Session 1: Study Goals and Design**
Session chair:
Bernard Goldstein, committee member and professor of environmental and occupational health, Graduate School of Public Health, University of Pittsburgh
Reaction panelists:
Robert Wallace, director of the Center for Aging and professor of epidemiology, College of Public Health, University of Iowa
Stephen Cole, professor of epidemiology, Gillings School of Global Public Health, University of North Carolina, Chapel Hill
David Kalman, professor and chair, Department of Environmental and Occupational Health Sciences, School of Public Health, University of Washington

GuLF Study investigator representative:
Larry Engel, Epidemiology Service, Memorial Sloan-Kettering Cancer Center

11:45 a.m. Lunch

12:45 p.m. Session 2: Data Collection and Cohort Surveillance and Maintenance
Session chair:
Francesca Dominici, committee member and professor of biostatistics, Harvard School of Public Health
Reaction panelists:
DeJuran Richardson, associate dean of the faculty and professor of mathematics and computer science, Lake Forest College
David Tollerud, professor and chair of the Department of Environmental and Occupational Health Sciences, School of Public Health and Information Sciences, University of Louisville
Leslie E. Wolf, associate professor of law, Georgia State University College of Law
GuLF Study investigator representative:
Richard Kwok, Epidemiology Branch, National Institute of Environmental Health Sciences

2:00 p.m. Session 3: Relating to the Community: Enrollment, Trust, Transparency, and Communication of Study Results
Session chair:
Susan L. Santos, committee member and assistant professor of health education and behavioral science, University of Medicine and Dentistry of New Jersey
Reaction panelists:
Roxane Cohen Silver, professor, Department of Psychology and Social Behavior Department of Medicine, University of California, Irvine
Maureen Y. Lichtveld, professor and chair, Freeport McMoRan Chair of Environmental Policy, associate director of Population Sciences, Louisiana Cancer Research Consortium, Tulane University
Howard J. Osofsky, Kathleen and John Bricker Chair and professor of psychiatry, School of Medicine, Louisiana State University
GuLF Study investigator representatives:
Aubrey Miller, Office of the Director, National Institute of Environmental Health Sciences
Dale Sandler, chief, Epidemiology Branch, National Institute of Environmental Health Sciences

3:15 p.m. Break

3:30 p.m. **Session 4: Interagency Collaboration on Studies of Health Effects from the Gulf Oil Spill**

Session chair:

Lynn R. Goldman, committee chair and dean, George Washington University School of Public Health and Health Services

Panelists:

Tracy Collier, adviser, Oceans and Human Health Program, and Shelby Walker, Office of Policy, Planning, and Evaluation, National Oceanic and Atmospheric Administration

Michele Conlon, assistant laboratory director, National Exposure Research Laboratory, Office of Research and Development, Environmental Protection Agency

RAdm. Scott Deitchman, associate director for terrorism preparedness and emergency response, National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention

James M. Galloway, U.S. Department of Health and Human Services representative to National Incident Command for Deepwater Horizon Oil Spill

Princess D. Jackson, supervisory public health analyst, Health Resources and Services Administration

CDR Erica Schwartz, preventive medicine officer and clinical epidemiologist, U.S. Coast Guard, and Jennifer Rusiecki, officer, U.S. Coast Guard Reserve and assistant professor of epidemiology, Uniformed Services University

Capt. James S. Spahr, associate director, Emergency Preparedness and Response, Office of the Director, National Institute of Occupational Safety and Health

NIH Representative:

Teri Manolio, director, Office of Population Genomics, National Institutes of Health

4:30 p.m. **Summaries of Panel Discussions**

Moderator:

Harvey V. Fineberg, President, Institute of Medicine

The chairs from each panel will have 10 minutes to present issues and options identified within the panel discussion.

5:15 p.m. **Public Comment**

Moderator:

Lynn R. Goldman, committee chair and dean of the George Washington University School of Public Health and Health Services

Comments limited to 5 minutes per person.

6:15 p.m. **Closing Remarks**
Lynn R. Goldman, committee chair and dean, George Washington University School of Public Health and Health Services

6:30 p.m. **Adjourn**