CROSS-ORGANIZATIONAL TRAINING ON THE UNIVERSITY OF MICHIGAN DIOXIN EXPOSURE STUDY: ENSURING CONSISTENCY, CONFIDENTIALITY AND COOPERATION IN DATA COLLECTION

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Introduction

The University of Michigan Dioxin Exposure Study (UMDES) was conducted in order to describe the pattern of serum, or blood dioxin levels among adults and to understand the factors that explain variation in serum dioxin levels. The UMDES conducted an interview and collected blood, soil, and dust samples from a random sample of 733 households in four counties in Michigan, USA. The primary goal of the project was to collect data that would help to inform the public, local, state and federal agencies about one aspect of this important and complex issue: does the presence of dioxins in the soil lead to dioxins in the blood? Without a high level of cooperation and participation in all aspects of the research, the goal of the project could not be met. Our challenge was to convince the members of this population, with many different attitudes and opinions already formed, to participate in this important research. Therefore, it was critical to ensure that all field teams were trained to be responsive to questions about the study and confidentiality concerns ultimately leading to participant cooperation. This paper reviews the training methods used for gaining respondent cooperation and maintaining confidentiality across all organizations participating in the UMDES.

Materials and Methods

The UMDES design included a complex data collection plan, incorporating a one hour face-to-face interview, an 80 mL blood sample, dust samples from the participant's home, and extensive soil sampling from different areas of the participant's property. Three administrative units within the University of Michigan (The School of Public Health, Department of Civil and Environmental Engineering and the Institute for Social Research) and multiple contractors worked together to complete the data collection. In particular, the teams included an interviewing corps of approximately 55 interviewers, 40 phlebotomists from four local health care organizations, 20 dust samplers from a contractor hired for the study, and 20 soil samplers from the College of Engineering at the University of Michigan.

First, the field interviewers contacted the randomly-selected housing unit, identified an eligible participant and collected an interview and consent for blood, dust and soil sampling. Next, the blood, dust, and soil sampling teams collected the actual samples in at least two and sometimes three separate appointments. Since each sampling team had employees making direct contact with the public, it was clear that a training program was needed to ensure consistency in the understanding of the study and ability to address participant concerns. Therefore, the Institute for Social Research (ISR) designed specialized training programs for the interviewing staff and sample collection team members, with common elements across each training program.

The interviewers were the first contact with the participants. This interaction was critical in convincing the respondents to participate in all parts of the study. The interviewers contacted housing units randomly selected into the sample by sampling statisticians at the ISR, determined eligibility and selected an eligible participant following

standardized procedures.[1] During this contact, the interviewers introduced the study to the participant, and attempted to convince the selected household that the study was worthwhile and that his/her participation was very important. The interviewer collected the interview data using standardized interviewing procedures,[2] and when eligible, obtained the participant's written permission for blood, dust and soil sampling.

Three documents reinforced the interviewer's obligation to treat as confidential all information they learned about the participant before, during, and after the interview: the Pledge to Safeguard Respondent Privacy, Statement of Professional Ethics, and Employment Commitment Statement. Protecting the anonymity of participants and the confidentiality of all research documents was paramount for this project.

All interviewing staff underwent an intensive in-person two-day General Interviewing Techniques training and five-day study specific training, in addition to receiving at-home materials and homework. Participation in these trainings and careful review of all materials was required before any member of the interviewing staff was permitted to administer interviews with selected households. In particular, the training focused on the following areas:

- use of computer and sample management programs;
- preparation in answering any questions the participants had about the project and how they were selected;
- completion of the informed consents forms for the questionnaire, blood, dust, and soil collections;
- administration of the questionnaire using standardized interviewing procedures in order to collect quality data;
- preparation in answering questions about confidentiality and data security; and
- addressing any other participant concerns.

At the end of the in-person training session, each interviewer was required to satisfactorily complete a certification interview with an ISR trainer. This certification indicated that the interviewer had mastered all of the tasks necessary to successfully complete and interview and enroll the respondent in the sampling program, if eligible. The interviewer was required to successfully complete a certification interview before beginning their work in the field.

In order to provide feedback on the quality and accuracy of the interviewer's work, a percentage of the interviews were subject to a verification process. Shortly after the interview was complete, the Quality Control team at ISR verified that the interview had been completed. This was done either by telephone or by sending verification letters to the participants. These telephone calls and letters asked five factual questions of each participant, and their responses were compared to the responses in the survey. The respondent was also asked about the professionalism of the interviewer during the interview. During the course of the study, the interviewer received continuous feedback on his/her performance in the form of ongoing written and verbal communication.

After the in-person interview, the Sampling Teams scheduled appointments with eligible participants to collect their blood, dust and soil samples. The blood samples were collected and handled by health care professionals local to the area. The dust sampling was conducted by professionals using specialized equipment. Four to seven sets of soil samples were taken from multiple locations on the participant's property. Sample collection team members were professionally trained in their area of expertise.

Additional training for the UMDES blood, dust, and soil sampling teams was developed with the understanding that they would also have contact with the participants of the study and would be responsible for maintaining cooperation, participation and confidentiality in the sample collection part of the study. A special "human subjects" training incorporating parts of ISR's General Interviewing Techniques training, along with UMDES specific

information regarding the study protocol and confidentiality issues was designed. Each blood, dust and soil sampling team member was required to attend a two to four hour long training session where the goals were:

1. to train UMDES sample collection professionals in the University of Michigan standards and procedures for confidentiality, professionalism, participant contact, and data collection; and
2. to give UMDES sample collection professionals enough knowledge about the UMDES project and the University of Michigan standards so that they could respond appropriately to participants questions and avoid non-response.

Relevant components of the training for the sampling teams mirrored the interviewers' training. At training, all sampling team members received a University of Michigan photo identification badge, identifying them as a member of the UMDES team, and informational brochures that could be left with sampled households, detailing the study procedures. It was assumed that the interviewers would handle most of the respondent questions and reluctance prior to the sample collector's arrival. Therefore the sample collectors did not need to develop the same expertise that interviewers needed, but required some basic skills in this area. Sample collectors did not have to pass any type of certification for contacting human subjects.

Sample collectors first learned about the UMDES in an overview discussion. The scientific and management oversight, the study goals and general study protocol were reviewed. The training on respondent contacts began with an explanation of the unique role of the sample collectors, and their importance to the study goals. Confidentiality concerns were discussed in detail, followed by sections on professional presentation, working with respondents, and averting non-response. A small amount of technical information on the standardized coversheet and response codes was given.

All samplers received a UMDES project manual, with information about the University of Michigan, a brief overview of the UMDES and copies of the written policies on confidentiality and protection of sensitive data. It also included written information on survey sample selection, working with respondents, safety in the field, and a standard list of Frequently Asked Questions and Responses specific to the UMDES. The booklet was not specifically used in training, but was designed to provide more in-depth written background information as reference for the sample teams.

In early trainings, all trainees participated in role-playing exercises designed to assist them with developing a standard doorstep introduction for the UMDES, and in answering technical and standard questions, or handling common non-response at the doorstep. In later trainings, exercises for blood samplers were dropped due to their existing expertise in working with the public. Similarly, the training length and emphasis were modified along the way as it became apparent that team members with different areas of expertise needed a slightly different emphasis. For instance, technical information on coversheet use was moved to the UMDES protocol training specific to each team. Coversheets differed slightly by sample and attempting to present coversheets to three specialties at once proved difficult. Training on result codes was dropped altogether. It was found to be more efficient for the team leaders for each group to assign result codes based on coversheet notes that were returned from the field.

Training in the specific, approved technical protocol for sample collection was held after the human subjects training. For the protocol, the teams divided into their specific specialties (blood, soil and dust).

All field team members, including subcontractors, were required to sign a Pledge of Confidentiality and maintain the highest level of security of the data at all times. Proper handling and storage of study materials, including the laptop computer and hard copy materials was critical to ensure against loss, breach of security or participant confidentiality, and other hazards. All UMDES materials had to be kept secure. Sampling team members were instructed to never leave project materials lying around for others to see; this included members of the participant's

household, members of their own household, or anyone else who was not a member of the UMDES staff. No one was allowed to accompany the interviewer or sample team to a household unless directed by a project manager. The protection of a participant's right to privacy and the confidentiality of the information that he/she provided was a serious part of their job. Failure to comply with the standards of confidentiality presented in the ISR pledge could have resulted in discipline up to and including termination of employment with the UMDES.

Many safeguards were put in place as a matter of practice to protect human subjects. All substantive data was kept physically separate from any identifying information. Each sample team was assigned a different set of identification codes for each participant so that no one outside of the immediate research team could construct a profile for a property or a participant. Discussion of these safeguards and their importance was a critical component of training.

Each unit brought different competencies to the data collection team. Each group had their own methods for tracking samples, different custody paperwork and approaches to data collection. A consistent training protocol allowed for a unified front for all components of the study team.[3]

Results

From the standpoint of the UMDES management team, the training for interviewers and sample collectors exceeded expectations. Confidentiality was successfully maintained, and cooperation and response rates exceeded expectations at all stages of sampling.[4] Interviewers indicated in debriefing meetings (meetings on processes that are routinely held after each data collection), that they felt well-prepared to handle UMDES specific questions leading to successful participant cooperation.

Detailed information on the sample collectors thoughts on the training are currently being collected and will be reported later. These debriefings are taking place somewhat after the end of data collection. This lag in time allows us to ask whether any trainees found the human subjects information useful in any other application or assignment after the UMDES. Initial results from the first round of debriefings indicate that the trainings served to emphasize the risks to respondents and the need for confidentiality. The trainings also reinforced the idea that the samplers were a very important part of the UMDES team, and that their work greatly contributed to the study as a whole. Sample team members have anecdotally reported that their job was smoother, because the interviewers prepared the respondents well for the sample collection process. Samplers generally did not need to use any refusal aversion or conversion skills. They fielded standard questions about respondent payments, scheduling and reporting of results.

Initial impressions from trainers and observers indicate that training each specialty team separately might be desirable in the future. Each specialty appears to need different areas of the training emphasized. For instance, phlebotomists and health care workers do not need the extensive emphasis on confidentiality and respondent interactions due to their technical training and daily contact with the general public.

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