CONSIDERATIONS FOR MANAGING A LARGE, MULTI-FACETED STUDY INVOLVING MULTIPLE ORGANIZATIONS

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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 collected interview, blood, soil, and dust samples from a random sample of 733 households in four counties in Michigan, USA. The study contained several unique components which presented management challenges before, during and after the data collection effort: a) the need to bring together a group of diverse organizations to complete the data collection and sample analysis; b) a critical need to maintain respondent confidentiality; c) a need to monitor and assess data collection efforts on a daily basis across all organizations so that the sample was managed successfully and data collection remained on budget. The full study design, field and laboratory methods, and study findings are reported elsewhere.[1,2,3,4,5,6] This paper reviews the management and monitoring infrastructure that were used to coordinate activities across all organizations participating in the UMDES that ultimately brought the data collection efforts to a successful conclusion.

Materials and Methods

The University of Michigan Dioxin Exposure Study (UMDES) was undertaken in response to concerns among the population of Midland and Saginaw Counties that dioxin-like compounds from the Dow Chemical Company facilities in Midland have resulted in contamination of soils in the Tittabawassee River flood plain and areas of the City of Midland. There is concern that people's body burdens of dioxins, furans and PCBs are elevated because of environmental contamination. The UMDES was designed to answer the following questions: Are dioxin levels in blood increased among people who live in the Tittabawassee River floodplain compared to people who live elsewhere in Midland and Saginaw Counties and elsewhere in Michigan (Jackson/Calhoun Counties), and what factors explain the variation in serum dioxin levels among the population? An additional central goal of the study is to communicate the results and the implications of the results in an effective manner to the population in the Saginaw and Midland region. In addition, the study pledged to be responsive to the concerns of the community, the stakeholders and a Scientific Advisory Board.

The UMDES design included a complex data collection plan, incorporating interviews, 80 mL blood samples, dust samples and extensive soil sampling. No single unit within the University of Michigan could provide the expertise or capacity to collect and process the volume of samples required in the study. Four administrative units within the University of Michigan (School of Public Health, Civil & Environmental Engineering, Institute for Social Research, and Center for Statistical Consultation and Research) came together with six subcontracting partners (Alta Laboratories, Environ, and four local hospitals and medical providers), to complete the data collection and analyze the samples collected. Each organization brought different competencies, cultures and viewpoints to the research team. All had different methods for tracking samples, different custody paperwork and approaches to data collection.

The involvement of multiple organizations with their own systems of managing information presented a major challenge to the team. Given the dynamic nature of the study design, the commitment that was needed to the overall success of the project and the confidentiality of the respondents, UMDES required all research partners and contractors to "buy in" to the overall success of the effort. The field data collection management plan followed a whole-team approach to complete the data collection program, integrating subcontractors with a unified training, paperwork and tracking system. Critical to the success of the UMDES was a method for passing respondent information from one team to another in a timely manner, ensuring that proper documentation of consent had taken place and that all paper documentation, including the consent form, was returned to the central office. Data from questionnaires, blood, dust and soil analyses needed to be successfully merged in a timely and efficient manner, while eliminating the opportunity for mismatching errors, missed sample persons or lost samples. A system-wide approach to managing confidentiality, supplemented by Institute for Social Research (ISR) survey management system formed the cornerstone of the management system.

Systems already in use in the Institute for Social Research (ISR) Survey Operations Unit were used to ensure confidentiality, manage multiple organizations, and pass respondent information from one organization to another. These systems also tracked sample completions and facilitated merging of data across the various sample types. The electronic systems were supplemented by a hierarchical telephone answering system that triaged phone calls from the field. Public and informational brochures were also developed for use by all of the survey and sampling teams.

Employees from almost all of the participating organizations would ultimately have direct contact with the public through the sample collection process. Early in the design process, the management team recognized that respondents would ask questions of the samplers from different organizations about the dioxin contamination issues in general and more specifically about the UMDES. It became imperative that all sample collection personnel understand the study, the study goals, and be able to answer questions about the project consistently. The challenge to the team was to integrate these different organizations in order to present a single organizational "face," a united front, to the community. This unified front was considered a necessary element to gain the confidence of the respondents and assure the community that the overall data collection was scientifically, ethically and efficiently managed without undue influence from the funder or any one of the stakeholders in broader community.

To create a unified front, ISR designed a specialized training program for the data and sample collection supervisors, staff members and processors. Anyone having contact with the public, respondents or respondent identifying information attended a two to four hour training on confidentiality, handling sensitive data, and interacting with respondents. This special "human subjects" training incorporated parts of ISR's General Interviewing Techniques training, along with UMDES-specific information regarding the study protocol and confidentiality issues. The training plan allowed UMDES to integrate the entire team, including all contractors and research partners. The training included background and design of the UMDES, information on the specific unit's role in the data collection and in the overall team, information regarding the risks to the communities and participants and the need for confidentiality, special procedures adopted to protect confidentiality, and to present Frequently Asked Questions (FAQs) and standardized responses. More information on the training program can be found elsewhere.[8]

In addition, confidentiality of respondents was of foremost concern for the UMDES. Focus groups held in the communities prior to data collection highlighted a number of issues and concerns of the area residents. Many residents feared that results of testing would not be kept confidential. Other residents worried that State of Michigan laws regarding toxic waste contamination would affect their rights as property owners, resulting in lawsuits (from neighbors exposed on their property) or affect the market value or insurability of their homes. Some feared that blood sampling might ultimately result in denial of life or health insurance.

To address these concerns, The UMDES team sought and received a Certificate of Confidentiality from the National Institutes of Health for the study.[7] A team-wide philosophy, modeled after the Institute for Social Research, University of Michigan Policy on Confidentiality and Protection of Sensitive Data was formally adopted by the UMDES. All UM staff working on the UMDES were required to sign a Pledge of Confidentiality as part of that policy. Furthermore, all research partners and contractors were required to contractually agree to the Policy on Confidentiality and their staff members working on the UMDES signed a Pledge of Confidentiality.

In addition to the confidentiality procedures set forth in the policy, separate anonymous 9-digit sample identification numbers (SID) were generated for blood, soil and dust samples. This anonymity of the SIDs meant that no person outside of the sample collection coordinating team of six people could put together a sample profile for a person or a property. This procedure ensured confidentiality through data collection, processing and analysis at the laboratory. All results were returned to the research team with individual samples identified only by the SIDs. Only the UMDES data analysts were provided the key to link the blood, soil and dust sample data with the questionnaire data.

The UMDES used SurveyTrak, a component of ISR's sample management system, for tracking and managing sample collection and interview progress in the field. Field interviewers contacted a selected housing unit, identified an eligible random respondent within the housing unit, and collected information in a 60 minute interview, including consents for blood, dust and soil sampling. An additional SurveyTrak application, WebLogging, documented the date of receipt of the consent documents in the main office. Data from the questionnaire relevant to the sampling teams, such as information about the selected respondent's eligibility and consent to blood, dust and soil sampling, was transferred to the main SurveyTrak database. A companion program, TeamTrak, was developed to allow simultaneous management of the blood, dust and soil sampling program. SurveyTrak transferred the respondent's name, address, contact information, eligibility and key pieces of information about the property (flooding, fill dirt, existence of gardens) to TeamTrak for use by the blood, dust and soil teams. TeamTrak allowed each sample collection team to print "coversheets," or paper documents on which respondent information and attempts to each household could be recorded. The coversheets were specific to each respondent and each team, and included the relevant respondent information (e.g., name, address, telephone number) and survey responses (e.g., whether the respondent had a garden). In addition, the coversheets provided the samplers with a script for introduction, information to confirm that the proper sample person was located, and space to record each contact with the household. Sample collectors faxed back completed coversheets to the main office, and the team coordinator entered the information into TeamTrak. The SurveyTrak database was updated in real time so all applications contained up-to-the-minute information about sample activity.

SurveyTrak, WebLogging and TeamTrak databases were accessible on a secure server by analysts at ISR. Staff members monitored completion data at least weekly and, at the height of data collection, daily. The monitoring system used data from the interview, blood, dust and soil sample teams to identify number of completes, rate of completion, and eligibility rates at each stage of the sample collection process. Staff members also provided feedback to the field managers on the completion of interview, blood, dust and soil sets. This information allowed the field managers to monitor the progress of the data collection effort as a whole, and to project whether the completed interviews would yield the desired 700 completed sample sets of interview, blood, dust and soil.

Results and Discussion

The University of Michigan Dioxin Exposure Study completed data collection with more than the required number of samples, and higher than anticipated response rates at all stages of sampling (interview, blood, dust and soil). Critiques of the training, sample management system and monitoring systems are still being collected and analyzed, although preliminary indications are that automated systems worked up to and exceeded expectations. Suggestions for future improvements are being compiled and will be reported later.

Information on the effectiveness of human subjects training is currently being collected using focus groups. Much of the feedback from the initial groups is that the training achieved its primary goals: imparting a concern for respondent confidentiality and implanting the idea that the subcontractors were a valuable part of the overall research team. The training succeeded in ensuring that all persons coming into contact with respondents had the same answers to questions. Team members have indicated that if they didn't know how to answer, they knew how to direct the respondent to a place where questions would be answered. More in-depth information on the training program will be reported later.

A monitoring report for interview completions already existed as part of the SurveyTrak program. This companion program (Webtrak) worked very well for the managers monitoring interview data collection. The study-wide monitoring spreadsheet that reported on all sample completions worked well. However the spreadsheet updating process was labor intensive and could not be automatically generated without human input. One issue with monitoring and reporting cooperation with blood, dust and soil samples is that the actual sample collection process lagged behind the collection of the interview, sometimes by several weeks. While we were able to report with certainty on how many individuals consented for a sample, it was more difficult to estimate actual completions, and an overall response rate, in a timely fashion. A more automated method for reporting for the blood, dust and soil completions, and sample completions overall would be desirable for future data collections involving multiple points of data and sample collection.

Overall the team feels that the integration of the research partners/subcontractors into the training, documentation and sample management of the study resulted in higher quality data collection. Study documentation was standardized, and samples were easily tracked, and resulting data easily merged with no loss of information due to mis-matching. Initial feedback from subcontractors indicates very positive feelings toward the data collection, and their participation in the UMDES.

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