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Overcoming Practical Challenges in Intervention Research in Occupational Health and Safety

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In addition to more familiar research issues, intervention research projects in naturalistic settings present the investigator with a number of practical challenges including gaining access to potentially resistant populations, maximizing participation rates in the face of weak incentives for cooperation, getting valid answers to sensitive questions, and meeting ethical obligations when health or legal problems are discovered in the course of study. Generalizable approaches to these challenges are addressed in the context of a retrospective evaluation of the implementation of OSHA's 1984 ethylene oxide standard in Massachusetts hospitals. In the evaluation study, enthusiastic cooperation was secured, a 96% participation rate was realized, sensitive questions were posed successfully, and worker health risks discovered in the course of study received attention without having to wait for the write-up of the study results. Key elements in the study population's receptivity appear to have been (1) the investigator's familiarity with the hazard, its setting, respondent concerns and needs, and (2) reciprocity in the form of providing follow-up consulting services as an integral part of the research process, delivered to each hospital at the conclusion of data collection. Specific techniques used in the study are presented in the hopes of aiding other investigators facing similar practical challenges in occupational health and safety intervention research.

KEY WORDS: intervention research, qualitative research, ethylene oxide, regulation, OSHA, social sciences, disease prevention

INTRODUCTION

In intervention research aimed at devising and evaluating ways to control identified work hazards, investigators must step into naturalistic workplaces and communities where controllable research conditions are the exception. Whether the study design is experimental, quasiexperimental, or purely descriptive, intervention research confronts the traditionally trained occupational health scientist with some new and daunting practical challenges.

These challenges include: (1) gaining access to study populations; (2) maximizing participation rates; (3) getting at sensitive questions; and (4) meeting ethical obligations when health or legal problems are discovered in the course of study. Although sometimes dismissed as nonscientific concerns, such considerations are critically important in intervention research. These are the kinds of issues that arise frequently in the fields of anthropology and sociology, where ethnographic and participant observation research are common [Fetterman, 1989; Lofland and Lofland, 1984]. Even the most rigorously designed field study can fail if these challenges are not addressed [Needleman and Needleman, submitted]. This paper reports on some of the strategies used to deal with these issues in a recent occupational safety and health study. The context for the analysis is a retrospective evaluation of OSHA's regulatory standard for ethylene oxide.

BACKGROUND

Ethylene oxide (EtO) is an acute toxicant, human carcinogen, and potential reproductive hazard used widely in

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hospitals as a sterilizing agent for heat- and moisture-sensitive medical devices [IARC, 1994]. In 1984, the Occupational Safety and Health Administration (OSHA) issued a full health standard to protect hospital workers potentially exposed to EtO [OSHA, 1984, 1988]. In order to assess how well the EtO standard has been adopted in practice, an evaluation study was undertaken in 1992 focusing on the implementation of the standard's provisions for medical surveillance, exposure monitoring, and worker training. The study included 92 Massachusetts hospitals and covered the period from the effective date of the standard in 1985 through 1993. Data were drawn from multiple sources including mailed questionnaires, telephone interviews, on-site interviews with hospital sterilization department supervisors and managers, and review of hospital records on worker training and exposure monitoring. Some of the operational details of the study are described in this paper; the study findings are described in detail elsewhere [LaMontagne and Kelsey, 1996].

Since this project focused on OSHA compliance, the researchers anticipated difficulties. Hospitals have been a recent focus of OSHA enforcement activities for a variety of hazards in addition to EtO; thus, it was expected that hospital administrators and sterilization department managers might be nervous about EtO regulatory compliance. Some participants might be reluctant to report EtO overexposures. Some might fear that participation would increase their chances of OSHA inspection. Medical surveillance providers might fear that hospital procedures did not match OSHA requirements or that some other flaws in the quality of their service would come to light. In some hospitals, labor–management relations might be strained, with health and safety being one of the issues of contention. In short, the targeted respondents had an array of powerful disincentives to participating in the study.

Under these unpromising conditions, it could be quite difficult to gain research access, achieve high participation rates, get honest answers to sensitive questions, and deal ethically with the setting's numerous social and political complexities. Yet ultimately, strong cooperation was secured, an exceptionally high participation rate was realized, sensitive questions were answered with frankness, and research subjects expressed overall satisfaction with the study process. The questions addressed in the present paper are: What techniques proved useful in overcoming the practical obstacles to this research? And how might such techniques be generalized to help other intervention researchers facing similar study situations?

GAINING ACCESS TO STUDY POPULATIONS

Sterilization department managers were chosen as the primary study population, being the persons most directly responsible for implementation of the EtO standard as well as the most knowledgeable about hospital history and records on EtO exposures, training, and medical surveillance. Successful contact with the sterilization manager was then used to identify and gain access to EtO medical surveillance providers, the secondary respondents in the study. In gaining cooperation from potentially resistant sterilization managers, three factors appear to have been critical: the study's perceived *credibility, relevance,* and *sponsorship.*

Credibility consists of a believable claim to expertise either by the researchers themselves or by prominently featured consultants to the study. In this case, credibility was established fairly naturally through the researchers' own professional work. They had previously published an EtO health and safety manual written for hospital use [LaMontagne et al., 1990]; and they had developed and provided hospital-based EtO health and safety training programs [LaMontagne et al., 1992]. These activities supported the respondents' perception that the researchers were well qualified for the proposed research. Otherwise, they would have needed to find other ways of demonstrating knowledgeability about the issues.

Perceived *relevance* is a major issue in gaining access wherever cooperation must be finessed. Proposed study subjects may have little time or patience for research agendas not directly related to their own work and interests. In this case, the researchers' prior experience had familiarized them with the concerns of various stakeholder groups, including the pertinent professional organizations, hospital workers, unions, medical surveillance providers, and others. They were able to describe potential benefits from the research in terms meaningful to the study population. Perceived relevance was further strengthened by the investigators' recent involvement with hospital-based EtO health and safety training, which served as evidence of their ability to make the study useful and their sensitivity to working people's concerns in this area. Without this kind of base to work from, preliminary discussions with key informants would have been needed to clarify how best to make a convincing case for the study's relevance to participants' interests.

Equipped with arguments for credibility and relevance, the researchers could then move on to seek *sponsorship.* This was important on two levels. First, the researchers had to identify appropriate *legitimizing sponsors.* In some research the sponsors best able to lend legitimacy are not obvious, requiring preliminary exploration with key informants in order to make a useful selection. In this case, based on prior experience with the research topic, the researchers quickly settled on the two professional organizations for sterilization managers in Massachusetts—the International Association of Healthcare Central Service Material Management (IAHCSMM) and the Massachusetts Association of Hospital Central Service Management (MAHCSM). They held formal discussions with representatives of both

organizations to explain the study goals, answer questions, and negotiate any concerns (particularly regarding confidentiality for those interviewed and maintaining the study's separation from regulatory enforcement). Drafts of the proposed contact letter were prepared for these discussions, functioning more or less as agreements on the terms of participation in the study. The talks resulted in official endorsement, reassuring members of the study population that the research was both safe legally and worthwhile professionally.

On the second level, the researchers had to identify relevant *authorizing sponsors,* in this case the hospital administrators who employed the proposed study participants. Administrators were contacted by mail at the same time as sterilization managers with a brief letter of explanation and a copy of the letter sent to sterilization managers; this afforded them a chance to approve or disapprove participation. Without assurance of administrative knowledge and consent, potential interviewees might have felt uncomfortable about joining the study—even with the endorsement from their professional organizations. In only one case did a hospital administrator disapprove participation.

The culmination of the access development process was a written contact packet for sterilization managers, representing the visible tip of a large iceberg of negotiations that had taken months of planning and discussion to build. The packet contained: (1) a strong endorsement letter jointly signed by the two legitimizing sponsors on combined letterhead; (2) a letter explaining the research and inviting participation; and (3) a brief questionnaire on EtO use. Contact packets were mailed to sterilization department managers at all Massachusetts hospitals (N = 159), followed up by postcard reminders and eventually telephone calls to nonresponders. Ultimately, only five hospitals failed to respond, for an initial response rate of 97%. The researchers determined that a maximum of 96 of the 154 responding hospitals used EtO; of these, 92 agreed to participate. Thus 96% (92/96) of the responding population of EtO-using hospitals in Massachusetts were successfully recruited into the study [LaMontagne et al., 1996a]. This high participation rate for the primary study population of sterilization managers could not have been achieved without the lengthy preliminary work to negotiate access. For the secondary study population of medical surveillance providers, the effort devoted to establishing access was considerably less, yielding a much lower participation rate of 65%, which is more typical for field-based research.

MAXIMIZING PARTICIPATION

Having gained initial access, the researchers hoped to keep participation high as the EtO study progressed. Attrition is the bane of field-based research—hard to avoid and control, and almost certain to introduce bias if it reaches high levels. In this study, a number of approaches helped in maintaining participants' commitment to the study, including *reciprocity, listening,* and *personal rapport.*

Reciprocity is a matter of individual study subjects feeling they get something out of the research in return for what they contribute. For example, it is usual to promise communication of study results to participants. Such communication is typically long delayed after completion of data gathering in the field, and sometimes consists simply of sending the participants a technical report or journal article describing the findings. In this study, participants were promised summary reports of the study's findings together with discussion of implications for practice (i.e., not copies of research articles). Respondents were to receive these reports by approximately 18 months after completion of the fieldwork. In order to provide a more immediate, direct, and individualized benefit, however, the researchers also provided a free site-specific EtO health and safety review following completion of the final study interview at that hospital. From the perspective of the sterilization managers, this review of strengths and weaknesses in their hospital's EtO health and safety program served as free management training and consultation from a respected source in the field. The fact that the research combined investigation with a tangible service was a very strong motivator for maintaining participation.

In terms of *listening,* the researchers needed to stay attuned to the sterilization managers' concerns about confidentiality and the nonregulatory nature of the study. Participants knew from the initial explanations that they could decide what to disclose and what not to disclose, and could drop out of the study at any time. They also had been assured that findings would be reported as anonymous group results only. However, repeated reassurances were needed throughout the data collection process, usually when potentially sensitive information came up in interviews. If the researchers had not listened closely enough to detect and address these concerns, participants might have started dropping out. Similarly, the researchers found they had to be particularly sensitive to scheduling issues for the 15 min telephone interviews and 1.5–2 hr on-site interviews they wanted from each of the sterilization managers. Numerous telephone calls were needed to arrange these interviews, which frequently had to be postponed or rescheduled. If the researchers had failed to listen carefully to the participants' scheduling needs, participants would probably have grown frustrated and refused further rescheduling. As it was, 100% of the 92 sterilization managers granted the telephone interviews, and 98% (90) of them granted the on-site interviews.

Finally, *personal rapport* appears to have been an important element in maintaining participation. Data collection involved repeated contacts by one researcher over a period of months with each individual participant; thus, the

study developed an undertone of familiarity and continuity akin to a friendship. This sense of personal connection or rapport, well known in social science participant observation studies [Denzin and Lincoln, 1994], helped keep the study subjects' commitment high. As the next section explains, it also improved the validity of the data.

APPROACHING SENSITIVE QUESTIONS

Getting valid responses to sensitive questions, a problem in many research contexts, was a special concern in this analysis of regulatory compliance. The study's focus required data collection on touchy subjects such as exceeding the EtO Action Level and Excursion Limit, overexposures of workers in EtO leaks and spills, problems with appropriate medical attention when exposures occurred, and shortcomings in mandated record keeping. While responses on such subjects are difficult if not impossible to validate in an absolute sense, two techniques do appear to have improved the validity of the data: *repeated contact* and *progressive levels of detail.*

The multistage and interview structure of the study allowed for relationships to be built with respondents over time. Interactions with each respondent, from initial mail contact through the follow-up consultation, typically lasted for several months with numerous contacts occurring throughout the period. Researchers and respondents got to know each other as the data collection evolved, building familiarity and trust in a way that one-shot data collection would not have allowed.

The researchers used the repeated contacts to collect data in progressively greater detail as more trust developed. Sensitive questions were avoided entirely in the first mailed questionnaire. They were raised briefly in the 15 min follow-up telephone interview, for example, by eliciting yes/no responses to questions on whether each hospital had experienced an accidental EtO leak or spill, or had exceeded the EtO Action Level or Excursion Limit. Then in the more lengthy on-site interview, responses from the telephone interview were reviewed and more details requested. For example, in the telephone interview, the researchers asked whether EtO medical surveillance had ever been provided and whether any EtO accidents had occurred since the time the standard went into effect (1985). Then in the on-site interview, they asked if medical surveillance had been provided more recently (1990–1992); and if yes, how many times, for how many people, and for what reasons (e.g., accidental release, exceeding the Action Level, simply for good measure, etc.). In the on-site interview, respondents were encouraged to add details and raise related issues, so as to capture exploratory data on unanticipated but significant problems or reasons for providing surveillance.

A revealing pattern of response changes emerged from the repeated contacts. With respect to experiencing EtO accidents, 15 of the 90 responses changed—in every case, from "no" in the telephone interview to "yes" in the on-site interview. A similar pattern of initial false negatives occurred in questions on exceeding the EtO Action Level and Excursion Limit [LaMontagne et al., 1996b]. After correcting for these initial false negatives, fully half of the hospitals in the study reported having experienced accidental EtO leaks or spills (46/92 = 50%). This pattern of increasingly frank disclosure as more trust developed radically altered the study results. Without the on-site interviews, relying simply on the more defensive earlier responses from the telephone interviews, the occurrence of accidents would have been underestimated by at least a third. Mailed survey approaches used alone would have resulted in an even larger underestimate.

MEETING ETHICAL OBLIGATIONS

Studies investigating regulatory standards are likely to discover noncompliance situations, which may or may not be already known to the research respondents. When this happens, researchers will face potentially conflicting moral imperatives. They need to honor promises of confidentiality and avoid biasing respondent reactions, but they also must meet ethical responsibilities for protecting worker health and safety.

In the present study of OSHA's EtO standard, conflicting ethical concerns were reconciled by linking the research with a service consisting of a free health and safety consultation for each hospital upon completion of the interviews. This approach protected the study's integrity by enabling the researchers to defer questions about compliance and enforcement raised by respondents during the interviews. For example, to a question such as, "Did that overexposure mean we were supposed to provide medical surveillance?", the researcher would respond, "We'll talk about that in the consultation meeting." This provided a supportive way to avoid introducing new knowledge or judgmental statements into the interview, which might have biased the research data and raised respondents' personal anxiety. At the same time, the researchers' responsibilities to workers at risk were met. Any health and safety problems detected through the interview process were brought to light promptly and directly in the consultation, and clear recommendations were made to remedy the situation. In general, the research process itself appeared to heighten managers' interest in and understanding of compliance, promoting a receptive attitude toward making changes for improved EtO health and safety. In hospitals where compliance was already strong, the consultation provided recognition and served to reinforce management commitment to health and safety.

In this study, no imminent danger situations came to light. However, because there was a possibility of finding such problems, the researchers had formulated at the outset

of the study a protocol for dealing with egregious situations. The protocol involved first raising the issue internally with the sterilization manager and hospital administrators. If adequate abatement progress did not follow within a reasonable time period, the researchers would then have considered themselves ethically obligated to call in relevant state agencies and OSHA. This protocol was supported in peer review with colleagues, but not shared with the research subjects. Whether or not protocols for addressing serious hazards discovered in the course of study should be discussed when negotiating access remains a difficult, unresolved ethical issue in intervention research.

CONCLUSIONS

The practical challenges described in this report seem likely to arise in most intervention research, perhaps joined by additional equally difficult issues. Other tools and strategies borrowed from the social sciences for addressing these issues are briefly summarized elsewhere in this special issue [Needleman and Needleman, 1996]. In the example discussed here, the researchers were greatly aided by having prior familiarity with the respondents' perspectives and potential needs. Also, as recognized experts in EtO health and safety, they were able fairly easily to establish credibility and to offer a valued service (the free health and safety consultation) by way of reciprocity. These starting advantages will not be present in all intervention research contexts. However, the challenges discussed here will remain, requiring different but functionally equivalent strategies to address them. Table I summarizes the strategies applied in the EtO study.

In cases where an investigator is new to a particular hazard context, preliminary groundwork is essential. The research plan should include adequate time at the beginning of the study for observation, informal interviews, and other ways of getting to know the day-to-day reality of the hazard and the perceived needs of those affected by it. The researcher needs to find out what the hazard means to the research subjects, what "diplomatic" considerations might affect research access, what would maximize respondents' participation, how sensitive questions should be approached, and what forms of reciprocity might be coordinated with the investigation. Without such understandings, intervention research may fail to gain cooperation, or may lose weakly motivated respondents as the study progresses. Worse yet, studies done without adequate groundwork may collect data so erroneous that misleading conclusions result.

Qualitative approaches would be the methods of choice in this preliminary stage, and the design should be flexible and exploratory. Where a base of information already exists, the initial exploration could constitute a fairly short needs assessment phase preceding and informing the implementation of a larger and more systematic study. But where research settings and issues are extremely unclear, systematic study may not be appropriate or even possible until quite extensive exploration has been conducted. In these circumstances, exploratory assessments would be most useful as free-standing projects fundable and publishable on their own merits, assuming they meet rigorous standards for qualitative research. As carefully crafted descriptive analyses of a hazard's social environment, such studies would provide insights indispensable for the conceptualization, design, and implementation of more elaborate intervention research.

TABLE I. Strategies for Overcoming Practical Challenges in Intervention Research

Gaining access to study populations
1. Demonstrate credibility
2. Consider relevance of research to subjects
3. Obtain sponsorship
a. legitimizing sponsorship
b. authorizing sponsorship
Maximizing participation
1. Build in reciprocity
2. Listen to study subject concerns
3. Develop rapport
Approaching sensitive questions
1. Include repeated contacts with subjects
2. Collect data in progressive levels of detail
Meeting ethical obligations
1. Anticipate hazards that might be discovered
2. Develop means to intervene in the context of the study
3. Develop strategies for addressing imminent danger situations

To summarize, the example of intervention research analyzed here offers two basic lessons. First, the research process as well as data quality can be helped enormously by embedding the data collection in a service context. Second, intervention research will benefit, sometimes in crucial ways, from preliminary qualitative exploration preceding large-scale quantitative studies.

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