

Enhancing the Quality of Epidemiologic Studies

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Three principles can improve epidemiologic studies (1) Conduct open scientific review of research protocols and final reports, (2) Disseminate study results to all appropriate parties, and (3) Incorporate new scientific methods into the research and utilize expertise from other disciplines. The procedures we describe are used within the Industrywide Studies Branch of the National Institute for Occupational Safety and Health to implement these principles.

The Industrywide Studies Branch (IWSB) of the National Institute for Occupational Safety and Health (NIOSH) has a responsibility for epidemiologic and industrial hygiene research mandated by the Occupational Safety and Health Act of 1970. Over the past 20 years IWSB has produced significant research on numerous chemicals, including benzene, asbestos, radon, ethylene oxide, dioxin, and video display terminals. Our experience has identified three principles that could be useful to other groups seeking to enhance the quality of epidemiologic studies: (1) Conduct open scientific review of research protocols and final reports, (2) Disseminate the study results to all appropriate parties, and (3) Incorporate new scientific methods into the research and utilize expertise from other disciplines.

The first principle, open scientific review of protocols and final reports, is the cornerstone underlying research conducted in the Industrywide Studies Branch of NIOSH. Our procedures foster the participation of scientific experts, and the companies and unions involved in the study, in the design of projects as well as in the review of completed studies, while retaining for the NIOSH researchers the ultimate responsibility for the final study design, analysis, and interpretation.

Studies usually are initiated in IWSB by the preparation of a short project concept memorandum describing the proposed project, justifying its importance, and indicating the methods to be used. Scientists in management positions within NIOSH decide which projects should progress, primarily on the basis of their public health importance. Feasibility projects are carried out, if necessary, and a detailed protocol is completed after enough information has been collected indicating that a study can realistically proceed. A formal review process is initiated at this point to provide an opportunity to receive advice during the design phase of the study from appropriate independent scientific experts and the companies and unions involved in the study. The review of the protocol may be conducted by mail or in a public peer review meeting announced in the *Federal Register* and open to all interested parties. Inclusion of "blue ribbon" peer reviewers and the openness of the process ensures that no single party has an undue voice in determining the study design. We have found that contributions from these parties foster technical accuracy and provide a broad perspective for evaluation of the various scientific aspects of a study. During the final revision of the protocol, however, decisions about the study design rest with NIOSH. The same review procedure is repeated at the conclusion of the study when the draft final report is completed.

We have found that review of our protocols improves the research design, leads to a better understanding of the study by all involved parties, and enhances the credibility of the research. At the conclusion of the study, the review of draft final reports ensures scrutiny by scientific experts and the involved companies and unions, and provides an opportunity for comment by parties who may have disparate views, leading to a carefully balanced interpretation of the data. The final decisions regarding the interpretation of the data rest with NIOSH. Because the reports are submitted to scientific journals, they receive yet another level of expert peer review. However, we have found that the

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quality of expert peer review conducted by the scientific journals is variable; therefore, we believe the NIOSH process of consistent review by external groups adds significantly to the quality of our studies and has enhanced the credibility of our epidemiologic research. In our opinion, if systematic review of protocols and draft reports were conducted by all companies, unions, and academic institutions, the quality of epidemiologic studies would be enhanced. The IWSB review process takes place in the context of the NIOSH legal right of access to data and our requirement to deal equally with labor and management. Thus, our review process is intended to provide checks and balances, especially for the occasional situations when NIOSH, labor, and industry may include "warring parties." When a review is held by other institutions where the parties are not equal, development of a system of checks and balances may be essential to avoid having a charade review.

A second principle underlying research at NIOSH is the responsibility to disseminate the information gained in the study to all appropriate parties: the scientific community, the nonscientific community in industry and labor, and the subjects of the studies. NIOSH research studies are submitted for publication in the peer-reviewed literature, thus initiating the open scientific process of commentary and additional studies. Additional dissemination of data from the study may be important for other workplaces with similar exposures that were not studied. Thus, the findings of the study may be communicated to the nonscientific community in trade journals and company/union newsletters. The original researchers also may contribute to other types of NIOSH publications (such as *Current Intelligence Bulletins* and *NIOSH Alerts*) that convey information about selected exposures and hazards. The effort to communicate a clear description of the study and its interpretation to the interested parties, as well as the interaction in the literature with other scientists, develops skills that ultimately improve the quality of analytic reasoning by the researchers and their written descriptions of subsequent epidemiologic studies.

Another aspect of dissemination of study results is the communication of the information to the study subjects. Through a NIOSH Worker Notification Program, the participants in our studies are informed about the risks found, regardless of whether the study was conducted from records or involved contacting or examining the subjects. The type of notification carried out depends on the degree of risk found in the study and the level of active participation by the workers. Methods of notification range from posting results in the workplace for record-based studies with low risks to individual notification by letter for record-based studies with high risks and for studies in which participants were individually contacted. When appropriate, meetings with workers also are held.

Knowing that results must be communicated to the study subjects improves the attention given by researchers to the interpretation of the study. We have found that preparing individual notification letters by the epidemiologists and the notification staff, responding to questions of study participants via the NIOSH 800-

telephone number sent in the letters, and meeting with workers puts the researchers in a position somewhat analogous to that of a clinician, who must tell the patient what the study found and must indicate whether the worker can do anything to reduce the risk. This process deepens the thoughtfulness with which the epidemiologic studies are interpreted.

The third principle that can contribute to improved epidemiologic studies is to incorporate new scientific methods into research studies and to use expertise from other disciplines, when appropriate. Examples of this principle include the need to incorporate better measures of exposures into epidemiologic research and the benefit of collaborating with experts from various relevant scientific fields.

Although occupational studies usually are intended to assess the relationship of particular exposures and specific outcomes, a critical weakness of many studies has been the inadequate characterization of exposure of the study subjects. Historical cohort studies, in particular, have been inherently limited by scarcity of industrial hygiene measurements and lack of detailed information about exposures to individual workers, requiring the use of more crude measures of exposure. Duration of exposure has been a useful surrogate for cumulative exposure in many epidemiologic studies, especially because it permits the use of years of exposure to estimate a dose-response. However, it may not adequately reflect intensity or specificity of exposures.

Academic, government, and industry epidemiologists alike are limited by the quality and quantity of the exposure data collected and maintained by industry. Thus, future improvements in the quality of exposure characterization may depend primarily on industry. Efforts to provide a safe workplace have sometimes provided data needed to better characterize exposure in epidemiologic studies. Some companies have developed programs involving (1) routine industrial hygiene monitoring that accurately characterizes the exposures of workers, and (2) record-keeping that permits linkage of industrial hygiene data with epidemiologic data such as work histories and health outcomes. These are complex efforts in themselves, involving considerations of cost, the development of strategies for representative exposure monitoring in addition to problem-oriented monitoring in the workplace and the development of methods to link record systems maintained by decentralized offices for purposes unrelated to epidemiology.

The Industrywide Studies Branch of NIOSH has devoted great effort to finding better methods of exposure characterization. IWSB employs an approximately equal number of epidemiologists and industrial hygienists, who work in teams on projects. In our studies we use current sampling methods as well as methods for historic reconstruction of exposures from records maintained by companies and unions. In the past few years we have devoted substantial efforts to using and validating statistical modeling techniques to fill gaps in historic records in studies of workers exposed to ethylene oxide, dioxin, and acrylonitrile. In 1989 and 1990, together with the National Cancer Institute, NIOSH sponsored two national conferences on methods of char-

acterizing exposure. Some IWSB studies are assessing the use of biomarkers of exposure as a new approach to characterize exposure of participants. However, this field is still early in development, and internal markers probably are best interpreted when external exposure measurements are made. Prospective epidemiology studies, involving collection of new data, offer researchers an opportunity to collaborate with industry to design the appropriate exposure characterization.

The second point in the principle is the need for epidemiologic studies to use experts from various scientific fields in the design, conduct, and interpretation of studies. Our experience in the IWSB suggests that there has been a dramatic increase in the variety of outcomes of interest in occupational epidemiology over the last two decades. Research studies in the early 1970s focused primarily on the carcinogenic effects of chemicals. Today, studies are being conducted in new areas such as job stress, cumulative trauma, injuries, and neurologic, reproductive, and cardiovascular disorders. Although many epidemiologic methods can be appropri-

ately applied in these areas of study, the active collaboration of appropriate scientific experts from other disciplines is essential to produce studies of high quality.

A second development over the course of two decades has been increased emphasis on the biologic plausibility of the epidemiologic results in light of physiological mechanisms. These observations suggest that the standard team of epidemiologist and industrial hygienist would benefit from collaboration with other experts in the design stage of complex studies. The experts might include a toxicologist, chemist, molecular biologist, occupational physician, psychologist, reproductive biologist, or ergonomist. As the variety and complexity of studies increase, the participation of collaborators from various disciplines becomes increasingly valuable.

In summary, the experience of the Industrywide Studies Branch of NIOSH suggests that research of high quality is fostered by open review of research protocols and final reports, by disseminating the results of studies to all appropriate parties, and by incorporating new scientific methods into the research and using expertise from other disciplines.