METHODOLOGIC AND ETHICAL ISSUES IN EPIDEMIOLOGIC RISK ASSESSMENT OF OCCUPATIONAL HAZARDS

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Quantitative analyses of the risks associated with occupational hazards has become a prerequisite for the development of occupational exposure limits in the U.S. and most western countries. In the past, many of these analyses were based on toxicologic data. However, there has been a recent trend toward the increased use of occupational epidemiologic data for these analyses. In large part, this trend has been fueled by the strong controversies that have emerged around the use of animal data for predicting human risks. There are a large number of unresolved methodologic and ethical issues surrounding the use of occupational epidemiologic studies, which are the subject of this presentation.

The first methodologic issue that must be recognized is that there are often severe limitations in our studies, which undermine their usefulness for developing quantitative predictions of risk. The most obvious is the lack of accurate estimates of exposure, potential confounding and other potential sources of bias related to study design. The size of our studies is also a severe limitation, since most occupational cohort studies cannot reliably detect lifetime risks much lower than 1 in 100, and can certainly not detect very low level risks (e.g., 1 per 1,000,000) that are of concern to some policy makers.

Other methodologic issues are related to the appropriate analytic methods to be used for risk assessment purposes, which often differ from those used for etiologic research. First, in risk assessment, one is generally interested in estimating measures of absolute risk rather than relative risk as conventionally used in Epidemiology. There is a move in risk assessment toward estimating other measures of disease impact, such as years of potential life lost. Second, the shape of the exposure-response relationship is a critical issue in risk assessment; whereas, most analyses of epidemiologic data simply assume a linear or log-linear relationship for testing trends. Third, models that incorporate mechanistic information (e.g., multistage models) are increasingly in vogue for risk assessment purposes, which are not conventionally used by epidemiologists. Fourth, there are some unique risk assessments being developed for non-cancer and other outcomes believed to have a threshold. Finally, there is a need in risk assessments using epidemiologic data to perform formal uncertainty analyses for issues such as exposure assessment, which go way beyond the usual treatment of these issues in conventional epidemiologic analyses. All of these analytic issues will be illustrated using examples from work we have done at NIOSH.

There is also a host of ethical issues that also need to be considered in conducting risk assessments using epidemiologic data. Of foremost concern, is the high potential for the influence of subjective biases to affect the end results of risk assessments. The temptation to manipulate analyses to yield results in a particular direction is at times extreme, since risk assessments form the scientific basis for regulatory decisions that can result in severe costs to industry and society. Scientists involved in this process must somehow strive to be independent of such pressures. There are a few guidelines

that can be offered to help insure this objectivity. First, scientists must be clear in their reports on what assumptions are being made in their analyses, and if possible demonstrate the impact of alternative credible assumptions on the risk assessment. Second, scientists should strive to characterize, and if possible quantify, the degree of uncertainty underlying their estimates of risk. Third, sharing of the data used in risk assessments is critical for the process to have credibility. The only way to validate an epidemiologic risk assessment is to repeat the analysis, since each epidemiologic study is unique and not replicable. Finally, there is a clear need for more occupational epidemiologists to become involved in the risk assessment and standard setting process. Our responsibilities as epidemiologists do not end when we publish the results from our investigations. We have an obligation to insure that the data from our studies are properly used in the risk assessment process, and that decision makers fully understand the policy implications of our findings.

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