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Preface

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International Workshop on Retrospective Exposure Assessment for Occupational Epidemiologic Studies

Preface

This issue of *Applied Occupational and Environmental Hygiene* presents the proceedings of the International Workshop on Retrospective Exposure Assessment for Occupational Epidemiologic Studies. Approximately 200 attendees heard presentations and participated in discussions on the rapidly emerging field of retrospective exposure assessment for epidemiologic studies of workplace hazards. The workshop, jointly sponsored by the National Cancer Institute and the National Institute for Occupational Safety and Health, was held in Leesburg, Virginia, from March 27–30, 1990.

Those in attendance agreed that the workshop was successful in bringing together a group of people who are working to improve the quality of studies of occupational disease. While the attendees benefited from the exchange of new ideas and experiences, the dissemination of this information will not end with them.

Through this issue of the journal, the 21 workshop presentations are available to everyone with an interest in improving occupational studies. In particular, industrial hygienists and other investigators who are involved in the study of exposures will find a wealth of information and ideas here, ranging from philosophical issues in health effect studies to recommendations for ways of improving the quality of exposure data collected in the future.

To introduce the workshop presentations in this issue, we invite you to consider a preliminary question. Why is exposure assessment done in retrospective epidemiologic studies? One answer is that such studies can address two tiers of questions. The first question, stated simply, is "Do they?" Do teachers have excess risk of mortality from rheumatic fever and rheumatic heart disease? Do welders develop more nonmalignant respiratory disease and lung cancer than is expected? Do residents of the Kanahwa Valley have elevated cancer rates?

These questions, while important, are preliminary to the question we must seek to answer, which is "Why do they?" This is the question we are seeking to answer when we investigate evidence of casuality in epidemiologic research, and this is the question that must be answered before we can develop measures to prevent occupational disease. An answer to the preliminary question is: we do exposure assessment in these epidemiologic studies because we need to know why, to identify causes, and to develop preventions.

The workshop program was organized for the purpose of improving these exposure assessments. It was structured upon the major aspects of exposure assessment, moving through the natural course of retrospective epidemiologic studies. There were five major sessions at the workshop:

- Selecting an Approach to Exposure Assessment
- Methods of Exposure Assessment for Industry-based Studies
- Methods of Exposure Assessment for Community-based Studies
- Evaluating Validity and Precision of Exposure Estimates
- Measures to Facilitate Future Epidemiologic Studies

The presentations made in each session are compiled here under the session topic. The presenters who were invited to prepare these papers took on a dual challenge: to summarize the current state of practice in each area and to look toward the future to identify the important issues and new methods to address them. The result of their efforts is this set of thoughtful and stimulating papers. Taken together, they push forward the boundaries in the assessment of exposure in health effect studies.

Selecting an Approach to Exposure Assessment

In this first session of the workshop, the presenters identified issues that should be considered in the initial stages of a study, including the characteristics of diseases, the worker populations, and the exposures themselves. The evaluation of these factors allows an investigator to determine whether the goals of a study are likely to be met, given the quality of information that is available. This preliminary evaluation also provides direction in selecting an exposure assessment strategy.

The first paper in this section, "Issues in Performing Retrospective Exposure Assessment," is an overview of the possible approaches that can be taken to include information on exposure in epidemiologic studies. As the starting point for the workshop, this article summarizes the approaches that have been used historically to assess exposures and the limitations of these approaches. It also encourages making more quantitative assessments in order to develop the best possible estimates of actual dose for the members of an epidemiologic study population.

One of the most important factors to consider in the early stages of a study is the disease of interest. The second paper, "Characteristics of Disease and Some Exposure Considerations," focuses on the ways in which disease characteristics influence the exposure assessment strategy. An understanding of the underlying mechanism of the disease process may provide vital information on the measure of exposure which may be associated with the health effect

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being studied. In some cases, the measure that is the best predictor of disease may be the total exposure accumulated over a working lifetime. In other situations, the intensity, or the frequency of short-term peak exposures, is more strongly associated with the health effect. In any case, an exposure assessment strategy should be developed in consideration of the mechanism by which exposure may cause the disease of interest.

Another important factor to consider in the early stages of a study is the study population itself. In epidemiologic studies, the characteristics of the people being studied may have a very strong, and frequently limiting, impact on the assessment of exposures. For example, workers engaged in the production of a chemical may have lower exposures than the end-users of materials containing that chemical. From an epidemiological point of view, it may be desirable to study the more highly-exposed workers who use the chemical; however, if these people are scattered through a number of diverse settings or if they are exposed to a variety of other materials, the exposure assessment may be extremely difficult. In the third paper, "Characteristics of Worker Populations: Exposure Considerations in the Selection of Study Populations and Their Analysis," these issues and the effect of population characteristics on epidemiologic studies are discussed. Recommendations for recognizing and addressing these problems are included as well.

In the fourth paper in this session, the focus shifts to the characteristics of exposure itself. In "Exposure Assessment for Epidemiology: Characteristics of Exposure," the nature of exposure is discussed, and two conceptual models are proposed to help the industrial hygienist evaluate exposures. The source–receptor model entails a detailed assessment of past operations, process materials, and job activities to make at least a qualitative estimate of exposure, even in situations where no historical monitoring data are available. The task–TWA approach allows the industrial hygienist to make optimum use of historical data on job activities and short-term exposure measurements to estimate full-shift average exposures and their variability.

The final paper, "Selection of the Measures of Exposure for Epidemiology Studies," continues the discussion of exposure with an emphasis on the implications of statistical variability in selecting an exposure measure. Variability in exposure occurs within individuals over time as well as between individuals who perform the same job. Because this variability can be large, and investigators usually assess exposure by job rather than for each individual in a study population, variability can be an important consideration in the evaluation of exposures. When workers are assigned an average exposure value in an epidemiologic study, the uncertainty in estimates derived from limited historical data may cause these values to be far from the true level of exposure. This may result in misclassification of people by exposure, substantially reducing the power of a study to identify exposure–response relationships, and may also lead to an erroneous conclusion regarding the association between exposure and disease.

Methods of Exposure Assessment for Industry-Based Studies

Session two of the workshop moved from the broad issues in selecting an approach to a more detailed discussion of exposure assessment methods generally followed in occupational studies. The five papers in this section consider the use of exposure measurements in epidemiological studies, the role of biological monitoring in exposure assessment, the derivation of exposure information from sources other than exposure measurements, the development of classification strategies for epidemiological analysis based upon exposure, and the reconstruction of historical exposures.

The first, "Use and Analysis of Exposure Monitoring Data in Occupational Epidemiology: An Example of an Epidemiological Study in the Dutch Animal Food Industry," discusses issues and methods for evaluating exposures using two types of monitoring strategies. In one strategy, all members of a study population may be monitored on several occasions over time; in the other, workers are assigned to homogeneous exposure groups and a single mean exposure value is assigned to all members of the group. Through the use of a detailed example, the results of these two exposure classification strategies are compared, and the advantages and limitations of each approach are described.

"Evaluation of Concomitant Biological and Air Monitoring Results" discusses the use of exposure measurements in biological media and in environmental exposure assessment. Both measures are indirect assessments of an agent's concentration at the target site in the body, and each approach has its limitations. The circumstances when one or the other may be appropriate are discussed through several detailed examples. The accuracy and bias of this information as a dose surrogate in epidemiologic studies is examined, and the effect of errors in dose assessment in epidemiologic studies is also discussed.

The use of exposure-related data in the reconstruction of historical exposures is described in the third paper, "Evaluation of Exposure Information." In many studies of chronic diseases, the exposures of concern may extend back in time to periods for which exposure measurements are not available. However, industrial hygienists may be able to collect substantial information on factors that influence exposures, such as production rates, engineering controls, and work practices. Several of these factors, known as exposure modifiers, were identified and used in a mathematical model, along with current exposure measurements to estimate historical exposures. Other approaches to obtain information on historical exposures were suggested; e.g., studying the composition of material deposited inside exhaust ventilation ducts, evaluating industrial processes in developing countries where antiquated equipment is used, or recreating historical operating conditions in experimental settings to simulate past exposures.

In the paper "Development of a Classification Strategy of Exposure for Industry-Based Studies," the advantages

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and limitations of several considerations in classifying exposures are discussed. Possible exposure measures for epidemiologic studies are outlined, including criteria for choosing an exposure measure. Simulated calculations that illustrate the relationships between several commonly used exposure measures are included.

The final paper in this session, "Analysis of Strategies for Reconstructing Exposures," proposes a set of general attributes by which an exposure reconstruction strategy can be evaluated. By identifying the necessary and desirable characteristics of a strategy, as well as some undesirable properties, it is possible to take a logical approach to evaluating the exposure assessment strategy. The need for a determination of the validity of the estimates developed through the strategy is emphasized.

Methods of Exposure Assessment for Community-Based Studies

In session three, the focus moved to the determination of exposure for subjects from a geographical area assembled based upon their having a particular disease, rather than by their place of employment. Questionnaires administered to the study subjects or their survivors are often the only source of exposure information available in community-based studies. The quality of information obtained from these methods was discussed in three presentations. The first of these, "The Occupational Questionnaire in Retrospective Epidemiologic Studies: Recent Approaches in Community-Based Studies," considered the three general types of questionnaire information: 1) those seeking general information on job histories, tasks, and the work environment; 2) those collecting occupation-specific details, such as information on work practices and processes; and 3) those collecting exposure-specific information including checklists on exposures to particular chemicals.

The second paper, "Methods of Exposure Assessment for Community-Based Studies: Aspects Inherent to the Validation of Questionnaires," continues the discussion of collecting exposure information through questionnaires by examining the sources of inaccuracy and bias in this approach. Internal verification methods are described, e.g., testing the completeness of answers and the frequency of erroneous responses. External verification methods, e.g., comparing questionnaire responses with information obtained from another source, are also presented; application of some of these approaches is demonstrated in a case–control study of lung cancer.

The final paper, "Loss of Statistical Power Associated With the Use of a Job–Exposure Matrix in Occupational Case-Control Studies," evaluates a commonly used method to evaluate exposures in epidemiologic studies known as the job–exposure matrix. Job–exposure matrices are cross-tabulations of job (and/or industry) titles with likely exposures. For example, a job–exposure matrix may identify a plumber as being exposed to lead, solvents, and soldering fumes. An alternative, but more expensive and time-consuming method is to have a team of chemists and industrial hygienists collect detailed information on each person's job. These experts then infer the probable exposures for each job based upon their professional experience and familiarity with the industry as well as their knowledge of the working environment. These approaches are compared in this paper, and the effect of exposure misclassification in epidemiologic study analysis is discussed.

Evaluating Validity and Precision of Exposure Estimates

The fourth session moved from a discussion of methods for exposure assessment to approaches for determining the validity and precision of the exposure assessment. These included the statistical evaluation of exposure assessment strategies, the validation of job information obtained from work histories, and the effect of misclassification of exposure in epidemiologic studies. The session opened with a discussion of statistical approaches to validation. In the paper "Statistical Evaluation of Exposure Assessment Strategies," evaluation techniques are proposed for several types of exposure assessments. Investigators may classify exposures into ordinal, nonquantitative categories, e.g., high, medium, or low exposure, or into categories which are assigned a single value to represent the exposure for all the jobs assigned to that category. In these cases, the appropriateness of the exposure assignments may be best determined by nonstatistical approaches, such as judgment by an expert panel. In cases where more quantitative approaches are taken to develop estimates of actual personal exposure levels, statistical approaches were suggested that may be applied to determine the degree of error associated with these estimates.

Another important source of uncertainty in exposure estimates is the information obtained from work histories. "Validation of Work Histories for the Purpose of Epidemiologic Studies" addresses the limitations of work histories generally collected in industry-based studies, i.e., from employer records, and in community-based studies using interviews. The effect of exposure misclassification resulting from incorrect work history information is discussed, and suggestions are made for improving the quality of work history data for future epidemiology studies.

In the paper "Assessing the Effects of Non-Differential Misclassification of Exposures in Occupational Studies," the effect of incorrect exposure classification on the results and findings of epidemiologic studies is examined. This paper presents several methods that may be used to examine the possible extent of bias in study results arising from misclassification of exposure. Techniques to adjust the risk estimate to correct for these biases are also described.

The fourth paper in the session continues this examination of the effect of exposure misclassification in epidemiological studies. In "False Positive Exposure Errors and Low Exposure Prevalence in Community-Based Case–Control Studies," a particularly troublesome source of bias is addressed. In studies where a small portion of the pop-

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ulation is actually exposed, a situation that is common in community-based case–control studies, exposure misclassification can be the principal source of bias in the study results. In particular, when people who are truly unexposed are classified as exposed, the study results may be strongly biased to the null, resulting in an incorrect conclusion that there is no association between exposure and effect. The paper identifies this bias as well as other sources of bias, and it offers suggestions to reduce these misclassification errors.

The description of a proposed European concerted approach to improve exposure assessments for retrospective epidemiological studies was the closing presentation in this session. This paper, "Retrospective Evaluation of Occupational Exposures in Cancer Epidemiology: A European Concerted Action of Research," describes a plan of action to address several other issues and limitations in exposure assessment. The proposal defines an ambitious and comprehensive approach to resolve many of the methodological problems relating to the evaluation of occupational exposures, and it provides a plan for improving the quality of future epidemiological research.

Measures to Facilitate Future Epidemiologic Studies

The closing workshop session was comprised of summary and commentary on past approaches and the future of exposure assessment in epidemiologic studies, including techniques to facilitate these studies in the future.

In the paper "Past Approaches to Retrospective Epidemiological Occupational Exposure Assessment: The Use and Misuse of Exposure Assessment," issues raised throughout the workshop are summarized, emphasizing the impact of exposure information on the interpretation of epidemiologic studies.

The second paper in the closing session, "Research Needs: Retrospective Exposure Assessment for Occupational Epidemiology," extends the discussion of the current practice of exposure assessment in epidemiologic studies to focus on improving the quality of exposure assessment. These improvements include recommendations for particular actions to make better use of existing data sources and changes in the current practices of exposure data collection so better data will be available for future studies.

The concluding paper, "Measures to Facilitate Future Epidemiologic Studies," continued this exploration of changes that can be made in the practice of industrial hygiene in hopes that future investigators will not face the limitations described by the workshop participants. These changes can be directed by responding to some specific questions about the quality of exposure information needed for future studies, the records that will allow better linkage of people and exposure, and the methods by which these records can be maintained and accessed. Improvements in the quality of epidemiologic studies which may result from these changes can lead to better identification and control of occupational hazards, and reduce the health risks for workers.

A Historical Perspective

As is often the case, those who seek to answer questions such as those taken up at this workshop find that they are not the first to travel this road. When Dr. Mary Amdur was presented the ACGIH Stokinger Award, she referred to an article Dr. Herbert Stokinger had written in 1953, "Toxicologic Perspective in Planning Air Pollution Studies" (*American Journal of Public Health,* Volume 43, p. 742). The article included a short discussion about the early investigations of health effects associated with air pollution:

> "Investigators are confronted with vexing questions. Is health actually injured or even endangered from continuous low grade exposures to chemical substances in the air? If so, how can such substances be recognized and their effects differentiated from those of other agents of disease? How can evidence best be obtained? No precedent or blueprint exists in medical annals of the manner of proceeding to obtain answers to the above questions. Indeed, according to some who have given the matter serious thought, there is no assurance that such an investigation would lead to results of value. On the other hand, there are some, believing the solution possible, who have begun a small-scale study of the problem."

This was written in 1953. Now, as then, we undertake studies without assurance that the investigation will lead to results of value. As Stokinger stated almost 40 years ago, there are those of us who believe the solution to be possible and that by seeking to answer these questions we are moving to a greater understanding of the causes of occupational diseases. In this issue of the journal, you will find the thoughts, research findings, and recommendations of some of the leaders in the assessment of exposure for the study of occupational disease. We hope you will gain information that you can apply to advance the practice of exposure assessment.

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