Managing the Quality and Conduct of Epidemiologic Studies

James J. Collins, PhD; C. Ralph Buncher, ScD; and William Halperin, MD

With some notable exceptions,[1,2] few documents have addressed systematically the importance of the conduct and quality in epidemiologic studies. Although epidemiologists have addressed various aspects of conduct and quality, such as data quality,[3–6] report writing,[7,8] and communication of results,[9] this attention has been focused on specific issues and not on the topic in general. A conference held in Salt Lake City in June of 1990 was to begin a dialogue between universities, government, and industry on the importance of study conduct and data quality in occupational epidemiologic studies. This issue of the journal is a summary of this conference.

Why are we addressing conduct of and quality in occupational epidemiologic studies now? There are two reasons. Firstly, epidemiology is becoming a more mature science. Epidemiologists are developing standard ways of writing reports,[8] reaching consensus on correct approaches,[4] and establishing criteria for inferring causes.[10] Their success is making the results of epidemiologic studies useful for not only helping to determine public health policy, but for setting workplace and environmental standards. Their success in these areas have made them much more visible to the regulators. As a result, there is a second reason for this conference.

Late in 1989, EPA modified the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to treat epidemiologic studies under "good laboratory practices" (GLPs).[11,12] Good laboratory practices are simply rules for conducting studies according to established practices and documenting these studies so they can be replicated. Under these regulation revisions, EPA will now evaluate epidemiologic studies the same as toxicity studies or "all studies including epidemiologic studies . . . [should] be performed under GLP standards. EPA recognizes that in such studies data used may not have been generated in conformance with . . . GLP standards. However, it is EPA's position that the study itself can be conducted and submitted to EPA in accordance with the GLP standards."[11] This small change in interpretation will impact forever the way industry does epidemiologic studies. We don't know how this change will affect the way universities, government agencies, or unions conduct and document studies, but we know such standards have a way of receiving wider acceptance, and could become the "Gold Standard" for judging the quality of all epidemiologic studies.

One might ask "Does epidemiology need good laboratory practices?" or "Are these good laboratory practices something to be feared?" It might be useful to look at the history of GLPs as they affected toxicology and, ultimately, toxicologists. When GLPs were first established in the early 1980s, toxicologists felt much the same way some epidemiologists feel today. When FDA tried to implement the GLPs, toxicologists feared GLPs would (1) stifle creativity, (2) adversely affect ability to publish in a timely fashion, (3) put management in a position previously reserved for scientists, and (4) provide too much oversight that would be embarrassing at best and unnecessary at the least.[13]

These fears were mostly groundless. Most toxicologists will agree today that the establishment of GLPs for toxicology studies was a good thing, although the transition, at least for some, has been distressing. The reasons GLPs have been accepted in toxicology, we feel have to do with the benefits they bring, because they do come at a cost. The purposes of GLPs are to assure: (1) quality and integrity of data; (2) that an independent reviewer can reconstruct the study and reach valid

From the Monsanto Company (Dr Collins), St. Louis, MO; University of Cincinnati, College of Medicine, Cincinnati, Ohio (Dr Buncher); and The National Institute for Occupational Safety and Health, Surveillance and Field Studies, Cincinnati, Ohio (Dr Halperin).

Address correspondence to Dr James J Collins, Epidemiology Director, The Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, MO 63167.

0096-1736/91/3312-1213$03.00/0

conclusions; and (3) that the process will contribute to and improve protection of health and the environment.[14] The goals of GLP, if realized, even if they come at a substantial cost, will be of lasting benefit to the field of epidemiology. The benefits of GLPs as seen by toxicologists we hope will also be realized by the epidemiologists.

Overview of the Proceedings

This issue has been divided into five sections. In the first section, the concept of "good epidemiologic practices" is introduced. Good epidemiologic practices (GEPs) as proposed by the Epidemiology Task Group of Chemical Manufacturers Association, modelled after "good laboratory practices" for toxicity studies, are a set of guidelines for doing epidemiologic studies in industry.[2] These GEPs propose minimum practices and procedures that the Task Group feels are necessary, but not sufficient, for ensuring integrity of data, quality in study conduct, and archiving for subsequent replication, data sharing, or study updating.

After the introduction of GEPs, we will look to experienced epidemiology program managers for their views of quality in studies. Because of the complexity of occupational epidemiologic studies, experienced management is a key component for a successful study done in a quality manner. To provide an experienced management overview, a representative from industry, Dr Barry Friedlander of Monsanto, and a representative from government, Dr Marilyn Fingerhut of The National Institute for Occupational Safety and Health (NIOSH), give their perspectives for the management of quality in studies. They have been asked to focus on three key principles they feel would improve the quality of studies.

After the overview from management, the importance of a good protocol is discussed.[15] The study protocol provides a platform from which a wide range of quality issues can be addressed under GEPs.[16] However, the importance of study protocols for epidemiologic studies has been discussed infrequently. Two articles focus on the importance of the study protocol including enhancing the integrity of the research, initiating the documentation process, increasing work efficiency and serving as a communication link. The importance of pre-study peer review of the protocol is also discussed.

Quality assurance and quality control in manufacturing are seen as ways to reduce cost while improving the product. In this section, the principles of quality are applied to epidemiologic study conduct. The papers in this section suggest that to improve the quality of epidemiologic studies requires continual improvement at each step in the research process. If reliable interpretations are to be made from epidemiologic studies, the results must be consistent, precise, accurate, and, if possible, reproducible. Epidemiologists should expect that quality assurance involvement will provide them not only with a determination of data integrity and protocol adherence, but technical insight by virtue of outside involvement in all aspects of the study.

Data access and data sharing is then discussed. Sharing of epidemiologic data has been done on a somewhat restricted basis and has usually been limited to certain governmental agencies. Yet, allowing outside researchers the opportunity to reanalyze data can both benefit and impede the goal of epidemiologic research—to find out the right answer. The two articles in this section will deal with how data sharing in epidemiologic data may take place. These papers will discuss what data, if any, should be shared, and what conditions should be in place when sharing the data.

To assist the reader we have provided at the end of this editorial a brief glossary of terms used throughout the individual contributions. Some of these terms are derived from previously published sources, but some have been crafted by the authors in this publication.

We will conclude the volume with our views on the formalization of good epidemiologic practices, and comment on some of the dilemmas that guidelines may present the epidemiologist. Finally, we hope these proceedings continue a dialogue among industry, government, unions, and universities on how to foster and support quality in epidemiologic studies. We will not reach a consensus any time soon on how this should best be accomplished, but let's continue to discuss it.

Definitions

The definitions below are taken from several sources including the proceedings of the conference on Managing the Conduct and Quality of Epidemiology Studies. Additional definitions are found in the CMA Epidemiology Task Group set of guidelines.[2] These terms may have additional or different meanings in another context.

Data Access—providing a complete database of individual records, either as paper or electronic copy.

Data Sharing—providing partial data sets or summarized data to identified researchers or institutions, or providing summaries by publication, presentation, or discussion.

Epidemiologic Data—the raw material (eg, facts, observations, opinions) that is gathered for an epidemiologic study.

Epidemiologic Information—the work product of research relating health outcomes and specific environmental or occupational factors in a defined population, where the health outcomes are systematically ascertained for individual members of the population.[2]

Epidemiologist—an investigator who through education, training, and experience is competent to study the occurrence of disease or other health related conditions or events in defined populations.[16]

Protocol—the plan, or set of steps, to be followed in a study or investigation, or in a clinical intervention program.[16]

Quality Assurance—the identified, planned, independ-

ent review function that provides management with the overall evaluation of a program's design, execution, and product's conformance to standards. The attributes of an identified and planned function indicate that a written, authorized, and disseminated plan that designates the responsibilities and frequencies for audit, report correction, and assurance is in place prior to initiation of a program. The attribute of independent review for management indicates that the responsibility of evaluation of conformance lies outside of those conducting the work.[17]

Quality Control—the portion of an individual's daily activities and tools used to assure that the functional process is in control or conforms to standards. Control tools include standard codes, reference materials, known standards, and statistical analysis of daily process variation. Quality control is a sub-part of an overall quality assurance plan.[17]

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The masthead of the *Journal* does not have sufficient space to list all those persons who make important contributions to each month's issue. The Editorial Board takes this opportunity to acknowledge the valued work of the publisher's staff: Cara Kaufman, Business Manager; Anne Craig, Account Manager; Charles Hirsch, Ad Production Coordinator; John Ewers, Marketing Manager; Raymund Didyk, Journal Production Editor; Donald Pfarr, Director of Advertising Sales; Robin Zimmerman, Advertising Sales; Ashley Pound, Designer.

—Lloyd B. Tepper, MD