
Chapter 8

Practical Issues in Study Implementation

Learning objectives

- Be able to describe the elements of the organization and conduct of a study.
- Be able to prepare a study protocol.
- Be able to describe approaches for ensuring the ethical clearance and conduct of a study.
- Understand the necessity for incorporating multidisciplinary expertise in a study team.
- Understand the importance of quality assurance procedures (e.g. standardization, validation).
- Recognize the typical problems encountered when undertaking a study under special circumstances, such as dealing with a highly concerned community or having very limited resources, and be able to identify possible solutions.
- Appreciate the benefits and special needs of conducting multicentre investigations.

8.1 Steps in study implementation

Before undertaking an environmental epidemiology study, the investigator must have a clear understanding of the nature of the problem to be addressed and the motivation for resolving it. The investigator should therefore inform him- or herself about the circumstances of concern by reviewing available scientific literature and documents, and discussing the problem with community representatives and government officials. A literature review should not be limited to published epidemiological research. Environmental, clinical, or toxicological research can often provide useful information for an epidemiological study. Similarly, many useful studies conducted by governmental agencies may be more analogous to the proposed study than research published in the scientific literature. These are often reported only in official publications.

After reviewing existing data and the state of knowledge regarding potential exposures and health outcomes, the investigator should formulate hypotheses to be addressed by the study. The final preliminary step is to choose the study design that appears to be most feasible and efficient in terms of addressing these hypotheses.

After choosing a study design, the first step in study implementation is to develop a protocol describing the study's purpose and methods. The protocol identifies the personnel and resources needed to conduct the study and serves as a guide for its implementation. With some modification, the study protocol can also be used for justifying the study's use of funds or to seek additional funding.