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Evaluating Health Impact
Water Supply, Sanitation, and
Hygiene Education

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Abstract

It is generally agreed that improvements in water supply and sanitation have direct beneficial effects on community health. This is especially relevant in developing countries where infant mortality and morbidity rates due to waterborne and water-related diseases are extremely high. However, for a number of reasons, the connection between clean water and adequate sanitation facilities, and improvements in health status has been difficult to establish. In this period of limited resources, water supply, sanitation, and related hygiene education programs must compete with other public health programs for limited resources. It is therefore important that relevant information be made available on the impact that water supply and sanitation programs have on health so that priorities can be assigned and appropriate decisions made. This monograph, sponsored jointly by the United Nations Children’s Fund (UNICEF) and the International Development Research Centre (IDRC), summarizes the results of a workshop, hosted by the International Centre for Diarrhoeal Disease Research, held in Bangladesh, November 1983, which addressed the conditions under which health impact evaluations should be undertaken; indicators for measuring health impact; study designs which can be used; and, how results can be interpreted.

Résumé

Il est généralement admis que l’amélioration de l’approvisionnement en eau et de l’assainissement a un effet bénéfique direct sur la santé communautaire. C’est particulièrement vrai dans les pays en développement où le taux de mortalité et de morbidité infantiles attribuable aux maladies transmises par le contact de l’eau et liées à la qualité de l’eau est très élevé. Cependant, pour plusieurs raisons, le rapport entre l’eau propre et de bonnes installations sanitaires, d’une part, et l’amélioration de l’état de santé, d’autre part, a été difficile à établir. En période de ressources restreintes, comme maintenant, les programmes d’approvisionnement en eau, d’assainissement et d’éducation en hygiène doivent concourir les autres programmes de santé publique pour l’obtention de fonds. Il importe donc de rendre disponible l’information pertinente sur l’effet des programmes d’approvisionnement en eau et d’assainissement sur la santé pour que les priorités soient établies et les bonnes décisions prises. Cette monographie, parrainée par le Fonds des Nations Unies pour l’enfance (UNICEF) et le Centre de recherches pour le développement international (CRDI), résume les résultats de l’atelier, qui s’est tenu au International Centre for Diarrhoeal Disease Research, au Bangladesh en novembre 1983, et qui a porté sur les conditions dans lesquelles les évaluations de l’effet de programmes sur la santé devraient être faites; sur les indicateurs à employer pour mesurer cet effet sur la santé; sur les plans d’évaluation susceptibles d’être utilisés et sur la façon d’interpréter les résultats des évaluations.

Resumen

Se admite generalmente que la introducción de mejoras relativas al suministro de agua y a las condiciones higiénicas conlleva efectos benéficos directos sobre las condiciones sanitarias de la comunidad. Esto es cierto sobre todo en los países en vías de desarrollo, que tienen índices muy elevados de mortalidad y morbilidad infantil debido a la contaminación de las aguas. Sin embargo, debido a muchas razones, ha resultado difícil demostrar los efectos que tienen sobre las condiciones sanitarias la pureza de las aguas y las instalaciones higiénicas adecuadas. Debido a los limitados recursos disponibles, los programas educativos sobre suministro de agua y condiciones higiénicas deben competir con otros programas de salud pública. Por lo tanto, es importante diseminar la información relativa a la repercusión de los programas de suministro de agua y de los programas de higiene sobre las condiciones sanitarias para poder asignar prioridades y tomar las decisiones apropiadas. En esta monografía, patrocinada conjuntamente por el Fondo de las Naciones Unidas para la Infancia (UNICEF) y el Centro Internacional de Investigaciones para el Desarrollo (CIID), se resumen los resultados de un seminario organizado por el International Centre for Diarrhoeal Disease Research, que se celebró en Bangladesh en noviembre de 1983. En el mismo se analizaron las condiciones en las que se deben llevar a cabo las evaluaciones de la repercusión de los programas sanitarios; los índices para medir dichos efectos; los diseños de estudio que se pueden emplear; así como la manera de interpretar dichos resultados.
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Foreword

Planners dealing with the allocation of resources to the water supply and sanitation sector have to consider two questions. First, they have to decide on how resources should be allocated between water supply and sanitation programs, on the one hand, and other development programs (including health programs), on the other. Second, once the level of resources available to the water and sanitation sector is set, planners have to decide on the appropriate allocations to specific water supply, sanitation, and hygiene education activities, and the levels of service to be provided.

Because water supply and sanitation programs have economic and social as well as health implications, these decisions are not, and should not be, made solely on the basis of health considerations. Nevertheless, reliable information on the impact of water supply and sanitation programs on health is often necessary if sound decisions are to be made.

In practice, however, studies designed to assess these impacts have been plagued by a variety of methodological problems, and it has been concluded by many that valid studies are necessarily of such long duration and such cost that they are of little use in formulating policy.

With this background, a workshop on measuring the health impact of water supply and sanitation programs, hosted by the International Centre for Diarrhoeal Disease Research, was held at Cox's Bazaar in Bangladesh in November 1983. The workshop participants identified and discussed four key questions: the conditions under which health impact evaluations should be undertaken, indicators for measuring health impact, study designs which can be used and how results can be interpreted. The participants charged the rapporteurs of the workshop with the responsibility of synthesizing and further developing the discussions of the workshop.

This monograph, sponsored jointly by the United Nations Children's Fund (UNICEF) and the International Development Research Centre (IDRC), is the outcome of this process. It is believed that this document is a promising first step in charting a course which will culminate in the development of a valid, coherent and comprehensive body of information on the health impact of water supply, sanitation and hygiene education programs.

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Acknowledgments

In November 1983, the International Centre for Diarrhoeal Disease Research, Bangladesh and the London School of Hygiene and Tropical Medicine organized an international workshop on “measuring the health impact of water supply and sanitation programs.” The workshop was held in Cox’s Bazaar, Bangladesh. Financial support for the workshop was provided by the International Centre for Diarrhoeal Disease Research, Bangladesh, the World Health Organization, the United Nations Children’s Fund, and the International Development Research Centre. The 42 scientists and planners (listed in Annex I) who attended the workshop contributed substantially to the development of the ideas presented in this report. In addition, the assistance of the following people, who reviewed drafts of this or related documents, is acknowledged: R.C. Ballance, J. Baltazar, R.E. Black, U. Blumenthal, S. Fernando, R. Gunn, R. Helmer, B.R. Kirkwood, D.G. Kleinbaum, L.L. Kupper, L. Laugeri, S. Lwanga, R.H. Morrow, L. Rodrigues, J.J. Schlesselman, P.G. Smith, and R. Waldman. The collaboration of Hugh Taylor and Gordon Smith of Johns Hopkins University and Michael Porter of the World Bank on the sections dealing with eye diseases, guinea worm, and skin diseases is appreciated. Finally, the authors wish to acknowledge the special contributions made by Sandy Cairncross and Beverly Young, who undertook detailed reviews of the various drafts of this document and made numerous suggestions for improvements, additions, and corrections.

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Chapter 1

Introduction

The Context

In the 19th and early 20th centuries, the "sanitary revolution" played a fundamental role in reducing sickness and death from infectious diseases in industrialized countries (McKeown and Record 1962; Preston and van de Walle 1978). It has generally been assumed that improvements in water supply and sanitation conditions have a similar role to play in reducing the high levels of morbidity and mortality that prevail in many poor countries today. This presumed impact on health was the main impetus behind the declaration of the United Nations' "International Drinking Water Supply and Sanitation Decade" and the inclusion of basic water supply and sanitation facilities in the "primary health care" package defined at Alma Ata in 1978 (WHO 1979a).

Although there is general agreement that water supply and sanitation facilities do play a role in health, there is disagreement on the priority that should be given to the sector as a whole or to specific activities within the sector. Improved information on the impact of different levels of specific water supply and sanitation activities and different mixes of these activities are thus needed for two purposes. First, planners have to decide how resources should be allocated between water supply and sanitation programs, on the one hand, and other health programs (such as oral rehydration and immunization programs), on the other. Second, once the level of resources available to the water supply and sanitation sector is set, planners have to decide the appropriate allocations to specific water supply, sanitation, and hygiene education activities, and the levels of service to be provided.

Because water supply and sanitation programs have economic and social, as well as health, implications, these decisions are not and should not be made solely on the basis of health considerations. Nevertheless, it is evident that reliable information on the impact of water supply and sanitation programs on health in some settings is necessary if sound decisions are to be made.

In 1975, the World Bank convened an expert panel to advise planners on reliable procedures for estimating and predicting the health effects of water supply and sanitation projects. The expert panel concluded that "long-term longitudinal studies of large size and expense are probably the only means through which there is any chance of isolating a specific quantitative relationship between water supply and health" and recommended, given "the very high cost, limited possibility of success and restricted application of results," that such studies not be undertaken (World Bank 1976). A decade later, with serious questions being asked about the relative merits of water and sanitation versus other health programs (Walsh and Warren 1979) and about the relative merits of different levels of water supply and sanitation services (McJunkin 1983;
Esrey et al. 1985), the need for reliable information has once again come to the fore.

With this background, a workshop on “measuring the health impact of water supply and sanitation programs,” organized by the International Centre for Diarrhoeal Disease Research, Bangladesh and the London School of Hygiene and Tropical Medicine, with support from UNICEF, the International Development Research Centre (IDRC), and the World Health Organization (WHO), was convened in November 1983 in Cox’s Bazaar, Bangladesh. The workshop was attended by 42 scientists and planners (Annex 1) representing the biomedical, engineering, and social sciences.

The overall purpose of the workshop was to take stock of the information that had been accumulated over the past decade and to determine whether it was now possible to chart a course that would culminate in the development of a valid, coherent, and comprehensive body of information on the health impact of water and sanitation projects. To this end, workshop participants presented papers (summarized in Annex 2) on ongoing or completed field studies, and working groups discussed the following four key questions:

- Under what conditions should health impact evaluations (HIEs) be undertaken?
- What indicators should be used to measure health impact?
- What study designs should be used in HIEs?
- How should the results of HIEs be interpreted?

Although there are no simple answers to any of these questions, it was generally agreed that the most difficult and important area discussed at the meeting was that of the pros and cons of different study designs for assessing the health impact of water supply and sanitation facilities. The Cox’s Bazaar workshop verified that, as was the case a decade earlier, the literature remains “heterogeneous in design, method and conclusion” (Bradley 1974), with serious methodological problems abounding (Blum and Feachem 1983). This pessimistic assessment of present knowledge was tempered by guarded optimism regarding future possibilities for assessing the impact on the most important of the outcome variables, severe diarrhea in young children. This optimism is based on recent advances in rapid epidemiological assessment techniques and an understanding of the pathogenic agents responsible for diarrhea: (1) Whereas case-control studies were traditionally regarded as being scientifically unsound, over the past 15 years many of the major methodological problems associated with these studies have been satisfactorily addressed; thus, the results of such studies are now widely accepted as being valid (Acheson 1979). (2) Whereas background documents for the World Bank Expert Committee of 1975 spoke of the “inscrutable syndrome” of diarrhea (Wall and Keeve 1974), 10 years later it is possible to identify the pathogenic organisms responsible for up to 80% of cases of diarrhea treated at health facilities (Black 1984).

The rapporteurs at the Cox’s Bazaar workshop were charged with the responsibility of synthesizing the discussions of the workshop and of further exploring the preliminary ideas discussed at the workshop on the development of methods for rapidly assessing the impact of water supply and sanitation projects on severe diarrheal diseases in young children. Over the past 2 years, working with the Division of Environmental Health and the Diarrhoeal Diseases
Control Programme of the WHO, and with funding from UNICEF, these methodological explorations have been carried out to the point where specific recommendations on study designs can now be made.

Two documents emanated from this work. The first is a technical paper, published by WHO, that assesses the potential of the case-control method for measuring the impact of water supply and sanitation facilities on diarrheal diseases (WHO 1985). This report, the second document emanating from the Cox's Bazaar workshop, is intended primarily for two more general audiences. First, it is intended to provide guidelines for planners in international, national, and local agencies on when and how evaluations of the health impact of water supply and sanitation projects should be undertaken. Second, it provides suggestions on the choice of outcome measures and study designs for researchers who are responsible for the implementation of HIEs in this and related sectors.

Some of the many limitations with respect to the scope of this report should be explicitly recognized. First, the report is intended as a “next step” in the ongoing process initiated by the Cox’s Bazaar workshop — it is definitely not the “last step” in that process. Second, the report deals solely with the health impacts of water supply and sanitation projects and does not address the extremely important economic, social, and political impacts of such projects. Third, even the treatment of the health impacts is selective. Water supply and sanitation projects may have impacts on mortality, morbidity, and growth. At the Cox’s Bazaar workshop, it was agreed that a rational approach to dealing with the many methodological problems associated with HIEs was first to address the problems associated with one of the most important impacts, namely morbidity due to diarrheal disease, and, after this had been done, to turn attention to the methodological issues associated with assessing impacts on other outcome measures (such as nutritional status, intestinal nematodes, and eye diseases). As a consequence, the discussion in this report has a heavy bias toward diarrhea morbidity and deals in less depth with approaches to measuring the impacts of other outcome measures (such as diarrhea mortality, nutritional status, intestinal nematodes, guinea worm, and skin and eye diseases). Finally, because recent comprehensive reviews of the literature on the health impacts of water supply (McJunkin 1983; Esrey et al. 1985) and sanitation (Feachem et al. 1983; Esrey et al. 1985) improvements are available, no attempt has been made to summarize available empirical data.

**Study Designs for HIEs**

Before addressing the four key questions outlined earlier, the options available for designing HIEs will be outlined. Among analytic or hypothesis-testing studies, there are some primary distinctions that define different basic approaches. These distinctions and the subsequent study designs are illustrated in Fig. 1. The first distinction separates those studies for which the measurements of exposure and disease refer to a single point in time (cross-sectional studies) from those that depend on measurements at more than one point in time. The second distinction deals with the method of control of variables other than

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1 The reader intending to conduct a HIE of a water supply or sanitation program is strongly advised to study this document.
Fig. 1. Analytic study designs used in HIEs of water supply and sanitation projects.
water supply and sanitation conditions: in “experimental” designs, control for the influence of these other variables (such as income and mothers’ education) is sought by setting up comparison groups that are equivalent to the “treatment” groups in every way except exposure to the treatment (which is, in this case, improved water supply and sanitation), whereas in “nonexperimental” designs the influence of these other variables on diarrheal disease is controlled through statistical means. The third distinction concerns only the experimental designs and deals with the method of assigning individuals to groups: where such assignment is made on a random basis, the design is a “true experimental” design; where assignment is made on a systematic but nonrandom basis (as is generally the case in water supply and sanitation interventions), the design is termed “quasi-experimental.” The fourth distinction concerns only the nonexperimental designs and deals with the sequence in which exposure to risk (in this case through water and sanitation) and health outcome are treated in the study: the “cohort” designs, like the experimental designs, proceed forward in time from exposure to disease, whereas the “case-control” designs work backward in time from disease to history of exposure. The fifth and final distinction deals with the timing of the health outcome relative to initiation of the investigation in both quasi-experimental and cohort designs: where the outcome occurs prior to the initiation of the investigation, the design is a “historical” quasi-experimental or cohort study; where the outcome occurs after initiation of the investigation, it is a “concurrent” quasi-experimental or cohort study.
Chapter 2

Conditions Under Which HIEs Should be Undertaken

The literature is replete with examples of HIEs of water supply and sanitation projects that have been undertaken under conditions in which a satisfactory evaluation was not useful, not sensible, or not feasible. Before examining how HIE studies should be designed and interpreted, therefore, an important first task is to define whether a proposed HIE is “useful” (do the benefits outweigh the costs?), “sensible” (is it reasonable to assume that a measurable health impact exists?), or “feasible” (are the necessary scientific and other resources available?).

Criterion I: Is a HIE “Useful”?

A HIE of a water supply or sanitation program makes two distinct contributions. First, each study contributes to a global store of knowledge upon which all scientists and planners can draw. Second, a study may contribute site-specific information to be used directly by planners in making investment decisions and designing projects in a specific location. Several factors determine which of these two contributions is of primary importance.

To illustrate a general point, consider the relative contributions of John Snow’s investigations of water and cholera in London in 1854 (Snow 1936), and of the unpublished recent investigation by the United States Center for Disease Control on sewerage and typhoid in Mauritius. Although Snow’s study provided valuable practical information to the city of London, this local contribution pales beside the contribution made to a universal understanding of the health impact of contaminated water. In contrast, the excellent epidemiological study of the effect of an inadequate sewerage system on typhoid in Mauritius, although making an important contribution to “local” policy, was considered to be of so little “global” importance that the study was not even published. The implication is that, as knowledge of the relationship between water supply and health has matured, so the primary contributions of HIEs have become the clarification of the way in which this general relationship operates under the specific epidemiologic, environmental, and cultural conditions pertaining in a particular locality.

An additional factor affecting the relative importance of the universal and the local contributions of a HIE is the nature of the agency that funds the evaluation. Whereas some HIEs are funded by agencies with a mandate to develop a global data bank, in most cases HIEs are funded by multilateral,
bilateral, national, or local agencies whose prime interest is providing improved data to planners at a national, regional, or local level.

Accordingly, while bearing in mind that each well-conducted HIE does make a contribution to the development of a global data base upon which all can draw, in this analysis it will generally be assumed that the usefulness of a HIE is to be judged primarily in terms of the contribution made to improved decision-making in the specific setting in which the HIE is undertaken.

HIEs may be undertaken for two quite different purposes. In some instances, information may be needed to decide whether health sector funds should be used for, say, a water supply or an immunization program. In far more instances, it has already been decided that a water supply and sanitation program will be undertaken, and the planners wish to specify the appropriate levels and mix of services to be provided.

Loosely interpreting a fundamental principle of optimization, the "usefulness" of a proposed HIE will depend on the balance between the expected benefits accruing from an evaluation, on the one hand, and the costs incurred by the evaluation, on the other. Although not providing a mechanical answer to the question of whether or not a particular HIE would be "useful," the principle provides guidance in answering some important questions.

**Under What Conditions are the Benefits of the Information Generated in a HIE Likely to be Large?**

First, it is important to bear in mind that health benefits are never the sole, and seldom the major, benefit of a water supply and sanitation project. For instance: in urban areas, where people are accustomed, and willing, to pay for water, investments in water supplies are usually justified solely on financial criteria; in arid rural areas, time saved by improving water supplies is often so highly valued that water programs have high priority for valid economic and political reasons; and in urban areas, improvements in excreta disposal facilities may permit increases in plot density, thus reducing the costs of other elements of urban infrastructure.

Because these economic and social considerations are frequently of greater significance than health considerations, most decisions to invest in water supply and sanitation projects are made without reference to the health impact of such projects. Under such conditions, the analyst responsible for the investment decision is correctly indifferent to the health impact of the project. Translated into the terms of the simple "principle" outlined above, the additional information on the health impact of the project has no effect on the decision and has, in this narrow context, no value. Under such circumstances, a HIE is not "useful."

The corollary is that it is only when these other, nonhealth, considerations leave the investment decision in the balance that health considerations become important and it becomes "useful" to develop specific information on the likely health impact of the proposed investment. Because these other (especially economic) justifications for water supply and sanitation programs are more
likely to be dominant in urban than in rural settings, it is usually in rural settings that information on the health impact of water supply and sanitation interventions becomes critical to investment decisions, and thus it is often in rural settings that HIEs will be most "useful" to planners deciding on the level of resources to be devoted to the water supply and sanitation sector.

Once the level of resources devoted to the water supply and sanitation sector is set, planners in developing countries have to decide the level and mix of services to be provided through water supply and sanitation programs. They have to decide, for instance, whether water will be provided through house connections, through yard taps, or through public standpipes; whether flush toilets or improved pit latrines will be built; and what proportion of resources should be devoted to hygiene education programs.

Even though other factors (such as the willingness of those served to pay for the services) are generally of major importance in such decisions, the anticipated health impact will often play a significant role in determining the appropriate level and mix of services to be provided.

In deciding the overall level of resources to be devoted to the water supply and sanitation sector, therefore, "other" impacts will generally be most important, and the value of a HIE correspondingly less important. In deciding the content of a water supply and sanitation sector project, however, information on the health impact of different levels and mixes of service will often be vital, and, in this context, HIEs will often be "useful."

A final consideration in assessing the usefulness of a HIE is the delay between formulation of the need for information and completion of the HIE. Although development of information for use by planners in the future is a legitimate task, in most practical cases the time horizon is far more limited. Information on the likely impact of different levels and mixes of services is generally needed when the planner does a preliminary screening and ranking of alternative projects (in World Bank terms, the "prefeasibility" phase). If it is possible to design, conduct, and analyze a HIE in a 9- to 12-month period, the results of the HIE would be "useful"; if the study design was such that it took several years to obtain results, the information would be of no use to the planners responsible for preparation of the current program.

In summary, the benefits of a HIE are likely to be large when other (especially economic) benefits are not decisive in specifying investment priorities and levels and mix of services, and when the results are available rapidly.

**Under What Conditions are the Costs of a HIE Likely to be Large?**

The cost of a HIE depends on the study design. Well-designed and well-conducted HIEs using the standard quasi-experimental design (Fig. 1) are extremely expensive, with a single study costing as much as a million dollars (World Bank 1976). When the cost of a HIE is this great, it is evident from the proposed "decision rule" that a HIE will be "useful" only if the benefit of the information, too, is great. After careful examination, the 1975 World Bank Expert Panel concluded that, even where large investment projects are
contemplated, the benefits of HIEs carried out using these conventional designs are not commensurate with the costs of the evaluations (World Bank 1976).

In Chapter 4 of this report it will be argued that the case-control method offers promise as an alternative method for assessing the impact of water supply and sanitation facilities on severe diarrheal diseases at much lower cost (of the order of USD 50 000 per study). If the information available from such an inexpensive HIE is of equal or even greater validity than the information generated through the conventional study designs, then there will be a sharp increase in the number of situations in which HIEs will be “useful.”

**Should a Fixed Proportion of the Budget of a Project be Allocated to Evaluating Health Impacts?**

Where consideration is being given to replication of a project on a large scale, the benefits from improved information on the health impact of the project will be large. That is, ceteris paribus, where large investment decisions are at stake, the likely benefit of a HIE will be large and vice versa. The benefits of the information generated by an evaluation of a project are, therefore, dependent on the size of the next project to be undertaken, and bear no particular relationship to the cost of the project that is to be evaluated. Similarly, because the sample sizes required bear no relation to the cost of the project to be evaluated, the cost of the evaluation (which is closely related to its sample size) should bear no particular relationship to the cost of the project to be evaluated. It is, thus, evident that the appeal of the “fixed proportion” criterion, which has been used for allocating resources to HIEs (Riecken 1979), is bureaucratic simplicity rather than scientific logic.

**Criterion II: Is a HIE “Sensible”?**

Having decided that a HIE would be “useful,” a judgment has to be made of the likelihood that the project will have had a measurable impact on health, i.e., is it not only “useful” but also “sensible” to conduct a HIE?

**What are the Characteristics of Projects that it May be “Sensible” to Evaluate?**

It is never sensible to conduct a HIE of a project that has been installed for a short time. Because new projects invariably face a variety of “teething problems,” it takes time for the system to function effectively. In addition, it takes time for users to decide how they will make use of the new opportunities and, in some cases, time to purchase the necessary ancillary equipment (such as washbasins) needed to effect the desired changes in behaviour. In most instances, it is advisable not to undertake a HIE before a prior evaluation of the functioning and utilization of the new facilities has been undertaken using the “minimum evaluation procedure” of the World Health Organization (WHO 1983a) or a similar procedure. Even then, it should be realized that, as has been shown for the impact of improvements in water supply and sanitation conditions in urban France in the 19th century (Preston and van de Walle 1978; Briscoe 1985), the full effects of a project may be realized only generations after the completion of the project.
Whether or not a HIE will be “sensible” also depends on the comprehensiveness of the intervention to be evaluated. Water supply and sanitation projects are frequently introduced not in isolation but as part of a complex set of changes in the medical, nutritional, social, political, and economic spheres. Where this is the case, evaluation of the specific effect of a single intervention is often very difficult, whence a HIE of water supply and sanitation interventions under such conditions is often not “sensible.”

**What Study Designs may Lead to More “Sensible” HIEs?**

In general, it is not “sensible” to choose a representative sample from the population of the study area. For instance, for a given sample size, the likelihood of demonstrating a significant health impact can be substantially increased by sampling only from the most vulnerable age group (young children), and even by sampling only from particularly vulnerable groups, such as non-breast-fed children (Butz 1984) or family members who are exposed to secondary infection from other family members who have become infected (Khan 1982; Khan et al. 1984). Likewise, under certain conditions, focused studies of “early adaptors” might provide clues to the impacts that might be forthcoming later in the population at large.

By choosing restricted rather than representative samples, an implicit choice is made to maximize “internal validity” (the capacity to discern a cause-and-effect relationship) by sacrificing “external validity” (the capacity to apply the findings to the community at large). As will be argued elsewhere in this report, in the future HIEs will no longer deal with “inscrutable” syndromes, such as “diarrhea identified through field surveillance,” but will become investigations of the role of water supply and sanitation on well-defined outcome variables (including restricted groups of diarrheal pathogens, nutritional status indicators, and specific eye infections). In other words, HIEs will assume many of the characteristics of focused aetiologic research studies. Experience with aetiologic research in other fields has shown that “internal validity is the sine qua non of aetiologic research” (Kleinbaum et al. 1982) and that “the ill-advised pursuit of representativeness has caused unnecessary work and reduced the precision of epidemiologic studies” (Cole 1979). We conclude that, although the search for external validity has been of primary importance in previous HIEs, internal rather than external validity will be the trademark of the “new” generation of HIEs. The strategy, then, should be to use HIEs to obtain valid answers to specific well-formulated questions, and to deal with the extrapolation of these specific findings to the broader questions of interest to policymakers in a poststudy phase.

**Criterion III: Is a HIE “Feasible”?**

If it is judged that a proposed HIE would be “useful” (the benefits accruing from the evaluation would exceed the costs of the evaluation) and if it is judged that a HIE would be “sensible” (it is likely that the project to be evaluated has had a significant impact on the outcome measure), then the final factor to be considered before undertaking the evaluation is whether or not, from both scientific and resource considerations, an evaluation is “feasible.”
Under What Conditions is a HIE Feasible Scientifically?

A major decision in undertaking a HIE is the study design to be used. The scientific issues to be dealt with include: the methods for accounting for the effects of extraneous variables, the sample sizes required, the effects of less-than-perfect information on exposure and outcome variables, and the effects of systematic errors in the selection of study subjects. As discussed in Chapter 4 of this report, each of the available study designs deals well with some of these issues and poorly with others. To illustrate the seriousness of just one of the problems with the conventional quasi-experimental HIEs, Table 1 specifies the sample sizes required to detect differences in diarrhea incidence of public health significance at reasonable levels of statistical significance and study power. Assuming that on the average a child under the age of 5 years has 2.2 attacks of diarrhea per year (Snyder and Merson 1982), if data on diarrhea are based on a 48-hour recall period, the frequency of positive answers to the question “has your child had an attack of diarrhea that started in the past 48 hours?” will be 1.2%. Assuming that the study is designed to detect a 33% reduction in diarrheal incidence, and assuming that a cluster sampling technique is used, over 20,000 questionnaires will have to be administered to the group with improved water supplies and a similar number to the group without improved facilities. If only severe episodes of diarrheal disease are included in the study, the number of episodes is reduced to about 10% of the total number, and the sample sizes are an order of magnitude larger. It is evident that for any reasonable assumptions, sample sizes very much larger than those used in most actual HIEs are needed for studies of this sort. In other words, many existing HIEs were not “scientifically feasible” simply because of the large sample sizes required.

As discussed in detail in Chapter 4, there are study designs for which the required sample sizes are less daunting. If a case-control design is used, and if between 30 and 70% of the population is exposed to unimproved

Table 1. Required sample sizes in experimental, cohort, and cross-sectional studies.

<table>
<thead>
<tr>
<th>Frequency of disease in the unserved population (%)</th>
<th>Reduction in frequency to be detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10%</td>
</tr>
<tr>
<td>0.2</td>
<td>160000</td>
</tr>
<tr>
<td>1</td>
<td>320000</td>
</tr>
<tr>
<td>5</td>
<td>62000</td>
</tr>
<tr>
<td>10</td>
<td>29000</td>
</tr>
<tr>
<td>25</td>
<td>10000</td>
</tr>
</tbody>
</table>

Note: The sample sizes are calculated so that there is a 90% chance of detecting the specified reduction at the 5% significance level. Because we are interested in reductions only, a one-sided test is used. The calculations are based on an approximate formula (developed by Cochran and Cox 1957), which slightly underestimates the sample sizes given by the exact formula (Fleiss 1981). When, as is usually the case, samples are drawn from clusters, there will generally be a positive correlation between elements in the same cluster; thus, assuming that the sample will be drawn from a given number of clusters, to show a specified difference with a specified precision, the required sample size is increased. In studies of diarrheal diseases, the sample sizes typically have to be 2–4 times larger to account for this intraclass correlation. The sample sizes given above assume an intraclass correlation coefficient such that the “design effect” (Kish 1965) is 2 and are thus twice the values that would pertain if there were no intraclass correlation. Because the numbers in the table indicate the numbers required in each group, in the standard case of a single treatment and a control group, total sample size is twice that indicated in the table.
Table 2. Required number of cases in case-control studies.

<table>
<thead>
<tr>
<th>Population using improved facilities</th>
<th>1.1  (9%)</th>
<th>1.2  (17%)</th>
<th>1.4  (29%)</th>
<th>1.5  (33%)</th>
<th>1.7  (42%)</th>
<th>2.0  (50%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>22000</td>
<td>6000</td>
<td>1900</td>
<td>1400</td>
<td>850</td>
<td>540</td>
</tr>
<tr>
<td>20</td>
<td>12000</td>
<td>3400</td>
<td>1100</td>
<td>740</td>
<td>450</td>
<td>280</td>
</tr>
<tr>
<td>30</td>
<td>9000</td>
<td>2600</td>
<td>780</td>
<td>540</td>
<td>330</td>
<td>200</td>
</tr>
<tr>
<td>40</td>
<td>8000</td>
<td>2200</td>
<td>660</td>
<td>460</td>
<td>270</td>
<td>170</td>
</tr>
<tr>
<td>50</td>
<td>8000</td>
<td>2100</td>
<td>610</td>
<td>420</td>
<td>250</td>
<td>150</td>
</tr>
<tr>
<td>60</td>
<td>8000</td>
<td>2100</td>
<td>620</td>
<td>420</td>
<td>250</td>
<td>140</td>
</tr>
<tr>
<td>70</td>
<td>9000</td>
<td>2400</td>
<td>680</td>
<td>460</td>
<td>270</td>
<td>140</td>
</tr>
<tr>
<td>80</td>
<td>11000</td>
<td>3000</td>
<td>860</td>
<td>580</td>
<td>330</td>
<td>190</td>
</tr>
<tr>
<td>90</td>
<td>20000</td>
<td>5300</td>
<td>1500</td>
<td>1000</td>
<td>560</td>
<td>310</td>
</tr>
</tbody>
</table>

Note: The sample sizes are calculated so that there is a 90% chance of detecting the specified relative risk (or equivalent reduction) at the 5% significance level. The calculations follow the method of Schlesselman (1982). It is assumed that one control is chosen for each case. Note that the implicit in the calculations is the assumption that the exposure rate among controls in the target population may be estimated from population information relating to overall exposure rate, an assumption that is reasonable when studying rare diseases (Schlesselman 1982), as in the case of diarrhea reported to a clinic over a 3-month period.

conditions, then (Table 2) about 600 subjects are required in each of the two study groups.

In some cases, the critical problem is not that of large sample sizes, but the control of biases in the estimated impact of the water or sanitation project. Because the most common and serious shortcoming in HIEs of water supply and sanitation programs, as in HIEs of other interventions (Klein et al. 1979), is poor design, execution, and analysis due to insufficient skill and experience on the part of the evaluation team, a key requirement for “scientific feasibility” is that the core skills (epidemiology and statistics) be adequately covered by the evaluation team.

What Resources are Required to Make a HIE Feasible?

As in other health-related areas (Riecken 1979), systematic information on costs of impact evaluations is not available. A primary determinant of the cost of a study is the sample size, although other factors, including the comprehensiveness of the study and the salaries of the researchers, are important too. To illustrate the orders of magnitude of the costs involved in HIEs, it is instructive to consider two recent studies, both carried out in the same developing country by joint groups of United States and national scientists. The first study, a quasi-experimental study of the impact of a water program, took 7 years to complete and cost about a million dollars. The second, a case-control study of the effect of water supply and sanitation facilities on severe diarrheal disease, took about a year to complete and cost about USD 70 000. Although there may sometimes be special circumstances under which sensible HIEs can be conducted at lower cost, in general the costs of such evaluations are substantial. Unless the necessary resources can be secured, HIEs should not be undertaken.
Variables to be Measured in HIEs

Intermediate Variables

A recent review of conceptual models for investigating the relationships between underlying socioeconomic conditions and health outcomes (Mosley and Chen 1984) has pinpointed the lack of attention to monitoring of the "intermediate" variables as a critical shortcoming in much of the literature. Similarly, many analyses of the health impacts of water supply and sanitation projects are unable to explain the outcome because of a failure to monitor the chain of changes that is necessary if the provision of improved facilities is to be translated into improved health outcomes (Blum and Feachem 1983). For this reason, it is desirable that HIEs are preceded by an evaluation, using the WHO "minimum evaluation procedure" (MEP) (WHO 1983a) or a similar procedure, of the functioning of the water supply and sanitation facilities and the ways in which these facilities are utilized by the population. The "intermediate" variables relevant in water supply and sanitation evaluations are discussed in detail in the MEP; the focus in this chapter is on the variables used to measure health outcomes.

Attributes of a Variable

A substantial body of theoretical and empirical epidemiologic research has examined the effect of using exposure and outcome measures that are systematically inaccurate, i.e., the so-called "misclassification bias." In the simplest case, when the misclassification of disease status is the same for both a treatment and a control group, or when misclassification of exposure status is independent of disease status, it has been shown that the effect of misclassification is always to deflate the difference between the rates in the two groups (Newell 1962). Thus, for example, if we are examining the effect of using better quality water on diarrhea in young children, and we use a poor measure of diarrhea (say 1-month recall), we will usually underestimate the beneficial effect of using an improved supply of water.

It is thus imperative that measures of all study variables not simply be considered a matter of "common sense," but that objective criteria be used to compare the performance of alternative measures of particular variables. In a recent review of methodological problems in impact evaluations of health and nutrition programs, attention is drawn to the fact that few measures of health impact have ever been properly tested (Habicht and Butz 1979). It has been proposed (Hennigan et al. 1979) that the criteria for such testing include:
Validity: There are two components to the validity of a measure of, say, diarrheal disease: What percentage of individuals actually having diarrhea are indicated to have diarrhea when the measure (such as 24-hour recall) is used (the so-called "sensitivity" of the measure), and what percentage of those who do not have the disease are so indicated by the measure ("specificity").

Reliability: A "reliable" measure is one that yields almost the same measurement each time the same person with the same attribute is measured.

Responsiveness: The most "responsive" outcome measure is that which gives the greatest response to changes in the underlying (in this case, water supply and sanitation) variable.

Although there is no substitute for detailed empirical investigations to compare the validity, reliability, and responsiveness of alternative measures of the impact of water supply and sanitation projects, there are some general principles that provide useful guidance in choosing outcome measures. Experience in related fields has shown that: (1) Usually, the closer and more direct the link between the outcome variable and the underlying variable, the smaller the influence of other factors, and the more responsive is the outcome variable (Cook and McAnany 1979). (2) Objective measures will be more valid and more reliable than subjective measures relying on ill-defined definitions and on the perceptions of particular respondents. As illustrated for diarrheal disease morbidity below, theoretical models, formulated on the basis of specific experimental data, can also provide guidance on the choice of indicator measures.

Attributes of Underlying and Intermediate Variables

For the reasons outlined earlier, the focus in this report is on outcome variables (with particular emphasis on diarrhea) rather than on intermediate variables (such as performance and utilization) and underlying variables (such as the availability of water and sanitation facilities and socioeconomic characteristics). Evidently, however, misclassification is a consequence not only of systematic inaccuracies in measuring outcome variables, but also of inaccuracies in measuring the intermediate and underlying variables that are determinants of the health outcomes. Just as biomedical scientists have devoted a great deal of attention to the development of valid and reliable health outcome measures, so other disciplines have concentrated on developing valid and reliable measures of other variables. Although these other variables (such as quality of water supply or household income) are conceptually simple, they are sometimes difficult to measure with high validity and reliability, and it is imperative that specialists in these fields (such as microbiologists and economists) be consulted so that sloppiness in dealing with determinants does not negate the rigour that is incorporated into the outcome measures.

Definition and Attributes of Specific Outcome Variables

Water supply and sanitation projects may affect a wide variety of health-related variables including: morbidity and mortality due to diarrhea, nutritional status, intestinal nematodes, eye infections, guinea worm, skin infections, and utilization of immunizations and other preventive health services.
In any particular setting, the choice of outcome variables will be influenced by the public health importance of the variable, the validity and reliability of the instruments used for measuring the variable, the responsiveness of the variable to changes in water supply and sanitation conditions, and the cost and feasibility of measuring the variable. Ideally this information should be presented for each of the above impact variables. In the first stage of the ongoing work on HIEs, it was necessary to focus attention on one particular outcome measure. Accordingly, the discussion in both this chapter and the subsequent chapter on study designs deals mainly with the problem of diarrhea morbidity. Once the methodological problems of evaluating the impact of water supply and sanitation projects on diarrheal disease have been satisfactorily resolved, then, under the ongoing leadership of WHO, it is expected that more detailed attention will be paid to the methodological issues involved in determining the impact on the other outcome measures.

**Diarrheal Disease Morbidity**

*Public Health Importance*

Diarrheal diseases are a major cause of sickness in most developing countries. Recent WHO estimates show that diarrheal diseases cause nearly 5 million deaths per year in children under 5 years of age in developing countries (excluding China). For each 100 children in this age group, there are, on the average, 220 episodes of diarrhea each year (Snyder and Merson 1982).

*Validity and Reliability*

Ten years ago, diarrhea was considered an “inscrutable syndrome” (Wall and Keeve 1974) because it was not possible to identify pathogenic organisms for more than 20% of diarrheas (WHO 1979b). The situation is radically different today as is illustrated on Tables 3 and 4, which are derived from aetiologic studies of diarrhea at a health centre and in a community in rural Bangladesh. These data (which were compiled prior to the identification of the association of *Campylobacter jejuni* with over 10% of diarrheas in Bangladesh (Glass et al. 1981)) and similar data from other settings in developing countries show that it is now possible to identify specific pathogenic organisms in about 30–50% of all episodes of diarrhea and in 60–80% of the more severe episodes treated at health centres (Black 1984).

This improved capacity to detect specific diarrhea pathogens has several implications for conducting HIEs. Because the hypothesis is that improved water supply and sanitation conditions affect the transmission of enteric pathogens, it is only those diarrheas that are caused by such pathogens that might be affected by these improvements. If, as is likely, a considerable proportion of the 50–70% of the unexplained diarrheas in community surveys are not caused by enteric pathogens, then the specificity of the outcome measure is very low, and the effect of improved conditions on diarrhea caused by enteric pathogens will be underestimated. The obvious remedy for this problem is to move from a symptomatic to an aetiology-specific definition of diarrhea, i.e., the effect of water supply and sanitation conditions on each of the important viral, bacterial, and protozoal causes of diarrhea could be analyzed one by one. Under some special circumstances, this will be possible; in general, this ideal is not attainable.
Table 3. Percentage of diarrheal episodes associated with enteric pathogens in a “clinic-based” study in Bangladesh.

<table>
<thead>
<tr>
<th>Pathogens identified</th>
<th>Age of patients (years)</th>
<th>&lt;2</th>
<th>2-9</th>
<th>≥10</th>
<th>All ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETEC</td>
<td></td>
<td>25</td>
<td>23</td>
<td>37</td>
<td>29</td>
</tr>
<tr>
<td>Rotavirus</td>
<td></td>
<td>46</td>
<td>12</td>
<td>9</td>
<td>24</td>
</tr>
<tr>
<td><em>Vibrio cholerae</em></td>
<td></td>
<td>2</td>
<td>31</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Nongroup 0:1 vibrios</td>
<td></td>
<td>7</td>
<td>5</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td><em>Shigella</em></td>
<td></td>
<td>4</td>
<td>9</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><em>E. histolytica</em></td>
<td></td>
<td>&lt;1</td>
<td>13</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td><em>G. lamblia</em></td>
<td></td>
<td>&lt;1</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Group F vibrio-like organisms</td>
<td></td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Note: A total of 14,491 clinical cases of diarrhea were examined over a 2-year period. Source: Black (1984).

Table 4. Percentage of diarrheal episodes associated with enteric pathogens in a “community-based” study in Bangladesh.

<table>
<thead>
<tr>
<th>Pathogens identified</th>
<th>Age of patients (years)</th>
<th>&lt;2</th>
<th>2-9</th>
<th>≥10</th>
<th>All ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETEC</td>
<td></td>
<td>20</td>
<td>28</td>
<td>20</td>
<td>23</td>
</tr>
<tr>
<td>Rotavirus</td>
<td></td>
<td>15</td>
<td>8</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td><em>Shigella</em></td>
<td></td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Other and mixed</td>
<td></td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Note: A total of 887 episodes of diarrhea were examined over a 1-year period. Source: Black (1984).

in practice and it becomes necessary to identify a practical, yet improved, procedure for use in field studies.

The essence of this improved procedure is the identification of methods for selecting from all diarrheas those that are most likely to be caused by enteric pathogens. From the community and clinic data presented in Tables 3 and 4, it is evident that it is the more severe diarrheas that are most frequently associated with known enteric pathogens. Thus, by including only the more severe diarrheas (either defined in the field on the basis of the degree of dehydration, stooling rate, stool volume, and presence of blood and mucus, or defined as those diarrheas that are serious enough to be brought to a clinic), the proportion of diarrheas caused by recognized enteric pathogens will be increased and misclassification biases correspondingly reduced.

Concern with the validity and reliability of an outcome measure provides strong reinforcement for the case that can be made for the use of aetiology-specific entities (or approximations thereof) as outcome measures. Whereas diarrheal data obtained through interviews with mothers are of notoriously low validity and reliability (Chen 1980), laboratory-confirmed diagnoses of specific pathogenic organisms are generally both valid and reliable.

It is interesting to note that this evolution, from the use of a broad syndrome to the use of aetiology-specific categories, parallels an earlier transformation in chronic disease epidemiology. It is now considered unproductive to study the epidemiology of, for instance, “cancer of the uterus” without making finer aetiologic distinctions (Cole 1979).
**Obtaining Information**

The validity of information on the outcome and underlying variables of interest depends on the cooperation that may be expected from the respondent (who is usually the mother). Where unsolicited and (to the respondent) peculiar questions are asked about diarrhea, cooperation may be given grudgingly or even withheld, particularly when (as is generally the case with longitudinal studies) the questions are asked repeatedly over a period of time. Where questions are asked about the health of a child that has been brought to a clinic by the mother, cooperation is generally freely given and information is likely to be more valid.

**Responsiveness**

The principle that the more direct the link between the outcome variable and the underlying variable, the more responsive the outcome variable, provides guidance in the choice of a responsive outcome measure for a HIE of a water supply or sanitation project. Because the outcome most directly affected by environmental conditions is infection with pathogenic organisms, the most responsive measure is likely to be that which measures this outcome most directly. Of the several potential measures of interest to policymakers (such as morbidity, mortality, and nutritional status), it is morbidity that is most directly related to infection.

Assuming for the moment that, for the validity reasons discussed earlier, severe diarrheal morbidity is used as the outcome measure, exclusion procedures can be used to define the measure such that responsiveness is maximized. In many developing countries there are two distinct diarrheal peaks each year, a cool-weather peak in which rotavirus is prominent, and a warm-weather peak in which *E. coli*, *Shigella*, and other bacterial pathogens are prominent. Preliminary evidence on the role of water and sanitation conditions in the epidemiology of viral and bacterial diarrheas suggests that the effect is likely to be small for viruses but may be larger for the bacterial diarrheas. Shigellosis and cholera, in particular, have frequently been shown to be affected by water supply and sanitation conditions (Esrey et al. 1985). By concentrating only on severe diarrheas in the warm-weather months, therefore, a study will be selecting primarily for morbidity due to bacterial enteric pathogens, the transmission of which may be more responsive to water supply and sanitation conditions. Morbidity due to the viral enteric pathogens, the transmission of which is believed to be less responsive to these conditions, will largely be excluded.

As indicated earlier, theoretical models have also been used to explore the responsiveness of specific outcome variables to changes in water supply and sanitation conditions. Thus, for instance, observing that volunteer studies have shown that a higher ingested dose of organisms is necessary to produce severe diarrhea than mild diarrhea, Esrey et al. (1985) have developed the exposure-response relationship depicted in Fig. 2. The figure provides a mechanism for assessing the response of different measures of diarrheal disease to changes in water supply and sanitation conditions.

Consider first a reduction in the ingestion of pathogens from F to E. In this range there will be no change in the incidence of either mild or severe
diarrhea (a phenomenon that has important consequences for the interpretation of HIEs that produce “negative” results and that is discussed in detail in Chapter 5). If the effect of a project is to reduce the number of pathogens ingested from E to D, however, there might be a substantial impact on severe diarrheas, but no impact on mild diarrheas and, therefore (because severe diarrheas constitute but a small proportion of total diarrheas), there will be little impact on total diarrheas. In the range D–C, where the rates of both mild and severe diarrheas are falling, total diarrhea will be as responsive a measure as severe diarrhea. In the range C–B, where mild diarrheas continue to fall but the severe diarrheas are no longer affected, “all cases” will provide a more responsive outcome measure than “severe cases.”

Developing similar analyses to assess the differential effect on, first, diarrheal mortality and morbidity and, second, organisms with high and low infectious doses, Esrey et al. (1985) have concluded that:

In poor communities with inadequate water supply and sanitation, reducing the level of enteric pathogen ingestion by a given amount will have a greater impact on diarrhea mortality rates than diarrhea morbidity rates, a greater impact on the incidence rate of severe diarrhea than mild diarrhea, and a greater impact on diarrhea caused by pathogens having high infectious doses than on diarrhea caused by pathogens having low infectious doses.

This assessment of the responsiveness of different measures of diarrheal disease shows that the situation is seldom clear-cut. Although consideration of the effect of confounding factors (the principle that the more direct the link between the outcome variable and the underlying variable, the more responsive the outcome variable) suggested that morbidity rather than mortality would be more responsive, the dose–response model suggests that just the opposite pertains in poor communities.

Esrey et al. (1985) have stressed that the model depicted in Fig. 2 is
"tentative and grossly simplified." Although it "provides some theoretical basis for the explanation of a number of observed features of childhood diarrhea," it completely ignores the complex role of immunity and other factors that determine host response. "A more complete modelling of the interrelationships between hygiene levels and diarrhea incidence is difficult because of the wide differences in epidemiology and immunology among the major diarrhea-causing agents." Further work will substantiate or refute the predictions of the model.

In practice, choice of an indicator does not depend solely on one attribute (such as responsiveness), but on a combination of attributes associated with each indicator and with other factors (such as the sample sizes required for each indicator and the cost of collecting information on the indicator).

Aetiology

Although aetiological information is desirable in any HIE, under field conditions prevailing in most developing countries such information is difficult to obtain. First, it is necessary to obtain rectal swabs or even fecal samples (if protozoa are to be identified) from those who have diarrhea and from a sample of those without diarrhea. Then, it is necessary to transport these samples to a laboratory that is adequately equipped and has personnel trained to carry out the necessary tests. At present, it is possible to identify the classical bacterial agents (V. cholerae, Salmonella, and Shigella), as well as the important recently recognized bacteria Campylobacter jejuni and Yersinia enterocolitica from rectal swabs in most reasonably equipped laboratories. As shown on Table 3, these organisms may account for 20-30% of diarrheas treated at health facilities. Similarly, the major diarrheal protozoa Entamoeba histolytica and Giardia lamblia can be identified relatively easily, but require a fecal sample rather than a rectal swab, thus complicating sample collection procedures. The situation with regard to the two most common diarrheal pathogens (rotavirus and enterotoxigenic E. coli) is more complex. Kits are now available that enable rotavirus to be identified in well-equipped laboratories that have staff experienced in immunodiagnostics techniques. For the present, identification of the toxigenic strains of E. coli still requires sophisticated laboratory facilities and personnel, but it is expected that within the next few years simpler techniques, possibly in the form of "kits," will be available.

A related concern is the cost of such procedures. Although a full workup of a single fecal specimen costs about USD 100 in a United States laboratory, only under unusual circumstances will it be of interest to undertake such a comprehensive identification of pathogens. Rather, for the most part, investigations will concentrate on a few organisms, which will usually be those that are most common and most serious. If a sample of, say, 500 episodes is required for a particular HIE, if 500 controls are also examined, and if the cost of identifying the two or three pathogens of principal interest is, say, USD 10 per specimen, then this amounts to a sum of about USD 10 000. Although this is not an insignificant amount, it is unlikely that it would constitute a major proportion of the overall costs of an evaluation.

In summary, although in most settings where HIEs are contemplated it is not feasible to conduct aetiological analyses, where facilities, personnel, and resources permit, such analyses should be performed because they add much useful information to an evaluation of the impact of a water supply or sanitation project on diarrheal disease.
Diarrheal Disease Mortality

Diarrheal diseases are a major cause of mortality among young children in developing countries, accounting for an average of 1.4 deaths per 100 children under 5 years of age per year (Snyder and Merson 1982). Information on diarrhea-associated mortality may be collected from vital registration records, clinicians' reports, or household surveys.

Where a substantial proportion of young-child deaths is registered, and where death certificates record the cause of death, such information should be used. Although there are not many settings in developing countries in which such data are available, there are some countries in which these data are available at a national level and some special settings in which such data are available for certain regions. In settings in which a high proportion of childhood deaths becomes known to the authorities, case-control methods may be used to inquire about the causes of these deaths and prior experience with the exposures of interest.

In principle, a second method of obtaining cause-specific mortality information might be through surveys similar to those that have been developed by the WHO Diarrhoeal Diseases Control Programme for estimating total and diarrheal mortality rates in children under 5 years of age (WHO 1981). Mothers are asked a series of questions to determine: the number of children under 5 years of age in the household at the time of survey, the number of deaths to children under age 5 in the previous year, and the possible causes of these deaths. The validity of data collected through these surveys can be compromised for several reasons: rural people often do not orient responses to a calendar year, deaths may be misclassified by age, deaths may not be reported, and it may be difficult to pinpoint the role of diarrhea (Black 1984). Based upon several years of experience in administering this survey, it has been concluded that it frequently underestimates both diarrheal and total mortality rates by a wide margin and is thus of little value in HIEs.

Nutritional Status

Nutritional status is probably the single most informative indicator of the overall health of a population (Mosley and Chen 1984). For evaluating the impact of water supply and sanitation projects, many (e.g., Chen 1980; Esrey and Habicht 1983; Magnani et al. 1984) have argued that this outcome variable is as important and appropriate a measure as diarrheal disease. Certainly, it is the outcome variable to which intensive attention needs to be paid in the next step of this process of clarifying the methodological issues involved in HIEs of water supply and sanitation projects.

In the past, the most commonly used anthropometric index was weight-for-age. This may still be the most useful measure when repetitive measurements are taken on particular children in a cohort study. However, weight-for-age has the disadvantage of not distinguishing between present and past malnutrition, and, for the assessment of nutritional status in cross-sectional studies, primary reliance should be placed on weight-for-height as an indicator of recent diarrhea and other nutritional insults (wasting), and on height-for-age as an indicator of the cumulative effect of nutritional insults over a longer period (stunting) (Waterlow et al. 1977).
One of the attractions of anthropometric measures in comparison with most measures of diarrheal disease is that they do not rely on the perceptions of the mother, but are "objective," in that they rely on measurements of weight, height, and knowledge of age. Although with reasonable care a child's weight can be measured accurately, the one measurement (height) that is common to both preferred indices is difficult to measure accurately and reliably, especially for the group of interest (namely young children). In addition, in some cultures it is difficult to determine the exact ages of people (including young children). Considerable care, therefore, has to be taken if the relevant anthropometric indices are to yield valid information.

The anthropometric indices most commonly used to assess the impact of a health intervention are the percentages of children falling below 100% or 90% of reference levels of weight-for-height and weight-for-age. In the case of a water supply or sanitation intervention, it is expected that well-nourished children will not be affected and, therefore, to maximize responsiveness the outcome measure should include only those children who are truly malnourished. Accordingly, an appropriate measure might be the prevalence of children who fall lower than two standard deviations below the United States National Center for Health Statistics Reference Standards (WHO 1983b).

The responsiveness of anthropometric indicators to changes in water supply and sanitation conditions is uncertain. Esrey and Habicht (1983) have argued that these indicators will be more responsive than measures of diarrheal disease collected through field surveillance. Other advocates of nutritional anthropometry have cautioned that, although biases due to misclassifying subjects according to outcome status should be a lesser problem when anthropometric rather than diarrheal indices are used as the outcome measure, there are more intervening steps between an improved water supply and nutritional status than between an improved water supply and diarrheal morbidity, thus reducing responsiveness and making the control of confounding influences a more difficult task (Chen 1980).

Ideally it should be possible to test the relative responsiveness through comparisons of well-conducted field studies that collect information on both diarrhea and nutritional status. Unfortunately, there have been very few assessments of the impact of water supply and sanitation improvements on nutritional status (with a recent, comprehensive review finding only six such studies (Esrey et al. 1985)), and only three studies (all presented at the Cox's Bazaar workshop) that have simultaneously assessed the impact of water or sanitation projects on both diarrheal disease and nutritional status. From only three studies it is obviously impossible to derive universal conclusions, yet, given the importance of the question of the relative responsiveness of diarrhea and nutritional status, it is useful to summarize the findings of these studies with respect to this question.

First, the findings of a quasi-experimental study in St. Lucia (Henry 1983) are summarized in Table 5. The impact on diarrhea is as expected. The limited impact of environmental improvements on height-for-age is "because height does not experience rapid changes . . . and is generally regarded as a more reliable indicator for long-term intervention projects" (Henry 1983). No direct explanation for the anomalous weight-for-age results is suggested, although the author does note that "the provision of improved environmental sanitation
Table 5. The effect of improved water supply and sanitation on diarrhea and nutritional status in St. Lucia (after Henry 1981, 1983).

<table>
<thead>
<tr>
<th>Incidence of diarrhea</th>
<th>Impact of water supply</th>
<th>Additional impact of latrines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of low</td>
<td>Moderate reduction</td>
<td>Moderate reduction</td>
</tr>
<tr>
<td>Height-for-age</td>
<td>Small reduction</td>
<td>None</td>
</tr>
<tr>
<td>Weight-for-age</td>
<td>Large reduction</td>
<td>Large increase</td>
</tr>
</tbody>
</table>

is only one of the factors . . . to be considered in efforts to reduce malnutrition” (Henry 1981).

Second, another quasi-experimental study, this one in Bangladesh (Rahaman et al. 1983), found that, although “an average 19% higher incidence of diarrhea was recorded in households using traditional water sources for bathing, washing, cooking, etc. . . . these interventions at this stage do not appear to produce any positive impact on the level of undernutrition (measured by weight-for-age) and stunting (measured by height-for-age).” The explanation offered for the findings on nutritional status is that “although a relationship exists with diarrhea, other contributory factors to malnutrition may be masking the effect of diarrhea per se.”

Third, an analysis of cross-sectional data from the Philippines (Magnani et al. 1984) found that “the statistical associations between the water/sanitation variables and diarrhea were consistently stronger than the associations between these variables and childhood nutritional status (measured by weight-for-age)” and suggests that this is because “childhood nutrition levels are more sensitive to variations in standard of living indicators than to variations in any of the water variables.”

Although no definitive conclusions can be drawn from so small a sample, the consistency of the findings is striking. It appears that even when diarrheal incidence data are collected through field surveillance (and are, therefore, of relatively poor quality), diarrheal morbidity provides a more responsive indicator than the anthropometric indicators investigated in these studies. In particular, it is notable that all three investigators attribute the poor responsiveness of the anthropometric measures to the large influences exerted on these indices by extraneous effects. Recalling that WHO recommendations for nutritional indicators are weight-for-height for short-term malnutrition and height-for-age for long-term malnutrition (WHO 1983b), and that each of the evaluations followed the interventions by no more than a few years, it is to be noted that none of the studies examined the effect on the appropriate short-term indicator (namely weight-for-height). In the St. Lucia and Bangladesh studies, both weight and height data have been collected, and it is anticipated that such analyses will be carried out.

In conclusion, it is evident that more research on the use of anthropometric indicators for assessing the health impact of water supply and sanitation projects is justified, both because of the public health significance of malnutrition and because such indicators offer the promise of being both valid and responsive. Issues relating to the study designs that may be appropriate for such evaluations are addressed in Chapter 4.
Intestinal Nematodes

The common intestinal nematodes (specifically hookworm, *Ascaris*, and *Trichuris*) may be appropriate measures of the impact of a sanitation project, first, as "markers" for the transmission of pathogens due to inadequate excreta disposal practices and, second, because infection with these nematodes can constitute a significant public health problem.

Where infection is used as a "marker," the relevant measure is the prevalence of infection. Where the intention is to categorize individuals who suffer adverse health consequences from infection with nematodes, the relevant measure is the prevalence of individuals with worm burdens of clinical significance (with worm burdens estimated by measuring the concentration of eggs in the stools). These two purposes will typically lead to quite different prevalences. In Bengal, for instance, although over 80% of people are infected with hookworm, not more than 1% of people are estimated to have over 150 worms (Chandler and Read 1961). Classification of individuals requires that stool samples be obtained and, if intensity rather than simple presence of infection is to be measured, eggs counted.

Because immunological factors have a greater influence on intensity of infection than on prevalence (Feachem et al. 1983), it is expected that prevalence may be a more responsive measure than intensity. However, because it is intensity that is of public health significance, it is usually intensity (as measured by the proportion of people with worm loads of clinical significance) that should be used as an outcome measure.

Eye Diseases

Trachoma is an infectious disease of the conjunctiva and cornea, caused by the microbial organism *Chlamydia trachomatis*. Trachoma is the world's leading cause of blindness, with possibly 7 million blinded and over 400 million afflicted with the disease (Dawson et al. 1981). Hyperendemic areas include much of Africa, the Middle East, many areas of Latin America, South Asia, and the Western Pacific.

Trachoma is considered to be of public health significance if more than 5% of the population has moderate to severe inflammatory disease. In the most severe hyperendemic areas, up to 75% of children may have inflammatory trachoma and up to 25% may have severe inflammation. Chlamydia may be demonstrated microbiologically in up to three-quarters of those with severe inflammation, but usually in less than 10% of those with mild inflammation. Inflammatory trachoma proceeds to cicatricial trachoma. In hyperendemic areas, up to 100% of adults may have some sign of scarring.

The correct measure of current transmission is the prevalence of inflammatory trachoma (not the prevalence of scarring). Fieldworkers can be trained to diagnose inflammatory trachoma with satisfactory precision (Taylor et al. 1985).

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1 This section was prepared with the collaboration of Dr Hugh R. Taylor, International Center for Epidemiologic and Preventive Ophthalmology, Johns Hopkins University, Baltimore, MD, USA.
One of the most important factors in the pathogenesis of clinical trachoma is thought to be the frequency of episodes of reinfection, and this, in turn, is directly related to transmission facilitated by poor personal hygiene. Accordingly, alterations in personal hygiene (usually as a consequence of increasing the availability of water) have been shown to have a marked impact on inflammatory trachoma (McJunkin 1983; Taylor et al. 1985). Because, in addition, the lag between changed hygiene practices and reduced prevalence of inflammatory trachoma is short (6–12 months), in hyperendemic areas trachoma is a reliable, responsive, and important measure of the health impact of a water supply or personal hygiene program. It should be noted that trachoma not only constitutes a direct measure of an important public health problem, but that by measuring changes in trachoma prevalence a study is obtaining an excellent indicator of changes in personal hygiene practices, changes that are expected to influence other significant outcomes, such as diarrheal diseases and nutritional status.

Skin Diseases

Society and health authorities have differing views on the importance of skin disease. The former attend health facilities in large numbers hoping to obtain relief from the stigma and irritation associated with skin diseases. With some exceptions, health authorities consider the problem insignificant relative to other sources of morbidity and mortality.

Skin diseases are common in developing countries, particularly amongst children between 6 months and 10 years of age (Porter 1979, 1984). Bacteria, fungi, viruses, and parasites cause about three-quarters of all skin diseases, with pyoderma (skin disease with pus) being the most common complaint. The epidemiology of skin diseases in developing countries is not well understood. For the most important cause of communicable skin disease (scabies), crowding and immunological factors are probably the most important determinants of transmission. Although access to water and attention to personal hygiene are unlikely to affect the underlying parasitosis, they might be expected to reduce the rate of secondary infection from scabies.

Biting flies and mosquitos play a major role in nonscabies-related pyoderma (because it is the scratching of bites that leads to inflammation and pus) and water supply and sanitation programs may reduce (or, in some cases, increase) the breeding grounds for these insects. Thus, both by affecting insect breeding and by reducing secondary infections, such programs may affect the prevalence of pyoderma. The prevalence of pyoderma is highest in the under-10 age-group, and, excluding secondarily infected scabies, ranges from 10 to 35%.

The obviousness and frequency of skin disease in developing countries has led to the suggestion that skin disease may be a useful indicator of environmental hygiene (Jelliffe 1972) and, thus, of the impact of water supply and hygiene education programs. For evaluating the impact of a water supply or hygiene education program, there are two prime candidates for measuring skin disease prevalence. First, all children under 10 years of age with pyoderma could be classified as "diseased." This outcome could be measured with high

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3 This section was prepared with the collaboration of Dr Michael Porter, Public Health Specialist, World Bank, Washington, DC, USA.
validity by trained observers. A major shortcoming with this definition of disease, however, is that secondary infections from scabies would constitute a substantial proportion of all cases. Because scabies transmission fluctuates wildly and is largely independent of sanitary conditions, this measure is unlikely to be responsive to changes in hygiene practices. The second candidate measure is pyoderma cases that are not associated with scabies. In this case, the index would probably be more responsive to changes in hygiene conditions. The drawback with this index is that the prevalence would be lower than the prevalence of all cases of pyoderma, and that valid information could be obtained only by interviewers with some degree of clinical competence.

In conclusion, although the prospects do not look particularly good, given present, imperfect, knowledge of the epidemiology of skin diseases, no definitive judgment can be reached on the usefulness of skin diseases as a measure of impact of a water supply, sanitation, or hygiene education program.

Guinea Worm

Guinea worm disease is a painful, debilitating parasitic disease that develops in humans who drink water containing a macroscopic crustacean that has been infected by the larvae of Dracunculus medinensis. The disease affects an estimated 10–48 million people in arid or semi-arid areas of Africa, the Middle East, and the Indian subcontinent (Hopkins 1983). The disease is focal in nature, affecting up to 40% of farm workers in some villages. Because the disease affects primarily otherwise healthy adults, and because the season of peak disability often coincides with the season of peak demand for agricultural labour, the economic effects of the disease are important.

The disease is unique in that it is the only communicable disease that is transmitted exclusively through contaminated water. Thus, it is the only disease that can be prevented entirely by protecting supplies of drinking water. Because there is a well-defined latency period of about 12 months between ingestion of the larvae and the appearance of the characteristic lesion, a case of guinea worm means that the infected person drank water from an unprotected source 12 months earlier. Guinea worm infections can thus be used as a sentinel health event with which to monitor whether or not a protected water supply is, in fact, being used for drinking purposes.

There are several important advantages to using guinea worm as a measure of the success of a program designed to improve the quality of drinking water. The occurrence of guinea worm can serve not only as a direct measure of an important public health problem, but also as a marker of drinking water practices. Because the link between exposure and disease is so simple and well understood, there is no problem in dealing with the effect of confounding variables. In addition, diagnosis of an active case (based on the presence of the worm beneath or extending from the skin) is simple; thus, individuals can be classified as “diseased” or “nondiseased” with a high degree of validity and reliability by minimally trained fieldworkers. Finally, because the seasonal nature of the disease is clearly defined, it is simple to conduct annual prevalence surveys to monitor progress.

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4 This section was written with the collaboration of Dr Gordon S. Smith of Johns Hopkins University, Baltimore, MD, USA.
Participation in Other Primary Health Care Activities

It has been suggested that, where they meet an important "felt need" of the community, water supply and sanitation projects provide an effective "entry point" for primary health care (PHC) activities in that community. Because community organization is expected to be strengthened by participation in a community-based water supply project, it has been hypothesized that communities with such projects will take greater advantage of other opportunities than communities without such projects. Specifically, it is hypothesized that participation in PHC activities will be higher, ceteris paribus, in communities in which water supply projects have been undertaken.

In choosing PHC activities, care must be taken to avoid activities for which participation is affected not only by the propensity to participate (which the evaluation is designed to assess), but also by the health status of the child. For example, use of oral rehydration therapy (ORT) as an outcome measure would not be appropriate because a finding of "no difference" would result if, in the community with improved water supply, diarrhea rates are lower, offsetting a higher propensity to use ORT. Similarly, because improved water supplies are expected to affect nutritional status, participation in activities (such as feeding programs) that depend on poor nutritional status should not be used.

Candidate PHC activities for which such effects would appear to be minimal include attendance at immunization and family planning clinics. From the records of local clinics, or from community coverage surveys, it would be possible to determine the level of participation in such PHC activities in served and unserved areas both before and after the water supply program. Close attention would have to be paid to ensuring that the inputs into the immunization programs were similar in both areas.
Study Designs to be Used in HIEs

The key methodological question is whether or not field studies of relatively limited cost can be designed such that logically defensible causal statements can be made about the impact of water supply and sanitation programs on outcome measures of public health importance. To answer this question, it is necessary to outline the options available for HIEs of water supply and sanitation projects.

There is no universally accepted method for classifying epidemiologic designs, in large part because in practice "hybrid" (rather than "pure") designs are used. Nevertheless, it is useful to characterize the key differences between the major study types, so that the advantages and disadvantages of each particular type may be assessed. Figure 1 depicts the key distinctions characterizing the study designs discussed in this report. Details of the method, role, advantages, and disadvantages of each study design are available in standard epidemiology texts (e.g., MacMahon and Pugh 1970); here, the discussion is limited to issues directly affecting the choice of a study design for an evaluation of the impact of a water supply or sanitation project. For the reasons described earlier, most of the discussion is focused on diarrheal disease, with more limited attention being given to other outcome measures.

Quasi-Experimental Designs

In true experimental designs (of which vaccine and drug trials are common examples), subjects are assigned to treatment and control groups by some formal method of randomization. Because random assignment is impossible if the preventive measure can be applied only to an entire community (as in the case of many water supply, sanitation, and hygiene education interventions), the "next best thing" is done, namely the treatment is applied to some (treated) communities and withheld from "similar" (control) communities. Because of the intuitive appeal of these designs as the closest practical approximation to the classical experimental design, they have been the most popular design in HIEs of water supply and sanitation interventions. There are several serious problems in implementing such studies.

Problem 1: Comparability of Treatment and Control Groups

In quasi-experimental studies the comparisons may be "internal," with, for example, the incidence of diarrhea in the group before the intervention being compared with the incidence after the intervention. Comparisons may
also be “external,” with the diarrhea incidence in the treatment group being compared with the diarrhea incidence in the control group some time after the intervention. A critical assumption in quasi-experimental studies is that of the comparability of the treatment and the control groups.

Rigorous statistical methods for the analysis of quasi-experimental designs were developed in the early 1960s (Campbell and Stanley 1963). In the subsequent 20 years, extensive experience with these designs has been accumulated, especially in the evaluation of social programs in developed countries. It is now generally recognized that the approach is fraught with formidable methodological difficulties, with even the major developer of quasi-experimental designs publicly regretting the influence his work has had (Cook and McAnany 1979). Experience has shown that the treatment and control groups are seldom comparable and that it is extremely difficult to adjust for this lack of comparability using statistical methods (Cook and McAnany 1979). In developing countries, as illustrated by the following examples, the same difficulties have been encountered.

In the classic studies of diarrhea and nutrition in Guatemala (Scrimshaw et al. 1967), comparisons were both internal and external, yet, after years of observation and analysis, the scientists found it impossible to determine how much of the difference in effects observed between villages was a result of the different interventions, the general secular trends that were different between the villages, or the sudden unexpected events (such as epidemics) that affected only certain villages. Similarly, a recent comprehensive assessment of evaluations of nutrition programs revealed that, because “the experimental context was unstable, unpredictable and unique in each case” (Drake et al. 1983), the assumptions of comparability of treatment and comparison groups were violated in every single case. These problems are equally common in quasi-experimental studies of water supply and sanitation interventions (Magnani et al. 1984).

**Problem 2: Sample Sizes Required**

A second major concern affecting these designs (and the cohort and cross-sectional designs to be discussed below) is that, when the outcome of interest (such as mortality or morbidity) is relatively rare, the number of study subjects required to detect changes of public health significance in the outcome variables is large. As discussed earlier, to detect a 33% reduction in mild diarrheal disease in young children, about 40 000 questionnaires need to be administered. If only severe episodes of diarrheal disease are included in the study, the number of episodes is reduced to about 10% of the total number, and the number of questionnaires to be administered is about 400 000!

Finally, it should be noted that the requirement for large sample sizes may be relaxed by studying groups having an exceptionally high frequency of diarrhea, such as families in which there is an identified index case. Although it is difficult to extrapolate the findings to address broader questions in the general population, the conclusions are valid for the particular study question in the particular population. Useful findings have emerged from studies of this type, such as the Bangladesh studies of the effect of washing one’s hands on secondary transmission of shigellosis (Khan 1982) and home water treatment on the secondary transmission of cholera (Khan et al. 1984).
Problem 3: Misclassification Biases

A further methodological concern with experimental (and other) studies relates to the effect on measures of the association between disease and exposure (such as the "relative risk" or the "odds ratio") of inevitable errors in classifying individuals as either "exposed" or "not exposed" to a risk factor and as either "diseased" or "not diseased."

A recent review of the methodological problems of HIEs of water supply and sanitation projects (Blum and Feachem 1983) has shown that problems with defining the health indicator and with failing to record facility usage are ubiquitous. Particularly common classification problems in HIEs using quasi-experimental, cohort, and cross-sectional studies are as follows:

(1) Disease status: As discussed by Martorell et al. (1976) and Chen (1980), in surveys of diarrheal disease, information on diarrhea is collected by recall and there are typically a large number of false negatives. The likelihood that the sensitivity of the information is poor is, therefore, "very high."

In surveys of diarrheal disease, a substantial portion of mild diarrhea may not be caused by enteric infections (Black 1984). Because the measure of disease status is intended to capture only those diarrheas due to enteric infections, there may be a large number of false positives. The likelihood that the specificity of the information on disease status is poor is, therefore, "very high."

(2) Exposure status: Using these study designs, sample sizes are large and it is, thus, difficult to obtain high-quality information on actual facility use. It may, therefore, be expected that substantial numbers report not being exposed (i.e., using the improved facilities) when, in fact, they continue to use unimproved facilities (either because they have not changed their practices, or because the improved facilities are not functioning). The likelihood that the sensitivity of the information on exposure status is poor is, therefore, "high."

It seems unlikely that there would be many who would report not using improved facilities when, in fact, they are using such facilities. It is, therefore, probable that there are few false positives. The likelihood that the specificity of the information on exposure status is poor is, therefore, "low."

A detailed investigation of the effects of misclassification errors on the estimate of the effect of improved water supply or sanitation facilities on diarrheal disease has shown that in most practical cases the effect will be to underestimate such effects and that such biases will often be large (WHO 1985). To take but one example, consider a population in which the frequency of infectious diarrhea in those using poor quality water is 10% and in which infectious diarrhea is actually 50% more common among those using poor water than among those using good quality water. If just 10% of those who actually do not have infectious diarrhea are incorrectly classified as having infectious diarrhea, then the apparent difference between those using poor and good quality water will be reduced to just 30% (WHO 1985). As the frequency of disease in the population decreases, the bias in the estimated effect becomes even more severe.

5 The reader intending to conduct a HIE of a water supply or sanitation program is strongly advised to study this document.
Problem 4: Ethical Problems

In addition to these methodological problems, there are other serious concerns related to the use of quasi-experimental designs where they involve conscious manipulation of the availability of water supply and sanitation facilities. Although there are disagreements about the magnitude of the effect of water supply and sanitation conditions on health, there is general agreement that such positive effects exist. Insufficient attention has been paid to the ethics of conducting “trials” with treatments of accepted efficacy, such as water supply and sanitation. Certainly by the standard criterion applied to the ethics of drug and vaccine trials — namely that a clinical trial is ethical only if the proposed treatment is promising and if there is a reasonable doubt about its efficacy under field conditions — these “trials” would be considered unethical. Although advantage may be taken of the fact that large water supply and sanitation programs are necessarily carried out in phases, it is evident that under such conditions the allocation of communities to “treatment” and “control” groups would be on the basis of political and other criteria that are different from the scientific procedures required for valid quasi-experimental designs.

In addition, as in any study that requires repeated observations of the same individuals, delicate ethical issues arise concerning the treatment of individuals who become sick during the course of the study.

Problem 5: Time and Resources Required for the Study

A final constraint on the use of the most valid of the quasi-experimental designs (those that rely on both internal and external comparisons) is that the evaluation cannot be initiated only after it has been verified that a particular project is performing well and is being utilized. Rather, such a study has to be initiated prior to the start of the project itself to establish that the diarrhea rates in the intervention and control groups were similar prior to the project. As a consequence, these studies often are of projects that are neither performing well nor being utilized. In addition, they take years to complete and are usually extremely expensive.

In summary, it is not surprising that the World Bank Expert Committee, which considered these quasi-experimental studies to be the most reasonable study design available in 1975, recommended that, because of “the very high cost, limited possibility of success and restricted application of results” (World Bank 1976), such studies not be undertaken.

Concurrent Cohort Designs

A concurrent cohort study (sometimes called a “prospective” or “longitudinal” study) involves identifying a population (a “cohort”) in which there are individuals or groups with differing levels of exposure (for instance to contaminated water) and following the population forward in time to determine and compare disease incidence.

Except for the method of controlling for confounding, concurrent cohort studies are similar to quasi-experimental studies, and suffer from many of the
same problems. First, the required sample sizes are very large (being identical to those required in the quasi-experimental designs). Second, with regard to the problem of misclassification, it is instructive to examine separately the likelihood of a given level of misclassification and then the consequences of that level of misclassification. The information on disease status is, as in a quasi-experimental study, collected through household surveillance. The likelihood of misclassification on disease status is, thus, similar in concurrent cohort and quasi-experimental studies. In cohort studies, data on exposure are collected through household surveys. Although the sensitivity and specificity of such information is often not high (Blum and Feachem 1983), it is probably generally somewhat better than the exposure information in quasi-experimental studies (in which the exposure status of individuals is often assumed). Because the consequences of a given level of misclassification are (for the same disease frequency and odds ratio) identical in concurrent cohort and quasi-experimental studies, the bias in the odds ratio due to misclassification is usually slightly less severe in concurrent cohort studies as carried out in this field than in quasi-experimental studies. Finally, because these are purely observational studies (with no manipulation of water supply or sanitation services), the ethical dilemmas faced in quasi-experimental studies are reduced.

Because of the large sample sizes required and the likelihood of bias, concurrent cohort studies are generally not appropriate for evaluating the impact on diarrhea of water supply and sanitation facilities. However, there are situations in which study designs of this sort may be used; for instance, where well-designed concurrent cohort studies are being carried out for other purposes, and where it is possible to broaden the scope of such studies to include water supply and sanitation considerations at modest expense, such opportunities should obviously be exploited.

**Historic Cohort Designs**

Sometimes it is possible to use existing records to determine the exposure status of members of a population at some time in the past, and also to determine the frequency of diarrhea at some subsequent time. Depending on the method of accounting for potential confounding variables, these studies may either be of the quasi-experimental or cohort type.

The obvious and great constraint on such studies is the availability and validity of adequate records. It is striking, however, that over the past decade a substantial literature of such studies, addressing, among other questions, the effects of improved water supplies and sanitation in 19th century Europe and North America, has been developed by demographers, economic historians, and historical geographers. This literature remains largely unknown to those concerned with evaluating the health impacts of water supply and sanitation programs, and, yet, is of surprising relevance to many of the key questions plaguing HIEs; for instance, these studies show: how the effects of improved water supply and sanitation facilities may be quite different in apparently similar settings (Haines 1977; Preston and van de Walle 1978); how these interventions initially affect only certain age-groups (Preston and van de Walle 1978; Higgs and Booth 1979; Condran and Cheney 1982); how multiplier effects operate to change the patterns of diseases other than those directly affected by the
intervention (Preston and van de Walle 1978); how long it takes for the full effect of an intervention to be felt (Preston and van de Walle 1978); and how, after transmission of pathogenic organisms had been reduced through improvements in water supply and sanitation conditions, subsequent reductions in transmission through other, parallel routes (such as person-to-person transmission and food contamination) may have a major impact on transmission of fecal-oral diseases (Condran and Cheney 1982).

It is generally assumed that similar studies cannot be carried out in developing countries because similarly rich data sets are not available. Although it is not likely that there are many opportunities for studies of this sort, it is pertinent to note that, until recently, this was assumed to be the case in developed countries too. The recent literature using historical cohort designs to examine the determinants of mortality in developed countries in the 19th century indicates that the major constraint was limited imagination and analytic skill rather than the absolute absence of reasonably reliable data.

At the very least there are certain settings in developing countries (e.g., the International Centre for Diarrhoeal Disease Research, Bangladesh and the Institute of Nutrition for Central America and Panama) where rich sets of longitudinal data are available and it is evident that much more could be done to evaluate the effects of improvements in water supply and sanitation conditions at modest cost in these settings. A study of tube-well use and cholera in Bangladesh (Khan et al. 1981) is one example of the use of such a data set; almost certainly there are other such opportunities to be tapped at modest cost.

There has been one notable recent attempt to construct a historical data set in a developing country (Malaysia) and to use a historic cohort study design to assess the effects of water supply and sanitation (and other determinants) on mortality (Butz et al. 1984). Although there are serious doubts as to the validity of the "30-year recall" data collected in the Malaysian study, there are well-established techniques for indirectly estimating age-specific mortality rates (Brass 1968), and the possibility exists of coupling these mortality estimates with existing historical data sets compiled for other purposes (such as agricultural sample surveys) to conduct low-cost historical studies in developing country settings. Specifically, from national censuses and the World Fertility Survey, estimates of young child mortality over time have been developed in many countries. In several cases (including Sri Lanka, Kerala State, and Costa Rica (Feachem 1985)), cross-sectional analyses of the effects of water and sanitation on infant mortality have been undertaken. To date, these mortality estimates have not been coupled (as was done in Malaysia) with similar historical traces of water supply and sanitation conditions. Such historic cohort analyses could be undertaken at modest cost where the necessary data could be assembled.

**Cross-Sectional Designs**

All of the above studies require observations at more than one point in time. In cross-sectional studies, by contrast, measurements of exposure and disease status are made at a single, common point in time. Because of the
simultaneous nature of the measurements of exposure and disease, in most settings cross-sectional studies are restricted to the generation of hypotheses and cannot be used for testing hypotheses. However, where the exposure status of an individual is more or less permanent (as is generally the case with exposure to inadequate water supply and sanitation conditions), then an individual's current exposure status may be an adequate measure of previous exposure status, and a cross-sectional study may be used to test causal hypotheses (MacMahon and Pugh 1970).

A characteristic of cross-sectional studies is that the most commonly used outcome variable, disease prevalence, is affected not only by the incidence of the disease but also by duration. Because duration is affected by many extraneous factors, it is usually considered preferable to measure the impact of an intervention on disease incidence; a task for which cross-sectional studies are not ideally suited. In the particular case of the impact of water supply and sanitation interventions on diarrhea, prevalence may be an appropriate outcome measure because the intervention may affect both incidence and duration (Esrey et al. 1985). If this occurs, prevalence will be a more responsive measure of impact than incidence. Alternatively, a measure of short-term incidence may be obtained in a cross-sectional study by asking not about diarrhea occurring in the previous 2 weeks (for instance) but about episodes that started in the past 2 weeks.

These differences aside, a cross-sectional study is similar in most respects to the quasi-experimental and cohort designs described earlier. For the specific case of diarrheal diseases, cross-sectional studies face similar sample size requirements, and the problems of misclassification and confounding are similar. As discussed later, for some other outcome measures these problems may be much less severe, and the great advantage of a cross-sectional approach (namely the collection of just one round of data) makes this an attractive option for rapidly conducting many HIEs.

Case-Control Designs

Unlike the standard study designs, which proceed logically from cause to effect, the case-control study proceeds “backwards” from effect to cause. For example, in a community that has improved and unimproved sources of water, individuals who report to a clinic with diarrhea (the cases) may be selected for comparison with individuals who report to the clinic with respiratory infections (the controls). Cases and controls are compared with respect to source of water that they have used. The odds of cases using unimproved water may be divided by the odds of controls using unimproved water to obtain an odds ratio. The significance of this odds ratio may be tested and used to estimate the relative risk of diarrhea among users of unimproved water compared with users of improved water. For rare diseases, the odds ratio is a good estimate of the risk of disease among the exposed relative to the risk of disease among the unexposed (the “relative risk”).

A case-control study is often the most readily and cheaply carried out of all analytic epidemiologic studies, and, in many areas of epidemiologic inquiry, is usually the first approach to determining whether particular characteristics or environmental factors are related to disease occurrence (Friedman 1980).
Because the ratio of cases to noncases can be fixed by the investigator, case-control analyses are statistically much more efficient than other designs for relatively rare diseases, particularly where exposure to the risk factor is relatively common (Table 2).

Advantages of a Case-Control Study Design

In evaluating the impact of a water supply or sanitation project on diarrhea morbidity, the case-control approach has several advantages over the quasi-experimental, cohort, or cross-sectional alternatives.

First, the sample sizes are smaller; for instance, if 40% of the study population uses an improved water supply and if, as before, the study is designed to detect a 33% reduction in diarrhea morbidity (i.e., the odds ratio to be detected is 1.5), then, as shown in Table 2, less than 500 cases and a similar number of controls are needed in a case-control study. The numbers required in the study are independent of the frequency of occurrence of the disease in the community, and are, thus, the same whether mild diarrhea, severe diarrhea, or aetiology-specific diarrhea is studied.

A second attraction of the case-control method is that the validity of exposure and disease information will generally be greater than in cohort or quasi-experimental studies: thus, misclassification biases might not be as serious.

A third advantage of the case-control method is that an impact evaluation using this method need be initiated only after a prior evaluation has demonstrated that the system is functioning adequately and that the improved facilities are being used appropriately.

Finally, case-control studies can be quick and easy compared with the standard designs, and the ethical problems associated with some quasi-experimental designs are avoided.

Reasons for Neglect of the Method

In view of the attractiveness of the case-control method for the analysis of the health impact of water supply and sanitation programs, why is it that the method has not been applied to this set of problems?

First, where the case-control approach is being used and several outcome measures are being monitored, separate studies have to be conducted for each of the outcome measures. In a cohort study, by contrast, the impact on more than one outcome measure can be analyzed using a single study design.

Second, there are some historical factors. Although epidemiologists have long used the effect-cause paradigm in conducting investigations of outbreaks of infectious diseases (Sartwell 1980), it is the rise of chronic disease problems in industrialized countries that stimulated the development of the modern case-control study. Because of several distinctive characteristics of chronic diseases (in particular the existence of multiple causal factors and long latency), the tools of classical epidemiology no longer sufficed and new methodologic tools had to be developed. Although most infectious disease epidemiology continued along well-established lines, statisticians came to assume a prominent role in
chronic disease epidemiology, with sophisticated mathematical methods rapidly becoming the stock-in-trade of the profession (Barrett-Connor 1979). The modern history of case-control studies forms an integral part of this development, specifically dating back to investigations of the relationship between cigarette smoking and lung cancer in the 1950s (Ibrahim and Spitzer 1979). Twenty years ago, case-control studies were seen as preliminary and rather unreliable exercises, with the burden of proof resting firmly on subsequent cohort studies (Acheson 1979). From the 1960s onward, however, great strides were made in clarifying the methodological problems (e.g., Schlesselman 1982) and in developing a bank of practical experience with case-control studies. As this experience has accumulated, it has been possible to test the reliability of the case-control method in practice: when it has been possible to conduct a cohort or experimental study to confirm the results obtained from a case-control study, the results have nearly always been consistent, thus confirming the reliability of the case-control method (Sartwell 1980).

Although the case-control method has been used to investigate diarrhea (and especially cholera) outbreaks, it is only recently that the possibilities of applying the case-control method to problems of endemic infectious diseases in developing countries have started to be explored (Hogue et al. 1983; Smith et al. 1984). It is, thus, not surprising that the case-control methodology has not yet been applied to HIEs of water supply and sanitation programs or that, in the deliberations of the World Bank Expert Committee in 1975 (World Bank 1976), it was implicitly assumed that only studies of the quasi-experimental or concurrent cohort design were appropriate in this field.

Problems in Applying the Case-Control Method

Case-control studies are subject to three major categories of potential bias in the odds ratio: distortions from misclassification of subjects with respect to disease and exposure status (“misclassification bias”); distortions resulting from the manner in which the subjects are selected into the study (“selection biases”); and distortions because the effect of the study factor is mixed with the effects of extraneous variables (“confounding”). Because these biases, and means for controlling for them, have been analyzed in detail for diarrheal morbidity (WHO 1985), diarrheal morbidity is used in the following sections to illustrate the nature of these problems.

Misclassification Biases

As was done for the previous study designs, an assessment can be made of the likelihood of different sources of misclassification bias in case-control studies in which cases and controls are recruited at a clinic. In the specific example followed through this section, “cases” are children under 5 years of age who report to the clinic because of diarrhea, whereas “controls” are children under 5 years of age who report to the clinic for one of a group of nondiarrheal diseases.

(1) Disease status: In a clinic-based case-control study, all prospective cases and controls are examined by a health professional and, in the course of that examination, asked whether or not the child is suffering from diarrhea. It is highly unlikely that a child who does not have diarrhea will be reported
as having diarrhea. The likelihood that the sensitivity of the information is poor is, therefore, “low.”

In dealing with diarrheas that are presented at a clinic, there are still some that are not caused by recognized enteric pathogens, but the proportion is smaller than for the mild diarrheas detected through field surveillance (Black 1984). The likelihood that the specificity of the information on disease status is poor is “moderate.”

(2) Exposure status: In a case-control study, as in a cohort study, data on exposure are usually obtained through questionnaires administered to the mother in the home. There will, thus, be the same tendency to overreport use of improved facilities. However, because far fewer mothers are interviewed in a case-control study, it is possible to pay closer attention to obtaining valid information. In many settings, the physical and chemical composition of the improved water will be distinct from that of the traditional water. In these settings, the validity of data on reported water use may be assessed by testing the composition of water found in the home. The likelihood that the sensitivity of information on exposure status is poor is, therefore, “moderate.”

As in a cohort study, it is unlikely that many would report not using the improved facilities when they, in fact, are using the facilities, i.e., “false positives” are unlikely. The likelihood that the specificity of the information on exposure status is poor is, therefore, “low.”

Table 6 summarizes information on the likelihood of poor validity of the disease and exposure measures for, first, quasi-experimental, concurrent cohort, and cross-sectional studies as they are normally conducted in this field, and, second, clinic-based case-control studies as envisaged in this document. As shown in Table 6, one of the major attractions of case-control studies as envisaged here, over quasi-experimental, concurrent cohort, and cross-sectional studies as normally conducted in this field, is a reduction in the likelihood of misclassification.

Selection Biases

In addition to the distortions that may arise from misclassification biases, the estimates of effect (such as the odds ratio) may also be biased because of the manner in which subjects are selected and because of confounding. Although the effects of selection biases sometimes appear to be similar to those of confounding, these are logically different problems and should be treated differently. Accordingly, it is useful to first define the differences between selection biases and confounding.

Table 6. The likelihood of poor validity in studies of the impact of water and sanitation facilities on diarrheal disease.

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Disease variable</th>
<th>Exposure variable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>Quasi-experimental, concurrent cohort,</td>
<td>Very high</td>
<td>Very high</td>
</tr>
<tr>
<td>cross-sectional</td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td>Case-control</td>
<td>High</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>
To produce confounding a variable must be associated, in the subjects actually studied, with the exposure under study and, independent of this association, must also be a risk factor for disease. Thus, "confounding in a case-control study is the same phenomenon as confounding in a follow-up study. It arises from associations in the causal network in the underlying population and cannot be removed by appropriate study design alone. An essential part of the analysis is examination of possible confounding effects and how they may be controlled" (Breslow and Day 1980).

Selection bias, by contrast, is not a bias that arises because of underlying causal relationships that exist among the variables in a population, but is a bias that arises because of the way in which cases and controls are recruited into a study. The case-control methodology assumes that, under the null state (of unit true odds ratio), cases and controls would have been equally exposed to the risk factor of interest. Avoiding systematic violations of this assumption, the problem of selection bias, is the "truly large problem of the case-control study" (Cole 1979).

Selecting controls One issue in defining eligibility for recruitment of cases and controls is how to deal with individuals who report to the clinic with nondiarrheal diseases that are known to be associated with water supply and sanitation conditions. Children who come to the clinic with diarrhea as a primary complaint are eligible as cases. If other water- and sanitation-related diseases (such as typhoid fever, hepatitis A, and a variety of nematode infections) are secondary complaints, this does not disqualify the child as a case. In recruiting controls, those children who come to the clinic with a water- or sanitation-related disease as the primary complaint are not eligible for recruitment as controls. However, children who come to the clinic primarily because they are suffering from one of the eligible control diseases (such as an acute respiratory infection) and are found to have a water- or sanitation-related disease as a secondary complaint should be included in the control group (WHO 1985).

A second issue is whether or not individuals can be recruited into the study more than once. With rare diseases (such as those severe enough to be brought to the clinic), the problem of how to treat those who become eligible a second time is of academic rather than practical interest. The intuitive procedure (namely of deleting controls who become cases from the control group and including them only in the case group, and of excluding cases from eligibility for later selection as controls) is acceptable (WHO 1985).

Other sources of selection bias There are other potential sources of selection bias that are specific to, and particularly important in, case-control studies of the impact of water supply and sanitation conditions on diarrheal morbidity. The problem arises when the probability that a child with diarrhea will be brought to the clinic is affected by whether or not the individual is exposed to, say, a poor water supply. This will happen when, first, the probability of reporting is affected by the level of a particular variable (such as distance from the clinic or socioeconomic status) and, second, the particular variable (such as distance or socioeconomic status) is not uniformly distributed amongst exposed and unexposed.

Conditions under which such biases may be serious, and procedures for dealing with such conditions, have been examined in detail (WHO 1985).
Considering first the case of distance, there will be no selection bias if either: the utilization of the improved facilities (such as water supply) is not correlated with distance from the clinic; or the effect of distance on the propensity to report diarrhea is the same as the effect of distance on the propensity to report the diseases from which the controls are chosen.

Although it is not possible to control the first factor, the second condition can be approximately satisfied by choosing diseases that are of similar severity to diarrheal disease. From an analysis of clinic and hospital records in developing countries, it has been suggested that, if "cases" are children under 5 years of age who report to a clinic with diarrhea as a primary complaint, selection biases will be small if controls are chosen from children under 5 years of age without diarrhea who report for the following complaints: chicken pox, whooping cough, measles, mumps, malaria, otitis, other ear diseases, sore throat, influenza, tonsillitis, pneumonia, bronchitis, other respiratory illnesses, and fever (WHO 1985).

For other potential sources of selection bias (such as a correlation of socioeconomic status with use of the clinic), the same procedure takes care of potential selection biases. However, because socioeconomic status (unlike distance) is a potential confounder, the effect of socioeconomic status as a potential confounder must be considered, along with the effect of all other potential confounders, at the analysis stage.

**Biases Due to Confounding**

Bias due to confounding emanates from the causal relationships linking the study factor (such as water quality) and extraneous variables (such as socioeconomic status) to each other and to the disease in the population of interest, and is a problem that has to be dealt with in all but pure experimental designs. An important distinction between confounding bias and misclassification and selection biases is that confounding is generally correctable at the analysis stage, whereas it is usually difficult, if not impossible, to correct for the other biases at that stage (Kleinbaum et al. 1982).

A first step in dealing with confounding is to ensure that misclassification errors are minimized, because misclassification can seriously distort the apparent degree of confounding (Greenland and Robins 1985). Then, on the basis of theory, potential confounders need to be identified and the study data used to determine whether or not the potential confounder is an actual confounder in the study (Kleinbaum et al. 1982). Where actual confounders are identified, the estimated odds ratio is corrected using standard analytic techniques.

**Implementing an Impact Evaluation Using a Case-Control Method**

In a case-control study of the impact of a water supply or sanitation project on diarrheal morbidity, bias in the odds ratio can be limited through judicious recruitment procedures, through careful design of the data collection protocol, and through adjustments at the time of analysis. If a field study using this design was to be conducted, what might be the catchment area required and what might be the duration of the study?
As discussed previously, by studying only severe diarrheas, and by confining the study period to the months that include the warm-season diarrhea peak, the analysis will be focused on a period of high diarrhea incidence in which most of the diarrheas may be susceptible to water supply and sanitation interventions.

The catchment area necessary to produce sufficient cases of severe diarrhea in the under-five population over a period of, say, 4 months surrounding the summer diarrhea peak will depend on the local incidence of diarrhea and on the reporting rates at the health centre. The required catchment area for the clinic is given by the formula:

\[ P_T = \frac{\text{Number of cases of severe diarrhea required for study}}{\% \text{ population under five} \times \text{cases of diarrhea per child in study during study duration} \times \% \text{ of total cases that are severe reporting to clinic}} \]

where \( P_T \) is the total population required in the service area. The values of each specific factor would need to be determined by consulting local records, and the values might be expected to vary considerably among countries, regions, and even local service areas. Using some plausible numbers, the total population required in such a study may be of the following order of magnitude:

\[ P_T = \frac{500}{0.20 \times 1.0 \times 0.10 \times 0.40} = 62 \, 500 \]

Taking a specific example from clinic records from the 32 health centres serving the 500 000 people living in the mixed urban and rural area of Metropolitan Cebu in the Philippines, during the warm, rainy months of July and August of 1984, about 20 children under the age of 6 years with diarrhea were seen at the weekly morbidity clinic run at each health centre (Cebu Health Department 1983). Choosing five health centres, each of which has its morbidity clinic on a different day, in 1983 it would have been possible to recruit the 400–600 (Table 2) cases required over a period of just 4–6 weeks. The total population served by these five clinics is about 80 000. (In choosing the number of clinics at which recruitment is to take place, complete reliance should not be placed on the records of a single year. Both secular trends and annual variations should be taken into account.)

Where the number of children with diarrhea reporting to a clinic is small, it may be appropriate to choose more than one control for each case. For example, by choosing two controls (rather than one control) per case, the number of cases required is reduced by 25% (WHO 1985). Because controls are usually abundant, the 50% increase in the number of controls and the 12% increase in total number of subjects in the study should not cause any difficulties.

**Conclusions on Case-Control Designs**

In assessing the impact of water supply and sanitation facilities on diarrheal disease, case-control designs are attractive because they are quicker and cheaper to execute than the standard quasi-experimental or cohort designs. This does not mean, however, that the case-control method can already be recommended
for widespread adoption. It is first necessary to field-test the methodology in a variety of settings. It is essential that some of these field trials be conducted in settings in which well-conducted prospective studies have taken place so that the results from the two methods can be compared. Finally, it should be emphasized that, if the case-control method does prove to be valid in this context, the design, execution, and analysis of such studies will never be simple, and will always require the participation of experienced epidemiologists with specific expertise in case-control methods.

**Study Designs for Assessing Impact on Various Outcome Measures**

**Diarrhea Morbidity**

In outlining a "new" strategy for choosing methodologies for assessing the impact of water supply and sanitation projects on diarrheal disease, the following factors must be considered:

1. Now that pathogenic agents can be identified for most severe diarrheas, the preferred outcome measures in HIEs are severe diarrhea (preferably confined to the warm-weather months) or aetiology-specific diarrheas.

2. Instead of dealing with a rare outcome (mild diarrhea), HIEs will increasingly deal with extremely rare severe or aetiology-specific diarrheas.

3. The methodologies that are statistically efficient in dealing with rare diseases (especially case-control studies) will become much more attractive than those (such as quasi-experimental, cohort, and cross-sectional studies) that require large sample sizes for diseases that are found in only a small proportion of the population at any point in time.

4. Not only are case-control designs statistically more efficient, but they are also much cheaper, results can be obtained quickly, and ethical problems are minimized. Furthermore, the potential methodological problems are now recognized and can probably be handled more satisfactorily than some of the problems that inevitably occur in long-term quasi-experimental and cohort studies.

It seems likely, therefore, that case-control studies will play a major role in future analyses of the impacts of water supply and sanitation projects on diarrhea. After the method has been adequately field-tested, it seems probable that, as it is common practice for chronic disease epidemiologists to conduct several case-control studies of a particular relationship before embarking on a cohort study (MacMahon and Pugh 1970), so, too, in assessing the effect of water supply and sanitation programs on diarrheal disease, the dominant methodology may become the case-control method. The more time-consuming and costly concurrent cohort and quasi-experimental designs may be used only infrequently and only in the context of specialized research objectives.

Despite the promise that the case-control method seems to hold in resolving some of the most serious problems faced in evaluating the impact of water and sanitation projects on severe diarrheal disease, these advantages remain potential rather than realized. Under the auspices of the Division of Envir-
onmental Health and the Diarrhoeal Disease Control Programme of WHO, a detailed review of the problems with, and prospects of, such studies has been undertaken (WHO 1985). Field trials of the methodology are being conducted in Malawi, Rwanda, and the Philippines (in the latter setting in conjunction with a large prospective study of the determinants of child health). It is anticipated that, after the results of these trials have been reviewed, a second generation of field studies will be conducted. Within a couple of years, it should be possible to issue detailed guidelines for use by experienced epidemiologists who wish to conduct such studies.

As indicated in Chapter 2, if reliable HIEs can be carried out at low cost, the number of situations in which HIEs will be judged “useful” will increase. It thus seems probable that, if the case-control methodology becomes established in this field, the number of HIEs will grow. Ten years ago, the generation of a body of knowledge that is valid, coherent, and comprehensive seemed unattainable (World Bank 1976); now it seems a possibility.

**Diarrhea Mortality**

Where a substantial proportion of young-child deaths is registered, and where death certificates record cause of death information, it may be possible to conduct a case-control study of the effects of water supply and sanitation conditions on diarrhea-related mortality. Because a study might be designed to detect a 50% change in diarrhea-related mortality, only about 200 cases and 200 controls (Table 2) would be required. If the death rate due to diarrheal diseases is 1.4 per 100 children per year (the mean for developing countries (Snyder and Merson 1982)), if 75% of deaths of children under 5 years of age are recorded, and if data covering 1 year are used, then the required population of under fives would be about 20 000. In most developing countries, this would imply a total population of about 120 000. The study would require that follow-up visits be made to families who have had children who have died (“the cases”) and to suitably chosen controls and that questionnaires concerning water supply and sanitation conditions and potential confounding variables be collected.

Although the small sample sizes make such an approach efficient, in most developing country settings it would be difficult to identify sufficiently large populations with relatively complete and reliable death registration information.

As described earlier, another potential source of data on mortality in young children is a survey using an instrument similar to that developed by the WHO Diarrhoeal Disease Control Programme (WHO 1981). This survey may be used as the basis of either a cross-sectional or a case-control study, but may seriously underestimate the true diarrhea-associated mortality rate.

Finally, it should be noted that several cross-sectional analyses of the effect of water supply and sanitation conditions on overall infant mortality have been conducted using data from national censuses and the World Fertility Survey (Feachem 1985).

**Nutritional Status**

As explained earlier, this report is seen as but one step in an ongoing process of theoretical and empirical work on methodological issues in HIEs.
To date, detailed attention has been given primarily to the difficult problems involved in assessing the impact on the most important outcome variable (morbidity due to diarrheal diseases) (WHO 1985). In this section and in the following sections on other outcome measures, only the broad outlines of an approach that presently seems feasible are presented. More definitive conclusions require more detailed work along the lines of that presented above for diarrheal diseases.

Following the recommendations of WHO (WHO 1983b), it appears that the appropriate anthropometric measures are weight-for-height (for short-term effects) and height-for-age (for longer term effects), and that a population should be characterized by the proportion who are more than two standard deviations below the National Center for Health Statistics (NCHS) reference levels. In Tables 7 and 8, the proportions of children in the second year of life falling below these cutoffs in different regions of the world are presented. From these tables it is apparent that: where short-term effects are assessed (i.e., weight-for-height is used as the index), for all but the better-off countries the proportion below the cutoff point is greater than 15%; where longer term effects are assessed (through height-for-age), in most developing countries the proportion below the cutoff point is greater than 30%.

In either case, it is apparent that in most populations the proportion who are severely malnourished (according to these definitions) will be substantial (and, of course, the proportion more than one standard deviation below the reference level even greater). In a quasi-experimental, cohort, or cross-sectional study, the sample sizes required to detect a reduction in the proportion malnourished of 33% — which is both realistic and of public health interest

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### Table 7. Percentage of children in the 2nd year of life who are more than two standard deviations below the median of the NCHS reference level for wasting (weight-for-height).

<table>
<thead>
<tr>
<th>Region</th>
<th>No. of countries represented</th>
<th>Low (country)</th>
<th>High (country)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>16</td>
<td>2 (Cameroon)</td>
<td>36 (Burundi)</td>
<td>18</td>
</tr>
<tr>
<td>Central America</td>
<td>11</td>
<td>0 (Nicaragua)</td>
<td>18 (Haiti)</td>
<td>7</td>
</tr>
<tr>
<td>Middle East</td>
<td>8</td>
<td>3 (Egypt)</td>
<td>32 (Democratic Yemen)</td>
<td>13</td>
</tr>
<tr>
<td>Europe</td>
<td>3</td>
<td>0 (France)</td>
<td>1 (Italy)</td>
<td>1</td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>7</td>
<td>17 (Indonesia)</td>
<td>50 (Bangladesh)</td>
<td>27</td>
</tr>
<tr>
<td>West Pacific</td>
<td>5</td>
<td>6 (Malaysia)</td>
<td>49 (Papua New Guinea)</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: Unpublished WHO data.

### Table 8. Percentage of children in the 2nd year of life who are more than two standard deviations below the median of the NCHS reference level for stunting (height-for-age).

<table>
<thead>
<tr>
<th>Region</th>
<th>No. of countries represented</th>
<th>Low (country)</th>
<th>High (country)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>13</td>
<td>27 (Botswana)</td>
<td>53 (Rwanda)</td>
<td>36</td>
</tr>
<tr>
<td>Central America</td>
<td>16</td>
<td>9 (Barbados)</td>
<td>77 (Guatemala)</td>
<td>35</td>
</tr>
<tr>
<td>Middle East</td>
<td>8</td>
<td>20 (Saudi Arabia)</td>
<td>66 (Yemen Arab Republic)</td>
<td>46</td>
</tr>
<tr>
<td>Europe</td>
<td>2</td>
<td>2 (Italy)</td>
<td>21 (Yugoslavia, rural)</td>
<td>11</td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>7</td>
<td>21 (Thailand)</td>
<td>87 (Bangladesh)</td>
<td>50</td>
</tr>
<tr>
<td>West Pacific</td>
<td>6</td>
<td>10 (Singapore)</td>
<td>67 (Philippines)</td>
<td>35</td>
</tr>
</tbody>
</table>

Source: Unpublished WHO data.
(Dr A. Pradilla, WHO, personal communication) — will be modest. If, for instance, a cluster sampling technique is used and if the frequency of malnutrition in the population is about 25%, then information is needed on approximately 800 people using improved facilities and 800 using unimproved facilities (Table 1).

As discussed earlier, if water supply and sanitation facilities have been operating and utilized for some time, present exposure patterns provide an adequate representation of past patterns, particularly when dealing with the experience of young children. Under such conditions, a cross-sectional study design may be used to test hypotheses about the relationship between water supply and sanitation, on the one hand, and nutritional status, on the other.

Although such designs are simple in concept, because of the numerous other factors that affect nutritional status, particular care has to be devoted to the collection of data on, and the analysis of the effects of, confounding variables. As illustrated by a recent analysis of this sort in the Philippines (Magnani et al. 1984), the statistical issues involved in such studies are considerable and require the involvement of statisticians in both the design and analysis stages.

In many settings, a case-control approach may also be feasible and efficient. If between 30 and 80% of the population served by a clinic use improved facilities, and if a reduction of 33% is to be detected, less than 600 cases and an equal number of controls are required (Table 2). As a starting point for such a study, consideration might be given to defining "cases" as those who come to the clinic for any reason and who happen to be malnourished, whereas "controls" might be those who come to the clinic for any reason but happen to be well nourished. Evidently, more careful thought, along the lines given to the application of case-control studies for assessing the impact on diarrheal diseases (WHO 1985), needs to be given to this problem before specific procedures can be recommended.

Except for specialized research studies, assessments of the effect of water supply and sanitation conditions on nutritional status will probably most frequently be cross-sectional studies and, possibly, clinic-based case-control studies.

Intestinal Nematodes

Earlier in this report, it was suggested that the common intestinal nematodes provide appropriate indicators, first, as "markers" for the transmission of pathogens due to inadequate excreta disposal practices and, second, because they can constitute a significant public health problem. These issues will be dealt with in turn.

Which of the nematodes is most common depends on climate and other ecological and behavioural factors (Feachem et al. 1983). Under conditions of inadequate sanitation, a high proportion of people is usually infected with one or more of these nematodes (Feachem et al. 1983). Because the prevalence of infected individuals is usually substantial where a HIE is being considered, the appropriate rapid assessment method would be a cross-sectional study. Stool samples would be collected from individuals (with primary school children
forming a practical and appropriate group) and the prevalence of infected individuals determined. For example, if the proportion infected with *Ascaris* is 25%, and if it is desired to detect a 33% reduction in prevalence due to improved sanitation, then, if a cluster sampling technique is used, about 800 children with poor sanitation and an equal number with adequate sanitation need to be sampled (Table 1). If the reduction to be detected is increased to 50%, the numbers in each exposure group drop to 330.

A second objective in assessing the impact of a water supply and sanitation project on intestinal nematodes may be to assess the impact on a significant health problem. Although the most commonly used measure is the prevalence of infection, of greater clinical and public health significance is the intensity of infection (Chandler and Read 1961). Where a HIE is designed to measure the prevalence of those with infections of health significance, the proportion classified as “infected” will be much smaller. For example, although over 80% of Bengalis are infected with hookworm, not more than 1% of the people are estimated to have more than the number of worms (about 160) considered to be of health significance (Chandler and Read 1961). Where the outcome measure is disease due to intestinal nematodes, a cross-sectional study would usually require large sample sizes. Where considerable numbers of individuals who report to clinics have disease due to intestinal nematodes, a case-control approach might be feasible. The details of such an approach have yet to be worked out.

Eye Diseases

Trachoma is considered to be of public health significance if more than 5% of the population have moderate to severe inflammation. In areas with hyperendemic trachoma, the overall prevalence of inflammatory trachoma is greater than 10% and may even reach 75% (Dawson et al. 1981). Where water is scarce, improvements in the availability and utilization of water may be expected to have substantial impacts on the prevalence of inflammatory trachoma. Studies may be designed to detect reductions of 50%.

The choice of an efficient study design depends on the prevalence of trachoma in the area being studied. Where the prevalence of moderate to severe inflammatory trachoma is 5% and a study is designed to detect a reduction of 50%, about 2000 children are required in each exposure group in a quasi-experimental, cohort, or cross-sectional study using a cluster sampling technique (Table 1). If the prevalence is higher, say 25%, the required numbers in each group are 330. If a case-control design is used, and if between 30 and 80% of the population use a water supply that provides larger quantities of water, about 200 cases and 200 controls are needed (Table 2). Thus, where case recruitment at a clinic is easy, a case-control approach might be most appropriate. However, where the prevalence of inflammatory infection is high, quasi-experimental, cohort, or cross-sectional designs are also efficient and may be easier to conduct.

For all study designs, a striking advantage of the use of trachoma as an outcome measure is the rapidity with which changes in inflammatory disease

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6 This section was prepared with the collaboration of Dr Hugh R. Taylor, International Center for Epidemiologic and Preventive Ophthalmology, Johns Hopkins University, Baltimore, MD, USA.
respond to changes in personal hygiene. In areas where trachoma is a significant disease, therefore, it provides an excellent outcome measure not only of an important eye disease, but as a marker of personal hygiene practices.

Skin Diseases

Earlier in this report, it was argued that skin diseases in children under 10 years of age might be a measure of impact that would be used either to monitor a significant (in the perception of the community, at least) health problem or as a marker of personal hygiene practices. It was argued that the measure that would be most responsive to improvements in hygiene practices would be pyoderma that is not associated with scabies.

The prevalence of pyoderma not associated with scabies in the under-10 age-group may range from 10 to 35%. If a quasi-experimental, concurrent cohort, or cross-sectional study using cluster sampling was to be used, and if the study was designed to detect a reduction in prevalence of 33%, the sample sizes required would range from about 5000 to about 1000. Aside from the substantial sample sizes, such studies would face two major difficulties. First, the classification of children as “diseased” or “nondiseased” would be made in the field, and it would, therefore, be necessary to have field interviewers with a degree of clinical competence that would be difficult to ensure in most settings. Second, because there are several factors (such as seasonality, crowding, and the presence of flies and mosquitoes) other than personal hygiene that determine the frequency of skin diseases, care must be taken to control for the effect of confounding variables.

If, instead, a clinic-based case-control study was conducted, the sample sizes would be substantially smaller (about 500 cases and 500 controls where exposure is neither too frequent nor too rare) and, because recruitment of cases and controls would take place at a clinic, there should be less difficulty in separating out the scabies-related pyoderma cases. As with other study designs, it would be necessary to account for the effect of potential confounding variables when estimating the effect of personal hygiene practices. In addition, as with all case-control studies, the possibility of selection biases constitutes a serious threat to the validity of the results. A detailed investigation (along the lines of that undertaken for diarrheal diseases (WHO 1985)) of the possible causes of selection bias, and of methods for controlling selection bias, should precede any field test of the method.

Guinea Worm

In areas with endemic guinea worm, prevalence is generally over 10% and sometimes as high as 60% in working-age adults in the peak season (Belcher et al. 1975). The prevalence of active infections can be reduced rapidly both by simple engineering changes that reduce contact of an infected person with the drinking water source (such as the construction of parapets on wells used

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7 This section was prepared with the collaboration of Dr Michael Porter, Public Health Specialist, World Bank, Washington, DC, USA.

8 This section was prepared with the collaboration of Dr Gordon Smith of Johns Hopkins University, Baltimore, MD, USA.
for drinking water) and by simple water treatment techniques. Studies may be designed to detect fairly large reductions (of the order of 50%) in the prevalence of active guinea worm disease.

In principle, a case-control approach appears promising, but in practice it has been shown that in most endemic areas few cases report to clinics for treatment. A more practical approach is a cross-sectional study in which information is collected during the season of peak disease incidence. Because peak disease incidence occurs in young and older adults, studies should be restricted to these age-groups. In many circumstances, a particularly accessible population to study may be secondary schoolchildren (with absentees followed up to determine their disease status). For an overall prevalence of 25%, and assuming that a cluster sampling technique is used, only 330 people using improved supplies, and a similar number using unimproved supplies, need to be examined (Table 1). If the prevalence of active infection drops to 10%, the numbers required in a cross-sectional study increase to about 1000 in each exposure group. Because of the value of guinea worm as a disease to monitor the progress of a project, in many situations it will be appropriate to conduct repeated annual surveys of the population during the peak disease season.

Other Primary Health Care Activities

In choosing an outcome measure to assess the impact of a water supply or sanitation project on the use of primary health care facilities, preference should be given to an activity (such as attendance at immunization or family planning clinics) in which, over a period of a year, 20-80% of families have participated. In this way, the simplest of study designs, a cross-sectional design, can be used without sample sizes becoming too large.

A key concern in such studies is confirmation that the communities with and without water supplies were, prior to the water supply, equal in all essential respects. Although it will be difficult to establish this with certainty, at least it should be verified that the water project was not established in one community because of its superior organizational capacity, and it should be verified that the provision of the outcome services (such as vaccinations and family planning services) are not similarly differentially distributed among the communities.

Conclusions on Study Designs for HIEs

The fundamental principle underlying this discussion is that HIEs of water supply and sanitation projects must give results of high validity to specific policy questions and that, except for specialized research projects, these evaluations must be conducted rapidly and at moderate cost. In broad outline, the above discussion suggests that there are just two options in most cases. Where the outcome is relatively common, cross-sectional designs are most frequently appropriate; where the outcome is relatively rare and where individuals with the condition report to a clinic, case-control studies may be appropriate. Although the methodology of cross-sectional studies is well established, it is only recently that the case-control method has been considered appropriate in such settings, and, thus, significant theoretical and practical issues still need to be resolved. For both study designs, a major concern in producing
valid results is that of accounting for the effects of confounding variables. In some settings, cross-sectional studies may be done on communities in which everything but the intervention may reasonably be supposed to be similar; in most settings, for both cross-sectional and case-control studies, statistical methods will be used to control for the effects of confounding variables.

A final important advantage of the cross-sectional method over the case-control method is that, in a cross-sectional study, multiple outcomes can be studied simultaneously. Thus, for instance, in an arid area a single cross-sectional study might collect information on the prevalence of trachoma, guinea worm, intestinal nematodes, and nutritional status, with the sample size being the largest required for each of the outcomes studied independently. Because the underlying variables will be similar, this represents a highly efficient "piggybacking" approach. By contrast, a case-control study of diarrheal disease can only be used to study diarrhea. If a case-control study of, say, trachoma is also contemplated, the same clinics and the same recruitment staff could be used, thus saving on costs, and it might be possible to devise a study design that uses some controls as controls in both studies, thus saving on the costs of home visits to collect information on underlying variables. By and large, however, it would be necessary to do two separate case-control studies.
Chapter 5

Interpretation of Results

Incorrect Inferences due to Problems of Design, Execution, and Analysis of HIEs

As discussed in a recent review (Blum and Feachem 1983), serious methodological problems exist in almost all published studies on the health impacts of water supply and sanitation projects. Evidently, correct inferences cannot be drawn from studies that are poorly designed, executed, and analyzed.

On first consideration, it might appear that the net effect of these errors might just be to increase the “noise” in an overall estimate of effect, but not to bias the effect. On closer consideration, however, it is evident that, although some common problems (such as small sample sizes) simply increase the noise, there are common sources of error that introduce systematic biases that lead to consistent underestimates of the effect of water supply and sanitation improvements on health. An obvious example is the bias introduced when the performance and utilization of water supply and sanitation facilities are not monitored. This neglect introduces biases only when performance or utilization is inadequate and, thus, can operate only to decrease the apparent effect of using improved facilities. A more subtle effect is that arising from inaccuracies in information on the health status or other characteristics of the study population. As discussed in detail in a recent analysis (WHO 1985), in HIEs of the impact of water supply and sanitation projects, the result of such misclassifications will almost always be to underestimate the effect of any improvement. On the other hand, there is also a tendency for authors to publish only “positive” findings. In one study, for example, the impact of water supply and sanitation facilities on both cholera and general diarrheal diseases was assessed. The improved facilities appeared to have a marked effect on cholera but no effect on general diarrhea. The results on cholera were published in an influential journal, but the results on general diarrhea were never published because the authors considered them “negative and, therefore, not worthy of interest.”

Although it is unrealistic to expect the development of a large literature of studies that are flawlessly designed, executed, and analyzed, it is evident that the general quality of HIEs of water supply and sanitation projects has been rather poor, and that improvement in both the number and quality of such studies, and the publication of the results from all well-conducted studies, are preconditions for the development of a reliable information base.

Extrapolation of the Findings to the Population

As discussed earlier, it is probable that “internal” rather than “external” validity will be the trademark of a new generation of HIEs. Accordingly, care
must be taken in stating what a study has shown, and what assumptions must be made in extrapolating the study findings to the general population. For example, a case-control study of diarrheal disease will not provide information on the relative frequency of diarrhea for those without and with improved facilities. Rather, from such a study one can estimate the relative frequency of severe diarrhea (being diarrhea of a type that causes a mother to bring her child to a clinic), during the summer months, among children under 5 years of age from families that use the clinic and do not use improved facilities, compared with similar children during the same season from families that also use the clinic but do use improved facilities. The meaning and importance of this relative frequency will require careful interpretation. The method may be used directly only to compare the degree of protection against diarrhea afforded by using the improved water supply during the months of maximum risk of severe diarrhea. Translation of these results into conclusions applicable to the community at large requires information on the relative importance of the summer and winter diarrhea peaks, on the effect of water supply and sanitation conditions on the transmission of diarrhea in the winter months, and on the degree to which those who attend the clinics at which recruitment of cases and controls takes place are representative of the entire population.

As a second example of the need for caution in generalizing from the results of focused studies, consider the Bangladesh studies that have shown that washing one’s hands reduces the secondary spread of shigellosis (Khan 1982) and that home water treatment reduces the secondary spread of cholera (Khan et al. 1984). Such studies are attractive in that the samples required are small and the internal validity high. However, because the epidemiology of the transmission of shigella bacilli and cholera vibrios among communities and among families is governed by factors that are quite different from those that govern the spread of these organisms within families, it is not possible to infer directly from such studies the effect of, say, a hygiene education program on overall transmission of shigella or cholera in the community.

Finally, to translate the measures of effectiveness emerging from some studies into the measures required for policy purposes, additional data may be needed. In the case-control study discussed in Chapter 4, for instance, the measure of effectiveness is an estimate of the ratio of severe diarrhea in the unserved versus the served population (for the particular season). A policymaker, however, will wish to know not this ratio, but the impact on the incidence of severe diarrhea that might be expected following various levels of investment in improved water supply and sanitation facilities. To estimate this impact, it is necessary to have information (which may often be difficult to obtain (Department of Health and Social Services 1981)) on the proportion of the population that is served and the incidence of diarrhea in the total population (Schlesselman 1982).

Incorrect Interpretation of “Negative” Findings

HIEs of water supply and sanitation programs are not unique among evaluation studies in terms of methodological shortcomings in design, conduct, and analysis. Because other areas of epidemiological inquiry, also beset by similar methodological problems, have generated a coherent (albeit not perfect) picture of the effect of particular factors on particular diseases, a legitimate
concern is why a similarly coherent picture of the impact of improved water supply and sanitation facilities on health has not emerged.

Some scientists (Walsh and Warren 1979) and agencies (USAID 1982) have argued that the record is in, that the health impact of water supply and sanitation projects is small, and that this sector is not competitive with other investments simply as a health intervention. Others have argued that, even when the direct health impact of such an intervention is small, a program based on that intervention may constitute a rational health investment. There are several reasons for this.

First, because these programs generally have substantial nonhealth benefits, only part of the overall cost should be used in computing the cost-effectiveness of the intervention in terms of health (Berman 1982; Briscoe 1984a).

Second, when there are multiple transmission routes and when there is a nonlinear relationship between dose and response, the reductions in exposure may not translate into corresponding reductions in disease (Briscoe 1984b; Esrey et al. 1985). Nevertheless, such reductions in exposure may be valuable in that the impact of subsequent interventions that affect the remaining transmission routes may be greatly increased by prior, apparently ineffective, interventions. There is broad empirical evidence in the literature supporting this contention. Specifically, it is striking, both in a comparative assessment of health impact analyses in different settings and in longitudinal analyses in particular settings, such as the United States in the early 20th century (Condran and Cheney 1982) and contemporary Chile (Brunser et al. 1983), that it is in communities in which prior, apparently ineffective interventions have taken place that subsequent, relatively minor interventions have had a major impact on health.

Finally, studies of the effect of environmental improvements on mortality in 19th century Europe (Preston and van de Walle 1978; Briscoe 1985) have shown that it takes generations for the full effects of such improvements to be felt and, presumably because of indirect effects operating through nutritional status, such improvements lead to reductions in diseases that are not directly related to water supply and sanitation conditions.
Ten years ago, an authoritative review of HIEs of water supply and sanitation projects concluded that the methodological difficulties and costs of HIEs are such that conducting such studies cannot be justified (World Bank 1976). A subsequent survey of the literature confirmed that methodological problems were serious in virtually all field studies (Blum and Feachem 1983).

Because of recent advances in epidemiological and microbiological techniques, there were, nevertheless, some faint glimmers of hope in this otherwise gloomy picture. To explore the implications of these recent advances for HIEs of water and sanitation projects, an international workshop was held in Cox's Bazaar in late 1983. Recent and current HIEs were reviewed and the prospects of developing an improved approach to conducting such studies assessed.

A general conclusion was that development in this field had been severely hampered by the fact that HIEs had been undertaken in an isolated and often ad hoc manner. In some instances, it is clear that the HIEs should never have been undertaken; in others, there were deficiencies in the design, conduct, analysis, and interpretation of the study. Nevertheless, in light of the recent methodological development of rapid epidemiological assessment techniques, it was generally agreed that there was cause for guarded optimism in this area, and that the first step was the development of a coherent framework that could be used to guide those who fund, execute, and interpret HIEs of water supply and sanitation projects.

In developing this framework, it was agreed that there were several key questions that needed to be addressed. First, it was necessary to define carefully the conditions under which HIEs of water supply and sanitation projects should be undertaken. Second, it was necessary to define which health outcomes should be used for assessing the effects of such projects. Third, and most important, the strengths and limitations of different study designs needed to be assessed, and methods for addressing the problems of the more promising study designs developed. Finally, it was considered necessary to examine the interpretations that should be drawn from such studies.

The objective of this report is to take a first step in developing the required framework by discussing each of the key questions. The report draws both on the discussions held at Cox's Bazaar and on an intensive research effort carried out with funding from UNICEF and under the auspices of WHO subsequent to the Cox's Bazaar workshop.

The first substantive section of the report (Chapter 2) defines the conditions under which HIEs of water supply and sanitation projects are likely to be
“useful,” “sensible,” and “feasible.” It is argued that the most important policy issue is that of the impact of different levels and mixes of services in specific settings, and that HIEs should be conducted where large investments are contemplated and economic criteria are not decisive in indicating one rather than another level or mix of service, where systems have been operated well and appropriately used for several years, and where sufficient resources, in terms of money and scientific personnel, are available.

The bulk of the report is devoted to the two key related methodological questions: the choice of outcome variables and the choice of study design. With respect to the choice of an outcome measure (Chapter 3), three major questions are addressed: Is the outcome measure of public health significance? What is the validity of information on the outcome variable under field conditions? What is the responsiveness of the outcome variable to changes in water supply and sanitation conditions? Because they are the indicators that are of universal public health significance, much of the discussion focuses on diarrheal disease and nutritional status. Other indicators, such as intestinal nematodes, guinea worm, skin and eye diseases, and participation in other primary health care activities, are also examined.

The Cox's Bazaar participants considered the most serious problem in evaluating the health impacts of water supply and sanitation projects to be that of study design. Accordingly, much of this report (Chapter 4) is devoted to an examination of the appropriateness of different study designs for different outcome measures, with particularly detailed attention being given to the most commonly used outcome measure, namely morbidity due to diarrheal disease. The discussion confirms that, as was concluded by the World Bank Expert Panel 10 years ago, for diarrheal diseases the standard longitudinal and cross-sectional designs fail on two critical counts: the required sample sizes, and thus costs, are great, and the methodological problems are often intractable. Detailed attention is given to the possibility of using case-control study designs for assessing the impact on diarrheal disease. It is concluded that this method offers a real possibility for the development of a rapid, low-cost, and valid method for assessing the impact of water supply and sanitation projects on severe diarrheal disease. The key elements in the design of such case-control studies are outlined, and steps that are being taken to field-test the method described.9

For other outcome variables, the discussion is limited to an overview of the issues that would affect the choice of an appropriate study design for each of these outcome variables.

Finally (Chapter 5), some pitfalls that have to be avoided by both scientists and policymakers in interpreting the findings of HIEs of water supply and sanitation projects are outlined.

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9 A companion report (WHO 1985) discusses the theoretical and methodological aspects of these case-control studies in much greater detail.
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Annex 2 Abstracts of Workshop Papers

Diarrheal Disease and Child Morbidity and Mortality

Robert Black

This is a survey paper. First, the major recent advances in knowledge of the aetiological agents of infant and childhood diarrhea are reviewed from an epidemiological perspective. Whereas 10 years ago studies of children in developing countries were able to detect a potential causal agent in fewer than 20% of stool specimens from children with diarrhea, it is now possible to identify pathogens for about 50% of cases identified through field surveillance and about 80% of cases identified at clinics. Second, the most important pathogens are identified and information on the transmission of these organisms summarized. Particular attention is given to the three agents (viz. enterotoxigenic E. coli, rotavirus, and Shigella) that contribute most to high diarrheal mortality. The paper also discusses the methods for measuring the frequency of diarrheal diseases and discusses the validity of diarrheal morbidity and mortality data derived from different sources. Finally, the paper discusses known information and critical gaps in knowledge about the effect of oral rehydration therapy, vaccines, and environmental interventions on diarrheal morbidity and mortality.

Evaluation of the UNICEF-Assisted Imo State Water Supply and Sanitation Project: Epidemiologic and Fieldwork Methods

Deborah Blum and Robert Emeh

The Imo State project in rural Nigeria consists of an intervention program based on the provision of boreholes and handpumps, ventilated improved pit latrines, and health and hygiene education through village-based workers. This paper presents a thorough description of the methodology used in designing and conducting an ongoing health impact evaluation of the project. The objectives of the evaluation are to (1) determine the impact on child morbidity and mortality; (2) study the intervening processes, such as hygienic attitudes and behaviour, necessary for health impacts to occur; and (3) develop a methodology for health impact evaluations that can serve as a model for

1 The paper was submitted to the workshop but the author was unable to attend.
replication in other areas. Consequently, much attention has been focused on the methodological problems common in impact evaluations — lack of adequate controls, confounding variables, health indicator recall and inadequate sample sizes.

The evaluation is a quasi-experimental design with pre- and postintervention data being collected in three intervention and two control villages. Outcome indicators monitored are mortality, time savings, and prevalence of water-related diseases; intervening variables monitored are water quality, water quantity, facility usage, and hygiene behaviour. Systematic samples of at least 200 households in each of the five villages are chosen for an annual sociodemographic survey and biannual surveys of water, sanitation, and hygiene attitudes and practices. All water sources in the villages are tested monthly for fecal coliforms and fecal streptococci, and 12 households in each of four villages have additional source-to-mouth water quality testing. Wet and dry season observations of these same households are made on water quantities used for various purposes.

The outcome variables include the incidence of diarrhea in children under 6 years of age and the prevalence of soil-transmitted helminths in children 6-15 years old. Sample sizes of 600 children per intervention and control group for diarrheal morbidity and 165 children per group for helminth prevalence were selected to ensure a 95% chance of detecting 15 and 20% differences between the two groups.

Details on the training, data collection and recording, and quality control and analysis techniques are given. Both before-and-after, and intervention-control comparisons of impact indicators are made.

**Impact of Improvement of Environmental Sanitation on Diarrheal Disease in Chile**

Oscar Brunser, Magdalena Ataya, Julio Espinoza, Guillermo Figueroa, Eugenio Spencer, and Nestor Montesinos

This paper reports on the before-and-after comparison of diarrheal aetiologies for a cohort of children under 7 years of age whose families moved from slum conditions to new housing in Santiago. The only significant independent variable was the new housing, with improved water supplies and sanitation. Nine months of baseline data collection in the slum on demography, diarrheal disease, and microbial contamination were followed by 6 months of comparable surveys after the 146 families were established in their new environment. The main causative agents of diarrhea in the slum were classic serotypes of *E. coli*, followed by shigellae and salmonellae. In the new housing, bacterial enteropathogens persisted but there was a significant decrease in *Shigella*- and *Giardia*-associated episodes. The number of episodes attributed to specific bacterial, viral, and parasitic pathogens decreased significantly, although the monthly incidence of diarrhea did not show statistical differences when comparable months were studied. This may reflect increasing awareness of, and sensitivity to, diarrheal episodes by the respondents as the study progressed. An analysis of risk factors showed no association between diarrheal
incidence and hygienic conditions for the slums, but some increased risk of diarrhea with less sanitary practices in the new housing.

Water and Health in Mueda, Mozambique

Sandy Cairncross and Julie Cliff

The results of two field studies evaluating impacts of piped water supplies in rural Mozambique are presented. Comparisons between a village with piped water and other villages where water supplies are some distance away were made for quantities of water used for various purposes, time and effort saved in carrying water, and impact on water-related diseases. The first study revealed an average water collection time of 20 min in the standpost-served village and an average collection time of 5 hours for the unserved village, where a 4-km walk and wait in long queues were necessary. Time budgets for women of the two villages showed that the time saved in water collection was spent on housework, food preparation, rest, and social activities. The average observed quantity of water used was almost three times larger for the served village than the unserved village. The greatest differences were reported in the amounts used for bathing, especially bathing of children, and washing clothes. The presence of the standpipe brought about a dramatic change in the daily hygiene habits of the population.

A subsequent health impact evaluation was undertaken as an epidemiological exercise for medical students. Again, one served and one unserved village were monitored, with questionnaires administered to some 100 households in each village. Clinical examinations were also performed. Health impacts were unclear because sample sizes were too small to detect any difference in infant diarrhea rates. No difference in skin disease prevalence for children 0–14 years old was observed. Although trachoma prevalence was significantly different in the two villages (38% for the unserved and 19% for the served), these results cannot conclusively be linked to the water supplies because the climatic conditions of the two villages were not comparable.

Behaviour and Diarrheal Transmission in Zimbabwe

Piers Cross

This ongoing research project examines social, cultural, and behavioural factors along with environmental variables in an epidemiological study of childhood diarrhea. The emphasis is on the use of social anthropological methodology to assess human behaviour and to develop indices of behavioural risk. Potential risk behaviours monitored for the year July 1983 – June 1984 include washing one's hands and body, defecation and excreta disposal practices, hand-to-mouth behaviour, water and food collection, and handling and use and management of childhood diarrhea. Such behaviours will be compared with environmental indicators of food and water microbiological quality and fly incidence and with data on diarrhea incidence, nutritional status, skin infection, and parasite prevalence in children under 5 years of age. The two
specific hypotheses being tested are (1) variations in certain behaviours between households with a similar socioeconomic status and equivalent environments account for differences in diarrheal incidence among children under 5 years of age; and (2) seasonal changes in certain behaviours affect the seasonal incidence of childhood diarrhea.

The Zimbabwe farm worker communities provide an opportune setting for examining populations with socioeconomic similarities but environmental, cultural, and behavioural differences. Approximately 250 households and 150 children under 5 years of age have been selected for surveillance through questionnaires, in-depth interviews, observation, self-reporting, and community meetings. This mix of data collection techniques allows both quantitative assessment and qualitative perception of the behavioural processes involved in disease transmission. Some preliminary observations indicate that weaning foods for infants and communal food bowls for other family members may be potential sources of infection. Another observation is that the major health benefit of latrines may be from their use as a site for washing one's body rather than use solely for excreta disposal.

Evaluation of the Impact of Water Supply and Sanitation

T. Dharmalingam

This project was conducted in a set of rural Indian villages to demonstrate the impact of the primary health care approach. As part of the overall evaluation, specific investigation into the effects of the water supply, sanitation, and health education programs was undertaken. Six months of baseline and 2 months of terminal data collection covered prevalence of gastrointestinal and skin diseases and the existing knowledge, attitudes, and practices of the villagers with respect to several environmental variables. All households in the 10 experimental and 5 control villages participated in the morbidity survey and a 20% sample of those was systematically selected for the behavioural survey. Progress in installing sanitation measures during the 3 years of implementation was scored on the changes in availability, accessibility, acceptability, and affordability of the water supplies and excreta, refuse, and sullage disposal systems. These quantitative rankings for water and sanitation and those assigned to hygiene knowledge, attitudes, and practices were then analyzed for before-and-after intervention differences and the association with morbidity rates.

Although it was found that significant improvement had been made for excreta, refuse, and sullage disposal in the experimental villages, both areas scored improvement in water supplies due to the unanticipated construction of borehole wells in the control area. The difference in improvements in health knowledge, attitudes, and practices was substantial, reflecting the impact of the health education activities in the experimental villages. However, no relationship between general and infant mortality rates and the water and sanitation scores was observed. This might be accounted for by the host of synergistic social, cultural, and behavioural factors that were not studied. Detailed analyses are continuing to further indicate the action of the study variables upon health.
A Community-Based Longitudinal Study on the Impact of an Environmental Intervention Program on the Prevalence of Enteric Pathogens and the Aetiology of Acute Diarrheal Diseases in a Rural Area of Nigeria: Microbiological Methods

O. Dosunmu-Ogunbi

This paper presents preliminary findings from an ongoing microbiological surveillance for aetiological agents of acute diarrheal diseases in children under 6 years of age in the rural Imo State water supply and sanitation project. A detailed discussion of materials and methods covers the collection and handling of stool specimens, quality control of culture and media, and isolation and identification procedures for bacterial agents, viral agents, protozoa, and helminths. The diarrhea pathogens investigated are enteropathogenic E. coli (EPEC), enterotoxigenic E. coli (ETEC), Campylobacter jejuni, Salmonella, Shigella, Yersinia, Vibrio cholera, rotavirus, Entamoeba histolytica, and helminth ova. Results of the examinations are divided into two periods, February-June, 1983, and July-September, 1983, because different transport media were used for these periods. A total of 280 specimens from well and ill children were examined in the first period and 176 in the second period.

ETEC appears to play a decisive role as an important agent of diarrhea in the study population, with isolation rates of 16.2% in ill subjects and 11.5% in well subjects. This was followed in order of frequency of isolation by EPEC, Salmonella, Shigella, Campylobacter, and Yersinia. Higher isolation rates of the established enteric pathogens, especially Campylobacter and Salmonella, observed from July to September, were attributed to the improved transport medium. Rotavirus was isolated at a 2% rate during February-June but not later; this may be a result of seasonal variations. Cholera, although endemic in the country, was not detected.

Nutritional Anthropometric Indicators for Evaluating Water and Sanitation Projects

Steven A. Esrey and Jean-Pierre Habicht

The inclusion of nutritional anthropometry to complement diarrheal data is suggested when evaluating water and sanitation interventions. The biological basis is well documented and specific to diarrhea because (much more than other diseases) diarrhea affects growth. In general, anthropometric measurements are well defined, do not rely on recall, require infrequent visits to homes, are easily and inexpensively performed, and encompass the effects of diarrheal incidence, duration, and severity. The statistical basis for inclusion of nutritional anthropometry can be justified on the following assumptions: the differential degree of diarrheal underreporting between control and treatment groups; the nonlinear association between cumulative incidence of diarrhea and growth; the effect of water and sanitation interventions on specific aetiologies of diarrhea

2 The paper was submitted to the workshop but the author was unable to attend.
that, in turn, affect growth differently; and the assumption that water and sanitation interventions affect child growth through more pathways than the infection-diarrhea mechanism.

Height and weight are the two anthropometric measures most likely to respond to water and sanitation interventions. Height/age and weight/height are recommended as the most descriptive indicators because they relate to chronic and acute malnutrition respectively. Older children are expected to respond more readily than younger children because the effects of cumulative incidence of diarrhea operate over time. It is recommended that benefits from water and sanitation interventions be measured 1-3 years after the improvements have been implemented, because waiting longer for improvements to be measured introduces interpretation problems due to the confounding effects of secular trends and other nonwater and nonsanitation interventions.

Health Impact of the Kampung Improvement Program in West Java: Methods and Results

Huub Gaymans

The Kampung Improvement Programme (KIP) in Indonesia is a multi-faceted upgrading of public facilities and physical infrastructure in these communities. One component is the provision of MCKs, a bathing/washing/toilet facility. This paper describes how, in the context of the overall development program, a series of large- and small-scale evaluations covered a range of aspects and impacts of these sanitary facilities. The smaller studies focused on the design and functioning aspects and environmental impacts of the MCKs. Interviews with kampung inhabitants revealed that semipublic MCKs were much better received, used, and maintained than public MCKs, so orientation was modified to provide more semipublic MCKs. Construction of the MCKs inspired housing improvements and resulted in better quality groundwater due to the associated drainage work.

The more extensive health impact study encountered various problems with data and many were discarded that were not reliable or relevant. The remaining indicators (ascaris, trichuris, amoebae, and skin infections in children) showed ascariasis and infectious dermatitis to be the most common diseases. Both diseases were associated with the source of drinking water, with the lowest prevalence seen for private drinking taps. The effect of the MCKs on the percentage of children with ascariasis was encouraging, except in one case where construction and drainage standards were not met. Although many validity and reliability problems arose in the data collection, convincing trends in health impacts were observed. Subsequently, these conclusions influenced technicians and policymakers with respect to the value of KIP as a useful sanitation program.

Health Impact of Water and Sanitation Interventions in St. Lucia

Fitzroy J. Henry

This paper focuses on the quantitative impact on childhood morbidity and malnutrition of water and sanitation intervention programs in three valleys in rural St. Lucia. It also attempts to identify the critical range of water use
that may affect morbidity patterns. A 2-year prospective study on a cohort of less than 6-month-old infants was initiated in 1977, after the installation of household water taps and water-sealed latrines in the intervention areas. One valley received both taps and latrines; the second, only water taps. The third valley, with unimproved public standposts and pit latrines, was used as the control area. Data collection consisted of surveys and observations on socioeconomic, dietary, and environmental conditions and water usage, and frequent testing of anthropometry and helminth infections accompanied by mothers' self-reporting of children's diarrheal incidence.

Children in the valley with household taps and water-sealed latrines had less infection and malnutrition than those children in the control area. The provision of improved water and sanitation was associated with greater reductions in diarrheal and trichuris prevalence and ascaris incidence than the improved water supply alone. Malnutrition, however, was not further affected by the use of water-sealed latrines. The quantity of water used was inversely related to child morbidity, with the greatest risk in families using less than 25 L/capita per day. Households using more than 40 L/capita per day did not have significantly fewer infections and the effect on malnutrition was slight.

Opportunities, Problems, and Pitfalls in Using Health Status Measures to Evaluate Water Supply and Sanitation Projects in Togo, Malawi, and Tunisia

Raymond B. Isely

The evaluations of three rural water supply and sanitation projects are examined for those aspects that impede or enhance procedures used in measuring health outcomes. A working evaluation model based upon project inputs, operation, use and user perceptions, and behaviour is presented and applied to some extent in all three projects. The Togo and Tunisia projects have completed data collection and some analyses; the Malawi project is still in the phase of evaluation planning. Important lessons learned from field experiences in Togo and Tunisia include the recognition of limits imposed by capacities and abilities of field staff to collect data; the need for a well-planned sampling scheme that will ensure statistical validity but ease in application; and the potential use of secondary data from national surveys, clinics, and hospitals, etc., to expand upon and verify the data base. The Malawi project demonstrates the need for an overall evaluation plan in which all concerned parties participate so their various interests can be addressed. Evaluations of health benefits should use a minimum number of easily administered procedures that are reflective of likely project impacts given the type and level of project inputs, and that indicate changes in prevalent diseases or health conditions.

Impact of Hygiene Promotion on Diarrheal Diseases

Moslem Uddin Khan

Previous studies in Bangladesh have suggested that a lack of hygienic practices is responsible for the spread of diarrheal disease pathogens in many situations. Three studies investigating specific hygiene and sanitation measures
among the very poor are reported in this paper. The first suggests that the provision of piped water supplies and latrines with underground sewerage could reduce cholera rates by as much as 62% in some urban areas of Bangladesh. Differences in cholera rates were highly significant in a year-long study of a refugee camp with these improvements and two camps with tube wells, ponds, and latrines contaminating surface waters. Another focus of interest was the effectiveness of community flush latrines when no other improvements or education were provided. No age-group differences in diarrheal incidence were observed between the intervention and control slums, nor could intestinal worm infection rates be distinguished based upon the availability of community latrines. The percentage of ascaris, hookworm, and trichuris infections did drop significantly in both areas after a deworming program but the reinfection rate remained similar for both areas.

The greatest success in diarrheal control appeared to result from an education project on washing one's hands conducted on families of hospitalized shigella patients. Those families washing with soap and water had an overall reduction in secondary shigella case rates of 84% over the control families during the 10-day follow-up. The effectiveness of washing the hands varied by shigella type, with Sh. dysenteriae showing less sensitivity than Sh. flexneri and other isolates. The results of these studies indicate an optimum intervention program would consist of a combination of piped water, adequate sanitation, washing one's hands with soap, and health education.

**Studies of the Impact of Improved Water Supply and Sanitation Upon Health in Malawi: Methods and Results**

Per Lindskog and Ulla Lindskog

This ongoing research project is evaluating the health and social impacts of the Zomba West Rural Piped Water Project. By conducting a before-and-after-intervention study of two affected groups of villages and one control group of villages, the researchers aim to assess the health impact on children 0–4 years old in terms of diarrheal disease, skin and eye infections, intestinal parasites, and nutritional status. One area will receive an improved water supply and a sanitation and health education program; the other intervention area will receive only an improved water supply. Comprehensive data collection includes twice-yearly household surveys of environmental, demographic, and socioeconomic conditions; water collection, storage, and use surveys and observations five times per year; 20 home visits per year for a child morbidity survey; and twice-yearly medical examinations of all children under 5 years of age.

A census was taken in January 1983 of all three areas, and a study group of all households with children under 5 years of age selected. A total population of 800 children from some 210 households in the control area and 150 households in each intervention area resulted. Results of the background surveys show good comparability of environmental and sociodemographic patterns among the three areas. Likewise, the sample of study households is representative of the larger study populations. Differences noted between the areas were in the frequency of children's attendance at under-fives' clinics and in vaccinations.
The morbidity survey revealed a marked seasonality in both diarrheal disease and skin and eye infections, with higher prevalences in the warm, rainy season. Significant relationships were detected between increased diarrhea prevalence and distance to the water source. There was no significant association between frequency of diarrhea and the type of traditional water source, however. Future data analysis from 1984 and 1985 surveys will focus on both quantitative and qualitative information to determine what changes have occurred post-intervention and why they have taken place.

**Impact of Rural Water Supply on Schistosomiasis mansoni**

Sebastiao Loureiro

Adverse health effects may result from the rapid expansion of water supply systems to rural areas without adequate sanitation and socioeconomic development. The increased volume of sullage may create breeding places for mosquitoes and snails, thus increasing the prevalence of filariasis and schistosomiasis. A recent sanitation program in the rural state of Bahia, Brazil, has the objective of reducing and maintaining low levels of schistosomiasis prevalence. An associated research project in the town of Muniz Ferreira is implementing and evaluating a community-based health education program to support schistosomiasis control. Social, economic, and environmental data have been collected and stool samples examined for *S. mansoni*. Empirical observations by the community indicate an association between increasing use of water and increasing density of snails. However, it has not been demonstrated that the population in houses with piped water or taps has an increased risk of contracting schistosomiasis. Further analysis of the data will be performed using multivariate methods. Egg output density, snail density, and snail infection rates will be used as the dependent variables to assess the effects of water supply and sanitation.

**Impact of Improved Urban Water Supplies in the Philippines: Methods and Results**

Robert J. Magnani and Steven C. Tourkin

A government-sponsored water supply improvement project provided areas of several cities with new wells, treatment plants, storage reservoirs, pumping and distribution systems, and administrative services. Baseline socioeconomic and health surveys were conducted in two of the cities on 2500 households in 1978 before systems became operational in 1979. Quarterly surveys continued thereafter for 2 years and a follow-up survey concluded data collection in 1982. The specific health impact variables and supporting data collection on water supplies, sanitary facilities and practices, diet, and household characteristics were extensive. In- and out-migration in the cities and the unexpected provision of improved water supplies in some control areas posed serious difficulties for the evaluation.

Benefits to those households in the served areas resulted from the convenience of the new water systems, which increased water availability and
accessibility. Increased gardening and the number of houses with toilets and enclosed bathrooms were both observed. Improvements in bacteriological quality of water at the source were consistent for both cities, but only one city had improved quality at the point of use, reflecting the inadequacy of water-handling practices in the other city. Results of the health impact analyses suggested positive health trends for the city water users but no conclusive associations could be drawn when a health versus service area regression was performed. A cross-sectional analysis of the follow-up data indicated that standard of living and diet variables had stronger associations with nutritional status than water and sanitation variables. However, when assessing diarrhea impact, the water and sanitation variables had a stronger net association. Because of these inconclusive results, the value and efficiency of these interventions are questioned as a means of realizing short-term health impacts.

The Role of Person-to-Person Contact and Family Environmental Conditions in Cholera Transmission in Tanzania

F. D. Mtango and F. S. Mhalu

Person-to-person spreading of cholera has been implicated in several cholera epidemics in Tanzania but never proven to be the mode of transmission. Communal washing of hands, eating, and burial practices all point to potential spreading of fecal organisms. This paper presents the rationale, objectives, and methodology for a proposed case-control study on the mechanisms of transmission of *Vibrio cholerae*. Other possible modes of transmission are saltwater fish and water supplies, and less likely vehicles such as vegetables, flies, alcoholic beverages, and fomites. A case-control design has been selected because cholera is not endemic in the country and occurs only in sporadic epidemics. Particular attention is given to the definition and selection of cases and controls, allowing for matching of age, sex, and locale. Detailed questionnaires will be completed for each participant and family on environmental, hygienic, and socioeconomic conditions. Bacteriological investigations of cases, controls, and their close contacts will include cultures from water, food, hands, and rectal swabs. Serological tests will also be performed. Recognizing the limitations of and problems with administering questionnaires, the researchers have emphasized the need for a knowledgeable, trained interviewer; pretesting of the questionnaire; and restricting questions to those requiring categorical, objective answers.

Health Monitoring Component of the Metro Manila Water and Sewerage Project

Ofelia D. Pardo-Saniel

This interim report on the 5-year study of health impacts from water and sewerage projects highlights several important research issues that affect the ultimate interpretation and use of the results. Two years into the project, it

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3 The paper was submitted to the workshop but the author was unable to attend.
has been recognized that the five study areas did not have initial comparability with respect to several health indicators. This will complicate drawing any associations between health improvements and the specific interventions applied. Also, the dynamic response of the project to health needs, revealed in the ongoing health and water monitoring program, has and will result in unexpected modifications to the interventions, which may further cloud interpretation of data. During the first 2 years of the study, four of the five areas received public works improvements ranging from new water systems or drainage to a complete package of many basic and social services, including housing, electricity, water, and sanitation. Whether or not the remaining 3 years is sufficient time for health effects to be measured is presently an unknown. The three rounds of comprehensive data collection on sociodemographic, environmental, and health trends will trace changes between the initial, midpoint, and final surveys, however.

Health indicators selected are overall morbidity and mortality, nutritional status of infants and young children, and the prevalence of helminthiasis and amoebiasis as estimated from a sample of the population. Preliminary results have shown the last two indicators to be both expensive to determine and impractical to study because prevalences are low. The methodological implication of low prevalence is that very large samples are required if significant reductions in rates are to be proven, and the difficulties in collecting stool samples for analysis compounds this. These issues are not uncommon to health impact studies and resolution of them is necessary if this and other projects are to accomplish their objectives.

Role of Anthropologists in Studying Diarrhea Epidemiology: A Case Study from the Gambia

Helen Pickering

The two-part study focused on a 6-month social and environmental survey of 493 children (6–36 months old) in peri-urban Bakau and a 15-week diarrhea surveillance of these children. Thirty-five social and environmental factors were observed, including child care, food preparation and storage, water sources and use, sanitation, housing, and parental education and occupations. The bacteriological quality of the water stored in the homes, as measured by total coliform count, was used as an index of domestic hygiene for 55 of the homes surveyed. The diarrhea surveillance relied upon the mothers’ definitions of diarrhea and their 1-week recall of diarrhea incidence and duration.

Diarrhea morbidity results showed a wide range in the diarrhea experience between individual children, with 12 days of diarrhea being the mean for the group. There was no statistical association between variability in diarrhea prevalence and any of the social and environmental factors recorded. A possible explanation given was the mobile and exploratory nature of the children, which could expose them to many more factors than those specific to an individual household. No significant association was shown between coliform counts and diarrhea rates or the social/environmental factors, but these results were inconclusive due to the limited samples of water tested.
Teknaf Health Impact Study: 
Methods and Results

Mujibur Rahaman, K.M.S. Aziz, Zahid Hasan, 
K.M.A. Aziz, M.H. Munshi, M.K. Patwari, and Nurul Alam

The Teknaf area of southeastern Bangladesh has had a long-standing surveillance program for the detection and treatment of dysentery and other diarrheal diseases. An intervention study initiated in July 1980 monitored the impact of water supply, family latrines, and health education in controlling diarrheal diseases and improving nutritional status of children under 5 years of age. Because even the control community had some private tube wells installed as the 3-year study progressed, the comparisons made were between more-accessible and less-accessible water supply communities. All households reported using tube well water for drinking, but in the control area traditional water sources were frequently used for washing, bathing, and cooking. Weekly diarrheal surveys and pathogen isolation investigations documented diarrhea incidence and aetiologies, and twice-yearly weight and height measurements gauged the nutritional status of the children.

Overall trends in diarrhea incidence in both communities, and differences between them, appeared to be strongly related to the proximity of the households to the tube wells. Analysis of the data by distance from the well showed that children living in households more than 150 yards (137 m) from the tube well experienced considerably more diarrhea than those nearer the tube wells. This was corroborated by an incidence/water source analysis that revealed 19% higher diarrhea incidence for those households using traditional water sources in addition to the tube wells. As more tube wells were installed in both areas over the 3 years, rapid declines in diarrhea were observed. Nutrition measurements found a very high rate of chronic malnutrition in both areas, with a rapid increase in malnutrition between infancy and 2 years of age. Children aged 1–2 years also suffered most from the diarrheal infections, with a peak prevalence of 30% and more frequent seasonal diarrheal peaks for these ages in both areas. Health education showed little impact on infection and hygiene practices, but this was probably a result of its late introduction into the project. The importance of continuing health education was emphasized for expanding the positive results already observed.

Can Environmental Sanitation Activities Improve Health Status? 
An Analysis in CIMDER Project Areas

Jorge A. Saravia

The CIMDER methodology for delivering health education services and monitoring the sanitary status in rural Colombian areas is described. Nine regional units have had CIMDER programs, dating from 1977 to 1981. Health promoters have made annual residential visits to assist in sanitation education and to collect data on water supplies, excreta and garbage disposal, local hygiene, and rabies control. A brief analysis of data gathered through 1982 shows that
notable gains have been made in sanitation activities dependent solely on health education, whereas those activities requiring investment in construction, repair, and maintenance of infrastructure have not been modified. As the surface water quality deteriorates, water treatment has gained increasing importance because the alternate sources are limited to rainwater and water tanks. Eighty-five percent of the homes need domestic water connections and 54% need water treatment. Burning of garbage is the only feasible waste disposal alternative, and although the CIMDER program has reduced surface and river disposal, some 53% of the households still have inadequate practices. Excreta disposal practices are even worse, with around 67% of the residences having no latrine or toilet. Even when such facilities are available, the ultimate waste disposal is often to the ground surface or rivers; almost three-quarters of the households have need of sewers or subterranean excreta disposal. The general lack of investment in rural sanitation infrastructure reflects the increasing attention, funds, and technical resources directed instead to the burgeoning urban problems.

Social and Behavioural Factors in Health Impact Methods and Analyses

Norman Scotney

The purpose of this paper is to suggest procedures for preparing for and assessing the social and behavioural impacts arising from water supply and sanitation programs. Preliminary considerations should include recognition of processes involved in changing behaviour, an understanding of the group dynamics and social structure in the program area, and anticipation of events that could hinder the implementation of the program. Methodology to assess changes in social and behavioural patterns consists of thorough planning, training, monitoring, and evaluation, always with community awareness and involvement. Such a project should include initial discussions with community leaders to develop clear targets and goals. Indicators selected to measure impacts should be concerned with changes in relationships and attitudes, as well as behaviour. The paper further outlines components of conducting surveys — both baseline and follow-up — such as questionnaire development, pretesting, training, sampling considerations, and analysis. Suggestions for timing and use of evaluative data are also given.

A Methodology for Studying the Impact of Water Supply and Sanitation on Soil-Transmitted Helminths in Indonesia

Noerhajati Soeripto

Soil-transmitted helminthic infection is a widespread and continual problem in Indonesia and chemotherapy alone has not proved to have long-lasting benefits. Thus, a population of high-exposure fieldworkers was selected for this 2-year investigation of the effects of improved water supplies, sanitation, and health education on helminthiasis used in conjunction with mass chemotherapy. The specific health indicators monitored are the reinfection rate and intensity of helminthic infection, and the positive rates for Ascaris eggs in soil
samples. The importance of the various interventions will be assessed by offering differing levels of service to the three villages: one with only chemotherapy serves as the control, another has received new or improved wells and health education, and the third has those services along with new latrines. The total population of 234 families has been initially surveyed for their socioeconomic status, environmental conditions, and personal hygiene, and a 40% sample of the 1100 people is used for fecal monitoring. Soil samples have been collected from several locations in and around 20 houses in each of the three villages. The postintervention sampling schedule should allow assessment of the chemotherapy efficacy 1 and 3 months after treatment, and 6- and 12-month evaluations of the impact of wells, latrines, and health education. Details of the laboratory methodologies and results of the initial sampling are provided. The only trend noted was the higher contamination with *Ascaris* eggs of the soils near wells, washing places, and latrines for all three villages.

**Jhansi Health Impact Study: Methods and Results**

R.N. Srivastava, B.L. Verma, and M. Saran

This longitudinal study has the objective of quantitatively measuring the health benefits in a population provided with safe and abundant water compared with a control population using traditional water sources. Three rural Indian villages serve as the study population: two received piped water supplies and health education in 1983 and one of those will have additional technical instruction for building waste soakage pits. A wide range of activities and health conditions is being monitored: point prevalence and annual incidence rates of water-related diseases, mortality and migration patterns, nutritional status of young children, socioeconomic conditions of households, behavioural patterns associated with water use, water quality, mosquito densities, and system costs for a cost/benefit analysis. Details of the many monitoring methodologies and schedules are outlined.

Because postintervention activities began only in 1983, only the baseline survey results from 1981/1982 are presented. Notable are some of the initial similarities and differences among the villages: similar demographic structure but caste, social class, literacy, and occupation variations. Mortality rates were not significantly different but annual incidence rates for enteric fever, acute diarrhea, conjunctivitis, and scabies did differ. Other observations of water quality and usage indicate that the traditional sources supply sufficient quantities, averaging 50 L/capita per day, but quality is variable and poor for handpumps and wells. A trend of increased water use for all purposes was observed when handpumps were the source. These data, along with the follow-up surveys, will enable the effects of the improved piped water supplies to be assessed.

**Measuring the Health Impact of the Blue Nile Health Project**

O. Tamim

The agricultural villages and farm labour camps along the Blue Nile River in the Gezira irrigation scheme in Sudan have been monitored for several years to assess the impacts of a massive health campaign against schistosomiasis,
malaria, and diarrhea. The health project began in mid-1980, with 2 years of organizational and preparatory work and the collection of baseline data in 21 villages on morbidity, mortality, snail and mosquito populations, and operations of the village water systems. Beginning in June 1982, a comprehensive program of health services was implemented. These services consisted of mass chemotherapy treatment for schistosomiasis, provision of malaria and schistosomiasis diagnostic facilities and technicians, spraying for mosquito control, installation of drainage systems around villages, snail control with molluscicides, health education committees and community meetings, oral rehydration therapy, construction or expansion of water supply systems, and local production of latrine slabs. The previous 2 years of preparatory work allowed the health project to focus on the critical health problems and actively involve the communities in planning and implementation.

Impact assessment occurred in the year following interventions and showed favourable results. Ninety percent of the population needing schistosomiasis treatment received it, and prevalence rates dropped from an estimated 40% in 1981 to 13% in 1983. Diarrheal disease prevalence among children 0-4 years of age declined from 53 to 34%, and a similar decline in the diarrheal mortality ratio from 61 to 44% was observed. Spraying for mosquito control covered about 93% of the households. A 1983 cross-sectional surveillance of over 2000 children yielded no positive malaria results, whereas the 1981 survey estimated an overall prevalence of 0.4%. These data appear to indicate the success of the project, but pre- and postintervention data collection methodologies differed and no rigorous statistical testing of the data was reported.

Health Impact Studies Related to Diarrheal Disease
(Conducted by INCAP)

Benjamin Torun, Luis Angel, Hernan Delgado, Leonal Gallardo, and John Townsend

The Institute of Nutrition of Central America and Panama (INCAP) has explored several approaches and conducted different intervention studies related to reducing the severity and incidence of diarrhea in rural areas. Some of these studies on water improvement, health education, oral rehydration, and nutritional improvement are summarized. One 4-year longitudinal study in a village receiving health education and a water treatment and distribution system showed no reduction in incidence of waterborne diseases when compared with a similar unserved village. Bacteriological quality of water in the distribution system was good, but water quality in household storage vessels was only somewhat better in the intervention village. Metabolic studies did suggest an improvement in dietary protein, fat, and total energy absorption in the village men when compared with a population of better-fed and better-housed soldiers. A follow-up study on health education in the control village showed improved domestic hygiene, although no changes in bacteriological contamination were observed. Nevertheless, the endemic level of diarrhea showed a slight reduction and there was an associated marked decrease in a diarrhea epidemic.

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4 The paper was submitted to the workshop but the author was unable to attend.
Another comprehensive primary health care program in eastern Guatemala, SINAP, had as one component the local production and distribution of oral rehydration salts (ORS) and a massive education campaign on their use. This program increased the availability of ORS in homes from 0 to 84%, and their proper use from 0 to 66% in 1 year. The associated reduced utilization of drugs and clinic services for diarrhea was significant. The decrease in child mortality by half of baseline figures may have been affected by the use of ORS, but conclusive verification of this was not available. The last study summarized in this paper dealt with the relationship between nutritional status of children and diarrhea. Anthropometric indicators showed that weight gain and catch-up growth was impaired by diarrhea. These observations suggest that good nutritional status may reduce the incidence and duration of diarrhea in susceptible populations.