

Monitoring Bathing Waters - A Practical Guide to the Design and Implementation of Assessments and Monitoring Programmes

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Chapter 13*: EPIDEMIOLOGY

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Epidemiological data are frequently used to provide a basis for public health decisions and as an aid to the regulatory process. This is certainly true when developing safeguards for recreational waters where hazardous substances or pathogens discharged to coastal and inland waters may pose a serious risk of illness to individuals who use the waters. Epidemiological studies of human populations not only provide evidence that swimming-associated illness is related to environmental exposure, but also can establish an exposure-response gradient which is essential for developing risk-based regulations. Epidemiology has played a significant role in providing information that characterises risks associated with exposure to faeces contaminated recreational waters. The use of epidemiological studies to define risk associated with swimming in contaminated waters has been criticised because the approach used to collect the data is not experimental in nature. This perception is unlikely to change, given the highly variable environments where recreational exposures take place. Although the variables may be difficult to control, it is possible to carry out credible studies by following certain standard practices that are given below. This Chapter discusses the place of epidemiological investigations in providing information to support recreational water management and the scientific basis of "health-based" regulation.

13.1 Methods employed in recreational water studies

Epidemiology is the scientific study of disease patterns in time and space. Epidemiological investigations can provide strong evidence linking disease incidence and environmental or other exposures. However, this statistical inference does not provide absolute proof of a direct cause and effect, although the combination of strong statistical association with biological plausibility offers strong evidence of causality. Epidemiological methods can quantify the probability that observed relationships occurred by "chance" factors. The methods employed can range from the study of recorded outbreaks of illness (i.e. seeking to infer the causes of morbidity from existing patterns of recorded individuals who are ill (and called "cases") and possible "controls" who are not ill), through to carefully designed studies in which volunteers are exposed to a hazard (such as faecally contaminated bathing water) and then followed up for a suitable period to investigate the incidence of illness. The type of study employed is dependent on:

- The objectives of the study, i.e. the required use of the data to be acquired.

- The nature of the exposure and illness under study.
- Available epidemiological and biostatistical expertise, together with economic constraints.

It is vital that these three elements are considered at the outset of any investigation. The first element, "objective(s) of the study", is perhaps the most important aspect because the available types of study discussed below each provide data with distinct potential uses. It is vital that the data produced by the more rudimentary epidemiological designs are not over-interpreted and that their limitations are understood clearly by the scientific and policy communities.

There have been a many epidemiological investigations for the health impacts of exposure to faecally polluted recreational waters reported in the scientific literature since 1953 (Table 13.1). These investigations fall into three main design categories described in the following subsections.

13.1.1 Retrospective case-control studies

Retrospective case-control studies are used to determine whether a particular personal characteristic or environmental factor is related to disease occurrence. Cases refer to persons who have a specific illness or disease. Controls, who do not have the illness or disease, are selected. The selection may seek to "match" for variables such as age and sex, or an unmatched design can be employed in which possible confounders are controlled during the analysis phase. Cases and controls are queried to determine if their exposure to environmental hazards have been similar. For example, cases of typhoid fever and their matched controls may be questioned about their past activity with respect to swimming events. The results of questioning may, for example, show that swimming activity is more likely to have occurred with typhoid cases than with controls, indicating a potential association between swimming and the disease. This type of study is most useful in disease outbreaks where a retrospective case-control study may be conducted to determine if certain activities or exposures were related to the disease or illness under investigation. This approach also may be useful in establishing the relationship between serious illness, such as hepatitis, and exposure to bathing waters. The advantage of conducting retrospective case-control studies is that they are not very costly and are reasonably easy to carry out. Their disadvantage is that, while the linkage between disease and exposure can be determined, it is seldom possible to determine the magnitude of the exposure.

Table 13.1 A summary of epidemiological studies

Country	Water body	Indicator	Symptom(s)	Reference
Australia	Sea	Faecal coliform Faecal streptococci	E/ENT/R	Corbett <i>et al.</i> , 1993
	Sea	Faecal coliform Faecal streptococci <i>C. perfringens</i>	GI/R/O	Harrington <i>et al.</i> , 1993
Canada	Fresh	Total staphylococci	R/GI	Lightfoot, 1989
	Fresh	Total staphylococci Faecal coliform Faecal streptococci	R/GI	Seyfried <i>et al.</i> , 1985a,b
Egypt	Sea	Enterococci <i>E. Coli</i>	GI	El Sharkawi and Hassan 1982
France	Fresh	Total conforms Faecal coliforms Faecal streptococci <i>Aeromonas spp.</i> <i>P. aeruginosa</i>	All + S S GI S S	Ferley <i>et al.</i> , 1989
	Sea	Faecal streptococci Total coliforms Faecal coliforms	E/S/GI	Foulon <i>et al.</i> , 1983
Hong Kong	Sea	<i>E. coli</i> <i>Klebsiella</i> Faecal streptococci Enterococci Staphylococci <i>P. aeruginosa</i> <i>Candida albicans</i> Total fungi	GI+S GI+S GI+S GI+S ENT GI+S O E+O	Cheung <i>et al.</i> , 1990
Israel	Sea	<i>S. aureus</i> Enterococci <i>E. coli</i> Total staphylococci <i>P. aeruginosa</i>	GI GI GI	Fattal <i>et al.</i> , 1991
	Sea	Enterococci <i>E. coli</i> <i>S. aureus</i> <i>P. aeruginosa</i>	GI	Fattal <i>et al.</i> , 1986
Netherlands	Fresh	<i>P. aeruginosa</i>	ENT	Asperen <i>et al.</i> , 1995
South Africa	Sea	Faecal coliform <i>E. coli</i> Faecal streptococci Total staphylococci	GI/R/S	Schirnding <i>et al.</i> , 1993
	Sea	Faecal coliform <i>E. coli</i> Faecal streptococci Total staphylococci	GI/R/S	Schirnding <i>et al.</i> , 1992
Spain	Sea	Faecal streptococci	S/E/ENT/GI	Mujeriego <i>et al.</i> , 1982

UK	Sea	Faecal streptococci Faecal coliform	E/S/ENT/R	Fleisher <i>et al.</i> , 1996
	Sea	Faecal streptococci	GI	Kay <i>et al.</i> , 1994
	Fresh	Total coliforms Faecal coliforms Faecal streptococci Total staphylococci <i>P. aeruginosa</i>	E/S/ENT/R	Fewtrell <i>et al.</i> , 1993
	Sea	Faecal streptococci	GI	Fleisher <i>et al.</i> , 1993
	Fresh	Total coliforms Faecal coliforms Faecal streptococci Total staphylococci <i>P. aeruginosa</i> Enterovirus	E/S/ENT/R	Fewtrell <i>et al.</i> , 1992
	Sea	Total coliforms Faecal coliforms Faecal streptococci Salmonella Enterovirus	ENT/GI/S/O	Alexander and Heaven, 1991
	Sea	Total coliform Faecal coliform Faecal streptococci	E/GI/ENT/R	Balarajan <i>et al.</i> , 1991
	Sea	Total coliforms Faecal coliforms Faecal streptococci	E/S/ENT/R	Jones <i>et al.</i> , 1991
	Sea	NR	GI	Brown <i>et al.</i> , 1987
	Sea	Total coliform	O	PHLS, 1958
USA	Fresh	Enterococci <i>E. coli</i>	GI	Dufour, 1984
	Sea	Enterococci	GI	Cabelli, 1983
	Both	Total coliform	ENT/GI/R	Stevenson, 1953

E Eye symptoms
 S Skin complaints
 GI Gastro-intestinal symptoms
 ENT Ear nose and throat symptoms
 R Respiratory illness
 O Other
 NR Not reported

13.1.2 Prospective cohort study

The second type of investigation is a prospective cohort study. In this study, individuals are recruited immediately before or, more commonly, after participation in some form of recreational water exposure. A control group is similarly recruited and both cohorts are followed up for a period of time. The exposure status of the bathers and non-bathers is self-selected and not randomised in this type of study. During the follow-up period, data are acquired on the symptoms experienced by the two cohorts using questionnaire interviews, either in person or by means of telephone inquiry. The quality of the recreational water environment is defined through environmental sampling on the day of exposure. The exposure data are often combined to produce a "daily mean" value for the full group of bathers using a particular water on any one day. Many days of exposure are required to define adequately the relationship between "exposure day" water quality and disease. Thus, data on "exposure" are available which can be related to "illness" outcome through an exposure-response curve predicting illness from indicator bacterial concentration. However, this approach will not provide a unique exposure measure (i.e. microbial indicator concentration) for each exposed individual and may lead to systematic misclassification bias. In addition, indicator organism counts are an indirect, and very often very inadequate, estimate of exposure to pathogens.

13.1.3 Randomised trials

A third approach, the randomised trial, is also a "prospective" study design but it differs from the cohort study outlined above in several respects. First, volunteers are recruited at the outset of the experiment. This group is generally interviewed prior to exposure, given medical examinations and then randomised into bather and non-bather groups. Both groups report to a test beach on a predetermined day. Typically, the bathers undertake a brief period of water exposure whilst the non-bathers remain on the beach. In well conducted studies, supervisors monitor each group and note the time and place of exposure undertaken by each bather. Both groups may also be given similar food, in the form of a packed lunch, and may undertake an identical short interview on the study day. Typically, volunteers report for a post-exposure interview and medical examination a week after exposure and complete a further postal questionnaire to examine any illnesses with longer incubation periods. During the exposure period, samples should be acquired from the bathing area in sufficient number to characterise fully water quality at the time and place of exposure for each bather, so that exposure can be assigned to each individual based on the time and place of exposure.

13.2 Major studies

13.2.1 UK Public Health Laboratory Service retrospective studies

The most widely quoted example of a retrospective case-control study was completed by the UK Public Health Laboratory Service between 1953 and 1958 (PHLS, 1959). This study was designed to identify any link between bathing in sewage-polluted waters and cases of poliomyelitis or enteric fever (paratyphoid). All cases of these two notifiable illnesses reported in seaside District Council areas were used in the study. Controls (matched for age and sex and selected, where possible, from the same street) were also identified. The availability of water quality records for the beaches used by the identified "cases" was also investigated, but microbiological information was rarely available for

the appropriate times and locations of the exposure event(s). All cases and controls were interviewed by local medical staff to determine their bathing history. The authors concluded that there was no evidence linking the incidence of poliomyelitis and a history of sea bathing.

Role of retrospective case control studies

Although the retrospective design is not useful for developing exposure-response relationships, it is appropriate for linking illnesses to environmental exposures.

13.2.2 US Environmental Protection Agency prospective studies

The United States Environmental Protection Agency (US EPA) conducted a series of retrospective studies in the mid-1970s (Cabelli, 1983). At the time, these studies were the most extensive and carefully conducted prospective epidemiological investigations ever attempted. The main elements of the design are described briefly below.

Trials were conducted on Saturdays and Sundays, i.e. weekend-only bathers and non-bathing beachgoers were recruited in the hope of avoiding the multiple exposure problem. Demographic data were acquired during the initial beach interview and during a subsequent telephone interview. Bathing activity was recorded during the initial beach interview; bathers were defined as those who had experienced full head immersion, thus risking ingestion of water via the nasal and oral orifices. Wet hair at the time of recruitment was used as an indicator of head immersion and defined the exposure status of the participant.

The recruitment of study participants targeted family groups that included non-bathing controls. A letter was posted 1-2 days after the beach contact to remind all participating families that they should be recording all illness. At 8-10 days after recruitment the respondents for each family group were contacted by telephone to record any symptoms that had developed since the day they were at the beach.

Only gastro-intestinal (GI) symptoms were considered to be related to both swimming and pollution and the water quality indicators chosen. A subgroup of highly credible gastro-intestinal (HCGI) symptoms was defined as vomiting, diarrhoea accompanied by fever or which was disabling, or nausea and/or stomach ache accompanied by fever.

A range of bacterial indicators was used to characterise water quality at different locations, namely 11 indicators at New York City beaches, 5 at Lake Pontchartrain and 2 in Boston. Water quality was measured at times of maximum swimming activity, with 3-4 samples collected from 2-3 sites at chest depth, 12 inches below the surface of the water. This sampling design was used to characterise water quality for each test day. The geometric mean of these samples was used as the exposure estimate for all bathers on that day.

A rate difference between the bather and non-bather groups was used to quantify the swimming-associated morbidity rate for any particular symptom. Each trial day was associated with a specific water quality and an attack rate. However, individual trial days were not used as the raw data of subsequent analyses because the non-bathing control group for each day was of insufficient size. Analyses, therefore, was performed on water

quality data gathered by summer and beach, or data from beach trial days that formed natural clusters of similar indicator densities.

Bivariate log-linear least squares regression was used to define the relationship between the seasonal swimming associated rate for GI symptoms (i.e. the rate difference between bathers and non-bathers) and water quality (as \log_{10} geometric mean faecal indicator concentration). Cabelli (1983) reported statistically significant relationships between enterococcus density and swimming associated GI symptoms (GI $r^2 = 74\%$; HCGI $r^2 = 52\%$ i.e. 52 per cent of the variance in HCGI symptom reporting was explained by the predictor variable enterococcus density). These relationships have been used to quantify the risk implied by the previous (NTAC, 1968) standards leading to the formulation of the most recent US Federal standard systems (US EPA, 1986).

Role of non-randomised prospective approach

Precise measurement of water quality at the time of exposure for each swimmer is not possible. The advantages of the non-randomised prospective approach include:

- Selection of participants after voluntary swimming activity allows a broad range of swimmers to be studied.
- Swimming-associated illness is expressed in terms of exposed populations rather than the probability of individual infection. Under some circumstances this approach may be meaningful from a public health perspective.

13.2.3 UK prospective randomised trial studies

The randomised trial involved recruitment of healthy adult volunteers at seaside towns with adjacent beaches that had traditionally passed EC Imperative Standards (Jones *et al.*, 1991; Kay *et al.*, 1994). After initial interviews and medical checks, volunteers reported to the specified bathing location on the trial day where they were randomised into bather and non-bather groups.

Bathers entered the water at specified locations where intensive water quality monitoring was taking place under the supervision of a marshall who recorded their activities. All bathers immersed their heads on three occasions. On exiting the water bathers were asked if they had swallowed water. The locations and times of exposure were known for each bather and, thus, a more precise estimate of "exposure" (i.e. indicator bacterial concentration) could be assigned to each bather (Fleisher *et al.*, 1993; Kay *et al.*, 1994). A control group of non-bathers came to the beach and had a picnic of identical type to that provided for all volunteers. One week after exposure all volunteers returned for further interviews and medical examinations and later they completed a final postal questionnaire, three weeks after exposure.

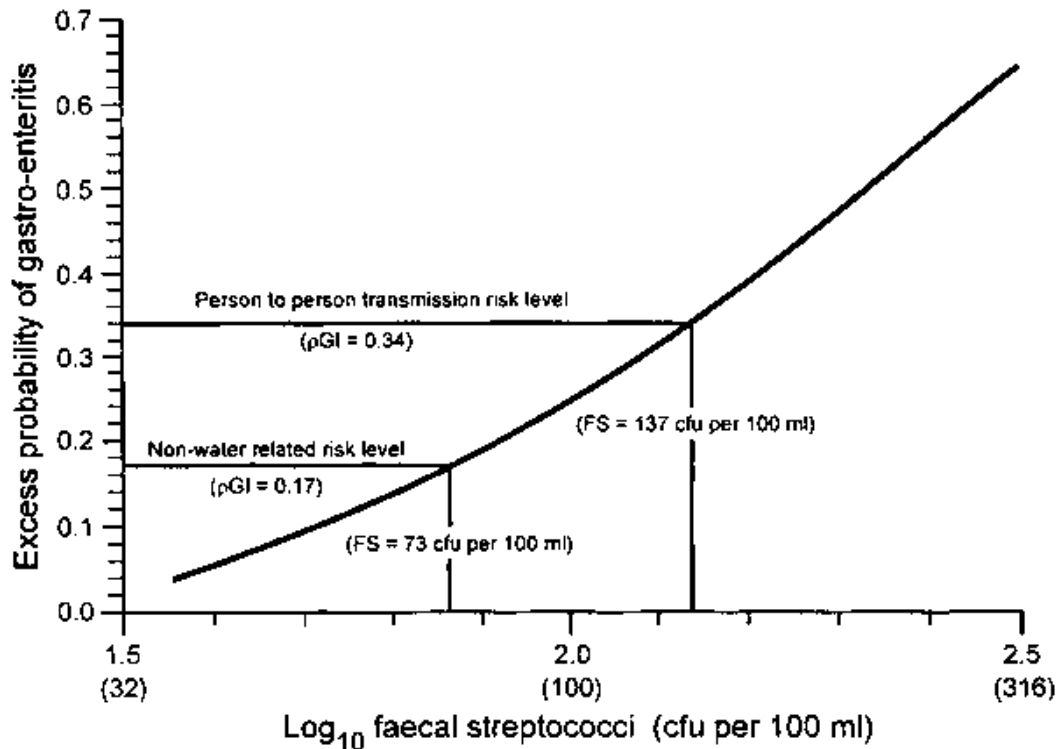
Detailed water quality measurements were completed at marked locations that defined "swim zones". Samples were collected synchronously at locations 20 m apart every 30 minutes and at three depths (i.e. surf zone, 1 m depth and at chest depth, 1.3-1.4 m). In the case of the latter two sampling depths, samples were collected at approximately 30 cm below the surface of the water. Five bacterial indicators were enumerated. Faecal coliforms and faecal streptococci were analysed using triplicate filtrations for each of

three dilutions (i.e. nine plates per bacterial enumeration) to narrow the confidence limits on enumeration of total coliforms. Total staphylococci and *Pseudomonas aeruginosa* were also enumerated.

The initial analysis of the data from the UK randomised trial experiments centred on the links between water quality and gastro-enteritis (see Fleisher *et al.*, 1993 and Kay *et al.*, 1994). The data were analysed for relationships between water quality, as indexed by any of the five bacterial indicators measured at any of the three depths (i.e. 15 potential predictor variables) and gastro-enteritis. Only faecal streptococci, measured at chest depth, provided a statistically significant relationship between water quality and the risk of gastro-enteritis. This result was replicated at three of the four sites examined and at the fourth site concentrations of faecal streptococci were generally below the threshold level at which an effect was observed at the other three locations. No site specific differences were observed in terms of the exposure response curve. The relationship between faecal streptococci concentrations in recreational waters and the excess probability of gastro-enteritis in the exposed population is shown in Figure 13.1. This trend was not apparent with any other bacterial indicator enumerated and the volunteers reporting symptoms (or the research team) could not have known the concentrations of faecal streptococci to which each bather was exposed.

Multiple logistic regression analyses also allowed for the assessment of the effects of concomitant factors (i.e. other predictors of GI symptoms) on the relationship between water quality and illness. The analysis showed that other factors were significant predictors of GI illness. These included non-water-related risk (NWR) factors such as certain food types (see Table 13.2) and person-to-person transmission (PPT) from sick household members. These factors were independent of, and did not confound, the relationship between water quality and gastro-enteritis and can therefore provide markers against which the risk of GI illness from sewage contaminated sea water can be measured (see Figure 13.1). For example, exposure to NWR related risk factors in Table 13.2 represents a risk equivalent to a faecal streptococci concentration of approximately 70 organisms per 100 ml, whereas sharing a household with a person exhibiting GI symptoms represents an equivalent risk to a single exposure to recreational water containing approximately 140 faecal streptococci per 100 ml.

Figure 13.1 The dose response curve linking faecal streptococci with excess probability of gastro-enteritis



This UK study, therefore, provides two sources of information. It presents an exposure-response relationship that defines the risk attributable to different levels of faecal streptococci exposure and, it quantifies the risk of other commonly experienced risks in society. As a result it provides scope for a system of risk-based standards.

These trials have also examined the relationships between non-enteric illnesses and exposure to sea water. Significant exposure-response relationships have been reported between acute febrile respiratory illnesses and faecal streptococci concentrations and between ear infections and faecal coliform concentrations. In addition, eye ailments were elevated in the bather group but unrelated to faecal indicator concentrations in the water (Fleisher *et al.*, 1996). Standard systems, to date, have centred on gastro-enteritis as the main outcome. However, as more evidence mounts on these non-enteric illnesses it may be prudent to consider their inclusion into future standard systems incorporating the concept of total disease burden through the use of Disability Adjusted Life Years (DALYs) or other means of cross-comparison between illnesses.

Table 13.2 Non-water-related risk factors for gastro-enteritis

Age (grouped by 10-year intervals)

Gender

History of migraine headaches

History of stress or anxiety

Frequency of diarrhoea (often, sometimes, rarely or never)

Current use of prescription drugs

Illnesses within 4 weeks prior to the trial day lasting more than 24 hours

Use of prescription drugs within 4 weeks prior to the trial day

Consumption of any of the following foods in the period from 3 days prior to 7 days after the trial day: mayonnaise, purchased sandwiches, chicken, eggs, hamburgers, hot dogs, raw milk, cold meat pies or seafood

Illness in the household within 3 weeks after the trial day

Alcohol consumption within the 7-day period after the trial

Frequency of usual alcohol consumption

Taking of laxatives within 4 weeks of the trial day

Taking of other stomach remedies within 4 weeks of the trial day

Additional bathing within 3 days prior and 3 weeks after the trial day¹

¹ This was included in order to control for possible confounding due to multiple exposures among bathers and exposure among non-bathers prior to or after the trial day

Limitations of the randomised study protocol

The scope of UK randomised trial protocol is limited and should not be over-interpreted. The limitations include the fact that the studies were conducted in north European marine waters with a high tidal range where all waters commonly passed EU Imperative coliform criteria and the US EPA enterococci criteria. It may not be as applicable, however, in the standards design process for Mediterranean bathing waters where solar radiation is more intense, turbidity is lower and tidal activity is limited. Similar comments could be made concerning the application of these results to freshwater environments.

Furthermore, the results apply only to healthy adult volunteers, and may not be applicable directly to infants or chronically sick people. This is of particular relevance in the consideration of sampling depth. Adult chest depth predicted gastro-enteritis in adult bathers, but the UK operational sampling depth of 1 m (or less) might be more appropriate for child bathers. Another limitation is that the results may not be applicable to special interest groups such as surfers, sail-boarders and other high exposure activities that may involve prolonged contact with the water (often at some distance from the beach).

Role of the randomised prospective design

Randomisation of the exposed (bather) and non-exposed (non-bather) groups removes the problem of self-selection bias that is always potentially present where the exposure status is self-selected. More precise definition of water quality to which each bather was exposed (ideally through measurements taken at the place and time of exposure) provides better definition of the exposure for each bather. The multiple interviews

facilitate data acquisition on a broad range of potential risk factors for the illness outcomes and allow accurate case definitions to be made.

13.3 Choice of study design

The primary criteria to be considered in the choice of an appropriate epidemiological study protocol are the objectives of the study and the validity of the findings, both of which determine the use to which the data acquired can be put. A secondary consideration is the scientific capacity and resource availability of the society in which the study is to be conducted. If, for example, the primary objective is to define an exposure-response relationship with maximum precision, then the randomised trial provides the most appropriate protocol. Its suitability derives from its tight control and relatively precise measurement of exposure (i.e. the water quality experienced by each bather) and the extensive data acquired on NWR risk factors. However, there are circumstances, even in affluent developed nations, where the implementation of the randomised trial is not feasible. For example, epidemiological investigations conducted to investigate the health implications of water sports activities, such as white water canoeing, would find a randomised design almost impossible to apply. It would clearly be inappropriate (and irresponsible) to expect a cohort of volunteers recruited from the general public to participate in a potentially dangerous activity for which they would not be skilled. Furthermore, randomisation of existing water sports participants would imply that the non-exposed group would agree willingly not to participate in their sport for a given period. In such circumstances an improved prospective cohort design (Cabelli, 1983) is the most appropriate. The application of this protocol to special interest groups of water sports enthusiasts in marine and fresh waters has been reported by Fewtrell *et al.* (1992, 1993, 1994).

Other circumstances may limit the application of the randomised design; for example, ethical constraints can preclude the inclusion of young people in the volunteer group. This was true for the UK studies but it was not found to be a problem in the randomised trial pilot investigation conducted in the Netherlands during 1996 (van Asperen *et al.*, 1997). The Netherlands randomised trial involved a volunteer group of children with no ethical constraints and studied their exposure to fresh recreational waters. Clearly, the identification and resolution of any potential ethical problems are an important preliminary step in the application of a randomised design.

Where a non-randomised prospective protocol design is applied, i.e. the activity status of the participants is not determined by the researcher, a number of points should be noted. The measure of exposure (i.e. water quality) should, as far as possible, be attributed to small groups of exposed individuals. In effect, daily mean values applied to large groups exposed on one day will mask variability in indicator concentration and underestimate the numbers exposed to high indicator concentration. If the misclassification is random, it will tend to underestimate the slope of the dose-response curve through systematic misclassification bias. Attributing an exposure level to as small a group as possible requires intensive spatial and temporal water quality sampling.

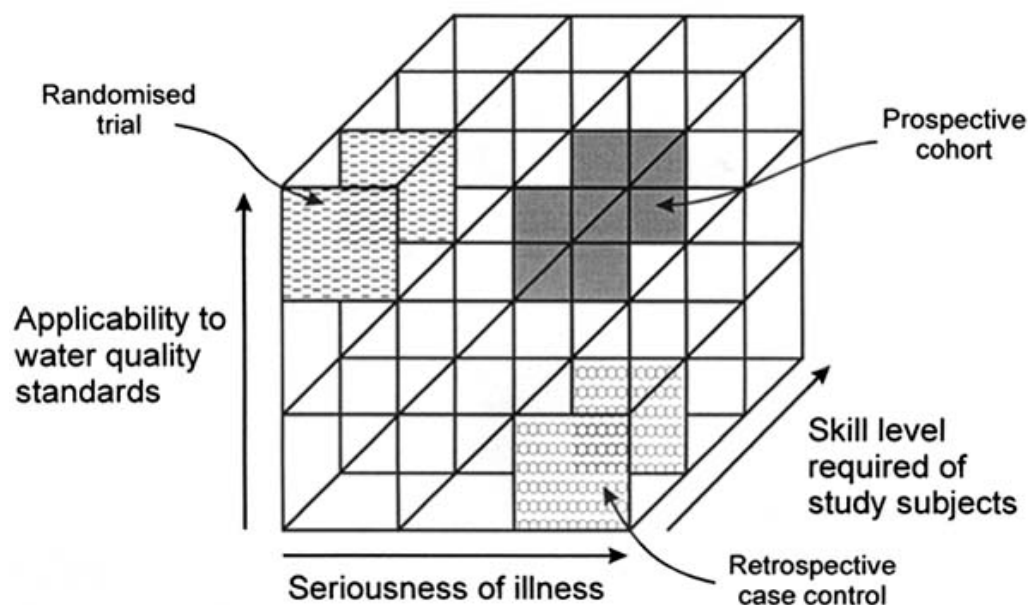
Similarly, such studies should seek to acquire extensive data on NWR risk (and other potential confounding) factors. This might imply recruitment and follow-up interviews of considerable length with well-trained specialist health professionals conducting the data acquisition exercise. As with all epidemiological investigations, tight statistical control

and early inputs to protocol design are essential to ensure that the information derived from the data acquired is maximised.

Through appropriate logistic regression analysis, the non-randomised prospective design can produce exposure-response relationships with information on NWR risk factors. However, such relationships should be treated with caution in standards design because of the possibility of misclassification bias and the potential underestimation of effect. Thus, if data on special interest groups or watersports activities are required, then a non-randomised prospective design may be appropriate, provided that any exposure-response relationships are treated with caution in their application to standards design of the type outlined in the *Guidelines for Safe Recreational Water Environments: Coastal and Fresh Waters* (WHO, 1998).

The retrospective case control design is clearly the only possible outbreak investigation tool and it does provide a means for establishing a link between specific pathogens and water exposure. It can provide guidance on maximum acceptable concentrations of pollution in recreational waters, provided that exposure data are available, but it is not designed to produce a credible dose-response curve of the type required in health-based standards design.

Figure 13.2 Choice of epidemiological protocols in recreational water epidemiology



In summary, the choice of epidemiological protocol design will be driven by the study objectives: i.e. the requirements of risk managers for precise exposure-response relationships, as well as logistical and ethical constraints on project implementation and the resources available. Figure 13.2 illustrates these choices in three dimensions as a guide to appropriate choice of epidemiological protocols in recreational water epidemiology.

13.4 Elements of good practice

- The design of any epidemiological component is critical because it affects every aspect of the recreational water study. It should address why the study is being done, i.e. what is the objective, and how it will be conducted. For example, it should address whether the research will use a case-control, cohort or cross-sectional approach to collect the data. It should also consider how the data will be analysed. These elements should be thoroughly described in the description of the design of the study.
- Health outcomes and exposure should be clearly defined. The endpoint result of exposure to microbiological hazards, as well as the exposure itself are key factors in describing the results of epidemiological studies. The endpoint might be self-reported symptomatology, indicative of exposure to a potentially broad spectrum of pathogens or it may be more specific, as with the isolation of an etiological agent or the reactivity of subject sera to known antigens. Efforts should be made to make the response to exposure endpoint as specific as possible.
- The population to be studied should be well defined in terms of the participating individuals. This will include demographic information, the means of selecting the population sample and the nature of exclusions, e.g. pregnant women or individuals being treated with steroids or immunosuppressive agents.
- The numerical size of exposed and non-exposed groups is another critical factor that must be considered in the conduct of epidemiological studies. The sizes of these groups are governed by the frequency of occurrence of the health effect under study. Illnesses or infections that occur at higher frequencies require smaller groups. The size of the required populations is also affected by the magnitude of the differences in the frequency of illness or infections between exposed and non-exposed groups. The smaller the differences to be detected between exposed and non-exposed groups the larger the number of subjects required in each group. Expert advice should be sought with regard to population size before conducting an epidemiological study.
- The approaches for collecting exposure and health effects data should be described in detail. This includes the use of questionnaires and other sources of health data, as well as methods used for collecting exposure data, such as microbiological analytical methods for enumerating microorganisms in water.
- Data analysis should include the steps taken to control selection, misclassification and confounding bias. The statistical evaluation procedures should be fully described.
- All of the measures taken to ensure the quality of the data should be described including the technical qualifications of all scientists participating in the study.
- The study plan should be submitted to a Human Investigations Committee, or its equivalent, to ensure that any regulatory limitations regarding human studies will be met, especially confidentiality restrictions and informed consent procedures.

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