Health Effects of Sea Bathing (WMI 9021) - Phase III

Final Report to the Department of the Environment

DoE 3412/2
JANUARY 1994

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Report No: DoE 3412/2

January 1994

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Contract Manager: E B Pike

Contract No: WMI 9021

DoE Reference No: PECD 7/7/377

Contract Duration: 1 April 1991 to 31 January 1994

This report has the following distribution:

DoE Nominated Officer - 100 copies

The work covered in this report was co-funded by the Departments of the Environment and of Health, the Welsh Office and the National Rivers Authority.

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PREFACE

In 1984 in its 10th Report, the Royal Commission on Environmental Pollution expressed widespread concern about pollution of bathing beaches by sewage and noted that, although the risks of contracting serious illness from bathing in such water appeared to be very small, the same could not be said of milder intestinal complaints such as 'travellers' diarrhoea'. It recommended that epidemiological studies should be carried out to establish the risks under UK conditions. There has also been concern that the microbiological standards of the bathing water Directive 76/160/EEC, were not based upon an assessment of risks. More recently, under the Water Resources Act 1991, the Secretary of State is empowered to impose statutory water quality objectives and the National Rivers Authority (NRA) to enforce them. The NRA has recently proposed that contact recreation should be recognised as a use class for controlled waters and that microbiological standards could be appropriate.

Since June 1989, WRc has been awarded by the Department of the Environment three successive contracts to investigate the Health Effects of Sea Bathing. These have been co-funded by the Department of Health, the Welsh Office and NRA (under their programme No. 228, Bathing Water Epidemiology). The present contract, was awarded from 1 April 1991 to 31 October 1993 (Reference PECD 7/7/377) to enable definitive studies to be conducted at a total of ten beaches in the summers of 1991 and 1992.

The report details the work undertaken under all three contracts, but particularly in Phase III and assesses the total knowledge obtained in the four years of the studies. It is believed that the complete study is one of the largest and certainly the most comprehensive in scope yet to be undertaken.

SUMMARY

This is the final report of the UK national study into the health effects of sea bathing. Two methods, tested and validated in pilot studies carried out in the summer of 1989, were used to establish the relationships, if any, between microbiological quality of coastal water and the risks to health of bathers. Research of this kind was recommended by the Royal Commission on Environmental Pollution in their 10th Report (1984) and commended by the House of Commons Select Committee on the Environment. It is relevant for the establishment of statutory water quality objectives for recreation by the Secretary of State, as proposed by the National Rivers Authority. The microbiological criteria of the bathing water Directive 76/160/EEC are not based on assessment of risk, for which this research will provide data.

Studies involving 16 569 holidaymakers and 1112 adult volunteers were carried out at ten and four beaches respectively, using two complementary methods - a survey to determine symptoms reported by holidaymakers participating in various beach activities at beaches differing widely in water quality and a controlled study using healthy adult volunteers divided into bathers and non-bathers, whose health is ascertained by detailed questionnaire, medical interviews and clinical examination. This is the most comprehensive study into health effects of sea bathing carried out to date.

Holidaymakers entering the sea perceived all symptoms more frequently than those who did not. These relative increases were related to degree of water contact and age, being greatest in surfers and divers and in 15-24 year-olds. Relative increases in frequencies of eye, ear nose and throat, respiratory and skin symptoms were not related to microbiological quality of the water. Relative increases in diarrhoea in those entering the water were related to mean counts of total coliform bacteria and enteroviruses. In the volunteer study, the incidence in bathers of symptoms suggesting gastro-enteritis was related to counts of faecal streptococci at chest depth. Other, effects, not related to bathing, were detected, such as sex, age, eating prepared foods and gastro-enteritis in the bather's household. These were comparable in the size of their effect to water quality upon the perception of symptoms by bathers.

Overall, the conclusions from both types of study are in agreement with the results of earlier major studies of the effects of water quality on health of bathers, thereby adding to their plausibility and the likelihood that true causal relationships exist. However, the adult volunteer studies did not demonstrate a relationship between recording of symptoms and the results of clinical examinations, or between bathing and subjects seeking medical advice or losing days of normal activity. The effects observed can be regarded as symptomatic or perceived, rather than of overt illness.

Recommendations are made for extracting further information from the data sets and for using the findings in risk analysis and development of microbial standards for marine recreation. Both methods have been reported to WHO/UNEP and recognised.

The work covered in this report was co-funded by the Departments of the Environment and Health, the Welsh Office and the National Rivers Authority.

ACKNOWLEDGEMENTS

The overall direction of the Phase III studies, was advised by the Department of Environment's Working Group on the Possible Health Risks of Bathing in Water Contaminated by Sewage. More immediate conduct of the studies was led by a Steering Committee, chaired by WRc, which contained representatives from the funding agencies - the Departments of the Environment and of Health, the Welsh Office and the National Rivers Authority - and from the subcontractors - the Institute of Public Health (IPH), University of Surrey and the Centre for Research into Environment and Health (CREH), St David's University College, Lampeter.

The Department of the Environment's Nominated Officer for the master contract, Health Effects of Sea Bathing - Phase III (Reference Nº PECD 7/7/377) was Dr Elizabeth McIntosh. The Department's Project Officer was Mr H Jones, with whom day-to-day contact was maintained. The Author also acknowledges advice given by the representative of the Department of Health, Dr Ann Dawson and of the Welsh Office, Mr J E Saunders (now retired) and Dr H J Prosser. Mr D Lowthion of the National Rivers Authority, Southern Region, acted as Project Officer for the NRA contract, Bathing Water Epidemiology (Reference Nº A11.1) and provided much local information on the beaches and on their choice.

The Beach Survey studies were conducted by a team directed by Professor R Balarajan (IPH). Dr G Rees, Farnborough College of Technology was retained as microbiological consultant.

The Cohort Study was directed by Professor D Kay and Professor F Jones of CREH. Epidemiological advice was provided by Dr R Salmon of the Communicable Disease Surveillance Centre, Welsh Unit, Public Health Laboratory Service and Professor J M Fleisher, State University, New York, was retained for statistical advice.

Permission for carrying out the Beach Survey studies was given by the relevant committees of the District Councils as shown below. The assistance of the officers of these Councils, shown in parentheses, is gratefully acknowledged.

Paignton - Borough of Torbay (Mr R Bowles, Environmental Health Officer; Mr R J Sweet, Director of Arts and Recreation).

Lyme Regis - West Dorset District Council (Mr D D Derrien, Director of Planning and Environmental Services).

Rhyl - Borough of Rhuddlan (Mr D T Owen, Borough Health Officer/Housing Manager)

Morecambe - Lancaster City Council (Mr G Shaw, Director of Environmental and Public Services).

Cleethorpes - Borough of Cleethorpes (Mr C J Kitt, Director of Health and Housing)

Skegness - East Lindsey District Council (Mr D O'Neill, Directory of Community and Housing Services).

Instow - North Devon District Council (Mr M A Tighe, Assistant Director of Services - Environmental Health Division)

Westward Ho - Torridge District Council (Miss G Bowering, Director of Housing and Environmental Health)

Permission was also sought by WRc and obtained, in principle, for studies at Hayling Island, Hants (Havant District Council), Newquay - Towans Beach, Cornwall (Restormel Borough Council) and at St Ives -Porthgwidden Beach, Cornwall (Penwith District Council). WRc wishes to thank these Councils and their officers for their consideration, even though it was decided not to proceed, because of logistic and sampling difficulties. WRc also wishes to thank the Borough of Eastbourne for an unsolicited offer to base studies at Eastbourne in 1992.

Details of the Beach Survey studies were notified in advance to the respective District Health Authorities.

Permission for carrying out the Cohort Study at Southsea was given by the City of Portsmouth's Environmental Health and Improvements Subcommittee, Chairman - Councillor A M Bentley. Much practical assistance was given by Councillor Bentley, and by Mr A M Higgins, Chief Environmental Health Officer, Mr J Briggs, Resort Manager and Ms Alison Rawlings, Assistant Communications Executive.

Permission for carrying out the Cohort Study at Southend-on-Sea was given by the Borough of Southend-on-Sea's Community Services Committee (Chair, Councillor Mrs J A Carlile). Much practical assistance was given by Mr L Barker (Director of Community Services), Mr D Moulson (Town Clerk) and Mr M G Pressling (Marketing Director).

Full details of the two Cohort Studies, with experimental protocols and interview instruments were submitted to Portsmouth and Southend District Health Authorities for local ethical clearance.

The Author acknowledges the statistical advice given by his colleague, Mr R F Lacey.

Relations with the press, radio and television and the issue of two press briefing notes were managed by Mr R I Odell, WRc Corporate Relations, assisted by Mrs S E Smith and Miss P Adams, in liaison with the Department of the Environment's Press Office, and the Author.

Full acknowledgements for assistance during Phases I and II have already been given in the respective final reports (Pike 1990, 1991).

1. BACKGROUND TO THE PROJECT

1.1 Sea bathing and health-development of UK policies

Although unquantified, the beneficial effects of seaside holidays and use of coastal waters for bathing and other forms of recreation are well known. Furthermore, tourism and industries supporting it are a major source of income of coastal towns. However, because the United Kingdom is a maritime nation, a significant proportion of waste water is disposed to the sea and there are about 200 discharges, serving 12.5 million people.

For many years, there has been discussion over the health risks to bathers from discharges of sewage into the sea. The first major study in the United Kingdom was that of the Committee on Bathing Beach Contamination of the Public Health Laboratory Service (PHLS 1959, Medical Research Council 1959), which considered two major diseases, enteric fever (typhoid and paratyphoid fever) and paralytic poliomyelitis. Careful epidemiology, with the methods available at the time, showed that enteric fever was not associated with coastal regions, that some cases at resorts were wrongly ascribed to bathing and that, in the few cases unequivocally linked with bathing, water had been grossly polluted. There was no significant association between bathing history and poliomyelitis.

The PHLS Committee concluded that the risks to health of serious illness from bathing in sewage-contaminated water were negligible, that chance cases probably arose from contact with intact, infected, faecal material and that public health requirements would be reasonably met by improving grossly unsanitary beaches and by preventing, as far as possible, pollution of beaches with undisintegrated matter during the bathing season.

The PHLS Committee could find no logical basis for setting microbiological standards for coastal water, for two reasons:

1. Considerable differences in dispersion of bacterial counts at individual beaches, as well as of mean counts between beaches, made comparison difficult.

2. Epidemiological information at the time (e.g. those of the US Public Health Service, Stevenson 1953) was inconclusive and current standards in other countries could not be justified epidemiologically.

The recommendations of the PHLS Committee influenced United Kingdom policy subsequently. Discharge of sewage by properly designed long sea outfall was encouraged by the Working Party on Sewage Disposal (1970) and by the Royal Commission on Environmental Pollution (1984) in its Tenth Report. However, the Royal Commission noted widespread concern about pollution of beaches and discharge of untreated or partly treated sewage. It particularly noted that, although the risk of contracting serious illness appeared to be very small, this could not be said of milder intestinal complaints, such as 'travellers' diarrhoea'. Controlled epidemiological studies had meanwhile been carried out by the United States Environmental Protection Agency (USEPA) in marine (Cabelli 1983) and fresh water (Dufour 1984) and showed positive relationships between bacteriological quality of the water and the swimming-associated risks of reporting gastro-intestinal symptoms, including those highly suggestive of viral gastroenteritis (highly credible gastro-intestinal symptoms). The Royal Commission indicated the need for epidemiological studies to be carried out in the United Kingdom, but recognised that there would be major problems in designing adequate studies. It also recognised that, in many cases, discharge of coastal sewage to the sea through well designed long sea outfalls, was the best practicable environmental option.

Another significant development has been the implementation of the EC bathing water Directive 76/160/EEC, particularly the extension of the scope of microbiological monitoring to include large numbers of identified beaches (414 in England and Wales in 1991), which are sampled weekly on at least 20 occasions throughout the bathing season and extension of monitoring for enteroviruses and salmonella to include all identified beaches twice per season. This has served to identify those beaches where improvements in discharge arrangements are needed to achieve compliance and has provided the public with information on quality, either through notice boards at the beaches or through reports compiled by the National Rivers Authority (NRA 1991a) and consumer organisations (e.g. Marine Conservation Society 1993).

The urban wastewater treatment Directive, 91/271/EEC will require all significant discharges of sewage, including those to the sea, to be given at least primary treatment.

The following responses to these developments have taken place since 1985:

1. In 1985, the UK water industry embarked on a major programme of construction of sewage works and sea outfalls, to be completed in 2000.

2. The announcement of a £1.4 billion, ten-year programme to improve identified bathing waters to meet the standards of the Directive 76/160/EEC.

3. The first phase of a £1.5 billion investment programme to treat sewage discharges to coastal waters.

4. The announcement by the Minister of State for the Countryside and Environment, on 17 May 1989, that WRc had been contracted to carry out a pilot study in 1989 to assess the risk of contracting illnesses from sea bathing.

5. The requirement, under the Water Act 1989, Section 105, consolidated in the Water Resources Act 1991, for the Secretary of State to draw up and the National Rivers Authority to implement a scheme of statutory water quality objectives (SWQOs) for all controlled waters (including coastal waters).

The National Rivers Authority (1991b) has submitted a discussion document to the Secretary of State concerning the form which SWQOs might take. One of the use categories defined is 'contact recreation', for which microbiological standards, including the bathing water Directive 76/160/EEC, might be appropriate.

In general, UK policies have been guided in the belief that the public health needs of coastal recreation are best served by a steady improvement in arrangements for treating and discharging coastal sewage. A review article (Pike 1993) has compared these policies with those which have applied in North America and Europe.

1.2 Previous epidemiological studies

1.2.1 The needs of epidemiology

One of the objectives of the work carried out by WRc under the two previous contracts (Phase I Pilot Study, 1989/90 and Phase II, 1990/91) was to review extensively past epidemiological and case history studies, in order to put the results obtained in context. Readers are referred to the two Final Reports (Pike 1990, 1991) for full details.

The difficulties of carrying out epidemiological research on health effects of bathing in sewage-contaminated waters were referred to by the Royal Commission on Environmental Pollution (1984). In general, they are as follows:

1. The need to control for confounding factors e.g. food and drink intake, spread of infection by personal contact, influences of age, sex, socio-economic factors.

2. The need for adequately-sized exposed and control groups in order that results can be expressed within a suitably-sized target level of statistical significance. Because probabilities are usually low, very large groups of subjects have to be recruited.

3. The need to define the illness. Because the viral agents thought to be responsible for the more minor complaints reported are not normally isolatable from clinical samples, reliance has to be made on reporting of symptoms.

4. The need to define exposure to the hazard, i.e. pathogens in sewage-contaminated water. Since the agents are not known or not identifiable directly, analysis must be made of faecal indicator bacteria in the water, since these indicate the presence of faeces and thus the possibility that enteric pathogens may be present. No constancy of correlation exists between numbers of pathogens and indicators.

5. Since numbers of indicator bacteria vary greatly with time at single places on a beach and along a beach, there are problems of relating individual bathers to quality of water to which they were exposed.

6. The need to relate to intensity and duration of contact with water, on the grounds that risk is increased with increased contact.

7. The need to comply with ethical requirements of medical research.

8. Information must be collected in an unbiased way. Where self-reporting of symptoms is used, external suggestibilities of subjects' perception e.g. by publicity and reports by the news media must be minimised or controlled.

9. The need to distinguish between real and spurious associations when attempting to draw conclusions about cause and effect. Nine criteria (Table 1.1) were proposed by Bradford Hill (1965) for use in assessing the likelihood of causality between environmental exposure and disease and those have been used in assessing the significance of published research into sea bathing and health (Pike 1990, 1991).

1.2.2 Previous studies already reviewed

The review sections of the two Final Reports on Phases I and II (Pike 1990, 1991) have shown that a great deal of epidemiology and case history of illness and symptomatology of bathing has been published. This will only be summarised here.

Case histories have shown that outbreaks of the following more serious illnesses have resulted from bathing in severely contaminated waters:

1. Typhoid and paratyphoid fevers (Medical Research Council 1959, PHLS 1959, Galbraith *et al* 1987, Harvey and Price 1981).
2. Shigellosis (Rosenberg *et al* 1976).
3. Infectious hepatitis (Bryan *et al* 1974).
4. Norwalk virus - headache, fever, myalgia (Baron *et al* 1982).
5. Adenovirus type 4 - pharyngo-conjunctival fever (D'Angelo *et al* 1979).
6. Enterovirus-like illness (D'Alessio *et al.* 1981).
7. Primary amoebic meningo-encephalitis - *Naegleria fowleri* (Galbraith *et al* 1987).
8. Leptospirosis (Waitkins 1986, Ferguson 1990).
9. Cryptosporidiosis (Gallagher *et al* 1989).
10. Cyanobacterial toxicoses (NRA 1990, Turner *et al* 1990).
11. Outer ear canal inflammation (*Otitis externa*) (Calderon and Mood 1982).
12. Swimmers' itch - cercariae of certain schistosomes, liberated by pond snails, attack the skin (Eastcott 1988).

Table 1.1 Criteria to be used in assessing causality between environmental exposure and disease (Bradford Hill 1965)

Criterion	Explanation
1. Strength of association	Difference in rates of illness between exposed and non-exposed groups, measured as a ratio.
2. Consistency	Has it been observed by different people at different places and times?
3. Specificity of association	A particular type of exposure is linked with a particular site of infection or a particular disease.
4. Temporality	A 'cart and horse' problem - does the exposure precede the disease rather than following it?
5. Biological gradient	A dose-response curve can be detected. The more severe the exposure, the greater is the incidence of disease.
6. Plausibility	Does the relationship seem likely in terms of present knowledge? But present knowledge may change.
7. Coherence	The cause and effect interpretation of the data should not conflict with what is known about the biology of the disease.
8. Experiment	Because of an observed association, some action is taken. Is the frequency reduced? If so, this is strong evidence for causation.
9. Analogy	If one agent is shown to cause disease, it would be reasonable to expect it of a related agent.

A consideration of the reservoirs and mode of spread of those infections will show that not all are associated with sewage-polluted waters (Cartwright 1992). For example, *Naegleria fowleri* is able to multiply in hot springs and infects by inhalation. Leptospires are passed with the urine of infected aquatic rodents and infect man through cuts and abraded skin. The schistosomes responsible for swimmers' itch are liberated by the secondary host, aquatic snails in warm, weed-infested pools harbouring snails. The toxins liberated by blooms of certain cyanobacteria ('blue-green algae') affect by skin contact and by swallowing water. None of these three examples has occurred in sea water or is directly related to faecal pollution, and incidents are not related to high counts of faecal bacteria. *Otitis externa* is caused by opportunistically pathogenic bacteria on the skin and outer ear canal being induced to infect by prolonged wetting of the ears and the high temperatures and humidity in indoor swimming pools (Calderon and Mood 1982, Robson and Leung 1990). In the early US studies (Stevenson 1953), users of an efficiently chlorinated swimming pool at Dayton, Kentucky reported predominantly eye, ear, nose and throat ailments, whereas swimmers in the nearby polluted Ohio River reported more gastro-intestinal symptoms, exemplifying those arguments.

The results of epidemiology are summarised in Table 1.2. It includes the results of the Phase I and II studies. Because the conclusions are repeatedly found, there is good reason to suppose that they are generally applicable. They also show the features of biological gradient, plausibility and coherence listed in Bradford Hill's (1965) criteria (Table 1.1).

1.2.3 The UK epidemiological studies, 1989-1991

In 1988, the Department of the Environment convened a group of experts to advise on the need for epidemiological study of the health effects of sea bathing and the way in which such a study could be carried out. This group contained experts from the Departments of the Environment and Health, the Public Health Laboratory Service, Health Authorities, Water Authorities (later, the National Rivers Authority), WRc, Universities, the Scottish Development Department, the Welsh Office and the Department of the Environment for Northern Ireland. Two types of study were recommended:

1. Beach Survey Study. Holidaymakers on the beach of their own volition are approached by trained interviewers to participate. Information on bathing history, personal details and confounding factors is collected by interview on the beach and subsequently by telephone a week later. Water quality is monitored intensively on interview days.

2. Controlled Cohort Study. Healthy adult volunteers are enrolled and are randomly divided into equivalent bathing and non-bathing groups on the day of exposure. They are medically examined and questioned about symptoms, previous or subsequent bathing history and confounding factors immediately before and some time after exposure. The beach is one which is known to meet the microbiological standards of the EC bathing water Directive and the experimental protocol has been approved by the Committee on Ethical Issues in Medicine of the Royal Society of Physicians.

Table 1.2 Observations from the UK Epidemiological Studies and others reviewed in the Phase I and II Reports (Pike 1990, 1991)

Observations	Qualifying remarks and investigation
Swimmers report a higher incidence of certain symptoms than non-swimmers	Chicago, Lake Michigan; Ohio River and pool; Long Island (Stevenson 1951) Brittany: eye, ear, nose and throat complaints (Foulon *et al* 1983) Marine and freshwater US EPA studies (Cabelli 1983, Dufour 1984) Head immersion related to ear and eye infections (Mujeriego *et al* 1982) No relationship for waters with <25 enterococci/100 ml (Fattal *et al* 1987) except for 0-4 year olds Differences not significant in Great Lakes pilot study (University of Toronto (1980) On Ontario beaches (Seyfried *et al* 1985a) In Ontario lakes and streams (Lightfoot 1989) Enterovirus-like illness with viral excretion in children swimming in lakes (D'Alessio *et al.* 1981) Hong Kong beaches: gastroenteritis, total illness, diarrhoea (Hong Kong Government 1986, Cheung *et al* 1988, 1990, 1991, Holmes 1989) Ardèche basin, France (Ferley *et al* 1989). Acute and 'objective' gastro-intestinal, ear, nose and throat, skin after river bathing Two UK beaches: general illness, stomach upset, nausea and diarrhoea (Brown *et al* 1987) Sydney, Australia (Water Board 1990): ear, eye, gastr-ointestinal, coughs, colds, sore throat, influenza UK Pilot Study, Langland Bay, 1989 (Pike 1990, Jones *et al* 1991): ear, eye, throat in Beach Survey and Cohort Studies; diarrhoea <u>less</u> common Blackpool 1990 Alexander and Heaven 1991): in waters failing EC Bathing Water Directive, children of 6-11 years using water show more vomiting, diarrhoea, itchy skin, fever, lack of energy and loss of appetite, but statistical analysis flawed UK 1990 Phase II studies (Pike 1991): Ramsgate (Balarajan 1991), gastro-intestinal diarrhoea; if waders excluded, respiratory. Moreton, Cohort Study - sore throat, dry cough, ear, stomach pain, loose motions, flu, cold, gastro-intestinal, chest; in accompanying children - increased perception of any symptom and of stomach upset in those bathing. Sydney Harbour, Australia (Water Board 1991, Harrington *et al.* 1992): swimmers reported illness 1.3 times more often than non-swimmers; respiratory symptoms commonest.

Table 1.2 continued/2

Observations	Qualifying remarks and investigation
The rate of symptoms is related to the degree or duration of exposure to water	Chicago, Lake Michigan; Ohio River and pool, Long Island Sound; rates rose with days of swimming experience (Stevenson 1953) Poorly chlorinated swimming pool, pharyngo-conjunctival fever (D'Angelo *et al* 1979) Negative relationship with number of days a week swimming (New York) or swimming events per day (Alexandria) (Cabelli 1983) Rates in head immersers >non head immersers > non-bathers (Foulon *et al* 1983) In windsurfers, St. Lawrence River (Dewailly *et al* 1986) Ontario lakes: ear, respiratory and gastroenteritis symptoms greater in head immersers than non-head immersers and non bathers (Seyfried *et al* 1985a) UK Pilot Study, Langland Bay, 1989 (Pike 1990): Beach Study suggests that risk follows the order non-participants > waders > swimmers > divers > surfers, for one or more symptoms aggregated Sydney, Australia (Water Board 1990, 1991, Harrington *et al.* 1992): ear, eye, gastro-enteritis; the increase being greater when ocean swimming and freshwater swimming were combined. High frequency of swimming related with eye symptoms. UK Phase II studies, 1990 (Pike 1991, Balarajan *et al.* 1991): Ramsgate - surfers/divers report more respiratory and eye infection than waders and bathers.
Children bathing report symptoms more frequently than older people	Under 5's >5-10 year olds > remainder: Alexandria (Cabelli 1983) In 0-4 year olds, significant excess of enteric and respiratory symptoms, compared with non-swimmers (Fattal *et al* 1987) Under 10's experienced more HCGI and skin rashes (NJDOH 1989) UK Pilot Study, Langland Bay, 1989 (Pike 1990): 15-24 age group most susceptible to ear, throat, respiratory and all symptoms aggregated Enteroviral illness and viral excretion in child lake swimmers highest in under 4 year-olds (D'Alessio *et al.* 1981).

Table 1.2 continued/3

Observations	Qualifying remarks and investigation
	UK Phase II studies 1990 (Pike 1991, Balarajan *et al* 1991): Ramsgate Beach Survey: for any symptom (except skin), eye, ear, nose and throat and respiratory, 15-24 age group > 25-34 > 5-14; for diarrhoea, 25-44 > 45+ > 5-14.
The rate of symptoms is related to the counts of faecal indicator bacteria	Higher illness rates on days when total coliform MPN > 2300/100 ml (Stevenson 1953) Ohio River swimmers (total coliform median MPN 2700/100 ml) experienced higher gastroenteritis rates than pool swimmers, but *vice versa* for eye, ear, nose and throat symptom (Stevenson 1953) Long Island Sound: non significant difference in symptoms for bathers at beaches with significantly different total coliform MPN's (814, 398/100 ml) (Stevenson 1953, USDHEW 1960) US EPA studies in marine (Cabelli 1983) and freshwater (Dufour 1984) Brittany: diarrhoea (Foulon *et al* 1987) In Hong Kong, highly credible gastro-enteritis symptoms, associated with swimming, related to count of *Escherichia coli*; significant for counts exceeding 180/100 ml (Cheung *et al.* 1988, 1990, 1991, Holmes 1989) Malaga, Spain: morbidity rates for mycoses and ear and eye infections greater on satisfactory than on unsatisfactory beaches (Mujeriego *et al* 1982) At Tel-Aviv beaches, grouping of 'low' and 'high' (>24 enterococci/100 ml) counts associated with illnesses in 0-4 year age group (Fattal *et al.* 1987) Enterococcus count related to ear infection (Mujeriego 1982) Relationships not significant in Ontario lake and river study (Lightfoot 1989) Relationships not significant in New Jersey Ocean Health Study; low bacterial counts in sea and lakes (NJDOH 1989) Ardèche basin, France (Ferley *et al* 1989): faecal streptococci best index of 'objective' and acute gastro-intestinal disease

Table 1.2 continued/4

Observations	Qualifying remarks and investigation
	UK Phase II study, 1990 (Pike 1991), Moreton Cohort Study: significant associations between reporting of various symptoms and various microbial indicators (Table 11) Sydney, Australia (Water Board 1991, Harrington *et al.* 1992): frequency of respiratory symptoms increased with counts of faecal coliforms above 50/100 ml and for up to 50 *Clostridium perfringens* spores/100 ml.
E. coli or faecal coliform bacteria are not as satisfactory as other faecal indicator bacteria in correlation with symptom rates	Enterococci superior, US marine waters (Cabelli 1983) Enterococci superior in grouping illness in 0-4 year olds (Fattal *et al.* 1987) *E. coli* showed higher correlation (0.804) than enterococci (0.744) for HCGI in freshwater (Dufour 1984) Total staphylococci better than faecal coliforms and faecal streptococci for predicting total illness, eye and skin disease, Great Lakes (Seyfried *et al* 1985b) Hong Kong beaches, *E. coli* superior in predicting highly credible gastro-enteritis symptoms related to bathing (Cheung *et al.* 1988, 1990, 1991, Holmes 1989) Ardèche basin, France (Ferley *et al* 1989): for freshwater bathing, faecal streptococci superior for predicting 'objective' and acute gastro-intestinal disease UK Phase II study, 1990) (Pike 1991): Moreton Cohort study: significant associations between various indicator bacteria Illness in freshwater pool swimmers related to total staphylococci and bather density (Calderon *et al* 1991)
Residents near the beach are less susceptible than visitors to swimming-associated gastroenteritis	Alexandria residents and Cairo visitors on Alexandria beaches (Cabelli 1983)
What are the most active age-groups for bathing?	10-19 years > 5-9 years: Chicago, Lake Michigan (Stevenson 1953) 5-9 years > 20-24 > 10-14 > 15-19: Ontario lakes and rivers (Lightfoot 1989)

The beach chosen for the Pilot Study (Phase I) in 1989 was Langland Bay, near Swansea (National Grid Reference SS 606871).

The Beach Survey Study was conducted over 20 days in August, with involvement of 4045 holidaymakers on the beach and a secondary, detailed telephone follow-up, seven days later, of a sub-sample of 791. The latter group provided the more internally consistent data and it was decided to base the collection of health information upon telephone interview in later studies. Despite fine weather, it was found difficult to recruit up to the target of 4000 subjects in the 20 days and, because 70 per cent of subjects were holidaymakers, avoiding multiple recruitment was a significant problem. However, 75 per cent of family groups approached were willing to be interviewed by telephone.

The Controlled Cohort Study took place on 2 September (a Saturday). Of 465 people who enrolled for the study 276 (59 per cent) completed the schedule of interviews, exposure and clinical examinations. It was found that recruitment was encouraged by favourable local publicity for the study and by recruitment in the city shopping centre and by active co-operation by the local authority in attending to transport and features on the beach. In this study, the schedule of interviews was as follows:

1. Interview, medical examination, collection of throat, ear swabs and faeces 2-3 days pre-exposure.

2. Exposure day - randomisation into bathing and non-bathing cohorts. Bathers were told to stay at least 10 minutes in the selected strip of water and to immerse themselves at least three times.

3. Interview, medical examination, collection of throat, ear swabs and faeces three days after exposure.

4. Postal questionnaire, three weeks after exposure.

During the conduct of the exposure, water was sampled for microbiological examination every 20 minutes at three depths and in each of the five 20 m-wide strips of water assigned for bathing.

The designs used in Phase I were generally found to be satisfactory and were used in subsequent years, with minor modifications. It was considered that both types of study should not be carried out at the same beach. Publicity was avoided as far as possible in conducting the Beach Survey, to avoid biasing subjects' perception of symptoms. This conflicted with the need for positive publicity to encourage recruitment for the Controlled Cohort Study.

Throughout the period November 1989 - March 1990, the House of Commons Environment Committee collected evidence for their Fourth Report, Pollution of Beaches (HCEC 1990). The Committee noted the conclusion of the Phase I report that the two methods of study were suitable, but that greatly extended studies would be required to obtain statistically significant results. It recommended (on p. xv, and in para 32) that extended studies should be undertaken as soon as possible.

The decision had already been made by the funding agencies to proceed with a definitive study in 1990, using the information gained in the pilot study. The Beach Survey Study was carried out at Ramsgate Sands beach in Kent (TR 387 650), involving 1883 successful telephone interviews and the Controlled Cohort Study at Moreton, Merseyside (SJ 257 918), involving 303 volunteers completing the one week post-exposure examination.

The overall main conclusions from Phases I and II are shown in Table 1.2, in conjunction with those from previously reported studies. Because of their success, in that few modifications needed to be made to the original design, it was decided to pool results, together with those from the Phase III studies in the final analysis presented in this report.

Recommendations were made for the size of the definitive studies to be carried out in Phase III (Section 1.3.3).

Based upon a background attack rate of 4 percent in non-bathers and a relative risk for bathers of 1.5, the size of a controlled Cohort Study needed to guarantee detection of a statistically significant effect of water quality on health was calculated as about 4000 subjects, broken down into separate studies at eight beaches known to be 'very clean' and 'just passing' the EC criteria. For the Beach Survey Study, it was recommended that a total of 18 000 interviews should be conducted, involving nine beaches, apportioned as 'very clean', 'just passing' and 'failure'. Taking into account this advice and that presented by the group of experts, the Department of the Environment and its co-funding agencies announced the intention to place the present contract for Phase III, to cover the two summers of 1991 and 1992 and to carry out Beach Surveys at eight beaches (each involving 2000 subjects) and two controlled Cohort Studies.

The needs of an epidemiological study into the health effects of sea bathing were listed in Section 1.2.1. The UK study is the only one so far to attempt to meet all the needs. The two types of study are complementary. The merit of the Beach Survey approach, which is developed from that of the USEPA, is that it enables large numbers of holidaymakers to be screened efficiently with little effect upon their perception of illness. However, it is weakened because the quality of water at the time and place that a person bathes is not precisely defined and health effects are measured by recording symptoms perceived by subjects. On the other hand, the Controlled Cohort Study obtains precise information upon those factors, although it is limited, for ethical reasons, to adult subjects and to waters meeting the quality requirements of the bathing water Directive. Recorded symptom rates have been higher in both bathers and non-bathers than in corresponding Beach Survey Studies, no doubt because the subjects are made more aware of the purpose of the study and have increased perception.

1.2.4 Recent research and developments

The reports upon the Phase I and Phase II studies (Pike 1990, 1991) contained detailed assessments of published case histories and epidemiology. Developments since March 1991 have been minor and are summarised below.

A paper describing further analysis of combined results from the Cohort Studies at Langland Bay and Moreton, showed than faecal streptococci, measured at chest depth, predicted probabilities of gastro-intestinal symptoms in the adult bathing cohort and reached significance in waters containing 40-59 faecal streptococci per 100 ml. The probabilities were similar to those involved in bathers eating convenience foods (purchased sandwiches, hamburgers, cold meat pies) around the time of bathing or in bathers with a predisposition to diarrhoea (Fleisher *et al.* 1993).

Calderon *et al* (1991) conducted a study of swimming and non-swimming members of 104 families in a small community, using the bathing area of a 1.2 ha recreational lake, supplied by a small brook, unpolluted by human discharges but liable to contamination by wild animals in the forest park. Subjects kept daily diaries, over June-August, of bathing activities and health symptoms. Illnesses contracted within three days of bathing were regarded as health-related. Water samples were taken at 1000, 1200 and 1400 at knee depth on 49 days. The symptomatic gastro-intestinal attack rate was 22.9 per 1000 person-days of exposure in swimmers and 2.6 in non-swimmers; relative risk 8.7 (highly significant), adjusted for age 6.3 (highly significant). A consideration of swimming activity following rainy days, when counts of indicator bacteria were elevated, and after dry weather, suggested that morbidity was not caused by pollution of brook water by wild animals. There was a significant association between ill swimmers and high counts of staphylococcus (>45 per 100 ml) or high numbers of bathers (>50 per day) in the water, which suggested swimmer to swimmer transmission of illness through the water.

New Guidelines for Canadian Recreational Water Quality have been published (MNHW 1992). These apply to both fresh and marine waters. The maximum limits for faecal indicator bacteria (geometric means of at least five samples in a period not exceeded 30 days) are those of the US Environmental Protection Agency (USEPA 1986), but with qualifications. No single-sample upper limits are defined. For marine waters, the geometric mean limit is 350 enterococci/litre. Resampling is required when any sample exceeds 700/litre. If it can be shown that *Escherichia coli* or faecal coliform bacteria adequately demonstrated the presence of faecal contamination in marine waters, these may be substitutes. The significances of enteroviruses, salmonellae, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, protozoal parasites, toxic phytoplankton and coliphages in recreational waters are reviewed in depth, but no criteria are set.

The following papers have been published in 1991-93 which are directly or indirectly related to the Health Effects of Sea Bathing contracts:

A description of the pilot controlled Cohort Study at Langland Bay in 1989 (Jones *et al* 1991).

A summary letter of the results of the beach study at Ramsgate in 1990 (Balarajan *et al* 1991). This was followed by a criticism of the lack of detail (Hall and Rodrigues 1992), which was answered (Balarajan *et al* 1992).

A paper describing studies carried out at Ramsgate in 1990, in parallel with the beach survey study (but not part of the contract), evaluating the value of F-specific RNA bacteriophages and somatic coliphages as indication of marine pollution (Morinigo *et al*

1992). The former were never detected in samples containing 1-10 pfu of enteroviruses/litre, whereas the latter were constantly found in such waters and at numerical levels exceeding the G and I values for faecal coliform bacteria (100 and 2000 per 100 ml respectively). Somatic coliphages were considered to be optimal indicators of water quality.

A comparative review of European, British and North American standards for recreational water quality and an analysis of the rationales used to devise them (Pike 1993.

Under the Water Act 1989, consolidated into the Water Resources Act 1991, the Secretary of State is empowered to prescribe and the National Rivers Authority (NRA) to enforce statutory Water Quality Objectives. The NRA has proposed (NRA 1991b) that the main elements will include, for each stretch of controlled water (including coastal water), identification of the class of use, corresponding quality standards (including those of relevant EC Directives) and dates for compliance. One of the use classes proposed is 'Water Contact Activities'. The bathing water Directive 76/160/EEC was implemented in the UK by Statutory Instrument Nº 1597, The Bathing Water (Classification) Regulations 1991.

1.3 Epidemiological and statistical background

This Section is provided for the general reader. The techniques will be familiar to the expert epidemiologist.

1.3.1 Expressing relative rates of illness between bathers and non-bathers

In the first instance, rates of recording symptoms or illness are expressed as numbers reporting per thousand subjects interviewed. This is not very meaningful, since it will depend upon the acuity with which the subjects perceive the symptoms and upon the efficacy of the questionnaire and the interviewer in eliciting responses. In the UK studies and most others the responses of the exposed and control groups have been compared to obtain a measure of the rates of recording symptoms related to exposure to water and thereby to eliminate responses related to other causes common to the control, as well as to the exposed subjects.

In the early US Public Health Service studies (Stevenson 1953) the index used was the rate per 1 000 person-days, either for swimmers or for non-swimmers. This was an attempt to relate risk to the degree of water activity. This study differed from later ones in that the prime objective was to compare rates of illness in swimmers using a polluted beach and a clean beach at three different cities and then to see if rates of reporting different symptoms were significantly elevated between clean and polluted water users and between bathers and non-bathers.

Other studies have attempted to separate bathing-associated risks from those not associated with bathing. The studies of Cabelli (1983) and Dufour (1984), for the US Environmental Protection Agency, defined two criteria 'gastro-enteritis' and 'highly credible gastro-enteritis' (ie symptoms of more severe intestinal disturbances meeting criteria proposed by the Communicable Disease Centers, Atlanta GA). 'Swimming-associated' rates were obtained by subtracting rates in non-swimming control groups from those in the bather groups. The model of infection used to interpret the data assumed that this differential swimming-associated rate would be correlated with the logarithm of the geometric mean count of faecal bacteria prevailing in the water.

This model assumes that the effect of bathing is additive to other causes of illness and has recently been criticised (Fleisher 1991) for biasing responses. Later epidemiological studies have used a concept of 'relative risk' or of relative odds of falling ill in bathers, compared with non bathers. These two approaches have the advantages of nullifying differences in the acuity of responses or success of the questionnaire and interviewing procedures.

For definition, if the baseline rate of illness unrelated to bathing is r (as a fraction of the total group) and the act of bathing increases this by an amount, b, the rate observed in bathers is obviously br and the 'relative risk' (RR) of bathing is

$$RR = br/r = b$$

Relative risk is easily calculated from raw data. A more sophisticated concept is that of 'odds ratio', since this can be derived directly from a method of analysis called logistic regression Section 1.3.2(d), which can automatically correct for concomitant factors. This technique has been used in the analysis of the Beach Survey and Cohort Study data and was also used by d'Alessio *et al.* 1981, Seyfried *et al.* (1985a, b) and Lightfoot 1989. This concept uses the odds of falling ill as a fraction of those in the group remaining well. The term 'odds' has the same meaning as in the odds against winning in horse racing, where the '50 to 1 outsider' has the likelihood of not winning in fifty out of fifty-one races. Thus the odds of a non-bather falling ill is given by r/(1-r), and of a bather falling ill, br/(1-br). Hence the odds ratio, OR, is defined as

$$OR = br/(1-br) \div (r/(1-r))$$

When the fractions falling ill, r or br, are small then relative risk approximates to odds ratio.

1.3.2 Statistical methods for analysing raw data

The principal techniques of statistical analysis which have been used in the two studies are as follows:

(a) Chi-squared test of contingency. This provides a measure of 'goodness of fit' of two or more independent sets of observations, both of which can take two or more discrete forms. Specifically, in this study, the method for '2 x 2 tables' is used. For example, subjects existed in two categories, bathers and non-bathers; each of these could either become ill or remain well, giving four separate classes. Perfect fit would exist if, for example, all bathers become ill and all non-bathers remained well. In real life this agreement never happens and all four possible outcomes will result. The test measures the relationship of the observed pattern of results to that expected if the data confirmed to an assumed theoretical distribution, expressing the results as a statistic, Chi-squared (χ^2). The higher the value of χ^2, the less the results are likely to be caused by chance. In general, a result showing a probability of being caused by chance in 1 out of 20 trials ($p = 0.05$) is regarded as barely significant.

(b) Exact probability (Fisher's exact test). The χ^2 test cannot be used when the expected numbers of subjects showing one (or more) of the four possible outcomes is less than 5. Fisher's test provides a way of calculating directly the probability of an outcome (and more severe outcomes) being due to chance.

(c) Linear regression analysis. This is a very commonly used technique for displaying the relationship between two sets of measurements, such as rate of illness and bacteriological counts in sea water. For example in the studies of Cabelli (1983), Dufour (1984) and Cheung *et al.* (1988, 1990, 1991), the rate of illness (the dependent or predicted variable, y) is predicted from measurements of the independent variable (x) the logarithm of the bacterial count, giving an equation of the form which yields a straight line:

$$y = bx + a$$

The coefficient b, is termed 'the slope of the line' and measures the increase in y for a one unit increase in x. The term, a is a constant, since it is the value of y when $x = 0$. Regression generates a statistic, r, the correlation coefficient. When the fit is perfect, all the values of x and y lie on the straight line and $r = \pm 1$. The value of r provides a measure of the fit of the points to the model equation and the value of r^2 is the proportion of the total information (variance in the dependent variable) which is accounted for by the model equation.

(d) Logistic regression. This widely available method of analysis is a natural extension of linear regression analysis. It was first used in bathing epidemiology by Seyfried *et al.* (1985b) and then by Lightfoot (1989). In this, the natural logarithm of the odds of falling ill (the dependent variable, $\log_e (p/(1-p))$) is predicted from more than one independent variable, such as bacteriological count, intensity of water activity, sex and age. This provides a model of the form

$$\log_e (p/(1-p)) = a + B_1x_1 + B_2x_2 ....B_nx_n$$

In this equation, p is the probability of falling ill (expected number ill/total population examined), a is a constant term (the value of $\log_e (p/(1-p))$ when the sum of the successive terms B_1x_1 to B_nx_n is zero) and the coefficients B_1 to B_n are the slopes for each of the independent variables x_1 to x_n (i.e. they indicate the amount by which in $\log_e (p/(1-p))$ increases for a unit increase in the respective values of x_1 to x_n). In this type of analysis, the independent variables can either be continuous (e.g. bacterial counts) or discrete (e.g. bather, non-bather, with values of 1 and 0) and can be used in a mixture. The model enables an independent variable (e.g. bathing, bacterial count) to predict the odds of falling ill, if all the remaining independent variables are held constant. The model therefore enables the effects of concomitant variables such as age, sex, visitor/non visitor to be controlled. The 'odds ratio' is the predicted ratio of the odds of falling ill in an exposed group to that in the control, unexposed group and is calculated directly from the logistic regression model.

A key text book dealing with the statistical application of logistic linear models is that by McCullagh and Nelder (1989).

1.3.3 Recommendations for sizes of studies in Phase III

The size of an epidemiological study needed to be sure of detecting a given effect depends principally upon the background rate of symptoms in the unexposed population and upon the increase in this rate caused by the factor being studied, as well as upon the critical level of significance adopted for rejecting the null hypothesis that no effect indeed exists. Such information was gained in Phases I and II.

At the outset the expert group advising DoE and the other funding agencies recommended a Pilot Study of two complementary methods, which were tested in 1989 at Langland Bay. The Report on this Phase I (Pike 1990) recommended greatly extended studies at beaches displaying different qualities of water and noted that a Cohort Study approach would be needed if it was desired to investigate the relationships between reported symptoms and clinical diagnosis of infection. Recommendations were also made upon the size of study which would be required in order to achieve a significant demonstration of excess in bathers risk for the prevailing incidence of symptoms in the control groups. The recommendations were noted by the funding agencies. A definitive trial of each method in 1990 (Pike 1991) on the scales recommended was successful and enabled the predictions of size for a full-scale study to be confirmed and methods to be optimised.

The original size recommendations made were as follows (Pike 1990, p.83).

1. A Beach Survey Study of 16 000 subjects across 10 beaches should render it possible to detect an odds ratio of 1.25 with a baseline incidence (control group) of 3.5 per cent.

2. A Cohort Study of 1800-3000 subjects at 10 beaches, recruiting twice this number to allow for drop-outs, assuming the attack rates observed at Langland Bay.

These recommendations were re-assessed statistically by WRc after completion of Phase II (Appendix C of Pike 1991) and can be summarised thus:

1. Using the controlled Cohort Study, it should be possible to reveal a doubling of symptom rates between beaches at the 'very clean' end of the spectrum and those rated as 'just acceptable'. This would involve three or four studies at each category of beach, involving 3-4000 subjects in all.

2. The Beach Survey methodology is somewhat removed from an ideal experiment (because of the poorer definition of exposure to pathogens and of control) and factors of safety are needed to compensate. Three studies in each of three classes of water

quality ('very clean', 'just acceptable', 'EC failure') would provide a basis for a reasonable study with 2000 interviews per beach.

Both predictions assumed an attack rate of 4 per cent in the control group, an odds ratio of 1.5 for the increase in symptoms amongst bathers at the cleanest beaches and of two at the 'dirtiest' beaches. These predictions were made on the assumption that there should be a 90 per cent chance ($\beta=0.1$) of demonstrating this doubling in a two-sided test at a level of $\alpha=0.05$.

The funding agencies adopted the second recommendation for Phase III, by requiring studies of a total of 16 000 holidaymakers at a further eight beaches in 1991-92, since this would give the broadest picture of different water qualities, beach-going activities, of all ages and sex, unlimited by restriction to healthy adult, local volunteers swimming at beaches, where water quality consistently met the imperative standards of the bathing water Directive. It was recognised that the strength of the Cohort Study approach was that it would enable the relationships between recording symptoms and medical/diagnosis of illness to be explored and a study of non-bathing related factors to be explored. A Cohort Study was recommended in 1991 and the need for a second in 1992 would be assessed on the basis of the results.

2. OBJECTIVES AND PROGRAMME

2.1 Funding and objectives

The Department of the Environment awarded WRc the master contract, Health Effects of Sea Bathing - Phase III (Contract Reference PECD 7/7/377) for the period 1 April 1991 - 31 January 1994. This was jointly funded by the Departments of the Environment and Health, the Welsh Office and the National Rivers Authority (under their Programme Reference 228, Bathing Water Epidemiology).

The objectives of the programme of research were:

1. To undertake an epidemiological study to determine the risks, if any, to health of swimming in coastal water contaminated by sewage.

2. To establish the relationship, if any, between microbiological quality of coastal water and the risk to health of bathers.

2.2 The role of WRc

The programme specified that, in each of the two summers of 1991 and 1992, four beach survey studies as developed in Phases I and II and a Cohort Study should be carried out, using subcontractor(s) engaged by open tender and supervised by WRc. The duties of WRc, as contractor, were specified as follows:

1. With prior approval of the Department of the Environment (DoE) and other funding agencies, to engage subcontractor(s), by the process of open tender, to organise and execute the studies document and conduct a statistical examination of the accumulated data.

2. To prepare the tender documents in consultation with the funding agencies.

3. To be responsible for the day to day management of the contract and oversee work to be carried out by the subcontractor(s) so as to ensure the efficient execution of the programme work. In particular, to ensure comparability of microbiological analyses between the two types of study and to supervise the inter- and intra-laboratory quality control.

4. In association with the Press Office of the DoE, to be responsible for the public relations for the study and contacts with the media and the Local and Health Authorities in the survey areas, including any necessary negotiations.

5. To advise the subcontractor(s) on the format of the questionnaires for both studies, which were based on those employed in the 1990 study, and on the methods of statistical analysis employed. The presentation of the results for all the studies undertaken to be produced in a compatible format.

6. In consultation with officials nominated by the DoE, and the National Rivers Authority, to determine the beaches to be used for the study. During the 1991 bathing season, to select four bathing waters of varying microbiological quality for beach surveys and one beach that passes the mandatory standard laid down in the Bathing Water Directive (76/160/EEC) for a Cohort Study. Similar studies to be undertaken in 1992.

7. To submit regular reports on progress and a final report to the DoE. To produce an interim report on the results of the 1991 surveys in 1992 and the final report, which will include analysis of all 14 studies (1989-1992), by June 1993.

Tender documents were prepared by WRc, in association with the four funding agencies and were widely distributed with invitations to submit tenders. Replies were considered by the funding agencies and the successful applicants were:

For a total of eight beach survey studies in the summers of 1991 and 1992, the Institute of Public Health (IPH), University of Surrey, Guildford, Director, Professor R Balarajan.

For a Cohort Study in 1991, and, if required, in 1992, the Centre for Research into Environment and Health (CREH), St David's University College, Lampeter, Directors Professor F Jones and Dr D Kay.

The two research organisations were subsequently engaged by WRc sub-contract.

WRc were requested by DoE to form and chair a steering group to guide progress of the research. This comprised representatives from the four funding agencies, the Public Health Laboratory Service, the Principal Investigators of the subcontracting organisations and WRc. It met on three occasions during the summer of 1991 and twice in the summer of 1992.

Answers to enquiries and requests for interviews by press and news media were dealt with as they arose, subcontractors being requested to direct all enquiries to WRc and DoE. The following press briefing notes were issued by WRc, in collaboration with DoE.

1. 21 May 1991. WRc awards sub-contracts to carry out studies on the health effects of sea bathing.

2. 13 June 1991. Health effects of sea bathing - Phase III: Healthy volunteer Cohort Study, Southsea.

3. 6 July 1991. Health effects of sea bathing - Phase III: Healthy volunteer Cohort Study, Southsea.

4. July 1991. Health effects of sea bathing - Phase III. Studies to be carried out at five beaches this summer.

5. 4 July 1992. Health effects of sea bathing - Phase III: healthy volunteer Cohort Study, Southend-on-Sea.

Additionally, WRc assisted in preparing articles published in *Water Bulletin* (28 June 1991, p7) and in NRA's *The Water Guardians* (March issue 1991, pp4-5).

To avoid holidaymakers' perception of symptoms being biased and to protect the tourist interest of the co-operating local authorities, the location of the beach survey studies was not revealed. Once studies were under way and noticed by news correspondents, they were requested to avoid sensationalism and to report fairly. Because recruitment for the Cohort Study required publicity and creation of a climate favourable for co-operation, press releases and briefings were organised by WRc, when the decision of the local authorities had been given, to launch recruitment and on the days of the studies, so that the correspondents could learn the objectives of the study and see the study in progress on the beach, without impeding the work of the research team.

A further role of WRc, implicit in the programme, has been to provide a peer review and statistical appraisal of the results of the two studies for the funding agencies.

2.3 Programme for the beach survey studies

WRc engaged the Institute of Public Health (IPH), University of Surrey to carry out the survey by questionnaire of holidaymakers on the beaches of their own volition to determine attack rates of symptoms and their relationships to microbiological quality of the sea water. The programme specified contractually was as follows:

1. The recruitment questionnaire, and procedures, to be used for selecting bathers and non-bathers at the beach and the follow-up questionnaire will be based on those used for the 1990 beach survey. Any modifications will require the approval of the contractor.

2. Surveys will be carried out in each of the bathing seasons of 1991 and 1992 at four bathing waters. The beaches will be chosen by WRc on the advice of the funding agencies. Each survey will be carried out over twenty interview days during four weeks of the bathing season at the selected beaches. At least six weekend days will be included. The aim will be to conduct two thousand completed interviews for each bathing water either with individuals or with family groups. The interviews will be divided about equally between bathers and non-bathers.

3. To monitor on survey days, at the 30 cm depth stipulated in the Bathing Water Directive 76/160/EEC, every two hours, starting no later than 10.00 a.m. and continuing until at least 4.00 p.m., at a minimum of three stations at the most frequented beach sections, for microbiological indicators. These will include total and faecal coliforms, faecal streptococci and bacteriophages. All samples must be kept refrigerated and processed within six hours of sampling. On each survey day replicate sub-samples of the first and last samples are to be taken and analysed. The subcontractor must satisfy the contractor of the analytical quality control of all analyses. In the event of more than one laboratory undertaking sample analysis, inter-laboratory comparisons must be carried out. The methods of

microbiological analysis for the indicator organisms must be identical to that used in the Cohort Study. In addition, at least twenty samples will be taken over the survey period for the determination of enteric viruses and oocysts of *Cryptosporidium* sp.

4. To collect information on the weather and sea conditions, including salinity on the survey days.

5. To engage professional interviewers to carry out the beach interviews and the agreed follow-up questionnaire by telephone seven days after the beach interview. Sufficient interviews will be conducted at each beach to enable 2000 follow-up interviews to be completed.

6. To statistically analyse, after discussions with the WRc, the data obtained and present an interim report of results to the contractor by 31 December 1991 with the final report submitted by 31 December 1992.

Bad weather in the August of 1991 and 1992 impeded recruitment of subjects at five of the beaches. The funding agencies agreed to extension of the sub-contract with IPH for up to ten days to enable sufficient interviews to be carried out.

2.4 Programme for the Cohort Study

WRc engaged the Centre for Research into Environment and Health (CREH), St David's University College, Lampeter to carry out Cohort Studies in 1991 and 1992. This involved the recruitment of volunteers and the use of questionnaires and clinical sampling to elucidate the health risks of sea bathing and its relationship to the microbiological quality of the sea water. The programme specified was as follows:

1. The questionnaires used in the study shall be based on those used in the 1990 Cohort Study. Any alterations to them must have the approval of the contractor. The design and execution of the study must follow the protocols already approved by the Royal College of Physicians Committee on Ethical Issues in Medicine. The study should have prior approval of the ethics committee of the District Health Authority.

2. The bathing water chosen each year by the contractor, with the advice of the funding agencies, will conform to the mandatory coliform standards laid down in the Bathing Water Directive 76/160/EEC.

3. To recruit sufficient healthy volunteers to enable four hundred completed analyses to be carried out. These uncoerced volunteers must be over eighteen years of age. The group will be randomly split into equal bathing and non-bathing cohorts. Subjects will not receive remuneration for their co-operation in this project, but essential out-of-pocket expenses will be refunded to an agreed maximum.

4. To sample the water prior to bathing, at different times and locations to determine the pattern of bacterial and viral contamination. On the day of exposure, two hundred samples will be collected for bacteriological analyses of which at least one third will be at the 30 cm depth required by the Bathing Water Directive 76/160/EEC. These analyses will include total coliform organisms, faecal coliforms, faecal streptococci and staphylococci. A subset of the samples will be analysed for enteroviruses, *Cryptosporidium* and bacteriophages. Analyses must be carried out within six hours of sampling and the analytical quality control specified. The methods of microbiological analysis for all indicator organisms must be identical to that used in the beach survey.

5. To collect information on weather and sea conditions throughout the test day.

6. To take bathing and non-bathing cohorts to the beach on one day during the bathing season. On that day packed lunches will be provided for both bathing and non-bathing cohorts. Samples of the packed lunches will be examined by the PHLS. The bathing cohort will be allowed free access to the water and instructed to immerse their heads in the water on at least three occasions during normal swimming activities. At least twenty trained and supervised field staff will be available to provide safety cover and closely monitor the activities of both cohorts. Non-bathers will not be allowed to swim and alcohol intake for both cohorts will be carefully controlled.

7. To interview on the day before bathing, on the day of bathing, and at seven days and four weeks after exposure, the participants and record their perceived assessment of any symptoms. On the day before bathing and seven days after bathing, they will be medically examined, and will provide faecal, nasal and oral samples for analysis.

8. To statistically analyse, after discussion with the WRc, the data obtained and produce an interim report by December 1991, with the final report submitted by December 1992.

DoE subsequently agreed to extend the sub-contract with CREH to 31 March 1992, to enable the data obtained in the Phase I pilot study at Langland Bay in 1989 to be re-coded and amalgamated with the Phase II and Phase III studies (Moreton, Southsea) to enable the effects of water quality (faecal streptococci) and of confounding factors, such as food intake, upon health, to be determined. The funding agencies subsequently recommended that a fourth Cohort Study should be carried out in 1992 and the sub-contract with CREH was accordingly extended.

2.5 Reporting

This report presents the major findings for the eight Beach Survey studies and two Cohort Studies carried out in Phase III in the summers of 1991 and 1992. This report also includes results from the Phase I Pilot Studies (1989) and Phase II (1990), because few changes needed to be made to the methods originally tested in the Pilot Study. Previous reports have been published by WRc with the permission of the DoE. These contain, as Appendices, the reports received from sub-contractors:

Phase I - Pilot Studies at Langland Bay (Pike 1990)

Phase II - Beach Survey at Ramsgate and Cohort Study at Moreton (Pike 1991)

Phase III - Interim report on Beach Surveys at Paignton, Lyme Regis, Rhyl and Morecambe and Cohort Study at Southsea (Pike 1992)

Because this Final Report analyses the findings from the four years 1989-1992, it was considered inappropriate to include the sub-contractors' reports for 1992. They are available separately from the sub-contractors (Balarajan 1993, Jones *et al.* 1993) or from WRc.

3. BEACH SURVEY STUDIES

3.1 Choice of beaches

In Phase III, the aim was to select eight beaches, recognised for monitoring under the bathing water Directive 76/160/EEC and displaying a gradation of water quality, so that a relationship between mean counts of faecal bacteria and of relative health risk could be ascertained. The desirable features of individual beaches were as follows:

1. Popular, well-defined and compact to assist interviewing of the target of 2000 holidaymakers within 20 days.

2. Attracting visitors, rather than residents.

3. Affected, if at all, by a single point source of sewage, rather than by estuaries or storm-sewage overflow.

4. The nearness of laboratory facilities.

5. Avoidance of the site used for the Cohort Study or one where news publicity or other activities might influence holidaymakers' perceptions of health.

6. Selection of beaches in different geographical regions of Britain.

Acting on advice on these factors supplied by NRA Regional Offices and from DoE, the following beaches were chosen for the studies and permission was obtained from the respective District Councils:

Paignton, Devon	(Borough of Torbay)	Figure 3.1
Lyme Regis, Dorset	(West Dorset District Council)	Figure 3.2
Rhyl, Clwyd	(Borough of Rhuddlan)	Figure 3.3
Morecambe, Lancs.	(City of Lancaster)	Figure 3.4
Cleethorpes, Lincs.	(Borough of Cleethorpes)	Figure 3.5
Skegness, Lincs.	(East Lindsey District Council)	Figure 3.6
Instow, North Devon	(North Devon District council)	Figure 3.7
Westward Ho!	(Torridge District Council)	Figure 3.8

For completeness, details are given of the beaches at Langland Bay, West Glamorgan (City of Swansea, Figure 3.9), used in the Phase I Pilot Study and of Ramsgate-Sands Beach, Kent (Thanet District Council, Figure 3.10) used in Phase II.

Rhyl replaced the original choice of Prestatyn, as the beach was closed to allow engineering work to take place on the sea defences. Figure 3.11 shows the distribution of beaches used in the Beach Surveys and in the Cohort Studies. This shows the success in locating studies evenly around the coasts of England and Wales, embracing a variety of beaches in size and in degree of compliance with the mandatory standards of the bathing water Directive 76/160/EEC.

District Health Authorities were notified that studies were envisaged and the experimental protocols were provided when requested.

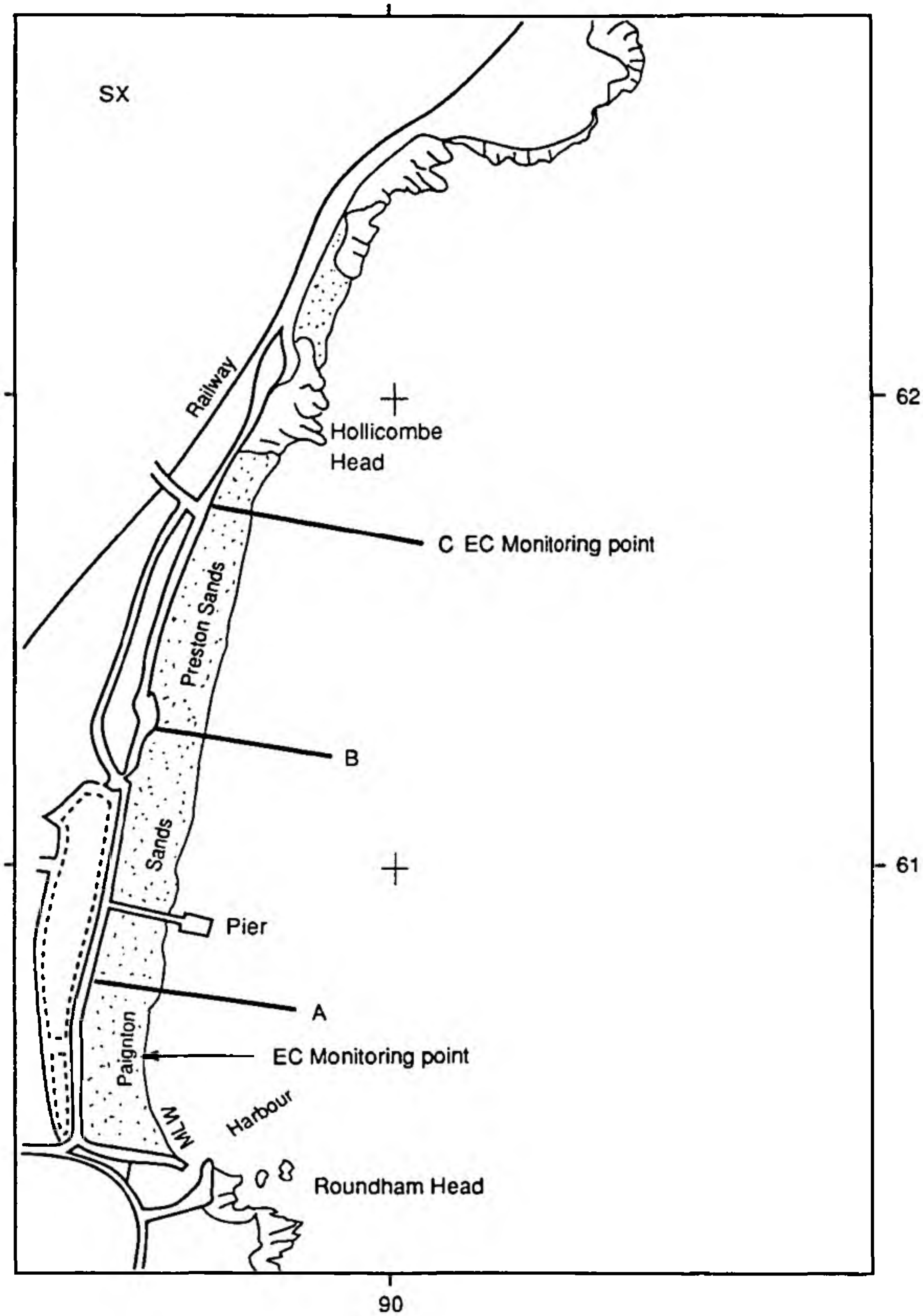

Figure 3.1 Paignton. Beach sampling stations and National Grid km co-ordinates

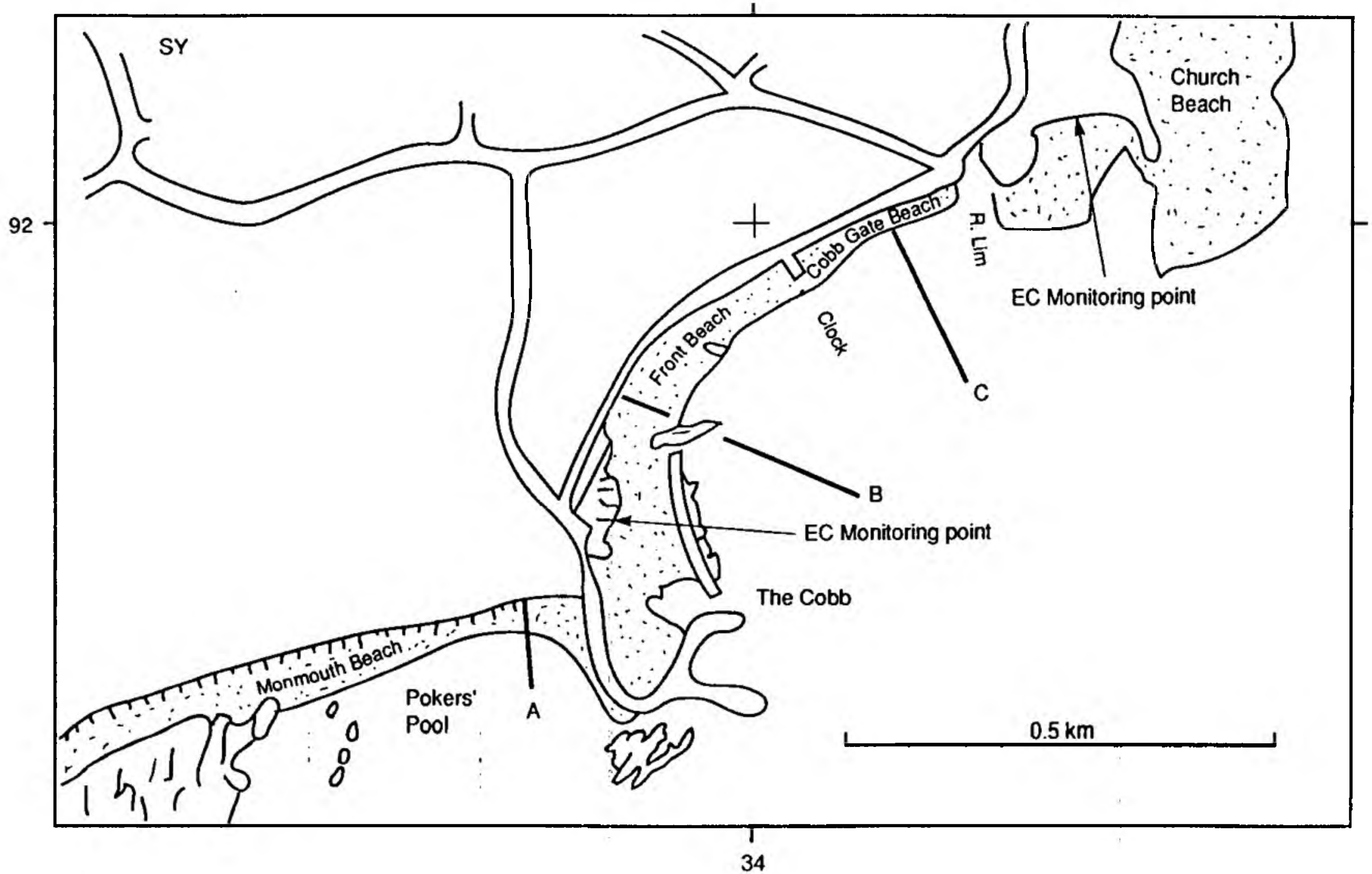

Figure 3.2 Lyme Regis. Beach sampling stations and National Grid km co-ordinates

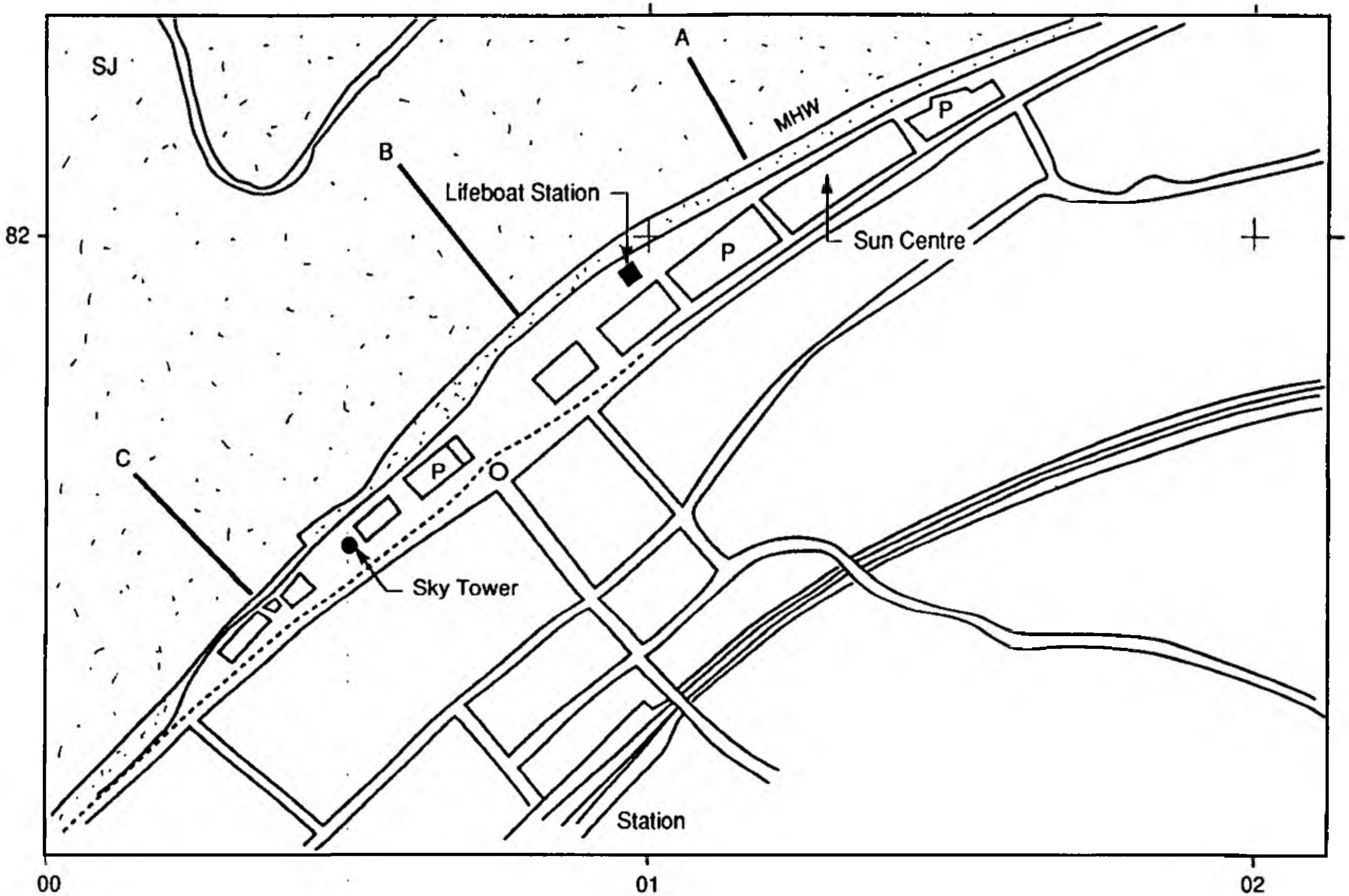

Figure 3.3 Rhyl. Beach sampling stations and National Grid km co-ordinates

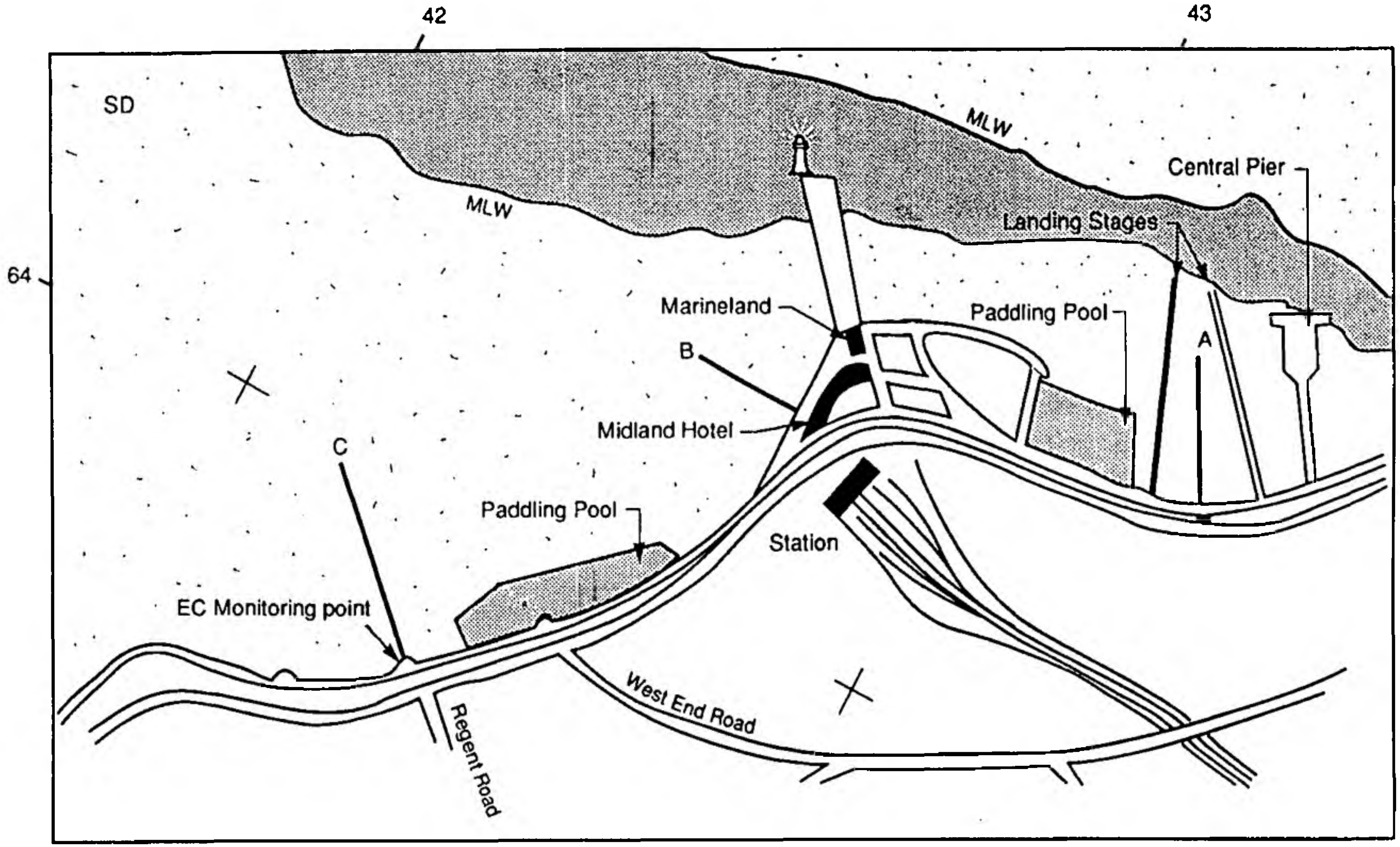

Figure 3.4 Morecambe. Beach sampling stations and National Grid km co-ordinates

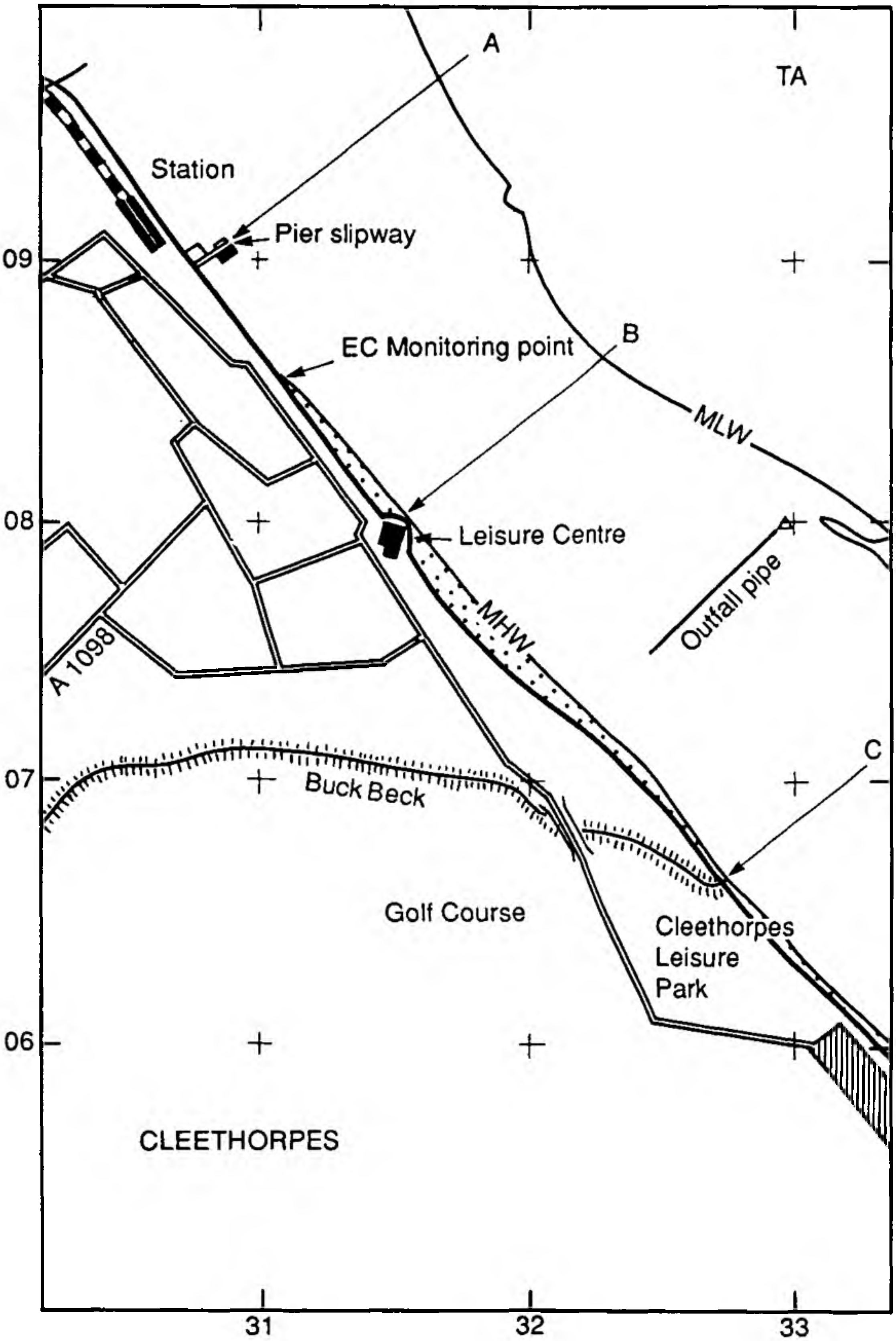

Figure 3.5 Cleethorpes. Beach sampling stations and National Grid km co-ordinates

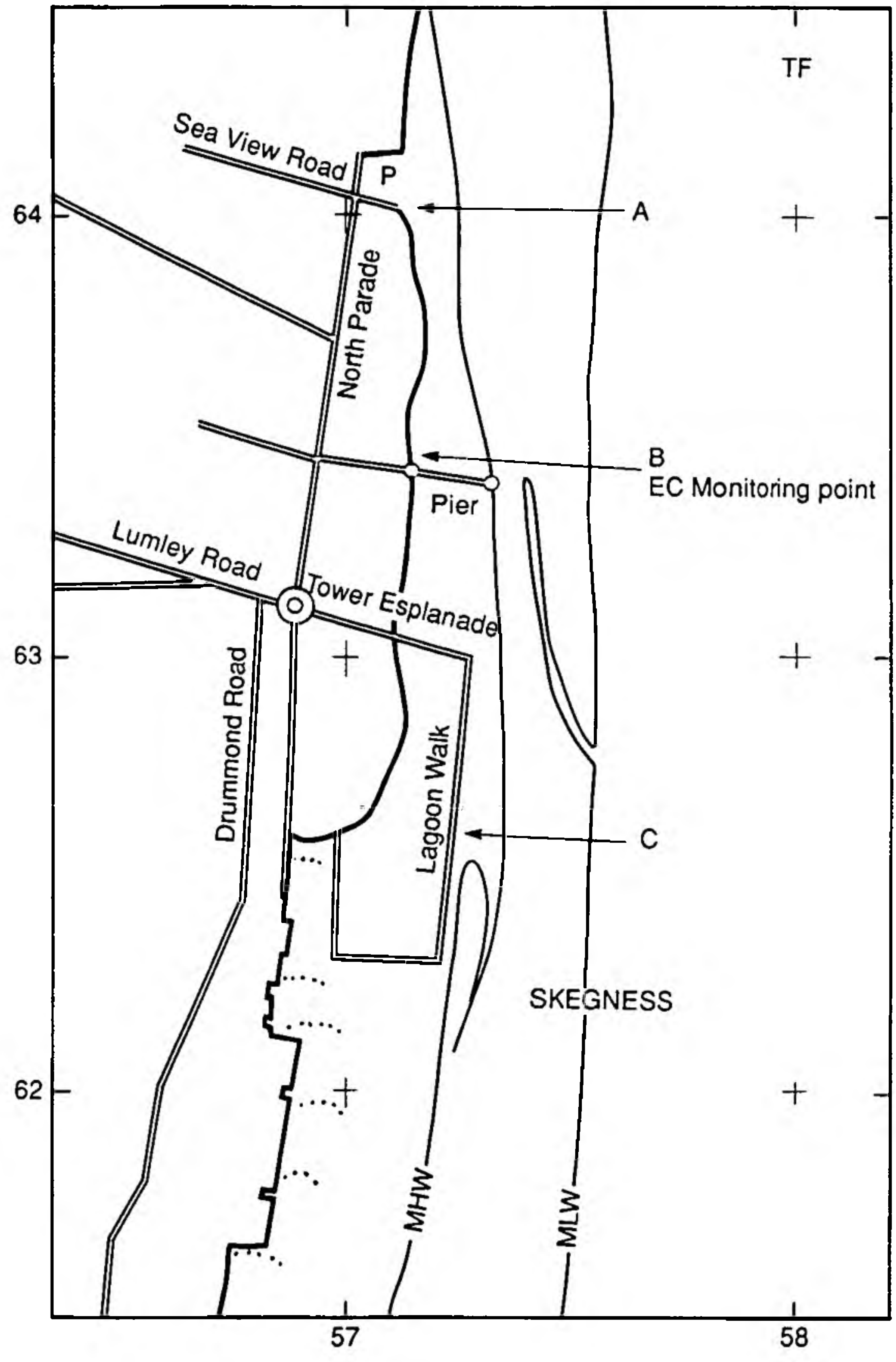

Figure 3.6 Skegness. Beach sampling stations and National Grid km co-ordinates

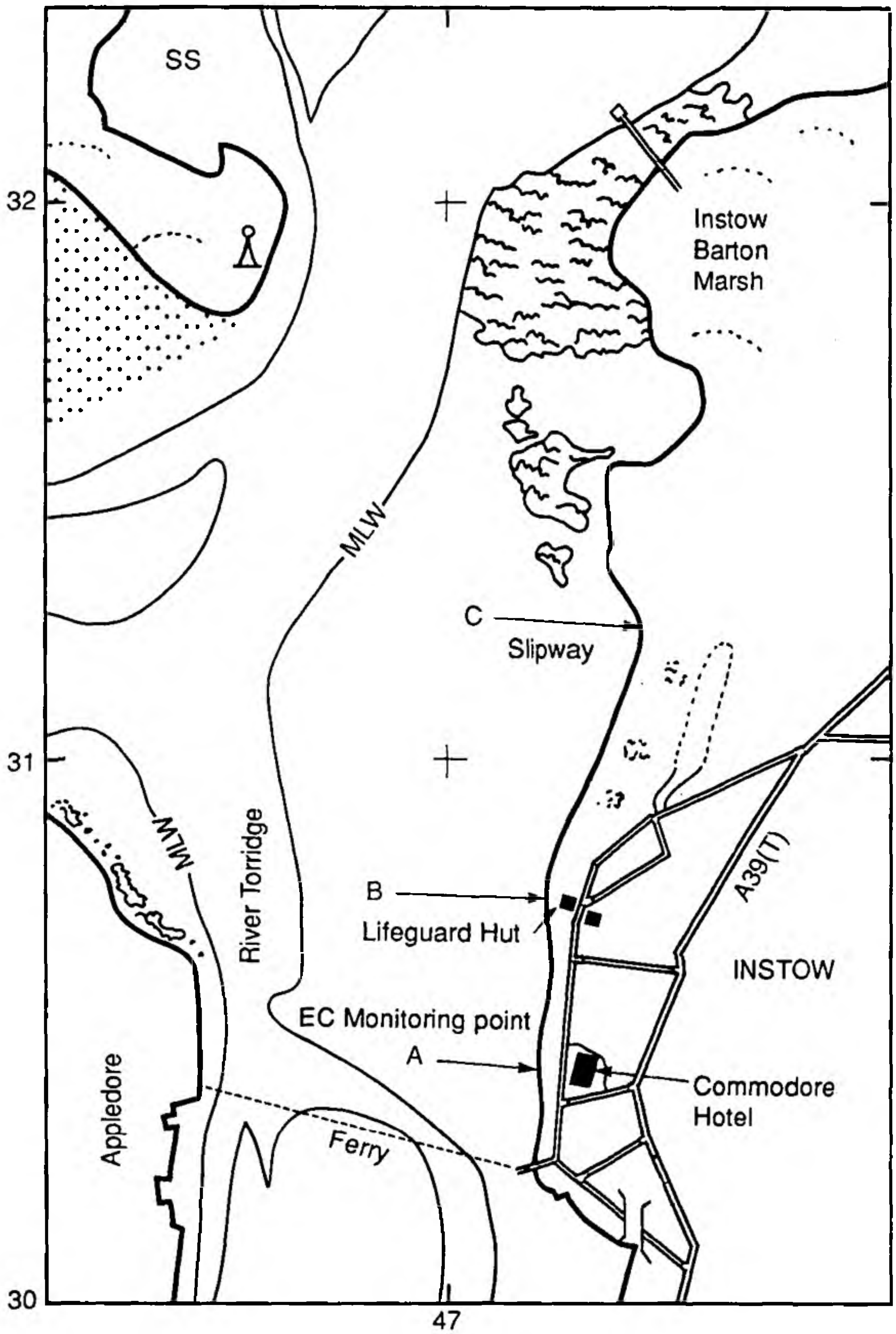

Figure 3.7 Instow. Beach sampling stations and National Grid km co-ordinates

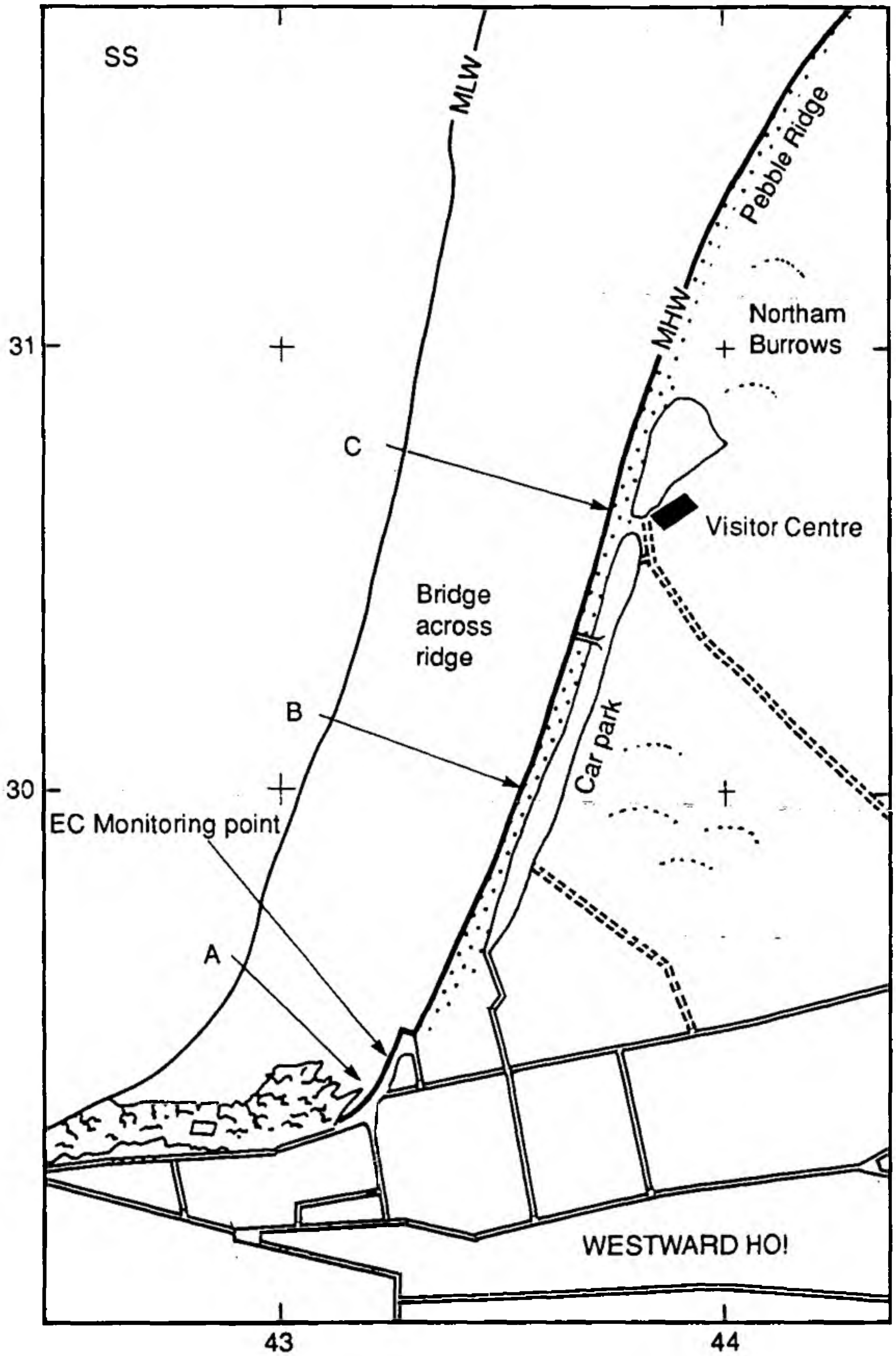

Figure 3.8 Westward Ho!. Beach sampling stations and National Grid km co-ordinates

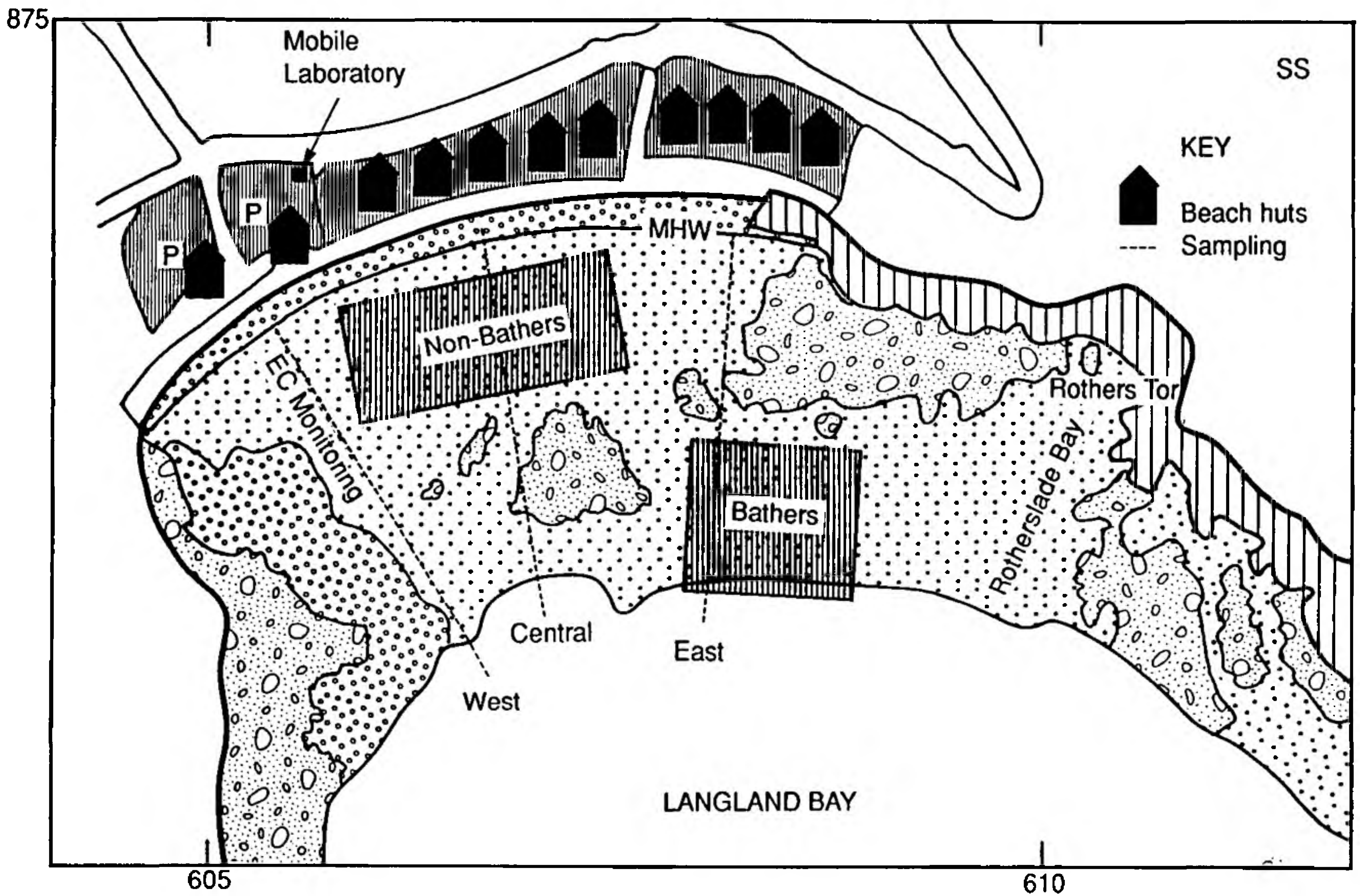

Figure 3.9 **Langland Bay. Sampling stations for Beach survey and location of cohort study, 2 September 1989. National Grid 100m co-ordinates shown.**

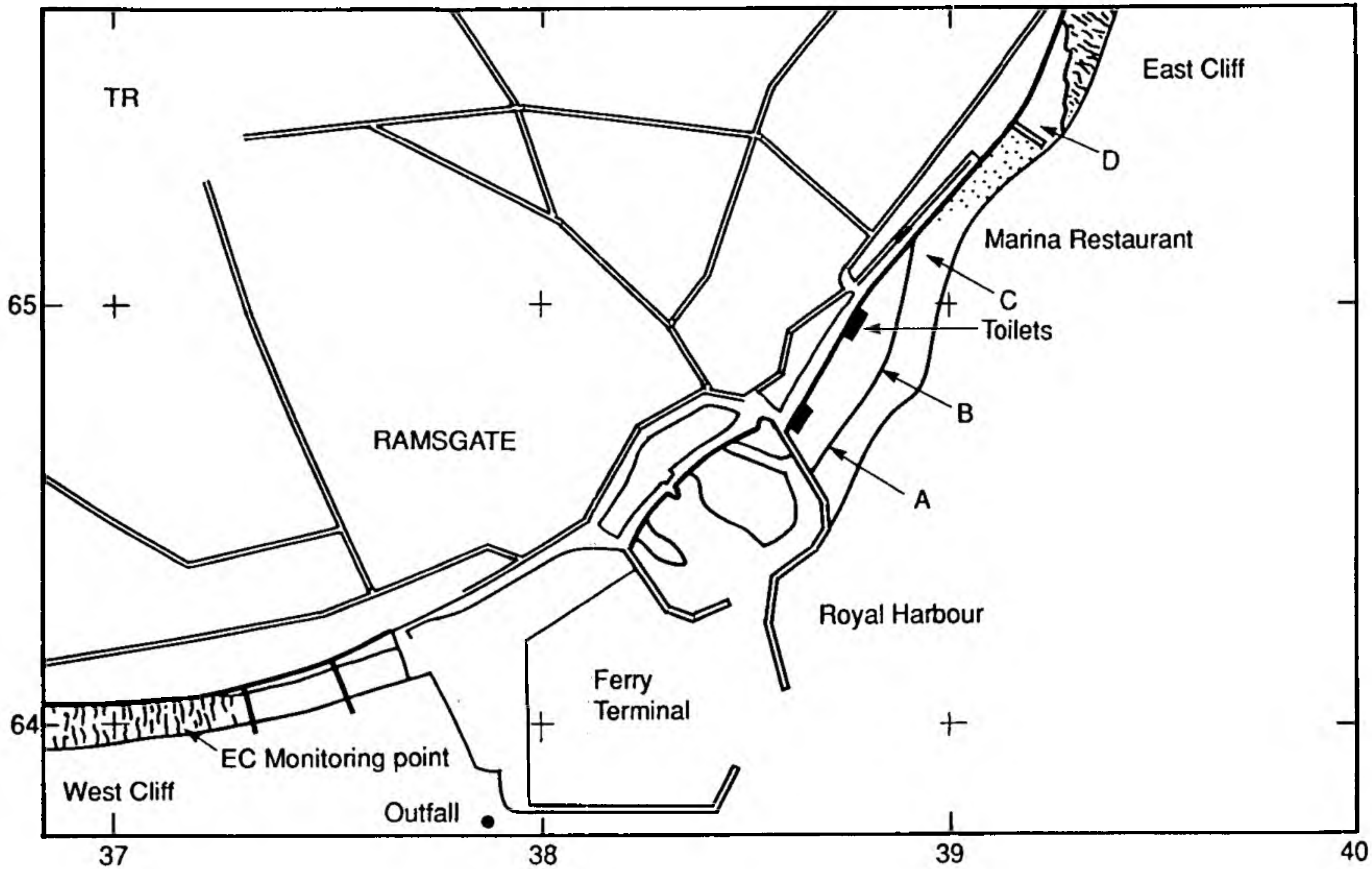

Figure 3.10 Ramsgate. Beach sampling stations and National Grid km co-ordinates

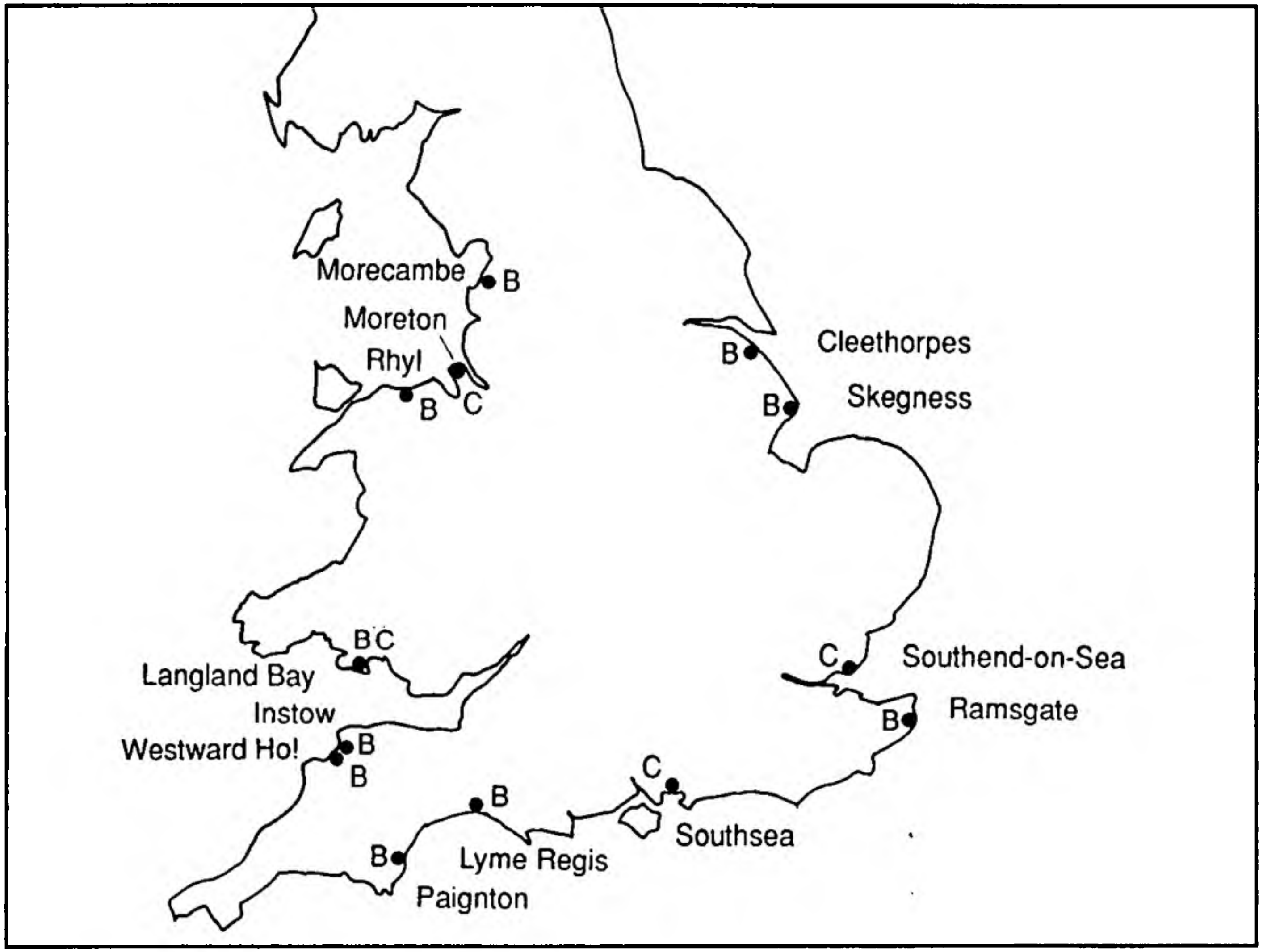

Figure 3.11 Location of beach survey (B) and cohort (C) studies

3.2 Description of beaches

In Figures 3.1-3-10, the microbiological sampling points are indicated by the capital letters A-C and lines normal to the shore. These were chosen within popular areas of beach and could be identified by landmarks or other features, to assist samplers. Streams or points of discharge on to the beach were avoided. Recruitment was carried out on the corresponding three stretches of beaches and promenade on either side of the sampling points. The scale of the maps is shown by the kilometre co-ordinates of the National Grid references. Permission to reproduce material shown in the respective currently published 1/25 000 sheets of the Ordnance Survey is acknowledged.

Table 3.1 shows the results of bacteriological monitoring, under the bathing water Directive, of the ten beaches used for the Beach Survey studies, extracted from the official report for the 1990 bathing season (NRA 1991a). This table, which avoids year-to-year variations, shows that there was a wide gradation of quality between the beaches selected and that there were wide variations in individual counts at each beach. Two monitoring points were not covered by the survey. Church Beach, Lyme Regis is stony and little used and Ramsgate, Western Undercliff is difficult to reach. Both were affected by discharges from short sea outfalls.

Table 3.1 Microbiological quality of water during the 1990 bathing season at the ten beaches (NRA 1991a)

Beach	Median counts (and range) per 100 ml: Total coliform bacteria		Faecal coliform bacteria	
Paignton, Preston Sands	36	(1-2700)	19	(0-1800)
Paignton, Paignton Sands	136	(15-5600)	110	(4-5000)
Lyme Regis, Church Beach*	2320	(30-31 600)	945	(10->30 000)
Lyme Regis, Cobb Beach	213	(21-7400)	68	(29 -2900)
Rhyl	3000	(190-30 500)	1030	(10 -10 100)
Morecambe, South	2500	(<200-22 000)	800	(<200-2500)
Morecambe, North	3500	(200-65 000)	1200	(<200-8000)
Cleethorpes	11 500	(1200-48 000)	2500	(500-33 000)
Skegness	43	(8-3400)	33	(2-3100)
Instow	740	(47-7500)	520	(32-5700)
Westward Ho!	138	(1-8700)	67	(1-5300)
Langland Bay	600	(10-3300)	90	(<10-600)
Ramsgate, Western Undercliff*	3000	(290-14 100)	865	(140-19 800)

* EC monitoring points not embraced by bacteriological sampling or recruitment in the Beach Survey studies.

One of the difficulties encountered in planning Phase III was that of locating beaches, consistently failing to meet the imperative (I-value) bacteriological criteria of the bathing water Directive, which did not have logistic drawbacks, such as remoteness, insufficient holidaymakers or closeness to other beaches, permitting multiple exposures to waters of different quality.

It should be noted that remedial work is being carried out or actively being planned to bring the following beaches into compliance (NRA 1991a).

1. Lyme Regis - urban resewerage, storage, interception of overflows and outfalls, primary treatment inland and long sea outfall, 1995.

2. Rhyl - construction of long sea outfall, preliminary treatment, primary and secondary treatment, 1993.

3. Morecambe -subject to modelling, likely diversion of sewage to Lancaster, secondary treatment, storm-water storage, discharge through refurbished outfall at Morecambe, 1997.

4. Cleethorpes - major improvements: storm-water interception, primary and secondary treatment, treated effluent (with ultraviolet disinfection) to Louth Canal, 1995 (Reynolds 1993).

5. Westward Ho!, Instow - Urban resewerage, storage, upgrading of Ashford and Velator sewage works; transfer of sewage from Yelland, Bideford and Westward Ho! to new secondary treatment works and 3.5 km sea outfall, 1997.

3.3 Survey methods

The methods were nearly identical to those used in 1990 at Ramsgate. Professional market researchers were engaged to recruit a target of 2200 holidaymakers at each beach over 20 days, including six weekend days. Quotas were assigned as follows and maintained, each day, as far as possible, thereby avoiding the situation in which bathers were recruited mainly on fine days and non-bathers on wet days:

- subjects aged 5 - 60 years;
- control group, not entering the water, one-third;
- subjects entering the sea in three days prior to interview, two-thirds;
- exposed subjects further stratified - equal proportions of waders and of swimmers and divers;

Subjects were identified as holidaymakers, day trippers and local residents and the areas in which they were recruited were noted for future identification with water quality. The questionnaire was designed to avoid alerting the subjects' perception of pollution and health by the order and nature of questions:

- Personal details;
- Aim given as improving facilities and the environment;
- Water activity over last three days?
- Residence at this or other resorts - duration?
- Foods eaten?
- Part of beach used?
- Water activities?
- Anticipated duration of stay?
- Appointment for telephone interview.

The follow-up by computer-assisted telephone interviewing was carried out a week later by a different team, not involved in the beach interviewing. The questionnaire followed the following order of questioning and evaded reference to symptoms until the end:

- Dates when the subject used the beach, where recruited;
- Foods purchased and eaten at the resort (a list was read out);
- Water activities and time in the sea at that beach since interview;
- Visits to and activities at other beaches;
- Duration of stay at the resort;
- Experience of defined symptoms (Tables 3.2, 3.3) after first interview:
  — At the resort since first interview?
  — Since leaving the resort?
  — Purchase of medicine or consultation of doctor? If so, "What medicine?", or "May we consult your Doctor?"

Water activities were grouped as:

- not entering the water;
- wading (including paddling);
- swimming;
- surfing/diving (including surfing, windsurfing, diving with or without mask or equipment, such as scuba-diving or snorkelling).

The questionnaire forms are reproduced as appendices to the Reports of IPH to WRc (Appendix A to Pike 1990, 1991, 1992 and Appendices 2 and 3 to Balarajan (1993)).

Table 3.2 List of symptoms used in the follow-up questionnaire of the Beach Survey studies

Runny nose
Sore throat
Sore or red eyes
Ear infection, any soreness or discharge
Nausea, that is feeling sick
Vomiting, that is being sick
Stomach cramps, that is pain in the lower abdomen or stomach
Diarrhoea, that is three or more loose or runny stools within 24 hours
Wheezing or shortness of breath
Cough
Fever, either high temperature or feeling hot and cold
Any skin rash or irritation

Notes: Each question was followed by "Yes or No?"
The starting order was rotated with successive interviewees

Table 3.3 Groupings of symptoms in Table 3.2, used in the statistical analyses

Group	Symptoms
One or more	All, except skin
Ear, nose and throat	Ear infection, runny nose, sore throat
Respiratory	Wheezing, cough
Gastro-intestinal	Nausea, vomiting, stomach cramps, diarrhoea
Diarrhoea	Diarrhoea
Fever	Fever (not analysed separately)
Skin	Skin irritation

The coding and analysis of the survey data was carried out by the Institute of Public Health, not by the market researchers, again to retain objectivity and anonymity.

The statistical methods have been explained in Section 1.3. Stepwise logistic regression analysis was used to predict the relative odds of reporting symptoms for the various classes of age group, sex, water activities and location of beach. This technique is now widely used in analysis of epidemiological data, its advantages being as follows:

1. It enables the effects of different variables to be examined hierarchically and tested for significance.

2. It corrects for the type of statistical distribution in the variables and can accommodate continuous data, numbers of occurrences and binary (yes/no) data.

3. The predicted odds ratios are provided with confidence limits, so that their significance can be assessed.

4. Odds ratios and relative risks assume a multiplicative model of risk, which takes proper account of the variabilities in the level of susceptibility shown by different persons, including those in the control group.

Subjects who remained on the beach, but did not enter the water were regarded as the control (unexposed) group. Water activity was first examined for all entering the water and was then categorized by increasing exposure from wading, through swimming to diving or surfing and by age and by sex. Symptoms were grouped according to the Table 3.3. Diarrhoea was examined both in the gastro-intestinal group and separately. For groups of symptoms, reporting of one or more symptoms counted as a positive response. The group 'one or more symptoms' excludes skin symptoms.

The odds ratios were presented using, as the reference categories, non-exposed persons, males and the 5 - 14 year age group. Data for the eight beaches of Phase III were first examined individually and then combined, using Paignton as the reference for 1991 and Cleethorpes for 1992.

3.4 Sampling and microbiological methods

The dates of sampling and interviewing at the beaches are shown in Table 3.4, together with the laboratories carrying out bacteriological analysis. Samples were taken 30 cm below the surface of the water in water 1 m deep at the three points A-C at each beach (Figures 3.1-3.10), starting at point A at exactly 1000, 1200, 1400 and 1600 hours. Samples were immediately placed in chilled, light-proof, insulated containers and delivered without delay for analysis. Logistic problems existed at Cleethorpes and Skegness, where, to ensure prompt delivery of samples, samples were taken at 1100, 1200, 1400 and 1500 hours. At low water at Cleethorpes, the foreshore extended for more than 1 km from the promenade and sampling was carried out by dune buggy.

Table 3.4 Sampling dates and laboratories carrying out bacteriological analysis of sea water

Beach	Dates of analysis and interviewing in August		Laboratory
Paignton	1991,	1-21	Exeter Public Health Laboratory (PHL)
Lyme Regis	1991,	1-21	Exeter PHL
Rhyl	1991,	1-26	Preston PHL
Morecambe	1991,	1-26	Preston PHL
Cleethorpes	1992,	3-31	Lincoln PHL
Skegness	1992,	3-22	Lincoln PHL
Instow	1992,	1-31	Exeter PHL
Westward Ho!	1992,	1-29	Exeter PHL
Langland Bay	1989,	1-30*	Robens Institute, on site
Ramsgate	1990,	6-24	Robens Institute, at Canterbury

* sampling on a total of 20 days, not including 6,11, 13, 18, 20, 21, 23, 25, 27 and 29 August.

These samples were analysed, using standard membrane filtration methods (Report 1983):

1. Total coliform bacteria: incubation upon 0.2% sodium lauryl sulphate broth for 4 h at 30 °C, followed by 14 h at 37 °C;

2. Faecal coliform bacteria: as (a) but incubation for 4 h at 30 °C, followed by 14 h at 44 °C;

3. Faecal streptococci: incubation upon Slanetz and Bartley's medium for 4 h at 37 °C, followed by 44 h at 44 °C.

Samples were taken simultaneously for somatic coliphage examination (Morinigo *et al* 1992). There were refrigerated and transported to the Robens Institute, University of Surrey, for examination.

Large-volume samples were collected every third day from sampling points A-C at each beach and submitted for analysis of cytopathic enteroviruses and rotaviruses (fluorescing foci) by Severn-Trent Laboratories, Finham, Coventry. In 1991, as in previous years, these were also examined for oocysts of *Cryptosporidium*, but this was not done in 1992, as none were found in 1990-91. The frequencies of large-volume sampling were as follows:

1. Paignton, Lyme Regis - seven occasions between 1-19 August 1991;

2. Rhyl, Morecambe - nine occasions between 2-26 August 1991;

3. Cleethorpes - ten occasions between 4-31 August 1992;

4. Skegness - seven occasions between 4-22 August 1992;

5. Instow, Westward Ho! - ten occasions between 2-29 August 1992;

6. Langland Bay - five occasions on 3, 8, 15, 22 and 30 August 1989;

7. Ramsgate Sands - six occasions between 7-23 August 1990.

The samples from Langland Bay and Ramsgate were also examined of cysts of *Giardia* spp. and for oocysts of *Cryptosporidium* spp.

3.4.1 Analytical quality control

In 1989 and 1990, analyses for faecal indicator bacteria were carried out by the same staff from the Robens Institute, University of Surrey. In Phase III, it was necessary to employ different laboratories, for logistic reasons, and the problem of assuring trueness of results between laboratories became paramount. To some extent, this was guaranteed by using laboratories within the Public Health Laboratory Service, which are subject to periodic checks on performance, administered from the Newcastle-upon-Tyne Public Health Laboratory.

In 1991, analytical quality control checks were carried out as follows for coliform bacteria and faecal streptococci;

1. Simultaneous samples: Examination of duplicate samples taken at point A-C at each beach on the 1000 and 1600 hours sampling runs.

2. Between laboratories: On four occasions (2, 8, 14, 17 August), six samples were taken at 1000 and 1600 from sites A-D at each beach and were split into two sub-samples, analysed respectively by the Preston and Exeter Public Health Laboratories.

3. Independent assessment: Preserved water samples were supplied by Newcastle-upon-Tyne Public Health Laboratory to Exeter and Preston for simultaneous analysis. Results were reported back to Newcastle.

On the advice of WRc, this was somewhat modified in 1992:

1. Replicate determinations on the same sample. The first and last samples handled daily were processed in duplicate. The actual counts of colonies were compared.

2. Independent assessment. Third-party comparisons were made using the Newcastle Public Health Laboratory's external quality assurance scheme. A specially prepared set of three seawater samples, containing added total coliform bacteria and *Escherichia coli* was sent out to the Exeter and Lincoln laboratories for examination on 25 August. Additionally, the Exeter and Lincoln laboratories participated in the routine distribution of samples (fresh water) No. W27 in September 1992.

3.4.2 Statistical analysis of data

Because bacteriological counts are usually distributed approximately log-normally, they were transformed to logarithms for analysis and results were presented as geometric means or medians. The frequent absence of detectable viruses or coliphages in many samples meant that the geometric mean could not be calculated and averages (calculated as total number of plaque-forming units divided by total volume of samples processed) are given instead. Analysis of variance and other more detailed procedures were used to examine the components of variability in replicated samples and analyses. Survey data were examined by logistic regression analysis or other methods. These are described in the background section, 1.3, on statistical methods.

3.5 Results and observations

3.5.1 General approach

The results are considered in great detail in the earlier Reports (Pike 1990, 1991, 1992) and in Balarajan (1993) both for individual beaches and for the four beaches combined. The reader is referred to these. In what follows, the results of the surveys and microbiological examinations are considered in summary, together with those obtained in Phases I (Langland Bay) and II (Ramsgate), so that the overall progress of the UK's research can be assessed.

3.5.2 Recruitment

Table 3.5 demonstrates the success of recruitment on the beach and by subsequent telephone interview at the ten beaches.

In 1991, the target of 2000 completed telephone interviews was achieved within 21 days of beach recruitment at Lyme Regis and Paignton, where the weather was generally good throughout. At Rhyl and Morecambe, cold, rainy weather in the first two weeks of August and the expanse of sand and mud flats at low tide impaired recruitment of the exposed categories. The recruitment period was extended to 26 days at both resorts. The target was almost achieved at Rhyl, but not at Morecambe. News reporting of pollution on north-western beaches, specifically mentioning Morecambe, may also have made visitors unwilling to bathe.

Table 3.5 Total number of subjects interviewed on the eight beaches and by telephone a week later; comparison with Langland Bay and Ramsgate

Beach	Interviews on beach	Interviewed by telephone	(% response)*
Paignton	2 181	2 038	93
Lyme Regis	2 159	2 065	96
Rhyl	2 138	1 964	92
Morecambe	908	790	87
Cleethorpes	2 046	1 846	90
Skegness	2 208	1 915	87
Instow	1 399	1 270	91
Westward Ho!	2 200	2 007	91
Langland Bay	4 045	791	20
Ramsgate	2 010	1 883	94
Totals	21 294	16 569	-

Notes: * Responses to telephone interviews are percentages of the 5-60 years age group interviewed on the beach, except for Langland Bay, where telephone interviews were a sample and Ramsgate, where there was no upper age restriction.

In 1992, August was generally wet, particularly in south-west England and the quota of beach interviews was only met at Skegness within the scheduled 20 days of interviews. Interviewing and sampling continued for a total of 29 days at Cleethorpes and Westward Ho! and 31 days at Instow. Contributory factors were the smallness and estuarial nature of the beach at Instow and the large expanse of sand uncovered at low tide at Cleethorpes, which meant, in both cases, that bathing took place mainly at high water

Table 3.5 shows that 21 294 subjects were recruited on the beach and telephone interviews were obtained for 16 569. Except for the pilot study at Langland Bay, where only 20% of the beach subjects were given a telephone interview, there was a high degree of consistency in the numbers of people recruited who responded to the telephone interview (92%). This response was excellent and suggests that no bias was introduced once recruitment was complete.

Table 3.6 compares the age and sex distributions of subjects completing the telephone interview and the percentage entering the water. At the eight beaches of Phase III quotas were imposed upon the beach recruiting (Section 3.3), limiting the non-exposed category to 30%, whereas the aim at Langland Bay and Ramsgate was to recruit exposed and non-exposed equally. The 70% exposed target could not be met at Morecambe or Instow. The Table also shows that two-thirds of all the subjects in Phase III were under 35 years old (excluding under-fives) and slightly more than half were female and that about three-quarters entered the water.

Table 3.6 Distribution of subjects by age, sex and water activity at the eight beaches and a comparison with Langland Bay and Ramsgate

Beach	Total subjects	Percentage of subjects: Aged 5-34	Male	Entered water*
Paignton	2 038	64.4	46.9	81.6
Lyme Regis	2 065	62.6	48.5	80.8
Rhyl	1 964	75.4	45.7	81.7
Morecambe	790	63.2	41.6	46.6
Cleethorpes	1 846	72.0	42.1	67.5
Skegness	1 915	73.0	43.8	73.5
Instow	1 270	62.8	49.6	67.0
Westward Ho!	2 007	59.0	50.3	79.2
Phase III combined	13 895	66.8	46.3	74.8
Langland Bay	791	50.0†	50.3	47.5
Ramsgate	1 883	55.7	49.2	55.4

Notes: Distributions are of those completing telephone interview, one week after beach interview.
* A quota of 30% not entering the water was imposed during beach recruitment, except at Langland Bay and Ramsgate, where it was 50%.
† Under-fives included.
Persons over 60 years old were not recruited in Phase III, because few entered the water.

3.5.3 Patterns of beach-going

Table 3.7 analyses beach-going patterns. Although holidaymakers were commoner overall than day-trippers or locals, there were differences between beaches. Rhyl and Skegness were equally popular with holidaymakers and day trippers, while people recruited at Paignton, Westward Ho! and Lyme Regis were mainly holidaymakers and at Instow, locals.

Table 3.7 Percentage distribution of subjects by beach-going pattern and a comparison with Langland Bay and Ramsgate

Beach	Holidaymakers	Day Trippers	Locals
Paignton	62	25	13
Lyme Regis	56	38	6
Rhyl	49	46	5
Morecambe	49	37	14
Cleethorpes	32	52	16
Skegness	53	45	2
Instow	25	4	71
Westward Ho!	84	4	12
Langland Bay*	74	-	26
Ramsgate	25	55	20

Notes: Distribution of those responding to telephone interview.
* Two classes only recorded, holidaymakers and locals

3.5.4 Patterns of water activity

Table 3.8 reflects the success in recruiting to the quotas of 50% non-exposed at Langland Bay and Ramsgate and 30% at the four beaches in 1991, rather than preferences for the activities. The proportions of non-exposed interviewed on the beaches in Phase III was greater than those subsequently interviewed by telephone, perhaps indicating that the non-exposed were less interested in participating further. Table 3.8 shows the difficulties in recruiting reasonable numbers of swimmers at Morecambe and Instow, or of divers and surfers at any beach.

Table 3.8 Percentage distribution of subjects by type of water activity and a comparison with Langland Bay and Ramsgate

Beach	Non-exposed	Waders	Swimmers	Surfers/ divers
Paignton	18	32	39	11
Lyme Regis	19	33	37	11
Rhyl	18	49	27	6
Morecambe	53	34	9	4
Cleethorpes	33	40	20	7
Skegness	26	37	35	2
Instow	33	37	18	12
Westward Ho!	21	33	23	23
Langland Bay	52	21	20	7
Ramsgate	45	30	21	4

Note: Distributions of those responding to telephone interview. Non-exposed quota 50% at Langland Bay and Ramsgate, 30% elsewhere.

There were no quotas imposed for interviewing locals, day-trippers and holidaymakers. Table 3.9 therefore shows that not entering the water and swimming were most popular with holidaymakers and wading with day trippers. Surfing and diving, which are activities requiring commitment, were most popular with locals and holidaymakers.

Table 3.9 Distribution of water activities by beach-going patterns

Water activity	Beach-going pattern by likelihood:		
	Most likely	Intermediate	Least likely
Not entering the water	Holidaymakers	Day trippers	Locals
Wading	Day trippers	Holidaymakers	Locals
Swimming	Holidaymakers	Locals	Day trippers
Surfing/Diving	Holidaymakers and Locals		Day trippers

Note: For Phase III. Likelihood estimated by ranking popularity of each activity by beach-going pattern and water activity, across beaches.

Table 3.10 analyses, for the eight beaches of Phase III, the age distribution of participants in the various water activities. Those not entering the water were most likely to be adults and more than half the swimmers recruited were children of 5-14 years.

Table 3.10 Age Distribution (%) of subjects by water activity

Age range	Not entering water	Waders	Swimmers	Surfers/divers
5 - 14	4.1	31.2	52.1	35.3
15 - 24	14.1	11.5	16.1	26.3
25 - 34	30.7	24.0	12.1	16.8
35 - 44	33.7	23.4	13.4	14.9
45 - 54	13.3	7.6	5.2	5.9
55 +	4.1	2.3	1.1	0.8

Note: For Phase III; unweighted averages.

3.5.5 Reporting of symptoms

Table 3.11 gathers together the crude incidence rates for recording the seven groups of symptoms for the five categories of water activity at the 10 beaches. Those activities where symptom rates were significantly elevated, compared with the unexposed, are marked with an asterisk. This table of crude rates generally shows that subjects entering the water tended to note any of the classes of symptoms more frequently than those who did not enter the water. This observation is least marked for eye symptoms and most marked for gastro-intestinal. This elevation of incidence rates is also greatest for surfers and divers.

Table 3.11 Crude rates (per 1000) of recorded symptoms at the 10 sites of Phase III

Class of symptom and location	Water activity No	Water activity Yes	Waders	Swimmers	Surfers/ divers
1. One or more					
Paignton	195	239	226	227	317*
Lyme Regis	205	234	231	218	294
Rhyl	267	266	259	277	269
Morecambe	235	293	290	279	357
Cleethorpes	198	227	191	254	348*
Skegness	178	208	199	217	222
Instow	136	188	167	185	255*
Westward Ho!	137	205*	163	188	280*
Langland Bay	68	122*	83	143*	182*
Ramsgate	215	263*	253	263	333*
2. Eye					
Paignton	19	37	28	38	60*
Lyme Regis	48	40	29	44	54
Rhyl	56	42	35	58	28
Morecambe	59	24	22†	15	71
Cleethorpes	20	30	16	40	81*
Skegness	22	21	24	17	44
Instow	12	35*	28	30	65*
Westward Ho!	24	33	20	22	64
Langland Bay	7	29*	12	39	54
Ramsgate	49	59	52	58	119*
3. Ear, Nose and Throat					
Paignton	107	142	134	138	179*
Lyme Regis	104	133	137	113	190*
Rhyl	169	146	142	153	148
Morecambe	145	160	151	132	321*
Cleethorpes	115	128	102	138	230*
Skegness	103	119	121	120	89
Instow	86	110	97	108	157
Westward Ho!	91	118	88	107	172*
Langland Bay	31	77*	48	78	164
Ramsgate	85	127	84	168	226

Table 3.11 continued

Class of symptom and location	Water activity No	Water activity Yes	Waders	Swimmers	Surfers/ divers
4. Respiratory					
Paignton	73	67	80	62	92
Lyme Regis	68	68	63	72	72
Rhyl	111	88	83	88	130
Morecambe	83	106	103	88	179
Cleethorpes	68	75	63	93	89
Skegness	57	72	74	68	89
Instow	48	60	67	56	46
Westward Ho!	48	72	48	72	106*
Langland Bay	12	19	6	39	<18
Ramsgate	54	65	59	68	95*
5. Gastro-intestinal					
Paignton	64	78	74	65	133*
Lyme Regis	58	85	84	75	122*
Rhyl	67	105*	106*	104*	93
Morecambe	64	122*	114*	147*	143
Cleethorpes	78	108	94	130	126
Skegness	75	85	75	94	111
Instow	57	65	49	60	118
Westward Ho!	48	78	65	68	106*
Langland Bay	39	32	36	32	18
Ramsgate	52	79*	66	93*	95
6. Diarrhoea					
Paignton	32	29	31	23	46
Lyme Regis	28	37	40	26	63*
Rhyl	33	47	57*	34	19
Morecambe	31	63*	66*	59	36
Cleethorpes	37	47	41	48	74
Skegness	45	40	34	45	67
Instow	19	32	30	22	52
Westward Ho!	24	31	33	24	36
Ramsgate	36	57*	53	65*	48

Table 3.11 continued

Class of symptom and location	Water activity No	Water activity Yes	Waders	Swimmers	Surfers/ divers
7. Skin					
Paignton	35	46	38	43	83*
Lyme Regis	10	41*	38*	40*	50*
Rhyl	44	48	43	58	43
Morecambe	45	43	40	29	107
Cleethorpes	20	41*	26	48*	104*
Skegness	44	48	43	58	46
Instow	17	22	21	22	26
Westward Ho!	36	28	23	29	89

Notes: * Significantly elevated compared with control group (no water activity) from results of logistic regression analysis (Table 3.12). † significantly lower.
No data recorded for diarrhoea or skin symptoms at Langland Bay, or for skin symptoms at Ramsgate - no significant effects of water activity found.

Table 3.12 summarises the corrected odds ratios (ORs) derived for seven classes of symptom and the ten beaches after logistic regression analysis comparing ORs for exposed against non-exposed, and (a) for type of exposure compared against the unexposed and (b) for age and sex across all activity groups, whether entering the water or not (the reference groups, OR = 1.00, being respectively 5-14 year olds and males).

Tables 3.11 and 3.12 will be discussed in Section 3.6.1.

Table 3.12 Odds ratios derived by logistic regression analysis for symptoms recorded at individual beaches.

Class of symptom and location	Entering water(a)	Waders (b)	Swimmers (b)	Surfers/ divers(b)
1. One or more				
Paignton	1.18	1.14	1.09	1.75*
Lyme Regis	1.08	1.08	0.98	1.43
Rhyl	1.00	0.96	1.12	1.07
Morecambe	1.28	1.24	1.25	1.87
Cleethorpes	1.09	0.87	1.20	1.99*
Skegness	1.08	1.07	1.11	1.14
Instow	1.29	1.16	1.19	1.91*
Westward Ho!	1.50*	1.27	1.39	2.07*
Langland Bay	1.90*	1.26	2.34*	3.04*
Ramsgate	1.31*	1.25	1.31	1.81*

Other significant values(b):

<u>Ages 15-24</u>: Rhyl 1.54*, Westward Ho! 1.74, Langland Bay 2.75*, Ramsgate 1.52*
<u>Ages 35-44</u>: Paignton 0.60†
<u>Ages 45-54</u>: Lyme Regis 0.34†, Morecambe 0.44†
<u>Females</u>: Rhyl, 1.27*

Class of symptom and location	Entering water(a)	Waders (b)	Swimmers (b)	Surfers/ divers(b)
2. Eye				
Paignton	2.00	1.48	2.14	3.72*
Lyme Regis	0.78	0.59	0.93	1.14
Rhyl	0.71	0.62	1.06	0.48
Morecambe	0.35	0.29†	0.23	1.43
Cleethorpes	1.54	0.84	1.98	3.39*
Skegness	1.10	1.17	0.86	2.39
Instow	2.98*	2.43	2.49	5.23*
Westward Ho!	1.16	0.82	0.80	2.03
Langland Bay	3.71*	nd	nd	nd
Ramsgate	1.24	1.10	1.22	2.65*
3. Ear, Nose and Throat				
Paignton	1.32	1.28	1.26	1.74*
Lyme Regis	1.13	1.21	0.89	1.59*
Rhyl	0.89	0.85	1.00	0.93
Morecambe	0.96	0.89	0.72	2.43*
Cleethorpes	1.16	0.91	1.26	2.12*
Skegness	1.16	1.19	1.12	0.77
Instow	1.12	1.03	1.00	1.53
Westward Ho!	1.26	1.06	1.20	1.65*
Langland Bay	2.77*	nd	nd	nd
Ramsgate	1.08	1.16	0.86	1.70

Table 3.12 continued

Class of symptom and location	Entering water(a)	Waders (b)	Swimmers (b)	Surfers/ divers(b)
Other significant values (b):	Ages 15-24: Paignton 1.63*, Rhyl 1.86*, Ramsgate 1.72*, Cleethorpes 1.68*, Skegness 2.05*, Westward Ho! 2.89* Ages 35-44: Lyme Regis 0.61† Ages 45-54: Paignton 0.51†, Lyme Regis 0.29†, Morecambe 0.34†			
4. Respiratory				
Paignton	1.02	1.21	0.81	1.20
Lyme Regis	0.78	0.80	0.77	0.80
Rhyl	0.73	0.70	0.75	1.14
Morecambe	1.40	1.37	1.12	2.22
Cleethorpes	1.10	0.95	1.45	1.26
Skegness	1.08	1.16	0.92	1.21
Instow	1.05	1.20	0.86	0.79
Westward Ho!	1.43	1.02	1.49	2.18*
Langland Bay	1.27	nd	nd	nd
Ramsgate	1.40	1.22	1.41	2.85*
Other significant values (b):	Ages 15-24: Ramsgate 2.39*, Langland Bay 9.38* Ages 25-34: Lyme Regis 0.55†, Instow 0.44† Ages 35-44: Lyme Regis 0.49†, Instow 0.43† Ages 45-54: Lyme Regis 0.42†			
5. Gastro-intestinal				
Paignton	1.09	1.08	0.89	1.95*
Lyme Regis	1.40	1.40	1.23	2.02*
Rhyl	1.76*	1.74*	1.85*	1.68
Morecambe	2.03*	1.79*	2.93*	3.08
Cleethorpes	1.21	1.05	1.42	1.71
Skegness	1.04	0.95	1.23	1.57
Instow	1.01	0.78	0.90	1.95
Westward Ho!	1.50	1.34	1.32	2.00*
Langland Bay	0.69	nd	nd	nd
Ramsgate	1.47*	1.36	1.74*	0.95
Other significant values (b):	Age 15-24: Cleethorpes 0.51† Morecambe: Age 25-34 1.63*, Female 1.66; Age 45-54: Lyme Regis 0.30†, Westward Ho! 0.41†			

Table 3.12 continued

Class of symptom and location	Entering water(a)	Waders (b)	Swimmers (b)	Surfers/ divers(b)
6. Diarrhoea				
Paignton	0.89	0.91	0.71	1.54
Lyme Regis	1.35	1.40	0.98	2.55*
Rhyl	1.85	2.07*	1.38	0.75
Morecambe	2.43*	2.40*	3.02	1.76
Cleethorpes	1.34	1.13	1.33	2.25
Skegness	0.83	0.73	1.01	1.56
Instow	1.38	1.30	0.81	2.36
Westward Ho!	1.26	1.43	0.99	1.23
Ramsgate	1.88*	1.66	2.26*	1.84
Other significant value (b):	Age: Paignton 45-54 2.33*			
7. Skin				
Paignton	1.22	1.06	1.11	2.35*
Lyme Regis	3.86*	3.70*	3.90*	4.49*
Rhyl	0.96	1.20	1.88	1.39
Morecambe	1.01	0.95	0.62	2.28
Cleethorpes	2.26*	1.37	2.67*	5.92*
Skegness	0.58	0.53	0.57	1.88
Instow	1.08	1.16	0.94	1.06
Westward Ho!	1.88	1.31	2.30	2.73
Other significant value (b):	Age 55+: Westward Ho! 4.17*			

Notes: (a) Analysis for two types of exposure (entering or not entering water), age and sex. Odds ratio for not entering water, male, age 5-14 is 1.00.

(b) Analysis for four types of exposure, age and sex. Odds ratio for male, not entering water, age 5-14 is 1.00. No records for skin symptoms and diarrhoea at Langland Bay or for skin symptoms at Ramsgate - no significant odds ratios found.

nd = no data

* Significantly elevated from basal ratio of 1.00

† Significantly lower than basal ratio of 1.00.

3.5.6 Results of microbiological analyses

Table 3.13 displays the geometric mean counts and the standard deviations of $\log_{10}$ counts at the ten beaches. Its shows that there is good overall, but not perfect, rank correlation between the results for the three determinands. Overall, the rank order of beaches in terms of increasing bacterial counts is Lyme Regis (lowest) <Skegness <Westward Ho! <Paignton and Langland Bay <Rhyl <Ramsgate and Morecambe <Instow <Cleethorpes. This relates to the days of study.

Table 3.13 Geometric mean counts (per 100 ml) of faecal indicator bacteria at the ten beaches. Standard deviations of $\log_{10}$ counts in parentheses

Beach	Nº of samples	Total coliform bacteria	Faecal coliform bacteria	Faecal streptococci
Paignton	360	235 (0.36)	103 (0.39)	32 (0.42)
Lyme Regis	360	104 (0.50)	40 (0.50)	14 (0.41)
Rhyl	468	3540 (0.30)	310 (0.59)	88 (0.30)
Morecambe	468	3380 (0.37)	447 (0.70)	100 (0.41)
Cleethorpes	348	2100 (0.79)	880 (0.79)	154 (0.77)
Skegness	240	104 (0.72)	65 (0.73)	31 (0.62)
Instow	372	1500 (0.87)	598 (0.84)	126 (0.91)
Westward Ho!	348	224 (0.86)	81 (0.99)	21 (0.89)
Langland Bay	162	260 (0.35)	158 (0.25)	29 (0.40)
Ramsgate	228	1200 (0.36)	550 (0.31)	100 (0.38)

The size of the logarithmic standard deviations indicates the total variability caused by changes in bacterial numbers with position on the beach, with time and by sampling and analytical errors. These values of logarithmic standard deviation are quite typical of beach water samples and indicate the very great degree of variability in count which can occur at a beach during the bathing season, For example, a geometric mean count of 100 per 100 ml with a standard deviation of 0.7 would indicate that 90 per cent of samples would show counts in the range 7 - 1417 per 100 ml.

Another way of comparing the bacteriological results is to examine percentage compliance with the maximum bacterial counts specified in the bathing Water Directive 76/160/EEC (Table 3.14). This shows that four beaches met mandatory requirements for both total and faecal coliform bacteria - Lyme Regis, Skegness, Paignton and Langland Bay - but that none met the guideline criteria for faecal coliforms and faecal streptococci. It must be pointed out, however, that this conclusion relates only to the period of the study, when sampling was intensive and that the level of compliance would be different and probably less for the schedules of weekly or fortnightly monitoring at single points on recognised beaches at one time of day during the bathing season, required in the harmonised monitoring of the bathing water Directive.

Table 3.14 Percentage compliance of samples taken at the ten beaches with the Mandatory (I-value) and Guideline (G-value) criteria in the Bathing Water Directive 76/160/EEC

Beach	Criteria (Counts/100 ml)				
	I Total coliforms <10 000	I Faecal coliforms <2000	G Total coliforms <500	G Faecal coliforms <100	G Faecal streptococci <100
Lyme Regis	99.6	98.0	83	71*	89*
Paignton	99.6	96.6	64*	45*	74*
Rhyl	78	87*	6*	20*	41*
Morecambe	74*	74*	8*	19*	45*
Cleethorpes	86*	69*	20*	10*	34*
Skegness	100	99	84	63*	78*
Instow	83*	68*	34*	20*	46*
Westward Ho!	98	93*	68*	53*	83*
Langland Bay†	100	100	88	59*	75*
Ramsgate	-	88*	-	-	

Notes: * Failure of 95 percent of samples to meet the mandatory criteria and of 80 percent (90 percent of faecal streptococci) to meet the guideline criteria.

† Triplicate samples thrice daily from two stations, 31 July - 2 September 1989

- No data

Table 3.15 summarises the incidence and average levels of enteroviruses, rotaviruses, coliphages and cryptosporidial oocysts at the six beaches.

Because of the influence of the River Torridge at Instow, particular reference was made to the salinity of water samples. The range was 16.7-36.3 parts per thousand. The bulk of determinations exceeded 30 and only four samples (13%) were below 20 parts per thousand.

Table 3.15 Detection rates (samples positive/samples examined) and average counts* of viruses and cryptosporidial oocysts in samples taken at the ten beaches

Beaches	Enteroviruses in 10 l	Rotaviruses in 10 l	Coliphages in 1 ml	Cryptosporidia in 10 l
Paignton	3/21 (0.14)	0/21	30/63 (1.1)	0/21
Lyme Regis	3/21 (0.33)	0/21	32/63 (1.1)	0/21
Rhyl	12/27(2.4)	0/27	47/78 (1.3)	0/27
Morecambe	12/27(4.7)	0/27	33/78 (1.0)	0/27
Cleethorpes	10/30(1.27)	0/30	79/87 (2.9)	-
Skegness	0.30 (0.00)	0/30	29/60 (0.2)	-
Instow	8/25 (2.13)	0/25	81/93 (7.9)	-
Westward Ho!	2/30 (0.13)	0.30	38/87 (0.3)	-
Langland Bay	5/15 (0.53)	5/15(15)	-	(4)†
Ramsgate	5/18 (0.50)	0/18	18/18(24)	-

Notes: * Shown in parentheses as total counted/total volume examined. For enteroviruses, pfu/10-l, for rotaviruses fluorescent foci/10-l, for coliphages pfu/ml and for cryptosporidia oocysts/10-l.

† In 15 samples, 5 oocysts found in total volume of 1260 ml.

No examination for cryptosporidia in 1992.

3.5.7 Quality control of microbiological analyses

Within laboratory variability

WRc's recommendation in 1991 was that duplicate analyses should be made of the first and last samples to be processed by each laboratory, giving a total of 40 comparisons over 20 sampling days at each laboratory. The aim was to measure residual within laboratory errors of analysis separately from those caused by variation between samples.

In the event, duplicate samples were taken on the first and last runs of sampling days at each beach and location. Full analysis of variability was not undertaken; however, WRc carried out a detailed analysis of variance of 84 Morecambe samples which were analysed for total coliform bacteria between 1-7 August.

The analysis of variance in Table 3.16 was carried out on $\log_{10}$ counts. It shows that there was a highly significant difference between days of the study, times of day and sampling stations and for their first and second order interactions. Such interactions are commonly found in such data because of tidal currents and wind affecting dispersion of pollution.

The residual mean square can be considered as an estimate of the variance attributable both to duplicate sampling and to analysis and these effects cannot be separated.

However, its size was low enough to permit these significant effects to be detected. The variations of the geometric means for the seven days does not suggest any 'learning curve', as the laboratory undertook the analysis, but that real differences in count occurred between days. This sample of duplicate results suggests that analytical procedures were being correctly carried out for total coliform bacteria.

Table 3.16 Analysis of variance of log_{10} total coliform counts from analysis of duplicate samples taken at 1000 and 1600 hours at Sites A-C at Morecambe on 1-7 August 1991

Factors	Degrees of freedom	Sum of squares	Mean square	F-Ratio
Times of day	1	2.4276	2.4276	24.2***
Stations	2	1.3740	0.6870	6.86**
Days	6	13.6616	2.2769	22.7***
Times x Stations	3	1.0436	0.3479	3.47*
Times x Days	6	8.9919	1.4987	14.96***
Stations x Days	12	5.3385	0.4449	4.40***
Times x Stations x Days	12	3.8441	0.3203	3.20**
Residual	41	4.1098	0.1002	
Total	83	40.7911		

Notes: * $0.05 > p > 0.01$
** $0.01 > p > 0.001$
*** $0.001 > p$

WRc's recommendation was carried out in 1992, A sample from the first or last sampling run of the day was chosen arbitrarily and processed in duplicate. Counts of colonies were noted. The sizes of the differences for each pair of colony counts was examined to see if they indicated significant departure from values expected from the Poisson distribution. The percentages of deviant pairs of counts at each laboratory were Exeter 4/366 (1.0%) and Lincoln 8/294 (2.7%). These frequencies are well within values expected by chance and indicate that within-laboratory errors were being correctly minimised. A similar conclusion was obtained by IPH, using a different statistical method (Balarajan 1993, pp 137-138).

Between-laboratory variability

The results from the analysis of split samples by the two Public Health Laboratories at Exeter and Preston in 1991 is shown in Table 3.17. The road journey between them took about 8 hours and was such that samples at the 'away' laboratory often could not be analysed until the day after. Counts of faecal bacteria in sea water steadily decline with storage, even in darkness at refrigeration temperatures. It was also discovered on 2 August that initial low temperature incubation ('resuscitation') was not being given at Preston in the analyses of faecal coliform and faecal streptococci. This was immediately rectified. Taken together, this could account for the non-equivalence of counts at the 'home' and 'away' laboratories, with the exception of the Paignton samples examined for faecal streptococci. The ratios 'Away/Home' in Table 3.17 are those expected as a result of decay of total coliform bacteria over 8-18 hours storage in the dark at 5-10 °C.

A way of overcoming the effect of delays in analysis is to arrange for both 'home' and 'away' samples to be stored identically and examined simultaneously by prior arrangement. This enables efficiencies of the laboratories to be compared, although counts are equally affected by storage.

Between laboratory variability assessed externally

Both laboratories participated in analysis of check samples provided by Newcastle Public Health Laboratory. It is a feature of this scheme that individual laboratories are notified whether or not their results lie between the 95 percent confidence limits of the mean result. Such a trial (No. W45) was carried out in September 1992 with three samples of simulated surface water.

Table 3.17 Examination of split samples from the four beaches of 1991 by the Exeter and Preston Public Health Laboratories to ascertain between-laboratory variability

Determinand	Beach (and home laboratory)	Average Counts (per 100 ml) Home Laboratory	Away Laboratory	Ratio Away/ Home
Total coliforms:	Lyme Regis(E)	137	94	0.69
	Paignton(E)	610	498	0.82
	Rhyl(P)	7024	5159	0.73
	Morecambe(P)	5845	4911	0.84
Faecal coliforms:	Lyme Regis	43	22	0.51
	Paignton	320	202	0.63
	Rhyl	1055	2784	2.6
	Morecambe	2090	2945	1.4
Faecal streptococci:	Lyme Regis	9.4	7.2	0.76
	Paignton	35	43	1.2
	Rhyl	198	259	1.3
	Morecambe	255	277	1.1

Note: Samples taken at Sites A-C, at each beach, at 1000 and 1500 on 2, 8, 14 and 17 August, split into duplicates and analysed by Exeter(E) or Preston(P) Public Health Laboratories.

Both Public Health Laboratories received, on 21 August 1992, three simulated sea water samples, for analysis on 25 August, from the Newcastle-upon-Tyne Public Health Laboratory. Table 3.18 compares the findings of the distributing laboratory with those of the recipient laboratories and shows a tendency for under-recovery by Laboratory B. It is stressed that this is the result of a single assessment, whereas there would be grounds for severe concern if such under-recovery were consistent over many assessments.

Table 3.18 Comparison of results obtained by the distributing and two recipient laboratories in analysis of simulated sea water, 25 August 1992

	Total coliform bacteria			Faecal coliform bacteria		
	A	B	C	A	B	C
Target results	25 000	50 000	50 000	0	10 000	1 000
Distributing laboratory:						
Replicate 1	23 000	61 000	49 000	<1	9 700	890
Replicate 2	30 000	71 000	53 000	<1	9 900	1 020
Laboratory A	20 000	38 000	49 000	0	13 000	1 100
Laboratory B	12 000	21 000	34 000	0	6 600	1 000

Note: Counts by membrane filtration methods, per 100 ml.

3.6 Analysis and discussion

3.6.1 Differences in relative risks between unexposed and exposed groups

It would not be surprising to find differences in absolute (crude) attack rates recorded by the exposed and unexposed at different beaches. Such differences could reflect any of the following factors:

The state of community health.
Circulation of pathogens in sewage and in the sea.
Immunity acquired in response to challenge by pathogens while bathing on previous occasions.
Past bathing history and day-tripper, holidaymaker or local resident status.
Weather conditions affecting how long people bathe and how long they are exposed to any pollution.
Subjects' perception of illness, modified by publicity from news media and environmental groups.

Scrutiny of the crude rates of recording symptoms by the unexposed control group ("no water activity" in Table 3.11) shows that they depend upon the type of symptom and the beach. Rates for combined symptoms, such as 'one or more' or ear, nose and throat are greater than for single symptoms, such as diarrhoea or skin irritation, which is self-evident. Ranking of beaches by mean rank orders of rates of recording the seven symptoms of Table 3.11, gave the following order of frequencies for recording of symptoms by those not entering the water (with mean rank scores in parentheses):

Langland Bay	(1.0)
Westward Ho!	(3.4)
Instow	(3.6)
Lyme Regis	(5.1)
Paignton	(5.4)
Ramsgate	(5.5)
Skegness	(6.2)
Cleethorpes	(6.5)
Morecambe	(8.0)
Rhyl	(8.6)

This rank order is quite different from the ranking of beaches by geometric mean counts of faecal indicator bacteria (Table 3.13 and Section 3.5.6). Hence, it cannot be said that the control group were pre-conditioned in their responses by what they might have learned about the relative qualities of water or degree of pollution. There is, however, a remarkable - though doubtlessly spurious - geographical relationship in the ordering which goes anti-clockwise around the coastline of England and Wales. These findings fully justify the care to select beaches differing in conformity with the bathing water Directive around England and Wales and with the selection of a non-exposed control group, so that attack rates in the exposed could be expressed relative to the non-exposed.

The object of the logistic regression analysis was to examine separately for the following effects, whilst controlling for others:

- water activity, compared with none;
- stratified water activity (wading, swimming, surfing/diving);
- age class;
- sex.

Scrutiny of Table 3.12 indicates that overall, for the symptom classes 'one or more', eye, gastro-intestinal and skin there is a consistent increase in ranked odds ratios for the order wading, swimming, surfing/diving. In the case of ear, nose and throat, respiratory and diarrhoea, odds ratios for wading and swimming are very similar but there is a marked increase for surfing/diving. Overall, the greatest frequency of significantly elevated odds ratios is for surfing/diving. There is thus an overall increase in odds ratio for these symptoms with the degree of water contact, which is least for those not entering the water and the greatest for surfing/diving. Table 3.12 shows that where age effect is significant it usually results in elevated recording in the 15-24 age group and reduction in older groups and that the only significant effect of sex was for elevation of one or more symptoms at Rhyl.

Generally, Table 3.12 shows that significant elevations in odds ratios for water activity at individual beaches are numerous only for surfing/diving, where they were elevated significantly in 24 of the total of 67 combinations of beach and symptom and were greatest, on average, for one or more and for eye and skin symptoms. By contrast, the effects of wading (5 of 67 cases) and of swimming (7 of 67 cases) are small.

Conventionally in epidemiology, relative risks or odds ratios less than about 1.5, if significantly elevated, show a weak effect, between 1.5 and 3.0 a moderate effect and only if greater than 3.0 a strong effect. For example, in a study of lung cancer, the following significant odds ratios were found: pet bird keeping 2.14, smoking 16.1, occupational exposure to carcinogens 3.1, passive smoking as a child 1.7, carrot consumption 0.74 (Kohlmeier *et al.* 1992). These examples are given as they will be readily appreciated by the reader. By this criterion, the effects of water activity on recording of the various symptoms must be gauged as bare, except for surfing and diving, when they could be regarded as moderate, where significant.

3.6.2 Relative risks and water quality

One of the main conclusions from previous epidemiological studies (Table 1.2) is that the rate of reporting gastro-intestinal symptoms is related to bacteriological quality of the water.

The second objective of Phase III was to establish whether, or not, a relationship existed between microbiological quality of coastal water and the risk to health of bathers (Section 2.1). This implies, in practice, determining whether or not a correlation exists between counts of faecal indicators in sea water and rate of recording symptoms. This is because it is not possible to determine directly the pathogens responsible for reports of illness in bathers, since for the most part they are not known, and because medical or clinical diagnosis could not be accommodated within the design of the study. The suite of microbiological examinations are therefore the best surrogate indicators of the likelihood of pathogens being present in the water and the questionnaire of symptoms the best surrogate for diagnosis of illness. At this stage, prior to statistical analysis, no *a priori* assumptions are made about the outcome and the null hypothesis - that no relationship exists - is made until disproven.

IPH did not pursue a search for correlations between counts of microbiological indicators and odds ratios, except for noting that there were positive rank correlations (Spearman's ρ) between the grading of the eight beaches in Phase III by geometric mean counts of total coliform bacteria and for odds ratios for those entering the water and diarrhoeal symptoms (ρ=0.72, $p<0.05$), indicating significant association between adverse water quality and diarrhoeal symptoms.

3.6.3 WRc's meta-analysis of water quality and recording rates

WRc considered that it was necessary to explore the last-mentioned finding in order to derive the best possible satisfaction of the second objective of the study. Without re-analysis of the data set, the following derived information was used from Phases I-III (ten beaches) :

1. Geometric mean counts of total and faecal coliform bacteria, faecal streptococci, somatic coliphages and enteroviruses (Tables 3.13 and 3.15). These were transformed to $\log_e$ values.

2. Odds ratios, adjusted from logistic regression analysis, for the symptoms and water activities of Table 3.12. These were transformed to $\log_e$ values.

Linear regression was carried out of $\log_e$ adjusted odds ratios (y) on $\log_e$ counts of indicators (x) to test the fitting of the data to the equation

$$y = mx + c$$

where m is the slope of the best fitting line (the fractional increase in y for unit increase in x) and c is the intercept constant (the predicted value of y, when x = 0). Significance of the product-moment correlation coefficient, r, was derived from statistical tables.

Examination of crude odds ratios for diarrhoea for the four classes of water activity and the four faecal indicators of Table 3.21 revealed only four which were statistically significant - for wading or water activity against total coliform bacteria or enteroviruses.

In no other case, other than those shown in Table 3.19 did the value of the correlation coefficient reach 0.5.

An opportunity has been taken to calculate predicted values of odds ratios for waters just meeting the imperative (I) and guideline (G) values of the bacterial and enterovirus indicators in the bathing water Directive 76/160/EEC in Table 3.22. However, the regression equations of Table 3.19 are for geometric mean counts. Allowance has been made for this by calculating the geometric means corresponding to the percentiles of the I and G values in the Directive, from the average standard deviations of Table 3.13, giving respective geometric means (per 100 ml) of 1237 and 172 for total coliforms, 198 and 31 for faecal coliforms and 19.7 for faecal streptococci. These values were inserted into the regression equations to derive predicted odds ratios. Similarly, from the theory of the Poisson distribution, the requirement for 95 per cent of 10-litre samples to be free from enteroviruses (i.e. for 5 per cent to contain one or more) corresponds to a true mean of 0.051 pfu per 10 litres.

3.6.4 General discussion

Diarrhoea is one of the symptoms characterising gastro-enteritis, which it is acknowledged, can be waterborne. Either vomiting or diarrhoea accompanied by disabling fever, or stomachache accompanied by fever, were the alternative criteria adopted by the USEPA (Cabelli 1983, Dufour 1984) as 'highly credible' gastro-intestinal symptoms and in the Phase II Cohort Studies as 'objective gastro-intestinal symptoms'. Hence, it is plausible to suggest that the relationships between diarrhoea and gastro-intestinal symptoms reported by subjects indulging in water activity and wading in Tables 3.19 and counts of total coliform bacteria and enteroviruses indicate a health effect. Reference to Table 1.1 will show that this observation shows the necessary criteria of strength of association, consistency, biological gradient, plausibility and coherence.

Table 3.19 Correlations between $\log_e$ geometric mean counts at beaches and $\log_e$ odds ratios from logistic regression analyses for various water activities and symptoms

Independent variable, $\log_e$ count (x)	Dependent variable, odds ratio (y)	Regression statistics: Correlation coefficient (r)	Slope (m)	Constant (c)	Predicted Odds Ratios for water meeting: I-value	G-value
Total coliforms (per 100 ml)	Diarrhoea, water activity	0.769*	0.1834	-0.8610	1.6	1.1
	Diarrhoea, wading	0.679*	0.1751	-0.8295	1.5	1.1
	Diarrhoea, swimming	0.610	0.1995	-1.0793	1.4	1.0
	Gastro-intestinal, swimming	0.574	0.1470	-0.6146	1.6	1.2
Faecal coliforms (per 100 ml)	Diarrhoea, water activity	0.581	0.1771	-0.6176	1.4	1.0
Faecal streptococci (per 100 ml)	Diarrhoea, water activity	0.529	0.2096	-0.5110	-	1.1
Enteroviruses (per 100 litres)	Diarrhoea, water activity	0.841**	0.1803	0.0250	0.91	-
	Diarrhoea, wading	0.802**	0.1861	0.0072	0.89	-
	Diarrhoea, swimming	0.520	0.1528	-0.0421	0.87	-

Notes: Regression model is $y = mx + c$; pairs of values for nine beaches (excluding Langland Bay). Values are shown only for those comparisons where r exceeded 0.5. Also examined were (a) all combinations of independent variables and four classes of water activity (water activity, wading, swimming, surfing/diving) with diarrhoea, gastro-intestinal and one or more symptoms and (b) all combinations of total and faecal coliform bacteria, faecal streptococci and enteroviruses with water activity and eye, ear, nose and throat, respiratory and skin symptoms. * Critical value of r is 0.666 for 7 degrees of freedom ($p<0.05$). ** Highly significant ($p<0.01$). I and G values of the bathing water Directive 76/160/EEC are for total coliform bacteria: I 10 000/100 ml (95%ile), G 500/100 ml (80%ile); faecal streptococci G 100/100 ml (90%ile), enteroviruses none in any sample of 10 litres (95%ile).

In the USEPA's studies (Cabelli 1983), one of the aims was to search for the 'best' indicator organism for assaying the health effects of bathing. Choice was made by selecting the indicator showing the highest positive correlation with swimming-associated gastro-intestinal symptom rates. On this basis, the enterococcus count was selected for marine waters in preference to *Escherichia coli.* It was also considered that this choice was consistent with the better powers of survival of the enterococci in salt water and in partially chlorinated discharges of sewage, compared with *E. coli,* and that this more nearly matched the survival powers of the viral agents which were considered to be the main agents responsible for gastro-intestinal symptoms in bathers. However, Table 1.2 shows that there has been no unanimity of findings in epidemiological studies on this point. Hence, the finding in Table 3.19 that superior correlation was given by geometric mean counts of total coliform bacteria to those of faecal streptococci, need not be surprising. At beaches near to undisinfected discharges of sewage, the total coliform group have the advantage over all other potential indicators, of very high counts and therefore, of sensitivity. Their disadvantage of rapid decay, compared with viral agents of gastro-enteritis, will not be apparent until biological decay (as opposed to physical dilution and dispersion) considerably reduces their counts relative to the viral pathogens. Furthermore, the four Cohort Studies were carried out in relatively clean waters, remote from pollution. It is in these that the less numerous, but more resistant, faecal streptococci might be expected to be superior. Table 3.19 also indicates that the counts of cytopathic enteroviruses were correlated to a greater extent than the total coliform counts with the odds ratios for diarrhoea in subjects recording water activity or wading. This is reasonable, because it is considered that the gastro-intestinal symptoms which are reported by bathers display viral aetiology, even though the role of cytopathic enteroviruses is not clear.

Certain negative findings of Table 3.19 may cause surprise and need comment. No significant correlations were found for 'one or more' symptoms, eye, ear nose and throat or for skin symptoms and any of the indicators for persons taking part in water activities, even though the general finding was that any water activity and particularly surfing and diving increased the recording of these symptoms over that by the control group. This finding is consistent with the view expressed by Cartwright (1991) that certain illnesses are associated with prolonged exposure to water, because opportunistically pathogenic organisms, carried transiently as commensals on the body, are enabled to infect as a result of the body's defences being lowered. One would not expect the symptoms associated with such infections, or indeed, those resulting solely from prolonged exposure to the irritating effect of salt water, to be related to the microbiological quality of sea water.

Another surprising finding is that diarrhoea in swimmers was poorly correlated with total coliform and enterovirus counts and surfing/diving not at all, even though the latter activities were the ones which were associated with the greatest elevation of odds ratios (Table 3.8). It must be considered, however, that sampling in the Beach Survey studies as required by the bathing water Directive, was carried out in one metre depth of water, 30 cm below the surface. This is not a depth which is sufficient for swimming, although sufficing for wading and activities by children. Diving, surfing and windsurfing explore offshore waters, over wide areas and depths of the sea and may well bring their participants into water grossly contaminated by discharges of sewage. Poor correlations of odds ratios and microbial indicators may merely mean that the sampling regime does not reflect the quality of water experienced in these pursuits or the duration of exposure.

At beaches like Rhyl, Morecambe, Cleethorpes and Instow, where the tide went out a long way from high water mark, swimming took place mainly at high water. With short outfalls, it is to be expected that water quality will be poorest at low water, when fewer will choose to bathe, and *vice-versa*. Apparent lack of correlation between water quality and relative risks of reporting symptoms may mean that the water quality experienced was poorly defined by sampling.

3.6.5 Significance of the health effects

It is highly relevant to ask what levels of risk might be experienced by holidaymakers using beaches under similar conditions to those experienced during the Beach Survey studies, where the bacteriological qualities were at the Imperative (I) and Guide (G) values specified in the bathing water Directive 76/160/EEC. This is addressed in Table 3.19, where the predicted odds ratios for diarrhoea and gastro-intestinal symptoms have been calculated, as indicated in the last paragraph of Section 3.6.3. Generally, it appears that wading or any water activity in waters meeting the Guideline bacterial values would involve risks of recording diarrhoea indistinguishable from sitting on the beach and not going in the water. Only for waters failing to meet the Imperative standards for total and faecal coliform bacteria do the predicted odds ratios for diarrhoea in water users and waders exceed 1.5 and indicate an effect of water quality other than weak. By contrast, for water meeting the enterovirus standard (none in 95 per cent of 10-litre samples, corresponding to an average count of 0.051 pfu per 10 litres), the odds ratios for diarrhoea predicted in water users and waders are only 0.9, i.e. at around the odds for those not going in the water.

The casual reader will need to be reminded that odds ratios are relative values and are derived from rates which are quite small. To take a fairly extreme example from Table 3.12 - at Ramsgate, odds ratios of 1.88 and 2.26 were found for diarrhoea in those entering the water and those swimming, respectively, both being significantly elevated in comparison with those not entering the water. Corresponding rates recorded (Table 3.11) were (per thousand subjects) 57 for water activity and 65 for swimming, compared with 36 for those not going in the water. The real differences implied by these odds ratios of 1.88 and 2.26 are only 2.1 and 2.9 per cent of holidaymakers.

It must be remembered that the four regression equations in Table 3.19 which achieve statistical significance, are derived from mean values of very imprecise numbers. The high degree of variability in bacterial and viral counts at each beach are indicated by the logarithmic standard deviations of the geometric mean values in Table 3.13. Figures 3.12 and 3.13 show the plotted points for the four regression equations and the 95 percent confidence limits for the $\log_e$ odds ratios. The uncertainties in the prediction of odds ratios are quite obvious. However, it is also clear that the odds ratios for water users and waders reporting diarrhoea increase as the counts of the two indicators increase and that the lower 95 per cent confidence limits for the odds ratios only exceed the base level of 1.0 (i.e. the odds of diarrhoea for those not going into the water) when geometric mean counts of total coliforms exceed about 1200-3400 per 100 ml. These counts were equivalent to 95 percentiles of 10 000 - 30 000 per 100 ml, with the variability implied by Table 3.13, and are equal to or greater than the imperative standard of 10 000 per 100 ml in the bathing water Directive. Similarly, the effects of enterovirus counts on diarrhoea reached significance at averages of 0.5-2.0 per 10 litres, i.e. at values which are 10-40 times greater than the average count of 0.051 per 10 litres, implied by the requirement for 95 per cent of 10-litre samples to be free from enteroviruses. These findings suggest that activity in sea water meeting these Imperative standards does not pose any significant risks to health.

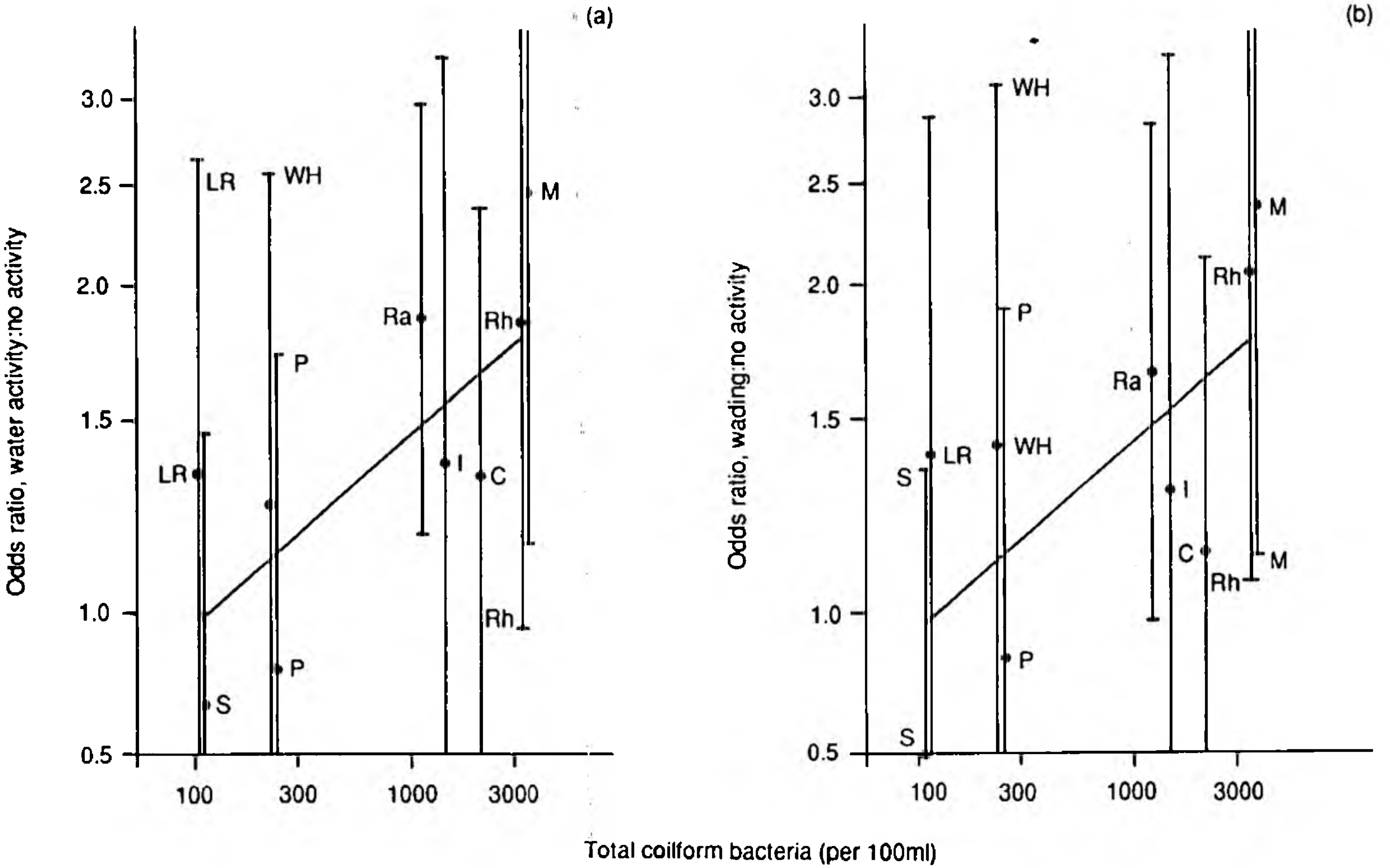

Figure 3.12 **Effect of geometric mean count of total coliform bacteria upon corrected odds ratios for diarrhoea in holidaymakers (a) entering the water and (b) wading at nine beaches, indicated by initial letters. Regression lines and 95% confidence intervals are shown**

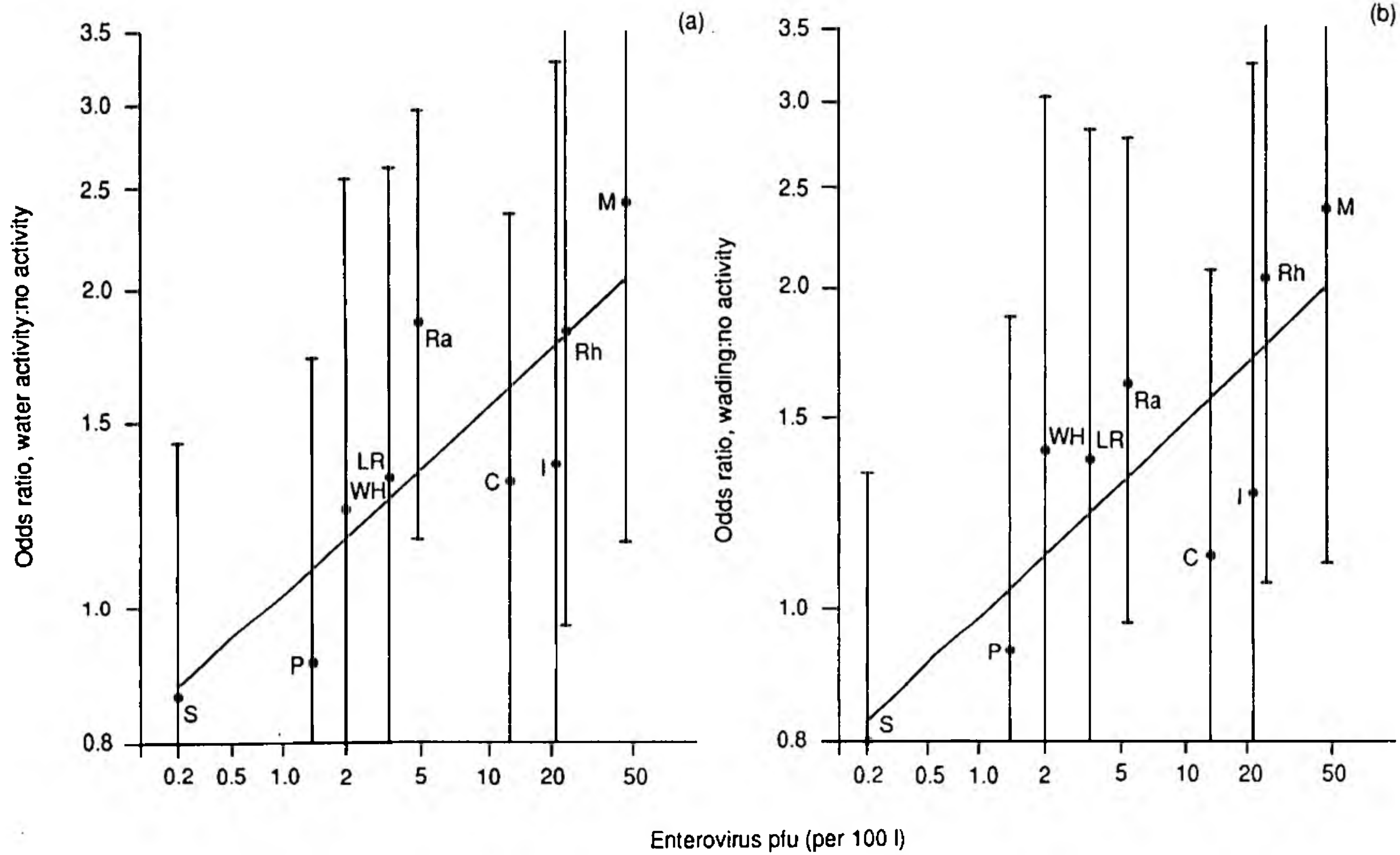

Figure 3.13 **Effect of geometric mean count of enteroviruses upon corrected odds ratios for diarrhoea in holidaymakers (a) entering the water and (b) wading at nine beaches, indicated by initial letters. Regression lines and 95% confidence intervals are shown**

3.6.6 Scope for future analysis

The Beach Survey studies have provided information upon symptoms for 16 569 holidaymakers at ten beaches varying in size, in location around the coast of England and Wales, in degree of pollution by discharges of sewage and by prevailing weather conditions over the main holiday period of August. It has fulfilled its two main objectives - of determining whether (or not) a risk to health of bathers exists from swimming in sewage-polluted water and of quantifying the risk. A large body of data has been collected, which is capable of producing refined results or of being used for related purposes, although the most important findings have already been obtained. Some of the possibilities for future analysis of the data are as follows:

1. Further examination of the symptoms comprising 'highly credible' or 'objective' gastro-intestinal symptoms as defined by Cabelli (1983) and by Jones *et al.* (1993). Those which do not appear to have been separately explored, since not reported individually, are fever, nausea, vomiting and stomach cramps.

2. The Beach Survey protocol identifies place of interview on the beach and therefore locates any water activity by microbiological sampling point (since interviewing centred upon sampling points), as well as by time. A more precise definition of exposure to microbiological quality of water is therefore possible than by geometric mean count over the whole interviewing period.

3. The two questionnaires of the beach and follow-up interviews asked for information upon the following:

   - consumption of purchased foods;
   - visitor status (holidaymaker, day tripper, local);
   - purchase of medicines or visit to doctor;
   - duration of water activity;
   - days of water activity

   Although such information is less detailed than that collected in the Cohort Studies, it is, nevertheless, suitable for examination by logistic regression analysis, as described in Section 4.6 and could provide information upon independent or confounding effects.

4. The microbiological data set is very large and could be further analysed to provide information upon variability of counts, relative to setting of water quality standards and to deriving protocols for microbiological quality assurance in laboratories. Some of the features which could be examined are:

   - variability with time and position on the beach;
   - errors in replicate sampling at one point;
   - within-laboratory replication errors;
   - correlations between counts of various indicators;
   - accommodation of variability within definition of standards.

5. Risk analysis, relating observed counts of microbial indicators to predicted levels of symptoms and derivation of risk-related standards.

4. COHORT STUDIES

4.1 Selection and description of beaches

4.1.1 Selection

One of the conditions agreed in the submission of the research protocol to the Committee on Ethical Issues in Medicine of the Royal College of Physicians was that a beach chosen for the Cohort Study should have met the mandatory microbiological requirements of the Bathing Water Directive. It is also desirable that the beach should adjoin a large centre of population, so as to obtain sufficient healthy adult volunteers who are not unduly inconvenienced by the need to attend appointments for interview and exposure. There is also a need for support from the local authority, because of the publicity needed for recruitment, the attention from news media and because of providing the venues for recruitment, interview, car parking and facilities on the beach exposure day, including life-guard coverage. It was considered desirable for the beach to be remote from large-scale catering facilities, 'fast-food' outlets, shellfish stalls and bars selling alcohol so as to minimise confounding of gut symptoms by factors unrelated to bathing.

At the outset of each Cohort Study, a short list of suitable locations was agreed between WRc and the funding agencies. Discussions were then held with the chief officers of the environmental health and publicity directorates of the District Councils followed by visits to the beaches to survey facilities for the exposure days and interviewing. Formal approval was then sought from the appropriate committees and the full council of the District Councils. Local ethical clearance was then obtained from the District Health Authorities.

During these processes, guidance and clearance was obtained from the project Steering Committee. Over the period 1988-1992, CREH set up *ad hoc* meetings with interested environmental health officers, water scientists and epidemiologists, most of who provided advice and voluntary assistance during the studies. The local advice obtained assisted materially in selecting beaches for the short list.

Details of progress in selection of beaches and the carrying out of the four Cohort Studies are given in Table 4.1

Table 4.1 Progress of the four Cohort Studies, 1989-1992

Activity	Langland Bay 1989	Moreton 1990	Southsea 1991	Southend-on-Sea 1992
Permission from District Council	5 July	13 July	24 May	10 June
Press briefings	18 Aug, 2 Sept	10 July	13 June, 6 July	4 July
Recruitment from	19 August	21 July	14 June	11 June
Pre-exposure interviews	3-31 August	2-3 August	4-5 July	2-3 July
Exposure day (Saturday)	2 September	4 August	6 July	4 July
Post-exposure interviews	5 September	10-11 August	12-13 July	10-11 July
Postal questionnaire	23 September	1 September	27 July	25 July

4.1.2 Langland Bay, Swansea

Langland Bay is one of several resorts on the south coast of the Gower Peninsula. It is about 9 km by road, south-west from the city centre of Swansea and is popular with day trippers from Swansea and South Wales, as well as with seasonal tourists. Swansea is traditionally an industrially based city but has considerable residential development in its suburbs and tourist centres are based at The Mumbles, Oystermouth, Limeslade, Langland and Caswell. Sewage from a contributory resident population of 1709 000 (design dry weather flow 45 500 m^3 d^{-1}) was pumped to the short sea outfall at Mumbles Head (National Grid Reference SS636871), where it is given preliminary treatment by 'Screezer' and is retained in tidal storage tanks before release to the outfall which discharges at low water mark. Langland Bay is located about 2 km south-west of the short outfall.

The locations of the study sites for bathers and non-bathers are shown on Figure 3.9. The bathing area was marked out with posts and ropes into five lanes, each 20 m wide at right angles to the shore line. This provided five strips of water, in which bathers were marshalled and observed and six lines, along which samples of water were taken for analysis. Water quality had met the mandatory standards of the bathing water Directive in 1987 and 1988.

Permission for the study to take place was given by the Public Protection Committee of Swansea City Council on 5 July 1989. Details of the study were also submitted for local ethical approval to West Glamorgan Health Authority.

In this pilot study, the cohort of volunteers was recruited from residents in the Swansea area. Initial attempts were centred upon staff at the Guildhall and the University College, but responses were low (50). Two weeks before the planned date of the exposure, the decision was taken to publicise the study in a positive manner and to seek recruits from the general public. This meant that it was necessary to abandon the media silence and to encourage volunteers by involving local and national news media. Silence had hitherto been maintained to avoid prejudicing the outcome of the Beach Survey by unwelcome publicity. WRc organised a press briefing session at a seafront hotel which was attended by over 30 representatives of press, radio and television. Recruitment in Swansea was rapid thereon and a total of 465 registered. Pre-exposure interviews, collection of faecal samples and swabbing of ears and throat were conducted 2-3 days before exposure.

On the exposure day, 2 September, low water occurred at 1435 (spring tide), leaving a considerable expanse of foreshore exposed and ensuring maximum separation between the group of non-swimmers and the swimmers (Figure 3.9). The water temperature was 17 °C and the weather conditions overcast - hazy sun. Subjects were transported to the beach from the City Centre, allocated randomly on arrival to bather or non-bather groups, questioned and assigned to a supervisor, who recorded their activities during the exposure period. The study took place from 1200-1500 hr. Bathers were asked to stay in the water for at least 10 minutes and to immerse completely at least three times. Bathers and their supervisors were assigned to one of the five strips of water sampled so that it was possible to identify each bather with the prevailing quality of water in the area in which he or she bathed. After exposure, all participants received a packed lunch (meat or vegetarian). A sample of the lunches were submitted for bacteriological analysis.

4.1.3 Moreton beach, Merseyside

The beach was selected by the North-West Region, NRA, having regard to the needs of the study. Permission to carry out the study was obtained from the Metropolitan Borough of Wirral on 13 July 1990 and ethical clearance from Wirral District Health Authority.

The location and general features of the beach are shown in Figure 4.1. Moreton beach (NGR SJ 257 927) is about 4.5 km west of Wallasey on the north coast of the Wirral. The nearest discharge is at Birkenhead into the Mersey Estuary at NGR SJ 328894, design dry weather flow 20 000 m^3 d^{-1}, contributory population 116 000. This is about 10 km away, measured along the coastline from the beach. The beach passed the mandatory requirements of the bathing water Directive (1976) in the years 1987-1990. In 1989 the range of counts for total coliform bacteria were 10-410 per 100 ml and for faecal coliform bacteria 10-130 per 100 ml. Salmonellae and rotaviruses were absent (on one litre and ten litre samples respectively). Thus, the quality of water in the 1989 bathing season was at the Guideline (G-value) levels, at least for coliform bacteria.

The beach is fronted by a substantial concrete sea wall, extending as a sloping apron to about one metre below mean high water mark. The sea wall contains substantial zigzag protrusions designed to absorb the energy of waves during storms. These are also used by holidaymakers as convenient shelters or sun-traps. A promenade runs along the top of the sea wall, making for easy observation during the Cohort Study and for safety cover. Landwards is a 100 m wide strip of grassy heathland which is used by visitors for car parking and for picnics. During the study, the approach road (Pasture Road) was closed off to general traffic by Wirral District Council. Subjects were transported by minibuses from the Moreton railway station to the registration Portakabin about 50 m from the beach. Other Portakabins were used for medical interviews, for virological filtrations, for press interviews and for distributing packed lunches. A grassy area near the Portakabin was assigned for the non-bathing cohort.

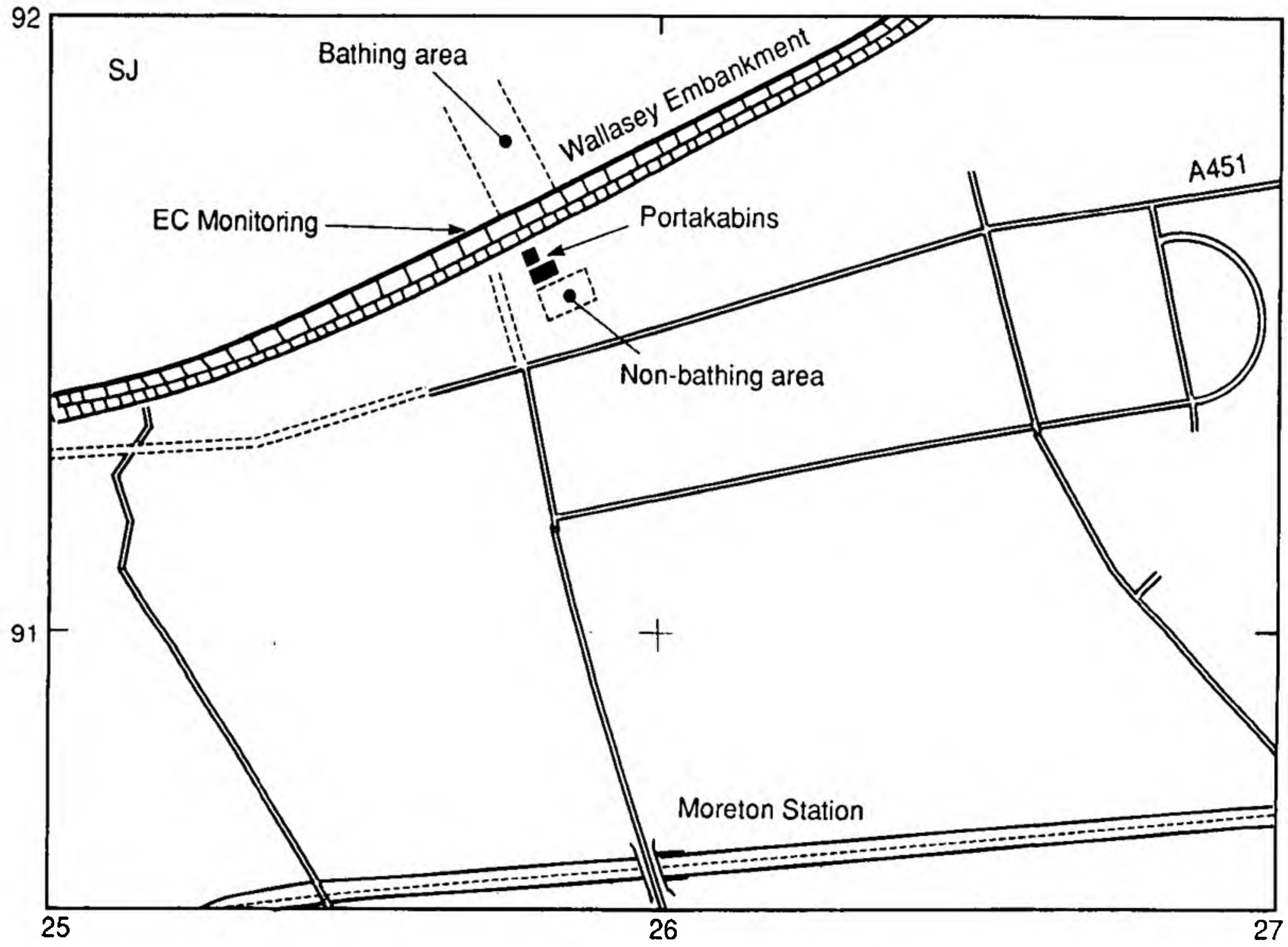

Figure 4.1 Moreton Beach, Merseyside. Location of cohort study, 4 August 1990 and National Grid km co-ordinates

On the seaward side of the promenade, the bathing area was marked out by boards and tapes into 20 m strips over 100 m, each strip being assigned to a bathing supervisor and to a sampler. Early on the morning of 4 August, before the arrival of the subjects, this area of beach and its surroundings were thoroughly cleaned of litter by Wirral DC.

The date, 4 August, was chosen because, at the time that the first bathers would enter the water (noon), the tide would be just at the level of the concrete step and receding. This was advised for safety reasons. The earliness of the date allowed contingency, in the case of bad weather, for holding the study on two further occasions (18 August, 3 September), when the tide would be at a similar state. The study took place between 1200 and 1500 hr.

The exposure day, 4 August, came at the conclusion of a heat wave, the day after the hottest day of 1990 and was cool and overcast. It is thought that these factors may have dissuaded those initial registrants, who failed to attend pre-exposure interviews and on the exposure day. The sea water temperature on 4 August was 16 °C.

4.1.4 Southsea

The South Parade Pier beach (NGR SZ 653 982) at Southsea had passed the mandatory criteria in 1989 and 1990 and it was considered that water quality would be considerably improved in 1991, since the commissioning of the new long sea outfall some weeks before the projected study date. In previous years, sewage from the existing Victorian sewer network and the modern intercepting tunnel, designed to prevent flooding and premature discharge of storm outfall, was pumped to Eastney Pumping Station for discharge to tidal retention tanks and the short sea outfalls at the mouth of Langstone Harbour. The new works involve improved pre-treatment at Eastney Pumping Station, conversion of the tidal tanks for storing storm water, improvement of the storm outfall to discharge below water at all tidal states and construction of a 5.7 km long sea outfall to discharge up to 197 000 $m^3 d^{-1}$, at an average depth of 17 m below mean low water spring tides. The new works came into operation a few weeks before the exposure day.

Permission was given by the Environmental Health and Improvements Sub-Committee of Portsmouth City Council on 24 May, for the Study to take place. Local ethical clearance was obtained through the Portsmouth Consultant Community Physician.

The site chosen, between the Pyramids Centre and the South Parade Pier is shown in Figure 4.2. The area of beach for the exposure was 60 m wide, divided into three 20 m wide strips, normal to the shore. The foreshore is of flat pebbles with some sand at low water. Exposure day was Saturday, 6 July and bathers entered the water between 1400 and 1700 on a rising tide. The conditions recorded were as follows:

High water	- 0612, 1856
Water temperature	- 17 °C (previous day)
Cloud cover	- none
Wind	- South-east 2-4
Wave height	- 1-2 feet, crest to trough.

A violent thunderstorm occurred at 2200-2300 the previous night. The seawater temperature, measured at 30 cm depth in 1 m of water was 20.7 °C during the exposure.

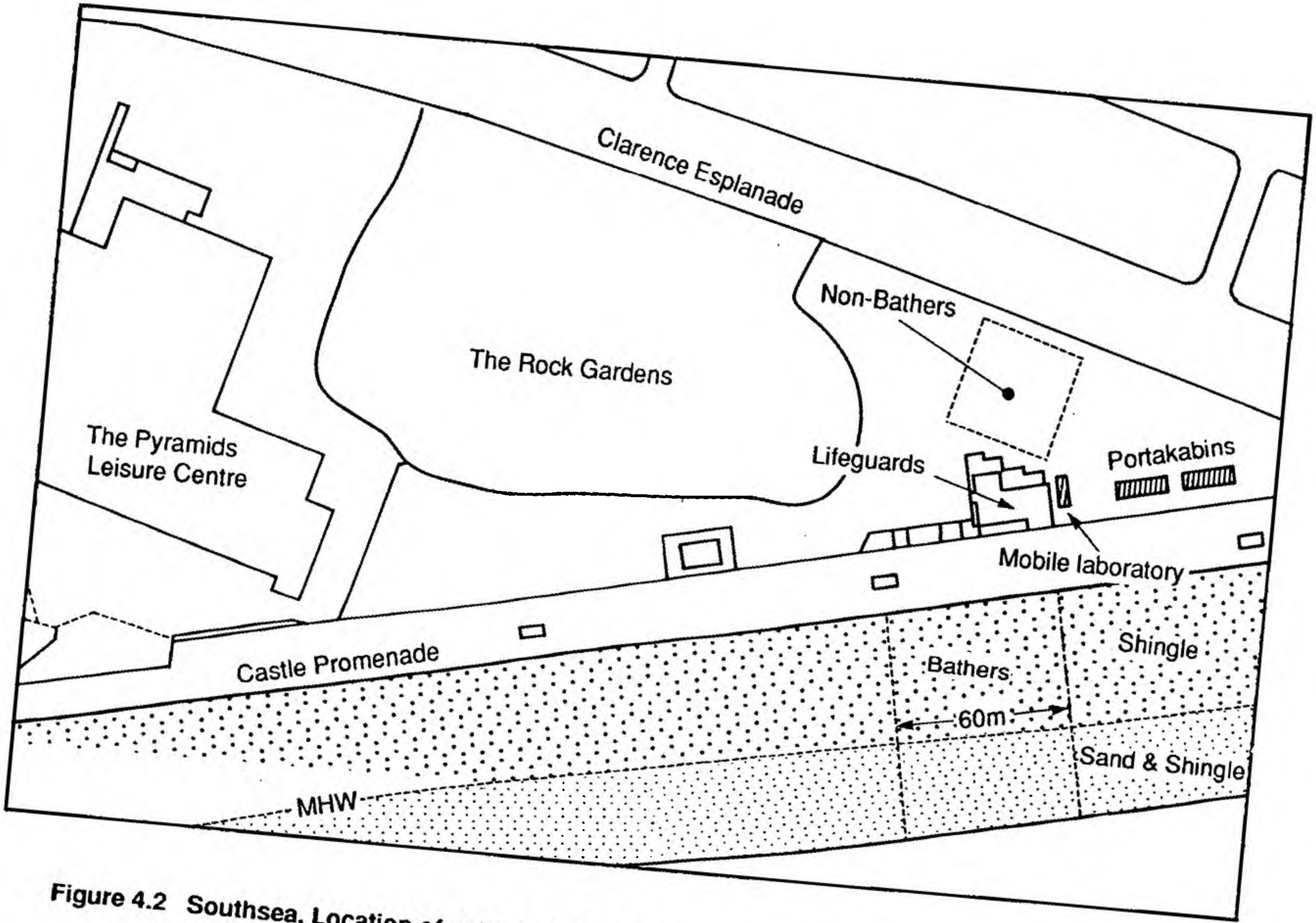

Figure 4.2 Southsea. Location of cohort study, 6 July 1991; National Grid Reference SZ 6480 9805

4.1.4 Southend-on-Sea

Shoebury Common beach, at Thorpe Bay, a suburb of Southend-on-Sea, was chosen from the three local beaches recognised for monitoring under the bathing water Directive, by the NRA. The location (Figure 4.3) at NGR TQ 9255 8414, is 1.6 km to the east of the monitoring point at Thorpe Bay, NGR TQ 911847. It was chosen because of the car parking area, toilet facilities and provision for siting the administrative portakabins and the mobile laboratory. Permission for holding the study was given by the Borough's Community Services Committee on 10 June 1993 and ethical clearance by Southend District Health Authority.

Sewage is presently given primary treatment before discharge through a long sea outfall. The contributory population is 210 000 and the average flow 52 000 m^3 d^{-1}. The beach at Thorpe Bay complied with the Imperative bacteriological standards of the bathing water Directive in 1989, 1990 and 1991 and remained compliant through 1992. There are, however, a large number of storm water outfalls between Leigh-on-Sea and Shoeburyness and plans are well underway for construction of storm tanks and for providing secondary treatment at the inland works.

The date selected for the bathing exposure was 4 July 1992. The previous day was extremely wet, clearing in the evening, and 22 mm of rain fell. Because there is a short storm water outfall only 100 m to the east of the study site, concern was expressed that it might have discharged on the exposure date. At 0930 on 4 July, the entire length of the pipe was examined on foot on the falling tide and no discharge of water or sign of debris was noted. During the exposure period 1400-1700, the following conditions existed:

High water	- 1615
Water temperature	- 19 °C
Cloud cover	- 7-8 eighths (overcast)
Rainfall	- drizzle 1600
Sea state	- calm, rippled

No evidence of sewage solids, foam, phenolic odour, oil films or abnormal colour were noted. A small fishing boat was landed and beached in the study zone.

4.2 Recruitment and interviewing

4.2.1 Setting-up the studies

The first and essential steps in setting-up the studies were to agree upon a short list of suitable locations with the funding agencies, then to hold discussion with the District Councils' Environmental Health and Publicity Departments, with visits to the beaches and then to seek formal approval from the appropriate committees of the District Councils and local ethical clearance from the District Health Authorities. The progress of the four studies is shown in Table 4.1.

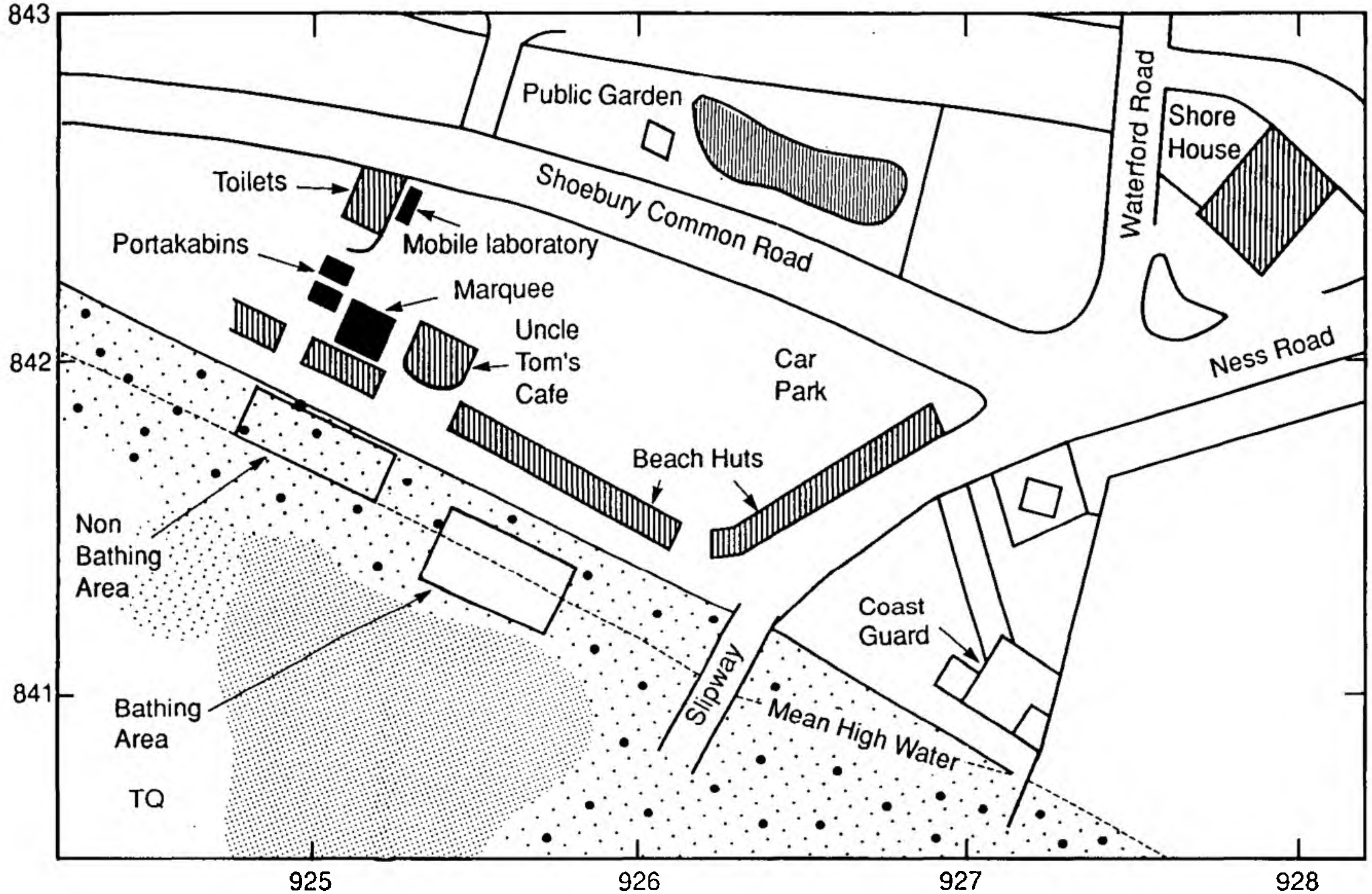

Figure 4.3 **Southend-on Sea, Shoebury Common Beach Location of cohort study, 4 July 1992 and National Grid 100m co-ordinates**

Once formal approval had been given, local and national news media were informed and a press statement was released. Recruitment commenced immediately and was vigorously promoted by the research team of CREH in a period of about 2-3 weeks before the exposure day. This was done by setting up a display booth in major shopping centres, manned by recruiters from CREH. This approach proved to be very successful, in contrast to the early attempts in 1989 to enrol university students or local authority staff in Swansea (Section 4.1.2). Provision was also made for enrolments to be made on the beach at the time of the exposure. The overall aim, established in the pilot study in 1989, was to enrol about 1000 persons to allow for a drop-out rate of about 40-60 percent by the pre-exposure interview. It was established in the pilot study that nearly all of the subjects attending the pre-exposure interview would remain committed to the rest of the study.

4.2.2 Pre-exposure interviews

The pre-exposure interviews, 1-3 days before exposure, were held in the civic buildings for convenience of the subjects. Volunteers were given a Subject Information Sheet setting out the aims of the study, the research method, health risks, details of insurance cover and expenses payable on completion and were asked to signify their consent to participate. The pre-exposure questionnaire was administered by experienced interviewers of the CREH research team and elicited personal and family details, general health, health problems and information upon holiday habits and leisure activities. At the conclusion of the interview, a physician examined the subject for evidence of ear or throat infection and reviewed the medical information to consider if there were grounds for excluding the subject from the study. These grounds included pregnancy. Otherwise, the study was restricted to healthy adults over the age of 18 years, giving their consent. In the pilot study, ear and throat swabs were taken at this interview and volunteers were asked to present a sample of faeces. This was not done in the later studies. Opportunity was provided for persons volunteering on the exposure days to be given the interview and examination in confidence in a temporary office on site, before proceeding with the exposure. The subject's doctor was informed of the study by letter and asked to telephone if there were any reasons for excluding the subject from the study.

4.2.3 Exposure day

Between the pre-exposure interviews and the exposure period details of registered volunteers were entered into the computer and volunteers were randomly assigned to bathing and non-bathing cohorts. Subjects were asked to report on site from noon onwards for the exposure from 1400-1700 hr. On reporting they were informed of their assignment and given either blue (bather) or red (non-bather) lists to assist them to find their allocated supervisor (in blue or red tee shirts respectively) in the allocated areas. The supervisors re-explained the aims of the study and presented the exposure day interview form, which elicited information on food intake and health and any water-based leisure over the previous three days. Bathing supervisors instructed subjects to remain within the marked boundaries, to stay in the water for at least 10 minutes, to immerse themselves completely at least three times and to report back on leaving the water. The bathing supervisor recorded the total time in the water, the location (lane marked-out, surf zone, over 50 cm depth, over 1 m depth), the activities (paddle/wade, swim, full immersion) and, when the subject left the water, asked if water had been swallowed. Non-bathing supervisors administered the questionnaire and ensured that their subjects did not go near the water. Children's entertainments were provided throughout by bouncy castles and other amusements. Safety cover was provided throughout by lifeguards on duty, an offshore craft and by the St John Ambulance Service. Volunteers were given packed lunches (wholly vegetarian in 1990-92), samples of which were submitted for analysis at the participating Public Health Laboratory.

4.2.4 Interviews, seven days and three weeks post-exposure

The post-exposure interviews were carried out in the Civic buildings seven days post-exposure (three days in the pilot study). These were given by the interviewers and medical staff of CREH. This elicited food intake and health symptoms since the exposure day. The physician examined the ears and throat for signs of infection and took ear and throat swabs for clinical examination. The subjects were also given a pot for collecting a sample of faeces and an envelope for returning it to the Public Health Laboratory. The schedule and examination of clinical samples evolved in the light of experience after the pilot study and is detailed in Table 4.2.

The final post-exposure questionnaire was sent by post to subjects, to arrive and be completed three weeks after the exposure day (four weeks in the study at Moreton in 1990). This elicited information upon symptoms, dates on which they were noticed, whether or not they were incapacitating (visited doctor or hospital, spent days off-work or from normal activities) and whether or not the subject ever experienced symptoms after bathing in the UK. Further questions concerned illnesses noticed by other inhabitants of the household, water-sport participation generally, any water activity since the exposure day and awareness of beach pollution. A faecal sample was again requested.

The CREH team issued reminders by telephone or letter to those not responding to the post-exposure requests. Those unable to attend personally seven days post-exposure were sent a postal pack of questionnaire form and swabs and asked to attend their doctors' surgeries for interview and examination.

Finally, those completing all stages of the study were sent a cheque for £10 to cover out-of-pocket expenses for taking part. This sum was agreed as a suitable level, not representing an inducement.

Great care was taken to ensure that the conduct of the Cohort Studies conformed to the protocol originally submitted to the Committee on Ethical Issues in Medicine of the Royal College of Physicians.

During the exposure day at Moreton in 1990, several adult volunteers brought their children to the beach and some accompanied their parents into the water. While the study design precluded use of under-age volunteers, the opportunity was taken to obtain some information on attack rates in the bathing and non-bathing children. A questionnaire was dispatched to adult volunteers who were parents or guardians of children who visited

Moreton beach on 4 August 1990. It was made clear that this was separate from the Cohort Study and no effort was made either to encourage the attendance of children or to influence their activities.

4.3 Surveying and clinical examination of subjects

4.3.1. Questionnaire design

A four-part set of questionnaire forms was devised, covering respectively the pre-exposure, the exposure day and the seventh day post-exposure interviews and the three-week post-exposure postal questionnaire. The forms were differently coloured to aid identification by staff. They were devised in consultation with Consultant Epidemiologists of the Public Health Laboratory Service's Communicable Disease Surveillance Centre and were reviewed in the light of experience from year to year. Changes were minor, because the original design developed for the pilot study in 1989 proved satisfactory, and extended slightly the information gained. The overall contents of the questionnaires were matched, as far as possible, with those used in the beach survey studies. The differences in approach should be recognised. Because the beach surveys aimed to interview a large cross-section of the beach-going public, the questions asked were fewer and more direct and designed not to alert the subjects to the aims of the study to avoid biasing perception. In the Cohort Study, the subjects were made aware of the aims at the outset of recruiting, so the questions could be made for more detailed and searching. This awareness of the aims of the study and the use of face-to-face interviewing in the first three questionnaires, together with involvement of the physician at the first and third interview was considered to obtain the truest possible record within the scope of the Cohort Studies.

The interview forms used in the four studies are reproduced as appendices to the reports of CREH to WRc (Appendix B to Pike 1990, 1991, 1992 and Appendix II to Jones *et al.* 1993). Table 4.2 summarises the information requested and Table 4.3 lists the symptoms which were recorded. For convenience they were grouped into categories. The groups of 'objective' and 'subjective' gastro-intestinal symptoms are equivalent respectively to the 'highly credible gastro-enteritis' and 'total gastro-enteritis' recorded by Cabelli (1983) and Dufour (1984) in the US Environmental Protection Agency's studies of bathing in marine and freshwaters.

The questions upon food intake over the period three days before to seven days after exposure specifically addressed those foods which are known to be associated with gastro-enteritis or food poisoning outbreaks and which are therefore likely to interfere with interpretation of a study into bathing and health. These foods were ice cream, bought sandwiches, chicken, eggs, fresh mayonnaise, hot dogs, hamburgers, salad, raw milk ('green top', unpasteurised), cold meats and pâté, meat pies and pasties, any 'take-away' food, or sea food (shellfish, cockles; specified by subject).

Table 4.2 Information elicited by the four questionnaires

Questionnaire	Information requested
Pre-exposure	Personal details, address occupation, general practitioner, other members of household, anyone unwell over last two weeks? General health - symptoms (see Table 4.3) in last three weeks. Smoking, drinking habits, taking medicine? Overseas residence? General leisure activities including watersports and swimming. Certification of medical fitness to participate by examining physician.
Exposure day	Food intake over previous three days. Symptoms (Table 4.3) over last three days with dates.
Post-exposure, 1 week	Food intake over past week. Symptoms (Table 4.3) over past week with dates. If experienced, did subject visit doctor, or was he/she admitted to hospital, or lose days at work or normal activities? Report of examination by physician.
Post-exposure, 3 weeks	Symptoms in previous three weeks with dates. If experienced, did subject visit doctor, or was he/she admitted to hospital, or lose days at work or normal activities? Has subject ever been unwell after bathing in UK waters - if so what illness? Any history of sunburn, motion sickness? Anyone in household ill in previous three weeks? If so, give dates. Any swimming or water sports activities since exposure date? If so give details of sport, location. Awareness of beach maintenance in UK, pollution, news/media coverage of study.

Table 4.3 Symptoms recorded in the Cohort Studies and their grouping

Group	Symptoms
'Flu'/cold (upper respiratory)	1. Fever (hot and cold shivers) 2. Severe, unusual headache 3. Aching arms, legs, joints 4. Sore throat
Chest symptoms (lower respiratory)	5. Chest pains/aches 6. Dry cough 7. Productive cough (phlegm, sputum) 8. Wheezing/shortness of breath 9. Runny nose
Ear/eye symptoms	10. Ear (sore, discharge) 11. Eye (sore red eyes, discharge) 12. Blurred vision (difficulty with eyesight)
Gut symptoms	13. Loss of appetite 14. Indigestion 15. Stomach cramps (colic/lower abdominal pain/ griping 16. Loose bowel motions (looser than normal) 17. Diarrhoea (three or more runny stools in 24 hours) 18. Nausea (feeling sick) 19. Vomiting (being sick)
Skin symptoms	20. Skin rash on body 21. Skin ulcer/sore 22. Itching (irritation)
Other symptoms	23. Excessive tiredness (unusual fatigue, lassitude) 24. Dizzy or giddy 25. Pins and needles/tingling 26. Muscle cramps (e.g. cramp in arm or leg)
Gastro-intestinal, objective	Vomiting (19) **or** diarrhoea (17) **or** a combination of fever (1) with either indigestion (14) or nausea (18)
Gastro-intestinal, subjective	Diarrhoea, indigestion, vomiting or nausea in any combination or alone
Bathing-related	Symptoms (1) fever to (22) itching in any combination or alone
Any	Any symptom (1) fever to (26) muscle cramps, in any combination or alone

Table 4.3 continued

Notes on questions asked:

Pre-exposure questionnaire -	"In the last three weeks, please answer whether you have had any of the following symptoms lasting for more than 24 hours?"
Exposure day questionnaire -	"In the last three days, including today, please tick whether you have had any of the following symptoms"
Seven days post-exposure questionnaire -	"Since the bathing day, please tick whether you have had any of the following symptoms"
Three weeks post-exposure questionnaire -	"In the last three weeks (since <date>) have you had any of the following symptoms? If you answer YES to any symptoms, please give the date, as far as you can recall, for when the symptom started and how many days it lasted".

4.3.2 Coding and analysis of data

The interviewers were required to tick pre-coded option boxes on the forms. The records from the coded questionnaire forms were transferred to the computer by over-writing a fixed template. The *Statistical Package for the Social Sciences* (SPSSX 1989, McGraw Hill) was used for analysis. For interpreting the degree of association between bathing/not bathing and perception of symptoms in the primary analysis of data in individual Cohort Studies, the chi-square test was used (or derivatives) and where the frequency in any cell of a comparison was less than five, the probability of occurrence was measured by Fisher's Exact Test or by calculating the exact probability directly. Relative risks and associated 95 percent confidence intervals were calculated using Epi Info Version 5 (Dean *et al.* 1990)

4.3.3 Clinical and medical examinations

The schedule of clinical examinations and the taking of specimens from the subjects is given in Table 4.4. This and the analyses carried out evolved from year to year in accordance with experience and advice given by the Public Health Laboratory Service and to meet improvements in analytical capabilities. The analyses were carried out at the Preston Public Health Laboratory and are shown in Table 4.5.

Table 4.4 Clinical examinations of ear; throat and faeces specimens from subjects in the four Cohort Studies

Interview	Langland Bay 1989	Moreton 1990	Southsea 1991	Southend-on-Sea 1992
Pre-exposure, 2-3 days	Ear, throat, faeces	None	None	None
Post-exposure, 7 days	Ear, throat faeces*	Ear, throat, faeces	Ear, throat, faeces	Ear, throat, faeces
Postal, 3 weeks post-exposure	Faeces	Faeces†	Faeces	Faeces

Notes: * At 3 days post-exposure
† At 4 weeks post-exposure
For details of clinical analyses see Table 4.3

Table 4.5 Microbiological and virological analyses of clinical specimens listed in Table 4.4

Specimen	Analyses
Ear	*Escherichia coli*, coliforms, β–haemolytic streptococci, faecal streptococci, *Staphylococcus aureus*, viruses[1]
Throat	As for ear, plus *Pseudomonas aeruginosa*
Throat, viruses	Enteroviruses (cytopathic), rotaviruses
Faeces	*Salmonella, Shigella*[1], *Campylobacter, E. coli* O157[2], *Cryptosporidium*[3], other parasites[3], enteroviruses (cytopathic)[4,5], rotaviruses[5], electron microscopy for viruses[6]

Notes:
1. Not used in 1989 study
2. Used in 1991 and 1992 for 7-day post-exposure samples
3. All faeces samples in 1989; otherwise only if subject reported gastro-intestinal samples at 7 days post-exposure
4. For 3 weeks post-exposure samples in 1989
5. In 1990, if subjects reported gastro-intestinal symptoms post-exposure
6. For samples taken 3 weeks post-exposure in 1991; if subjects reported gut symptoms at both post-exposure interviews, or in 1992 if reported 7-days post-exposure.

4.4 Microbiological sampling and analysis

4.4.1 Faecal indicator bacteria

During the three-hour exposure periods, samples were taken simultaneously every 30 minutes (every 20 minutes in 1989 and 1990) along the four marked lines (0, 20, 40 and 60 m of the bathing area (in 1989 and 1990 along the six lines including 80 and 100 m) and at three depths: in the surf, at 30 cm below the surface in 1 m depth of water (as required in the bathing water directive) and at chest depth. These were thus 84 samples taken in the bathing area during the exposure (162 in 1989 and 1990). This was supplemented by a further 18 samples taken by boat in 1989 and 20 in 1991. Samples were analysed by Altwell Ltd/Acer Environmental staff in the mobile laboratory on site (in 1989 and 1990 in nearby facilities) for total coliform bacteria, faecal coliform bacteria, faecal streptococci, using standard methods (see Section 3.4) and for total staphylococci (presumptive *Staphylococcus aureus* in 1989) and *Pseudomonas aeruginosa*.

4.4.2 Pathogens

In each study, 15 samples (10 litres) were taken from the bathing area and examined for cytopathic enteroviruses and rotaviruses. In 1991, an additional two samples were taken offshore by boat. Except in 1989, residual samples of water left over from the analyses for faecal bacteria were pooled and examined for *Salmonella* and *Cryptosporidium* (*Salmonella* only in 1991). In 1991, portable filtration equipment was used to concentrate 151 litres of water from the middle of the bathing area for *Cryptosporidium* analysis.

Virological analyses were carried out by Dr Helen Merritt (Wallace Evans and Enviros Ltd) and other pathogen analyses by Altwell Ltd/Acer Environmental, supervised by Mr A F Godfree.

4.4.3 Examination of packed lunches

Subjects registering on the exposure day were given packed lunches from an accredited caterer to reduce the likelihood of gastro-intestinal symptoms being attributable to food.

Random samples of the packed lunches were submitted to the local public health laboratory to analyse for coliform organisms, *E. coli*, *Salmonella* and faecal streptococci. Analysis was carried out on sandwiches and chocolate biscuits.

4.4.4 Quality control of microbiological analyses

Because the four Cohort Studies were carried out in different years and in different locations, it was considered very important to be able to guarantee the trueness of the microbiological data across the whole study. To some extent, this was assured by using only one sub-contractor, under the same direction, each year. Altwell Ltd (later part of the Acer Environmental group) received NAMAS accreditation for their microbiology laboratory prior to the 1990 study.

The approaches to analytical quality control of analyses for faecal indicator bacteria, differed from year to year, but depended upon demonstrating no significant differences in counts made upon replicated samples (demonstrating the combined errors of sampling and analysis) or upon replicated determinations of the same samples (demonstrating errors of analysis alone).

In 1989 eighteen duplicated samples were taken, nine from the surf and nine from 30 cm depth in 1 m of water. No such approach was made in 1990.

In 1991 and 1992 the number of duplicated samples was seven. Duplicates were examined for the five faecal indicator bacteria of Section 4.4.1.

Further approaches were made in 1991. Eight duplicate samples from each of the 1430 and 1630 runs were analysed by Altwell Ltd and by the Southern Region Laboratory of the National River Authority for total and faecal coliform bacteria and faecal streptococci. Triplicate analyses were made for faecal coliform bacteria of samples taken on all runs at all locations and depths, presented as counts on three replicate membrane filters.

In 1991 and 1992, quality control was also measured by analysis of prepared samples, delivered by the PHLS, Newcastle-upon-Tyne Laboratory and containing estimated numbers of total coliform bacteria and *E. coli*.

4.5 Results and observations

4.5.1 Recruitment, exposure and interviews

Table 4.6 compares the progress of recruitment and participation at the four beaches. The patterns are similar. The drop-out rates between initial recruiting and the pre-exposure interviews are high (40-57%), but with a willingness, once at this stage, to continue to the end of the study.

Table 4.6 shows that 1256 of the 3361 originally recruited (37%) completed the full course of interviews. When the data from all four studies were combined to examine for dose-response relationships and significance of confounding factors, it was found possible to use information from 1112 subjects, comprising 605 bathers and 507 non-bathers.

Table 4.6 Numbers of subjects recruited and participating in the four Cohort Studies

Stage of the study*	Participants			
	Langland Bay	Moreton	Southsea	Southend
Initial recruiting	465	832	1044	1020
Pre-exposure interviews	276	390	449	413
Exposure day	266	303	387	372
Follow-up questionnaire and medical interviews	262	303	339	323
Further telephone or postal responses to follow up questionnaire	-	-	47	21
Final postal questionnaire	259	287	360	350

Notes: * Dates are given in Table 4.1

4.5.2 Equivalence of the bathing and non-bathing cohorts

If randomisation has been successful and no bias exists in the responses given by the bathing and non-bathing cohorts, they should be equivalent, except for differences caused by chance, in terms of sex, age distribution, socio-economic status, leisure habits and perception of symptoms pre-exposure and on the exposure day. Generally this was so, but at Southsea bathers were significantly older (mean 33.6 years) than non-bathers (mean 29.8 years), although the real difference in mean age is small. At Southend-on-Sea, non-bathers were less likely never to go dinghy sailing or sub-aqua diving than bathers, but the absolute differences were small. More to the point are the comparisons between the cohorts for reporting symptoms before and on the exposure day (Table 4.7). Because 26 individual symptoms and 10 grouped symptoms were recorded and examined (Table 4.3), one would expect purely on grounds of chance with random data, to find one or two symptoms at each location to show significantly ($p<0.05$) different rates in reporting between cohorts. Hence, the differences shown lose some force. Pre-exposure, the subjects were unaware of their assignment to a cohort. It is intriguing that the non-bathing cohort at Southsea recorded four types of symptom significantly more frequently than the bathing, pre-exposure, and at Southend-on-Sea, it recorded two types of symptom more frequently. It is likely, then, that at least some of these differences were real. On the exposure days, no differences in recording between the two cohorts were found at Southsea, but at each of the other three locations two classes of symptom were noticed more often over the previous three days by the bathing cohort than by the non-bathing cohort (Table 4.7). At Langland Bay and at Southend-on-Sea, these all fell in the class of 'gut symptoms' and this is of some concern, since it is this type of symptom which is more likely to be associated with swallowing or inhaling water contaminated with waterborne pathogens. If the differences are not as a result of the chance factor mentioned in the last paragraph, it must be concluded that the pairs of cohorts were not identical in respect of reporting these symptoms in the three days prior to the exposure.

Table 4.7 Relative risks (and 95% confidence intervals) of those symptoms which were reported significantly differently between the bathing and non-bathing cohorts, pre-exposure and on the exposure days

	Site			
Interview	Langland Bay	Moreton	Southsea	Southend-on-Sea
Pre-exposure				
Symptoms experienced in previous 3 weeks	Not given	Not given	Chest, 0.63 (0.44-0.91) Runny nose, 0.55 (0.34-0.88) Ear/eye, 0.39 (0.16-0.98) Any, 0.80 (0.66-0.98)	Skin, sore 36.5* Bathing, 1.30 (1.04-1.63)
Exposure day				
Symptoms experienced over previous 3 days	Gut 37.9* Diarrhoea or nausea 37.9*	Productive cough, 12.1 (1.57-93.4) Chest, 2.42 (1.17-4.99)	None found	Diarrhoea, 9.3 (1.17-73) Loose motions, 2.8 (1.20-6.62)

Notes: Relative risk is ratio of rate of recording by bathers: rate by non-bathers. Where the relative risk is less than 1, non-bathers recorded the symptom more frequently than bathers, and *vice-versa*.

*No non-bathers recorded the symptom and the relative risk and confidence intervals cannot be calculated. Figures shown are rates per 1000 bathers.

4.5.2 Symptoms significantly elevated post-exposure in bathers

Table 4.8 shows the relative risks and their associated 95 per cent confidence intervals, for those symptoms which were recorded significantly more frequently ($p<0.05$) in the two post-exposure questionnaires by the four bathing cohorts.

The class of symptom is interesting. At all locations, gut symptoms collectively, or individual symptoms of that set, were significantly elevated in bathers. Chest (lower respiratory) symptoms figured only at Moreton. More symptoms were found to be elevated in the first questionnaire than in the second. Since the periods covered ran concurrently from the exposure day, there is a suggestion that most of the symptoms tend to be noticed by the time of the first post-exposure questionnaire.

4.5.3 Temporal changes in rates of recording symptoms

There is a problem of interpretation in the case of those symptoms, or their parent group of symptoms, which were significantly elevated in bathers both pre- and post-exposure. These are shown in Table 4.9, which shows the temporal changes in the reporting rates and in the relative risks. The highest values in the time series are shown in bold type. Two types of difficulty are apparent:

1. When one of the rates is zero, because none in the cohort record a symptom. On the exposure day at Langland Bay, none of the non-bathing cohort recorded a gut symptom. The relative risk in each case was therefore infinitely great. This was also so for reporting of sore skin at Southend-on-Sea in both pre-exposure interviews. The only rational conclusion must be that bathing decreased the relative risk of these symptoms, because the absolute rates of reporting in non-bathers increased after the exposure day.

2. Table 4.9 gives no assurance that the absolute rates of recording symptoms remain reasonably constant over the period of recording.

It must be concluded that temporal changes in rates of recording, unrelated to bathing exposure could be important. This justifies the pre-exposure interviewing of the two cohorts for symptom experience. The value is not only to check that randomisation of the cohorts has been thorough, but to provide a means for correcting the data for the exposed for temporal changes caused by uncontrolled factors. The changes in the recording rates by non-bathers entirely justifies the use of the concept of relative risks. In the analysis of pooled data (Section 4.6) for factors affecting the rates of reporting gastro-intestinal symptoms, the difficulties above were avoided by rejecting from the analysis, subjects with a history of illness pre-disposing to gastro-enteritis or reporting gut symptoms on the exposure days.

Table 4.8 Relative risks (and 95% confidence intervals) of those symptoms which were recorded significantly more frequently by the bathing cohorts in the two post-exposure questionnaires

	Site			
Questionnaire	Langland Bay	Moreton	Southsea	Southend-on-Sea
First post-exposure:	Sore throat, 2.08 (1.01-4.27) Eye infection, 8.25 (1.09-65.0) Ear infection, 39.1†	Sore throat, 3.01 (1.50-6.05) Dry cough, 3.59 (1.19-10.9)* Ear 5.38 (1.18-24.5) Stomach pain, 2.77 (1.09-7.02) Loose motions, 2.30 (1.15-4.60) Flu/cold, 2.26 (1.40-3.65) Chest, 1.83 (1.04-3.23)* Gut, 1.70 (1.06-2.72)	Loose motions, 1.56 (1.01-2.40) Nausea, 2.51 (1.36-4.63) Gut, 1.76 (1.31-2.38)	Ear 5.10 (1.48-17.6) Ear/eye, 2.86 (1.22-6.73) Gut, 1.81 (1.22-2.71)* Skin, 2.50 (1.16-5.38)*
Second post-exposure:	Diarrhoea, 3.22 (1.22-8.55)*	Flu/cold, 1.40 (1.08-2.75) Gut, 1.57 (1.01-2.44	Nausea, 3.70 (1.65-8.32) Gut, 1.51 (1.11-2.06) Skin, 1.97 (1.02-3.84) Any 1.22 (1.02-1.47)	Sore throat, 1.61 (1.08-2.41) Ear infection, 3.94 (1.49-10.4) Ear/eye, 2.78 (1.37-5.64)

Notes: First post-exposure - symptoms experienced in past 7 days (3 days at Langland Bay). Second post-exposure - symptoms experienced in past 3 weeks (4 weeks at Moreton).
* Symptoms belonging to the same set as those significantly elevated in bathers pre-exposure (Table 4.7).
† Not recorded by non-bathers; value shown is rate per 1000 bathers

Table 4.9 Temporal change in rates of recording symptoms and their relative risks by the two types of cohort

Location and symptom	Recording rates per 1000 subjects, bathers/non-bathers (and relative risks) at: Pre-exposure	Exposure day	First post-exposure	Second post-exposure
Langland Bay:				
Diarrhoea	-	15.2/0 = ∝	62.0/**52.6** = 1.18	**121.2**/37.6 = 3.22*
Nausea	-	22.9/0 = ∝	38.8/7.5 = **5.17**	**56.0/67.7** = 0.82
Gut	-	37.9/0 = ∝*	100.8/75.2 = 1.34	**169.2/101.6** = 1.66
Diarrhoea/nausea	-	37.9/0 = ∝*	100.8/60.2 = 1.67	**169.2/101.6** = 1.66
Moreton:				
Productive cough	-	75.2/6.2 = **12.1***	51.1/30.5 = 1.68*	**83.3/64.9** = 1.28
Chest:	-	150.4/62.1 = 2.42*	189.8/103.7 = **1.83***	**206.1/167.7** = 1.23
Southend-on-Sea:				
Diarrhoea	73.6/**36.5** = 2.02	48.8/5.3 = **9.27**	42.9/15.6 = 2.75	**77.4**/32.4 = 2.38*
Loose motions	109.8/62.5 = 1.76	103.7/36.8 = **2.81**	147.2/83.3 = 1.77*	**185.9/119.6** = 1.55*
Gut	196.3/140.6= 1.40	146.3/89.5 = 1.64	294.5/162.3 = **1.81***	**301.3/209.0** = 1.44*
Skin	115.9/**83.3** = 1.39	85.4/42.1 = 2.03	**117.2**/46.9 = **2.50***	103.2/54.1 = 1.91
Skin, sore	**36.6/0** = ∝*	24.4/0 = ∝*	24.7/10.4 = 2.38	6.4/**10.9** = 0.59

Notes: *Rate in bathers significantly elevated above non-bather rate, $p<0.05$

- no data

This table displays those symptoms, or those belonging to the same class, which were significantly elevated in bathers pre- and post-exposure. None met this criterion at Southsea.

Bold figures are the highest values for that symptom and location

4.5.4 Microbiological examinations of clinical samples and packed lunches

The entire findings of the four studies are shown in Table 4.10. The only statistically significant findings were the greater frequencies of isolation of coliform bacteria in ear swabs from bathers at Langland Bay and of faecal streptococci in bathers' ear swabs at Southsea. The single salmonella isolation and the three isolations of *Giardia* cysts in faeces pre-exposure at Langland Bay were confirmed in the same subjects post-exposure. There were therefore no infections attributable to the exposure. The isolation of *Giardia* in the one subject at Moreton in the second post-exposure faecal sample was of a single cyst and does not represent an overt infection. The two isolations post-exposure at Southsea were in a bather and a non-bather. The virological examinations of faeces in 1990-1992 were made upon faeces samples of subjects reporting gut symptoms post-exposure and were uniformly negative. The virological examination of throat swabs was made because this often enables early infections by enteroviruses to be detected. Only three isolations were made and these were of the cold sore virus (*Herpes simplex*), which is not waterborne.

No pathogens were isolated from the packed lunch samples, although sandwiches at Southsea and chocolate biscuits and sandwiches at Southend-on-Sea contained faecal streptococci, which are not necessarily indicative of faecal contamination in these foods (Table 4.10).

4.5.5 Other health findings

The records of the results of medical examinations of subjects' throats and ears, seven days post-exposure in 1990-1992 do not show any significant associations with bathing or not bathing (Table 4.11). Similarly, there was no significant association between recording of sore throats and isolation of bacteria on throat swabs.

At the post-exposure interviews at Southsea and Southend-on-Sea, subjects were asked if they had encountered health problems severe enough to cause them to visit their doctor, to lose days of work or normal activity or to seek hospital treatment. The recording is shown in Table 4.12. There were no significant associations between bathing and health either at each resort or as a whole.

These two findings are important, since they indicate that, neither from the results of the medical examinations nor from the rates of symptoms requiring medical intervention or loss of normal activity, were any significant differences found between the bathing and non-bathing cohorts.

The separate postal questionnaire survey devised for children less than 18 years old who accompanied their parents on the exposure day at Moreton (Section 4.2.4) yielded 131 responses. Bathing juveniles were reported by their parents to have experienced significantly higher rates of stomach upset (relative risk 5.23, 95 per cent confidence interval 1.19-23.0) or reporting of any symptom (2.62, 1.09-6.33) than non-bathers. The attack rates for the various symptoms were similar in size to those of adults.

Table 4.10 Isolations of faecal bacteria and pathogens from clinical samples and packed lunches in the four Cohort Studies

Specimen	Langland Bay	Moreton	Southsea	Southend-on-Sea
Ear swab	PE, coliforms RR 3.5	NS	1 PE, FS RR 3.0	NS
Throat swab	NS	NS	NS	NS
Throat swab, viruses, first post-exposure		1/69 (Herpes simplex)	0/334	2 Herpes simplex (1 B, 1 NB)
Faeces: pre-exposure	1 Salm, 1 Camp, 3G, 0 Ent	ND	ND	ND
first post-exposure	1 Salm, 3 G, 0 Ent	0/180	1 Camp/352 (NB)	0/350
second post-exposure	1 G, 5 Ent (3 Coxsackie, B4, Echovirus 7, enterovirus)	1 G/66, 0 Ent/69	2 G/108 (B, NB)	0 VEM/111 0 Parasites/70 0 VEM/70
Packed lunches:		NR	NR	*Enterococcus faecalis*
sandwich				20-200 FS g^{-1}, in 5
chocolate biscuit	NR	NR	>500 g^{-1} in 1/5	20-200 FS g^{-1}, in 5

Notes: ND - none detected; NR - not recorded, presumed negative; NS - no significant differences in isolation between bathers' and non-bathers' samples; RR - ratio of isolation rates, bathers/non-bathers; PE - pre-exposure examination; 1 PE - one week post-exposure examination;
B - bather; NB - non-bather; Camp - *Campylobacter*; G - *Giardia intestinalis* cysts; Ent - cytopathic enteroviruses; FS - faecal streptococci; VEM - viruses detected by electron microscopy

Table 4.11 Appearance of subjects' ears and throats at the medical examinations, seven days post exposure

Examination and result	Moreton	Southsea	Southend-on-Sea	All sites
	Numbers of subjects (bathers/non-bathers) at:			
Throat:				
Normal	100/128	137/147	121/145	358/420
Red or infected	22/36	29/23	30/27	81/86
Ear:				
normal	126/154	162/166	155/164	433/484
red or infected	3/2	1/1	2/2	6/5

Table 4.12 Noteworthy recording of illnesses by bathers and non-bathers in the Cohort Studies at Southsea and Southend

Criterion for illness	At 7 days post-exposure				At 3 weeks post-exposure			
	Bathers		Non-bathers		Bathers		Non-bathers	
	Yes	No	Yes	No	Yes	No	Yes	No
Visited GP	15	324	19	357	20	297	14	334
Lost days of normal activity	10	326	9	367	28	293	18	327
Treatment at hospital	2	335	1	375	3	318	1	349

Associations between bathing, or not bathing, and illness not significant. Numbers are of subjects recording outcomes.

4.5.6 Results of microbiological examinations of water quality

Geometric mean counts of bacterial determinands for all samples of water taken during the bathing exposures are shown in Table 4.13 and of viral determinations in Table 4.14. There is reasonable agreement between the rankings of beaches given by total and faecal coliform bacteria, but some discrepancies between these and the other bacteria of Table 4.13 and of viral determinations in Table 4.14. Counts of faecal streptococci were higher at Langland Bay and of total staphylococci at Southsea, than expected from the counts of coliform bacteria. These may reflect local differences in the nature and sources of pollution or different rates of bacterial decay after release into the sea. Salmonellae were not detected in the bulked samples examined in 1990-1992 and *Cryptosporidium* oocysts were not detected in the 151 litres of water examined at Southend-on-Sea. There is no consistency between the rankings of the beaches by frequencies of isolation or counts of viruses (Table 4.14) and that given by any of the bacterial determinands (Table 4.13).

Table 4.13 Geometric mean bacterial counts (per 100 ml) during the exposure periods of the Cohort Studies

Determinand	Langland Bay	Moreton	Southsea	Southend-on-Sea
Total coliform bacteria	37	258	71	280
Faecal coliform bacteria	19.7	157	75	134
Faecal streptococci	32	26	18.5	40
Pseudomonas aeruginosa	0.17	3.7	5.5	2.2
Total staphylococci	ND	134	360	134
No. of samples taken	180	162	104	84*

Note: ND - analysis not done
* For total staphylococci, 48 samples

Table 4.14 Frequencies of isolation of viruses in 10-litre samples during the exposure periods of the Cohort Studies

	Frequencies of isolation			
Viruses	Langland Bay	Moreton	Southsea	Southend-on-Sea
Enteroviruses	1/15 (0.13)	5/15 (2.0)	4/17 (2.6)	0/15 (0.0)
Rotaviruses	3/15 (1.1)	2/10 (0.2)	0/17 (0.0)	0.15 (0.0)

Notes: Frequencies are number of samples positive/number of samples taken
Average count of enterovirus plaque-forming units and rotavirus fluorescent foci in 10 litres shown in parentheses

As was expected when the beaches were selected, the percentages of samples taken at 30 cm in 1 m depth of water which contained not more than 10 000 total coliform bacteria or 2000 faecal coliform bacteria per 100 ml were greater than required (in 95 percent of samples) under the imperative (I-value) requirements of the bathing water Directive (Table 4.15). The guideline (G-value) requirements for 80 per cent of samples not to exceed 500 total coliform bacteria, or 100 faecal coliform bacteria per 100 ml or for 90 per cent of samples not to exceed 100 faecal streptococci per 100 ml, were not universally met at any beach during the bathing periods. It should be noted that, for the purposes of compliance with the Directive, these percentages strictly relate to samples taken at least fortnightly during the bathing season, and not as frequently as taken in the bathing exposures. Greater variability would be expected in results from the normal monitoring under the requirements of the Directive, because of long-term effects, such as of bad weather and season.

Table 4.15 Percentages of samples, not exceeding the Guideline (G) criteria of the bathing water directive 76/160/EEC during the exposure periods

Determinand	Langland Bay	Moreton	Southsea	Southend-on-Sea
Total coliforms	100	83	100	89
Faecal coliforms	92.6	9.3*	28.6*	25*
Faecal streptococci	87.0*	96.3	96.4	92.9

Notes: Samples were taken 30 cm below the surface in 1 m deep water.
Nº of samples taken: Langland Bay 54, Moreton 54, Southsea 28, Southend-on-Sea 28.
All determinands at every beach met the Imperative (I) criteria for total and faecal coliform bacteria
* Not complying with percentile requirement

At all sites, without exception, geometric mean counts of the coliform bacteria and faecal streptococci were greatest in the surf and least at chest depth. Significant differences were also detected between times of day within each exposure period. The detailed analysis is presented in the reports for each study (Pike 1990, 1991, 1992, Jones *et al.* 1993).

The results of the analytical quality control procedures, outlined in Section 4.4.3 were entirely satisfactory and do not indicate that the precision of analysis could have been improved. Individual results are provided in the reports for each study (Pike 1990, 1991, 1992, Jones *et al.* 1993).

4.6 Examination of pooled data

4.6.1 Objectives

In 1991/92, CREH reported to the funding agencies that the design of the Cohort Study permitted an assessment to be made of the separate effects upon symptom rates of factors such as duration in the water and whether or not water was swallowed and of other, factors not related to bathing, such as sex, age, intake of certain foods or presence of another person in the household with illness, prior to the exposure date. It was important to demonstrate that these non-bathing related factors acted independently of water quality in predicting odds ratios for reporting gastro-intestinal symptoms, i.e. that there was no confounding. The team realised that this assessment could be carried out by subjecting the data to multiple logistic regression analysis, which has already been used for extracting the effect of age, sex and degree of water exposure by the Institute of Public Health in the beach survey studies. This technique has also been used by Seyfried *et al.* (1985a,b) and by Lightfoot 1989). It was also realised that changes to the experimental protocol of the Cohort Study had been minor and that it would be possible to amalgamate the data from the four studies, making necessary allowances for changes in the times of the post-exposure interviews shown in Table 4.1.

The funding agencies recognised that the additional information would be of considerable value in increasing understanding of the health problems of holidaymakers in general, as well as of bathing in the sea and that such information could not be so readily attained otherwise. The sub-contract with CREH was therefore extended to enable the data from all studies to be pooled, multiple logistic regression analysis carried out to examine, in more detail, the relationships between health effects in bathers and counts of faecal indicator bacteria and to attempt separate measurement of the effects on health of factors not related to bathing in the sea. It was decided to concentrate this part of the study upon gastro-intestinal symptoms, since previous studies have related their incidence with changes in water quality (Table 1.1).

This part of the study was initiated in 1991/92, following completion of the analysis of the data for Southsea and the combined data set was then integrated with results from the study carried out at Southend-on-Sea.

4.6.2 Methods

The data sets for participants were re-examined to exclude the following.

1. Persons reporting a history of illnesses pre-disposing to gastro-enteritis, e.g. colitis or irritable bowel syndrome.

2. Persons perceiving gastro-intestinal symptoms on the exposure day.

3. Bathers lacking data on the time and place that they entered the water.

The usable data set was smaller than implied by Table 4.6 and comprised 1112 subjects.

Langland Bay:	111 bathers, 122 non-bathers
Moreton	98 bathers, 154 non-bathers
Southsea:	160 bathers, 164 non-bathers
Southend-on-Sea:	138 bathers, 165 non-bathers
All beaches:	507 bathers, 605 non-bathers.

The mean ages were: bathers 35.5 years and non-bathers 34.9 years. There were 564 men and 648 women.

Prior to analysis, two categories of gastro-intestinal symptom were re-defined, for consistency with the definitions used in the studies of the US Environmental Protection Agency in marine (Cabelli 1983) and fresh waters (Dufour 1984) and in the later studies in Hong Kong (Holmes 1989, Hong Kong Government 1986, Cheung *et al.* 1988, 1990, 1991), New Jersey (NJDOH 1989), the Ardèche River, France (Ferley *et al.* 1989) and in Canadian lakes and rivers (Seyfried *et al.* 1985a,b, Lightfoot 1989). The definitions used are given in Table 4.3 and comprise:

1. Objective gastro-intestinal symptoms, equivalent to 'highly credible gastro-enteritis' (HCGI), used by Cabelli (1983). This definition is considered to give the nearest agreement with clinically defined viral gastro-enteritis and to be less susceptible to bias at recall.

2. Subjective gastro-intestinal symptoms, equivalent to 'total gastro-intestinal symptoms' (GI) of Cabelli (1983).

The statistical analyses were designed to investigate the following points:

1. To demonstrate that it was appropriate to pool the data from the four studies;

2. To examine the pooled data for any dose-response relationship between water quality and its effect upon reporting of gastro-intestinal symptoms.

3. To investigate and measure the effects of any confounding of factors affecting gastro-intestinal symptoms.

A combination of categorical statistical methods and logistic regression analysis was used. The former were tests of association of 'goodness of fit' yielding a chi-square statistic or an exact probability. Separate analyses were made at the State University of New York (Professor J F Fleisher) and the University of Wales (CREH) using different statistical packages to cross-check results. Multiple logistic regression analysis was carried out in New York, using the BMDP package. This was checked by the Welsh Unit, Communicable Disease Surveillance Centre (Dr R Salmon), using different software (Epi Info, version 5 and MULTR) and different variable selection and model building criteria. The steps taken in analysing the pooled data are given in some detail, because each subsequent step demonstrates important statistical results, essential to understanding the validity of the conclusions reached.

4.6.3 Results

Differences between sites in bacterial counts and in symptom rates

Because the beaches were chosen for past compliance with the imperative requirements of the bathing water Directive, the differences between median counts of indicator bacteria between beaches were not as great as for British beaches as a whole. Nevertheless, the intensity of the sampling and the precision of the analysis enabled significant differences in bacterial count to be found in 50 of the total number of 81 comparisons between groupings of beaches, sampling depths and indicator bacteria (excluding self-comparisons). The results are given in the report of CREH (Jones *et al.* 1993) and are too complex to report here. However, the only grouping of comparisons which failed to show any significant differences was for faecal streptococci, between samples taken at 30 cm and at chest depth at the four sites.

Because differences were found, preliminary analysis proceeded to examine for site-specific rates of recording subjective and objective gastro-intestinal symptoms (Table 4.16) in the first or the second post-exposure questionnaires. Significant differences between bathers and non-bathers were found only at Southsea for subjective symptoms (relative risk 1.66). However, for all sites combined, the differences were highly significant:

Objective symptoms - relative risk 1.52 (p=0.001)
Subjective symptoms - relative risk 1.53 (p=0.01)

Table 4.16 Site-specific and overall rates (per thousand subjects) of recording gastro-intestinal symptoms in the first or second post-exposure questionnaires

Symptoms and site	Bathers	Non-bathers	*p*
Objective:			
Langland Bay	207	131	0.12
Moreton	133	71	0.11
Southsea	131	116	0.67
Southend-on-Sea	130	79	0.14
All sites	148	97	0.010*
Subjective:			
Langland Bay	234	156	0.13
Moreton	153	117	0.41
Southsea	294	177	0.013*
Southend-on-Sea	181	139	0.32
All sites	223	147	0.001*

* Statistically significant ($p<0.05$)

Selection of most appropriate indicator and depth of exposure

This finding made it appropriate to continue by a simple examination of the relationships between exposure of bathers to different levels of bacterial counts for the five different indicator bacteria and reporting of objective and subjective gastro-intestinal symptoms. It will be realised that recording, or not recording, a symptom is binary information, whereas bacterial counts are recorded as continuous numbers (or at least as whole numbers). For screening purposes, to enable categorical techniques to be used, it was decided to group exposures to indicator bacteria by arbitrary, but rational criteria, based upon bacteriological standards which have been used in the United States and those in the bathing water Directive, or where no standard exists, using the median count as the point of division.

The exposure groups tested were as follows (with references to standards in parentheses):

1. Non-bathers: no exposure;

2. Total coliform bacteria: 0-2399 and 2400+ per 100 ml (NTAC 1968). This was repeated, using 0-499 and 500+ per 100 ml.

3. Faecal coliform bacteria: 0-199 and 200+ per 100 ml (USEPA 1976).

4. Faecal streptococci: 0-34, 35-69 and 70+ per 100 ml (35 per 100 ml is the geometric mean criterion of the USEPA (1986) and Canadian (MNHW 1992) guidelines for marine recreational waters).

5. Total staphylococci: 0-172, 173+ per 100 ml.

6. *Pseudomonas aeruginosa* 0, 1+ per 100 ml.

Tests of goodness of fit and of trend, using the Mantel-Haenszel chi-square statistic, were carried out for all individual comparisons of rates of reporting subjective and objective symptoms by exposure to indicator bacteria at three depths in the sea. The results were examined not only for significant associations between exposure to indicator bacteria at the three depths, but also to see whether the trends in recording rates increased consistently with increasing exposure to bacteria, with and without including the reference group of non-bathers (no exposure). When this was done, the only consistent significant relationship was shown between faecal streptococci and exposure at chest depth in the sea (Table 4.17). It was decided to use the criterion of exposure to faecal streptococci at chest depth in all further analysis.

Table 4.17 Rates of recording objective and subjective gastro-intestinal symptoms by subjects exposed to different levels of faecal streptococci at chest depth

Level of exposure (count per 100 ml)	No. of subjects	Subjective symptoms Rate (per 1000)	Subjective symptoms *p* (trend)	Objective symptoms Rate (per 1000)	Objective symptoms *p* (trend)
Non-bathers	605	147	<0.001,	97	<0.001,
Bathers (0-34)*	307	205	bathers only	111	bathers only
Bathers (35-69)	149	215	0.056	161	<0.001
Bathers (70+)	51	353		333	

* Faecal streptococci per 100 ml

It is not possible to show the complete results of these screening tests in this report (see Jones *et al.* 1993). However, it may be mentioned, that of the 25 comparisons which showed significant statistical association between exposure to indicator bacteria and rate of recording gastro-intestinal symptoms, no fewer than 18 showed a reduction in rate in the highest exposure group, compared with the next lower group - a state of affairs which is inconsistent. The test for *Pseudomonas aeruginosa* is also rejected because these bacteria are only present in small numbers and therefore lack sensitivity of indication.

Identification of risk factors not related to bathing

Twenty-two factors, not related to bathing, were selected for examination to see if significant differences in rates of reporting existed between the bathing and non-bathing cohorts (Table 4.18) and between bathers reporting, or not reporting, objective (Table 4.19) and subjective (Table 4.20) gastro-intestinal symptoms. The fact that this analysis revealed 29 separate, statistically significant effects shows the sensitivity of the study design. The data were later examined to determine the effects of risk factors not related to bathing.

Appropriateness of pooling data

Fleisher (1991) had reported that the relationships between recording gastro-intestinal symptoms and counts of faecal streptococci varied greatly between the three locations used in the USEPA's epidemiological studies in marine/brackish waters (Cabelli 1993). It was therefore important to exclude this possibility, before proceeding further with analysis of pooled data. It was found that at all four sites separately the rates of objective and subjective symptoms increased reasonably consistently with exposure to the four categoric levels of faecal streptococci, with the exception of objective symptoms at Southsea. The consistency was complete for data pooled between all sites. For subjective symptoms, only the 0-34 per 100 ml category showed significant difference in reporting rates between sites. No significant differences in rates of objective symptoms were found for any category of exposure at any site. It was therefore decided to pool data from the four sites for further analysis.

Effects of water quality and unrelated factors

Pooled data were examined by logistic regression analysis, to determine the effects of exposure to faecal streptococci and non-bathing factors upon odds ratios for objectives and subjective gastro-intestinal symptoms. The odds ratio (which approximates to relative risk, when rates of reporting are small) is defined as the ratio of odds of reporting symptoms in the exposed group to odds of reporting symptoms in the defined reference group (here, non-bathers). Exposure was defined by the four categories for faecal streptococci used previously. To simplify the analysis, composite variables were defined for exposure to non-bathing factors. Details and results of the analysis are given in Table 4.21 and visually in Figure 4.4. Both for subjective and objective symptoms, odds ratios increase with exposure. However, the increase in the adjusted odds ratio above the base level of 1.0 for non-bathers was not unequivocally significant for subjective symptoms (Figure 4.4a), until bathers experienced 70 or more faecal streptococci at chest depth and for objective symptoms until they experienced 35 or more per 100 ml. Furthermore, the 95 percent confidence intervals appear to increase with increasing counts. This is probably because the numbers of bathers falling into the three categories would have decreased as counts increased. Inspection of the data shows that the percentages of chest depth samples falling into the three bands <35, 35-69 and 70+ per 100 ml were respectively about 59, 25 and 16 percent.

Adjustment for unrelated factors slightly increases the odds ratios, but without changing their statistical significance. The effects of confounding were therefore small.

Subsequent analyses were carried out for bathers only.

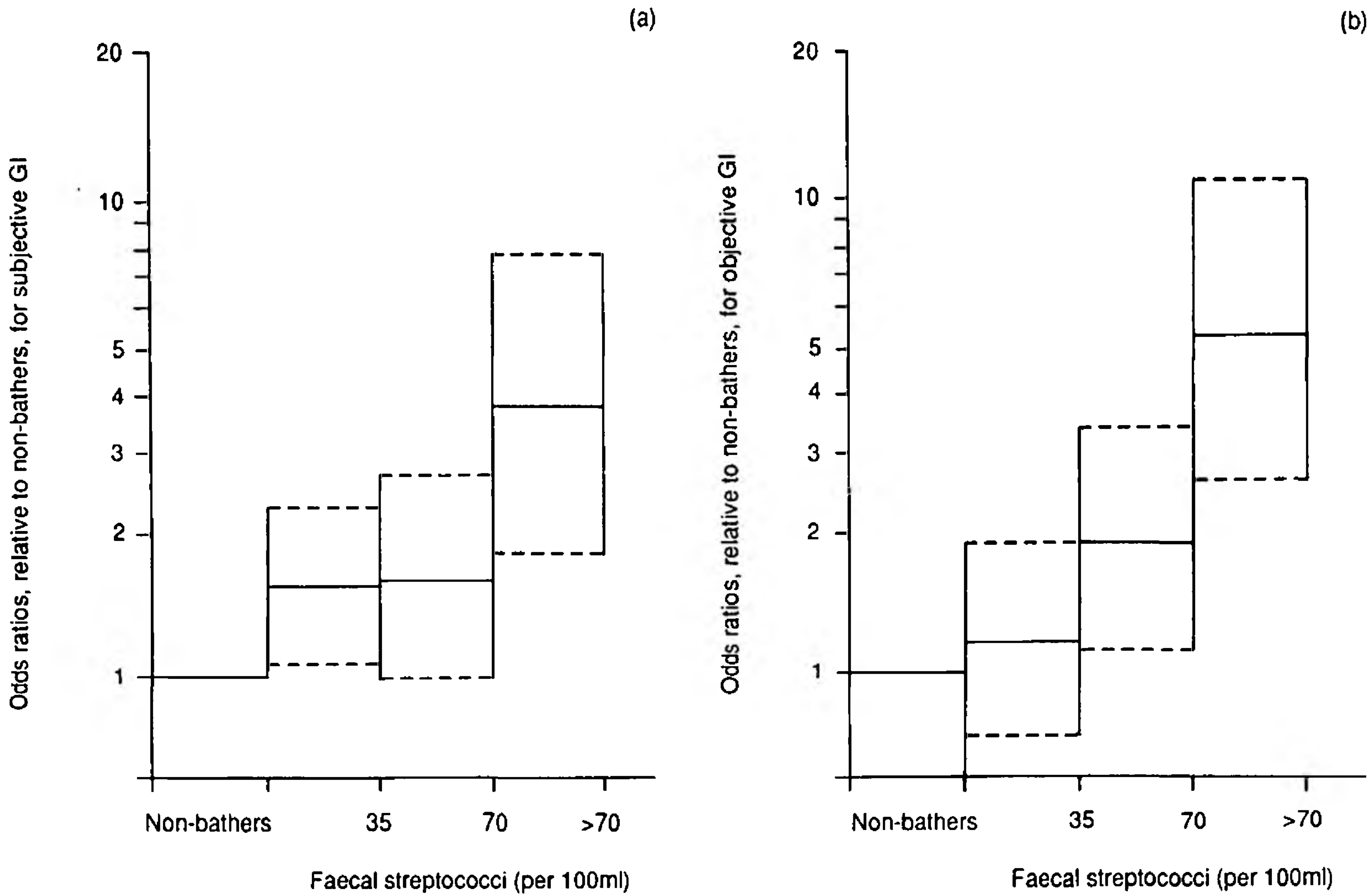

Figure 4.4 Adjusted odds ratios for (a) subjective and (b) objective gastro-intestinal symptoms, in bathers, post-exposure, with 95% confidence limits, from data of Table 4.21

Table 4.18 Percentages of bathers and non-bathers recording risk factors unrelated to bathing at the post-exposure interviews

Risk factor	Site	Percentage reporting: Bathers	Non-bathers	p^*
Predisposition to diarrhoea[1]	all	11.1	7.5	0.037
Indigestion lasting more than 24 hours within 4 weeks of initial interview	all	8.5	5.0	0.019
Taking of prescription or non-prescription drugs within 4 weeks of initial interview	all	44.0	50.3	0.035
Bathing within 3 weeks of exposure date	all	24.7	18.3	0.011
Sex (% males)	all	54.4	47.5	0.022
Food items:[2]				
Mayonnaise	Langland	21.5	8.5	0.006
	Southend-on-Sea	25.5	12.2	0.003
Raw milk	Southsea	23.3	8.6	0.0003
Seafood	Southend-on-Sea	30.1	15.8	0.003
Meat pies	Moreton	38.1	24.3	0.023
Purchased sandwiches	Moreton	21.6	59.1	<0.0001
	Southend-on-Sea	45.2	32.1	0.024

Notes: [1] Predisposition to diarrhoea = having diarrhoea at least once per month, rather than having diarrhoea less than twice per year

[2] All food items were consumed within the time period of 3 days before exposure to 7 days after the exposure day

* All significant at $p<0.05$

Table 4.19 Percentages of bathers, reporting or not recording subjective gastro-intestinal symptoms, who reported risk factors unrelated to bathing post-exposure

Risk factor	Site	Percentage reporting: Ill bathers	Percentage reporting: Well bathers	p^*
Bathing within 7 days subsequent to trial date	all	21.4	13.6	0.045
Unusual fatigue lasting for more than 24 hours within 3 weeks of initial interview	Moreton	20.0	2.4	0.025
Unusual stress or anxiety lasting for more than 24 hours within 3 weeks of initial interview	Southsea	6.5	0	0.023
Sex (% females)	all	61.1	41.1	<0.0001
GI symptoms in family members*	all	5.3	1.8	0.047
Food items:[2]				
hamburgers	Moreton	64.3	25.3	0.009
meat pies	Moreton	60.0	32.5	0.042
purchased sandwiches	Moreton	42.9	18.1	0.022

Notes: [1] GI symptoms among family members that preceded any GI symptoms that occurred among individual bathers

[2] All food items were consumed within the time period of within 3 days prior to exposure or within 7 days subsequent to the exposure day

* All were significant at $p<0.05$

Table 4.20 Percentages of bathers, recording or not recording objective gastro-intestinal symptoms, who reported risk factors unrelated to bathing post-exposure

Risk factor	Site	Percentage reporting: Ill bathers	Well bathers	p^*
Predisposition to diarrhoea[1]	Langland	8.7	0	0.041
Diarrhoea lasting for more than 24 hours within 3 weeks of initial interview	all	17.3	8.1	0.012
GI symptoms in family members[2]	all	6.7	1.8	0.015
Sex (% females)	all	57.3	43.5	0.027
Unusual fatigue lasting for more than 24 hours within 3 weeks of initial interview	Moreton	13.3	6.3	0.030
Food items:[3]				
hamburgers	Moreton	66.7	25.9	0.004
take-out foods	Moreton	76.9	41.7	0.018
purchased sandwiches	Langland	39.1	19.3	0.046
Age:				
less than 25	all	16.3	-	*p* (trend)
25-34		17.8	-	=0.044
35-44		14.3	-	
45-54		9.1	-	
55 and over		7.4	-	

Notes: [1] Predisposition to diarrhoea = having diarrhoea at least once per month vv having diarrhoea less than twice per year.

[2] GI symptoms among family members that preceded any GI symptoms experienced by individual bathers

[3] All food items were consumed within the time period of within 3 days prior to exposure or within 7 days subsequent to the exposure day

* All significant at $p<0.05$

Table 4.21 Multiple logistic regression estimates of odds ratios of subjective and objective GI symptoms in bathers and non-bathers, with and without adjustment for non-water-related risk factors*

	Crude odds ratio	95% CI	Adjusted odds ratio	95% CI
a. Subjective GI symptoms				
Non-bathers	1.00	-	1.00	-
Bathers (0-34)**	1.53	1.05-2.22	1.58	1.07-2.33
Bathers (35-69)	1.49	0.92-2.42	1.64	0.99-2.72
Bathers (70+)	3.01	1.44-5.85	3.81	1.84-7.88
b. Objective GI symptoms				
Non bathers	1.00	-	1.00	-
Bathers (0-34)	1.16	0.72-6.75	1.18	0.73-1.91
Bathers (35-69)	1.84	1.07-3.15	1.94	1.11-3.36
Bathers (70+)	4.31	2.15-8.61	5.29	2.58-10.82

Notes: * Non-water-related risk factors, selected from Tables 4.19 and 4.20, were grouped into a composite variable for this analysis

** Faecal streptococci per 100 ml of sample shown in parentheses

Effects of exposure to faecal streptococci and other factors upon perception by bathers

Subsequent analyses of the pooled data were confined to the bathing cohort only, in order to explore relative risks of various factors to the individual bathers.

Logistic regression analysis of subjective gastro-intestinal symptoms among bathers showed that faecal streptococci at levels of 80 or more per 100 ml, location at Moreton, non-water factors and sex were all significant in effect on odds ratios, using exposure to less than 40 faecal streptococci per 100 ml males, and location at Langland Bay as the baselines (Table 4.22). When the count of faecal streptococci was entered as a continuous (i.e. not grouped) variable, its effect became significant and the odds ratio for each increment in count of 20 per 100 ml was 1.40 (95 per cent confidence interval 1.03-1.90). The odds ratios for other factors were unchanged. None of the factors interacted, so they can be regarded as acting independently.

Logistic regression analysis of objective gastro-intestinal symptoms among bathers showed that faecal streptococci exceeding 39 per 100 ml, age, symptoms of gastro-enteritis in other family members preceding bathing exposure and sex were all significant and independent predictors of odds ratio for objective symptoms (Table 4.23 and Figure 4.5). Non-water related factors had no significant effects. The results show that the rates of recording objective gastro-intestinal symptoms by bathers decrease with increasing ages but are greater in women and are very greatly influenced by other members of the family recording such symptoms prior to the act of bathing. Indeed, the effect of prior gastro-intestinal symptoms in the bather's family is the largest single effect upon recording of objective gastro-intestinal symptoms.

Figure 4.5, like Figure 4.4b, shows that the degree of uncertainty in the adjusted odds ratios increases as the levels of faecal streptococci increase. The four categories of 0-39, 40-59, 60-79 and 80+ faecal streptococci per 100 ml at chest depth corresponded to about 65, 15, 8 and 13 percent of samples taken at all sites, suggesting that the majority of bathers experienced water in the lowest, reference category.

Table 4.22 Logistic regression analysis of subjective gastro-intestinal symptoms reported by bathers post-exposure

Variable	Likelihood ratio, χ^2	p	Odds ratio	95% CI
Faecal streptococci[1]:	4.81	0.19		
0-39			1.00	-
40-59			1.24	0.65 - 1.54
60-79			1.90	0.87 - 4.19
80+			3.00[2]	1.02 - 8.83
Study location:	16.30	0.001		
Langland Bay			1.00	-
Moreton			0.28	0.10 - 0.80
Southsea			1.49	0.69 - 3.22
Southend			1.05	0.50 - 2.21
Non-water[3]	10.79	0.001	3.51	1.62 - 7.57
Sex[4]	12.09	0.0005	2.21	1.40 - 3.47

1 Faecal streptococci per 100 ml of sample

2 p (Trend) = 0.032

3 Non-water = consumption of hamburgers, cold meat pies, or purchased sandwiches at Moreton, or bathers suffering from unusual fatigue or unusual stress at Moreton and Southsea respectively

4 Reference group - males.

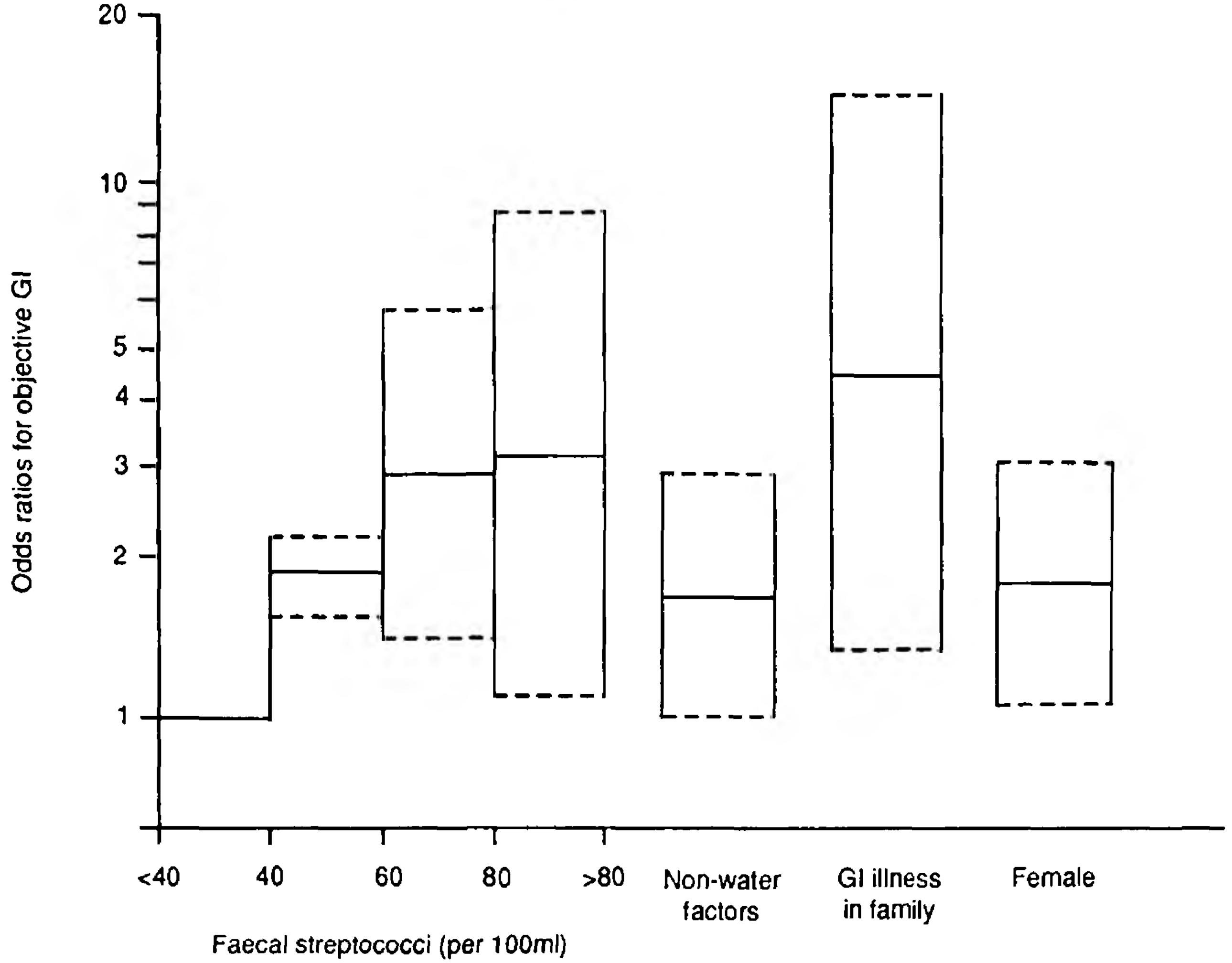

Figure 4.5 Adjusted odds ratios for objective gastro-intestinal symptoms, with 95% confidence intervals, showing effects of swimming in water containing different ranges of faecal streptococci and of factors unrelated to bathing, from data of Table 4.23

Table 4.23 Logistic regression analysis of objective gastro-intestinal symptoms reported by bathers post-exposure

Variable	Likelihood ratio, χ^2	p	Odds ratio	95% CI
Faecal streptococci[1]:	11.83	0.008		
0-39			1.00	-
40-59			1.91	1.60 - 2.28
60-79			2.90	1.43 - 5.88
80+			3.17[2]	1.12 - 8.97
Non-water[3]	3.54	0.06	1.72	0.98 - 2.99
Age[4]	3.66	0.056	0.81	0.65 - 1.01
GI symptoms in family members[5]	5.21	0.02	4.44	1.34 - 14.64
Sex[6]	5.09	0.02	1.81	1.08 - 3.04

1 Faecal streptococci per 100 ml of sample

2 p (Trend) = 0.009

3 Non-water = consumption of hamburgers, or take-out foods at Moreton, consumption of purchased sandwiches at Langland Bay; bathers having a predisposition to diarrhoea at Langland Bay, or bathers suffering from diarrhoea or unusual fatigue which lasted for more than 24 hours within 3 weeks prior to the initial interview from all studies

4 Modelled continuously. The odds ratio refers to an age increment of 10 years

5 Objective GI symptoms in family members that preceded any symptoms in individual bathers

6 Reference group - males.

Effect of duration of bathing

Analysis of variance showed that the average times spent in the water did vary significantly by site, being greatest at Langland Bay and Moreton. Duration had no effect upon rates of objective gastro-intestinal symptoms. The average time spent in the water was 14.5 minutes (± 6.90).

Effect of swallowing water

Bathers at Southsea and Southend-on-Sea were asked, on leaving the water, if they had swallowed any. At Southsea, there was no significant association between the swallowing of water and subjective or objective symptoms. Conversely, at Southend-on-Sea both associations were significant:

1. swallowing water by 72.0 per cent of bathers recording subjective symptoms, compared with 44.2 percent not recording symptoms (p=0.012);

2. swallowing water by 77.8 per cent of bathers recording objective symptoms, compared with 45.0 per cent not recording these symptoms (p=0.009).

To some extent, these results can be explained by the greater proportion of bathers who were exposed to waters containing 40 or more faecal streptococci per 100 ml at Southend-on-Sea.

4.7 Analysis and discussion

4.7.1 Recruitment

The experiences at Langland Bay in the Pilot Study, that a vigorous local campaign involving news media and recruitment in central shopping areas was needed were confirmed in the later studies. It also confirmed that recruiting needed to be accomplished within a period of not more than three weeks between announcement of the study and the pre-exposure interviews. The co-operation of the local authorities was vital, since they were able to provide rooms for interview and examinations, beach facilities, car parking and effect introductions for services, such as transport, safety cover and catering.

At each site, there was a considerable drop-out of volunteers between the initial approach and the commencement of interviewing pre-exposure. Based upon the overall observation of 37 per cent of registrants completing the course, it would be reasonable to recruit about 1100 volunteers to be assured of a study size of 400 completing the course of interviews and exposure.

4.7.2 Recording of symptoms

The questionnaires asked subjects if they had experienced any of the symptoms in Table 4.3 over the periods covered. They also requested dates during which the symptoms had been noted. Because the second post-exposure questionnaire covered the period of the first, there was a cross-check upon the consistency of replies. Because the aims of the study were made aware to volunteers by the researchers and through media publicity and because interviews were concluded face-to-face by experienced interviewers, it would not be surprising to find a high rate of responses to the questions. This was noted in the Pilot Study (Pike 1990). For example, in the USEPA's marine studies (Cabelli 1983, his Table 6) average rates (per 1000) for highly credible gastro-intestinal symptoms were 28.7 in swimmers and 12.9 in non-swimmers, whereas in the pooled data of the Cohort Studies (Table 4.16) they were 148 and 97, i.e. 5.1 and 7.5 times greater, respectively.

Table 4.9 shows that the rates of various symptoms recorded by the non-bathing groups fluctuated widely over the periods covered by the four questionnaires.

These comments show that little meaning can be attached to individual symptoms rates at a single site and in a single cohort. For this reason, analyses of the data have been carried out using either relative risks (bather rate/non-bather rate) or odds ratios (odds of bather recording symptom, relative to odds of non-bather recording symptom) and further examination of the factors affecting rates of gastro-intestinal symptoms in the bathing cohort alone have not been pursued further.

4.7.3 Relationship between recording symptoms and results of medical and clinical examinations

Section 4.5.4 records that there were no significant associations between recording of sore throats and isolation of bacteria on throat swabs or between the results of medical examinations of ears and throats and bathing or not bathing. Similarly bathers and non-bathers alike did not differ in the frequency of seeking medical attention or losing days of work and normal activity after exposure (Table 4.12). The significance of these negative findings are discussed in the report on Phase II (Pike 1991, p59) and can be explained as follows:

1. Subjects were reporting minor symptoms and few were overtly ill, because few found it necessary to buy medicine or visit the doctor or a hospital for attention.

2. The pathogens which might have been responsible for some of the symptoms were not detectable by the methods used.

3. Subjects reporting symptoms may have had their perception of symptoms raised by publicity connected with recruitment and the aims of the Study or by articles produced by news media.

4.7.4 Factors affecting recording of gastro-intestinal symptoms

The Cohort Studies were planned and conducted without any prior assumptions concerning the types of symptom which might be related to bathing in the sea or, indeed, whether any relationship might exist between water quality and the rate of recording symptoms by bathers. The statistical analysis undertaken followed the normal procedure of 'disproving the null hypothesis' that no relationship existed. The range of symptoms considered (Table 4.3) and the range of indicators and pathogens analysed in the sea water were therefore as wide as possible.

Preliminary analysis of the data, using categorical methods showed that the main relationships worthy of further study were the classes of symptom grouped as 'subjective' and 'objective' gastro-intestinal and water quality measured at chest depth, using faecal streptococci as the index. The validity of this relationship was confirmed as the analysis of the pooled data proceeded by the following important findings:

1. The relationships between counts of faecal streptococci and rates of recording gastro-intestinal symptoms did not differ significantly between any of the four sites.

2. Although rates of recording gastro-intestinal symptoms by bathers were significantly associated with various factors not related to bathing, such as age, sex, food intake prior to bathing or to gastro-intestinal symptoms in the household prior to bathing, these factors were shown to act independently of water quality, measured by faecal streptococci at chest depth.

These relationships also show variously the features of biological gradient, plausibility and coherence of Bradford Hill's (1965) criteria, used to assess the likelihood of causal relationships within associations:

1. Faecal streptococci are an index of faecal pollution; the higher the count in the water, the higher is the predicted rate of recording gastro-intestinal symptoms by bathers - biological gradient and plausibility.

2. Faecal streptococci and gastro-intestinal symptoms have been related in the studies of Cabelli (1983) in marine waters, of Dufour (1984) and of Ferley *et al.* (1989) in freshwaters and in grouping illness in 0-4 year olds (Fattal *et al.* 1987) - coherence.

3. The relationship was confined to counts of faecal streptococci at chest depth, i.e. the location where bathing and immersion take place - plausibility.

Similar remarks can be made about the independent relationships discovered between gastro-intestinal symptoms and the factors not related to bathing, as shown in Tables 4.18 - 4.20 and 4.22 - 4.23.

1. The most susceptible age group was 18-24 years and susceptibility declined with increasing age. This is also a finding of the Beach Survey studies - coherence.

2. Gastro-intestinal illness in the household prior to bathing - plausibility, because of the likelihood of person-to-person transmission by the faecal-oral route.

3. Food intake - plausibility, because prepared meat and dairy products are the principal agents of 'food poisoning'.

4. Plausibility also attaches to the other non-bathing factors of bathers at Langland Bay predisposed to diarrhoea and to bathers recalling diarrhoea or unusual fatigue lasting more than 24 hours within three weeks prior to the initial interview.

4.7.5 Implications of the findings

The results from the Cohort Studies are strictly applicable only to healthy adults bathing at chest depth in sea water at beaches which have had a history of meeting the mandatory requirements (I-values for total and faecal coliform bacteria) of the bathing water Directive 76/160/EEC. This must be pointed out in any discussion of their relevance. The Cohort Studies represent a refinement of epidemiology, in that the attention to statistical control of exposure was as great as could be reasonably designed, within practical and ethical limits. A drawback is inevitably, that their scope was restricted.

The conditions of exposure are those that a bather might experience. The findings are not applicable, for example to children playing at the water's edge, persons who only wade or to those indulging in very vigorous water activities such as diving, surfing and sailboarding. The nature of recruitment means that most subjects live locally and are not day trippers or holidaymakers. This demonstrates the complementary nature of the Cohort Study method to that of the Beach Survey. The tightness of the statistical control possible in the Cohort Study has permitted the effects of factors unrelated to bathing to be evaluated with a combined sample size of only 1112 subjects. This may be compared with the prediction made in Phase II (Pike 1991), that, for a background attack rate of 4 percent in non-bathers (actual value 9.8 per cent) and a relative risk for bathers of 1.5 times the non-bathing rate (actual value 1.53 for objective gastro-intestinal symptoms), about 4000 subjects would be needed to guarantee detection of a statistically significant effect (see Section 1.3.3).

A general conclusion of the analysis of the pooled data is that bathing in water containing less than 40 faecal streptococci per 100 ml - as experienced at the four sites - carried a lower risk to bathers of recording objective gastro-intestinal symptoms than prior contact with a family member recording gastro-intestinal symptoms or a combination of consuming the foods of Table 4.22, being pre-disposed to diarrhoea or suffering from diarrhoea or unusual fatigue within three weeks of the initial interview or of being a woman bather.

The implications of these findings for setting standards must also be considered. It was not an objective of the Health Effects of Sea Bathing contracts to prepare recommendations for standards of water quality for bathing or other water sports. However, WRc wishes to make the following observations.

The relationship between exposure to faecal streptococci at chest depth and probability of a bather recording objective gastro-intestinal symptoms is a continuous one. It is convenient to suggest that a standard could be set at a reference point - such as at the level of risk already inherent in accepted legislation, such as the EC Directive 76/160/EEC, or at the level of indicator bacteria at which the risk becomes statistically significant, or at the level at which the excess of risk in bathers equals the risk in the non-bathing group. However, such arguments are entirely arbitrary, because no cut-off point exists in a continuous distribution, except with zero exposure.

It is tempting to relate the degree with which samples taken during the bathing exposures complied with the Imperative and Guideline criteria of the bathing water Directive (Table 4.15) with actual compliance with the requirements of the Directive. However, the Directive requires sampling at least fortnightly during the bathing season, which introduces variability in count caused by seasonal effects, tides and changing weather. The variabilities encountered for samples taken 30 cm below the water in 1 m depth of water during the bathing exposures are much less than would be met in a season of harmonised monitoring. This has two implications:

1. compliance during the study period does not necessarily infer compliance during the bathing season;

2. the risks predicted for bathers refer to point exposures to defined counts of faecal streptococci, whereas at any resort a spectrum of risks will be presented by the variations in water quality. The most likely risk will, however, be that corresponding to the geometric mean count and not to the percentile points used to assess compliance.

Table 4.21(b) and Figure 4.4(b) show that the odds of bathers recording objective gastro-intestinal symptoms, compared with non-bathers, was significantly elevated when they experienced more than 35 faecal streptococci at chest depth. This represents a point exposure and cannot easily be related to the sampling conditions and Guideline criterion of the Directive, requiring 90 percent of fortnightly samples taken in 1 metre depth of water, 30 cm below the surface not to exceed 100 faecal streptococci per 100 ml. Nevertheless, the data show that significant elevations in reporting of subjective and objective gastro-intestinal symptoms were found in bathers using waters where the overall geometric mean count in 1 metre depth was 51 per 100 ml and the estimated 90 percentile was 140 per 100 ml.

5. GENERAL ANALYSIS AND DISCUSSION

5.1 Achievement of objectives

It is opportune to examine how far the objectives set out in Section 2.1 have been attained.

The first objective was "To undertake an epidemiological study to determine the risks, if any, to health of swimming in coastal water contaminated by sewage".

The second objective was "To establish the relationship, if any, between microbiological quality of coastal water and the risk to health of bathers".

Phase III has succeeded in both objectives by demonstrating and quantifying an effect of water quality upon excess recording of diarrhoea in the Beach Survey studies at eight beaches, involving 16 569 subjects and for gastro-intestinal symptoms in the pooled Cohort Studies at four beaches involving 1112 subjects. The statistical conditions approximate quite closely to those assumed in making the recommendations for the sizes of the studies (Section 1.3.3) except for lower odds ratios for the cleanest category of beach.

1. Beach Survev studies: background rate of diarrhoea, average 31 per 1000; odds ratio at cleanest beaches (Skegness, Lyme Regis, Paignton 1.09 average), at 'EC failure' beaches (Rhyl, Morecambe, Instow, Cleethorpes) 1.63; increase in rate 1.5.

2. Cohort Studies: background rate of objective gastro-intestinal symptoms 97 per 1000 average; odds ratio at cleanest beach (Southsea) 1.15, at beach with highest counts of faecal streptococci (Southend-on-Sea) 1.74, increase 1.5.

The volume of data collected in both studies was considerable, because no prior assumptions were made about the types of symptom which might prove to be related to water quality, or about the microbial indicator which would show the highest degree of correlation

5.2 Value of the combined approach

It was realised at the outset of the programme in 1989 that the two methods of study were complementary. This became clearer as the study progressed and, as a result, this study on the health effects of sea bathing can not only claim to be among the largest, with usable data from a total of 17 681 subjects, but the most comprehensive. The merits of the two approaches were set out in Section 1.2.3.

The low or absent correlations between diarrhoea and gastro-intestinal symptoms recorded by swimmers, surfers and divers in the Beach Survey studies and microbial indicators could be explained by the inability to sample at the points in the water used by these participants at the time of exposure. This is symptomatic of the design of epidemiological studies. It is inevitable that strict attention to control will narrow the scope of investigation, unless the study is to become too large and expensive to be feasible. Because of the statistical power of the design, the pooled analysis of the Cohort Study was able to detect an effect of faecal streptococci, measured at chest depth, upon objective and subjective gastro-intestinal symptoms. This correlation was not significant for faecal streptococci at other depths used by the bathers or for any other faecal pollution indicator at any depth in the sea. For ethical reasons, the Cohort Study could not include children or people under the age of 18. These points mean that the findings of the Cohort Study strictly relate only to bathing, as prescribed.

The main value of the Beach Survey studies is that they have enabled a cross section of beach users and activities at ten typical British resorts, varying in degree of water quality, to be examined over the main holiday month of August under typical British conditions of weather and thereby best meeting, in a practical fashion, the objectives of the research. It has distinguished between those symptoms which are experienced more frequently by persons entering the water, regardless of quality, and diarrhoea and gastro-intestinal symptoms, which are related to microbiological quality of the water and has provided a quantitative relationship. The approach is similar to that of the USEPA but with the refinements of a multiplicative model of bather-related risk, a greater degree of microbiological sampling and analysis (the potential of which was not fully realised), the consideration of a wider degree of symptoms and the use of logistic regression analysis to measure the effects of different water activities, age and sex.

Initially it was a major aim of the Cohort Studies to explore the relationships between perception of symptoms by subjects and medical and clinical diagnoses. It was found that no significant association existed. This and the negative association between the few subjects who reported losing time off normal activities or seeking medical advice and bathing suggests that the study was addressing symptoms and not overt illness or infection. By pooling the data from four studies and conducting an in-depth study of factors affecting recording of gastro-intestinal symptoms, useful comparative information upon the magnitude of factors other than bathing and water quality has been obtained for the first time in such a study. There seems little more that could be extracted from the data, except a study of the constancy of symptoms in the unexposed over the duration of the studies.

5.3 Comparison of findings with those in previous studies

Concordance of findings is very important, because it adds to plausibility of the results and the greater likelihood that the effects are real.

Table 5.1 summarises past findings and those of Phases I-III are added to show the extent of concordance. Table 5.1 compares the overall observations of Table 1.2 and shows that the findings of the UK studies generally support them or amplify them. Important aspects are the greatest susceptibility of the 15-24 age group, which may represent the most vigorous and adventurous of water-goers and indications that there may be two classes of symptoms covered by the study - those representing attack by faecally-borne organisms (since related to water quality and exposure) and those related only to exposure and not to water quality. The most suitable indicators for predicting risks from gastro-intestinal symptoms differ between the two studies, but this may reflect that the Cohort Studies were carried out in relatively clean waters.

Table 5.1 Comparison of observations from past epidemiological studies (Table 1.2) and those obtained in the UK studies

Past observations	Observed in UK studies
1. Swimmers report a higher in incidence of certain symptoms than non-swimmers.	Confirmed for all symptoms investigated, but statistically significant only in certain cases. (Beach Surveys). Confirmed for a variety of symptoms (Cohort Studies) but most consistently for gastro-intestinal.
2. The rate of symptoms is related to the degree or duration of exposure to water.	A general trend found, which is most marked with one or more, eye, skin and gastro-intestinal symptoms and increases in the order: no activity < wading < swimming<surfing/diving.
3. Children bathing report symptoms more frequently than older people.	Not measured in under fives, but the highest relative risks are shown by the 15 - 24 age group in the Beach Surveys. Cohort Studies reveal declining risk of gastro-intestinal symptoms with increasing age from 18 years to 80+.
4. The rate of symptoms is related to counts of faecal bacteria	In the Beach Survey studies the correlation is greatest for total coliform bacteria and enteroviruses with diarrhoea in subjects entering the water. In the Cohort Studies, only faecal streptococci, measured at chest depth, correlated with objective and subjective gastro-intestinal symptoms in bathers
5. *E. coli* or faecal coliform bacteria are not as satisfactory as other faecal indicator bacteria in correlation with symptom rates.	See remarks for observation 4
6. Residents living near the beach are less susceptible than visitors to swimming-associated gastroenteritis.	Not investigated from the data so far but could be determined from data collected in both studies.
7. What are the most active age-groups for bathing?	In the Beach Surveys, more than half the swimmers recruited were 5-14 years old and those not entering the water were most likely to be adults.

5.4 Relationships of findings to the bathing water Directive

It is relevant to ask whether the findings have implications for the microbiological criteria of the bathing water Directive, 76/160/EEC. The Directive was promulgated before many of the major epidemiological studies of Table 1.2 had been carried out. It is not surprising that the basis for the Imperative and Guideline values for the microbiological determinands appear to be arbitrary. Indeed, it is probably true, that, even were such information available, the decisions upon the levels to be adopted in a health-related water quality standard would be arbitrary, since the relationships between water quality and health are continuous and no thresholds appear to exist. It is tempting to suggest that a standard might be imposed at a level where statistically significant elevation occurs against background rates in the unexposed, but this too is arbitrary, since the level at which this occurs depends on the size and power of the study. Ultimately, the decision will depend upon value judgements, such as the level of risk acceptable (Pike 1993).

With the sampling regime specified in the Directive, i.e. taking samples in 1 m depth of water from 30 cm below the surface at places where bathers are most numerous, the Beach Survey studies showed that the strongest overall correlations with diarrhoeal symptoms in water users and waders were shown by total coliform bacteria and enteroviruses. Table 3.19, however, does not provide strong evidence for discounting faecal coliform bacteria, or faecal streptococci. The Cohort Studies, which were carried out in relatively clean water at beaches meeting the Imperative criteria, revealed only one significant relationship, between gastro-intestinal symptoms and faecal streptococci, measured at chest depth. It has been pointed out that sampling at chest depth routinely is scarcely feasible in practice, being neither convenient nor safe on foot or by boat under all weathers and tidal states.

The arguments given in Section 3.6.5 suggest that water activity in sea waters meeting the Imperative criteria for total coliform bacteria and enteroviruses does not involve any significant risk to health from diarrhoea. Similar arguments were used in Section 4.7.5 to suggest that significant elevations of gastro-intestinal symptoms were detected in the Cohort Studies in waters at or near the Guideline values for faecal streptococci.

The two types of study do not provide any support for the view that the levels of the Imperative or Guideline criteria for total coliform bacteria, faecal streptococci or enteroviruses should be revised because they are not stringent enough. Indeed, the lack of any significant association between reporting of symptoms and medical/clinical examinations or the need for medical intervention (Section 4.5.5) suggests that the criteria are conservative and provide adequate protection.

However, the significance of faecal streptococci measured at chest depth, referred to above and the problems of sampling beaches with large tidal excursions at low tide, when water quality is probably poorest, but water activity least, suggests that proper care must be given to design of sampling strategies.

It is surprising that, although there was high mutual correlation between logarithms of counts of total and faecal coliform bacteria, faecal streptococci and enteroviruses, their abilities to predict odds ratios for diarrhoea and gastro-intestinal symptoms varied between and within both studies. This may result from differences in their decay rates and those of pathogens in the sea. This is relevant when considering health effects at beaches which differ in distance from discharges of sewage, as well as when assessing the effects of disinfection of sewage before discharge. Disinfection will kill faecal indicator bacteria and viral pathogens at different rates. It is recommended that modelling studies should be carried out with known decay rates of indicators and pathogens to determine the effects of different decay rates and counts on prediction of morbidity rates in water users. This will enable the relative values of the different indicators to be assessed for different local conditions.

6. CONCLUSIONS

Data have been obtained in the Beach Survey studies for 16 569 holidaymakers at 10 beaches around the coasts of England and Wales varying in quality from very good to those consistently failing to meet the Imperative standards of the bathing water Directive. About one-third of these were a control group who did not enter the water and the remainder were categorised according to degree of water contact.

The Cohort Studies were carried out at four beaches, meeting the requirements of the bathing water Directive, in 1989-92, and have provided data upon 1112 subjects equally divided into bathers and non-bathers.

The conclusions of the report are as follows:

1. In the Cohort Studies, the results of medical clinical examinations after exposure and the numbers of subjects who bought medicines, who sought medical advice or who lost days of normal activity, did not show any significant differences between bathers and non-bathers. There was also no agreement between the medical diagnoses of red or infected ears and throats after exposure to the water, and subjects' reporting of those symptoms. These findings suggest that in the Cohort Studies bathing was not associated with overt infection or serious illness.

2. In the Cohort Studies certain factors, unrelated to bathing, were found to operate independently of water quality. This enabled their effects to be assessed separately from water quality, the first time that this has been achieved in any study of water quality and health. Among bathers, the older people were, the less they reported objective gastro-intestinal symptoms. Females reported these symptoms slightly more than males. Other factors which were not related to water, such as consumption of certain prepared foods, predisposition to diarrhoea, or unusual fatigue prior to bathing, increased the rates at which bathers reported subjective gastro-intestinal symptoms. Prior exposure to gastro-enteritis in the bathers' household increased the reporting of objective gastrointestinal symptoms. This factor had a greater effect than exposure to the most highly contaminated water recorded in the cohort studies (80 or more faecal streptococci per 100 ml).

3. In the case of the Beach Surveys, those participating in water activities reported more frequently than non-participants a number of categories of symptoms. These categories were eye; ear, nose and throat; skin and one or more symptoms. The relative likelihood (odds ratio) of participants doing so did not correlate with the concentrations of any microbial indicator of faecal pollution, but did correlate with increasing degree of water contact by those reporting the symptoms. It must be assumed that these symptoms result from prolonged contact with water and not from contact with waterborne pathogens.

4. Those subjects in the Beach Surveys who entered the water recorded all classes of symptoms more frequently, up to seven days after exposure, than those who did not enter the water. The relative frequencies at which the symptoms were reported by all

participants were consistently related to the degree of water contact, in the following ascending order: no activity (i.e. those not entering), wading, swimming, surfing and diving.

5. Depending upon the beach used in the Cohort Studies, certain symptoms were recorded significantly more frequently by bathers than by non-bathers. However, only gastro-intestinal symptoms were consistently recorded more frequently at all beaches.

6. In the Beach Surveys there were significant correlations between the number (geometric mean) of total coliform bacteria in the water and the likelihood of diarrhoea being recorded by those subjects who entered the water or waded in it, compared with the likelihood for those not having contact with water. In the case of enteroviruses, the correlation was highly significant. However, the likelihood of diarrhoea did not become statistically significant until total coliform counts reached or exceeded the imperative (mandatory) standards of the Bathing Water Directive or the average counts of enteroviruses were 10-40 times greater than implied by its imperative standard.

7. Data for objective and subjective gastro-intestinal symptoms from all four Cohort Studies were pooled and each category of symptoms was examined by logistic regression analysis. The only consistent relationship between water quality and the rates of gastro-intestinal symptoms occured with faecal streptococci when measured at chest depth and when counts exceeded 35-40 per 100 ml.

8. The above results of both studies show considerable consistency with those of previous studies of the effects of water quality on health of bathers. This adds plausibility and increases the likelihood that the effects are real and universal.

9. The results of the Beach Survey studies for diarrhoea in those using the water and wading in it and of the Cohort Studies for objective gastro-intestinal symptoms in bathers, suggest that the Imperative standards of the Directive for total coliform bacteria and enteroviruses, and by implication for faecal coliform bacteria, give adequate protection to health and do not support the introduction of more stringent standards.

10. When water was sampled at the standard depth required in the Directive, the quality of the water had no significant effect on rates of diarrhoeal symptoms in bathers, surfers and divers in the Beach Surveys or on rates of gastro-intestinal symptoms in bathers in the Cohort Studies. These findings and the relationship detected in Conclusion 7 suggests that sampling strategies should reflect the depths of water, locations and tidal states most used in marine recreation.

7. RECOMMENDATIONS

The following recommendations are made for extracting further information from the data sets collected in the Beach Survey and Cohort Studies of 1989-92.

For the Beach Survey studies

1. Further exploration of data for symptoms comprising objective gastro-enteritis, such as fever, nausea, vomiting and stomach cramps.

2. Refining the analysis of health effects and water quality by attempting more precise definition of exposure to polluted water, taking into account time of day and place of water activity as elicited at beach interview and relating them to microbial quality at the time and place.

3. Separately analysing for effects upon health of factors not related to water exposure, such as consumption of purchased foods, visitor status (holidaymaker, day tripper, local), purchase of medicines or visit to doctor, duration of water activity and days of water activity.

4. An examination of microbiological data to analyse variability, since the statistics obtained could be used in devising sampling protocols, deriving standards and in carrying out risk analysis.

For the Cohort Studies:

5. Determining the constancy, or otherwise, of symptom rates in the non-exposed over the periods covered by the studies, to determine whether there are any temporal effects upon relative risks or odds ratios for symptoms.

For both studies:

6. Determining by modelling, the effects which different numbers of faecal indicators and pathogens and their rates of decay in sea water and in disinfection, have on the efficacy of the indicators in predicting symptom rates in bathers at beaches differing in distance from discharges and those where sewage is disinfected before discharge.

7. Carrying out risk analysis, to relate the derived models for water quality and symptom rates to variability and percentile points in existing or modified standards.

8. Attempting a derivation of health-related standards for water at marine bathing beaches, using the information obtained.

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