Coordinated Mediterranean Pollution Monitoring and Research Programme

HEALTH CRITERIA AND EPIDEMIOLOGICAL STUDIES RELATED TO COASTAL WATER POLLUTION



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Report of a Group of Experts jointly convened by WHO and UNEP



Athens, 1–4 March 1977



WORLD HEALTH ORGANIZATION

Regional Office for Europe Copenhagen, 1977 This report contains the collective views of an international group of experts and does not necessarily represent the decision of the stated policy of either the World Health Organization or the United Nations Environment Programme.

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Note

PREFACE

A series of conferences was convened in 1974 and 1975 to discuss the pollution situation in the Mediterranean and ways and means of providing the pollution abatement measures required. Some of the proposed programmes were adopted by the Intergovernmental Meeting on the Protection of the Mediterranean (Barcelona, January 1975) and endorsed by UNEP.

The UNEP Coordinated Mediterranean Pollution Monitoring and Research Programme resulted from the decisions made at the above meeting. It consists mainly of seven pilot projects which are generally concerned with baseline studies and monitoring of various pollutants. Research into the effects of pollutants on marine organisms and on marine communities and ecosystems, problems of the coastal transport of pollutants and the sanitary quality of beaches and coastal waters also forms part of these projects.

One of these seven projects is the Joint WHO/UNEP Coordinated Pilot Project on Coastal Water Quality Control in the Mediterranean (MED VII). Its main objective is the assessment of the potential health hazards connected with the coastal waters of the Mediterranean needed for the rational design and efficient implementation of national programmes for the control of coastal pollution from landbased sources in the area.

Among the immediate objectives of the above pilot project is the initiation of a scientific study on the epidemiological evidence of health effects resulting from inadequate sanitary conditions in coastal areas, and the promotion of related studies. In this connexion, a consultation meeting was organized in Athens by WHO and UNEP in collaboration with the Government of Greece. Its task was to review the epidemiological factors and health criteria on which quality standards for coastal water are based and to develop a methodology for epidemiological research programmes intended to provide reliable data for application in the field.

This peport contains the detailed findings and recommendations of the consultation meeting. The agenda and list of participants are given in Annexes III and IV respectively.

It is expected that the epidemiological studies proposed in this document will be initiated, implemented and strengthened and that they will attract the required interest and support from the countries bordering the Mediterranean.

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1. INTRODUCTION

A WHO/UNEP Expert Consultation was held in Geneva from 15 to 19 December 1975 (1). Its purpose was to outline a WHO/UNEP Coastal Water Quality Control Programme in the Mediterranean. This project was one of seven pilot projects recommended and adopted at the Inter-governmental Meeting on the Protection of the Mediterranean, held in Barcelona from 28 January to 4 February 1975, to develop a UNEP Coordinated Mediterranean Pollution Monitoring and Research Programme (2).

The scope of the pilot project outlined at the Geneva meeting was limited to the health hazards arising from the pollution of coastal waters in the Mediterranean and coincident with man's activities in those waters. The specific items considered were: (a) infection and intoxication resulting from the consumption of seafood, and of shellfish in particular; (b) infection associated with bathing; and (c) sanitation and amenity of beaches and coastal waters.

The first objective of the pilot project, as stated in the Geneva document, is to produce the statistically significant data, scientific information and technical principles required for assessing the present level of coastal pollution in relation to human health. The second is the development of a rational scheme for efficiently implementing national programmes for controlling coastal pollution from land-based sources in the Mediterranean area.

The immediate objectives of the pilot project are:

(a) to design and implement a programme for the sanitary and health surveillance of coastal recreational areas and of water from which shellfish are harvested in selected coastal areas of the Mediterranean;

(b) to initiate a scientific study of the epidemiological evidence for health effects caused by inadequate sanitary conditions in coastal areas and to promote related studies;

(c) to review methods of assessing coastal pollution and to recommend principles for controlling pollution from land-based sources;

(d) to make supplementary equipment available to institutes collaborating in the monitoring network;

(e) to provide training facilities for professionals working on coastal water quality monitoring and control;

(f) to make technical and scientific information available by publishing guidelines and other information.

The Expert Consultation on Health Criteria and Epidemiology of Health Risks Related to Beach and Coastal Pollution, held in Athens on 1-4 March 1977, was convened in pursuance of the second of the above-mentioned objectives.

2. OBJECTIVES

The overall objective of the 1977 Expert Consultation was to make recommendations as to the design of short- and long-term epidemiological studies aimed at providing the necessary data base for evaluating health effects and developing water quality criteria for the recreational use of coastal waters in the Mediterranean. The specific objectives of the Consultation were:

(a) to review existing health effects criteria, guidelines and standards for the quality of coastal waters used for recreation in the Mediterranean, including the microbial water quality indicators through which they are expressed and the data available to support them;

(b) to define the specific nature of the health effects water quality criteria needed and the means whereby guidelines and standards can be derived from these criteria, including risk analysis and its application;

(c) to develop recommendations for, and the design of long- and short-term epidemiological studies to produce the required criteria;

(d) to examine the feasibility of developing interim criteria pending the implementation of the above research.

3. DEFINITIONS

The definitions given below were drawn up in the light of those put forward at the UN Conference on the Human Environment in Stockholm, 1972 (3).

3.1 Health effects water quality indicator

This is defined as a microbiological, chemical or physical substance which indexes the potential risk of infectious disease coincident with man's use of the aquatic environment as a source of recreation. Ultimately, the best indicator - at present no ideal indicator exists will be the one whose densities correlate best with associated health effects. It can be selected, therefore, only on the basis of epidemiological analysis. However, before such analysis is carried out, potential indicators can be matched against the following requirements. They must:

(i) be consistently and exclusively associated with the source of the pathogens or noxious substances;

(ii) be present in sufficient numbers or quantities to provide an "accurate" density estimate whenever the level of each of the pathogens is such that the risk of illness is unacceptable;

(iii) approach the resistance to disinfectants and environmental stress, including that resulting from toxic materials deposited in the aquatic environment, of the most resistant pathogen potentially present at significant levels in the source; and

(iv) be quantifiable in recreational waters by reasonably easy and inexpensive methods, and with considerable accuracy, precision and specificity.

3.2 Water quality criterion

This is developed from the use of indicators and is defined as a quantifiable exposureeffect relationship between the density of the indicator in the water concerned and and the potential human health risks involved in using that water. Above all, it is a set of facts or a relationship on which a judgment can be based.

3.3 Water quality protection standard

This is derived from the criterion and is an accepted maximum level for the density of the indicator in the water associated with unacceptable health risks. The concept of acceptability implies that social, cultural, economic and political, as well as medical, factors are involved and that these may vary in both time and space.

4. HEALTH EFFECTS RECREATIONAL WATER QUALITY INDICATORS

4.1 Indicator characteristics

Raw or inadequately treated human faecal wastes discharged directly or indirectly into the aquatic environment present the greatest risk of infectious, waterborne disease to recreationists. Historically, therefore, microorganisms indigenous to the gastrointestinal tract of man and of certain lower animals have been used to index the quality of recreational waters from the point of view of the possible presence of enteropathogenic microorganisms in those waters. It is of interest that, between 1890 and 1900, three organisms or groups of organisms, Bacillus coli-communis (E. coli), faecal streptococci and Bacillus enteritidis sporogenes (C. perfringens), were suggested for use as faecal indicators, and that these three are those most widely used today (4).

There has recently been some interest in using the pathogens themselves as water quality indicators. A number of problems are, however, associated with this approach, including the large number of pathogens involved, unsatisfactory methods of enumeration or the absence of any method at all and fluctuations in pathogen density. These will be discussed later.

A third group of potential water quality indicators consists of pathogenic microorganisms which multiply significantly in the aquatic environment. The environment itself is thus the source of these organisms, and even if originally derived from sewage, they cannot be expected to index any potential health hazards.

page 2

¹ In the present consultation microbiological indicators were dealt with exclusively.

Because pollution by human faecal wastes is undoubtedly the most hazardous form of pollution, it is important that health effects water quality indicators should:

(a) be consistently and exclusively present in human faecal wastes at reasonably high densities; and

(b) be capable of survival during sewage treatment and transport from source to target to an extent comparable to that of the pathogens potentially contained therein. The relatively small degree of contact must, however, be taken into account.* It is estimated that only 10-50 ml of water are ingested during a swimming experience (see definition of swimming in section 8.3.1); and ingestion appears to be the significant route of entry, except under certain relatively rare circumstances.

4.2 Evaluation of indicators

Three methods of evaluating health effects water quality indicators are available. The preferred method is to compare the densities of candidate indicators with what is ultimately of concern, namely illness or symptom rates specifically associated with the recreational use and to select that indicator which gives the best overall correlation. Such comparisons are best made by means of prospective epidemiological studies as discussed in sections 6.1 and 6.2.

The second, and less desirable, method is to compare the densities of the various candidate indicators with the densities of those pathogens in sewage which have been or are likely to be the etiological agents of outbreaks of waterborne disease associated with recreation. This method, which has been used by certain workers, has a number of associated problems. Firstly, if guidelines and standards are to be based on the indicator selected the use of this method begs the question of the pathogen density associated with an unacceptable risk of disease; to determine this density, good human dose-response data by the oral route are required together with information on indicator-pathogen relationships for most if not all of those pathogens for which this route of transmission is significant. Such data are meagre. Secondly, it requires good enumerative methods for the pathogen as well as for the indicator. Recovery methods for use with environmental samples are unavailable for three important - and possibly the most important - viral agents, namely hepatitis A virus, and the Norwalk and Reo-like agents; these methods are relatively poor for viral agents and for <u>Shigella</u>, and they are only just adequate for Salmonellae. This still leaves those pathogens not, or not exclusively derived from faecal wastes; there are in general, no human dose-response data for these agents.

The third method, that of comparing the densities of one indicator with those of another, is self-defeating. The fallacy is obvious. If the densities of the two indicators are not in agreement, it is impossible to decide which of the two is the better. If, however, good agreement is obtained, a marked improvement in assay logistics would be the only justification for replacing a more widely used and accepted indicator system by one that is less so.

4.3 Indicator sources

A number of potential sources of pathogenic microorganisms are present in estuarine and coastal waters used for recreation, most of which are discussed elsewhere in this section. Furthermore, a large number of pathogens may be present in these sources. In fact, the faecal wastes of man, and to a lesser extent those of lower animals, are the major source; and there have been a limited number of disease outbreaks clearly associated with the recreational use of waters polluted by such wastes. However, if coastal and estuarine waters are alone considered documentary evidence is available for rather rare wound infections caused by a biotype related to Vibrio parahaemolyticus, skin lesions caused by a species of mycobacterium, otitis externa due to P. aeruginosa, and 2 - 3 outbreaks of salmonellosis. However, a number of other agents must be considered because they have been responsible for outbreaks of infectious disease associated with the recreational use of fresh water and because they are present in coastal and estuarine waters, sometimes in large numbers. These agents include Shigellae, hepatitis A virus, Aeromonas hydrophilia and Coxsackie A virus. In addition, a number of agents should be considered because: (1) they are faecal in origin; (2) they have been associated with disease outbreaks transmitted by drinking water; and (3) they have been recovered from marine waters. They comprise adeno-, reo- and polioviruses, enteropathogenic E. coli, V. cholerae, Entamoeba histolytica, Giardia lamblia, various helminths and possibly Yersinia enterocolitica and Candida and some other fungi.

Much of the information presented above has been obtained by the analysis of disease outbreaks. In general, sporadic cases of disease are not detected by the usual reporting procedures. The findings of a United States Environmental Protection Agency (USEPA) (5,6,7) study suggest that an acute but benign and self-limiting gastroenteritis is the commonest form of recreation-associated illness. This is what would be expected for some of the etiological agents noted above and also for the Norwalk and Reo-like viral agents.

4.4 Potential indicators

A large number of potential health effects recreational water quality indicators are available, and to describe each of them fully would be beyond the scope of this report. The reader is therefore referred to a number of reviews on the subject, including the most recent one by Cabelli et al. (5). These indicators may be divided broadly into four groups as follows.

4.4.1 Faecal indicators

Their source is exclusively and consistently the faecal wastes of man and of warmblooded animals. They include <u>E. coli</u>, <u>Enterococci</u>, <u>C. perfringens</u>, <u>Bifidobacterium</u>, Poliovirus (the vaccine strain) and Candida albicans.

4.4.2 Sewage indicators

Although these may be present in faecal wastes, they are not consistently so, and then only in small numbers. However, they are consistently present in sewage where they multiply. Some are opportunistic pathogens. They include <u>Klebsiella sp.</u>, <u>Enterobacter sp.</u>, faecal and total coliforms, <u>P. aeruginosa</u>, <u>A. hydrophila</u>, and coliphage. The limitations on their use are given later in this section.

4.4.3 Faecal pathogens

These are pathogenic microorganisms whose source is exclusively faecal. They have been described and discussed in the earlier parts of this section; the disadvantages of their use as water quality indicators will be given later.

4.4.4 "Aquatic" pathogens

These are microorganisms which multiply in the aquatic environment to a significant extent under conditions of nutrient enrichment or thermal pollution. As already pointed out (see page 2) their source is the aquatic environment, even though they may have originally been derived from faecal wastes. They potentially represent the interaction of ecological and health effects. With the possible exception of <u>Naegleria</u>, they are all opportunistic pathogens which could cause health effects, particularly in compromised individuals, when the organisms are present in very large numbers. Since their presence cannot be indexed by faecal indicators, their enumeration may be required under special circumstances.

4.5 Constraints on indicator use and data interpretation

The use of water quality indicator systems is subject to certain limitations. This is especially true in the examination of recreational waters since the objective is usually one of risk assessment by means of a faecal indicator system. The constraints discussed below are important not only in the interpretation of indicator data but also in the design of the epidemiological studies in which they are used.

4.5.1 Faecal indicators or water quality indicators

Because the discharge of human faecal wastes is the most hazardous form of pollution of water used for recreational purposes, and because this type of pollution is most amenable to corrective action, the terms faecal indicator and water quality indicator have been used synonymously.

This is usually, but not invariably appropriate (see Section 4.4.4.). Where the aquatic environment is itself the source, use of an indicator which indexes the human or animal faecal wastes discharged into that environment will tend to give an underestimate of the potential hazard, unless the agent concerned also multiplies under identical environmental conditions. Aeromonas hydrophilia, Vibrio parahaemolyticus, pathogenic <u>Naegleria</u>, <u>Pseudomonas aeruginosa</u> <u>Klebsiella</u> and possibly <u>Yersinia enterocolitica</u> may fall into this category. Obviously, if the source of an infectious agent is not faecal, a faecal indicator will be of no value in indexing an associated health hazard. However, except for the otitis externa caused by <u>P. aeruginosa</u>, cases of disease caused by these organisms, and associated with the recreational use of water, are very rare. <u>Naegleria</u> may also be considered; however, further studies are required.

4.5.2 Small point sources

The rationale underlying the use of criteria and standards based on faecal indicator densities for indexing health hazards in sewage-polluted waters is that, for average morbidity in the discharging population, the indicator-to-pathogen ratio in the sewage and the receiving waters into which it is discharged is reasonably constant. An acceptable probability of illness

caused by the pathogen can thereby be extrapolated to a given indicator density, which is then recommended as a Protection Standard (see Section 3.3). Such relationships appear to hold for waters receiving the discharges from relatively large municipal sewage treatment plants. However, as the number of individuals contributing to the source of the faecal wastes becomes smaller and smaller, until only the individuals in a single pleasure boat or the occupants of a single dwelling, whose sewage is discharged directly or indirectly into a body of water, are concerned, the indicatorpathogen ratio will increasingly depart from the average upon which the standards are based. In the extreme case where the faecal wastes of a single ill individual or carrier are discharged into the water, the number of pathogens may equal or exceed the number of indicator microorganisms. This consideration is most important in the selection of test beaches for an epidemiological study.

4.5.3 Illness rates in the discharging population

It is axiomatic that the faecal indicator pathogen ratios will change with the incidence of enteric diseases in the population whose faecal wastes contaminate waters used for recreation. This has two consequences. Firstly it follows that illness-faecal indicator relationships obtained at several places, or even at different times at the same place, will not necessarily be the same. The best that can be expected is some "average" relationship. Secondly, the relationship may not hold, if an epidemic of a particular enteric disease occurs.

The magnitude of the change in the ratio may be such that the acceptable tisk of illness associated with a standard derived from this ratio (criterion) will be exceeded unless a stricter standard is temporarily introduced. In the recent swimming-associated outbreak of shigellosis on the Mississippi River below Dubuque, Iowa (8) it appears that although the 200 per 100 ml faecal coliform guideline was probably exceeded for several years, the outbreak did not occur until the number of ill individuals and carriers in the discharging population had reached a critical level.

Conversely, if, through good public health measures (e.g. immunization, better sanitation and the elimination of carriers), there is a significant and consistent decrease in the illness rate of the discharging population, the probability of a specific illness associated with an existing standard based on a faecal indicator may be considerably lower than predicted. The absence of outbreaks of salmonellosis associated with the recreational use of water may be a case in point.

4.5.4 Faecal indicators or pathogens

The use of faecal indicators, such as coliforms or portions of the coliform population, faecal streptococci and <u>Clostridium perfringens</u>, for indexing the health hazards in drinking and recreational waters dated back to the late 1800s and early 1900s, shortly after these organisms were first isolated and associated with the faecal wastes of warm-blooded animals. With the limitations noted above, such practices were and are sound both on theoretical and practical grounds, since it is recognized that:

(a) a large number of pathogenic bacteria and viruses may be present in municipal sewage, each with its own probability of illness associated with a given dose;

(b) routine monitoring of each of the pathogens would be a herculean task;

(c) enumeration methods are not available for some of the more important pathogens, and are difficult for the others;

(d) pathogen density data are difficult to interpret because the methodology is generally time-consuming, expensive and not always quantitative, and because in some instances dose-response data are meagre or not available; and

(e) on theoretical grounds, the real purpose is not to index the presence of the pathogen but rather the likelihood that it may be present in sufficient numbers to constitute an unacceptable health risk.

These considerations argue against the development of water quality criteria and standards based on the faecal pathogens themselves or even the use of one faecal pathogen as an indicator for all the others. However, there is ample justification for the examination of recreational waters for pathogens during disease outbreaks and where the aquatic environment is potentially the source of the pathogens.

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4.5.5 Sewage indicators or faecal indicators

A number of potential, microbial water quality indicators are consistently isolated in appreciable but variable numbers from raw as well as treated sewage but have been infrequently isolated from the faeces of "normal" individuals, and then only in small numbers. They include

<u>Pseudomonas aeruginosa, Aeromonas hydrophila, Klebsiella sp., Citrobacter sp.</u> and <u>Enterobacter sp.</u> Three of these five organisms are opportunistic pathogens which, under certain rare conditions, may require enumeration because of their potential ability, when present at high densities, to cause adverse health effects among swimmers. If the term faecal indicator, as the name implies, applies only to microorganisms or chemicals specifically, consistently and exclusively associated with the faecal wastes of warm blooded animals, these species cannot be designated as such. "Sewage indicators" would be a more appropriate designation, and the species would be expected to give a variable index of the health risks involved, depending on the extent of their multiplication in sewage. Four of the organisms noted above - namely, <u>A. hydrophilia, Enterobacter</u>, <u>Citrobacter</u> and <u>Klebsiella</u>, satisfy the definition of coliforms as used in the USA, and a significant portion of the <u>Klebsiella</u> population from certain types of industrial wastes satisfies the requirements for faecal coliforms. One consequence of distinguishing between sewage indicators and faecal indicators and rejecting the former would be the abandonment of total and faecal coliforms in favour of <u>E. coli</u> for indexing the contamination of surface waters with the faecal wastes of warm-blooded animals.

4.5.6 Human or animal faecal wastes

Several pathogenic microorganisms are potentially transmissible to humans by the contamination of water with the faecal or urinary wastes of animals. With the possible exception of <u>Salmonella</u>, enteropathogenic <u>E. coli</u> and some of the intestinal parasites, the transmission of these agents from the faecal wastes of animals to man via recreational water use has occurred under limited and unusual circumstances in the USA. In addition, there are no definitive data to prove that the possibility of transmission of salmonellosis from wild or domestic animals to man via recreational water use can be indexed by faecal indicators or that disease outbreaks attributable to this chain of events, have occurred. Nevertheless, existing guidelines and standards based on the commonly used recreational water quality indicators make no distinction between pollution arising from human as opposed to lower animal faecal wastes. Furthermore, the major etiological agents of concern associated with the faecal contamination of recreational waters are probably the enteropathogenic viruses, and significant transmission of these agents to man via animal wastes has not been reported. There are no accurate and precise methods for estimating the proportions of human, as compared with animal faecal pollution in waters.

The above discussion is not meant to suggest that there are no health hazards associated with the contamination of recreational waters by the faecal wastes of animals. Rather, it is suggested that the currently used indicator systems do, in fact, equate the health hazards from human and from animal faecal wastes, that this has no scientific basis, and that more information is needed on the relative risks. This issue is relevant to the question of recreational waters subject to contamination from waterfowl and wild animals, runoff from agricultural land, and urban storm water runoff to which municipal wastes are not added.

4.5.7 Bathers themselves as a pollution source

It is generally accepted that, in artificial bathing places, particularly where water exchange and disinfection are inadequate, bather density is a major factor in determining the probability of swimming-associated illnesses. However, in natural bathing places, pathogenic microorganisms carried by the bathers themselves probably contribute insignificantly to hazards associated with recreational use, except maybe some skin and eye pathogens, and indicator bacteria shed by these individuals contribute little to the microbiological quality of the water. The exceptions are small inland bodies of water, such as ponds, where water exchange is minimal, or bathing places where the bather density is extremely high. Cases of otitis externa caused by <u>P. aeruginosa</u> have frequently been associated with swimming in such bodies of water, and limits for <u>P. aeruginosa</u> densities therein have been suggested. However, until the water itself is clearly shown to be the source of the causative agent, this does not appear to be justified.

5. EXISTING CRITERIA, GUIDELINES AND STANDARDS

The information available on recreational water quality criteria and standards for countries bordering on the Mediterranean will be presented in the context of the standards recommended or adopted by WHO, the European Economic Community, and three countries (the United Kingdom, the USA and the USSR) outside the Mediterranean area. Although it is recognized that microbiological parameters form only one part of the overall standards, such parameters will alone be considered here as being those most consistent with the definition of criteria used here.

Existing microbiological guidelines and standards are generally expressed in terms of coliforms or portions of the coliform population, faecal coliforms and <u>E. coli</u>. Faecal coliforms are used in the USA; most European countries use a specific portion of the faecal coliform population - namely, <u>E. coli</u>. A recent WHO Working Group (9) noted that the detection of <u>E. coli</u> (coliforms which produce gas in a lactose medium at 44° C and which are indole-positive)

"... was one of the most sensitive indicators of the degree of sewage pollution and sewage dispersion around points of wastewater discharge".

Various mathematical expressions or combinations thereof have been used in defining microbiological guidelines and standards for recreational waters. They include (a) the geometric mean; (b) the median; (c) the arithmetic mean; (d) values not to be exceeded in more than 10% or 20% of the samples; and (e) an upper limit which is not to be exceeded in any of the samples. For obvious reasons, the form in which a standard is given is as important as the numerical value itself; and the form used depends on the nature of the microbial population, as well as on sampling and on assay variability.

5.1 International criteria and standards

The consensus view of the WHO Working Group previously mentioned (9) was that since "..potential health risks do exist in connexion with bathing or swimming in polluted coastal waters..." it was therefore .. generally feasible and desirable to set broad upper limits for the number of faecal indicator organisms in coastal bathing waters ... expressed in broad terms of orders of magnitude rather than rigidly stated specific numbers. Highly satisfactory bathing areas should, however, show <u>E. coli</u> counts of consistently less than 100 per 100 ml and to be considered acceptable bathing waters should not give counts consistently greater than 1000 <u>E. coli</u> per 100 ml". Although it was agreed that this guideline was not at the present time backed by direct epidemiological data, the level of faecal microorganisms should on general public health grounds be kept at as low a level as feasible in bathing-waters.

In 1975 the Council of the European Communities (10) adopted a directive on the quality of bathing water setting limit values of relevant parameters to be applied no later than 10 years following the notification of the directive. As far as microbiological parameters are concerned it includes the following:

Bathing water shall be deemed to conform to the value of the relevant parameters:

(1) if samples of this water taken at the same sampling point and at intervals specified in table 1, show that it conforms to the relevant parametric values for the quality of the water concerned, in the case of:

- 95% of the samples for parameters corresponding to those specified in Column I of the table;
- 90% of the samples in all other cases with the exception of the "total coliform" and "faecal coliform"parameters where the percentage may be 80%.
- and (2) if in the case of the 5, 10 or 20% of the samples which do not comply:
 - the bathing water does not deviate from the parametric values in question by more than 50% except for microbiological parameters, pH and dissolved oxygen;
 - consecutive water samples taken at statistically suitable intervals do not deviate from the relevant parametric values.

5.2 Countries bordering on the Mediterranean

A brief outline of the position in the various countries is given here; for more detailed information reference should be made to a recently published survey (12).

5.2.1 Albanla

No information available.

5.2.2 Algeria

In 1976 a draft ordinance embodying the principles of water legislation was being prepared. This ordinance is essentially enabling in character and contains no norms or standards. The necessary regulations are to be issued at a later date. This ordinance in its objectives includes the protection of water resources against pollution. Water resources are subdivided into three categories, namely, surface waters, ground waters, and territorial waters. From the described functions of various authorities concerned with water, it appears that the National Service for Drinking Water and Industrial Water Supplies and Environmental Sanitation, and the National Service for Water Legislation and Control have the greatest relevance. The ordinance defines the responsibilities for ensuring that sources containing pollutants do not discharge into waters.

Table 1

MICROBIOLOGICAL QUALITY REQUIREMENTS FOR BATHING WATER (COUNCIL OF THE EUROPEAN COMMUNITIES)

	Parameters		G	I	Minimum sampling frequency	Method of analysis and inspection
1.1						
1	Total coliforms	/100 ml	500	10 000	Fortnightly (1)	Fermentation in multiple tubes. Subculturing of the positive tubes on a confirmation medium. Count according to MPN (most
2	Faecal coliforms	/100 ml	100	2 000	Fortnightly (1)	probable number) or membrane filtration and culture on an appropriate medium such as Tergitol lactose agar, endo agar, 0.4% Teepol broth, sub- culturing and identification of the suspect colonies.
						In the case of 1 and 2, the incubation temperature is var- iable according to whether total or faecal coliforms are being investigated.
3	Faecal streptococci	/100 ml	100	-	(2)	Litsky method. Count according to MPN (most probable number) or filtration on membrane. Cul- ture on an appropriate medium.
4	Salmonella	/l litre	- 1	0	(2)	Concentration by membrane filtra- tion. Inoculation on a standard medium. Enrichment - subcultur- ing on isolating agar - identi- fication.
5	Entero viruses PFU/1	0 litres	-	0	(2)	Concentrating by filtration, flocculation or centrifuging and confirmation.

G = guide.

I = mandatory

(0) Provision exists for exceeding the limits in the event of exceptional geographical or meteorological conditions.

(1) When a sampling taken in previous years produced results which are appreciably better than those in this Table and when no new factor likely to lower the quality of the water has appeared, the competent authorities may reduce the sampling frequency by a factor of 2.

(2) Concentrations to be checked by the competent authorities when an inspection in the bathing area shows that the substance may be present or that the quality of the water has deteriorated.

Moreover, the Minister responsible for hydraulic works is to establish standards governing the utilization and conditions for the discharge of waste water or polluted water. He is also required to establish:

(1) measures for the protection of water resources and the prevention of pollution;

(2) standards for the protection of water resources against pollution of industrial, domestic, or other origin;

- (3) measures for preventing and eliminating harmful effects of water; and
- (4) standards for discharges from sewers.

The state secretariat for hydraulic works is implicitly responsible for water pollution control and it would appear that it will be assigned the functions delegated to the Minister in the above draft ordinance.

5.2.3 Cyprus

There is no comprehensive legislation dealing with the control of water pollution, but a Water Code is in the course of preparation. Cyprus has introduced strict limitations on the use of agricultural chemicals and detergents.

Under the Foreshore Protection Law of 1934, as amended, the District Officer is empowered to prohibit or to impose restrictions on the dumping of any kind of wastes, lubricating oils, etc., on any specified part of the shore, or into the sea within a specified distance from the low watermark, or from any pier.

Mining operations are governed by special provisions dating from 1953. Regulations issued in 1971 under the Fisheries Law of 1931 prohibit the contamination of maritime waters. There is a Sub-Committee for Prevention of Water Pollution, established by the Executive Committee for Nature Conservation.

5.2.4 Egypt

The major items on legislation on water pollution control in Egypt are Law No. 93 of 1962 on the discharge of liquid wastes and the regulations for its implementation issued by Decree No. 649 of 1967. The Law deals with discharges of waste waters into public sewers, discharges into water courses, private discharges, with sampling and analytical procedures and other general provisions. In the promulgated regulations by the above Decree detailed quality criteria for waste water discharged into public sewers and into water courses are also included. The latter are classified in three classes while the waste water is classified in two categories. The disposal of waste water into the various classes water courses comply with are given standards for various parameters.

Egypt is now conducting a programme to develop recreational water quality criteria.

5.2.5 France

France has adopted a many-sided approach to the question of water pollution. An inventory of all surface waters on the basis of physical, chemical, biological and bacteriological criteria is being carried out by a number of Ministries and coordinated by the Ministry for the Quality of Life. Economic measures, such as the "polluter pays principle" have been adopted, the amount payable by the polluter being proportional to the quantity of pollutants discharged into the water. France, together with other countries, has taken measures against detergents and other noxious substances.

Conditions for the licensing of discharges have been determined by various provisions in 1973, but stricter requirements are to be imposed. Effluents must satisfy certain well-defined criteria based on the condition and use of the receiving waters.

Quantitative guidelines for sea-bathing areas are as follows:

- (a) Total coliforms: less than 2000 per 100 ml of sea-water
- (b) Faecal coliforms: less than 500 per 100 ml of sea-water
- (c) Faecal streptococci: less than 100 per 100 ml of sea-water

5.2.6.Greece

The health risks of sea bathing are being systematically investigated. The health authorities take the view that the high incidence of intestinal diseases in countries in this latitude justifies stricter criteria than are needed in more northerly countries. Bathing and other recreational activities are forbidden on polluted coasts. Bathing is forbidden in ports and at a distance of up to 200 m on either side of any point where sewage is discharged into the sea. The most important residential and tourist beaches are continually surveyed to assess and control pollution.

5.2.7 Israel

In 1950, the Israel Ministry of Health initiated studies to evaluate the degree of contamination of bathing beaches along the Tel Aviv foreshore, and established internal water quality guidelines for the guidance of health officers. The guidelines stated that beaches showing a total coliform count greater than 2400 per 100 ml in 20% of the samples in a given month, were not recommended for public bathing. As a result of those early surveys, a number of bathing areas were designated as not recommended.

Later, these early guidelines were enforced by legal decisions to require local authorities to close beaches not meeting the above requirement, under the legislative powers given to the Ministry of the Interior under the Bathing Places (Regulation) law of 1964, concerning the licensing and operation of public beaches by local authorities. In 1974, a committee of experts drew up recommendations for marine water quality guidelines (13,14). These recommendations have not yet received official approval.

5.2.8 Italy

The possible health risk of bathing along the Italian coast must be viewed against the background of a high endemic incidence of enteric infection, infectious hepatitis and parasitic infestation, especially in southern coastal regions. No direct evidence linking illness with bathing has been found in Italy, but the cholera outbreak of September 1973 is a stern reminder of the fact that shellfish can become a dangerous vehicle of disease, as was already known from the seasonal peaks of enteric infection due to the consumption of raw sea-food.

Special measures were enforced during and after the 1973 cholera outbreak. Swimming and the use of beaches was forbidden along the coasts in the Naples, Bari, and Cagliari regions, and many other beaches were also declared out of bounds by local health authorities. The consumption of sea-food was forbidden for many months and thereafter special regulations governing its sale were promulgated. The swimming prohibitions were revoked before the start of the 1974 bathing season. A special law, known as the "Anticholera Law", the purpose of which is to finance basic sanitation works in the provinces afflicted by the cholera epidemic, came into operation in 1974.

Up to 1974, swimming was allowed in sea-water with fewer than 100 <u>E. coli</u> per 100 ml. General conditions meeting aesthetic requirements have also been applied, but no specific parameters have been defined.

5.2.9 Lebanon

According to available information no legislation dealing with water pollution has been enacted in Lebanon since 1933. Previous legislation deals with sea fisheries protection and with provisions relating to waste water disposal and drainage equipment.

A law on cleanliness is reported to have been promulgated in 1975 but no information is available as to whether it is applicable to discharge of wastes into the sea.

5.2.10 Libya

Water pollution control is covered by a number of items of legislation. Since May 1974, however, a comprehensive draft Water Resources Law has been under study. In this law, water pollution is defined so as to include any direct or indirect reduction in water quality in any phase of the hydrological cycle so as to render it unfit for the purpose for which it is or may be used. The General Water Authority would be responsible for isolating, treating and disposing of polluted water supplies, or for using them.

5.2.11 Malta

A report containing suggestions and recommendations for improving the laws in respect of water, and liquid and solid wastes has been issued which may lead to new legislation. There are also Port Regulations governing oil disposal, promulgated in 1966.

5.2.12 Monaco

There are plans for the treatment of wastes before they are discharged into the Mediterranean. Dumping of any kind of wastes in bathing places is prohibited, pursuant to a Municipal Order of 1972.

5.2.13 Morocco

According to available information no major legislation on the control of water pollution has been promulgated in Morocco since 1925.

A Dahir of 1925 on water administration contains provisions prohibiting the dumping of any substances harmful to public health or to animals into water courses.

In 1974 a decree established a National Committee for the Environment. This Committee among others is empowered to commission studies on the control of pollution and nuisances, and to take steps for the drafting of laws and regulations on this subject.

5.2.14 Spain

The trend is towards the coordination of efforts aimed at the protection of the environment including control of water pollution. A National Environmental Protection Code is in the process of being prepared. Marine pollution is dealt with by a special committee set up specifically for that purpose.

For effluents, an Order lays down the organic, physical, chemical and biological characteristics to be met by the discharger. There are also a number of standards on industrial waste waters and their treatment or dilution when discharged into the sea.

5.2.15 Syria

Water pollution control is dealt with by two legislative decrees issued in 1964 and 1972. The latter is more specifically concerned with preventing the pollution of maritime coastal waters. However, its coverage is limited to pollution from petroleum or petroleum products.

5.2.16 Tunisia

A comprehensive water code was introduced in 1975. Water pollution control is dealt with in specific sections as well as in part of the code which contains general provisions on water resources, and also have a bearing on that subject.

The provisions of the code concerning water pollution control include the jurisdiction of discharge or dumping into maritime waters of material of any nature, particularly domestic or industrial wastes, liable to adversely affect public health and marine fauna and flora or to endanger the economic development or the touristic potential of coastal regions. Discharge of waste water is only possible under specified conditions.

The code empowers the Government to issue a decree laying down the provisions governing discharges, dumping, spills, etc., of liquids and materials liable to cause deterioration of the quality of natural waters. The decree is to define the technical specifications and criteria to be satisfied by water courses, lakes, etc.

The discharge of sewage into water courses, the sea, or lakes, according to the code, is contingent upon prior consultation with the services responsible for the conservation of public fresh water, resources and maritime waters concerning the proposed arrangement for treatment of the sewage. Criteria to be met by the effluents would be established by a relevant Order.

Urban environmental sanitation is also dealt with and provision is made so that the ultimate disposal of urban waste water should not contaminate the ground water, water courses, lakes and the coast and become hazardous to the urban population or other possible users.

The following bacteriological standards for bathing waters during the bathing season were laid down under Sanitary Regulations Elb/221/1965 of 1965:

	Grade	Mean	colife	orm	count	per	100	ml
Α.	Safe for bathing		0	-	50			
в.	Acceptable for bathing, with reservations		51	-	500			
с.	Doubtful; not recommended		501	2	1000			
D.	Unsafe for bathing		Over	100	00			

5.2.17 Turkey

The principal current measures are contained in the 1971 Law on Water-derived Resources and in measures for its implementation. A draft law on the prevention of pollution and the inspection of waters is also under consideration. This law will be the first in the Mediterranean area to incorporate the "zero emission" principle. Regulations made under the 1971 Law restrict or prohibit the use of agricultural chemicals, detergents, and other substances harmful to health, fish and environmental quality, define the quality of the discharge and the extent to which it affects that of the receiving water, and also identify a wide range of substances that may not be introduced into waters.

5.2.18 Yugoslavia

A comprehensive series of measures for dealing with marine pollution control is contained in the Basic Law on waters of 1965 and in the 1973 Law on inter-republic and international waters. A Yugoslav Commission for the Protection of the Sea and of Waters used for Domestic Shipping Routes against Pollution was established by an Order of 1969. For toxic materials, the Basic Law distinguishes between "dangerous" and "harmful" substances. The former should not be introduced into waters and the latter can be introduced only after treatment. Authorization is required from the agency responsible for water resources management for the construction of any plant that is to discharge waste water. A licence is granted if provision is made for the construction of waste water treatment facilities. Maritime coastal waters are classified on the basis of parameters such as coliform count, hydrocarbons, visible wastes and colour.

5.3 Countries outside the Mediterranean

5.3.1 United Kingdom

In the United Kingdom, the main holiday areas are in the south and south-west of England, and relatively little bathing takes place on the east coast. Because of the great variability of the results obtained from one sampling period to the next, it is considered impractical to categorize British beaches in bacteriological terms by means of any realistic sampling programme. However, it was emphasized that the United Kingdom in no way condones the discharge of crude untreated wastes into coastal waters. The recent establishment of new water authorities gives sufficient proof of the capability and the intention to deal in a practical and realistic way with the task of conserving and improving the aquatic environment.

5.3.2 USSR

Sanitary protection of coastal waters is governed by the "Regulations for the sanitary protection of coastal sea waters" (1975). The objectives are the prevention and elimination of pollution in coastal sea waters (including the coastline of the open sea, gulfs, and bays) and the creation of satisfactory sanitary conditions for the use of these waters by the public for recreation, health improvement, and for desalination. Priority is given to human health considerations. Water usage is protected, classified and administered by enclosing the area of use within two protective zones. The first of these protects the area of use and must not be less than 10 km wide. The second protects the first and its borders are determined by those of the territorial waters.

As a general rule, the discharge of sewage is prohibited if it is technically possible to eliminate it. Discharge of purified industrial and domestic sewage is prohibited within the limits of the water-use area. If it is necessary to discharge sewage into coastal sea waters, discharge of biologically purified and disinfected sewage within the boundaries of the first sanitary protection zone may be permitted, provided that special requirements and standards are satisfied and that agreement is reached with the agencies of the sanitary and epidemiological service, and with the fishing and other industries likely to be affected.

Microbiologically, <u>E.coli</u> densities in the area of use and the first zone should not exceed 100 per 100 ml and pathogenic microorganisms should be absent.

5.3.3 USA

The United States Environmental Protection Agency (11) uses guidelines based on faecal coliform organisms. They recommend that the geometric mean of not less than five samples collected over a one-month period should not exceed a value of 200 faecal coliforms per 100 ml. In addition, not more than 10% of the samples should have a density greater than 400 faecal coliforms per 100 ml.

6. DATA ON WHICH CRITERIA AND GUIDELINES ARE BASED

During retrospective and prospective studies in the epidemiological investigation of disease etiology two approaches are commonly used. In a retrospective (or case-control) study, individuals who have developed the disease are compared with a group of similar individuals who did not, with respect to exposure to the etiological factor in question (e.g. bathing in the sea). In a prospective (or cohort) study, groups differing only in their exposure to a certain etiological factor are followed up and disease incidence is compared in relation to such exposure. A retrospective study is convenient, especially when the disease incidence is low. Its main difficulty lies in the fact that it is almost impossible to guarantee complete comparability between the cases and the control group and hence to ensure the validity of the conclusions drawn. In addition some of the data relating to the exposure may not be available as data collection was not planned in advance. For this reason, a prospective study is preferred. A prospective study, however, may require the follow-up of a large number of people. This will be both costly and time-consuming, and the results may be biased if there is a high drop-out rate during the course of the followup.

6.1. Prospective epidemiological studies

There have been only two prospective studies directed towards determining the health risks associated with swimming in sewage-polluted waters, namely the United States Public Health Service (USPHS) study conducted in the late 1940s and the early 1950s (15)(USEPA) now in progress (7,8).

The USPHS study consisted, in fact, of studies at three different places in the USA. The first was conducted at two beaches at Chicago on Lake Michigan, the second was a comparison of a beach on the Ohio River at Dayton, Ky., with a nearby recirculating swimming pool, and the third covered two salt-water beaches on Long Island Sound in New York State. The same basic design was used at all three places. In each case, two beaches thought to have substantial differences in water quality were identified from the historical records. Nearby residents were identified, visited in their homes and recruited for the study. Calendars were distributed to the families with instructions on how to record swimming and illness experiences (in terms of symptomatology). Follow-up visits were made during the swimming season, and, at its end, the calendars were collected from the participating families. Water quality measurements and bather load observations were made periodically during the season. In the Ohio River study, a swimming pool was used because a "clean", nearby natural bathing place was not available.

In the Chicago study, the mean coliform levels during the swimming season at the two beaches were not significantly different, nor were the symptom rates. However, significant differences in symptom rates were obtained at one of the beaches when those for three "high" days (based on coliform densities) were compared to those for three "low" days. The mean coliform density during the "high" days was 2300 per 100 ml.

In the Ohio River study, the rate of symptoms of all types was higher for pool swimmers (coliform density <3 per 100 ml) than for those who swam in the river (mean coliform density 2700 per 100 ml). When the illness rates for all groups combined, but specific for age and amount of swimming, were used to calculate the "expected rate" for gastrointestinal symptoms among the river swimmers, the observed rate was significantly more than that expected.

Neither the analysis of the overall data nor of those for "high" compared with "low" days revealed a significant association of coliform densities with symptom rates in the Long Island Sound study.

The author noted that these results should not be taken as conclusive. However, as the only evidence available, they were used as the basis for the federal guidelines used in the USA.

The findings obtained thus far from the USEPA study are as follows: (1) during each of the first two years of the study, the rate of gastrointestinal (GI) symptoms for swimmers was significantly higher than that for nonswimmers at the "barely acceptable" beach but not at the "telatively unpolluted" beach; (2) children were identified as having the highest rate of GI symptoms; (3) over the two years of the study, a good correlation was obtained between the rate of GI symptoms and two microbial indicators; and (4) the two indicators which gave the best correlation with GI symptomatology were E. coli and Enterococci.

6.2 Retrospective epidemiological studies

In a retrospective epidemiological study, all the relevant events (causes and effects) have already occurred when the study is initiated. Fundamentally, it is an investigation of the past histories of affected persons, whether sporadic cases or cases occurring during an outbreak or an epidemic of a disease. The distinction between outbreaks and sporadic cases is a real one in terms of the probability of obtaining an association between a given disease and some suspected cause, e.g. swimming in polluted waters. This is especially true when other routes of transmission account for the large majority of cases of the disease concerned. Thus, during an outbreak suspected of being associated with a single environmental factor (e.g., the recent swimming-associated outbreak of shigellosis on the Mississippi River), the clustering of cases would itself suggest a greater possibility of obtaining a statistically significant association.

The aim is usually to test a specific hypothesis, as, for example, the existence of a relationship between swimming and a certain illness. However, if there is no specific hypothesis, the method is used to investigate the total environmental background of the affected persons. The objective is then to identify those factors more prevalent among them than among those not affected. For example, in investigating an outbreak of a disease in a certain population, a common food or a common experience such as swimming may be examined.

6.2.1 Identification of cases

If the retrospective approach is to be applied, there is a great need for comprehensive data on the diseases concerned to be continuously collected and analysed. This requires a continued watch over the distribution of, and trends in the incidence of the disease through the systematic collection of morbidity and mortality reports and other relevant information. Comprehensive surveillance serves to detect what is happening, and, in the first place to detect outbreaks. The distribution of diseases is liable to continual change due to changes in the behaviour of the agent, environmental circumstances and population. In the various Mediterranean countries, however, the morbidity and mortality reporting systems are largely designed to be of documentary importance rather than significant indicators of current problems. If surveillance data are to be used effectively in setting criteria, provision should be made for well-integrated and comprehensive national surveillance.

6.2.2 Collection of data

Surveillance depends on the collection of information from various sources, and especially from existing records and through interviews. Each of the two main sources mentioned has its merits and weak points. The records, when properly maintained, have the advantage of not being affected by particular beliefs or theories about the causative factors involved in the disease, a fact which limits the possibility of bias.

The interview is the method most commonly used in the investigation of outbreaks. Here the main source of data is the patient's memory or that of his relatives (in the case of children or of persons who have died). The most obvious disadvantage of this source is that, although the human memory may record an event when it occurs, this record is liable to be distorted or not easily recollected depending on the time that has elapsed since the event and the degree of associated trauma. Lapse of time causes faulty recall, and forgetfulness by a respondent is common. Ability to remember depends not only on time but also on subsequent occurrences that have affected the person concerned. Those suffering from illness are expected to remember more than non-sufferers about certain events suspected of being of importance in causation.

6.2.3 Available information

Two retrospective analyses of cases or outbreaks of disease are worth mentioning. In the 1950s Moore and his colleagues (16) examined sporadic cases of poliomyelitis among children along the coast of England and Wales and compared such children with paired controls. Swimming was no more common among the former than among the latter.

On the other hand Rosenberg and his colleagues (8) clearly associated swimming, and more specifically swallowing water, with an outbreak of shigellosis on the Mississippi River below Dubuque, Iowa, USA. There were 49 cases in this outbreak of which 36 required hospitalization. The shigellae isolated from the water had the same antibiotic resistance pattern as those isolated from the cases. The faecal coliform density in the water, as determined after the outbreak had subsided, was 17 500 per 100 ml. It is of interest that the shigellosis rate in Dubuque had been rising steadily from 1970 to 1974 when the outbreak occurred.

6.3 Statistical analysis

Analysis of data from prospective studies involves basically calculation of incidence rates of a specific disease condition among the exposed and the non-exposed. Table 2 shows a typical classification of the subjects according to the disease experience and the exposure to an etiological factor. Table 2

TYPICAL CLASSIFICATION OF SUBJECTS IN A PROSPECTIVE STUDY

Exposure to etiological	Dis	ease	Total
factors	+	-	
+	a	<u>c</u>	<u>a+c</u>
-	b	<u>d</u>	<u>b+d</u>
Total	<u>a+b</u>	<u>c+d</u>	a+b+c+d

The incidence rate in the exposed and the non-exposed is $\underline{a}/(\underline{a+c})$ and $\underline{b}/(\underline{b+d})$, respectively. The magnitude of the risk may be expressed either in terms of attributable risk or in terms of relative risk.

The attributable risk indicates the rate of disease in the exposed group that is attributed to exposure and is obtained by subtracting the rate among the non-exposed from the rate among the exposed - namely,

attributable risk =
$$\frac{a}{a+c} - \frac{b}{b+d}$$

This is based on the assumption that the rate among the non-exposed is a measure of the background illness not associated with exposure. The attributable risk should be used as the response parameter in the analysis of dose-response relationship. The attributable risk also gives an idea of the magnitude of the impact that a successful control programme might have.

The relative risk is computed as the ratio of the incidence rate of the disease among those exposed to the corresponding rate among the non-exposed - namely,

relative risk =
$$\frac{\underline{a}/(\underline{a} + \underline{c})}{\underline{b}/(\underline{b} + \underline{d})}$$

If the incidence rate is small, than \underline{a} is much smaller than \underline{c} and \underline{b} is much smaller than \underline{d} , and hence

relative risk =
$$\frac{a/c}{b/d}$$
 = $\frac{ad}{bc}$

The relative risk expresses more clearly than the attributable risk the strength of association between exposure and the disease involved.

In a retrospective study, those exposed and those not exposed, are not included in the same proportions as occurring in the population. The attributable risk cannot therefore be computed. However, the ratios a/b and c/d in the above formula may be considered as representative of both the diseased population and the control group. For this reason the risk ratio can also be computed from the last formula mentioned above in a retrospective study.

In retrospective studies it is often so arranged that each case is matched with a control individual for various factors such as age, sex and place of residence. A method has been developed by Mantel and Haenszel (17) to compute relative risk for matched case-control studies.

6.4 Predictive mathematical model

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This approach was recently attempted by Mechalas and his colleagues, and their latest paper (18) dealt with practical applications of the model to predict the probability of disease incidence from a given pathogen through ingestion of polluted sea-water at the coast.

The model is based on the assumption that an individual falls ill when the dose of the pathogen ingested has exceeded his threshold tolerance value. The incidence rate among the recreational population at a seaside is thus considered as resulting from the combination of two probabilities, namely: (1) the individual dose-response curve showing the chances of an individual having a particular threshold value; and (2) the probability that an individual will encounter a particular dose of the pathogen. Based on available observations mathematical formulae have been fitted to the two probability distributions, namely the lognormal distribution for the dose-response effects observed in volunteers, and the gamma distribution for the dose of the pathogen encountered. The arithmetic procedure for calculating the combined probability is complex and lengthy, but can be carried out easily with a computer programme.

Once the base-line value for the incidence rate is established representing the "normal" situation, changes in the model can be introduced that reflect altered probability distributions. For example, Dudley et al. (18) mentioned four possible health measures that might be applied in practice, either separately or in combination, and could be simulated by means of the mathematical model:

Option 1: deny use of water to recreationists;

Option 2: treat water to reduce the density of the pathogen to which recreationists will be exposed;

Option 3: immunize recreationists; and

Option 4: examine recreationists prior to use of water.

A numerical simulation was carried out for option 1 by considering the situation in which bathing is to be prohibited when the density of the pathogen in the water exceeds a stipulated limit.

The greatest merit of such a mathematical approach is to link, in a systematic and logical way, the various factors involved so that the relative importance of the impact of each factor can be more easily evaluated. It is, however, difficult to use such a model for precise numerical prediction, e.g., for the determination, in numerical terms, of the specific level of pathogen density which would constitute an unacceptable health risk. In the numerical example given by Dudley et al. (1976), (18) the data available on the distribution of pathogens in a recreational area were particularly meagre; the authors had to apply a factor of 100 to the observed density in water samples in order to obtain a density compatible with the dose-response relationship so that a meaningful incidence level was produced by the mathematical model. The model is useful, however, even with this degree of approximation, in comparing the advantages of different measures, such as the four options listed above.

7. DERIVATION OF STANDARDS FROM CRITERIA

Recreational water quality criteria, as defined here, are a dose-response type of relationship between illness and water quality. Their translation into guidelines requires a decision as to the "acceptable risk" of symptoms of varying degrees of severity, or of specific diseases. This decision is influenced by social, economic, and political as well as health factors. Decisions as to standards and the pollution control programmes necessary to achieve them are essentially political. They should be followed by the choice of the appropriate strategy, based on cost-effectiveness analysis. However, some types of cost-benefit analysis may be instructive and useful in defining the economic inputs. Due attention should be given to identifying all the social benefits, including those difficult to express in monetary terms and not easily quantified, namely the benefits of positive health, well-being, and improved quality of life. In addition, the social consequences of denying the recreational resource to the public must be considered.

While the highest standards are obviously desirable from the point of view both of health and of the quality of life, the resulting cost may represent too heavy an economic burden, particularly for developing countries.

Initially, therefore, less stringent requirements may be both more feasible and economically justifiable, while efforts continue to be made to improve the quality of recreational water and to raise the quality standards.

Discussion of the methods to be used in determining the acceptable risk goes well beyond the scope of this report. However, it is recommended that studies should be initiated on how this is to be done. In the meantime, the useful information that can be obtained requires consideration. At the very least, such information should include the cost of illness, including that of hospitalization, medical treatment, and time away from work or school. With regard to tourism, both individuals who fall ill and controls might be questioned as to the possible effect on their return to the same place the following year.

8. RECOMMENDATIONS FOR LONG- AND SHORT-TERM EPIDEMIOLOGICAL STUDIES

The data base for the development of microbiological criteria for recreational waters can be obtained in three ways, namely from:

- (a) the output from predictive models;
- (b) retrospective epidemiological studies of case reports and disease outbreaks; and
- (c) prospective, controlled, epidemiological-microbiological studies.

8.1 Predictive models

Difficulties with this particular approach are that:

- (a) such calculations would have to be made for each pathogen of interest;
- (b) good, human dose-response data are meagre for most of the pathogens of interest and are completely unavailable for some of the most important; and
- (c) methodology for quantifying these pathogens in environmental waters is generally poor and in some cases totally absent.

This particular approach, therefore, does not appear practical as a means of providing a reliable basis for the establishment of microbiological criteria in numerical terms - in spite of its potential usefulness in terms of long-range objectives.

8.2 Retrospective epidemiological studies of swimming-associated disease

For the reasons discussed in section 6.2 retrospective cohort studies of cases of enteric disease would appear to be unlikely to produce the data base required to develop criteria as defined here. A major factor is that this type of analysis is unlikely to yield a doseresponse relationship. Retrospective epidemiological studies of individual cases or of disease outbreaks, such as the recent swimming-associated outbreak of shigellosis on the Mississippi River, can, however, be used to show a clear association between recreational use of polluted waters and a specific disease entity (8). If indicator densities are available, valuable data can be obtained.

As far as possible, every effort should be made to identify and follow up potential swimming-associated outbreaks of disease in the Mediterranean area. This is particularly applicable to outbreaks associated with waters being monitored as part of a local, national, or other programme.

Whenever possible, local, national, and UNEP water monitoring programmes in the Mediterranean should include measurements of the two organisms, <u>E. coli</u> and Enterococci, which to date have shown the best correlation with health effects coincident with swimming and which will be examined in the epidemiological studies.

8.3 Prospective epidemiological-microbiological studies

A design for a prospective epidemiological-microbiological study is given in Annex I, based on that of the study now being conducted in the USA by the Environmental Protection Agency, already mentioned (5).

An additional design for prospective studies is given in Annex II. This uses children or other groups at summer camps near the sea or tourists on organized tours at the seaside. The advantages of studying such groups are that:

(a) they probably are less immune than the resident population to local disease agents;

(b) each group is relatively homogeneous with regard to socioeconomic status; and

(c) their activities are fairly restricted with regard to the food they eat, the beaches at which they swim and the people with whom they come in contact.

They sometimes have their own medical staff with them.

The disadvantages are that:

- (a) there will be fewer children in hotel-based groups;
- (b) most members of the groups will be swimmers as defined here;
- (c) groups using beaches at different pollution levels will have to be matched; and

(d) the pollution level at any given beach must remain reasonably constant from one day to the next, since it must be assumed that swimming will be a daily occurrence.

Some other advantages and disadvantages of the two designs above may be considered in the context of a number of issues discussed below.

8.3.1 Definition of swimming

Swimming must be defined rigourously as the significant exposure of the upper body orifices to the water. Two study populations are then obtained, both of which are on the beach at the same time and place and come from the same family groups but only one of which is at risk in the sense defined above. Furthermore, since the information to be obtained is to be used in a dose-response type of relationship, the swimming-associated illness rate is the difference between the rate for swimmers and that for the non-swimming controls.

8.3.2 Control beaches

Ideally, it would be desirable to examine illness or symptom rates for swimmers, as compared with non-swimmers, at a number of beaches on a pollution gradient produced by a known source(s) of pollution. This is not always possible. In any event, beach areas should be chosen that differ clearly from each other in terms of the amount of pollution reaching them.

8.3.3 Duration of a trial

Two interrelated factors are considered here, namely the duration of the trial itself and that of the observation period for symptomatology. In the first study in the USA, previously mentioned (15) a calendar approach was used, illness rates for lake or seaside residents over the entire summer being compared for two beaches presumed to have different pollution levels. In the second study in the USA, illness rates were examined among swimmers, as compared with nonswimmers, during short trials conducted at weekends; individuals who had gone swimming mid-week prior to and following the trials were eliminated from the study. The first approach has the obvious advantages of simpler logistics, in terms of the acquisition of illness information, a larger study population, and providing information on diseases having longer incubation periods (greater than 7 days). In fact, this approach could be used to look for a specific association with infectious hepatitis. However, it is unsatisfactory if there is considerable day-to-day variability in the pollution levels at the beaches or if the habits of the bathers are such that they visit a number of beach areas during the trial period (in this case, the entire summer).

The second design avoids the problems of day-to-day fluctuations in pollution levels and the use by swimmers of beaches other than those covered by the trial. It is more amenable to the use of a beach-going but non-swimming control group and reduces the logistic difficulties of microbiological sampling. However, the observation period for symptomatology is limited; it is not amenable to the search for a specific association with illnesses, such as infectious hepatitis, which have a long incubation period; and it restricts the size of the study population, because a large number of individuals may have to be excluded from the study.

Either or both of the above approaches may be tried in a given study. However, it is essential to obtain background information on the habits of the bathers and the constancy of the pollution sources in deciding which approach is best.

8.3.4 Beach activity

Irrespective of which approach is taken, information should be obtained on (a) whether or not the swimmer's head is immersed in the water; (b) the time spent in the water; and (c) where and when the individual went swimming during the trial and in between trials.

8.3.5 Recruitment of participants

Participants should be recruited as family groups. This will simplify the logistics of recruitment and follow-up inquiries, provide a distribution by age and tend to balance the swimming and non-swimming control populations with regard to home location, ethnicity and socioeconomic status. Two additional possibilities warrant discussion. On the assumption that children generally constitute the most susceptible portion of the population, an attempt should be made to locate children or adolescents who come to the beach in organized groups. They should be recruited for the trials for small, separate studies.

Tourists coming from other places within the country or from outside it constitute an excellent study population since it may be assumed that, as already mentioned, they will be more susceptible to infection by those agents being discharged into the water than the resident population. However, those who swim will do so daily; studies with tourists should therefore be conducted only at beaches where pollution levels are reasonably constant from one day to another. The duration of the tourist's stay should be long enough to permit follow-up illness inquiry or they must be queried when they return home. Furthermore since the individuals concerned may be more susceptible to illness acquired via other routes of transmission, it is important to have a non-swimming but beach-going control group of adequate size.

8.3.6 Demographic information

The demographic characteristics of the test and control populations should be reasonably matched. Information should therefore be obtained on age, sex, ethnic origin, country of origin and socioeconomic status. This information will also permit analysis of the illness data by demographic characteristics in order to identify the most susceptible portion of the population.

8.3.7 Examination for water quality indicators

Ideally, there should be no preconceived idea as to which water quality indicators are the best. However, both the large number of possible indicators and logistic considerations make examinations for all of them prohibitively expensive and time consuming. Some screening process is therefore needed. As previously discussed, potential water quality indicators include sewage indicators, faecal indicators, faecal pathogens, whose source is exclusively the faeces of man and other warm-blooded animals, and aquatic pathogens, whose source is the aquatic environment itself (this includes any microorganism that multiplies in that environment irrespective of its original source).

(i) Faecal indicators

Ideally, of the various indicators whose source is consistently and exclusively the faecal wastes of man and other warm-blooded animals, an indicator should be included which exclusively indexes human faecal contamination. Such an indicator is not available at the present time, so that, where possible, consideration should be given to chemical indicators, such as coprostanol.

(ii) Pathogens whose source is exclusively faecal

It would appear that, in general, enumeration of these pathogens will not yield results of sufficient value or data of such quality as to justify the effort involved. However, in those instances where an attempt is to be made to associate water quality with a disease entity such as shigellosis or salmonellosis, or with certain enteric viruses capable of being enumerated, and when the identity of the etiological agent by species and biotype, is confirmed by laboratory examination, it will be useful to count the pathogen itself. However, this should be done only where it is known that significantly large numbers of the particular pathogen are being discharged into the water.

(iii) Aquatic microorganisms pathogenic for man

Several "aquatic" microorganisms have been implicated in cases of recreation-associated waterborne disease, e.g., <u>Pseudomonas aeruginosa</u>, Candidá sp. and <u>Aeromonas hydrophilia</u>. Examinations for all these possible indicators will add to the logistic burden. Some

preliminary examinations should therefore be made, and those pathogens present in the water in significantly large numbers relative to what is known about their infectious dose can be included for enumeration in the study.

8.3.8 Microbiological sampling and assay methods

Samples should be collected at chest height, approximately 4 - 5 cm below the surface of the water. They should be collected at several points along the test beaches and periodically during the period of maximum swimming. The exact number of sampling points and the number of samples to be collected at each point will depend upon such factors as the hourly fluctuations in pollution levels (presumably due to tidal and other factors), the precision of the assay methods being used, the length of the beach, etc. Some preliminary measurements will be required in order to arrive at a satisfactory sampling protocol. As far as possible, colony counting, as opposed to most probable number procedures, should be used in order to increase the precision of the estimates obtained. Certain hydrographic and climatological measurements of the water and the air at the beach may be useful, e.g., temperature, salinity, wind speed and direction, etc.

8.3.9 Other beach-associated routes of transmission

Aerosols generated by surf and polluted sand are possible routes of transmission of infectious agents to people on the beach. Although these routes are probably less effective than swimming, they should be examined epidemiologically and microbiologically. In the studies considered herein, the effect of these other routes is controlled by the use of non-swimming but beach-going controls.

Food, and especially polluted shellfish, is an important route of transmission. This route is also presumably eliminated from consideration by the use of beach-going but non-swimming controls. Nevertheless, inquiries should be made as to food consumption and food habits on the beach, and the consumption of shellfish there and elsewhere.

Transmission of swimming-associated illness to non-swimming individuals within the same family group may be significant. The present design does not make any allowance for this. Where the observation period is short, it may not be significant. An analysis of the onset and duration of symptomatology may provide some insight into this matter.

8.3.10 Follow-up inquiries

Except in those instances where information on specific disease entities is being sought, no assumptions should be made as to which diseases or symptoms are important, in spite of the generally held view that, with faecally polluted waters, gastrointestinal symptoms will predominate. Inquiries should therefore be made concerning a variety of potential symptoms, their day of onset, and their duration. The questionnaire should include several questions aimed at providing information on the "severity" of the symptoms or illnesses. The duration of the observation period has been discussed earlier and will depend on the design of the study. A number of other factors should be considered in the experimental design, as follows: (a) irritations of the skin may be caused by the bites and stings of various marine invertebrates and vertebrates; (b) irritations of the skin and upper respiratory tract may be caused by chemical or biological materials in the water that are not pollution-associated; (c) it is estimated that the reliability of information on symptomatology decreases sharply when the interval between illness and the request for information exceeds 1.5 - 2 weeks; (d) in certain instances, particularly when information on a specific disease entity is being sought, follow-up medical and laboratory examination of individuals who report significant symptoms is desirable and should be provided: (e) experience to date indicates that questionnaires sent by post are not particularly useful;(f) if the participants are recruited on the beach, it should be remembered that the fewer questions asked there the better the chance of recruiting the participants. As a general rule, individuals should be recruited as soon as possible after they leave the beach; (g) it is generally accepted that, if less than 75% of those questioned reply, a sample of the non-responding population will have to be sought, located and questioned in order to determine that no significant bias is involved.

8.3.11 Verification of inquiry information

Verification of some of the information obtained from the participants is essential. This includes the information on bathing activity, socioeconomic status and symptomatology.

(i) <u>Bathing activity</u>. This can be verified early in the pretest period (see Annex I) by having teams observe family groups during a day's activity, then question a representative near the end of the day, and compare the replies with the observations. It was found in the second study in the USA that: (a) information concerning the immersion of the head

in the water was generally accurate; (b) the respondent's perception of the total time spent in the water by himself or his family was not very reliable; and (c) respondents had no idea of the length of time their heads were immersed in the water. A photographic record might perhaps be made.

(11) <u>Socioeconomic status (SES</u>). In the pretest period, several measures of SES should be considered, the best chosen, and the validity of the information checked by some other means.

(iii) <u>Symptomatology</u>. Verification of symptomatology in this type of study is rather difficult. It can be accomplished by sending nurses or medical students to participants' homes when they are visited (passive verification); this has not been effective. Alternatively nurses can be sent to a number of homes on a daily basis since it is impossible to know when symptoms will appear. This is logistically difficult and expensive.

9. ASSOCIATION OR CAUSATION

Sir Austin Bradford Hill, in his 1965 presidential address to the Section of Occupational Medicine of the Royal Society of Medicine cited (19) nine aspects of an association between two variables which should be carefully considered before it is decided that association most probably implies causation. The study design for a prospective epidemiological investigation may be considered with regard to those nine aspects as follows.

9.1 Strength

This is the difference (whether in absolute terms or as a ratio) between the responses of the test and control groups.

It is recognized that, in the field of the health hazards of the recreational use of water, the association is likely to be rather weak because the etiological agents concerned are more frequently transmitted, e.g., by contact and by food, than by the use of polluted waters for such purposes. The strongest association will probably be found with the higher risk groups, namely children, tourists, and individuals whose sanitary conditions and habits are better than those of the resident population. Furthermore, for the pretest and phase II trials (see Annex I) the difference between the pollution levels at the test and control beaches should be made as great as possible, by the use of "barely acceptable" and "relatively unpolluted" beaches, respectively.

9.2 Consistency

This is defined as the repeated observation of the same findings by different persons in different places, under different circumstances and at different times. The obtaining of similar results in quite different ways, e.g., prospectively and retrospectively, would help to demonstrate consistency. For the reasons stated in section 6.2, retrospective epidemiological studies are unlikely to yield a positive correlation between disease and swimming in sewage-polluted waters. An exception would be case-control studies of suspected swimming-associated outbreaks of disease.

As noted earlier, a consistent indicator-illness relationship cannot be expected because of the spatial and temporal variation in tha pathogens discharged in sewage and in the susceptibility of swimmers to them. It therefore becomes important to conduct a number of epidemiological studies both at different times in the same place and at a number of different places by different groups of investigators. Even then, however, the best that can be expected is some "average" relationship.

9.3 Specificity

The case of causality is enhanced if swimming at particular sites is found to be associated with specific types of disease. The need for the non-swimming and unpolluted beach controls is clear from this statement. It would be advantageous if swimming in polluted waters could be clearly associated with a specific disease entity. However, Bradford Hill (19) points out that the importance of this characteristic must not be overemphasized, since several etiological agents could be spread by the same route of transmission. Using milk-borne disease as an example, he notes the harm that would have been done if evidence of specificity had been required before dairies were persuaded to institute the necessary control measures. This situation is completely analogous to that of swimming-associated illness, especially since some of the etiological agents presumed to be operative cannot be quantified.

9.4 Temporality

One aspect of temporality can confuse the experimental design noted above and should be considered in analysing the results. There are indications that, with beaches designated as unsafe for

swimming or among individuals from certain socioeconomic groups, the rates for respiratory symptoms in non-swimmers were higher than those for swimmers. Firstly, it is conceivable that some individuals in the early stages of respiratory illness (i.e., a cold) may have visited the unsafe beach on the assumption that they would benefit from exposure to sunshine at a relatively uncrowded beach, as long as they did not go in the water. Individuals who were not ill, however, might actually go swimming in such waters. Thus the rate for respiratory symptoms could be higher for non-swimmers than for swimmers. Secondly, certain mothers, particularly those in the upper socioeconomic classes, recognizing that their children were in the early stages of respiratory illness, might stop those children from going in the water. Here again, the rate of illness for non-swimmers might exceed that for swimmers. This type of situation might also be found with tourists. This problem can be dealt with by making careful inquiries into the reasons why individuals do not go swimming, and possibly by using "waders" as controls.

9.5 Biological gradient

The experimental design noted above and the definition of a criterion as a dose-response type of relationship clearly satisfy this requirement.

9.6 Plausibility

It is biologically plausible to expect that, at a given place and time, quantifiable relationships should exist between swimming in faecally polluted waters and illness caused by pathogenic microorganisms contained therein. However, the constraints noted earlier on the use of water quality indicators must be considered.

9.7 Coherence

Bradford Hill (19) states that the interpretation of the data should not seriously conflict with the generally known facts of the natural history and biology of the disease.

9.8 Experiment

The studies as described are observational not experimental. However, the use of nonswimmers and "unpolluted" beaches as controls has some of the features of an experimental study.

9.9 Analogy

The analogy between recreational water use and drinking-water consumption would suggest that at some pollution level, an indicator-illness relationship would be expected.

The definition of a criterion as a dose-response type relationship calls for a study to measure disease occurrence against several different levels of microbial water pollution. The study design noted above fulfills this requirement.

10. INTERIM CRITERIA

After examining the available evidence, the Working Group came to the conclusion that there is as yet no basis for recommending changes in the conclusions reached at the WHO Working Group on Guides and Criteria for Recreational Quality of Beaches and Coastal Waters, which met at Bilthoven on 28 October - 1 November 1974 (9) - namely

"Highly satisfactory bathing areas should, however, show <u>E. coli</u> counts of consistently less than 100 per 100 ml and to be considered acceptable, bathing-waters should not give counts consistently greater than 1000 <u>E. coli</u> per 100 ml".

Recreational water criteria are used for several purposes, of which some of the most important are:

- 1. Decisions as to the acceptability of existing beaches
- 2. Decisions on permits for the establishment of new recreational facilities and beaches
- 3. Design criteria for treatment and disposal systems for liquid wastes.

The Working Group felt that, while it may be justified to use the more lenient criterion of 1000 <u>E. coli</u> per 100 ml for the quality control of recreational waters at existing facilities, new facilities should be designed to ensure a higher recreational water quality.

Decisions on criteria for the design of treatment and disposal systems for liquid wastes, involving large investments and having long-term implications for water quality, should be based as far as possible, on the stricter criterion of 100 $\underline{\text{B}}$. coli per 100 ml.

The Working Group felt that the numerical criteria should be more closely defined statistically and recommended that the criterion of 1000 <u>E. coli</u> per 100 ml should be defined as follows: No more than 10 per cent of at least ten consecutive samples collected during the bathing season should exceed 1000 <u>E. coli</u> per 100 ml.

11. FURTHER RECOMMENDATIONS

It is recommended that:

(1) a number of studies, in addition to the two in progress or planned, be initiated and especially one or two in the western Mediterranean area;

(2) the protocols as given in Annexes I and II be used in these studies;

(3) in addition to the need for a programme to provide health effects data on the consumption of shellfish, microbial indicators, such as viruses, in shellfish should be examined as potentially sensitive indicator systems;

(4) in the interim period before the results from these studies become available (about 3 - 4 years), the "acceptability criteria" as given in section 10 should be adopted; and

(5) an Epidemiological-Microbiological Review Committee of experts should be convened annually to review the progress of these studies.

1.

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ANNEX I

GUIDELINES FOR THE CONDUCT OF "WEEK-END TYPE" EPIDEMIOLOGICAL-MICROBIOLOGICAL STUDIES FOR DEVELOPING RECREATIONAL WATER QUALITY CRITERIA

The following model is intended as a guide in the design and conduct of prospective, controlled epidemiological-microbiological studies whose objective is the development of health effects recreational water quality criteria. The desired criteria are quantitative relationships of the dose-response type between untoward health effects attributable to the recreational use of water, e.g., swimming, and the water quality as measured by some microbiological, chemical or physical indicator of its pollution (usually by municipal sewage wastes).

It is assumed that a situation exists in which hydrographic, pollution and beach-usage conditions complicate the epidemiological design, that there is marked day-to-day variability in pollution levels at the beaches, and that swimmers visit different beaches on different days during a given 1 - 2 week period. This design is based on the one used by the United States Environmental Protection Agency (5, 6). A second design in which the conditions noted above are not assumed and which is directed at special study groups (tourists and campers) is given in Annex II.

1. Features of the study design

(1) Swimming is defined as the significant exposure of the head to water.

(2) Participants for the study are recruited at the beach, preferably as family groups. In addition, whenever possible, groups on organized outings should be identified and recruited as substudy groups.

(3) Studies are conducted at "week-ends".

(4) During phases I and II¹, trials are conducted simultaneously at at least two beaches, one 'barely acceptable' (i.e., with the lowest water quality at which swimming is not prohibited and the other "relatively unpolluted" i.e., with the highest water quality at which the demographic composition of the population is similar to that at the "barely acceptable" beach).

- (5) As a consequence of items 1 4 above:
 - (a) There are four study populations, namely swimmers and non-swimmers at two beaches.

(b) The data collected can be analysed for the entire swimming season or segregated and examined by trial (week-end).

(c) Taken as a whole, the non-swimming controls belong to the same groups as the swimmers. Since all the participants have been at the beach, a swimming-associated symptom rate can be obtained by subtracting the rate for non-swimmers from that for swimmers.

(d) Illness information is obtained, some 7 - 10 days after a week-end trial, in the form of symptomatology, and relating to symptoms which develop in the week following the exposure.

(e) At the very least, the water should be examined for $\underline{E. \ coli}$ and enterococci by membrane filter procedures.

2. Phasing

The study should be conducted in three phases: phase I - pretest; phase II - comparison of a barely acceptable with a relatively unpolluted beach; and phase III - examination of beaches along a pollution gradient.

The phasing of the study is described below.

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2.1 Phase I: Pretest

2.1.1 Objectives

The objectives of the pretest are:

(a) To determine the suitability of tentatively selected beaches as regards population density, demographic distribution, family groupings, rate of mid-week swimming, numbers of swimmers as compared with non-swimmers, and pollution levels at the beaches.

(b) To test the epidemiological techniques as regards cooperation at the beach interview, the availability of home telephones (questionnaires sent by post have been found to be of little use), and the return rate on follow-up interviews.

(c) To obtain an estimate of the background (non-swimmer) illness rate (needed in estimating the sample size for the phase II and III trials).

(d) To test the reliability of the information to be obtained on beach activity.

(e) To test the microbiological methodology and refine the sampling schedule. Several beaches tentatively identified as "barely acceptable" and "relatively unpolluted" should be examined.

2.1.2 Tentative selection of beaches

Available information on pollution levels, beach usage, bathing habits and demography should be used in selecting the beaches to be examined for suitability during phase I (Pretest). Within-day and between-day variations in E. coli and Enterococcus densities should be examined.

2.1.3 Reliability of beach activity information

Just prior to the pretest trials, the reliability of the information to be obtained on beach activity should be tested, as follows. Teams of observers should go to the beaches. Each observer should focus on a single family group, noting which members enter the water, which immerse their heads in it, if possible, which swallow water, and the type and duration of activity in the water. At the end of the day, he should ask an adult member of the family to describe the activity of each member. Comparison of answers and observations should make it possible to estimate the reliability of the information to be obtained in the actual trials.

2.1.4 Sample size

A total of about 600 usable responses at each beach (about 125 families) should be obtained over 2 - 3 week-ends. A usable response is defined as the information obtained from a respondent who was not a mid-week swimmer and from whom follow-up information was obtained. Obviously, records should be kept of the numbers of people whose responses were not usable and why those responses were rejected.

2.2 Phase II: Comparison of a "barely acceptable" with a "relatively unpolluted" beach

2.2.1 Sample size

This may be as large as 8 000 - 12 000 participants distributed between the four study populations. The exact number required should be determined from the analysis of the pretest data, and depends on: (1) the expected background (non-swimmer) illness rate; and (2) the magnitude of the excess incidence among swimmers as compared with non-swimmers which, if it exists, should be detected by the study. The Table provides a guide in determining the minimum number of persons to be included in the study for each of the swimmer and non-swimmer groups on each beach.

Incidence among	Excess incidenc	e among swimmers	to be detected		
non-swimmers (%)	30%	50%	100%		
1	21 100	8 500	2 600		
2	10 700	4 200	1 300		
3	7 100	2 800	850		
4	5 300	2 100	600		
5	4 200	1 600	500		
10	2 000	750	250		
	1	La Tradita de V	1		

Minimum sample size for each of swimmer and non-swimmer groups on each beach.

Note: Based on $\alpha = 5\%$ (probability of type-one error) and $\beta = 10\%$ (probability of type-two error).

For example, if the expected background illness rate is 5% and if an excess incidence of 30% or more (i.e., an incidence rate of 6.5% or higher) among swimmers is to be detected, at least 4 200 swimmers and 4 200 non-swimmers should be studied on the beach.

2.3 Phase III: Examination of beaches along a pollution gradient

The objective of this phase of the study is to produce the data which, with those available from phases I and II, will define the indicator-illness ratios (criteria). Ideally, the trials should be conducted at beaches situated along a pollution gradient produced by a single pollution source or cluster of sources. Often this is not possible, but two alternative procedures are then available: (1) trials can be conducted at a number of beaches whose pollution levels, as measured by the water quality indicators, fall on a gradient but which have different sources of pollution; or (2) trials (at week-ends) can be conducted at a beach which shows considerable day-to-day variability in the indicator density. The trials can then be analysed by regression analysis, in which each trial provides a point on the expected indicator-illness regression line.

3. Protocol

3.1 Recruitment and information to be collected

Beach interview participants should be recruited as family groups about the time they are preparing to leave the beach. Contact should be established with an adult member of the family. The interviewer should introduce him/herself, present his/her identification, explain the purpose of the study and request the participation of the subject family in the study. The interviewer should then ask the subject if he/she or any member of the family has been swimming mid-week just prior to the trial. If the answer is yes, that individual should be rejected from the study. If this is true of most of the children in the family group, the family should be excluded and the interview terminated. The interviewer should then obtain the following information:

(a) Name, address (local and permanent), telephone number, relationship of respondent to other members of the group (all of whose telephone numbers and addresses should be obtained).

(b) Demographic and swimming activity information on each member of the group; head wet; when in water; total time in water; whether water was swallowed; relevant health information; why non-swimmers are not swimming.

(c) The interviewer should observe the bathing suit and hair of each member of the group to see whether they are wet.

3.2 Sampling and assay

As this is a general protocol, it will have to be modified, depending on local conditions (hydrography, climatology, beach usage, etc.). As far as possible, the sampling and analytical

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procedures described at the Copenhagen (1975) and Rovinj (20) meetings should be followed. However, because of the special nature of this study, the following should be carried out instead of, or in addition to those procedures:

(1) Samples should be collected at 2 - 4 sites where the population is densest and at 100 - 300 m intervals on each site.

(2) Samples should be collected every two hours from about 10 - 11 a.m. to 4 - 5 p.m.

(3) Samples should be cooled with ice and returned to the laboratory for assay within six hours.

(4) As far as possible, membrane filter methods should be used.

(5) The required indicators for this study are <u>E. coli</u> and enterococci. Other water quality indicators may be included, depending on local conditions and logistic considerations.

(6) It is recommended that, for <u>E. coli</u> and enterococci, the mTEC (21) and mE (22) methods be used.

(7) Measurements should be made of water temperature, pH, salinity and turbidity, and possibly of certain nutrients, such as total soluble carbon and nitrogen. Surf activity should be noted; air temperature, speed and direction should be measured.

(8) The information from a sanitary survey, including the location of outfalls, and the required hydrographic information should be available.

3.3 Reminder letter

A letter should be sent as soon as possible after the trial, and preferably on the following day, to remind those recruited at the beach that: (i) they are participants; (ii) they should watch for symptoms; and (iii) if they are ill, they should contact a physician whose telephone number is provided.

3.4 Follow-up questionnaire

The follow-up inquiry should be conducted by telephone or personal interview some 7 - 10 days after the week-end trial (questionnaires sent by post are generally unproductive). If the proportion of participants with telephones is less than 50%, telephone questionnaires should be abandoned. If the return on the follow-up inquiry is less than 75%, a sample of the appropriate population will have to be located and questioned. The information to be obtained is as follows:

(1) Whether participants went swimming mid-week following a week-end trial (those who did so should be excluded from the study).

(2) Additional demographic information (particularly on socioeconomic status).

(3) Symptomatology. This information should be obtained by questions on symptoms subsequent to the trial, and on symptoms or illness in the week prior to the trial, and questions designed to indicate the severity of the illness, i.e., whether the participant was hospitalized, visited a physician, received medication, remained home from school or work, or stayed in bed. The symptoms covered should include the following:

Gastrointestinal

vomiting diarrhoea stomach ache) colic nausea) colic

Respiratory

sore throat bad cough running nose pain in chest

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General

skin lesions (rash) sunburn red or runny eyes earache or discharge fever (more than 38°C) headache (severe, several days)

AMEA II

GUIDELINES FOR CONDUCT OF STUDY ON ORGANIZED VACATION GROUPS

1. These guidelines have been prepared for the conduct of longitudinal, prospective, epidemiological studies with organized groups of tourists who visit the Mediterranean area from northern Europe and with organized groups at children's summer camps. In so far as possible, such studies should be carried out following the principals of controlled field trials (23) in which the rates of beach water associated illnesses among swimmers are compared to those for non-swimmers at beaches having different levels of water quality.

These guidelines should be considered in the light of the principles stated in Annex I with the following exceptions.

1.1 Duration of the trial

The duration of the trial should extend through the vacation period of the organized group. The duration of the follow-up observation period should include an additional four weeks at the home location for the organized group.

1.2 Diseases to be studied

Although illness information will be obtained in the form of the symptomatology (e.g., gastroenteritis), whenever possible efforts should be made to confirm the diagnosis and the etiology of the disease by microbiological and/or serological tests.

1.3 Test beaches and study populations

The groups to be studied should be carefully selected and defined as ones which travel, arrive and leave a hotel or camp together. In addition, the logistics of follow-up inquiries will be enhanced if the group arrives from and returns to the same city. The groups should be located at well defined and confined areas (hotels, camps) and, preferably, should use a single private or public beach.

The source of pollution is important; the number of individuals who contribute to this source should be in excess of 1000. It is preferable that the sewage comes from raw or treated wastes of local inhabitants rather than from the tourists themselves.

Ideally, the population involved should be relatively homogeneous and they should be under the medical supervision of a single practitioner or health centre.

1.4 Other routes of transmission

The study design and information obtained therewith must include the means to rule out exposure to contaminated food and/or beverages as the vehicle of transmission.

1.5 Control populations

These will consist of (a) non-swimmers among the study population (they may not be large in number) and (b) swimmers and non-swimmers of comparable demography at another beach of different (preferably a high) water quality.

1.6 Constraints

The major constraints on the use of this experimental design is that, during the stay of the group being studied, the quality of the water should be relatively constant and the individuals should not visit other beaches whose quality is significantly different from the one being used for the study.

ANNEX III

AGENDA

- 1. Introduction (Dr V.J. Cabelli)
- Assessment and comparison of the various criteria, guidelines and standards for the quality of coastal waters:
 - (a) in countries along the northern shore of the Mediterranean and in western Europe (Dr Meropi Violaki-Paraskeva);
 - (b) in countries along the southern shore of the Mediterranean and in the western hemisphere (Professor H. Shuval);
 - (c) in eastern Europe and Asia (Dr E.A. Možaev)
- Review of potential health effects, water quality indicators (including pathogens), as they can be used in epidemiological investigations:
 - (a) bacteria and mycotic agents (Professor J. Brisou);
 - (b) viruses, bacteriophage, chemicals (Professor M. Balducci)
- 4. Review of epidemiological evidence and other data on which criteria, guidelines and standards are based:
 - (a) retrospective epidemiological analysis and analysis of outbreaks (Prof M.H. Wahdan);
 - (b) prospective epidemiological analysis (Professor M.H. Wahdan);
 - (c) predictive models and biostatistics (Mr K. Uemura)
- 5. Cost-benefit analysis as used in determining "acceptable risk" (Dr B. Cvjetanović)
- Development of methodology and recommendations for long and short-term epidemiological studies (Dr V.J. Cabelli)
- 7. Feasibility of developing interim criteria pending the implementation of the above research, including ongoing and proposed studies on the Mediterranean

ANNEX IV

LIST OF PARTICIPANTS

TEMPORARY ADVISERS (Experts)

Professor M. Balducci Institute of Health, Rome, Italy

Professor J. Brisou Toulon, France

Dr V.J. Cabelli (Rapporteur) Health Effects Research Laboratory, Environmental Protection Agency, West Kingston, Rhode Island, USA

Dr B. Moore*

Public Health Laboratory, Heavitree, Exeter, UK

Dr E.A. Možaev Sysin's Institute, Moscow, USSR

Professor H.I. Shuval Environmental Health Laboratory, Hadassah Medical School, Jerusalem, Israel

Dr Meropi Violaki-Paraskeva (Chairman) Ministry of Social Services, Athens, Greece

Professor M.H. Wahdan (Vice-Chairman) Institute of Public Health, Alexandria, Egypt

REPRESENTATIVES OF OTHER ORGANIZATIONS

Mr H. Kamberg United Nations Development Programme, Athens, Greece

OBSERVERS

Mr G. Markantonatos Ministry of Social Services, Athens, Greece

Professor J. Papadakis School of Public Health, Athens, Greece

Professor J. Papavasiliou University of Athens, Greece

Ms S. Sotirakopoulou UNDP/WHO Project Office, Athens, Greece

Professor D. Trichopoulos University of Athens, Greece

Dr M. Zafiropoulos UNDP/WHO Project Office, Athens, Greece

WORLD HEALTH ORGANIZATION

Regional Office for Europe

Dr A. Gilad (Secretary) Project Manager, UNDP/WHO Project, Athens

Mr G. Ponghis Consultant, Promotion of Environmental Health

* Unable to attend.

Regional Office for Europe (continued)

- Dr M.R. Radovanovic Regional Officer for Communicable Diseases
- Dr A.H. Wahba Regional Officer for Biology, Pharmacology and Toxicology

Regional Office for Eastern Mediterranean

Dr R.W. Jones Consultant, Regional Adviser, Environmental Health

Headquarters

- Dr B. Cvjetanovic Chief, Bacterial and Venerial Infections
- Mr K. Uemura Director, Division of Health Statistics

Coordinated Mediterranean Pollution Monitoring and Research Programme

HEALTH CRITERIA AND EPIDEMIOLOGICAL STUDIES RELATED TO COASTAL WATER POLLUTION

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Report of a Group of Experts jointly convened by WHO and UNEP

Athe.s, 1-4 March 1977

CORRIGENDUM

Section 5.2.6, page 10, "Greece"

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At the end of this section should be added the last two paragraphs appearing under section 5.2.16 "Tunisia" (pages 11 and 12) (on bacteriological standards for bathing waters).

Section 5.2.16, page 11, "Tunicia"

The last two paragraphs of this section (pages 11 and 12) should be deleted.