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Health Effects Criteria for Marine Recreational Waters

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HEALTH EFFECTS CRITERIA FOR MARINE RECREATIONAL WATERS

by

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FOREWARD

The many benefits of our modern, developing, industrial society are accompanied by certain hazards. Careful assessment of the relative risk of existing and new man-made environmental hazards is necessary for the establishment of sound regulatory policy. These regulations serve to enhance the quality of our environment in order to promote the pubic health and welfare and the productive capacity of our Nation's population.

The complexities of environmental problems originate in the deep interdependent relationships between the various physical and biological segments of man's natural and social world. Solutions to these environmental problems require an integrated program of research and development using input from a number of disciplines. The Health Effects Research Laboratory, Research Triangle Park, NC and Cincinnati, OH conducts a coordinated environmental health research program in toxicology, epidemiology and clinical studies using human volunteer subjects. Wide ranges of pollutants known or suspected to cause health problems are studied. The research focuses on air pollutants, water pollutants, toxic substances, hazardous wastes, pesticides and nonionizing radiation. The laboratory participates in the development and revision of air and water quality criteria and health assessment documents on pollutants for which regulatory actions are being considered. Direct support to the regulatory function of the Agency is provided in the form of expert testimony and preparation of affidavits as well as expert advice to the Administrator to assure the adequacy of environmental regulatory decisions involving the protection of the health and welfare of all U.S. inhabitants.

This report provides an assessment of the relationship between microbiological indicators of water quality and illness that may have resulted from swimming. The data base resulted from a series of in-house and extramural epidemiological-microbiological research projects designed to develop the criterion for marine waters. The development and periodic reevaluation of such criteria is mandated by Section 304(a)l of Public Law 92-500: Federal Water Pollution Control Act Amendments of 1972; Clean Water Act of 1977.

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PREFACE

Shortly after they were published by the National Technical Advisory Committee to the Federal Water Pollution Control Administration in 1968, the microbiological guidelines for direct contact recreational waters were attacked as being too restrictive. The basis for the attack was the meager and questionable epidemiological data from which they were derived, limitations of the microbial indicator of water quality (fecal coliforms) to be used, and defects in the methodology available for monitoring environmental waters for its presence. It was noted that these guidelines were recommended in the face of seemingly conflicting epidemiological findings from the studies conducted by Stevenson and Moore and a very limited number of outbreaks of infectious disease clearly shown to be associated with swimming in sewage polluted waters.

Early in 1969, it was suggested to the author of this report that he "look into the matter." During 1969 and early 1970, he and his colleagues developed a design for a prospective epidemiological-microbiological study differing from that used by Stevenson in a number of essential ways. A decision was made to look first at saltwater and later at freshwater beaches, and some beaches in New York City were identified for the conduct of a study.

The project was established in 1972 with a target date for completion in 1978-79. Studies were to be conducted at beaches in a number of locations in addition to New York City. The objective of the program was to produce criteria, defined as a mathematical relationship of some untoward effect from swimming in sewage polluted water to the quality of that water as measured by any of a number of potential microbial or chemical indicators; thus, they were to be amenable to risk analysis. The objective was achieved, and this report documents the output from that effort.

In addition, methods were developed and published for a rather large number of potential water quality indicators, and information and methodology were generated and published relative to several other problems in human infectious disease potentially or actually resultant from pollution of marine and fresh recreational waters. Included are the discharge of *Klebsiella* in industrial effluents, the relationship of *Aeromonas hydrophila*, *Acinetobacter* sp., *Pseudomonas aeruginosa*, and *Vibrio parahaemolyticus* densities to nutrient enrichment of aquatic environments, the potential for individuals to become colonized by multiantibiotic resistant coliforms via their activities in sewage polluted waters, the effect of environmental parameters on the survival of human pathogens and indicator microorganisms in marine and fresh waters, transfer frequencies for multiple antibiotic resistance into fecal isolates of *E. coli*, the characterization of a highly chlorine resistant, male specific coliphage from sewage, and the microbial colonization of the external ear canal.

ABSTRACT

This report presents health effects quality criteria for marine recreational waters and a recommendation for a specific criterion among those developed. It is the mathematical relationship of the swimming-associated rate of gastrointestinal symptoms among bathers to the quality of the water as determined by the density of a fecal indicator, enterococci. Thus, it can be used to provide guidelines based upon acceptable rather than detectable risk and is consistent with risk analysis.

The criteria were developed using data collected from an extensive in-house extramural, microbiological-epidemiological research program conducted by the U.S. Environmental Protection Agency over the years 1972-1979. Central to this program was the conduct of prospective epidemiological-microbiological studies using a design developed at the Marine Field Station of the Health Effects Research Laboratory. These multi-year studies were conducted at beaches at three locations in the United States (New York City, NY; Lake Pontchartrain, New Orleans, LA; and Boston Harbor, MA). An additional study was conducted in Alexandria, Egypt; however, for the reasons given, only the United States data were used in the development of the criteria.

The two input parameters to the recommended model (criterion), the type of symptomatology and the specific water quality indicator, were determined from the analysis of data with a design which considered a number of symptom types and potential indicators. In addition, swimming was carefully defined as the exposure of the head to the water, the non-swimming controls were at the beach, and the trials were conducted over relatively short periods of time (1-2 days).

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FIGURES

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ACKNOWLEDGMENTS

The author gratefully acknowledges the contributions of many individuals who took part in the overall program, especially those of his colleagues, Drs. Alfred P. Dufour and Morris A. Levin of the Marine Field Station, HERL-Cincinnati, who worked with him on the in-house portion of the program. Also included are: Mr. Paul Haberrnan of the Center of Policy Research for his work on the New York City study (R802240, R803254); Drs. K. E. Hakim, M.K. Wahdan, A. El Molla and M: Hussein of the High Institute of Public Health, Alexandria University for their work on the Alexandria study (PM8O 3-542-3); Mrs. Virginia K. Ktsanes, Dr. John E. Diem and Dr. Anne A. Anderson of Tulane University for their work on the Lake Pontchartrain study (R805341), and Dr. David W. Drummond of Tufts University for his work on the Boston study (R806178).

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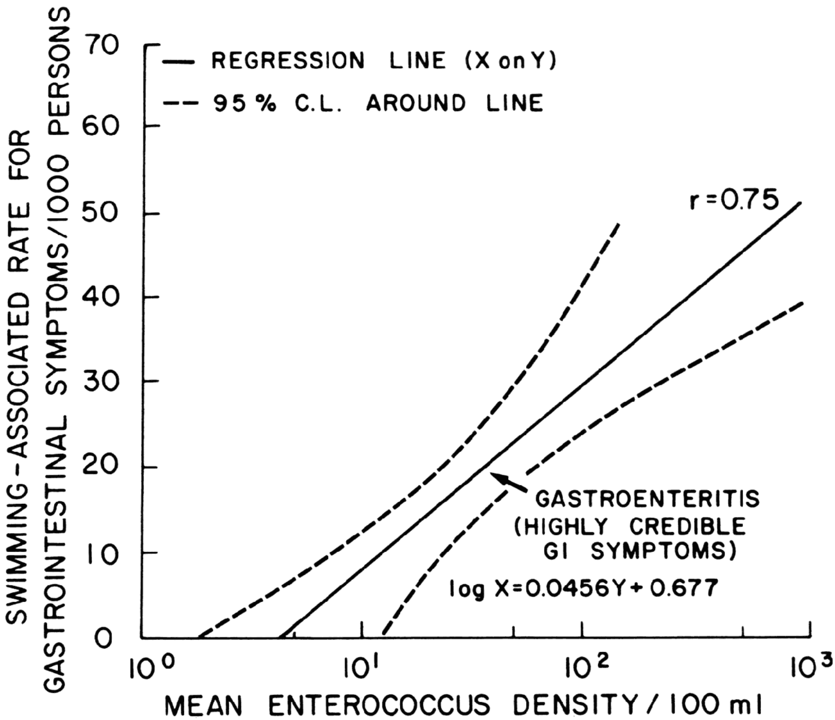
SECTION 1
INTRODUCTION

Existing health effects, water quality guidelines (often referred to as criteria) and standards for primary contact recreational waters, as recommended or promulgated by federal, state and local agencies, are generally stated as upper limits for fecal indicator densities. The current EPA guideline's state that, "Based on a minimum of five samples taken over a 30-day period, the fecal coliform bacterial level should not exceed a log mean of 200/100 ml, nor shall more than ten percent of the total samples taken during a 30-day period exceed 400/100 ml." Without exception, these guidelines suffer from two major deficiencies. The first is the paucity of epidemiological data which support some of them and the absence of any such support for others. At best, they relate to a "detectable risk" of infectious disease; at worst, they are based solely upon "attainment." The second, a consequence of the first, is that officials responsible for making decisions are given a "number," and this inherently limits the options available in decision making to compliance or noncompliance.

With the availability of a sufficient epidemiological base, a second option is available. In general terms, it is the promulgation of a criterion as defined herein; that is, a mathematically expressible relationship (model) of untoward effects among "users" to the quality of the water used. With reference to recreational waters, it is the relationship of the incidence or risk of disease among swimmers to the quality of the water as measured by the density of the infectious agent itself or an appropriate indicator. As shown herein, the major pollution-associated risk to recreationists is that of infectious disease consequent to swimming in waters polluted with human and, to a much lesser extent, lower animal fecal wastes. Therefore, the criterion relates infectious disease among "swimmers" to some measure of fecal pollution of the water. This approach then permits a decision as to "acceptable risk" based upon social, economic, medical, public health, and even political considerations (some form of cost-benefit or cost-effectiveness analysis). The acceptable risk of illness or its incidence can then be extrapolated from the criterion to yield a water quality limit (guideline), and the guideline can then be fixed in law to provide a standard.

This report presents such a criterion for marine recreational water quality, documents its epidemiological base, and discusses its applications and limitations. The recommended criterion shown in the figure below is the mathematical relationship (X on Y regression line) of the quality of the bathing water (X), as measured by the density of a specific fecal indicator (enterococci), to the incidence of swimming-associated gastroenteritis ("highly credible," gastrointestinal symptoms, Y). It is a deterministic model empirically derived from epidemiological and microbiological data obtained at multiple locations over several years. The deterministic form appears to lend itself more to cost-benefit types of analyses. The two input parameters to the model were not chosen arbitrarily. Rather, they were the output from an experimental design formulated to respond to the questions: Which are the "important" types of illnesses, and which is the "best indicator? This is detailed in the body of the report.

This criterion is directed against potential human health effects consequent to the pollution of marine recreational waters with human fecal wastes, notably municipal sewage. It is a generalization which may not always hold true. Nevertheless, the fact that it has been found to be applicable at several locations has some implications concerning the ecology of the etiological agent(s) and the nature of the infectious process,



Recommended health effects criterion for marine recreation waters.

notably, the ubiquity of the agent in feces, sewage, and its receiving water. A similar criterion for freshwaters will probably be required, and the establishment of this criterion does not preclude the possible' need for others, i.e... against the proliferation of aquatic organisms pathogenic for man (e.g.,*Aeromonas hydrophila*; *Vibrio parahaemolyticus*) which respond to nutrient loading of the water.

The criterion may be used to develop guidelines for sewage treatment and outfall location. Knowledge of the transport and fate of both pathogens and indicator bacteria would provide a refinement for translating these target area criteria into effluent guidelines. It is hoped that the criteria will not be used to close swimming areas but rather to expand the available recreational resource.

Finally, when the study design for the EPA program was being developed in 1969-1970, it was thought that swimming in sewage-polluted waters would constitute a relatively minor route of transmission for gastrointestinal illness and that relatively high levels of pollution (as indexed by microbial indicator densities) would be required before gastrointestinal illness could be detected. These assumptions were made on the basis of existing notions and available information. Both these assumptions were incorrect. If the nonswimming rates for gastrointestinal symptomatology can be considered as those for the population at large, then it must be concluded that swimming in sewage-polluted waters constitutes a significant route of transmission for the illnesses obtained, at least for individuals of "swimming age."

SECTION 2
RECOMMENDATIONS

1. The health effects criterion for marine recreational waters presented herein should be considered for use by EPA since it is a relatively reliable generalization which is amenable to risk analysis, allows a wider choice of options at both the federal and local levels, and can be defended on the basis of epidemiological data.

2. A cost-benefit or cost-effectiveness type model should be developed for determining the acceptable risk or incidence of illness with regard to general and local factors.

3. Work should be continued toward the development of similar criteria for fresh recreational waters.

4. An intensive prograrn should be initiated towards establishing the etiology of the gastroenteritis observed in these studies and developing methods for quantifying the agent(s) in environmental waters. This should be followed by a program to compare the biological decay of the agent(s) to its indicators under conditions best simulating those in open water.

5. The most resource responsible use of these criteria is their translation into effluent guidelines governing the design of sewage treatment facilities, the location of their outfalls and the decisions to be made relative to the degree of treatment and disinfection required. This and the preceding recommendation require the reinitiation of the program towards the development of realistic and facile methods for obtaining decay coefficients for indicators and pathogens on a case-by-case basis.

6. Nonspecific gastroenteritis is the major cause of outbreaks of disease from drinking water and shellfish consumption. The criteria suggest that there are measurable health effects associated with enterococcus or *E. coli* water densities as low as 10/100 ml via a route in which only 10-50 ml of water is ingested. Therefore, prospective epidemiological studies should be conducted as part of the reevaluation of existing standards for drinking water and shellfish-growing areas mandated by Sections 104(n)(l), 304 (a)(1) and 403(c)(l) of Public Law 92-500.

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SECTION 3
BACKGROUND

Historically, the development of health effects, water quality guidelines and standards for recreational waters has followed a pattern characteristic of many such efforts to control pollution-associated health and ecological effects. The first step is the development of guidelines and standards dictated largely by *attainment* with the best available control technology. These are usually based upon limited epidemiological and ecological evidence and little, if any, data quantifying the risk in relation to the level of the pollutant in the environment. The second stage is the modification of these guidelines and standards on the basis of *detectable* risk using a limited quantity of data relating untoward effects to the environmental level of the pollutant. The last step in the process, the development of guidelines based upon *acceptable* risk, requires an epidemiological or ecological data base broad enough to mathematically model the relationship of some measure of water quality to the risk, degree or rate of untoward effects. With reference to health effects, water quality guidelines and standards for recreational waters, we have progressed through the second stage. This report will describe and substantiate criteria from which guidelines and standards based upon acceptable risk can be derived by risk analysis. Sewerage systems for the disposal of domestic wastes from urban areas into nearby fresh and marine waters have been in existence in the United States since the turn of the century. By that time, it was clearly established that agents of enteric disease are excreted in large numbers in the feces of ill individuals and, hence, are potentially present in sewage and its receiving waters. A swiruming-associated outbreak of typhoid fever was reported in 1921(1). Yet, it was not until 1951 that Scott (2) proposed microbial guidelines for the quality of recreational waters; these were based solely upon attainment. It was 1968 (3) before guidelines related to detectable risks were recommended by the National Technical Advisory Committee (NTAC.) to the Federal Water Pollution Control Administration (FWPCA). Criteria permitting the development of guidelines based upon acceptable risks are now available a decade later.

EXISTING GUIDELINES AND STANDARDS

As of 1972, the two guidelines or standards most commonly used by the various states and territories in the United States were a total coliform value of 1000/100 ml of water and a fecal coliform limit of 200/100 ml. The former appears to have developed from two sources, the anticipated risk of salmonellosis as obtained from calculations made by Streeter (4) on the incidence of *Salmonella* species in bathing waters and attainability as determined by Scott (2) from surveys conducted of Connecticut bathing waters. The Joint Committee of the American Public Health Association and the State Sanitary Engineers (5) adopted the Connecticut standard as did many of the state agencies. The fecal coliform limits will be considered in more detail since, as can be seen from Table Al†, it is the most prevalent one used by the various states and it is the guideline currently recommended by the EPA (6). This guideline will be considered in terms of the data base which supports it, how it was derived, and the indicator system used.

The microbial guideline for primary contact recreational waters recommended by the

†When a table number is preceded by "A," the table is to be found in the Appendix.

EPA and adopted by most of the states (Table Al) is essentially that recommended by NTAC in 1968. Their recommendation was as follows:

> Fecal coliforms should be used as the indicator organism for evaluating the microbiological suitability of recreational waters. As determined by multiple-tube fermentation or membrane filter procedures and based on a minimum of not less than five samples taken over not more than a 30-day period, the fecal coliform content of primary contact recreational waters shall not exceed a log mean of 200/100 ml, nor shall more than 10 percent of total samples during any 30-day period exceed 400/100 ml.

Their rationale for specific limits was as follows:

> The studies at the Great Lakes (Mich.) and the Inland River (Ohio) showed an epidemiologically detectable health effect at levels of 2,300-2,400 coliforms per 100 ml. Later work on the stretch of the Ohio River where the study had been conducted indicated that the fecal coliforms represented. 18 percent of the total coliforms. This would indicate that *detectable** health effects may occur at a fecal coliform level of about 400/100 ml; a factor of safety would indicate that the water quality should be better than that which would cause a health effect. . . .The Santee project correlated the prevalence of virus with fecal coliform concentrations following sewage treatment. Virus levels following secondary treatment can be expected to be 1 Plaque-Forming-Unit (PFU) per milliliter with a ratio of 1 virus particle per 10,000 fecal coliforms. A bathing water with 400 fecal coliforms per 100 ml could be expected to have 0.02 virus particles per 100 ml (1 virus particle per 5,000 ml).

The committee pointed out that the Public Health Service's three epidemiological studies on bathing water quality and health were the only base available for setting criteria, that these studies were far from definitive, and that they were conducted before the acceptance of the fecal coliform as a more realistic measure of a health hazard. The committee concluded that there is an urgent need for research to refine the correlation of various indicator organisms, including fecal coliforms, to waterborne disease.

Shortly after its publication, the NTAC guideline was attacked by Henderson (7) as being too restrictive. He set forth several arguments against the promulgation of microbiological standards on a nationwide basis; included were the broad confidence limits on the Most Probable Number (MPN) test (whether for total coliforms or fecal coliforms), temporal and geographic variability in pathogen to indicator levels, and the effect of differing sources of pollution (i.e., treatment plant effluents, stormwater run-off, farm lot wastes, etc.). However, the thrust of his attack was the paucity of defined epidemiological data in support of the NTAC guideline. To the contrary, he used the British experience (8); the observations from Santa Monica Bay, California (9); and the lack of morbidity or mortality data associated with swimming in support of a much less restrictive microbiological standard for bathing beaches, or even no standard at all

In 1972, a panel of the National Academy of Sciences, National Academy of Engineering (10) came to the following conclusion:

> No specific recommendation is made concerning the presence or concentrations of microorganisms in bathing water because of the paucity of valid epidemiological data.

In explaining their inability to recommend a specific value they noted that many of the diseases that seem to be causally related to swimming and bathing in polluted waters are not enteric diseases or are not caused by enteric organisms. Hence, the presence of fecal coliforrn bacteria or of *Salmonella* sp. in recreational waters is less meaningful than in drinking water. Nevertheless, the substance of the NTAC guideline was adopted by the EPA in 1976 (6); and, by 1978, the large majority of the states and territories used it as a guideline or a standard (Table Al). Because of the seeming contradictions in the conclu-

*Author’s emphasis.

sions drawn by different individuals from the same information, it is worthwhile to critically review that information.

DATA BASE IN SUPPORT OF EXISTING GUIDELINES AND STANDARDS

The data base in support of existing microbial guidelines can be sought from three different sources. These are (i) available morbidity and mortality statistics (including retrospective epidemiological analyses of case reports and disease outbreaks), (ii) output from predictive models, and (iii) the findings from prospective, controlled, epidemiological-microbiological studies.

Recreational Waterborne Outbreaks of Disease and Their Retrospective Analyses

Potentially, all the diseases which are spread by the anal-oral route and whose etiological agents are shed in the feces of ill individuals or carriers could be contracted by swimming in sewage-polluted water. This includes (i) bacterial diseases, such as salmonellosis (including typhoid and paratyphoid levers), shigellosis (bacilliary dysentery), cholera, and gastroenteritis caused by enteropathogenic *E. coli*, *Yersinia enterocolitica*, etc., (ii) viral diseases such as infectious hepatitis, illnesses caused by enteroviruses (poliovirus, coxsackieviruses A and B, echoviruses, reoviruses and adenoviruses), and "nonspecific" gastroenteritis caused by the human rotavirus and parvo-like viruses, and (iii) diseases caused by a variety of protozoan and metazoan parasites, i.e., amoebic dysentery, giardiasis, ascariasis, etc.

In actuality, most of the reported outbreaks and cases of infectious disease in the United States associated with swimming in natural bathing places were nonenteric and included cases and outbreaks of otitis externa, swimmers' itch, leptospfrosis, granulomas of the skin, and even very rare cases of tuberculosis and tularemia (11). The existing guidelines do not prevent these diseases. There have probably been less than 18 reported outbreaks of enteric disease, encompassing less than 700 cases, associated with swimming in sewage-polluted waters. Included are: four outbreaks of typhoid fever, three relatively small ones in the United States (1,12,13) and one of ten cases in Australia (14); an outbreak of shigellosis on the Mississippi River below Dubuque, Iowa (15); two very small and questionable outbreaks of enteroviral infections, one caused by Coxsackie A (16) and the other Coxsackie B (17); and an equally questionable outbreak of infectious hepatitis (18). The largest reported outbreak by far occurred in 1979; 187 individuals developed gastroenteritis within three days from swimming at two lakes within a park in Michigan during a three-day period in July (19).

Thus, it is understandable why workers such as Henderson (7) and Moore (8), after examining such reports, have questioned the need for water quality guidelines, much less standards, for recreational waters. There are, however, a number of considerations which suggest that case and outbreak reports by their very nature markedly understate the actual incidence of swirming-associated enteric disease. First of all, there are a number of other modes of transmission for these enteric diseases (i.e. drinking water, food, person-to-person contact) so that it is difficult to establish an association to a specific route. Second, much of the swimming occurs at beaches used on a daily basis or on weekends by urban and suburban populations who return to their homes each evening. This too adds to the difficulty of establishing a common source association with swimming at a given beach for "sporadic," geographically spaced cases of enteric disease. This is in contrast to drinking water where there is a geographic clustering of cases. It is of interest in this regard that the reported shigellosis and gastroenteritis outbreaks were detected under conditions where the population was geographically restricted, campers at state parks. Third, the levels of pollution at such beaches are relatively constant; thus, one would not expect outbreaks (recognized because of temporal or spacial limits) but rather sporadic cases. Fourth, as will be pointed out later in this report, the immune status of the population to some of the potential etiologic agents will also tend to produce sporadic cases. Finally, the most commonly reported illness associated with drinking water and shellfish-associated outbreaks, a nonspecific gastroenteritis, is not a "reportable" disease. The usefulness of information from case and outbreak reports in developing criteria, guidelines, and standards is also limited because, with few exceptions and for obvious reasons, data on the quality of the water at the time of exposure are usually not available.

Prior to 1974, the only retrospective epidemiologic analysis concerning the risk of illness associated with swimming in sewage-polluted waters was carried out by Moore and his associates at some coastal communities along the coast of England and Wales (8). The basic design was to compare the incidence of swimming in a two-week period (for the ill individuals, it was the two weeks prior to the onset of illness) between two groups of individuals. The first was children ill with clinical poliomyelitis, and the second was a group of demographically paired controls (cohorts). Using this approach, Moore found no greater association of swimming among children ill with poliomyelitis than among their cohorts. In addition, he found very few cases of salmonellosis for which there was even the remotest association with swimming in polluted waters.

There were a number of problems with the experimental design used: (i) swimming was not defined rigorously; (ii) the time span between the actual swimming experience and the query as to its occurrence was protracted in many cases; (iii) it was difficult to establish a relationship to the quality of the water in which the individuals bathed; (iv) of necessity with this type of analysis in contrast to that used by Stevenson, there was a presumption as to which diseases were "important," poliomyelitis and salmonellosis; and (v) this type of analysis is rather insensitive except; when conducted during an outbreak situation. In their report (8) Moore and his associates (the Committee on Bathing Beach Contamination of the Public Health Laboratory Service) noted some of these limitations and pointed out that, "A survey of this type could clearly not prove that poliomyelitis was never caused by bathing, and in any case such a presumptive finding might be contradicted by future events, but the results of the survey give no indication that further investigation along those lines is likely to be fruitful except in the negative sense recorded." Nevertheless, their findings do not warrant the conclusions drawn: that there is little, if any, risk of enteric disease from swimmii:1g in sewage-polluted waters unless aggregate fecal material is found therein and that aesthetic considerations will limit beach usage long before there is a significant risk of swimming-associated enteric disease. However, with regard to the two specific diseases in question, Moore's conclusions were probably correct since, even in the period subsequent to his report, there have been no outbreaks or cases of poliomyelitis shown to be associated with the recreational use of water, and there has only been one outbreak of this disease even remotely associated with any of the waterborne routes (20).

There have been some cases of salmonellosis attributed to the recreational use of polluted waters, but, as Moore predicted, these have been associated with swimming in heavily polluted waters which were probably aesthetically unattractive. In the Australian outbreak, there was a broken sewage outfall (14); swimming in a sewage-contaminated drainage ditch (fecal coliform MPN 10^7/100 ml) was reported for the Alabama cases (13); the individuals in the Louisiana outbreak had been swimming in a river impacted by a broken sewer line (12); and four cases of typhoid fever detected in the Alexandria, Egypt bathing beach study to be described were all associated with swimming at a heavily polluted beach immediately impacted with raw sewage (21). The relatively few cases of swimming-associated salmonellosis which have been reported in the United States and the findings from those outbreaks are consistent with the high ID_{50}* for salmonellae (22), the decrease in *Salmonella* cases and carriers, and the increase in sewage treat-

*The number of microbial cells required to infect 50 percent of the exposed individuals.

ment. The removal of suspended solids during treatment decreases the number of multisalmonellae-containing particles. When the human ID_{50} data for salmonellae are considered, it would seem that such particulates would be required to produce swimming-associated disease, and the epidemiological setting for the above outbreaks are consistent with this hypothesis. Moreover, prior to 1979, the only outbreak of enteric disease unequivocally shown to be associated with swimming in sewage-polluted waters was a shigellosis outbreak on the Mississippi River below Dubuque, Iowa (15); and the ID_{50} for shigellae has been shown in volunteer studies to be several orders of magnitude less than that for salmonellae (22,23).

The information provided by the retrospective epidemiological analysis of the shigellosis outbreak (15) is of such importance in understanding the criteria which will be described that some detail is warranted (the equally important Michigan outbreak (19) will be discussed later in another context). Of 45 culture-positive cases studied, 43 (96 percent) of the individuals consulted a physician and 18 (40 percent) were hospitalized. Twenty-three individuals had a history of swimming in the area within three days of the onset of symptoms. Thirteen of them were swimming at a park area which, when sampled periodically during the month following the end of the outbreak, had a mean fecal coliform density of 17,500/100 ml *S. sonnei*. The same antibiogram and colicin type as the isolates from seven swimmers, also was recovered from these waters. A case-control analysis and a retrospective, cohort analysis of an additional 262 individuals revealed a statistically significant association of gastrointestinal illness with swimming but not with drinking well water or with food consumption. The illness was defined as diarrhea with fever or cramps occurring within three days. The rate among swimmers at the park was 12 percent. Of the swimmers, the highest attack rate and the best correlation to illness was among individuals who took water in their mouths and among children and adolescents (less than 20 years of age).

These findings must be used with caution since water quality measurements could be obtained only after the end of the outbreak and since the source(s) of the *Shigella* and indicator organisms in the water could not be unequivocally established. In addition, the data relate primarily to shigellosis, one of several swirnming-associated diseases. Nevertheless, the report documents a *consequential outbreak of illness clearly associated with swimming in water polluted with fecal wastes*. More important, it would appear that the health effects occurred in the *absence of aesthetic deterioration sufficient to deter individuals from swimming in the area*. The concern with salmonellosis notwithstanding, this was a shigellosis outbreak, and the incidence of shigellosis in Dubuque had been steadily increasing over the four years prior to the outbreak.

Prospective Epidemiological Studies

Prior to 1973, the only prospective epidemiological studies dealing with recreational waterborne disease were those conducted by Stevenson and his associates in the 1950s (24). Since they were the basis for the NTAC and, hence; EPA guidelines and a point of departure for the studies to be described in this report, they will be described and analyzed in some detail. There were three studies. The first was conducted at two beaches on Lake Michigan in the vicinity of Chicago. The second examined illness rates among individuals at two locations, a swimming pool in Kentucky and a nearby stretch of polluted beach on the Ohio River. The third study was conducted at two marine beaches on Long Island Sound, one in New Rochelle, New York and other in Mamaroneck, New York. A calendar approach was used in all three studies, and this led to a number of problems with the experimental design. First of all, swimming was not defined rigorously enough so that any subsequent illnesses could be attributed exclusively to contact of the upper body orifices with polluted water as opposed to consumption of food at the beach, personal contact between beachgoers, aerosols potentially generated by toilet facilities, etc. Secondly because the trials were conducted over the entire summer, the effects of day-to-day fluctuations in the pollution levels at the beaches were not eliminated. The consequence of this was that the mean indicator densities and, hence, the illness rates at the paired beaches in the first and third studies were not significantly different from each other. A third problem was that measurements were reported only for one indicator, total coliform bacteria.

In the first study, symptom rates among the beachgoers at the South Beach were no different than those at the North Beach. Howeyer, a statistically significant difference was obtained in the rate of total symptoms among individuals who were at South Beach during three "high" coliform density days as compared to those there during three "low" days. This was not true at the North Beach. The mean indicator density during the high days at the South Beach was 2300 total coliforms/100 ml. In the Ohio River study, the rate for total symptoms was higher among people at the chlorinated swimming pool than those at the polluted beach on the Ohio River. However, the age adjusted rate for gastrointestinal symptoms was higher for the individuals at the river beach than those at the swimming pool. The mean coliform density in the stretch of the Ohio River was 2700/100 ml. In the third study, conducted at the marine beaches in the vicinity of New York City, no differences in symptom rates could be obtained even when illness rates during "high" days and "low" days were compared.

Aside from those in the experimental design, there are a number of problems with the analyses of the data and the conclusions drawn thereof. First of all, Stevenson concluded that swimming per se resulted in a higher rate of illness; because of the experimental design, it can only be concluded that going to the beach results in a higher illness rate. Second, the comparison of illness rates for three high days versus three low days during the Lake Michigan study has been criticized in that the differences were shown for only one set of high versus low days, and no data are given for all the other possible combinations. Third, in the first study, the differences were reported for total symptoms, while in the second they were for gastrointestinal symptomatology; yet, both sets of data were used identically in the derivation of the NTAC guidelines. Because of the limitations in the experimental design and analysis, one could conclude the positive results were spurious and that there was no effect of swimming in sewage-polluted waters. Alternatively, the limitations in design and analysis notwithstanding, it might be argued that the findings described a reality obtained with a relatively insensitive epidemiological instrument.

There were also problems in the use of these findings in the derivation of the microbial water quality guidelines as set forth in the NTAC document. As noted earlier, there was no consistency in the type of symptom used in the derivation. Secondly, the authors of the NTAC document converted total coliform values into fecal coliform values in order to state the criteria in terms of "a more fecal specific indicator system." In fact, the lack of specificity in the total coliform values would be carried over into the fecal coliform guidelines in spite of the fact that the relationship between the two indicators was later determined on the same stretch of the Ohio River. Fourthly, it is now evident that the so-called fecal coliforms are not as fecal specific as was thought at the time that the NTAC guidelines were formulated. Finally, the findings from the Stevenson study and their use in deriving the NTAC and hence EPA guidelines are conceptually deficient in that they are not amenable to risk analysis. That is, they describe detectable not acceptable risks. Nevertheless, these were the best guidelines available, and, as noted by Shuval (25), target area guidelines are needed by engineers as the basis for the design of sewage treatment facilities.

Predictive Models

Predictive models based on pathogen densities in the water, the infective dose of the pathogens in question, and the relationship of pathogen to indicator densities have been equally unproductive in terms of producing the kinds of definitive information needed to support the existing guidelines. Attempts by Streeter (4) which were similar to those used by Kehr and Butterfield (26,27) for other waterborne routes of transmission, assumed an ID_{50} for salmonellae of one, and this is several orders of magnitude less than those obtained later from human volunteer studies (22). A more recent study by Mechelas *et al.* (28) was equally unproductive, not because of the mathematical approach used but rather because of the poor quality of the input data to the model and the assumptions made as to which disease agents are important.

An attempt is made to justify the existing EPA guidelines from information on the relationship of fecal coliform densities to the frequency of *Salmonella* isolations in surface waters (6, 29). As pointed out elsewhere (30), this relationship has not been confirmed, especially when *Salmonella* densities rather than isolation frequencies are examined. Furthermore, it is conceptionally unsound to expect a consistent relationship between a fecal indicator and a pathogen which is not extremely prevalent in the population at large. Finally, considering the ID_{50} for salmonellae, a relationship to the frequency of its isolation hardly seems appropriate as a justification for a guideline. In spite of the absence of epidemiological data showing swimming-associated cases of poliomyelitis, an attempt has been made to justify the guidelines based on some relatively poor data on poliovirus densities (including those of the vaccine strains) in the water, their relationship to fecal coliform densities, and the assumption that ID_{50} of poliomyelitis is one, if the virion is in the right place at the right time (31). This approach also is entirely unconvincing for the reasons stated earlier.

HEALTH EFFECTS RECREATIONAL WATER QUALITY INDICATORS

Ideally, recreational water quality indicators are microorganisms or chemicals whose densities in the water can be quantitatively related to potential health hazards resulting from recreational use therein. Historically, the concern has been with infectious enteric diseases, such as cholera and typhoid fever, whose etiological agents are excreted in feces and are spread by the. contamination of water and food with fecal wastes.

There are a number of reasons why the pathogens themselves are not used for this purpose, and most of these are as valid today as they were at the turn of the century when the indicator concept was developed. First of all, as noted earlier, there is a wide variety of infectious agents potentially transmitted by the waterborne route, and, since the density of each will vary both temporally and spacially independent of the others, measurements would have to be made for each agent. Secondly, facile and reliable methods for quantifying most of the pathogens are unavailable, even today; in fact, there are no methods for quantifying what may be the most important (infectious hepatitis) and most prevalent (rotaviruses and parvo-like viruses) agents of enteric disease. Thirdly, and most important of all, because of the temporal variability in pathogen densities in feces and sewage (and hence their receiving waters), monitoring for the pathogens themselves is more akin to measuring the actual rather than the potential for disease. Thus, it is not surprising (i) that the indicator concept was developed shortly after fecal transmission of enteric pathogens was established, (ii) that the first three indicators suggested, *Escherichia coli*, *Streptococcus faecalis* and *Clostridium perfringens*, were fecal organisms (32), and (iii) that these, or groups to which they belong, are the three most commonly used indicators today (33,34). The regrettable fact is that, in each case, methodological rather than conceptual considerations led to the expansion of the group measured, i.e., coliforms and fecal coliforms instead of E. coli, fecal streptococci instead of S. faecalis, and spore-forming, sulfite-reducing anaerobes instead of *C. perfringens*. The health effects, water quality indicators which have been considered and the methods for their enumeration which have been developed under the EPA recreational water quality criteria program are presented in Table 1.

The coliform systems require some further discussion because they are the ones most

TABLE 1. METHODS DEVELOPMENT IN SUPPORT OF THE USEPA EPIDEMIOLOGICAL PROGRAM

Indicator	Method	Ref[1]	Indicator	Method	Ref[1]
Coliforms	mC	(35)	*P. aeruginosa*	mPA	(43)
E. coli	mTEC	(36)	*A. hydrophila*	mA	(44)
Klebsiella	mK	(37)	*V. parahaemolyticus*	mVP	(45)
Enterococci	mE	(38)	*Salmonella*	HVS	(46)
C. perfringens	mCP	(39)	Enteropathogenic *E. coli*	—[2]	(47)
Bifidobacteria	—[2]	(40)			
Coliphage	—[2]	(41)	Coprostanol	—[2]	(48)
C. albicans	—[2]	(42)			

[1] Literature citation for the method.
[2] No specific name.

commonly used and because most of the existing criteria are stated in terms of coliform or fecal coliform densities.

The total coliform population as commonly enumerated includes four genera in the family *Enterobacteriaceae*: *Escherichia*, *Kiebsiella*, *Citrobacter*, and *Enterobacter*. It may also include other organisms, notably lactose positive members of the genus *Aeromonas* (49). Only *E. coli* is consistently and exclusively found in feces (50), although all five genera can be routinely recovered from domestic sewage in rather large numbers (51).

Belatedly, the total coliform system is being discarded for many applications because it is finally recognized that *Citrobacte*r and *Enterobacter* species are not fecal specific. However, it is being replaced with the so-called "fecal coliforms," a group which includes thermotolerant Kiebsiella as well as *E. coli* biotypes. There never was any evidence that the adjective "fecal" was properly applied. In fact, it has been known for some time that there are substantial extra-fecal sources of *Kiebsielia*, (50, 52, 53), even for the thermotolerant biotype. In addition, *Kiebsielia* is infrequently present in human feces, and then generally as a minor portion of the coliform population (50). A number of reasons have been given to justify the use of this coliform system instead of *E. coli*. It has been argued that much of the historical data is in terms of fecal coliforms, that the existing standards for recreational and shellfish waters are stated as fecal coliform densities, and that *Kiebsielia* should be enumerated as a fecal indicator because it is an opportunistic pathogen. First of all, much of the historical data is in terms of total coliforms not fecal coliforms; secondly, the little epidemiological data in support of existing recreational or shellfish standards were developed in terms of total coliforms and extrapolated to fecal coliforms (3); thirdly, *Kiebsielia* is an opportunistic pathogen of the respiratory and genito-urinary systems and not the gastrointestinal tract; finally, there are no data showing that *Kiebsiella* infections have been obtained via the waterborne route, much less that they occur at environmental fecal coliform densities of less than 200/100 ml or 14/100 ml, the present EPA guidelines for recreational and shellfish-growing waters, respectively (6).

GUIDELINES BASED ON ACCEPTABLE RISK

Another problem with the existing microbial guidelines for direct contact recreational waters is that they are not amenable to, compatible with, or derived in the context of risk analysis. That is, the data from which the guidelines were derived and the manner of the derivation are related to detectable rather than acceptable risk. Therefore, decisions beyond acceptance or rejection of the specific limits cannot be made on the basis of scientific, health, economic or sociological considerations This does not allow for deliberate decisions by local, state, or federal officials as to the costs to be paid for incremental decreases in the health risks involved. Finally, it presents a philosophical dilemma to individuals or groups who recommend guidelines based upon detectable risks. Once more sensitive epidemiological instruments are developed for measuring the risks involved or extrapolating them from existing information, they are forced to make the limits more restrictive in order to be conceptually consistent. In fact, this is precisely the position in which the EPA finds itself because of the results to be presented. The logical solution is to proceed to the next stage in the evolution of the guidelines, the use of those developed on the basis of acceptable risk.

The microbial water quality criteria for primary contact recreational waters to be recommended in this report and, hence, the guidelines and standards which can be derived from them are a radical departure from the guidelines currently recommended by the EPA and the guidelines and standards currently used by the various states. They differ conceptually from the existing guidelines (referred to as criteria) in that the usable information is presented in the form of dose-response type relationships rather than limiting microbial densities. Because the conceptual basis is different, it becomes important to define certain terms as they will be used throughout this document.

A health effects recreational water quality *criterion* developed for use with indicator systems is defined as a quantifiable relationship between the density of the indicator in the water and the potential human health risks involved in the water's recreational use. It is a set of facts or a relationship upon which a judgment can be made. A water quality *guideline* derived from the criterion is a suggested upper limit for the density of the indicator in the water which is associated with health risks which are considered unacceptable. The concept of acceptability implies that there are social, cultural, economic, and political as well as medical inputs to the derivation and that these may vary in time as well as space. A water quality *standard* obtained from the criterion is a guideline fixed by law. The relationship of guidelines to the criteria from which they are derived is shown graphically in Figure 1. Derivation of the guidelines from the criteria requires a

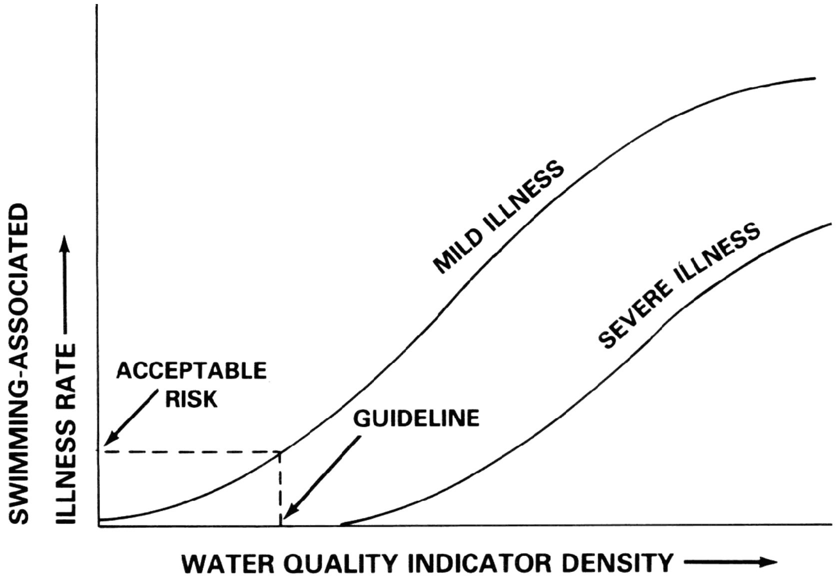

Figure 1. Graphic representation of the desired recreational water quality criteria. It is assumed that only an extremely small risk of "serious" illness will be accepted.

decision as to acceptable risk. This, in turn, is best obtained from some manner of cost-benefit or cost-effectiveness analysis which should include economic and socio-logic considerations. Guidelines derived from such criteria differ from those currently in use in that they are consistent with risk analysis, allow for decision making, and are based on acceptable rather than detectable risks. This report presents such a criterion for marine recreational water quality, documents its epidemiological data base, and discusses its applications and limitations.

SECTION 4
STUDY DESIGN

The design of the epidemiological-microbiological program to develop health, effects recreational water quality criteria was started in January 1969, shortly after the publication of the NTAC guidelines, and concluded in 1970. From the onset, the objective was to develop criteria amenable to risk analysis rather than guidelines based upon detectable risk (54). The experimental work was initiated in 1972 and concluded in 1978. A prospective approach similar to that used by Stevenson (24) was taken, in part to avoid prejudgements as to which diseases are spread by the recreational route, in part because a "nonspecific" gastroenteritis was the most common illness associated with the drinking water (55) and shellfish (56) routes of transmission, and in part because of Moore's (8) conclusion that further retrospective studies are unlikely to yield results other than those obtained in his study. Marine beaches were chosen for the initial program because Stevenson's study at marine beaches did not produce demonstrable swimming-associated health effects, yet his freshwater findings were being applied to such beaches. Furthermore, if swimming-associated health effects were not obtained, this would tend to confirm the observed differences between fresh and saltwater beaches. If they were obtained, this would signal the need for a freshwater program, and the saltwater criteria could be used on an interim basis for freshwater beaches as well. The freshwater program was initiated in 1976. Finally, there were a number of heavily used and sewage-impacted marine beaches which could be studied along the Middle Atlantic and New England coasts.

PERCEIVED DEFICIENCIES IN STEVENSON DESIGN

An analysis of Stevenson's (24) study design, relative to the difficulties encountered and the results obtained, revealed several deficiencies which may have contributed to the inconclusiveness of his findings. To a large measure, they were due to the necessity of using the less expensive and time-consuming "calendar approach."

Definition of Swimming

Neither Stevenson, in defining his bathers as opposed to his nonbathing controls, nor Moore (8), in his inquiries concerning bathing, appears to have defined swimming such that individuals actually *at risk* - those whose upper body orifices were significantly in contact with the water - were isolated and examined. Thus, if swimming is not defined precisely, it is possible that differences in pollution-associated illness may be sought between two populations in both of which most of the individuals never were appreciably exposed. We considered this to be important from the assumption that less than 10 percent of the beachgoers would be classified as swimmers when immersion of the head in the water was used as the criterion for swimming. In fact, we were wrong. In almost every study, more than 60 percent of the beachgoers were classified as swimmers.

Multiple Exposures

The day-to-day variability in pollution levels requires that, ideally, the study group be limited to individuals who have had a single (one-day) swimming experience during the observation interval associated with a given trial. In both the freshwater (Lake Michigan) and saltwater (Westchester) studies, the day-to-day variability as measured by coliform indicators was considerable; in fact, the range of indicator densities at each pair of beaches appreciably overlapped each other. Furthermore, in both these studies, the use of "calendars" to record illness made it necessary to limit the study to seashore residents. This maximized the probability that multiple exposures would occur. Stevenson, in comparing the incidence of illness during "high" and "low" pollution days, obviated only part of this difficulty.

Nonswimming Controls

Stevenson's nonswimming controls were individuals who did not go to the beach. Thereby, beach-going but not swimming-associated illnesses, such as gastroenteritis from improperly stored food, increased personal contact, use of communal toilets, etc., could be erroneously included in calculating the illness rates of the swimming as opposed to nonswimming populations. This could have affected illness-rate comparisons between "high" and "low" days as well as between beaches.

Demographic Considerations

Stevenson analyzed his data with consideration to age and sex but not to ethnic or socioeconomic (SES) factors. However, especially in the saltwater study, the test beaches appear to have been paired with reference to ethnic and SES factors of the resident populations. Susceptibility to disease, background rate of illness, nature of the swimming experience, and even the reliability of the respondents' information concerning illness and the swimming experience could vary by ethnic or social class.

Tidal Effects

Hourly variability in the pollution levels due to tide, wind, rainfall, etc., can present a problem in the interpretation of findings from epidemiological-microbiological trials. In Stevenson's study this was uncontrolled. Except in those instances where a "captive" study population is available, such as institutionalized individuals or organized groups, there is little that can be done to mediate such effects. Individuals at the beach during a given day can be expected to swim on several occasions during a half tidal cycle.

Indicators of Pollution

At the time of Stevenson's study, the state of the art was such that only two microbiological parameters were measured. Coliform determinations were made in accordance with confirmed test procedures described in the 13th Edition of "Standard Methods" (57). Enterococcus levels were also examined. These data were not used in the analysis because it was subsequently determined that, because of problems in assay methodology, the density estimates were too unreliable.

DESIGN CHARACTERISTICS

In response to the perceived deficiencies in the Stevenson studies, the calendar approach was not used (58). Rather, the participants were recruited at the beach and queried some 7-10 days later by phone or personal interview (mail questionnaires were tried and found to be unsatisfactory) concerning symptomatology which developed subsequent to the swimming experience. Other features of design were as follows:

1. Only individuals whose upper body orifices were exposed to the water were classified as swimmers, and subjects. were queried on the nature and duration of swimming activity. The validity of this information was pretested in the New York City study by observing family groups over a day at the beach and comparing these observations with information obtained at the day's end from a representative of the group. The more rigorous definition of swimming allowed for a beach-going

but nonswimming control group and thereby eliminated the bias from nonswimming associated illnesses.

2. Beach interviews were conducted only on weekends. Exposure was limited to a single day or at most two successive days on a weekend. This was accomplished by eliminating individuals who swam in midweeks before and after the weekend trials from the study. The use of weekends maximized the size of the study population but limited the illness observation period to 8-10 days. This feature of the study facilitated the analysis of the data "by days," thereby obviating the effect of day-to-day variability in pollution levels. However, it eliminated from consideration illnesses with incubation periods exceeding nine days, notably infectious hepatitis (this was examined in the portion of the Egyptian study which dealt with Cairo visitors to the Alexandria beaches).
3. The impact of within-day variability in pollution, primarily attributable to tidal effects, could not be eliminated. However, in the first two years of the New York City study, an attempt was made to minimize this effect by choosing test and control beaches which were markedly different in the pollution levels reaching them. There also was an attempt to select trial dates when minimal tidal effects coincided with peak beach usage periods (usually 11 A.M. to 5 P.M.). This problem was potentially even more acute in the Boston Harbor study because of the greater tidal excursions and the unappealing nature of the intertidal zone. Because of this, swimmer and even bather densities were very low during low tides, Therefore, trials were conducted on those weekends when high or mid-tide corresponded to the hours of peak activity (11 A.M. to 5 P,M,). This forced the acceptance of lower mean indicator densities for this study.
4. Demographic effects, which could assert themselves as differences in susceptibility to infection, in swimming activity and in the reliability of respondent information, were minimized. This was done by selecting test and control beaches whose populations were demographically similar and by obtaining age, sex, ethnic, and SES information that could be used in isolating and identifying the influence of these factors.
5. The respondents were asked whether they remained home, remained in bed or sought medical advice because of the symptoms. This information was used to indicate disability.
6. In the pretest year of the New York City study, an attempt was made to validate the illness information provided by the respondents. This was done by providing the name of a physician in the reminder letter sent on the Monday following a trial and by requesting the names of other physicians consulted during the observation period. This was unsuccessful, and an alternative system was devised for validating gastrointestinal (GI) symptomology. Highly credible GI symptoms (HCGI) were defined as (i) vomiting, (2) diarrhea with a fever or disabling enough for the individual to remain home, remain in bed or seek medical advice, or (ii) stomachache or nausea accompanied by a fever, The rates for HCGI symptoms were calculated and compared to those for total GI symptoms in order to determine if the trends were the same.
7. The illness questionnaire solicited information on irritations and disturbances of the skin, upper respiratory tract, eyes, and ears. This was done not only against the possibility of pollution-associated infectious processes but also against that possibility of toxic and hypersensitive conditions attributable to chemical pollution and to pollution-associated changes in marine biota.

The sequence of events during and subsequent to the beach interview is shown in Table 2.

The experimental design as stated was generally followed for all the studies conducted. The notable exception was the Egyptian study and especially the portion dealing with health effects among Cairo visitors to the Alexandria beaches.

TABLE 2. SEQUENCE OF EVENTS FOR EPIDEMIOLOGICAL-MICROBIOLOGICAL TRIALS

Day of week	Day number	Activity	Function
Saturday	1	Beach interview, water sampling	(a) Obtain name, address, phone, etc. (b) Reject pre-trial midweek swimmers (c) Query on beach activity (d) Assay of water samples
Sunday	2	Same as Saturday	As above
Monday	3	Reminder letter	(a) Provide name of physician (b) Reminder to note illness
Monday	10	Phone or mail interview	(a) Obtain illness information (b) Reject post-trial midweek swimmers (c) Obtain remainder of demographic information.

INDICATOR ASSAYS

Water samples were collected in sterile bottles from just below the surface of the water, at "chest high depth," and periodically during the time when people were in the water. They were collected at 2-3 locations along the beach; and, in general, 3-4 samples were collected between the hours of 11 A.M.-5 P.M., the period of maximum swimming. The samples were "iced" and returned to the laboratory for assay within six hours of collection.

Assays of the water samples were performed to determine the densities of a number of potential microbial indicator systems. These are given in Table 1. Appropriate, evaluated methods were not available for bifidobacteria, coliphage, *Candida albicans*, and enterophathogenic *E. coli* or for the chemical, coprostanol, by the second year of the New York City study. Therefore, these indicators could not be included in the study. Membrane filter procedures were developed and used for most of the indicator systems examined. The methods are noted and referenced in Table 1. Membrane filter procedures were chosen because they provide more precise estimates than MPN determinations and allow larger samples to be examined than pour or streak plate procedures. A high volume (55.5 liters), MPN procedure (46) was used for *Salmonella*, *Klebsiella*, and *Enterobacter-Citrobacter*. Densities were determined by the mC procedure (35), although a method specifically for *Klebsiella* (37) was developed subsequent to the completion of the New York City study. In addition, fecal coliform densities were determined by the MPN procedure given in *Standard Methods for the Examination of Water and Wastewater* (57). Staphylococci were enumerated by a modification of the Chapman-Stone method for use in a membrane filter procedure (M. Levin, personal communication).

ANALYSIS OF THE DATA

Since the objective of the program was to relate the swimming-associated rates for symptoms, classes of symptoms or syndromes to some measure of the quality of the water, a temporal and spacial control population was provided. This was nonswimmers (head not immersed in water) who were at the beach and, in general, came from the same family groups as the swimmers. Therefore, in most of the analyses, the swimming rate for a given symptom or group of symptoms was first compared to the nonswimming rate. Such differences were then examined relative to the pollution levels at different beaches or on different days or groups of days at the same beach. During the first two years of the New York City study, two beaches were used which, according to existing standards, varied widely with regard to their pollution levels. One was “barely acceptable” (BA) in that it was immediately adjacent to a beach posted as being unsafe for swimming; the other was “relatively unpolluted” (RU) according to existing guidelines and was at a much greater distance than the BA beach from any known pollution source. The choice of the beaches permitted making a decision as to “important” symptoms without recourse to a direct comparison with indicator densities. Chi-square analysis was used for this purpose. The second premise of the program was that there would be no prejudgment as to which is the “best” indicator. Therefore, regression analyses of the geometric mean densities of each indicator against the symptom rates were used to determine which indicator provided the best correlation and, hence, was the best water quality indicator.

In the regression analyses, each point was defined by the symptom rate for a single trial (day), a cluster of trials with similar indicator densities or all the trials conducted over a given summer at a given location and by the corresponding geometric mean indicator density for all the samples collected at the beach. Regression analysis was also used to define the final criteria.

The studies conducted under the EPA program to develop recreational water quality criteria, the number of individuals from whom usable information was obtained, and the success rate for follow-up interview are presented in Table 3. The detailed findings from individual studies have been or will be presented in individual reports (21, 59-64).

TABLE 3. SUCCESS OF FOLLOW-UP PHONE INTERVIEWS AND THE NUMBER OF USABLE RESPONSES BY BEACH AND YEAR FOR STUDIES CONDUCTED UNDER THE EPA PROGRAM

		% Follow-up During Study Year[1]			Number of Usable Responses During Year		
Location	Beaches	1	2	3	1	2	3
New York City, NY	Coney Island	82.3	78.3	78.3	641	3146	6491
	Rockaway	86.6	82.9		681	4923	
Lake Pontchartrain, LA	Levee	77.2	77.9[2]		3432	2768	
	Fontainebleau					551	
Boston Harbor, MA	Revere	81.2			1824		
	Nahant	81.2			2229		
Alexandria, Egypt	Maamoura[3]	88.6	84.8	84.4	819	1492	1786
	—[4]		91.2	88.3		1696	2173
	Ibrahemia[3]	81.2	87.8	90.4	823	1117	2050
	—[4]		87.5	87.2		1159	1820
	Mandara[3]	82.9			1163		
	Sporting[3]		90.7	90.6		1257	2025
	—[4]		84.9	88.5		1243	2457

[1] Coney Island, Rockaway, 1973-1975; Levee, 1977-1978; Fontainebleau, 1978; Revere, Nahant, 1978; Maamoura, Ibrahemia, 1976-1978; Manara, 1976; Sporting, 1977-1978.
[2] Fontainebleau included with Levee.
[3] Alexandria residents.
[4] Cairo visitors.

SECTION 5
RESULTS OF THE STUDIES

NEW YORK CITY STUDY

This study was conducted in three phases (years) at Coney Island and Rockaway beaches selected with the assistance of the Bureau of Public Engineering, New York City Department of Health. The first phase, conducted in 1972 and 1973, was a pretest of the microbiological and epidemiological methodology and an evaluation of the suitability of the test beaches. In 1972, the reliability of information obtained from the interviewees concerning their bathing activities was examined using the method described earlier. Their responses were quite accurate regarding entrance into the water and immersion of the head therein. However, their perceptions as to how long they were in the water were less reliable, possibly because many of them bathed or swam on several occasions during the day. In l973, trials were conducted at two beaches: the first, located between 18th and 22nd Streets on Coney Island, was designated as the BA beach; and the second, around 67th Street at the Rockaways, was designated as the RU beach (61).

The demographic distributions of the populations at the two beaches were similar (60); about two-thirds of the beachgoers were classified as "swimmers," and there were no striking differences between the Coney Island and the Rockaways populations with regard to the percentage so classified. Swimming was more frequent among males, Hispanic Americans, and the 0-19 years of age groups (Table A2). The differences in pollution levels as seen from the densities of a number of potential water quality indicators were markedly different (Table A3). The success rate for follow-up phone (not mail) interviews was acceptable (Table 3); however, an alternative to medical follow-up examination for validation of the respondents' information on symptomatology was required. The differential (swimming minus nonswimming) rates for the individual GI symptoms were generally greater at the Coney Island than at the Rockaway beach (Table A4), and statistically significant differences in the rates for GI symptomatology were obtained at the Coney Island but not the Rockaway beach (Table A5). The rate for respiratory symptoms was higher among swimmers than nonswimmers at the Rockaways, presumably due to the aerosolization of noninfectious material because of the heavy surf activity at the beach. Assays for *Salmonella* densities in the water were omitted from subsequent studies because. of the low densities obtained (Table A6).

A detailed analysis of the second phase (1974) trials is presented elsewhere (60). The RU beach was changed from 67th Street to Riis Park at the Rockaways in order to in-crease the size of the study population. The consequence of this was a somewhat greater discrepancy between the BA and RU beaches with regard to ethnic and SES factors (60). With two exceptions, nearly all the 1973 findings were confirmed in 1974. They were the much lower mean indicator densities (Table A3) and the absence of differences between swimmers and nonswimmers for the individual respiratory symptoms or respiratory symptoms taken as a whole (Tables A4 and AS). Of the nonswimmers at the Coney Island and the Rockaway beaches, only 8.5 percent and 5.4 percent, respectively, did not go swimming because of existing symptoms or illness. None of the individuals at the BA beach and only 0.1 percent of those at the RU beach did not go swimming because of GI symptomatology.

Because of the larger study population, the rates for GI symptoms could be examined by demographic groups. However, the increase notwithstanding, data for disabling GI symptoms by type could not be analyzed statistically because of the small size of the resultant cells. The disabling GI symptom rate for swimmers was 10/1000 people higher than that for nonswimmers at the BA beach. At the RU beach, the rate for nonswimmers was higher than that for swimmers by 2/1000.

The results from the analysis of GI symptom rates by demographic groups for swimmers and nonswimmers at both beaches are presented in Table A7. The rates among children, Hispanic-Americans, and low-middle SES individuals who swam at Coney Island were significantly and appreciably higher than among those who did not. This was not so for the residual from each demographic category (adults, blacks plus whites, and the highest SES group). The GI symptom rate for nonswinmers among the children at the RU beach was appreciably higher than that for the corresponding group at the BA beach. The rate for nonswimming children at the RU beach was significantly higher than that for children who swam. This anomalous finding probably was not due to over-reporting, since this was also true of the "highly credible" portion. The nonswimming children may have been more prone to illness, although only 0.1 percent of these children or their respondents reported that they did not swim because of existing GI symptoms. The investigators favor the explanation that predominately white or black, higher SES children did not or were not allowed to swim because they were in the early stages of the illnesses for which they later reported symptoms (60).

Secondary transmission of illnesses within a family did not appear to provide an erroneous picture of the symptom rates associated with swimming (60). The credibility of the information on gastrointestinal symptomatology was assessed by comparing the trends of all responses to those considered "highly credible." The rates for the "highly credible" symptoms among the four study groups were examined for the total population and separately for the children, Hispanic-Americans, and the low to middle SES groups. The trends for the highly credible portion were similar to those for all GI symptoms (Tables AS and A7). Rates of HCGI symptoms for the three most sensitive groups of swimmers also were significantly higher than those for their nonswimming controls.

The finding of a statistically significant, swimming-associated rate of GI symtomatology at a BA but not at a RU beach showed that such effects could be determined and suggested that measurable health effects do occur even within existing guidelines and standards. However, these results did not speak to the overall objective of the EPA program, the development of criteria amenable to risk analysis as described earlier. The data from the third phase (1975) of the New York study along with the data obtained the previous two years were analyzed to further explore this possibility since a preliminary examination of the data from 1973 and 1974 suggested that criteria could be developed and that either *E. coli* or enterococci was the most appropriate indicator (61). Four beaches on Coney Island were studied in 1975. These were a "posted" area between 34th and 38th Streets and nonposted beaches between 18th and 24th Streets, 8th and 10th Streets, and 2nd and 4th Streets, Brighton.

As noted earlier, the data from the three years of the New York City study were examined by regression analysis in two ways. The first was by clusters of trials with similar mean indicator densities during a given summer. The second was by summers, that is, all the trials at a given beach during a given summer. Clustering was necessary in order to avoid data points with N values of less than 100 persons. This was accomplished with one exception, a N of 96 for nonswimmers in the analysis of *E. coli* densities. In a few instances, however, this was accomplished at the cost of grouping some trials with widely divergent densities. In almost all cases, this occurred with trials at the upper end of the density distribution for a given indicator. Where possible, "natural breaks" in the distribution of mean densities were utilized in clustering the trials. Nevertheless, this was somewhat arbitrary.

In both approaches, the attack rates for GI symptoms or the "highly credible" portion thereof (HCGI) were regressed against the mean indicator density. The log-linear regression equation:

$$Y = a \log X + b$$

was used in which X was the mean indicator density and Y the symptom rate.

The clustering of the trials for each of the indicators along with geometric mean density and range for each cluster is shown on Tables A8 through A18. The mean densities along with the data used in calculating the swimming-associated rates (swim-nonswim) of GI and HCGI symptoms for each cluster (some single trials were unavoidable) are shown for each indicator in Tables A19 through A29. The coorelation coefficients are presented in Table 4.

TABLE 4. CORRELATION COEFFICIENTS FOR TOTAL GASTROINTESTINAL SYMPTOMS AND THE "HIGHLY CREDIBLE" PORTION AGAINST THE MEAN INDICATOR DENSITIES FOR 1973-1975 TRIALS CONDUCTED AT NEW YORK CITY BEACHES

	Correlation Coefficients (r) for				Number of Points (N)	
	Highly Credible GI[1]		Gastrointestinal (GI)[2]			
Indicator	Summ[3]	Clust[4]	Summ	Clust	Summ	Clust
Enterococci	.75	.96	.84	.81	8	9
E. coli	.52	.56	.56	.51	8	9
Klebsiella	.32	.61	.35	.47	8	11
Enterobact.-Citrobact.	.26	.64	.23	.54	8	13
Total coliforms	.19	.65	.12	.46	8	11
C. perfringens[5]	.19	.01	.38	−.36	5	8
P. aeruginosa	.19	.59	.25	.35	8	11
Fecal coliforms	−.01	.51	.01	.36	8	12
A. hydrophila	−.09	.60	−.08	.27	7	11
V. parahaemolyticus[5]	−.20	.42	.19	.05	5	7
Staphylococci[5]	−.23	.60	.71	.09	5	10

[1] Highly credible GI symptoms (see text for definitions).
[2] Total gastrointestinal (GI) symptoms.
[3] Analysis of data by summer by beach.
[4] Analysis of data by summer, by cluster of trials (days) with similar indicator densities.
[5] No data for 1973.

The mean densities and the ranges for each indicator for all the trials conducted during a given summer at a given beach are presented in Table A30. The corresponding data on GI symptom rates are given in Table A31, and the correlation coefficients for the regression of the swimming-associated rates on the mean densities in Table 4.

When the results from both approaches for examining the relationship of the indicator densities to GI symptoms (and especially the highly credible portion thereof) were considered, it was apparent that enterococcus densities provided the best correlation. Nevertheless, as planned; the two best-correlated indicators, enterococci and E. coli, were used in subsequent studies. It is of equal importance that total coliform and especially fecal coliform densities were less well correlated with gastrointestinal symptomatology.

The regression lines obtained for swimming-associated GI and HCGI symptorns against the mean *E. coli* and enterococcus densities when examined by summers and clusters of trials with similar indicator densities are presented in Figure 2.

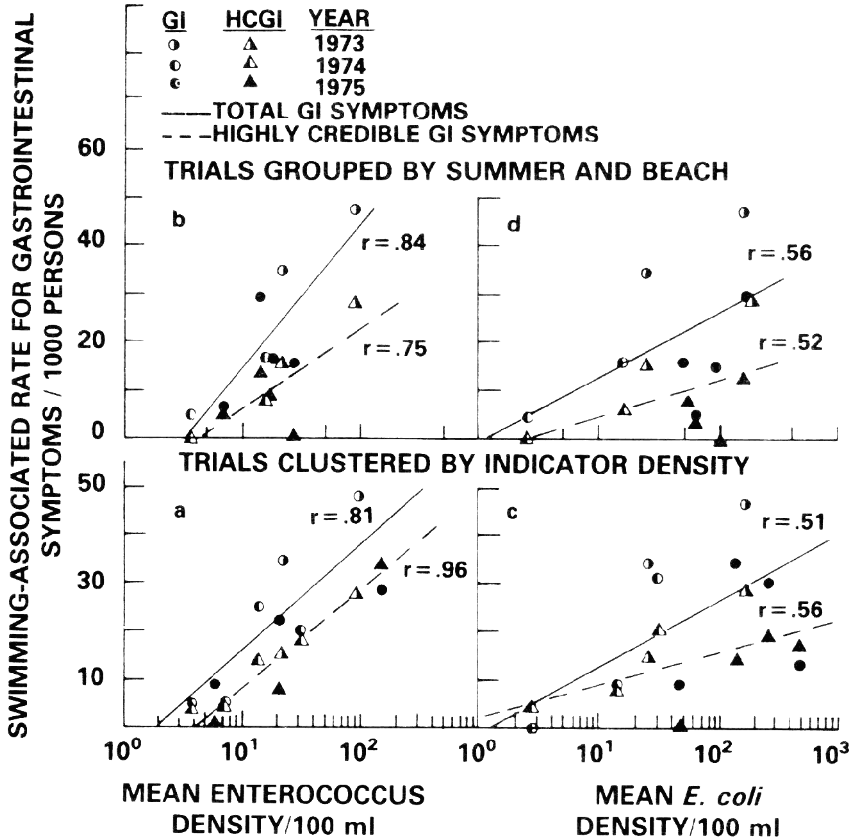

Figure 2. Swimming-associated (swimmer minus nonswimmer) gastrointestinal symptom rates against the mean enterococcus and *E. coli* densities in the bathing water for New York City study (1973-1975). Highly credible GI symptoms defined in text. In "a" and "c," trials clustered by similar indicator densities to yield points as shown. In "b" and "d," trials clustered by summer and beach. The actual trials clustered are given in Tables 8A through A31, Appendix A.

ALEXANDRIA, EGYPT STUDY

Animal infectivity studies conducted with most infectious agents yield sigmoid dose-response curves. At the inception of the EPA program, the relationship of illness among swimmers to indicator densities in the bathing waters was also expected to be sigmoid in nature. However, when the swimming-associated rates for GI symptoms were plotted in percentages on a scale that was not expanded to show differences (see Figure 3 as an example), the slopes of the lines were quite shallow relative to those seen in most dose-response curves. They may have represented the first parts of sigmoid curves, from which the expectation was accelerated increases in the symptom rates with further increases in the indicator densities at the beaches. An equally plausible explanation was that the regression lines obtained were the linear portions of basically sigmoid relationships (i) in which a measurable response was associated with the ingestion of very low enterococcus or *E. coli* densities (note the Y axis intercepts in Figure 2) because of the differential survival of the indicators relative to the etiologic agent(s) over the travel time between the beaches and the sources of pollution, (ii) in which the shallow slopes of the regression lines were due to high levels of immunity to the infective agents(s) in the swimming populations, and (iii) from which the expectation was that the rates for the specific illness(es) involved would not accelerate with increasing levels of pollution as seen from the indicator densities.

Ideally, Figure, 3 should be a log probability plot; practically, it makes no difference because of the low rates and relatively good "r" values obtained. Furthermore, since this is an indicator-illness rather than agent-response relationship, a log probability plot may not be appropriate.

It was thought that the nature of illness-indicator relationships obtained from studies conducted at beaches more heavily impacted with more immediate sources of raw sewage could be used to differentiate between the two possibilities. Therefore, an extensive search was made for beaches in the United States which not only met the above requirements but also were used by large numbers of individuals and were not posted as unsafe. No such beaches were found in the United States; however, several saltwater beaches which met these requirements were identified in Alexandria, Egypt and could be studied under the sponsorship of the PL480 program. Most of them were very heavily used during the summer, and, according to existing information, they varied in their pollution levels from some which were heavily polluted (even aesthetically undesirable) to some which were acceptable according to the EPA guidelines. The sources of pollution to the beaches were a number of short (about 50 meters) outfalls originally designed to accommodate overloading of the disposal systems due to rainfall. However, they now discharge sewage daily because the growth of the city created demands for sewage disposal which exceeded the capacity of the existing system.

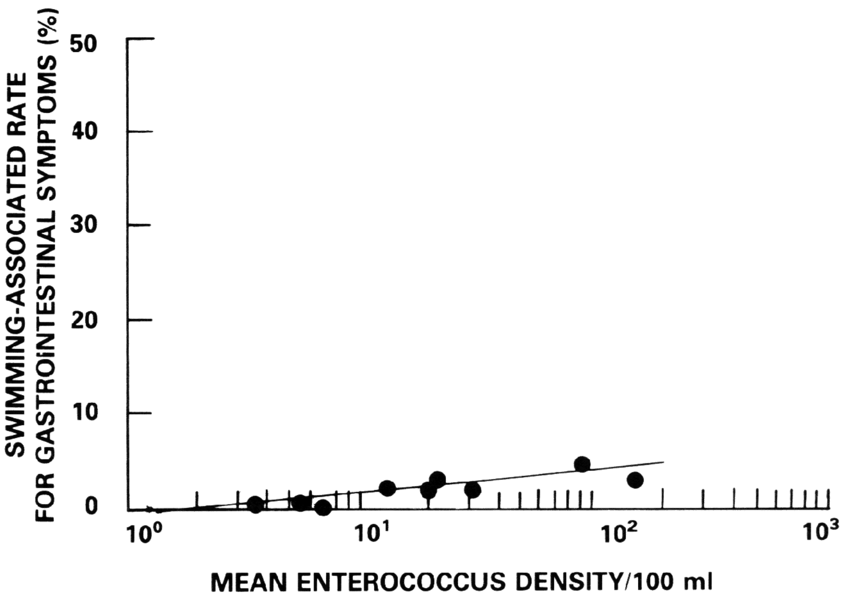

Figure 3. Data from Figure 2a shown as percentages on a scale more akin to that used in dose-response representations.

A preliminary survey of microbiological, demographic and user characteristics identified three beaches for the study - one very heavily polluted (Mandara), one moderately polluted (Ibrahemia), and one acceptable, but barely so according to the EPA guidelines (Maamoura).

The findings from the first year (pretest) of the study were similar to those obtained at the New York City beaches. Greater differences in the rates for vomiting and diarrhea among swimmers relative to nonswimmers were obtained at the heavily and moderately polluted beaches than at the acceptable one; and gastrointestinal symptomatology alone seemed to follow pollution as seen from *E. coli* and enterococcus densities, although the rates for most symptoms were higher for swimmers than nonswimmers at all three beaches. Children appeared to be the most susceptible portion of the population. However, a preliminary examination of the indicator-GI symptomatology relationship suggested an even shallower response curve than that obtained in the New York City study, this in spite of the higher pollution levels. Furthermore, there were indications that the GI symptom rates plateaued at mean *E. coli* and enterococcus densities of 200-300/l00 ml (see data points for 1976 Alexandria residents in Figures 4 and 5). Finally, the *E. coli* and enterococcus densities associated with a "detectable" illness response (X axis intercepts) were higher than those obtained in the New York City study; those for enterococci were higher than those for *E. coli* the indicator with the poorer survival characteristics in saltwater (65) These findings recommended the second hypothesis noted earlier in this section. discharge sewage daily because the growth of the city created demands for sewage disposal which exceeded the capacity of the existing system.

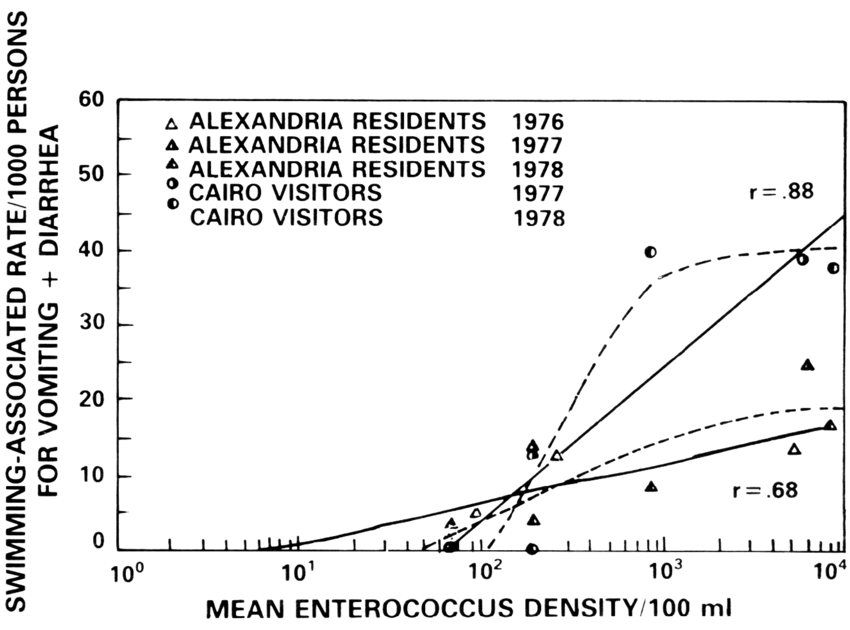

Figure 4. Swimming-associated rates for vomiting or diarrhea against the mean enterococcus density in the water (Egyptian study). The correlation coefficients (r) are those for the linear relationship. The dotted lines are the author's interpretation of the overall relationship from those seen for the individual years. Data given in Table A38, Appendix A.

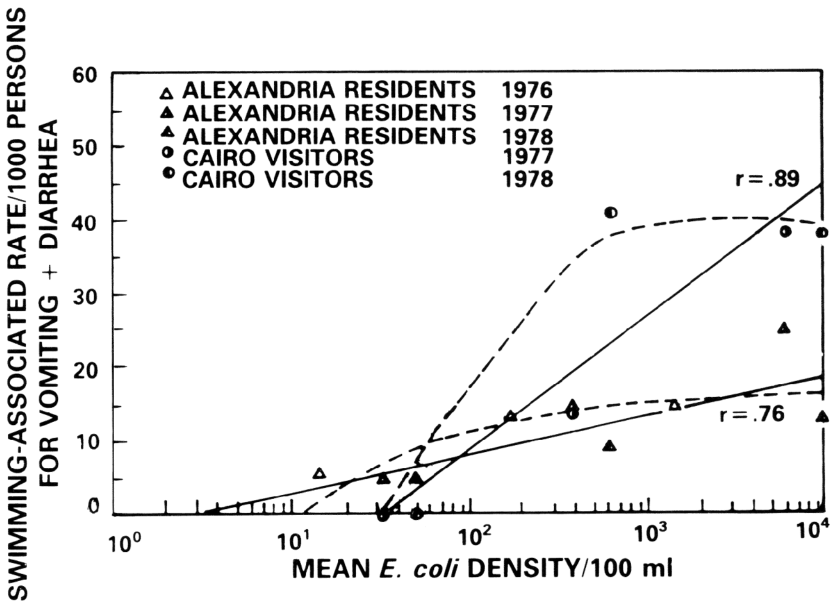

Figure 5. Swimming-associated rates for vomiting or diarrhea against the mean *E. coli* density in the water (Egyptian study). See Figure 4 caption for explanations.

Because of the above findings, the study was not only continued but extended to examine Cairo tourists at the Alexandria beaches as a population which, with regard to its immune status, might be more akin to that in the New York City study. In addition, the follow-up period with the Cairo population was extended to consider infectious hepatitis which, along with typhoid fever, is much more prevalent in Egypt than in the United States. This required a somewhat altered experimental design. The "Cairo visitors" were recruited at the beach shortly after their arrival in Alexandria. Follow-up inquiries were made in Alexandria and, as required, in Cairo at weekly intervals over a 30-35 day observation period. Follow-up in Alexandria was facilitated because most of the tourists remained in Alexandria for 2-4 weeks in rented cabanas at the beach. The altered design with the Cairo visitors precluded the use of "weekend trials" and, therefore, made the results more subject to the vagaries of day-to-day variability in pollution levels. However, the levels were relatively constant since there was little rainfall during the summer and the sewage impacting these beaches was untreated.

The pumping schedule at the Mandara outfall was changed in 1977, presumably because of the 1976 findings; this was reflected in the lower *E. coli* and enterococcus levels obtained at this beach in the spring of 1977. Because of this, "Sporting" was substituted for Mandara as the heavily polluted beach in the 1977 and 1978 trials.

The swimming and nonswimming rates for the various symptoms among the Alexandria residents and the Cairo visitors for each of the three years of the study are given in Tables A32 through A34. The swimming-associated (swimmer minus nonswimmer) rates are summarized in Table A35. Only data from the first weekly follow-up with the Cairo visitors were used in the analyses of the 1977 findings in order to maintain comparability with the data obtained for the Alexandria residents. For the same reason, the symptom rates given for the Cairo visitors in 1978 are those for individuals who swam

1-2 days during the week. Because of the resulting decrease in usable responses and because of the disparity in the rates of GI and upper respiratory tract symptoms for nonswirnmers obtained from the first as compared to the second follow-up inquiry (Table A36), the data for the first two follow-up inquires were used to calculate the symptom rates for Cairo visitors in the 1978 trials. It can be seen from Table A35 that, with only three exceptions, the rates for the various symptoms were higher for swimmers than nonswirnrners. However, only with the gastrointestinal symptoms (vomiting or diarrhea) and possibly fever did the rates generally increase with the pollution levels at the three beaches as seen from the *E. coli* or enterococcus densities (Table A35). The rates were higher for children than adults (Figure 6).

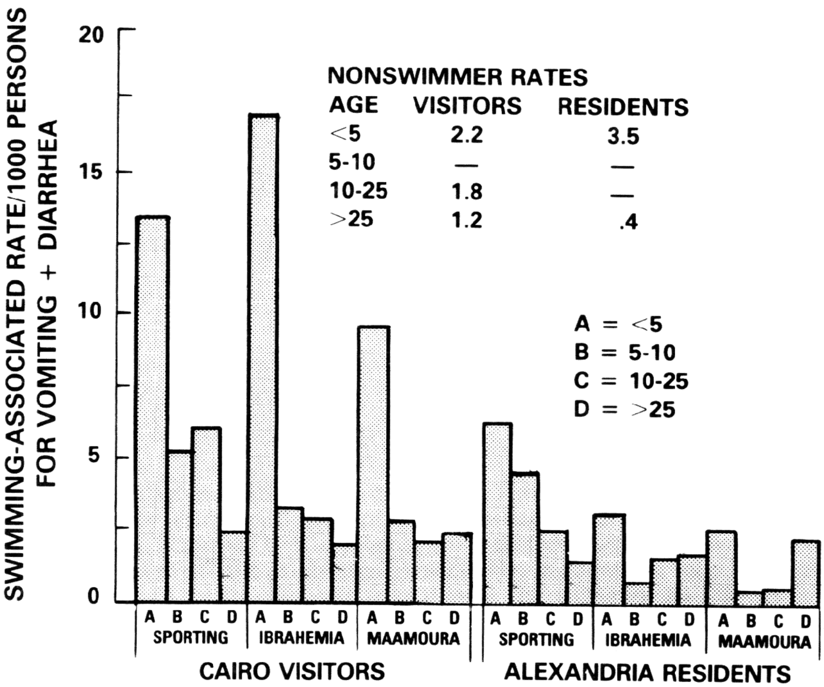

Figure 6. Age-specific, swimming-associated rates for vomiting or diarrhea by beach and study population for the 1977 Egyptian trials. The age-specific rates for the nonswimming Alexandria residents and Cairo visitors are shown as an insert.

Another finding that paralleled one obtained in the New York City study was that, with the exception of GI symptoms (vomiting or diarrhea) at the least polluted beach (Maamoura) and ear complaints at the other three beaches, the swimming-associated symptom rates per 1000 person-days decreased with increasing swimming activity. This can be seen from the analysis of the 1978 data from the Cairo visitors by the number of swimming days per week (Table A37).

Only three cases of jaundice were detected among the Cairo visitors, and there was no association to swimming, much less swimming in polluted waters. Four cases of typhoid fever were found among swimmers at Sporting, the most heavily polluted beach. The regression lines for the swimming-associated rates for vomiting or diarrhea against the enterococcus and *E. coli* mean densities for the Alexandria residents and Cairo visitors are shown in Figures 4 and 5. The data from which the lines were drawn are given in Table A38. As expected, the slopes of the lines for the Cairo visitors were greater than those for the Alexandria residents. Straight lines could be fitted to these illness-indicator relationships for the data from both the Cairo visitors and the Alexandria residents. However, examination of the relationships for the individual years suggests that there are plateaus as shown.

The plateaus, the differences in the indicator-illness curves for the Cairo visitors as compared to the Alexandria residents, and the higher GI symptom rates for children as compared to adults support the premise that the swimming populations were largely immune to the etiological agent(s). Moreover, from the similarities in the symptomatology and age distributions of symptoms in the Egyptian and New York City studies and the differences in the slopes and intercepts on the Y axis of the indicator-illness curves, we recommend the second explanation for the relationships obtained in the New York City study. However, these predictions relate only to the specific agent(s) responsible for the observed GI symptomatology. Swimming-associated illness rates exceeding those predicted by the illness-indicator relationships obtained from the New York City and Egyptian studies could occur with etiologic agents to which there is little immunity in the population . Thus, an attack rate of 13 percent appeared to be associated with fecal coliform densities of about 17,500/100 ml in the Dubuque shigellosis outbreak (15).

In addition to providing insights into the widespread distribution of the swimming-associated, pollution-associated gastroenteritis, its etiology and the role of immunity, the results of the Egyptian study suggest the circumstances under which typhoid fever could become a problem via the recreational route, i.e., near an outfall for untreated sewage. This finding, along with the available ID_{50} data for these agents (22), suggests the importance of the removal of particulates during primary and secondary sewage treatment in preventing the recreational transmission of this disease and other diseases whose agents have high infective doses. The absence of swimming-associated infectious hepatitis in an area where the endemic rate is high would suggest that, by the time they start to swim, even the Cairo children have been exposed and are immune to infection with hepatitis A virus.

LAKE PONTCHARTRAIN STUDY

This study was conducted during the summers of 1977 and 1978 at Levee beach which is located near the “mouth” of Bayou St. John on Lake Pontchartrain. Individuals swam both in the mouth of the Bayou and in a nearby roped-off area. In 1978, a second beach (Fontainebleau) located across the Lake was also included. The setting for the study differed in a number of important ways from that for the New York City study; there is very little tidal activity; the water is brackish (about 5 percent) and warmer during the summer; there is no beach as such but rather a series of steps leading downward from the grassy bank into the water. Most important of all, the sources of pollution were much less defined. According to local authorities, there were no discharges of sewage wastes mto the Lake or Bayou St. John. However, high coliform densities were observed at the beach following rainfalls during “wet years.” Presumably these were due to stormwater discharges reaching the beach via canals and bayous which empty into the Lake west of the beach.

Because of the ill-defined pollution sources, there was some reluctance to conduct a study at this location. However, the findings from sampling conducted in 1976 confirmed the high indicator densities following rainfalls and revealed moderate enterococcus densities during dry weather. Because of this, because of the desire to test the illness-indicator relationships under a different set of environmental conditions and because this study could be a vehicle for separating the two indicators which emerged as the best ones from the New York City study, trials were conducted in the summer of 1977.

When the rates for the individual symptoms were compared for swimmers versus nonswimmers, statistically significant differences were obtained only for vomiting, diarrhea, stomachache, earache, and skin complaints (Table A39). When the symptoms were grouped into categories, significantly higher rates for swimmers were obtained only for GI and "highly credible" GI symptoms, although there were differences for all the categories (Table A40). In general the GI symptom rates were higher for children than adults (Table A41). There were, several striking aspects of the findings which suggested (i) that the major source of the infective agents was in the Bayou and not stormwater runoff arriving from west of the beach, (ii) that enterococcus densities were better correlated with the GI symptom rates, and (iii) that, because of this, the source of the pathogens was rather remote (in time) from the beach.

First of all, the mean enterococcus densities in the "mouth" of the Bayou were generally higher, and at times markedly so, than those at the beach (roped-off area); this was much less true of *E. coli* (Table A42). Secondly, in contrast the findings from the New York City and Egyptian studies wherein the *E. coli* and enterococcus densities tended to parallel each other, high *E. coli* densities were associated with low enterococcus levels and vice versa. The former occurred during the period 7/30-8/28 when the average daily rainfall exceeded 0.43 inches per day. The overall swimming-associated GI symptom rates for the trials conducted during this period were less than those for the trials conducted prior to July 30 when the average daily rainfall was 0.12 inches per day and the enterococcus densities exceeded those of *E. coli* (Table A43). Thirdly, the indicator densities in the roped-off area approached those in the Bayou only during the rainy period and then only for *E. coli* (Table A43). Moreover, the lower enterococcus densities and GI symptom rates during the "wet period" suggested that stormwater reaching the beach from the west reduced the pathogen and enterococcus densities at the beach by dilution or exclusion of organisms whose source presumably was in the Bayou. Fourthly, the trials during which there were high rates of swimming-associated GI symptoms corresponded better with high enterococcus than high *E. coli* densities (Table A44); in fact, when the swimming-associated GI and HCGI symptom rates for the four lowest *E. coli* days were compared to those for the four highest days, the former were higher than the latter.(Table A45). Finally, it has been reported (65) that enterococci survive better than *E. coli*, especially in salt water.

The input data to the criteria model are given in Table A44. The considerable trial-to-trial variability in the indicator densities required that, even for the regression analysis by summers, the trials be clustered according to their indicator densities. The findings from the 1978 trials differed from those obtained in 1977 in a number of ways, and some of the differences made the interpretation of the illness-indicator density data even more difficult: 1978 was a somewhat "drier" year than 1977, and, in general, the densities of both indicators were reduced. Nevertheless, the swimming-associated rate for GI symptoms was almost the same (39/1000 persons in 1978 as opposed to 42/1000 in 1977). This suggested that rainfall induced stormwater runoff to the beach (and the resulting elevated indicator densities) was not the source of the infective agents responsible for the observed symptomatology.

The rationale derived from the examination of the 1977 information was applied to the 1978 data as follows. It was assumed: (i) that, during a "relatively dry" year, the travel time down the Bayou was even more protracted, (ii) that because of this, even the enterococcus densities were reduced relative to the pathogens, and (iii) that these lower enterococcus densities would be masked at the beach and even at the Bayou by those carried in with the stormwater. Three trials were associated with especially high *E. coli* and enterococcus densities in which the levels at the beach were as high or higher than those in Bayou (Table A46). Because these were the same three days during which there was a half-inch or more rainfall (Table A46), the data from these three trials were eliminated from the analysis. Since the premise was that the source of the infective agents was the Bayou and since the roped-off area was expected to be more heavily impacted by stormwater, the remaining trials were grouped into high and low. days based upon the Bayou indicator densities (Table A46), and these were used to calculate the mean indicator densities to which the symptomatology rates were compared. The mean indicator densities and associated GI and HCGI symptom rates as used later in the development of the criteria are given in Table A47.

The data from Fontainebleau beach, because of the relatively little trial-to-trial variability in the indicator densities, were used to derive a single relationship.

The 1978 data differed from the 1977 data in yet another way. In 1978 there were also statistically significant differences between swimmers and nonswimmers for the respiratory, other, EEN (ear, eye and nose) as well as disabling GI symptoms. This may have reflected a change in the pathogens present.

The Lake Pontchartrain study achieved its major objective. It, along with the third year of the New York City study, clearly showed enterococci to be superior to *E. coli* as a recreational water quality indicator. In addition, there were some important implications of the results obtained. First, they suggested some conditions under which even the enterococci may be deficient as a recreational water quality indicator. Second, they suggested that the etiological agent(s) of the swimming-associated gastroenteritis survives transport in the aquatic environment extremely well. Third, they provided a reasonably clear indication that stormwater runoff is less hazardous than wastewater discharges, and, because the two indicators are not specific for human fecal wastes, they may overstate the risk under these conditions.

BOSTON HARBOR STUDY

This study was conducted at two beaches in Boston Harbor in 1978. Its objective was to expand the data base for the criteria being developed and to confirm the observation that the measurable swimming-associated health effects were obtained at strikingly low indicator densities. As in the Lake Ponchartrain study, the sources of pollution to the two beaches, Revere and Nahant, were not as well defined as those in the New York City or Alexandria, Egypt studies. At the time it was screened for suitability in 1978, the mean enterococcus and *E. coli* densities at Revere beach were about 80/100 ml and exceeded those at Nahant by about an order of magnitude.

Four trials were conducted at each beach during June and July of 1978. The rates for the symptom categories are presented in Table A48. At both the Revere and Nahant beaches, the highest swimming-associated rates were for the total and HCGI symptoms, although the differences between the swimmer and nonswimmer rates were not significantly different. The differential rates were consistently greater at Revere than at Nahant beach, even though the mean indicator densities at the two beaches were not appreciably different (Table A49). This observation underscores the fact that the relationships being derived are generalities which may vary somewhat with a number of factors in the swimming population (i.e., their immune status, background illness rates, and even in the temporal and spacial relationship of the beach to its source of pollution). Nevertheless, the swimmer rates for GI symptoms were consistently higher than those for nonswimmers even at rather low levels of pollution as seen by the enterococcus or *E. coli* densities. The mean enterococcus and *E. coli* densities at Revere beach were less than those observed the previous year. These and the corresponding rates for GI and HCGI symptoms calculated by summer and by clusters of trials are given in Tables A49 and A50. The relationship of the swimming-associated rates to the indicator densities were more akin to those obtained at Lake Pontchartrain rather than New York City, i.e., higher rates for given indicator levels. This suggests differential biological decay of the indicators relative to the pathogens over more protracted transport times between the sources of pollution and the impacted beaches.

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SECTION 6
DEVELOPMENT OF CRITERIA

In order to reach the objective of the overall program, the development of health effects criteria for marine recreational waters, four questions needed to be answered. They were:

1. *Does swimming in sea water per se carry with it an increased risk of illness and, if so, to what type?*

Stevenson's findings (24) suggested that it is so for fresh, but not sea, waters Those from the EPA program indicated this was true of sea water swimming as well. In the Stevenson study, it was observed most with ear, eye and nose complaints, less so with upper respiratory symptoms and least with gastrointestinal symptomatology.

2. *Is there an association of the illness rates to pollution from domestic sewage; and if so, to what type of illness?*

Stevenson's results (24) suggested there is such an association for swimming in freshwater but not in seawater. His results were equivocal as to the type of symptom. Moore (8) could find no association for poliomyelitis or salmonellosis. The conclusion from the EPA program is unequivocal; there is an increased risk of gastroenteritis associated with swimming in waters more as opposed to less polluted with sewage. Furthermore, the increased risk occurs at beaches which meet and even exceed the existing EPA guidelines and those of most of the states. Both the Egyptian and American studies suggest that fever often accompanies the GI symptoms. There were no indications in any of the American studies that anyone required hospitalization.

With the Cairo visitors to the Alexandria beaches, no association between swimming and infectious hepatitis (IH) could be detected, even among individuals who swam in waters so heavily polluted that they were aesthetically undesirable. The assumption was that the children of the Cairo visitors, coming from better sanitary environments and swimming in waters receiving waste loads from a population with a high endemic rate of IH, would be the most susceptible portion of the swimming population. However, even these children may have been exposed and rendered immune to the agents by the age they start swimming (immersion of the head in the water). A different study population is needed to resolve this question.

It is of interest that four cases of typhoid fever did occur among swimmers at the heavily polluted, aesthetically undesirable beach. This was not statistically significant and may have been a spurious result. However, since the ID50 for salmonellae is high (22), and that for IH is thought to be fairly low, these results lend credence to the postulated immunity explanation for the absence of IH among swimmers. There was no indication of poliomyelitis in any of the studies. Thus, Moore's conclusions (8) with regard to poliomyelitis and salmonellosis remain as true today as they were then.

3. *Which, if any, of the potential indicators of water quality best defines the association of GI symptomatology to water quality?*

The New York City study was designed to answer this question for beaches impacted with the sewage effluents from large urban areas. The Coney Island beaches were affected primarily by sewage emerging from the mouth of the Hudson River, and although these were combined effluents subject to the effect of rainfall, treated to various degrees, and chlorinated only in part, they nevertheless represented a relatively well defined source. The criterion used to select the "best" indicator was the degree of association between its levels in the bathing water and the swimming-associated rate for gastrointestinal symptoms. It was evident from the New York City study that enterococci and, to a *much lesser extent, E. coli* were the best indicators of those examined (Table 4). *Fecal cohforms were a relatively poor indicator system.*

The marked superiority of enterococci over *E. coli* as a recreational water quality indicator was confirmed in the subsequent studies conducted in the United States. Higher correlation coefficients (r) for the mean indicator densities in the water against the swimming-associated rates for total or highly credible GI symptoms were obtained with enterococci than with *E. coli* (Table 5). However, comparable correlation coefficients were obtained for the two indicators in the Egyptian studies (Table 5). One explanation for this difference lies in the nature and proximity of the pollution sources. The sources of fecal pollution to the Alexandria beaches were untreated, not disinfected, and relatively close to the beaches. A portion of those to the New York City beaches were both treated and disinfected, and they were more distant from the beaches. Furthermore, more of the sewage emerging from the Hudson River and Upper Hudson Bay was treated and/or disinfected in 1975 than in 1974. This appears to correspond with poorer correlations of the indicator densities to gastrointestinal symptomatology, especially for *E. coli* (compare the 1973-74 to 1973-75 "r" values in Table 5). Insofar as could be determined, there were no nearby sources of human fecal wastes to either the Lake Pontchartrain or Boston Harbor beaches.

Implicit to the above explanation is the conclusion that enterococci more closely resembles the pathogen(s) than does *E. coli* with regard to its survival characteristics during sewage treatment, disinfection, and transport in the marine environment. Furthermore, as the level of sewage treatment and disinfection increases and/or the transport time becomes more protracted, even the densities of the enterococcus indicator are not maintained comparable to those of the pathogen. This and other considerations to be discussed notwithstanding, the mean enterococcus density does provide a meaningful and useful index of the potential for the observed gastrointestinal symptomatology.

Four possible indicator Systems were not evaluated in the course of the New York City studies. As part of the EPA program, new methods have been developed or existing methods have been modified for each of the four indicators, *Candida albicans* (42), bifidobacteria (40), coprostanol (48) and male specific DNA, coliphage (41). Some preliminary evaluations were made with the first two. The densities of *C. albicans* were too low and variable in sewage-polluted waters to be of much value. Bifids were found to be fecal specific and reasonably human specific; however, their use as the basis for the criteria is precluded by their exceedingly poor survival during chlorination and transport in aquatic environments. Nevertheless, the recovery of these bacteria from environmental water samples indicates an "immediate" source of undisinfected human or, to a lesser extent, porcine fecal wastes (40). Coprostanol and the f-1 male specific coliphage need to be evaluated as water quality indicators and as conservative tracers.

4. *Can the relationship of swimming-associated health effects to the quality of the water, as determined by a microbial or chemical indicator, be quantified sufficiently to produce health effects quality criteria for marine recreational waters?*

The response to this question will be considered in the next section.

The Criteria

The regression lines for the rates of swimming-associated GI and HCGI symptoms against the mean enterococcus and *E. coli* densities when examined by trials clustered by indicator density or by summer are presented in Figure 7. The input data for the analyses

TABLE 5. CORRELATION COEFFICIENTS FOR ENTEROCOCCUS AND *E. coli* DENSITIES AGAINST THE GASTROINTESTINAL SYMPTOM RATES FOR UNITED STATES AND EGYPTIAN STUDIES

Symptom	Studies	Years	Correlation Coefficients (r) for trial clustered by: Indicator Densities[2]		Summers[3]	
			Enterococcus	*E. coli*	Enterococcus	*E. coli*
Gastrointestinal	New York City	1973-74	.90	.94	.95	.96
	New York City	1973-75	.81	.51	.84	.56
	L. Point.-Boston Harbor[1]	1977-78	.84	.16	.86	.02
	All U.S.	1973-78	.82	.25	.86	.20
Highly Credible GI	New York City	1973-74	.98	.96	.96	.97
	New York City	1973-75	.96	.56	.75	.52
	L. Point.-Boston Harbor	1977-78	.62	.57	.74	.54
	All U.S.	1973-78	.75	.54	.72	.52
	Alex., Egypt (Resid.)[4]				.69	.76
	Alex., Egypt (Visit.)[5]				.88	.87

[1] Lake Pontchartrain and Boston Harbor studies analyzed together.
[2] Trials clustered by similar indicator densities.
[3] Trials grouped by summers.
[4] Alexandria residents at Alexandria beaches.
[5] Cairo visitors to Alexandria beaches.

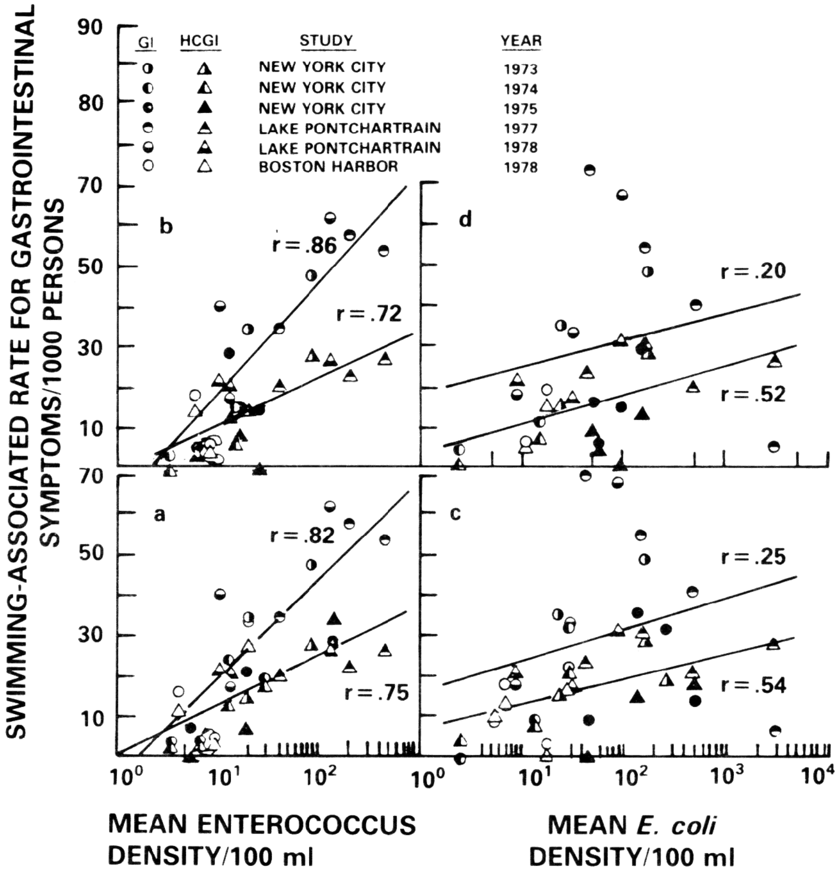

Figure 7. Swimming-associated rates for GI symptoms against the mean enterococcus and *E. coli* densities in the water. Data from all U.S. studies. Values for the points given in Tables 6-9. Definition of highly credible GI symptoms given in text, as is the rationale for clustering the trials. See Figure 2 for the meanings of a, b, c, and d. The actual trials clustered are shown in Tables A8 through A31, A44, A46, A47 and A50 in Appendix A.

are given in Tables 6-9 and the results of the regression analyses are given in Table 10. It is obvious that enterococcus densities in the bathing water provide the most meaningful and useful relationship to the observed GI symptomatology. The formulae for the two pairs of enterococcus regression lines, the correlation coefficients (r) for the lines, and the corresponding p values are given in Table 10 along with the equations obtained by averaging the slopes and intercepts of each pair of lines. The “fits” for quadratic equations were no better than those for linear equations. These lines are shown in Figure 8 along with the 95 percent confidence limits around the lines. These were obtained from the data for the clustered trials. The confidence limits of the predicted rates for the clustered trials are given in Table A51.

The Y and X regression lines, given in Table 10 for enterococcus and shown with their confidence limits in Figure 8, predict the illness rates for the indicator densities. However, as noted earlier in this report, the conceptual framework for the program was that a decision would be made as to the *acceptable* risk level and this would be