PROPOSED PROTOCOL FOR EPIDEMIOLOGICAL INVESTIGATIONS IN RECREATIONAL BATHING WATERS FOR LATIN AMERICA AND THE CARIBBEAN

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SUMMARY

An International Experts Consultation sponsored by PAHO with the participation of world renowned experts such as Dr. David Kay and Dr. Alfred Dufour, among others, took place in Mexico City from the 28 to 30 November 2005. The specific goal of the meeting was to contribute in the development of a research Protocol for Epidemiological Investigations in Recreational Bathing Waters related to the impact on health for Latin America and the Caribbean (LAC) to be applied by the countries to determine the applicability of the WHO Guidelines for Safe Recreational Water Environment to the tropical waters and conditions of LAC. A review is made of the technical basis of Volume 1, Coastal and fresh waters, of the World Health Organization (WHO) Guidelines for Safe Recreational Water Environments that was officially released in October 2003. WHO recognizes that the United Kingdom randomized controlled trials, used as the key epidemiological studies for the derivation of the WHO Guideline Values for recreational waters, were primarily indicative of adult populations bathing in marine waters in temperate climates. As such, WHO recommended that the countries, especially developing countries where priorities often must be established for projects of first necessity in the context of limited economic resources, conduct local epidemiological studies directed at establishing the relationship between health risk and indicator organisms. The paper proceeds to summarize the major issues, conclusions and recommendations of the Experts Consultation. The initial concepts of a preliminary Protocol for Epidemiological Investigations in Recreational Bathing Waters for Latin America and the Caribbean are discussed. This protocol will consider both prospective cohort and randomized control trial approaches and will be generic in nature taking into account the tropical waters and the social economic conditions in LAC and the disparity of those conditions among the countries.

KEY WORDS
Epidemiology, Recreational Waters, Guidelines, Health.
INTRODUCTION


The preliminary publication of the guidelines was made in 1998 (WHO, 1998). As part of this process, Prüss (1998) summarized the epidemiological studies conducted worldwide. Of the 37 studies evaluated, 22 qualified for inclusion in the evaluation. Figure 1 presents the relation between indicator organism density and illness risk for marine waters. Of the 22 studies selected, 18 were prospective cohort studies, two retrospective cohort studies and two were randomized controlled trials, as summarized in Table 1. In 19 of the 22 epidemiological studies examined in the Prüss’ (1998) review, the rate of certain symptoms or symptom groups was significantly related to the count of fecal indicator bacteria in recreational water. Hence, there was a consistency across the various studies, and gastrointestinal symptoms were the most frequent health outcome for which significant dose-related associations were reported. The overwhelming evidence provided by most of the epidemiological studies conducted worldwide over the past 30 years and reviewed by the World Health Organization (WHO, 2003) has shown that the indicator organisms which correlate best with health outcome were enterococci/fecal streptococci for marine waters. Other indicators showing correlation were fecal coliforms and staphylococci.

In marine bathing waters, the United Kingdom randomized controlled trials (Kay et al., 1994; Fleisher et al., 1996) probably contained the least amount of bias. These studies gave the most accurate measure of exposure, water quality and illness compared with observational studies where an artificially low threshold and flattened dose–response curve (due to misclassification bias) were likely to have been determined.

The United Kingdom randomized controlled trials were adopted by WHO as the key epidemiological studies for derivation of the WHO Guideline Values for recreational waters. However, WHO recognized that they are primarily indicative for adult populations in marine waters in temperate climates. Studies that reported higher thresholds and case rate values (for adult populations or populations of countries with higher endemicities) may suggest increased immunity, which is a plausible hypothesis but awaits empirical confirmation. Most studies reviewed by Prüss (1998) suggested that symptom rates were higher in lower age groups, and the United Kingdom studies may therefore systematically underestimate risks to children.

WHO concluded that the controlled randomized trial studies were the most accurate and the WHO Experts’ Committee based the new guidelines for marine waters on the only study of this type for enteric illness, reported by Kay et al. (1994), in the United Kingdom. It is noted that these are temperate waters and not characteristic of the tropical waters of most of Latin America and the Caribbean.

The guideline values for microbial water quality given in Table 2 are derived from the key randomized control studies described above. The values are expressed in terms of the 95th percentile of numbers of intestinal enterococci per 100 ml and represent readily understood levels of risk based on the exposure conditions of the key studies. WHO defined a 1% risk for illness occurrence due to bathing as “an excess illness of one incidence in every 100 exposures”, compared to non-bathers. The values may need to be adapted to take account of different local conditions.

Figure 2, upon which the WHO guideline values of Table 2 are derived, shows the dose-response relation between health risk and the 95th percentile value of the intestinal enterococci indicator for contracting gastro-enteritis and acute febrile respiratory illness (AFRI) (Fleisher, et al. 1996) by bathing in microbiologically contaminated water.
As such, WHO recommended that the countries, especially in developing countries where priorities often must be established for projects of first necessity in the context of limited economic resources, conduct local epidemiological studies directed at establishing the relationship between health risk and indicator organisms. The WHO guidelines present the state-of-the-art. Notwithstanding, the application of these guidelines to the tropical waters of most of Latin America and the Caribbean is of concern.

The cost of epidemiological studies is considered justifiable in the context of the large potential capital expenditures associated with control systems. Also, the adaptation of a particular risk level for human health should be based on the local socio-economic situation if it is to be viable.

Figure 1: Risks of illness in swimmers against bacteria count in marine waters
Table 1: List of selected studies

<table>
<thead>
<tr>
<th>First author</th>
<th>Year</th>
<th>Country</th>
<th>Study design</th>
<th>Water</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fleisher</td>
<td>1996</td>
<td>UK</td>
<td>Randomized controlled trial</td>
<td>marine</td>
<td>D</td>
</tr>
<tr>
<td>Haile</td>
<td>1996</td>
<td>US</td>
<td>Prospective cohort</td>
<td>marine</td>
<td></td>
</tr>
<tr>
<td>Van Dijk</td>
<td>1996</td>
<td>UK</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>C</td>
</tr>
<tr>
<td>Bandaranayake</td>
<td>1995</td>
<td>New Zealand</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>D</td>
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<tr>
<td>Kueh</td>
<td>1995</td>
<td>Hong Kong</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>B</td>
</tr>
<tr>
<td>Medical Research Council</td>
<td>1995</td>
<td>South Africa</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>a, c</td>
</tr>
<tr>
<td>Kay</td>
<td>1994</td>
<td>UK</td>
<td>Randomized controlled trial</td>
<td>marine</td>
<td>D</td>
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<tr>
<td>Pike</td>
<td>1994</td>
<td>UK</td>
<td>Prospective cohort/**</td>
<td>marine</td>
<td>a, b, c</td>
</tr>
<tr>
<td>Corbett</td>
<td>1993</td>
<td>Australia</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>a, d</td>
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<tr>
<td>Fewtrell*</td>
<td>1992</td>
<td>UK</td>
<td>Prospective cohort</td>
<td>fresh</td>
<td>D</td>
</tr>
<tr>
<td>UNEP/WHO no 46</td>
<td>1991</td>
<td>Israel</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>b, d</td>
</tr>
<tr>
<td>UNEP/WHO no 53</td>
<td>1991</td>
<td>Spain</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>a, b, d</td>
</tr>
<tr>
<td>Cheung1</td>
<td>1989</td>
<td>Hong Kong</td>
<td>Prospective cohort</td>
<td>marine</td>
<td>a, b</td>
</tr>
<tr>
<td>Ferley1</td>
<td>1989</td>
<td>France</td>
<td>Retrospective cohort</td>
<td>fresh</td>
<td>a, b, c</td>
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<tr>
<td>Lightfoot1</td>
<td>1989</td>
<td>Canada</td>
<td>prospective cohort</td>
<td>fresh</td>
<td></td>
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<tr>
<td>Fattal, UNEP/WHO no 20</td>
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<td>Israel</td>
<td>prospective cohort</td>
<td>marine</td>
<td>b, d</td>
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<tr>
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<td>Canada</td>
<td>prospective cohort</td>
<td>fresh</td>
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<tr>
<td>Dufour</td>
<td>1984</td>
<td>US</td>
<td>prospective cohort</td>
<td>fresh</td>
<td>a, b</td>
</tr>
<tr>
<td>Cabelli</td>
<td>1983</td>
<td>Egypt</td>
<td>prospective cohort</td>
<td>marine</td>
<td>a, b, c</td>
</tr>
<tr>
<td>Cabelli</td>
<td>1982</td>
<td>US</td>
<td>prospective cohort</td>
<td>fresh &amp; marine</td>
<td>a, b</td>
</tr>
<tr>
<td>Mujeriego</td>
<td>1982</td>
<td>Spain</td>
<td>retrospective cohort/**</td>
<td>marine</td>
<td>b, a</td>
</tr>
<tr>
<td>Stevenson, 3-day study</td>
<td>1953</td>
<td>US</td>
<td>prospective cohort</td>
<td>fresh</td>
<td>b, c, d</td>
</tr>
</tbody>
</table>

a: Only use of seasonal mean for analysis of association with outcome reported.
b: Control for less than three confounders reported, or no reporting at all.
c: Exposure not defined as head immersion/head splashing/water ingestion.
d: <1700 bathers and 1700 non-bathers participating in the study.
* Exposure is white-water canoeing; similar to swimming, water intake is likely, while turn-over or through ingestion or inhalation of droplets.
** Cross-sectional study.

Remark: Two studies analyze the same data sets but come to different conclusions.

Furthermore, at the global launching of the WHO Guidelines for Safe Recreational-water Environments during the XXVIII AIDIS Congress held in Cancun Mexico on 30 October 2002, the following conclusions were made:

“…Concerns were expressed about the broad applicability of the WHO Guidelines to Latin America and the Caribbean. Issues discussed included: tropical waters, local endemic illnesses, susceptibility of children and the elderly, tourists, and length of exposure.

It was concluded that epidemiological studies should be conducted in the Region to evaluate the applicability of the Guidelines to Latin American and the Caribbean temperate and tropical environments. It was also recommended that pilot studies be conducted applying the Annapolis Protocol for beach management. Generally, there was recognition of the need for the guidelines and an appreciation was expressed for the efforts of WHO/PAHO.”
### Table 2: Guideline values for microbial water quality of recreational waters

<table>
<thead>
<tr>
<th>95&lt;sup&gt;th&lt;/sup&gt; percentile value of intestinal enterococci/100 ml (rounded values)</th>
<th>Basis of derivation</th>
<th>Estimated risk per exposure</th>
</tr>
</thead>
</table>
| ≤40 A | This range is below the NOAEL in most epidemiological studies. | <1% GI illness risk  
<0.3% AFRI risk |
| | | The upper 95th percentile value of 40/100 ml relates to an average probability of less than one case of gastroenteritis in every 100 exposures. The AFRI burden would be negligible. |
| 41–200 B | The 200/100 ml value is above the threshold of illness transmission reported in most epidemiological studies that have attempted to define a NOAEL or LOAEL for GI illness and AFRI. | 1–<5% GI illness risk  
0.3–<1.9% AFRI risk |
| | | The upper 95th percentile value of 200/100 ml relates to an average probability of one case of gastroenteritis in 20 exposures. The AFRI illness rate at this upper value would be less than 19 per 1000 exposures, or less than approximately 1 in 50 exposures. |
| 201–500 C | This range represents a substantial elevation in the probability of all adverse health outcomes for which dose–response data are available. | 5–10% GI illness risk  
1.9–3.9% AFRI risk |
| | | This range of 95th percentiles represents a probability of 1 in 10 to 1 in 20 of gastroenteritis for a single exposure. Exposures in this category also suggest a risk of AFRI in the range of 19–39 per 1000 exposures, or a range of approximately 1 in 50 to 1 in 25 exposures. |
| >500 D | Above this level, there may be a significant risk of high levels of minor illness transmission. | >10% GI illness risk  
>3.9% AFRI risk |
| | | There is a greater than 10% chance of gastroenteritis per single exposure. The AFRI illness rate at the 95th percentile point of >500/100 ml would be greater than 39 per 1000 exposures, or greater than approximately 1 in 25 exposures. |

**Notes:**

a. Abbreviations used: A–D are the corresponding microbial water quality assessment categories (see section 4.6) used as part of the classification procedure (Table 4.12); AFRI = acute febrile respiratory illness; GI = gastrointestinal; LOAEL = lowest-observed-adverse-effect level; NOAEL = no-observed-adverse-effect level.

b. The “exposure” in the key studies was a minimum of 10 min of swimming involving three head immersions. It is envisaged that this is equivalent to many immersion activities of similar duration, but it may underestimate risk for longer periods of water contact or for activities involving higher risks of water ingestion (see also note 8).

c. The “estimated risk” refers to the excess risk of illness (relative to a group of non-bathers) among a group of bathers who have been exposed to faecally contaminated recreational water under conditions similar to those in the key studies.

d. The functional form used in the dose–response curve assumes no further illness outside the range of the data (i.e., at concentrations above 158 intestinal enterococci/100 ml; see Box 4.3). Thus, the estimates of illness rate reported above this value are likely to be underestimates of the actual disease incidence attributable to recreational water exposure.

e. The estimated risks were derived from sewage-impacted marine waters. Different sources of pollution and more or less aggressive environments may modify the risks.

f. This table relates to risk to “healthy adult bathers” exposed to marine waters in temperate north European waters.

i. This table may not relate to children, the elderly or the immunocompromised, who could have lower immunity and might require a greater degree of protection. There are no adequate data with which to quantify this, and no correction factors are therefore applied.

j. Epidemiological data on fresh waters or exposures other than swimming (e.g., high-exposure activities such as surfing, dinghy boat sailing or whitewater canoeing) are currently inadequate to present a parallel analysis for defined reference risks. Thus, a single series of microbial values is proposed, for all recreational uses of water, because insufficient evidence exists at present to do otherwise. However, it
is recommended that the length and frequency of exposure encountered by special interest groups (such as bodysurfers, board riders, windsurfers, sub-aqua divers, canoeists and dinghy sailors) be taken into account (chapter 1).

k. Where disinfection is used to reduce the density of index organisms in effluents and discharges, the presumed relationship between intestinal enterococci (as an index of faecal contamination) and pathogen presence may be altered. This alteration is, at present, poorly understood. In water receiving such effluents and discharges, intestinal enterococci counts may not provide an accurate estimate of the risk of suffering from gastrointestinal symptoms or AFRI.

l. Risk attributable to exposure to recreational water is calculated after the method given by Wyer et al. (1999), in which a log10 standard deviation of 0.8103 for faecal streptococci was assumed. If the true standard deviation for a beach is less than 0.8103, then reliance on this approach would tend to overestimate the health risk for people exposed above the threshold level, and vice versa.

m. Note that the values presented in this table do not take account of health outcomes other than gastroenteritis and AFRI. Where other outcomes are of public health concern, then the risks should also be assessed and appropriate action taken.

n. Guideline values should be applied to water used recreationally and at the times of recreational use. This implies care in the design of monitoring programmes to ensure that representative samples are obtained.

Source: WHO (2003), Guidelines for safe recreational water environments.

**Figure 2: WHO- Risks for GI and AFRI due to EI Exposure**

Source: Commission of European Communities (2002)

**INTERNATIONAL EXPERTS CONSULTATION**

The goal of the International Experts Consultation was to coordinate with national and international institutions in a collaborative effort in epidemiological research for tropical recreational bathing waters to ascertain the applicability of the *WHO Guidelines for Safe Recreational Water Environments* to the tropical waters and conditions of Latin America and the Caribbean (LAC). The specific goal of the International Experts Consultation meeting (3 days) held in Mexico City was to contribute in the development of a said research protocol for epidemiological investigations. The international experts who participated included: Dr. David Kay (University of Wales, Great Britain), Dr. Nicholas J. Ashbolt (University of New South Wales, Australia), Dr. med Albrecht Wiedenmann (Communicable Diseases and Environmental Hygiene Section in the Public Health Department of the Administrative District Loerrach, Germany), Dr. Alfred Dufour (USEPA) and Ms. Claudia Condé Lamparelli (CETESB, Brazil). PAHO/WHO was represented by Dr. Jacobo Finkelman (PWR-MEX),
Henry Salas (CEPIS-BS/SDE), Sally Edwards (FEP- FO/USMB) and Keira Robinson (CEPIS-BS/SDE). Five counterpart professionals of Mexico also participated representing the following Mexican institutions: Federal Commission for Protection Against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios- COFEPRIS); Mexican Institute of Water Technology; Centre for Food and Development Research, Sinaloa, Mexico; University of Guadalajara; and National Autonomous University of Mexico. The consultation took place in Mexico City, D.F. on November 28 to 30, 2005 in the offices of the Department of Sanitation and Water Quality of the National Water Commission of Mexico (Gerencia de Saneamiento y Calidad del Agua de la Comisión Nacional del Agua). The University of Guadalajara had developed a preliminary epidemiological protocol for beaches that was commented on by the international experts.

A subsequent meeting financed by the Mexican Government was held in Acapulco, Mexico immediately thereafter on December 1 and 2, 2005 to present the results of the Experts Consultation to a larger audience to obtain insight and comments as to the implementation viability of the proposed protocol in Mexico and other countries in LAC.

EXPERTS CONSULTATION MEETING: SUMMARY HIGHLIGHTS

While a number of previous epidemiologic investigations for bathing beaches have been conducted around the world, substantial methodological variation exists across these studies. For example, each individual investigation may apply a unique case definition or water quality measure, or employ distinctive procedures for case and control selection thereby resulting in a lack of coordination and hence the inability to apply the results for WHO guideline development.

In the absence of a universal and specifically outlined peer-reviewed protocol, LAC based studies are subject to the aforementioned potential fallacies, as well as designing a plethora of flawed investigations with opaque protocol or logistics design and inappropriate sample sizes. In addition, without a guiding protocol, the region may produce a multiplicity of uncoordinated or incomparable investigations due to dissimilar exposed and bathing groups, poor or diverse exposure and outcome measures, or a heterogeneous definition measurement of confounders. This lack of harmonization between studies will render the data pooling impossible and cross-study comparison from such unsystematic investigations may likely not be feasible. It is improbable that the results from these studies will relevantly contribute to standardized WHO guideline development for tropical recreational waters. Advance awareness of these specific dangers is thus necessary to design the best possible protocol, which will lead to coordinated investigations that will contribute to future WHO guidelines for LAC-specific recreational waters.

Indications of the above flaws were made evident upon reviewing the epidemiological bathing beach study protocols that have been or are being applied in Mexico that were different and unrelated; the results of which will not be compatible.

To develop a suitable and sound regional protocol, the process for developing WHO guidelines needs to be well understood. In addition, an embedded peer review process of a draft protocol, before establishing a specific and finalized LAC protocol is needed. This final protocol should comprise LAC-specific logistics and should ensure that all ethical considerations have been met, that the statistical analysis to be undertaken is well-defined and that a suitable number of people for the study population (which can be determined by power calculations) is decided upon in order to detect the effect between the exposure and the disease outcome being investigated.

Defining Variables

The appropriate practice for defining exposure and outcome variables means defining and measuring these variables as precisely as possible. In terms of exposure, the measurement should be attributed precisely to the smallest group possible, i.e., the individual.

For sampling purposes, it is recommended that a few water quality measures be done well and intensively, with all resourced internal and external laboratory analytical water quality control.
Three primary indicator organisms should be measured. These are Enterococci, *E. coli* (particularly for freshwater) and the Coliphages. The following three organisms may also be considered: *Clostridium perfringens* (general human, persistent fecal marker), total *Staphylococcus*, and *Staphylococcus aureus* (both indicate bather density). Given the likely role of human enteric viruses and emerging methods for quantitative-PCR for human adenoviruses and Norovirus, the addition of these latter two pathogens could also be valuable research parameters.

As with the exposure measure, it is crucial that future studies carefully define all outcome measures, with initial steps involving outlining a very specific case definition. Once decided upon, the case definition(s) should be peer reviewed and comprehensively researched to acquire data on these case definitions.

**Confounding Factors and Bias**

Information garnered from this research should also offer awareness about areas of potential concern in the study design, such as confounding factors as well as other areas of bias. Once aware of these potential confounders (diet, risky activities, lifestyle habits, and socio-economic status, to name a few), a confounder identification process needs to be incorporated into the study design. The most appropriate way to facilitate this identification process is to utilize a questionnaire. Previously utilized and approved questionnaires from international and regional studies should be gathered for the purpose of comparison. Existing questionnaires should be reviewed (Salas & Robinson, 2006) and additional LAC-specific confounding factors (water source, sewage, farm/domestic animal contact) can then be incorporated. A newly formed questionnaire should undergo pilot testing to ensure the validity, reliability and reproducibility of the items. Data collected from the questionnaires can be subsequently incorporated into statistical analysis, likely logistic regression analysis, to determine the effect of these potential confounders.

In addition, recall bias in terms of symptom reporting, as well as bias due to perception, both of which play a part in altering participants’ self-report and should be controlled for as much as possible in the design of the study. A method that may be used to minimize bias due to participants’ perception involves including dummy questions in the questionnaires. Including several dummy items will elicit whether the participants are falsely reporting symptoms solely due to their awareness of the study objective.

Other types of bias to be aware of are misclassification, which may occur due to measurement technique of indicator organisms; self-selection bias, which occurs when the population is a volunteer sample; and pre-condition bias. Another bias (no-specific name) may arise due to the varying interpretations that occur when translating from a determined concentration of indicator organism to a comprehensible definition of individual exposure.

Preparing and acquiring the foresight on potential areas that may present bias and hinder study results will facilitate the construction of the most appropriate study for the region.

**Statistics**

A sample size sufficient to detect the effect of the exposure on the disease burden is required. Establishing the correct size is a matter of utilizing appropriate statistical power calculations.

The epidemiologic statistician should search for dose response relationships by quartiles, quintiles and deciles of indicator organism concentration to which the bathers were exposed. Logistic regression analysis, the most frequently used statistical procedure for exposure-disease assessment, may be used to quantify the effects of the exposure on the outcome as well as the effects of the confounding factors on the exposure-outcome relationship being investigated. Finally, all statistics, should be conducted in such a way that the investigations may be presented as international peer reviewed literature.
Latin America and the Caribbean Specific Implementation Factors

There are LAC-specific implementation factors that need to be considered. For instance, relative to Western European countries, there may be a large proportion of individuals who do not have access to phones or email and consequently may be lost after the initial interview. This group may have a unique characteristic in common - in this case, membership in a lower socioeconomic bracket. The loss of a large proportion of this lower economic class will introduce bias into the study rendering the study results to only mid to higher socioeconomic class individuals. These considerations need to be accounted for in the study design as much as possible. Remuneration for the participants in the form of travel expenses coverage may provide an incentive to return. The study coordinators may also consider a home follow-up visit or alternatively, request that the participants return to the place of study for follow-up interviews (ensuring that the participants are compensated for their cooperation).

It is essential, when conducting epidemiological studies, to familiarize with the region where the study is being conducted. For instance, the high background incidence of diarrhea is another unique characteristic of LAC that must be taken into account when developing the epidemiological protocol. Likewise, cultural differences may dictate that one method of recruitment or follow-up may be more efficient than another in a certain region. Therefore, to motivate the people, local customs and culture should also be well-researched.

Ideas for the Study Design

The design of the study, whether it is a randomized control trial (RCT) or a prospective cohort, should aim to obtain the best results possible under the conditions at hand, and to minimize and quantify bias.

There are a number of advantages and disadvantages for both the RCT and the prospective cohort study (see Table 3). For instance, a certain disadvantage of the prospective cohort design relative to the RCT, is that a larger sample size will be required in order to detect any effect between the exposure and outcome variables. Alternatively, an advantage of the prospective cohort is that it allows for a more realistic setting. An advantage in favor of the RCT design is that confounding factors such as socio-economic status (SES) or class differences (living conditions and preferences) may be balanced between the groups due to the randomization process.

List of Essentials for the Protocol Document

It is of the utmost importance that an appropriate protocol design and logistics document, including all aspects aforementioned, has been established at least six months pre-study commencement to allow for appropriate peer-review. Several recommendations to ensure that a protocol is appropriate have been mentioned above (thorough research of the subject area with regional considerations, suitable sample population and sample size, most appropriate study design, appropriate exposure/outcome definitions, appropriate methodological procedures, accounting for confounding factors and biases, and appropriate statistical analysis). These items are all pertinent to epidemiological investigations and should be clearly described in the protocol. In addition, an appropriate study site, where a human or animal fecal indicator source is nearby, should be chosen. Furthermore, it is essential that this sample of participants should appropriately represent the true population to whom the investigation results are being generalized.

Compliance Monitoring

The concept of the Annapolis Protocol (WHO, 1999) is recommended. Basically it attempts to accommodate ‘natural’ background variability and allows for discounting of samples. It states that non-compliance is predictable and aims to protect public health through appropriate management action, e.g. ‘Advisories’ using real-time signage.

It was recommended to follow Chapter 4 of the WHO Guidelines (2003), which include 95%ile, HACCP and monitoring. In terms of the public perception of conducting the study, again, it is recommended that the guidelines from Chapter 4 should be followed.
Table 3 - Advantages and disadvantages of potential study designs that may be used to assess risk of bathing water exposures

<table>
<thead>
<tr>
<th>Study Design</th>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
</table>
| 1. Randomized Control Trials (RCT) | Suitable for ‘normal’ bathing beach risk assessment  
Extensive ‘confounder’ data are acquired  
Medical examination and other bio-medical test are possible  
Concentration precisely defined in terms of water quality and time  
Will produce the most precise exposure-response curve (concentration response)  
Accommodates spatial and temporal variability on the beach  
WHO recommended approach to provide data to extend the 2003 WHO Guidelines  
Costs will likely be less than the prospective cohort | May be ethical considerations  
Exposure may be somewhat ‘artificial’ (may need to consider the affect of longer exposures with respect to epidemiological studies)  
Limited to ‘compliant’ locations |
| 2. Prospective cohort studies | Highly polluted sites may be studied  
Can be applied to activities needing ‘skill’ and special user groups (canoeists)  
No ethical constraints e.g. children and those with ‘own volition’  
Exposed population may be more representative to the actual swimmer population  
Lends itself to ‘regulation’  
Exposure may be more realistic relative to actual swimming conditions | Exposure-response less precise due to exposure measures used  
Potential misclassification bias due to exposure measures used to date  
Confounding is introduced by self-selection of bather/non-bather status  
Needs within day water quality homogeneity  
Difficult precisely to define a NOAEL |
| 3. QMRA (Quantitative Microbial Risk Assessment) | Can be modeled and populated with literature sourced data including pathogen indicator inactivation in temperate and tropical water environments  
Tourist/resident problem can be addressed via susceptibility weights  
Could be applied to ‘new’ sites with no monitoring in developing nations  
Facilitates scenario hindcasting and forecasting  
Can model uncertainty, variability  
Can incorporate fate and transport data from other studies which is cost effective  
Relatively inexpensive | Requires many assumptions to fill-in data-poor areas  
Often need populating with pathogen flux and fate/transport empirical data which can be logistically difficult  
Ingestion data often, at best an estimate |
FUTURE ROADMAP

Based on the discussions and conclusions of the International Experts Consultation in Mexico, the next stage will involve developing a LAC-specific research protocol for epidemiological investigations of bathing beaches. Previously conducted epidemiological investigations pertaining to recreational water quality will provide a prototype which will serve as a guideline in order to ensure the success of future investigations to be conducted in LAC.

The development of said protocol has been initiated by PAHO and a peer reviewed Protocol for epidemiological investigations in recreational bathing waters for Latin America and the Caribbean will be available at the end of 2006.

REFERENCES


