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Water Research 38 (2004) 1296–1304

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## Derivation of numerical values for the World Health Organization guidelines for recreational waters

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Received 17 February 2003; received in revised form 17 November 2003; accepted 26 November 2003

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### Abstract

In April 2001, draft ‘Guidelines’ for safe recreational water environments were developed at a World Health Organization (WHO) expert consultation. Later the same month, these were presented and discussed at the ‘Green Week’ in Brussels alongside the on-going revision of the European Union Bathing Water Directive 76/160/EEC. The WHO Guidelines cover general aspects of recreational water management as well as define water quality criteria for various hazards. For faecal pollution, these include faecal indicator organism concentrations and an assessment of vulnerability to faecal contamination. Central to the approach set out in the WHO Guidelines are: (i) the concept of beach profiling to produce a ‘sanitary inspection category’ which implies a priori hazard assessment as a core management tool and (ii) the prediction of poor water quality to assist in real time risk assessment and public health protection. These management approaches reflect a harmonized approach towards the assessment and management of risk for water-related infectious disease being applied by WHO. Numerical microbiological criteria for intestinal enterococci are proposed in the new Guidelines. These were developed using a novel approach to disease burden assessment, which has been applied to both recreational waters and urban air quality. This paper explains the scientific rationale and mathematical basis of the new approach, which is not presented in the WHO Guidelines for recreational waters.

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**Keywords:** WHO guidelines; Recreational waters; Standards; Disease burden; Epidemiology

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### 1. Background

Standards for recreational water quality have been designed and applied by many agencies worldwide. Early United States Environmental Protection Agency (USEPA) water quality criteria were founded on epidemiological studies by Stevenson [1], and led to

the USEPA standards published in 1976, which required recreational water to have a geometric mean of less than 200 faecal coliform organisms per 100 ml and less than 10% of samples over 400 faecal coliform organisms per 100 ml [2,3]. It was suggested that five samples should be collected over a 30-day period in evaluating a recreational location against these criteria. This standard system was heavily criticized in the late 1970s by Cabelli. The principal grounds for this critique were the quality and interpretation of the early epidemiological study on which the numerical water quality criteria were based.

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Table 1

Proposed USEPA standards for marine waters [7], based on Cabelli et al. [5]

|             | Acceptable swimming-associated gasteroenteritis rate% swimmers | Steady state geometric mean indicator density/100 ml <sup>a</sup> | Single sample maximum allowable density <sup>b,c</sup> |  |  |   |
|-------------|--|---|--|--|--|---|
|             |  |   | Designated beach area (upper 75% CL)                   | Moderate full body contact recreation (upper 82% CL) | Lightly used full body contact recreation (upper 90% CL) | Infrequently used full body contact recreation (upper 95% CL) |
| Enterococci | 19   | 35  | 104  | 158  | 276  | 500   |

Sampling regime: Not less than five samples per 30-day period. During that period, the geometric mean should not exceed 35 cfu per 100 ml, and no sample should exceed the one-sided confidence level depending on use.

<sup>a</sup> Calculated to the nearest whole number: mean enterococci density = antilog<sub>10</sub> [(illness rate % – 0.20): 12.17].

<sup>b</sup> Single sample limit = antilog<sub>10</sub> (log<sub>10</sub> geometric mean enterococci + distribution factor × 0.7). Distribution factors are based on the normal probability function for one-sided confidence levels (CL): 75% CL = 0.675, 82% CL = 0.935, 90% CL = 1.28, 95% CL = 1.65.

<sup>c</sup> Based on the log<sub>10</sub> standard deviation for the EPA studies of 0.7 for enterococci in marine water. Each jurisdiction would establish its own log<sub>10</sub> standard deviation value appropriate for its recreational waters. A value of 0.7 to be used where data are insufficient to establish the actual log<sub>10</sub> standard deviation.

This resulted in a second research phase in the United States which led to a new set of Federal water quality criteria for marine and fresh waters [4–7]. These moved the emphasis from faecal coliform organisms to intestinal enterococci (faecal streptococci) for marine recreational waters summarized in Table 1. The epidemiological studies which underpinned these standards were the most sophisticated that had been conducted in recreational waters up to 1982. However, they were, in turn, criticized in a detailed statistical re-analysis by Fleisher [8–11] and Fleisher et al. [12]. These critiques suggested that the scientific rationale behind the US Federal standards might be removed if more appropriate statistical treatment of the data had uncovered extreme differences in the dose-response relationships observed at the three sites where the field studies were conducted (two marine and one fresh water).

In Europe, member countries of the European Union (EU) are required to implement the *Imperative* standards specified in Directive 76/160/EEC. The standards for faecal indicators are summarized in Table 2 [13]. There is no clear epidemiological rationale for the microbiological standards specified in the 1976 Directive, although one early British study did suggest that serious health effects might be associated with total coliform levels in bathing waters exceeding 10,000 per 100 ml [14,15]. The implementation of Directive 76/160/EEC has certainly produced a significant improvement in the quality of European bathing waters. Notwithstanding the absence of a clearly specified scientific foundation, EU member countries seeking seaside awards, such as the Blue Flag scheme, strive to achieve the *Guide* standards which are amongst the most stringent criteria applied world wide [16,17]. Recognizing the dated nature of the standards specified in Directive 76/160/

Table 2  
Standards for faecal indicator bacteria per 100 ml specified in Directive 76/160/EEC

|                     | <i>Imperative</i> <sup>a</sup><br>(Mandatory) | <i>Guide</i><br>(Recommended) |
|---------------------|---|-------------------------------|
| Total coliform      | 10,000 (95%)                                  | 500 (80%)                     |
| <i>E. coli</i>      | 2000 (95%)                                    | 100 (80%)                     |
| Faecal streptococci |   | 100 (90%)                     |

<sup>a</sup> Member states must achieve the *Imperative* parametric values with the compliance level specified in the brackets and should strive to achieve the *Guide* values at identified bathing waters.

EEC, the Commission of the European Communities proposed to revise the standards specified in the Directive and issued a Commission Proposal [18]. This received detailed scrutiny, in particular, by a UK House of Lords Select Committee enquiry, which sought to identify the scientific rationale behind a proposed new *Imperative* standard of 400 faecal streptococci per 100 ml [19–21]. After detailed discussion, the Commission representatives could not define a body of evidence or specific research study to underpin this value [19–21]. There has been considerable subsequent interest in the development of more appropriate bathing water quality standards in Europe with Commission papers produced in 1997 and 2000 [22,23], the latter seeking explicitly to embed revisions to the Bathing Water Directive into the Water Framework Directive [24], which could have significant implications for inland recreation sites within river basins [25]. In October 2002, a further draft directive was made public by the Commission of the European Communities and this is now under international consultation [26]. It is worth noting that, to date,

very considerable expenditures have been committed throughout the EU to achieve Directive 76/160/EEC standards. In the UK alone, this has exceeded £10,000 million [19].

The context for the development of the World Health Organization (WHO) Guidelines for Safe Recreational Water Environments was, thus, a policy environment in which recreational water quality, faecal indicator values, and the consequent infra-structure expenditures were justified to the taxpayer on the basis of protection from gastrointestinal illness acquired from bathing in sewage polluted water. Unfortunately, the scientific data used to underpin any specific water quality parameter or numerical value in existing standards was either non-existent or had been discredited in Europe and North America. This situation clearly caused some difficulties for the competent authorities, whether national governments, the European Commission or the USEPA.

WHO has also sought to initiate a harmonized examination of water quality norms across sectors designed to minimize transmission of waterborne infectious disease [27]. Recreational water guideline development is one element of this effort. This paper centres on the scientific basis of numerical faecal indicator guidelines for recreational waters now published in the first volume of the WHO Guidelines for safe recreational water environments [28]. This paper describes the mathematical and scientific derivation of the numerical guideline bacterial standards which are not outlined in the WHO publication. It does not address the various approaches for sanitary surveys or other hazards encountered in the recreational water environment, which are dealt with in WHO [28] and elsewhere, such as drowning and traumatic injuries and issues related to cyanobacterial and algal toxins [29,30]. Swimming pool and spa environments are addressed in the second volume of WHO Guidelines [31].

## 2. Epidemiology

The WHO seeks to define Guidelines for environmental quality, based solely on the best available epidemiological and public health information. This may result in bias towards standards relevant to the developed nations, since resource availability will result in more scientific data being available. To acquire and evaluate the existing data, a WHO review of epidemiological evidence was published by Prüss [32]. The conclusion of this review was that faecal streptococci was the most appropriate indicator of health risk in marine and fresh recreational waters and that relative risks of, generally minor, self-limiting illness (principally gastroenteritis) were in the range 1.0–3.0. *Escherichia coli* was also found to be predictive of illness in freshwater recreational areas. Importantly, Prüss [32]

noted the observation of many investigations that illness elevation was evident at faecal indicator concentrations lower than published standards in force (Tables 1 and 2).

Prüss [32] does not provide a meta-analysis in the classical sense, i.e. a pooling of data from several studies to form a single analysis. Rather, it provided a rigorous systematic literature review which was used to define the study or studies with the most precise dose-response relationship(s) which could be used to underpin a standard system. In the review, studies were excluded if:

- (i) the health outcomes were not clearly related to water quality;
- (ii) the study only compared the symptom attack rates reported by swimmers in polluted waters against swimmers in relatively unpolluted waters and the associations of interest could not, therefore, be calculated;
- (iii) the exposure or outcome variable differed significantly between different groups;
- (iv) the study was not sufficiently documented;
- (v) the study size was too small;
- (vi) the response rate was low (i.e. <50%); and
- (vii) the water to which exposure took place was chlorinated.

Twenty two papers passed these criteria and comprised 18 prospective cohort studies, two retrospective case-control studies and two reporting different symptom outcomes in the same randomized trial (using healthy adult volunteers). The reported studies were conducted in Australia, Canada, Israel, Egypt, Hong Kong, New Zealand, South Africa, Spain, the UK and USA. The dose-response relationships from these studies were plotted by Prüss [32] and it was noted that the UK randomized trial results [33] showed steeper dose-response curves than the prospective cohort studies. This was attributed to the enhanced control of bias facilitated by the randomized trial design. Put simply, the more precise measure of exposure facilitated by measurement of water quality close to the time and place of bathing by a healthy adult volunteer limited the ‘misclassification bias’ produced when a daily mean water quality is attributed to large groups of people participating in a prospective cohort study. The latter approach masks the considerable ‘within-day’ variability of faecal indicator concentrations, which produces both high and low actual ‘exposure’ values for some individuals who are falsely attributed the lower daily mean indicator value and vice versa. This misclassification of individuals, with both high and low exposures, tends to reduce the slope of the dose-response curve.

It is for this reason that microbiological data acquired to characterise recreational water quality provides the basis of a probabilistic assessment of exposure incorporating the small proportion of bathers exposed to high and low bacterial concentrations (see Section 3 below).

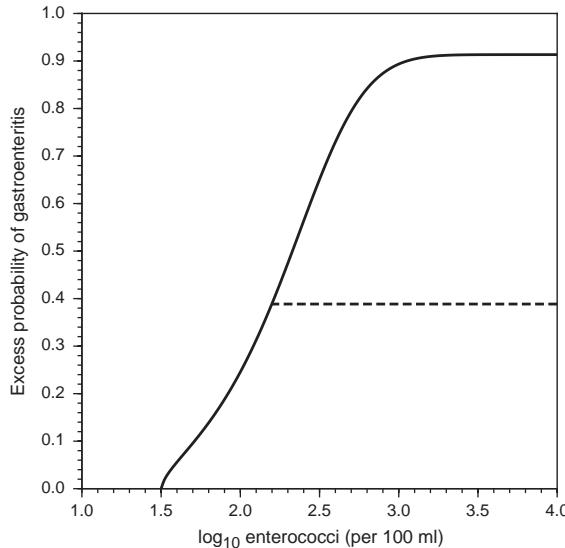


Fig. 1. The solid line is the mathematical form of the dose–response relationship derived from Kay et al. [33]. The dotted line is the functional form used in the derivation of the WHO Guideline values derived from Kay et al. [33], but assuming no increase in risk beyond the data range of the UK sea-bathing trials.

Prüss [32] demonstrated that the body of evidence worldwide showed clear dose–response relationships linking faecal indicator concentrations with rates of minor illness acquisition. Indeed, most studies had reported measurable rates of disease acquisition within current compliance ranges. In view of the probably higher accuracy of their reported dose–response relationships as compared to observational studies, it was decided to use the results of the randomized trials reported by Kay et al. [33] and Fleisher et al. [34] to underpin the guideline design process. Furthermore, a WHO expert group meeting in 2001 supported the application of the intestinal enterococci (i.e. and EU-defined group synonymous with the enterococci) concentrations as a suitable health criterion for both marine and freshwater environments. The dose–response model relating enterococci concentration to the probability of gastroenteritis from the UK trials is illustrated in Fig. 1.

### 3. Statistical description of exposure

It is first important to note that ‘zero risk’ is not an achievable goal when developing recreational water quality guidelines, due to the extreme local variability in faecal indicator and pathogen concentrations in recreational waters. This variability in enteric bacterial concentrations in environmental waters generally fits a  $\log_{10}$  normal distribution [35,36]. Thus, the ‘exposure’ at

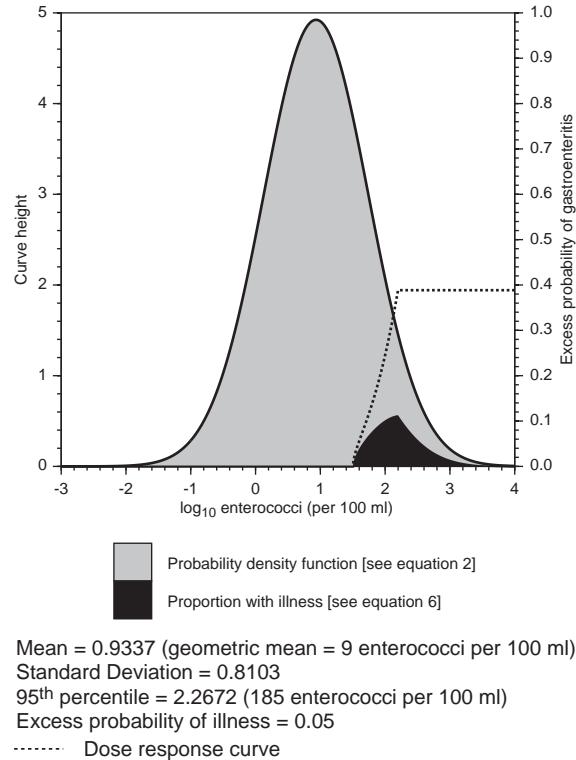


Fig. 2. Probability density function for intestinal enterococci derived from 11,000 EU bathing waters superimposed studies by Kay et al. [40], with the dose–response relationship derived from Fig. 1 dotted line.

any beach location is best considered in terms of the normal probability density function (pdf) of  $\log_{10}$  transformed indicator concentration experienced at a site (Fig. 2). Assuming  $\log_{10}$  normality, this can be determined from the mean ( $m$ ) and standard deviation ( $s$ ) of  $\log_{10}$  transformed faecal indicator concentrations for any recreational water.

### 4. Relating water quality to health risk

The pdf provides a simple means of assessing the probability of exposure to bacterial concentrations greater than and less than, for example, a threshold of effect or some upper limit value or standard. When combined with an appropriate dose–response curve, the pdf facilitates the calculation of the population percentage getting ill at each increment of water quality above any threshold level and, through integration, the proportion of the exposed population becoming ill overall [36]. The computation of gastroenteritis (GI) rates in the population is accomplished as follows.

The pdf of enterococci concentrations is described by

$$y = \frac{1}{s\sqrt{2\pi}} e^{-(\log_{10} c - m)^2/2s^2}, \quad (1)$$

where  $c$  is the enterococci concentration per 100 ml and  $y$  is the normal curve height with mean ( $m$ ) and standard deviation ( $s$ ) of  $\log_{10}$  transformed concentrations. The associated probability of exposure across a given range of enterococci concentrations, i.e. ca to  $c_b$ , for a given distribution is expressed by

$$\Phi(c) = \int_{c_a}^{c_b} y \, dc, \quad (2)$$

which is the area under the normal pdf curve between the limits  $c_a$  and  $c_b$ . The proportion of bathers with GI is then calculated from the area under the curve described by

$$z = py, \quad (3)$$

where  $p$  is the excess probability of gastroenteritis calculated as outlined by Wyer et al. [36] from

$$b = 0.20102\sqrt{(c - 32)} - 2.3561, \quad (4)$$

where  $b$  is log<sub>n</sub> odds of gastroenteritis [33] and

$$p = (1/(1 + e^{-b})) - 0.0866. \quad (5)$$

The constant 0.0866 is the total probability of gastroenteritis amongst bathers for  $c = 32$  enterococci per 100 ml, at which the excess probability  $p$  is zero [33]. The upper limit is set at 158 enterococci per 100 ml (i.e.  $p$  is constant when enterococci concentration exceeds 158 per 100 ml, see Fig. 1 and explanation below). The term  $z$  is proportional to the expected number of illnesses attributable to exposure to a given concentration. The associated probability of gastroenteritis across the range of enterococci concentrations,  $c_a$  to  $c_b$ , is then expressed by the following integral:

$$\Phi(c) = \int_{c_a}^{c_b} z \, dc. \quad (6)$$

The integral is represented by the dark shaded area in Fig. 2. The integration of these areas, and thus the calculation of the total illness, or disease burden, associated with a given pdf, was performed using iterative algorithms described by Khabaza [37] via a customized software interface. Algorithms were checked against standard tabulations of the normal pdf curve [38] and an accuracy of at least four significant figures was obtained over the specified range of the normal pdf.

Using this novel approach, it is possible for the policy community to specify an acceptable excess probability of illness and then to define the parameters of the pdf required (i.e. a geometric mean value, or a 95th percentile value given the knowledge of the standard deviation of  $\log_{10}$  transformed values) to limit the likely symptom incidence to this level or lower.

It was decided that the new WHO Guidelines should employ the pdf disease burden assessment method outlined above and in Wyer et al. [36] to calculate the risk of illness from exposure. Calculations would be based on the dose-response curve derived from Kay et al. [33] (Fig. 1b); and should employ a single value or parameter to characterise the pdf (i.e. its mean  $\log_{10}$  value or some percentile value such as the 95th percentile).

The dose-response curve was based on the epidemiological data collected at UK beaches. For ethical reasons, the beaches used had traditionally passed Directive 76/160/EEC standards and study participants were limited to healthy adult volunteers (i.e. over 18 years of age). The volunteers were exposed to sea water for a period of 10 min each; each immersed their heads on three occasions. The highest recorded enterococci exposure in this study was 158 per 100 ml. It was felt inappropriate to extrapolate the dose-response curve into an area of 'no data', as predicted by the mathematical form defined in the upper region (Fig. 1). It was, therefore, assumed that the excess illness probability remained constant, at just under 40%, at dose levels exceeding 158 enterococci per 100 ml (Fig. 1 dotted line). This might produce an underestimate of the actual risk for healthy adults and a larger underestimate for the very young and old, which should be noted in the application of the WHO Guidelines. Indeed, high minor illness attack rates, approaching 40% of those exposed, have been reported in recreators exposed to other polluted waters such as rivers [25].

The square root function employed in Eq. (4) above derives from Kay et al. [33]. A series of other potential functional relationships were explored in a reanalysis of these data reported in Kay et al. [39] and the original risk estimates were found to be robust and insensitive to the model functional forms employed.

## 5. Water quality criteria or guidelines

Many standard systems define only one value of a distribution. For example, the current standards in Directive 76/160/EEC require 80%, 90% or 95% compliance which, given a sufficiency of data, is approximately equivalent to the same percentile values of a  $\log_{10}$  normal pdf. The NTAC [2] standards defined a geometric mean faecal coliform value of 200 per 100 ml and also specified an allowed percentage (i.e. <10%) over 400 per 100 ml. In defining a single pdf parameter for the WHO Guidelines, either the geometric mean or some percentile value could have been selected. The upper 95th percentile value was chosen as an appropriate descriptor of the pdf because it describes the probability of encountering polluted water, focussing on water quality, which is likely to cause illness (i.e. the

Table 3

Guideline values for microbiological quality of recreational waters

| 95th Percentile value of enterococci per 100 ml (rounded values) | Basis of derivation  | Estimated risk  |
|--|--|---|
| ≤40  | This value is below the NOAEL in most epidemiological studies.   | <1% GI risk<br><0.3% AFRI risk<br>This relates to an excess illness of less than 1 incidence in every 100 exposures. The AFRI burden would be negligible.   |
| 41–200   | 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 risk<br>0.3–1.9% AFRI risk<br>The upper 95th percentile value of 200 relates to an average probability of one case of gastroenteritis in 20 exposures. The AFRI illness rate at this water quality would be 19 per 1000 exposures, or approximately 1 in 50 exposures.  |
| 201–500  | This level represents a substantial elevation in the probability of all adverse health outcomes for which dose-response data are available.  | 5–10% GI risk<br>1.9–3.9% AFRI risk<br>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   | Above this level, there may be a significant risk of high levels of minor illness transmission.  | >10% GI risk<br>>3.9% AFRI rate<br>There is a greater than 10% chance of illness per single exposure. The AFRI illness rate at the 95th percentile point of 500 enterococci per 100 ml would be 39 per 1000 exposures, or approximately 1 in 25 exposures.  |

Abbreviations used: AFRI = acute febrile respiratory illness; GI = gastrointestinal illness; LOAEL = lowest-observed-adverse-effect level; NOAEL = no-observed-adverse-effect level.

The “exposure” in the key studies [33,34] was 10 min bathing involving three immersions. It is envisaged that this is equivalent to many immersion activities of similar duration, but it may underestimate the risk for longer periods of water contact or for activities involving higher risks of water ingestion.

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.

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 be assessed and appropriate action taken.

upper part of the indicator distribution). However, the use of this single parameter of the pdf assumes that a constant standard deviation value applies to all waters for which a disease burden is calculated. Fortunately, a large data set describing enterococci concentrations at EU beaches was available and the standard deviation of  $\log_{10}$  transformed concentrations in this data set, i.e.

0.8103, was used in the derivation of the ‘risk’ levels in the WHO Guidelines [40]. This value was based on data from over 11,000 bathing locations across eight EU member states and involved over 121,000 individual intestinal enterococci enumerations. In effect, the use of individual enumerations from multiple locations is likely to result in a larger standard deviation than would be

experienced at an individual site for a particular bathing season. This would tend to result in a slight overestimation of the risk of illness or calculated percentage disease burden.

## 6. Deriving the guideline values

The specification of appropriate 95th percentile points of the enterococci pdfs with a uniform standard deviation of  $\log_{10}$  transformed concentrations of 0.8103 simply requires agreement on appropriate population risk levels. The WHO expert advisory group decided on a banded system, where the band divisions are equivalent to a risk of acquiring gastroenteritis for (i) <1 in 100 exposures, (ii) <1 in 20 exposures, (iii) <1 in 10 exposures and (iv) >1 in 10 exposures. These are equivalent to approximate 95th percentile intestinal enterococci concentrations of <40, <200, and <500 per 100 ml, respectively. Table 3 outlines these break points and also includes equivalent risk levels for an alternative outcome, namely, acute febrile respiratory illness (AFRI; see *ICD 9th Revision* codes 461 through 466, 480 [41]) for which the dose-response relationship is taken from the UK randomized trials described by Fleisher et al. [34]. Fig. 2 illustrates the pdf and dose-response function used to derive the WHO Guideline value of 95%ile 200 intestinal enterococci per 100 ml. This figure indicates that a 5% (or one in 20 exposures) risk of illness is associated with a pdf 95%ile value of 185, which was rounded to 200 intestinal enterococci per 100 ml by the WHO expert advisers.

It was fully appreciated that the more stringent of these water quality standards would be difficult to achieve in many locations. This is particularly true where non-sewage contributions of faecal indicators from diffuse sources elevate the background faecal indicator concentrations in recreational waters or, more commonly, produce short-term episodes of faecal indicator loadings after rainfall events [42,36]. For this reason, the Guidelines include a process of ascribing a beach to a sanitary inspection category, which is designed to underpin appropriate application of the ‘health-based’ microbiological criteria to the range of socio-cultural and economic environment experienced worldwide [43,44,28]. For example, during periods of higher beach faecal pollution, if recreator activity is limited, a beach can still rate well if water quality is acceptable during the period of recreator exposure.

## 7. Discussion and conclusions

The WHO Guidelines for Safe Recreational Water Environments (Vol. 1, 2003), provide an opportunity for harmonization between the many national and multi-

national agencies concerned with recreational water quality standards. They represent the conclusions of over 10 years of consultation and scientific discussion seeking to generate a consensus on the best available evidence on which to base water quality criteria. They also represent, perhaps, the most substantive attempt, to date, to derive ‘health-based’ criteria for any water exposure. However, the Guidelines are certainly not perfect and it is vital that all regulatory agencies and researchers appreciate the assumptions that have been made in designing the WHO recreational Guidelines for the microbiological criteria. There is certainly a need to acquire epidemiological data on younger bathers, other water types and from other regions in which recreational exposure takes place. For this reason, WHO has noted the need for further research studies using the randomized design outlined in Kay et al. [33]. The first such study, conducted at German fresh water recreation sites, has now been completed [45]. As additional information becomes available, the Guidelines should be reviewed and updated in light of local circumstances better to fit the needs of other regions and water users.

Whilst this paper has focussed on the derivation of the numerical bacterial criteria, it is also important to note that the new WHO Guidelines address the issues of background variability in recreational water quality not related to faecal indicator inputs from the sewerage infrastructure [43,44,28,50]. In addition to the numerical ‘health-based’ criteria, this approach to recreational water management suggests a novel regulatory paradigm in which a battery of tools are combined to protect public health involving: (i) sanitary inspection to identify pollution sources and their significance, (ii) real time prediction of water quality linked to management systems designed to protect public health through zoning and/or advisory systems [46,36,47–49] and (iii) numerical compliance assessment as outlined above. The new paradigm represents a concerted design effort, led by WHO, but involving regulators, government scientists and academics from many nations.

## Acknowledgements

The authors acknowledge the inputs and ideas of the expert advisors who served on the WHO expert advisory groups including the Bad Elster meeting in 1996, the Jersey meeting in 1997, the Farnham meetings in 1998 and 2001, the Annapolis meeting in 1999 and the participants of the EU Green Week in 2001. Many agencies have provided financial support and expertise for these consultations including the WHO, the European Union, the US National Science Foundation, the USEPA, the States of Jersey and the UK Government. The software interface for the disease burden calculator was developed partially with support from the UK

Engineering and Physical Sciences Research Council (WITE programme GR/M99774/01). The views expressed are those of the authors and not the organizations to which they are affiliated.

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