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## Discussion

# Reply to comments on “Derivation of numerical values for the World Health Organization guidelines for recreational waters”

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### ABSTRACT

The contribution addressed reveals an optimistic design philosophy likely to systematically underestimate risk in epidemiologic studies into the health effects of bathing water exposures. The authors seem to recommend that data on the ‘exposure’ measure (i.e. water quality) in such studies should be acquired in a similar manner to that used for regulatory sampling. This approach may compromise the quality of the epidemiologic investigations undertaken. It may result in imprecise estimates of exposure because it ignores the fact that regulatory timescales and spatial resolution (even if artificially compressed to a bathing day) can mask large spatial and temporal variability in water quality. If this variability is ignored by taking some mean value and attributing that to all of those exposed in a period at a study location, many bathers may be misclassified and the studies may be biased to a ‘no-effect’ conclusion. A more appropriate approach is to maximise the precision of the epidemiologic investigations by measurement of individual exposure (or water quality) at the place and time of the exposure, as has been done in randomised volunteer studies in the UK and Germany. The precise epidemiologic relationships linking ‘exposure’ with ‘illness’ can then be related to the probability of exposure to particular water quality by a ‘normal bather’ using the known probability distribution of the exposure variable (i.e. faecal indicator concentration) in the regulated bathing waters. We suggest that any research protocol where poor sampling design for water quality assessment is justified because regulatory monitoring is equally imprecise may be fundamentally flawed. The rationale for this assessment is that the epidemiology is the starting point and evidence-base for ‘standards’. If precision is not maximised at this stage in the process it compromises the credibility of the standards design process. The negative effects of the approach advocated in this ‘comment’ are illustrated using published research findings used to derive the figures illustrated in Wymer et al. [2005. Comment on derivation of numerical values for the World Health Organization guidelines for recreational waters. *Water Research* 39, 2774–2777].

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**1. Introduction**

Wymer et al. (2005) present an analysis and comment on the risk models used to underpin the numerical water quality criteria published in WHO (2003) and which also form the basis of the ‘good’ standards for intestinal enterococci outlined in the draft revisions of the European Union (EU) Bathing Water Directive (CEC, 2000, 2002, 2004). They calculate the risk from what they term ‘ecological risk’ using the ‘personal exposure’ risk equation published in Kay et al. (1994). By ‘ecological risk’ they imply some longer-term measure of water quality for example a compliance measure which, in the EU, might be 20 samples taken over a bathing season. By ‘personal risk’ they mean the water quality measured at the time and place of exposure as measured in the UK epidemiologic studies which employed a randomised trial protocol (Fleisher et al., 1996; Kay et al., 1994) advocated previously by WHO (1972).

This allows them to construct Fig. 1 (reproduced below) which relates the geometric mean enterococci level at a beach (measured over a period of time) to the excess risk of gastroenteritis. They make the qualitative observation that the slopes of the two curves derived from the UK and US epidemiologic studies appear similar. This claimed ‘similarity’ is further reinforced by the apparently similar relative risks of the two investigations outlined in Wymer et al.’s (2005) Fig. 2.

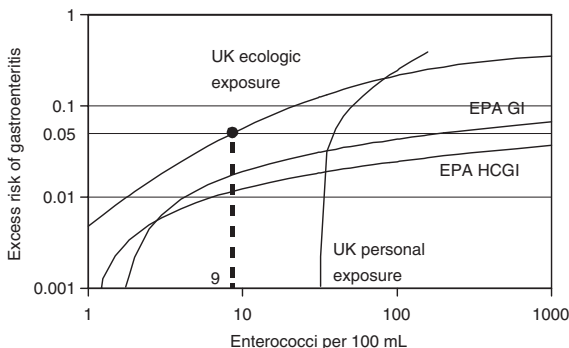
In constructing Fig. 1, Wymer et al. (2005) imply that the US epidemiologic studies, (Cabelli et al., 1982) used an ‘ecological’ measure of exposure rather than a ‘personal’ level of exposure.

They go on to state:

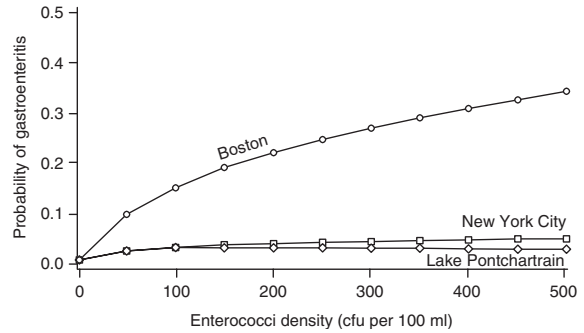
1. Although the personal exposure assessment of the original UK model has theoretical interest, it has little regulatory or advisory value in its raw form given that knowledge of a bathers specific exposure level is virtually unobtainable

and

2. Simply inserting a mean exposure value into the UK personal exposure model is likely to result in bias in the



**Figure 1 – Predicted excess risk of gastroenteritis (from Wyer et al., 2005, p. 2775, Fig. 1).**



**Figure 2 – Recalculated dose-response relationships for the three study sites used in the original USEPA investigations reported in Cabelli et al. (1982) (from Fleisher 1992, p. 123, Fig. 9.3).**

opposite direction, overestimating the increase in overall risk

they then conclude:

3. Marine and freshwater studies that that have been conducted by the USEPA were designed to predict expected incidence of illness given monitoring results that are available in practice, i.e. mean indicator levels based on sampling. When a research design utilises these same water sampling techniques and involves health surveys on the target population ... modelling is simplified.

Minor critical points, such as the assumption of a uniform standard deviation (SD) for bathing water log<sub>10</sub> enterococci concentration by the WHO (2003) and the lack of confidence intervals on the original risk model published in Kay et al. (1994) are also made in this paper.

**2. Responses**

**2.1. The SD assumption**

The utilisation of uniform SD is required if a consistent ‘Guideline’ value is to be published (in terms of geometric mean (GM) or some percentile value). The alternative approach, which was explored in Wyer et al. (1999), is to set an ‘acceptable’ risk level of say 5% additional illness. In this pure ‘risk’ approach, the regulator would set the risk level and this would be calculated from the standard deviation and mean log<sub>10</sub> faecal indicator value for each beach. Following a series of consultations and meetings of WHO international technical advisers between 1996 and 2002, it was decided that a pure ‘risk’ approach utilising both the GM and SD would cause confusion and that a single parametric value was needed if an international ‘Guideline’ was to be published, i.e. the 95th percentiles (95%ile) for intestinal enterococci outlined in Chapter 4 of WHO (2003). The 95%ile 200 intestinal enterococci cfu 100 ml<sup>-1</sup>, approximates to a 5% excess illness rate (which in fact is associated with a 95th percentile of 184 intestinal enterococci cfu 100 ml<sup>-1</sup>) assuming a SD in log<sub>10</sub> intestinal enterococci of 0.8103. This value was derived from an earlier study of over 11,000 European bathing waters for

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