

26 November 2012

FAO: Mr Amit Bose
Department of Health
Skipton House
80 London Road
London SE1 6LH

Dear Sir

Consultation on the arrangements for consideration of proposals on the fluoridation of drinking water

I am pleased to enclose a response to the above consultation from the Nuffield Council on Bioethics, an independent body that examines and reports on ethical issues in biology and medicine.

Please do not hesitate to contact me if you would like further information or assistance.

Yours sincerely



Hugh Whittall
Director

Chair
Professor Jonathan Montgomery

Deputy Chair
Professor Ottoline Leyser CBE FRS

Members
Professor Tom Baldwin
Dr Amanda Buris
Professor Robin Gill
Professor Sian Harding FAHA FESC
Professor Ray Hill FMedSci
Dr Rhona Knight FRCGP
Professor Graeme Laurie FRSE
Dr Tim Lewens
Professor Anneke Lucassen
Professor Michael Moran FBA
Professor Alison Murdoch FRCOG
Dr Bronwyn Parry
Professor Nikolas Rose
Dr Geoff Watts FMedSci
Professor Jonathan Wolff

Director
Hugh Whittall

Assistant Directors
Dr Peter Mills
Katharine Wright

Response from the Nuffield Council on Bioethics: Consultation on the arrangements for consideration of proposals on the fluoridation of drinking water

Introduction

In 2007, the Nuffield Council on Bioethics considered the issue of fluoridation of water in its report *'Public health: ethical issues'* (available at www.nuffieldbioethics.org/public-health). The Council's response to this consultation draws on the recommendations and conclusions of that report. While we cannot comment on some of the practical aspects of your consultation, for example on Committee membership and procedures, we set out here some general principles we believe should underpin procedures for decision making about water fluoridation, as background to your inquiry.

Notes in brackets below refer to the paragraphs of the Council's report (www.nuffieldbioethics.org/public-health).

Decision making

The Government's strategy for public health in England *Healthy Lives, Healthy People*¹, referred to the Council's 'intervention ladder' which sets out a range of levels of interventions that can affect people's health choices. The ladder was suggested as a way of thinking about the acceptability and justification of different public health policies: interventions that are higher up the ladder are more intrusive and therefore require a stronger justification. A more intrusive policy initiative is likely to be publicly acceptable only if there is a clear indication that it will produce a desired outcome. The positive outcome can be weighed favourably against any loss of liberty that may result (paragraphs 3.37-3.38). To support practical decision making, the intervention ladder was coupled with a 'stewardship model' which sets out guiding principles for making decisions about public health policies.

We identified three central goals of the stewardship model that are relevant to water fluoridation: the reduction of ill health; and the reduction of health inequalities and concern for children, who constitute a vulnerable group. However, these interests need to be balanced against the principles of avoiding coercive interventions and minimising interventions in personal life (paragraph 7.14).

In addition, the acceptability of any public health policy involving the water supply should be considered in relation to (i) the balance of risks and benefits; (ii) the potential for alternatives that rank lower on the intervention ladder to achieve the same intended goals and (iii) the role of consent where there are potential harms (paragraph 7.26).

Consultation and assessing public opinion

Because of the way fluoridated water is provided, it is clear that an approach requiring individual consent is not feasible in practice. However, both the decision to introduce fluoridation programmes and a decision not to do so would require justification, as both have potential advantages and disadvantages to some

¹ Department of Health, *Healthy Lives, Healthy People: Our strategy for public health in England*, 30 November 2010, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127424.pdf

groups of people. A mechanism is therefore needed to consider the views of the public in order to provide a mandate for either option.

We suggest the adoption of a 'procedural justice' approach using local level democratic decision-making procedures, taking into account the context in each affected or potentially affected area. In particular the health needs, the degree of benefit anticipated in a given community, the local perceptions of the measure, and possible alternatives need to be considered (paragraph 7.50). Additional key elements of a 'procedural justice' approach are:

- transparency of decision-making processes (in terms of the evidence, reasons and rationales cited in favour of an intervention that reduces some choice of individuals or otherwise inconveniences them);
- a focus on rationales that those affected recognise as being helpful in meeting health needs fairly; and
- involvement of individuals and stakeholder groups in decision-making processes, with opportunities to challenge interventions in preparation and in practice (paragraph 2.25)

In practice, this will typically involve publishing plans for fluoridation programmes in ways and formats that are suitable for the public; a period of consultation; and a response to the issues raised during the consultation. The outcome should be a justification of a policy proposal which engages the scientific and health-related evidence on the benefits of water fluoridation for the respective regions in relation to alternative approaches, the consultation responses and relevant ethical considerations. Two important elements that feature in the process are the evidence base for an intervention (and its alternatives) and the availability of information for policy makers and individuals, particularly where they are to be asked to vote or contribute to policy decisions through these approaches (paragraph 7.41).

Evidence and information

In our report we noted a lack of high quality research on fluoridation, which is particularly noteworthy given the interest in this intervention and the length of time over which it has been considered and implemented as a policy option (paragraphs 7.8, 7.29–7.33). Nevertheless, we recognise that inconclusive evidence by itself is not necessarily a sufficient reason to halt an otherwise promising strategy. Such strategies may be pursued as long as there is mandate for the intervention and appropriate monitoring is conducted. Therefore, **the UK health departments should monitor the effects of water fluoridation, including the incidence and severity of fluorosis and other possible harms.**²

We also note other research priorities suggested in the York review, and by the MRC, WHO and National Research Council of the National Academies in the USA.³ These have included investigating total fluoride exposure, and how this relates to harm, and the impact of using lower levels of fluoride in water. **We recommend that water fluoridation policy should be objectively reviewed by the UK health departments on a regular basis in light of the findings of ongoing monitoring and further research studies. Furthermore, the conclusions and their basis should routinely be published** (paragraph 7.42)

² Consideration should, however, be given to possible difficulties in detecting harms (see paragraph 7.31 of the full report).

³ McDonagh M, Whiting P, Bradley M *et al.* (2000) *A Systematic Review of Public Water Fluoridation* (York: NHS Centre for Reviews and Dissemination); Medical Research Council (2002) *Water Fluoridation and Health* (London: MRC); WHO (2002) *Environmental Health Criteria 227 Fluoride* (Geneva: WHO); Committee on Fluoride in Drinking Water, National Research Council of the National Academies (2006) *Fluoride in Drinking Water* (Washington, DC: National Academies Press).

Finally, neither the public nor policy makers are helped by information that makes it difficult for the non-expert to obtain a good understanding of current evidence⁴. All the groups involved in the fluoridation debate should ensure that the information they produce presents a balanced account of risks and benefits, and indicates accurately the strengths and weaknesses of the evidence base (paragraph 7.47).

⁴ Cheng KK, Chalmers I and Sheldon TA (2007) Adding fluoride to water supplies *Br Med J* **335**: 699–702.