Response from the Nuffield Council on Bioethics
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The Nuffield Council on Bioethics is an independent body that examines and reports on the ethical issues in biology and medicine. We have published three relevant reports to the Bioethics Commission’s enquiry:

- The ethics of research related to healthcare in developing countries (April 2002)
- The ethics of research related to healthcare in developing countries: a follow-up discussion paper (March 2005)
- Public health: ethical issues (November 2007)

1. The stewardship model

Our Public health: ethical issues report starts from the position that the state has a duty to enable people to lead healthy lives. Everyone should have a fair opportunity to lead a healthy life, and therefore governments should try to remove inequalities that affect disadvantaged groups or individuals (paragraphs 2.41-2.44).

We propose a ‘stewardship model’ that outlines the appropriate goals and constraints of public health measures. Acceptable public health goals include:

- reducing the risks of ill health that people are exposed to as a result of other people’s actions or behaviours, for example reducing drink-driving and passive smoking;
- reducing causes of ill health relating to environmental conditions, such as drinking water safety and housing standards;
- protecting and promoting of the health of children and other vulnerable people;
- helping people to overcome addictions and other unhealthy behaviours;
- ensuring that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;
- ensuring that people have appropriate access to medical services; and
- reducing unfair health inequalities.
At the same time, public health programmes should:

- not attempt to coerce adults to lead healthy lives;
- minimise interventions that are introduced without individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate;
- seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.

2. Precaution and proportion

The ‘precautionary principle’ is often invoked in discussions about public health. It is regarded by many as the key to responsible risk management where there is some evidence of a serious threat to health, safety, or the environment. In applying the precautionary principle it is important to recognise that it is not a single inflexible rule, but a way of applying a set of interacting criteria to a given situation. For this reason we prefer the term precautionary *approach*, rather than precautionary *principle*.

The central feature of the precautionary approach is that it is dynamic. Drawing on a Communication by the European Commission, five main elements can be distinguished: (a) scientific assessment of risk, acknowledging uncertainties and updated in light of new evidence; (b) fairness and consistency; (c) consideration of costs and benefits of actions; (d) transparency; and (e) proportionality. Stated this way, the approach seems so sound as to be unexceptionable, but of course the challenge arises in making judgements when applying it. To justify precautionary action, the nature or degree of acceptable uncertainty needs to be assessed on a case-by-case basis, as do the risks of ‘doing nothing’, and the risks of other alternatives (paragraphs 3.15–3.16, Public health).

In any policy decision, it is furthermore important to consider the seriousness of the problem and the urgency with which it should be addressed. Policy makers have limited time and resources, and issues that pose severe and urgent threats to the health of many people are rightly prioritised over those that are only ‘possible threats’, affect health in a relatively minor way or involve fewer people. The need for a public health intervention may be dictated by urgency, most obviously with the emergence of an epidemic of a serious infectious disease (paragraph 3.17, Public health).

One of the most difficult decisions that policy makers need to take relates to identifying which policy response is appropriate in each particular case. A central criterion for judging appropriateness is highlighted in the European Commission’s Communication on the precautionary approach: that of proportionality. There are several different aspects to the concept. First, in the form of a balancing test, it enjoins us to assess whether the aims of public health goals are sufficiently important to permit consideration of particular means, such as laws, policies or specific interventions. Secondly, a suitability test concerns an assessment of the degree to which a certain means will achieve the desired end. Thirdly, a necessity test requires that if a particular objective can be achieved by more than one means, then the means should be chosen that causes the least intrusion in the lives of the
individuals or communities concerned while still achieving adequate effectiveness (paragraph 3.18, Public health).

In summary, application of the precautionary approach and of proportionality comes down, not simply to applying a formula, but to a judgement that takes into account the particular circumstances of the problem to be addressed. The different dimensions we have highlighted above help guide our scrutiny of justifications given for particular polices or interventions (paragraph 3.19, Public health).

3. The Intervention Ladder

We propose the ‘intervention ladder’ as a useful way of thinking about the acceptability and justification of different public health policies (paragraphs 3.37-3.38, Public health). The ladder of possible government actions is as follows:

- **Eliminate choice.** Regulate in such a way as to entirely eliminate choice, for example through compulsory isolation of patients with infectious diseases.
- **Restrict choice.** Regulate in such a way as to restrict the options available to people with the aim of protecting them, for example removing unhealthy ingredients from foods, or unhealthy foods from shops or restaurants.
- **Guide choice through disincentives.** Fiscal and other disincentives can be put in place to influence people not to pursue certain activities, for example through taxes on cigarettes, or by discouraging the use of cars in inner cities through charging schemes or limitations of parking spaces.
- **Guide choices through incentives.** Regulations can be offered that guide choices by fiscal and other incentives, for example offering tax-breaks for the purchase of bicycles that are used as a means of travelling to work.
- **Guide choices through changing the default policy.** For example, in a restaurant, instead of providing chips as a standard side dish (with healthier options available), menus could be changed to provide a more healthy option as standard (with chips as an option available).
- **Enable choice.** Enable individuals to change their behaviours, for example by offering participation in an NHS ‘stop smoking’ programme, building cycle lanes, or providing free fruit in schools.
- **Provide information.** Inform and educate the public, for example as part of campaigns to encourage people to walk more or eat five portions of fruit and vegetables per day.
- **Do nothing or simply monitor the current situation.**
Specific issues of interest to the Bioethics Commission

1. U.S. public policies that restrict association or movement

Our Public health: ethical issues report outlines some of the main ethical and policy issues raised by public health measures relating to infectious disease, including issues raised by quarantine and isolation of individuals known or suspected to have a particular infection (paragraphs 4.58-4.62).

Liberty-infringing measures to control disease, such as compulsory quarantine and isolation, rank towards the top of the intervention ladder. The ethical justification for such measures involves weighing the classical harm principle on the one hand, and individual consent and the importance of avoiding intrusive interventions on the other (paragraphs 2.13-2.15, 2.22-2.26, 2.43). Where risk of harm to others can be significantly reduced, these considerations can be outweighed (paragraph 3.18).

2. The ethics of placebo-controlled trials in the context of public health emergencies

Our report The ethics of research related to healthcare in developing countries defines the ethical standards for healthcare research in developing countries.

We recommend that in setting the standard of care for the control group of a particular research project, the context in which the research is to be conducted should be carefully evaluated. A suitable standard of care can only be defined in consultation with those who work within the country and must be justified to the relevant research ethics committees. Wherever appropriate, participants in the control group should be offered a universal standard of care for the disease being studied. Where it is not appropriate to offer a universal standard of care, the minimum standard of care that should be offered to the control group is the best intervention available for that disease as part of the national public health system (paragraph 7.29).

Placebo controlled trials would therefore only be acceptable if there were no treatment available within the national health system of the country where the research is taking place. Underpinning this, there should be a requirement that the research is relevant to the people in that country (paragraphs 10.9-10.10).

3. The ethical considerations relevant to collecting and storing biospecimens during a public health emergency

Our Public health: ethical issues report discusses two types of infectious disease surveillance. First, population surveillance of infectious disease trends, which involves the systematic collection, analysis and interpretation of data about disease incidence and prevalence. With this type of surveillance, data are generally collected anonymously (paragraphs 4.36–4.38). Secondly, notifiable disease surveillance, in which individual cases of particular diseases must be notified to the relevant authorities for the purpose of monitoring and disease control (paragraphs 4.41–4.42, also Box 4.5).
The collection of anonymised surveillance data on trends in infectious disease ranks low on the intervention ladder. Without sufficient data, it may not be possible to assess and predict trends and risks in infectious diseases. It is acceptable to collect and use anonymised data for assessing and predicting trends in infectious disease without consent, as long as any invasion of privacy is reduced as far as possible (paragraph 4.39).

Legislation on notifiable diseases requires the collection of data about individuals with particular infections which includes identifying information. One of the main aims of such measures is to prevent harm to others from the spread of disease, which means that they can be justified under the classical harm principle (paragraphs 2.13–2.14).

The avoidance of significant harm to others who are at risk from a serious communicable disease may outweigh the consideration of personal privacy or confidentiality, and on this basis it can be ethically justified to collect non anonymised data about individuals for the purposes of implementing control measures. However, any overriding of privacy or confidentiality must be to the minimum extent possible to achieve the desired aim (paragraph 4.43).