

## Correspondence

### Ethical considerations in developing a national vaccine policy

Sir,

The article on evidence-based national vaccine policy making in India by Madhavi *et al*<sup>1</sup> is timely and explores a crucial public health issue. The authors have made a comprehensive list of recommendations relevant to the proposed policy, including the establishment of a more effective vaccine regulatory environment in the country and reviving the public sector vaccine production units. With immunization rates in the country remaining abysmally low and new vaccines flooding the market, a clear and lucid vaccine policy would be a welcome step.

Objective 6 of the draft vaccine policy enunciated by the authors aims “to promote ethical conduct in the development, trials, adoption and administration of vaccines, especially aimed at children and pregnant women”. This is vital in the background of the recent controversies in trials for vaccines for human papilloma virus (HPV)<sup>2</sup> and human immunodeficiency virus (HIV)<sup>3</sup>, where ethical concerns were raised. It is also relevant given the rampant advertising of newly marketed vaccines, and financial incentives offered to doctors by the pharmaceutical companies<sup>4</sup>.

Further work on developing the vaccine policy would benefit from recommendations made elsewhere. Verweij and Dawson in 2004<sup>5</sup> proposed the following set of guidelines to steer ethical reflection and decision making in the field of collective vaccination programmes:

- (i) Collective vaccination programmes should target serious diseases that are a public health problem.
- (ii) Each vaccine, and the programme, as a whole must be effective and safe.
- (iii) The burdens and inconveniences for participants should be as small as possible.

- (iv) The programme’s burden/benefits ratio should be favourable in comparison with alternative vaccination schemes or preventative options.
- (v) Collective vaccination programmes should involve a just distribution of benefits and burdens.
- (vi) Participation should, generally, be voluntary unless compulsory vaccination is essential to prevent a concrete and serious harm.
- (vii) Public trust in the vaccination programme should be honoured and protected.

Houweling and colleagues in a publication this year<sup>6</sup> have described the following criteria developed over many years by the National Immunization Program of the Health Council of Netherlands for inclusion of new vaccines in (national) public programmes:

#### *Seriousness and extent of the disease burden*

1. The infectious disease causes considerable disease burden within the population.
  - (a) The infectious disease is serious for individuals, and
  - (b) The infectious disease affects or has the potential to affect a large number of people.

#### *Effectiveness and safety of the vaccination*

2. Vaccination may be expected to considerably reduce the disease burden within the population.
  - (a) The vaccine is effective for the prevention of disease or the reduction of symptoms.
  - (b) The necessary vaccination rate is attainable (if eradication/elimination or the creation of herd immunity is sought).
3. Any adverse effects associated with vaccination are not sufficient to substantially diminish the public health benefit.

*Acceptability of the vaccination*

4. The inconvenience or discomfort that an individual may be expected to experience in connection with his/her personal vaccination is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.
5. The inconvenience or discomfort that an individual may be expected to experience in connection with the vaccination programme as a whole is not disproportionate in relation to the health benefit for the individual concerned and the population as a whole.

*Efficiency of the vaccination*

6. The balance between the cost of vaccination and the associated health benefit compares favourably to that associated with other means of reducing the relevant disease burden.

*Priority of the vaccination*

7. Relative to other vaccinations that might also be selected for inclusion, provision of this vaccination serves an urgent public health need at reasonable individual and societal costs.

Both these sets of criteria provide useful suggestions which should be considered in drafting sections of the proposed vaccine policy dealing with introduction of new vaccines for public health system provisioning. These criteria highlight (i) the importance of ensuring that benefits are maximized and risks minimized; (ii) that vaccine acceptability and (promotion of) maintenance of faith in the public health system vaccine provision

should be factored in; (iii) that informed choice (to get vaccinated) should be offered to people where relevant; and (iv) that alternative and supplementary mechanisms of disease reduction are considered in parallel. These steps are paramount to ensure high uptake of vaccines, which will help in bringing down the burden of vaccine-preventable diseases.

**Conflicts of interest:** none.

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