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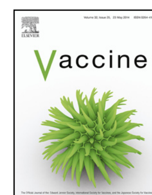

What is the responsibility of national government with respect to vaccination?☆

Marcel F. Verweij [a,*], Hans Houweling [b]

[a] Department of Social Sciences, Section Communication, Philosophy and Technology, Wageningen University, The Netherlands
[b] Health Council of the Netherlands, The Netherlands

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ABSTRACT

Given the ethical aspects of vaccination policies and current threats to public trust in vaccination, it is important that governments follow clear criteria for including new vaccines in a national programme. The Health Council of the Netherlands developed such a framework of criteria in 2007, and has been using this as basis for advisory reports about several vaccinations. However, general criteria alone offer insufficient ground and direction for thinking about what the state *ought* to do. In this paper, we present and defend two basic ethical principles that explain *why* certain vaccinations are the state's moral-political responsibility, and that may further guide decision-making about the content and character of immunisation programmes. First and foremost, the state is responsible for protecting the basic conditions for public health and societal life. Secondly, states are responsible for promoting and securing equal access to basic health care, which may also include certain vaccinations. We argue how these principles can find reasonable support from a broad variety of ethical and political views, and discuss several implications for vaccination policies.

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1. Introduction

All industrialised countries and more and more developing nations have well-working and effective national immunisation programmes [1]. Building such programmes where they are not yet in place and sustaining them is essential for promoting global health and protecting populations against dangerous infections. At the same time, vaccine development is an on-going process and more and more vaccinations are becoming available, which raises questions to what extent new vaccinations should be included in existing national programmes – especially given that, in many countries, state budgets are under pressure. Given the obvious ethical dimensions of immunisation [2], and threats to public trust in vaccination [3] clear criteria for adoption are necessary. The Health Council of the Netherlands developed such a framework of criteria in 2007 [4,5], and has been using this as basis for advising the government of the Netherlands about vaccinations against cervical cancer, hepatitis B, influenza H1N1 (2009), and Q-fever [6–9]. However, general criteria alone offer insufficient ground and direction for thinking about what the state *ought* to do. In this paper we outline two more basic ethical principles for national immunisation programmes that offer explanation *why* certain vaccinations are the state's moral-political responsibility, and that may further help guiding decision-making about the content and character of immunisation programmes.

2. Criteria for including vaccinations in the Netherlands' national immunisation plan

The Netherlands have had a National Immunisation Programme since 1957. The programme is voluntary but, in general, participation rates are very high: 95% and more of all children complete their vaccination schedules [10]. In some protestant Christian communities it is more common to forego vaccination because people considered it as acting against divine providence and these regions have seen various outbreaks of vaccine preventable diseases, including measles (2008, 2013), rubella (2004–2005, 2013), and, longer ago, polio (1992–1993) [11]. These limited outbreaks in specific unvaccinated groups underscore the success and benefits of immunisation. The success of the programme is in an important respect due to the way it is embedded in local/municipal infant and toddler clinics – which are highly trusted institutions – and

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* Corresponding author at: Section Communication, Philosophy, and Technology, Wageningen University, P.O. Box 8130, 6700 EW Wageningen, The Netherlands. Tel.: +31 317 48 43 10.
E-mail address: marcel.verweij@wur.nl (M.F. Verweij).

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Table 1
Criteria for inclusion of vaccinations in public programmes [4].

Seriousness and extent of the disease burden
1. The infectious disease causes considerable disease burden within the population.
• The infectious disease is serious for individuals.
• 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.
• The vaccine is effective for the prevention of disease or the reduction of symptoms.
• 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.

the centralised organisation and monitoring of the programme. The Minister of Health decides which vaccinations are included in the package, after advise from the Health Council. In 2007, the Health Council published seven criteria guiding this advisory role, thus aiming to strengthen transparency and coherence of decision-making about the national programme (see Table 1). Vaccinations in a public programme should target diseases that pose public health threats (be serious to individuals and affect (potentially) large numbers); be effective and safe; involve acceptable burdens for the population; be cost-effective and, compared to other preventive options, have priority from a public health point of view [4,5].

These criteria have not only guided recent policies for vaccination for young children (Hepatitis B, pneumococcal disease) and adolescents (cervical cancer), but also collective vaccinations for other groups (Influenza A H1N1; Q-fever). The assessment is done by a multidisciplinary review committee including expertise from paediatrics, youth health care practice, public health, immunology, microbiology, public health, philosophy, communication science, health economics, and epidemiology [4]. Applying the criteria is not a matter of ticking boxes, it involves discussing and weighing the available scientific evidence, assessing burden of disease, and weighing of risks, benefits and burdens.

One of the most difficult issues in the review committee is how to find consensus about the burden of disease of infections that are very common but only rarely require intensive medical treatment, like rotavirus and varicella infections. Immunisation against varicella is common in some countries, but most parents in the Netherlands see chicken pox as an inconvenient but minor disease. In some cases however, small children may develop severe complications due to chicken pox [12]. Rotavirus is a slightly different story. Most children are infected with rotavirus before their 5th birthday and often experience severe diarrhoea. In the Netherlands, every year up to 5000 small children (3% of a year cohort) are admitted to hospital to treat dehydration caused by rotavirus-induced diarrhoea. More serious complications do occur, especially among immunocompromised patients and infants with low birth weight or congenital disease, and probably several children die as a result of such complications [13]. In almost all other cases, however, the disease is self-limiting, and can be treated, if necessary, with relatively simple means. Rotavirus infections are responsible for seasonal high peaks in paediatric hospital admissions [14] but does that sufficiently support a judgement that rotavirus is a serious health problem for individuals and population? Certainly, parents may have good reasons for requesting rotavirus vaccination for their child. But should the state offer vaccination – and offer it in a pro-active way?

In order to bring more clarity in such controversies, it makes sense to reflect on *why* the state has responsibilities in relation to vaccination. Alternatively one could opt for specification and operationalization of the first criterion (burden of disease), but such specification would still require a normative justification that explains *why* the criterion should be more, or possibly less stringent. The scope of responsibility of the state for public health is of course a highly politicised topic. However, we argue that it is possible to find reasonable consensus on some principles for national immunisation plans. In a previous paper we have outlined how the Health Council's criteria build upon two more general ethical considerations: optimal protection and justice. Collective vaccination should aim at the best possible protection of the population as a whole, and benefits are to be distributed in a fair way, with priority for those groups for whom protection is most urgent [5]. In this section we elaborate on these considerations and explain how these can be considered as a reasonable basis for reflecting on what vaccinations can be considered the responsibility of the state.

3. Responsibility for government: protecting public health and societal life

The first consideration is closely linked to one of the most basic tasks for government: to create conditions for societal life, which includes protecting people against threats within societal life (harmful behaviour) as well as protecting them against external threats. Such forms of protection are basic public goods that still fit with liberal political views that emphasise only a modest role for the state [15]. The spread of infectious diseases can have severe effects on communal life and protection against such infections is necessary for a flourishing society. This is most clear in case of a large outbreak of a dangerous disease like measles, SARS or tuberculosis. Such outbreaks may impede people going to work, customers do their shopping, children going to school, etc. Even if there is no outbreak occurring, just *fear* of the possibility of infection – especially where individuals cannot easily protect themselves – may make it more difficult for individual persons to interact. Hence, protection against infections that occur in social life, is a basic condition for a flourishing society, and in many cases, vaccination will offer such protection most effectively: collective vaccination makes it possible for people to trust that, in normal circumstances, talking, shaking hands, laughing and even sneezing does not create severe health risks. Moreover, collective vaccination can lead to eradication of a pathogen, to herd immunity, or at least to a substantial reduction in the spread of the virus or microbe, and hence creates a form of protection that is beneficial to anyone, now and in the future, irrespective of whether they have gained immunity or not.

If liberalism and other views that leave only a modest role for the state can accept that the state still has a primary responsibility to protect basic functioning of society, including offering protection against infections, this will certainly hold for egalitarianism or utilitarian political philosophies that would favour a more expansive

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