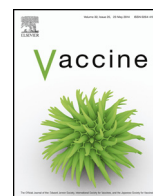




ELSEVIER

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

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

Marcel F. Verweij^{a,*}, Hans Houweling^b^a Department of Philosophy, Wageningen University, The Netherlands^b Health Council of the Netherlands, The Netherlands

ARTICLE INFO

Article history:
Available online xxx

Keywords:
Ethics
Vaccination policies
State responsibility
Public health
Justice
Rotavirus
Human papilloma

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.

© 2014 Published by Elsevier Ltd.

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

☆ Submitted for the Vaccination Ethics Special Section in Vaccine (guest edited by A.M. Viens and Angus Dawson).

* Corresponding author at: Subdepartment 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).

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

role for government to promote health. Hence, there is broad support for a principle that the state has responsibility to protect public health and societal life against dangerous infections. This responsibility involves creating conditions in which people can live together safely, in particular by preventing that people may (unintentionally) harm one another, but also protecting against potentially dangerous infection risks in environment that may affect large groups of people.

4. Responsibility for government: health justice and access to basic care

The second consideration guiding government's responsibility for public health is justice. In our previous work, we discussed this primarily as a principle for fair distribution, e.g. among subgroups, of the benefits of vaccination, and not so much as a principle that would guide choices as to *why* the state should offer certain vaccinations. However, in public health ethics – and notably the ethical literature on universal health insurance – justice is seen as argument par excellence for the state to take responsibility for health care. Health is a special value for each individual because it protects her range of opportunities in life; equal access to care that is necessary to regain or maintain health, can therefore be supported as it promotes fair equality of opportunity [16] for all individual persons. The idea that all citizens should have equal access to basic health care is shared widely, and indeed most industrialised countries have some form of universal health care coverage [17]. There is no reason to limit this idea to patient care and not also include certain preventive vaccinations. In order to promote fair equality of opportunity the state should create equal access to vaccinations that are necessary for individual persons to maintain health. If persons run substantial risk to develop a serious disease, and vaccination can take away or significantly reduce the risk, it might be unfair if some can afford vaccination and others can not. If so, the state has moral reasons to offer equal access to this vaccination – of course within the limits of reasonable health care expenditures. In some cases, preventive vaccination may be closely linked to patient care. Given that rotavirus infections seem to be especially risky for specific patient groups, vaccination should be considered as part and parcel of basic health care for these groups.

This consideration of justice explicitly focuses on the importance for *individual persons* to be protected. In that sense it is different from the first principle that aims at protecting public health and the conditions for societal life. Hence, jointly the principles acknowledge that vaccination policies yield collective as well as individual benefits [18] and that the state has responsibilities in regard to both. Obviously, vaccinations that protect basic conditions for societal life do so by means of protecting individual persons against infection. The two principles, however, are important for understanding the different rationales for government to offer vaccination. For many vaccinations, including vaccinations against polio, diphtheria, and measles, both principles will be relevant. It is, however, less obvious that the state should protect societal life by means of vaccination against human papilloma virus (HPV); yet the idea of promoting equal protection against cervical cancer is a reasonable basis for a state responsibility. This argument in fact played a role in the Health Council advisory report on vaccination against cervical cancer [6].

5. The inevitability of evaluations of severity of disease

Acknowledging these two principles for the state's responsibility to offer vaccination does not make assessments of the seriousness of infection and of related disease burden irrelevant. To the contrary, applying the principle of equal access to basic health

care requires evaluative judgments about what vaccinations are indeed basic for maintaining health – and this involves evaluating the burden of disease of risk for individuals and populations. As we explained, finding reasonable consensus on such judgments can be very difficult. Alternatively one could argue that the state should avoid such judgments and just offer any safe vaccination that is sufficiently cost-effective. We think however that this will not do. Cost-effectiveness as such is not a clear reason to offer vaccination – certainly given that vaccination is normally offered pro-actively. Acting on such policy would neglect that nowadays the public does not just accept anything that is offered by government. The success of vaccination depends on public trust in such programmes. To protect public trust in vaccination, public programmes should focus on protecting against diseases that are generally considered to be serious, hence evaluative judgments about the severity of disease for infected persons are inevitable. Apart from expert assessment this may require involvement of parents and other stakeholders (e.g. in focus group studies) as well.

6. Implications

We have argued that collective vaccination is not just a matter of protecting the public and societal life against threats of infection, but also of providing equal access to basic vaccinations. For vaccinations that aim to protect the population at large, it is undesirable that individual persons decide about vaccination solely on the basis of their individual risk and benefits, as this would overlook the population-level benefits at stake. Pro-active policies are necessary to attain vaccination rates as high as possible. Depending on the context, even compulsory vaccination could be justified [2].

For vaccinations that are offered as basic individual care, high participation rates can be relatively unimportant. A pro-active, routine offer may still be justified, but as means to promote equal access, not to persuade everyone to participate. If vaccination against human papilloma virus (HPV) would be considered primarily as individual preventive care for girls, and not so much as a public programme aiming to reduce HPV infection risks then there should be room for adolescent girls and their parents to make their own judgments about personal risks and benefits and alternative forms of protection, like screening. On the other hand, if parents are to decide on behalf of their small children about vaccination that is considered 'basic health care', or if decisions are often not well-informed, then persuasion is of course appropriate.

Yet vaccination against cervical cancer can simultaneously be seen in a different light. Not just as a matter of equal access to basic preventive care for each girl, but also as reducing the chance that people infect one another with HPV, and thus expose one another to a risk to develop cancer. Given the high prevalence of HPV infections, and the limited effect of condom use to prevent infection, a reduction of spread of the virus is a reasonable public health goal. If vaccination against HPV is framed and accepted in this way, it may also fit in the responsibility of government to protect public health and societal life. Striving for high vaccination rates then does make sense, and stronger forms of persuasion can be appropriate. For that matter, if the aim is to reduce the spread of HPV, one should at least consider vaccination of all adolescents, girls and boys.

Our reflection on the responsibility of government was raised by the practical question whether rotavirus vaccination would fit in a national vaccination programme. In countries where severe diarrhoea and dehydration cannot be treated easily, hence pose significant risk to the lives of children, vaccination against rotavirus is to be considered both as essential preventive care (to which children should have equal access), and as a collective good (protecting conditions for public health and societal life). But what about high-income countries in which such risks are much lower? Should,

for example, the Dutch government include rotavirus vaccination in the national programme? Arguably, for immunocompromised infants and other paediatric patients for whom rotavirus infection poses a significant threat, vaccination is to be considered as belonging to basic care, and these patients should have access to vaccination. For almost all other children however, gastrointestinal rotavirus infections are self-limiting, and the risk of serious complications is very low. It is therefore less obvious that rotavirus vaccination is to be considered basic necessary care for healthy infants, and that the state should secure equal access to such vaccination. The other pillar for state responsibility for vaccination, protecting conditions for public health and societal life, may offer a more promising basis for universal vaccination. If rotavirus infections are indeed a major cause for seasonal high peaks in admissions in paediatric hospitals, and if such peaks are undermining access to health care, then vaccination may help to maintain access and quality of health care, and thus contribute to protection of public health. Whether that argument is strong enough to support universal vaccination depends on a variety of factors, including the severity of such peaks, and the availability of alternative options to reduce pressure on hospitals

References

- [1] WHO. State of the world's vaccines and immunization. 3rd ed. Geneva: WHO; 2009. http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf [accessed 18.07.13].
- [2] Verweij M, Dawson A. Ethical principles for collective immunisation programmes. *Vaccine* 2004;22(August (23-24)):3122-6.
- [3] Larson HJ, Cooper LZ, Eskola J, Katz SL, Ratzan S. Addressing the vaccine confidence gap. *Lancet* 2011;378(August (9790)):526-35. [http://dx.doi.org/10.1016/S0140-6736\(11\)60678-8](http://dx.doi.org/10.1016/S0140-6736(11)60678-8).
- [4] Health Council of the Netherlands. The future of the National Immunisation Programme: towards a programme for all age groups. Health Council of the Netherlands; The Hague; 2007 [Publication no. 2007/02E] <http://www.gezondheidsraad.nl/sites/default/files/200702E.0.pdf> [accessed 18.07.13].
- [5] Houweling H, Verweij M, Ruitenberg EJ. National Immunisation Programme Review Committee of the Health Council of the Netherlands. Criteria for inclusion of vaccinations in public programmes. *Vaccine* 2010;28(April (17)):2924-31. <http://dx.doi.org/10.1016/j.vaccine.2010.02.021>.
- [6] Health Council of the Netherlands. Vaccination against cervical cancer. The Hague: Health Council of the Netherlands; 2008 [Publication no. 2008/08E] <http://www.gezondheidsraad.nl/sites/default/files/200808E.pdf> [accessed 18.07.13].
- [7] Houweling H, Spaendonck MC, Paulussen T, Verweij M, Ruitenberg EJ. Preparing for the next public debate: universal vaccination against hepatitis B. *Vaccine* 2011;29(November (48)):8960-4. <http://dx.doi.org/10.1016/j.vaccine.2010.02.021>.
- [8] Health Council of the Netherlands. Vaccination against pandemic influenza A/H1N1 2009: target groups and prioritisation. The Hague: Health Council of the Netherlands; 2009 [Publication no. 2009/10E] http://www.gezondheidsraad.nl/sites/default/files/influenza.A-H1N1_2009.pdf [accessed 18.07.13].
- [9] Health Council of the Netherlands. Human vaccination against Q fever. The Hague: Health Council of the Netherlands; 2010 [Publication no. 2010/08E] <http://www.gezondheidsraad.nl/sites/default/files/201008E.pdf> [accessed 18.07.13].
- [10] van Lier EA, Oomen PJ, Oostenbrug MW, et al. Hoge vaccinatiegraad van het Rijksvaccinatieprogramma in Nederland. *Ned Tijdschr Geneesk* 2009;153:950-7 [in Dutch].
- [11] Ruijs WL, Hautvast JL, van der Velden K, et al. Religious subgroups influencing vaccination coverage in the Dutch Bible belt: an ecological study. *BMC Public Health* 2011;11:102.
- [12] van Lier A, van der Maas NA, Rodenburg GD, Sanders EA, de Melker HE. Hospitalization due to varicella in the Netherlands. *BMC Infect Dis* 2011;11(April):85. <http://dx.doi.org/10.1186/1471-2334-11-85>.
- [13] Bruijning-Verhagen P, Mangen MJ, Felderhof M, Hartwig NG, van Houten M, Winkel L, et al. Targeted rotavirus vaccination of high-risk infants; a low cost and highly cost-effective alternative to universal vaccination. *BMC Med* 2013;11(April):112. <http://dx.doi.org/10.1186/1741-7015-11-112>.
- [14] Bruijning-Verhagen P, Sankatsing V, Kunst A, van den Born C, Bleeker E, Thijsen S, et al. Rotavirus-related hospitalizations are responsible for high seasonal peaks in all-cause pediatric hospitalizations. *Pediatr Infect Dis J* 2012;31(December (12)):e244-9. <http://dx.doi.org/10.1097/INF.0b013e31826a5ba1>.
- [15] Anomaly J. Public health and public goods. *Public Health Ethics* 2011;4(3):251-9. <http://dx.doi.org/10.1093/phe/phr027>.
- [16] Daniels N. Justice, health, and healthcare. *Am J Bioeth* 2001;1(Spring (2)):2-16.
- [17] Garrett L, Chowdhury AMR, Pablos-Méndez A. All for universal health coverage. *The Lancet* 2009;374(9697):1294-9. [http://dx.doi.org/10.1016/S0140-6736\(09\)61503-8](http://dx.doi.org/10.1016/S0140-6736(09)61503-8).
- [18] Verweij M. Individual and collective considerations in public health: influenza vaccination in nursing homes. *Bioethics* 2001;15:536-46. <http://dx.doi.org/10.1111/1467-8519.00260>.