

# Inducing immunity for the sake of others. Ethical analysis and justification of indirect vaccination strategies

## Summary

The introduction of vaccination against infectious diseases has been one of the most important contributions to public health of the last century. For this reason, governments actively promote collective immunization in various ways –notably through general programs as the Dutch Rijksvaccinatieprogramma. A characteristic feature of most vaccinations is that they not only directly immunize the individual involved but also indirectly protect people who are not or cannot be immunized themselves. Still, most vaccination programs are primarily justified in terms of the interests of the person involved. The success of these direct vaccination programs is beyond dispute, but further health benefits can be gained if governmental agencies would promote indirect vaccination strategies that primarily aim at achieving external benefits. Examples thereof are maternal immunization to protect newborns (pertussis; influenza, and in the future possibly RSV, zika), the vaccination of professionals, notably health care workers to protect vulnerable patients against, for example influenza or pertussis; or public health programs that aim to vaccinate persons who run a relatively small risk themselves but might spread infections to vulnerable others (e.g. influenza of children to protect elderly or HPV vaccination of boys). Even though such indirect vaccination strategies are increasingly endorsed and recommended by for example the WHO and the Health Council of the Netherlands, a systematic ethical justification of such programs is up to now lacking. This proposal seeks to fill that gap by gathering and critically analyzing relevant normative arguments for and against indirect vaccination strategies that primarily aim at achieving external benefits. Indirect vaccination strategies are defined as vaccination programs that target individuals who do not belong to the group or subgroup for whom the most important health benefits are expected and aimed for. These indirect strategies may raise ethical issues and public controversy, especially if benefits for vaccinees themselves are very small, and this problem becomes only more urgent given emerging vaccine hesitancy and slowly declining vaccination rates for regular childhood immunization. On the other hand, indirect immunization does appeal to such ethical notions as non-maleficence (not harming others), benevolence and solidarity. In this project we explore the possibilities of developing an ethical justification for indirect vaccination, as offered or supported in a programmatic and pro-active way by government, aiming at high vaccination uptake among relevant target groups. We focus on three contexts, namely maternal immunization, professional immunization, and indirect vaccination for public health. (1) Under what conditions are vaccination policies aiming at external effects ethically justified? (2) When are health authorities justified in implementing such vaccinations in a routine, persuasive or otherwise pro-active manner? (3) What communicative approach to promote such programs would be appropriate and trustworthy? We analyze these questions in the context of current and future vaccination options and against the background of increasing vaccine hesitancy. The research project is a study in practical ethics, focusing on normative and conceptual analysis, yet informed by focus group studies with target groups, expert/stakeholders discussions, and, above all interaction with advisory and policy practice.

The project results in ethical recommendations for vaccination policy and practice including guidance for targeted communication strategies.

## Problem

Immunization has an essential role in prevention and control of infectious diseases, offering protection at individual and population levels (Greenwood 2014). Protection is, however, often not complete. Sometimes the most vulnerable persons may not be sufficiently protected against a common infection because they cannot (yet) be vaccinated themselves, or because their immune response to the vaccine is less than optimal. Examples are pertussis risks for newborns (van Hoek et al 2013) and influenza for elderly. Gaps in population immunity may further increase given slowly declining vaccination uptake due to increasing vaccine hesitancy and refusal (Van Liert 2017; Dube 2013; Larson 2016). An increasingly relevant strategy to reduce these gaps is by protecting vulnerable individuals indirectly through immunizing others. We define indirect vaccination strategies (IVS) as vaccination programs that target individuals who do not belong to the group or subgroup for whom the most important health benefits are expected and aimed for. This is considered or recommended in various domains: 1. Maternal immunization can protect the fetus/future infant by means of transfer of maternal antibodies, from mother to child. WHO recommends maternal influenza immunization; the Health Council of the Netherlands recently advised for vaccination against pertussis (Gezondheidsraad 2015). 2. Cocooning: vaccinate family members 'around' a person at risk. Cocooning is not a collective, programmatic vaccination approach and will not be discussed specifically in this proposal. 3. Professional immunization (notably of health care workers) to protect patients at risk. Influenza is the most common case but other vaccinations (e.g. pertussis) are also recommended (van Dool 2009). 4. Indirect vaccination for public health: vaccinate important vectors in the community as a means towards reducing risks for groups at high risk. This has been proposed for example as justification of influenza immunization of children (Sugaya N, 2014) and HPV vaccination of boys (Malmqvist 2011). Indirect vaccination can generate significant health benefits but it also raises ethical questions and may well lead to public controversy. If benefits for the vaccinees are relatively small, some will only experience burdens, whereas other groups enjoy the benefits of vaccination, might be considered as unfair. Moreover, if benefits for the vaccinated are almost absent while side-effects are more common, people may see vaccination as not in their own best interests. In such cases, the commonly used ethical justifications for vaccination programs do not self-evidently apply: to protect individual vaccinees, protect public health and societal life, and promote a fair distribution of benefits and burdens (Gezondheidsraad 2013; Verweij & Houweling 2014). This project seeks to fill this gap by gathering and critically analyzing the ethical arguments pro and con indirect vaccination strategies. Moreover, it will analyze how these arguments are assessed by relevant focus groups, and how these can be translated into and implemented in effective and trustworthy vaccination policies. Gaps in the ethical underpinning of IVS are especially problematic given emerging vaccine hesitancy which results in slowly decreasing vaccination rates in developed countries such as the Netherlands (Van Liert 2017), and, consequently new outbreaks and spread of 'old' diseases like measles (Woudenberg 2017; Muscat 2013). After all, if governments embrace indirect vaccination strategies they admit that current programs do not offer sufficient protection – which is in

line with beliefs of vaccination critics who have doubts about the benefits anyway. Moreover, critics will emphasize that this vaccination is not in the interest of the vaccinated persons themselves. In the worst case, negative responses could undermine confidence (or stimulate hesitancy and distrust) in regular vaccination as well. Arguably, if specific forms of indirect vaccination are justified, these will require good information strategies to be successful. Yet the character of communication itself raises an ethical problem given that it also has a role to play in informed consent: how should the competing aims of informed choice and persuasion be weighed? Can governments promote altruism? These questions require the same ethical arguments that are needed for justifying indirect immunization itself. This translates into the following research questions: (1) under what conditions are vaccination policies aiming at external effects ethically justified? (2) When are health authorities justified in implementing such vaccinations in a routine, persuasive or otherwise pro-active manner? (3) What communicative approach to promote such programs would be appropriate and trustworthy?

### Societal relevance and impact

Vaccination is of high importance in protecting public health but the benefits are becoming less visible for the general public, while at least some groups emphasise the possibility that vaccination comes with risk (Callender 2016). This is one of the explanations of the emerging vaccine hesitancy and declining immunization rates in developing countries. Immunization policies are therefore in need of a strong and clear ethical justification, especially if for target groups burdens of vaccination are more tangible than benefits. Indirect vaccination, primarily aiming at external effects, is then a case in point, as it can only protect public health if people who might not substantially benefit themselves are still willing to cooperate. There are increasing possibilities for indirect vaccination, including maternal immunization (tetanus, pertussis, influenza; in the future, among others zika, RSV), vaccination of health or child care workers (influenza, pertussis), or vaccination of 'spreaders' in a community – often children (influenza, pneumococcal disease, etc.). The Netherlands Health Council takes external effects into account in the evaluation of vaccination effects (Gezondheidsraad 2013), but the general criteria for assessing new vaccination strategies have not been developed for indirect vaccination. One exception is vaccination in occupational contexts for which the Health Council did specify criteria, in line with the fact that this area (and notably the vaccination of health care workers) has been debated and analysed in more detail (Gezondheidsraad 2014). An overall ethical justification of indirect vaccination strategies is however lacking and that is what this project is after. In this way, the project aims to offer support to advisory processes in the Health Council and WHO and guidance for implementing new vaccination policies by the RIVM. Under what conditions are vaccination policies aiming at external effects ethically justified? When are health authorities justified in implementing such vaccinations in a routine, persuasive or otherwise pro-active manner? And what communicative approach would be effective and trustworthy? The analysis and clarification of central ethical arguments for and against, and relevant features of specific cases, are necessary to develop an ethical basis for indirect vaccination policies, now and in the future; and a legitimate basis for (persuasive) communication aimed at high compliance. Perspectives of relevant target groups are included via focus group studies and expert/stakeholder sessions during the project. The

focus group discussions will offer us a perspective of members of target groups on some of the central ethical arguments, and may generate other relevant considerations as well. The expert/stakeholder discussions will ensure that the outcomes of the study are relevant and useable for practice. The research will run parallel to several relevant advisory processes at the Health Council and their possible implementation by RIVM from 2017, for example pertussis immunization of pregnant women (Gezondheidsraad 2015) and of health care workers (Gezondheidsraad 2017), HPV vaccination of boys, and influenza vaccination of children. As such, the results will directly inform immunisation policy-making and practice, given the key roles of project members, advisory group and involvement of end-users. Case studies about specific vaccinations will be adapted to what is most relevant to WHO, Health Council and RIVM.

### Dissemination plan

Our dissemination/knowledge transfer plan has two central aims. (1) to contribute to scientific debate in practical philosophy and applied ethics (2) to support actual advisory and public policy processes on vaccination. Connected to these aims we also seek to stimulate and enrich public debate about indirect vaccination, and to enrich education programs (communication and ethics/philosophy of law).

1. As a research project in practical philosophy and applied ethics, the project will of course aim at scientific publications, both in bioethics/public health ethics journals as well as in vaccinology/health policy journals. We expect at least 5 papers (a general overview of ethical aspects of indirect vaccination; the focus group study; two philosophical papers on people's responsibility to contribute to protecting others and on the role of government in this; and a paper presenting the normative framework for indirect vaccination programs. These papers jointly constitute a PhD thesis in public health ethics. As part of the ethical study foresee two international symposia with invited scholars in bioethics and public health, one of these in collaboration with WHO.

2. Practical philosophy and applied ethics require a strong interaction with professional or societal practices. This is especially the case if research is meant to support advisory and public policy processes. To realise this aim, our philosophical/ethical research take place in interaction with RIVM, WHO, and Health Council in various ways, and this interaction goes well beyond dissemination of research findings. First, the choice for specific cases in the three contexts will be based upon what is most relevant for these organizations. The Health Council has already agreed that staff can be interviewed on this specific topic. Second, throughout the project two of the core research teams function as linking pin with advisory/policy processes (Roland Pierik as member of the Health Council committee on vaccinations; Helma Ruijs as working at the RIVM). Furthermore, the expert/stakeholder meetings and focus group discussions are not only offering input for the research project, at least the former are also set up in such a way that they will lead to ethical reflection among experts and stakeholders about the justification of and limits to indirect vaccination. An additional workshop will be set up in collaboration with the WHO. Finally, the final workshop with communication specialists will be organized at the RIVM to offer direct input to relevant communication policies. Given the nature of this subject, ethical reflection should not be limited to (policy) experts and professional and academic circles. This is a matter for public debate and dialogue. Hence, apart from scientific and professional output, we will contribute to discussions in popular media such as op-eds in newspapers, but also enrich the

education programs to which we contribute (e.g. Health & Society, and Communication Sciences in Wageningen, and Legal Studies in Amsterdam). The focus group studies will also be set up and carried out with MSc students in social sciences in Wageningen. To enrich and provoke reflection on all occasions, as part of the project cartoons will be produced and printed, to be used during focus group studies, expert meetings, and publications.

## Objectives

The aim of this study in public health ethics is to develop a theoretically grounded normative framework for indirect vaccination programs. The framework should offer a comprehensive ethical justification for indirect vaccination programs that (a) specifies criteria that need to be fulfilled for indirect vaccination to be acceptable and fair in different contexts, (b) explains under what conditions governments or public health professionals should offer vaccination in a persuasive, pro-active way, and (c) guides trustworthy communication strategies. The framework will support health organizations, advisory bodies and government bodies, notably RIVM, the Health Council of the Netherlands, and the WHO. These aims are accomplished by means of exploratory studies (literature; expert interviews), focus group studies, normative and conceptual analysis, and expert meetings.

## Expertise of the research team

Marcel Verweij is professor of philosophy at Wageningen University. His research area focuses on the ethics of public health and prevention. As member of the Health Council committee on vaccinations he was involved in almost all of the Council's advisory processes on vaccination between 2001 and 2016, and he had in major role in the formulation and justification of the current framework of criteria for assessing the national immunization program. Verweij wrote two white papers for the World Health Organization, one on equitable access and priority setting in an influenza pandemic, and one on maternal immunization. He has published on a variety of theoretical and practical ethical topics in public health relevant to this project. For example on the role of solidarity in health care, the question as to whether individuals have a moral obligation to take precautions against infecting others, on government responsibility for collective immunization, and on the role of informed choice in vaccination. Together with Roland Pierik he works on a monography on the regulation of vaccination in a liberal democracy. Verweij has been involved in collaborative projects with RIVM before (e.g. in two ZonMW projects, on ethics in infectious disease control, and on antibiotic resistance), always with a strong focus on promoting ethical reflection in practice. Together with Angus Dawson he is founding editor-in-chief of the journal Public Health Ethics. Roland Pierik is associate professor of legal philosophy at the University of Amsterdam Law School. In 2016, he joined the Vaccinations Committee of The Health Council of the Netherlands. His research lies at the intersections of legal philosophy, political theory, law and public policy. Since 2013, his research mainly focuses on the (legal) regulation of vaccination against infectious diseases, having written several academic articles on the regulation of childhood vaccination. In addition, he participates actively in public debates on these issues. Together with Marcel Verweij he works on a book on the ethics and regulation of collective vaccination. Bob Mulder, PhD, is a

Lecturer Strategic Communication at Wageningen University. His research focuses on how communication addresses and changes health behaviors such as diet, physical activity and medication intake, as well as vaccination uptake. He is experienced in using both quantitative and qualitative research methods to study these topics. Theoretically, his work is strongly rooted in social and health psychology, by using theories and concepts from psychology and communication science to study human behavior. Helma Ruijs, MD, PhD, is a senior consultant infectious disease control at the National Coördination Centre for Communicable Disease Control (LCI) with focus on vaccine preventable diseases. She is a member of the advisory group of the National Immunization Program and coordinates guidance and information on vaccines not included in public health programs. Her main research interest is acceptance of vaccination. Her PhD thesis was on acceptance of vaccination among orthodox protestants in the Netherlands.

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