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ethiek van vaccinatie

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Inleiding en leeswijzer

Vaccinatie is een thema dat de maatschappelijke gemoederen bezig houdt. Vanaf het midden van de negentiende eeuw voerden landen verplichte inenting tegen pokken in, en dat riep vanzelfsprekend weerstand op. Vrees voor bijwerkingen, twijfels over het nut, en – zeker in Nederland – weigering op grond van godsdienstige of levensbeschouwelijke overwegingen zijn nooit echt uit het maatschappelijk debat verdwenen, ook niet toen vaccinatie in het huidige Rijksvaccinatieprogramma ‘vrijwillig’ werd. Ondanks allerlei bezwaren is de deelname aan het Rijksvaccinatieprogramma zeer hoog, zo’n 95%. Die hoge deelnamegraad is nodig om de groepsimmunitet tegen een aantal infecties, in stand te houden. Het succes van vaccinatie creëert ook problemen: veel ‘kinderziekten’ doen zich nauwelijks meer voor en mensen vragen zich af of vaccinatie nog wel zo nodig is. Het besmettelijke karakter van infectieziekten, het creëren van groepsimmunitet, en eventueel de mogelijkheid om bepaalde gevaarlijke infecties uit te roeien vormen echter redenen om de keuze voor vaccinatie niet louter af te laten hangen van de inschatting van het risico voor het individu. Collectieve vaccinatie is een *public health* interventie; een collectieve aanpak die de *volksgezondheid* beoogt te beschermen. Dat speelt niet alleen een rol bij de vraag naar keuzevrijheid, maar ook bij beslissingen over welke nieuwe vaccinaties voor het collectieve programma in aanmerking komen.

Bij reflectie op ethische vragen inzake vaccinatie is het perspectief van maatschappelijke gezondheidszorg dan ook cruciaal. Vandaar dat de tekst voor dit NVBE-advies begint met een introductie tot de ethiek van public health – een thema dat veel breder is dan ethiek van vaccinatie. Daarna volgen twee teksten over collectieve vaccinatie, eerst een waarin verschillende ethische vragen met betrekking tot vaccinatie worden besproken, en ten slotte een tekst die specifiek ingaat op de kwestie of de keuze voor vaccinatie aan individuen moet worden overgelaten. Alle drie de teksten zijn geschreven als ‘encyclopedie’ artikelen en hebben daardoor een inleidend karakter. De tweede en derde tekst overlappen in beperkte mate, een overlap die hopelijk niet storend is. Meer informatie over de principes achter het huidige Rijksvaccinatieprogramma is te vinden in een advies uit 2007 van de Gezondheidsraad *De toekomst van het Rijksvaccinatieprogramma: naar een programma voor alle leeftijden* (www.gezondheidsraad.nl).

Marcel Verweij, februari 2013.

Public Health Ethics¹

Marcel Verweij and Angus Dawson

Introduction

In the first decades of its development, bioethics has mainly focused on ethical issues in clinical medicine and medical technology. Since the end of the twentieth century, however, more and more attention has been given to moral and legal issues in public health. The field of public health encompasses a broad range of health problems and societal responses that inevitably raise ethical questions. Infectious disease control, mass screening, and health promotion have the potential to reduce the burden of disease within populations, but they can also be in tension with other values such as liberty or individual well-being, or raise questions about justice in relation to priority setting. However, public health ethics is not just about a new set of topics, but can also be thought of as a distinctive approach to biomedical ethics for at least three reasons. First, public health interventions are generally aimed at populations rather than individuals, and therefore cannot easily be tailored to individual choice. Hence, whereas “autonomy” and “informed consent” are seen as core elements of clinical bioethics, their role in public health ethics is less.

Second, most public health programs are preventive in nature, aiming to reduce the risks associated with disease rather than treat patients. Such risks are everywhere in the physical environment, in society, and in the way we lead our lives. As a result, public health interventions aim to change the conditions in which we live, as well as our behavior towards ourselves and to others. The possibilities of prevention are all-pervasive, raising concerns about medicalization (Verweij 1999). Moreover, whereas clinicians normally act in response to a patient’s request or complaint, preventive actions are motivated by the assumption that it is better for the public to avoid illness, risks, or unhealthy behavior. Health promotion is therefore sometimes criticized for its “paternalist” nature. Paternalism has a bad name in bioethics and is often considered to be a *prima facie* wrong (Dworkin 2005), but in public health it is far from obvious that this is true.

A third feature of public health ethics is the central role of the state. Arguably, government has an obligation to protect its citizens, and citizens have certain obligations to contribute to such protection. Many debates in public health ethics are concerned with the justification and scope of such obligations – topics that are less prominent in clinical bioethics.

The Nature of Public Health

Public health is a disputed concept (Institute of Medicine 1988; Gostin 2000; Rothstein 2002; Goldberg 2009). It refers to the health of the population as a group, as well as to organizations

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and practices that aim to promote health. In order to avoid confusion it is helpful to use the term “population health” for the former, and to define public health as *collective interventions to promote or protect the health of the population*. Public health not only has a collective “target,” it is itself a collective enterprise. Moreover, both aspects of public health are *collective* or *public* in various ways (Verweij and Dawson 2007). Population health refers to the state of health of a large group of people, and can be measured in terms of mortality or morbidity figures for specific diseases, or, more generally, in terms of average (disability-free) life expectancy. It would be a mistake, however, to see the collective nature of population health simply in terms of aggregate health for two main reasons. First, how health is distributed *within* a population is also relevant to our assessment of population health, and especially relevant from an ethical perspective. If the average life expectancy in two populations is equal, but in one population there are significant health inequalities associated with different socioeconomic groups, whereas in the other there are no such inequalities, we may consider the former “population health” to be worse than the latter. Second, if we see population health as “simply” the aggregation of the health of all individuals, this would ignore the fact that the health status of individuals is surely at least partly determined by that of others. This is most visible in the phenomenon of herd immunity: if, say, 90 percent of the population has immunity against measles, the remaining 10 percent will be protected as well. Many other protective and risk factors for health result from individuals’ embeddedness in the social and physical environment. In assessing the health of a population it makes sense to include such factors as well.

The other element in our concept of public health, the organization and practice, is collective in different ways as well. Public health programs are normally joint enterprises, set up and carried out by (local or national) societal institutions. Where law is an important instrument for public health, a central role for government is inevitable. Moreover, to be successful, programs normally require public participation. Public health professionals do not just “treat” a passive population: often the public must be mobilized and participate actively. They have to comply with hygienic recommendations, get vaccinations, choose healthy meals, etc. Even small changes in common behavior such as a slight reduction of salt intake across the population may have large effects on preventing morbidity and mortality (Rose 1992). In this way, the general public is not just the target group, but also an important collective agent for delivering public health ends.

Moral Problems in Public Health

Many moral problems in public health can be understood in terms of a conflict between promoting public health and respecting autonomy (Jennings 2009). For example, if citizens are given complete freedom to decide whether or not to accept vaccination, this may result in low vaccination rates and increase the risks of outbreaks of severe infectious diseases. Some countries have mandatory vaccination programs, but does the aim to prevent such outbreaks

justify liberty-limiting measures? Another prominent theme in public health is the rising prevalence of obesity. Suppose that imposing extra taxes on “unhealthy” food would be effective in reducing the number of people that are overweight. Can it be justified for the state to interfere with the personal choices of citizens, for the sake of promoting population health?

However, though it is tempting to focus on moral conflicts between public health and liberty, there are several reasons for being reluctant to see this as *the* fundamental problem of public health ethics. First, presenting a conflict between the practice of public health and respect for liberty as the central problem runs the risk that any public health program that interferes with the lives of individuals is just assumed to be *prima facie* wrong. As a result many programs that are well accepted would be considered morally problematic (Dawson 2011). For example, even if a childhood vaccination program is voluntary, the vaccinations will be offered in a routine way, on the assumption that vaccination is the right choice and that parents will accept the offer. This may well be a form of paternalism, but if this implied that even such voluntary vaccination programs are *prima facie* wrong, this would distort well-accepted public health practices.

Second, highlighting conflicts between public health and individual liberty may lead one to overlook the variety of values at stake in public health, including equity, social justice, privacy, security, well-being, solidarity, etc. These values give rise to a broad range of practical moral problems. Moreover, a variety of values are central to the practice of public health itself (Munthe 2008). For example, offering special protection to disadvantaged groups, or combating health inequities, are legitimate aims for public health. Determining which disadvantages and health inequalities are unjust – and on what grounds – are central problems in public health ethics (Wilson 2011), and these issues cannot and should not be analyzed in terms of a conflict between public health and individual liberty.

Theoretical Approaches and Debates in Public Health Ethics

Although there is a lot of ethical debate in public health, few attempts have been made to develop a full normative theory for public health or health promotion (Powers and Faden 2006; Buchanan 2000). In this section we explore some such possible theoretical foundations. The central place that is often given to conflicts between promoting the health of the population and protecting individuals suggests that theoretical debates will mainly center around utilitarianism, as opposed to liberal or human rights approaches (Holland 2007). Although theoretical work is much richer than this two-dimensional scheme suggests, debate in public health ethics is often presented either as starting with a roughly utilitarian account, which then gives rise to thinking about constraints in terms of human rights or other individualist values, or as commencing with a narrow version of liberalism, followed by a discussion on the extent to which this needs to be modified or rejected in order to do justice to the values of public health.

Utilitarianism versus human rights

Utilitarianism is often assumed to be the normative theory that best “fits” the aims of public health. Utilitarians hold that actions and policies are right if they best promote aggregate welfare. Health is undeniably a central source of well-being, and it seems reasonable to assume that, if one succeeds in promoting the health of a population, this will result in increased welfare as well. Moreover, policy makers and governments will welcome such emphasis on aggregate health and on efficiency. Epidemiological studies and cost–benefit analysis produce information that is necessary to determine which policies are most efficient in terms of promoting aggregate health. Utilitarianism has often been criticized because of its apparent neglect of how effects are distributed within a population. Efficient health policies may actually increase health inequities. For example, tobacco discouragement policies seem to have been more effective amongst well-educated than socially deprived populations (Voigt 2010). However, it is not obvious that utilitarianism will neglect disadvantaged groups. First, many health policies are generic. They are aimed at the whole population, but that population will include disadvantaged groups that will benefit. Second, promoting the health of groups that are better off anyway may have less effect on aggregate population well-being than promoting the health of groups that are really disadvantaged. Other forms of consequentialism might also seek explicitly to promote other values such as equality besides utility.

Another general concern that has been raised about utilitarianism is that in some cases individual well-being may be sacrificed if this is necessary to protect the health of the many, and this seems to undermine human rights. Infectious disease control is a good example: isolation and quarantine of the infected (or possibly infected) are efficient ways to protect the larger population. This can be highly controversial. For example, from the 1980s onwards, after the emergence of AIDS activism, public health professionals and bioethicists fighting against marginalization, discrimination, and detention of HIV-infected persons often appealed to human rights as a way to provide constraints to public health protections. However, in practice, promoting public health and protecting human rights may well go together. Utilitarians will recognize that detention of infected persons may mean that people avoid medical care, which in turn contributes to the further spread of disease. Proponents of human rights, on the other hand, must accept that in some cases, for example during outbreaks of extreme drug resistant tuberculosis, an infected person’s right to freedom will clash with many other people’s right to life, and that coercive isolation can be inevitable and justified (Singh et al. 2007).

Liberalism and the anti-paternalist critique

The last point can also be put in terms of the harm principle, which originates with Locke and Mill, and has been developed extensively by Joel Feinberg (1984) and other liberals: interventions which involve coercion, or otherwise put constraints on freedom of individuals, can be justified only if these are necessary to prevent harm to others. If the behavior of persons is harmful to

others, as in the case of smoking near children or other non-smokers, there is a clear moral basis for the state to intervene. The harm principle also supports various interventions in the context of infectious disease control, like forced isolation and social distancing measures. Moreover, each society has laws and institutions that regulate the safety of food and other goods.

There is a broad consensus among scholars in public health ethics about the idea that prevention of harm to others offers a moral basis for coercive measures. John Stuart Mill (1859) however is generally held to have understood the principle not just as offering a strong justification for setting constraints to liberty, but as the only valid reason for coercion. Mill stressed that individuals should be free to lead their own lives, and therefore he rejected coercing persons *for their own good*. Liberals in this tradition generally reject paternalism; but doesn't this imply also a rejection of many public health activities that go beyond merely informing individuals about health issues? There are exceptions. Liberals will agree that the anti-paternalist strand of the harm principle does not apply to children and others who are incapable of determining their own good, or those who are held to act involuntarily, like addicts. Hence, compulsory policies that aim to protect children from harm, like a policy that makes it illegal for them to buy tobacco and alcohol, may be justified even in the liberal framework.

But what about mandatory interventions that affect the lives of adults who are capable of making their own choices? The charge that such interventions in public health are often paternalist in nature and therefore *prima facie* morally problematic can be disputed in various ways. First, even within the liberal framework one may argue that such interventions do not aim to constrain individuals *for their own good*. They aim at the good of the public at large, and as such should be justified not by appeal to individual consent, but by means of a democratic process (Nys 2008). For example, urban environments and buildings may stimulate or even necessitate people to walk instead of drive to shops or their houses, or to take the stairs instead of using the elevator. It is a matter of debate whether the label "paternalist" is appropriate for such interventions in the first place.

Second, many preventive policies do aim to promote the health of as many individuals as possible, but by means of the creation of public goods which will benefit everyone, even those who do not contribute. Public goods will be undermined if many people opt out, and this may be a reason to accept some form of coercion. Even Mill acknowledges that coercion is justified to ascertain that that people do "their fair share" in the protection of all (Dawson and Verweij 2008). A good example is the possible creation of herd immunity by means of vaccination, which may ultimately lead to eradication of a disease.

Third, one may argue that an anti-paternalist critique of routine public health activities overemphasizes values like liberty and autonomy. If many health-related choices are made with little reflection as to the long-term consequences, health policies may be paternalist *and* justified if they support people in making the choice most would make if they took all relevant information into account. For example, it may be argued that policies that *nudge* people towards

making the reasonable and healthy choice rather than constrain their choices are justified (Thaler and Sunstein 2008). Examples will include making certain healthy options (e.g., in restaurant menus) the default option, or offering vaccination and screening programs in a routine (opt-out) way.

Liberalism and egalitarian concerns

These responses to the anti-paternalist critique can be further expanded by taking considerations of distributive justice into account, and developing an account of the role of the state (and public health in particular) that goes beyond preventing harm to others, but also includes obligations to protect groups whose health status is especially weak and vulnerable or the disadvantaged more generally. Initially, theories of justice in health focused on promoting equal access to healthcare (Daniels 1985). However, if health is important from the point of view of justice, securing equal access to healthcare may not have much impact on protecting groups that run the greatest risks of disease and premature death. There is ample evidence that groups that are worst off in terms of income, wealth, and education are also worst off in terms of health status. Moreover, inequalities in health occur across the whole income spectrum. The magnitude and pervasiveness of these health inequalities underline the importance of promoting just distributions of wealth, health, and access to education. The empirical and conceptual relationships between income and health are complex (Sreenivasan 2009; Wilson 2010), but it is reasonable to assume that health inequalities caused by unjust social factors are themselves unjust. Moreover, Daniels et al. (1999) and others have argued that promoting socioeconomic equality along the lines of John Rawls' theory of justice promotes population health.

If the low health status of disadvantaged groups is indeed to be considered unjust, there are strong reasons for public health authorities to promote the health of such at-risk groups. However, interventions aiming to counter common causes of disease in these groups (smoking, lack of exercise, unhealthy nutrition) may be ineffective in reducing inequality if they only aim at rational persuasion to adopt healthy lifestyles. Some forms of coercion, like higher taxes on cigarettes, may have more effect. Hence, if liberals take the relatively low health status of deprived groups seriously – as most liberal egalitarians will do – they have reason to reject a narrow liberal approach to public health. The Nuffield Council on Bioethics (2007), for example, suggests amending the harm principle by appeal to a notion of “stewardship” – implying that society has special responsibilities to protect and promote the health of vulnerable groups.

Welfare and social justice

The previous section suggested that promoting the health of systematically deprived groups requires targeted, and possibly even coercive, interventions. Yet doesn't this suggest that ways of living among these groups deserve less respect than the lifestyles and choices of the well-educated and better off? Powers and Faden (2006) discuss the example of testing pregnant

women for HIV. Should such a program be targeted at high-risk groups only and hence reinforce common prejudices about the behavior of women in those groups, or should screening be offered to all pregnant women? Targeted programs may potentially lead to stigmatization, discrimination, and other burdens for already deprived people. This may protect their health, but will it really make their lives better off? Powers and Faden take these concerns as a starting point for developing a more substantive idea of well-being, which includes not only health but also other dimensions like respect, attachment, and self-determination. On this view, social justice requires that everyone is ensured a sufficient level of well-being, which includes a sufficient level of health. Moreover, they see social justice as the basic moral foundation for public health. In this way, concerns about justice and respect are not external constraints on public health; they are part and parcel of public health practice itself.

Powers and Faden's account of well-being partly builds upon theories of capabilities and functionings as developed by Sen and Nussbaum. Liberals may find the capabilities approach in this context attractive as it combines a substantive idea of human flourishing (including health) without imposing on individuals an idea about how they should live: health policies should secure basic capabilities for a flourishing life, not good functioning itself. Powers and Faden however claim that public health sometimes should go beyond protecting capabilities only, and aim at securing a *sufficient* level of functioning. Nevertheless, their account of social justice, with an emphasis on respect and self-determination, is still coherent with the central tenets of liberal political theory.

Public health ethics beyond liberalism

The anti-paternalist critique of public health can also be rebutted in a more direct way. Perhaps the values of liberty and personal autonomy are themselves overemphasized and should, on occasions, be outweighed by other values like health, well-being, justice, or solidarity. One problem for liberalism is that it makes a strict distinction between self-regarding and other-regarding choices. Paternalist interventions that aim to steer me towards behavior that is better for my own health are wrong, while interventions that restrict behavior that negatively affects the health of others can be justified. However, public health experts will respond that few patterns of health-related behavior are completely self-regarding or private in this way. Even if people avoid smoking in the neighborhood of non-smokers, they still contribute to the fact that smoking is seen as a common practice or an acceptable norm. This, in turn, means that it is easier to start smoking and more difficult to quit (Verweij 2007). Food preferences are, similarly, developed and sustained in a cultural context, in which families and other groups influence each other's choices. An important aim for public health activities is to shift social norms and practices that undermine people's health. One step away from liberalism is the idea that citizens jointly create the societies they live in – including the many factors that influence the health-related choices of each individual – and that they have responsibilities toward each other to contribute

to this common good. These ideas may fit better within a republican or communitarian political theory, which gives a larger role to values like solidarity and mutual aid, and emphasizes a substantial role for the community in all our lives. Within a classical liberal framework it will be difficult to justify mandatory seat belts in cars. Yet such laws can be conceived as measures people take jointly to create conditions that protect the health of all. If it is left to each individual to decide whether to use seat belts, it will probably take decades before it becomes a common practice. Many more deaths and injuries (and distress of care providers and other witnesses) can be prevented if citizens accept some rules that bind them all. Dan Beauchamp (1985), one of the first authors in public health ethics, stressed the role of the community, and the idea that public health represents a common good. More recently, various authors have suggested civic republican approaches to public health ethics (Jennings 2007; Buchanan 2000). Republicans share with liberals a commitment to liberty, but they interpret liberty in terms of non-domination rather than negative freedom (or “right to be left alone”): the republican ideal is that people live together without being dominated by arbitrary power. This approach still leaves room for normative reflection on the common good, and for democratic deliberation about how citizens can and should contribute to the common good. Obviously this line of reasoning leads to practical and theoretical problems about which goals in public health can be considered a common good, and to what extent this is a sufficient basis for justifying particular public health measures.

International Affairs and Global Health

So far we have presumed that governments have a key responsibility for the welfare of their citizens and that this is an important justification for much public health activity. However, not all governments are able or willing to act on such obligations. Are there any obligations to respond at the global level where pressing public health needs exist? This is a contested issue (Hunter and Dawson 2011). If a preferred account of public health ethics can accommodate strong obligations towards those unable to care for themselves, it seems natural to extend such a view to the global level. We defined “public health” earlier as collective interventions to promote or protect the health of the population. It seems arbitrary to limit the notion of “population” to always refer to one’s own nation. However, even if it is not accepted that we have general obligations to others in need, there are often purely pragmatic or prudential reasons to care, particularly given the fact that infectious diseases do not respect borders.

Public health ethics covers a large number of topics, some of which have received little discussion in the bioethics literature. However, increasingly, public health ethics is also stimulating the development of thinking about moral and political theory and its application across the field of bioethics, including how these issues relate to global health.

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Ethics of immunization²

Marcel Verweij

Immunization Programs and Tensions between Collective and Individual Perspectives

Immunization programs are a fascinating subject for ethical reflection. Moreover, such reflection is mandatory for well-considered and responsible vaccination policies. One of the salient aspects of immunization programs is that they may not only affect the vaccinated individuals but also the population at large. The most effective way to avoid diseases such as poliomyelitis, measles, meningitis, or hepatitis is to have oneself immunized. And if many people choose similarly, this might lead to herd immunity, thus protecting the population at large, including those who are not vaccinated. It might even give the prospect of worldwide eradication of the infectious agent. Collective vaccination programs have a large impact on the spread and transmission of certain viruses and microbes. Remarkably, the fact that a potentially dangerous virus or microbe becomes less prevalent might have negative implications for at least some individuals. Prior to immunization programs, some people developed long-lasting immunity against many infectious diseases because they were infected regularly, thus repeatedly boosting their immune system. The less an infectious agent is present in a population – thanks to successful vaccination programs – the weaker one's immunity against the agent becomes. Hence, older persons and persons who have foregone vaccination might face some negative effects of successful childhood immunization programs. Moreover, this scenario illustrates how immunization may become an ongoing process: as childhood vaccination becomes more and more successful, it may become necessary for people to have repeated vaccinations at a later age, given that many vaccines do not offer lifelong protection. It might also make a person's decision to forego vaccination even more risky. On a population level, such negative effects will often be outweighed by the overall reduction of morbidity and mortality that can be achieved in a successful program, but some individuals might disagree with that assessment. Still other individuals might consider it unnecessary to participate in a vaccination program or to have their children immunized, given that most vaccines protect against diseases that seem to have been almost forgotten – at least in developed countries. In this way, the very success of a vaccination program may undermine people's willingness to participate.

Clearly then, immunization policies may raise conflicts between the common good of public health and the interests of particular individuals – particularly for collective immunization policies, that is, vaccinations that are offered to the whole population or to high-risk groups and

² Text from *International Encyclopedia of Public Health*, First Edition, vol. 2. Edited by Kris Heggehouden and Stella Qua. San Diego: Academic Press (2008)482-486.

that aim not just to protect each participating individual but also to protect the health of the public at large. This article focuses on such collective programs and not on the ethical dimensions of special topics in vaccination, such as vaccine research and vaccination of health-care workers.

New Vaccines, New Ethical Questions

The possible tensions between public and private interests underline the necessity that immunization programs be based upon well-considered decisions, including not just systematic review of epidemiological and immunological evidence but also ethical evaluation and justification. Such evaluation should concern the implementation of vaccination programs (voluntary or compulsory, requirements of informed consent, and so on), as well as the contents of the program (which vaccines should be offered). Until recently, the introduction of new vaccines in a collective program did not raise ethical debate. Childhood immunization programs grew slowly as new vaccines became available. Also, vaccines against poliomyelitis, pertussis and diphtheria, and measles, mumps, and rubella were timely and relatively inexpensive responses to clear public health threats. Nowadays, new vaccines are much more expensive, and they offer protection against diseases that are not as common and dangerous as, for example, measles used to be. Moreover, there are quite a large number of new vaccines in development, and it is far from self-evident that all can and will be incorporated in national vaccination programs. For the future it is hoped that effective vaccines against malaria and HIV will become available. Examples of new vaccines that are either in development or that have recently become available are meningococcal B and C, varicella zoster, human papilloma virus, rotavirus, and respiratory syncytial virus. Which vaccines should be given priority? Some vaccines raise new and specific questions, as they protect against sexually transmittable infections (human papilloma virus, herpes genitalis). Quite a few parents might object to the idea of immunizing their 11-year-old child against a sexually transmittable disease, especially if they endorse the ideal that their son and daughter should only have unprotected sex within marriage.

Serious Public Health Problems

As the number of available vaccines increases, priority setting seems inevitable. A first consideration is the magnitude of the public health problems that could be avoided through introduction of a new vaccine. This factor involves not only mortality and morbidity figures but also evaluation of the seriousness of the disease for individuals and of the risks for the public at large. In general, it seems reasonable to assume that universal vaccination programs should target diseases that might be fatal or that could lead to permanent disability, such as poliomyelitis, hepatitis B, or pneumococcal disease. Yet a vaccine that is to be given priority in a public program should also aim at preventing diseases that are major problems from the perspective of public health. Especially diseases that can spread rapidly in the public sphere and against which individuals cannot easily protect themselves should be given priority. This might

hold for potentially dangerous infections that are very common, such as influenza or pneumococcal infection, but also for viruses that, although uncommon or even absent, would represent a major threat to public life, for example through a bioterrorist attack. Giving priority to public health risks against which individuals cannot easily protect themselves is consistent with the core responsibilities of government. If individuals have sufficient possibilities to protect themselves against infection and avoid infecting other persons, universal vaccination in a collective program might be given less priority. Vaccines against sexually transmitted diseases are a case in point, although it is clear that a new HIV vaccine would be of highest priority in many countries worldwide.

Especially if priorities need to be set, it is important to specify disease-specific goals that must be attained with particular vaccines. If a disease cannot be completely eradicated, and if it is clear that the vaccine does not offer lifelong protection, one must weigh how much protection one should at least achieve (or, to put it more controversially, what levels of disease-specific morbidity and mortality one is willing to accept). For example, vaccines against pertussis do not give lifelong protection, nor do they produce 100% protection in all individuals. As a result, pertussis is still spread through adolescents and adults, and although these groups might only experience mild forms of whooping cough, they might infect newborn babies, who have not yet completed their first DTTP series. In the Netherlands, the goal of pertussis vaccination is to protect children until at least the age of five against the whooping cough. This specific goal might be considered as a reason to start a vaccination program for young adults or parents to be, with the primary purpose of protecting newborn babies rather than just the adults. In a balanced immunization policy it might sometimes be better to improve current vaccination strategies before introducing a completely new vaccine. Formulating vaccine-specific goals can contribute to the consistency and clarity of such programs.

Safety and Effectiveness

Collective vaccination programs aim to protect healthy persons against diseases that, at least in a number of cases, are relatively uncommon. These aspects support the claim that vaccination should be a highly safe procedure. Side effects of therapeutic drugs can often be well explained and justified to patients who need a drug to regain health. Yet such explanations are much more complex in the case of vaccination. Even very rare risks of immunization might be considered unacceptable. A good example is the oral polio vaccine, which, when given to millions of children, might cause a form of poliomyelitis in some of them. It is hardly acceptable that the only cases of poliomyelitis in a country are induced by the vaccine itself. Parents might consider forgoing vaccination of their children for that reason, which could undermine the global effort to eradicate the virus. Many countries have therefore replaced the oral polio vaccine with the Salk vaccine, which is much more expensive but does not have these risks. This example shows how the necessity to maintain high vaccination levels further increases safety standards.

Although many vaccines do not offer lifelong protection, vaccination still needs to be highly effective. Yet even if one focuses on protection for a limited number of years, 100% efficacy will still often be unattainable. As discussed above, at some point one must decide what level of effect is necessary. New vaccines for young children are often tested in a three-plus-one schedule, involving three injections during the first months, and one injection a year later. Such a schedule might offer the best chance of attaining the highest level of protection. Yet a reduced two-plus-one schedule might sometimes also render sufficient protection, as recent developments concerning conjugate pneumococcal vaccines show. This raises interesting ethical issues concerning vaccine research. After all, if a three-plus-one scheme has been proven effective, is it still feasible and morally acceptable to test a reduced two-plus-one scheme in a randomized trial? A head-to-head comparison of both schedules will require very large research populations if the expected differences are small. An alternative research design is to test the reduced schedule against placebo, but this would violate the Declaration of Helsinki, an important international ethical framework for research with human subjects. One of its principles states that new medical interventions should be tested against the best proven prophylactic, therapeutic, or diagnostic methods, and this would rule out a placebocontrolled trial of a two-plus-one vaccination schedule when a three-plus-one schedule has already been proven effective. Given these problems, it makes sense to start ethical reflection about the required level of protection at the time of vaccine trials, not after all trials have already been completed.

Inconveniences and Burdens for Participants

Most participants only experience inconvenience and small burdens from vaccination: on the one hand, successful vaccination results in a nonevent that one cannot really experience, and on the other hand, real risks are normally rare. Hence the most salient features of vaccination will often be the temporary fear and pain of an injection. Therefore it makes sense to take even such small inconveniences seriously by limiting the number of injections and developing needle-free immunization procedures. Minimizing small burdens is important not only because it benefits vaccinees, it may also contribute to the willingness of people (especially parents) to participate and hence may promote high vaccination rates.

Cost-Effectiveness Analysis and Considerations of Justice

The introduction of new vaccines should be assessed in terms of the full range of benefits, burdens, and costs resulting from the intervention, compared to alternative preventative options. A core element in such assessment can be provided by cost-effectiveness analysis (CEA), which aggregates effects in terms of quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) gained and aims to specify the financial costs of a QALY that can be gained by introduction of the vaccine. Even though CEAs are a fruitful method for setting priorities, as they enable comparative evaluations of different interventions, such analyses can only be part of the

overall evaluation of new vaccines. Many of the previously discussed factors that count in priority setting cannot be easily framed in CEA: inconvenience, feelings of safety, individual versus public responsibilities, protection against potential bioterrorist attacks, and so on. Moreover, quantitative analysis as such raises methodological and ethical controversies. There is an ongoing debate about whether health effects should be discounted over time in the way financial costs are: from an economical point of view it is better to have €1000 now than to get €1000 next year, yet does the same apply to benefits and health effects more specifically? Decisions about discounting and about discount rates are highly important for priority setting because they have a huge impact on the outcome of costeffectiveness analysis. A last important ethical concern is that economical analyses such as CEA take an aggregate perspective on health benefits and costs; hence they ignore how benefits and burdens are distributed among a population. This might raise issues of distributive justice. For example, from a justice point of view, one might want to give priority to protecting the health of people who are worst-off in terms of health and financial resources. Yet CEA-guided decision making might give more priority to preventing diseases that are of less concern to those groups. Almost everyone will get chicken pox (varicella) at some point during childhood, and experience relatively mild symptoms. Only in some cases does chickenpox lead to serious complications requiring hospitalization. Yet all parents will face the problem that they must care for their child and be unable to work for some days. In aggregative economic terms, these latter negative effects of the disease are highly important and might even lead to the conclusion that vaccination against varicella reduces costs for society. Yet the disturbing and possibly unjust implication would be that vaccination against varicella may imply giving priority to prevention of a mild disease of children of working parents, over prevention of diseases that are more relevant for socioeconomically deprived groups.

Should Vaccination Be Compulsory?

So far the focus has been on ethical evaluation of the contents of vaccination programs: which vaccines should be introduced in a collective program? Obviously, there are also ethical concerns about how programs are implemented within society. During the last decades, patient autonomy and informed consent have become obvious principles in many areas of health care. Physicians must obtain informed consent before treatment. Does the same apply to preventative vaccinations? There are two reasons that voluntary informed consent might be less obvious and decisive in immunization than in regular health-care practices. First, choices about immunization do not just concern the candidate-vaccinee but also other persons. People have a common interest in attaining high immunization rates and herd immunity. If many people decide to forgo vaccination, this will undermine the common good of herd protection. Governments therefore have good reasons to promote immunization and persuade or even press people to participate by means of sanctions or other forms of compulsion. Second, in childhood vaccination programs, parents decide about protection for their children. If vaccination involves a very simple and

burdenfree procedure that effectively averts significant risk for the child, this raises the question of whether parental choice against vaccination can be morally justified. After all, parents should decide in the best interests of their child. Again, this would be reason to set limits to voluntary informed consent.

Notwithstanding these considerations, there are good reasons for thinking that immunization programs should be voluntary. Voluntary programs can be as successful and attain immunization rates that are as high as compulsory programs, as policies, for example, in the Netherlands or New Zealand show. Hence, compulsion is not a necessary condition for herd protection. Second, although parents have a moral obligation to act in the best interests of their children, this does not yet justify compulsory immunization programs. In some cases, a parent might reasonably argue that her child does not need vaccination against, for example, hepatitis B. Moreover, compulsion and enforcement have all kinds of social costs and problems of their own. One problem is that if people are not given a say in immunization, this might undermine trust in the program, thus, in the long run, having detrimental effects on the success of immunization policies. Indeed, public trust should be considered one of the essential features of immunization policies. In order to secure confidence in immunization, it is important that people know that their concerns (e.g., the health of their children, the possibility of side effects) are taken seriously. Consent, on the basis of reliable information about risks and benefits, can play an important role in this respect.

Conclusion

Choices about which vaccines to offer and how to implement a vaccination program have important ethical dimensions. These can be summarized in seven ethical principles:

1. Collective vaccination programs should target serious diseases that are a public health problem.
2. Each vaccine, and the program as a whole, must be effective and safe.
3. The burdens and inconveniences for participants should be as small as possible.
4. The program's burden-to-benefits ratio should be favorable in comparison with alternative vaccination schemes or preventative options.
5. Collective vaccination programs should involve a just distribution of benefits and burdens.
6. Participation should generally be voluntary unless compulsory vaccination is essential to prevent a concrete and serious harm.
7. Public trust in the vaccination program should be honored and protected. The seven principles offer general guidelines to be taken into account in ethical and scientific assessment of new vaccines, vaccination schemes, and procedures. They stipulate the topics that should be taken into account when deciding about vaccination priorities.

Immunization programs are an essential element in the protection of public health. The importance not only of immunization but also of people's confidence in collective immunization underlines the necessity that decisions about vaccines be well considered and ethically justified.

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Vaccination Policies³

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Vaccination involves priming the immune system with an antigenic agent that mimics a virus or bacterium, which results in immunity against the “real” microorganism. Collective vaccination policies have played an important role in the control of infectious disease worldwide. They can serve the utilitarian aim to protect public health – hence welfare – and also promote fairness: making essential vaccines accessible to all members of the public. Yet as more and more vaccines are developed, societies face the question of how far to go in expanding public programs. Decisions about adopting new vaccines in the program will require combining scientific evidence about the disease and the vaccine, with value judgments about, for example, the extent to which a disease poses a threat to public health (Verweij and Dawson 2004; Houweling et al. 2010). It makes sense to promote transparency of such (expert) deliberations because one cannot expect that citizens simply accept every government vaccination policy.

Vaccination programs only rarely lead to serious adverse events like an anaphylactic shock or vaccine-induced disease, but minor side-effects or burdens (pain, inflammation, minor fever) will occur more regularly. Given that vaccination is targeted at large populations of healthy persons, it is appropriate to maintain very high safety standards. Nevertheless, since the first programs in the beginning of the nineteenth century, groups of people have resisted vaccination because they suspected that the risks of vaccination outweighed the benefits (Wolfe and Sharp 2002). Given the central role of informed choice in modern healthcare, it may therefore seem reasonable to let individuals – mostly parents – make their own risk– benefit assessment and decide for or against vaccination. This approach however faces problems in a public health context.

First, given that many dangerous infections are now less common, parents can have reasonable doubts about the necessity of vaccination of their children, e.g., against measles. Yet if many parents forgo vaccination, the diseases in question will be on the rise again. Individual decisions about vaccination have impact on the spread of disease within the population at large. In a liberal society this may be accepted as long as the possible harms only befall the individuals who have decided to forgo vaccination. In most cases however, the benefits of vaccination and the harms of forgoing vaccination go beyond the individual herself.

If almost all members of a population are vaccinated against, say, poliomyelitis, then this virus will not be able to spread within the population, and this offers protection to all members in the population. This is called herd immunity (Anderson and May 1990). Herd immunity implies that

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not only vaccinated persons are protected, but also nonvaccinated persons, infants who haven't received the full series of vaccinations, persons for whom the vaccine is insufficiently effective, and patients whose immune-system is weakened due to their disease or due to immunosuppressive therapy. If herd immunity is sustained over a longer period, the infectious agent can even be eradicated completely, like in the case of smallpox. Herd immunity can therefore be considered as a public good: the benefits are open to all members of the public, irrespective of whether they are vaccinated. Such population benefits are neglected if harms and benefits of vaccination are only assessed on the level of individuals who deliberate about whether or not to participate.

Second, if immunization protects third parties, the question arises as to whether refusal can be morally objectionable. Possibly we have a moral obligation to accept safe and effective vaccination. Two lines of argument can be invoked in support of this. One is to see nonvaccination as a form of free riding that is unfair to others: it may involve deliberately benefiting from the actions of others, but refusing to contribute oneself (Dare 1998). A variety of factors will be relevant to assessing whether this is indeed unfair, including how burdensome vaccination is, how much protection vaccination refusers will enjoy from herd immunity, and whether the "free rider" deliberately opted for these benefits. Another line of argument is that nonvaccination is morally objectionable because it imposes risks on others (Dawson 2007). Vaccination not only protects oneself, but also prevents one from infecting others. The more likely it is that one will spread an infection (possibly harmless to oneself) to others who might get severely ill, the stronger such an obligation will be. One example is influenza vaccination in nursing homes: nonvaccinated staff may infect frail residents who are at high risk for complications and who themselves do not respond well to vaccination.

A third reason for questioning the idea that everyone should make their own assessment of risks and benefits of vaccination is that, in most cases, it will be parents who decide for their children. Even if parents have the authority to make such decisions, they are expected to decide in the best interests of their child. This may be a reason to argue that parents, as laypersons on medical affairs, should follow evidence-based expert advice on vaccination (Sorell 2007).

Although there are moral concerns about allowing individuals their own risk– benefit assessment regarding vaccination, it is debatable whether these are sufficient to justify mandatory vaccination. In countries like Sweden, the Netherlands, and the United Kingdom it appears possible to attain very high vaccination rates in voluntary programs, and in such cases, compulsion is not warranted. Moreover, coercion and compulsion tend to undermine trust, and presumably no public vaccination policy will be sustainable if it lacks public trust.

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