1 Controversies and Complexities of Vaccination: An Introduction

Since Edward Jenner's first tests inoculating people with a cowpox-infected substance to protect them against smallpox at the end of the eighteenth century, and the immunization movements and policies that developed rapidly afterward, vaccination has become simultaneously a lauded and a controversial phenomenon. It has been highly successful in reducing outbreaks of infectious diseases and has been embraced by a large majority of populations in all countries, but at the same time, it has always been met with criticism, doubt, and resistance. Coverage of vaccines that protect against diseases such as diphtheria, tetanus, polio, pertussis, and measles is high in high-income countries, as well as in many middle- and low-income countries. Vaccination has led to the global eradication of smallpox and to the elimination of polio in almost all regions worldwide. Measles and other diseases that only decades ago were still considered inevitable and potentially dangerous childhood diseases are now relatively rare, at least in affluent countries.

Not all citizens take the benefits of immunization for granted, however: some people question the necessity of vaccination, claim that the risks of vaccination outweigh the benefits, or argue that preventive vaccination conflicts with their religious or secular worldviews. People thus appeal to a variety of concerns to forgo or resist vaccination for themselves or their children. Even countries with a high immunization coverage usually face local pockets of undervaccination (e.g., religious communities in the US and the Netherlands) in which outbreaks of vaccine-preventable diseases remain a constant threat. Moreover, the same general doubts about immunization complicate proposals for introducing novel vaccines and vaccination programs, like in the recent COVID-19 pandemic. We start this chapter with three examples that illustrate these concerns: the reemergence of measles outbreaks due to declining immunization rates, the low uptake of the relatively new vaccine

against human papillomavirus, and deep controversies about immunization during the COVID-19 pandemic. The three cases set the stage for our analysis of the central problem in this book: what policies can be ethically, legally, and politically justified in response to vaccine hesitancy?

1.1 The 2014 Measles Outbreak in the US

Measles is one of the most contagious infectious diseases. An unvaccinated person who is exposed to the virus has a 90 percent chance of becoming infected. The disease kills one person in every 5,000 cases in high-income countries and as many as one person in every 100 cases in low-income countries (Oxford Vaccine Group, 2015). The risk of serious complications and death is increased in children younger than five years and adults older than twenty years (Strebel, 2018). On a global scale, measles kills 135,000 persons each year, mostly children (World Health Organization, 2019). In the 1960s, a live-attenuated measles vaccine was introduced for children aged around fourteen months. A decade later, this vaccine was included in the MMR (measles, mumps, rubella) triple vaccine, which is mostly given to children at around the age of fourteen months and again at nine years old. Vaccination has contributed to a stark reduction in measles cases in many regions, but outbreaks are still observed in regions with clusters of undervaccination, such as the Bible Belt in the Netherlands. In 2000, the disease was declared eliminated in the US (Nigel et al., 2004). Since then, however, new outbreaks have occurred there. Among the twenty-three outbreaks in the US in 2014, there was one large outbreak, 383 cases, that occurred primarily among unvaccinated Amish communities in Ohio (Sundaram et al., 2019). Early in 2015, a multistate outbreak occurred that originated from infections in Disneyland in California, causing illness in around 150 mostly unvaccinated persons, children as well as adults (Jalabi, 2015). Even though the number of outbreaks in 2015 was not dramatically higher than in earlier years, the Disneyland outbreak caught the attention of vaccinating parents who realized that the emerging vaccine hesitancy could bring back diseases that had been under control for decades (Hausman, 2019). The Disneyland outbreak thus focused both societal and political attention on the impact of vaccine hesitancy, vaccine refusers, and the antivaccination movement. Although childhood vaccinations are mandatory in all states in the US, more and more parents have been granted personal belief exemptions, facilitating

new outbreaks such as the one in Disneyland. The controversy about such clusters of infectious diseases led to new state legislation (in California and in other states) tightening mandatory immunization programs or abandoning personal belief exemptions altogether (Navin & Attwell, 2023).

1.2 Unpopular from the Start: Vaccination against Human Papillomavirus

In 2006, a vaccine became available against human papillomavirus (HPV), and it was relatively quickly adopted over the next few years in many countries worldwide. HPV infections are the most important cause of cervical cancer, which causes around 270,000 deaths a year, mostly in low- and middle-income countries. Compared to existing vaccines, the HPV vaccine was relatively novel as the aim was not so much to protect against HPV as a symptomatic infectious disease but against the harmful effects of sustained infection over time. Two other novelties were the fact that HPV is first and foremost a sexually transmittable infection and that the main target group for vaccination was, at that time, girls who were not yet sexually active. These aspects and concerns about alleged side effects featured in public debate, and at least in some countries, such as the Netherlands, the initial vaccine coverage was much lower than envisaged (Gefenaite et al., 2012). The Dutch program was initiated in 2009, targeting eleven- and twelve-year-old girls and including a one-off catchup program for thirteen- to sixteen-year-old girls. In the first few years, immunization coverage barely exceeded 50 percent, which was much lower than the 95 percent vaccination rates that were normally realized in infant immunization schemes in the Netherlands (van Lier et al., 2011). For the first time, governments were confronted with a massive public debate on social media featuring hesitance about and active resistance toward vaccination, showing distrust in health authorities, and highlighting rumors and fears.

1.3 Polarization in the COVID-19 Pandemic

The COVID-19 pandemic that began in 2020 and was caused by the SARS-CoV-2 virus has made it patently clear that massive epidemics are not phenomena that only affected a distant past—they can still acutely disrupt current societies. In many places in the world, dramatic societal measures

were imposed to control infection rates, to protect the health and save the lives of citizens, and to sustain health care facilities that were overwhelmed by the influx of seriously ill patients. Around half of the world's populations faced national lockdowns that included travel restrictions and the closure of schools, universities, shops, and other businesses, and people were often expected, and sometimes forced, to stay at home as much as possible. Large public and private investments in vaccine development resulted in the development, approval, and mass production of vaccines in less than a year, and those vaccines appeared to be highly effective. Mass vaccination was generally considered the most important strategy for containing the pandemic and abandoning or relaxing lockdown measures, but many people also had doubts about the safety of these novel vaccines. Vaccine hesitancy and refusal were reinforced by misinformation: it was claimed that the vaccines resulted in many adverse events, and the pandemic itself was considered a lie made up by governments that just wanted to control citizens. It was also suggested that vaccines would modify people's genetic makeup or that they contained microchips that enabled governments to track citizens. Not all vaccine hesitancy, however, should be directly linked to (some of the more outrageous forms of) fake news. For example, given the speed of vaccine development, it should not have been a surprise that people had concerns about safety. Regardless of the background of hesitancy in different societies, debates about vaccination became more and more polarized during the later waves of the pandemic, especially when health care systems and intensive care units were flooded and sometimes overwhelmed with mostly unvaccinated patients.

In contrast to other vaccination-related controversies, this time it was not so much about childhood immunization but about the vaccination of adults, who, unlike children, are considered to have a far-reaching authority to make their own choices about medical treatments. Yet the context of a global pandemic, with dramatic infection control measures already in place, gave governments a very broad palette of policy opportunities, including more coercive approaches, to persuade or force citizens to get vaccinated. For example, some citizens were required to show so-called COVID-19 admission passes (cf. section 8.3) to access social events, pubs, and restaurants and, in some cases, even to be allowed into their workplace. All these discussions led to further polarization and division between citizens who

embraced the immunization program, including subsequent boosters, and those who refused COVID-19 vaccines.

1.4 Vaccination Policies in Times of Resistance: An Uphill Battle?

Public health authorities are struggling with questions concerning how to respond to a lack of confidence in or even public distrust of vaccines and vaccination programs and how to shape policies that ensure the protection of public health. The controversies about vaccine hesitancy in the preceding sections (measles, HPV, and COVID-19) illustrate some of the key complexities that surround immunization policies.

One complexity is that vaccination involves individual choices that have public consequences and vice versa. The COVID-19 pandemic has shown how polarized debates can reinforce vaccine hesitance and refusal, which in turn impede societal attempts to overcome the pandemic. In relation to measles and other childhood diseases, many vaccine-hesitant parents assume that the benefits of vaccinations for their child, or for society in general, do not outweigh the risks they associate with vaccination. Yet their choice to forgo immunization not only affects the interests of their own child but also contributes to a decreased level of protection on a group level, which creates increased risk for those who cannot be vaccinated, for example, children who are too young to receive their first shot or (vaccinated) persons whose immune systems are weakened due to disease or other conditions. For various reasons, these aspects are less prominent in relation to HPV vaccination, but HPV did show how a public immunization policy has implications for issues that are considered rather personal and private matters: preadolescent girls and their parents were forced to think about sexual activity and the risk of acquiring sexually transmitted infections. For many parents and girls, this is a sensitive topic that they might prefer to avoid discussing.

A second complexity of immunization programs is that they aim to *prevent* disease, so their success is often a remote, if not invisible, entity to individuals. This may not be the case during an epidemic, but it is certainly so for most routine (childhood) vaccination programs. In normal circumstances, programs are implemented when there is no threat of an acute outbreak. Teenagers are vaccinated against HPV to protect them against a disease in the distant future. As humans, we consider ourselves rational

beings, but we can easily neglect or discount long-term risks. Moreover, our knowledge of the benefits of vaccination is often distorted because its success is only visible on a population level. For individual persons, the effect of a successful vaccination is a nonevent: they are not infected and thus remain healthy. Yet no one will ever know whether they would have become ill if they had not been vaccinated. This complexity makes it more difficult to persuade people by pointing out the benefit of immunization. And vaccination failure—cases of infection that occur notwithstanding the fact that the person was vaccinated—always stands out, and so do (alleged) side effects of vaccinations. Hence, it is no surprise that public health authorities and medical professionals sometimes struggle to persuade hesitant parents to accept immunization of their children. A full assessment of the benefits and burdens cannot be made by appealing to individual observations but requires a population perspective—that is, an evaluation of the epidemiological evidence concerning infection risks and vaccination safety.

This also brings a third complexity and controversy to the surface. Vaccination programs should be based on robust scientific evidence about infection risks and vaccine effectiveness and safety. Ideally, such evidence also helps to persuade citizens to endorse immunization and participate in programs. Most people, however, do not make up their mind on the basis of a rational assessment of the available evidence. They often defer to expert assessment or simply trust their general practitioner or other health care professionals. But choices are also affected by experiences with previous vaccinations, personal anecdotes of friends, and stories shared on social media—and these can easily exaggerate concerns about safety and downplay the importance of immunization. Nowadays, people are confronted with an abundance of information and perspectives via the internet and other media—including some sources that are reliable and others that are not. Moreover, a lot of deliberate misinformation and messages are available that aim to trigger doubt and skepticism about vaccines (Donzelli et al., 2018; Ginossar et al., 2022; Wolfe et al., 2023). Governments cannot and should not assume that the provision of good, reliable information will guarantee a high uptake in collective immunization programs. Such (often abstract) information is certainly necessary, but it will also be rather ineffective in persuading citizens who are already skeptical about experts or governments.

The diversity of the vaccine-hesitant population (cf. chapter 3) constitutes a fourth complexity for public health programs. Given the—often invisible—benefits of immunization, it is not strange that many people pay more attention to possible side effects and therefore postpone or forgo immunization. Yet it is not just the alleged side effects of immunization that lead people to avoid vaccines. Several religious groups consider immunization (or some forms of disease prevention in general) to be an act that seeks to preempt divine providence. If parents assume that the health of their children is in the hands of God, they may conclude that it is not up to them to prevent illness by means of immunization. Nonreligious worldviews can also motivate vaccine hesitance, for example, a view that emphasizes "naturalness," "purity," or the innocence of infants—suggesting that vaccination interferes in natural processes that are good in themselves. Anthroposophist groups see "childhood diseases" as important stages in childhood development and consider coming through such an illness as ultimately beneficial for the child. Finally, some groups reject vaccination programs for more political reasons. If one sees any government policy as intruding in the private lives of citizens, then it may easily follow that government-imposed collective immunization programs are evil. These diverse motives for vaccine hesitance can also reinforce one other, and different groups may find each other when fighting for a similar objective: to resist government-led immunization programs.

The complexities surrounding collective vaccination pose a deep problem for public health authorities and governments. High immunization rates are necessary to protect against potentially dangerous diseases. Vaccine hesitancy may well result in a comeback of almost forgotten diseases such as measles, diphtheria, or polio, and it inhibits effective government responses to pandemics or other disease outbreaks. But if, given the complexities just mentioned, it is not to be expected that evidence-based information will persuade vaccine-hesitant persons to get vaccinated, the question arises what public health authorities should do. To what extent should citizens with doubts about immunization or those who actively resist it be persuaded, pressured, or legally obliged to accept it? What is the role of government in this controversy? These are the main questions that we will explore in this book. Before outlining our approach, let us first look in more detail at what vaccination is and how collective immunization programs have evolved throughout the centuries.

1.5 Immunization and Immunization Programs

Vaccines have become one of the most important tools of preventive medicine against certain virus- and bacteria-induced diseases. For infections with viruses, there is often no curative therapy; they can only be countered by an organism's immune system. Vaccination is the deliberate exposure of an organism to a weakened or killed version of a pathogenic microbe, or just a part of that pathogen, to induce the organism to produce antibodies. This initial production of vaccine-specific antibodies enables the immune system to recognize a "real" pathogen if exposed to it and to rapidly produce antibodies to fight it. Hence, a successful vaccine triggers the immune system and thus "immunizes" the organism against the pathogen, without inducing the actual disease and the risks it generates. Throughout the book, we will use the terms "immunization" and "vaccination" as synonyms, although, strictly speaking, "immunization" also includes other ways to induce immunity—such as via "real" infections or inoculation.

Long before Edward Jenner started experimenting with *variola vaccinae*, or cowpox, as a way to protect humans against *variola*, or smallpox, it was common in some societies to inoculate persons with smallpox pus or scabs, either by inserting some pus from a patient with smallpox into an incision in the skin of another person or by blowing powdered scabs into a person's nostrils. In China, the practice of inoculation, or *variolation*, was described as early as the eleventh century, but it probably started in India, perhaps before the Christian era (Hopkins, 2002, p. 109). One description of early inoculation can be found in *Zhou Hou Bei Ji Fan* by Ge Hong (283–363), published around AD 303. Ge Hong describes a form of preventive exposure to rabies: "killing the dog that bites, and using its brain for the people who will be safe without relapse of rabies" (Cao, 2008). Presumably, the risks of such inoculations themselves causing and spreading the disease were significant.

Smallpox inoculation was introduced in Western Europe early in the eighteenth century and was enthusiastically practiced by several physicians throughout the century, including the Gloucestershire physician and scientist Edward Jenner. Jenner started studying cowpox that developed on the hands of milkmaids; he was fascinated by stories about milkmaids who had been infected with cowpox—a rather innocent condition in cattle—but remained healthy when they were exposed to smallpox at a later date. His first experiments, however, involved swine pox. Jenner did tests on several

persons, including his own son, exposing them via an incision to swine pox pus and later on inoculating them with smallpox. On May 14, 1796, he carried out the famous experiment on James Phipps, the eight-year-old son of his gardener. Jenner first inoculated the boy with pus from the blisters of Sarah Nelms, a Gloucestershire milkmaid who had recently been infected with cowpox. One and a half months later, James Phipps was inoculated again, this time with pus from a patient with smallpox. This caused only a mild infection. Edward Jenner's first scientific report was not well received by the British Royal Society—the opinion was that if he valued his reputation, he would have been better not promulgating such ideas. But after he had done more experiments and published them in his *Inquiry*, the idea of *variolation vaccinae* swiftly became more accepted—although never without controversy. Within three years after its English publication, the *Inquiry* was translated into French, Dutch, Spanish, Russian, Italian, and Latin. Jenner and many others strongly promoted vaccination, and by the beginning of the nineteenth century, the procedure was carried out regularly in many European countries. By 1801, more than 100,000 persons had been vaccinated in Great Britain, and in the decade afterward, several million vaccinations were administered in countries such as Russia and France (Hopkins, 2002, p. 81).

It took almost a century before other vaccines became available. Louis Pasteur developed the idea that a virulent pathogen could be attenuated (i.e., weakened), most famously with his rabies vaccine, paving the way for a series of live-attenuated vaccines like yellow fever, polio, and measles in the twentieth century. Other vaccines were based upon killed pathogens, including cholera, the inactivated polio vaccine, and hepatitis A. From the last part of the twentieth century onward, a variety of novel vaccine technologies were developed. These include subunit vaccines that contain only a specific protein of the pathogen, such as pneumococcal, hepatitis B, and HPV vaccines. In the twenty-first century, viral vector and messenger RNA (mRNA) technologies were developed, which have been especially employed in several COVID-19 vaccines (Gergen & Petsch, 2020; Plotkin, 2014, p. 12284).

From the 1950s, government-led national immunization programs became more and more common, combining different vaccines and having a clear impact on outbreaks of diseases such as polio and measles. However, it is difficult to quantify the effects of collective vaccination, given that morbidity and mortality due to contagious diseases were already declining

throughout the twentieth century (van Wijhe et al., 2016). Infectious diseases thrive in unhygienic conditions, poor households, and undernourished populations, so the improvement of hygiene and living conditions that came with increased economic prosperity in Western countries was already resulting in a steep decline of major infectious diseases. Good living conditions alone, however, will not rule out infections altogether, and children and adults—especially those who are relatively vulnerable—may still become seriously ill with infections that cause only mild disease in many others. Even healthy children are vulnerable to infections like measles, polio, and pertussis, and unless many individuals are immune, a contagious microbe can still spread rapidly within a population.

1.6 Vaccination Strategies

We can distinguish three major objectives for collective immunization. The most effective aim is the elimination or eradication of a serious infectious disease. The elimination of an infection implies the exclusion of the disease from a defined region, but a risk would still remain of reintroduction from another region. Eradication is the total exclusion of the relevant pathogen from the environment, so it cannot return. Less than 200 years after Edward Jenner's experiments, the global struggle against smallpox came to an end. The last victim of endemic smallpox was a Somalian boy in 1977.[1] In 1980, the World Health Organization declared that this disease, which scars those who have it and can often be fatal, had been eradicated globally, which also implied that the last remaining smallpox vaccination programs could be discontinued. The complete eradication of a dangerous disease offers not only perfect protection but also the opportunity to discontinue a specific vaccination, not only immediately but in the future. However, it is extremely hard to achieve this goal, and smallpox will probably remain more of an exception than a general rule, given the epidemiological properties of many other vaccine-preventable diseases.[2]

The eradication of a contagious disease can only be attained if a large part of the (global) population is vaccinated. Mass vaccinations can inhibit and eventually stop the spread of infection by inducing immunity in a large part of the population. Individuals who are immune to an infection, after vaccination or as a result of a previous infection, cannot transmit the pathogen

to other persons. If many persons in a collective are immune, this reduces the chance that persons who still are vulnerable will be exposed to infection: they are relatively safe within the "herd." It also implies that there are few possibilities for the pathogen to find an organism in which it can survive and reproduce. As a result, eventual outbreaks will fade out soon. A high vaccination rate can thus result in group-level protection, or *herd immunity*. If elimination of the disease is unfeasible, achieving group-level protection can still be a second objective that is attainable. With such protection, outbreaks will rarely occur, the disease will not gain a foothold in the population, and individuals who are not (yet) vaccinated or not immune for other reasons are well protected in the crowd. For example, measles is an extremely contagious disease, which implies that a patient is not only a victim of the disease but also a vector in its further spread. Even if a child experiences only relatively mild symptoms, they remain an infection risk to others. Vaccination protects individuals, but infants six to twelve months old are too young to be vaccinated, and therefore they depend on group-level protection. The higher the vaccination rate, the better these vulnerable children are protected as well.

Not all vaccination programs can achieve herd immunity or elimination of a disease, for example, because the pathogen might not be contagious or because there may be other (nonhuman) hosts in which the microbe can reproduce. In such cases, a third objective of collective vaccination programs is to offer individual protection to as many individuals as possible.

1.7 The Effectiveness of Vaccination Programs

The extent to which vaccines and vaccination programs can generate individual and collective protection against a particular infectious disease depends on various factors. The first factor is contagiousness: the more infectious a disease is, the harder it is to fight the disease via vaccination programs. The second factor is the extent to which the vaccine protects the individual vaccinee against the disease and, negatively, the extent to which this protection decreases over time. The third is the extent to which the vaccine provides sterilizing immunity (i.e., prevention of transmission of the wild-type pathogen to curb an outbreak) and, negatively, the extent to which this protection wanes over time. A vaccine does not have to provide full sterilizing immunity to curb an outbreak. The whooping cough

Box 1.1
Herd Immunity

The commonly used term "herd immunity" might be slightly misleading because "immunity" falsely suggests full protection against outbreaks of a disease (Fox et al., 1971; Jones & Helmreich, 2020). Moreover, it also seems to assume that there is a threshold—a proportion of the population who have attained immunity through infection or vaccination—at which this full collective protection is achieved. For example, it has been estimated that 92 to 94 percent of a population needs to be vaccinated in order to achieve herd immunity for measles (Orenstein et al., 2007, p. 1434). In the case of polio, the threshold is around 80 percent (Macmillan, 2021). In theory, it might be possible to calculate a herd immunity threshold based on R_0, the average number of persons who are infected by one infectious individual.

In practice, however, such thresholds are highly problematic due to population heterogeneity: a country with a very high vaccination coverage will often still have local areas where fewer persons are immune, for example, because such communities resist immunization. Moreover, high-risk persons may have a very high number of interactions, facilitating the spread of disease in the larger population. It is therefore not obvious that a theoretical national immunity threshold is sufficient for preventing outbreaks.

The term "herd immunity" also suggests that in the herd, no infections can occur at all, and if it is absent, the population is at risk—but this dichotomy is too simple. Even if an ideal threshold vaccine coverage (e.g., 94 percent in the case of measles) is not attained, the crowd can still offer a very high level of protection to vulnerable individuals. In this sense, herd immunity is not a threshold concept, although in policy making, it will be useful to aim at and ascertain specific minimum thresholds for vaccine coverage.

In this book, we often use the term "group-level protection" to refer to collective protection that arises as a result of many individuals having immunity against a disease. When we use the common term "herd immunity," it refers to a very high level of such collective protection—something that comes close to theoretical thresholds as indicated above.

vaccine, the rotavirus vaccine, and the inactivated polio vaccine do not provide full sterilizing immunity, but a vaccine does contribute to controlling an outbreak when the number of infections remains limited, and it helps to reduce hospitalizations by curbing the severity of individual cases of the disease (McKenna, 2021). The fourth and last factor is the percentage of the population that is immunized.

The infectiousness of a disease is a background factor that often can't be changed. The second and third factors, however, can be adjusted. The effectiveness of different vaccines varies regarding preventing disease or infection. The measles vaccine is extremely effective in protecting against both severe disease and the spread of infection, and these protective effects hardly decline at all over time. The flu vaccine, on the other hand, reduces the risk of illness by only 40 to 60 percent among the overall population,[3] and its effect wanes very quickly because every year, new strains of the virus emerge; hence, the target group usually needs to be revaccinated every year. The effectiveness of vaccinations can be improved by changing their composition or other pharmacological innovations. But in a collective program, it is also possible to increase collective protection by optimizing *who* is vaccinated. If a vaccine is offering a large degree of sterile immunity, it becomes possible to protect the most vulnerable groups, not (or not only) by vaccinating them but by immunizing all individuals who play the largest role in the spread of infection—even if the latter would run no risk of contracting a severe case of the disease themselves. This would amount to what some have coined "altruist vaccination" (Kraaijeveld, 2020).

Our argument in this book primarily addresses the fourth factor that determines the effectiveness of collective immunization: the vaccination rate. Herd immunity for many diseases can be achieved only through mass vaccination programs. As previously mentioned, the measles vaccine is very effective, but the disease is extremely contagious, and therefore herd protection requires a vaccine coverage of approximately 92 to 94 percent (Orenstein et al., 2007, p. 1434). COVID-19 also requires a high vaccination rate, but as the current vaccines offer only limited protection against infection and their effect wanes over time, a robust herd protection seems unattainable. Given that the four factors just described differ significantly for different vaccines and given that effectiveness is crucial for the regulation of vaccination policies, it is important to discuss regulation not merely in a general way. It is possible to develop a normative (ethical and legal) argument for vaccination policies, and this is what most of this book aims to do. Determining which specific policy is justified in which circumstances and for what vaccines and diseases requires taking many contextual features into account, which we will do in chapters 7 and 8 in particular.

1.8 Regulating Vaccination in Times of Distrust and Controversy

The eradication of smallpox is clearly one of the greatest achievements of collective vaccination programs, but this is still the only disease that has been eliminated on a global scale. Other dangerous infectious agents like polio and diphtheria have been eliminated in most regions but not everywhere, so there is still a risk of reintroduction in areas where vaccine coverage is not optimal.

Given the scientific evidence about the effectiveness and safety of vaccines used in basic programs, governments and (non)governmental health agencies have strong reasons to promote such vaccination programs, to strive for immunization rates that are as high as possible, and to aim for herd immunity where that is technically possible. Throughout the second half of the twentieth century, achieving optimum vaccination coverage appeared feasible—at least in most high-income countries. Large-scale programs gained momentum thanks to the discoveries of new vaccines such as those against polio, the novel possibilities of mass vaccine production, and the involvement of charities and other nongovernmental health organizations such as the March of Dimes in the US and the White-Yellow Cross and Green Cross in the Netherlands.

Before vaccines were introduced, epidemics and child mortality due to common infections were still very common, and nonlethal diseases could leave patients permanently disabled or disfigured. All this contributed to broad acceptance of vaccines and vaccine policies, once they arrived. This is not to say that controversy and doubts about vaccination faded away completely. Some religious groups have resisted vaccination from the start because they see immunization as disrespecting divine providence. Outbreaks of diseases such as polio are more likely to occur where people are living together in close, homogenic communities, as happened, for example, in the Netherlands in 1971 and 1992. Many other people question either the safety or the medical benefits of vaccines and therefore forgo immunizations, as we have illustrated with the cases at the beginning of this chapter.

In this book, we discuss the ethical and political-philosophical questions concerning how immunization programs should be regulated by government, given the fact that certain groups wholeheartedly and vocally reject vaccination and that many parents are at least hesitant about having their

child or themselves vaccinated. The principled argumentation in this book is generic, but we focus primarily on childhood vaccination because most programs target children. In chapter 8, we shift the focus to immunization of adults, using COVID-19 as a controversial illustration.[4]

1.9 Basic Assumptions, Research Question, and Theoretical Approach

In this book, we presuppose a constitutional liberal-democratic government, usually abbreviated as "liberal democracy" or "democracy," which refers to a political regime that favors the protection of fundamental rights, democratic decision-making, and the rule of law. There are at least four foundational values underlying legislation and policy making in such regimes (Pierik & Werner, 2010, p. 2). The first characterization of liberal-democratic thought is *normative individualism*. All persons, both adults and young children, are taken to be "self-originating sources of valid claims" and, as such, the ultimate units of concern (Rawls, 1980, p. 543). Liberal-democratic thought differs in this respect from political theories that take, for example, the family or ethnic or religious communities as units of moral concern in and of themselves. Such aspects are only considered valuable instrumentally if they play a role in making an individual's life better. Second, liberal-democratic thought is characterized by a strong commitment to *personal autonomy*: individuals have a right to live their life in accordance with their idea of the good life and to be free from unjustified interferences in their personal sphere by others, including the state. Third, liberal-democratic thought recognizes the fact of *reasonable disagreement* among the different conceptions of the good in current plural societies and that the state should aim to be neutral toward the various (reasonable) conceptions of the good. The fourth and final characteristic is *statism*: liberal-democratic thought presupposes a central role for the state in promoting personal autonomy and state neutrality and in proposing policies that solve the inherent conflicts between those goals in pluralist societies.

Yet, as minimal and general as this description of liberal-democratic thought might be, it does offer a fruitful starting point for analyzing the responsibility of governments in relation to public health, including the responsibility of the state to prevent diseases through collective immunization programs. Given the possible disruptive effects of such diseases, the

state has a compelling interest in preventing outbreaks. Indeed, although it remains contested within some circles whether the liberal-democratic state should promote individual health and health equity through collective institutions,[5] it is not disputed that it should *protect* society against major threats to public health (Verweij & Houweling, 2014). This implies that the state must guarantee a basic level of protection against infectious diseases that undermine or disrupt societal life and threaten people's options for shaping their lives as they see fit, individually and with others—as long as the cost of doing so does less to undermine or disrupt societal life than the diseases do. After all, the cure should not be worse than the disease.

The argument in this book addresses societies with well-functioning public health infrastructures. Vaccination programs are an essential element of such infrastructures, and most people endorse immunization as an indispensable protection against infectious diseases, for their children or themselves. At the same time, there has always been a minority that opposes vaccination and questions the evidence behind immunization. This opposition becomes problematic when, first, it leads to vaccine hesitancy, defined here as the delay in acceptance or the refusal of vaccination despite the availability of vaccines through national programs (MacDonald, 2015, p. 4163) and, second, when this vaccine hesitancy ultimately undermines the effectiveness of vaccination programs and threatens the health of individuals and populations. At the same time, these controversies surrounding vaccination reflect the diversity of moral and epistemic views that characterize plural societies. Hence, the normative question this book seeks to answer is as follows:

> How should a constitutional liberal-democratic government deal with deep controversies concerning vaccination, given the fact that these may lead to vaccine hesitancy, which can subsequently pose a genuine threat to public health? If encouragement of voluntary participation in vaccination programs is not sufficient, can coercive measures be justified—and, if so, under what conditions?

We take for granted the broad consensus in the biomedical and epidemiological sciences that vaccines as used in collective programs are effective in preventing disease and that they can be safely used; moreover, on a population level, these vaccines have a very positive risk–benefit ratio (Dudley et al., 2020). We also endorse the general idea that government policy on infectious diseases should be based on state-of-the-art biomedical and epidemiological evidence. At the same time, discussions and the

antivaccination movement emerging at the time of writing make it clear that there are evident epistemic and moral disputes about these issues that cannot simply be pushed aside by appealing to a scientific and professional consensus. Indeed, the very aim of this book is to discuss the regulation of childhood vaccination in the face of these disputes.

Two caveats apply. The focus on affluent liberal-democratic societies does not imply that we think that vaccination policies—and the ethical questions they raise—in less affluent countries are less important. On the contrary: low- and middle-income countries face much higher mortality rates due to infectious diseases. Nevertheless, this book explicitly engages with the current discussion of vaccine hesitancy in pluralistic democracies. The problem of vaccine hesitancy might also be relevant in other countries, including many low- and middle-income ones, but we think that in those contexts, the question of how to deal with pluralism is vastly overshadowed by the absence or scarcity of basic public health infrastructures and by the inequitable access to health care and vaccinations.[6] This generates important discussions, for example, on vaccine nationalism and the unilateral actions of affluent countries to provide their own populations with access to vaccines ahead of other countries, which deprives low- and middle-income countries of access to vaccines—as has become very clear during the COVID-19 pandemic (Gruszczynski & Wu, 2021; Katz et al., 2021). We acknowledge the importance of these global justice debates, but in the context of this book, we seek to engage with a different discussion.

The second caveat is that our focus on vaccine hesitancy may suggest that it is a widespread phenomenon in liberal democracies. This is not the case. Vaccinating is still the norm; large majorities in most countries participate voluntarily and wholeheartedly. The discussion is about the ragged edges: the small part that categorically opposes vaccination and the somewhat larger group of parents that is on the fence. The problem is that for some diseases, the vaccination rate must be very high to prevent outbreaks, and even a relatively small percentage of vaccine refusers can undermine societal protection against vaccine-preventable diseases.

In the next two chapters, we set the stage for our analysis by discussing state responsibilities and policy options, and by exploring objections against vaccination and the grounds for respecting those objections in a liberal democracy. Subsequently, we develop a principled argument for

liberty-limiting vaccination policies that is largely based on John Stuart Mill's *On Liberty* (chapters 4 and 5), and we explore contextual factors that are decisive in the justification of specific immunization policies, targeting children (chapters 6 and 7) and adults (chapter 8). In the last part of the book, we discuss how public health authorities can be trustworthy in times when many dispute the scientific evidence on which immunization policies are built, and we offer a critical reflection on our appeals to John Stuart Mill's liberal philosophy.

Inducing Immunity?

Justifying Immunization Policies in Times of Vaccine Hesitancy

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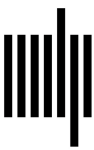

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