

# **Ethical concerns in the debate about pediatric vaccinations, with special reference to MMR (Mumps, Measles and Rubella)**

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## Declaration

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## Abstract

This dissertation examines the ethical aspects of vaccination in children by focusing on vaccination against measles using the MMR vaccine. Applying a principlist ethical framework to the relevant medical and scientific facts, I articulate two ethical principles or action guides that can be used to formulate obligations resting on persons or institutions, as well as to guide measles vaccination policy. These ethical action guides are:

(1) All children eligible for measles vaccination should be vaccinated against measles, at least to the point of sustained measles elimination.

(2) Respect for parental decision-making and the parent-child relationship guide the response to parental vaccine refusals.

Ethical action guide (1) describes the obligations of those who stand in significant relationships with children and of the just society – to protect children against measles using vaccination. Action guide (2) guides the individual and societal response to vaccine refusal, describing morally important considerations that should be kept in mind when responding to vaccine refusal.

The dissertation proceeds as follows. First, the introductory chapter examines ethical tensions regarding measles vaccination in children, and identifies some deficiencies in the existing literature. Next, two chapters provide an overview of the scientific and medical facts regarding measles and MMR vaccination. Third, the principlist framework of Beauchamp and Childress is defended as an appropriate ethical framework for analysis of the problematic. Fourth, the individual case of measles vaccination is considered, using a medical decision-making framework based in the principlist approach. Fifth, the obligations of the just society with regards to measles vaccination is considered, using different conceptions of justice in turn. In the last section of this work, it is argued that action guides (1) and (2) bring all four principles into balance, a state of reflective equilibrium, and various ethical obligations and policy suggestions are derived from these two action guides.

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# Chapter 1: Problem statement, ethics literature review, and overview of the project

## (1) Introduction

### *Background: Vaccines*

Vaccination has been heralded as one of the greatest medical achievements (CDC 1999). Vaccines have been shown to improve the overall health of the public through its dramatic impact on the incidence of infectious diseases (CDC 1999). Due to the success of vaccinations and the ongoing threat of vaccine preventable disease, influential health organizations such as the American College of Preventive Medicine (Adetunji et al. 2003), the Centers for Disease Control and Prevention (CDC 1999) and the American Academy of Pediatrics (Committee on Practice and Ambulatory Medicine and Council on Community Pediatrics 2010) recommend ongoing childhood vaccination programs in order to provide protection for individuals and populations from vaccine preventable infectious diseases.

Consider the illustrative example of measles vaccination. In the United States high rates of measles vaccination lead to elimination of measles transmission so that measles is no longer endemic in the United States (CDC 2008). However, outbreaks of measles still happen and are largely associated with unvaccinated persons (CDC 2008). The Netherlands has a high measles vaccination rate (around 95%) and endemic measles is considered eliminated (Knol et al. 2013). Yet, outbreaks occur among unvaccinated people. For example there has been an outbreak of measles in 2013 that is largely associated with unvaccinated populations within Dutch society (Knol et al. 2013). Although the Netherlands has a very high rate of measles vaccination, the 2013 outbreak by August 2013 comprised of 1,226 cases of which 96% were unvaccinated persons (Knol et al 2013). These outbreaks are thought to occur because of pockets of unvaccinated communities within Dutch society who congregate together, typically members of religious communities who object to vaccination and who live in close cohesion (Knol et al 2013). So, even a highly vaccinated population can have pockets of susceptibility where measles outbreaks are possible, speaking to the need for ongoing expansion of vaccination coverage. More troublingly, measles can return to become endemic after elimination if immunity levels within society drop. This has been illustrated by experience in the United Kingdom (Euro Surveillance Editorial Team 2008). Although measles was considered non-endemic/eliminated in the UK in 1994, in 2008 it was declared endemic in the United Kingdom once again (Euro Surveillance Editorial Team 2008). The reason for the return of measles in the UK is the drop in vaccination rates below the threshold required to maintain measles elimination in the UK over the corresponding period (Euro Surveillance Editorial Team 2008). It is considered that vaccination coverage rates of 90-95% with two doses of measles containing vaccine are needed to achieve and maintain a non-endemic status for measles within a population (Gay 2004).

With measles vaccination, the concept of herd-immunity is an important one. If enough people are immune to measles within a population, the spread of measles will be halted within the community so that those with no immunity against measles are protected against the illness.

Those who are not eligible for the vaccine because of medical reasons or those who do not become immune through vaccination depend on herd-immunity for protection against measles. To achieve herd-immunity and thus halt the spread of measles within a population, vaccine coverage rates of at least 93%-95% with two doses of measles vaccine is required (CDC 2008; Gay 2004). The concept of herd-immunity is an important one when the ethics of vaccination is considered; the actions of individuals with regards to vaccination impact the health of others and society as a whole. As seen in the Netherlands, where unvaccinated individuals congregate the protection of herd immunity is lost, and outbreaks can happen within these populations despite an overall high vaccination rate within the country (Knol et al. 2013).

### *Vaccine opposition and vaccine refusals*

It is therefore necessary from a public health perspective to maintain high rates of vaccination in order to protect individuals and populations from vaccine-preventable diseases. However, it is evident that there are numerous individuals who do not undergo vaccination to the point that outbreaks occur in the US and the Netherlands, and that a disease once eliminated from the UK is now endemic there once more. Reasons offered as to why parents refuse vaccination for their children include concerns about vaccine safety, and underestimating the serious harm that may result from vaccine-preventable diseases (Omer et al. 2009). In that sense, vaccines may almost be victims of their own success. It appears as if concerns regarding vaccine safety among the general public have been growing, and as if there is a consequent gradual decline in vaccination rates in many Western countries (CDC 2008; Euro Surveillance Editorial Team 2008; Omer et al. 2009).

Vaccine skepticism and opposition is nothing new. Ever since the advent of vaccination, which effectively occurred with Jenner's cowpox virus inoculation, there has been a vocal anti-vaccination movement (Allen 2007, p. 64-111). In the early days of inoculation, the objections were perhaps more reasonable and well founded. Cowpox inoculation was not always successful in protecting one from illness, and could introduce a range of horrific side effects. Vaccine refusal was the only weapon that ordinary people had to defend themselves against a procedure where risks and benefits were not quite clear.

However, contemporary vaccination is markedly different, and there is good evidence that the benefits of vaccination substantially outweigh the risks (Adetunji et al. 2003; CDC 1999). Despite this, objections to vaccinations abound. Such objections are part of the "anti-vaccination movement" (Kata 2010). These objections are typically disseminated on the Internet and in the media, and often contain misinformation (Kata 2010). There are aspects of these objections that are rooted in the rejection of scientific explanations, alternative models of health, rejection of authority, conspiracy theories or skewed science (Kata 2010).

One of the biggest concerns raised regarding the mumps-measles-rubella combination vaccine (MMR) in particular, is an alleged causative link between MMR and autism (Goldacre 2008; Kata 2010). The idea of a supposed link first came to light in a fraudulent study published in the *Lancet* by Wakefield, after which the idea was distributed in the media and through the public voices of some celebrities (Goldacre 2008). This was an important moment in the contemporary anti-vaccination movement, and the idea that MMR causes autism is still prevalent in anti-vaccine

messages (Goldacre 2008; Kata 2010). The Lancet retracted Wakefield's article, and subsequent articles appeared indicating the fraudulent nature of Wakefield's study (Godlee, Smith & Marcovitch 2011; The Editors of the Lancet 2010; Goldacre 2008). The supposed link between autism and MMR has been the subject of many studies since then, and it has been found that there is no link between MMR and autism (Demicheli et al. 2012; Moss & Griffin 2012). Despite this, opposition to MMR on grounds that it causes autism persists within the anti-vaccination movement.

### *Implicit ethical questions, the focus of this dissertation and the use of MMR as case study*

Reflecting on these considerations raises numerous ethical questions that are implicit to the practice of vaccination in children. What are the ethical principles involved in vaccination? Is there a moral obligation to see children immunized, and if so on whom does this obligation rest? How do we weigh the benefits to society from high vaccination rates against the autonomy of individuals? How do we respond to parental refusal of immunizations? Bearing in mind herd-immunity and the societal implications of vaccination, what are the demands of justice on the individual with regards to vaccination?

The task of this dissertation is to engage with these questions and to address gaps in the literature regarding the ethics of vaccination. In doing so I shall focus primarily on the example of measles disease and MMR vaccination. MMR as a preventive intervention against measles disease is the ideal candidate for such a study for a number of reasons. Measles is a serious and very contagious disease with serious consequences (Moss & Griffin 2012). High vaccination rates can eliminate measles, and a drop in vaccination rates leads to the re-emergence of measles transmission in populations (CDC 2008; Euro Surveillance Editorial Team 2008; Gay 2004). The vaccine is very effective and has a low risk of harm (Demicheli et al. 2012; Moss & Griffin 2012). With MMR vaccination, herd-immunity can be attained if sufficient vaccination rates are reached (Gay 2004; Moss & Griffin 2012). Lastly, despite being well researched and proven to be safe, MMR is quite controversial in the eyes of the anti-vaccine movement and is one of the prime targets for false anti-vaccine messages (Allen 2007; Goldacre 2008; Kata 2010).

It should also be noted that MMR vaccine has efficacy in preventing mumps and rubella in children (Demicheli et al. 2012). I will not focus in detail on these diseases or on this preventive action of MMR, but instead focus on measles disease and MMR as vaccine against measles disease. The reasons are simple: measles disease (as I have pointed out in the previous paragraph) has characteristics that make it the ideal candidate for the focus of this project, whereas mumps and rubella do not have all of the same characteristics and specifically is associated with lower mortality and morbidity than measles; MMR has high effectiveness in preventing measles disease (Demicheli et al. 2012; Moss & Griffin 2012); MMR is the most widely used and most available vaccine against measles, used in over 90 countries and almost exclusively used as measles vaccine in many countries (Demicheli et al. 2012; Moss & Griffin 2012); MMR is very well studied, and its effectiveness, cost, cost-effectiveness and adverse effects are well known (as I will show in chapters 2 and 3 of this dissertation). So, while prevention of mumps and rubella in addition to effectiveness in preventing measles undoubtedly can be seen

as beneficial, I will in this dissertation specifically focus on the arguments as pertain to measles infection and MMR as the vaccination most commonly used to vaccinate children against measles.

Thus, MMR as preventive vaccine against measles is the ideal candidate for focused study on the ethics of vaccination where a safe and effective vaccine is available for the prevention of a serious, highly communicable infectious disease.

An important observation is that MMR vaccination appears to inhabit two different contexts. In one sense, it is a medical intervention administered to an individual child, and governed by medical ethics considerations of decision-making for children. In another sense, it is a societal level intervention, governed by ethical considerations regarding health of the population and society. It is therefore important that ethical analysis incorporates both these contexts, and that recommendations provide guidance for both individual medical decision-making and public policy.



## **(2) Ethics of MMR vaccination in the literature**

### **(2.1) Presenting and discussing the ethics of MMR vaccination in the literature (medical, nursing and public health literature)**

There is a lively discussion in the medical, nursing and public health literature examining the ethics of vaccination. In this section, I shall present a snapshot of the state of the discussion in the literature. The goal is to provide a general overview of the present discussion on the topic in this literature, in order to identify important themes and issues. To do so, I will present a number of papers that have been published on the subject, summarizing the content and then briefly offer critical discussion of each.

To identify papers, I performed a search on Medline and PubMed for vaccination ethics, measles vaccination ethics, and MMR ethics. I also perused the contents of relevant public health journals, such as *Public Health Ethics*. Furthermore, I examined the references of identified papers to identify further sources.

The papers I include in discussion here are those that focus on the ethics of measles vaccination in children, and that seek to provide ethical analysis and recommendations for both the medical decision-making context as well as the societal context. Some of these papers focus more on the individual context, that is on the medical decision-making for an individual child, while others focus more on a societal or public health context. The papers presented in this section, therefore, appears in the medical, nursing, and public health literature, and aims to provide ethical analysis and practical ethical guidance on an individual-medical and societal-policy level with regards to measles vaccination.

Some of these papers focus on vaccines and vaccine programs in general, but in their argumentation either refer to MMR/measles or rely on medical considerations that are inherent to MMR/measles. All these papers are therefore relevant to my project, which is a consideration of the ethical aspects of MMR vaccination to prevent measles in children.

In my critical discussion I will show that there are regularly recurring themes in this literature that highlights the central ethical tensions with regards to measles vaccination in children. I will also show that there are notable deficiencies in this literature on the subject as it stands.

Although I will be critical of these papers, it should be kept in mind that some of the deficiencies may relate to the nature of the journals, the type of literature it is, and the limitations within which these authors are asked to write. For example, medical journals typically ask authors to focus on practical considerations, and have fairly low word count allowances. The point of the critical discussion is therefore not meant to imply that this literature has no value, but rather to identify deficiencies in the literature which provide an opportunity for my work to add to the literature and contribute meaningfully in addressing these deficiencies.

In the next section I shall discuss these themes more fully, highlighting the present deficiencies in the literature on MMR vaccine ethics. From there I shall embark on a consideration of the goals and aims of this doctoral thesis in providing a substantial contribution to the field.

### (2.1.1) Diekema and Marcuse (2007)

Diekema and Marcuse (2007) address three ethical questions with regards to vaccination. First, they ask whether parents who refuse vaccinations harm their children to the point that parental refusal should be overridden. This question is considered from a “first-do-no-harm” paradigm as well as a “best-interests-of-the-child” paradigm. In essence, parents act as surrogate decision-makers for their children, and have to weigh the benefits and risks of vaccination for their child. These benefits and risks are dependent on the level of communicable disease in the population, vaccination coverage in the population, as well as vaccine efficacy and adverse effects. Diekema and Marcuse argue that it is not always obvious to parents that vaccination is in the best interests of their child, and the risk of harm in highly vaccinated populations through not vaccinating is likely not sufficient to override parental decisions. However, where risk of harm to the child is high, parental refusal should be set aside in favor of vaccination.

Second, they ask what duties a parent has to avoid harms that may accrue to other members of the community through an unvaccinated child. They point out communal harms that may occur through non-vaccination of a child: the child may spread disease to those who are susceptible, the cost of the child’s medical care if she contracts disease accrues to society, and there are considerations of fairness in that non-vaccinators “free-ride” the public good of herd immunity and vaccination programs without paying their fair share. Arguing from a “first-do-no-harm” perspective and invoking a communitarian justice paradigm, they conclude that parents do in fact have duties of vaccination to the community.

Thirdly, they ask whether the value to the community of high vaccination rates and consequent herd immunity are sufficient to justify coercive vaccination policies. Arguing from Mill’s harm principle, which states that the free choices of individuals may be overridden if those free choices would result in harm to others, they conclude that vaccine refusals can be overridden through coercive vaccination policies when the risk of harm to members of the community is very high. They have two caveats. One is that voluntary vaccination uptake will probably be high in the case of an epidemic, so that coerced policies may be unnecessary and undesirable. The second is that if risks from disease are low and vaccination levels are high, coercive policies towards vaccine refusals would be hard to justify. They make an exception for measles, where there is always a susceptible group of people in society through vaccine failure. Until measles is eliminated, they argue, very few measles vaccine refusals can be justified.

Discussion: Diekema and Marcuse outline three important questions as relate to the vaccination of children, and the conclusions they offer seem reasonable. I am not convinced, however, by their method and approach.

In presenting their arguments, they jump around from one ethical paradigm to another without any indication of how these different paradigms are linked to one another. First they rely on the revered old medical adage “first do no harm” as a tool for ethical analysis, and then abruptly incorporate the “best interests standard” in a way that makes it appear as if these two different ethical approaches are similar to one another. Halfway through, they suddenly appeal to a communitarian justice standard without any warning that this is coming or without showing how this relates to the previous discussion. Shortly after that, they appeal to the work of John Stuart

Mill in *On Liberty* (2010a), who is a renowned utilitarian and whose liberty paradigm is decidedly at odds with the previously preferred communitarian standard. Their method reminds of a smorgasbord from which they pick whichever approach suits them, no matter how contradictory to previous approaches used. Although some of their conclusions seem on the surface to be reasonable and intuitively acceptable, their method leaves serious questions as to whether their conclusions are actually supported by the arguments they raise.

There is also an element of *ad hoc*-ness to some of their recommendations. For example, after concluding in question 2 that parents do have duties of vaccination to other members of the community through a communitarian perspective, they suddenly in question 3 appeal to Mill's harm principle, and state that in many instances the risk from harm to others is not high enough to justify coercive vaccination policies. One feels that these statements should be backed up by more thorough argument and empirical examples. But more importantly, we have here two conflicting conclusions through invoking two different ethical paradigms. Overall, even though Diekema and Marcuse highlight important questions and delineate the important issues that should be addressed in the ethics of vaccination, their way of analyzing these matters leaves one with a lot of uncertainty and does not resolve the obvious ethical tensions present.

### (2.1.2) Diekema (2005)

The arguments raised in this paper are fairly similar to the arguments raised by Diekema and Marcuse (2007). There are a few differences in aims and scope: in this paper Diekema is mainly concerned with giving practical guidance to pediatricians on how to respond to parental refusals for vaccination, and the harm principle is not overtly stated as an ethical paradigm in the constructing of arguments.

Diekema argues that the American Academy of Pediatrics strongly endorses vaccination, but that many pediatricians (reportedly up to 7 out of 10) face situations of parental refusals. These refusals, argues Diekema, are mainly because of misinformation regarding vaccines.

Diekema offers two sets of ethical arguments to provide grounding for recommendations as to how pediatricians should respond to such refusals. The first set of arguments surround parental decision-making and the best interests of children. The best interests of the child should be the primary focus, and parents should be allowed to make medical decisions on what they perceive to be the best interests of the child. The only time anyone should interfere with these parental decisions is when such decisions place children at risk of considerable harm. Thus, in a highly vaccinated society, although vaccination is probably in the best interest of a child, the risk of harm does not rise to the level where the parental decision can be interfered with. The exception is always serious harm; for example, a child who has an injury and needs a tetanus vaccination is at risk of serious harm, and a pediatrician should consider calling in state assistance in response to such refusals.

The second set of arguments surround community interests. An unvaccinated child can harm the community in a number of ways: through spreading disease to those who are susceptible (such as unvaccinated people, people who have experienced vaccine failure, and people who are not eligible for vaccination), and through the cost of medical care should the child become sick

due to non-vaccination. Furthermore, those parents who rely on herd immunity while not vaccinating their own children are “free-riders”; taking advantage of the benefit of herd immunity while not paying their fair share for participation. Assuming a communitarian justice perspective, Diekema establishes by these arguments that parental refusals means that parents “reject what many would consider to be a moral duty”, namely the “civic responsibility” of having one’s children vaccinated. Nevertheless, Diekema argues, coercive vaccination policies should only be enacted to prevent serious harm to others, and therefore coercive approaches should only be used if parental refusal places others at risk.

Diekema uses these ethical considerations to provide practical recommendations to pediatricians. The main role of pediatricians is to educate, correct misinformation, and encourage vaccination. If a child is at risk of serious harm, or places others at risk of serious harm, a pediatrician should involve state agencies such as social services to protect the child.

*Discussion:* This paper is mainly focused on practical advice to pediatricians, but Diekema does offer ethical arguments in support of his recommendations. As I already pointed out, the line of argument is fairly similar to the paper by Diekema and Marcuse (2007).

For the first set of ethical arguments, Diekema relies on a best interest standard. Parents are to make decisions for their children based on the best interests of children. It is not clear on what ethical considerations the best interests standard is based, and it is merely assumed to be the best way in which to proceed. Ethical arguments and justifications for using this standard are not provided.

Furthermore, it is not clear that the work has been done to show that vaccination is in fact in the best interest of children. This seems to be assumed as a basic premise before launching into argumentation rather than established and justified with valid reasons. Perhaps this can be excused to some extent, given the target audience of the paper. One would assume that pediatricians are familiar with the risks and benefits of the vaccinations in question and have shared assumptions regarding the best interests of children in this regard. However, it seems that some more grounding is needed for this assertion, in terms of providing ethical arguments and justifications for asserting why vaccines are in a child’s best interests, and in which ways vaccines are in a child’s best interests. The idea of “best interests” is after all vague and undefined; a child may have many different competing interests, such as familial, developmental, cultural, medical, and immediate interests. Different people may have different perceptions as to what “best interests” means, and which of these interests should be prioritized. All this is to say, the best interest standard is open to interpretation, and some work needs to be done here to show that vaccines are, in fact, in the child’s best interests, and to clarify what it means to say that it is in the child’s best interests.

It also seems clear that Diekema is in fact not relying solely on a best interest standard. He argues that providers should only interfere with parental decisions when there is a serious risk of harm. But this is not based on the best interest standard. Instead, this appears to be based on Diekema’s conception of the harm principle, an idea used in the paper with Diekema and Marcuse (2007). In fact, in other papers, Diekema argues that the best interest standard is an inappropriate ethical paradigm to use when thinking about the limits of parental decision-making

authority, and that instead the harm principle should be used (Diekema 2004; Diekema 2011). Thus, according to Diekema (2004; 2011), talk of restricting parental decision-making due to concerns of potential harms to the child is nestled in a harm-principle paradigm and not in best interests. In these other papers Diekema forcefully argues that the best interest standard is not feasible at all as a standard for restricting parental authority; yet in this paper on vaccines (2005) he gives the appearance of relying on the best interest standard to limit parental decision-making in precisely the way he rejects elsewhere.

Returning now to the paper under consideration (Diekema 2005), it is evident that Diekema, without acknowledging it, subtly moves away from a best interest standard and uses the harm-principle instead, arguing that the risk of serious harm is the threshold for the use of state power. This shift is never acknowledged, but it is clearly present. The conclusion reached through this process has the appearance of being intuitively appealing, but the method leaves much to be desired. The harm-principle (as I have pointed out before) is based on the work of Mill, a well-known utilitarian (Mill 2010a). It is not clear how this relates to Diekema's use of the best interest standard. Having said that, it is not clear what ethical paradigm Diekema bases the best interest standard on either.

On the whole, these ethical "arguments" appear to be a presentation of Diekema's intuitions regarding vaccination of children, and after the fact different ethical concepts are loosely appealed to in order to provide the look of substance to the conclusions. Careful dissection of the arguments and conclusions show that there is very little substantive backing for the conclusions reached, and that as such the ethical case has not been sufficiently made. No doubt, many will find Diekema's conclusions and appearance of supporting argumentation appealing, since they seem to be right and acceptable on some intuitive level. Indeed, it seems that Diekema is heavily relying on shared assumptions and intuitions in providing his ethical justifications and practical recommendations.

For the second line of argumentation, regarding community interests, Diekema assumes a communitarian conception of justice. Specifically, appeals to "free riding" and the unfairness of not paying one's fair share is steeped in communitarian thinking. This is in order, for those who share this view of justice. But these arguments are unlikely to appeal to persons who adhere to other conceptions of justice.

### (2.1.3) Krantz et al. (Krantz, Sachs, & Nilstun 2004)

Krantz et al. argue from a principlist paradigm and specifically consider the ethics of measles vaccination. They reference three principles, namely beneficence, justice and autonomy. First, they argue from autonomy that parents have the "right to act as proxies" for their children, and to go against the will of the parents would incur "ethical costs". Second, they consider the principle of beneficence. They argue that in a highly vaccinated society such as Sweden, the risks of incurring disease is "negligible" and there is an "ethical cost" to vaccinating the child, as there is always risk of vaccine adverse effects. These risks and "ethical costs" change with the vaccination rate, and if vaccination rates drop below herd immunity levels, there is an argument from beneficence to institute public health immunization programs. They conclude that an "individual child, however, would be better off vaccinated than not vaccinated, especially if

travelling into areas where measles is still common.” Lastly, they consider justice. They assume a communitarian justice perspective, appealing to the value of solidarity. That is, members of the community have duties of solidarity to one another, and parents should therefore have their children vaccinated to ensure herd immunity. These obligations do not rest on children, for “there can be no justice requirement for a child”. Herd immunity is meant to protect vulnerable children in society, as failure to establish herd immunity can incur “ethical costs” to individual children as “even a vaccinated child is not fully protected against measles”.

Krantz et al. reject coercive policies out of hand, stating that “coercion is neither possible nor desirable in a Swedish immunization programme.” They recognize a tension between individual interests/autonomy and community interests/justice. Their recommended solution is to appeal to the value of solidarity to motivate parents to get their children vaccinated. Integral to this approach is that parents trust the messages that come from health institutions. Community members may then act on these through the shared values within the community.

*Discussion:* Krantz et al. addresses the ethics of MMR vaccination by reference to the principles of autonomy, beneficence and non-maleficence. This presumably relies on the principlist approach of Beauchamp and Childress (B&C) (2013), although they do not specifically reference B&C.

Interestingly, Krantz et al. omits the principle of non-maleficence from their analysis. I am not sure why this is done, it is not explained. The difficulty this presents, is that the method of principlism relies on bringing the various principles that impinge on a case into a state of balance with one another, known as reflective equilibrium. It seems obvious that non-maleficence is of value in this instance, and some of their statements regarding “ethical costs” seem to be a recognition that harms that can accrue are ethically relevant. As such, their ethical analysis is likely not complete, as they have not brought all the relevant principles into reflective equilibrium.

Their consideration of the implications of the principle of beneficence is puzzling. Having considered benefits and risks to the extent that Swedish society has high vaccination rates and that vaccinating a child in such circumstances may incur “ethical costs”, they suddenly conclude without further explanation that it is probably best for the individual child to be vaccinated rather than not be vaccinated, especially if they travel to an area with low vaccination rates. This is a most extraordinary conclusion given the argument preceding it, and seems to be a loose-standing assertion rather than related to the arguments offered. In all, having considered “ethical costs” of vaccination, they seem to assert without further justification that it is probably in the best interests of a child to be vaccinated anyway. One can only assume that this is an intuitive assumption based on the general efficacy of vaccines. Suffice it to say, the assertion that beneficence supports vaccination and is ethically in the interests of the child is not sufficiently supported through arguments; instead it seems to be a sort of intuitive assumption.

With regards to the principle of justice, Krantz et al. assume a communitarian paradigm and a related societal value of solidarity. This seems to be based on the idea that it is the prevailing view in Sweden, and that the paper is aimed at a Swedish audience. Communitarianism is not the

only justice paradigm, and Krantz et al.'s arguments are unlikely to appeal to adherents of other theories of justice.

Lastly, Krantz et al. reject coercive or mandatory vaccination policies as “not possible or desirable in Sweden” without any further argumentation. This amounts to the rejection of the use of State power out of hand. This is rather surprising; the question over whether coercion is justified is a point for serious ethical reflection, and is central to any discussion on vaccination ethics, as pointed out by Diekema and Marcuse (2007). This seems intuitively right; given what is at stake in vaccination policies, and the role that state power can play in enforcing vaccination, the question of the ethical nature of coercive approaches is a central theme in vaccine ethics. To just reject the question as “not possible or desirable” begs the question: why is it not possible or desirable? Krantz et al.'s rejection of coercive approaches has the appearance of an appeal to cultural relativism, a position fraught with inherent contradictions and as such an implausible ethical framework. Krantz et al. do not sufficiently defend this rejection of coercive approaches, and this is a serious deficiency in their argument. What would they recommend if appeals to solidarity fail? Or if their society moves towards a different conception of justice, where their arguments from communitarian justice no longer speak to members of society?

#### (2.1.4) Verweij and Dawson (2004)

Verweij and Dawson present ethical considerations of collective vaccination programs from a public health perspective. Their goal is to state a set of guiding principles that can be used to create ethically justified vaccination programs. The following assumptions form the basis of their guiding principles.

Firstly, government is tasked with the obligation of protecting the general health and well-being of the public. This means that governments have an interest in vaccination programs. Vaccinations work well in protecting the health of the public, but optimally so if it is not left to individuals or small groups. Rather, a concerted, population-level effort will ensure optimal population health. Collective vaccination efforts are in the public interest, as such type of vaccination programs realize important public benefits.

Secondly, people are not just citizens or members of the public, but are also individuals with rights that should be respected. Government has an obligation to protect the rights of individuals. There can be a tension between the public health obligations of government and respecting the rights of individuals. The “second assumption can run into conflict with the first” (p. 3123).

Furthermore, the principles that they derive from these two assumptions can also be in conflict with each other. The two assumptions and the derived principles are to be thought of as general guidelines that can conflict with one another, and in order to resolve conflicts or to apply these assumptions and principles, “further reflection, interpretation and judgement” is needed (p. 3123). These principles are “starting points for ethical reflection – not... devices which simply close discussion.” In essence, Verweij and Dawson present a framework of principles, based on public health ethics assumptions, which stand in need of further reflection and “balancing of the different principles” and “consideration of relevant empirical facts about the nature and incidence of the disease” (p. 3123).

They present the following seven principles and provide a brief discussion of each (p. 3123-3125):

1. *Collective vaccination programmes should target serious diseases that are a public health problem.*
2. *Each vaccine and programme as a whole must be effective and safe.*
3. *The burdens and inconveniences for participants should be as small as possible.*
4. *The programme's burden/benefits ratio should be favourable in comparison with alternative vaccination schemes or preventative options.*
5. *Collective vaccination programmes 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 programme should be honoured and protected.*

The discussion of each principle amounts to further clarifications of the principle and consideration of its implications. It is not clearly shown how the principles are derived from the ethical framework/assumptions initially presented.

I am particularly interested in the discussion around principle 5 and principle 6.

Principle 5 states that benefits and burdens should be justly distributed. In their discussion of this principle, Verweij and Dawson state the example of influenza vaccination of children and adolescents purely to protect elderly adults as an unjust distribution of benefits and burdens. But what is unclear is what theory of justice they are appealing to. No theory of justice is stated, and it is not clear how to determine what would be a just or an unjust distribution.

Principle 6 states that vaccinations should be voluntary unless compulsory vaccination is essential to avoid harm. This is, they argue, because of the importance of autonomous decision-making in medical care. It would be hard, they say, to imagine scenarios where compulsory vaccination of adults is ethically justified. However, in children respect for autonomy relates to respecting the decisions of parents with regards to their children. They argue parental decisions may be overridden if such decisions are thought to be harmful to their children. Also, compulsory vaccination may be used if it is necessary to protect the general public. For instance, if compulsory vaccination is needed to reach sufficient vaccination rates to secure herd-immunity, such compulsory vaccination can be justified. In this way, compulsion "could serve the common good" (p. 3125). This argument is not always successful, they say, because usually the common good of herd-immunity can be achieved without compulsory measures.

Discussion: Verweij and Dawson set out to establish ethical principles that can be used to formulate ethically justifiable vaccination programs. Their stated starting point is public health ethics, and they clarify their two main assumptions. Ostensibly, they derive their seven principles from these two assumptions. However, they never show how the principles are related to the



two basic assumptions or how they are derived from the basic assumptions. The way in which the seven principles are presented and discussed leaves one with valid questions as to where exactly these principles come from, and how they relate to the stated ethical framework.

Whatever they purport their ethical framework to be, it appears as if they are in fact using an ethical framework related to the principlism of B&C (2013) and the moral theory of Ross (1930). Consider. They formulate a framework of principles that can be in conflict with one another. In order to know how to resolve these conflicts and to apply these principles in practice, one has to enter into a process of deliberation and balancing. The principles are stated as if they are true in themselves, without showing how they related to previous moral commitments or the previously stated ethical frameworks. It is almost as if these principles are intuitively arrived at; indeed, they do have a common-sense intuitively true appearance about them. Further discussion of these principles then focus on how they should be applied and balanced in specific situations, with the exception of principle 6. When discussing principle 6, it is indicated that this principle is derived from the principle of autonomy. Because we respect autonomous decision-making in the provision of medical care, we should accept the validity of principle 6. But this is extraordinary. Up to now there has been no mention of autonomy or of a principlist paradigm. The supposed paradigm is public health ethics, and the supposed underpinning for respecting individual choice is that governments have the obligation to respect the rights of individuals. Suddenly, in their discussion of principle 6, we find ourselves in a principlist paradigm. On the one hand we have autonomy and respecting parental decision-making in caring for children, and on the other hand we have justice, with discussions around the common good and obligations owed to each other.

It appears to me, therefore, that Verweij and Dawson actually argue from a paradigm that is a combination of Ross and B&C's principlism. In their discussion of principle 6 they clearly revert to a principlist paradigm in stating the ethical obligations of different parties and the ethical tensions that exist. In order to resolve the tensions, they appeal to the methods of Ross and B&C – specifying and balancing conflicting and non-specific principles in order to determine what actual duties are conferred by their intuitively grounded principles.

I note two further things. One is that at the center of their work is the tension between individual freedom or autonomy and collective responsibility or justice. The second is that they assume a communitarian justice perspective, at least when discussing principle 6. Talk of the common good and obligations owed to each other is at home within a communitarian perspective. It is true that they mention what could be thought of as a libertarian justice perspective when they state their initial ethical assumptions – namely that government has the obligation to respect the rights (presumably liberty rights) of individuals. However, in their discussion of principle 6 they abandon this concept and instead appeal to autonomy, reverting to a principlist paradigm, and assume a communitarian theory of justice in tension with the demands of autonomy.

In conclusion, Verweij and Dawson's principles appear intuitively useful and right. Applying these principles requires further balancing and deliberation, and they are considered a starting point for ethical reflection. Their method of justification is unclear, and they appear to be actually using a different paradigm than their stated paradigm. Like the other papers I have considered, they conceive of the tension between autonomy and justice as a central ethical theme in the ethics of vaccination. They also assume a communitarian theory of justice when dealing with this

issue. Lastly, their discussion of the limitations of parental decision-making is very similar to that of Diekema already considered.

Verweij and Dawson's seven principles are further explored in a paper by Isaacs (2012). Isaacs discusses each of these seven principles in turn, and attempts to further "outline the ethical basis" for the seven principles (Isaacs 2012, p. 111). To do so, he discusses each of the principles in turn, engaging in some discussion as to how the principle can be applied in different vaccination programs. He does not identify a specific guiding ethical framework in his discussion, and seems to appeal to ethical concepts that he believes are generally well accepted. For example, when discussing the first principle, benefits, he writes, "It is generally accepted that an immunization program should benefit the individual and the community" (Isaacs 2012, p. 112). His discussion of specific immunization programs invokes many different types of vaccination, and he only in cursory fashion refers to measles vaccination. He also does not go into any great depth in exploring the empirical foundations of many of the vaccines he employs as examples.

Though Isaac's paper adds to our understanding of how to apply Verweij and Dawson's principles, it does not add much greater depth to the ethical grounding of these principles in a consistent ethical framework. The discussion appeals to a myriad of different ethical concepts that are at home in different ethical approaches. Lastly, it is also scant on establishing empirical facts.

### (2.1.5) Sheather (2013)

Sheather considers three questions. First, do parents have a moral duty to get their children vaccinated? Second, should this obligation (if it exists) be enforced by the state? Third, if it is enforced, how should this best be done?

To answer the question of a moral duty, Sheather considers two moral dimensions involved in the decision to vaccinate. The first dimension is the interests of the individual child, or the "welfare decision" as Sheather calls it. Parents are tasked with making medical decisions for their children along the best interest standard. This involves weighing of benefits and risks, and then choosing that which brings about the greatest balance of benefit over risk. In most cases, Sheather argues, the benefits of vaccination outweigh the risk substantially. There is therefore a "strong prima facie duty on parents to ensure their children are vaccinated" with MMR at the earliest opportunity (p. 1390). The exceptions would be medical contra-indications to MMR.

The second dimension is the public good. Sufficient levels of vaccination lead to "population immunity". When this has been reached, the balance of risks and benefits to the individual child changes somewhat, so that benefits from vaccination are slightly less. Overall, harms from vaccination are usually "trivial" and "children may still be exposed to diseases carried by people moving into the population", so that vaccination still looks "prudential" (p. 1390). If a parent were to rely on population immunity in order to protect their child, foregoing vaccination, a problem of free-riding is created. Such people act unfairly; someone who benefits from collective action has a duty to take their share of the burden. Sheather also mentions the issue of potential harm to others. An unvaccinated child may spread disease to others who are not immune to the disease, and may put others at risk of harms that are avoidable.

Thus, in answering the first question, Sheather argues that parents have a prima facie duty to have their children vaccinated with MMR from individual considerations. This duty is strengthened by considering the public good and potential harms that may accrue to others through non-vaccination.

To answer questions two and three, Sheather proceeds as follows. Liberal democracies recognize individual liberty as a primary good. When parents refuse to vaccinate their children, there is a moral tension between individual liberty and the moral considerations in favor of vaccination. Compulsion may be justified in two circumstances: when there is risk of serious harm to the child, and when there is risk of serious harm to others in the community. A caveat is that the “desired good cannot be achieved in a way less restrictive of liberties” (p. 1390).

Sheather states that in his opinion, once population health has been achieved, the legal case for mandating vaccination no longer exists. Furthermore, he cautions that using of compulsion can lead to public discontent and resistance. There are also other options that can be considered, such as educational measures.

*Discussion:* Sheather outlines a number of ethical issues that are primarily at stake when considering MMR vaccination in children. Once again, we see the central focus falling on the tension between individual freedom and collective responsibility. The discussion moves on to a consideration of circumstances in which free choices can legitimately be challenged under the law in a liberal democracy, and suggestions are offered for resolving these tensions.

Once again, the ethical paradigm used is not clear, and the ethical conclusions are not clearly grounded. For example, Sheather appeals to the best interest principle as the ethical guiding principle parents use when deciding for their children. He states that parents should make decisions that optimizes the welfare of their children. But this seems to be assumed rather than argued for. It is not clear on which ethical foundation these assertions and conclusions rest. Of course, they seem intuitively true – it seems like a truism that parents should want what is best for their children. However, there is more work to be done here in firmly grounding the best interests approach in an ethical framework. It also is not clear that the work has been done to show that vaccination would indeed be in the best interests of children. This is assumed rather than argued for in Sheather’s work.

When it comes to collective responsibility, Sheather assumes a communitarian perspective. He conceives of herd immunity as a public good, and considers those who benefit from the public good without paying their fair share “free riders”. He takes it as a given that individuals have duties to the collective. These are all considerations that are firmly at home in a communitarian justice perspective.

Sheather considers the question of compulsory vaccination mostly from a legal and political perspective, and sometimes muddles the two. For example, when he argues that liberal democracies have an obligation to respect individual liberty, it is not always clear if he is advancing an argument based on legal considerations or on libertarian or egalitarian justice notions of liberty. Sometimes he appeals to both.

The conclusions reached with regards to mandatory vaccination have the appearance of common sense about them, but it is not clear whether these are well grounded in ethical argument. For example, he states that it is his “opinion” that the case for compulsory vaccination falls away when sufficient population immunity is reached. Such an assertion needs grounding in substantive ethical argumentation. Next, he changes track and considers the consequences of the use of compulsory vaccination policies. He states, “although we have been dealing largely with questions of rights and duties, the consequences of any state action in the real world need to be assessed” (p. 1390). It is not clear whether he is invoking utilitarian or pragmatic considerations here.

Like with some previous authors, it is hard to pin down the exact framework that Sheather is appealing to. He jumps around from one framework to the other, and seems to use whichever approach is useful for the current purpose. At one point, liberalism is useful, so a liberalist approach of rights and duties conflated with legal considerations is used. At another point, communitarian considerations are useful, so a communitarian justice perspective is invoked. Elsewhere, parental decision-making in medical care and the best interest standard forms the basis for ethical argumentation without it being clear how these are justified in the overall scheme.

Once again, the conclusions and recommendations advanced have a common sense intuitive appeal as to being sensible and right, but the method of argumentation and the grounding of assertions in a consistent ethical framework is wanting.

### (2.1.6) van den Hoven (2012)

I examine this article fully in chapter 6 when I consider vaccine refusals and communitarian justice. Here, I will just make a few brief remarks as to van den Hoven’s approach.

In this article, van den Hoven addresses the problem of vaccine refusals from a public health perspective. She argues that herd immunity is a public good, something established by collective action that benefits all. Those who use this public good without “paying their fair share” are free-riders. Therefore, every instance of vaccine refusals for reasons other than medical contra-indication to vaccination constitutes an unjust act. There may, however, be reasons for not forcing people to get their children vaccinated even though free riding is unfair. For example, if forcibly vaccinating a child will not add to the herd immunity already established, it is difficult to justify forcible vaccination. Another reason is that public trust is an important factor in ensuring vaccination uptake. Eventually van den Hoven recommends approaches relying on education and building of public trust.

Discussion: Van den Hoven engages with the problem of vaccine refusals from a communitarian justice perspective. She appeals to notions such as the common good, collective action, and the idea that individuals have an obligation to the collective. From this perspective she addresses the problem of vaccine refusals, acknowledging one of the main ethical themes within the vaccine ethics literature: the tension between individual freedom and collective responsibility. Concluding that every case of vaccine refusal is unjust (apart from medical contra-indications to

vaccination), she establishes a moral case for compulsory vaccination measures. However, there may be legitimate reasons why an alternate approach may be used to ensure vaccination uptake.

Van den Hoven's arguments remain consistent within the communitarian justice paradigm. Van den Hoven's article deals extensively with vaccine refusal, providing a thorough moral analysis of the concept of free riding. Many other writers rely on this concept when writing about the ethics of vaccination, perhaps without realizing that it relies on the communitarian justice paradigm that van den Hoven assumes.

Although these arguments are consistent and present a detailed consideration of the unfairness of free riding, a potential limitation is that it relies only on a communitarian justice perspective. As such, these arguments may not be persuasive to people who argue from different theories of justice, such as libertarians or egalitarians.

### (2.1.7) Wood-Harper (2005)

I shall examine this article more fully in chapter 6 as well, along with the van den Hoven article mentioned above. Here I will make a few short remarks.

Wood-Harper examines the tension between individual autonomy and collective responsibility as it pertains to MMR vaccination in children. She argues that there is a "moral and legal requirement, and a general assumption, that the right of parents to make medical decisions on their child's behalf is exercised in his or her best interests" (p. 46). This parental right can be interfered with, however, when the decisions of parents are contrary to the child's best interests. In arguing this point Wood-Harper cites examples from a legal perspective, and concludes that the state has the authority to overrule any parental decision that interferes with a child's "physical integrity" (p. 46).

MMR vaccines, however, have more to them than that: they are also a matter of public interest. Sufficient vaccination uptake benefits the community as a whole, establishing herd immunity and protecting the health of the current and future community. Individuals share a "collective responsibility for promoting the health of future generations of children" since they "themselves have gained health benefits as a result of past vaccination programs". Wood-Harper argues that individuals have a responsibility to the wider community and future children to have their children vaccinated. To strengthen the argument, she appeals to the value of altruism. According to this value, parents have to consider the effect of their decision on others, not just on their own children. The idea, once more, is that we have duties to members of society other than ourselves and our immediate family. From here, Wood-Harper launches a discussion of free riding, appealing to collective responsibility and the unfairness of not doing one's share.

She then shifts to a discussion of autonomy, and the need for providers to respect the free choices of individuals, applying this to parental refusals of vaccination. Thus, here Wood-Harper relies on a principlist paradigm, and she highlights the tension between demands of autonomy and (communitarian) justice.

This leads her to ask – is there a case for mandatory vaccination? She is skeptical. Because "measles can be, but seldom is, fatal," it is hard to justify mandatory policies (p. 52). As long as

there are any risks associated with vaccination, it would be “difficult to rationalize” overriding parental refusals (p. 52). Instead, she advocates persuasive techniques such as education as a way to respond to vaccine refusals.

*Discussion:* Wood-Harper relies on different ethical approaches, and moves from one to the other without acknowledging a switch. It appears as if these different approaches are seen as complementary or equivalent. In one section she argues from a rights perspective, examining the rights of parents and legal limits to the rights of parents. Later, she argues from the principle of autonomy. It seems as if she moves unacknowledged from a rights and legal approach to a principlist paradigm. It is not clear whether she is aware of this change in ethical paradigm; but it appears as if she views these paradigms as similar. Like with many other authors who engage with the ethics of MMR vaccination, it appears as if Wood-Harper appeals to many different ethical paradigms without showing the connection between each or how different modes of justification are related to each other. Again we see the approach where an ethical paradigm that happens to suit the current argument is invoked, without it being clear how it is related to what preceded the present argument.

In engaging with the tension between justice and autonomy, Wood-Harper assumes a communitarian justice paradigm. She takes it that individuals have obligations to the collective, and she also examines the problem of free riding – benefiting from collective action without paying one’s fair share.

She also considers another central ethical question – whether there is a case for mandatory vaccination. Her argumentation and conclusions here are fairly puzzling. She argues that measles is, after all, not really that dangerous and as long as there is any risk from the vaccine one cannot override parental refusals. But what about her previous arguments regarding duties owed to the community and legal limits on parental rights? Her argument against mandatory policies do not address these. Essentially, in considering mandatory vaccination questions she pits autonomy against communitarian justice and then abandons the ethical conclusions she has drawn from communitarian justice earlier, making it inevitable that autonomy will win. Instead of dealing with the conflicting obligations, she merely focuses on autonomy. Measles is not often fatal, there are risks to vaccinations, so an argument for mandatory vaccination can never work. This is a very questionable argument. Even if measles is not often fatal, it has a whole host of other dismal complications that leads to immense burdens on the individual. And even though MMR carries risks with it, these risks are thought to be negligible. But more importantly, these considerations are relevant to the individual case of measles vaccination. It tells us nothing of how to balance individual autonomy against the obligations we have to the community.

In conclusion, then, Wood-Harper’s article raises interesting ethical issues, but has serious deficiencies. One is the unacknowledged moving from one ethical approach to another, what I have previously called the smorgasbord approach, where the author picks whatever ethical approach suits their present argument under consideration. The other is that she assumes a communitarian justice perspective when considering the tension between autonomy and justice. This is not a deficiency per se, but it does limit the persuasive scope of her argument. Lastly, having done all the work to establish obligations derived from communitarian justice, she virtually ignores these obligations when considering the question of mandatory vaccinations, and

introduces a questionable new argument based on questionable premises for why mandatory vaccination is never justifiable.

### (2.1.7) Gostin (2015)

Against the backdrop of a measles outbreak in the USA, Gostin examines the extent to which parental opt-out from the USA's state vaccination requirements can be tolerated. He states the ethical question as, "whether parents' rights to raise their children justify decisions that place the community at risk" (p. 1099). He briefly reviews some of the different state opt-out policies in the USA, concluding that states with easier opt-out procedures have lower vaccination uptake than those where parental opt-out is more difficult. He then analyzes such parental opt-outs and the provision of opt-out in a brief ethical argument, contrasting parental rights with community rights, an ethical principle of not imposing harm on others, and the consequences of specific types of opt-out policy on the public, such as "inflaming public opinion" (p. 1100). Eventually he concludes that more difficult opt out policies are ethically justifiable, but that harsher penalties should be avoided as it could lead to public resistance.

*Discussion:* This is a short little paper in the "viewpoint" section of a medical journal, and as such does not aim at great rigor in ethical analysis, but rather to emphasize one or two important points with regards to ethical guidance for medical practice. In particular, Gostin emphasizes his view that state opt-out requirements in the US should be narrower than they are at present in many states, and that such an approach can be ethically justified. It can be noted, however, that Gostin appeals to different ethical frameworks and theories within the same argument. For example, in just one paragraph, he uses medico-legal considerations, rights theories, and consequentialism. The problem is that these theories conflict with one another, but in this paper it is used as if these theories are equivalent to one another, and supplement one another. Again, the article does not aim at great rigor, but it remains a sizeable deficiency to use conflicting ethical approaches and modes of ethical justification within the same argument in the way this paper does: moving from one framework to the next unacknowledged, using the different theories as if they are equivalent and complementary to each other, and not providing a framework or method for resolving the tensions between the conflicting methods of justification.

### (2.1.8) El Amin et al. (2012)

This paper conceives of vaccination primarily as a public health problem, while considering some issues within individual medical decision-making. It also focuses mostly on small pox vaccine and human papilloma virus vaccine, with only a few cursory references to measles and measles vaccination. However, there are some instructive themes that can be taken from this paper.

El Amin et al. examine the ethical implications of state vaccination requirement in the USA, and state the central ethical tension to be the "balance of personal autonomy and choice versus protection of the entire at risk population" (p. 1).

Their stated ethical framework is a set of public health principles articulated by Childress et al. (2002), consisting of nine ethical principles that apply to public health programs. The extent of their justification for using this framework is that vaccination programs is a public health issue,

and that there is “some consensus” that the Childress principles are “the most relevant” of the public health principles (El Amin et al. 2012, p. 2-3).

Following this declaration, they also invoke the work of Diekema and Marcuse (2007), appealing to their do-no-harm approach as an ethical framework.

Next, they invoke Gostin, Bayer, and Fairchild’s (2003) articulation of the “precautionary principle” as an important framework in public health. This is a principle that is traditionally more related to environmental issues and where scientific knowledge is uncertain; when there is a threat to the environment the government should not use scientific uncertainty to avoid instituting measures that are known to prevent environmental damage (Goldstein 2001). There have been many different articulations of this principle and it has gradually been modified and applied as justification model for different public health measures (Goldstein 2001). Gostin, Bayer and Fairchild (2003), for example, uses it in a public health ethics analysis of the governmental response to SARS virus, describing the principle as being a central public health tenet. They write (p. 3232):

*“We take as a starting point the centrality of the precautionary principle for the ethics of public health. The principle stipulates an obligation to protect populations against reasonably foreseeable threats, even under conditions of uncertainty. First articulated in the context of environmental hazards, the precautionary principle seeks to forestall disasters and guide decision making in the context of incomplete knowledge. Given the potential costs of inaction, it is the failure to implement preventive measures that requires justification. Proponents of the precautionary principle explicitly defend their position by noting that entities that threaten the environment are best able to bear the burdens of regulation. Opponents warn that the imposition of such burdens may stifle economic progress and scientific innovation. The principle has not been explicitly invoked in the context of epidemic threats where preemptive actions may burden individuals and impose limits on their freedoms. Nevertheless, the precautionary principle has implicitly guided public health interventions designed to limit or forestall epidemic outbreaks.”*

It is not clear what the grounding ethical framework is for the precautionary principle. In the cited articles, it appears as if it was first an environmental risk management principle that over time became incorporated into public health efforts.

Having identified three different ethical frameworks, the paper proceeds with an ethical analysis of compulsory vaccination programs of small pox vaccine and human papilloma virus vaccine. In their arguments, they present some precedent setting legal cases and legal arguments, consider the issue of paternalism, and public perception of vaccine related harms. Curiously, the presented arguments do not appear to draw on the stated ethical frameworks. Eventually the paper provides a set of recommendations, such as reviewing vaccination mandates, using more non-compulsory approaches, and addressing parent/guardian safety concerns. It is not always clear how these recommendations are connected with the ethical frameworks provided, although there are some passages that make reference to the ethical framework. For example, on page 13 it states, “It is compatible with the ethical principles previously discussed to assign to



government the responsibility for compensating persons who experience adverse events that have been documented to be causally related to vaccination,” without it being clear which specific ethical principles are referred to, or how this conclusion related to such ethical principles.

*Discussion:* Once again, there is the use of different and divergent ethical frameworks as if they are similar or complementary to one another. The ethical argumentation presented do not clearly show how these different frameworks are employed, or how they support the eventual conclusion.

The ethical grounding of the precautionary principle and its role in ethical argumentation is also not clear. From cited sources it appears to be a risk management principle that originated within government’s responsibilities towards environmental harms and risks, which gradually became reformulated and incorporated into public health. Its relation to the other two stated frameworks, the principles of Childress et al. (2002) and the do-no-harm of Diekema and Marcuse (2007), is unclear. It does not appear as if these principles are directly applied during the argumentation stage of the paper. They are mentioned to some degree when the conclusions are presented, but it is not always clear which principle is being referenced.

One can see, however, that the same ethical tensions are stated in this paper as were identified in other papers with regards to vaccination programs: the tension between individual freedom and public interest.

#### (2.1.9) Dawson (2011)

In this paper Dawson defends routine vaccination programs, assuming a public health perspective of the problematic. The paper examines vaccinations as a whole, lumping diverse vaccinations together, but does in places specifically refer to measles and measles vaccination in argument construction. It also aims to provide recommendations towards both the individual case of vaccination and public policy. It therefore matches my inclusion criteria.

Dawson considers vaccination using a variety of ethical concepts. First he considers harm and harm avoidance through a benefit lens, arguing that vaccines are morally justified in that they prevent harm to children. Next he embarks on a best interest analysis, and argues that vaccines are usually in the best interests of children. In this analysis he considers the tension between a parental vaccine refusal and the community’s conception of what is best for the child. Thirdly he considers the problem from a community perspective, and argues that herd immunity (or community immunity as he calls it in this paper) is in the public interest. For this analysis he uses the concepts of the common good and a public good, using language and arguments that are reminiscent of a Communitarian view of justice and society. Fourth, he constructs an argument from justice, arguing that justice is “a highly disputed concept”, but that it “generally requires us to do what is right and fair” (p. 1032). From here he argues that all children in the world, even those in less well-off settings in the third world, should have the same opportunity to enjoy the protection vaccines afford.

*Discussion:* The aim of the paper appears to be to highlight certain ethical tensions within vaccination programs in general and to provide a moral justification for the practice of public vaccination programs in general, and not a specific analysis of the ethics of measles vaccination.

The paper draws interesting conclusions and highlights interesting themes. It provides an analysis of the ethical tensions present in the individual case of vaccination, using concepts such as harm and best interest. It then provides an analysis of community interests and obligations we owe each other. Again, one of the central tensions identified is the tension between individual freedom and community interest. The argument surrounding justice is an interesting one, highlighting the specific need of people in resource poor countries.

The paper does not commit itself to a specific ethical framework, and uses different ethical concepts that are at home in different ethical frameworks as if they are related to one another. It is for example not clear how the discussion of community interests, justice, best interest, and harm avoidance fit together. These concepts are used as if they are complimentary and related to one another, without it being clear how, or what framework is used to ground them.

The paper also commits itself to a Communitarian view of justice in discussing community interest and obligations owed to the community. It does embark on a further discussion of justice, but no specific theory of justice is invoked, and it is not clear how these different arguments fit together.

Furthermore, the paper does not provide a lot of empirical information regarding vaccine efficacy, disease complications, disease epidemiology, vaccine side effects, and so forth. Such matters are critical in order to apply specific ethical concepts to a specific vaccine.

#### (2.1.10) Dawson (2005)

Dawson here examines the role of the best interest standard in the provision of vaccinations in general. His focus is specifically to examine whether the best interest standard can be used to justify overriding parental vaccine refusal. He does not consider a particular vaccination, but rather vaccinations in general. Towards the end of the paper he makes a particular point about measles vaccination which is of particular relevance to my work.

Dawson states that many commentators argue that the idea of the child's best interests is central to vaccine delivery. This claim appears to be true, given the analysis of the ethics of measles vaccination literature I have provided. He defends using a conception of the best interest standard as found in the work of Buchanan and Brock (1990). That is, the best interest standard requires that medical choices be made that optimize the child's welfare or good. This requires that the various interests of the child be weighed with the potential benefits and harms of the available choices in question, and that the choice should be made that optimally promotes the child's interests.

Dawson makes an interesting point on page 82:

*"The 'best interests argument' is a general argument, but it will only be applicable in the real world once we consider both a particular type of disease and the relevant vaccination that is available to combat that disease. This is because the argument as a whole is dependent upon the idea of the relative risk of harm produced through two incompatible decisions (to vaccinate or not vaccinate). A sound judgment cannot be made in the abstract, but only in the light of the relevant and available empirical evidence."*

On pages 83 and 84, he then considers some vaccinations in a short and abstract manner. When it comes to measles vaccination, he provides a brief one-paragraph summary stating that measles is highly contagious, can cause serious medical problems, and that the MMR vaccine is available. He states, however, that the “relevant evidence for its effectiveness and its risk of causing harm are contested” (p. 84). He concludes that it is difficult to decide whether measles vaccination is in the best interests of a child. It would depend on a careful weighing of the empirical evidence and the circumstances.

*Discussion:* Dawson here provides a consistent ethical framework and ethical grounding for the best interest standard in a way that other authors have not done. Dawson cites the work of Buchanan and Brock in this regard, and employs their ethical framework in using the best interest standard. This is important work, and emphasizes the importance of the best interest standard in vaccination decisions for children.

Dawson also argues for the importance of empirical evidence in analyzing the ethics of a specific vaccination. His consideration of measles vaccination is brief, and he states that the safety and efficacy of MMR is contested. This paper was written in 2005, and I will demonstrate in this dissertation that there is a high degree of empirical certainty at present regarding the safety and efficacy of MMR. The point is well made, though – a thorough empirical analysis is essential to the ethical analysis of MMR vaccination in children.

A potential deficiency in this paper is that it is not clear how this ethical framework focusing on best interests relates to community obligations and the public good that Dawson often employs. This paper highlights the best interest standard quite well, and I will return to it when I consider the individual case of measles vaccination in chapter 5. A lingering question, however, is how one should think about the individual case in relation to the public interest and justice considerations, how a paradigm of consideration for the individual can be reconciled with a societal paradigm.

## **(2.2) Emerging themes and deficiencies in the medical, nursing and public health literature**

Having presented an overview snapshot of the discourse on the ethics of MMR vaccination in this literature, it is apparent that some themes emerge with regularity. In this section I shall highlight these themes as well as the deficiencies. The highlighted themes suggest important questions and tensions within the issue of measles vaccination in children that my work should explore in making a contribution to the discourse. The identified deficiencies show areas in which my work can meaningfully add to the literature through addressing these.

### **(2.2.1) The smorgasbord approach – moving haphazardly between different and competing ethical paradigms**

Almost all the authors employ what I have called a smorgasbord approach to ethical justification. That is, they move from one ethical paradigm to the next when it suits the purpose at hand without acknowledging that a shift has happened and without showing how the different ethical paradigms are related to one another. An author may start off in a rights-based paradigm,

then invoke principlism, then communitarian justice, then a liberal view of justice, and for good measure add a dose of utilitarianism. Notable exceptions are the article examining free riding by van den Hoven (2012) using a communitarian justice approach and the article by Dawson (2005) focusing on the best interest standard.

I am not sure that the authors are even aware that they argue in this way. They may, in fact, view these different ethical paradigms as equivalent and handy tools, not aware of the inherent internal conflict in the arguments so constructed. Indeed, many of the authors don't even acknowledge an ethical paradigm or defend certain ethical assumptions.

One possible explanation for this strange manner of justification is what can be considered putting-the-cart-before-the-horse argumentation. In reading these articles, the impression is in some instances created that the author has started off with a certain set of conclusions in mind – say, for example, that society should protect children but at the same time respect the free choices of their parents, and that a potentially good way to do this in practice is some combination of using educational interventions and state power. Having these conclusions in mind, the author would then after the fact construct arguments that would lead to these conclusions. To do so, they would scour the “ethical marketplace” and use any theory, concept, or manner of justification that seems handy or remotely relevant at different stages of argument construction. Once the conclusions are “established through moral argumentation”, we are left with the question of coercive vaccination policies, and here an author may then find it convenient to launch into a legal discussion on the limits of state authority. This may be why the conclusions presented invariably have a level of intuitive acceptability about them, while the methods employed to reach these conclusions leave one puzzled.

Another possible explanation for this smorgasbord approach is that the authors themselves think that this is the best way to proceed when constructing ethical arguments. Consider the critique of the method of contemporary bioethics by Clouser and Gert, appearing in their critical essay on principlism (Clouser and Gert 1990, p. 231).<sup>1</sup> Instruction in medical and applied ethics, they argue, proceed as follows. First, a brief summary of major ethical theories are presented, such as utilitarianism, deontology, virtue ethics and contractarianism. Then, some insurmountable problem is pointed out in each theory, showing why the theory is inadequate. These inadequacies are never corrected, and students are not presented with a better theory. Instead, students are encouraged to use whatever of these defective (and competing) theories as they see fit when the problem at hand calls for it. “Having acknowledged that all of the standard theories are inadequate, one is then told to apply them anyway, and even to apply

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<sup>1</sup> Clouser and Gert's main aim is a critique of principlism. I will consider and respond to their critique on principlism further in chapter 4. Here, I am interested in their observations regarding the practice of contemporary bioethics as a discipline. To my mind, they raise considerations that are vital for us to heed as we go forward within the field of bioethics. Their objections to principlism, however, I do not consider insurmountable as I will point out in chapter 4. Perhaps Clouser and Gert's are subconsciously conflating the approach of principlism with contemporary bioethics as a whole. Given the prominence of the principlist approach within the field of bioethics, this seems like an easy assumption to make. Be that as it may, Clouser and Gert's critiques of contemporary bioethics are salient and to the point when considering the articles I presented here regarding the ethics of MMR. In chapter 4 I shall indicate that I consider principlism robust enough to rise above the critiques of Clouser and Gert, especially when principlism moves away from seeking justification in a specific theory but rather relies on the idea of the common morality.

competing theories, without any attempt to show the theories can be reconciled” (Clouser and Gert 1990, p. 231). When examining the articles I presented, it does seem as if the authors proceed in the way that Clouser and Gert describes. This leaves the conclusions they draw hanging in the air without firm, consistent ethical justification.

Returning now to the MMR ethics articles under consideration. Whatever the reasons are for the use of the smorgasbord approach to justification, the effect of using such an approach on the arguments and conclusions is substantial. In general, the arguments offered do not provide substantive ethical justification for the conclusions and recommendations advanced. Numerous internal contradictions and unsupported assertions litters this literature. Ultimately, the conclusions reached are not firmly grounded in a consistent approach or in sound arguments, with the consequence that the conclusions cannot be considered substantively ethically justified. At best the conclusions offered in virtually every paper amounts to nothing more than the author’s intuitive conclusions as to what is ethically justified with regards to MMR vaccination, intermingled with loose and fragmented appeals to diverse and conflicting ethical concepts.

To correct this defect in the literature, the ethical questions inherent to the ethics of MMR vaccination have to be examined in a consistent and systematic way, staying within a robust and justifiable ethical framework and supporting conclusions firmly in consistent argumentation.

### **(2.2.2) The individual case of vaccination: insufficient argumentation and justification**

Almost all the authors consider the ethical aspects of the individual case of vaccination. Typically, there is a recognition of the fact that the central figure is a child that does not have the capacity to make medical decisions, and that parents direct the medical care of their children in accordance with the best interest standard. But in no paper is the best interest standard grounded in an ethical paradigm or justified through ethical argumentation. Rather, it is merely asserted that the best interest standard is the best way to proceed with decision-making, and the reader has to take this at face value. It is not clear, then, which ethical considerations ground such decision-making and what provides ethical force to conclusions reached through a best interest standard.

As an important and interesting aside, it is significant to note that the best interest standard has become a legal standard in many countries, forming an important legal paradigm used to make legal judgments where children are involved (Diekema 2011). The general idea with the legal application of the best interest standard is as follows. When faced with various options regarding the fate of a child, or when a decision should be made that substantially impacts a child, the option should be preferred that optimally promotes the welfare of the child (Diekema 2011). For example, if a court is asked to make a decision on which parent to award custody in a divorce proceeding, the court should favor the arrangement that works most towards the welfare of the child. Or, if the court is asked to make a judgment regarding the use of a specific medical treatment for a child, the court should choose among available courses of action that option that most works towards the child’s overall welfare and benefit. Courts and their delegates may interfere with or overrule parental decisions that are not in keeping with a child’s best interests (Diekema 2011), for example, courts may mandate life-saving blood transfusions for children in

spite of parental refusal of such procedures (Woolley 2005). In South Africa, the idea that the best interests of a child should be paramount in legal decisions pertaining to a child developed gradually throughout the country's history, and mostly so through legal precedents in court cases where custody and guardianship of children were at stake (Walsh 2013). Eventually, the best interest standard was written into the South African Constitution during the writing of the Constitution for a new democratic South Africa after the end of apartheid, stating that, "a child's best interests are of paramount importance in every matter concerning the child" (Walsh 2013). In 2006, the South African Children's Act was signed into law (also known as Act Number 38 of 2005). This law was meant to be a comprehensive legal framework for defining and protecting the rights of South African children (Walsh 2013). The act defined children as persons under 18 years of age, and dealt in detail with issues such as child protection, custody, parental rights, child trafficking, and adoption (Children's Act 38 of 2005; Walsh 2013). The Act declares the best interests of the child as guiding principle in all matters concerning a child, stating, "In all matters concerning the care, protection and well-being of a child the standard that the child's best interest is of paramount importance, must be applied" (Children's Act 38 of 2005, Chapter 2). The Act does not specify a definition of the best interest standard, but provides a list of factors that must be considered by courts in determining best interests. This includes the relationship between the child and parent(s), the capacity of the parent(s), the effect on the child of any change in the child's circumstances, the child's age and maturity, the child's emotional security, and the child's intellectual, cultural, social, and emotional development (Children's Act 38 of 2005, Chapter 2). The Act provides guidelines for various situations thought to be relevant in the South African context, for example prohibiting certain cultural and religious practices such as the genital mutilation of girls. Furthermore, the Act specifies parents as medical decision-makers for their children, and forbids refusal of required medical treatment purely on the basis of religious or other beliefs, unless the parent(s) can show that a medically accepted alternative treatment exists (Children's Act 38 of 2005, Chapter 7).

Getting back now to the articles I have reviewed regarding the ethics of measles vaccination and the use of the best interest standard in advancing recommendations. Authors in virtually all the articles use the best interest standard in their ethical argumentation, but never ground it in an ethical framework. Rather, it appears as if they use it partly as a legal standard and partly as a widely accepted ethical standard, without it being clear what the grounding is for the standard. This is an example of the smorgasbord approach I have previously mentioned, but it also makes another crucial mistake. It does not keep into account the difference between law and ethics. Legal argumentation and legal justification are very different from ethical argumentation and ethical justification.

When it comes to the content of the arguments surrounding the individual case of vaccination in these papers, the usual conclusion is that vaccination is thought to be in the best interests of the child, but that the parents' decisions should be respected. Most authors argue that parental decisions can be interfered with if such decisions place children at substantial harm, but often legal considerations are conflated with ethical considerations, making it unclear what the basis for this conclusion is. One author (Diekema 2005) argues from a best interest standard, but then also appeals to an ethical principle he calls the harm principle, based on the work of Mill, without it being clear what the relationship is between the harm principle and the best interest standard.

He argues in accordance with this principle that parental decisions leading to substantial harm of the child can be interfered with.

From here, authors typically proceed with an argument as follows. Parental decisions can be interfered with if such decisions would lead to substantial harm to the child. In societies where MMR vaccination rates are high, the risk to the individual child through foregoing vaccination is low, since the child is protected through herd immunity. Thus, parental refusals of MMR should not be overturned when MMR vaccination rates are high. The general idea is that the moral obligation to vaccinate the individual is weakened or set aside when population immunity is high. Some authors respond to this by pointing out the problem of free riding, and the obligations to the community. Others just leave this conclusion as it is, but then strangely don't take it into account further when they consider the question of mandatory vaccination policies. I shall discuss this specific aspect later, but when presenting arguments for or against coercive vaccination policies, some authors completely ignore the conclusions they have drawn from the best interest standard in the individual case of vaccination, and instead present a host of other considerations of which it is not always clear how it relates to the preceding argument. For example, Krantz et al. (Krantz, Sachs, & Nilstun 2004) consider the individual case of vaccination and concludes that it is in the best interests of children to be vaccinated, "probably" even when there is high population immunity. There is therefore presumably an ethical obligation on parents to have their children vaccinated. But when it comes to discussing mandatory vaccination policies, this conclusion is completely ignored; rather, it is argued that coercion is "not possible" and "not desirable" in Sweden, without it being clear what the underlying ethical justification for this assertion is. Sheather (2013) also argues from a best interest standard that vaccination is usually in the best interests of children, and that if population immunity is high that vaccination is still "prudential". But when arguing around coercive vaccination policies, suddenly we read of liberal democracies and legal considerations and limitations of liberty. Such limitations to the legal right of liberty surround the risk of harm to a child, and in the author's opinion (!) the legal case for coercive vaccination policies disappears when high levels of population immunity is reached.

Again we see the switching from one approach to the other, haphazard argumentation, and it being unclear to what extent conclusions are supported by the preceding argumentation.

The result of all these deficiencies in argumentation is that nobody actually substantively justifies the individual case of vaccination. It is merely asserted that MMR vaccination is in the best interests of children and that it is therefore ethically obligatory. Except when population immunity is higher, then the ethical obligation is said to be less clear, but this argument is also left open to individual interpretation and not precise. Other ethical issues surrounding the individual case of vaccination, such as the limits of parental authority and the ethical status of mandatory vaccinations, are often not consistently explored from a consistent ethical perspective, often times appealing to conflicting ethical paradigms or legal arguments.

What is required is a substantive consideration of the individual case of MMR vaccination, consistently grounded in a robust ethical approach. Therefore, rigorous analysis of the individual case of vaccination will be an important step in this dissertation.

### **(2.2.3) Obligations we owe to each other: assuming a communitarian justice perspective**

One of the central ethical questions emerging from the literature is the tension between individual freedom and responsibility to others. Using principlist language, this can be roughly conceived of as a tension between autonomy and justice.

Without fail, every author assumes a communitarian theory of justice when dealing with this question. Under communitarian theories, individuals have obligations to the collective, and the collective to the individual. It is not hard to see that such a theory would favor public vaccination programs. Communitarian theories also focus on the common good, and collective action that establishes public goods. Prominent within this literature is the argument around free riding, which is when individuals make use of a public good without paying their share – joining in the collective action that brings about the good. This argument is typically used to show why it is unfair or wrong for people to refuse to vaccinate their children.

The trouble is that there are other, competing, theories of justice – liberal theories such as libertarianism or Rawls' contractarian egalitarianism, utilitarian justice, and well-being justice. These are prominent theories and are influential in the contemporary discourse on justice. But nowhere are the implications of these theories for MMR vaccination considered. Instead, all the authors proceed as if communitarian justice enjoys universal appeal and as if their communitarian arguments would be persuasive to everyone.

This is a serious defect in the literature on MMR/measles vaccination. In this project I shall respond to this defect by considering the implications of various influential theories of justice with regards to the ethics of MMR vaccination in children.

### **(2.2.4) Empirical assumptions, lack of referencing, and pervasive impreciseness**

It is in the nature of the ethical questions at hand that empirical medical facts regarding measles infection and MMR vaccination are of the utmost importance in argument construction. For example, if an author wants to determine whether MMR vaccination would be in the best interests of a child, some medical data as to efficacy of the vaccine, potential harms from vaccination, and the nature of measles infection are crucial considerations. But these details are invariably lacking. Instead, most authors make fairly vague empirical assumptions and often times these are not adequately referenced.

A number of examples. None of these articles highlight to what extent the MMR vaccination is effective against measles infection, and how many doses of vaccination is needed. None of the articles deal with the concept of vaccine failure, the fact that some people just don't become immune even if they are vaccinated. Many of the articles refer to herd immunity or population immunity, but nowhere do we see a clear explanation of what this is, what rate of vaccination would provide her immunity, or references to measles eradication.

The effect of this deficiency is that empirical premises used in argumentation appear vague, imprecise and unsupported by sufficient references to empirical sources. The reader is left to make up her own mind as to what exactly herd immunity is, what the efficacy of the vaccine is,



how dangerous or frequent vaccine adverse effects are, and the like. This introduces yet another source of doubt as to how substantive and robust eventual recommendations offered by authors are.

What is needed to correct this deficiency in the literature is a thorough analysis of the empirical medical facts with regards to measles infection and MMR vaccination, and to connect these empirically grounded facts with substantive normative ethical arguments within a consistent ethical paradigm. As Dawson (2005) points out, any comprehensive study on the ethics of measles vaccination will require careful analysis and weighing of the relevant empirical information regarding disease and vaccine characteristics.

### **(2.3) Papers and work not included in the analysis above**

There are a number of papers that touch on issues within the ethics of vaccination which I have not included in my review above. Some of these are in the medical literature, and some are in the philosophical literature. These papers are not directly applicable to my work; for example, some may not examine measles vaccination at all, or some may not seek to provide ethical recommendations for policy or medical decision-making. Others are too scant on empirical data to meaningfully construct arguments applicable to MMR in particular. I briefly list some examples here.

Tim Dare (1998) considers mass vaccination policy from a philosophical perspective. His goal is two-fold: to address a shortage of vaccination work in philosophy at the time, and to analyze and justify the idea of governmental pro-vaccination policies. The first half of this essay focuses on empirical uncertainty regarding vaccines; it should be said that in the time since this article appeared, a lot of empirical work has appeared that has substantially reduced uncertainties, specifically regarding measles vaccination. The second half of his essay is an analysis of the public vaccination policies of the US and New Zealand, using a utilitarian framework. There are a number of reasons this paper does not directly speak to the ethical analysis I am embarking on. First, this paper does not focus on measles vaccination, and in fact appears to lump all vaccinations together as if they are the same. There are major differences between different vaccinations, so that it is not clear to what extent the arguments are generalizable to measles vaccination in particular. Second, this paper is very scant on empirical data regarding matters such as vaccine efficacy and adverse effects, and in fact states that it does not aim at analyzing empirical data. Third, it only focuses on selected issues within the debate, and states that its goal is more to raise these issues than to fully explore them. Fourth, the paper does not aim to provide ethical analysis and guidance for medical decision-making for the individual child, and only provides limited guidance on the policy level. An important observation is that the paper generally employs a utilitarian approach and mostly stays within this approach.

Roland Pierik examines mass vaccination policy in two articles (2016; 2014). In his more recent article (2016), he aims to provide a defense of mandatory mass vaccination policies by arguing that vaccination does not fall into the domain of free choice, but rather on a non-negotiable legal duty. In doing so, he appeals to different ethical and legal norms without declaring a clear ethical

framework, or how these ethical norms and arguments are related to one another. In the earlier article (2014) he contemplates the return of measles infection to certain areas within the Netherlands, and offer a suggestion that mandatory vaccination policies could increase vaccination uptake in these areas. In neither article does he declare or defend an ethical framework. He stipulates some duties, but doesn't ground them in a framework, so that it is not clear how these duties relate to each other. The focus of his work seems to be to draw legal conclusions, and he does not provide guidance for individual medical decision-making, and only some guidance on a public health level. These papers are also fairly low on empiric information; for example, there is almost no discussion on the potential adverse effects of vaccination, or the risks that vaccinated people assume. These papers do not quite meet the criteria I've set for inclusion above. As far as they do, it appears that these articles show similar themes (individual autonomy vs public responsibility) and similar deficiencies (use of different unrelated moral and legal approaches in an unsystematic way) to the literature I have included.

T Heller writes an article from the perspective of a general practitioner questioning the safety of the MMR vaccine with responses from D Heller and S Pattison (Heller, Heller, & Pattison 2001). This article voices T Heller's uncertainties, and asks for a deepening of the debate regarding MMR vaccination. It should be kept in mind that he writes shortly after the publication of the Wakefield article in 1998, which launched the MMR-autism scare. Many of the points raised mirror the questions vaccine hesitant parents may have – is the MMR safe? Can we trust the experts? Is vaccination not just recommended because of financial gain? This article is insightful in that it shows how such uncertainties can even affect practicing physicians. Since then, much work has appeared which directly addresses some of the uncertainties and address some of the questions in Heller's article. Indeed, in this thesis I will address the safety, efficacy, and cost of MMR vaccine. I did not include this article in the analysis above, as it does not aim to provide ethical analysis or recommendations, but rather functions to raise a physician's uncertainties and questions.

An article by Dawson in the journal *Vaccine* (2014) is an editorial aimed at introducing certain ethical questions in a medical context. It discusses that a small number of scholars are examining ethical issues in vaccination, and mentions vaccines such as influenza vaccine and zoster vaccination. This paper does not do much ethical analysis, does not consider measles vaccination, and does not provide much empirical data. Another paper by Dawson (2004) examines vaccine programs as a whole from a public health perspective. Here Dawson seeks to defend the concept of prevention over cure, providing an ethical defense of preventive programs in general. He defends vaccination programs by conceiving of herd immunity as a public good, therefore escaping the objections of unfair benefits and burdens as raised by the prevention problem. This is interesting, but one wonders if this is as relevant to illnesses such as measles where no cure exists, and prevention is essentially the only medical intervention available. Dawson's defense of vaccination programs conceives of herd immunity as a public good, much along the lines of his 2011 paper and van den Hoven's paper (2012). As I've pointed out before, this argument relies on Communitarian assumptions. Of note, this paper does not consider measles vaccination in particular, appears to lump all vaccinations together as a whole, does not aim to provide guidance in both the individual and societal contexts, and does not provide sufficient empirical review.

### **(3) The aims and scope of this project and substantive contributions to the field**

The current project has the goal of adding substantially to the discourse on the ethics of MMR vaccination in children to prevent measles infection. The goal is to provide ethical recommendations regarding vaccination with MMR that can guide individual decision-making in the medical context, as well as societal and government policy. To do so, I will structure this project in a way that will address the main deficiencies identified in the existing literature.

I shall perform a thorough analysis of the relevant medical facts surrounding measles infection and MMR vaccination. In chapter 2 I shall consider measles infection, including the epidemiology, complications, cost of measles infection to the health system, the concept of herd immunity, and measles virus characteristics of note. In chapter 3 I shall analyze measles vaccination with the focus on MMR, the most widely used vaccine to prevent measles infection. Here I shall address questions such as vaccine efficacy, vaccine cost, potential adverse effects, the autism controversy, vaccine history, vaccine opposition and refusal, and the anti-vaccine movement. I shall also present a comparison between the complications of measles and the potential adverse effects of MMR vaccination. The medical facts regarding measles and MMR vaccination will provide the necessary empirical background for the consideration of normative ethical arguments.

Next, I shall turn to the process of analyzing ethical considerations involved and advance ethical arguments. In the literature on the ethics of MMR vaccination, the following important ethical issues are addressed:

(1) Ethical considerations of the individual case of MMR vaccination. To my mind this is an appropriate ethical question, as vaccination surrounds a (usually) healthy and (usually) young child. Looking at this situation, ethical questions of justification for providing an intervention which can have adverse effects to a child who cannot provide consent arise. Although these questions are addressed in the existing literature, they have not been substantively answered due to the defects I previously identified.

(2) Individual freedom/autonomy versus responsibility to others/justice. This is a central question within MMR vaccination, and every author attempts to come to terms with this tension. However, invariably the author assumes a communitarian justice perspective. Nowhere do we find a serious analysis of the implications of other theories of justice for this question, which is strange since communitarianism does not enjoy universal appeal. Furthermore, I argued before that the way in which authors engage with the tension is highly unsystematic and unsubstantive, meaning that the tension is never satisfactorily dealt with through grounded ethical arguments that stay within a consistent ethical paradigm.

(3) Are coercive vaccination policies, using state power, ethically justified? This is another central ethical issue that virtually all the authors address. Again, it is addressed in a very unsystematic and haphazard way. Often times it is not clear how preceding arguments and stated ethical paradigms are connected with arguments offered when considering the issue of coercive

vaccination. Consequently, the recommendations offered do not appear to be substantively grounded in ethical justifications.

I shall address all three of these central ethical questions with the goal of reaching ethically justifiable and ethically grounded recommendations for vaccination practice and policy. During this process, it would be important to analyze the ethical aspects of the individual case of MMR vaccination, the implications of different theories of justice, and to bring the conclusions of these arguments to bear on vaccination policy considerations.

I aim to make recommendations that are widely applicable and widely accepted, and not restricted to a specific country, community or context. Rather than writing a set of recommendations for the 'American' context, the 'South African' context, or the 'European' context, I aim to provide analysis and recommendations that can guide ethical decision-making for a variety of communities, countries, and individuals. Therefore, when I cite different countries in the empirical or policy section, it should be seen as examples of specific disease and vaccination trends or examples of different types of policy. These considerations function as premises in an ongoing argument throughout this dissertation, aimed at providing a set of ethical recommendations that can be used to formulate policy in the just society, and guide medical decision-making for the individual child.

To engage in ethical analysis, I shall make use of the principlist paradigm of Beauchamp and Childress. Principlism has arguably become the most popular approach to resolving knotty bioethical questions, and can arguably be considered the *lingua franca* of bioethics. One of its strong points is that it relies on widely shared moral judgments; conclusions reached through the application of principlism would appeal to persons of different ethical theoretical persuasion. For example, the four principles can be at home within both a utilitarian and a Kantian paradigm. This is not to say that they are relativistic: instead, they rely on those moral convictions that persons from such competing theories share. After all, there is a large amount of agreement about which actions are morally right between Kantians, utilitarians, contractarians, and so forth. They all know that it is wrong to steal, murder, torture innocents, and the like. The strength of the principlist approach is that the four principles appeal to adherents of the different theories in the same way these shared moral judgments do. Thus, in using the principlist paradigm I expect to reach conclusions that will enjoy wide appeal to persons all over the spectrum of ethical theory. If I were to ground arguments in a specific classical theory – say, for example, utilitarianism – the conclusions reached would only be persuasive to those who share the theoretical background. Using the principlist paradigm has the advantage of providing normative ethical justifications that would appeal to all people who see the sense of our shared moral judgments.

More importantly, the principlist paradigm is ideally situated to engage with the three central ethical questions identified in the MMR vaccination ethics literature. All four of the principles are engaged – autonomy speaks to the issue of respecting individual freedom and the individual case of MMR vaccination; beneficence and non-maleficence are relevant to the individual case; justice is relevant to the tension between individual freedom and what people owe each other. The four principles show themselves to be excellent starting points for the consideration of the main ethical questions at hand. The method of principlism requires application of the four principles

to the issue at hand, and then through a process of specifying to arrive at specified action guides. Through a process of balancing one then brings these action guides into equilibrium with one another, so that it is clear what the actual moral obligations in the given scenario is. Thus, the principlist paradigm offers the tools and methods necessary to bring all three central ethical questions in MMR vaccination into balance with one another, leading to clarity on ethical conclusions and obligations.

I shall therefore proceed as follows. In chapter 4 I shall examine the principlist paradigm, its method, some objections against it, and eventually endorse it as the paradigm of choice for the task at hand.

In chapter 5 I shall analyze the individual case of vaccination, bringing the principles of autonomy, beneficence and non-maleficence to bear on the empirical facts. I shall ground a best interests approach firmly in these principles, and indicate how parental choices guided by best interests meet the requirements of these three principles. I shall also consider and defeat the argument that in a highly vaccinated society a child's best interests may be to forego MMR vaccination. In conclusion I shall offer two ethical action guides, two principles derived from the analysis of the individual case of vaccination.

In chapter 6 I shall consider MMR vaccination from the perspective of five different theories of justice. I shall demonstrate how each theory of justice leads us to adopt two ethical action guides, delineating the ethical obligations of the just society. The goal of this chapter will not be to provide a comprehensive analysis of a specific theory of justice, such as libertarianism or Rawls' egalitarian contractarianism. Instead, I will briefly introduce the main points of each theory of justice to the extent that is necessary to engage in meaningful ethical argumentation around MMR vaccination. The aim of this chapter is to show how each different theory of justice supports the same two ethical action guides. In terms of the overall principlist framework, the principle of justice would then endorse these two action guides derived from the different, competing theories of justice.

In chapter 7, the concluding chapter, I shall point out that the two action guides from chapter 5 are similar to the two action guides from chapter 6. Therefore, we are able to bring all four principles into balance by stating two ethical action guides. These action guides are:

(1) All children eligible for measles vaccination should be vaccinated against measles, at least to the point of sustained measles elimination.

(2) Respect for parental decision-making and the parent-child relationship guide the response to parental vaccine refusals.

These two action guides of principles can be used to derive ethical obligations and to regulate policy. In chapter 7 I shall engage in this process, and offer recommendations as to ethically justifiable MMR vaccination policies.

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## Chapter 2: Scientific review of measles disease and epidemiology

In this chapter the scientific data regarding measles disease will be reviewed and discussed. Measles illness, complications and transmission will be considered as well as the historical and present-day epidemiology of measles. As important examples of the impact and spread of measles and the feasibility for eradication, the epidemiology of measles within the United States, Canada, South Africa and selected European countries will be examined. At the end of the chapter the most important aspects of measles as pertains to the ethics of measles vaccination will be summarized.

### (1) Measles disease

#### (1.1) Virus and infection basics

Measles is a serious infectious disease caused by Measles Virus (MV) (Buchanan & Bonthius 2012; CDC 2013a; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). MV is highly contagious (Buchanan & Bonthius 2012; CDC 2013a; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). It has been called “the most communicable of childhood exanthems” and “one of the most communicable of all human diseases” (Buchanan & Bonthius 2012). It is almost certain that a non-immune individual will contract measles disease if exposed to MV (CDC 2013a). Outbreaks of measles can occur within a population even if fewer than 10% of people in the population are non-immune to the disease (Moss & Griffin 2012).

Measles does not cause prolonged or latent infections, and there are no human carriers without clinical disease. There are also no animal carriers or non-human reservoirs for MV; rather, MV spread is maintained through acute infections and interlinked measles outbreaks (Moss & Griffin 2012). Those individuals who successfully fight off measles infection through their immune system gain life-long immunity to measles and cannot become infected again if they remain immune-competent (CDC 2013a; De Vries et al. 2012; Moss & Griffin 2012).

Central to the concept of acquired immunity against MV is the humoral immune response, where antibodies against MV are created and memory cells are formed. These memory cells provide life-long immunity (Buchanan & Bonthius 2012; De Vries et al. 2012; Moss & Griffin 2012). The cellular immune response also plays an important role in combating acute measles infection, but the gaining of life-long immunity is a function of activation of the humoral immune system (Buchanan & Bonthius 2012; De Vries et al. 2012; Moss & Griffin 2012). A way in which immunity against MV can be acquired without measles disease is measles vaccination (Buchanan

& Bonthius 2012; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). Measles vaccination will be reviewed fully in chapter 3.

Infants born to immune mothers are typically protected against measles infection by acquiring maternal antibodies. When this passively acquired immunity disappears, infants become susceptible to infection with MV and consequently measles disease (Leuridan et al. 2010; Moss & Griffin 2012). The maternal antibodies are transferred to the fetus through the placenta, and the duration of protection of the infant after birth is determined by the amount of maternal antibodies, gestational age (preterm birth leads to lower antibody transfer) and rate of decay of antibodies received from the mother (Leuridan et al. 2010). A prospective study compared the duration of maternal antibody protection between two groups of infants (Leuridan et al. 2010). One group of infants was born to vaccinated mothers (n=87), and another group of infants was born to mothers who had acquired measles immunity through natural infection (n=120). Measles antibodies (IgG) were measured using an ELISA test in mothers (36 weeks/birth) and infants (1 month/3 months/6 or 9 months), and the amount of antibody present for the two groups were compared. They found a good correlation between amount of maternal antibody and amount of fetal antibody. Vaccinated women had lower antibody counts than naturally immune women. It also seemed that maternal protection waned quicker in the vaccinated group: the median time to loss of maternal protection was 0.97 months for the vaccine group and 3.78 for the natural immunity group. By six months, 99% of the vaccine group infants had lost all maternal immunity and 95% of the natural immunity group had lost maternal immunity. It would therefore appear that maternal immunity is lost fairly rapidly, and more so in infants born to vaccinated mothers. This study is not without limitations; one of which is that it is not clear how it was ensured that the two comparison groups were similar or how potential confounders were removed. However, this study does provide some important evidence. One is that infants are susceptible to measles disease fairly early on (median 2.61 months for all infants in this study.) The other is that infants born to vaccinated mothers have a much shorter duration of maternal protection than those born to mothers who had acquired passive immunity, a finding which reflects similar ideas from previous studies as cited by the authors.

MV is considered a respiratory virus, and is usually spread from one person to the next through respiratory droplets produced by coughing or sneezing (Buchanan & Bonthius 2012; CDC 2013a; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). Less often it can be spread by small particles aerosols that can float in the air for some periods of time (Moss & Griffin 2012). It is estimated that MV can remain contagious in such particles for up to 2 hours (CDC 2009). The CDC (2009) states that it is highly probable that non-immune persons will become infected when they come in close proximity to someone who is infected, to the degree that about 90% of non-immune people who come close to an infected person will get measles. Persons infected with measles become contagious a number of days before the onset of the rash, when coughing and sneezing is prominent, until a few days after the onset of the rash (Moss & Griffin 2012). For people with normal immune systems, the 4 days before the onset of the rash and the 4 days after the onset of the rash is the time of highest infectivity, where the virus is optimally spread

(Buchanan & Bonthius 2012). In those persons with immune compromise, virus shedding can happen for long periods after the rash has come on, however it is not clear to what degree the infectious period is affected by this (Buchanan & Bonthius 2012; Moss & Griffin 2012).

It is generally thought that once MV enters the respiratory system through infected droplets the virus invades the respiratory epithelial cells, and after replicating in these cells it spreads to the local lymphatic tissue (De Vries et al. 2012; Moss & Griffin 2012). After replicating in the lymphatic tissue, it invades the bloodstream to cause a measles viremia. Through the blood stream the virus then spreads to various tissues, such as the lymph nodes, kidneys, liver, and GI tract. In these organs it invades epithelial cells as well as immune cells and replicates. Another model has been suggested based on studies in monkeys, whereby it is thought that MV initially infects lymphocytes and monocytes, and where viral replication occurs mainly in lymphoid organs and tissues (De Vries et al. 2012; Moss & Griffin 2012).

The response of the immune system to MV is substantial and aggressive, including activation of both cellular immunity and humoral immunity (Buchanan & Bonthius 2012; De Vries et al. 2012; Moss & Griffin 2012). It is the immune response that is mainly responsible for the development of the symptoms that are associated with measles. During the aggressive and forceful immune response to MV, the reaction of the immune system to other pathogens are suppressed, leading to a period of general immune-suppression during and following measles infection. This may last a few weeks up to a number of months after measles infection. The measles-infected person is therefore susceptible to secondary infections by other bacteria and viruses, which contributes greatly to the complications and impact of measles (Buchanan & Bonthius 2012; De Vries et al. 2012; Moss & Griffin 2012).

MV is a member of the family of Paramyxoviruses, of the genus Morbillivirus (Buchanan & Bonthius 2012; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). It is a single-strand RNA virus. MV has two membrane proteins that are of importance within its pathogenesis: a haemagglutinin protein (H-protein) and a fusion protein (F-protein). These proteins facilitate infiltration of host cells by the virus. The H-protein allows binding of virus to host cell by binding to cell receptors and the F-protein allows the membrane of the virus to merge with the membrane of the host cell (Buchanan & Bonthius 2012; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). Viruses with an RNA genome mutate at a high rate, and this usually makes it a challenge to develop an anti-viral agent (Moss & Griffin 2012). However, the membrane proteins of the measles virus remain fairly stable, and this allows immune memory which confers life-long immunity to those who fight off the disease or receive the vaccine. It is specifically thought that the H-protein is important in terms of immune memory; it is relatively stable over time with little antigenic change, and it provokes a strong response from the immune system. Not only is this important when it comes to naturally acquired immunity, but it also provides for the feasibility of preventing measles infection through vaccination (Moss & Griffin 2012).

## (1.2) Clinical disease and diagnosis

After infection with MV, there is an incubation period of 10-12 days before symptoms appear. During the incubation period there are no symptoms (Buchanan & Bonthius 2012; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). From the time of infection there is an average of 10 days until fever appears, and 14 days until the rash appears (De Vries et al. 2012; Moss & Griffin 2012).

The first stage of the illness is a prodromal phase, during which the following occur (Buchanan & Bonthius 2012; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012):

- Fever
- Coryza (“cold” symptoms: stuffy, runny nose and coughing, sneezing)
- Conjunctivitis (red, watery eyes)
- Koplik spots (small white spots on the buccal mucosa, inside of the mouth)

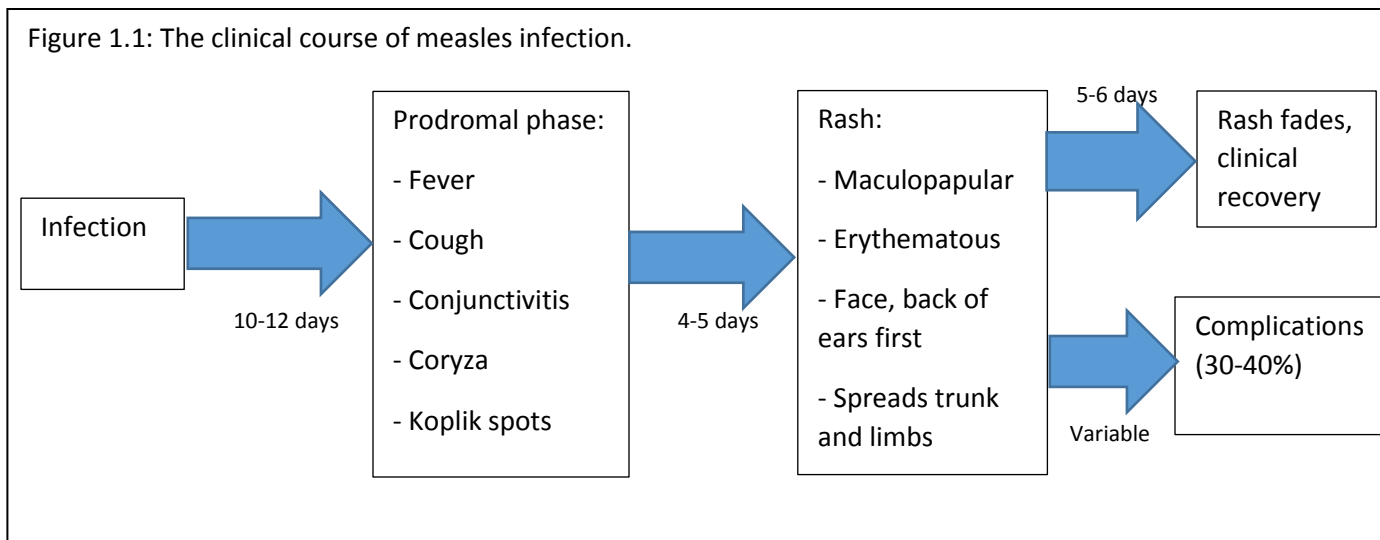
(Koplik spots are not always present, but if they are present they are pathognomonic.)

Typically, the prodromal phase lasts about 4-5 days before the onset of the rash. During the prodromal phase, MV is shed in respiratory secretions during coughing and sneezing and the illness is therefore most communicable before the rash appears.

The rash is erythematous and maculopapular in appearance. It usually starts on the face and behind the ears, after which it spreads to the trunk and limbs (Dardis 2012; Moss & Griffin 2012). The duration of the rash can be variable, but seems to be about 5 days. One source reports that the rash is present 3-5 days (Moss & Griffin 2012), while another reports it as present for 5-6 days (Dardis 2012). Recovery begins soon after the rash appears and a full recovery is made unless complications set in (Moss & Griffin 2012). The rash gradually fades away (Dardis 2012).

The diagnosis of measles is usually based on the typical clinical presentation and can be confirmed with laboratory testing (Dardis 2012; Moss & Griffin 2012). The WHO case definition for clinical diagnosis of measles is fever with a maculopapular rash and cough, coryza or conjunctivitis (Moss & Griffin 2012). Additionally, the presence of Koplik spots are helpful for clinical diagnosis as they are pathognomonic for measles (Buchanan & Bonthius 2012; De Vries et al. 2012; Moss & Griffin 2012).

Laboratory testing to confirm measles infection includes serology, culture and PCR (Moss & Griffin 2012). Serology is the most often used method, and usually means testing serum for the presence of anti-MV IgM and IgG antibodies. A test is considered positive if anti-MV IgM is present, or if there is a four-fold increase in MV-IgG antibodies when comparing acute phase vs convalescent phase titres. Culture can be performed using nasopharyngeal or conjunctival swabs, blood, urine or respiratory secretions. A test is positive if measles can be isolated from cell



culture using these clinical samples. Some laboratories also have the ability to perform PCR and detect MV RNA within clinical samples (Moss & Griffin 2012).

If it is decided that laboratory confirmation of measles is to be done, it is important to take infective precautions to prevent transmission of virus during the process of obtaining samples (Moss & Griffin 2012). For example, in Alberta the Medical Officer of Health recommends that naso-pharyngeal swabs be taken at the physician's office, that these patients be isolated from other patients (in a negative pressure room if available) and that the room these patients were seen/swabbed in not be used for at least 2 hours after departure of the patient. The MHO further advises that if a patient is sent to a laboratory for blood/urine testing, the laboratory should be contacted before the patient arrives to ensure infective precautions are in place (Medical Officer of Health, Alberta 2014).

### (1.3) Complications of measles

Measles has a high rate of complications, with between 30-40% of persons infected with measles developing complications. One review reports a complication rate of 40% (Moss & Griffin 2012), while the CDC reports a complication rate of 30% (CDC 2013b; Dardis 2012). Complications are worse in the very young and the very old, and those who are malnourished (Moss & Griffin 2012).

Respiratory complications are frequent with measles infections (Moss & Griffin 2012). A serious respiratory complication of measles is pneumonia; the CDC estimates that up to 1 out of 20 children with measles will develop pneumonia (CDC 2013b). Pneumonia is the leading cause of measles-related death (Buchanan & Bonthius 2012; CDC 2013b; Moss & Griffin 2012). Other respiratory complications are croup and otitis media (middle ear infection) (Moss & Griffin 2012). Otitis media occurs in about 1 out of 10 cases of measles and can lead to permanent hearing loss (CDC 2013b).

Gastro-Intestinal complications of measles include stomatitis (mouth inflammation with ulcers of the mouth) and diarrhoea (Moss & Griffin 2012). These contribute to inadequate nutrition, which can worsen or cause malnutrition, which in turn can worsen the complications of measles (Moss & Griffin 2012). Diarrhoea is thought to be present in about 8% of measles cases (CDC 2013b).

Eye infections can set in as a complication of measles, most significantly keratoconjunctivitis (Moss & Griffin 2012). The risk for this type of complication is higher in those who have vitamin A deficiency. Blindness is a possible result, particularly in children who lack vitamin A.

For pregnant women, measles infection can lead to premature delivery or miscarriage (White et al. 2012). Additionally, MV can be transferred from mother to fetus if a susceptible mother is exposed to MV just prior to delivery, which could result in serious measles infection in the baby after delivery (White et al. 2012).

Central Nervous System (CNS) complications of measles can be devastating (Buchanan & Bonthius 2012). Measles virus can infect the brain directly and cause measles encephalitis. Primary Measles Encephalitis (PME) can happen in 1-3 of 1000 measles cases, and has a poor prognosis (Buchanan & Bonthius 2012). Ten to fifteen percent of persons with measles encephalitis will not survive, and 25% will have neurologic damage leading to outcomes such as seizures or mental retardation. Encephalitis usually starts within 7 days of the prodromal phase of measles infection, and clinically features a variety of neurological abnormalities. Another inflammatory complication of measles is Acute Post infectious Encephalomyelitis (APME) (Buchanan & Bonthius 2012). APME is an inflammatory condition of the brain caused by the immune response to measles, which leads to demyelination. It occurs in about 1 in a 1000 children who has measles. APME generally has better outcomes than PME, but some who have APME are left with various forms of permanent neurological damage. Another very rare CNS complication of measles Subacute Sclerosing Panencephalitis (SSPE) (Buchanan & Bonthius 2012; CDC 2013b). SSPE is a progressive, chronic, degenerative brain disease following measles infection. It occurs in 4 to 11 of 100,000 cases of measles infection. Symptoms include personality change, mental deterioration, muscle spasms and eventually motor dysfunction. SSPE is fatal, and average survival is 1-2 years (Buchanan & Bonthius 2012; CDC 2013b).

Measles can lead to death. The highest death rate is in infants and young children (Moss & Griffin 2012). The CDC (2013b) estimate the mortality rate from measles infection in children to be 1-2 out of a 1000.

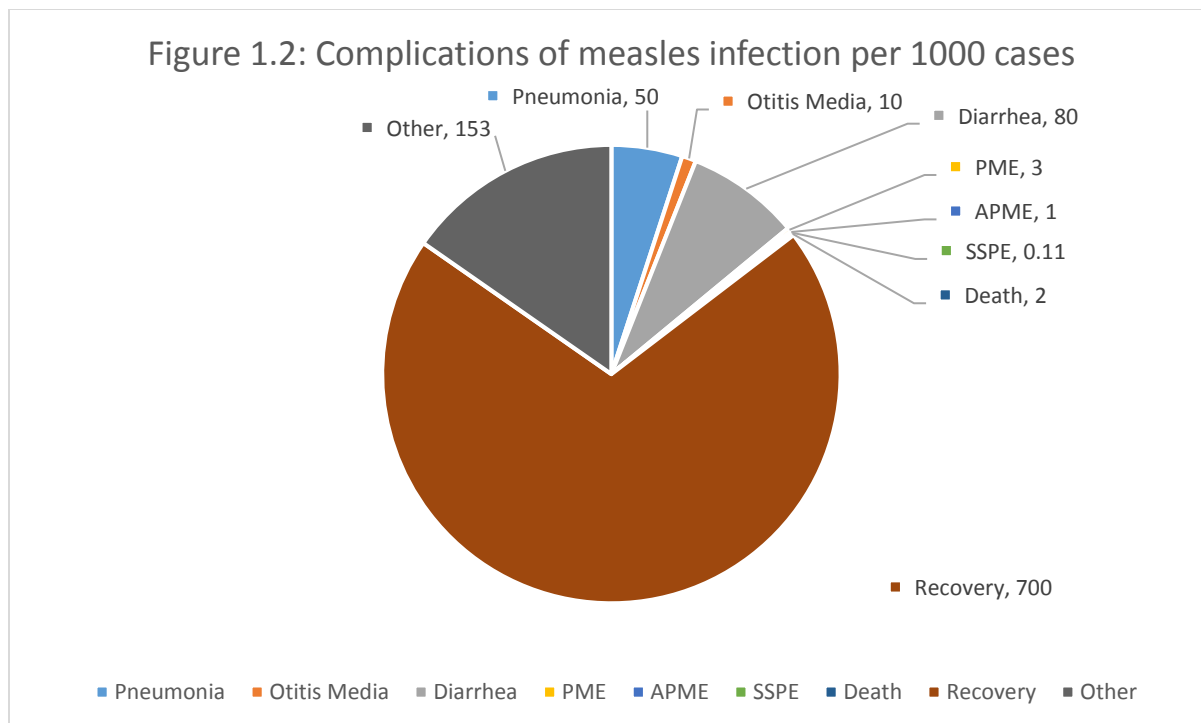


Figure 1.2 is a graphic representation of the outcomes of measles infection, using estimates out of a 1000 cases of measles infection. In this graph, it is accepted that 30% of measles cases will have some complication, and that 70% will therefore recover with no complication.

#### (1.4) Treatment of measles

There is no effective anti-viral therapy for measles infection. However, there is some evidence that vitamin A administration may limit mortality and morbidity associated with measles infection in some patient groups. A Cochrane review analyzed studies in which vitamin A was compared with placebo for the treatment of measles infection (Yang, Mao, & Wan 2005). Pooled analysis of study data showed no significant benefit to overall mortality associated with measles, and no reduction in mortality with a single dose of Vitamin A (RR 0.70; 95% CI 0.42-1.15). However, two doses of vitamin A at 200,000 International Units seemed to lower the mortality in children below 2 years of age (RR 0.21; 95% CI 0.07-0.66). Also, two doses of Vitamin A also decreased incidence of croup (RR 0.53; 95% CI 0.29-0.89), but not pneumonia (RR 0.92; 95% CI 0.69-1.22) or diarrhoea (RR 0.8; 95% CI 0.27-2.34). It therefore seems that vitamin A may have some benefit in reducing some of the complications of measles, particularly in young children. Moreover, two doses of vitamin A is not associated with significant adverse effects. The level of evidence with regards to preventing complications is moderate, and the study authors state that they would recommend further study in this area. Therefore it is not clear what the role of Vitamin A is in preventing complications in general, but it does seem clear that overall deaths



and pneumonia-related deaths are decreased in children under two years when two large doses of Vitamin A is administered.

Another review advances the use of Vitamin A as treatment as per the WHO recommendation (Moss & Griffin 2012). This recommendation is that vitamin A should be administered for two doses of 200 000 IU on consecutive days for children over 12 months who have acute measles infection. For children 6-12 months of age, the recommendation is for two doses of 100 000 IU vitamin A, and for children under 6 months two doses of 50 000 IU. In children where vitamin A deficiency is diagnosed, a third dose of vitamin A is recommended 2 to 4 weeks after the initial two doses.

As stated before, measles complications are more severe in children who are malnourished and blindness/keratoconjunctivitis specifically is more common in children with vitamin A deficiency.

Other treatments have been tried for measles infection and specifically for serious complications such as PME, including ribavirin and interferon alpha, but this is not standard practice and it is not clear how effective they are (Moss & Griffin 2012). Ribavirin does seem to have activity against measles virus in experimental, laboratory-type studies but there are no clinical studies on management of PME with ribavirin (Buchanan & Bonthius 2012). Ribavirin is not licensed in the US for the management of measles (Buchanan & Bonthius 2012).

Of course, secondary bacterial and viral infections contribute to measles mortality and morbidity and as such secondary infections should be looked for and managed appropriately (Moss & Griffin 2012). Examples of this includes managing bacterial pneumonia with appropriate antibiotics, and managing diarrhoea with appropriate rehydration and supportive care.

### (1.5) Epidemiology of measles – a snapshot of the impact of measles

Country	2013	2012	2011	2010	2009	2008	2007	2006	2005
	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%	Cases Vacc%
USA	187 91	55 92	222 92	63 92	71 90	140 92	43 92	55 92	66 92
Canada	82 95	10 98	759 98	99 97	14 96	62 95	101 94	13 94	6 94
UK	1919 95	2092 93	1112 90	443 89	1212 86	1445 86	1022 86	764 85	79 82
Netherlands	2653 96	10 96	51 96	15 96	15 96	109 96	10 96	1 95	4 96
South Africa	25 66	32 79	92 78	12499 74	5857 78	39 64	31 62	81 64	615 63

Table 1.1: Measles cases and vaccine coverage percentage among 1 year olds for selected countries, 2005-2013. Compiled using WHO data (WHO 2014a; WHO 2014b).

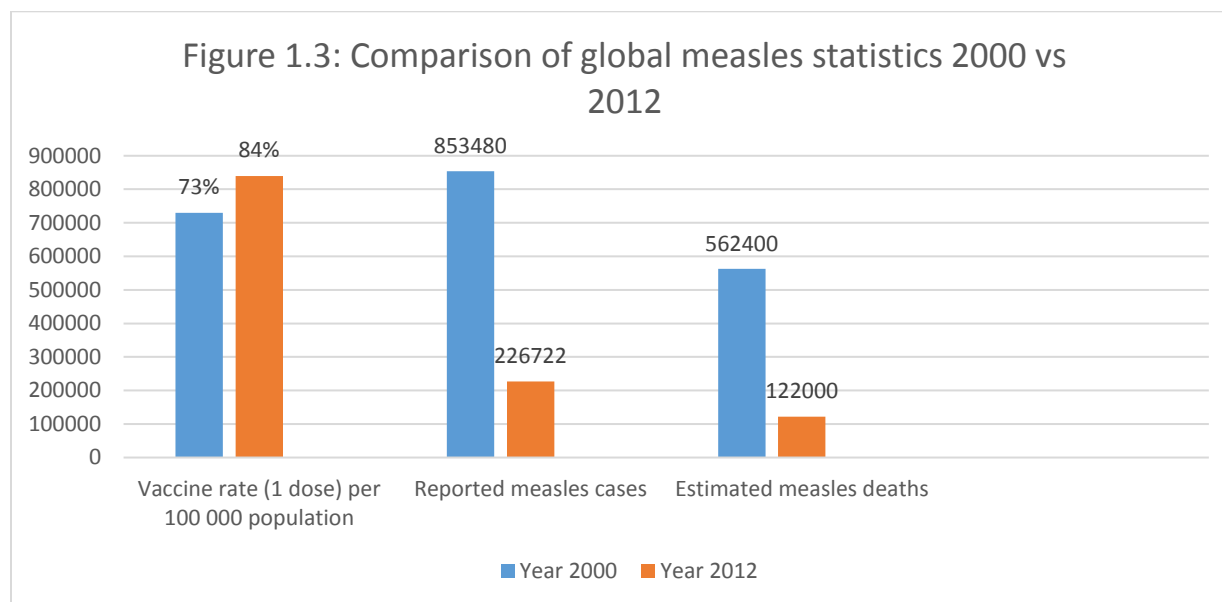


Figure 1.3 compares global vaccine rate and global measles disease burden for the years 2000 and 2012. Compiled using WHO data (CDC 2014a).

The different countries cited here are examples of different vaccination patterns and how these affect epidemiology. These considerations are important in informing eventual ethical argumentation. I also include a section showing the global burden of measles, demonstrating the need for ongoing expansion of global vaccination uptake. Table 1.1 and Figure 1.3 on the previous page provides a summary of measles cases and vaccination rates from 2005 to 2013 for these example countries as well as global measles burden and vaccination coverage comparing the year 2000 to 2012.

## USA

Measles statistics is well studied and well documented in the United States; measles is a notifiable disease by law (Fiebelkorn et al. 2010; Gastañaduy et al. 2014), and the CDC publishes regular updates on measles data in the Mortality and Morbidity Weekly Report (Gastañaduy et al. 2014). Additionally, the WHO records data on US measles rates, including vaccination rates and case incidence (WHO 2014a; WHO 2014b).

Prior to the introduction of the vaccine in 1963, almost everyone acquired measles infection in the US (Orenstein, Papania, & Wharton 2004). More than 90% of people in the US were infected with measles by their 15<sup>th</sup> birthday. Between 1912 and 1916 there was an average of 5 300 measles deaths per year. In the 1950s measles deaths were decreasing because of the general improvement in public health, including better nutrition and general health care. Yet, from 1956 to 1960 there was an average of 542 000 cases reported every year. It is thought that there were more cases than these, and that there was a degree of under reporting. In this time period, there were an average of 450 measles deaths per year (about 1 per 1000), 150 000 cases of measles related respiratory complications per year, 4 000 cases of measles encephalitis each year and an average of 48 000 measles related hospitalizations each year (Orenstein, Papania, & Wharton 2004).

Measles vaccine was licensed in the US in 1963 (Orenstein 2006). In 1966 a project was undertaken to attempt elimination of measles in the US. This effort focused on ensuring vaccination of infants and those who were unvaccinated when first entering school, as well as measles surveillance and epidemic control measures. These steps had a significant impact on measles in the US. In 1968 the number of cases reported was 22 000. This represents a decrease in measles incidence of over 90%. Measles eradication was not achieved by this effort; it is estimated that a population immunity level of 72% was achieved during this time, which was inadequate for measles eradication (Orenstein 2006).

In 1970 and 1971 an important outbreak occurred in a city that straddles the border between Arkansas and Texas (Orenstein 2006). The state of Arkansas had school entry measles vaccine requirements, and there was consequently very few measles cases on the Arkansas side of the city. Texas had no measles vaccine school entry requirements, and a large number of cases was reported on the Texas side of the city during this outbreak, and thus this outbreak demonstrated the effectiveness of school entry vaccine requirements. Another important outbreak happened

in 1977 in Los Angeles. It was during this outbreak, where large numbers of measles cases were reported, that a “no shots no school” policy was first implemented, paving the way for such type of policies in the future (Orenstein 2006).

Another major return of measles happened in the period between 1989 and 1991, thought to be due to two reasons (Orenstein, Papania, & Wharton 2004). One reason was the use of only one dose of measles vaccine. It was discovered that a percentage of persons do not develop immunity to just one dose of vaccine, and presently a two dose vaccine policy is advocated. A second reason was insufficient vaccine coverage among children prior to school entry in this time period. This 89-91 resurgence of measles brought with it 55 000 cases, 123 measles deaths and about 11 000 measles related hospitalizations (Orenstein, Papania, & Wharton 2004).

In 1993 a concerted effort was once more undertaken to achieve elimination of measles in the US (Orenstein, Papania, & Wharton 2004). This included ensuring very high rates of vaccine coverage in children under two years of age, using two doses of vaccine rather than one dose, implementing state requirements for ensuring measles vaccine coverage among school attendees, and tracking measles virus closely using molecular epidemiology (Orenstein, Papania, & Wharton 2004). The central goal for the vaccine program undertaken at this time period, called the Childhood Immunization Initiative, was to ensure coverage rates of at least 90% for children before school entry (Orenstein 2006).

These efforts to eradicate measles in the US through vaccination have proven successful. High rates of vaccination have been achieved in the US since these efforts have been undertaken, typically over 90% coverage (Gastañaduy et al. 2014; Orenstein 2006).

Measles was declared eliminated in the US in the year 2000 (Fiebelkorn et al. 2010; Orenstein, Papania, & Wharton 2004; Gastañaduy et al. 2014). This means there is no longer transmission of endemic measles virus year round in the US. Even though measles is no longer endemic in the US, cases are imported from outside the US so that measles outbreaks occur every year. These outbreaks are highly associated with persons who have not been vaccinated (Fiebelkorn et al. 2010; Gastañaduy et al. 2014). For example, in the period 1 Jan 2014 to 23 May 2014, a total number of 288 measles cases were reported in the US. This is the highest number of measles cases reported for the same period of time since 1994, and these outbreaks seem to be related to vaccine refusal (Gastañaduy et al. 2014). Of these 288 cases, 200 (69%) were unvaccinated and 58 (20%) had unknown vaccination status (Gastañaduy et al. 2014). Of those who were unvaccinated in these outbreaks, 85% were unvaccinated because of some objection against vaccination. Only 6% were missed opportunities for vaccine administration, and 5% were ineligible for vaccination because they were too young to receive the vaccine (Gastañaduy et al. 2014).

In the US the pattern is that of imported measles cases causing outbreaks in susceptible groups of persons. Although the vaccination rate in the general population is high, there are some local populations and communities where vaccination rates are lower. Those who refuse vaccinations

seem to be geographically clustered, creating pockets of susceptibility to measles outbreaks within the general population. Presently, the majority of measles outbreaks in the US are associated with persons who refuse vaccination because of an objection against vaccines (Fiebelkorn et al. 2010).

## Canada

Similarly to the US, measles was very common and caused substantial disease burden prior to introduction of vaccination in 1963 (King et al. 2004). Since 1924 measles is a notifiable disease in Canada except for the period between 1958 and 1969, so that there is good historical data on the disease burden of measles in Canada with the exception of the years between 1958 and 1969. Prior to vaccine introduction, measles occurred in epidemic cycles and reported cases varied from 10 000 to above 83 000 per year (King et al. 2004).

In 1992, the goal was set to eliminate measles in Canada by 2005 (King et al. 2004). In 1996-1997 a two-dose measles vaccine strategy was adopted and increased surveillance of measles was started. The last case of endemic measles in Canada was diagnosed in 1997, and measles is considered to be eliminated in Canada since 1998. This means that there is no more endemic transmission of measles, and that measles cases that occur are imported from elsewhere (King et al. 2004; Public Health Agency of Canada 2014a).

Even though Canada has maintained a general vaccination rate of over 90% (WHO 2014b), outbreaks still occur among the non-immune sections of the population. Such an outbreak occurred in Quebec in 2007, involving a total of 94 people (Dallaire et al. 2009). This outbreak affected various different clusters of unvaccinated individuals. It started with a one man importing measles to Quebec after travel; from him it spread to three people, and from one of these 3 people to 9 people. One of these 9 people attended an alternative type school with very low vaccination rates (47%), where 31 cases were confirmed. It is thought that the 31 is an underestimation, as many people in this school were skeptical of medical care and likely did not seek out medical attention. From this school it spread to other networks. In all, this outbreak had between 12 and 17 generations of transmission, and it was not clear exactly how each of these were linked. Of the 94 cases involved in this outbreak, 68 were unvaccinated (72%) and 11 had received only one dose of measles vaccine (12%). The main reason for non-vaccination was objection against vaccination (Dallaire et al. 2009).

There are pockets of susceptible communities within the general population, vulnerable to spread of measles from imported cases despite high levels of vaccination in the general population (Dallaire et al. 2009; King et al. 2004; Public Health Agency of Canada 2014a). Such pockets particularly exist in communities of objectors, typically communities that are tightly knit, such as certain religious communities (Dallaire et al. 2009; King et al. 2004). The Quebec outbreak shows that such outbreaks within these susceptible pockets can be sustained through various networks and can affect numerous susceptible persons. In 2011, for example, Canada had 759 reported cases of measles (WHO 2014a) – a substantial number for a country with no endemic

transmission. This high number of cases occurred despite a very high rate of vaccination in the general population (WHO 2014b), and shows how vulnerable pockets of unvaccinated individuals are to measles disease from imported sources. It also demonstrates that measles can easily come back and become endemic once more within a country; Canada would certainly be vulnerable to the re-emergence of endemic measles if the traditionally high vaccination rates are not sustained.

## South Africa

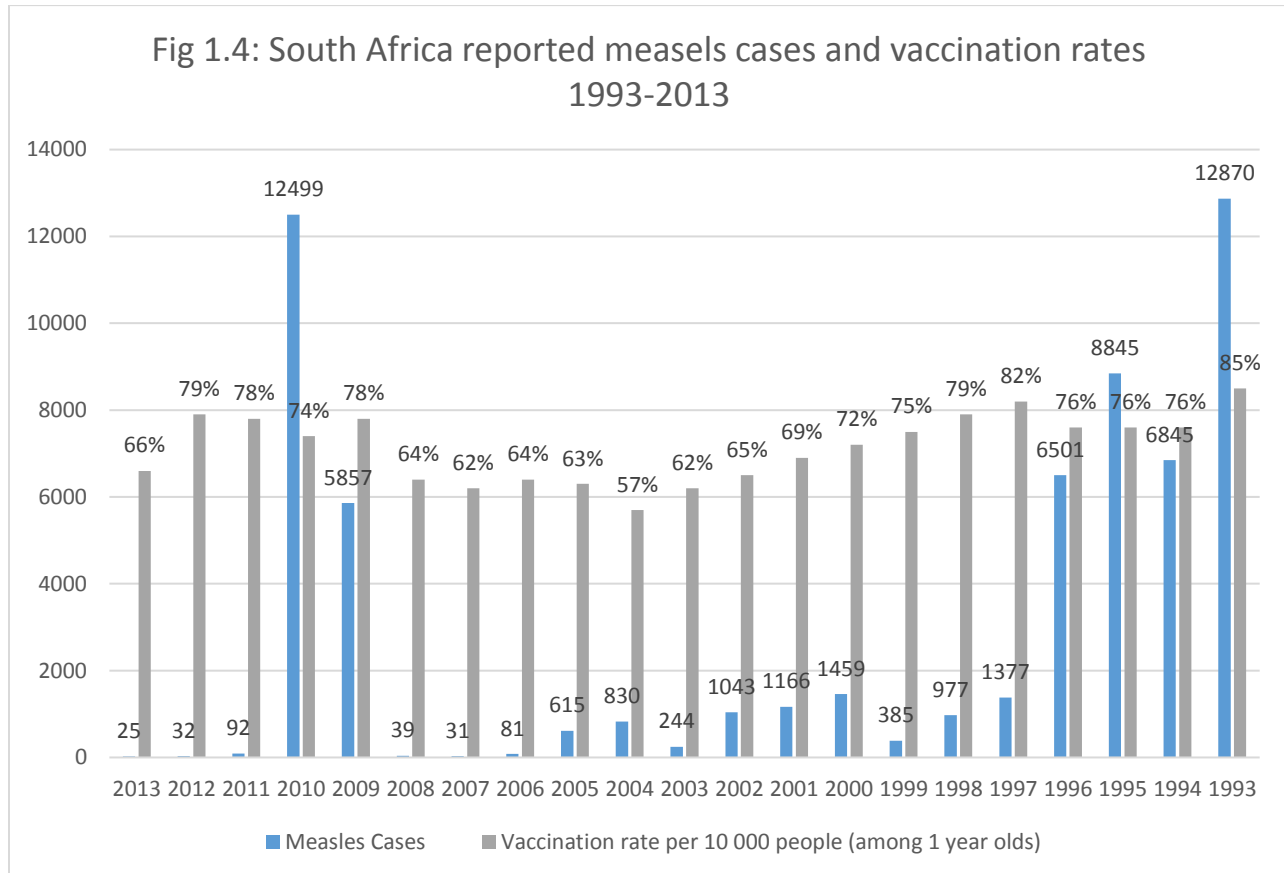
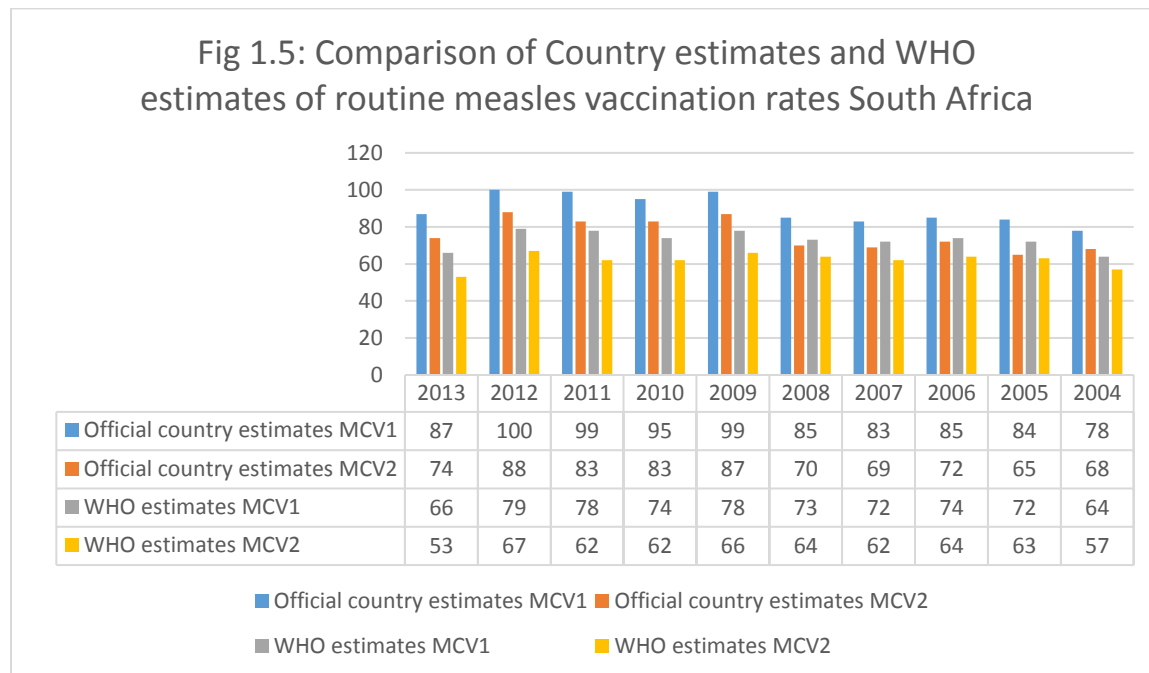


Figure 1.4 was compiled using WHO data on measles cases and measles vaccination rates in 1 year olds (WHO 2014a; WHO 2014b). A number of important conclusions can be drawn from this data. Measles is not eliminated in South Africa, and is still spread by endemic transmission. Over the past 20 years the vaccination rate in 1 year olds has never been above 90%, and the best year was 85% in 1993. Further perusal of the WHO data shows that there were over 22 000 cases in 1992, which counts as a massive epidemic. Measles epidemics occur in South Africa and in between the epidemics there can be numerous years where fairly low numbers of measles cases are reported. There were major epidemics in the years 1992-1996, and then smaller epidemics 2000-2005. In 2005-2008 the number of measles cases was quite low, with a major epidemic following in the years 2009-2010. In the years with lower case burden it appears as if the vaccination rate drops, and then it appears to pick up after the surfacing of a major epidemic. Of

concern is that vaccination rates have dropped again in 2013, after increasing in the wake of the epidemic in 2009-2010.

In 1996, South Africa together with six other Southern African countries who had relatively high vaccine rates (about 80%) adopted a strategy to decrease measles cases and measles deaths (Shibeshi et al. 2014). This strategy included WHO recommended measures such as a high rate of first dose measles vaccination at age nine months through routine health services (MCV1), catch-up supplemental immunization activities (SIA) and improved measles surveillance and management. In 2010 the WHO added some measures to their recommendation, which was also adopted by South Africa: adding a second dose of measles vaccine at 18 months, and ensuring 95% or greater vaccine rates every year for both doses of measles vaccine. Thus, the stated present measles vaccination approach in South Africa comprises routine immunization with the first dose at 9 months (MCV1) and the second dose at 18 months (MCV2), and then supplementary immunization activities (SIA) - specific outreach activities aimed at targeted population groups which aim to supply vaccinated to persons who did not receive the routine vaccinations (Shibeshi et al. 2014).

There are some differences between the WHO estimates of measles vaccination rates and the official South African estimates of vaccination rates. The estimates coming from official sources in South Africa report higher coverage of measles vaccination; the WHO estimates are generally lower. Figure 1.5 is compiled from WHO data (WHO 2014c) and shows the differences between the WHO estimates and official country estimates of MCV1 and MCV2. The reason for the discrepancy between these two data sets seems to be related to inadequate official reporting from some districts within South Africa.



Which of these two data sets is more accurate is not clear, yet they both show a similar picture: vaccination rates are generally below 90%. Rates increased dramatically, presumably because of SIAs, in the aftermath of measles epidemics. As previously stated, outbreaks of measles occur readily in populations where more than 10% is susceptible to measles infection, as is the case in South Africa. Generally the official South African estimates seem more optimistic with regards to vaccine coverage than the WHO estimates. Yet, even if we accept the official South African estimates we can see that the vaccination rates in South Africa are too low to achieve elimination of measles transmission.

To achieve elimination of measles within a country and to sustain elimination, the WHO recommends vaccination with two doses sustained at levels upwards of 95% (Shibeshi et al. 2014). The data from the US and Canada confirms the effectiveness and necessity of such sustained levels of vaccination to eliminate measles.

It is therefore clear that current vaccination levels in South Africa are inadequate to attain elimination of measles. If vaccination levels are maintained at current estimated levels, South Africa will remain susceptible to large epidemics. After an epidemic there appears to be increased vigilance to ensure adequate vaccination and an increase in the coverage of routine vaccinations as well as SIAs. The subsequent rise in vaccination coverage combined with increased levels of natural immunity acquired from measles infection lead to decreased susceptibility to measles outbreaks in the population. During these times population immunity to measles is high and the number of measles cases fall. If vaccination rates remain below the elimination threshold, the number of susceptible persons in the population accumulates over time. It then is inevitable that at a certain point the susceptibility within the population will again lead to a large epidemic.

The HIV epidemic does not seem to have influenced measles spread or the epidemiological pattern of measles in South Africa substantially (Helfand et al. 2005; Shibeshi et al. 2014). It is so that there is an increase in the proportion of the population susceptible to measles because of a higher rate of vaccine failure among HIV positive children. This is estimated to be a 2-3% increase in the susceptible pool of each new birth cohort. This increase in susceptibility is largely neutralized by the higher all-cause death rates among HIV positive children, so that the overall susceptibility to measles within the population does not seem to be substantially increased by the HIV pandemic (Helfand et al. 2005). The experience with measles spread during the HIV pandemic in South Africa confirms that the impact of the pandemic has been minimal (Helfand et al. 2005; Shibeshi et al. 2014). Rather, it is that absence of sufficient vaccination coverage that is responsible for the measles epidemics in South Africa. It has been shown that the most significant factor leading to increased susceptibility of children in South Africa to measles infection is lack of a second measles vaccination opportunity (Helfand et al. 2005).

Even though HIV has not affected the pattern of measles spread significantly, individual HIV affected children are more vulnerable to measles illness and its complications (Helfand et al. 2005; Shibeshi et al. 2014). Children born to HIV positive mothers have less maternal protective antibodies, and such children are therefore more susceptible to measles infections (Helfand et



al. 2005; Shibeshi et al. 2014). It also appears that HIV positive children have a lesser response to measles vaccine and have a decline in vaccine protection more quickly (Helfand et al. 2005; Shibeshi et al. 2014). Therefore, although HIV has not increased the spread of measles, children who are affected by HIV are more prone to becoming infected by measles and therefore are more vulnerable than the general population. It is different for adults or adolescents who become infected with HIV after getting measles vaccine when they were not HIV positive; these persons seem to keep their immunity to measles (Helfand et al. 2005). It is specifically HIV infected/affected children that are at higher risk, and it makes sense to offer such children measles vaccination at a younger age. For example, there is a WHO recommendation adding a measles vaccine at 6 months in addition to the usual 9 month/18 month schedule for infants who are born in areas with very high HIV and measles levels (Shibeshi et al. 2014).

It seems clear given the epidemiological data that simple steps to curb measles spread and epidemics in South Africa would include high rate of routine coverage with MCV1 and MCV2, while ensuring numerous strategic SIA outreaches to reach those who do not have sufficient access to routine vaccine coverage.

## Europe

Fourteen years after measles was eliminated in the United Kingdom, measles was once again declared to be endemic in that country in June 2008 (CDC 2008; Euro Surveillance Editorial Team 2008). The statement from the Health Protection Agency at that time was that “the number of children susceptible to measles is now sufficient to support the continuous spread of measles” (Euro Surveillance Editorial Team 2008). The reason for this was that vaccination rates had dropped to 80-85% for a number of years, so that the susceptible portion of the population increased each year (CDC 2008).

The case of the United Kingdom provides evidence that even if measles is eliminated in a country, it is necessary to maintain high levels of immunity against measles in the population through vaccination to prevent measles from returning to a pattern of continuous spread. When vaccination rates fall in countries where measles has been eliminated, every year with every birth cohort the pool of people susceptible to measles infection grows within that country. As the United Kingdom example bears out, the country then becomes vulnerable to the return of measles as an endemic illness with continuous spread within the country. This is no surprise; measles is highly contagious and cases can be imported quite easily from countries where measles still occur endemically to countries where measles had been eliminated.

Table 1.1 shows the number of measles cases per year in recent years in the United Kingdom, as well as vaccination rates. Just recently vaccination rates seem to have returned to higher levels in the United Kingdom, showing rates of 90% or higher since 2011.

A recent outbreak in the Netherlands provides interesting insights with regards to the spread of measles in a country that has a high vaccination rate. In the Netherlands measles vaccination

rates are typically over 95%. Yet, in 2013 the Netherlands experienced a measles outbreak affecting well over a 1,000 cases. In fact, in table 1.1 it is shown that the reported number of measles cases in the Netherlands for 2013 was 2,653 which is a marked increase from the previous year's 10 cases. This reflects the magnitude of the outbreak in 2013.

One article reported statistics from this 2013 epidemic as on 28 August 2013 and discussed the implications of this outbreak (Knol et al. 2013). At that stage there had been 1,226 reported measles cases with 82 hospitalizations. There was a strong correlation with being unvaccinated, with 96.5% of the cases occurring in unvaccinated people. There was also a strong correlation with being an orthodox Protestant, with 91.7% of affected people being orthodox Protestants. The authors also estimate that the official statistics (reported measles cases) represent an underestimation of the true magnitude of the outbreak, since experience with previous measles outbreaks in the Netherlands have shown that many people infected by measles do not seek physician treatment. If the same level of under-reporting existed in the 2013 outbreak as in previous outbreaks, the number of measles cases in the 2013 outbreak would actually be around 13,000. The author also argues that although most cases had been Protestants in the 2013 outbreak, it is likely that this epidemic will eventually spread to non-Protestants as well. Only 15% of vaccine-refusers in the Netherlands are Protestants. The Protestant vaccine-refusers tend to live close to each other in congregated communities, making measles spread within these communities easy. Non-protestant vaccine-refusers tend to be more widely distributed and interspersed within the highly vaccinated population, so that they are protected by herd-immunity. Herd-immunity will be discussed in a separate section below.

From the Netherlands outbreak we can see that even if a country has very high levels of vaccination, pockets of susceptible populations can still exist within the country due to the congregation of vaccine-refusers in communities. Where susceptible persons live in close proximity or congregate together, measles outbreaks are likely. Where susceptible persons are spread out within a highly vaccinated population, they seem to be relatively more protected against measles by virtue of the high vaccination rate in the general population. This is similar to the experience in the US and in Canada, where high vaccination rates exist but where pockets of susceptible populations exist within the country. When measles is imported from elsewhere, these pockets of susceptible populations are at high risk of experiencing measles outbreaks.

## **Global**

The World Health Organization is engaged in ongoing efforts to increase vaccination coverage globally and to decrease the global burden of measles (CDC 2013c). Their strategy focuses on increasing MCV1 and MVC2 coverage world-wide through various monitoring and intervention measures. These measures have been met by some success; estimates of global MCV1 coverage has increased from 72% in the year 2000 to 84% in the year 2011, and the number of countries providing MCV2 has increased from 97 (50%) in 2000 to 141 (73%) in 2011. Correspondingly, the estimated number of measles cases per population has decreased in this time period as did the

estimated number of measles deaths. In 2000, the estimated global measles cases per 1 million population was 146 per year, while in 2011 this number dropped to 52 per year. In 2000 the estimated number of global measles deaths were 542,000 while in 2011 the estimated number of global measles deaths were 158,000 (CDC 2013c).

According to figure 1.3, compiled from WHO statistics, the estimated number of measles deaths globally was 564,200 in 2000 and 122,000 in 2012. The estimates of global mortality for 2000 vary very slightly between the two sources, within the range of being acceptable. The estimate in figure 1.3 (564,200) is the latest estimate by the WHO of measles deaths in 2000. Both sets of estimates show a similar decline in measles case rates as well as global mortality rates over the corresponding time period.

In 2010-2011 there was an increase in the global measles incidence rate with many countries experiencing an increase in reported measles cases. There were numerous countries that experienced substantial measles outbreaks in 2011: the DRC, India, Indonesia, Nigeria, Somalia, France, Zambia, Chad, Philippines, Sudan, Italy, Pakistan, Romania, Spain, Uganda, Ethiopia and Afghanistan. Investigations into some outbreaks in this time period suggested the main cause of these outbreaks was “persistent gaps in immunization coverage, despite overall increased measles vaccine coverage” (CDC 2013c).

It should also be pointed out that the estimated global measles mortality is based on a WHO model that is dependent on reported vaccination rates and reported measles cases. This explains the slight difference between the two estimates highlighted earlier; as updated vaccine and measles case reporting becomes available, the WHO updates the estimates according to their model (CDC 2013c).

Some of the countries who have the highest disease burden do not have the ability to report exact number of cases accurately (CDC 2013c). Also, it seems reasonable given the socio-political realities in most of the countries with high measles burden that the actual number of cases are underreported while vaccination coverage may be overestimated. Yet, it does seem that there has been a marked decline in global measles burden that is attributable to an increase in global measles vaccine coverage.

Even though this is good news, it is clear that measles still presents a worldwide health challenge and that measles is responsible for substantial global burden of disease. It also seems that there are many countries experiencing outbreaks and continuous measles spread from where measles can be imported to countries where measles have been eliminated. Thus, although progress has been made the numbers bear out that measles is far from a vanquished foe when speaking in global terms.

## (2) Measles elimination and the concept of herd immunity

### (2.1) Can measles be eradicated?

Two concepts in need of clarification here: measles elimination and measles eradication (Moss & Griffin 2012; Moss & Strebel 2011).

*Measles elimination* is when measles spread is halted within a specified geographical area, such as a country. This means that there is no longer a chain of ongoing measles infection within that geographical area, and cases that occur are brought in from outside the geographical area. Another way of referring to this idea is the halt of endemic transmission of measles. To declare measles elimination, there should be no ongoing measles transmission within the geographical area for 12 months.

*Measles eradication* would be when measles infections no longer occur anywhere in the world, so that no further preventive action is needed to stop the spread of measles.

A good example of a country that has achieved measles elimination is the United States. Measles has been eliminated in the United States since the year 2000, so that ongoing transmission of measles no longer occurs (Fiebelkorn et al. 2010; Moss & Strebel 2011; Orenstein, Papania, & Wharton 2004). In the WHO region of the Americas, measles has been eliminated since 2002 (CDC 2013c). However, elimination is not necessarily permanent. As was seen with the United Kingdom, ongoing measles transmission can return to a country where measles once was considered eliminated. *Re-establishment of endemic transmission* is when measles transmission occurs uninterrupted for 12 months or more in a geographical area where measles had previously been eliminated (Moss & Griffin 2012).

It is theoretically possible to achieve measles eradication. Three factors are needed to achieve eradication of an infectious disease (Moss & Griffin 2012; Moss & Strebel 2011):

- (1) Humans are the only pathogen reservoir
- (2) Availability of accurate diagnostic tests
- (3) An effective intervention at reasonable cost.

Measles meets these criteria quite well (Moss & Griffin 2012; Moss & Strebel 2011).

- There are no animal reservoirs or natural reservoirs for the spread of measles virus. Thus, measles virus spread is dependent on transmission between humans.
- There are no latent or prolonged infections, nor are there carrier states where healthy-looking individuals can spread measles virus. Transmission only happens during acute measles illness, and a person with measles is generally infectious 4 days before the rash appears to 4 days after the rash appears.
- Measles can be diagnosed accurately. The illness is therefore easily identifiable and its spread can be monitored. In areas where high rates of measles infection exist, clinical diagnosis is easy. In places where low rates of measles exist or when the diagnosis is

unclear, accurate laboratory testing is readily available. It is not likely that measles outbreaks will be missed.

- An effective and cost-effective intervention to prevent the spread of measles is available (vaccine).

It is therefore biologically possible to eliminate measles within a geographical area and eventually to eradicate measles globally. If transmission of the virus is halted for a sufficient period of time within a geographical area, measles will no longer be present in that area unless it is imported from the outside. And globally, once transmission between humans has been halted for a sufficient period of time, measles will be absent from the world.

The challenges for measles eradication are not biological; rather they are logistical, political and financial (Moss & Strebel 2011). Ongoing measles outbreaks have been attributed to insufficient vaccination coverage. There are many reasons for this, ranging from vaccine opposition to military conflict to lack of sufficient funds or infrastructure. If these can be overcome and sufficient vaccination rates be maintained globally, measles can be eradicated.

The WHO has the goal of working towards measles eradication through strategic increase of measles vaccine coverage globally (CDC 2013c). These goals include reduction or elimination of measles transmission in four WHO regions by 2015, and reduction or elimination of measles in five WHO regions by 2020 (CDC 2013c). Another WHO goal is to reduce the estimated annual number of global measles deaths by 90% from 2000 to 2015 (Moss & Griffin 2012). There are six WHO regions in all. Thus far, the WHO region of the Americas has achieved elimination of measles, and four other WHO regions have set the goal to eliminate measles by 2020. South East Asia is the remaining WHO region (Moss & Griffin 2012). The Western Pacific WHO region was approaching measles elimination in 2011/2012, while the other regions (Africa, Europe, Eastern Mediterranean, and South East Asia) have experienced large outbreaks in the period 2008-2011, resulting in a large setback for the elimination goals. These outbreaks are attributed to ongoing deficiencies in vaccination coverage, both inadequate routine first-measles vaccine (MCV1) coverage and inadequate supplemental immunization activities (SIAs) (CDC 2013c).

## **(2.2) Herd immunity**

If sufficient members of a population acquire immunity to measles the spread of measles within the community will be interrupted. As we have already seen, it is possible to reach a stage where continuous transmission of measles no longer occurs within a population. In such populations, those who do not have immunity against measles are provided with a measure of protection against measles they would not have otherwise enjoyed. This protection derived from high immune levels in the general population is generally referred to as herd immunity.

In one article (John & Samuel 2000) three definitions of herd immunity as it is encountered in the medical literature is identified and explored:

- 1) “Herd immunity. The resistance of a group to attack by a disease because of the immunity of a large proportion of the members and the consequent lessening of the likelihood of an affected individual coming into contact with susceptible individual.”
- 2) “Herd immunity. It is not necessary to immunise every person in order to stop transmission of an infectious agent through a population. For those organisms dependent on person-to-person transmission, there may be a definable prevalence of immunity in the population above which it becomes difficult for the organism to circulate and reach new susceptibles. This prevalence is called herd immunity.”
- 3) “Herd immunity. It is well known that not everyone in a population needs to be immunised to eliminate the disease – often referred to as herd immunity. This is because successful immunisation reduces the number of susceptibles in the population and this effectively reduces the efficiency with which the microbe is transmitted from one person to the other.”

The authors point out that there is some confusion in how the term is used. They suggest changing the term to “herd effect” and propose the following definition:

“The reduction of infection or disease in the unimmunised segment as a result of immunising a proportion of the population” (John & Samuel 2000).

Other authors have maintained the term “herd immunity” to refer to the concept of unimmunised individuals deriving protection from measles through high immunity rates within a population (CDC 2008; Fiebelkorn et al. 2010; Meissner, Strebel, & Orenstein 2004). What is said of “herd immunity” in these sources is:

- There is a threshold of required population immunity that affords herd immunity within that population. If immunity rates fall below the threshold, herd immunity decreases or evaporates (CDC 2008; Fiebelkorn et al. 2010; Meissner, Strebel, & Orenstein 2004).
- Herd immunity depends on “maintaining high immunization rates in the community” (Meissner, Strebel, Orenstein 2004).
- The herd immunity threshold is 93%-95% (Fiebelkorn et al. 2010), meaning that between 93% and 95% of persons in a population need to be immune to measles to attain herd immunity within the population.
- Herd immunity decreases everyone’s risk of exposure to measles and therefore affords protection to persons who cannot receive measles vaccination (CDC 2008).

On reflection it seems that the concept of herd immunity lacks a standard definition, but that it includes important ideas. If enough people are immune to measles within a population, there is a measure of protection against measles infection for those in the population who are not immune. There is a threshold of population immunity that is required for this herd immunity effect. Herd immunity seems dependent on the interruption of measles transmission within the population, so that it seems the idea of herd immunity is closely related to the interruption of endemic transmission (measles elimination). It appears that most authors have the idea of

measles elimination in mind when they refer to herd immunity. In essence, the “herd immunity” threshold is the same as the “measles elimination” threshold in the way the term is used so that it is not clear whether there is a distinction between these two concepts.

I shall in future retain the term “herd immunity” and include the following concepts when I use that term:

- Herd immunity refers to the protection afforded to non-immune individuals against measles by virtue of high levels of measles immunity within the population.
- This protection is dependent on a high threshold of population immunity.
- Non-immune individuals are at high risk of acquiring measles if there is uninterrupted/endemic spread of measles within their population, so that the immunity threshold for herd immunity is the same as the threshold for measles elimination within a population (93-95%).

Thus, herd immunity in reality seems to reflect the fact that sufficiently high levels of measles immunity within a population will halt the spread of measles within that population. So the “herd immunity” threshold is really the “measles elimination” threshold. However, the concept of herd immunity includes the idea that those who are susceptible to measles infection derives protection against measles by virtue of this interruption in measles transmission.

To demonstrate the dependence of some individuals in society on herd immunity, consider the CDC report in 2008 that two children had died in the period April 2008 – June 2008 in Europe from measles complications (CDC 2008). Both of these children were ineligible to receive the measles vaccine because of an inherited immune disease. The CDC writes, “such children depend on herd immunity for protection from the disease, as do children aged <12 months, who are normally too young to receive the vaccine” (CDC 2008).

It is clear that a high level of population immunity is needed to achieve this herd immunity benefit. To interrupt measles virus transmission, and thus attain this herd immunity protection, a rate of measles immunity of 93-95% is needed within a population (Fiebelkorn et al. 2010; Meissner, Strebel, & Orenstein 2004; Moss & Strebel 2011). To achieve this, a 2-dose routine measles vaccine schedule is needed with coverage near or above 95% (Moss & Strebel 2011), as is made clear by the following considerations.

At 9 months of age, 85% of children will develop immunity against measles after one dose of measles vaccine (MCV1) and at 12 months of age 95% of children will develop measles immunity with one dose of vaccine (MCV1) (Moss & Griffin 2012; Moss & Strebel 2011). Almost everyone will however develop measles immunity after the second dose of measles vaccine (MCV2) [29]. So, for example, if only a single vaccine dose is given at 12 months it will have 95% effectiveness. If the vaccination rate is 95% of children with one dose of vaccine, it will only lead to a population measles immunity of 90% (Moss & Strebel 2011).

Take another example given by one group of authors of how susceptibility to measles can increase in a population with inadequate levels of vaccination (Helfand et al. 2005). Consider a hypothetical society where 100,000 children are born each year, and 90% of them are vaccinated with the routine first measles vaccine (MCV1). Without the second vaccine the routine vaccination at 9 months is only about 85% effective. So if no second vaccine is given to these children, every year 23,500 susceptible children are added to the population. Over 5 years 117,500 susceptible children accumulate.

In both examples it can be seen that a two dose schedule (almost everyone becomes immune) in very high rates (around 95%) is needed to achieve the herd immunity threshold.

In an article on the elimination of measles in the US the authors write, “the absence of endemic exposure to measles means few persons in the United States will be infected and risk complications of measles. This decreased risk of exposure provides protection to groups not protected directly by vaccination: children too young for routine vaccination; the few persons who, although vaccinated, are not protected, primarily from failure to mount an adequate response to vaccine; persons for whom vaccine is contraindicated (e.g. those with immunodeficiency)” (Orenstein, Papania, & Wharton 2004, p. S2). Here, the groups that benefit from herd immunity is identified. As will be seen later, this is ethically speaking a very important idea. For there are always those within society who do not have immunity to measles because of valid reasons: they cannot get the vaccine due to medical reasons or they lose immunity to the vaccine over time. These persons depend on herd immunity to protect them against measles. Those who are non-immune to measles through no fault of their own depend on high levels of vaccination within the population to protect them against the complications of measles.

Thus in summary. There are individuals who derive protection from measles by the interruption of measles transmission within their population. To maintain this interruption of transmission, a 2-dose vaccine approach is needed in coverage rates of 95% or higher. This is to ensure a population immunity against measles of 93-95%. If this level of vaccination coverage is lost, susceptibility to measles will accumulate within the population over time and those who are not immune to measles will be at increased risk of measles infection. There are some persons in the community who depend on the herd immunity effect for protection from measles: those who lose their immunity from the measles vaccine (about 5% will lose their immunity over 10-15 years) (Moss & Griffin 2012), the very young who have lost maternal protection but cannot yet receive the vaccine, and those with contra-indications to receiving the vaccine.



### (3) The financial burden of measles

Measles infection caused a large disease burden prior to the vaccination era, and this disease burden translated to a substantial financial burden in terms of health care expenditure.

An article that appeared in 1985 calculated the impact that measles vaccine has had in the United States with regards to reduction of disease burden and health care expenditure since its introduction in 1963 (Block et al. 1985). From these estimates we can get an idea of what the financial burden of measles was pre-vaccine. The authors included cost of health care provided to measles cases, ongoing health care for measles induced disability, lives saved by measles prevention, and additional years of normal productive life added by preventing disability or death. They estimate that in the period 1963-1982, measles vaccination has prevented measles disease burden as follows:

- 52 million measles cases
- 5,200 measles deaths
- 17,400 cases of mental retardation

It is estimated that these reductions in disease burden led to a net decrease in health care expenditure of \$5.1 billion. Of course, that estimate is in 1985 dollars and one would likely have to convert it to a higher number to get an accurate estimate in contemporary US dollar value. Yet, the savings already gained by 1985 gives one an idea of the tremendous cost that measles disease incurred to the healthcare system prior to the vaccine era.

In a more recent article, the healthcare costs per case of measles in the US is calculated using a complex formula (Zwanziger, Szilagyi, & Kaul 2001). The aim is to calculate the healthcare cost saving per averted case of measles, so that a complete cost/benefit analysis of measles vaccination can be performed. The basis of the calculation is that Total Benefit per Averted Case = Costs saved + Health Loss Averted. To obtain “costs saved” and “health loss averted”, the authors include: doctor visit costs, days absent from work with lost wage, probability of hospitalization with cost of hospitalization, probability of disability with costs of disability, health loss and loss due to death. According to their calculation, every case of measles averted leads to cost savings of \$2,089. Thus, according to this 2001 estimate every case of measles incur an average of \$2,089 of healthcare expenditure.

Now of course, this is an average estimate and uncomplicated measles cases will cost far less while measles cases with complications will cost far more. It should be remembered that the authors took variations of that nature into account in their calculation by using likelihood of complications in their calculation. Thus, the \$2,089 is an average cost per case of measles all things considered. Again, it is an estimate in 2001 dollars and one would have to adjust the number to get a contemporary US dollar value. But it does give one an idea of cost of measles in dollars, and especially how it multiplies with larger outbreaks. For example, if an outbreak of a

1,000 cases happen in the US, it would incur an estimated \$2,089,000 in healthcare expenditure according to the 1999 US dollar estimate.

A retrospective observational study was performed in a Pediatric Intensive Care Unit in South Africa in 2010 to determine the cost of measles incurred due to resource use in this ICU unit (Coetzee, Morrow, & Argent 2013). As previously seen there was a major measles outbreak in South Africa in 2009-2010, and this study therefore falls within the time frame of the epidemic. In the year 2010, this Intensive Care Unit admitted 58 measles cases. This represents 4.6% of their total admissions for the year (total admissions were 1,274). These 58 measles related admissions had a median of 5.5 days' duration of stay and these patients occupied 379 bed days in the ICU. The estimated costs associated with this were R 4,813,300 or \$543,900 given the exchange rate at that time. Also of note is that during this time 67 elective surgeries were cancelled and 87 other referrals for admission to this ICU were refused.

This study was conducted in Red Cross War Memorial Children's hospital, and therefore shows costs accrued to the state-funded health care system in South Africa. Therefore the more-or-less \$500,000 measles related ICU costs just from this one unit represents direct cost to South African public funds and thus to South African society. Also bear in mind that there were other costs incurred by society: the decreased availability of scarce ICU resources due to the measles outbreak led to the cancellation of surgeries and the refusal of access to other persons in need.

Thus, it would be reasonable to argue that the cost of the recent measles outbreak was likely tremendous, both in healthcare expenditure and in the limitation of resources for non-measles illnesses. Exact numbers and estimates of the cost of the 2009-2010 outbreak is not clear, but if we just take the ICU study into account we can see that the costs were probably substantial. If we use the US 1999 estimate of \$2,089 per case, the 12,499 reported cases in 2010 cost South Africa \$26,110,411 in healthcare costs. Of course, the US estimate does not translate directly to the South African situation, and the costs between the countries per case of measles are likely different. But given the cost related to just 1 ICU for 2010 of about \$500,000, the sheer number of measles cases, and the cost of lost lives and ongoing disability, the healthcare costs were likely in the millions of dollars if not exactly around \$26 million as per the US 1999 estimate. This of course only means the costs incurred by the healthcare system, and does not include the knock-on effect of limiting resources and access for people with other illnesses. The cost of measles to the South African healthcare system is large, and this burden falls directly on South African society.

It can be seen from these studies that measles outbreaks create substantial healthcare costs. These costs often come down directly on society at large, especially in societies with publically funded healthcare systems like South Africa. The burden of measles is therefore more than just the illness experienced by an individual. Rather, the burden of measles is felt by society as a whole in various ways: by increased healthcare costs, by limiting of healthcare resources and by increasing the burden of disability and lost lives to society.

## (4) Summary

- Measles is a highly infectious viral illness with a relatively high rate of serious complications. Measles is so infectious that outbreaks can be sustained if 10% or more of a large enough population are susceptible to measles.
- In the pre-vaccine era measles was very common and almost everyone got it. This caused substantial costs to society through health care spending, ongoing disability, illness burden and lives lost. In the vaccine era there has been a marked decrease in measles cases and deaths.
- Continued measles cases and measles outbreaks incur substantial healthcare costs to society.
- Measles has no animal reservoir, and does not cause latent or subclinical infections. It is dependent on an ongoing chain of human to human spread. If the chain of spread can be interrupted within a population, measles can be eliminated from that population. It is therefore possible to eliminate measles from countries and eventually to eradicate measles from the Earth.
- Measles has been eliminated in the Americas, yet cases are imported every year. From these cases measles can be transmitted to non-immune individuals. In the US and in Canada there are vulnerable pockets of measles susceptibility within the highly vaccinated general population where measles outbreaks can occur due to such importing of measles. Recent outbreaks in these countries have been associated with non-vaccination, and clustering of such non-immune individuals to create these susceptible pockets within the largely immune population.
- South Africa experiences cyclical large outbreaks of measles related to persistent inadequate levels of vaccination to ensure elimination. HIV has not had a significant impact on the distribution and spread of measles in South Africa; rather it is ongoing low vaccination that explains the ongoing outbreaks.
- Countries where measles is not eliminated typically experience measles outbreaks every few years when enough susceptible persons have been added to society to sustain a large outbreak.
- Experience in the United Kingdom provides evidence that measles can return and become endemic once again after it had previously been eliminated from a country. If vaccination rates drop, every birth cohort will add to the pool of susceptible individuals within the country. Over time enough susceptibility accumulates to enable ongoing measles spread within the country, meaning the disease is endemic once again. This proves that even after elimination vigilance in vaccination is essential to ensure that elimination is maintained. This will be the case until measles is completely eradicated globally.
- If enough people in a population is immune to measles, those who are not immune derive a measure of protection against measles by virtue of the fact that it is unlikely for them to come into contact with measles. This is called herd immunity. Herd immunity

protection seems to be dependent on the interruption of measles spread within a population, and therefore seems to be related to elimination of measles from a population. Thus, what is required for successful protection of non-immune individuals in a population is measles elimination so that the “herd immunity threshold” is the same as the measles elimination threshold.

- To eliminate measles from a population, 93-95% of the population has to be immune to measles. In order to achieve that number, a two-dose measles vaccination program with coverage of at least 95% is needed. This is the requirement to reach the elimination or the herd-immunity threshold.
- There are members of society that are dependent on herd-immunity for protection from measles infection. These include the very young (who cannot yet receive the vaccine), those who have lost their vaccine acquired immunity (about 5% of people will lose their measles immunity in 10-15 years, called secondary vaccine failure) and those with medical contra-indications for receiving the vaccine.

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## Chapter 3: Measles vaccine (with focus on MMR)

In chapter two it was seen that the disease burden of measles has markedly decreased and that much of the success has been attributed to measles vaccination. Global efforts to combat measles focus on increasing measles vaccination levels. It was also discussed that measles is amenable to eradication because it fulfills the criteria for eradication; among these criteria is the existence of an effective intervention at reasonable cost. The measles vaccine is thought to be an effective intervention at reasonable cost, making eradication of measles feasible. Measles vaccines have been well studied. A number of authoritative reviews have recently been published, all highlighting the safety and efficacy of measles vaccine (Demicheli et al. 2012; Lievano et al. 2012; Maglione et al. 2014; Moss & Griffin 2012).

Yet, measles vaccine has faced opposition from some quarters and consequently, as we have seen, vaccination rates have dropped in some parts of the world. The United Kingdom was highlighted as a specific example where measles vaccination rates decreased so much that the once-eradicated illness made its return. Examples of the effects of vaccine opposition were also cited from Canada, the USA and the Netherlands. We have seen that in these countries pockets of susceptibility to measles exist, largely associated with the congregation and geographic concentration of some who oppose vaccination.

In this chapter the scientific data regarding measles vaccine will be reviewed. The central questions I shall examine are: is the vaccine safe and effective, and is it at reasonable cost? The issue of vaccine adverse effects and a supposed link between autism and the measles vaccine will specifically be highlighted. There will also be a section on vaccine opposition and trends in the anti-vaccine movement, and some focus on the factors that influence parental decision-making when it comes to vaccination.



## **(1) Measles vaccine history and vaccines currently available**

### **(1.1) Vaccine history (Allen 2007, pp. 215-247)**

In 1963 the first measles vaccine was licensed in the United States; this was a single component vaccine containing an attenuated live measles virus (Allen 2007; Demicheli et al. 2012; Moss & Griffin 2012). In the 1950's a scientist by the name of John Enders isolated measles virus from a young boy named David Edmonston. Swabs and blood were collected from the 11-year old Edmonston while he was symptomatic from measles infection, and the virus captured in tubes containing human kidney cells. This strain of virus became known as the Edmonston strain. Under the direction of Enders, a whole laboratory of scientists worked on augmenting the virus, until they had created a strain of virus that could induce measles immunity in children without causing clinical measles infection (Allen 2007). Thus, the captured Edmonston strain was passed through cultures in chicken embryo cells to give rise to the attenuated Edmonston B virus. This attenuated Edmonston B virus was the first live virus measles vaccine (Moss & Griffin 2012).

At a later stage the Edmonston B virus was further changed and attenuated to form the Schwarz vaccine, also an attenuated virus originally derived from the Edmonston measles virus strain (Allen 2007). Schwarz adopted methods originally used by Sabin in the making of the polio vaccine to arrive at an attenuated virus strain that was less aggressive than the original Edmonston B strain, thus causing less adverse symptoms. The Schwarz strain became popular because of its more favourable side effect profile, and eventually formed the basis of most of the measles vaccinations used in the present day (Allen 2007). The Schwarz vaccine was licensed in 1965 in the US (Allen 2007; Moss & Griffin 2012). In 1968 a further strain became available and was licensed in the US, called the Moraten strain. This strain was also developed from the Enders virus strain to form an attenuated live virus vaccine and was developed by Hilleman (Moss & Griffin 2012). However, genetic testing in later years showed that the Schwarz strain and the Moraten strain were identical, and many scientists claimed that Hilleman had stolen Schwarz's ideas or virus. Hilleman denied these claims and it had been impossible to prove the contrary (Allen 2007).

Over the next few years vaccines against mumps and rubella were developed, also being attenuated live virus vaccines (Allen 2007). Hilleman had the goal of creating a combined vaccine, which would impart immunity to three different diseases while needing only one injection. This became a reality in 1971 with the licensing of MMR (Allen 2007). The 1971 Merck vaccine M-M-R™ (measles, mumps, and rubella virus vaccine live) was followed up by the M-M-R™II in 1978. In the new M-M-R™II the rubella component of the vaccine was changed while the measles and mumps components remained unchanged (Lievano et al. 2012). Since then, combination MMR has become the most widely used way to vaccinate against measles, as I will show in the next section.

## **(1.2) Available vaccine preparations – single component and MMR**

For brevity I shall refer to combination mumps, measles, and rubella vaccines as MMR. Various MMR preparations are available and in use. A recent Cochrane review on measles, mumps, and rubella vaccines (Demicheli et al. 2012) identifies five MMR vaccines known, and they are the following:

- Triviraten Berna. (It contains Edmonston Zagreb measles stain, Wistar rubella strain and Rubini mumps strain. Also contains lactose, human albumin, sodium bicarbonate, medium 199 and distilled water.)
- M-M-R (and subsequently M-M-R II, according to Lievano et al. 2012) by the company Merck. (It contains Enders' attenuated Edmonston measles strain grown in chick embryos, Jeryl Lynn mumps strain and Wistar rubella strain. Also contains medium 199 and the antibiotic neomycin as stabilizer.)
- Morupar by the company Chiron. (It contains Schwartz measles strain grown in chick embryos, Urabe mumps strain and Wistar rubella strain. It has neomycin as stabiliser.)
- Priorix by the company Glaxo SmithKline Beecham. (It contains Schwartz measles strain grown in chick embryos, CCID50 mumps strain which is derived from Jeryl Lynn, and Wistar rubella strain. There is also a small dose of neomycin in the vaccine.)
- Trimovax by the company Pasteur-Merieux Serums and Vaccines. (It contains the Schwartz measles strain, the Urabe mumps strain and the Wistar rubella strain.)

Combination MMR is used in over 90 countries in the world, including many countries in Europe and North America. The advantage of MMR is that three vaccine doses are delivered through one administration, thus improving vaccine coverage and at the same time decreasing costs. Most African countries (44 out of 47) use a single-component measles vaccine as opposed to MMR. Apart from these African countries, there are also 24 other countries who use single-component measles vaccine rather than MMR, which includes Russia (Demicheli et al. 2012).

## **(1.3) The emergence of MMRV**

In some countries a combination measles, mumps, rubella and varicella vaccine (MMRV) is available. For example, according to the Public Health Agency of Canada, the measles vaccines available in Canada are M-M-R II, Priorix and Priorix-Tetra. Priorix Tetra is a combination of measles, mumps, rubella, and varicella vaccine in a single dose. Single-component measles vaccine is not available in Canada (Public Health Agency of Canada 2014b).

A review of the safety and immunogenicity of MMRV (specifically Priorix-Tetra by GlaxoSmithKline Biologicals) appeared in 2009 (Czajka et al. 2009). This review included eight studies with well over 3,000 study subjects. The aim of these studies were to see whether MMRV was non-inferior to the separate administration of MMR and Varicella vaccines. The review

concludes that MMRV is non-inferior to the separate administration of MMR and Varicella vaccines in conferring immunity to the four illnesses up to 3 years after vaccination. There seems to be a higher fever response and a small increase in localized reactions such as redness and swelling with MMRV.

It should be mentioned that there is substantial potential for conflict of interest with this review. Some of the authors of this review are employees of GlaxoSmithKline and are actively involved in industry-sponsored clinical trials. Also, the trials included appear to be GlaxoSmithKline sponsored clinical trials, specifically aimed at evaluating their Priorix-Tetra vaccine.

MMRV can be used either as a two-dose vaccine by itself, or it can be used as a second dose after an initial MMR (Czajka et al. 2009). In Germany, MMRV has been part of the immunization schedule since 2006. In the USA, MMRV was preferred in some recommendations over MMR after the initial introduction of MMRV. However, this has now been modified to giving equal preference to MMR alone after it was found that MMRV causes a higher rate of febrile convulsions than MMR (Czajka et al. 2009).

Czajka et al. (2009) argue that there are benefits to MMRV over MMR. Mainly, it will facilitate varicella immunity. Parents and children prefer fewer shots, and thus MMRV will lead to greater acceptance for varicella vaccination. Thus, if MMRV is introduced in the place of MMR it will have the high uptake that MMR has currently with the added advantage of bringing about varicella immunity without an additional injection.

Since this review more studies have been published on MMRV, such as the study by Rümke et al. (2011). The results of this randomized controlled trial published in 2011 were largely similar to the results of the 2009 review. The study found that the MMRV (Priorix-Tetra) was satisfactory in stimulating immunity against measles, mumps and rubella when compared with MMR. There was a marginal increase in after-vaccine fever in the MMRV group that only had 4 weeks between MMRV doses. Apart from the fever response, the adverse effects between the MMRV and MMR groups were not significant (Rümke et al. 2011).

Again, there are some things to keep in mind when interpreting this study:

(1) The study was funded by industry and some of the authors were employees of the company that manufactures the vaccine. This creates room for possible bias in performing the study and in interpreting and reporting the data.

(2) When looking at the study itself it seems that the number of people being studied were sufficient: there were three study groups with 188, 184 and 187 children in each group. Two of the groups were MMRV groups, with one group having 4 weeks between MMRV doses and the other 12 months between MMRV doses. The MMR group had 4 week between the doses. It could therefore be said that the MMRV groups and the MMR group were not exactly equivalent; the MMR group only had 4 weeks between doses. It could perhaps be that the MMR would perform much better in terms of adverse effects if a 12-month period was allowed between MMR doses.

It is the 4-week MMRV group, for example, that was mainly responsible for the increased fever adverse effects when compared to the 4-week MMR group. The MMRV groups and the MMR groups were therefore not exactly equivalent.

(3) The immune response elicited by MMRV and MMR was tested 4-6 weeks after vaccination. This study therefore tells us about the immune response directly after vaccine administration but does not tell us about the long term effectiveness against measles infection or the long term retention of immunity between MMR and MMRV. Yet, it could be inferred that equivalent immune responses after vaccination would most probably lead to equivalent long-term immunity against measles. It should be kept in mind though that both the 2009 and 2011 publications cited provide short term immunity data, and that long term immunity data on MMR has not been established through studies.

Thus, the 2011 study (Rümke et al. 2011) gives us important information about the MMRV, as does the 2009 review (Czajka et al. 2009). Both of these studies, however, have some deficiencies that should be remembered when the results and the conclusions of these studies are considered.

Two additional studies looked at MMRV and febrile seizures. One was MacDonald et al (2014), which found that there was indeed an increased risk for febrile seizures after MMRV when compared to MMR, but that this increase in risk was quite small and needed to be weighed against the benefit of having a combination vaccine that includes a varicella component. This study had no industry links and seems to have been done in a rigorous manner. It is a cohort study, however, which is a lower level of evidence than a randomized-control trial.

The second was Gavriellov-Yusim et al. (2014), which looked specifically at the proportion of febrile seizures in the period after vaccination that is vaccine-attributable and compared MMRV with MMR. This study found that there was a slight increase in vaccine-attributable febrile seizures after MMRV when compared with MMR, but that this increase was marginal and that the overall risk-benefit ratio of the vaccine is good. This study has some industry links, with funding from the company making the vaccine in question and with one of the authors being employed by a pharmaceutical company.

### **MMRV: discussion and conclusion**

There are some data that show MMRV is equivalent to MMR with one difference being that MMRV is associated with a slightly increased rate of fever and febrile seizures than MMR. Although febrile seizures can be terrifying for parents, they have no long term adverse outcomes (Sadleir & Scheffer 2007). Febrile seizures are in essence benign clinical phenomena. Children with febrile seizures have normal outcomes and development (Sadleir & Scheffer 2007). One of the important aspects of management of febrile seizures is parental reassurance and education (Sadleir & Scheffer 2007).

It should be kept in mind, however, that MMRV has not been as well studied as MMR and that there is no long-term data on the immunity conferred by MMRV as opposed to MMR. In addition to this, the current available studies on MMRV have some defects, such as industry influence. This does not completely disqualify these studies, it only means that we should bear in mind that these studies are not perfect and have some defects.

Thus, in conclusion, it seems likely that the MMRV is equivalent to the MMR given the current level of evidence with the exception of marginally increased risk of febrile seizure with MMRV. I shall however focus my attention on MMR in this project, and consider the evidence behind MMR when arguing for the ethics of measles vaccination. The reasons for this are plentiful: MMR has been very well studied, with high-quality studies and reviews available on MMR. There is long-term data available on the effectiveness of MMR. The data on MMRV are less complete and less robust with no long-term studies on MMRV effectiveness. Additionally, MMR is widely used and remains the vaccine of choice in many countries.

In what follows I shall therefore focus on MMR. When the ethics of measles vaccination in children is considered in future chapters, it will specifically focus on the MMR vaccine. If long term studies find that MMRV is equivalent, these arguments will likely be applicable to MMRV as well.

## **(2) MMR effectiveness, adverse effects and cost**

### **(2.1) Vaccine effectiveness**

As discussed in the previous chapter, measles vaccination is highly effective and is credited with the elimination of measles in countries like the US and Canada. It was also seen that measles elimination requires two doses of measles containing vaccine at population coverage rates of 95%. As shown in the previous chapter, the historical experience with measles vaccines and their effect on measles epidemiology are well known; these historical and epidemiological considerations provide compelling evidence for the effectiveness of measles vaccines in preventing measles infection.

One review of the literature gives the following vaccine efficacy and recommendations (Moss & Griffin 2012). For a single dose of measles containing vaccine, about 85% of children will develop antibodies against measles at 9 months of age and about 95% of children will develop antibodies at 12 months of age. The age at which the first vaccine is administered varies, and is dependent on the balance between the best age for developing measles immunity and the likelihood of getting measles before vaccination. So, for example, the age at which WHO recommends the first measles dose is 9 months. Before this age it is thought that too few will develop immunity to measles from the vaccine. In some countries where measles is not endemic the first dose is sometimes delayed to 12 months or up to 15 months. This ensures greater rates of immunity from the first dose, and since the risk of a child getting measles is small the delay in giving the vaccine is seen as acceptable.

A Cochrane review of MMR effectiveness and adverse effects concluded that one MMR vaccine dose is 95% effective in preventing measles and 92% effective in preventing the spread of measles to household contacts (Demicheli et al. 2012). This review included five randomized controlled trials, one controlled clinical trial, 27 cohort studies, 17 case-control studies, five time-series trials, one case cross-over trial, two ecological studies and six self-controlled case series studies. This amounts to around 14,700,000 study participants. In this review, studies were critically appraised for sources of bias and methodology. This MMR Cochrane review represents high quality evidence for the effectiveness of the MMR vaccine in conferring measles immunity.

Another review article also comments on the effectiveness of measles vaccine (Meissner, Strebel & Orenstein 2004). According to this review, 95% of children who receive measles vaccine after 12 months of age will develop immunity against measles. With a second dose of measles, more than 99% of children will develop immunity against measles. A single dose measles vaccine is not enough to ensure elimination of measles from a population; a two-dose regimen is needed. This is not a systematic review, and is therefore a lower level of evidence than the two systematic reviews already cited. However, the results seem to be in keeping with the findings of the systematic reviews and the review itself seems rigorous. It therefore adds to the body of evidence and increases the certainty we have of the effectiveness of measles vaccine.

It can be noted that the vaccine is highly effective, but not 100% effective. Two review articles describe two different kinds of vaccine failure (Meissner, Strebel, & Orenstein 2004; Moss & Griffin 2012).

*Primary vaccine failure:* As stated, a single dose of measles containing vaccine after 12 months is 95% effective in conferring measles immunity. The 5% of children who do not develop measles immunity remain susceptible to measles. This is referred to as primary vaccine failure. Of course, the rate of primary vaccine failure is higher if the first dose of measles is given at 9 months; at this age only 85% of children develop measles immunity. It is because of primary vaccine failure that a two-dose approach is recommended. After a second dose of measles vaccine >99% of children develop immunity.

*Secondary vaccine failure:* It can happen that some people who developed measles immunity after vaccination can lose their immunity to measles. This is called secondary vaccine failure. It is estimated that secondary vaccine failure rates are about 5% after 10 years. It may actually be lower than that in people who have been vaccinated after 12 months, for example in those who have received the second vaccine at 15-18 months.

## **(2.2) Adverse effects**

### **(2.2.1) Cochrane review (Demicheli et al. 2012)**

The MMR Cochrane review mentions aseptic meningitis, febrile seizures and thrombocytopenic purpura as possible adverse reactions based on the studies included in their review.

Aseptic meningitis was associated with MMR that contained either the Urabe or the Leningrad-Zagreb mumps strains. The relative risk (RR) for aseptic meningitis was 14.28 (95% CI 7.93-25.71) with the Urabe strain and 22.5 (95% CI 11.8-42.9) with the Leningrad-Zagreb strain. This means that the risk is about 14 times higher than baseline and 22.5 times higher than baseline with the respective vaccines. It is important to note that this adverse effect is not associated with the measles strains, and therefore is not associated with vaccines containing only measles. It is also important to note that aseptic meningitis is not associated with the MMR formulations that are most commonly used. For example, MMR-II is exclusively used in the US (Lievano et al. 2012) and it does not contain the Urabe or Leningrad-Zagreb strain, and thus is not associated with aseptic meningitis. Similarly, Canada uses MMR-II and Priorix (Public Health Agency of Canada 2014b), neither of which contains the Urabe or Leningrad-Zagreb mumps strain. It is therefore possible to avoid the adverse effect of aseptic meningitis by using MMR the commonly-used MMR formulations that do not contain the Urabe or Leningrad-Zagreb strain, or to use a single-component measles vaccine. Even though aseptic meningitis can be painful and cause short term suffering, the long-term outcome of aseptic meningitis is good and it does not seem as if aseptic meningitis causes adverse neurological outcomes (Rorabaugh et al. 1993).

The review included two studies that associated MMR with febrile seizures. One was a good person-time cohort study, including 537,171 children under 5 years of age. This study found that the risk for febrile seizure was slightly raised for the two weeks after MMR administration with a RR of 1.10 (95% CI: 1.05-1.15). Thus, this study showed an increase in risk for febrile seizure of about 10% from baseline. The other was a self-controlled case series study in 894 children, which had a moderate risk of bias and thus is not of the quality of the first study mentioned. The second study found an increased incidence of febrile seizure after MMR in children 12 to 23 months old (relative incidence between 3 and 5 times higher than baseline). As already mentioned, febrile seizures have good long term outcomes and are thus considered benign clinical entities (Sadleir & Scheffer 2007).

The reviewers identify an increased risk for thrombocytopenic purpura in the first six weeks after MMR administration. Thrombocytopenic purpura refers to a decrease in platelets, which are instrumental in blood clotting. It is not clear how high the risk is for this adverse effect from the studies included; the confidence intervals are large and the estimated increased risk ranges from 2 fold to 30 fold higher than baseline.

Based on the available evidence, the reviewers reject any significant association between MMR vaccine and autism, asthma, leukemia, hay fever, type 1 diabetes mellitus, gait disturbances, Crohn's disease, demyelinating diseases (such as multiple sclerosis), bacterial or viral infections. The authors also could not find statistically significant associations between MMR and encephalopathy in the included studies.

In the light of the available evidence, the authors endorse the current approach of mass vaccination against measles disease with MMR. They are critical, however, of many of the studies that they have included. Specifically, they are concerned with inconsistent reporting between some of the study types and inconsistent methodology with regards to vaccine contents, study populations, time from exposure and so forth. These issues affect the generalizability of the results. They were also concerned that with some of the studies there were potential sources of bias present, such as selection and performance bias, affecting the internal validity of the studies. Thus, although this review provides evidence for the effectiveness and safety of MMR vaccines, the authors would like to see improvement in studies on MMR in the following two areas: improved design with standardisation of safety outcome reporting for MMR studies, and more studies examining to what extent measles immunity decreases over time after MMR vaccine.

### **(2.2.2) Moss/Griffin review (Moss & Griffin 2012)**

The Moss/Griffin review identifies the following adverse reactions from measles vaccination:

- Fever in 5% of recipients who have no measles immunity
- Transient rash in 2% of recipients
- Transient thrombocytopenia with a median incidence of 2-6 cases per 100,000 MMR doses



The authors argue that measles vaccines are effective and safe for children and adults who do not have immune compromise. They also cite evidence against any association between autism and MMR; they state that “several comprehensive reviews and epidemiological studies found no evidence of a causal relation between MMR vaccination and autism” (p. 160).

### **(2.2.3) MMR II review (Lievano et al. 2012)**

This review includes adverse events reported for MMR II by the company Merck, the MMR vaccine that has been exclusively used in the United States for the reporting period (1978 to 30 September 2010). The data for this review were located in Merck’s adverse event database, containing records of vaccine adverse events that were reported to Merck. This database was also updated with reports to the US government’s Vaccine Adverse Event Reporting System (VAERS). There were 17,536 adverse events reported in this 32 year time period, and 4822 of these adverse events were considered serious by regulatory criteria. If the amount of MMR II vaccine given to the population is taken into account, this leads to a rate of 8.4 serious events for every 1 million doses of MMR II distributed (8.4/1,000,000).

The authors of this review consider the following reported adverse event outcomes, and consider whether these event outcomes were related to MMR vaccination or not:

#### *- Death*

136 temporally associated deaths were reported after MMR II in the 32 years. Investigation of these showed that these deaths were mainly associated with infections that were unrelated to the vaccine. There was no unusual pattern of significance.

14 of the deaths were in immunocompromised patients; six of these died due to measles complications and in four of these the vaccine measles strain was identified as the cause of the complications.

It does not seem, therefore, that there is a causative link between MMR II and the reported deaths, except for the immunocompromised patients who developed measles related complications from the vaccine measles strain.

The contraindications for receiving MMR includes known severe immunodeficiency, such as hematologic and solid tumours, chemotherapy, congenital immunodeficiency, HIV patients with severe immunodeficiency, and long-term use of medications that suppress the immune system. It is important to note in the South African context that HIV positive children are eligible for the MMR vaccine if their CD4 lymphocyte count is above 15%.

#### *- Subacute Sclerosing Panencephalitis (SSPE)*

18 cases of SSPE were reported. 12 of these ended in death. In 10 out of the 18 cases, the children had a positive history of measles infection. One case out of the 18 was reportedly attributed to MMR II, but the investigations used to make this claim were not specified. The authors point out that there has been no cases of SSPE where the vaccine virus has been identified through PCR testing as being the causative agent. It therefore does not appear as if SSPE is linked to MMR II, but rather is caused by a prior measles infection with SSPE.

- *Aseptic meningitis*

57 cases of aseptic meningitis after vaccination were reported. One case was fatal, and one case reported hearing loss in one ear, three years after vaccination.

Of the 57 cases, 50 did not meet the criteria for aseptic meningitis after review. Of the other seven reports, five had no specific organism isolated as cause, and two had mumps strains isolated as cause. It was reported that there may have been community acquired mumps infection in these cases, but the temporal association with MMR II could not be ignored, and thus it was reported as such. The authors point out that the Jeryl Lynn mumps strain was not positively identified in any of the 57 reported cases.

- *Encephalitis*

120 cases of encephalitis after vaccination were reported. 58 recovered, 21 did not recover, in 30 the outcome was unknown and 11 died. Of the 120 reports, 60 had insufficient information to make a conclusion.

The authors state that the relative rate of occurrence of encephalopathy is 0.22 per million MMR doses. Of these, about 50% are reported to recover. This means that for every 4,545,454 doses of MMR given to non-immune individuals, 1 will develop encephalitis.

- *Autism*

433 events of autism were reported. Time to onset of autism after MMR was known in 130 cases, and ranged from 1 day to 19 years with a median onset of 339 days after MMR.

The authors cite evidence against the causative association between MMR and autism; they argue that “by 2011, both biologic implausibility and the support of over 20 epidemiologic studies have confirmed that MMR II does not cause autism.”

- *Febrile seizures*

773 events of febrile seizures were reported after MMR II; median time to onset after MMR II is 9 days. In 12 % of these cases other infections were also present, contributing to fever.

The authors state that the body of evidence supports a causal relationship between MMR II and febrile seizures. They argue, however, that the risk for febrile seizure is smaller with MMR II than with measles infections, where the febrile seizures happen in 0.6-0.7% of cases. They do not exactly quantify the risk of febrile seizures from MMR II.

- *Deafness*

89 reports of deafness after MMR II. In 27 of these there were other medical conditions present that may have contributed, such as otitis media. In these reports deafness onset was also quite long after MMR II exposure (median 57 days after vaccination). The authors argue that these considerations make it seem like these cases of deafness were not caused by MMR II.

- *Thrombocytopenia*

259 events of low platelets (thrombocytopenia) were reported, within 77 days after MMR II. 159 of these recovered to normal platelet counts, 31 did not recover and in 60 outcome is unknown. The authors write that the most common cause for low platelets in children is excessive breakdown due to immune thrombocytopenic purpura (ITP). The 31 children in their data who did not return to normal platelet levels presumably had some diagnosis such as ITP. There does

appear to be a slightly increased risk for lower platelets and ITP with MMR II, but this risk is lower than with viral infection prevented by MMR II.

The rate of thrombocytopenia for MMR II is less than 1 per 30,000 doses. The authors compare this with the rate of thrombocytopenia of 1/3,000 for rubella infection.

- *Hypersensitivity and anaphylaxis (allergic reactions)*

158 reports of hypersensitivity were described, and 228 reports of anaphylaxis (severe allergic reaction) were described. Of these, 14 cases progressed to anaphylactic shock. There was only one anaphylaxis related death in the authors' data, and this child received pneumococcal vaccine at the same time as MMR vaccine.

Allergy to MMR may be because of allergy to vaccine components, such as chick embryo, gelatin and neomycin. The relative rate of allergic type reactions to MMR II is less than 1 per million doses.

Taking the above data into consideration would give the following known serious adverse events for MMR II vaccination: Encephalitis (0.22 per million MMR doses), Febrile seizures (increased risk, not quantified but said to be less than measles infection), thrombocytopenia (less than 1 per 30,000 MMR doses), and allergic reactions (less than 1 per million MMR doses).

On review of the data, the authors reject a significant causative association between MMR II and death, SSPE, aseptic meningitis, autism and deafness.

The authors also mention the following significant but non-serious adverse events: fever (5.49 reports per 1 million MMR doses), rash (4.63 reports per 1 million MMR doses), injection site reaction (2.19 reports per 1 million MMR doses), vasovagal/syncope/fainting (0.85 reports per 1 million MMR doses), and arthritis (0.67 reports per 1 million MMR doses). They cite evidence indicating that there is no association between MMR vaccine and chronic arthritis in women. Also, it is thought that the rate of local injection site reactions are underreported. Of note is that the vaccine, being a live virus vaccine, is contraindicated during pregnancy.

#### **(2.2.4) Childhood vaccine safety review, 2014 (Maglione et al. 2014)**

This review examined adverse effects associated with all childhood vaccines. For MMR they found the following:

There is convincing evidence of: a causal relationship between MMR vaccine and febrile seizures; anaphylaxis in allergic patients; a causal relationship between MMR and inclusion body encephalitis in immunocompromised children; a causal relationship between Urabe mumps strain and aseptic meningitis, although there is no evidence of a link between Jeryl Lynn mumps strain and aseptic meningitis.

The available evidence "favors acceptance" of a causal relationship between MMR and transient joint pain in children. There is also moderate quality evidence indicating a link between MMR and thrombocytopenic purpura for a short period after vaccination.

The available evidence “favors rejection” of a causal relationship between MMR and autism.

### **(2.2.5) CDC: measles vaccine adverse effects (CDC 2012)**

The CDC gives the following adverse effects of measles vaccine (MMR):

- Fever (5-15% of recipients)
- Rash (5% of recipients)
- Joint pain/arthralgia (25% of recipients)
- Thrombocytopenia (low platelets) – less than 1 in 30,000 of recipients. They also state that the thrombocytopenia is usually transient and benign, although very rare episodes of bleeding have occurred.
- Parotitis (inflammation of the parotid salivary gland) – rare, but there have been some reports.
- Deafness (rare)
- Transient lymphadenopathy (temporarily enlarged lymph nodes) – rare.
- Allergic reactions (rare, uncommon, and usually limited to rash/urticarial. Anaphylactic reactions are extremely rare.)
- Encephalopathy (less than 1 per 1,000,000 doses)

According to the CDC, these adverse effects represent mild illness following replication of the live vaccine virus. As can be seen, the adverse effect rate is low.

Citing two independent non-governmental groups, American Academy of Pediatrics and the Institute of Medicine, the CDC states that the research evidence available shows no link between autism and MMR, and consequently that autism should not be considered an adverse effect of MMR.

### **(2.2.6) Summary of findings: Measles vaccine adverse effects**

I shall summarize here the adverse effect of measles containing vaccines, derived from the various reviews cited above. I shall focus on the adverse effects of commonly used MMR formulations, and will therefore not include aseptic meningitis. Aseptic meningitis is associated with a mumps strain that is not commonly used, and can be avoided by using MMR that does not have the offending mumps strain.

These adverse effects can be divided into minor and major categories.

#### Minor adverse effects:

These are mild, benign and have no long term adverse outcomes. They may be bothersome or distressing to the patient and family in the short term, but carry no long term implications.

- Fever (5-15%; 50 to 150 per 1,000)
- Rash (about 5%; 50 per 1,000)
- Joint pain (up to 25%; 250 per 1,000)

- Parotitis (very rare, not quantified)
- Lymphadenopathy (very rare, not quantified)
- Febrile seizures (calculated to be between 0.3 and 0.8%; 3 and 8 per 1,000)

The prevalence of febrile seizures in the general population is between 3% and 8% before age 7 (Sadleir & Scheffer 2007). That means that for every 1,000 children in the general population, between 30 and 80 will have a febrile seizure by age 7. There is an increased risk of febrile seizures with MMR of about 10% over baseline (Demicheli et al. 2012). This means that if MMR is added to our group of 1,000 children, the number who will have a febrile seizure will be between 33 and 88. Thus, for a 1,000 doses there will be between 3 and 8 extra cases of febrile seizure due to the addition of MMR.

#### Major adverse effects:

These can have serious outcomes and are thus worrisome. I include thrombocytopenia in this list, although I provide an explanation that this usually is transient and mild. I do not include deafness: although there have been some reports of hearing loss after children have received MMR, it seems that there is no evidence that these were linked to MMR. Three reviews do not mention it (Demicheli et al. 2012; Maglione et al. 2014; Moss & Griffin 2012), and Lievano et al. (2012) cites considerations that would favour rejection of a link between MMR and deafness.

- Thrombocytopenia (less than 1 per 30,000)

This usually seems to be transient, and in the vast majority of cases the low platelets are self-corrected without serious complications. Since there have been some reports of bleeding because of the low platelets, and because there may be a very slightly increased risk of conditions such as ITP where platelets will remain low due to increased destruction, I include these in the list of major adverse effects.

- Anaphylaxis (less than 1 per million doses)

Allergic reactions to MMR are very rare. When they occur, they seem to usually be minor reactions. Anaphylactic reactions are therefore extremely rare. However, when they occur they are life-threatening and require emergency medical treatment.

- Encephalitis/Encephalopathy (0.22 per 1 million doses)

One review stated that there is no evidence of a statistically significant association between MMR and encephalitis (Demicheli et al. 2012). This is a significant finding; it means that there is doubt as to whether the reported cases of encephalopathy following MMR were indeed caused by the vaccine. In the review by Lievano et al. (2012) there is mention of 120 reported cases of encephalitis in 32 years of MMR II use. In half of these cases (60) there was not enough data to determine what the cause of the encephalitis was. It may therefore have been MMR related. The authors estimate a rate of 0.22 per 1 million doses for encephalitis; this correlates well with the CDC's (CDC 2012) figure of less than 1 per 1 million doses.

It seems doubtful whether there actually is evidence for a causative connection between MMR and encephalitis. Yet, because this is a serious adverse effect and there have been reports of cases that could potentially be linked to MMR, I include this as a potential adverse effect.

The common adverse effects of MMR are not serious and pass quickly. These include rash, fever and joint pain. Febrile seizures are distressing to parents, but essentially are benign with good long term outcomes.

The potentially serious adverse effects of MMR are thrombocytopenia, anaphylaxis and encephalitis. MMR thrombocytopenia is relatively rare, and when it occurs it usually passes without causing trouble. Anaphylaxis is extremely rare, but when it occurs is a serious complication. There is doubt as to whether MMR really causes encephalopathy, but if it does it is extremely rare.

Based on these data, measles vaccines are safe for use and the risk of serious adverse effects are very low.

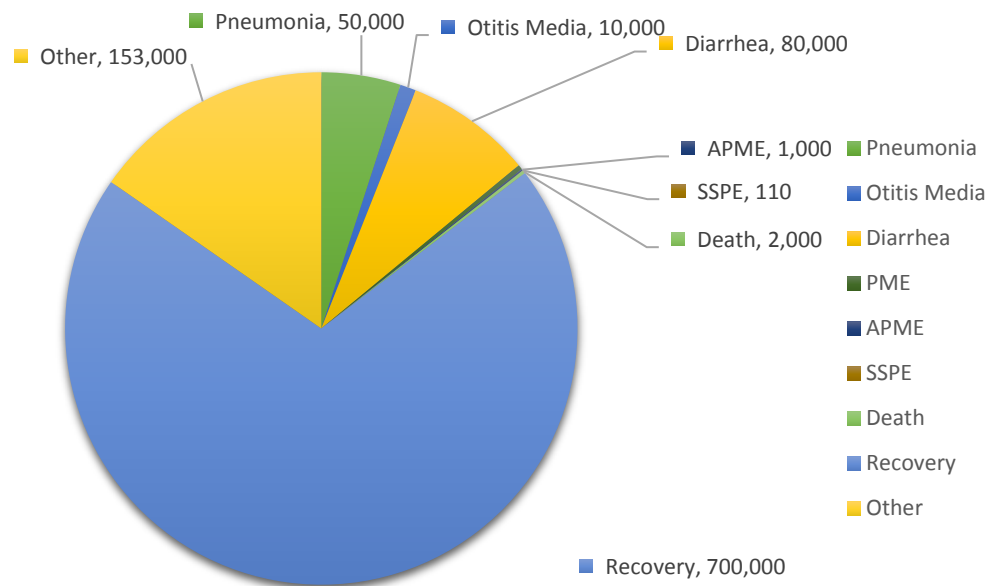
### **(2.2.7) Comparing MMR adverse effects with complications of measles**

Figure 3.1 and 3.2 compare the complications of measles with the adverse events following vaccination. Data presented in chapter 2 on the complications of measles were used and compared with data presented in chapter 3 on measles vaccines. As can be seen, the serious complications of measles vaccines are not clearly visible on the chart as a separate colour, simply because there are so few serious adverse events following measles vaccines.

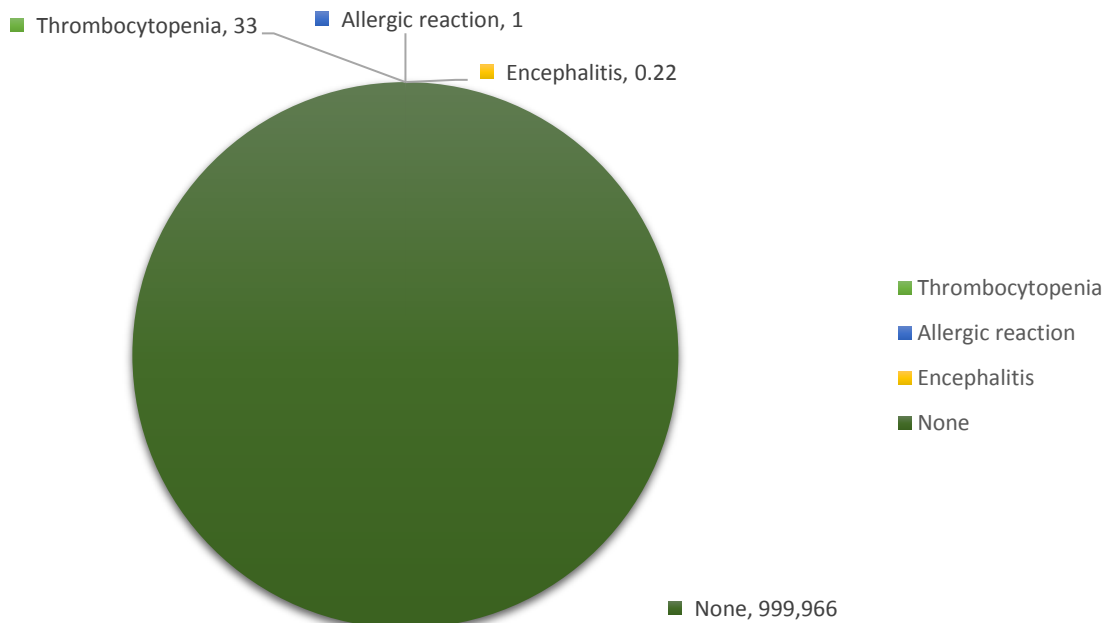
If a million children were infected with measles, 700,000 would recover and 300,000 would have some complication. About 50,000 would have pneumonia, 80,000 diarrhea, and 10,000 otitis media. There would be 1,000 cases of primary measles encephalitis and 110 cases of Subacute Sclerosing Panencephalitis. This is a large burden of disease, leading to many hospitalizations and cases of disability. There would be an estimated 2,000 deaths out of the million children.

If a million children were given measles vaccine, 33 would develop a transient thrombocytopenia, there would be about 1 significant allergic reaction, and there would be less than 1 (0.22) cases of encephalitis. Out of the million, 999,966 children would not have a serious adverse reaction. It should also be pointed out that the thrombocytopenia usually passes without any serious complications, so that essentially less than 2 per million children have a serious adverse event. These numbers include the assumption that MMR can cause encephalopathy; as stated before, there is some doubt about this, but if it does it is extremely rare.

**Figure 3.1: Complications of measles per 1 million cases**



**Figure 3.2: Major adverse effects per 1 million MMR doses**



### **(2.3) Contra-indications: Who should not get the vaccine?**

The CDC indicates the following contra-indications to MMR (CDC 2012):

- Known severe allergy to measles vaccine or components of the vaccine, such as gelatin. Egg allergy is not a contra-indication, as studies have shown that MMR is safe in children with egg allergy.
- Pregnancy. Additionally, women should not fall pregnant within 4 weeks after MMR administration.
- Severe immunodeficiency. This would include advanced HIV disease, leukemia, or use of immunosuppressive drugs for a long time or in large doses. HIV positive children may receive MMR; only those with evidence of severe immunodeficiency should not receive the vaccine. Severe HIV immunodeficiency is either diagnosed clinically or by CD4 count of less than 15% of total lymphocytes. It is not necessary to test children for HIV prior to giving MMR if they do not have clinical features of severe immunodeficiency.
- Moderate or severe illness. MMR should not be given to a child who has an acute illness that needs treatment, such as pneumonia. This is to avoid making the management of the illness more difficult by adding a potential vaccine adverse reaction into the clinical picture. Vaccination should in these cases be delayed until improvement of the child. However, minor illnesses such as viral upper respiratory infections are not a contra-indication to MMR.
- Recent administration of a blood product. If a child has recently received a blood product that contains immunoglobulins, these could prevent the child's becoming immune to measles following vaccination. The waiting period for vaccination after blood product administration can range from a few months to almost a year, depending on the product given.

### **(2.4) Vaccine cost and cost-effectiveness**

In 1985 a review was conducted which examined the impact of 20 years of measles vaccination in the United States (Bloch et al. 1985). Measles vaccination was introduced in 1963, and the review estimated the net effect of measles vaccination by 1983. The results of this review were quite impressive. By 1983 measles vaccination in the US has prevented an estimated 52 million cases of measles, 5,200 measles deaths, and 17,400 cases of mental retardation. An estimated net savings of \$5.1 billion in healthcare expenditure was the result.

In 2004 an analysis of the cost-effectiveness of the measles vaccination program in the US was published (Zhou et al. 2004). In this review they followed a hypothetical birth cohort of 3,803,295 children until age 40. They compared the costs of the MMR vaccination program with the costs of absence of vaccination, and they also analyzed the cost-benefit of adding the second dose of MMR. They argue that the first dose of MMR protects most children, and thus is the most cost-effective, but that the second dose adds the population immunity that is required to achieve



interruption of endemic transmission and thus eradication of measles. They furthermore assume vaccination rates that are consistent with actually achieved vaccination rates for the time period when the children were born; this means that by age 6, 95% of the children would have had the first MMR dose and 79% would have had the second MMR dose.

The 2004 analysis found that net savings from the MMR program for this hypothetical birth cohort were \$3.5 billion in direct savings to healthcare expenditure, and \$7.6 billion savings in societal perspectives (Zhou et al. 2004). The benefit-cost ratios were impressive, with a ratio of 14.2 saved for every dollar spent in direct costs and 26.0 saved for every dollar spent in societal perspectives. Direct costs refer to medical spending, hospitalization, special education and the like. Societal perspectives include aspects such as loss of productivity in patients and caregivers. In this analysis, cost savings from rubella and mumps reduction was also included in the cost-benefit calculation.

At the time the 2004 review was conducted, the price for MMR vaccine in the US was \$15.08 in the public sector and \$28.19 for the private sector (Zhou et al 2004). The total costs of the MMR vaccination program were \$0.27 billion in direct costs and \$0.30 billion in societal perspectives. In direct costs only, the MMR program spent \$78 to prevent one case of measles while saving \$1,023 by preventing one case of measles.

A 2001 analysis found that the total savings in cost to society for each averted case of measles were \$2,089 (Zwanziger, Szilagyi & Kaul 2001). If the \$78 cost to prevent one case through MMR is taken as correct, that translates into impressive savings in societal cost through a program of MMR vaccination, with a cost-benefit of 26.78 saved for every dollar spent.

In the United States, MMR currently costs \$19.91 per dose if procured through a publically funded agency such as the CDC, and \$56.139 per dose if privately bought (CDC 2014b). This is fairly affordable, and access to vaccination is readily available through a variety of means in first world countries. For example, Canada has a publically funded health systems that pay for basic health care such as vaccines. In the United States there are a variety of ways in which to access vaccination through either public or private funding.

In the developing world, close to \$20 for a vaccine is not affordable. Through UNICEF the vaccine can be procured for \$0.30 per dose, which includes \$0.15 for the vaccine and \$0.15 for injection equipment (UNICEF 2007). This means that a child can be immunized against measles for less than one US dollar, including injection equipment and operational costs.

Measles vaccination is therefore inexpensive and cost-effective, with substantial savings in medical expenditure and indirect societal costs.

### **(3) Does MMR cause autism?**

#### **(3.1) Autism and Wakefield's paper**

Allen (2007, p. 371-420) describes some of the relevant preceding history. Autism was discovered as a separate disease entity in 1943. It was poorly understood and very rare; by 1971 the prevalence of autism was thought to be 3 to 5 in 10,000 children. The cause of autism was not clear, and theories ranged from psychological causes to nutritional and environmental. In the 1990s scientific consensus was that autism was caused by biological factors, yet it remained unclear how much of the cause was genetic and how much was environmental. By the year 2000 the diagnosis rate of autism had increased dramatically, and the prevalence rate was 3 to 5 in a 1,000 children. For numerous years some alternative medicine adherents had been voicing claims that increased vaccine use had been responsible for the increase in autism diagnoses. For example, a navy psychologist by the name of Bernard Rimland who had an autistic son advocated in the 1960s that medications were dangerous, Diphtheria-Tetanus-Pertussis (DTP) vaccines caused autism, and that natural supplement treatments were safe. Thus, the idea that there may be a causative link between vaccines and autism has a fairly long history.

The thought that vaccines, and MMR in particular, may be the cause of autism gained scientific traction and public attention by the publication of an article by Andrew Wakefield in 1998 in the *Lancet* (Allen 2007; Demicheli et al. 2012; Godlee, Smith, & Marcovitch 2011; Kemp & Hart 2010; Peterson & Barbel 2013). The Wakefield article postulated a causative association between autism and MMR vaccination. Taken at face value, the scientific merits of the paper were questionable: the study consisted of a case series of 12 children with no control cases, included three common medical conditions, and based its conclusions mainly on the recollections and beliefs of the parents of the affected children (Godlee, Smith, & Marcovitch 2011). These are indeed very unimpressive and doubtful scientific methods, with ample room for bias and skewed conclusions.

Further investigation by a journalist by the name of Brian Deer revealed that Wakefield's article was fraudulent (Godlee, Smith, & Marcovitch 2011). Wakefield had falsified information and had altered facts to fit his conclusions. It also became apparent that Wakefield had substantial conflicts of interest, and sought to gain financially through the MMR scare that would follow from his article. In 2004, 10 of the co-authors of this article had retracted this article's interpretation of a link between autism and MMR vaccines. Wakefield kept insisting that his article and ideas were credible (Godlee, Smith, & Marcovitch 2011). Wakefield has been found guilty of "ethical, medical and scientific misconduct in the publication of the paper"; his work had clearly been fraudulent (Demicheli et al. 2012). Wakefield has since been stripped of his medical and academic credentials (Godlee, Smith, & Marcovitch 2011).

### (3.2) The role of the media in the MMR-autism scare

Although Wakefield's paper has been withdrawn by the Lancet and been discredited in various ways, it remained a defining moment (Demicheli et al. 2012; Godlee, Smith, & Marcovitch 2011; Kemp & Hart 2010; Peterson & Barbel 2013). Large scale, unbalanced media coverage of Wakefield's article caused the public to doubt vaccines, vaccine safety and public health led vaccine programs. The idea that there may be a causative link between MMR and autism was presented in large print to the public, and latched onto by many. This directly led to a decline in MMR vaccine rates, with re-emergence of measles in the United Kingdom (Demicheli et al. 2012; Godlee, Smith, & Marcovitch 2011; Kemp & Hart 2010; Peterson & Barbel 2013).

Ben Goldacre (2008) describes the role of the media in creating the MMR scare in the early 2000's. He specifically examines the role of the media in the UK with the subsequent drop in MMR vaccination rates and the consequent return of measles to the UK. He writes (p. 209):

*"But as we shall see, Dr Wakefield cannot carry the blame for this scare alone, however much the news media may now try to imply that he should; the blame lies instead with the hundreds of journalists, columnists, editors and executives, in every single news outlet in the UK, who drove this story cynically, irrationally, and willfully onto the front pages for nine solid years.*

*...they overextrapolated from one study into absurdity, while studiously ignoring all reassuring data and subsequent refutations. They quoted 'experts' as authorities instead of explaining the science, they ignored the historical context...*

*... they pitched emotive stories from parents against bland academics (whom they smeared), and most bizarrely of all, in some cases they simply made stuff up."*

Goldacre (2008) describes how the MMR scare peaked in the British media in the year 2002. About 10 percent of science stories in this time period were devoted to MMR. In 2002 there were over 1,000 MMR stories in the media, in 2003 and 2004 over 500 each, and in 2005 and 2006 over 250 each. These stories were generally not covered by science reporters, but instead about 80% were by generalist reporters. Less than a third of the stories referred to the scientific evidence that MMR was considered safe. In many of the stories a false impression was created that there was a body of medical opinion doubtful of the safety of MMR.

Instead of presenting evidence, the media focussed on placing statements from experts such as "science has proven the safety of the vaccine" against emotional narratives from distraught parents and celebrities (Goldacre 2008). Although the media largely demanded "more evidence", whenever negative studies were published in peer-reviewed journals the media largely ignored them. Instead, they focussed on unsubstantiated claims from persons who did not publish their "findings" in peer review journals. As an example, some of the United Kingdom MMR headlines from 2006 are as follows (Goldacre 2008):

“US scientists back autism link to MMR” – *The Telegraph*

“Scientists fear MMR link to autism” – *The Daily Mail*

“US study supports claims of MMR link to autism” – *The Times*

All three of these headlines were based on claims in interviews with the media by Dr Arthur Krigsman that he had been able to replicate Wakefield’s findings in experiments. These findings had never been published in peer review journals. However, a study that was published in a peer-review journal which showed that Wakefield’s findings could not be replicated and followed similar methodology to the claims of the unpublished Krigsman was ignored by the media (Goldacre 2008).

Goldacre summarises the main points conveyed by the UK’s media with regards to MMR from 1998 until the mid-2000s as follows (p.212). Autism is more common, and it is not known why. Dr. Wakefield published a scientific study which shows a link between MMR and autism. More research since then has agreed with Dr. Wakefield’s findings. Single vaccinations may be safer, but government health officials and big pharma have discredited these findings. Tony Blair’s son did not get the MMR vaccine. Measles is not really that serious, and measles declined despite the vaccine, not because of it.

It appears that the media coverage of the MMR scare following Wakefield’s article was in a large part responsible for creating and propagating the MMR scare, fuelling public fears and doubts with skewed and irresponsible reporting. This directly led to decreased vaccination rates in the United Kingdom with the result that measles, mumps and rubella infections soared.

Goldacre’s work provides a good and very readable summary of the role of the media in the MMR-autism scare. It has also been well documented elsewhere that media reporting has played a significant role in the establishment and propagation of the MMR controversy, with consequent loss of trust by the public in vaccinations, vaccination programmes, government initiatives and the like (Allen 2007; Demicheli et al. 2012; Flaherty 2011; Hilton, Petticrew, & Hunt 2007).

### **(3.3) The scientific evidence regarding MMR and autism**

#### **(3.3.1) The American Academy of Pediatrics (AAP 2013; AAP 2014)**

The AAP indicate on their website that they have arranged several panels of independent scientists who have reviewed the available evidence regarding MMR and autism (AAP 2014). These independent reviews have found that there is no link between autism and MMR. Furthermore, on the AAP website there is a list of all the relevant studies that examine a potential link between MMR and autism. This list summarises the statistics and findings of the studies. This list includes summaries of 45 publications, with the overwhelming conclusion that there is no association between MMR and autism (AAP 2013).

### **(3.3.2) The Institute of Medicine (IOM 2004)**

The IOM consists of independent scientific experts. They reviewed the available evidence regarding MMR and autism independently, and concluded in their 2004 report that the “evidence favours rejection of a causal relationship between MMR vaccine and autism” (IOM 2004).

In their review, the included nine controlled observational studies, three ecological studies, and two passive reporting studies, all of which showed evidence of no link between MMR and autism. Thus, the review included 14 studies providing credible evidence in support of a rejection of a link between MMR and autism.

Two studies did show a possible link between MMR and autism: one was an ecological study that showed a potential correlation between measles containing vaccine doses and the cases of autism reported to the special education system in the 1980s; the other was a study of passive reporting data by the same authors that showed a positive correlation between autism and doses of MMR in the Vaccine Adverse Events Reporting System in the US. However, both studies were characterised by serious methodological flaws and lack of clarity. No clear conclusions could be drawn from these two studies. These studies were so unclear and uninterpretable, that they were considered non-contributory to the IOM review on the link between MMR and autism.

The evidence reviewed by the IOM therefore is strongly against an association between MMR and autism.

### **(3.3.3) Cochrane systematic review (Demicheli et al. 2012)**

A comprehensive review of the literature regarding measles, mumps and rubella vaccines was published by the Cochrane collaboration in 2012. They reviewed and analyzed numerous studies addressing the question of a link between autism and MMR vaccines.

This included the following study types: three retrospective cohort studies, three case-control studies, two time-series studies, and two self-controlled case series.

#### **Three retrospective cohort studies:**

These three studies included over 500,000 children in their various cohorts. Each of the studies were designed to evaluate an association between MMR and autism spectrum disorders.

One of the studies (Madsen et al. 2002) was conducted in Denmark, and included children born between Jan 1991 and Dec 1998, for a total of 537,303 children included in the study. No significant association was found between MMR and autism spectrum disorder; children who had MMR vaccines did not seem more likely to have autism or autism spectrum disorder. The Cochrane review demonstrated this study to be at moderate risk of bias with high generalizability of the study findings. Given the study design and type, this is acceptable and the Madsen study provides fair evidence against a link between autism and MMR.

The other two cohort studies also found no association between MMR and autism, but these studies were felt to be at high risk of bias and low generalizability. They also included fewer participants, 904 in one and 195 in the other. These two studies therefore provide weaker evidence than the Madsen study, although their conclusions are similar to the Madsen study.

### **Three case-control studies:**

The Smeeth et al. (2004) study was a case-control study that compared 1294 children with autism type diagnosis with 4469 controls. Data was collected from the United Kingdom General Practice research database. This study found no significant association between MMR and pervasive developmental disorder, with an odds ratio of 0.86 (95% CI 0.68-1.09) for an association between MMR and pervasive developmental disorder. (An odds ratio above 1 indicates an association between two entities, although it does not prove causation.)

The Cochrane review found the Smeeth et al. study to be at moderate risk of bias and the generalizability to be medium. Furthermore, the 95% confidence interval for the odds ratio is fairly broad, with a top end above 1. These issues decrease the strength of the conclusion somewhat, but even with those problems the Smeeth et al. study provides moderately trustworthy evidence that there is no link between MMR and autism.

The DeStefano et al. (2004) study was a case-control study with 624 children with autism and 1824 controls. There was no significant difference in MMR vaccination rates between cases and controls up to age 24 months. At age 36 months, those with autism had slightly higher rates of MMR vaccination than controls. This seemed to be because of vaccination requirements imposed on autistic children when they enter early intervention programs to manage their autism. This study was assessed to be at moderate risk of bias and medium generalizability.

The Mrozek-Budzyn study (Mrozek-Budzyn, Kieltyka, & Majewska 2010) included 96 children with autism diagnosis, and 192 control cases. This study found that MMR vaccination was associated with lower risk of autism if the vaccine was given before diagnosis, with an impressive odds ratio of 0.17 (95% CI 0.06-0.52). The risk for vaccinated children (MMR and single-vaccine) compared to non-vaccinated to develop autism was 0.28 (95% CI 0.10-0.76), which means that the estimated risk to develop autism was 72% lower in vaccinated children. Furthermore, the risk for autism was lower in those who had MMR versus those who had single measles vaccine. This study was found by the Cochrane review to be at moderate risk of bias and medium generalizability. Therefore, this study provides moderate quality evidence against an association between MMR and autism.

### **Two time-series studies:**

The Honda study (Honda, Shimizu, & Rutter 2005) in Japan followed children born between 1988 and 1996 in the Kohoku Ward of Yokohama, approximately 300,000 in total. MMR declined significantly in 1988-1992, and in 1993-1996 no child received vaccination in this Ward. Autism spectrum diagnosis increased significantly in 1988-1996, and the rise after 1993 was dramatic.

The conclusions drawn from this study is that MMR is unlikely to be the cause of autism spectrum disorders, that MMR cannot explain the increase in autism diagnoses and that cessation of MMR vaccination will not lead to a decrease in numbers of autism spectrum diagnoses. The Honda study was assessed to be at moderate risk of bias and medium generalizability by the Cochrane reviewers.

The Honda study is fairly persuasive. If MMR is withdrawn and yet numbers of autism diagnosis rise dramatically, it seems to provide convincing evidence that MMR is not the cause of autism and that withdrawal of MMR will not halt the rise in autism diagnoses. However, given the identified limitations of the study, the Honda study is also considered moderate level evidence against an association between autism and MMR.

The other time-series trial, Fombonne et al. (2006), followed 27,749 children born 1987-1998 in Montreal over time. A total of 180 children with pervasive developmental disorder were identified. The study found a statistically significant, linear increase in pervasive developmental disorder in the study time period. MMR vaccination rates decreased significantly during their study period, while pervasive developmental disorder increased significantly. Also, in 1996 a second dose of MMR was introduced to vaccination schedules and there was no effect on the rate of increase of pervasive developmental disorder. These findings suggest that there is no association between MMR vaccine rates and pervasive developmental disorder rates. They conclude that the increase in pervasive developmental/autism diagnoses were because of better diagnostic procedures and identification of children with these problems, and that there is no association between MMR vaccines and pervasive developmental disorders. This study was found by the Cochrane review to be at high risk of bias and medium generalizability, which somewhat diminishes the confidence one can have in the results. Still, this provides some evidence against an association between autism and MMR vaccines.

### **Two self-controlled case series:**

The Cochrane review included two self-controlled case series that provide evidence against a possible link between autism and MMR vaccines. These two studies include over 500,000 children and found no association between MMR vaccines and autism. Both were found to be at moderate risk of bias and medium generalizability.

### **Conclusion: the Cochrane review**

The authors conclude that it is unlikely that there is an association between MMR vaccines and autism, given the available evidence. They argue that the present evidence “supports current policies of mass immunisation aimed at global measles eradication in order to reduce morbidity and mortality associated with mumps and rubella” (Demicheli et al. 2012).

On review of the studies included in the Cochrane review, one can see that the current evidence available is moderate in quality, and is against a possible association between MMR vaccines and autism.

### **(3.3.4) The causes of autism**

A review of the literature point out that the cause of autism is not fully understood, but that various theories have emerged, all the subjects of further study (Peterson & Barbel 2013). These include associations between autism and advanced paternal age, neonatal jaundice, and genetic factors. This review also refers to the evidence that there is no association between MMR and autism, and argues that foregoing MMR to avoid autism would lead to harm. The treatment for autism relies on early identification and intervention, as many children can improve significantly with the appropriate developmental interventions (Peterson & Barbel 2013).

The increase in recent diagnosis rates of autism is thought to be because of greater diagnostic clarity, a change in the diagnostic criteria and greater awareness of autism in the general public (Hilton, Petticrew, & Hunt 2007; Peterson & Barbel 2013).

The American Academy of Pediatrics also point out that the MMR vaccine is usually given between the age of 12-15 months, and the first signs of autism is usually seen at 15-18 months (AAP 2014). It may therefore be natural for some parents to infer a causal association between MMR vaccine and autism, especially given the backdrop of the MMR scare in the media. However, such temporal associations seem incidental and unfortunate, and inferences regarding causal associations are not borne out by the available studies (AAP 2014).

### **(3.3.5) Summary: scientific evidence regarding MMR and autism**

There are no randomized control trials available to address the question of a link between autism and MMR. The reason for this is simple: the benefit of the MMR vaccine is enormous and the epidemiological evidence is against a possible link between the vaccine and autism, so that conducting a randomized control trial to answer this question would be unethical.

Thus, we are limited to epidemiological evidence, case-control studies and case series. The available evidence is by nature only moderate level evidence, but does give us conclusions that we can be reasonably sure of.

Of note, no single study has ever found a possible association between autism and MMR vaccines. The only study that purported to find such a possible association was a fraudulent study by Wakefield, which has since been retracted.

Numerous independent reviews of the available evidence have agreed that there does not appear to be a link between MMR and autism. The IOM review goes into depth, arguing that there is an absence of biological plausibility and no epidemiological association so that the available evidence favours rejection of any hypothesis of a link between autism and MMR vaccine.

We therefore have moderate level evidence, the best we can do given the ethical considerations, of which we can be reasonably certain. This evidence is against the possibility of an association between MMR and autism. Those persons who continue to hold to a belief that



MMR vaccines cause autism do so in opposition to the available evidence, and with no evidence in support of their belief.

The idea that MMR causes autism should be rejected on the basis of the available studies. Since no RCT will be forthcoming, it seems reasonable to continue further epidemiological and case-control studies to provide further strength to the body of evidence regarding this issue.

## (4) Vaccine opposition

### (4.1) The historical roots of the anti-vaccination movement

Ever since the advent of vaccination, which was born with Jenner's cowpox virus inoculation, there has been an anti-vaccination movement. In his book on the history of vaccination, Allen (2007, pp. 64-111) describes this movement in detail: how it started with some dissenting voices; how the movement grew in Britain and opposed the 1871 Vaccination Act which subjected refusers to fines, loss of property or sentence to the workhouse; how objections against vaccinations were a mixture of well-founded criticisms and erroneous criticisms of vaccines; and how the British parliament eventually passed a law in 1898 to allow objectors to forego vaccination. In the face of organized resistance, Britain finally ended mandatory vaccination in 1948.

Of course, these struggles and anti-vaccine movements were all surrounding small pox vaccine. Commenting on the issues surrounding smallpox vaccination in the years leading up to 1948, Allen writes (p. 69):

*"Having struggled for half a century with compulsory vaccination, Britain made peace with the antivaccinators by essentially surrendering to them. In the United States, compulsory vaccination was only beginning, and so was the struggle over it. There was no federal vaccination law, but as the public health movement grew, state laws tightened, and many cities began excluding unvaccinated pupils from schools. These laws and practices galvanized the previously passive resistance to immunization. The more the public resisted, the more stridently the newly empowered public health officials defended the vaccine. The smarter among them understood the need for improvement in the smallpox vaccination. Vaccines were unreliably available, of uncertain origin, and difficult to make safe. They did not always offer good protection. But medicine was not powerful enough to be self-critical, so it persisted in its blinkered unanimity: whatever the dangers and drawbacks of vaccinating, it had to be done, unquestioningly."*

It appears that, both in the UK and the US, anti-vaccination voices and sentiments were initially private and passive, whereas increased pressure to forcibly vaccinate created a more organized and cohesive anti-vaccination movement. In the early days of inoculation, the anti-vaccine movement may have had some legitimacy as the cowpox vaccine was not always safe and not always effective. Not all the concerns raised by the anti-vaccine movement were correct, though. These included that smallpox was an "impurity of the blood" which does not need vaccination but sanitation; that vaccination is unnatural; that vaccines only work by causing blood poisoning; that smallpox was easily preventable and curable by simple lifestyle measures (Allen 2007). There was also a strong focus on taking personal responsibility for oneself and control over one's own health. Allen writes (p104) "The antivaccinists were fueled by a spirit of rebelliousness, a sense of being right and outside the law."

The anti-vaccine movement in the UK and the US were quirky mixtures of legitimate objections and false claims, of fact and fiction, of the conceivable and the bizarre, intermingled with a sense of personal control and personal rights. It is hard to condone such a strange movement with such strange components. Still, vaccine refusal was the only weapon that ordinary people had to defend themselves against a procedure where risks and benefits were not always clear. Thus, resisting forced vaccinations in that time period seems reasonable, given the value of hindsight.

It is evident that the anti-vaccine movement has a long history and a complex heritage. Against the backdrop of the medical system of the 1800's, the anti-vaccine movement may have had some legitimacy. The contemporary medical system, however, is very different from the one that existed when cowpox inoculations were first performed. Contemporary vaccinations are safe and effective, and contemporary medicine is self-reflective and self-correcting. Taking the MMR vaccine as an example, conclusive evidence exists of its safety and efficacy, making it an outstanding intervention to prevent the dreaded complications of measles, mumps and rubella. The legitimacy of the anti-vaccine movement in the present vaccine age is therefore in serious doubt.

Despite the overwhelming evidence for the safety and effectiveness of contemporary vaccines, the anti-vaccination movement still exists and is very vocal in its opposition, particularly against the MMR vaccine. Given the evidence, these objections may appear hard to understand. Recent publications in the scientific literature have provided some insight into the contemporary anti-vaccination movement.

## **(4.2) The contemporary anti-vaccination movement**

As described in a previous section, sensationalized and irresponsible media coverage of Wakefield's fraudulent study has been responsible for a dramatic increase in concerns regarding vaccines and consequent decreased vaccination rates, particularly so for MMR vaccination. Recently, however, the Internet has become more prominent in spreading and maintaining anti-vaccination groups and their beliefs. This is borne out by three recent studies that have looked at the role of the Internet in the present day anti-vaccination movement. I shall briefly discuss these three relevant papers, mentioning their main findings, and then summarize some important conclusions that have important implications for those who seek to engage with anti-vaccine views.

### **(4.2.1) Kata 2010**

Kata shows in this paper that the anti-vaccination movement has in recent times created a visible presence on the internet, and that they use the internet to disseminate their ideas. This is to be thought of against the background of a contemporary culture that relies heavily on the Internet for health information. Kata cites statistics that 75-80% of Internet users search for health information using the Internet, and 70% of these indicate that the information on the

Internet influences their healthcare decisions. Furthermore, 52% of users believe that most of the health information they access on the Internet is true and accurate. It has also been shown that parents who decline vaccinations are more likely to have gained information on vaccination from the Internet, and that they use certain anti-vaccination websites.

Kata performed vaccination related searches on Google.com and Google.ca, and analyzed the content of the websites so retrieved. American searches overall returned 24% anti-vaccine information, and Canadian searches 6%. Certain search terms retrieved much higher rates of anti-vaccine websites, such as the term “vaccination” returning 71% anti-vaccination results.

The websites abounded in emotive appeals, featuring pictures of injured children and of scary needles. Main themes were:

- Denying safety and effectiveness of vaccines. For example, this includes claims that vaccines cause Sudden Infant Death Syndrome, autism and asthma. There are also claims that vaccines do not confer immunity and actually weaken the immune system. Another common claim is that the vaccine-preventable diseases such as measles and smallpox are actually not harmful, and that these diseases were already disappearing before vaccines were created.
- Promoting alternative medicine and alternative views of health. This includes ideas such as “moving back to nature” and using more natural ways of treating illness. There is a large scepticism in these posts towards science and the scientific method.
- Focus on civil liberties. A number of the websites contain allegations of totalitarianism and government control, and encouraged parents to take up their rights and protect their children.
- Conspiracy theories or “search for the truth”. All the anti-vaccination websites had some component of conspiracy theory. This included the idea that important information is systematically being hidden from the public by government agencies and/or pharmaceutical companies. Typically people like Andrew Wakefield is seen as a martyr who dared to stand up to the system.
- Religious themes. Only 25% of the websites cited religious arguments against vaccination, such as God making a perfect immune system and using vaccines therefore being an affront to God.
- Falsehoods and incorrect information. Misinformation was found to be widespread, on at least 88% of anti-vaccination websites analyzed. This included half-truths and blatant falsehoods. There were many claims that were not evidence based, such as that polio is caused by sugar. Interestingly enough, the Wikipedia vaccination page contained no misinformation and was the most accurate of all the websites viewed. Kata argues that this is probably because of the way Wikipedia works, where all users can edit content. This created a sort of informal “peer-review”, where errors and misinformation was corrected by users.

- Emotional appeals. Many of the websites contained emotionally laden stories and appeals, meant to sway opinion by use of emotion. This would be something like “do what is best for your children by protecting them from these harmful vaccines”.

Three main themes emerge from the analysis of the websites. They are:

- 1) Belief in and promotion of alternate models of health. This includes rejection of biomedicine, and focus on combination of “natural” views and mind-body-spiritual type views.
- 2) Parental autonomy and responsibility. Parents are encouraged to be “experts” on their own child and take responsibility for their own child, against a healthcare system that does not care.
- 3) Suspicion of expertise. The anti-vaccination movement propagates the idea that the healthcare system is not trustworthy, and that “experts” should be viewed with suspicion.

Kata argues that these themes are part of a view of the world that may be thought of as postmodern. Typically, adherents of a postmodern view would seek alternate explanations for illness, not limiting themselves to “evidence” or “facts”. The postmodern view also is skeptical of truth-claims, of experts, and of authority figures. Many of the arguments are that parents themselves are the experts, and that parents should educate themselves in order to not be taken in by the perspectives of the “expert” or “authority”. Postmodernism does not accept one version of the truth; therefore the misinformation and misleading statements in the anti-vaccine movement is not seen as false, but rather as their version of the truth.

Thus, Kata argues that it is not effective to try and combat the anti-vaccine movement solely with education or arguments based on scientific data. These types of approaches are seen either as part of a conspiracy, or is seen as “your version of the truth”. Education and evidence therefore does not remove “my version of the truth”. Thus, although education is important, it really is not enough to remove the arguments typically forwarded within the anti-vaccine movement.

#### **(4.2.2) Kata 2012**

In this paper, Kata does a follow up analysis of the anti-vaccination movement, specifically on the Internet. Since the previous paper, the Internet has become much more focused on user-generated content, called “Web 2.0”. This means that information is readily shared and accessed through social media sites and other ways of user-generated content such as posted videos and comments.

The main content of anti-vaccine messages includes various strategies, such as shifting hypotheses, censorship of pro-vaccine information, attacking critics, misinformation and misrepresentations of science. There are also certain often repeated tropes, such as “I am not against vaccines, I am for safe vaccines” and that “vaccines are unnatural”. These approaches are usually in the form of compelling narratives and are not based on scientific evidence.

Kata argues that the contemporary medical paradigm is postmodern, and this means shared decision making instead of medical authority, emphasizing values in conjunction with evidence

and prioritizing risk over benefit. Web 2.0 plays an important role in this. Users can access health information on their own, and educate themselves at “the University of Google”. Many think of this as the empowered patient. The trouble, however, is that not all the information is reliable and that many users have no way of distinguishing reliable from non-reliable information. Kata argues that the contemporary medical paradigm is one where authority is not always trusted, anyone can be an “expert”, and suspicion towards science.

Mainstream media, such as news and television, have now swung away from the anti-vaccine messages and recently are against the anti-vaccination movement. Yet, the anti-vaccination movement thrives and flourishes online through various social media sites. They form their own communities, in which the mentioned anti-vaccination messages are shared and distributed.

It is once again clear in Kata’s analysis that the anti-vaccination movement embraces a postmodern view. This means they are skeptical of authority and experts, there are many different truths, facts and evidence are less important than narrative and belief/values. Kata therefore argues again that education and correcting of flawed arguments, though important, are not enough engage the anti-vaccine movement. The anti-vaccination paradigm is sceptical of a scientific paradigm, and views evidence and facts as “just another opinion”.

### **(4.2.3) Bean 2011**

Bean also analyzed anti-vaccine content on the Internet. Similarly, it was found that anti-vaccine websites are plentiful. On such sites, safety and effectiveness of vaccines are denied, there is a focus on civil liberties and totalitarianism from government, there are alternative explanations for sickness and health and there is a large focus on conspiracy theories.

A new theme identified is an increase in anti-vaccine testimony that is alleged to be from physicians. This can persuade people who are otherwise uncertain or on the fence, since it brings in a supposed “expert view”. This is rather ironic, since the anti-vaccine movement is sceptical of authority but seems to embrace those expert and authority figures that supposedly agree with their point of view.

Bean argues that vaccine refusers are often well-meaning parents who want the best for their children, and who are confused by the anti-vaccine messages. Such people attach value to the opinions of their social group, those people with whom they share commitments. “The people they trust, naturally enough, tend to be the ones who share their worldview.” Thus, taking this argument Bean forwards, the healthcare provider who wishes to address concerns with the parent will need to be in a position of trust.

Secondly, Bean shows that anti-vaccine messages are typically in narrative form, with substantial emotive appeal. Such messages are compelling for emotional reasons. Merely trying to combat such messages through evidence is not enough. Bean suggests that narrative and emotive components also be incorporated in pro-vaccine messages. This would mean that sound scientific evidence be communicated in a way that is gripping and narratively interesting. As an

example, Bean mentions a video on the CDC parents' portal, where parents have a conversation with a pediatrician regarding their vaccine fears.

#### **(4.2.4) Summary and conclusions**

Whereas the post-Wakefield MMR scare was largely created and sustained by mainstream media, the anti-vaccine movement now relies on the Internet for its existence. Anti-vaccine messages abound on the Internet, are readily accessible, and influence the actions of those who are uncertain regarding vaccinations.

The anti-vaccination movement now relies a lot on user-created content and social media/social networking. The movement also embraces a view of the world that is suspicious of biomedicine, scientific evidence and experts. There is also a sustained belief in conspiracies and government totalitarianism. All of this means that health authorities are not trusted by adherents of the anti-vaccine movement. Furthermore, anti-vaccine adherents typically reject biomedical evidence in favour of alternate views of health and illness.

Engaging with anti-vaccine messages is more complex than merely correcting poor arguments or providing evidence and education. Anti-vaccine messages embrace a completely different view of the world, one that Kata describes as post-modern, where there are many different "truths" and where facts are "just one more opinion".

Two factors seem to be important in correcting anti-vaccine messages or in engaging with parents who have been the subject of such messages. One is the building of trust; being a figure of trust is essential in being taken seriously by such parents. Another is the use of narrative and emotion in a way that aids the communication of evidence and education, techniques that engage the recipient. The idea is not to be deceptive or to appeal to emotion, but rather to make it easier for people with an alternate view of the world to engage scientific evidence. These approaches may be helpful in correcting the erroneous messages and the way in which they are presented on the Internet.

## **(5) What influences parental decision making on vaccination?**

A systematic review concludes that vaccine refusal was often associated with concerns regarding safety and effectiveness of vaccines, dissatisfaction with vaccine information provided through health resources, and lower trust in the government and healthcare system (Brown et al. 2010). Also, some studies showed that media reports influenced opinion. Rather than official sources, other parents were more likely to be trusted because they were thought to have no agenda. The authors argue that fostering trusting relationships between healthcare providers and parents is important. They also argue that efforts at correcting vaccine refusal should be multifactorial, but that it should not antagonise vaccine refusers on issues that they strongly hold to – this may lead to an increased anti-vaccine stance. Therefore, it seems that an individualized approach is needed, and that trusting relationships between providers of healthcare and parents are important in addressing vaccine refusal. The authors also warn against changing current approaches too much: using current approaches, vaccine uptake is actually quite high. Any new methods incorporated should be such that it would not decrease vaccine uptake in those who already accept vaccination. Thus, to reach vaccine refusing parents tailoring an individualized, multi-factor approach with a large focus on trust relationships between individual providers and parents seems key (Brown et al. 2010).

A recent randomized control study studied educational interventions and their effect on parental attitudes towards vaccination (Nyhan et al. 2014). The four interventions studied were (1) information explaining the absence of evidence for a link between MMR and autism, (2) written information of the dangers from vaccine preventable diseases, (3) images of children who have vaccine preventable diseases and (4) a dramatic narrative type educational intervention about a baby who was close to dying of measles. This trial found that the educational interventions corrected misconceptions regarding MMR, but it actually decreased parental intent to vaccinate in those parents who started out with low intent to vaccinate. Also, images of sick children and a dramatic narrative increased concerns about vaccine side effects. Thus, these types of educational interventions do not seem to alter unfavourable parental attitudes towards MMR, but rather to strengthen them. Parents who start out with moderate or favourable views of vaccination may benefit from educational interventions of the kinds mentioned, but anti-vaccine parents are likely to be strengthened in their resolve not to vaccinate by such educational interventions.

Another study conducted focus groups with mothers of infants, and exposed these mothers to typical pro- and anti- vaccine messages they may encounter (Leask et al. 2006). Mothers in these groups were surprised and concerned by the anti-vaccine messages, but could quickly mitigate these anti-vaccine messages and regain their favourable view of vaccines through a variety of techniques. This included trust in physicians or healthcare providers, specifically related to personal experiences. Family physicians specifically seemed to play an important role in vaccination decisions and in negotiating risk. Other techniques used by mothers to dispel anti-vaccine messages were typecasting of vaccine opponents, anticipation of regret over not



immunising, being a good parent and social responsibility. Core influences were doctors, social networks and personal experience in seeing the vaccine-preventable diseases.

It seems therefore that parents can be influenced by anti-vaccine messages in the media and on the internet, and that those parents who refuse vaccination are more likely to be influenced by such messages. It also seems as if educational interventions correcting misinformation on vaccines can strengthen anti-vaccine attitudes in those who hold unfavourable views on vaccination. An important factor that protects parents against anti-vaccination misinformation is trust in a healthcare provider. Those who trust their healthcare provider and who have had positive experiences with a provider explaining vaccination information seem relatively protected against vaccine misinformation.

It would seem that two things are important in educating parents. One is ensuring that correct information on vaccination is portrayed in the media, in ways that engage parents. A second is fostering trusting relationships between parents and healthcare providers. The role of a family physician seems particularly important in this regard, and it underlines the importance of relationship-centered care in contemporary healthcare.

## (6) Summary

- Measles vaccine, whether single dose or combined MMR vaccine, is effective in preventing measles infections. One dose of MMR after 12 months of age is 95% effective in preventing measles, and two doses over 99% effective.
- The most common adverse effects of measles vaccines are not concerning and are transient: rash (5%), joint pain (25%), fever (5-15%), and febrile seizure (slightly increased risk).
- The serious adverse effects of MMR are very uncommon. Thrombocytopenia (1 per 30,000 doses) is transient and usually passes with no complication. Anaphylaxis and other allergic reactions (less than 1 per million doses) are very rare. It is unclear whether MMR truly causes encephalitis, but if it does it is extremely rare (estimated 0.22 cases per 1 million doses).
- Epidemiological evidence and various other studies indicate that there is no association between autism and MMR vaccination. Independent authoritative reviews of the evidence by various organizations have concluded that the evidence is against any association between MMR and autism.
- The benefits of MMR vaccination are sizeable, far outweighing any risk from vaccination.
- The mainstream media played a large role in creating and sustaining the MMR controversy after the publication of Wakefield's article. This led to a decrease in MMR vaccination rates, which directly led to the return of measles as endemic disease to the United Kingdom.
- The anti-vaccination movement now largely depends on the Internet to spread its ideas. Anti-vaccination messages depend on an alternate worldview that is sceptical of facts, evidence, authority and scientific explanations of health. Central to anti-vaccination messages is the idea of a conspiracy and untrustworthiness of health providers and health systems. Recently the anti-vaccine movement has moved towards using social media and user-generated content.
- Educational messages from public health to correct misinformation on vaccination can benefit those who have moderate or favourable views of vaccines, but they increase anti-vaccine attitudes in parents who have unfavourable views of vaccination.
- Some authors have suggested using narrative and emotive content when presenting pro-vaccine messaging. Although this has its place in helping parents engage with evidence, one should guard against solely using emotive appeals. This could alienate parents who are successfully reached by current approaches. Best is the use of multiple methods, focused on multiple populations. It is best to know the population at which the intervention is aimed, rather than a one-size-fits-all approach.
- A trust relationship with a healthcare provider is key. Such a relationship can protect parents against misinformation, and can be a source of credible vaccine information. Specifically the role of family physicians seems important.

- Since it is known that the mainstream media have influence over the opinions and beliefs of parents regarding information, the media have a responsibility to ensure that their information is reliable and truthfully presented.

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## Chapter 4: The principlist approach of Beauchamp and Childress

To analyze the ethical aspects of measles vaccination in children, I shall make use of the approach to bioethics espoused in *Principles of Biomedical Ethics* by Beauchamp and Childress (B&C) (Beauchamp & Childress 2013). This approach, which I shall refer to simply as principlism, has been extremely influential in the field of bioethics, and specifically B&C's work in this regard. This fact is even acknowledged by the opponents of principlism; take as an example the following, from authors that are highly critical of principlism:

*"This approach is taken by most bioethicists, but all three of us regard Beauchamp and Childress's Principles of Bioethics (in its various editions) as the field's most influential book espousing principlism"* (Green, Gert, & Clouser 1993, p. 477).

Another author, writing on the debate surrounding principlism, states the following:

*"Widely regarded as the most popular and influential product in the current bioethical marketplace, principlism – as it has come to be known – is perhaps best exemplified in Beauchamp and Childress's Principles of Biomedical Ethics (1994)"* (Davis 1995, p. 85).

The principlist approach of B&C is widely used, extremely influential, and has shown staying power. I consider it to be a good framework to use to analyze the ethical issues at stake in specific cases, as well as to address practical problems in bioethics.

In this chapter, I shall examine the principlism of B&C. This will be done as follows.

- (1) Provide a brief overview of the principles and the method of B&C.
- (2) Examine the grounding of the principles and the idea of the common morality.
- (3) Consider some important criticisms of the principlist approach, and the responses to these criticisms.
- (4) Use of the principlism to approach measles vaccination in children.

In section 4, I will outline how principlism will be brought to bear on the issue of measles vaccination in children; this will lay the foundation for the work of the next few chapters, and indicate the method I will use in going forward to reach my eventual conclusions.



## (1) The principlism of B&C

Although the main text in this regard is B&C's *Principles of Biomedical Ethics* (Beauchamp & Childress 2013), both authors defend and expound on their work in other places as well. Notably, Beauchamp wrote a number of essays that have been collected into one volume, *Standing on Principles* (2010a), and Childress wrote an essay that has been published in *A Companion to Bioethics* (Childress 2001).

### (1.1) The central idea

The central idea in B&C's work is that there is a set of four principles that can be used to analyze and approach bioethical concerns. They are: (1) respect for autonomy, (2) beneficence, (3) non-maleficence, and (4) justice (Beauchamp & Childress 2013, p. 13; Beauchamp 2010b). These four principles are general guides for action, and are described by B&C as a "starting point" for bioethics (Beauchamp & Childress 2013, p. 13), central to bioethics, and as the foundation for many other moral judgements and justifications [Beauchamp & Childress 2013, p. 13; Beauchamp 2010b, p. 36].

It is important to note that these four principles are thought by B&C to be binding on all persons engaged in biomedicine, everywhere. B&C claim that these four principles are derived from the common morality; that is, a set of moral norms that is agreed upon by all persons who are serious about living a moral life (Beauchamp & Childress 2013, p. 3-5, p. 13-14; Beauchamp 2010b, p. 43-44). The common morality is the result of a series of universally recognised and accepted intuitions that, according to B&C, all moral agents in all cultures adhere to and identify with. The common morality is not only recognized by all persons committed to morality, but is also binding on all persons everywhere. It is a universal morality with universal binding force. Because the four principles are derived from the common morality, they are binding on all persons engaged in biomedicine everywhere. Another important implication of this idea is that the principles are binding no matter what ethical theory one adheres to. Adherents of differing moral theories all recognize the validity of the four principles of bioethics, because everyone recognizes the force of the common morality. Consequently, the principlist approach provides a means for proceeding with ethical deliberation even when persons disagree in theoretical matters. People from different backgrounds and persuasions find common ground in the principles of bioethics, and can jointly work towards resolving moral problems by use of the principlist approach. The principlist approach therefore fosters agreement and common ground, and provides a framework to use in interacting with bioethical principles even when people disagree on ethical theory. I shall return to the idea of the common morality and the universal nature of the principles in more detail a little later.

In short, the four principles form a basic summary of the ethical obligations resting on those who within biomedicine and biomedical research, and can be used to analyze ethical issues

within all spheres of biomedicine and related fields. What is remarkable in this regard, is that our moral intuitions cannot be “summed up” or reduced to a *single* moral principle, as some of B&C’s critics insisted it ought to do (more about that later). There are not *one, two, three, five*, etc. such principles, but *four*. That, according the authors, is an empirical fact and one that we simply must live with, until such time as an analysis of the common morality yields an entirely different, yet adequately argued and demonstrated result.

Consider this passage written by Beauchamp:

*“The principles are understood as standards of conduct on which many other moral claims and judgments depend. A principle, then, is an essential norm in a system of moral thought and one that is basic for moral reasoning. More specific rules for health care ethics can be formulated by reference to these four principles, but neither rules nor practical judgements can be straightforwardly deduced from the principles”* (Beauchamp 2010b, p. 36).

Two of their four principles are historic or traditional principles, which have been historically recognized as central to medical ethics. These are beneficence and non-maleficence. Non-maleficence has a long history within medical ethics, usually associated with the oft-quoted adage *primum non nocere* – “first do no harm” (Beauchamp 2010b, p. 38). Both beneficence and non-maleficence find expression in the Hippocratic tradition of medicine and the Hippocratic Oath (Beauchamp & Childress 2013, p. 150). Thomas Percival’s 1803 publication on medical ethics, considered to be the first modern account of medical ethics, also contains an account of these two principles (Percival 1803). Percival presented beneficence and non-maleficence as the two main ethical obligations of the physician, even arguing that a patient’s wishes should be overridden if the patient’s wishes were to conflict with the physician’s duties of beneficence and non-maleficence. B&C acknowledge and incorporate the two historical principles of beneficence and non-maleficence in their principlist approach to bioethics (Beauchamp & Childress 2013, p. 13; Beauchamp 2010b, p. 38]. In addition to these two historical principles, B&C’s account contain two newer ones: justice and respect for autonomy. Recognition of the principles of justice and autonomy developed throughout the 20<sup>th</sup> century and after, so that contemporary principlism contains four principles of bioethics: beneficence, non-maleficence (the two Hippocratic/historical principles), autonomy, and justice (the two newer principles that developed during and after the 20<sup>th</sup> century).

In two essays on the development of the principles and the Belmont report, Beauchamp describes the historical context for these principles (Beauchamp 2010c; Beauchamp 2010d). The principles in the Belmont report and the principles in *Principles of Biomedical Ethics* developed side by side, one influencing and informing the other. Beauchamp was involved in both these projects, and these ideas therefore necessarily influenced each other. Whereas the Belmont report focused specifically on principles that would govern research ethics, B&C’s work in *Principles* had a wider scope, and sought to set our principles that would form the foundation for all bioethical matters. The background is important though. Public outrage in the face of various abusive research practices, such as the Tuskegee syphilis study, gave rise to the National

Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Beauchamp 2010c; Beauchamp 2010d). The National Commission was tasked with developing guidelines and ethical principles that govern biomedical research. One of the important documents that was produced, was the Belmont report, with the full name of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Belmont report identified three ethical principles, meant to protect research subjects: respect for persons (treating people as autonomous agents and protecting those without autonomy), beneficence (protecting the well-being of participants) and justice (ensuring equitable distribution of research burdens and benefits) (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). Beauchamp was a leading figure in the development of the Belmont report, and it is easy to see how the ideas in the Belmont report and in *Principles* developed side-by-side. When *Principles* was completed, B&C included the two newer principles of autonomy and justice alongside the traditional medical ethics principles of beneficence and autonomy.

## **(1.2) The four principles**

Beneficence describes the moral obligation to work towards the benefit of others (Beauchamp & Childress 2013, p. 203-248; Beauchamp 2010b, p. 39-41). Thus, in bioethical terms, to say that a healthcare provider has a duty of beneficence means that the provider has the duty to provide benefits to their patients. These benefits can be varied, but are usually understood to mean benefits appropriate to the role of persons engaged in biomedicine; that is, promoting health and healing, diminishing suffering, treating pain and so forth. Providers who are actively working to further the best interests of their patients in keeping with the scope of biomedicine are said to be acting in accordance with the principle of beneficence. Basically stated, beneficence means furthering the patient's best interest through the practice of biomedicine. It is the simple yet noble notion of "helping people".

Non-maleficence is the moral obligation to avoid doing harm (Beauchamp & Childress 2013, p. 150-201; Beauchamp 2010b, p. 38-39). It places an obligation on persons engaged in the practice of biomedicine to consider their conduct in the light of potential harm that might result, and to avoid such actions that may lead to harm. Whereas the principle of beneficence includes taking action to remove harm and remove suffering, the principle of non-maleficence is more to be thought of as placing a prohibition on actions that would result in harm. There is thus a distinction in scope and intent of these two principles. Yet, it seems that there are some areas of overlap and that the distinction is not always as clear. In general, the principles of beneficence and non-maleficence seem to act in unison in placing an obligation on those practicing biomedicine to further the best interests of their patients through removing and avoiding harm while providing benefits where possible. Of course, it is not always possible to do "no harm." Performing surgery is quite harmful, and can even be quite violent. It was also recognised as such in the Hippocratic

tradition of medicine; hence the strict ban on surgery in the classical Hippocratic Oath. The question is whether the risk of harm is justified by the benefit of the action. Taking an antibiotic may cause harm through adverse effects, but if the benefit through the healing action of the antibiotic is necessary to save a life, it is thought that the risk of harm is acceptable. Non-maleficence does not in such cases prohibit the use of surgery or the use of antibiotics because it may cause adverse effects. It should therefore be said that non-maleficence asks of persons in biomedicine not to do “net harm” or “overall harm”. Thus, correctly understood, the principle of non-maleficence does two things. First, it provides a check on actions of persons involved in biomedicine. Persons in biomedicine should consider their actions and if it is so that their actions would lead to harm, such actions are prohibited through non-maleficence. Second, those involved in biomedicine may not do “overall harm” or “net harm” when the sum of the result of actions are considered. Whenever a treatment or project is undertaken and it is clear that there are possible resultant harms, it should be that the net end result is not overtly harmful. Furthermore, when potential harms can be foreseen, the potential harm has to be justified. Persons in biomedicine cannot accept inflicting potential harms unless morally justified. Thus, the principle of non-maleficence provides an ethical check on the actions of persons within biomedicine. They may not cause overt or overall harm, and when it seems that harm may result from a certain course of action that harm must be justified, as in the case of life-saving surgery that may result in adverse effects.

The principle of Respect for autonomy (autonomy) refers to the obligation on persons within biomedicine to respect the free decisions of patients themselves (Beauchamp & Childress 2013, p. 101-147; Beauchamp 2010b, p. 37-38). The idea is that people should be given the freedom to make their own decisions with regards to their healthcare and best interests without coercion or interference. B&C argue that the principle of autonomy encompasses a negative and a positive obligation (Beauchamp & Childress 2013, p. 107). The negative obligation is to avoid controlling or manipulating the free choices of persons. In other words, providers may not place obstacles in the way of the free choices of individuals. The positive obligation is to promote autonomous decision making. For example, this may mean disclosing information that is relevant to the decision making of the person in question, or explaining relevant treatment options and outcomes in ways that make it possible for the person to decide freely. Thus, health care workers not only have the obligation to avoid burdening the free choices of individuals through coercion and manipulation, they also have the obligation to promote the capacity of individuals to decide for themselves through relevant disclosure and explanations. Of course, the principle of autonomy rests on the assumption that a person is capable of making decisions for themselves. This requires the ability to understand the options before them, to engage in a process of reasoning and to eventually choose the option that they deem to bring about their desired goals. The capacity to engage in this sort of activity is a necessary requirement for autonomous decision making. Many of the challenges posed by autonomy happen when a patient lacks this capacity, or when there are doubts as to a patient’s capacity to make their own decisions.

The principle of justice refers to ensuring that people are fairly treated with regards to what is owed them (Beauchamp & Childress 2013, p. 249-293; Beauchamp 2010b, p. 41-42). Thus, justice requires that people are treated in accordance with what they deserve; to be treated justly is to get what is rightfully yours. Distributive justice in the bioethical context, specifically, refers to a fair distribution of burdens and benefits within society. This means that people get the benefits that they deserved, based on criteria of desert, and that patients are not recipients of undeserved or undue burdens. Drawing on Aristotle, B&C formulate a “formal principle of justice”: equals must be treated equally, and unequals must be treated unequally. But how to determine the criteria for desert, how to determine who are equals and in what sense, is controversial. To specify criteria for a just distribution, one needs a material principle of justice. Such a material principle of justice identifies the relevant properties of desert, and specifies how distribution should happen in accordance with these properties. B&C identify six different material theories of justice, each of which specifies a set of criteria along which a just society distributes benefits and burdens.

Thus, substantial controversy and disagreement can arise as to what exactly constitutes a just distribution of, for example, medical benefits and burdens. Proponents of a specific theory of justice could disagree completely with proponents of alternate theories of justice, while each party claims the authority of the principle of justice as providing justification for their own conclusions. This is a serious shortcoming in the explication of this principle. B&C’s solution is to appeal to qualities of all the different conceptions of justice. They argue that none of the different theories of justice are perfect or complete, each having a set of defects. Yet, each theory of justice highlights something of importance in understanding the principle of justice, and therefore each of these different theories can be used in the making of health policy. Over time, health policy will sometimes emphasize one theory of justice and at other times other theories of justice. It appears as if B&C mean to say that the different theories of justice can be used together. Rather than viewing them as opponents of one another, one can use features of each in addressing problems of distributive justice within society, in a sort of a “mixed use” of the varying principles (Beauchamp & Childress 2013, p. 293; Beauchamp 2010b, p. 41). It is not quite clear how this is to be done, or how to avoid arbitrarily appealing to the theory of justice that happens to suit one’s fancy in the particular circumstance. For my present project, this is a problem to take seriously. I shall show that the main material theories of justice in the B&C account can be brought into agreement on the subject of measles vaccination in children. Consequently, I will be able to claim the support of the principle of justice for my eventual conclusions, without being dogged by the nagging doubt that one or two alternate theories of justice do not line up with my conclusions.

### **(1.3) Specification**

The principles are general guides for action, and confers duties on persons engaged in biomedical matters. But these principles are very general, and in their general forms lack the focus and specificity required to provide specific guidance for specific situations. The general principles are meant to be used to formulate specific action guides that provide ethical guidance in specific situations. That is to say, in order to give concrete guidance to actions, these general principles need to be further specified. Specification means that the vague nature of these moral norms are reduced by giving them concrete content that can be used to guide actions (Beauchamp & Childress 2013, p. 17; Beauchamp 2010b, p. 45). For example, the principle of non-maleficence is too vague in itself to guide action when confronted with a questions in end-of-life decision making. The physician knows the principle states not to do harm to the patient; but in order to know how to ethically proceed with care, the physician needs to know what would constitute a harm in this situation, and how best to avoid it.

Specification can take the form of narrowing the scope of the norms, by answering the questions “where, when, why, how, by what means, to whom, or by whom the action is to be done or avoided” (Beauchamp & Childress 2013, p. 17; Beauchamp 2010b, p. 45). Specification furthermore adds information to the general principles, to clarify the norms in specific contexts. So, for example, autonomy may be specified in a specific context to say, “Respect the autonomy of persons when they become incapacitated by following their advance directive” (Beauchamp & Childress 2013, p. 17; Beauchamp 2010b, p. 46). This creates a clear ethical action guide for a concrete situation by specifying the implications of the principle of autonomy for a specific set of circumstances. If further specification is needed, progressive specification can continue until a clear action guideline emerges. The proviso is that there must be a visible connection between the specification and the original principle all the way through (Beauchamp & Childress 2013, p. 17; Beauchamp 2010b, p. 46).

Elsewhere Beauchamp explains that specification augments indeterminate moral principles by supplying them with specific moral content. Specification adds details that removes conflict and incompleteness from generalized rules and principles. Thus, principles are “explicated and made suitable” for application to certain situations, by developing concrete rules or policies through a process relying on moral judgement and decision making (Beauchamp 2010e, p. 157).

### **(1.4) *Prima facie* versus actual obligation and weighing of principles**

Each principle confers an obligation on a person engaged in biomedicine. But how do we know when a specific principle is applicable to a specific situation, and what do we do if the different principles demand different courses of action? Before I consider these questions, I will take a step back and briefly introduce the work of W.D. Ross. The work of Ross has influenced the

development of B&C's principles, and particularly the idea of resolving conflicts between principles (Beauchamp 2010b, p. 44).

## The work of Moore and Ross

Ross advances a theory of ethics based on the work of GE Moore. Moore has theorized that we intuitively recognize the property of "good" when it is attached to a specific thing or set of circumstances, and that right action consists in maximizing good (Moore 2004). Moore argued that the term "good" can never be defined in some naturalistic sense. For example, utilitarians would define "good" as "that which produces the most happiness". But, then it would be to say "good is the greatest happiness", which is to say "the greatest happiness is the greatest happiness", which is essentially meaningless. Another way to think of this is the following. We may say that "good means to promote happiness". But then, if we are faced with a specific circumstance, we may ask: "we are now creating happiness; but is it good?"

Moore is particularly interested in what the term "good" – the fundamental category of morality and ethics – denotes. He claims that "good" is one of the simple, indivisible notions/qualities (like "yellow") in the world that are *indefinable*. To say "yellow is that which produces a certain vibration in the light", or that "good" is "that which produces pleasure", is not to define these terms. When the effects of a simple property are confused with the property itself, we see the "naturalistic fallacy"

Moore's point is that if the utilitarian definition of "good" is correct, the question "is happiness always good?" would be a tautology, since it would amount to the question: "is the good always the good?" Moore's point, however, is that the question "is happiness good?" is *not* a tautology; in fact it is a quite meaningful question. That demonstrates that "the good" cannot be equated or reduced to something else, like happiness. What the good is, is something that we simply intuitively know. In this sense the term "good" is indefinable. Yet, although it is indefinable, we have a pretty good idea of what "good" is. It's one of the "irreducibles" of language in terms of which other definitions are constituted.

Thus, Moore argues that ethics is concerned with the study of the good; and that "good" is an indefinable, non-naturalistic property that is present to a greater or lesser degree in different sets of circumstances. Humans can look at a set of circumstances and judge how much "good" is present in it by direct judgement (Moore 2004, p. 36,148). In this sense, it is like the property "yellow". "Yellow" may be defined as the physical effects of certain light-vibrations on the eye (Moore 2004, p. 10). But that is not what is meant when we say something is "yellow". Humans do not perceive light vibrations when they look at a yellow object – they simply see a yellow object. These light vibrations are "what corresponds in space with the yellow we perceive." Similarly, "good" is a property of some sets of circumstances that we can recognize when we see it. Describing instances of good or things that are good, such as pleasure or happiness, does not constitute a definition. Thus, on Moore's theory, good is an indefinable non-naturalistic property that we can recognize when we see it. Right actions, then, are those actions which cause more

“good” to exist – “Our ‘duty’, therefore can only be defined as that action, which will cause more good to exist in the Universe than any possible alternative” (Moore 2004, p. 148). Thus, judgements about what is “good” is made intuitively, seen directly as being self-evidently “good” (Moore 2004, p. 148); and duty then consists in those actions that brings about the greatest amount of this intuitively recognized “good”.

Moore’s theory is therefore a form of intuitionism. That is, we as humans can directly and intuitively see how much good is present in a situation, and how much more good will be present if we bring about a different set of circumstances through performing our duty. Ross accepts Moore’s theory as “attractive” (Ross 1930, p. 16), and formulates it as follows: “that what makes actions right is that they are productive of more *good* than could have been produced by any other action open to the agent” (Ross 1930, p.16). Ross, however, expands Moore’s theory substantially. Being critical of Moore, he writes that Moore’s theory simplifies the relations in which we stand. Specifically, Moore’s theory conceives of all people as merely “being possible beneficiaries by my action” (Ross 1930, p. 19). But, this is not the only morally significant relationship in which a person stands. A person may stand in different relationships that may confer different duties; Ross recognizes the following: promisee to promiser, creditor to debtor, wife to husband, child to parent, friend to friend and fellow countryman to fellow countryman (Ross 1930, p. 19). A person who stands in any of these relationships is in a position to bring about good in a way that other persons can’t. These relationships create special avenues for bringing about the maximal amount of good, and therefore each of these relationships create a special obligation or a specific duty.

Ross argues that each of these relationships creates a *prima facie* duty (Ross 1930, p. 19). That is, each of these confers a duty which is at first glance binding. This duty should be discharged if it is not overruled by some other duty or morally relevant set of circumstances that negates the *prima facie* duty (Ross 1930, p. 19-20). So, one’s *actual* duty depends on the interplay of the different *prima facie* duties. Ross recognizes the following groups of *prima facie* duties (Ross 1930, p. 21):

- (1) Duties that rest on previous acts of my own (those resting on a promise or an implicit promise, or those resting on a wrongful act I have committed)
- (2) Duties that rest on the acts of others (services performed to me).
- (3) Duties of justice (the duty to upset distributions of pleasure and happiness that are not in accordance with merit).
- (4) Duties of self-improvement.
- (5) Duties that can be summed up in “not injuring others” (non-maleficence).

Ross considers these *prima facie* duties as self-evident in a way that is akin to mathematical axioms (Ross 1930, p.29-30). Mathematical axioms are self-evidently true and are not in need of proof. Rather, one can see intuitively by direct judgement, when apprehending these axioms,



that they are true. But one is not at every stage in one's life able to appreciate this fact. One needs a certain level of cognitive development and "sufficient mental maturity" to appreciate the truth of the axioms. Yet, the axioms are undoubtedly true. The same can be said of these *prima facie* duties. They are self-evidently true, and intuitively seen to be true. They are "as much a part of the fundamental nature of the universe (and, we may add, of any possible universe in which there were moral agents at all) as is the spatial or numeric structure expressed in the axioms of geometry or arithmetic" (Ross 1930, p. 29-30).

Thus, there are two influential themes in Ross's work. One is that there is a set of *prima facie* duties that confers obligations on a person. These obligations are binding and should be discharged, except when they are overruled by another compelling moral reason. So, when different duties are in conflict, one arrives at one's actual duty by weighing the *prima facie* duties against each other. So, Ross states that we all know it may sometimes be necessary for us to break a promise to relieve someone's distress or to lie to protect someone from harm (Ross 1930, p. 28). In these cases, a person's actual duty is determined by weighing the various *prima facie* obligations against each other. The second theme is that one can intuitively see the presence of these *prima facie* duties in the situations and relationships one finds oneself in. It does require what Ross calls "sufficient mental maturity". If one has this capacity, as presumably most adults do, then one can intuitively see these 5 duties impinging on one and demanding certain actions from one. To then arrive at one's actual duty, one has to weigh the different *prima facie* duties.

### ***Prima facie* obligations and weighing in B&C's principlism**

The principles function in practical situations fairly similarly to the *prima facie* duties that Ross describes. A person engaged in some field of biomedicine, finding themselves confronted with a specific situation, will be able to intuitively see which of the four principles are involved in the case. It may be that more than one principle is involved. These principles may even be (and often are) in conflict. Each of the principles confer a *prima facie* obligation on the person. That is, the principles each create a duty that has to be discharged, unless a sufficient moral reason exists to overrule the *prima facie* duty. Should a person have conflicting *prima facie* duties, these have to be weighed against each other to find the person's actual duty.

B&C argue that moral norms can often justifiably be overridden by other moral norms with which they are in conflict (Beauchamp & Childress 2013, p. 15; Beauchamp 2010b, p. 44). For example, we may be morally justified in not telling the truth to prevent one person from murdering another. When principles are in conflict, one has to determine one's actual obligation through a process of weighing the conflicting principles. B&C argue that this distinction of *prima facie* vs actual obligation resembles our moral experience very well, and is in practice an essential framework for resolving bioethical problems (Beauchamp & Childress 2013, p. 16).

Weighing is the process of using supporting reasons to assign relative importance to conflicting principles in a specific situation (Beauchamp & Childress 2013, p. 20). Thus, when one is faced with conflicting principles in a certain situation, weighing involves considering reasons as to why

one of the conflicting principles should be followed over another. Through supplying of supporting reasons and reasoned argument, relative weights are assigned to conflicting moral considerations, until a supportable ethical decision is made.

A distinction between specification and weighing should be highlighted. Weighing is concerned with finding reasons to follow one moral principle over another in a specific instance of conflict. It is more suited to specific cases and practical deliberations. Specification has to do with narrowing the scope of principles and supplying them with additional information that will lead to clear action guides. Specification is therefore more suited to formulating of policies (Beauchamp & Childress 2013, p. 20).

Beauchamp gives the following example of weighing when principles conflict (Beauchamp 2010b, p. 45). Suppose a physician has a patient that works at the same hospital as the physician. The physician knows that this patient has mental health concerns and does not cope with stress well. The patient and fellow-employee is applying for a position at the hospital that would mean a significant promotion for the employee, but it is a very demanding and stress-filled position. The physician knows that the information regarding the employee's mental health concerns are confidential. But, the physician also feels concerned about the effects this promotion may have on the patient/employee. Thus, the physician has conflicting duties: confidentiality (supported by respect for autonomy), beneficence and non-maleficence. Should the physician break confidence in order to protect the health of the patient? Are there other alternatives, such as directly talking with the patient even though this may harm the physician-patient relationship? In order to know how to proceed, a process of weighing should take place. That means finding the action alternatives, seeing which principles support which action alternatives, and finding reasons that would assign relative weight to one principle over another.

Such a process of weighing can be vulnerable to arbitrariness or biases. To prevent this, B&C suggest six conditions that have to be met before one principle can be allowed to overrule another (Beauchamp & Childress 2013, p. 23).

- (1) Good reasons can be offered to act on the overriding norm rather than on the infringed norm.
- (2) The moral objective justifying the infringement has a realistic prospect of achievement.
- (3) No morally preferable alternative is available.
- (4) The lowest level of infringement, commensurate with achieving the primary goal of the action, has been selected.
- (5) All negative effects of the infringement have been minimized.
- (6) All affected parties have been treated impartially.

If these six conditions are met, one principle may be given weight over another so that the actual obligation in the circumstances would emerge.

## **(1.5) Justification in principlism and the idea of reflective equilibrium**

Once we have engaged in a process of specification or weighing, we need to be sure that our judgements are ethically justifiable. This brings in the question of justification – how do we know if a specific judgment or belief is ethically justified?

Justification in ethics refers to showing that there exists sufficient reasons to accept the ethical judgment in question. Our judgments and decisions are ethically justified if we can demonstrate that we have adequate reasons to accept the judgment. These reasons need to be sufficient to support the judgment, and have relevance to the judgment itself (Beauchamp & Childress 2013, p. 390).

B&C argue for a method of justification based on achieving reflective equilibrium (Beauchamp & Childress 2013, p. 404-410). Reflective equilibrium in this sense refers to bringing practical judgments and the four principles in balance with one another in a way that brings about the most coherence possible. It is based on the concept of reflective equilibrium espoused by Rawls (Rawls 1971, p. 19-21, 46-55).

### *Rawls' reflective equilibrium*

Rawls (1971) is engaged in a project of identifying contractual principles of justice based on a hypothetical “initial position” where all persons are called upon to agree on the most just way to distribute societal goods in a situation where these goods will become available in a society in which they do not beforehand know what their socio-economic position will be. In other words, they have to deliberate about what a just distribution of goods will be while they all still are behind a “veil of ignorance”. This initial position is hypothetical, and asks us to imagine all people who are to make up society behind a veil of ignorance, where everyone is equal and no-one knows what their position or level in society is to be. Now, says Rawls, we want to identify the principles of justice that people behind this veil of ignorance would agree to. People who are rational and concerned with their self-interest would want to make sure that whatever principles are chosen to govern the society they are about to enter would ensure the best possible situation for themselves in society. Because no-one knows what position or place they will occupy in society, they would want to ensure that the position of the worst off is nevertheless acceptable; that the worst possible life in society would still be a fairly acceptable life. Thus, says Rawls, people in such an original position behind the veil of ignorance would choose a specific set of principles of justice to govern society. Rawls eventually adopts these principles as the central tenets of his theory of justice (Rawls 1971, p. 60).

However, there is a second way in which to proceed in order to justify the principles coming from the original position. This is to see if the principles that we come up with when we think of the original position match up with our “considered convictions” of justice (p.19). That is, do these principles of justice Rawls have identified match up with our considered practical judgments regarding what is just and what is not? To answer this question, we must compare

these principles with what Rawls calls our considered judgments – the practical judgments we have a lot of confidence in. Thus, does the newly identified principles deliver the same judgements as those intuitive judgments we have a great degree of confidence in? Rawls uses the examples of religious intolerance and racial discrimination. We have a great degree of confidence that religious intolerance and racial discrimination are unjust, and that we are free from bias and swaying influences when we make this judgement. But, there are other things we are much less sure of intuitively – how wealth should be distributed in society or how authority should be distributed, for example (p.20).

So, argues, Rawls, we begin by matching our principles to our considered judgments. If we see discrepancies, we can do one of two things. We can either modify our principles of justice to match our considered judgements more closely, with the implication of having to adjust the conditions of the initial position. Or, we can modify those aspects of our considered judgments that conflict with the principles. This process can continue in a back-and-forth way, introducing judgments of different levels of certainty along the way. This will mean sometimes we modify the original position and our principles, and sometimes we modify our judgments to more closely line up with our principles. Eventually, the goal is to reach a stage where our judgements and our principles are matched. In Rawls' words, "I assume that eventually we shall find a description of the initial situation that both expresses reasonable conditions and yields principles which match our considered judgments duly pruned and adjusted" (p. 20). This is called "reflective equilibrium", and refers to that point where we can on reflection appreciate that our judgments are balanced with our principles.

*B&C's justification through reflective equilibrium (Beauchamp & Childress 2013, p. 404-410)*

Reflective equilibrium, then, refers to a way of bringing harmony between our practical judgments (arrived at through weighing and specification in a given situation) and the four principles. Once we have specified and weighed, we want to reach the point where there is maximal coherence between our set of moral judgments or beliefs. If we note instances of conflict between some of the judgments arrived at through weighing, or conflict between a current set of judgments and a prior set of moral beliefs we hold to, we have to enter into a process that would restore equilibrium. This would mean that we could modify some of the judgments we have just arrived at to harmonize them with our other moral beliefs, or we could slightly modify prior moral beliefs to align all our judgments with each other. The goal is always the greatest amount of coherence in our moral beliefs; if incoherence and internal conflict between different moral judgments remain, we should continue to work back and forth. B&C describe the process as follows:

*"The goal of reflective equilibrium is to match, prune, and adjust considered judgments, their specifications, and other beliefs to render them coherent. We then test the resultant guides to*

*action to see if they yield incoherent results. If so, we must further readjust the guides.”* (Beauchamp & Childress 2013, p. 405)

This process is ongoing; it is unlikely that we will ever fully settle every moral question or arrive at a final solution of sorts. What we should be in search of is the maximal amount of coherence we are capable of, making our moral beliefs and judgments line up with the principles in a way that brings the most harmony between all our beliefs and principles possible. When new cases arise that test our moral beliefs, we embark on the process again.

The approach is perhaps best summed up in this paragraph, taken from an essay by Beauchamp:

*“A specification is justified, in the four-principles approach, if and only if it maximizes the coherence of the overall set of relevant, justified beliefs. These beliefs could include empirically justified beliefs, justified basic moral beliefs, and previously justified specifications. This is a version of so-called wide reflective equilibrium”* (Beauchamp 2010b, p. 47).

Thus, once a person has considered a specific biomedical issue from the perspective of the principles, and arrived at action guides for this specific issue, it is necessary to keep working until reflective equilibrium is reached. To do this, the various action guides are brought into harmony with each other, and with other moral beliefs the person already affirms and adheres to, by the process described by Rawls and B&C. This is only at an end once a maximal coherence is reached between the various action guides and other moral beliefs. That is, the newly formed moral judgments are on reflection in balance with one another and with other moral beliefs in a way that maximizes coherence in the person’s set of moral beliefs. If conflicts remain, the work of justification is not yet done. Only once maximal coherence is reached can a set of moral beliefs be viewed as ethically justified.

## (2) The grounding of the four principles in the common morality

In the earlier versions of B&C's *Principles*, the principles were seen as midlevel constructs, in-between ethical theory and action rules. According to this view, ethical theories are the highest levels of abstraction. Principles are then supported by the ethical theories. In their turn, principles are used to specify ethical rules. Lastly, rules are used to justify concrete moral judgments and actions. For example, in their second edition a diagram of this sort appears (Beauchamp & Childress 1983, p. 5):

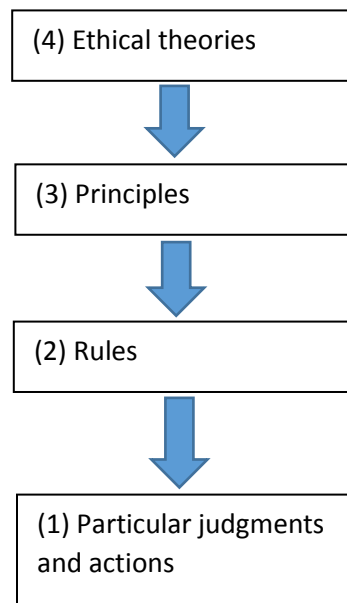


Diagram 4.1: From B&C 2<sup>nd</sup> Edition (format modified, content the same)

This diagram is accompanied by the following explanation (Beauchamp & Childress 1983, p. 5):

*“According to this diagram, judgments about what ought to be done in particular situations are justified by moral rules, which in turn are justified by principles, which ultimately are justified by ethical theories.”*

This is therefore a deductivist way of thinking about the role of the principles: the principles are deduced from ethical theories. From the principles rules are deduced. And from the rules, particular judgments and actions are deduced. According to B&C, it does not matter which theory one would place in position (4) on the diagram: deontological or consequentialist theories would all lead to support for the same four principles they have identified. Thus, even though there is

sustained controversy around which ethical theory is to be preferred, and no single ethical theory enjoys universal support in moral philosophy, we can all agree on the validity of the four principles. People from different ethical backgrounds would all support the four principles, B&C argued. Competing moral theories would each lead us to support the validity of the four principles. Therefore, discussions on rules and on particular judgments rightly start with the principles. In fact, Beauchamp and Childress apparently are adherents of different moral theories – one deontological, the other utilitarian – and the implication is that both of these competing theories lead to support for the four principles of bioethics.

In later editions (such as the 7<sup>th</sup> edition which I used as the basis for this work), B&C move away from the deductivist mode of thinking in favour of the reflective equilibrium method of justification, which I have described above. Thus, the principles are not to be applied deductively. Instead, they are to be used for specification and practical judgments in a process of back-and-forth application and pruning, until a balance is achieved between principles and judgments that allows the greatest amount of coherence possible between moral beliefs.

In addition to this, B&C have also moved the grounding of the principles to the common morality. Instead of the claim that the principles are deduced from ethical theories, with different theories all leading to the same principles, the claim is now that the principles are directly found in the common morality. To understand this claim, one has to first understand B&C concept of the common morality. I shall here briefly outline two different discussions of the common morality; the first from two different editions of *Principles*, and the other from the essays of Beauchamp.

*The common morality of B&C* (Beauchamp & Childress 2001, p. 2-4, 401-408; Beauchamp & Childress 2013, p. 3-5, 410-423)

The common morality can be thought of as follows. There are areas of great agreement between people who live a moral life, even though their moral commitments may be based on different ethical theories or different cultural backgrounds. There are a set of moral norms that would be agreed to by Kantians, utilitarians, Catholics, virtue adherents and human rights theorists – people who have widely disparate theoretical commitments and backgrounds. This set of moral norms that everyone would agree on, no matter their theory of persuasion, is the common morality.

Within the common morality, there are various action guides, for example: (1) Do not kill, (2) Do not cause suffering, (3) Prevent harm, (4) Rescue those in danger, (5) Tell the truth, (6) Nurture the young and the dependent, (7) Keep your promises, (8) Do not steal, (9) Do not punish the innocent, and (10) Obey just laws [1, p.3]. The common morality also contains moral character traits, or virtues. Within the common morality is also found principles and human rights. Various different types of moral norms find a place within the common morality, all of these agreed on by everyone who is serious about living a moral life.

Based on the work of Frankena and Ross, B&C identify the following features of common morality theories (Beauchamp & Childress 2001, p. 402-403; Beauchamp & Childress 2013, p. 410-411): (1) The common morality relies on every day, shared moral beliefs and judgments for its starting point. (2) If an ethical theory cannot be made consistent with the contents of the common morality, this theory is suspect. (3) The common morality is pluralistic, containing two or more principles that are not absolute (*prima facie*) nor reducible to a single one.

Thus, the common morality can be thought of as pre-theoretical. It is not based on a specific moral theory, and it is not dependent on the validity of a specific moral theory. In fact, the common morality provides support for theories. An ethical theory that contradicts the norms of the common morality is not a feasible ethical theory. Note also that the common morality has at least two (and in fact more) principles that confer a *prima facie* duty. In keeping with the work of Ross (1930), these *prima facie* duties have to be weighed to find the actual duty of a person.

B&C state that the four principles of bioethics are found within the common morality, and derive their binding force from the common morality rather than any specific ethical theory (Beauchamp & Childress 2013, p. 13). Thus, the validity of the four principles is based on our shared moral judgments, so that everyone who is serious about living a moral life can recognize the moral force of the four principles without appealing to a specific moral theory. B&C argue that there is no single ethical theory that enjoys universal consensus or that is widely accepted as the standard moral theory (Beauchamp & Childress 2013, p. 411-412). There is no single moral theory that enjoys the wide acceptance that the norms in the common morality does. The closest we get to such an ideal, are four principles. The common morality is therefore, according to B&C, the correct starting point and grounding for the four principles.

The implication of these arguments is that a unified ethical theory does not hold a central place in practical bioethics, at least according to the principlism paradigm. The correct starting point is not theory, say B&C, but the common morality – from which the four different principles are derived. It is not possible to find a single theory that would deliver these insights or enjoy the same amount of moral consensus as the common morality and the four principles do. Thus, to say that the principles should be derived from a specific theory would be to “put the cart in front of the donkey” (Beauchamp & Childress 2013, p. 411). The common morality is the appropriate starting point, and the appropriate grounding for any theory. Not the other way around.

B&C therefore argue for four different principles, derived from the common morality, as the starting point for bioethical reflection rather than a single unified ethical theory. In their view, an ethical theory would not allow the same amount of nuance and depth as the four principles do, a single theory would not enjoy the same amount of validity and binding force, and a single theory would always come second to the shared judgments found in the common morality.

It is clear from their work that B&C have been markedly influenced by the work of Ross (Beauchamp & Childress 2001, p. 402) and that their account of the common morality relies heavily on Ross. To recall, Ross (1930) argued for the existence of a set of irreducible moral



principles that can be intuitively seen as being valid. Each of these principles confer a *prima facie* duty on a person. There is no hierarchy and there is no rule for deciding between them in times of conflict; rather, one determines one's actual duty through weighing the demands of the principles against each other.

Thus, we can see this theme in B&C's common morality account as well: a set of principles that we can all recognize to be self-evidently true and valid. They are not reducible to one another, and there is no hierarchy between them. Each principle confers *prima facie* duties in a given situation; to arrive at one's actual obligation one has to enter into a process of weighing.

So, the four principles each have a different ethical focus and bring about a different set of ethical duties. They are derived from the common morality, a set of pre-theoretical and universally valid moral judgments we can all see intuitively to be true. In a sense, a unified ethical theory is superfluous and does not add anything to bioethical reflection. Rather, the more appropriate starting point is the four principles of bioethics.

*The common morality in the essays of Beauchamp* (Beauchamp 2010b, p. 43-44; Beauchamp 2010e, p. 155; Beauchamp 2010f]

Beauchamp in his essays affirm that the source of the four principles is the common morality. He conceives of the common morality as "the morality that all reasonable persons share and acknowledge – common-sense ethics, as it is sometimes called" (Beauchamp 2010e, p. 155). He repeats the claim that the common morality is a universal morality, and that it contains moral norms by which the actions of individuals are rightly judged. However, he takes a slightly different route towards the grounding of the common morality.

In the B&C account previously mentioned, the argument was that the common morality consists of those moral norms that is agreed upon by everyone serious about living a moral life. This appeals to either a Ross-like intuition, where we all can intuitively see the value of the norms within the common morality, or to a broadly shared consensus, namely that everyone who thinks about moral matters come to these same conclusions. In his essays, Beauchamp does not appeal to consensus among those who are morally serious or to Ross-like intuitionism. Instead, he starts with something he calls "the objectives of morality" (Beauchamp 2010b, p. 43; Beauchamp 2010f, p. 176).

Beauchamp modifies the concept of the common morality slightly, to be "the set of norms shared by all persons committed to the objectives of morality" (Beauchamp 2010f, p. 176). What are the objectives of morality? Beauchamp specifies one overall goal of morality: To promote human flourishing by counteracting conditions that cause the quality of people's lives to worsen (Beauchamp 2010b, p. 43; Beauchamp 2010f, p. 176). The norms of the common morality prevent deterioration of the quality of people's lives by working against the things that cause such deterioration: things such as indifference, conflict, scarce resources, and limited information. Where we see indifference, hostility, conflict, scarce resources and so on, we see

that people's lives fall into misery and confusion. The goal of morality is protect human flourishing by working against the forces that lead to misery and suffering. Over time, claims Beauchamp, the norms within the common morality have shown themselves to be the most suited for this purpose. The norms of the common morality are therefore the surest anti-dote to the evils that would bring misery and suffering. The common morality is the best set of norms to ensure that human flourishing is protected. If another set of norms could be found that would do this job better, that set of norms should be preferred. But there is no such set of norms; the common morality is the best we have (Beauchamp 2010b, p. 43; Beauchamp 2010f, p. 176-177).

Here are three paragraphs taken from Beauchamp's essay on the common morality (Beauchamp 2010f) to illustrate his views in his own words:

*"I understand the common morality as the set of norms shared by all persons committed to the objectives of morality. The objectives of morality, I will argue, are those of promoting human flourishing by counteracting conditions that cause the quality of people's lives to worsen"* (p. 176).

*"The common morality is not merely a morality that differs from other moralities. It is applicable to all persons in all places, and all human conduct is to be judged by its standards"* (p. 176).

*"In every well-functioning society norms are in place to prohibit lying, breaking promises, causing bodily harm, stealing, fraud, the taking of life, the neglect of children, and failures to keep contracts. These norms occupy a central place in the moral life because they have proven that they successfully achieve objectives of morality. This success in the service of human flourishing accounts for their moral authority"* (p. 177).

Beauchamp's work in these essays seem to base the norms of the common morality on different ground than consensus or intuition. Instead, Beauchamp argues that the common morality is justified by the objectives of morality. This argument appears almost consequentialist in nature, like a type of rule-utilitarianism. Utilitarians argue that morality is concerned with assuring the greatest happiness for the greatest number (Mill 2010b); rule-utilitarians like Mill hold that we should recognize those moral rules that promotes the greatest happiness for the greatest number. As an example of this, Mill argues for a strong conception of liberty on the basis of the principle of utility (Mill 2010a). Beauchamp's argument for the common morality has that kind of look to it – we should endorse those norms that bring about human happiness (which he calls flourishing, presumably after Aristotle). Beauchamp's claim is that this morality is a universal morality, and that everyone can see the value of this fact.

### *Discussion of the common morality and potential objections*

Beauchamp in his essays moves away from the mere observation of wide moral agreement to something he calls "the objectives of morality". When reading B&C's *Principles*, their argument revolves around the remarkable fact that people holding to different and conflicting ethical theories nevertheless share a wide range of moral commitments and moral judgments, things such as not to steal, not to kill, not to harm others and the like. This grounds the common morality

either in a type of intuitionism, the idea that we can all intuitively see the value of these judgments no matter what theory we hold or what background we come from, or in widely shared social consensus. Beauchamp's argument removes the possibility of an intuitionism and does not base the validity of the norms on the fact of remarkable widely shared agreement, but on a type of rule-utilitarian argument.

This has one positive outcome for Beauchamp: he is able to respond to a specific objection against the idea of the common morality more readily. When reading the account of the common morality in *Principles*, an immediate question and objection presents itself: is the common morality merely based on consensus? Are B&C arguing that widely shared consensus on the norms of the common morality establishes the validity of the common morality? That would be rather troubling. For if we all were to change our minds tomorrow that, in fact, torture of innocents is morally praiseworthy, then the norms of the common morality would change to include that fact. That would make light of the claims by B&C that the common morality contains universal norms with binding force, which we can use to judge the conduct of all persons in all places. Rather, it would seem then that the common morality is nothing but a sort of widely shared agreement that could change if we all wanted it to, with no real binding force except what the majority wish it to have. Furthermore, if the common morality was merely based on a broad consensus, how would one account for the reality of moral growth? Using historical examples, racism and slavery were widely considered to be acceptable practices in various countries in the past. In contemporary times, racism and slavery are widely viewed as great evils. These changes in widely held moral views regarding racism and slavery can be considered moral growth or moral development; it can be argued that societies of times past were in error when they considered slavery and racism to be morally acceptable. But if the common morality is merely based on the consensus of the majority of people who are serious about living a moral life, how can one account for this idea of moral growth? If the common morality derives its normative force from consensus, isn't it simply the case that whatever the majority approves is the common morality, and that there really is no objective rightness or wrongness about slavery or racism except what the majority of persons ascribe to it? Thus, basing the common morality on consensus faces serious objections; Beauchamp takes these seriously in his essays.

Beauchamp responds to the objection of basing morality on consensus in four ways (Beauchamp 2010f, p. 181):

(1) B&C engage in both normative and non-normative claims to defend the common morality. Describing widely shared consensus is an example of a non-normative claim. They are merely stating that we see widely shared agreement on the norms of the common morality, an empirical claim. Whether the common morality is to be seen as a universally binding moral code rests on normative justification. Here, Beauchamp appeals to the objectives of morality as being the normative justification for the binding force of the common morality.

(2) It is not assumed that all people everywhere accept the common morality. There are many people who reject it – those who are immoral, selectively moral or amoral. Some are morally

weak, others are just evil. The common morality is not irresistible. This does not change its universal nature or its normative force.

(3) Beauchamp categorically rejects the idea that the common morality is based on consensus. It is “preposterous” to hold that a set of consensus norms have moral authority just because of consensus (p. 181). “The proposition that moral justification derives from custom or consensus is a moral travesty” (p. 181). Local consensus moralities may prevent people from acting on the universal moral norms of the common morality.

(4) Fairly universal agreement on the content of the common morality does not justify the norms of the common morality. Rather, the justification for these norms rests in the fact that they are the best suited set of norms to achieve the objectives of morality. Thus, universal agreement explains why we see the existence of a common morality, but it does not provide normative justification for the validity of the norms of the common morality.

Beauchamp’s addition of the “objectives of morality” does allow him to successfully counter the objection of mere consensus. That is, the normative force of the common morality does not rest merely on the arbitrary fact that there is widely shared consensus. Rather, argues Beauchamp, the normative force of the common morality is supported by the fact that these norms fulfill the objectives of morality. Beauchamp argues that the object of morality is to “counteract the inconvenience, misery, violence, and distrust” that the “human condition tends to deteriorate into” (Beauchamp 2010f, p. 176). According to Beauchamp, morality is meant to decrease avoidable human misery and death. He maintains that complying with the norms of the common morality ensures that human suffering is limited, that society functions well, and that people’s quality of life and social relationships are protected from breakdown (Beauchamp 2010f, p. 176-177). Thus, in Beauchamp’s view, what gives normative force to the common morality is that it fulfills the objectives of morality he has described. Beauchamp argues that those set of norms that works most towards preventing deterioration of the human condition into suffering are the very norms found in B&C’s concept of the common morality. Every society that functions well and buffers people against deterioration into suffering recognizes prohibitions against lying, breaking promises, causing of physical harm, lying, killing, abuse of children and so forth (Beauchamp 2010f, p. 176). Thus, Beauchamp argues that the common morality is not dependent on mere consensus, but finds its normative force from the fact that it fulfills the objectives of morality, that is to say, limits human suffering.

I wonder, however, if this does not backtrack on the B&C argument that ethical theory is superfluous. Beauchamp has done nothing more than provide a justification for a universally objective morality based on a rule-utilitarian argument. Perhaps ethical theory is after all important, and perhaps the B&C argument that ethical theory is not necessary in bioethics has been refuted by Beauchamp himself.

Personally, I find the statement of the common morality in B&C’s *Principles* to be a promising starting point for bioethics. It does appear that people who are committed to morality share a

wide range of commitments, of the kind B&C state. Perhaps the best explanation for this is a kind of intuitionism, such as Ross' intuitionism. Perhaps it is just so that serious moral reflection reveals the self-evident validity of the norms of the common morality. It is reassuring that other people who are committed to serious reflection on morality also come to the same conclusions, and affirm the same norms, even if they have a different background or ethical theory. And certainly, the B&C claim that the common morality provides grounding for ethical theories is very plausible. An ethical theory that proclaims norms in conflict with the common morality would be worthy of rejection indeed. Imagine what such an ethical theory would look like – condoning of lying, congratulating us for deception and harming others, encouraging torture and killing of innocents, or demanding that we break our promises. A theory that comes up with such “moral duties” would rightly be rejected, and precisely because it collides with moral norms that we just know to be right. Beauchamp moves away from his Rossian roots in his later essays, in his view to provide normative force to the common morality. This does allow him to successfully respond to the potential objection that the common morality is merely dependent on consensus. But in my view, it does little else, and in fact leaves the common morality open to criticism and rejection by people who reject the rule-utilitarian way of justifying moral claims. I therefore overall do not regard it as a strength, but as a potential vulnerability. To my mind, retaining roots in the theory of Ross is more promising. The common morality does not depend on consensus. Instead, we see consensus because morally serious people upon reflection can see the validity of the norms in the common morality. This is a Ross type intuitionist argument with much more bite to it; to reject this argument one would have to explain the remarkable amount of agreement in some other more plausible way.

This brings me to a second possible objection against the common morality. Is it really so that there is widely shared agreement on the common morality? What about all the disagreement we see between the different codes of morality found in different cultures or in different points of time? After all, moral disagreement is a real thing. This objection centers around whether we can empirically show that there is in fact widely shared agreement on the norms of the common morality. One can think of many potential examples which suggests such moral disagreement, historical and contemporary. Think of apartheid South Africa, a culture where systematic racial discrimination was promoted as morally praiseworthy. During its existence, the values and tenets of apartheid South Africa were heavily criticized as being morally objectionable by various persons, countries, and cultures from different corners of the world. This would therefore seem to present a historical example of real moral disagreement. For a contemporary example, think of the moral status of abortion. Many persons argue “pro-choice”, that abortion is an issue of women's liberty rights, and that abortion therefore is morally justifiable. Other persons argue “pro-life”, that a fetus should be considered endowed with a right to life and that abortion is therefore the same as murder. There is an ongoing (and seemingly intractable) debate on this issue, in what seems to be genuine moral disagreement.

Beauchamp responds to objections regarding the very real existence of moral disagreement between different moral codes, and objections regarding empirical justification in the following three ways (Beauchamp 2010f, p. 178-180):

(1) One should make a clear distinction between the common morality and particular moralities. Of course there are differences between the moral codes of different cultural groups; but these are examples of particular moralities. Particular moralities are formed by specification and application of the norms in the common morality to specific situations and contexts. Thus, it is possible for people to arrive at different conclusions as to how exactly the norms of the common morality should be applied in given situations. For example, in the abortion debate, both “pro-choice” and “pro-life” adherents may affirm the norms of the common morality. That is, they may all agree that causing bodily harm is wrong, that killing is wrong, that people should be free, and so forth. However, they disagree about how to apply these moral norms in the context of abortion, disagree about the moral status of the fetus, and weigh the calculus of women’s freedom versus moral concern for the fetus differently. Or, for another example think of the contemporary controversy surrounding physician aid in dying (PAD). Some persons morally approve of PAD in some circumstances, and some countries allow physician aid in dying. At the same time PAD is considered illegal in some other countries and found morally objectionable by some persons. Here, people who all agree that killing is wrong and that murder should be condemned may weigh the moral norms regarding killing and prevention of suffering differently, and come to different conclusions: some affirming PAD as morally justifiable, others condemning it as morally wrong. Thus, although there is moral disagreement here, the disagreement is about how the common morality should be applied in certain contexts, and how particular moralities should be constructed by using the norms of the common morality. The common morality itself is not in doubt; in none of these examples is anyone arguing that causing bodily harm is, in fact, morally praiseworthy or that killing in the absence of a compelling moral reason is, in fact, laudable.

(2) Beauchamp states that there are no empirical studies known to him that show that some cultures reject and other accept the norms within the common morality. Empirical studies, he says, show how different rules are embedded within cultural moralities; these studies usually accept general moral norms and then show how these norms are differently specified and interpreted in different cultures. For example, studies do not examine whether cultures reject norms against killing and theft. Rather, studies examine how cultures think about these norms; when a specific culture would think killing and theft has happened, and how cultures recognize exceptions.

(3) Empirical studies can be done to test the Beauchamp hypothesis regarding the common morality, but then it should be clear what that hypothesis is. Beauchamp says that he defends the hypothesis that the common morality is the “set of norms shared by all persons committed to the objectives of morality” (p. 179). Thus, any empirical study should test this hypothesis, and not mere agreement and disagreement. As yet, no such study has been done. Such a study would

include participants who are committed to the objectives of morality, and the study would then examine their views on the best norms that would achieve those objectives. If a different set of norms emerge than the B&C common morality, the hypothesis has been falsified.

I do not think it worthwhile to do any such study as Beauchamp proposes. I take it as self-evident that everyone who is serious about living a moral life, who is committed to moral reflection, will see the binding force of basic moral tenets such as not lying, not killing, keeping one's promises and not causing harm. B&C point out the fact that there is remarkable agreement among people who are committed to morality on these matters, and that these principles are not controversial. I agree with them. These norms, which B&C call the common morality, form objective and universal moral standards against which we can measure the actions of individuals and cultures. For example, we know that apartheid was wrong, and those who perpetrated apartheid's racial discrimination performed acts of injustice. We do not need to specify a theory of ethics or a theory of justice to recognize the injustice of apartheid. Similarly, we know that the Nazi moral code was a travesty. Judging Nazi precepts against the content of the universal, objective set of moral norms of the common morality shows us that the Nazi moral code contained serious moral defects.

It is so that disagreements exist between different cultures, but I take Beauchamp's point to be correct. There is a difference between particular moralities and the common morality. Furthermore, some cultures did reject some of the precepts of the common morality; but this is an error on their part rather than a reflection on the common morality.

If empirical evidence of sorts is necessary, then one could point to the work done by CS Lewis. Lewis took the time to compare various different historical moral codes with each other. This list appears as an appendix to his book, *The Abolition of Man* (Lewis 2002). In this work, he lists the principles of morality as are found in the moral traditions of the Chinese, the Ancient Babylonians, the Ancient Egyptians, the Jews, Hindu morality and Christian morality. These different moral codes come from different cultures and from different times in history – some more ancient, some fairly recent. With regularity, we see the same core principles in each of these moral theories – principles of beneficence and of justice, principles to avoid harm and for special consideration of the young and dependent. The specifications differ, and the contexts and applications of these principles differ. But there is a striking amount of agreement between the central and basic principles of these moral codes. Remarkably, the principles Lewis so identifies shows a fair amount of agreement with Ross' list of intuitive principles and with B&C's conception of the contents of the common morality. Consider the list Lewis identifies (2002, p. 430-437):

- (1) The law of general beneficence (includes a negative component, to refrain from doing harm, and a positive component, showing good will to others).
- (2) The law of special beneficence (special obligations based on social roles or relationships, such as parents to children).

- (3) Duties to parents, elders, ancestors (duties of care and beneficence to those who are aged and to one's parents).
- (4) Duties to children and posterity (duties of care to those who are dependent and to protect the interests of future generations).
- (5) The law of justice (including sexual justice, honesty, treating people as they deserve in courts, rules against stealing and unjust gain).
- (6) The law of good faith and veracity (refraining from deceit and manipulation).
- (7) The law of mercy (taking care of the sick and the poor).
- (8) The law of magnanimity (protecting the innocent, sacrifice of one's own interests to further what is right and good).

Lewis has argued for something similar to the common morality – a set of universally binding, objective moral principles that people can intuitively see to be true and that has normative binding force for all persons everywhere. In formulating this list of principles as found with repeated frequency in historical moral codes, he is trying to show instances of these principles and their occurrence in different moral codes. But he says this should not be seen as empirical proof of the idea that such an objective, universal morality exists. He writes:

“I am not trying to *prove* its validity by the argument from common consent. Its validity cannot be deduced. For those who do not perceive its rationality, even universal consent could not prove it” (Lewis 2002, p. 430).

This again is very similar to the B&C argument for the common morality, a set of norms that everyone would agree to if they were committed to morality, and to the argument of Ross, that there is an intuitively true set of irreducible moral principles that confer *prima facie* duties on us.

### *Conclusion*

B&C defend a specific conception of a universal, objective morality they call the common morality. This conception of the common morality can be successfully defended against objections such as mere reliance on arbitrary factors such as consensus and empirical claims that moral disagreement exists.

The four principles of bioethics are derived from the common morality, and therefore has moral force for all persons in all places. Because of this fact, the principles cross the boundaries that disagreements in ethical theory would otherwise create. The principles rely on our shared moral convictions and commitments, being founded on moral norms we know to be true and binding. The principlist approach therefore is powerful in its moral force and in building consensus among people with different theoretical commitments, and is therefore a good starting point for bioethical reflection.



Strong objections have been raised against the principlist approach of B&C as such. To these objections I will now turn.

### **(3) Criticisms of B&C's principlism and alternate approaches to bioethics**

#### **(3.1) Clouser and Gert (C&G) and the role of ethical theory**

##### **(3.1.1) The main criticisms of C&G**

C&G provide strident criticisms of the principlist approach, using B&C's principlism as an example of the principlist paradigm. These criticisms appeared initially in an essay they co-authored (Clouser & Gert 1990). In response to their essay, Lustig (1992) published a "critique of the critique", defending principlism and criticizing the approach to morality advanced by Gert. Together with co-author Green, C&G respond to Lustig's arguments while re-emphasizing their objections to principlism (Green, Gert, & Clouser 1993). This literature presents a well-known and lively discussion on principlism. In this section, I shall consider C&G's two main criticisms of the principlism of B&C and consider B&C's responses to these criticisms.

##### *Criticism 1 – Lack of systematic unity and an overarching/unifying moral theory*

According to C&G one of the serious shortcomings of the principlist approach is the lack of a single or unifying moral theory. Among other things, such a theory would explain how and when to apply a specific principle to a practical scenario, and how to resolve conflicts when principles are in opposition. Instead, C&G argue that it is left to the individual to decide when and how to apply which principle, and how to resolve conflicts between principles in individual situations. What is lacking, is systematic guidance on how the principles function and how they are to be used (Clouser & Gert 1990, p. 222).

In essence, the four principles are also not what they purport to be – moral action guides. Instead, they are like "chapter headings" and "checklists" (Clouser & Gert 1990, p. 222) of important moral considerations that people should keep in mind when considering bioethical issues. Each principle includes widely different moral considerations, thrown together under the same heading, with no clear guidance on how to apply them (Clouser & Gert 1990, p. 222). There is no clear guide to action, or how these differing moral concepts thrown together are to be universally applied in moral situations. In fact, C&G argue that each "principle" is actually just an "eclectic discussion that emphasizes a different type of ethical theory, so that a single unified theory is not only not presented, but the need for such a theory is obscured" (Clouser & Gert 1990, p. 228).

C&G maintain that the four principles are in fact manifestations of four very different moral theories, and therefore "applying" the four principles amounts to considering the same practical circumstance from conflicting theoretical points of view (Clouser & Gert 1990, p. 223). Beneficence is based on Mill's utilitarianism, justice is based on Rawls' Theory of Justice, autonomy on the work of Kant, and non-maleficence on the work of Gert. So, applying the four principles means that a case is analysed from various conflicting theoretical points of view. In

presenting the four principles as a unified work, B&C create the impression that there is some unified way in which these four principles are related to one another, when this is not true. In fact, there is marked conflict between the four principles as they are each a representative of a conflicting moral theory.

The problems created with the principlist approach are therefore troubling. Principles are in fact not action guides, and it is not clear how to apply them, so that a haphazard and non-systematic way of ethical reasoning takes place. In fact, true ethical reasoning is obscured, as the need for a unifying or systematic approach to ethics is obscured by the use of principles. Using the principles will then lead to people making instinctive or highly individualistic ethical judgments, after which the language of the principles will be “applied” to justify such idiosyncratic or personally preferred judgments. The principles end up hindering moral reasoning instead of being a tool that is useful for moral deliberation.

What is needed, say C&G, is an ethical theory that can clarify moral reasoning and explain moral agreement and disagreement (Clouser & Gert 1990, p. 232). Such a theory would help us see how ethical rules are formed, how they are applied to concrete situations, and how to resolve conflicts between rules. It would specify different types of duties and how to discharge them. Such a theory would take away guesswork and *ad hoc* applying or weighing of principles.

So, turning to principlism. Each of the principles capture some morally relevant aspects; beneficence reminds us that consequences are important, autonomy emphasizes the individual person, and justice speaks of the equitable distribution of benefits and burdens. An adequate moral theory would then tell us how each of these moral considerations are connected with one another, and when and how these different moral considerations should be applied (Clouser & Gert 1990, p. 233). An adequate ethical theory would therefore include (Clouser & Gert 1990, p. 233):

- (1) a concern for consequences;
- (2) a concern for how consequences are distributed;
- (3) acknowledgement of the importance of the individual; and
- (4) a prohibition against harming individuals.

Such an ethical theory will provide clear and coherent answers, which can be understood and used by all. Those who work on problems in bioethics will have a single decision-making system, and will be able to communicate with each other clearly. Rather than a haphazard or *ad hoc* application of principles, it will be clear how and when moral rules are to be applied, and how to deal with disagreements. With principlism, it is not always clear what the basis of a disagreement is, or how to proceed with resolving it; with an adequate ethical theory, it will at least be clearly understood what the basis for disagreement is and what needs to happen to resolve disagreements.

In their second essay, C&G together with Green advance the following features of morality (Green, Gert, & Clouser 1993, p. 481):

- (1) It is systematic; no rule or ideal can be fully understood until it is clear how it functions in the entire moral system (and therefore not haphazard or *ad hoc*).
- (2) It is a public system (and not an individualistic affair; acceptable to all to whom it applies).
- (3) It applies to all rational persons and is accepted by all rational persons as far as they reason impartially (again, not an individualistic or preference-based system).

This underlines their views of the need for an adequate moral theory. Furthermore, this emphasizes their rejection of a pluralism of principles; the principlist approach (in their view) is a highly *ad hoc* and haphazard application of whichever moral considerations strike one's fancy, with no specific way to foster agreement in judgments and applications.

To summarize C&G's first objection: the principlist approach lacks a systematic, unified theory. This means that the principles cannot be applied to moral reasoning, do not function as action guides, and in fact obscures moral reasoning. What is needed for accurate moral reasoning is an adequate ethical theory, that will show how rules and duties function within a system, when and how to apply them, and how to resolve disagreements in an impartial and universally acceptable way.

### *Criticism 2 – Relativism*

In this critique, C&G conceive of the principles as mid-level constructs, standing between theories and ethical rules (Clouser & Gert 1990, p. 231). As I have shown before, B&C had this conception of the principles in their earlier editions of their work, but in the later editions moved away from it. According to this idea, the principles are supported by ethical theories, such as utilitarianism and deontology. From these principles, rules are then derived for application in concrete situations.

It is apparent, say C&G, that there is an inherent relativism present in using a principlist approach. Each of the four principles are in essence a set of ethical considerations, derived from a specific ethical theory and set of arguments. But the different principles are all derived from competing and conflicting theories, and therefore are at odds with one another. In essence, C&G say that the principles each have a "life and logic of its own, as well as a number of internal conflicts" (Clouser & Gert 1990, p. 231).

In essence, each of the four principles are dependent on a different ethical theory. Each principle commits one to a different perspective. This means that the only way in which one can accept all four principles at the same time, is to subscribe to relativism – the view that all these competing theories are equally true. But of course, relativism has at its essence the core absurdity that conflicting truth-statements are all equally true. This premise can *a priori* be rejected out of hand as absurd. C&G's criticism is therefore that principlism cannot be a reasonable approach to

morality, as its internal structure commits one to the philosophically fatal position of ethical relativism.

C&G go further with their argument, and say that this approach is actually endemic to applied ethics as a whole (Clouser & Gert 1990, p. 231). It is typical practice in applied ethics courses and anthologies to present various ethical theories, such as utilitarianism and Kantianism, then point out the fatal flaws in each of these theories, and then to proceed with using the theories anyway as if no flaws exist. Students and adherents are typically encouraged to apply any of these competing theories as they see fit, if the situation (in their judgment) calls for it. So, if a concrete ethical problem calls for utilitarianism, by all means use utilitarianism. If it calls for Kantianism or Rights Theory, go ahead and use those. This, says C&G, is “an extraordinary way to proceed. It is difficult to imagine any respectable discipline proceeding in a similar fashion. Having acknowledged that all of the standard theories are inadequate, one is then told to apply them anyway, and even to apply competing theories, without any attempt to show how the theories can be reconciled” (Clouser & Gert 1990, p. 231). This, say C&G, is exactly the approach of B&C’s principlism. They discuss varying theories, find them all inadequate, apply them anyway to derive the principles, and then encourage the practitioner to apply whichever principle/theory seems relevant or applicable in a given situation.

The second critique of C&G is therefore: principlism has an intrinsic relativism in its structure, making it an incoherent and unacceptable method to approach ethical deliberation.

### *Criticism 3 – Critique of individual principles*

C&G also critique individual principles as being confused and conflicting internally. For example, note their discussion of the principle of beneficence (Clouser & Gert 1990, p. 228). It is not possible to have “duty” of beneficence, they argue, to all people all the time. It is not possible for us to do good impartially and equally to all people all the time. Instead, beneficence should be seen as an ideal, a supererogatory moral act. That is, doing good to others is something to be desired, but cannot be a duty if we consider the impossibility that a “duty” of beneficence would convey upon individuals. At best, there is a duty to refrain from harming others, but there cannot be a duty to actively and impartially do good and beneficial actions to everyone all the time.

Thinking of beneficence as a “general duty” also misses the point as to where duties come from. Duties, say C&G, come from social roles or special relationships. So, a healthcare practitioner has duties towards her patients, but to lump these duties in with moral ideals of general beneficence under a catch-all principle of beneficence, confuses the issue and leads to error.

Once again, this can be rectified by having an overarching and unifying ethical theory, clarifying the distinction between moral ideals and duties. Yet, the principlist approach obfuscates the need for such a theory.

### (3.1.2) B&C's responses C&G

B&C defend their principlist approach vigorously from the criticisms of C&G. They identify the main critiques, and then rebut them each in turn (Beauchamp & Childress 2013, p. 393-397).

It will be recalled that C&G's first major critique was the lack of a systematic theory that unifies the principles, and shows how they are related to each other. This includes three issues to which B&C respond in turn.

Firstly, C&G argue that the principles are not action guides as such, being very vague and not providing clear direction. Rather, they are merely chapter headings or checklists of morally interesting aspects. It is not clear how to apply these principles to a given situation. B&C respond by pointing out that any moral norm that is not adequately specified for a given situation will face this problem. Principles are in their essence very broad moral norms that lack specific guidance for concrete situations. For the principles to be of practical use, they need to be specified in order to be applied to concrete situations. B&C point out that even the moral rules advanced by C&G as being superior to the principlist approach are similar in that they also need additional specification to be useful as action guides. C&G advance rules such as "Don't kill", "Don't deceive", "Keep your promise", and "Do your duty" (Clouser & Gert 1990, p. 234). These form part of a comprehensive moral system, undergirded by a systematic moral theory, and are in C&G's view an improvement on the four principles. B&C point out that these rules are at a lower level of abstraction than their four principles, so that one could consider them to be specified principles. Yet, they stand in need of further specification before they can be applied to concrete situations. Furthermore, when considering the whole of B&C's work, one would find an account of specified principles and rules that do not differ much from the rules advanced by C&G. Beauchamp emphasizes this in one of his essays (Beauchamp 2010e). Consider the following (Beauchamp 2010e, p. 169):

#### *Beauchamp and Childress*

4 rules based on nonmaleficence

1. Do not kill.

2. Do not cause pain.

3. Do not incapacitate.

4. Do not deprive of goods.

#### *Gert & Clouser*

4 of the 10 basic rules

1. Don't kill.

2. Don't cause pain.

3. Don't disable.

4. Don't deprive of pleasure.

In essence then, there is not much to choose between the rules advanced by C&G and the specified principles and rules of B&C. B&C contend that the principles stand in need of additional specification in order to arrive at more specific action guides with more directive moral content. It is therefore not so that principles can merely be applied *ad hoc* or in a way that merely relies on personal preference, and it is not so that the principles are devoid of moral content. One

should understand though at which level of abstraction they function, and that their task is to provide support for more specified principles and rules. Principles can be applied directly in some circumstances, in cases where conflict between obligations is at a minimum or straightforwardly resolved (Beauchamp 2010e, p. 168). Generally though, the principles need to be specified in order to arrive at more substantive and specific action guides. Principles are meant to be abstract starting points.

Secondly, C&G argue that since there is no systematic theory to show how principles are related and how to resolve conflicts between principles, weighing proceeds in an unclear and arbitrary fashion. B&C acknowledge that the principles often conflict, but argue that this does not mean that they lead to incommensurable moral commitments. The principles require specification and balancing, so that eventually a state is reached where various moral commitments are in equilibrium with each other. In order to make progress in such matters, one needs some experience and the capability of good ethical judgment, practical wisdom in a sense. It is simply not so that a full account of all healthcare duties can be drawn up without conflicts between various duties and the existence of moral dilemmas. No such theory exists or has ever existed. In fact, B&C argue that they consider conflict between various norms and ambiguity as part and parcel of morality; a commitment to the moral life includes dealing with such difficulties. C&G are asking for no less than a moral theory that eliminates all conflict and disagreement between principles. This is simply not possible, argues B&C, and instead they offer a version of moral deliberation that makes sense of moral ambiguity and conflicting moral obligations. In their view, dealing with such conflict requires the use of practical wisdom and providing good reasons for weighing one principle over another.

Thirdly, B&C respond to the charge that they lack a unifying ethical theory in general. They acknowledge that they lack such a theory, but they dispute that such a theory is necessary. They are, in fact, skeptical of such theories in general. None of the most popular theories come to terms with our whole moral experience; none of them give us a complete description of all that is important in the moral life. With their principles, B&C do not mean to replace these theories and they do not attempt to provide a theory that would make sense of our entire moral experience. Instead, they offer a common-ground moral starting point, basing their principles on those moral judgments that find wide acceptance among people who are serious about living a moral life. B&C think it unlikely that we will ever have an ethical theory that will gain universal acceptance, that will eliminate moral disagreement, or that will do everything C&G demand from an ethical theory. Instead, we should rely on those moral judgments of the common morality, those judgments that are shared and uncontroversial despite differences in theoretical commitments. This leads us to an adoption of a principlist approach. So, according to this response by B&C, an ethical theory is not only unnecessary when engaging in practical bioethics, it may even be undesirable.

Fourthly, C&G have criticized individual principles. For instance, they have argued that the principle of beneficence is nonsensical; beneficence can at most be a moral ideal. To this B&C

respond by saying that this is mistaken: the common morality undoubtedly commits one to a principle of beneficence. Beauchamp addresses this point in one of his essays, pointing to several examples which make it apparent that there are instances where beneficence is a moral duty (Beauchamp 2010e, p. 169-170). Take this example: Mr. X's life is in danger, but if I warn him through a phone call, he will be fine. According to C&G's critique of the principle of beneficence, it would be a moral ideal but not a duty to make the phone call. But this seems wrong; and as such, this example (along with three others Beauchamp provides) illustrates that there is in fact a moral duty of beneficence in some circumstances. B&C argue that this point is even acknowledged in Gert's work on morality. Indeed, Gert does seem to endorse a duty of beneficence in one of his books (Gert 1988, p. 154-155). In this work, for example, Gert argues that one has a duty to seek help when a child collapses in one's arms. It would be wrong to, say, lie the child down on the ground and walk away without procuring help. Gert argues that one generally has a duty to help if someone else is in serious danger, one is close by, and it would be fairly free of costs for one to provide that help. Gert justifies these duties by invoking the rule "Do your duty," but in truth his arguments are nothing more than strong reasons to accept duties of beneficence. What is interesting is that Gert also relies heavily on the idea of the common morality in his work, and derives his rules also from the common morality. Thus, the B&C claim seems credible – Gert does seem to recognize a principle of beneficence to be present in the common morality, and uses this principle to specify more direct moral rules and guidelines. The C&G critique of beneficence can therefore rightly be disputed: not only do B&C maintain that beneficence clearly is present in the common morality, they also point to Gert's apparent acceptance of this fact in his own work. In fact, much of what B&C find problematic in principlism is actually present in the rules and methods they proscribe, specifically in the work of Gert as illustrated.

### **(3.1.3) Discussion**

C&G's criticism of principlism are worthwhile to reflect on, and indeed add much to the discussion on principlism. B&C's responses are interesting and in my view successful. The principles are indeed action guides, but they are in need of further specification. Balancing and specification require the use of good reasons and a form of practical wisdom. The moral rules of C&G do not seem that far removed from the principles of B&C; when one specifies the principles of B&C one ends up with a similar list of rules as we find in C&G.

With regards to the charge of relativism, it is interesting to note that B&C have moved away from ethical theory as the basis for the principles. The principles are not derived from specific ethical theories; rather, the principles are derived from the contents of the common morality. In a sense, the four principles encapsulate moral commitments we all agree on, no matter what our theoretical background is. And to me, this is the strength of the B&C principlist approach: it takes as starting point moral commitments that are universally shared, and use these commitments to create a framework for ethical deliberation. The four principles therefore foster consensus and ethical agreement, even among people with differing theoretical commitments. It is possible for



people of different faiths and who adhere to different moral theories to use the principles and arrive at moral conclusions that are defensible and acceptable. This is not because of an inherent relativism, but rather because of the wide agreement on the contents of the common morality.

I am also not convinced by C&G's argument that the four principles rest on four different theories. It is possible to argue for all four principles from a single theoretical perspective. Take utilitarianism as an example. It is easy to see how beneficence and non-maleficence can be derived from utilitarianism; such principles will likely lead to the greatest good for the greatest number. But Mill shows us how the other two principles can be derived from utility. In *On Liberty*, Mill argues for a conception of personal freedom that reminds strongly of the principle of autonomy, on the basis that such liberty is derived from utility. In *Utilitarianism*, Mill argues that utilitarianism forms the basis of justice; utility would demand that society be just. A utilitarian would therefore subscribe to all four principles. It is not necessary to be a Kantian to see the value of the principle of autonomy.

B&C argue that we have no universally acceptable theory, and that it is not likely we will ever have one. Disagreements will remain. This point is persuasive, and is one of the most compelling reasons to prefer a principlist approach; while we may disagree on which ethical theory is preferable, we can all agree on the moral force of specified moral principles. The claim B&C makes is that everyone who is serious about morality will see the moral force of the four principles, no matter what theory they adhere to. This almost makes ethical theory redundant in practical bioethical deliberation; if we all agree on the principles, then principles are the appropriate starting point in deliberation, not theory.

The principlist approach has also stood the test of time. C&G published their criticisms more than two decades ago. Yet, principlism is still an attractive and popular approach to bioethics, widely influential and enduring. C&G's criticisms have in fact strengthened the principlist approach. B&C have clearly considered the criticisms carefully, and strengthened their principlist approach in response. One example of this is that the four principles now are derived from widely shared moral judgments, rather than from ethical theories. Ironically, C&G's critique has driven principlism further away from a unifying theory than closer towards it.

In summary, B&C successfully rebuts the criticisms of C&G. Added to this are that the principlist approach has improved owing to B&C's reflection on these criticisms, and the fact that a unifying ethical theory is elusive. I am confident that using a principlist approach in my inquiry will yield robust and morally compelling conclusions, which will be acceptable to all people who are serious about living a moral life.

### **(3.2) Casuistry as an alternate approach**

Casuistry as an alternative to the principlist approach finds its expression in the work of Stephen Toulmin and Albert Jonsen (Jonsen & Toulmin 1988; Jonsen 1991; Jonsen 2010; Toulmin 1981).

In essence, casuistry is case-based reasoning. The process of moral deliberation starts with paradigm cases, where we can be sure of our moral judgments. By use of analogous reasoning, conclusions reached in paradigm cases are extended to other cases that share similar characteristics. Casuistry relies on case analysis and comparisons between cases, using a form of practical knowledge to reach moral conclusions. Casuists maintain that we should not start with universal moral rules or moral principles, arriving at moral judgments by trying to apply these in practical cases. Rather, what is morally relevant in a case is wrapped up within the details of the case. It is evident to those involved in the case what the morally relevant features are; once we know what moral conclusions can be drawn from a paradigm case, these conclusions can be used to reason through analogous cases. Particularly, adherents of casuistry are concerned about a principlist approach. They feel that the application of conflicting principles will lead to gridlock, impeding moral reasoning. In essence the principles will lead to interminable disagreements and halt progress in making judgments. It is often in practical cases clear what moral judgments should be drawn, but not clear which principles should be used or are relevant. Insistence on using principles will then hinder, and not help, moral deliberation. This can lead to a “tyranny of principles” (Toulmin 1981), where the inflexible application of principles dominate discussion at the expense of real moral deliberation. Instead, they argue, we should proceed with moral judgments by appealing to the moral aspects of cases, without use of principles.

As an example of how principles are superfluous, Toulmin and Jonsen refer to the work done by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in drawing up the Belmont report (Jonsen & Toulmin 1988, p. 16-19). Both Jonsen and Toulmin were part of this process. They recall that individual participants would frequently agree on specific moral judgments, but they could not find common ground on justification for these judgments. They agreed on moral conclusions, but it was not clear what drove the agreement. Eventually it became clear that participants were not appealing to universal principles or ethical theory; they would frequently mention principles, but in justification they invariably relied on shared insights as to what was morally relevant in individual cases. In essence, what drove moral agreement and moral reasoning at the National Commission was a case-based approach, and not the application of principles. Beauchamp responds to Toulmin and Jonsen by agreeing that case-based reasoning was an important aspect of the work at the National Commission, but that development and use of the principles were also intricately involved (Beauchamp 2010c, p. 10-12). There was “a constant movement from principle to case and from case to principles. Principles supported arguments about how to handle a case, and precedent cases supported the importance of commitment to principles” (Beauchamp 2010c, p. 11). This is, in fact, the way B&C respond to casuistry: casuistry is complementary to a principlist approach and not a rival. Casuistry is consistent with a strong commitment to the principles.

In their response to casuistry, B&C defend principlism by considering casuistry as entirely at home within a principlist paradigm (Beauchamp & Childress 2013, p. 398-404; Beauchamp 2010c, p. 10-12). Within the method of casuistry, the idea is to draw on paradigm cases and use analogous reasoning. The morally relevant aspects of the case are embedded within the facts of

the case. But this means that there are two aspects of importance in every case: the facts of the case (such as, 'the patient refused treatment') and the settled generalizable values (such as, 'competent patients have the right to refuse treatment') (Beauchamp & Childress 2013, p. 401). There is therefore a practical component and a value component within each case. But it is possible to bind cases together that share similar value components, and to draw general sets of value judgments from such groups of cases. These connecting norms can be generalized into rules and principles, which can then be applied to other cases where the factual circumstances are similar (Beauchamp & Childress 2013, p. 401). Take as an example Jonsen's method of casuistry (Jonsen 1991; Jonsen 2010). The morally relevant aspects of a case forms a rule, or a maxim. There may be several maxims at play in a specific case, and they may even conflict. The casuist must then decide which maxim is most relevant and should be given preference. B&C argue that this is very similar to their account of *prima facie* principles and rules needing specification and balancing (Beauchamp & Childress 2013, p. 401). Thus, B&C argue that casuistry actually presupposes the existence of moral principles and rules, identifies them within a case, and then proceeds by use of analogy and practical reasoning to apply conclusions to similar cases.

I agree with B&C's argument. In essence, casuists argue that we can see the morally relevant features of a case by intuition. When we have settled cases where our intuitions are straightforward and clear, we can use the conclusions from these cases to resolve other more problematic cases. In a sense, it is not so much different from the B&C approach of intuitively seeing which principles apply to a case, engaging in specification and balancing, and then using our conclusions (considered judgments) to reach reflective equilibrium in cases where we are less sure of our conclusions. Also, it appears as if the casuists take the same starting point as B&C do – moral judgments that we can all agree on and that we are sure of. Casuists appeal to paradigm cases, whereas B&C appeal to the common morality. But in both instances, there is a reliance on shared and widely endorsed moral judgments rather than on a specific ethical theory.

There are some important differences between a purely casuistical approach and principlism, and B&C point these out (Beauchamp & Childress 2013, p. 400-404). Principlists have the four principles as a guide, making sure that conclusions are safe-guarded against bias such as individual or popular preferences. It is not clear how casuists avoid prejudice or incorrect judgments, such as can be caused by the swaying influence of (unjust) popular opinion. Principlists can challenge their own incorrect assumptions by reference to the principles. In casuistry, case analysis of similar cases leads to generalizations – but without a guide of bulwark such as the principles, such generalizations can become biased or morally suspect by not having a check against individual or cultural biases.

In summary, I find nothing in the work of the casuists that provide an insurmountable challenge to a principlist paradigm. Casuistry highlights the important place that cases and practical considerations play in reaching our moral judgments, and reminds us of the usefulness of analogy and practical reasoning in ethics. As such it can be seen as a complementary approach to the principles. It does not, however, replace a principlist approach. As Beauchamp states in his

comments on the National Commission, principles and case-based reasoning worked together through “a constant movement from principle to case and from case to principles. Principles supported arguments about how to handle a case, and precedent cases supported the importance of commitment to principles” (Beauchamp 2010c, p. 11).

### **(3.3) The ethics of care as criticism of traditional ethics and possible alternate approach**

The ethics of care developed in the 1980’s through the work of feminist philosophers such as Gilligan (1982) and Noddings (1984). Gilligan (1982) was critical of the work done by Kohlberg on moral development, which she conceived of as biased towards a masculine perspective. Gilligan argued that women often have a different voice and a different perspective when it comes to principles of justice than men, informed by a primary concern with relationships and the moral significance of caring. Noddings (1984) wrote along similar lines, arguing that women bring a different perspective to moral deliberation than traditional theories afford. This different perspective, she argued, is grounded in a recognition of the central role that caring relationships play in moral deliberation. For both these writers, caring relationships play a central role in moral theorizing, and traditional “masculine” ethical theories such as utilitarianism and deontology fail to take such caring relationships into account.

Contemporary adherents of the ethics of care, such as Held (2006), view the ethics of care as a fully-fledged ethical theory that is meant to be an alternative to other theories such as Kantianism, utilitarianism, and virtue ethics. The central focus of the ethics of care, Held argues, is “the compelling moral salience of attending to and meeting the needs of the particular others for whom we take responsibility” (Held 2006, p. 10). Traditional moral theories are preoccupied with rational, independent, autonomous selves – in contrast to the care ethic which focuses on the primacy of relationships. In developing the theory further, Held applies the ethics of care frame work to areas such as medicine, politics and international relations between countries. Held argues that there is a tension between theories of justice and the ethic of care, and how these two are to be “meshed without losing sight of their different priorities is a task still being worked on” (Held 2006, p. 17). Her suggestion is to keep both frameworks, and apply them to different areas. For example, in making of society’s laws the impartiality of justice and a rights-paradigm should have priority, without forgetting the importance of care relationships. In the area of relationships, such as friendships and families, care ethics should be the primary consideration without forgetting the principles of justice. In international affairs, universal human rights discourse is important, but placing a primary focus on an ethic of care will reach the goal of universal respect for human rights much better than the traditional rationalistic paradigm (Held 2006, p. 17). Thus, in a sense, the important insights of the ethics of care are to be seen as an alternative to a justice paradigm or a rights-paradigm, but depending on the situation and context, these differing theories may inform one another.

A central and important insight delivered by the ethics of care is the primacy of relationships, questioning the validity of a paradigm that construes humans as individualistic, autonomous, unsituated selves. In this way it reminds of the work of communitarians and virtue-ethicists such as MacIntyre, who also is deeply critical of this conception of human beings (MacIntyre 2007). MacIntyre's solution is a return to the virtues and an espousal of communitarian conceptions of justice, whereas the ethics of care focuses primarily on caring relationships. Although there is some clear overlap, there are also some differences.

As a critique of principlism, it would therefore primarily focus on criticizing the principles of justice and autonomy, arguing that these are entrenched in the "masculine" paradigm which overemphasizes the rational, adult, independent, fully developed human being at the expense of the dependent and weak and at the expense of caring relationships. To my mind, these critiques miss the point in the case of principlism, and I will offer reasons why.

First, this criticism misses the paradigm in which principlism usually operates, and in which the principles developed. The principles developed primarily against the context of medical care and biomedical research. Medical care is delivered through caring relationships – the relationship between nurse and patient, doctor and patient, therapist and patient, and the like. Such relationships are essentially caring relationships, and often the patient is a vulnerable person who does not epitomize the rational, adult, independent, unsituated self. Often these relationships have an asymmetry to them: picture the young, learned, financially well-off, empowered physician on one side and the frail, suffering, weak, sick patient on the other side. The person whose interests are primarily at stake, the patient, is also the one who is weaker and more disadvantaged. Against this backdrop the principles developed – caring clinical relationships with power imbalances. The principlist approach espouses the four principles as the starting point for reasoning about the ethical implications of such relationships. Within such caring relationships, physicians have to respect the autonomy of their patients where such autonomy exists. This idea developed directly as a response to abuses of the past and unjustifiable paternalism of yesteryear. Furthermore, within such relationships beneficence, non-maleficence and justice are primary considerations.

This is not much different than the conclusions a care-ethicist would come to. Consider: if we take the prototype case within the ethics of care and think about a mother who has four children. Clearly, here we have caring relationships in place, and similar to the clinician and patient there is an imbalance of sorts. If we were to ask the mother – what are your obligations to your children? – would we not hear her say that she has to provide for them, love them, and protect them from harm? And what is this other than the principles of beneficence and non-maleficence applied? Should we then ask the mother how she decides to distribute resources between her four children, and how she distributes her love and time between her four children – do we not enter on a discussion on the principles of distributive justice? Suppose her children range from 20 years of age to 8 years of age. The 20 year old has her own values, ideas, and the capacity to rationalize them, while the 8 year old still does not have a fully developed decision-making

capacity. Will we not hear some recognition of different degrees of autonomy, and consequently a mother's discretion in how to promote and respect the decision-making capacity of her children in different ways? For the 8 year old, she may simply restrict her respect of decision-making to choice of clothes and flavour of juice. For the 20 year old, she respects and promotes significant life choices, such as the choice of a future career or an avenue of study.

Thus, the main objection raised against traditional ethical approaches by care ethicists does not obtain in the case of principlism. Principlism can readily incorporate the important insights delivered by the ethics of care, namely the importance of caring relationships in moral deliberation. To an extent, it depends on the baseline assumptions taken into moral deliberation. If a person is committed to individualistic, rational selves, and applies the principles in this way, the conclusions reached will no doubt be skewed towards an individualistic perspective. Care ethicists would point out that such conclusions are skewed and mistaken; but it would not be the fault of the principlist approach. If we use principlism in the context that it developed – namely, caring clinical relationships – the conclusions reached should be acceptable to the care ethicist.

Secondly, care ethics is not so much an alternative to principlism as it is to traditional ethical approaches. The ethics of care should be seen as an opponent of Kantianism or utilitarianism, not principlism. The strength of principlism is that it relies on widely shared moral judgments, and that the conclusions delivered through principlism is acceptable to people from differing theoretical backgrounds. These shared moral judgments include that it is wrong to kill innocents, to steal, or to break promises. But these shared moral judgments also include the value of caring relationships and of friendships. Principlism is not much concerned with the theory that a person espouses; it is more interested in the moral judgments that the person shares with most other persons serious about morality. The ethics of care operates more at a theory level – as an alternative to Kantianism or utilitarianism – and does not operate at the same level that principlism does. Thus, I would argue, the ethics of care is not really an opponent nor critic of principlism, but rather of specific ethical theories. And if a principlist approach is used to address an ethical problem, taking into account widely shared moral values as espoused in the four principles – the conclusions reached would be acceptable to care ethicists, Kantians, and utilitarians.

For the purposes of my project, principlism is the appropriate ethical paradigm rather than the ethics of care. Basing this inquiry in principlism will yield conclusions that will be persuasive to persons from varying ethical theoretical backgrounds. Basing the work in care ethics would deliver conclusions that would persuade people who adhere to care ethics, but no one else. Furthermore, principlism is able to take the considerations dear to care ethics into account – namely the central position of caring relationships and family.

Lastly, I am not convinced that the ethics of care can adequately deal with the ethical problem of individual freedom versus responsibility to others, a central issue in the ethics of MMR vaccination of children. Principlism is ideally suited to manage this tension, and the problem can be best conceived of as autonomy in tension with justice. Held points out that the relationship

between the ethics of care and justice is not fully clarified yet, but suggests that both frameworks be used in practical situations. I take this to mean that one applies principles of justice where this seems appropriate and principles of care where these seem appropriate. This reminds a lot of the haphazard approach which characterizes the current state of the literature on the ethics of MMR vaccination in children. I have been critical of what I have called the smorgasbord approach to the problem – using whichever ethical approach seems to be most useful for the problem at hand. The fact that a prominent thinker within the ethics of care proposes just such an approach to issues of societal concern shows that the ethics of care is not the appropriate framework from which to consider the tension between individuals and society in MMR vaccination.

For these reasons, I consider the principlist approach superior to the care approach for my project. The central insight delivered by the ethics of care, namely the centrality of caring relationships, is nevertheless an important ethical insight and I will in my analysis of the individual case of vaccination consider family and relational interests as important moral considerations.

### **(3.4) A public health ethics framework as alternate approach**

Some public health ethicists have approached vaccination and vaccination programs from a purely public health perspective (Dawson 2004; El Amin 2012; Isaacs 2012; Pierik 2016; Verweij & Dawson 2004). This raises the question as to whether a public health ethics framework is not a better or more suitable ethical framework for the ethical analysis provided in this dissertation. I will offer three reasons why the Beauchamp and Childress principlist approach serves the aims and goals of this thesis better as an ethical framework over a public health ethics framework.

#### *Guidance for both the medical and public contexts*

First, one of the aims of this dissertation is to provide ethical analysis that can provide guidance both for medical decision-making for the individual patient, as well as for societal responsibilities and policy. Whereas a public health ethics framework appears well suited to analysing policy from a population perspective, it is not quite clear to what extent it can provide guidance for individual of medical decision-making. The focus of public health is on populations, not on individuals (Kass 2001; Childress et al. 2002). Public health is concerned with a community perspective, and not with guiding the individual physician (Kass 2001; Childress et al. 2002). It considers the government and its institutions as playing a unique role in delivery of services and interventions, and does not focus as much on the professional responsibilities of individual healthcare workers or parents (Kass 2001; Childress et al. 2002). In a sense, the ‘patient’ is the community or population, and the ‘doctor’ is the government and its public health institutions. The principles-paradigm of B&C is much better suited to ethical analysis for medical decision-making, while it also incorporates consideration of societal perspectives and policy through specification and application of the principle of justice.

## *Public health ethics frameworks are conflicting and contested*

Second, there does not seem to be a unitary or agreed-upon framework of public health ethics. Rather, there are various different ethical approaches, sets of principles, or ethical frameworks within public health ethics which give the impression of a quagmire of loosely related ethical concepts rather than a clear and consistent ethical approach grounded in a systematic and coherent foundation. What should be included in a public health ethics framework seems controversial. Given this situation, it is not clear to me which public health ethics framework to choose out of the ones available, and what reasons one could ultimately give for one's choice apart from arbitrary personal preference. Indeed, this issue seems to me to be a worthwhile topic of focus for a doctoral dissertation on its own!

Consider the following examples.

(1) Childress et al. (2002) formulate a set of 9 principles for public health ethics. It appears as if these are influenced by the B&C principlist approach: these principles are general guides, provide *prima facie* duties, can be in conflict with one another, and should be specified and weighed when applied in ethical analysis. They call these principles 'general moral considerations' (p. 171), and the 9 principles are:

- producing benefits;
- avoiding, preventing, and removing harms;
- utility (producing maximal balance of benefits over harms and other costs);
- distributing benefits and burdens fairly (distributive justice) and ensuring public participation;
- respecting autonomous choices, and liberty of action;
- protecting privacy and confidentiality;
- keeping promises and commitments;
- transparency (disclosing information, speaking honestly and truthfully); and
- building and maintaining trust (Childress et al. 2002, p. 171-172).

The general method of ethical analysis seems similar to the method of B&C. These principles are applied to public health interventions and when in conflict weighed against each other. Five additional principles or conditions are stipulated to aid in weighing the principles and deciding which principle in a conflict to prioritize over another: effectiveness, proportionality, necessity, least infringement, and public justification (p. 173).

The trouble is, it is not clear where these principles exactly come from. What is the foundation of these principles? What grounds them? Why *these* principles, and not others? A variety of different ethical frameworks are mentioned throughout the paper. On page 171 the authors



describe the commitments of public health, including communal action and communal good, in what appears to set the stage for a Communitarian justification. Further down on page 171 they invoke the paradigm of casuistry as being “compatible with” and “indispensable” to their conception of public health ethics. On page 173 they invoke the concept of a “social contract” and a “liberal, pluralistic democracy”. On page 174 they cite Norman Daniels, who is a known Rawlsian egalitarian. On page 175 they argue from Mill’s work in *On Liberty*. To complete the full circle, on page 176 they cite a human rights paradigm. The authors appeal to these different and conflicting ethical paradigms within the same overarching argument as if they are somehow related to one another, moving from one to the other almost unacknowledged. Serious conflicts between these different approaches are not addressed, and no systematic approach for how these different theories are reconciled is offered. But even more surprisingly, the 9 principles offered are not in any noticeable way based on these ethical frameworks or derived from these ethical frameworks. Instead, the authors write:

“We can establish the relevance of a set of these considerations in part by looking at the kinds of moral appeals that public health agents make in deliberating about and justifying their actions as well as at debates about moral issues in public health” (p. 171).

So then, the 9 principles are derived from the “moral appeals” that public health agents make during the course of their work, and from debates on specific public health issues. It is not shown how this is done. It is also not shown what then provides normative grounding for these principles. It appears as if the authors imagine that simply because public health officials generally appear to appeal to principles of this sort, they enjoy binding normative grounding. Interestingly, the authors appear to be somewhat aware of these deficiencies, as they write:

“The terrain of public health ethics includes a loose set of general concepts and norms that are variously called values, principles, or rules – that are arguably relevant to public health. Public health ethics, in part, involves ongoing efforts to specify and to assign weights to these general practices, and actions, in order to provide concrete moral guidance” (p. 171).

Thus, I find in the paper by Childress et al. (2002) not a coherent and adequately grounded ethical framework for analysis to the same extent as can be found in the principlism of B&C. Rather, this seems to be an attempt at a starting point to draw out some important themes within public health ethics.

(2) Kass (2001) attempts to provide an ethics framework for public health. Like the Childress et al. article, she describes public health as focusing on the health of populations, and not individuals. She describes the communal nature of public health, collective communal actions leading to improved health for the entire community, and describes the particular role of the government in delivering public health. She then stipulates the need for an ethical framework for public health, distinct from medical ethics: public health institutions and governments can exercise a lot of power and consequently a code of ethics functioning of as a code of restraint is

important. “A code to preserve fairly... the negative rights of citizens to non-interference” (p. 1777). In her argument she cites various components and requirements of such a framework – the need to include “positive rights”, “affirmative obligations to improve the public’s health, and arguably, to reduce social inequities”, and the “social justice functions of public health” (p. 1777). From this foundation, she proceeds to develop a 6-step framework for public health ethics, containing the following components (p. 1777-1781):

- What are the public health goals of the proposed program?
- How effective is the program in achieving its stated goals?
- What are the known or potential burdens of the program?
- Can burdens be minimized? Are there alternative approaches?
- Is the program implemented fairly?
- How can the benefits and burdens of a program be fairly balanced?

This framework is described as an “analytic tool” (p. 1777) which can be used to analyze the ethical implications of specific interventions and public health programs. According to this framework, a public health intervention has to adhere to all of these different elements in order to be ethical. First, it should be clear what the goals of the program are, how the program improves the health of the public, and to whom the benefits accrue. Second, it should be demonstrated to what extent the program can reach the stated goals. Third, risk for harms should be identified. The majority of such harms, she argues, include risk to confidentiality, risks to liberty and self-determination, and risks to justice if only certain groups are targeted by interventions (p. 1779). She does not here consider physical harms that may result from public health interventions. Fourth, consideration should be given to modifying programs to minimize the harms identified in step three. Fifth, the program should distribute benefits and burdens fairly, using principles of distributive justice. Initially she does not state a specific theory of justice when considering a fair distribution of benefits and burdens. But when she comes to a second argument, considering whether public health has a role in addressing existing societal inequities, she cites the theory of justice of John Rawls, and argues that justice requires society to help the least well-off. She does acknowledge that this theory of justice is not supported by all philosophers. Sixth, if a program is such that there is clear public health benefit that outweighs the burdens, the program should go forward. She acknowledges that citizens would disagree on how benefits and burdens are to be balanced, and therefore fair procedures should be in place to address such disagreements. This could include societal discussion on public health programs, including avenues such as public hearings to encourage the inclusion of minority views.

This framework is evidently very different from the framework in the Childress et al. article, yet starts off with similar assumptions regarding the nature of public health, its Communitarian commitments, and the role of government in public health practice. Once again a variety of ethical approaches are invoked to provide ethical grounding for the framework and norms elicited, without it being clear how different and conflicting ethical approaches are related to one

another. The ethical framework for public health that is presented provides a tool with six questions to which every public health intervention must adhere. There is some role for individual liberty or autonomy, the violation of which is considered a potential harm of public health interventions. In the balancing section in question six, it is mentioned that disagreements about benefits vs. burdens have to be settled by public discourse, without it being clear what framework can be used to settle such conflicts between ethical goals. For example, is one dissenter to a public health program enough to invalidate the program? Or can the majority overrule a dissenter and force compliance with the program? The provided framework does not provide a clear avenue for resolution of this tension, which is a central tension in public health in general, and in vaccination programs in particular.

(3) Gostin and Gostin (2009) considers the tension between individual autonomy and the public good. They state that they consider the problem using a Millian framework. In this article they argue for a hard form of paternalism in public health, arguing that public health interventions aimed at limiting the autonomy of individuals for their own good can be tolerated. Examples of the kind of interventions they have in mind are laws that prohibit smoking, laws that enforce helmet use for motorcycle riders, and regulations that combat obesity. Laws of this kind can be shown, they argue, to improve the overall health of the population. Since public health focuses on the health of the public and is communal in nature, and does not focus on individuals, infringements on autonomy that promote the overall good and wellbeing of the population can be justified.

Apart from using different ethical theories in their process of justification in a typical smorgasbord way, there is another serious objection to the entire overarching argument in this paper. Gostin and Gostin do not seem to realize the degree to which their argument engages in value-imposition, and underestimates the nature of value-pluralism in contemporary societies. Contemporary societies contain various different conceptions of the good life, and an important precept in such societies is the idea that people should have the freedom to seek their own conception of the good as long as the same freedom is extended to others. In contrast with this, Gostin and Gostin argue that personal choices are the leading causes of death and disability in society, and that benign paternalism therefore have a valid role in society. Gostin and Gostin state that as opposed to various subjective conceptions of the good, the aim of public health is “positivistic and objective” (p. 218). This represents a gross misunderstanding of the value-based assumptions that inform public health interventions. The Gostin and Gostin line of argument would actively engage public health officials and the government in choosing conceptions of the good on behalf of members of society, and justifies this by stating that its own conception of the good is the ‘objective’, preferable, and value-neutral one. But this flies in the face of respecting the values of other people and value pluralism. For example, let us consider their example of motorcycle helmets. Gostin and Gostin argue that many lives can be saved by paternalistic motorcycle laws (p. 217). Take now a fully informed motorcycle rider who hold independence and an active lifestyle in such high regard, that he would rather be dead than disabled or living in

a nursing home. Such a rider may know that his risk of dying is higher without a helmet, but thinks to himself that he would rather be dead than survive in a disabled state. Furthermore, he knows that his risk of injury and disability is quite high should he be in an accident and survive. Thus, he knowingly and in fully informed fashion refuses a helmet, because living in an injured or disabled state are unacceptable to him, given his values and his view of the good life. He would rather be dead than survive in a disabled state. Gostin and Gostin would impose on him their value of lives saved, and potentially force him into accepting a state of life that conflicts with his own values and goals. In other words, the “positivistic and objective” laws aimed at saving lives through enforcing helmet use overtly imposes a value judgment and a conception of the good life on the individual in the name of scientific objectivity.

Gostin and Gostin therefore advocate an approach to public health that is overtly paternalistic, where the public health official imposes value judgements on individuals in the name of improving the health of populations. This view faces serious objections, but I will not go into further detail here. Suffice it to say that this is highly controversial and contestable, and in my view indefensible. Be that as it may, the point I am trying to make in reviewing this article is to show how decidedly at odds this approach to public health ethics is with the approaches of Childress et al. and Kass. Yet, they all start off with the same set of assumptions regarding the goals and nature of public health, as well as the role of the government.

Having now considered three different public health ethics frameworks, it is clear that using a public health ethics framework for the analysis in this dissertation would present serious problems. The three presented frameworks conflict with one another, and it is not clear how the conflict can be resolved. There is no unified conception of what a public health ethics framework would look like. For example, the conception and application of individual autonomy differs radically in the frameworks I reviewed above. Which framework should therefore be used to analyze public health interventions where there is tension between individual freedom and the public good? To answer this question would be to engage in a body of work which would itself be a worthwhile focus of doctoral study.

Furthermore, it is not always clear how the different norms and frameworks are grounded. The argumentation does not always provide a clear connection between a stated public health ethics principle and the stated ethical framework. The authors also typically engage in an unsystematic use of conflicting ethical theories within the same argument, raising questions as to the validity and groundedness of conclusions.

I have demonstrated how B&C’s principlism is much better grounded, a more systematic approach, is based on widely shared moral judgments and therefore enjoys wider endorsement, and much more coherent than the controversy regarding public health ethics frameworks. Once again, B&C’s framework is preferable for the purposes of this dissertation than using a public health ethics framework.

### *Intrinsic communitarian assumptions in public health*

Third, using a public health ethics framework commits one to the Communitarian assumptions intrinsic to public health. All of the public health literature cited share these intrinsic assumptions: collective action producing a public good and promoting the common good; the role of governments; and a focus on communities rather than individuals.

I have noted in chapter 1 that most writers who seek to analyze the ethics of measles vaccination invariably employ communitarian assumptions when considering the obligations of the individual to others in society. This is in order, but leaves the conclusions unacceptable to those who reject Communitarian theories of justice. In this dissertation I aim to additionally consider how other theories of justice and different conceptions of the just society grapple with this problematic. For this reason, a public health ethics framework is not suitable for this dissertation. Using the B&C principles instead would allow the exploration of different and competing theories of justice, as I will show in Chapter 6, and will lead to conclusions that are more widely accepted and more generally applicable. I also believe this will be a substantial contribution to the literature on the subject.

### **(3.5) Limitations of using B&C's principlism**

I've defended B&C's principlism as the appropriate ethical approach for ethical analysis in this dissertation. In particular, I've shown how B&C is superior to alternate approaches for this particular thesis, and shown how B&C's principlism can be defended against its critics. That does not mean, however, that the B&C approach has no limitations.

The B&C principlist approach does not enjoy universal support, and has some detractors who are persuaded by other approaches to bioethical reasoning. This should not be surprising; no ethical theory or approach enjoys universal support, and it is a given that selecting any bioethical approach for ethical analysis will immediately leave one with a number of detractors who disagree with the ethical approach chosen. Specifically in this regard, it should be remembered that B&C's principlist approach was developed by philosophers in the United States, and therefore adopts assumptions reflective of its geographical and societal context. The emphasis on individual autonomy, for example, can be criticized from a variety of different perspectives. As I've pointed out, feminist philosophers argue that the autonomy paradigm in B&C misunderstands the importance of care relationships and what it means to be a child. On the other hand, more Communitarian thinkers may place greater emphasis on a situated self, on communal and familial decision-making.

Thus, it should not be supposed that B&C's principlist approach appeals to everyone or settles every possible ethical question. However, a similar deficiency would be present no matter which

ethical approach is chosen. One of the strengths of B&C's principlist approach that buffers it somewhat against this deficiency is the fact that the four principles are based in widely shared moral judgments. There are a number of moral judgments on which adherents of different ethical approaches agree, and B&C base their principlist approach on these shared moral agreements. In this way the conclusions reached through application of the principles enjoy wider endorsement, I would argue, than if I were to select a single ethical theory such as utilitarianism for ethical analysis.

Being mindful of the limitations of the B&C approach, it will be important to consider a Communitarian approach among the different conceptions of justice and it will also be important to carefully consider the status and interests children.

Another possible limitation is that inappropriate use of the principles can easily lead to a similar sort of "smorgasbord" approach as the one that I've been critical of in the measles vaccination ethics literature. In order to avoid this it will be important to clearly specify and balance the principles, and bring them all into a state of reflective equilibrium. I've argued that B&C's principlism does allow for a systematic and consistent application of the principles in a way that avoids the problem of ad hoc argumentation and conclusion, and ultimately avoids the smorgasbord approach.

#### **(4) Principlism and measles vaccination in children**

In the next few chapters of this work, I shall apply the principles of bioethics to the issue of measles vaccination in children. To do this, I will explicitly draw on the conclusions of the previous two chapters on measles disease and measles vaccination. The four principles will be applied directly to these known facts, in order to draw out moral considerations involved in measles vaccination.

I shall proceed as follows. First, I shall consider the principles of autonomy, beneficence and non-maleficence as they apply to the individual case of measles vaccination. Through a process of argued reflection and specification, I shall arrive at two moral action guides as pertains to measles vaccination in children: (1a) Morality requires vaccination against measles for all children that are eligible for vaccination, and (2a) Respect for parent-child relationships regulates the response to measles vaccine refusal, type of policy preferred and places limits on the amount of coercion that can be justified. Principle (1a) indicates a moral commitment towards vaccinating those who are eligible, and is a strong moral principle at least to the point of measles elimination from society. Principle (2a) regulates the types of responses favored in dealing with parental vaccine refusal, such as placing limits on the types of State coercion that can be used or favoring non-coercive responses to vaccine refusal.

Next, I shall consider the issue from a justice perspective. In doing so, I shall use the six theories of justice identified by B&C as being influential in contemporary discourse regarding justice. In turn, I shall consider measles vaccination in children from the perspective of each of these major theories. It will be shown that each of these theories commit us to two moral action guides as pertains to measles vaccination and the just society: (1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society, and (2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal. The thesis I will defend is that these two action guides are dictates of justice, no matter which theory of justice one subscribes to; I will do so by showing how each of the 6 different theories of justice lead us to adopt (1b) and (2b). Principle (1b) defines a moral commitment for societies to vaccinate all children who are eligible, at least to the point where measles vaccination is sustained. Principle (2b) regulates the societal response to vaccine refusal, and makes room for respecting of parental vaccine refusal.

It is clear that principles (1a) and (2a) are very similar to principles (1b) and (2b) from the justice perspective. That is an important insight, and one of the major findings of this work: that consideration of measles vaccination from different principles bring us to similar action guides and lead to similar conclusions. These action guides represent the four principles of B&C's principlism in balance with one another, and using these action guides to derive actual ethical obligations with regard to MMR vaccination brings the moral force of the four B&C principles to bear in a practical way.

The goal is to reach a stage of reflective equilibrium, where all of these moral commitments are balanced with one another, removing conflict and uncertainty. Further balancing and consideration of these specified action guides will be the task of the last chapter in this work. These action guides can be blended, further specified, and combined to give us the following:

(1) All children eligible for measles vaccination should be vaccinated against measles, at least to the point of sustained measles elimination.

(2) Respect for parental decision-making and the parent-child relationship guide the response to parental vaccine refusals.

In light of (1), vaccinating children with MMR is a moral imperative, and vaccine refusals demand a response from society and healthcare providers. In light of (2), non-coercive responses such as building of trust and education are preferred. If the use of State power becomes necessary because other measures fail to ensure sufficient vaccine uptake, the types of coercion is limited by considering the impact on the family unit and on liberty.

In conclusion I shall consider who has which moral responsibilities, and apply action guides (1) and (2) to vaccination policy to arrive at morally justified policy suggestions. In essence, I shall argue that parents have a strong moral obligation to have their children vaccinated. They are not always in the ideal situation to discharge this obligation, either through barriers to vaccination or through mistaken beliefs regarding vaccination. Healthcare providers have a strong obligation to provide vaccinations and to assist parents in discharging the obligation to vaccinate through various means such as vaccine education and the building of trust relationships. The State has obligations to ensure that measles vaccines are readily available, that vaccine policies are in place that would ensure adequate uptake of measles vaccination, and to respond to vaccine refusal through education and through use of State power as needed.

I shall argue that measles vaccination policies will focus on three areas:

- Use of a tightly worded opt-out system which only allows exemptions for religious objections to vaccination. Thus, all children will be vaccinated unless the parents actively show their objection to vaccination on religious grounds, or medical contra-indications exist.
- The use of educational methods that have been tested and shown to be effective in increasing vaccination uptake.
- The building of trust relationships between primary care providers (such as family doctors or primary care nurses) and parents. This should be the building block of all care provided to children, and the cornerstone of vaccination delivery.

These conclusions and recommendations will bring us to a place of reflective equilibrium, where all the principles have been specified, weighed, and balanced to clarify moral obligations and



remove doubts and conflicts. Furthermore, it will also be clear how these conclusions affect real-world considerations such as vaccination policy and vaccination delivery.

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## Chapter 5: The individual child and measles vaccination

In this chapter the ethical principles of beneficence, non-maleficence and autonomy as they pertain to measles vaccination will be considered. To do so, these principles will be applied and specified as they relate to the individual case of measles vaccination. The focus here is on the interests of the individual child and the individual case of measles vaccination. The analysis will rely on the medical and scientific facts presented in chapter 2 and chapter 3.

In chapter 3, scientific analysis mostly related to MMR vaccines. There are good reasons for this: MMR is widely used to vaccinate against measles (over 90 countries, including North America and Europe), and a lot is known regarding the efficacy and potential adverse effects of MMR (Demicheli et al. 2012). Of course, MMR also contains vaccine components that protect children against mumps and rubella. But for the sake of this analysis, I will only focus on the effects against measles. In going forward, I will therefore simply use the term “measles vaccination” when referring to the vaccine. It is the protection against measles I am most interested in. Bear in mind, however, that the benefits of MMR includes protection against other diseases as well, which strengthens the benefit of the vaccine when considering benefit vs risks.

I shall furthermore assume that high quality measles vaccinations are reasonably available and administered by knowledgeable professionals. Of course, if one were in a situation where measles vaccines were of doubtful quality, or were expensive to the point of being unaffordable by the general public, it would change the analysis. The reality is, however, that measles vaccines of safe and reliable quality are reasonably available at low cost; for example, it is possible even in the developing world to vaccinate a child against measles for less than one US dollar (UNICEF 2007). Furthermore, various national and international public health agencies are doing excellent work in ensuring availability and access to measles vaccination globally (CDC 2008, UNICEF 2007). These efforts have led to an increase in the global vaccination rate and a decrease in the global measles mortality burden (CDC 2008, UNICEF 2007).

Thus, the question I shall consider in this chapter will be as follows: In a society where measles vaccination is reasonably available, what are the ethical considerations when thinking of the individual case of measles vaccination? Or put differently: what would ethical considerations demand when it comes to an individual child and measles vaccination? Of course, there are but two courses of action, to vaccinate a child or to not vaccinate a child. So, the question also arises: do ethical considerations instruct us to vaccinate a child against measles, or do they favor non-vaccination? Or is it neither; is the question perhaps ethically neutral?

To answer these questions, I shall analyze the individual case of measles vaccination by using the principlist approach of Beauchamp and Childress (2013). In this chapter, specifically the principles of autonomy, beneficence and non-maleficence will be applied to the questions as stated. At first glance, autonomy is an issue: at the centre of the question is a young child who

does not have the capacity for autonomy. I will therefore firstly consider an ethical framework for medical decision-making for young children, namely that parents act as surrogate decision-makers for their children in accordance with the best interest standard. I will also argue that a best interests standard can readily be grounded in the B&C principles: when people make decisions for a child in accordance with the best interest standard they are considering which course of action would bestow the greatest benefit and best limits harm to the child, so that in reality this is nothing other than weighing the implications of the principles of beneficence and non-maleficence against each other. I pointed out in chapter 1 that many authors who deliberate about the ethics of measles vaccination in children employ parental decision-making in accordance with a best-interest standard as a way in which to analyze ethical considerations involved. However, the best interests approach is never grounded within a specific ethical paradigm, and the argumentation often suffers from a haphazard, smorgasbord approach in which different and competing ethical considerations are appealed in an inconsistent and unsystematic fashion. I argued that the implications of this approach are that conclusions reached appear arbitrary and *ad hoc*, not being grounded in a consistent ethical approach or in substantive ethical argument. Essentially, the moral case for the individual instance of the vaccination of a child has not been adequately made in the literature up to this point. In this chapter I therefore argue that parental decision-making according to perceived best interests of the child is grounded in the ethical principles of beneficence and non-maleficence, and then proceed to examine the individual case of vaccination using this framework.

I shall conclude that the principles applied to the individual case of vaccination will lead us to adopt two specified ethical action guides or specified moral principles. From these two action guides or specified principles, moral obligations can be derived that will bring considerations of autonomy, beneficence and non-maleficence into balance with one another with regards to measles vaccination in children. The two action guides I will establish are:

(1a) Morality requires vaccination against measles for all children who are eligible for vaccination.

(2a) Respect for the parent-child relationship regulates the response to measles vaccine refusal, type of policy preferred and places limits on the amount of coercion that can be justified.

In chapter 6, I shall consider measles vaccination in children from a justice perspective, examining the ethical implications of 5 different theories of justice. I shall argue that when it comes to measles vaccination in children, each of these different theories of justice would be committed to the formulation of two ethical action guides or principles, which I shall call (1b) and (2b). Remarkably, moral action guides (1a) and (2a) derived from the principles of autonomy, beneficence and non-maleficence are strikingly similar to action guides (1b) and (2b), derived from the principle of justice.

In the concluding chapter of this project, I shall show how these action guides can be combined with one another in formulating two ethical action guides or principles, (1) and (2). These two

action guides or principles will represent the four principles of principlism in balance with one another. As such, these two specified action guides can then be used to derive ethical obligations and ethical guidance with regards to measles vaccination in children on a societal and individual level. Such ethical conclusions will be grounded in the ethical foundation of the principles of B&C, bringing these different ethical considerations into a state of reflective equilibrium.

## **(1) The best interest standard and medical decision-making for children**

When faced with situations where patients do not have the capacity to make their own medical decisions, there are different strategies that can be followed to make sure that autonomy is respected (Beauchamp & Childress 2013; Buchanan & Brock 1990; Elliot 2001). One such strategy is to take into account previously expressed autonomous choices. If an incompetent patient previously expressed a decision on a matter while competent, these wishes can be taken into account as the autonomous choices of a competent individual. This is the idea that advance directives are based on: autonomous persons make their wishes known with regards to healthcare decisions should they lose medical decision-making capacity in future.

Previously expressed wishes of currently incapacitated patients are not always known in this way. Another possible approach is to have a surrogate decision maker. If someone previously had the capacity to make their own decisions, and now through a car accident and concomitant brain injury (for example) is incapacitated, the surrogate decision maker can state what the patient would have decided with regards to their medical care. This is called the substituted judgement standard. It is assumed that the surrogate decision maker knows the patient well, and cares for the wishes of the patient, and can therefore reliably and faithfully decide on behalf of the patient as the patient would have done. Usually it is a spouse or close biological family who acts as surrogate.

The approaches mentioned above are defended by B&C, (2013, p. 226-228) Buchanan & Brock, (1990, p. 98-138) and Elliot (2001). The basis for the respect of individual autonomy is in respecting what the currently incapacitated presumably would have chosen, either by taking into account previously expressed wishes such as is found in an advanced directive, or by relying on the knowledge of next of kin who can judge how the patient would have chosen in the given circumstance. These approaches therefore assume an incapacitated patient who had medical decision-making capacity at some point in the past.

When it comes to measles vaccination in children, it appears that neither of these two approaches would be helpful. The first measles vaccine is given at 12-15 months of age and the second vaccine anywhere from age 18 months until school age in societies where the risk for contracting measles is low (Demicheli et al. 2012; Moss & Griffin 2012). In societies where the risk for contracting measles is higher, the recommendation is usually for earlier administration of the first vaccine, such as at 9 months age (Demicheli et al. 2012; Moss & Griffin 2012). It is therefore clear that in the individual case of measles vaccination, we are dealing with a very young child. A child of 18 months or younger is not capable of autonomous decisions, and has never at any previous time been capable of autonomous decisions. There are therefore no previously expressed wishes to go by, and there is no way in which a substituted judgment can be made since no-one knows how this individual would have decided if competent.

In cases where the individual in question has never been competent, various authors argue that the appropriate guide for substituted decision making is the best interest standard (Beauchamp



& Childress 2013; Buchanan & Brock 1990; Elliot 2001). There is simply no way of knowing how a never-competent individual would have chosen if competent in a set of circumstances. But it is usually possible to weigh how different treatment choices would impact the overall welfare of the never-competent patient by weighing potential benefits and risks of each treatment option. In the absence of specific knowledge regarding the choices of an individual, making decisions on behalf of that individual that optimally promotes their welfare, and is therefore in their best interest, is argued to be ethically defensible and reasonable.

Buchanan & Brock (1990, p. 122) maintain that in cases where substituted judgement and advanced directives are not feasible the best interest standard should apply. If faced with an incapacitated patient and a health care choice, clinicians and surrogate decision-makers should weigh the benefits to the patient from each decision against the potential “disinterests” from each choice. In the end, they should opt for the choice that provides the most net benefit to the incompetent patient. Usually, the incapacitated patient’s family (closest biological relatives or adopted relatives, or spouse) is seen as the appropriate agents to make decisions in the patient’s best interests (p. 136-139). Buchanan and Brock provide reasons for this – of all available persons the patient’s closest family members are most concerned with the patient’s best interests and are thought to have the best knowledge of the incompetent patient’s best interests (p. 136-139). Also, family is highly valued within society as a means of community and meaning, and this should not be interfered with by society unless to prevent harm to individuals outside the family (p. 136-139).

Buchanan and Brock (1990, p.246) argue that for young children the best interest standard is “the only appropriate guidance principle.” B&C (2013, p. 228-229) argue along similar lines that patients who were never competent should have a surrogate decision maker direct their health care decisions in accordance with the best interest standard, as does Carl Elliot (2001). The interests of the young child are thought to include immediate interests such as absence of pain or suffering and the presence of pleasure, as well as future interests or developmental interests such as development, future opportunities and relationship interests (Buchanan & Brock 1990, p. 247).

These considerations apply directly to the individual case of measles vaccination in children. Central to measles vaccination is the very young child, usually between 9 months and 18 months of age. This child is not competent to exercise autonomy, and has never been competent to express autonomous decisions on health care previously. The correct guiding principle is therefore the best interest standard. I also take it that the best surrogate decision maker is usually the child’s parent(s). The parents care most for the child and for the child’s interests. The parents live with the child and will bear the consequences of any infringement on the child’s best interests. Harming the child will result in the most substantial distress to the parents, even to harm to the parents themselves, so that the best interests of the child is of the utmost concern to parents. Thus, the task to direct health care decisions in the best interests of the child is usually left to the parent(s).

Most often, parents are thought to be the best judge of the child's best interest and most parents discharge their responsibility well. But this is not always the case. Sometimes parents can be genuinely mistaken about their child's best interest. At other times, some parents may be indifferent to their child, or a child-parent relationship may be abusive. In the analysis of the individual case of vaccination, I will assume a healthy child-parent relationship where the parent can act as appropriate proxy. It is obvious that in cases of child abuse or neglect, the State should intervene. It is also obvious that in the absence of parent or family, society at large has a responsibility to intervene through the agency of the State. What is more difficult is a healthy parent-child relationship where parents are clearly mistaken regarding the best interests of their child. I shall consider this scenario as part of the analysis.

The best interest standard has become the guiding standard of choice for decision-making for children, and is considered to be both an ethical standard as well as a legal standard (Birchley 2016; Buchanan & Brock 1990, p. 216-260; Diekema 2011; Pope 2011). In chapter 1 I reviewed the status of the best interest standard within South African law (chapter 1, section 2.2.2). The best interest standard is also a guiding legal standard for courts in their decision-making for children in other countries, such as the USA, Canada, and the UK (Birchley 2016; Pope 2011). But the best interest standard is also an ethical standard, as defended by the authors and arguments cited above, describing the ethical obligations of those who stand in morally significant relationships with the child and who are tasked with making medical decisions for and providing medical treatments to the child.

The central consideration in all decisions regarding a child, therefore, is what is best for the child. For medical decision-making, the framework is as follows (Birchley 2016; Buchanan & Brock 1990, p. 216-260; Pope 2011). Parents have the authority to make and authorize medical treatment decisions for their children, and should be guided by the best interest standard. Healthcare professionals who stand in a therapeutic relationship with the child offer treatment plans and options that are in keeping with the best interests of the child, and looks to the parent to choose between available treatment plans and to provide informed consent when necessary. Thus, physicians offer and recommend appropriate treatment options, parents choose and authorize treatment options. Both parties are guided by the best interest standard. The authority of parents are not unlimited. Parental decisions that are not in keeping with the best interest standard should be challenged by other parties who stand in morally significant relationships with the child, such as the physician. The best interest standard describes the obligations of parents and healthcare professionals towards children when it comes to medical decision-making, and places limits on the decisions that can be made. The best interest standard therefore serves both as guiding principle, describing the ethical obligations of those who make decisions for children, and as limiting principle, describing the limits that are placed on parental decision-making authority (Birchley 2016; Pope 2011).

### *Grounding the best interests standard in the principles*

I shall now argue that the best interest standard is implicitly grounded in considerations of beneficence and non-maleficence. The young child does not have the capacity for autonomy, and has not been autonomous at any prior time. There is therefore no autonomy of the child to weigh in the consideration, and decision-making is purely guided by what is best for the child. The child's parent(s) of course usually have the capacity for autonomous decision-making. But the parents are here making decisions on behalf of their child, and not for themselves. Their decision-making authority is therefore not unlimited, but is limited by the best interest standard.

In order to use the best interest standard, decision-makers need to weigh the options before them in light of the benefits and costs or harms of each, eventually choosing the option that has "the greatest net benefit to the patient" (Buchanan & Brock 1990, p.123). Therefore, the decision-maker has the obligation of making decisions that would maximize benefit and reduce overall harms to the minimum. But this in its essence is what the principles of beneficence and non-maleficence are about. Beneficence justifies actions which bring about increased welfare or the conference of some benefit. Non-maleficence justifies actions that limits harm. Therefore, a parent who chooses what will confer the greatest net benefit is operating in accordance with the principle of beneficence, and a parent who is concerned with limiting harm to their child is operating in accordance with the principle of non-maleficence.

B&C conceives of the best interest standard as mainly grounded in beneficence. They state, "The term *best* applies because of the surrogate's obligation to act beneficently by maximizing benefit through a comparative assessment that locates the highest probable net benefit" (Beauchamp & Childress 2013, p.228). It is not hard to see, however, that the best interests standard also has a substantial focus on limiting harm in weighing overall benefit, and it is therefore clear that non-maleficence is also an important grounding principle for the best interests standard. Sometimes the healthcare choice involving the child centers on a decision as to which course of action would mitigate harm to the highest degree. One would imagine that this is particularly so in the case of preventive actions. A preventive medical intervention does not focus so much on providing benefit as it does on preventing future harms. This is precisely the paradigm of vaccinations in children. An intervention is given to a healthy child to prevent future illness and future harms. In one sense it is a benefit; foregoing a serious infectious illness is a tremendous benefit. In another sense it is purely a harm-reduction exercise, where the potential harms of the intervention pales in comparison with the potential harms of not giving the intervention. There is therefore a degree of overlap between the principles of beneficence and non-maleficence. The exact delineation between the two is not clear; it is not certain where one ends and the other begins in this context. What is clear, is that both are grounding principles for the best interests standard, and a parent who chooses in accordance with best interests are motivated by considerations of beneficence and non-maleficence.

On reflection, it seems as if parental decision-making in accordance with the best interest standard satisfies the demands of the bioethical principles of beneficence and non-maleficence. To act in a child's best interests is the same as considering beneficence and non-maleficence with regards to the child. Children are uniquely dependent on their parents, and have interests that are intertwined with the interests of their parents (Elliot 2001). Thus, to allow parental decision-making according to the perceived best interests of the child promotes and respects important interests of the child (Elliot 2001; Buchanan & Brock 1990). Generally, the judgment of parents should be respected due to the nature of the parent-child relationship. Not only do parents usually care most deeply for their children, and are thought to be best situated to make decisions for their children, but the interests of the child are also closely intertwined with their relationship with the parent. Harming the parent-child bond will ultimately compromise the interests of the child. Thus, the freedom of parents to choose should be given wide latitude. Once again, this is not an unlimited freedom to choose: parental decisions that clearly compromise the interests of the child should be challenged by others who stand in morally significant relationships with the child.

### *Best interest and vaccinations: The argument of Angus Dawson (2005)*

Dawson (2005) considers the best interest standard as guide to medical decision-making for children in relation to vaccinations in general. He defends the use of the best interest standard in decision-making on behalf of children, using the ethical framework of Buchanan and Brock (1990). On pages 82 and 83 he argues from the principles of beneficence and non-maleficence and seems to assume the grounding of the best interest standard in beneficence and non-maleficence. When it comes to vaccines, he then argues that the relevant risks and benefits should be weighed in order to decide whether a specific vaccination is in the best interest of the child, underlining the need for empirical facts in the determination. Parents and physicians should choose those vaccines where benefits outweigh risks. If parents refuse vaccines, such refusal can be (and should be) overridden by the state if such decisions pose a threat to the child's welfare. Important in such determinations is consideration of empirical data.

Overall, the argument that Dawson defends is summarized as follows (p. 75):

- “1. Medical decisions about incompetent patients should be made on the basis of what is in their best interests (where prior wishes are unknown or non-existent).*
- 2. Pre-school infants are incompetent (and have no prior wishes).*
- 3. Therefore, decisions about the medical care of infants should be made on the basis of what is in their best interests.*
- 4. Best interests in relation to infants should be determined by seeking to balance the potential harms and benefits of possible actions and inactions.*

5. *Where the parents make a decision about an infant's care which is likely to result in substantial risk of significant harm to that infant then third-parties (such as the state) have an obligation to intervene to protect the infant from the consequences of that decision.*

6. *Given 4, what is in the best interest of infants in relation to vaccinations is to be decided by seeking to balance the harms and benefits associated with vaccination versus non-vaccination.*

7. *Given 3,5 and 6, where it is in an infant's best interests to be vaccinated (or not vaccinated) and the parents decide the other way then the state (or other legitimate third-parties) have an obligation to ensure that the infant is protected from the consequences of such a decision."*

Generally, Dawson's argument seems to be in agreement with the argument and framework I have defended thus far, and Dawson shows how these considerations can be directly applied to vaccinations in general. On page 84, however, Dawson states that with measles vaccination the evidence for the benefit and risks of MMR is unclear, and it therefore follows that it is unclear whether measles vaccination is in a child's best interest. This, I will argue, is mistaken – the empirical evidence exists to make this determination regarding measles vaccination. To be fair to Dawson, Dawson's article appeared in 2005 and since then much more empirical evidence has become available and the Wakefield-autism article has been discredited and retracted.

In what follows, I will consider the best interest framework in the light of the empirical evidence I presented in chapters 2 and 3. I will show that measles vaccination is undoubtedly in the best interests of children. However, in cases of vaccine refusal, a variety of the child's interests have to be considered. I therefore now turn to applying the best interest standards to the individual case of measles vaccination. In doing so, it is important to analyze the expected benefits and harms of each possible option of the decision in question, and choose the option that leads to the best possible outcome for the child. This would have to incorporate a variety of the child's interests: avoidance of suffering and pain, enhancement of pleasure, familial relationships, and development. What will emerge are two action guides, (1a) and (1b), which would represent specified moral principles derived from the principles of beneficence and non-maleficence.

## **(2) The individual case of measles vaccination in a child**

### **(2.1) Best interests of the child**

The medical facts with regards to measles vaccination have been extensively presented in the previous chapters, but I summarize some relevant details here as we embark on providing benefit and reducing harms. Measles is a serious disease with serious complications (Buchanan & Bonthius 2012; CDC 2013a; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). It is also highly infectious, so that the unvaccinated child is almost certain to get measles if brought into contact with measles virus (Buchanan & Bonthius 2012; CDC 2013a; Dardis 2012; De Vries et al. 2012; Moss & Griffin 2012). If the child were to get measles, there is a 30%-40% chance of some kind of complication from the illness (CDC 2013b; Moss & Griffin 2012). This includes a 5% chance for pneumonia, the leading killer, a 10% chance for otitis media which can lead to deafness, an 8% chance for diarrhea (CDC 2013b; Moss & Griffin 2012). For every 1000 measles cases, 4-5 children will suffer a serious neurological complications such as encephalitis (Buchanan & Bonthius 2012), and there will be 1-2 deaths (CDC 2013b). There is also a risk for eye infections and blindness of uncertain magnitude, but of substantial concern (Moss & Griffin 2012). Added to this, children who get measles will suffer the effects of active infection, which is similar to an influenza type infection. This includes fever, coughing, sneezing, eye irritation and pain, and the like (Moss & Griffin 2012). This syndrome is certainly unpleasant, as anyone who has had a serious case of the flu will be able to testify.

If a child were to get vaccinated against measles, protection against measles infection is conferred (Demicheli et al. 2012; Meissner, Strebel, & Orenstein 2004). One dose of measles vaccine at 12 months of age or later is 95% effective in protecting against measles, while two doses are over 99% effective (Demicheli et al. 2012; Meissner, Strebel, & Orenstein 2004; Moss & Griffin 2012). At 9 months of age a single dose is thought to be about 85% effective in preventing measles (Moss & Griffin 2012). The adverse effects seen with measles vaccine are transient and minor – fever in 5 to 15%, rash in 5%, joint pain in up to 25% and the like (see detailed analysis of MMR adverse effects, chapter 3 section 3). These do not cause the same amount of discomfort and suffering as do acute measles infection. Measles vaccination does increase the risk of febrile seizure by 0.3-0.8%; however, febrile seizures are thought to be benign in their outcome, and certainly the risk of febrile seizure with measles infection is higher than with the vaccine. The potential serious adverse effects of measles vaccination are extremely rare. This includes allergic reactions in less than 1 per million, a transient thrombocytopenia in less than 1 per 30,000 that usually passes without problems, and a doubtful connection with encephalitis (brain infection) in 0.22 per million or less.

Taking these facts into account, it is very clear that receiving measles vaccination to protect against measles infection is in the best interests of the child. The child is protected against a potentially devastating infectious disease by a highly effective vaccine. Furthermore, the risk of serious adverse effects from vaccination is extremely low, to the point where they are negligible

when considering the tremendous benefit conferred through vaccination. From one perspective, protection against a devastating illness can be seen as a tremendous positive benefit, and thus vaccination can be justified by appealing to beneficence. On the other hand, vaccination can be viewed as a harm reduction strategy; the potential harms from non-vaccination are severe, while potential vaccine-associated harms are minor and not worrisome. Serious vaccine related harms are incredibly rare to the point of being negligible when compared with the serious and common harms from measles infection. Measles vaccination can therefore also be justified by the principle of non-maleficence.

Of course, this assumes that there is no medical contra-indication to vaccination. In children who are severely immunocompromised, or who are known to be allergic to vaccine components, or are under 9 months of age, the vaccine benefit is lower to the point of being negligible and the risk for adverse effects potentially higher (Moss & Griffin 2012; CDC 2012). In such children measles vaccination is not in their best interests. Once again, this can be justified by considerations of both beneficence and non-maleficence. In a child who has a contra-indication to vaccination, the benefit received does not outweigh harms incurred. Therefore, the principle of beneficence can no longer be used to justify vaccination. If expected harms outweigh benefits, the principle of non-maleficence would be against vaccination. As highlighted previously, in any given population there will be a small subset of people who are not eligible for vaccination because of medical reasons (CDC 2008; Orenstein, Papania, & Wharton 2004). These include children who are too young to receive benefit from the vaccination. In such children, the potential harms and costs of vaccination are present, but no benefit is expected. Clearly beneficence does not justify vaccination in such cases, and non-maleficence would guide parents and clinicians to not vaccinate. Children under 9 months are therefore not vaccinated against measles, as they will not receive benefit. Consider, on the other hand, a child who has allergy to a vaccine component. Such a child may well receive the benefit of protection from measles through receiving vaccination, and the harms of measles infection are prevented. However, the harms that may result through a serious allergic reaction are tremendous, and far outweigh any benefit that the child may receive through protection against measles. Once again, the argument from beneficence is diminished, and considerations of non-maleficence would be strongly against vaccination in this case.

In all other children where no medical contra-indication exists, it seems that there is significant benefit to measles vaccination. In what follows, I shall consider three different sets of interests of the individual child, as per Buchanan & Brock (1990, p. 247): immediate interests, developmental interests and relational interests. Buchanan & Brock include relational interests under developmental interests, but I consider the child's relational interests to contain morally relevant aspects that are different from other developmental interests, and therefore worth considering as a separate category of interests.

### *Immediate interests*

The first set of interests of note are the immediate interests of the child; that is, presence of pleasure and absence of pain or suffering (Buchanan & Brock, p. 247). Vaccinating a child against measles protects the best interests of the child through protecting the child from the suffering caused by the illness syndrome associated with active measles infection, and also through protecting the child against serious complications associated with measles disease. Now of course, the injection itself is painful and the minor adverse effects of the vaccination can be unpleasant. I would argue though that these can be minimized, say through using distraction techniques when administering the injection or using topical anesthetic on the skin, and by treating the joint pain and fever that may result with appropriate analgesics and antipyretics. Furthermore, the illness syndrome caused by measles infection results in much more suffering over a longer duration than does the fever or joint pain that can result from vaccination. With measles infection, the fever is high and the illness lasts for more than a week or two (Moss & Griffin 2012). With the vaccine, the fever and joint pain only occurs in 25% of cases or less, is minor in intensity, and lasts only 1-2 days (see chapter 3 section 3 of this work). Thus, when thinking of the immediate interests of the child with regards to active measles infection, it seems clear that vaccination is in the best interests of the child. When it comes to the complications of measles and the effect these can have on the immediate interests of the child, the protection offered through vaccination is even more compelling. The complications of measles can cause devastation for the health of a child, and cause immense pain and suffering. The vaccine protects against these devastating complications while carrying a negligible risk of serious adverse effects.

### *Development and future opportunities*

Children also have interests with regards to future opportunities and development (Buchanan & Brock 1990, p. 247). It is in the child's best interests to be free from illness and disease that could hamper physical development and cognitive development, which in turn would limit future opportunities for the child. The complications of measles infection can substantially burden the development of the child and thus limit future opportunities. If infected with measles, a child acquires a risk of blindness, deafness, mental retardation, neurological damage and death. Measles vaccination protects against these risks, thereby protecting the development interests of the child. Opponents of vaccination sometimes claim that measles vaccinations carry unacceptable adverse effects, such as autism, and thus that measles vaccination would hamper the development interests of the child (Bean 2011; Kata 2010; Kata 2012). This is not true; reliable evidence shows that the common adverse effects of measles vaccination are minor, and do not burden the development of children substantially (see chapter 3, section 3 of this work).

### *Relational and familial interests of the child*

The third set of interests are the relational interests of the child (Buchanan & Brock 1990, p. 247). Carl Elliot (2001) points out that a potential problem faced by the best interests standard is



that it focuses on the child as an individual only, not taking into account the localization of the child within a family [6]. In Elliot's words:

*"This can leave us with a kind of misplaced individualism, as if the only ethically important considerations are those that have to do with the child himself – intrinsic abilities like his intellect, his awareness, his physical abilities and so on. But this is an odd way to look at children, since what is most striking about children is not their intrinsic abilities but their dependence. Children exist in relationships of dependence on their families... It seems ungainly to try to consider children's interests apart from the interests of their families because their interests are bound up together. This is more than simply saying that parents are best placed to judge the interests of their child; it is saying that very often their interests are the same. It would not be exaggerating to say that very often the worst thing that could happen to parents would be for something to happen to their children... What matters morally about a child is connected to the fact that they are loved by their parents, and what we value about human beings is not just their intellect but also their capacity for these deep human relationships"* (Elliot 2001, p. 458-459).

Elliot's point is that a child's relational interests are extremely important, and that these interests are linked with a child's position within the family. Parents are not just important as surrogate decision-makers; they are important as integral parts of the child's best interests. The interests of the child are intricately interwoven with the interests of the parents, so that these interests are inseparable. Harming the child will harm the parents and harming the parents will harm the child. Thus, any complete account of the best interests of the child will have to take into account the vested interests the child has as a member of a family, and the relationship that the child has with the parents. The parent-child relationship is of substantial moral worth, and will need to be considered seriously as a separate set of interests of the child in question. So, the child does not only have interests as an isolated individual such as physical and developmental interests, but also interests that are bound up in the parent-child relationship. So much so, that an assault on the child will be an assault on the family unit, and an assault on the family unit will be an assault on the child.

The idea that the family unit has moral worth and is to be protected seems fairly widely acknowledged. One can see this for example in the declarations on human rights by the United Nations. In these documents the family unit is described as deserving of protection by all States and all societies. This protection and consideration given to the family unit is thought to transcend divisions of geography, state lines or local custom. A few of the relevant articles from the UN rights declarations will be cited as examples.

I clarify: the intention is not to invoke a rights-paradigm. Undoubtedly, the ethical paradigm of the UN declarations is rights-based, but that is not my focus here. What I intend to show is that the family unit is widely considered to carry moral weight and to be worthy of moral consideration and protection. The B&C principlist account is based on the idea of widely shared moral intuitions. By citing the UN and their injunctions I am illustrating the fact that families, and parent-child relationships in particular, are widely recognized moral entities, worthy of moral

consideration and protection. This is meant to strengthen my principlist argument by demonstrating that the moral worth ascribed to parent-child relationships is a widely shared moral judgment, and therefore rightfully included in the principlist argument that I am constructing. Note specifically that the UN argues for universal recognition of the moral worth of the family, and specifically the moral relationships that exist between parents and children. I agree; this, I would argue, is a widely shared moral judgment which should form part of our considered judgments as we weigh the principles.

Here are the relevant articles from the UN declaration on Human Rights:

UN Universal Declaration of Human Rights (United Nations 1948):

*Article 16(3): "The family is the natural and fundamental group unit of society and is entitled to protection by society and the State."*

The Convention on the Rights of the Child, adopted by the United Nations General Assembly in 1990 (United Nations 1990):

*Article 5: "States Parties shall respect the responsibilities, rights and duties of parents or, where applicable, the members of the extended family or community as provided for by local custom, legal guardians or other persons legally responsible for the child, to provide, in a manner consistent with the evolving capacities of the child, appropriate direction and guidance in the exercise by the child of the rights recognized in the present Convention."*

*Article 7(1): "The child shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by his or her parents."*

*Article 9: "1. States Parties shall ensure that a child shall not be separated from his or her parents against their will, except when competent authorities subject to judicial review determine, in accordance with applicable law and procedures, that such separation is necessary for the best interests of the child. Such determination may be necessary in a particular case such as one involving abuse or neglect of the child by the parents, or one where the parents are living separately and a decision must be made as to the child's place of residence.*

*2. In any proceedings pursuant to paragraph 1 of the present article, all interested parties shall be given an opportunity to participate in the proceedings and make their views known.*

*3. States Parties shall respect the right of the child who is separated from one or both parents to maintain personal relations and direct contact with both parents on a regular basis, except if it is contrary to the child's best interests.*

*4. Where such separation results from any action initiated by a State Party, such as the detention, imprisonment, exile, deportation or death (including death arising from any cause while the person is in the custody of the State) of one or both parents or of the child, that State Party shall, upon request, provide the parents, the child or, if appropriate, another member of the family with*

*the essential information concerning the whereabouts of the absent member(s) of the family unless the provision of the information would be detrimental to the well-being of the child. States Parties shall further ensure that the submission of such a request shall of itself entail no adverse consequences for the person(s) concerned.”*

It is evident that the family unit is widely seen as carrying considerable moral worth. The family unit is worth protecting. The reasons for this are clear when considering Elliot’s argument with regards to the place of the child in the family unit. The child’s interests are intertwined with the parents’ interests. From a principlist perspective, we may argue as follows. Parent-child relationships are considered to be of moral worth, and forms part of our moral starting point. When we then consider beneficence and non-maleficence in relation to a child, it is important to also consider the parent-child relationship. Promoting parent-child bonds is an act of beneficence to the child, and avoiding actions that may strain or injure the parent-child relationship is an act of non-maleficence. Of course, this refers to normal, loving parent-child bonds. If a parent is abusive or if there is a substantial breakdown of the parent-child bond, the other interests of the child outweigh the moral considerations usually afforded to protecting parent-child relationships.

Now, when considering the familial interests of the child and measles vaccination, it appears that the moral weight lies on the side of vaccination. If a child is harmed the family is harmed. Measles infection has the potential to cause harm to the child, and in turn harm to the parents, and eventually harm to the child’s relational interests. Suffering in the child will bring suffering to the child’s parents; thus the suffering is shared and multiplied, not only affecting one person. Furthermore, if a child is severely disabled, as may happen with measles infection, the normal familial bonding and interaction may be hampered. Of course, if a child dies, these familial bonds are broken, leaving heartbroken parents behind.

Vaccinating against measles protects against a disease that may wreak havoc on the family unit and family attachments, and consequently vaccination protects the familial interests of the child. It is also noteworthy that the parents of the child are protected from heartache and suffering that may result from measles infection in their child. All around, the child’s best interests and the family’s best interests seem to be protected through measles vaccination. In its turn, the risk of harm from measles vaccination is negligible, so that the child’s family and the child’s relational interests are not harmed through vaccinating.

## **(2.2) Relying on herd immunity**

In chapter 1 I pointed out that most authors in the current literature on measles vaccination ethics at some point consider the issue of a parent who foregoes vaccination and relies on herd immunity to protect their child (Diekema 2005; Diekema & Marcuse 2007; Krantz, Sachs, & Nilstun 2004; Sheather 2013; van den Hoven 2012; Wood-Harper 2005). This is a specific category

of vaccine refusals; a child otherwise eligible for vaccination does not receive the vaccine because of a specific mode of parental reasoning. The argument is as follows. In a highly vaccinated society, the risk that an individual child would contract measles is very small. The benefit that such a child would get from vaccination is therefore also small. Some parents may then reason that it may be in their individual child's best interests to forego vaccination, in so doing not running the risk of vaccine side effects, while relying on herd immunity for protection against measles. Authors generally respond to these arguments in two ways: from an individual perspective, and then from a societal perspective.

### *Responses in the literature*

First, they consider whether state interference with such parental decisions can be justified by ethical considerations central to the individual perspective. Diekema and Marcuse (2007) argue that the risk of harm to the individual child is likely not sufficient to override parental decisions. Diekema (2005) similarly argues that the risk of harm to the individual child does not rise to the level where parental decisions can be interfered with. Krantz, Sachs, and Nilstun (2004) argue that the risk of getting measles is "negligible" in highly vaccinated societies, while there are "ethical costs" to being vaccinated, but the individual child would probably still be better off vaccinated, especially if traveling to areas with lower vaccination uptake. Sheather (2013) argues that children in highly vaccinated societies may still be exposed to measles through cases being imported, and the harms resulting from vaccinations are usually "trivial", so that vaccination seems "prudential". Compulsion can only be justified, however, if there is substantial risk of harm to the child; in Sheather's opinion the case for such interference with parental decisions disappears once herd immunity has been established. Wood-Harper (2005) argues that the state has the moral and legal right to interfere with parental decisions that are not in the best interests of the child, but concludes that measles vaccine refusal in a highly vaccinated society does not fall under this category. Her motivation is that "measles can be, but seldom is, fatal," so that as long as there are any risks associated with receiving a vaccine, it is "difficult to rationalize" overriding parental vaccine refusals.

In none of these responses is it clear whether the refusing parent's reasoning is sound or whether the argument is successful from an ethical point of view. Furthermore, the authors seem to emphasize different aspects of the benefit-risk ratio while making very different factual claims. Some authors focus on the benefit of still being vaccinated and call vaccine adverse effects "trivial", while others minimize any benefit from vaccination in this scenario while being very concerned about vaccine associated harms. It is almost as if they are reasoning from different sets of empirical facts. Invariably, these claims are not well referenced so that it is not clear where such claims come from. For example, Krantz et al.'s claim that the risk of getting measles being "negligible" in highly vaccinated societies is not well referenced and it is not clear what set of facts this claim is based on. Sheather claims that vaccination still seems "prudential" because harms from vaccinations are "trivial" and measles may still be imported. I agree with this argument, but it is not clear on what data Sheather is basing these claims, and it is not clear what

is meant by “prudential” – does Sheather mean that it is a moral requirement of beneficence or not?

All the authors agree on one thing. The threshold for interference with parental decision-making is risk of harm to the child. The implications of other ethical considerations are never quite fully clarified, but at least all seem to agree that if there is substantial risk of harm to the child, the state is morally justified to interfere with parental decision-making. The burden of proof is implicitly placed on those who would want to interfere – there has to be an unequivocal high risk of harm to the child before the state can interfere. But what would this look like? Is the state and its agents to guess, or is there some test or measure that can be applied to each individual case? No objective criteria are offered by which risk of harm to the child can be evaluated, and no specific threshold of risk is quantified, except one: vaccination levels below the threshold required to establish herd immunity. Risk of harm is only demonstrably high enough when vaccine uptake in society falls below a herd immunity threshold.

What emerges from this is quite surprising. In effect, the authors all agree with the arguments raised by such vaccine refusing parents: such refusals are only morally relevant when population vaccination uptake falls below a certain level. Reading these responses, one would conclude that one should really only be worried about the moral implications of such vaccine refusals once herd immunity disappears. The moral case for overruling parents, they argue, is only made once a society does not have herd immunity. No other arguments are offered to provide moral guidance to parents in this scenario. No arguments are offered to challenge the logic of the argument that motivates such refusals. Varying claims are made without reference to appropriate empirical sources; this leaves recommendations and conclusions very vague. Telling us that vaccination is perhaps still “prudential” in such circumstances without making a clear arguments as to what this morally commits parents to leaves things very open to individual interpretation.

Second, authors typically argue that such vaccine refusals are instances of “free riding” and are unfair (Diekema 2005; Diekema & Marcuse 2007; Krantz, Sachs, & Nilstun 2004; Sheather 2013; van den Hoven 2012; Wood-Harper 2005). Parents who rely on herd immunity in this fashion make use of a public good, herd immunity, created by co-operative public efforts, without paying their fair share. Authors uniformly assume a communitarian justice perspective in these arguments. I shall consider the issue of free riding more fully in the next chapter. Here, I shall continue with the focus on the individual case of vaccination.

Thus, in highly vaccinated societies, some parents may reason that their child is best served by not being vaccinated. The available responses in the literature do not challenge the underlying argument. I think that the underlying argument is a mistaken view for a number of reasons.

### *Challenging the underlying argument*

The argument is based on the premise that an individual child is better off not being vaccinated against measles in a highly vaccinated society. Thus, to act in the best interests of the child would

be to forego vaccination and rely on herd immunity. I challenge this argument on two grounds. One, the underlying premise is incorrect; I will argue that the individual child is still better off vaccinated in a highly vaccinated society such as the US or the Netherlands. Two, the argument suffers from a fatal internal contradiction: it is self-defeating.

### Vaccination is better than herd immunity

Even in highly vaccinated societies measles outbreaks can occur and spread among chains of susceptible individuals. We have seen evidence of this in the US, Canada and the Netherlands – all countries where measles has been eliminated, but imported cases can cause epidemics that spread among susceptible people (Dallaire et al. 2009; Fiebelkorn et al. 2010; Knol et al. 2013). In these countries there are pockets of susceptibility, where local vaccination rates are low. Consider the Netherlands as an example (Knol et al. 2013). Although the overall vaccination rate in the country is very high, there are localized areas where the vaccination rate is well below the threshold required to confer herd immunity. For example, the vaccination rate in the Netherlands' so-called "Bible belt" is quite low. Recently there has been a sustained measles outbreak in this community, which highlights the problem. So, even though vaccination rates in the country are quite high, there are susceptible people and susceptible geographical pockets. Countries such as the US and the Netherlands see outbreaks resulting from imported cases which are transmitted along chains of contact between susceptible individuals (Dallaire et al. 2009; Fiebelkorn et al. 2010; Knol et al. 2013).

The average parent does not know whether they live in a susceptible geographical pocket within the highly vaccinated society, or whether their child has contact with susceptible people in public. People do not carry signs to show whether they are immune to measles or not. The only way to ensure that a child is protected against such imported epidemics is through vaccinating the child. Herd immunity or measles elimination does provide a measure of protection against measles for those individuals in society who are susceptible to measles. But this protection relies on uniformly high rates of vaccination; if a susceptible individual lives within a geographical low-vaccination pocket, herd immunity is not present for that individual. Furthermore, given the fact that imported cases can still be spread among chains of susceptibility, herd immunity is evidently a lesser form of protection than is afforded through direct vaccination of a child. A child is much better protected against measles through vaccination than through reliance on herd immunity. Some people cannot receive the vaccination, and they have no choice but to depend on herd immunity: those who are ineligible for measles vaccination find protection through the herd effect. It is preferable that a child be directly protected, as this eliminates the risk of measles infection for the individual child, usually life-long. Relying on herd immunity for protection against measles when your child is eligible for vaccination is like playing Russian roulette with your child's health: imported measles outbreaks can strike unpredictably and therefore cannot be protected against but by vaccination. This is brought home more strongly when one considers the high level of mobility in contemporary societies, frequent travel, and increasing globalization. In such a world, I would argue, direct protection through vaccination is much better than relying

on herd immunity, where the risk for coming into contact with imported or active cases of measles appears on reflection to be increased.

A second consideration is this. Measles vaccination rates are variable through time. Evidence of this can be seen in the United Kingdom, where measles returned to become endemic after being previously eradicated (Euro Surveillance Editorial Team 2008). Children who live in highly vaccinated societies have no guarantee that vaccination rates will remain high in the future. If vaccination rates fall in the next few years, unvaccinated children will be placed at substantial risk of measles vaccination. This once again shows that dependence on herd immunity/measles eradication from society is a lesser protection than getting vaccinated. The only way to provide life-long and assured protection against measles infection is to receive measles vaccination. To this, some may retort that they will then get the vaccination for their child once vaccination rates fall. I find this very unconvincing; which parent monitors CDC statistics to see what the level of vaccination coverage in their country or region is? Even if a parent went to these lengths, such statistics always appear in print at a later time than when the vaccination rates actually fall in the real world. Statistics are always after-the-fact. So even a diligent parent who follows this reasoning may vaccinate too late. It seems dubious and chancy to risk a child's welfare in this way.

#### The argument is self-defeating

The argument is inherently self-defeating. The argument asks us to imagine a specific child standing before us in a highly vaccinated society. This child, according to the argument, is at low risk of getting measles and is protected by herd immunity. Therefore it is in this child's best interests to forego vaccination and not risk the harms associated with vaccination.

A central point to the argument is that it relies on the presence of herd immunity. In other words, vaccination uptake has to be above 93-95% of two measles vaccine doses within the population (see the section on herd immunity in this work, chapter 2 section 2.2). That means a whole lot of children has to be vaccinated. But in the society and child we are imagining, vaccination uptake is above the required level; a whole lot of children has been vaccinated previously and herd immunity has been established. The only reason to vaccinate this child would be if there was no herd immunity, and the risk for getting measles was consequently high.

So, if we accept the argument as it stands, we agree that this child should not be vaccinated. The parents forego vaccination. Now, let us move on to the next case. The next set of parents also make decisions for their child along the best interest standard. They reason similarly that non-vaccination is in their child's best interests. They forego vaccination. Again, move to the next case. The parents of the third child reason similarly (and correctly, if our argument obtains) and foregoes vaccination for their child. And so on, and so on. At some point vaccination rates will fall below the threshold for maintaining herd immunity. But in the day to day delivery of vaccinations it will not be obvious which case it is that causes the vaccination rate to fall below this level. In any case, it is not necessarily important which case stands chronologically prior to

the loss of herd immunity; it is more important which case stands causally prior to the loss of herd immunity. In other words, which case is responsible for decreasing the vaccination rate below the herd immunity level? This is almost impossible to answer on a practical level; imagine a super computer standing behind a nurse about to deliver the vaccine, calculating whether this instance of vaccination is necessary to sustain herd immunity. It is absurd. In actual fact, all of these cases contributed to the loss of herd immunity. No single case can be pointed to as “the straw that broke the camel’s back”. No single case is responsible for the loss of herd immunity. Rather, it is the cumulative effect of numerous individual decisions that is to blame. The collective failure to vaccinate led to the destruction of herd immunity. Another way of stating this is that the argument is not universalizable: it cannot be universally and uniformly applied, as doing so would lead to loss of herd immunity and vulnerability of children to measles, denying unvaccinated children protection against measles, and thus defeating the very aim and conclusion the argument is supposed to support.

Here is another way to argue this point. If parents use this argument to forego vaccination, and rely on herd immunity, it will inevitably lead to a dramatic fall in vaccination rates and the eventual loss of herd immunity. The parent can therefore not reach their goal of securing the best interests of their child by relying on herd immunity and foregoing vaccination. Parents can reliably protect their child against measles by choosing vaccination.

Thus, using the argument of relying on herd immunity will in the end result in the loss of herd immunity. In that way the argument is self-defeating, and suffers an inherent internal contradiction. Parents who want to protect their children cannot do so by reverting to this argument. If this argument were successful, and parents decided to forego vaccination, it is inevitable that vaccination rates would plummet and measles would become endemic once more. The argument undermines itself, and ultimately fails.

### *Ethical conclusions regarding this argument*

I conclude that this argument is not successful. The underlying premise is untrue: it is in the best interests of children to be vaccinated even in highly vaccinated societies. The argument is also self-defeating.

Therefore, measles vaccination should still be considered to be in the best interests of the child, even in highly vaccinated societies. There is an obligation on parents to choose what is in the best interests of their child. They are therefore ethically obligated to choose vaccination, even in a highly vaccinated society.

Even if parents or providers reject my arguments and maintain that their children are better off in relying on herd immunity, we should realize that this argument would only be valid for as long as herd immunity exists. In geographical pockets of susceptibility, such as the Bible belt in the Netherlands, or in countries with lower vaccination rates, such as South Africa, this argument



does not even enter into consideration. In such circumstances parents are undoubtedly obliged to choose vaccination.

### **(2.3) Conclusions: Best interests and the principles**

Taken together, it is clear that vaccinating is in the child's best interests. The child is protected from measles infection and consequently the child's immediate interests, developmental interests and relational interests are protected from the potentially harmful effects of measles infection. The child's parents are also protected from the suffering that would result from harm to their child. Measles vaccination does not significantly burden children or their families, having very low risk for harm. Measles vaccination is readily available, at reasonable cost.

Thus, vaccinating the individual child can both be seen as an act of beneficence and an act of non-maleficence. It confers a benefit to the child that substantially outweighs risks, and it is a powerful harm-reduction strategy. These considerations obtain even in highly vaccinated societies. The principles of beneficence and non-maleficence therefore confer a *prima facie* obligation on those who are in caring relationships with the child to have the child vaccinated. This falls primarily on the parents. In accordance with the medical decision-making framework for children which I have defended, parents are tasked with making healthcare decisions for their children according to the best interest standard. The obligation to have a child vaccinated falls primarily on the parents.

There are, however, other interested parties who stand in caring relationships with the child. The primary clinician, whether a nurse or doctor, has obligations of beneficence and non-maleficence towards the child. The clinician therefore has to do their part in ensuring vaccination: the clinician is obliged to enable the parent to discharge their duty to choose vaccination. This would include offering vaccination, education, allaying fears, ensuring safe administration of vaccines according to the correct schedule and as painlessly as possible, and so forth. This approach respects the parent, and the role of the parent in the child's life, while discharging the obligations the healthcare professional has towards the child patient.

The government or state in its role as governor and protector also stands in a relationship with the child. The state therefore also has obligations in this regard: removing barriers to vaccination, ensuring access to high quality vaccines, and enabling parents to discharge the obligation to choose vaccination for the child.

On the whole, a principles-based analysis *prima facie* demands the vaccination of the individual child against measles as long as no contra-indication exists. If a child is medically able to be vaccinated, the child should be vaccinated. This moral obligation falls on the parents of the child. The parent is the child's surrogate decision-maker and primary caregiver, and is tasked with acting in the best interests of the child. There are also responsibilities on other persons or groups who are morally tasked with the wellbeing of the child: healthcare providers of children to ensure

that vaccination is offered, and is provided safely and as painlessly as possible, and the government and its agents.

### **(3) The objecting parent**

Most parents discharge their moral obligation with regard to measles vaccination, and we see fairly high vaccination rates in many countries. However, it is clear that some parents do not get their children vaccinated, even though measles vaccine is readily available. Many people in the anti-vaccination movement are concerned parents who hold mistaken views on vaccination (Bean 2011; Kata 2010; Kata 2012). Parents who refuse vaccination often do so on the grounds that they believe they are acting in their child's best interests, and not through nefarious motivations (Brown et al. 2010). These parents believe that vaccination is harmful, or part of some conspiracy, and that they have a duty to protect their child (Bean 2011; Kata 2010; Kata 2012). Such parents still have a moral obligation to get their children vaccinated. However, they are not in a position to discharge their moral duty. They are mistaken as to what their duty is – they believe that withholding vaccination is the right thing to do. This is therefore not the same situation as when a parent wilfully neglects their child.

In the case of an objecting parent, a response from other parties with moral obligations to the child is required. Clinicians and the government have obligations of beneficence and non-maleficence to the child, being situated in a position of moral responsibility towards the child. These parties also have obligations to respect autonomy. In the case of measles vaccination, I have argued that a child of vaccination age does not have autonomy, and that the appropriate decision-making framework is to allow parents to choose on behalf of their children in accordance with a best interest standard. Another way to say this, is that parents have the authority to act as medical decision-makers for their children and should use the best interest standard as guiding principle. However, I have also argued that parental authority is not absolute; their authority is limited by the best interests of the child. If a parent is clearly not choosing what is in the child's best interests, such parental decisions falls outside of the limits demarcated for the exercise of parental authority, and it is the obligation of healthcare professionals and the state to challenge and potentially overrule such decisions in order to protect the interests of the child.

I shall consider the implications of this framework using a number of examples as thought experiments. Consider this example. If a parent chooses not to feed their child because they want the child to starve, such a parental decision is clearly not in the best interests of the child. The parent does not care about the best interests of the child, and acts in a way that is harmful to the child. Clearly, the parental decision here falls outside of the limits I have indicated on the principle of autonomy in parental decision-making. In such a situation, clinicians and the state have the obligation to intervene, overruling the authority of the parent. The principles of non-maleficence, beneficence are in unison here, placing limits on parental authority in making decisions for the child. Parents cannot appeal to respect for their own autonomy or own liberty in order to avoid discharging their obligation to the child. These principles place an obligation on the other parties with interests in the welfare of the child, namely healthcare professionals and the state, to protect the child from the harms that would result from starvation and neglect. The principle of

beneficence places an obligation on these parties not only to promote the welfare of the child. Clinicians and the state are morally obligated to interfere in this situation and secure the best interests of the child. This would mean feeding the child, and protecting the child from further neglect by the parent.

Consider a second example. Imagine a parent who chooses to only feed their child rooibos tea because they believe it to be healthier and better than other foods. The child is denied the benefit of healthy food, and is placed at risk of harm through starvation. The parent is clearly not choosing what is in the best interests of the child, but the parent is not acting from nefarious motives. The parent truly believes that the choice of rooibos only is in the best interests of the child. In this instance, clinicians and the state also have an obligation conferred through non-maleficence and beneficence towards the child. They have to act to secure the child from harm and to bring the benefit of nutritious food to the child. The parent's choice is overruled out of concern for the best interests of the child. This example is different from the first, since the parent's motive is different. In the first example, the parent doesn't care about the child. In the second, the parent does care about the child and wants to secure the child's best interests, but is mistaken about what this is. Thus, although both are examples where parental choices fall outside of the limits placed on parental authority. However, there is an important difference between the two examples. In the second, the child has morally important relational/family interests invested in their relationship with their parent. In the first, the relationship has broken down, and the child-parent relationship is not an important consideration in weighing the interests of the child.

Let us return now to parental refusals of measles vaccination. Measles vaccination is, I have argued, in the best interests of the child (unless a medical contra-indication to vaccination exists), and the principles of beneficence and non-maleficence place an obligation on those in relation to the child to ensure that the child is vaccinated: the parents, the healthcare workers, and the state/government. If a parent refuses to vaccinate their child, it can be for two reasons. One reason is that these parents do not care for the welfare of their child. In this scenario, failure to vaccinate is part of a general pattern of neglect. Other parties have the obligation to act in the best interests of the child grounded in the principles of beneficence and non-maleficence. The healthcare worker, for example, should call state agents such as social services to intervene. The agent of the government should protect the child against neglect, including ensuring measles vaccination. Parental wishes that a child should be harmed should not be respected. Here, a child needs to be protected from their parent. Admittedly, this scenario is probably fairly rare.

The second, and more common, reason a parent may choose not to vaccinate their child is because the parent is convinced that vaccination does not serve the best interests of the child (Bean 2011; Kata 2010; Kata 2012). Indeed, many parents who refuse vaccination do so because of concerns that vaccination may be harmful (Brown et al. 2010). Such parents hold mistaken views, and have likely been influenced by the incorrect messages and tropes of the anti-vaccination movement (Bean 2011; Kata 2010; Kata 2012). These parents are mistaken; their

choice does not in fact serve the best interests of their children. While their obligation to secure the best interests of their children remain in place, they are not able to discharge this obligation because of mistaken beliefs regarding measles vaccination. Again, other parties such as healthcare providers and the state (and its agents) who have obligations of beneficence and non-maleficence to the child now have to act to further the best interests of the child. Here, however, there are additional moral considerations at play. One is the relational or familial interests of the child. The child-parent relationship is a morally significant relationship, and when calculating the best interests of the child, these familial and relational interests should also be counted into the equation. The parent still plays an important role in the life of the child, and the interests of the child are still intertwined with the interests of the parent. The parent is evidently not choosing in accordance with best interests – *but they want to*. This is different than a general pattern of neglect. Considering these morally relevant factors directs the type of responses that healthcare providers and the state employ. They have to respond to vaccine refusal; they have a moral obligation to do so. But they should respond in ways that also protect the parent-child relationship and respect the role of the parent in the child's life as much as is possible while also ensuring vaccination.

Ideally, the healthcare workers and the state would partner with the parent, and enable the parent to discharge the obligation of choosing vaccination. One avenue is to empower parents through a bulwark of educational approaches and trusting healthcare relationships. The focus in this approach falls on morally supportable persuasive techniques. The goal would be to get the parents to see what their duty is, thus placing them in a position where they can recognize and discharge their duty to vaccinate.

Another approach is to use state power. This would mean intervention by the State, which would impose some form of penalty and thus force parents to vaccinate their children or face consequences. The use of state power can be justified if it is effective in persuading parents to discharge their duties and if it does not substantially harm the relational and familial interests of the child.

The use of state power can at first glance seem appealing, since the moral obligation to see a child vaccinated is so strong. However, reflection on this will show that not all types of coercion is the right answer. The penalty for non-vaccination imposed on parents will bring harm to the family unit, and will end up harming the child in question. Imagine for example that parents are placed in jail for not vaccinating their child. This surely is a most damaging action imposed on a child whose interests are supposed to be protected through the action. When it comes to the objecting parent, it seems then that the familial and relational interests of the child place a check on the amount of use of state power that can be justified. It appears as if the justification for mandatory vaccination policies has to be balanced between the risk of measles infection and the relational interests of the child.

I shall consider different policy options and make recommendations for measles vaccination policy in chapter 7. Suffice it to say here that parental refusals demand a response, which could

include persuasive approaches such as building of trusting relationships and education, and the use of state power in a way that brings about vaccination while not harming the familial and relational interests of the child. How this can be done will be suggested in chapter 7.

#### **(4) Conclusion – two ethical principles/action guides**

In the young child who does not have the capacity for autonomous decision-making, beneficence and non-maleficence place an obligation on those who stand in relation to the child to secure the child's best interests. This means that parents, healthcare workers and the state (and its agents) have obligations to ensure vaccination against measles, provided that no contra-indication exists. Furthermore, the complex interests of the child justifies a framework where a parent chooses healthcare options in the best interests of their child; this means that parents play an important role in choosing vaccination for their child. These applications of the principles to the case of measles vaccination can be distilled into the following action guide:

(1a) Morality requires vaccination against measles for all children who are eligible for vaccination.

It is clear that the welfare of the child is the ultimate driving force for these moral obligations. When a parent decides not to get their child vaccinated, this is not in the best interests of the child. Therefore, healthcare workers and the state should respond to this refusal. In their response, the morally significant parent-child relationship should be respected. This obligation is motivated by beneficence and non-maleficence. These ethical obligations are optimally discharged when parents choose vaccination in the best interests of their child; healthcare workers and the state should ideally support parents and move them towards choosing vaccination. A parent choosing vaccination would ultimately be the best. However, the primary driving force is vaccination; and the use of state power may be necessary and is morally justifiable in order to ensure vaccination, as long as it is done in a way that does not harm the complex familial and relational interests of the child. These considerations can also be distilled into an action guide:

(2a) Respect for the parent-child relationship regulates the response to measles vaccine refusal, type of policy preferred and places limits on the amount of coercion that can be justified.

It is apparent, then, that children should be vaccinated against measles as a mandate of morality. Ideally, parents would realize their obligation in this regard and discharge it. In the case of an objecting parent, the moral obligation to vaccinate remains and healthcare providers, public health organizations and the state have a duty to respond to ensure vaccination. However, there are moral considerations that place limits on the state and the use of power. The child's familial interests are important and are to be respected, and these place a limit on the use of coercion. Any action that causes a substantial burden to the child's familial interests will be hard to justify.

The next step in this work is to consider measles vaccination from a justice perspective. This will lead to two similar action guides, (1b) and (2b). The eventual goal, which will be realized in the final chapter, is to balance (1a) and (2a) with (1b) and (2b) in order to arrive at a place of reflective equilibrium, where moral obligations are in balance with one another and conflicts have been clarified and removed.

## Chapter 5 References

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## Chapter 6: Justice and measles vaccination in children

In this chapter I shall review the implications of justice with regards to measles vaccination in children. To do so, I shall consider measles vaccination from the perspective of five different theories of justice. I shall argue that each theory of justice confers similar moral obligations on a just society and its members. These obligations can be summarized by the statement of two ethical action guides:

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

I shall argue that every conception of justice here considered is committed to these two action guides. It will therefore follow that societies that do not vaccinate to the point necessary to sustain measles elimination are unjust, no matter which of these theories of justice one adheres to. If vaccination does not happen to the point of measles elimination, it constitutes an injustice to which society has an obligation to respond. But at the same time, I will show that an important second consideration is that just societies take parent-child relationships seriously. Consequently, in the ideally just society parents will freely choose to vaccinate to the point of measles elimination.

Vaccine refusal is a problem that requires specific consideration. In these cases, there is a tension between points (1) and (2). The question then becomes: what does justice require when there is significant vaccine refusal within society, to the point that measles elimination is threatened? I shall argue that in view of principle (1), the obligation to vaccinate demands of society to respond when vaccine refusal happens. There are various ways in which society can respond; in view of principle (2) society should favor responses that place refusers in the best possible position to choose vaccination freely. The best responses are those that enable parents to freely choose vaccination. Even if this is done, it may happen that an impasse is reached: there may be parents who refuse vaccination and are not persuaded through societal interventions to freely choose vaccination. In such cases, society may respond through use of state power. However, principle (2) places a limit to the amount and types of coercion that can be used. In essence, when faced with a significant tide of vaccine refusal, principles (1) and (2) are to be balanced with one another when it comes to government coercion.

The conclusion I will defend is therefore as follows. A just society vaccinates against measles, at least to the point of measles elimination. This means that children can rightly expect protection against measles infection through sufficient vaccination uptake. It is an obligation of parents to get their vaccine-eligible children vaccinated. Obligations rest on healthcare providers to offer

vaccination and administer it safely, while there rests an obligation on societal institutions and the State to ensure reasonable access and availability to measles vaccination. Preferably, parents freely choose vaccination for their children. Vaccine refusal demands a response from society; in view of respect for individual liberty within just societies, responses that encourage parents to freely choose vaccination should be preferred. If vaccine refusal threatens measles eradication, use of state power can be justified. However, principle (2) places limits on the amount and type of power or coercion that can be used.

It will be noted that principles (1b) and (2b) are very similar to the two main principles (1a and 2a) in the individual case of measles vaccination I argued for in the previous chapter. Thus, whether one argues from justice, or whether one argues from individual considerations, the ethical conclusions are similar. There is a moral obligation to vaccinate children who are eligible, and ideally to vaccinate through parental free choice. If there is vaccine refusal, there is an obligation on the State and on society in general to respond to vaccine refusal in a variety of ways. If mandatory vaccination policies are adopted, the duty to vaccinate is balanced against the cost of coercion. The moral weight of these two guiding principles in childhood vaccination is therefore very strong, being supported by an individual/best-interests/principlist approach as well as by a societal/justice approach.

The implications of these conclusions for public policy will be discussed in the next chapter. In this chapter, the goal is to show how justice leads us to the action guides (1b) and (2b). In order to do so, I shall proceed as follows.

First I shall engage in conceptual analysis around the concept of justice. The idea is to understand what the questions are that the principle of justice tries to address, and what is morally at stake when we speak of justice. To do so, I shall consider the conceptual analysis of justice by Aristotle, Mill, and Beauchamp and Childress. I choose these authors for this purpose because each of them has provided a conceptual analysis of justice from which general themes can be deduced regarding the focus of justice, and the questions that justice seek to answer. Their work has influenced the work of others, and has identified specific themes central to the study of justice which will enable me to stipulate the questions a theory of justice attempts to answer. I shall not here slip into assuming alternate ethical frameworks such as the virtues or utilitarianism. I shall also not invoke a purely Aristotelian notion of justice or a purely Millian notion of justice. Rather, I shall use their conceptual analyses of justice to identify what the underlying questions are that justice tries to address. These I will summarize before moving on, in order to provide clarity in moving forward.

Next I shall consider the question of measles vaccination from the perspective of different and competing theories of justice. I shall use the main theories of justice that have been influential in bioethics and in the principlist approach, as identified by Beauchamp and Childress (2013). B&C identify six influential theories of justice: utilitarian, libertarian, egalitarian, communitarian, capability theory, and well-being. I shall, in turn, consider the implications of each of these for the question of measles vaccination in children. Capability theory and well-being justice are fairly

recent arrivals and are remarkably similar in underlying assumptions, scope and focus and will consequently lead to similar modes of argument and conclusions. I shall therefore only focus on one of them in this analysis, namely well-being.

The goal in this chapter is not to present a thorough examination or defense of each of these conceptions of justice. I shall not defend one theory of justice over another or give preference to a specific theory of justice as the “correct” one. Instead, I am interested in exploring what each different theory of justice would commit adherents of those specific theories to. I shall therefore examine each theory of justice to the extent that is necessary in order to analyze the implications of the various theories for measles vaccination.

I shall eventually conclude that each theory of justice is committed to the action guide/principles (1b) and (2b), and that these two principles therefore articulate the ethical considerations regarding measles vaccination from a justice perspective. In chapter 7 I shall unify the action guides from the individual case (1a and 2a) and the justice perspective (1b and 2b) to yield two specified action guides (1 and 2) that bring the principle of autonomy, justice, beneficence, and non-maleficence into balance with one another. These two action guides (1 and 2) will then be used to make policy recommendations.

## **(1) What is justice? A conceptual analysis**

In this conceptual analysis I shall consider what justice is, and what the underlying moral questions are that a theory of justice has to answer. To do so I shall present the conceptual analyses of Aristotle, Mill and Beauchamp & Childress with regards to justice, and then from these create a summary as to what justice is and what the underlying questions are that justice should answer.

### **(1.1) Aristotle on justice (Aristotle 1996)**

Aristotle describes justice as consisting of two fundamental ideas.

In one sense, “the just” means that which is equal or fair, and “the unjust” is therefore that which is not equal and not fair. So, if you were to take a bigger share of some good than is due to you, you would be acting unjustly. In the first instance then, justice is about what is due to people and making sure that they get what is due to them.

In another sense, “the just” refers to the laws within society. The laws of society aim at some good that is in the public interest, such as preserving peace or happiness within society. Justice in this sense requires the passing of good laws, laws that promote the public good, and persons who break such laws are unjust.

Some of Aristotle’s words in this regard (Aristotle 1996, 1129a26-b11):

“...the term ‘unjust’ is held to apply both to the man who breaks the law and the man who takes more than his due, the unfair man.”

“Let us call him ‘unfair’, for that is a more comprehensive term, and includes both taking too much of good things and too little of bad things.”

“‘The just’ therefore means that which is lawful and that which is equal and fair, and ‘the unjust’ means that which is illegal and that which is unequal or unfair.”

Furthermore, justice has a relational component. Aristotle argues that justice regulates actions in relations to other persons, and is a virtue that involves relationships with others. Justice is concerned with actions towards others, and specifically towards ‘the good of others’ (1129b12-30a13).

Justice can also be thought of as either universal or particular (1130b8-31a3). Universal justice is concerned with virtuous living, regulating behaviour towards others in accordance with virtue. In this sense justice is the primary virtue, needed to regulate the living out of all other virtues. Particular justice deals with objects such as money, safety, possessions, means to acquire these and so forth. It seems that Aristotle has in mind that particular justice has to do with the goods of life, those things that one may acquire or desire in order to reach one’s goals. Thus, to

summarize: Universal justice speaks to every person in every circumstance, and requires living in accordance with virtue in our relations with others in general. This is the view that a virtuous person will recognize that there are universal principles of justice which ought to govern behaviour towards others in relation to what is right and virtuous, no matter where one finds oneself. Particular justice has to do with the goods of life, those things that one would value as necessary to a good life, and seemingly with the distribution of these between persons.

Particular justice can again be divided in two. There is one type of particular justice which deals with the distribution of the goods of life within a society. In Aristotle's words: "...the distribution of honour, wealth, and the other divisible assets of the community, which may be allotted among its members in equal or unequal shares" (1131a2-3). The other type of particular justice is corrective, focusing on actions between private individuals. Thus, Aristotle divides particular justice, concerned with the goods of life, into two types – one which seeks to correct injustices done, which may be thought of as corrective justice, and one which seeks to address the distribution of the goods of life within the community, which may be called distributive justice.

When it comes to distributive justice, the principle is assignment by desert (1131a4-33). The idea is that persons should get a share of the goods distributed within society (honour, income, and the goods of life in general) in accordance with what they deserve. In this sense, equals should receive equal shares. It would be unjust to give equal shares to those who are not equal. A share is allocated according to what is deserved by each person, and those who deserve equal portions should get equal portions. Those who deserve less should receive a lesser portion. Aristotle mentions some possible criteria for determining desert, without it being clear which one is to be preferred:

"All are agreed that justice in distributions must be based on desert of some sort, although they do not all mean the same sort of desert; democrats make the criterion free birth; those of oligarchic sympathies wealth, or in other cases birth; upholders of aristocracy make it virtue" (1131a30-33).

## **Conclusions – Aristotle**

From Aristotle we can take the following ideas with regards to justice.

Justice is relational, and speaks of duties to others within society. Justice is also concerned with the way in which the community is ordered.

A particular kind of justice that is of importance is distributive justice. Distributive justice has to do with the fair distribution of valued goods within society. The principle is 'assignment by desert' – those who deserve equal portions should get equal portions, and those who deserve lesser portions should have lesser portions.

It seems that even in Aristotle's day there was disagreement between people about how to determine desert. In contemporary society, there are different theories of distributive justice,

each espousing a different way of determining which criteria are relevant in determining distribution.

## **(1.2) Mill on justice (Mill 2010b, p.99-113)**

In his essay on utilitarianism, John Stuart Mill spends a whole section on the connection between justice and the principle of utility. In order to do so, he embarks on a conceptual analysis of justice. From Mill's analysis of justice important characteristics of justice may be gleaned.

In order to understand what justice is, Mill says we have to find the "distinguishing characteristics" of the just and the unjust. There are various examples of situations and things that can be considered to be just, and also various situations and things that we can consider unjust. If we can see a common thread in these, we can perhaps understand what it is that makes things just or unjust. In essence, what is that quality in a state of affairs that makes it either just or unjust?

His first strategy is to consider various instances of justice and injustice, so as to find qualities that belongs to the idea of justice. These instances are as follows:

- 1) It is unjust to deprive anyone of freedom, personal possessions, or anything else that legally belongs to that person. In other words, it is unjust to deprive persons of those things they have a legal claim to.
- 2) Sometimes laws give people legal rights that they should not have had. In other words, laws may sometimes be wrong or unjust themselves. However, when a law is considered unjust, it is also considered unjust because it disallows someone something they have a right to. This right is not legal, because it does not derive from the law; this right therefore has to be moral. Laws are therefore unjust if they encroach on the moral rights of a person.
- 3) Justice requires that a person get what they deserve. Someone receiving an evil they do not deserve suffers an injustice; someone who receives a proportionate good for the good they have done is being treated justly.
- 4) It is unjust to break promises, or to disappoint knowingly created expectations.
- 5) Justice is impartial to matters that are not directly concerned with determining desert in the case before it. For example, a tribunal that has to decide which of two persons rightfully owns an object, can only be influenced by matters that determine desert. That is, the tribunal should only consider those aspects that determine which person has a right to the object, such as legal transfer of goods. The tribunal should not consider aspects such as social status, gender, personal preference for one of the candidates and the like. Thus, the impartiality required in matters of justice is the impartiality of solely considering matters of desert. If other matters influence distribution or decision-making, it would be unjust.



After examining these five instances of justice and injustice, Mill embarks on a second strategy. He looks at the history of justice, and specifically how the term *justice* was used in historical contexts. He states that justice originally referred to acting in accordance with law. However, the Roman and Greek civilizations that referred to justice in this way were fully aware that societies could sometimes enact laws that were not perfect. Over time, the idea of “injustice” came to refer to acts which were contrary to laws that *ought to exist*, even if they did not exist. Thus, an important aspect of justice is that it requires obedience to laws that should exist within society, even if such laws do not exist. Mill argues that it is not always desirable for governments to enact laws to punish all acts of injustice. For example, it would be very cumbersome and place a high burden on society if people were sent to prison for every broken promise. However, the notion that “one should not break promises, it is unjust to break faith” implies a law that ought to be, even if it is not practical or desirable for governments to enforce such laws.

As a third strategy, Mill argues that justice can be distinguished from general morality in the following way. Moral duties can be divided into duties of perfect obligation and duties of imperfect obligation. Imperfect obligations are those duties where a duty exists, but not to a particular person or to particular circumstance. For example, being generous is a moral duty, but there are no specific persons that can claim this generosity. The persons and the circumstances to which generosity applies are not stipulated as part of the duty of generosity. On the other hand, with perfect obligations the specific person(s) and circumstances to which the duty applies are specified. In other words, perfect obligations give rise to a corresponding moral right in the person(s) to whom the duty is due.

Mill argues that justice is to be distinguished from general morality in the same way. Justice imposes a duty of perfect obligation; in other words, justice refers to those moral duties that are associated with a corresponding right. Obligations of justice involve some moral duty resting on one party, the discharge of which someone else can claim as a right. Thus, injustice happens when someone is denied something they have a moral right to through the neglect of moral duty by a person or group of persons.

## **Conclusions – Mill**

From Mill’s analysis of justice, we can take the following:

Justice is a specific category of moral obligation, where a moral duty resting on one person or group of persons accompanies a corresponding moral right in another person or group of persons. Thus, someone is treated unjustly if they are deprived of a good that they have a moral claim to. This deprivation is the result of failure on the part of a group or person to fulfill the corresponding moral obligation.

Justice also has with it the idea of desert. The moral right of a person to some good is in accordance with criteria of desert. Saying that someone has a moral right to some good, is the same as saying they deserve that good.

Justice requires impartiality with regards to distribution of goods, in the sense that only the criteria that determine desert are considered in the distribution of goods. So, the moral right of a person to some good should not be waived because of considerations that have no bearing on desert. In this sense, people should be treated equally when it comes to claims of justice.

Mill's ideas are similar to Aristotle's with regards to desert and distributing in proportion to desert. An important addition in Mill's thought is that justice implies a moral duty on one person/group of persons that corresponds to a moral right to something in another person/group of persons. If the former neglect their duty, the latter suffer an injustice. If the former fulfill their duty, the latter is treated justly.

### **(1.3) Beauchamp and Childress (2013) – the principle of justice in bioethics**

Beauchamp and Childress (B&C) (2013) conceive of justice as treating persons fairly and appropriately, in keeping with what is due to persons. A subsection of justice that is of particular concern to bioethics is distributive justice. Distributive justice deals with the fair and equitable distribution of goods within society, and in healthcare terms there is a specific way of conceiving of this:

“The term *distributive justice* refers to fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social cooperation” (p. 250).

B&C recognize a formal principle of justice, crediting Aristotelian ideas: Treat equals equally, and treat those who are unequal unequally. In other words, to all persons should be given in proportion to what is owed them; those to whom equal portions are owed (based on criteria of desert), equal portions should be given.

The formal principle of justice does not specify which criteria should be used to determine desert. To know what is owed to whom one needs a material principle of justice. Material principles of justice describe characteristics of persons that can be used to determine desert. Burdens and benefits ought then to be distributed in accordance with desert. B&C identify six different theories of justice, each of them stipulating their own material principle for determining desert: utilitarian, libertarian, egalitarian, communitarian, capability, and well-being.

### **Conclusions – B&C**

B&C incorporate the ideas of Aristotle with regards to justice, arguing that each member of society should get what is owed them according to criteria of desert. However, they attach to the notion of distributive justice the concept of benefits and burdens. When it comes to distributive justice and medicine, the focus is on fair distribution of benefits and burdens. For example, some persons should not be unduly burdened for the benefit of others. Similarly, some should not receive benefits beyond what is owed them at the expense of others. Rather, benefits and

burdens should be fairly distributed – according to what is deserved by persons according to criteria for desert.

Distributive justice speaks to the equitable distribution of goods within society, and therefore in terms of bioethics speaks of equitable distribution of medical benefits and burdens. Thus, it is possible to look at any given society, study the distribution of medical burdens and benefits, and ask: “Is this distribution just?” To answer this question, specific criteria for desert need to be adopted, which speaks to the need for employing a material theory of justice.

#### **(1.4) Conclusions – what is justice?**

Taking all of these into account, I conceive of justice as follows.

Justice is a moral principle that specifies that persons should be treated fairly, getting what they deserve. Within bioethics, distributive justice deals specifically with the equitable distribution of medical benefits and burdens in society. People should not receive more or less benefits than they deserve, and should not receive more or less burdens than they deserve.

Justice places a duty on one person/group of persons, with a corresponding moral right to something in another person/group of persons. As a hypothetical example: if someone claimed that justice requires free basic health care for children, this would mean that children have a moral right to receive free health care. There would then be a corresponding duty on society or its delegates (such as the state) to provide children with free health care. If society then failed to provide free health care to children, the claim would be that this situation is unjust.

In order to determine who is owed what, a material principle of justice is needed. Material principles of justice specify criteria of desert, and therefore how burdens and benefits should justly be distributed. There are different theories of justice, each comprising of a different material theory of justice. I will examine each of these in turn later.

Justice speaks to society as a whole. We can therefore look at the distribution of burdens and benefits within a society and ask, “Is this distribution just?” A society can be thought of as a just society if it meets the demands of justice; among other things, this would mean that the distribution of burdens and benefits in the medical system is just. If this distribution is unjust, a society can be thought of as unjust. Thus, a just society is organized in a way that a just distribution of burdens and benefits are reached.

## **(2) Theories of justice influential in bioethics as identified by Beauchamp and Childress**

B&C identify six different theories of justice, each containing a different material principle of justice (Beauchamp & Childress 2013, p.252-262). Each of these theories describe criteria for deciding who deserves what, and consequently what justice requires in terms of distributing burdens and benefits. They recognize four traditional theories, and two newer ones:

### *Traditional theories in B&C:*

*Utilitarian justice* is concerned with maximizing the greatest happiness for the greatest number. The material principle of this theory: “To each person according to rules and actions that maximize social utility.”

*Libertarian justice* places the focus on individual rights, fair process and liberty. The material principle is: “To each person a maximum of liberty and property resulting from the exercise of liberty rights and participation in fair free-market exchanges.”

*Egalitarian justice* is concerned with equal distribution of access to the goods of life, that is, those things that are necessary for a good life. The material principle can be stated as: “To each person an equal measure of liberty and equal access to the goods in life that every rational person values.”

*Communitarian justice* is an approach to justice that focuses on promoting the good life, as conceived of by a moral community. The material principle is: “To each person according to principles of fair distribution derived from conceptions of the good developed in moral communities.”

### *Recent theories in B&C:*

*Capability justice* is a contemporary theory of justice, and argues that social and political institutions should be arranged in such a way that the capabilities and freedoms required for each individual to flourish are protected. The material principle is: “To each person the means necessary for the exercise of capabilities essential for a flourishing life.”

*Well-being justice* is also a contemporary theory, arguing that society with its social and political institutions should be ordered in a way that the dimensions of well-being of each individual is protected. The material principle: “To each person the means necessary for the realization of core dimensions of well-being.”

### **(3) The different conceptions of justice and measles vaccination in children**

In this section I shall examine the ethical considerations of measles vaccination in children from the perspective of the different theories of justice. For each theory, I shall first provide a brief summary of the main points of the theory. Then I shall apply the theory to measles vaccination in order to arrive at ethical action guides.

#### **(3.1) Utilitarian justice – maximizing welfare**

Utilitarianism states that moral actions are those which lead to the greatest happiness for the greatest number. JS Mill describes the principle of utility as follows:

*“The creed which accepts as the foundation of morals, utility, or the Greatest Happiness Principle, holds that actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness.”* (Mill 2010b, p. 77).

The idea with utilitarianism is therefore that moral actions increase the overall happiness while immoral actions decrease overall happiness. In considering overall happiness, the happiness of every person counts the same as the happiness of every other person. Thus, one’s own happiness counts the same as the happiness of every other person. The principle of utility would therefore ask of us to maximize happiness for the greatest amount of individual persons.

Mill defends a fairly rigorous concept of justice based on the principle of utility. According to Mill, justice is concerned with what is due to persons; to say that someone has been done an injustice is to say that something has been withheld from someone to which they have a moral right. Every moral right has a corresponding moral duty: if I have a moral right to X, someone else has the duty to provide me with X. This duty may fall on government, society as a whole or some societal institutions, or on some individual. The person on whom the duty falls would be committing an injustice if they did not fulfill their duty to provide me with X.

The utilitarian will maintain that this concept of justice is grounded in the principle of utility. Justice leads to greater happiness, and just societies are happier societies. It is therefore a moral mandate of the principle of utility that society be ordered according to principles of justice.

Mill puts it as follows:

*“To have a right, then, is, I conceive, to have something which society ought to defend me in the possession of. If the objector goes on to ask why it ought, I can give him no other reason than general utility”* (Mill 2010b, p. 106).

Mill (2010b) defends rights to security, liberty, equality and fair punishment on this basis. If these rights are protected by society, it leads to a greater amount of overall happiness within

society. The rights of persons that are theirs in virtue of justice therefore rest solely on the basis of utility. The material principles of justice, deciding who should get what, are determined by utility.

B&C (2013) describe utilitarian justice similarly. Defining the principle of utility as maximizing welfare within society, they state that utilitarian considerations of justice “establish correlative rights for individuals that should be enforced by law. These rights are strictly contingent upon social arrangements that maximize net social utility” (Beauchamp & Childress 2013, p. 254). The just society defends a set of individual rights which would lead to greater social welfare. Society should therefore be so set up that the overall welfare of the greatest number of individuals possible is maximized. Individual rights should be recognized that lead to the maximum amount of overall social welfare.

It is of course conceivable that occasions may arise where the respecting of individual rights clash with the greatest happiness for the greatest number. Sandel (2009) gives the example of a minority religion. Imagine a society where a minority religion is oppressed by the majority. In this society, the majority derives exceedingly high levels of happiness by stamping out what they regard as an offensive religion. If the greatest happiness for the greatest number is served by this arrangement, then it is hard to see how an individual right to religious liberty could survive in this society purely on utilitarian considerations. Or think of another example. Imagine a town where a police officer shoots an unarmed black man. There are riots in the streets, and the populace demands criminal charges against the police officer. After authorities investigate they find no basis for charges against the police officer, and on the basis of the principle of justice decide not to file charges. Consequently, the entire society is unhappy and take to the streets in anger. It is clear that the greatest happiness for the greatest number would be served by filing charges against the police officer, but it seems as if the individual’s right to just treatment before the law trumps this. This example loosely resembles McCloskey’s famous story to illustrate the incompatibility of justice and utilitarianism (Rachels & Rachels 2007, p. 103-104). I have modified the details slightly to be more in keeping with contemporary events, but kept the core of McCloskey’s story to illustrate the point of a perceived tension between requirements of justice and requirements of utility.

Perhaps Utilitarians can respond that one should not look at isolated incidents as in the examples above, but rather at those societal arrangements that would lead to the greatest happiness for the greatest number over time. In other words, an enduring ‘maximized welfare’ rather than a quick ‘make me happy right now’ approach. They could therefore argue that although charging the officer would appease the masses right now, maximizing happiness in the moment, society will over time experience more unhappiness if individual rights are trampled on in this way. We therefore have to accept momentary unhappiness by upholding the rights of the individual against the clamor of the crowds, because doing so consistently will over time create the kind of society where social welfare is maximized. Indeed, this seems much like the utilitarian

justice found in the pages of Mill. We are therefore to adopt criteria for distribution that lead to the maximal enduring optimal welfare of society.

### **Utilitarian justice and measles vaccination in children**

We are concerned with a just distribution of benefits and burdens within society. The idea of utilitarian justice states that we should arrange the distribution of benefits in such a way that social welfare is maximized. Justice in this view wants society and individual rights to be arranged in such a fashion that it leads to the greatest welfare/happiness for the greatest number.

#### *The greatest happiness for the greatest number through measles elimination from society*

If we look at measles disease and the effects it has on society, it is clear that societies without measles are better off than societies where measles disease is present. In completely unvaccinated societies, measles spreads quickly and causes a high illness- and financial burden to society. To recall the numbers in the US as an example: prior to the vaccination age, almost 90% of people in the US got measles before their 15<sup>th</sup> birthday. In the early 1900's, 5 300 people died of measles each year. Despite better medical care, nutrition, and various public health improvements, measles remained a large societal concern in the mid 1900's. From 1956 to 1960 there were 450 measles deaths per year, 4 000 cases of measles encephalitis each year, and 48 000 measles hospitalizations each year (Orenstein, Papania, & Wharton 2004). After the introduction of measles vaccination in the US, measles infection rates dropped sharply. This translated to a healthier society with improved societal welfare. To recall the 1985 review of the effects of measles vaccination in the US after 20 years of vaccination: By 1983 measles vaccination in the US has prevented an estimated 52 million cases of measles, 5,200 measles deaths, and 17,400 cases of neurological disability. An estimated net savings of \$5.1 billion in healthcare expenditure was the result (Bloch et al. 1985).

It is possible to eliminate measles from a society through measles vaccination. To achieve elimination of measles, we need to vaccinate upwards of 93% of children with two doses of measles vaccine (see chapter 2, section 2.2 of this work). Countries that fall below this threshold experience cyclical outbreaks of measles epidemics. As was seen in the example of South Africa, a country where vaccination falls below the elimination threshold, such measles epidemics cause substantial financial- and illness burdens on society.

Decreasing the burden of measles leads to greater welfare in a society. Societies where measles infections do not occur are healthier, happier and have greater overall welfare than societies where measles is present. Measles can be eradicated from a society through sufficient levels of measles vaccination in children. Vaccination is safe, with a very favourable adverse effect profile. Vaccinating children as required for measles elimination does not cause substantial harm and does not decrease the welfare of society.

Given these considerations, Utilitarians would view vaccinating children to sustain measles elimination as a moral imperative. A society where measles has been eliminated is better off than one where sporadic measles outbreaks occur or where measles is endemic. Furthermore, vaccinating at the levels required for measles elimination does not impose meaningful harm on society. Utilitarians would therefore conceive of a just society as one where measles is eradicated through vaccination. This means that a just society, as conceived of by Utilitarians, vaccinate upwards of 93% with two doses of measles containing vaccination. Of course, there are always those in society who are not eligible to receive measles vaccination: the very young, those who are allergic, those with severe immune compromise. This group usually comprises 5% or less of society, so that the target of vaccinating above 93% is manageable (see chapter 2, section 2.2 on herd immunity).

The obligation to vaccinate can be stated as the following principle: everyone who can be vaccinated against measles, should be vaccinated against measles at least to the point of measles elimination. A society that does not adopt this approach does not fulfil the obligations of justice according to utilitarian standards.

There are, however, two other utilitarian considerations that should also be considered. One is liberty, the other is the parent-child relationship.

### *Respect for liberty*

Mill (2010a) defends a comprehensive account of personal liberty based on the principle of utility. The argument is that the greatest happiness for the greatest number is secured when society respects the right to personal liberty. Mill contends that this right to personal liberty means that a person is free to think, act and speak as they choose as long as their conduct does not harm others. Under this conception of liberty, society cannot force people to do things that are in their own best interests, but society can stop individuals from harming others. The boundaries of liberty is the welfare of others.

A free society is, under this conception, a happier society. The principle of utility would therefore indicate that the free choices of individuals should be respected. If we therefore wish to maximize utility with regards to measles vaccination, the second principle we need to respect is liberty to choose and direct one's own medical care. In the case of children, it is the duty of parents to direct the healthcare of their children on the basis of the child's best interests (Buchanan & Brock 1990, Beauchamp & Childress 2013, p. 228; Mill 2010a, p. 10, 67-68). Respect for liberty would require society to respect such decisions.

Some people could argue that they can legitimately refuse vaccination because utilitarian justice requires a strong principle of personal liberty in the just society. It is not the business of government to tell me how to raise my children or what medical treatment to accept in my or my children's bodies, they may say. Indeed, as we have seen in the initial chapters of this essay,



many anti-vaccine activists portray vaccination programs as totalitarian and as an infringement on liberty rights.

The argument does not entirely succeed. It is so that society has an obligation to protect individual liberty. But the limits of individual liberty is the welfare of others. My liberty ends at the point where my actions cause harm to others. Therefore, if refusal to vaccinate leads to the harm of others, society can and should intervene. In the case of measles vaccination we have seen that falling below the elimination threshold leads to epidemics of measles within society, and substantial societal burden. Furthermore, there is always a susceptible subgroup in society, the more or less 5% of people who are not eligible for measles vaccination. This vulnerable subgroup depends on herd immunity (which is the same as measles elimination in society) to protect them against harm from measles infection.

Apart from harming others people in society by not vaccinating their children, parental refusals of vaccination may also harm their own children. An unvaccinated child is at risk for getting measles, and specifically if such free choices allow vaccination rates to fall below the herd immunity threshold. Under utilitarian theory, society should respect free choices and protect liberty, but not if free choices harm others. Therefore, if the free choices of a parent harm their child, society is not under any obligation to respect such choices.

Thus, appeals to liberty are limited by harm caused to others. It is clear that others in society are harmed when the measles vaccination rates fall below the threshold for measles elimination. Society must therefore interfere with the choices people make to refuse vaccination if such choices will result in a fall of vaccination rates below the elimination threshold. However, liberty is important, and respect for liberty guides societal response towards vaccine refusal.

### *Respect for the parent-child relationship*

The interests of children are narrowly intertwined with their parents (Elliot 2001). The welfare of society is undoubtedly best served when children are protected and nurtured. Adopting measures that harm parent-child relationships will be detrimental to the welfare of society. Therefore, maximizing the welfare of society includes adopting measures that protect and foster parent-child relationships, and empower parents to choose healthcare options that align with the best interests of their child. This important ethical consideration therefore also guides the societal response to vaccine refusal. Responses that harm the parent-child bond will lead to diminished welfare for individual children, and eventually to diminished welfare of the whole society if implemented in a large scale.

### *Two ethical action guides – utilitarian justice*

Ideally, the societal approach to measles vaccination will encourage measles vaccine uptake in a way that maintains measles elimination from society, while respecting liberty and the parent-child relationship as much as is possible. These ethical considerations can be summarized as two action guides.

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

These two principles can be in tension with one another when parents choose not to vaccinate their children. According to utilitarian justice, principle (2) becomes limited when measles elimination in society is threatened. It would be ideal if all people vaccinated freely, but in cases of tension between (1) and (2), a just society should respect (2) as long as no harm accrue to others. Free choices that harm others demand a societal response, and such a response should incorporate respect for liberty and the parent-child relationship as far as is possible.

### **(3.2) The liberal theories – libertarian justice and egalitarian justice**

Sandel (2009) points out the underlying shared commitments between the two major liberal theories – libertarianism and egalitarianism. The liberal theories are based on the premise that justice is primarily concerned with freedom. A society is just if it is so arranged that individual freedom is extended equally and maximally to all individuals in the society. The focus is not on welfare of individuals, but on freedom of individuals. The liberal theories share a commitment to the idea of the choosing individual: the individual as a rational and free subject, choosing its own conception of the good life. The state is to be neutral between different conceptions of the good life, and a just state will ensure that the members of society are free to choose and live out their own conceptions of the good life.

Sandel (2009) argues that the basic assumptions of these theories are Kantian in nature. Kant, he argues, thought that persons not only acted from desire, pleasure and pain; rather, persons are endowed with the capacity of free will. Therefore, persons are not merely dictated to by laws of nature or by desires and aversions. Rather, every person is able to act in accordance with laws that they give themselves. Every person is able to act as a lawgiver. Now, persons only act freely when they act in accordance with these laws they make as rational persons. When someone acts in accordance with their desires or merely the laws of nature, they are not acting freely. Rather, such behaviour is determined by something else, and not by the free will.

Sandel furthermore argues that in Kantian thought to act morally is to act from the will. Moral actions are done in accordance with a good will, and are not merely determined by desire or natural/physical laws. So, if you will a moral action and the action is done from that motivation, it is moral. If an action is done from motivations of desire, they are not moral actions. Thus, as Sandel points out, for Kant there is a link between acting freely, acting morally and acting rationally. One is either acting freely, obeying rational laws given by the choosing self, or one is acting non-freely, non-rationally and non-morally, directed by desire or natural law. Thus, to say one is acting morally entails within it the idea that one is acting freely. Kant therefore strongly

defends a political system where the freedom of individuals are protected, and freedom is only limited by the freedom of others. The idea of the free, choosing individual is in its essence Kantian, according to Sandel, and the liberal theories are grounded in this Kantian conception.

Although adherents of these two theories, libertarian and egalitarian, are often times bitter enemies in the political sphere (think Republicans and Democrats in the American political arena), they really are two sides of the same coin. That is, these theories share a commitment to the free, choosing individual. As Sandel points out, they disagree on *how* freedom is best to be achieved, but they do share a commitment to the principle of liberty. This commits both theories to the liberal individual, free to choose her own conception of the good life. The state is to ensure that society is such that freedom is protected, and the state is to be neutral between different conceptions of the good life. The state is not to promote a specific conception of the good life, but should ensure that individuals are free to live the good life as they themselves choose. Libertarian justice maintains that the best way to reach the goal of freedom, is through equal individual rights, an unfettered free market and a minimal state. Egalitarian justice states that freedom is secured by equal access to the goods of life. That is, everyone should have equal access to those things that make for a good life, at least minimally. The State is then tasked with the obligation to ensure that social institutions are structured in this fashion.

### **(3.2.1) Libertarian justice – maximal individual liberty**

One of the most influential defenders of Libertarian justice is Nozick (1974). Nozick develops a theory using a foundation of assumptions garnered from Kant and Lock. These basic assumptions include that people may never be used as a means only, but always as an end in themselves, and that people belong to themselves, and not to another. Nozick therefore argues foundationally that individuals are self-owners and should be morally respected as ends in themselves. These considerations place constraints on what governments or other people can do to the individual, and furnishes the individual with certain rights – the right to life, the right to liberty, and rights to control the fruits of one's labour.

Such moral rights place constraints on others. Others may not forcibly take possessions that an individual has worked for and has rightful ownership of. Others may not deprive the individual of life, harm the individual's body, or infringe the liberty of the individual. As such, many activities that contemporary governments engage in – redistribution of property, taxation, welfare programs and the like – infringe on the rights of individuals and are unjustifiable. In fact, the only government that can be tolerated is a minimal government – one that protects people from harm and the infringement of their liberty by others. Such a government protects citizens against theft, fraud, and other forms of crime by instituting police and military forces. It also establishes law courts for administration of laws and settling disputes. But such a government cannot interfere with the lives of its citizens, or interfere at all with their rights to liberty, life, and ownership. Thus, the state cannot decide what can be printed and circulated, read and viewed, created and consumed; nor can it regulate economic or private relational decisions of individuals. If a

government were to interfere in any of these areas – for example by banning certain types of publications or by heavily taxing certain kinds of foods – it would infringe on the rights of individuals, and be unjust.

With regards to distributive justice, Nozick's focus is mainly on economic issues and goods created through work. The individual has the right to own what she has worked for, and the right to dispose of it as she sees fit. The labor of the individual and the products of that labor belongs to the individual. When we examine the distribution of such goods in society, and want to determine whether the distribution is just, there are only three principles of justice that need to be considered. These principles are justice in acquisition, justice in transfer, and justice in rectification. Acquisition refers to how a good was initially acquired or created. For example, if someone made use of a freely available natural resource and mixed her labour with it, the product belongs to the individual. Transfer refers to change in ownership from one person to another. Goods are justly transferred between people if there is a voluntary exchange of ownership of goods from one person to another. Rectification refers to actions that correct previous injustices; for example, if previous transfers were based on deceit or coercion leading to the infringement of the rights of one of the parties, actions that correct the injustice are actions of rectification. When these principles are followed, the resulting distribution is just. There is then no need for redistribution. In fact, government redistribution would be unjust. If there was justice in acquisition, justice in transfer and justice in rectification, any resulting distribution of economic goods should be considered just.

It is not clear to what extent these principles can be applied to the distribution of benefits and burdens within a healthcare system: Nozick's focus is quite evidently on economic matters and on goods created through work. What is clear, is that the state cannot redistribute wealth to create a publically funded healthcare system; this would infringe ownership rights. Also, the state cannot interfere with free decisions with regards to healthcare. Individuals are free to accept or reject healthcare interventions as they see fit, even to their own detriment. People belong to themselves and can govern themselves. A minimal state would protect other people, however. If the actions and decisions of individuals cause harm, fraud, theft and the like – the minimal state is tasked with intervening.

The libertarian Nozick argues that only a minimal government can be tolerated. The only interference from government that can be accepted is the protection of members of society's liberty and property rights. Any coercive actions on behalf of government apart from protection of liberty and property rights, or indeed any government action beyond these parameters, is seen as an infringement on the rights of individuals. According to Libertarian conceptions of justice, the main focus of justice is not the welfare of people in society, but rather liberty. Justice requires of us to respect the right to individual liberty of all members of society. Under Libertarianism, the freedom to choose one's own goals and to live out one's own choices is paramount. Coercion and government intrusion are frowned on, and the only type of government that can be tolerated is a minimal government that enforces liberty rights and national security.

B&C interpret the implications of libertarian justice for distributive justice in healthcare matters (Beauchamp & Childress 2013, p. 255-256). In distributive justice and healthcare benefits and burdens, libertarians are not so much concerned with the end distribution as with fair procedures. As long as the procedures that lead to the current distribution were fair, and as long as everyone's liberty was respected, the resulting distribution is fair (Beauchamp & Childress 2013, p. 255-256). Therefore, end distributions with inherent inequalities may be just, if the processes that led to that distribution were just. As long as nobody was coerced or deceived, and everyone's liberty was respected, resulting inequalities in healthcare outcomes and healthcare access is thought to be just.

Sandel interprets the main points of Nozick's libertarianism as follows (Sandel 2009, p. 60-70). Libertarians endorse a minimal state, one that "enforces contracts, protects private property from theft, and keeps the peace" (Sandel 2009, p. 60). If a state interferes with the free choices of its citizens beyond this, it is morally unjustified and an infraction on liberty. Libertarians reject the following (Sandel 2009, p. 60):

- Paternalism. Libertarians maintain that government cannot decide on my behalf what is in my best interests. As long as no one is harmed, government cannot limit my free choices. Government cannot even force me to act in my own best interests.
- Legislation of morality. Libertarians argue that government should be neutral among different conceptions of the good life and different conceptions of morality. Government cannot enforce a specific view of morality through law.
- Redistribution of wealth or material goods. Libertarians reject any government programs that redistribute wealth. Nobody can be forced to give help to others, and nobody's goods can be forcibly taken away.

Simply stated, libertarians argue that justice requires an utmost respect for individual liberty. Society or government cannot interfere with individual free choices, not even when the individual makes choices that clearly is against that individual's best interests. I am the only one who can decide what is in my best interests. Any societal coercion beyond a minimal government represents a violation of liberty, and is therefore unjust. The only legitimate role of the State is to protect property rights and to protect liberty rights. Thus, the State (and society in general) can only interfere with my actions when my actions limit the liberty rights of others. In essence, this can be summarized as: I am free to do whatever I choose, as long as I don't harm others. Or, as per the well-known colloquial adage: I am free to swing my arm, but the right to swing my arm ends where your nose begins.

## **Libertarian justice and measles vaccination in children**

Under the libertarian conception of justice people cannot be forced to accept healthcare interventions of any sort that go against their free choices. Thus, when it comes to measles vaccination individuals should be free to choose. Given the sizeable benefits of measles

vaccination and the very low risk for harm, it seems reasonable to assume that by far most people who are shown the benefits of vaccination over non-vaccination will choose vaccination.

People who oppose vaccination could however forward an argument based on libertarian principles as follows. Government and society have no business interfering with my free choices when it comes to health care. I alone can choose what is in my best interests. I have the right to make decisions with regards to my own body, my own good, and my own healthcare. It is not up to government to decide what is in my best interests, and I can therefore not be coerced to accept vaccination. When it comes to children, parents are the substitute decision-maker. Parents decide on behalf of their children according to the best interest standard. Parents who oppose vaccination may therefore similarly argue that they alone can judge the best interests of their children, and that government and society cannot interfere with free decisions they make on behalf of their children.

This argument does not succeed, as it overlooks the limits of liberty. There are three ways in which this argument can be refuted:

Firstly, liberty cannot be used to defend actions that would harm others. Liberty is limited by the rights of other individuals in society. Actions that lead to the harm of others within society are not protected by the right to liberty. We know that approximately 5% of individuals within society cannot receive the measles vaccine and therefore remain susceptible to measles infection and its potentially devastating consequences. These susceptible people depend on herd immunity to protect them from measles infection. With measles, the herd immunity threshold is similar to the measles elimination threshold; only when measles is eliminated from a society are these 5% of susceptible individuals protected. Thus, any action taken by individuals that threaten the elimination of measles from society is unjust under the libertarian conception of justice. If personal refusal or the spreading of misinformation leads to a decline in measles vaccination rates beneath the elimination threshold, harm will accrue to individuals susceptible to measles. Such personal refusals or spreading of misinformation would therefore be unjust according to Libertarian theory.

Secondly, the point of libertarian justice is that society be so ordered that the liberty of *everyone* is respected. The liberty of all persons in society weighs equally. There is therefore a positive obligation on members of society to respect the liberty of others, and to not take actions that limit the liberty of others. There is also an obligation on the State to protect the liberty of all members of society. Now, as stated before, there are always members of society who will be ineligible for measles vaccination and therefore susceptible to measles. In order to protect such individuals, elimination of measles in society is required. If measles is not eliminated from society, it restricts the liberty of susceptible individuals in two ways. (1) To protect themselves against measles infection, as reasonable people would want to do, susceptible persons have to take extreme measures such as social isolation and protective clothing to protect themselves against measles infection. Since they cannot receive measles vaccination, they have no other way of protecting themselves. Living in such a way is severely restrictive to liberty. (2) If such susceptible

people get measles, there is a fair chance they will suffer a complication. This could lead to hospitalization, disability, or death. Any of these outcomes restrict the liberty of persons. Furthermore, if it is a child that is affected by measles infection, it may hamper their development and growth, harming the full development of faculties necessary for liberty.

Thirdly, with measles vaccination the free decisions of parents impact on children. When parents decide whether or not to have their child vaccinated, parents are not deciding on their own behalf, but on the behalf of their children. Under Libertarian thought, the individual is sovereign over her own life, and has the final say in decisions that impact her. But the individual is not sovereign over the life of another, and does not have the final say over choices that impact the life of another. It follows that there are limits to parental authority over their children. Parents do not have unlimited authority over their children in the libertarian theory, and the question is raised what the limits of parental authority is. In the previous chapter, I argued that the best interest standard is the only acceptable guide when deciding for children, that parents are thought to be in the best position possible to direct care in the best interests of their children, and therefore parents act as surrogate decision-makers. Parental authority is therefore linked with the best interest standard. When parents make decisions that are clearly not in the best interests of their children, it is not obvious that appeals to parental liberty rights provide the necessary moral force to overrule the best interests of the child. The freedom of the parent to choose must be limited by the interests of the child, and if parents make choices that are wildly incompatible with the best interests of the child, such choices should rightly be limited. Of course, the threshold for interference with such parental decisions should be quite high. I argued in the previous chapter that it is undoubtedly in the best interests of children to be vaccinated against measles if they are medically eligible to receive measles vaccination, and presented arguments to justify a response to such parental decisions from other persons who stand in morally relevant relationships with the child. Consequently, it seems hard to accept that parental liberty should override the best interests of children. It is not clear that parents' appeal to liberty rights can justify non-vaccination of their child.

Some may object that forcing those who are eligible to receive measles vaccination so that harm to non-eligible subgroups may be prevented is unjust, because it inflicts harm to the recipient of vaccination. If this were true, and measles vaccination were quite harmful, this line of argument would perhaps be correct. There can be no moral duty on some individuals to accept substantial harm to themselves so that harm to others may be avoided. Of course, this objection is mistaken. Measles vaccination has a negligible risk for adverse events, and does not lead to substantial harm. Furthermore, the benefits to the individual through receiving measles vaccination are sizeable so that the recipient benefits exceedingly from the arrangement.

There are therefore good reasons to argue that vaccine refusal would require a societal response. When individual free choices by parents impact the freedom of others and risk harming their own children, society has to respond. The minimal state has to secure the freedom of all members of society, and has the duty to limit individual free choices that harm others within

society. Measles vaccination in children therefore is a matter of societal concern, and is rightly within the jurisdiction of the minimal state.

Taking all of these considerations into account, we can state the following with regards to measles vaccination in children according to Libertarian justice:

- If individual free choices harm others/limit the liberty of others, such choices are unjust, and society should respond to such choices. If measles vaccination rates drop beneath the threshold for measles elimination, there is a high chance that harm may accrue to others in society, children of vaccine refusers may be harmed, and that the liberty of those who are not vaccine eligible will be severely restricted. It therefore follows that individual choices that lead to decline in measles vaccine coverage rates below the elimination threshold are unjust. Here, we encounter again a problem that I previously highlighted: it is in practice virtually impossible to state which individual case of vaccination is the one that leads to the loss of herd immunity. We cannot, in practice, identify the individual case of vaccine refusal that is the straw that breaks the camel's back. When we additionally take into account that the threshold for elimination is coverage of 93-95% of children with 2 doses of measles vaccine, and that 5% of society is typically vaccine ineligible [8], we may conclude that very few vaccine refusals can be tolerated. Thus, according to Libertarian justice it would be unjust to allow parental refusals that threaten herd immunity. In practice we cannot identify the individual case that would endanger herd immunity. Every case of vaccine refusal should therefore require a societal response, and libertarian justice would endorse a system where every eligible child receives measles vaccination.

- In just societies personal liberty is respected when it comes to healthcare decisions. This means that parental free choices should be respected, as long as such free choices do not harm others in society. Small children do not have the capacity to express individual free choices; choosing on behalf of children without capacity requires allowing parents to choose in accordance with the best interest standard. These considerations have implications for societal responses to vaccine refusal. Libertarians want to respect liberty to the maximal degree; in this case it would mean respecting the parents' role as decision-maker for their child, and the parents' liberty rights, as far as is possible, while ensuring adequate measles vaccine uptake. Thus, vaccine policies that afford the greatest amount of respect for the child-parent bond and parental liberty are preferred, keeping in mind that loss of the measles elimination threshold would be unjust.

It turns out therefore that under the libertarian conception of justice, a just society vaccinates up to the point of measles elimination while respecting the liberty of individuals to choose freely. Once the measles elimination threshold is threatened, libertarian justice views this as unjust, and requires society to respond. In such cases government coercion could be justified under the conception of the role of the minimal state. Yet, societal responses to vaccine refusal are guided by respect for parent-child decision-making and parental liberty.

These considerations can be stated as two principles, (1b) and (2b):



(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

### *A possible objection*

Here is one possible objection to this line of argument.<sup>2</sup> Perhaps there are other ways in which an individual can protect the susceptible portion of the population against measles infection while refusing to receive measles vaccination. For example, perhaps an unvaccinated individual can freely choose to live the life of a hermit, avoiding contact with all susceptible people and therefore not cause harm to susceptible individuals in society by not vaccinating. Thus, I could freely choose to forego vaccination even if this would compromise the threshold for measles elimination if I then agree to avoid contact with susceptible persons and thus refrain from causing them harm.

This objection fails for two reasons.

Firstly, given the realities of contemporary society, it is virtually impossible to consistently live in such a way that one could guarantee that one would not spread measles infection to susceptible people. Contemporary society forces us to depend on other people for food, for shelter, for transport and the like. We often come into contact with other people, and it is not possible for us to merely look at people and know whether they are susceptible to measles or not. To make good on my commitment to avoid all contact with measles infection and all contact with those who are susceptible, it would mean a type of isolation that results in withdrawal from society. Consider the measles outbreaks that happen in susceptible people in the US and Canada. Even in these highly vaccinated societies, outbreaks happen where measles spreads between susceptible people. It is not always clear how and when these people came into contact with each other. Thus, to avoid spreading measles if you are unvaccinated you would have to largely avoid human contact altogether. The hermit type of existence foreseen by this objection is extremely restrictive and is basically incompatible with life in a contemporary society. There just seems to be no way to remain a participating member of society and yet live in such a way that one could guarantee that one would not spread measles if you declined vaccination. If one wanted to remove oneself from society, then of course one would be exempt from the argument I have made; the argument presented here is focused on a just society, and individuals who remove themselves from society and live in remote isolation are obviously exempt from such arguments.

Secondly, even if a person may be able to choose such a restrictive life for themselves, it is hard to see how choosing such a life for one's child is in the best interests of the child. Parents are

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<sup>2</sup> Brought to my attention by Dr. Paul Ford, (Center for Ethics, Humanities and Spiritual Care, Cleveland Clinic) during a presentation of this argument at the Cleveland Clinic in January 2015.

tasked with choosing what is in the best interests of their children. It is simply not reasonable to maintain that utter isolation is in the best interests of one's child in order to avoid vaccination against measles.

The objection therefore does not succeed. It follows that libertarian justice requires societal vaccination against measles up to the point of measles elimination. If this level of vaccination is not maintained harm will accrue to those who are susceptible and cannot get measles vaccination for themselves. The actions of some (vaccine refusal) therefore leads to harm to others. Under libertarian justice such a situation is unjust, and society has to respond.

### *A second possible objection*

A second objection might surround the idea that parents have to agree to pay the costs of measles vaccination and the healthcare encounter. The objection may go something like this. Since libertarian justice traditionally makes no provision for government subsidized healthcare, but usually leaves medical care to regulation by the market, how can one argue that it is a duty for parents to choose MMR when they have to pay for it? I will respond to this objection in two ways, because there are essentially two different objections rolled into one here.

(1) The central claim here is that parents cannot be held financially responsible for discharging a duty towards their own children. But this is quite mistaken. Parents have a host of duties towards their children that require of parents to expend time, money, and/or effort in order to discharge these duties. For example, it is not hard to see that parents have a duty to ensure that their children receive food and clothing. But government does not typically provide food and clothing free of charge; parents usually have to pay for these. The same goes for housing and security – parents have a duty to provide these items to their children, usually at personal cost. It would be wrong and quite mistaken for a parent to claim that, because government does not pay for food or clothing, they have no duty to provide these for their children. One of the essential duties of parenthood is to provide for their child, and this means securing the means in order to provide for one's child.

I have argued that parents have the duty to choose measles vaccination for their child, based on a number of reasons. Firstly, non-vaccination threatens measles elimination, and if measles becomes endemic it will lead to harm for those people who cannot receive measles vaccination. Secondly, non-vaccination limits the liberty of people who cannot be vaccinated. Thirdly, measles vaccination is in the best interests of the child, and parents cannot compromise their child's interests through their own choices. Rather, parents have a duty to choose what is in their child's best interests. This last point perhaps needs further reflection. Not only can measles vaccination be shown to be in the immediate best interests of a child, but non-vaccination can be shown to be liberty limiting to the child. A non-vaccinated child is at risk of measles illness, and the only way to avoid measles is to avoid active cases. This harkens back to my response to the first objection: in order to avoid getting measles and/or spreading measles, a child would have to live outside of mainstream society, a life of isolation, and devoid of the normal travel and social

contact we take for granted in contemporary life. Such a child has their range of life options and social contact markedly restricted because of a parent's choice not to vaccinate. The child's interests and developing liberty are therefore markedly restricted by the parent's choice. Under libertarianism, this cannot be: decisions of individuals that limit the rights or that harm others should be interfered with, and require interference by society's delegates such as government.

Thus, parents plainly have the obligation to choose measles vaccination, and if needs be to pay for it. This assumes that measles vaccination is not cost prohibitive and is readily available. This assumption mirrors the reality in many countries; I have for example shown in chapter 3 that measles vaccination is readily available in countries such as the US, Canada, and South Africa, and is not cost prohibitive. The alternative parents face in this case is not paying for the vaccine; this would mean paying for the measures needed to avoid/prevent measles infection, and paying for the costs associated with the child's medical care should the child get measles, while at the same time neglecting the parent's duty towards the child and society.

(2) But perhaps the objection is made stronger if measles vaccination was not freely available or was cost-prohibitive. It could be thought of as follows. Since government does not have the duty to regulate health care (and thus not vaccination), and vaccines are just regulated by market forces, it could foreseeably happen that measles vaccination is not available in some society, or that it is priced so high that it is simply unaffordable for parents. Or, if it is technically affordable they must choose between paying for measles vaccination and some other good such as food or clothing. After all, one cannot argue that a parent has the duty to vaccinate instead of paying for secure housing or food.

Firstly, I agree that it is perverse to argue that parents have the duty to vaccinate if vaccination is not available. Clearly, if vaccination is not present in a society or is cost-prohibitive, such a parent cannot discharge her duty to vaccinate. Here, parents are not making a free decision, but a coerced decision: the decision to vaccinate or not is essentially not a free decision but is determined by societal factors outside of the parent's control. And there is therefore more to the story.

I have argued that measles vaccination is undoubtedly in the best interests of children, and that non-vaccination is liberty limiting to both the child and to society. If children therefore are not vaccinated against measles, and parents are coerced into non-vaccination by societal factors, then the focus of justice moves towards the societal institutions responsible. Given that we live in a world where measles vaccination is readily available and not expensive, the question presents itself: what is it about this country that makes measles vaccination unavailable to its members? The answer is a question of justice. Since non-vaccination leads to harm and limits liberty, measles vaccination is a question of justice. If parents face a coerced choice to forego vaccination, libertarian justice requires a societal response, since non-vaccination is in essence liberty limiting. The responsibility would fall on government and its delegates; the role of government in a libertarian society is to protect the liberty of all its members, and to protect members from harming each other through their actions.

So, in this society, one would have to examine the social and governmental institutions to find out why parents are coerced into non-vaccination. Is it a matter of unethical business practices? These are ultimately individual choices that prioritize individual gain over the liberty rights of others. Is it a matter of government corruption? Again, here we have the prioritization of individual gain and the exercise of power for individual gain over the liberty of others.

The argument is simple. If parents are coerced into non-vaccination, there is a problem of justice in the society. Coerced non-vaccination limits liberty for various members of society. Government is tasked with ensuring liberty, and therefore has the obligation to respond when non-vaccination is mandated through societal forces. In essence, the non-availability of measles vaccination in a specific country in the contemporary world raises substantial questions regarding the nature of the societal and governmental institutions within the country under the libertarian conception. Since government has the obligation to ensure liberty for all, it means making sure that no barriers exist to access to measles vaccination, and to ensure that parents have the opportunity to freely choose vaccination.

Another way to say this, is as follows. Parents have the duty to vaccinate their children, and foregoing vaccination risks harm to the child and others, and limits the liberty of the child and others. If parents do not choose vaccination, it requires a response from society's institutions, such as the government and the health care sector. If the reason parents forego vaccination is because of safety fears or mistaken beliefs, the response from society should be aimed at those factors, employing government power (such as state mandates) and education. (I will focus on this type of policy in more detail in Chapter 7.) If the reason parents forego vaccination is because of non-availability of vaccines due to the business sector importing cheap vaccines and pricing them very high at point of delivery, government has the duty to intervene and ensure reasonable access for parents to vaccination.

The point is that non-vaccination requires a societal response. Again, we see the two principles I have derived reflected here. A just society vaccinates to the point that sustains measles elimination. If this does not happen, a societal response is required. A just society respects the parent-child bond and parental decisions making; thus, a just society places a parent in the position where she can freely choose vaccination. It is important to see that these follow from a purely libertarian view of justice. And, as I have pointed out in chapters 2 and 3, what is encouraging is that many countries take these obligations seriously, making vaccinations available to children, responding to non-vaccination. Consequently, vaccination rates are being raised globally, and vaccinations are readily available and not cost prohibitive in many countries (such as the US, Canada, Netherlands, and South Africa that I referenced in chapters 2 and 3).

### **(3.2.2) Egalitarian justice**

Egalitarian justice is a liberal theory of justice, meaning that it is committed to the idea of the freely choosing individual self. But egalitarian justice is also committed to the idea of equality of persons. All persons are morally equal and deserve to be treated equally. With regards to

distributive justice, egalitarian theories hold that persons should be treated equally “in certain respects” in the sharing of the benefits (and burdens) of society, although no major egalitarian theory is in favour of a strictly equal sharing of all social benefits (Beauchamp & Childress 2013, p. 256).

A prominent and extremely influential view of Egalitarian justice is the theory of justice of John Rawls (1971). Rawls’ theory is contractarian in that he invokes as basis for his theory a hypothetical social contract according to which the goods necessary to live a good life are distributed among the members of the just society. From this imaginary contract, Rawls deduces principles of justice that can be used in order to frame the commitments of the just society. Rawls claims that his statement of the “initial position” and the terms of the contract, together with the principles he derives from it, best matches our “considered judgments” regarding justice. That is to say, the theory of justice he proposes, based on the principles he derives from the initial position, provides the best explanatory framework that matches those moral judgments regarding justice we have the greatest degree of confidence in. In the next few pages I will gradually unpack Rawls’ theory of justice and the essential commitments of his egalitarian contractarian theory of justice.

Rawls asks us to imagine all members of society behind a “veil of ignorance” where no-one knows what their eventual social position within society will be, and that behind this “veil of ignorance” the members of society are deciding how to arrange the society they are to be part of. This is called the “initial position”, the hypothetical starting position from which Rawls derives his principles of justice. In such a society, Rawls argues, one would want to make sure that, whatever one’s eventual social position in society, one is the best off one could possibly be. One would for example want to ensure one is not the target of discrimination or in dire, unliveable poverty.

Rawls’ theory has strong Kantian underpinnings, as pointed out by Sandel (2009, p. 138-144): Kant argues that legitimate government derives its power from a contract with the governed. This contract is not necessarily an actual contract, but a hypothetical one. This hypothetical contract asks of the government to only pass such laws that members of society would have chosen for themselves. Important in Kantian thinking is the idea of the free, choosing self. The decisions and moral commitments of this choosing self should be respected, and thus government can only govern over a society of free individuals insofar as they have the permission of these free individuals to do so. It is not clear from Kant’s writings how such a model of government and societal justice would work in practice. Sandel argues that Rawls’ theory of justice is an attempt to answer these Kantian questions in a practical way. This means that the egalitarian theory of Rawls has strong commitments to the Kantian conceptions of the liberal individual and the contractarian basis of government.

Based on the hypothetical contract, Rawls argues for two central principles of justice (Rawls 1971, p. 60-61).

(1) *“Each person is to have an equal right to the most extensive basic liberty compatible with a similar liberty for others.”*

(2) *“Social and economic inequalities are to be arranged so that they are both (a) reasonably expected to be to everyone’s advantage, and (b) attached to positions and offices open to all.”*

Principle (1) guarantees a maximum amount of basic rights for all members of society. This includes things such as freedom of speech, freedom of thought, freedom of religion, political rights such as voting, and freedom from unreasonable arrest. Principle (2) focuses on things that all human beings need to live a good life. Rawls calls these things the primary social goods. The primary social goods are those things that all human beings want and need to live their lives, whatever their conception of the good life may be (“...things which it is supposed a rational man wants whatever else he wants”) (Rawls 1971, p. 92). This includes rights, liberty, opportunities within society, power, income, and material wealth. Thus, Rawls argues for maximal rights and liberties for all in principle (1) and for power, wealth, income and opportunities to be distributed according to (2).

The implications of principle (2) can be further considered so that the commitments of justice become even clearer with regards to distribution of the primary social goods. One thing that is apparent when looking at the distribution of the primary goods within actual societies, is that there is a marked inequality in distribution. Some people have more power, wealth and opportunities whereas other people have less. Some people are less well-off than others. According to principle (2), such inequalities should benefit everyone in society, not just those who happen to be well-off. It is obvious that those who have a lot of power, income, and wealth benefit from such an arrangement. But how would one ensure that everyone, including those who are less fortunate, benefits from the unequal way in which these primary goods are distributed? This leads Rawls to argue for a principle he calls the difference principle: inequalities in the distribution of the primary goods can only be tolerated if these inequalities ensure that society’s least well-off people are maximally benefited. In other words, there should be no other possible distribution of primary goods where the least well-off will be benefited more. The idea is to maximize the welfare of the least well-off as ‘good as it gets’. If this is arrived at through an unequal distribution of primary goods, such a distribution is just.

Rawls furthermore argues that justice should correct the unfairness of “life’s lottery”, stating a principle of fair equality of opportunity, and then uses this idea to further amend principle (2). Rawls argues that if one were to think about how primary goods such as income, wealth and power are distributed in society, one would see that they are closely tied to certain social roles and positions. This includes certain modes of employment, or political office. Thus, to ensure that persons have access to primary goods, one has to ensure that they have access to such positions and offices. There should therefore be equality of opportunity; everyone should have access to

those opportunities that distribute the goods of life. Looking a little closer, however, one notices that not everyone has a fair shot at such opportunities. Some have barriers in the way. The playing field is not level; not everyone has fair access to such positions and offices. For example, someone who is born in extreme poverty and is consequently uneducated and physically weak cannot compete with someone who is born in affluence, who has an Ivy-league education and excellent physical qualities, when it comes to occupations and positions. Thus, Rawls argues that we have to ensure fair equality of opportunity; we have to ensure that everyone has fair access to these opportunities. That means that those who are disadvantaged and have obstacles in the way of their path to such opportunities should receive some help to overcome these obstacles. Society should be so set up that systematic obstacles in the way of equal access to opportunities be removed.

Principle (2) can therefore be restated as follows (Rawls 1971, p. 83):

*“Social and economic inequalities are to be arranged so that they are both (a) to the greatest benefit of the least advantaged and (b) attached to offices and positions open to all under conditions of fair equality of opportunity.”*

Norman Daniels (1985) has extended Rawls’ theory to health care, examining the implications of Rawls’ theory of justice for health care policy within the just society. Daniels argues that illness and disease limit the access persons have to opportunities, and therefore decrease their access to social goods. Rawls’ fair equality of opportunity principle would require of a just society to respond to such barriers which would unfairly prevent persons from accessing the goods of life. If we are sick, we cannot secure positions, income, power or opportunities like when we are healthy. A just society therefore requires a health care system that prevents illness when people are healthy and responds with appropriate care when people are sick. It is a matter of justice to prevent, in so far possible, those illnesses and disabilities that would create a barrier to opportunities.

*“Health care has normal functioning as its goal: it concentrates on a specific class of obvious disadvantages and tries to eliminate them. That is its limited contribution to guaranteeing fair equality of opportunity”* (Daniels 1985, p. 46).

This implies that everyone in society should have access to that degree of health care that would protect them from the disadvantages that disease conveys. Of course, it is not always possible to heal all diseases or ameliorate all afflictions. Daniels argues for a basic minimum health care standard, a decent level of health care that is considered to be adequate given the limitations of finite resources and the level of scientific advancement. Thus, according to Daniels, everyone in society should have access to an adequate level of health care (sometimes called a decent minimum), regardless of their societal position, income, or wealth. B&C summarizes this idea as follows:

*“The allocation of health care resources, then, should be structured to ensure justice through fair equality of opportunity”* (Beauchamp & Childress 2013, p. 257).

*“On this account, each member of society, irrespective of wealth or position, would have equal access to an adequate, although not maximal, level of health care – the exact level of access being contingent on available social resources and public processes of decision making” (Beauchamp & Childress 2013, p. 257).*

## **Egalitarian justice and measles vaccination in children**

### *Measles vaccination and fair equality of opportunity*

Health care plays an important role in ensuring fair equality of opportunity. Health care so conceived has various functions: preventing illness as far as possible, and restoring normal function when illness does strike as far as possible. According to the Daniels/Rawls argument, each member of society should have access to such a basic minimum of health care.

Measles vaccination is an important and very effective way in which to protect the health of children from the onslaught of a serious infectious disease. If a person contracts measles, there is a risk of complications setting in that would pose a threat to the person’s access to the primary goods of life. For example, a child who contracts measles may end up with encephalitis and consequent disability. Or, a child may die and not realize their life goals at all. Even in the best case scenario, where measles lead to no complications, measles infections carry a financial and societal burden to parents and other members of society.

Measles vaccination therefore protects against the effects of measles infection on health, and consequently plays a role in ensuring fair access to opportunity and to primary goods. It therefore follows that measles vaccination should form a central part of the decent minimum health care to which every person in society should have access. Everyone in society should have access to the protection afforded by measles vaccination in order to ensure that measles infection does not interfere with their access to the primary goods of life.

As stated before, there are some in society who cannot be vaccinated because of medical reasons. This, and vaccine failure, leads to about at least 5% of the population being susceptible to measles infection at any given time. It is possible to arrange health care provision in such a way that these persons are protected against measles infection: through elimination of measles within society. This requires vaccinating children with two measles containing vaccine doses at a population rate of 93-95%.

Another way to put it is this: Measles vaccination is a benefit. According to Egalitarian justice, everyone in society should have equal access to this benefit. Consequently, every child that is eligible should receive measles vaccination. There are some in society who are not eligible for vaccination. They are able to benefit from measles vaccination of others, provided that such vaccination leads to adequate levels of immunity to prevent the spread of measles in society. Given that the risk of measles vaccination is very low, and that receiving the vaccine is considered a benefit, it is a requirement of Egalitarian justice that society vaccinates at least to the point of



measles elimination. This ensures that both those who are eligible for vaccination and those who are not eligible for vaccination themselves receive the benefit that is due them.

### *Protecting the least advantaged/the vulnerable and the difference principle*

Some may object to this last idea based on an unequal distribution of burdens associated with measles vaccination. Measles vaccination comes with some burdens – a needle jab in the arm, potentially some minor adverse effects such as rash and fever, and a financial cost. There is also the extremely small risk of serious adverse events; this risk though is extremely small. Those who receive vaccination bear these burdens, while those who do not vaccinate do not share these burdens. Is it not unfair that some persons in society get all the benefits of vaccination while not sharing in the burden? To this objection we may respond in a number of ways.

Firstly, receiving measles vaccination is considered a tremendous benefit, whatever potential burdens may be associated with it. A child who receives vaccination is being helped, not harmed. This undermines concerns regarding unequal burdens.

Secondly, the protection from getting the vaccine yourself is much stronger than the protection that depends on measles eradication. Those who do not receive the vaccine remains susceptible to measles, and if they come into contact with measles virus they will be at risk of measles complications. On the other hand, those who receive the vaccine will be protected with over 95% certainty.

Thirdly, one can consider the difference principle in this context. For our purposes, we can state it as follows: benefits and burdens should be equally distributed, unless the unequal distribution of such benefits and burdens ensures that the most disadvantaged group is maximally well-off. In other words, we can tolerate unequal distributions of benefits and burdens as long as it maximally favors the welfare of those who are most disadvantaged. If we consider the case of measles vaccination, we will see that 5% of society cannot receive the vaccine or remain susceptible to measles infection. These people are, with regards to protection against measles, the most disadvantaged group. Consider as well that this 5% group includes people who are quite vulnerable to measles infection and its complications, even more so than the general population, for instance the very young and the immune-compromised. The 95% of people who actually receive measles vaccination therefore are the advantaged group. Now clearly we have an unequal distribution of benefits and burdens here; the 95% have more protection and more benefit than the 5%, but they also shoulder more burden. This inequality in distribution of burdens and benefits can however be justified, since this is the distribution that ensures the maximal protection and thus maximal welfare of the most disadvantaged group. Now, this argument would of course not work if the burden of vaccination was very high, for instance if the vaccine was very costly or had serious side-effects. It works quite well with the measles vaccine, however.

Egalitarian justice therefore requires that all children who are eligible for vaccination be vaccinated against measles, and that vaccination in society happens at least to the point of measles elimination.

### *Respect for liberty*

Egalitarian justice is strongly committed to the liberal, choosing individual. This means that people should be free to do as they wish, provided that the freedom of others are respected. Rawls argues for the “most extensive basic liberty compatible with a similar liberty for others” (Rawls 1971, p. 60). Egalitarian justice therefore respects the freedom of people to make their own health care choices, in keeping with their own view of the good life. The idea of egalitarian justice is not to force an adequate level of health care on people, but rather to ensure that it is available to them. Freedom of choice with regards to one’s own health care is paramount under the egalitarian conception.

This is very akin to the liberty defended by Mill or the liberty defended by libertarians. Against claims that individual liberty should excuse one from the egalitarian distribution of burdens and benefits, one could appeal to the same argument that I used when I considered the claims of libertarian justice and liberty in general. The freedom of the individual cannot be used to limit the freedom of others. Thus, a free choice on behalf of some individuals should not endanger the rights of those who are not eligible for vaccination. Liberty is always restricted by the liberty of others. In the case of egalitarian justice, the argument is even stronger. Under the egalitarian conception, access to basic health care such as protection against measles infection is a basic right, necessary to ensure fair equality of opportunity. Personal liberty comes to its limit when it endangers the rights of others within society.

In general, the same arguments and limits to liberty apply as was considered under libertarian justice: Parents have the authority to make decisions on their children’s behalf, guided by the best interest standard. There are limits to parental authority, and these are demarcated by the best interest of the child. The choices of individuals can also be limited when others are harmed by such choices, and therefore parental choices in favor of non-vaccination can be challenged if it would lead to harm to others in society. Thus, in accordance with egalitarian justice the family unit and familial/parental decision-making is respected as long as free decisions do not result in compromising the interests of the child, or harm to others in society.

### *Two ethical action guides*

We therefore see the same two principles emerge in the egalitarian conception of justice:

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society’s response to vaccine refusal.

Once again, as seen with the other conceptions of justice, principle (1b) is a very strong consideration, but should be balanced with (2b) in cases of vaccine refusal. Vaccine refusal can at minimum not be allowed to harm others within society, and thus should not endanger measles elimination. Given the protection afforded by receiving the vaccine, and the duty of justice to ensure fair equality of opportunity, a case of vaccine refusal demands some kind of societal response. That does not always mean coercion; there may be other approaches that could be used, and principle (2b) guides the types of societal response and vaccine policy response to vaccine refusal.

### **(3.3) Communitarian justice**

Various different theories are collected under the banner of communitarian justice (Beauchamp & Childress 2013, p. 257). Instead of focusing on individual liberty, these theories focus on the idea of the common good. As such, tradition, loyalty and social relationships along with shared communal decision making play an important role in these theories (Beauchamp & Childress 2013, p. 257). The focus of communitarian theories is on the common good of members of the community. As an example of the implications of this for public health institutions, B&C reiterate Callahan's view that public policy should be based on "a shared consensus about the good of society rather than the basis of individual rights" (Beauchamp & Childress 2013, p. 258).

Sandel is a proponent of communitarian justice, and argues that communitarian views of justice are preferable over liberal or utilitarian views (Sandel 2009, p. 208-269). The argument proceeds as follows.

The liberal views of justice, libertarianism and egalitarianism, are both based on the Kantian concept of the freely choosing, individual self. The implication is that apart from respect for the rights of others, the individual only has those moral commitments which has been chosen by the self. Society under the liberal views is therefore made up of a collection of individuals, each of which has its own conception of the good life and each of which only has those moral commitments which the self has chosen. The role of government is to ensure that liberty and other rights are respected while maintaining a strict neutrality between different views of the good life. Government is therefore not to promote a specific view of the good life, but rather to protect the freedom of individuals to pursue their own view of the good life.

The communitarian argues that this view of society and of the self is mistaken. I am not just an individual: I am someone's son, someone's brother, someone's father, someone's friend, someone's neighbor. I find myself within a society and within a social role that I myself have not chosen. This place in society and these relationships furnish me with moral obligations that are not merely dependent on those commitments I myself have chosen. For example, I recognize duties of special obligations to my children, my parents and other close family members; obligations I have not chosen but that are nonetheless binding. The communitarian argues that

individuals have moral obligations in virtue of their place in society and their relationships. Examples are moral values such as loyalty, patriotism, special obligations to relations, correction of historical injustices and the like; these cannot be explained under liberal conceptions of justice, but rather these values assume a communitarian perspective.

An important moral value in communitarian thought is solidarity, or membership. The idea is that an individual has concern for the good of fellow members of the community, and that the community as a whole has concern for the good of individual members. Thus, I have the responsibility to seek the good of the collective, and the collective in turn has the responsibility to seek my good.

The communitarian does not think of people as unencumbered selves, or primarily liberal choosing selves. Rather, the Communitarian argues that people are encumbered selves, situated selves, and that people find themselves with certain relationships and histories. The fact that we are situated has implications for our moral responsibilities. Sandel argues that there are three categories of moral responsibility (p.225):

- (1) Natural duties (This applies to everyone, and is basically respect for the rights of others.)
- (2) Voluntary obligations (These obligations are those moral commitments that the self has chosen.)
- (3) Obligations of solidarity (These are particular obligations on a person, derived from the historical and relational situation of the person. These are not chosen and do not require consent.)

The liberal views urge a neutrality towards different conceptions of the good in public life. Sandel argues that this is not always possible, and is often not desirable (p. 251). Resolving matters of justice in the public sphere often requires weighing of opposing moral claims and giving preference to one over the other. Take the example of abortion rights (p. 252). Opponents of abortion often argue that abortion is akin to murder, since the fetus is a human being with the right to protection under the law. Now, if the State allows abortion, the State is effectively saying that it disagrees with the argument raised by the opponents of abortion. That is, the State disagrees that abortion is murder. No-one would think that murder should be allowed by the State in the name of neutrality between different conceptions of the good life. Therefore, when the State makes a decision that abortions are legally permissible, it commits itself to a position on the morality of abortion and the moral status of the fetus – that is, that abortion is not the same as murder and that the fetus does not have the moral status of personhood. The same issue applies to other dilemmas of justice in the public sphere, such as stem cell research and same-sex marriage: making a decision on these issues requires consideration of substantive moral questions. It is therefore not possible, and sometimes not desirable, to maintain neutrality between different conceptions of the good life.

Instead of trying to remain neutral on conceptions of the good, the communitarian argues that communities should engage in active discourse on the good. Communitarian justice is therefore Aristotelian in the sense that a society should be engaged in understanding and promoting the good. In Aristotle's view, a just society should encourage citizens to be good and virtuous, rewarding virtue and discouraging vice. Similarly, communitarians think that a just society encourages the good within society. For a society to be just, under the communitarian conception, the society has to engage in deliberating together about what is good, and promote the good. Societies should actively promote the good for all its members through social and political institutions, and encourage its citizens to be good people. Communitarian justice is committed to the idea of the common good: we all work together to promote everyone's good. In this respect, Sandel argues that justice requires a commitment to a robust civic life and dialogue, to promoting everyone's good through social and political institutions, to a politics of moral engagement. Instead of arguing for neutrality, we should engage in moral dialogue about the good life and actively promote the good life for all.

Sandel argues that Communitarian theories are improvements over utilitarianism and liberal theories. Utilitarianism is inadequate, because it reduces moral values and engagement to a mere calculation of welfare and reduces all the things people value into a single measure of value. Liberal theories are an improvement in that they respect rights over Utilitarian considerations, thus ensuring justice is not a mere welfare calculation. But liberal theories cannot provide grounding for many of the moral commitments we recognize as requirements of justice. According to Sandel, communitarian justice provides a solution to serious deficiencies in utilitarian and liberal theories of justice.

### *A potential objection: communal tyranny*

Of course, communitarian views are open to criticism. What if the community or family is oppressive? What if I find myself in Nazi Germany or Apartheid South Africa? What of the impoverished woman in rural Africa that is told that her moral commitments include forced servitude and genital mutilation? Sandel acknowledges this objection by pointing out that liberal theories historically developed in response to oppressive communal systems where people were consigned to a horrible fate through being born to a certain class, race or caste (Sandel 2009, p. 221). This is a serious objection to communitarian theories. If we go the route communitarians suggest and abandon societal neutrality in favor of a specific conception of the good, it seems that some persons will be forced to abandon a conception of the good that they prize dearly. For example, if society as a whole reaches a consensus that black people are morally undesirable for some reason, and society then promotes this "conception of the good", it will force those who are black either out of society or to endure subjugation and discrimination. Or, if a minority religion is found undesirable by "social consensus", persons who hold to that religion would either have to leave or recant. This sounds more like tyranny of the majority and ruling of the strong over the weak than it sounds like justice. Of course, the antidote to communal tyranny is a respect for liberty and for human rights, but to resort to this would be an acknowledgement

that communitarianism alone is not feasible; it needs the help of the liberal theories at least in part. Sandel acknowledges and addresses this objection, but does not entirely resolve it. His solution is a “robust and active civic life”, an ongoing public deliberation about social and moral issues in which progress is made towards the common good. Sandel writes (2009, p. 268):

*“Politics and law should not become entangled in moral and religious disputes, we often think, for such entanglement opens the way to coercion and intolerance. This is a legitimate worry. Citizens of pluralist societies do disagree about morality and religion. Even if, as I’ve argued, it’s not possible for government to be neutral on these disagreements, is it nonetheless possible to conduct our politics on the basis of mutual respect?”*

*The answer, I think, is yes. But we need a more robust and engaged civic life than the one to which we’ve become accustomed. In recent decades, we’ve come to assume that respecting our fellow citizens’ moral and religious convictions means ignoring them (for political purposes, at least), leaving them undisturbed, and conducting our public life – insofar as possible – without reference to them. But this stance of avoidance can make for a spurious respect. Often, it means suppressing moral disagreement rather than actually avoiding it. This can provoke backlash and resentment.”*

Sandel’s communitarianism seems to be a response to the problems faced with the commitment to political neutrality found in the liberal theories of justice. Neutrality on moral and religious questions is not possible and is not always desirable, as it may lead to “backlash and resentment” in that certain moral points of view are suppressed. This is a valid concern, and one liberal theorists need to take seriously. In this way, communitarian justice has some strengths. It reminds us of moral obligations in virtue of our relationships and histories; we are also situated selves and not only individuals. Communitarian theories revive civic engagement, solidarity, and actively deliberating about and pursuing the common good.

Sandel’s suggestion hints at respect for the individual; in his communitarianism, individual moral views need to be engaged with through civic dialogue in order to make sure that everyone’s voice is heard, and that no-one is excluded. However, it is not quite clear if Sandel’s solution to the problem of communal tyranny entirely solves the problems communitarian theories face. What if “robust civic engagement” does not lead to a solution or to a clear answer regarding the common good? What if we still have a minority religion with customs that are repugnant to the majority, and any amount of moral deliberation cannot establish a view of the common good that is acceptable to everyone? Should the majority opinion rule, and the minority views be squashed? But this is exactly the type of tyranny that liberal views provide an escape from. To my mind, communitarian theories have value, but need some way of coming to terms with this objection. If the objection of impotence to tyranny cannot be overcome, it would present a knock-down argument against the feasibility of communitarian theories. Here one can think of an example. Should the practice of ritual female genital mutilation be tolerated in Western countries among immigrant communities? Such immigrant communities may view female genital mutilation as a culturally important practice, and as an important part of their conception of the

good. These communities therefore would argue that the practice should be allowed and promoted under communitarian views of justice. However, Western societies at large views such practices as female genital mutilation as wrong and abusive, and contrary to the good. The broader Western conception of promoting the good would include a ban on female genital mutilation. How would one bring these two competing notions of the good together under the communitarian view of justice? What if no compromise can be reached through civic engagement and dialogue? Should the practice be allowed? It is not clear that communitarian theories have the necessary tools to resolve such intractable disagreements on what constitutes the good, or disagreements between various communities within one society.

### *Two possible solutions to the objection*

I can think of two possible ways of overcoming this crippling objection.

#### (1) Retain respect for liberty rights.

One way of overcoming this objection is to retain a respect for basic rights within the theory of Communitarian justice. This would mean that a building block of the moral commitments of all communities should be a respect for basic liberty and political rights, such as freedom of speech, thought and conscience. It seems as if Sandel appeals somewhat to this idea by giving us three sources of moral commitments: Natural duties (respect for rights, non-voluntary), voluntary duties (those commitments the individual chooses, voluntary), and obligations of solidarity (duties the individual has due to membership of a group/community, non-voluntary) (Sandel 2009, p. 225). So, any individual would have the obligation to respect the rights of other individuals, and in addition we have obligations of solidarity in view of our historical and societal situation.

The difficulty with this solution is that a strict communitarian theory rejects the idea of the freely choosing self as the basis for moral duties in favor of a situated self with a set of moral obligations in view of history, tradition and society. It is unclear what the basis would be for “natural duties” and liberty rights once the liberal basis for these rights has been removed. Trying to retain respect for liberty rights and individual freedom may be necessary to avoid communal tyranny and suppression of minorities, but that seems to be an admission that an appeal to liberalism is unavoidable. This may undermine the whole communitarian scheme. A possible solution to this difficulty can perhaps be to look once again at what solidarity involves: the individual is concerned with the good of the collective, and the collective is concerned with the good of the individual. Thus, there is room in communitarian thought for considering the good of the individual and assigning weight to the thoughts of the individual.

#### (2) Liberty is a common good.

According to communitarian theories, a just society promotes the common good and encourages its citizens to pursue the good. It could be argued that individual liberty is such a good: respecting the freedom of others is in itself a good thing. Thus, a community that seeks the

common good and seeks to encourage pursuit of the good in its members, has to encourage respect for liberty rights.

This is perhaps a promising way of retaining the communitarian project and maintaining respect for liberty, which would protect minorities and individuals against oppression. It is not clear if this entirely solves the problem though. What if, through a process of civic engagement and moral dialogue, a majority of society feels convinced that liberty is not essential compared to other goals of the community? Say, for example, the majority feels that criticism of community leaders threaten the peace and cohesion of society, peace and cohesion is a greater good than individual liberty, and therefore freedom of speech should be curtailed in order to promote the common good? In this hypothetical scenario, it is not clear how respect for liberty rights such as freedom of speech can be defended purely on communitarian grounds.

Seeing liberty as a societal good that should be promoted and respected is a potential solution to the problem, but it seems as if this places individual liberty on shaky ground. If a majority of people in a community feel that liberty is after all not important, it is unclear that a basis for individual liberty would remain within that community, if one were to argue from purely communitarian grounds. To maintain respect for individual liberty against the opinion of the masses, one would seemingly have to appeal to liberal theories.

### **Communitarian justice: Summary**

Communitarian justice focuses on moral obligations that exist because of membership of a group or community. An important aspect of communitarian theories is the idea of solidarity: the individual has moral obligations to the collective, and the collective has moral obligations to the individual. Furthermore, in communitarian theories the just society promotes a specific view of the good, and encourages its members to seek the good. Communitarians are thus concerned with the common good, and the just society seeks to promote the common good.

A serious objection to communitarian theories is the problem I have called communal tyranny. That is, in the absence of a firm grounding for individual liberty, it seems as if minorities are vulnerable to oppression by the suppression of their views and rights by the collective. If the collective has a specific view of the good that is at odds with the views of the views of minorities, communitarian justice seems to require society to promote the view of the good favored by the collective, which would bring pressure and potential hardship to bear on minorities within society. Communitarians like Sandel seem aware of this objection, and seem troubled by it. I have suggested potential ways around this objection, both of which leave the communitarian with difficult problems to solve. It is important to find a satisfactory way around this problem if communitarian theories are to be taken seriously: a theory that seemingly allows oppression of minorities under certain circumstances is morally extremely suspect.

It appears as if communitarians like Sandel take the problem of individual freedom seriously, and try to incorporate individual freedom within their moral thought. In my analysis of measles



vaccination and communitarian justice, I will take this into account. There are ways in which individual freedom and consequently autonomy can be incorporated within the communitarian way of thought, even though it does leave the communitarian with some questions to answer.

## **Communitarian justice and measles vaccination in children**

### *Measles vaccination and the common good*

According to communitarian theories, just societies seek and promote the common good. There can be no doubt that measles vaccination promotes the common good: individuals are much better off in societies where measles disease is absent than in societies where measles is present. Protecting individuals against measles infection is a good thing. Thus, according to communitarian justice, a just society would promote vaccination in order to rid society of measles infection, thereby promoting the common good.

Furthermore, according to communitarian theories, obligations of solidarity exist within communities and societies. That is, individuals have a moral obligation towards society to further the common good and the good of others within society. Society also has an obligation to further the good of its members. According to the communitarian, I have the duty to seek the good of the community, and the community has the duty to seek my good. Of course, the duty of the individual to act in the best interests of the community is limited by other considerations, such as harm to the individual in question or moral commitments to other persons or groups. Thus, when it comes to measles vaccination, we find that a just society has obligations to its members, and members have an obligation to society. Society has the obligation to employ measles vaccination to protect its members against measles disease. This means that everyone that is eligible should be vaccinated against measles, and those who cannot be vaccinated should derive protection from the herd effect. As I have argued before, herd immunity for measles happens at the same point that measles is eliminated from society, so that a just society would at least vaccinate to the point of measles elimination.

Because of the obligation to promote the common good, individuals have an obligation to get vaccinated against measles. It is in the best interests of society if measles is eliminated from society. There are some members of society that should justly benefit from protection against measles, but who cannot receive direct protection from measles vaccination, for example through medical contra-indication to measles vaccination. This susceptible segment of society is usually around 5%. According to communitarian justice, society has the duty to protect these susceptible members of society through establishing herd immunity. It is therefore the duty of every individual who can receive vaccination to contribute to the creation of herd immunity in order to serve the common good. It is therefore a civic duty of every individual to receive vaccination in order to protect society as a whole. Not only through protecting the individual at stake, but also through the creation of herd immunity and eventual elimination of measles from society. Another way to put it is this. Through sustained measles vaccination, it is possible to eliminate measles from society. The common good is served through measles elimination.

According to communitarian justice, individuals have a duty to seek the common good, to act in such a way as to promote the good of the collective. The individual therefore has the duty to contribute to the project of measles elimination through receiving measles vaccination.

Of course, we are dealing with children here, and therefore the civic duty we speak of falls to parents. It is a civic duty of parents to have their children vaccinated against measles in order to promote the common good. The only possible objection to this arrangement would be if the measles vaccine was harmful. The duty to contribute to the common good can perhaps rightfully be limited when the harm to the individual is substantial. However, the potential harms from measles vaccines are minor and negligible. Serious harms from vaccination are incredibly rare. The benefit to the individual and to society through measles vaccination far outweighs any potential adverse effects from vaccination.

In communitarian thought, measles vaccination can be seen as a public good. Some can benefit directly from this public good through receiving the vaccine themselves. Those who are ineligible to receive the vaccine or who experience vaccine failure benefit from it through measles elimination. Measles vaccination therefore can be seen as both a right and a duty. It is the right of every child to receive protection against measles disease through the public good that is vaccination. It is also the duty of every child that is eligible to contribute to the herd effect (elimination of measles) in order to give access to the public good of protection against measles to those who cannot access the vaccines for themselves.

### *Vaccine refusals*

It is not clear to what extent communitarian theories are tolerant of vaccine refusals. As I have argued before, it appears that communitarian theories do not provide a solid grounding for the respect of individual rights and especially for refusal to participate in the common good. If society views action A as furthering the common good, and some individuals reject A as morally dubious or as harmful to society, it is not clear that individuals can legitimately object to A on purely communitarian grounds. I view this as a serious objection to Communitarian theories, and have argued that communitarian theories need some way around this in order to succeed as a theory of justice. When it comes to measles vaccination, the point is pressed even further. Respect for autonomy and informed choice is one of the building blocks of medical ethics, and medical care that excludes consideration of the wishes of the individual is morally wrong. It would therefore be strange to advocate a theory of justice that seems to exclude individual choice entirely.

A further consideration when it comes to vaccine refusals is the role of the family and parent-child relationships. In communitarian thought, people are situated selves and not merely Kantian choosing selves. When we look at society, we see that people are situated in morally significant relationships that involve various moral obligations. One such morally significant relationship is the parent-child bond. I have previously pointed out Elliot's arguments in this regard: that the interests of children and parents are narrowly intertwined with one another, and that a striking characteristic of children is their utter dependence on their parents (Elliot 2001). The parent-

child bond is a morally significant one, and fits in well with the communitarian notions of a situated self. Within the communitarian theory of justice, society seeks to promote the common good, and seeks to advance the good for its members. The just society would therefore seek to protect the parent-child bond, recognizing it as a morally significant relationship. Protecting the parent-child bond fits in well with the communitarian view of justice. But how do we weigh two competing goods? The communitarian wants to promote the good of measles vaccination, but also wants to promote the good of flourishing parent-child relationships. In the case of parental vaccine refusal, one can appreciate a tension between these two moral values.

Given these considerations, one wonders to what extent Communitarian theories can allow vaccine refusals for non-medical reasons. I will examine two articles where the authors consider this question.

### *Article 1: The unfairness of free riding (van den Hoven 2012)*

Van den Hoven argues that herd immunity constitutes a public good. Collective action through adequate levels of vaccination establishes herd immunity, and this benefits those who remain susceptible through vaccine failure or medical contra-indication to receive vaccination themselves. Thus, the establishment of herd immunity creates a publically available good, free and accessible to all who are susceptible to immune-preventable disease. Some people may consider it in their own best interests (or their child's best interest) to depend on herd immunity for protection against measles, and forego vaccination for themselves in order to avoid the potential for vaccine related adverse effects. Such intentional use of a public good without contributing to establishing the public good can be deemed as unfair. Using a public good without paying one's fair share is not fair and cannot be justified.<sup>3</sup>

It is clear that intentional use of a public good without paying one's fair share is unfair. This is called free riding. Usually, free riding is thought of as the deliberate, intentional use of a freely available public good without contributing to the public good, and it is always considered morally unjustifiable.

Van den Hoven proceeds to ask: What is it that makes free riding unfair? Is it the intention of the person to free ride the public good or something else? To answer the question, she applies

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<sup>3</sup> I have argued in the previous chapter that it remains in the individual child's best interest to be vaccinated against measles, even if there are high levels of vaccination within the population. We have seen that in countries with high vaccination rates such as the Netherlands, USA, and Canada, measles can be imported and can be transmitted through chains of susceptible individuals even though measles is eliminated from the country. Furthermore, measles vaccination has very low risk of adverse effects; it is a safe intervention and the benefit far outweighs the risk. Thus, the best is to vaccinate the individual child, and reliance on herd immunity should really only be reserved for those who cannot receive the vaccine or who experience vaccine failure. Protection through herd immunity is a lesser protection than through receiving the vaccine; however, some persons have no choice but to rely on herd immunity. Even though it would be faulty to think that it is better for the individual child to rely on herd immunity and forego vaccination so that harmful effects from vaccination can be avoided, I can accept for the sake of the argument that some people may reason in this way and thus intentionally refuse vaccination for their children.

the Extended Principle of Fairness of Garet Cullity to the idea of free riding. According to this principle, it is unfair if a person benefits from a scheme or arrangement without meeting the requirements of participation, under the following three conditions: (1) Participating in the scheme confers a net benefit to the person; (2) It is not true that practically everyone would be made worse off if contribution to the scheme would be obligatory for those who participate; (3) There is no plausible or legitimate moral objection to the scheme.

Van den Hoven applies this principle to vaccine refusal as follows. Vaccination confers a net benefit to the individual. (Condition 1). Requiring vaccination of everyone who benefits (with the exception of those who have medical contra-indications) does not lead to a situation where practically everyone is worse off; in fact, practically everyone is better off if they have to comply with vaccination. Thus, Van den Hoven argues: “Demanding the contribution of all to achieve collective protection is a fair requirement: not practically everyone would be made worse off by the requirements of the practice of vaccination.” (Condition 2). There is no legitimate moral objection to the practice of vaccination, since credible evidence shows that vaccinations are safe and in the best interests of those who receive vaccination. (Condition 3). Thus, refusing to participate in vaccination programmes while benefiting from them through herd immunity is an instance of free riding. The question is not whether a refuser wishes to benefit from herd immunity; the fact that they do benefit makes it free riding.<sup>4</sup>

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<sup>4</sup> I think van den Hoven’s argument that those with religious objections cannot raise legitimate moral objections to the vaccination scheme can be disputed by some persons. Van den Hoven writes: “Thirdly, could they raise a legitimate moral objection? It is difficult to see what the objection would consist of, unless they view vaccines as poisonous or satanic. Thus, condition three also holds.” She does not address what would happen if a religious objector viewed vaccines as “poisonous” or “satanic”. It seems to be implied that if someone were to claim that vaccines are “poisonous” or “satanic”, their objection may be legitimate, although this is not further discussed by van den Hoven.

It is not clear in her article what would constitute a legitimate moral objection to van den Hoven. Perhaps a religious objection to vaccines could be similar to a Jehovah’s Witness objection to blood transfusion? Some may be tempted to argue that no ‘legitimate moral objection’ can be offered by the Jehovah’s Witness adherent to receiving a life-saving blood transfusion. After all, the blood-transfusion is quite beneficial to the individual. But the Jehovah’s Witness sees blood transfusion as morally objectionable for religious reasons – the blood transfusion would have negative consequences for the afterlife. This is widely recognized as a legitimate moral claim for refusal of blood transfusions; could a religious objection against vaccination not be similar?

So, if moral objections raised by religious objectors cannot be dismissed, does the charge of free riding disappear? On first glance, it appears as if it may. If condition (3) of the Extended Principle of Fairness is not fulfilled, then presumably the charge of free riding disappears. Except, van den Hoven’s main argument is that those who benefit from a vaccination program without contributing to it is acting unfairly, no matter what the reason is that vaccination is refused. It is not the reason for refusal that makes refusal unfair; it is the fact that someone benefits without contributing. This still seems to apply for those who refuse vaccination, even if they have a moral objection to vaccination itself.

Perhaps then the idea of a ‘legitimate moral objection’ in condition (3) should be reframed to say ‘a moral objection to which virtually everyone would agree’. This would mean that if virtually everyone would agree that a specific scheme is morally wrong because it tortures innocents (for example), refusal to participate in the scheme would not amount to free riding.

The conclusion van den Hoven comes to is that any instance of vaccine refusal (except those where medical contra-indications to vaccination exists) qualifies as an instance of free riding, and is unfair. The unfairness of free riding does not depend on the nature of the objection to vaccination or on the intention of the free rider. The fact that someone benefits from the vaccination program without contributing their fair share is what makes it an instance of free riding, and what makes it unfair. This even applies to those with religious objections to vaccination, van den Hoven argues. Those who refuse vaccination because of a religious objection such as “God doesn’t want us to master our health” still fulfill the three conditions of the Extended Fairness principle. They receive a net benefit from the vaccination program, whether they embrace the benefit or not. Their participation in a vaccination program would not leave “practically everyone worse off.” Moral objections against the scheme does not hold. If they claim that vaccines cause harm, this can be shown to be untrue. Van den Hoven concludes that even those with religious objections to vaccination could face the charge of free riding. They benefit from a public good (protection against infection) without contributing to the public good (accepting vaccination) in a way that satisfies the Extended Principle of Fairness.

The implications of the argument thus far are quite far reaching: every instance of non-medical vaccine refusal, no matter what the reason for vaccine refusal is, is unfair. It is the duty of everyone to contribute to the wellbeing of the collective by doing their bit and receiving vaccination. Not receiving vaccination while enjoying the protection of herd immunity amounts to free riding a public good. The collective engages in a vaccination program, and thereby the public good of herd immunity is created. Those in the collective who cannot receive vaccination for medical reasons or in whom the vaccine fails, receive protection against infection through herd immunity. It is unfair for those who are eligible to receive vaccination to refuse vaccination while benefiting from herd immunity, because they free ride a public good without contributing their fair share.

One can recognize in the argument themes consistent with communitarian thinking; the argument in this article is in fact based in a communitarian perspective. It appeals to communitarian ideas and uses communitarian language. The collective has a duty to the individual, namely protecting those who are vulnerable against infection through herd immunity. The individual has a duty towards the collective, namely to participate in the vaccination program and contribute to herd immunity (unless a contra-indication to vaccination exists). Herd immunity is a public good, created by the actions of individuals within the collective, leading to the benefit of the collective overall.<sup>5</sup> Those who do not contribute to herd immunity while benefiting from herd immunity takes advantage of the protective actions of the collective while not doing their part in protecting the collective. This is unfair, and in communitarian thought,

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<sup>5</sup> I have argued that measles vaccination can be seen as a public good under communitarian thought, and that all should have access to the protection that measles vaccination offers – through individual vaccination if eligible, or through herd immunity/measles elimination if not eligible for vaccination. However, while considering van den Hoven’s argument, I will stay with her argument that herd immunity is a public good rather than measles vaccination/vaccination programs as a whole.

unjust. If the argument thus far is correct, any instance of non-medical vaccine refusal is considered to be unjust according to communitarian theories of justice. This is a rather strong claim, and would mean that vaccine refusal should not be tolerated as it is unjust.

Van den Hoven realizes how far reaching this conclusion is, and moderates her conclusion by appealing to three reasons why vaccine refusals can be tolerated. The first reason is that it is not reasonable to force someone to pay costs to contribute to a public good if it would not add anything to the public good. If herd immunity exists, and the case of vaccine refusal does not threaten herd immunity, forcing the refuser to vaccinate does not add anything to the public good. Thus, the argument goes that even though it is unfair for people to free ride the public good, it is not reasonable to force people to vaccinate if doing so does not add any additional benefit. The second reason is that it seems as if public trust is an important component in vaccination uptake. It is frequently seen that some countries have high vaccination rates, yet does not have mandatory vaccination. In these countries, such as the UK and the Netherlands, public controversies regarding vaccine safety decreased public trust in vaccinations, which led to a decrease in vaccination rates. This decrease in trust in vaccinations can affect herd immunity, as was seen in the UK with measles. So, van den Hoven argues, we shouldn't accuse people of free riding as it is not necessarily helpful. Even though vaccine refusals are unfair, labeling it too forcefully as such when trust in vaccinations is absent can make parents feel they have to choose between their own child's wellbeing and public duty. Instead, the strategy should focus on establishing trust in vaccinations. The third reason is that the reasons offered by vaccine refusers for their refusal should be considered seriously. The motives for refusing vaccination should be seriously engaged with. Labeling people as free riders can have negative consequences that can decrease vaccine uptake, such as alienating parents and polarizing the debate. Instead, parents should be engaged, their motives discussed, and a strategy of reassurance and persuasion should be followed.

### *Summary – article 1 (van den Hoven 2012)*

Van den Hoven's argument can be summarized as follows. Collective vaccination establishes a public good. This good protects the health of the entire collective, especially those individuals who cannot receive vaccination for themselves. Except where a medical exemption to vaccination applies, those who benefit from the public good without contributing their share are acting unjustly. No matter what the reason is for vaccine refusal, vaccine refusal can rightly be seen as a particular instance of injustice named free riding. It may seem that this conclusion constitutes a basis for an argument for mandatory vaccinations, but there are reasons why vaccine refusals can be tolerated to a certain extent. Firstly, if herd immunity already exists, mandating vaccination will add nothing to the public good. Secondly, trust in vaccinations are an important aspect of vaccine uptake, and a focus should be on establishing and nurturing such trust. Thirdly, accusing parents of free riding while they have doubts about vaccinations may lead to unwanted complications such as polarizing the debate, eroding trust and so forth.

Van den Hoven argues from communitarian principles, and reaches the conclusion that any instance of non-medical vaccine refusal can be deemed unfair. This is in keeping with communitarian thought: the individual has a duty to act in the best interests of society. Yet, there are good reasons to make room for vaccine refusals, even if this does not follow directly from the communitarian theory itself. Some of these reasons are moral, some are more pragmatic. But it does lead to the endorsement of the idea that vaccine refusals can be tolerated in communitarian thought, as long as it doesn't threaten the health of the collective.

### *Article 2 – Balancing Individual Freedoms and Collective Responsibilities (Wood-Harper 2005)*

In this article, Wood-Harper examines the tension between individual liberty rights and the demands of justice with regards to MMR. She starts off with the assumption that parents can make medical decisions on behalf of their children in their children's best interest. This right to direct the healthcare of one's child is a fundamental right, but is not absolute. There are times when this right can be overridden by other considerations. Wood-Harper cites an example of a Roman Catholic family where parents did not want conjoined twins to be separated, yet surgical separation would save one of the twins' life. In situations like this, the wishes of the parents can be overridden. Now Wood-Harper asks: is measles vaccination an instance of medical treatment where parental refusals can be overridden, or should such refusals be respected on the basis of individual freedom?

The argument then proceeds to consider principles of communitarian justice. Measles vaccination is different than other healthcare decisions, because other people are also affected by the decision made. Measles vaccination influences not only the health of the individual, but also the "present and future health of the wider community." Wood-Harper argues that members of a community have responsibilities to ensure the health of the community (present and future). This means that the moral acceptability of individual vaccine decisions that threaten the health of the community can be questioned. Furthermore, individuals who have benefited from health interventions (such as vaccine programmes) owe a debt to society to contribute to the general health of society. An example would be nontherapeutic medical research on children. The individual child is unlikely to benefit, but the medical knowledge gained may be beneficial to society as a whole. Because individuals have benefited from such knowledge themselves, they have a duty to consent to being involved in such research due to the debt to society.

From these communitarian considerations, Wood-Harper argues that it is reasonable to expect of people to take on some individual risks so that the public good may be promoted. She quotes Leask and Chapman:

*"Furthermore, immunization requires that a parent take a small but active risk with their child for the benefit of disease prevention in the community and for future generations who face a world free of such disease, as has been the case with smallpox. Some may see the risk that they are being asked to take as a risk that will bring little benefit to their child, with the arguments for*

*vaccination embracing communitarian rather than individualistic values*" (Leask & Chapman 1998, cited in Wood-Harper 2005, p. 48).

Thus, according to this communitarian justice view, individuals have a duty to contribute to the health of the community by accepting measles vaccination for themselves and their children. Wood-Harper states that the benefits to society from collective vaccination action is threatened by those who benefit from the vaccination program without contributing. She asks whether such free-riding should be tolerated.

In general, she says, free riding is tolerated if vaccination rates are high and the health of the general society are not threatened by them. But if vaccination rates fall and free riding compromises the public good, it should be viewed more seriously and perhaps requires some response. Possible responses would be to make sure free riders incur some consequences for their decision, such as treating vaccinated children differently from non-vaccinated children. This would mean that scarce healthcare resources would be allocated preferentially to vaccinated children. However, punishing the unvaccinated child for decisions made by the parents seems troublesome. Perhaps, she argues, if free riding is to be tolerated in a society a better response may be to expect parents to "redress the additional burden to the health system resulting from their decision." Thus, parents would be penalized for non-vaccination, perhaps through higher taxes or financial measures. Another option is to not tolerate free riding at all, and deliberate about increased paternalism in vaccination decision, but this will "restrict individual freedom of choice."

Wood-Harper acknowledges the tension between the principle of autonomy and the communitarian view of justice. As long as any risk from vaccination remains, she argues that it is difficult to see how parental refusals can rightly be overridden.

*"As long as there exists any risk of side effects, however small, associated with a vaccine, it is extremely difficult to rationalize overriding parents' right of refusal"* (Wood-Harper 2005, p. 52)

*"Because measles can be, but seldom is, fatal, it is arguable whether enforcing vaccination is ethically sound. The position could become more defensible only if vaccination uptake, by falling below a critical level, constitutes a serious threat to public health either in localized areas or on a national basis"* (Wood-Harper 2005, p. 52).

As a solution to the tension between justice and autonomy, she recommends educational interventions that would enable parents to choose vaccination. Such educational persuasion should focus on informing decision-making while respecting the final decision. This would take seriously the demands to respond to vaccine refusal, while respecting individual liberty rights.

*"Persuasive approaches that aim to encourage the public to comply with mass vaccination policies may be favoured over methods of enforcement"* (Wood-Harper 2005, p. 53).



### *Summary – Article 2 (Wood-Harper 2005)*

Wood-Harper examines the tension between autonomy and justice in cases of vaccine refusals. She defends a communitarian perspective of justice. She argues that individuals have a duty to contribute to the health of society, future and present, and therefore have the duty to accept measles vaccination for themselves and their children. Those who benefit from the vaccine program without accepting vaccination are free riders, and are acting unjustly. Arguing from justice, such free riders should face some form of penalty if the herd immunity is threatened. However, Wood-Harper takes individual rights seriously and eventually argues that autonomy trumps justice. Her commitment to liberty rights does not stem from her communitarian conception of justice; rather, she starts off with a commitment to individual liberty rights/autonomy as a foundational assumption, and then balances these rights against the requirements of justice.

In this argument, the liberty rights that form the foundational assumption are not derived from communitarian justice. Instead, they form a starting point prior to introducing considerations of justice. I have previously argued that communitarian justice faces the objection that it does not take individual liberty rights into account, and therefore is potentially vulnerable to communal tyranny. In Wood-Harper's article we see one of the possible solutions to this problem at work. This solution is to incorporate respect for liberty rights along with the communitarian conception of justice. These rights are not derived from communitarian theories as such, and perhaps are an admission that communitarian theories 'need help' from the liberal theories. An appeal to individual liberty rights is perhaps an admission that some form of liberalism with its conception of the freely choosing self is unavoidable in discussions on justice.

Be that as it may, Wood-Harper's article shows a possible way in which communitarian thinkers respond to vaccine refusals. Although vaccine refusal is unfair in communitarian thought, such refusals can be accommodated through appealing to respect for individual liberty rights. In Wood-Harper's argument, it is specifically when herd immunity is threatened and the health of the society in general is at stake that the argument for invoking some form of penalty on refusers becomes more relevant. Interestingly, Wood-Harper's eventual conclusion is that vaccinations should not be mandated even though refusals may be unfair, but rather that persuasive educational interventions should be employed to ensure adequate vaccine uptake.

### *Communitarian justice and measles vaccination in children – two ethical action guides*

I have argued that measles vaccination is a public good which should be encouraged by society. The just society vaccinates those who are eligible for vaccination, and protects those who are not eligible through collective action. Individuals have a duty to contribute to the good of the collective, and the collective has the duty to protect individuals. With measles vaccination, this means that a just society vaccinates against measles at least to the point of measles elimination. An individual child can justly expect to be protected against measles by society. At the same time,

individuals have a duty to contribute to this protection. Thus, according to communitarian justice, we find the following principle once again:

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

I have examined two arguments from communitarian thinkers with regards to vaccine refusals. Both have argued that non-medical vaccine refusals are unjust, labelling such vaccine refusal as free riding. However, both have argued that such refusals may be tolerated. The first author argued that refusals can be tolerated if the health of the public is not threatened, and also that pragmatic considerations such as public trust should be considered. The second author argued that liberty rights should be respected, and that in view of these rights refusals can be tolerated even if unfair. When the health of the collective is threatened, arguments for penalties on refusers or not tolerating refusals become stronger. It is clear that there is scope for tolerating refusals within communitarian thought, by appeal to various other moral considerations.

I have argued that respect for individual choice should be incorporated in some fashion in communitarian thinking as an antidote to the problem of communal tyranny. In the case of medical decision-making for children, I have before established that young children cannot exercise free choice, but that parents make decisions for their children based on the best interest standard. Such parental authority should be respected. I have also argued that the parent-child bond is a morally significant relationship, and can be seen as a good thing. Communitarian justice seeks to promote the good, and the just society would therefore protect and promote the parent-child relationship.

Thus, we once again find a second principle:

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

In a communitarian justice perspective, the focus falls on protecting the public good and thus the imperative to vaccinate those who can be vaccinated is quite strong. Vaccination is a public good, and children within a just society should have access to this good – either through individual vaccination or through herd immunity when a medical contra-indication to vaccination exists.

Once again, we see the emergence of the same two ethical principles: (1b) and (2b). Once again, (1b) is an absolute requirement in the just society, meaning that the just society vaccinates to the point of sustained measles elimination, with (2b) regulating the societal responses and policies in reaction to vaccine refusal.

### **(3.4) Recent theories of justice – capabilities theory and well-being theory**

In their catalog of theories of justice, B&C identify four traditional theories of justice and two recent theories (Beauchamp & Childress 2013, p. 252-261). The four traditional theories are the four theories I have considered in detail thus far: utilitarian, libertarian, egalitarian and communitarian. The two recent theories are capability theory and well-being theory.

Both of the recent theories are fairly recent arrivals on the philosophical landscape, and both have strong Rawlsian and Aristotelian influences (Beauchamp & Childress 2013, p. 258-259). Both theories have a commitment to the idea of human flourishing, an Aristotelian idea. That is, a just society is one that is ordered in such a fashion that each member of society has access to those things required to function properly, or to flourish. Thus, flourishing (human functioning and well-being) is seen as a good that has moral importance. The just society ensures that every member of society has access to this good. In this sense these theories are Aristotelian: it assumes a telos, a specific view of the good, and tasks a just society with the obligation to ensure the furthering of this good. The social, political and economic institutions of society should be so ordered and arranged that everyone has access to those things needed for human flourishing. If some members of society or some groups within society do not flourish, justice requires an examination of the various institutions within society to see whether these institutions are set up in accordance with the demands of justice.

The two theories differ as to how we should evaluate human functioning, and thus what the focus of justice should be in ensuring human functioning; the capability approach focuses on capacities for functioning, while the well-being approach has actual well-being as focus.

The capability approach to justice was initially developed by Sen (1985), and subsequently further developed by Nussbaum (2001; 2011). The capability approach places the focus of justice on securing the development of human capabilities or capacities that allows flourishing. Society should be such that every person in society has access to the means required to develop a set of basic capabilities, capacities of human functioning, each of which is necessary for a minimally decent level of human functioning. Capabilities in this sense refer to abilities that, if realized, allows flourishing. Nussbaum provides a list of 10 such essential capabilities (Nussbaum 2011, p. 33-34): (1) life, (2) bodily health, (3) bodily integrity, (4) senses, imagination, thought, (5) emotions, (6) practical reason, (7) affiliation, (8) other species, (9) play, and (10) control over one's environment. If any of these capacities are missing from an individual's life, it diminishes proper functioning and affronts the individual's dignity. Each of these capabilities are seen as essential to proper human functioning, and the just society should ensure access to these capabilities for each of its members. The just society is so ordered that all of its members are granted the opportunity to develop all of these capabilities at least to the minimal extent required for human flourishing.

The well-being theory of Powers and Faden (2006) does not focus on capacities that enable well-being, but on well-being itself. Social justice requires that every member of society reaches a

sufficient level on each of 6 core dimensions of well-being. Rather than just thinking of capabilities that allow people to flourish, this theory states that justice requires that people should actually flourish. Thus, in this theory of justice, people should actualize well-being and not just have the capabilities to pursue well-being.

Thus, both theories maintain that justice requires of society to further human flourishing, and both theories argue for a specific conception of human flourishing. These are overtly Aristotelian themes, as I have already pointed out. However, there are Rawlsian components present in both theories as well. For example, both theories incorporate a liberal conception of self-determination. The capability theory includes “practical reason” as one of its core capabilities that each person should have access to. This means being able to reason about the good, and form a conception of the good life, and form life plans to pursue the good (Nussbaum 2011). We also see other capabilities such as “control over one’s environment” (Nussbaum 2011) – the ability to be politically active and contribute to societal government and goals – that remind strongly of the liberal conception of rights. The well-being theory includes “self-determination” as one of its core dimensions of well-being (Powers & Faden 2006). Thus, an optimally functioning life can determine its own version of the good life and make life plans to pursue the good life. The optimally functioning person can engage in political activity, societal government, and decisions that affect the individual (Powers & Faden, p. 261). Apart from a commitment to the liberal foundation of Rawls’ egalitarianism, both theories also share a strong commitment towards ensuring protection for the least well-off in society, so that those who are least well-off are as well off as they can possibly be (Nussbaum 2011; Powers & Faden 2006). A just society is concerned with the wellbeing of the least well-off, and one of the jobs of justice is to be on guard against systematic patterns of discrimination and injustice that allows people to fall below acceptable standards of wellbeing (Powers & Faden 2006). These are ideas that seem inherently Rawlsian in nature, and reminds strongly of Rawls’ difference principle.

It seems therefore as if these two new theories of justice, well-being and capabilities, are quite similar. They both have strong Aristotelian components, and see justice as promoting a specific conception of human flourishing. But both theories are also committed to liberal conceptions of the choosing self, where proper human functioning includes the idea that individuals should reason and deliberate about the good life and choose life plans that help them reach the good. These theories therefore incorporate liberal conceptions of individual liberty and respect for basic rights within its conception of optimal human functioning. It can also be said that these theories draw on aspects of utilitarianism. Every person’s flourishing is important, and the just society cares about every member of society reaching levels of proper human functioning. The difference between the recent theories and utilitarianism are two-fold. Firstly, the recent theories are not concerned with a unitary conception of human happiness or welfare as is the case with utilitarianism. It is not simply a case of “the greatest happiness for the greatest number”. Rather, the conception of flourishing in the recent theories are much more nuanced and complex, and seem to be much more complete. Secondly, the recent theories do not seek to maximize well-being for the greatest possible number. Rather, the idea is to ensure a minimum

level of human flourishing for everyone. This means that everyone in society should have access to enough of the 10 capabilities, or should have a sufficient level of 6 dimensions of well-being.

It can be argued that these theories draw on the strengths of the traditional theories and seeks to combine them in a single theory of justice. It takes what is good from utilitarianism, liberal theories, and Aristotelian notions of flourishing and combines them.

These two recent theories are also remarkably similar, and in the discussion of measles vaccination and children will yield similar arguments and similar conclusions. It is therefore not necessary to focus in depth on both theories. Rather, I will focus on the well-being theory of Powers and Faden. The arguments I raise and the conclusions reached with regards to measles vaccination in children would hold for capability theory, and could readily be extrapolated to a capability account of justice.

### **Well-being justice (The social justice theory of Powers and Faden) (Powers & Faden 2006)**

In the well-being theory of justice, the focus falls on ensuring optimal human functioning, conceived of as well-being. In a just society the institutions and practices within society are so arranged and ordered that each member of society attains well-being. Well-being consists of six dimensions, and to achieve well-being an individual must reach a sufficient level on each of these six dimensions. Powers and Faden (P&F) introduce their theory as follows (Powers & Faden 2006, p. 15):

*“Social justice is concerned with human well-being. In our view, well-being is best understood as involving plural, irreducible dimensions, each of which represents something of independent moral significance. Although an exhaustive, mutually exclusive list of discrete elements of well-being is not our aim (and may not be possible), we build our account around six distinct dimensions of well-being, each of which merits separate attention within a theory of justice. These different dimensions offer different lenses through which the justice of political structures, social practices and institutions can be assessed. Without attention to each dimension, something of salience goes unnoticed.”*

The six different dimensions of well-being are as follows:

#### 1) Health (p. 16)

In this respect and for the purposes of the well-being theory, health is to be understood as bodily health and mental health in the plain-language sense of the word. It refers to a body functioning properly, free from injury or disease, and a healthy mind, free from mental illness.

#### 2) Personal security (p. 18)

This dimension refers to the absence of the fear of harm and the psychological threats of harm, and the presence of a sense of safety. Some injustices do more than cause physical injury or

physical harm – they invade one’s sense of security and safety and cause psychological scars. Among these are things such as slavery, rape, abuse, and torture.

### 3) Reasoning (p. 19)

The dimension of reasoning refers to all forms of cognitive and intellectual capacities necessary for “practical and theoretical reason” in the Aristotelian sense. Theoretical reasoning is the ability to think about and understand truths about the world. Practical reasoning refers to being able to consider possible versions of the good life and to make suitable plans to reach these. In order to engage in these forms of reasoning, various skills are required, such as memory, attention, the ability to learn, skilled motor function, and executive cognitive functions (decision making and goal setting). Whatever shapes cognitive development, learning and reasoning ability is therefore of significance to justice.

### 4) Respect (p. 22)

Respect refers to considering others as beings who should be afforded equal moral consideration. Being treated with respect by others in society is an important component of well-being. P&F also argue that there is a relationship between respect for others and self-respect, where self-respect is the ability to consider the self as an entity endowed with moral worth and deserving of equal moral treatment with other moral beings. A life not receiving respect and a life without self-respect falls short of the standard of well-being. Discrimination on the basis of gender, race, ethnicity or social class are examples of patterns of injustice that diminish well-being by not affording the respect due to people.

### 5) Attachment (p. 24)

Attachment refers to the forming of relationships and bonds with other members of society. It includes friendship, love, solidarity, and intimacy – some of the most central of human emotions and concerns. Such relational attachments are an important aspect of humanity, and is endowed with moral worth. P&F argue that the ability to form attachments is not only important because it facilitates respect for others, but also because they are morally relevant in themselves.

One important societal institution in this regard is family. P&F argue that there is evidence which suggests that the bonds formed between children and parents are related to the ability children have to later form bonds with others. Such bonds between parents and children are responsible for the transmission of social values from one generation to the next. Where the familial bonds between parents and children are compromised, children struggle to form other social attachments and this can in turn lead to a variety of behavioural and societal problems.

### 6) Self-determination (p. 26)

The dimension of self-determination appeals to the liberal conception of liberty and political rights. That is, a just society has a set of political rights and liberties designed to protect individuals from arbitrary interference by the state or others, affording individuals the ability to

make decisions regarding their own best interests. P&F state such liberties and rights are recognized in “many moral and political systems”. Furthermore, P&F argue that a life where all the dimensions of well-being is present but self-determination is absent would be deficient in what is required to live a fully flourishing human life; a life that is self-determined is better than a life that is determined by others. They write: “Our defense of self-determination as an essential dimension of well-being thus rests on simple and we believe widely shared views about having some control over who we are and who we will become. It does not depend on some controversial metaphysical claims about the nature of the self or the sources of all value.”

When it comes to health policies or public health issues, it is often the case that multiple different dimensions of well-being are at stake rather than just the dimension of health. P&F use the issue of female genital mutilation as an example (p.17). Female genital mutilation affects health in that it causes bodily injury and harms normal sexual functioning. The dimension of health is therefore negatively impacted in the life of the individual. But female genital mutilation also impacts other dimensions of well-being: it affects personal security, and it affects self-determination. Thus, a policy concerning female genital mutilation would rest on three different moral foundations, each represented by a different dimension of well-being. P&F argue that it is often the case with public health policy of this kind that multiple dimensions are involved and should be considered in framing of policy. I shall come back to this point when discussing measles vaccination in children, as it is also the case with vaccination policy that more than one dimension of well-being is at stake.

The focus of justice, then, is to ensure that every person has enough of each of these six dimensions to ensure that their life is worth living. If an individual lacks in any of these six dimensions, their life falls below the standard for a decent life. These six dimensions can interact with each other, and it is often so that an injustice that focuses on one of the six dimensions can spill over to the other dimensions. For example, racism is an affront to the respect due to individuals. If such disrespect is institutionalized and pervasive in society, it would lead to decreased opportunities for the disrespected individuals. Decreased educational opportunities can lead to compromise in development of those faculties necessary for the dimension of reasoning. Decreased economic opportunities and unequal access to health care can lead to adverse effects on health. Decreased access to political liberty can hamper self-determination. Thus, in this instance disrespect can lead to insufficiency over multiple different dimensions of well-being. Furthermore, compromise over all these different dimensions of well-being leads to further discrimination. If the stigmatized group ends up being less advantaged, less educated and less politically free than other members of society, it can perpetuate and “confirm” unfair stereotypes, which will entrench disrespect of the stigmatized group even further. In this way, it forms a vicious cycle of injustice. For this reason, systematic patterns of disadvantage is of particular importance to justice. Justice requires society to be on guard against systematic disadvantage and social determinants that perpetuate such disadvantage. Justice requires of

society to recognize such patterns of disadvantage, and to adjust its social and political institutions and practices so that systematic disadvantage may be eliminated. P&F write (Powers & Faden 2006, p. 78):

*“As we see it, the job of justice in its most pressing role demands a permanent vigilance and attention to social and economic determinants that compound and reinforce insufficiencies in a number of dimensions of well-being.”*

And on page 79:

*“The permanent background condition of the job of justice is, as Hume also reminds us, the enduring tensions of cooperative living in a world characterized by limited resources, limited imagination, and limited sympathy. In one historical context, it may be the monarchical state that poses the gravest threat. In another context, it may be the hierarchy of an official religion, the tyranny of the uneducated masses, or the unchecked power of concentrated capital.*

*The job of justice under any of these conditions often involves the re-medial task of ensuring that the basic social structure is one in which each person has a sufficient material, cultural, and political basis for the pursuit of his or her own life through the development of all the distinctly human dimensions of well-being that are the central focus of justice.”*

Children have a particular place of importance in the well-being theory of justice. Children are in a phase of growth and development, still acquiring the abilities necessary for reasoning and attachment. If social determinants negatively impact a child’s health and development, it could lead to lifelong problems with reasoning, attachment and health. Thus, if children are exposed to injustices it has the potential to impact them for the rest of their lives. Disadvantage is locked in at an early age, affecting all future life prospects. Furthermore, children are completely dependent on others. They are therefore particularly vulnerable to injustices, which may then lead to lifelong disadvantage and injustice. P&F point to particular issues that are of importance in protecting children from injustice. Children should be protected against injustice, with particular focus on protecting their health, development of reasoning abilities and development of abilities to form attachments. They can develop these only if they are nurtured and protected in the appropriate way at the appropriate development stage (p. 39). So, during critical development periods, insults to health could lead to lifelong problems. For example, inadequate food or exposure to toxic materials in the womb or in the period after birth can lead to irreparable damage to a child’s health (p. 77). Similarly, serious infections or injuries early in life can compromise physical and cognitive development, hampering several dimensions of well-being over the course of future life. There is no doubt that measles infection should be counted as an infection that can have disastrous consequence for the future prospects of a child, and that a just society should seek to protect its children from measles infection wherever possible. Furthermore, the family environment influences the development of children (p. 77). Parents are responsible for the protection and nurturing of children, and as argued before, also play an important role in the ability of children to form attachments later in life. It would therefore seem



that it is important that family relationships be viewed as worthy of moral consideration and protection. A just society protects parent-child relationships, and encourages healthy families.

### *A possible objection*

To my mind, there is a possible objection to this kind of theory of justice. If one were to assume the theory as correct, justice requires of a society to be so ordered that every member of society has a sufficient amount of each dimension. Dimension 6 is self-determination, which can be thought of in the same terms as the liberal conception of liberty and political rights.

Now, the objection is thus. What if some people fall below the sufficient level in some of the dimensions purely through exercise of dimension 6, which is their free autonomous choices? I am not thinking here of persons who are coerced into unfortunate choices by things such as economic inequalities or by asymmetric power relations in society. Rather, let us imagine a just society according to the well-being theory, meaning that society is so structured that everyone in society achieves a sufficient amount on all the dimensions. Let us now further imagine that in this society, some members or groups make deliberate autonomous choices that eventually lead to decline in some of the dimensions of well-being. How should society respond?

The problem is a difficult one. For if we conclude that it is unjust that people are allowed to fall below the level of sufficiency in some dimensions, and therefore ask society to intervene to stop those free choices that led to decline in some of the dimensions, it would mean that society interferes with self-determination. This would let people fall below the level of sufficiency in dimension 6, by compromising their self-determination. So even if society interferes with the free choices of people to prevent them from falling below the level of sufficiency in other dimensions, a problem of injustice would remain: people would fall below the level of sufficiency in self-determination.

In a sense, this is precisely the point of liberal views, and libertarianism in particular. Liberal views are strongly committed to a principle of liberty that is suspicious of paternalism. It is the thought that no-one can decide what is in my best interest, except I myself. Society and its institutions have no business in deciding on my behalf what is in my best interests. This is then the problem that the recent views will run into: how to balance personal liberty with societal promotion of a specific version of the good. If personal liberty (required by their theory of justice) clashes with the conception of the good life society should promote (required by their theory of justice), it is not clear how to balance these competing obligations of justice. It appears as if the attempt to combine Aristotelian notions of flourishing and teleology with liberal individualism is endowed with an inherent tension, the solution to which is not obvious. If one were to weigh personal liberty higher, it seems little different than just endorsing a liberal theory and dispensing with notions of human functioning. If one were to weigh promotion of the good and of human flourishing above personal liberty, it seems little different than a communitarian theory, where a specific view of the good life has been decided upon.

I suspect that people with a strong commitment to a robust principle of personal liberty will balk at the recent theories (capability and well-being theories). For to my mind, the only way to harmonize the different dimensions of well-being with self-determination in a way that leaves room for existence for both, is to place caveats and conditions on self-determination. But such an approach would be hard to swallow for those who take personal liberty seriously. Of course, the principle of liberty does admit to exceptions. Liberty is rightly limited when free choices impact others. If individual choices harm others or limit the freedom of others, the principle of liberty rightly states that those individual choices can be interfered with. Any other intrusions to liberty (self-determination) should not be allowed. Which is the source of the tension within the well-being theory.

One can think of examples of such free choices that could cause individuals to fall below the level of sufficiency on other dimensions: refusal to work, refusal of educational and development opportunities, adoption of unhealthy eating habits, and adoption of high-risk pleasurable behaviours. For example, extreme sports place an individual at high risk of injury and can pose health problems. Should society interfere with the free choice to participate in extreme sports if it emerges that those who do so as a group fall generally below the health indicators society finds acceptable? Or, what of people who decide they want to eat unhealthy fast food every day because they like it and find no other life worth living. Should society mandate them to eat healthy meals instead, in order to prevent them from falling below the levels of sufficiency?

It is not clear how to resolve this tension, but it does present a problem to the well-being theorist. One solution would be to say that people's free choices should simply be respected, and if there is no other source for their insufficiency in some dimensions than their own free will, justice is satisfied. Thus, there is no problem with justice in a society where some individuals do not flourish because of their own free will alone. Another solution could be to go the other way: to say that it is imperative that people flourish, and that free choices should be interfered with if it limits flourishing on some dimensions. I would argue that the first option is preferable, given the commitment of the well-being theory to individual liberty. The problem then would be to discern between actual free choices, and choices that appear free but are coerced through some unjust societal factors such as economic inequality or discrimination.

## **Well-being justice and measles vaccination in children**

### *Measles vaccination and the well-being of children*

Measles infection represents a threat to the health of children, and measles vaccination provides protection against threat. Thus, in order to protect the health of children, measles vaccination is important. Simply by considering the first dimension of well-being, health, we can see that an argument for vaccination of children can be made on the basis of well-being justice.

The argument can be strengthened considerably by also looking at the other dimensions of well-being. In the well-being account of justice, children are afforded particular concern. Because

children are still developing the abilities needed to ensure well-being later in life, insults to health and well-being during childhood can lock in disadvantage at an early age, and cause individuals to fall below the standard of well-being later in life. For example, an injury or illness that affects physical development can lead to ill health later in life, or an illness that affects cognitive development can affect reasoning ability later in life. A just society therefore protects the health and development of its children insofar as possible. Measles can cause havoc on the health and development of a child. If a child gets measles, a 30% chance of complications exist. These complications can include pneumonia, brain infections, eye infections, blindness, hearing loss and so forth. Many of these can interfere with normal development, cause disability and interfere with normal functioning later in life. In the worst case scenario, measles can lead to death in 1-2 out of a thousand cases. All of these complications and deaths can be avoided through adequate levels of vaccination against measles: those who are eligible can receive direct protection through vaccination, and those who are not eligible for vaccination can receive protection through measles elimination from society. As said before, usually the portion of society that is ineligible for direct vaccine protection is about than 5%, so that adequate levels of vaccination to protect the vulnerable is possible (92-95% coverage with two measles vaccines is required).

P&F make an interesting point regarding what is possible and what is not possible in society (Powers & Faden 2006, p. 60-61). In the early days of the AIDS epidemic, when AIDS was poorly understood and no effective treatment existed, the high death rate from AIDS was simply a tragedy. However, with recent advances in both the understanding and treatment of AIDS, similarly high death rates would not just be tragic, but would also be unjust. Since society has the tools to prevent these deaths, justice requires of society to respond to the AIDS epidemic that threatens the well-being of members of society. Differential death rates are context-specific as to whether they should be considered injustices or not. So, when no treatment for AIDS exists, and when society does not understand what AIDS is, a proportionately higher death rate among people with AIDS is not unjust. But when it is possible to treat AIDS effectively, disproportionate death rates among people with AIDS become unjust. The same can be said for measles. In the pre-vaccination age, the burden of disease caused by measles was astronomical. Many children became ill, many suffered complications, many were hospitalized, many were left disabled, and some died. Before an effective preventative measure existed, these complications and deaths were tragic, but were not unjust. However, since the advent of the vaccine age, it is possible to eliminate the effects of measles infection from society. No society need to have measles infection present, provided that they vaccinate children to sufficient levels. Added to this, the risk of harm from measles vaccination is sufficiently low that it can be considered negligible when compared to the tremendous benefits conferred by sufficient levels of measles vaccination. It would therefore follow that complications from measles infection can now be considered unjust. It is possible for society to eradicate all measles complications; those who suffer measles complications suffer an injustice.

Well-being justice would therefore require of society to protect its children against measles. At a minimum, this would mean vaccinating against measles to the point of elimination. As I have

argued before, being vaccinated is preferable than having to rely on herd-immunity/measles elimination. Because measles infections can be imported and spread through chains of susceptible contacts in society, as we have seen in highly vaccinated countries such as the US, Canada and the Netherlands, it is preferable that every child that is eligible should receive measles vaccination. Those who are ineligible should be afforded every protection that society can give, and this means eliminating measles from society.

### *Respect for liberty and for the parent-child bond*

Well-being justice also recognizes self-determination as a domain of well-being. In bioethics terms, this can be thought of as akin to respect for autonomy: respecting the free choices of autonomous individuals. In the case of children, this means that parents decide on behalf of their children according to the best interest standard. Given the facts regarding measles vaccination, it seems reasonable to accept that most parents would freely choose vaccination for their children if they were fully informed of the benefits and risks of vaccination. Some however may not, and this brings us once again to the problem of vaccine refusal.

Another consideration in this regard is the focus of well-being theory on protecting the development of children. P&F have argued that the parent-child bond should be protected, because a healthy parent-child bond is important in protecting the development of the child (Powers & Faden 2006, p. 24, 77). This is similar to the argument I made in the previous chapter, regarding the varied interests of children. Children have interests that stretch beyond their physical health or other immediate interests (Elliot 2001). Children have interests vested in their familial relationships. Well-being justice incorporates these interests into its account of justice and considers the child's familial relationships an issue of justice. Thus, any interference with the parent-child bond that affects the relationship adversely is an injustice. This places a limit on the societal response to vaccine refusal. For example, if the State vigorously enforces vaccination by placing parents who refuse vaccination in jail, the parent-child relationship is severely damaged by the removal of the parent. This directly harms the interests of the child, and the well-being of the child. The State in this instance would be committing an injustice in its response to another injustice. The societal response to vaccine refusal is therefore a complex issue, for in responding to vaccine refusal, care must be taken to protect the other interests of the child.

According to well-being justice, free choices should be respected and the parent-child bond should be protected. This means that autonomous decisions with regards to healthcare should be respected, and that familial decisions in this regard should also be respected. Of course, if the familial decision is not in the best interests of the child, it may behoove society to intervene; care should be taken not to harm the interests of the child in so doing.

### *Well-being justice and measles vaccination in children - two ethical action guides*

The arguments and conclusions presented regarding well-being justice and measles vaccination can be summarized by the same two action guides (1b) and (2b):

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

According to the well-being theory of justice, we see the same two principles as we have seen with the other conceptions of justice. Namely, that a just society vaccinates at least to the point of measles elimination, and preferably every child that is eligible for vaccination. Secondly, that respect for liberty and the parent-child bond places limits on the type of societal response to vaccine refusal.

#### **(4) Justice and measles vaccination in children: Two ethical principles/action guides**

I have considered various different influential theories of justice, and have shown how each of them leads us to adopt two specified principles or ethical action guides with regards to measles vaccination in children. These two principles are:

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

It does not matter which of these theories of justice one turns to; the ethical implications are similar. No matter which of these different influential theories of justice an individual or society adheres to, the obligations of the just society with regards to measles vaccination are the same.

A just society vaccinates its children against measles in a way that sustains measles elimination. This means that vaccine refusal is taken seriously and demands a response. Just societies respect freedom and the parent-child bond, and the societal response to vaccine refusal is therefore in keeping with these values. Approaches that maximize vaccine uptake while respecting the parent-child bond are favored.

I would consequently argue that a society that does not vaccinate to the point of measles elimination is simply unjust, whatever theory of justice is appealed to. This places obligations on members of society, and society's institutions such as government. In the next and final chapter, I shall examine the implications of the ethical action guides for parents, healthcare workers, and the state.

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## Chapter 7: Applying the ethical action guides

### (1) Bringing the four principles into balance: reaching reflective equilibrium

In chapter 5 I showed how two ethical action guides can be derived by applying the principles of beneficence, non-maleficence and autonomy to the individual case of measles vaccination. These two action guides represent specified principles in accordance with the principlist framework, and can be used to derive obligations and direct action as far as the individual case of measles vaccination is concerned. These two action guides are:

(1a) Morality requires vaccination against measles for all children who are eligible for vaccination.

(2a) Respect for the parent-child relationship regulates the response to measles vaccine refusal, type of policy preferred and places limits on the amount of coercion that can be justified.

In chapter 6 I demonstrated how two ethical action guides can be derived by considering measles vaccination in children from a justice framework. I showed how the two ethical action guides follow from various different theories of justice, meaning that the two ethical action guides are valid and binding no matter which theory of justice one finds persuasive. These action guides can be used to derive the obligations of the just society and to guide the societal response to parental vaccine refusals. Furthermore, they represent specified principles in the principlist framework, being the product of a process of further specification of the principle of justice with regards to measles vaccination in children. These two action guides are:

(1b) A just society vaccinates every child against measles that is eligible for vaccination, at least to the point that sustains measles elimination from society.

(2b) Respect for liberty and the parent-child relationship regulates the just society's response to vaccine refusal.

It is not hard to see the similarity between these two sets of action guides. Their scope and focus are different, but their ethical content and wording is similar. The first set (1a and 2a) focuses on the individual case of vaccination, and sees vaccination from the perspective of the individual child. Thus, from the first set we can derive ethical obligations which pertains to the persons who stand in close relationships with the child, and who are tasked with securing the child's best interests. The second set (1b and 2b) views vaccination from a societal perspective, and can be used to derive obligations that rest on individuals and societal institutions. Thus, the focus here is on measles vaccination as a societal enterprise, and not on what is best for the individual child. Yet, from these different perspectives we find very similar sounding action guides with similar moral content. In fact, these action guides can be merged with one another and stated as follows:

(1) All children eligible for measles vaccination should be vaccinated against measles, at least to the point of sustained measles elimination.

(2) Respect for parental decision-making and the parent-child relationship guide the response to parental vaccine refusals.

Ethical action guides (1) and (2) bring autonomy, beneficence, non-maleficence and justice in balance with one another. Thus, (1) and (2) represent two specified principles or ethical action guides that bring the four principles into reflective equilibrium. They can be used to derive ethical obligations either in the individual case of measles vaccinations, where practitioners or parents are tasked with providing care to an infant, or to derive ethical obligations on a societal level. Such derived ethical obligations would be grounded in the four principles of the principlist approach, bringing the different prima facie obligations into balance, and can directly be applied to different potential actions in a given situation.

Principlism is not dependent on a specific ethical theory or theoretical approach, and in fact finds its grounding in moral commitments that are widely shared across the theoretical spectrum. Therefore, action guides (1) and (2) can be used whatever one's theoretical commitments or ethical background. These action guides contain moral force for everyone who is committed to living a moral life, whether they are consequentialists, deontologists, religiously affiliated or not, or whatever theory of justice they subscribe to. In any situation where individuals are faced with moral questions regarding measles vaccination, or any society considering the issue of measles vaccination, can apply these two action guides in order to find morally defensible guidance with regards to individual action and societal policy.

The strengths of these action guides are numerous. They will enjoy wide appeal, delivering conclusions with moral force. They can be applied on a societal level and on an individual/care level. They bring the four principles and various different theories of justice into balance, leading to reflective equilibrium.

## **(2) Who has which obligation?**

### **(2.1) What is owed to children?**

According to action guide (1), children are owed protection against measles infection through vaccination. This means that children who are eligible for measles vaccination should be protected through measles vaccination. Children who have a medical contra-indication for measles vaccination are also owed protection against measles vaccination. Such children cannot receive the benefit of direct vaccination, but can be protected through the collective action of others in society through measles elimination. This is the herd immunity point, where those who are not eligible derive protection through the immunity within the population. As I have shown previously, this requires an uptake of measles vaccination of 93-95% with two doses of measles vaccine.

For the individual child, the case is clear: children should receive measles vaccination unless a medical contra-indication exists. On a societal level, the case is also clear: children should be vaccinated, at least to the point that sustains measles elimination from society. If an individual child who is eligible for vaccination does not receive vaccination, that individual child is wronged in that she is deprived of something that is morally owed her. On a societal level, children who are not protected from measles vaccination through direct vaccination or measles elimination are wronged. This means that children who live in a just society can rightly expect to be vaccinated. Children who receive all that is morally due to them receive, among other things, protection against measles infection.

Action guide (2) reminds us that children have other interests besides protection against measles. Elliot (2001) and Powers and Faden (2006, p. 77) point out that children's interests are narrowly intertwined with their parents' interests, and that the parent-child bond is important. This morally significant relationship is integral to the future wellbeing of the child, and to many of the child's present and future interests. Thus, actions meant to secure the protection against measles owed to children should not harm the parent-child bond, and should be respectful of the importance of this relationship.

Children are owed protection through vaccination, both from an individual and societal perspective: This places obligations on individuals who stand in caring relationships to children, such as parents and healthcare providers, as well as on societal institutions such as government.

### **(2.2) What obligation rests on parents?**

Parents play an important role in the lives of the child, and are primarily responsible for the child. They have the obligation to make decisions on behalf of their child, furthering the child's best interests (Buchanan & Brock 1990). This task falls to whoever fulfills the role of parent for the child, whether it be biological parents, adoptive parents, foster parents or the like. For

simplicity sake I shall keep using the term “parent” for whomever stands in this critical relation to the child.

Parents have the obligation of seeing that their child is vaccinated against measles, if the child is eligible for vaccination. This means taking the child for vaccination to a healthcare provider where such vaccination can be administered. Parents, as members of society, also have the obligation to have their eligible children vaccinated in order to establish herd immunity and protect those in society who cannot be vaccinated. Parents have a civic duty to have their children vaccinated, an obligation they owe as members of society to other children in society who are dependent on herd immunity.

Of course, this assumes that vaccination is readily available and affordable or free; this is an assumption that I took into the construction of the initial argument when considering the best interests of the individual child. Indeed, measles vaccination is readily available all over the world, and even in the third world is it possible to vaccinate a child against measles for less than \$1, including injection equipment and operational costs (UNICEF 2007). It should go without saying that parents cannot be blamed if vaccination is not available or if it is simply unaffordable.

Most parents discharge the obligation to take their children to be vaccinated; this is borne out by the epidemiology and statistics I referenced in chapter 2. But it is so, as I have also previously shown, that there are many parents who do not take their children for vaccination, and that there exists a fairly active opposition to measles vaccination. Such parents fail to discharge their duty to their child, and wrong their child, and also fail to discharge the civic duty owed to other members of society, wronging those who are dependent on herd immunity. But it is often the case that such parents do not withhold vaccination through neglect or abuse. In fact, many parents who oppose vaccination are well-meaning parents who do so because of a mistaken belief that it is in the best interests of their child not to be vaccinated (Bean 2011). Such parents need the assistance of other individuals who stand in morally significant relationships with the child (such as healthcare providers), and societal institutions (such as government). The challenge is to enable vaccination of children while not unjustifiably burdening the parent-child relationship.

### **(2.3) What obligation rests on society (members of society and societal institutions)?**

Society has the obligation to ensure that children are protected against measles through vaccination. This means that the members of society and societal institutions should ensure that vaccination takes place and respond when it doesn't. A society that falls below the elimination threshold wrongs its children, and falls below the threshold of what is required of a just society.

## *Government/The state and its delegates*

Government is an important institution in society, and has the obligation to respond to injustices within society. Children within a society are owed protection through adequate levels of vaccination: direct vaccination to those who are eligible, and herd immunity to those who are not. This means that government has the obligation to respond to anything that threatens vaccination uptake, or that wrongs children by withholding vaccination from them.

Government therefore ought to respond to barriers to vaccination. One such obligation is to ensure that measles vaccines are readily available and not cost prohibitive. If, for some reason, vaccines become too expensive and many parents cannot afford vaccination, it is the duty of government to respond and ensure that this barrier is removed. For example, in 2000-2003 there was an unexpected vaccine shortfall in the USA which included MMR and DTaP vaccines (The Lancet Infectious Diseases 2004). UNICEF warned of a shortfall of 70 million vaccine doses worldwide, which included vaccines against measles and tetanus (The Lancet Infectious Diseases 2004). The reason for these shortfalls was decreased production as individual vaccines became less profitable. Whereas there were 30 companies making vaccines for the US in the 1970's, this decreased to 5 companies in the early 2000's (The Lancet Infectious Diseases 2004). In the face of such shortages, the US government provides financial investment towards securing adequate vaccination production (The Lancet Infectious Diseases 2004); this is an excellent example of how a government may respond towards a barrier against vaccination uptake.

Another such obligation is to respond to parental vaccine refusals. There are many ways in which government could respond: coercive measures, using its police power; addressing incorrect messaging and misinformation on vaccination; persuasive educational approaches directed at parents; access to health expertise through the health system and the like.

At minimum, the government needs to establish a policy towards measles vaccination which includes access to vaccination and response to vaccine refusals. This policy should be tailored towards sufficient vaccination uptake to ensure sustained measles elimination from society, while not harming the parent-child bond.

## *Business/Corporate institutions*

Companies manufacturing vaccines are an important societal institution in ensuring adequate vaccination uptake. One obvious obligation resting on such companies is that they cannot cut corners with quality or place an inferior product on the market. Measles vaccinations must meet the minimum standards set by those vaccine formulations which have been the subject of extensive research; producing inferior product which may not perform as the research would predict would fall foul of their societal responsibility.

Vaccinations should also not be cost prohibitive. Now, it may not be possible for companies on their own to realize this goal, and they may need the help of government (as I argued before) to discharge this obligation. But at the very least, drug companies have the obligation to not raise

prices to an unreasonable level. This would mean striking a balance between the making of profit and keeping measles vaccines affordable and accessible. This is a delicate balance; on the one hand profit margins need to be large enough to keep companies incentivised and interested in making vaccines, while on the other measles vaccination needs to be of a certain quality and needs to be reasonably available. This means that, when it comes to measles vaccination, profit is not the only consideration. Minimum quality standards and reasonable availability and affordability are also important considerations.

This may at first glance seem difficult to do. Vaccines account for only 1.5% of a drug company's profit, and the process to test and produce a vaccine is extremely onerous and costly (The Lancet Infectious Diseases 2004; Salinsky & Werble 2006). However, it is possible to ensure adequate vaccine availability through the working together of government and the corporate sector, for example through government investment, government incentives, regulated insurance vaccine payment schemes and so forth (The Lancet Infectious Diseases 2004; Salinsky & Werble 2006). Such obligations fall on governments no matter which conception of justice of the theories I reviewed one appeals to; I have shown (in chapter 6) that even in a libertarian conception of a minimal government, these obligations fall on the government as an important societal institution tasked with safe-guarding the liberty of its members and protecting members from harm by others in society.

I will not go into further details on specific actions in this regard, but will underline the ethical obligations. The corporate sector, as a societal institution, has obligations towards society. With regards to measles vaccination, corporations have to adhere to minimum standards of production, and have the obligation to ensure that they place no barriers to measles vaccination. It may be difficult for corporate institutions to discharge this obligations on their own, and it would likely be necessary for them to work with government along a number of policy lines to discharge their shared obligations to ensure adequate societal measles vaccination uptake.

According to action guide (1), a society that falls below the elimination-vaccination threshold, children are wronged and the society cannot be considered a just society. If it is purely because of the actions of the corporate institutions in this society that the vaccination threshold is not reached, for example through excessive pricing or inferior quality of product, such institutions are responsible for injustice in society, and are themselves unjust. It is then the responsibility of the society to respond to these barriers to vaccination by addressing the injustices present within the corporate institutions. One way in which such injustice could be addressed is through the use of governmental power. To reiterate, it is unlikely that any corporate institution could be considered to carry sole responsibility to ensure adequate vaccine uptake; rather, corporate institutions would ideally partner with other societal institutions such as government to ensure that society's moral obligations to ensure adequate vaccination are discharged. But corporations certainly have the obligation to ensure that they place no barriers to vaccination, and if they do a societal response is required.

## *Healthcare Providers*

Providers who stand in clinical relationships towards children have an important role to play in ensuring measles vaccination uptake. Such providers should offer and encourage vaccination, and initiate discussions on vaccination with parents. Providers are also a resource to parents, providing education and information regarding measles vaccine, answering questions and addressing concerns.

Trust is an important factor in parental decision-making with regards to vaccination. Parents are more likely to value vaccine information received from sources and people they trust (Bean 2011). Lack of trust in official organizations or those perceived to have an agenda is an important factor in vaccine refusal, as is dissatisfaction with vaccine information provided through health resources (Brown et al. 2010). On the other hand, there is evidence that a trusting relationship with a healthcare provider can assist a parent in resisting anti-vaccine messaging and misinformation (Leask et al. 2006). An important factor that protects parents against anti-vaccination misinformation is trust in a healthcare provider. Those who trust their healthcare provider and who have had positive experiences with a provider explaining vaccination information seem relatively protected against vaccine misinformation. Healthcare providers have obligations to foster trusting relationships with parents of the children they provide care for, and to deliver positive vaccine messaging and information against the background of this trusting relationship. Such an approach fulfills the requirements of both action guides (1) and (2).

This implies the need for ongoing provider self-education in the area of measles vaccination, making sure that the provider knows the relevant facts, or at least where to find them. Furthermore, the provider cannot end the clinical relationship because a parent refuses vaccination. Such a course of action would be nothing short of disastrous. A trusted provider is an important cog in the wheel of vaccination uptake, and ending a clinical relationship purely because of non-vaccination robs the child of medical care, potentially erodes parental trust in the system further, and removes an important avenue through which positive vaccine messaging can be communicated.

Providers are the in the front lines of care delivery, and have obligations towards the individual children they care for and society as a whole to ensure adequate vaccination uptake through the building of trusting relationships and the provision of education.

## *Members of society/Institutions of society*

Societies have the obligation of ensuring the vaccination of its eligible children. Individual members of society and institutions of society (such as churches, clubs, organizations and so forth) share in this obligation. At minimum, this obligation includes not creating barriers to measles vaccination or not obstructing measles vaccination. Any action by an individual or institution that hinders the vaccination of children is therefore unethical. One example to be thought of here is the number of celebrities and internet users who instruct parents not to have

their children vaccinated, stridently advocating non-vaccination as the only responsible parental choice (Kata 2010; Kata 2012).

Perhaps one should differentiate between honest questioning, where someone may have serious doubts about vaccination and raises these in a public forum, and directly advising parents not to have children vaccinated. The latter can even be construed medical advice, and it is alarming that such advice is given by those who are not medically qualified. Persons and institutions who engage in such actions, whether they are well-meaning or not, violate their duty to society of not placing barriers to the vaccination of children. Furthermore, such actions foster mistrust and suspicion against healthcare providers and authorities. Indeed, one of the recurring themes in the vaccine opposition movement is the idea of a grand conspiracy and the implied untrustworthiness of the healthcare system and the government (Bean 2011; Kata 2010; Kata 2012). In the long run, if parents lose trust in their providers and the healthcare system, it may lead to reluctance in accessing such services and eventually compromise the best interests of the child.

If barriers to vaccination exist, society has an obligation to respond. Because of respect for liberty, the free speech of individuals cannot be unduly burdened. However, there are a myriad of ways in which society can respond to barriers of the kind I have mentioned. This could include countering erroneous messaging by correct messaging, engaging those who place barriers in various ways, maintaining trusting relationships with parents, encouraging vaccination through public policy and so forth. Such duties fall in varying ways to the government, healthcare providers, and other members/institutions within society. In essence, ensuring sufficient vaccine uptake is a societal endeavour, and requires the co-operation of various levels of society. The goal is to empower parents to choose vaccination, in order that parents can discharge the duty they owe to their children and to society.



### (3) Suggestions for measles vaccination policy

I have argued that government should institute a measles vaccination policy that would encourage maximal uptake of measles vaccination in children, while not harming the parent-child bond. In what follows, I offer some suggestions as to what such a policy would look like. The focus here is on encouraging vaccine uptake among the public, and specifically responding to vaccine refusal.

In suggesting policy options in response to vaccine refusal and to encourage vaccination uptake, two options are usually presented: the use of government power, and persuasive/educational interventions (Diekema 2005; Diekema & Marcuse 2007; Krantz, Sachs, & Nilstun 2004; Sheather 2013; Wood-Harper 2005).

Coercive policies, by which I mean the use of State power to force vaccination, has a long history as a tool to ensure vaccine uptake. In the battle against small pox, Britain had a mandatory vaccination policy from 1871 that subjected refusers to fines, loss of property, or a sentence to the workhouse (Allen 2007, p. 64-111). Eventually, in the face of organized resistance, Britain ended mandatory vaccination in 1948 (Allen 2007, p. 64-111). The United States also implemented forced vaccination policies in the early 1900's in response to vaccine refusal (Allen 2007, p. 64-111). In 1905 the *Jacobson v. Massachusetts* case set legal precedent, and formed the basis for compulsory vaccination State laws in the US (Omer et al. 2009). Currently, in the US, all States have laws mandating vaccination for school entry, with 48 states allowing some non-medical exemptions to vaccination requirements (Omer et al. 2009).

Educational interventions are frequently recommended as a response to vaccine refusal (Kata 2010). Some have suggested that parents can be “vaccinated” against misinformation and erroneous arguments through promoting correct vaccine information (Kata 2010).

These approaches are not necessarily either-or, and coercive policies and educational policies can be combined. Consider a recent article, where the author examines forced vaccination and educational interventions by the use of a hypothetical Ebola outbreak in the United States (Brown 2014). The author asks us to imagine an outbreak of Ebola in the US and the availability of a vaccine that is 80% effective and recommended for children. Would we allow people to refuse vaccination in such a scenario? If we would not, we should perhaps reconsider exemptions to vaccine mandates for disease like measles, where the disease is serious and the vaccine highly effective. The author furthermore argues that we should use the Ebola outbreak as a means to educate people regarding other contagious disease for which effective vaccinations do exist, and suggests using avenues such as media and pop culture to disseminate such educational messages. Thus, in this article we see an argument for using a combination of government coercion with various innovative and diverse educational interventions.

These responses, coercion and education, have a common-sense appearance about them. In accordance with action guide (1), it is imperative to engage vaccine-refusers in order to ensure

that their children benefit from vaccination and that society benefits from high vaccination uptake. However, it is not as straightforward as it seems. Policy should be guided by action guide (1), meaning that respect for parental liberty and the parent-child bond are important considerations. This means, for example, that persuasive approaches should be favored where possible, and that there are limits to the types of coercion government can engage in. In what follows, I will show that coercion can present serious difficulties and education has some limitations. These two approaches certainly have their place, but vaccination policy needs to go further in its response to vaccine refusal. Specifically, given the limitations of coercive and educational responses, a further step is needed. I shall argue that this amounts to rebuilding of trust; that an important focus of policy should be building of trusting relationships between parents and healthcare providers, using this as the basis for a multi-faceted approach towards vaccine refusal. I propose here a three-pronged approach that optimally satisfies the requirements of action guides (1) and (2): using government power within its limitations, using educational interventions that are well researched, and fostering trusting relationships between providers and parents.

### *The limits of coercion*

Coercion is limited by action guide (2). Government actions that place an undue burden on the parent-child bond violate action guide (2) and are unethical. Consider an extreme example of imprisoning parents for not getting their child vaccinated. It is clear that an undue burden is placed on the parent-child bond.

There are different types of mandatory vaccination policies, aimed at increasing vaccination uptake through use of state power (Ross & Aspinwall 1997).

- A) Force all parents to vaccinate their children or face legal consequences.
- B) Vaccinate children at school without the consent of the parents, or allow vaccine refusal only for home-schooled children or private schools.
- C) Mandatory vaccination of children with the option to opt-out (the current situation in many States in the United States).

Option (A) seems problematic as it would introduce substantial costs to families and consequently society (Ross & Aspinwall 1997). Prosecution would fall on parents that fail to vaccinate their children, incurring harm to these parents, consequently harming the family, and eventually harming the child. Thus, in an attempt to protect the best interests of the child, the child ends up being harmed. Since families are the building blocks of society, harming families in this way would also harm society.

Yet, this approach can perhaps be justified when the costs to individual children and to society are very high should vaccination be refused. Consider Brown's thought experiment of a hypothetical Ebola epidemic in the United States (Brown 2014). Ebola is a contagious illness, difficult to treat and with high mortality rates. If it were so that Ebola were endemic in the United

States, and it were so that there was a safe and effective vaccine, it could be argued that mandated vaccination would be reasonable despite the costs of government power. This was the background of the famous 1905 US case, *Jacobson vs Massachusetts*: the United States faced a small pox epidemic, and a vaccine was available (Ross & Aspinwall 1997). The Supreme Court decided that the state has the authority to mandate vaccination in these circumstances to protect public health (Ross & Aspinwall 1997). Brown (2014) argues that endemic Ebola would be a similar situation. According to this line of thinking, government should have the power to intervene through various coercive ways to protect the public against a public health disaster.

Justifying the use of such power is less clear if the risk from the disease is very low, say for example an illness is not really that serious or is not endemic in society, or if the protecting vaccine has substantial harms associated with it. Punishing parents who fail to vaccinate in the absence of a public health emergency (such as a large disease outbreak) seems to incur unduly high levels of harm for minimal benefit (Ross & Aspinwall 1997). Policy option (A) can therefore perhaps be justified as an emergency measure to prevent public health disasters, such as to contain a measles outbreak in a society where vaccine uptake has fallen well below the elimination threshold. One should realize that this compromises action guide (2), and should only be used when the need is dire. Furthermore, the fact that vaccination levels have already fallen below elimination thresholds in this society points to the fact that action guide (1) has already been compromised. For some reason, this society is not giving children the protection against measles due to them. If policy option (A) becomes necessary, it points to the fact that the society in question is already not discharging its ethical obligation, and a serious reflection on the underlying problem with an appropriate remedial response is needed. Option (A) is therefore not an optimal policy option in order to satisfy the requirements of action guides (1) and (2), and should rather be seen as an emergency response in societies where action guide (1) has been compromised and a public health disaster has to be averted.

Another consideration with regards to the use of legal consequences as per option (A) is this. The history of mandatory policies show that coercion can sometimes have the unintended effect of galvanizing the resistance to vaccination. Britain introduced a mandatory vaccination policy in 1871, with rather harsh penalties for vaccine refusal such as loss of property or a sentence to the work-house (Allen 2007). They eventually abandoned mandatory vaccination in 1948 in the face of organized resistance (Allen 2007). In the United States, the introduction of compulsory vaccination laws also changed the anti-vaccine movement from a passive resistance to a more organized, active resistance (Allen 2007). An aspect that is present in some sectors of the contemporary anti-vaccine movement is the idea that parents should take responsibility for their own child, resisting those who would coerce them to act against the best interests of their child (Kata 2010). Some types of coercion may therefore paradoxically strengthen resistance to vaccination; using too strong a hand may hinder the goal of ensuring vaccination uptake, compromising not only the requirements of action guide (2), but also of action guide (1).

Policy option (B) may have some merit, in that it respects liberty and the parent-child bond while using government power to ensure vaccination, but it does face some difficulties. One such difficulty is that it has the potential of unfairly denying children the good of a publicly funded education (Ross & Aspinwall 1997). If one were to imagine that the refusal is based on adherence to a minority religion, this could introduce social isolation of members of this religion, and introduce systematic discrimination against this religion. The other problem is that this option may lead to the geographic congregation of susceptible individuals, through attending the same private schools (Ross & Aspinwall 1997). In fact, geographical clustering of non-medical exemptors is readily observed (Omer et al. 2009), and the use of option (2) may encourage such geographical clustering. These are ideal circumstances for outbreaks of vaccine preventable diseases. In this case, children are not protected from measles disease through vaccination, and in fact find themselves quite susceptible to outbreaks. This falls afoul of ethical action guide (1). Home schooling is not exempt from these concerns; home schooled children are at risk of being the index case (first case of an outbreak) and put others at risk as well (Ross & Aspinwall 1997). It is also not clear that home schooling would prevent geographical clustering, as all the factors that lead to clustering are not understood (Omer et al. 2009). Thus, though policy option (B) at first glance seems possibly in line with both action guides (1) and (2), further reflection reveals some difficulties and objections.

Option (C) allows respect for parental choice and the parent-child bond while using government power to encourage vaccination uptake. This option includes legal mandates to have children vaccinated, but allows refusal by opting out. There is evidence that this type of opt-out approach increases vaccination uptake (Omer et al. 2009). In the US, States that allow only religious exemptions have higher vaccine uptake than States that also allow philosophical exemptions (Omer et al. 2009). Furthermore, in States where the opt-out process is more difficult (such as parents having to come in to school to signing a form) have higher vaccination rates than States where opt-out is easier (Omer et al. 2009). Thus, if policy option (C) is implemented, the opt-out policy should be fairly tightly worded, so as to encourage maximal vaccine uptake. On balance, this approach seems to better align with action guides (1) and (2) than the other coercive policy options thus far considered. Option C would optimally make use of government power to encourage vaccine uptake, while providing an avenue of refusal for those who strongly oppose vaccination. In this way, room is made for parental decision-making and the parent-child bond is not overly burdened. Since it allows opt-out, option (C) is unlikely to be sufficient on its own to ensure sustained high vaccination uptake, but it certainly seems the best option of the three for use of state power, all things considered.

### *The limitations of education*

Parents who refuse vaccinations are more likely to have garnered anti-vaccination information from the Internet, specifically from certain anti-vaccination websites (Kata 2010). These parents therefore have been exposed to a variety of misinformation and tropes regarding vaccination, influencing their attitude towards vaccinations (Kata 2010). One could easily reason that this

misinformation merely has to be corrected to regain parental trust in vaccinations. If this were successful, it would satisfy both action guide (1) and (2): children would be vaccinated, and the parent-child bond be respected.

However appealing such notions are, education is not always successful in changing parental attitudes about measles vaccination. Kata, for example, argues that many people in the anti-vaccine movement adhere to alternate views of health, alternate explanatory models, and what she calls a “post-modern paradigm” (Kata 2010; Kata 2012). Thus, Kata argues that it is not effective to engage the anti-vaccine movement solely with education based on scientific data and scientific arguments. These types of approaches are seen either as part of a conspiracy, or is seen as “your version of the truth” (Kata 2010). Education and evidence therefore do not change “my version of the truth” (Kata 2010). Thus, although education is important, it may not be enough to remove the arguments typically forwarded within the anti-vaccine movement.

A study has shown the limitations of different types of educational interventions aimed at correcting mistaken beliefs and attitudes regarding vaccination (Nyhan et al. 2014). Parents were randomly assigned to one of four measles vaccine educational interventions: (1) information focused on correcting misinformation, (2) written information on the dangers of vaccine preventable diseases, (3) a dramatic narrative of a child hospitalized due to measles, and (4) a visual intervention using images of children suffering from vaccine-preventable diseases. The study found that none of these interventions increased the intent of parents to vaccinate their children. In fact, parents who had a negative view of vaccination prior to these educational interventions communicated a decrease in intent to vaccinate after the interventions, meaning that they were strengthened in their resolve not to vaccinate. Also, the use of dramatic narratives or visuals of sick children increased fears and misconceptions regarding vaccine adverse effects. The study shows that parents who have moderate or favourable views of vaccination may benefit from educational interventions such as was used in this study, but parents who are resistant to vaccines may be strengthened in their resolve not to vaccinate by such interventions. The authors conclude that educational interventions can often have unexpected and even opposite effects to what was intended, and that vaccination educational interventions need to be carefully researched and tested before being used on the public.

Brown et al. (2010) advance the following argument with similar conclusions in their systematic review regarding factors that influence vaccine decision-making. Individual vaccine refusers may hold strong views on some anti-vaccine issues and arguments, and less strong views on others. Persistently confronting vaccine refusers on issues on which they hold strong opinions may lead to a more deeply held anti-vaccine position. In this way, educational interventions may have opposite results than what was intended. The authors recommend that educational interventions be tested before being used in the public, to ensure they have no detrimental effects on vaccine uptake.

The point is that educational interventions are not a cure-all as an approach to vaccine refusal, and can often have the opposite effect than intended. The goal, in accordance with action guide

(1), is to encourage measles vaccine uptake in a way that maintains measles elimination from society. To reach this goal, educational interventions must be effective in changing the attitudes of refusers, while also reassuring those who have moderate or strongly positive views of vaccination. To this end, it is crucial that educational interventions be well researched and tested to be sure of their effect on parental attitudes towards vaccination.

### *Rebuilding trust as an important policy focus*

Many things can influence parental attitudes towards measles vaccination: media reports, information on the internet, and information from other parents, among others (Brown et al. 2010). As I pointed out before, two important issues emerge as factors in parental vaccine refusal: dissatisfaction with vaccine information provided by healthcare sources, and lack of trust in the healthcare system, providers, or government agencies that promote vaccination (Brown et al. 2010).

On the other hand, there is evidence that a trusting relationship with a healthcare provider assists parents in being able to resist anti-vaccination messages and maintain positive attitudes towards vaccination (Leask et al. 2006). Clear communication regarding risks and benefits of vaccines from a trusted health care provider plays a large role in promoting vaccination uptake, whereas poor communication or inadequate knowledge on the part of a provider impedes vaccination uptake (Simone, Carrillo-Santistevé, & Lopalco 2012). Receiving correct and understandable information from a healthcare worker whom parents trust is an important factor in ensuring acceptance of vaccination (Simone, Carrillo-Santistevé, & Lopalco 2012).

There appears to be a breakdown of trust between the health care system and many vaccine refusers, fuelling vaccine refusal and placing a barrier against vaccine uptake. The response of the government through policy and the healthcare system through action must address this trust issue, and must seek to restore trust. It may not necessarily be possible to engender trust on the large scale through educational interventions, but it may be possible to build trust with individuals. This would mean a strong focus on building of trust relationships between healthcare providers and parents, and maintaining a strong patient-centered health care model. Individual providers establishing trusting relationships with individual refusers has the potential to eventually have a large influence on vaccine uptake. The obligation falls on individual providers and on government health policy. Providers have to foster and maintain such relationships in professionally appropriate ways. Government healthcare policy should see clinical relationships as the building block of care provision to children, and should adopt a relationship based, patient-centered model of care delivery. Every parent should have access to a provider they trust, whether this be a nurse, a family physician, or a pediatrician. Such providers should be expert in fostering a clinical relationship, and in communicating vaccine facts in a manner that engenders trust. Coercion and education are not enough; trusting health care relationships are an essential component in ensuring high levels of vaccine uptake and should be the focus of any policy response to vaccine refusal.

This conclusion is similar to a conclusion in Brown et al.'s systematic review (Brown et al. 2010). They similarly argue that the focus in responses to vaccine refusal should be on multifactorial interventions which improve parents' satisfaction with vaccination consults and information, as well as encouraging the formation of trusting clinical relationships between providers and parents.

### *Summary and recommendations*

In summary, I would argue that the following policy approach satisfies the requirements that action guides (1) and (2) place on government and the healthcare system:

- A strong focus on building of trust relationships between providers and parents. This should be the primary building block of health care delivery to children, and also the pillar in our strategy to ensure adequate vaccine uptake and education. This would mean moving from a mere systems healthcare approach to a relationship-based and individualized patient-centered approach.
- Educational interventions that are well researched, known to improve attitudes towards vaccination, and complement the building of trust through relationship-based care.
- Mandatory school vaccination policies with provisions for opting out, with a carefully worded opt-out policy that maximizes vaccine uptake.
- Forego opt-out only to prevent or respond to public health emergencies.

Action guide (1) underlines the ethical imperative for those in government and in healthcare leadership to ensure maximal uptake of vaccinations against measles. Action guide (2) reminds us that how government and the healthcare leadership go about this duty is important: parent-child relationships and parental decision-making should be afforded respect. The policy options I have suggested offers ways in which government and healthcare leaders can discharge these dual duties in an ethically justifiable way.

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