# Deutscher Ethikrat





## Vaccination as a Duty?

OPINION



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#### 1 INTRODUCTION

There has barely been another invention in medical history that has contributed to reducing child mortality and to promoting the health of adults to the extent that the development of vaccines against contagious diseases and their systematic, scientifically supported ("evidence-based") implementation in public health care have. Especially against many contagious diseases caused by viruses, vaccinations are the most important measure to prevent severe health risks. Apart from avoiding contact with sources of infection, a lot of these virus diseases can only be treated symptomatically up until today.

As a result of worldwide efforts after World War II, which were mainly based on mandatory vaccination policies ordered by national authorities (also in both parts of Germany)<sup>1</sup>, smallpox was the first and so far the only contagious disease that has been declared eradicated in 1980 by the World Health Organization (WHO), which means it has been globally stamped out.<sup>2</sup> As a consequence, vaccination programmes against smallpox could be terminated. It was the proof that it is possible to achieve the ultimate eradication of certain contagious viral diseases that can only be transmitted from person to person. Also poliomyelitis (infantile paralysis) could be largely eliminated in Europe by means of systematic international vaccination programmes that were predominately based on recommendations for voluntary vaccination.<sup>3</sup> However, it has not yet been possible to completely eradicate polio at a global level.

A contagious disease is considered eliminated if, "through the introduction of corresponding measures, it no longer occurs in a geographically defined region, or if only individual

<sup>1</sup> Cf. Thießen 2013, 412 f.

<sup>2</sup> Cf. World Health Organization 1980, 12 f.

<sup>3</sup> Cf. World Health Organization 2019.

cases are imported from areas where the disease still exists".<sup>4</sup> The elimination of a disease is only a temporary success, which can be lost again if the protection of the population weakens. A reference definition for the elimination of measles and rubella is the "interruption of an endemic measles or rubella transmission over a period of at least 36 months after the last occurrence of an endemic case in a specific geographic region. The term endemic transmission refers to the occurrence of a continuous chain of infection of measles or rubella in Germany over a period of 12 months or longer."<sup>5</sup> A lasting eradication of a disease is only achieved "if the disease is successfully eliminated in all regions of the world".<sup>6</sup> National vaccination programmes may therefore only aim at eliminating a disease. However, taken as a whole, successful programmes in each individual country are the necessary precondition to achieve worldwide eradication.

Measles are an objectively dangerous – albeit often underestimated – contagious disease that can be prevented by means of a well-tolerated and generally accessible vaccine. These facts make measles a prime example of a contagious disease whose global eradication is absolutely feasible. However, temporary successes notwithstanding, not even the elimination of measles has been sustainably achieved in many parts of the world.<sup>7</sup> Although they were declared eliminated in the Americas by the Pan American Health Organization in 2016 after the successful completion of vaccination programmes<sup>8</sup>, this status was lost again due to several outbreaks of measles, including in the US.<sup>9</sup> In 2017, measles were considered as eliminated in 37 of 53 states of the WHO European Region.<sup>10</sup> In May 2019,

<sup>4</sup> https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ praevention\_inhalt.html [2019-04-30].

<sup>5</sup> https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ elimination\_04.html [2019-05-29].

<sup>6</sup> https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ praevention\_inhalt.html [2019-04-30].

<sup>7</sup> Cf. Holzmann et al. 2016.

<sup>8</sup> Cf. Pan American Health Organization 2016.

<sup>9</sup> Cf. Graham et al. 2019, 584.

<sup>10</sup> Cf. World Health Organization 2018, 13 f.

however, the WHO warned of a resurgence of the disease in this region because there had been over 100,000 cases and over 90 deaths within 14 months." Germany could only produce an interruption of endemic transmission in 2016, a status it lost again in 2017.<sup>12</sup> In the years 2016, 2017 and 2018 Germany counted 325, 929 and 543 cases of measles respectively.<sup>13</sup> The benchmark of less than one case per one million inhabitants recommended by the WHO was therefore exceeded in each of these three years.

Despite the great historic success due to international efforts in the fight against smallpox and poliomyelitis, local outbreaks of measles have revealed major shortcomings in the protection against contagious diseases in Germany and all over Europe in recent years. Vaccinations could have prevented these deficits. Germany regularly renews its self-commitment towards the WHO to strive for the achievement of the WHO vaccination targets in order to sustainably eliminate measles. These targets include a vaccination coverage of more than 95 percent not only for the first, but also for the second dose of vaccine, and a rate of less than one person infected with measles per one million inhabitants.<sup>14</sup> Whether these targets can be achieved does not only depend on the immunisation of the total population at a rate of over 95 percent, but especially on the question whether such an immunisation exists nation-wide. Measles will only be eliminated if no places or regions exist which might become the origin of epidemics because they show an increased density of unvaccinated individuals ("pockets of low herd immunity"<sup>15</sup>).

<sup>11</sup> Cf. http://www.euro.who.int/en/media-centre/sections/press-releases/ 2019/over-100-000-people-sick-with-measles-in-14-months-with-measlescases-at-an-alarming-level-in-the-european-region,-who-scales-upresponse [2019-06-04].

<sup>12</sup> Cf. Nationale Verifizierungskommission Masern/Röteln 2018.

<sup>13</sup> Cf. https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ elimination\_04\_01.html [2019-05-29].

<sup>14</sup> Cf. Bundesministerium für Gesundheit 2015, 13.

<sup>15</sup> Buttenheim/Cherng/Asch 2013, 1819.

In 2011, the year 2015 was set as the target for the elimination of measles in Germany.<sup>16</sup> This target was not met. Given a measles prevalence of 6.6 infections per one million inhabitants in the year 2018<sup>17</sup> it is clear that Germany could neither fulfil its own objectives in combatting measles, nor did it comply with the WHO requirement of eliminating measles and maintaining this elimination by taking national measures. It is apparent that also the "Nationaler Aktionsplan 2015–2020 zur Elimination der Masern und Röteln in Deutschland" (National Action Plan 2015–2020 to Eliminate Measles and Rubella in Germany)<sup>18</sup> initiated by the national government and the federal states will fail to achieve this aim.<sup>19</sup>

The reasons are that both the first and second doses of the vaccine are given to children too late, whilst the critical second dose is given at an overall insufficient rate.<sup>20</sup> At the federal level, 97.1 percent of children had received their first vaccination by the time they started school in 2017, but only 92.8 percent had received the second.<sup>21</sup> Moreover, there is still a large number of adults without sufficient immunisation. This can be attributed to the age group of people born after 1970, whose share of the population is growing. No immunity acquired through individual infection can be assumed for this age group, and their vaccination rates are low.<sup>22</sup> For lack of a national immunisation register, the only available data are those of the DEGS1 surveys of 2008 until 2011 ("German

<sup>16</sup> Cf. the decisions of the 84<sup>th</sup> Conference of the Ministers of Health on 29 and 30 June 2011 in Frankfurt on the Main regarding agenda item 8.3 (especially the reasons given under 2.4): https://www.gesundheit.bremen.de/sixcms/ media.php/13/DG+2011-08-23+L-5-18+GMK+Beschl%FCsse\_ Beschlussfassung.pdf [2019-04-30].

<sup>17</sup> Cf. https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ elimination\_04\_01.html [2019-04-30].

<sup>18</sup> Cf. Bundesministerium für Gesundheit 2015.

<sup>19</sup> Cf. Nationale Verifizierungskommission Masern/Röteln 2018.

<sup>20</sup> Pursuant to the vaccination calendar of the Standing Committee on Vaccination the first vaccination against measles should be given at the age of 11 to 14 months, the second at the age of 15 to 23 months (cf. Ständige Impfkommission 2018, 338).

<sup>21</sup> Cf. Robert Koch-Institut 2019, 150.

<sup>22</sup> Cf. Rieck et al. 2019, 429.

Health Interview and Examination Survey for Adults"). They show that only 79.8 percent of the 18- to 29-year-olds and 46.7 percent of the 30- to 39-year-olds have ever received a vaccine dose against measles in their life.<sup>23</sup> Therefore, there are actually in Germany far more serious vaccination gaps in the adult population than in children.

The limited success of previous strategies has led to the insight that measures need to be intensified. As a consequence, important ethical and legal questions regarding national and international methods to fight the disease must be dealt with. Specifically, the question arises whether obligatory/binding measures are justified, i.e. a mandatory vaccination policy, and if so, to what extent, in order to achieve the elimination of measles and the ultimate target of its complete eradication. In the current discussion in Germany, the term "mandatory vaccination policy" is often used without further clarification, although it can refer to a wide range of measures. It might include indirect consequences (e.g. liability in case of non-compliance) and individually ordered temporary exclusion of unvaccinated persons from specific places or professional activities, as well as imposing fines or even a general duty to vaccinate for all age groups enforced by means of statutory coercive measures.

These issues are currently the object of a lively debate in Germany. It focuses on the question whether a mandatory vaccination policy against measles should be introduced, and if so, for whom and at what conditions. On 5 May 2019 the Bundesministerium für Gesundheit (Federal Ministry of Health) submitted a draft bill of an "Gesetz für den Schutz vor Masern und zur Stärkung der Impfprävention" (Act on Protection against Measles and Strengthening Vaccine Prevention)<sup>24</sup>, which was received by the public with mixed reactions. In

<sup>23</sup> Cf. Poethko-Müller/Schmitz 2013, 849.

<sup>24</sup> https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/ 3\_Downloads/Gesetze\_und\_Verordnungen/GuV/M/ Masernschutzgesetz-RefE.pdf [2019-06-04].

particular, the duty to vaccinate children and their educators in child-care centres and schools, sanctionable with fines, triggered a controversial debate.

The present opinion of the German Ethics Council addresses these issues. For the reasons mentioned above, the Council focuses on measles, but aims to develop general ethical standards that are also applicable to other vaccine-preventable infectious diseases.

#### 2 CURRENT SITUATION

#### 2.1 Medical significance of measles

Measles are caused by a virus that is transmissible from person to person and occurs exclusively in humans. For centuries, they have been an endemic contagious disease in Europe. Just like smallpox, measles was not endemic in other parts of the world, for example North and South America or Australia and Oceania, before the arrival of the Europeans. This led to the outbreak of catastrophic epidemics among the indigenous peoples during the colonial era.<sup>25</sup>

With a contagion index<sup>26</sup> and a manifestation index<sup>27</sup> of close to 100 percent, measles is among the most contagious diseases of all.<sup>28</sup> Their harmfulness is often underestimated, and public awareness often perceives them as a harmless "childhood illness". However, in Germany just as in most other countries, they fall into the category of notifiable diseases pursuant to the *Infektionsschutzgesetz* (Protection against Infection Act, IfSG) due to their actual harmfulness.

In Germany, the vast majority of patients who contract measles recover within just a few weeks without any major sequelae. Nevertheless, there are some measles sufferers who have access to good health care and no prior health issues but still experience various complications even during the "normal" course of the disease. 7 to 9 percent of children with measles develop an inflammation of the middle ear, 8 percent suffer from diarrhoea and 1 to 6 percent develop pneumonia.<sup>29</sup>

<sup>25</sup> Cf. Shanks et al. 2011.

<sup>26</sup> Contagion index: Share of actually infected persons in relation to the total number of non-immune persons exposed to the pathogen.

<sup>27</sup> Manifestation index: Share of the persons showing manifest symptoms in relation to the total number of infected persons.

<sup>28</sup> Cf. the section on the path of infection in the Robert Koch Institute's booklet on measles: https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/ Ratgeber\_Masern.html [2019-06-11]; Holzmann et al. 2016, 201.

<sup>29</sup> Cf. World Health Organization 2017, 209 with further evidence.

About 0.1 percent of people infected with measles develop a post-infectious encephalitis (inflammation of the brain). 10 to 20 percent of these people die and another 20 to 30 percent suffer from lasting, sometimes most severe brain damage. Between 2001 and 2012, fifteen people died from measles in Germany.<sup>30</sup>

Even after several years, the patient might develop subacute sclerosing panencephalitis (SSPE) as a late complication of measles if the virus persists in the central nervous system. There is currently no curative treatment for SSPE, and it is usually fatal.<sup>31</sup> In Germany, the frequency of SSPE among patients infected with measles is about 1 : 1700 to 1 : 3300.<sup>32</sup>

Worldwide, measles are one of the leading causes of death in children.<sup>33</sup> The disease and especially the mortality of measles are context-sensitive, i.e. they particularly affect countries with poor socio-economic conditions.<sup>34</sup> The main reason for this is the impairment of the immune response to other pathogens during the course of the disease, which might lead to secondary complications like pneumonia, diarrhoea or tuberculosis.<sup>35</sup> If measles lead to death in 0.01 to 0.1 percent of the cases under European conditions<sup>36</sup>, it is usually due to pneumonia or, in individual cases, due to encephalitis. In poor countries, and particularly for underweight people, diarrhoeal diseases play a crucial role, because they lead to death in up to 28 percent of the cases in those places.<sup>37</sup> According to a WHO notification, more than 1,200 people died in a measles epidemic on Madagascar in 2019.<sup>38</sup>

<sup>30</sup> Cf. the section on clinical symptoms in the Robert Koch Institute's booklet on measles: https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/ Ratgeber\_Masern.html [2019-05-06].

<sup>31</sup> Cf. Kannan et al. 2013, 1.

<sup>32</sup> Cf. Schönberger et al. 2013.

<sup>33</sup> Cf. Abad/Safdar 2015.

<sup>34</sup> Cf. Kyu et al. 2016, 281.

<sup>35</sup> Cf. Mina et al. 2015; Laksono et al. 2018.

<sup>36</sup> Cf. World Health Organization 2017, 209 with further evidence.

<sup>37</sup> Cf. Perry/Halsey 2004, S10.

<sup>38</sup> Cf. https://www.afro.who.int/news/madagascar-mothers-show-gritprotect-their-children-government-partners-battle-measles [2019-06-11].

Since 1963, vaccines against measles are available; the attenuated<sup>39</sup> live vaccine used today was originally developed in 1971. Usually, measles vaccinations are given in combination with vaccines against mumps and rubella (MMR vaccination; in combination with a vaccination against chickenpox and later shingles: MMRV vaccination). Approved single vaccines against measles have no longer been available in Germany since 2017. The MMR/MMRV vaccination is officially recommended in all of the German states, but there is no explicit, let alone sanctionable mandatory vaccination policy. Infants should be given the first dose of vaccine at the age of 11 to 14 months and the second dose of vaccine at the age of 15 to 23 months.<sup>40</sup> For people over 18 years of age and born after 1970 who have not been vaccinated or who have an unclear vaccination status, it is recommended to receive one dose of the MMR vaccination.<sup>41</sup> The vaccination is considered to have extremely low side effects and is covered in Germany and all over Europe by the statutory health insurance; private insurers also cover the costs.

#### 2.2 Epidemiologic fundamentals

#### 2.2.1 Basic terminology

The aim of vaccinations is to reduce the prevalence of a disease (morbidity) and the frequency of its complications, as well as to prevent deaths resulting from the disease (mortality), as both targets are interdependent. The double MMR vaccine prevents measles-associated morbidity, complications and mortality

<sup>39</sup> Attenuated live vaccines against viral diseases contain biologically modified viruses, which can multiply, but – contrary to wild viruses – they are not contagious (transmissible to other persons) nor pathogenic (causing medical signs of the disease). Inactivated vaccines, on the other hand, contain no complete viruses, but only parts of the virus that trigger the immune system to produce specific antibodies.

<sup>40</sup> Cf. Ständige Impfkommission 2018, 338.

<sup>41</sup> Cf. Ständige Impfkommission 2010.

with a very high probability. Since vaccinations in general are preventive measures, vaccines must comply with stricter safety requirements not only at the time of their approval, but also in the course of their application (pharmacovigilance), than therapeutic interventions for pre-existing diseases.

Whether a vaccination will be officially recommended depends on the question if it is regarded as necessary and safe in the light of available epidemiological data. It is the Ständige Impfkommission (Standing Committee on Vaccination, STIKO), housed by the Robert Koch Institute, that provides recommendations (Section 20 (2) sentence 1 no. 3 IfSG) which serve as a basis for the highest health authorities of the federal states to issue public recommendations (Section 20(3) IfSG). The STIKO's recommendations also serve as a basis for the decisions of the Gemeinsamer Bundesausschuss (Federal Joint Committee), that sets out the details with regard to requirements, modalities and extent of the services covered by statutory health insurance in its directives on vaccinations. If it intends to deviate from the STIKO recommendations, the Federal Joint Committee must give specific reasons to justify its decision. The approval of vaccines is issued by either the Paul Ehrlich Institute, the Federal Institute for Vaccines and Biomedicines, or by the European Medicines Agency.<sup>42</sup>

Should a person suffer from health damages caused by the side effects of officially recommended vaccinations ("vaccine injury"), this person is entitled to a pension pursuant to Section 60 (1) sentence 1 no. 1 IfSG. In the "Nationaler Impfplan" (National Vaccination Schedule) of 2012, data on the frequency of requests for the recognition of vaccine injuries for the years 2005 until 2009 have been analysed. Independent of the type of vaccine injuries were submitted in Germany in the year 2008, and 43 vaccine injuries acknowledged. To put these numbers in perspective it should be taken into account that

<sup>42</sup> Cf. Pfleiderer/Wichmann 2015.

in 2008, almost 45 million vaccine doses were paid for by the statutory medical insurance companies alone.<sup>43</sup> During the entire five-year-period, only five vaccine injuries resulting from vaccination against measles (including the various multiple vaccinations) were acknowledged in seven federal states (no data were available for the other federal states).<sup>44</sup>

With regard to the medical fundamentals behind vaccination recommendations, it is first of all necessary to establish the morbidity of a vaccine-preventable disease in Germany on the basis of its incidence and prevalence<sup>45</sup>. Moreover, it must be determined how contagious the disease is and how many people infected with it develop manifest symptoms (contagion index and manifestation index). In addition, it is important to establish the complication rate among those who actually develop the disease. In this context it needs to be clarified what complications occur due to the disease, how severe these are and what the mortality is (if applicable, broken down by age cohort). On the other hand, it must be determined how reliably the vaccination protects against the respective disease, whether there are other strategies of intervention, and if so, how effective these are. Lastly, the question must be raised how frequent and, if applicable, how severe complications due to the vaccination are. In order to do so, the following epidemiological parameters must be taken into account, among others:

» The vaccine efficacy (VE) indicates how well the vaccination protects from contracting the disease by quantifying the percentage reduction of disease manifestation in a vaccinated group in comparison to an unvaccinated group.<sup>46</sup>

<sup>43</sup> Cf. Gesundheitsministerkonferenz 2012, 119 f.

<sup>44</sup> Cf. ibid., 122.

<sup>45</sup> Incidence is the rate of new cases of the disease; prevalence is the sum total of all existing cases of the disease.

<sup>46</sup> If the VE is established in controlled trials and therefore only shows the immediate effect, it is referred to as vaccine efficacy; if the VE is determined in field studies and therefore shows both direct and indirect effects, it is referred to as vaccine effectiveness (cf. Wichmann/Ultsch 2013, 1261 table 1).

The double MMR vaccine prevents the outbreak of measles in 92 to 99 percent of vaccinated persons and usually leads to very long-term immunity.<sup>47</sup> According to a worldwide meta-analysis, the VE of a single dose vaccination against measles has a median of 77 percent for vaccinations between the ninth and eleventh month of life and of 92 percent for vaccination after the first year of life. The VE of a double dose vaccination has a median of approximately 94 percent, independent of the age.<sup>48</sup>

- >>> The number of vaccinations required (number needed to treat / to vaccinate, NNT) indicates how many persons must be vaccinated within a given period of time in order to achieve the desired reduction in morbidity resp. mortality. It is the benchmark for the risk reduction by means of the corresponding vaccination. A higher NNT for a particular vaccination means a lesser reduction of the risk of disease in the vaccinated population.
- The NNT must be compared with the number of vaccinated persons who suffer from an adverse drug reaction (ADR) in the sense that the vaccination causes complications or death (number needed to harm, NNH). The rarer an ADR occurs after a vaccination, the higher will be its NNH. Known possible mild ADRs of the measles vaccination are local swelling at the site of injection or short-term mild general symptoms like headaches or fatigue. They occur in approximately 5 of 100 vaccinated persons. About 2 to 5 of 100 vaccinated persons develop a fever, along with a weak, measles-like rash that is not transmissible to another person.<sup>49</sup>

<sup>47</sup> Cf. the section on prevention and combating measures in the Robert Koch Institute's booklet on measles: https://www.rki.de/DE/Content/Infekt/ EpidBull/Merkblaetter/Ratgeber\_Masern.html [2019-06-04].

<sup>48</sup> Cf. for the VE with single dose vaccination Uzicanin/Zimmerman 2011, S145; for the VE with double dose vaccination ibid., S135.

<sup>49</sup> Cf. the section on possible adverse reactions of the vaccination on the BZgA's Internet portal on vaccination: https://www.impfen-info.de/ impfempfehlungen/fuer-kinder-o-12-jahre/masern [2019-06-04].

There is a widespread recognition that mild ADRs are not opposed to the indication for vaccination.

» The severe ADRs reported of the measles vaccination are an increased risk for fever convulsions<sup>50</sup>, a reduction of the number of blood platelets (thrombocytopenia) that occurs in 1 of 40,000 vaccinated persons<sup>51</sup>, and rare allergic reactions to components of the vaccine.52 No case has been confirmed yet where the attenuated live vaccine that is currently used caused symptomatic infections or measles infections transmissible to other persons.53 Nor could a cause and effect relationship be established between encephalitis and the vaccination.<sup>54</sup> It has been proved that there is no connection between the measles vaccination and autism: the publication from 1997 in which this claim was made was withdrawn and has been rated by almost all authors as containing gross errors and as having intentionally been manipulated.55 Moreover, it has been proved wrong in numerous prospective studies.<sup>56</sup>

An evaluation whether a vaccination is a suitable means to reduce the morbidity and mortality of a given disease is only possible if all the parameters mentioned above are taken into account. In particular, the corresponding vaccination must have a high VE, and the opportunity-risk ratio must be clearly positive.

The extent of the reduction in morbidity among the total population for the respective disease can usually only be estimated by means of mathematical modelling. In this context it must be considered how long the immunisation induced by the vaccination lasts, whether it requires boosts at a later point

<sup>50</sup> Cf. Demicheli et al. 2012, 19.

<sup>51</sup> Cf. France et al. 2008. 52 Cf. Patja et al. 2001.

<sup>53</sup> Cf. Greenwood et al. 2016.

<sup>54</sup> Cf. Tosun/Olut/Tansug 2017.

<sup>55</sup> Cf. e.g. Murch et al. 2004; Éditors of The Lancet 2010.56 Cf. e.g. Hviid et al. 2019.

in time, and whether there is a threat that the vaccination shifts the manifestation of the disease to later decades in life, with a possibly more severe course of disease.

#### 2.2.2 Community immunity (herd immunity)

Community immunity - in epidemiological terminology also referred to as "herd immunity" - describes a condition where also non-immune individuals in the population are protected, because a sufficient number of other people are immune and therefore can no longer transmit the pathogen to unprotected individuals. The immunity of individuals in a population can be acquired either through vaccination or through previous infection with wild viruses. With regard to measles, the latter, "natural" path of acquiring immunity is relevant mainly for the older age groups in Germany. According to the Robert Koch Institute the assumption applies that virtually all people born before 1970 have immunity against measles because they were exposed to the wild virus. Given the fact that this age group becomes demographically less significant, vaccination programmes with a high vaccination coverage become increasingly important in order to achieve or maintain community immunity against measles.

Community immunity can only be achieved for diseases which, like measles, are exclusively transmissible from person to person. It is not possible for contagious diseases that may also be passed on via other paths, e.g. tetanus (transmission through soil bacteria) or tick-borne encephalitis (TBE, transmission through ticks as the pathogen reservoir). The effect of vaccinations against these diseases is therefore limited to the protection of the individual only. Community immunity particularly serves the purpose of protecting vulnerable individuals: those who are yet to young for being vaccinated or those who cannot be vaccinated due to a disease or immunodeficiency (e.g. as a consequence of immunosuppressive therapy in oncology or transplantation medicine, among others) on the one hand, and those who have been vaccinated but have not developed protective antibodies (seroconversion), and therefore have not acquired immunity. However, also individuals who have not been vaccinated although there is no medical reason, and who thus profit from other people's willingness to be vaccinated without contributing their share, benefit from community immunity - independent of the question whether they are willing to be vaccinated in principle, but have not been reached by vaccination offers, or whether they consciously do not want to make use of the vaccination offers accessible for them. In order to protect from infection also the unvaccinated vulnerable individuals and the vaccinated individuals without seroconversion mentioned above by means of sufficient community immunity, increased efforts are required to achieve an adequately high vaccination coverage.

The vaccination coverage required to achieve effective community immunity depends on the contagion index of a contagious disease, i.e. on the question of how easily transmitted it is. The higher the average number of unprotected individuals who get infected by an ill person or by a symptom-free, but contagious person within a specific period of time under the given epidemiological conditions (school, home for the elderly, family etc.), the higher is the "herd immunity threshold" (HIT). This threshold indicates how large the share of people immune to the disease must be in order to achieve community immunity. For measles, this threshold is at 91 to 94 percent, for poliomyelitis it is at 80 to 86 percent.<sup>57</sup> The herd immunity threshold is not the same as the vaccination coverage rate of the corresponding disease, but defines the necessary percentage of actually immune people among the population.

In this context the strategic problem arises for all vaccination programmes that through their successful implementation the number of circulating wild viruses decreases. This in

<sup>57</sup> Cf. Plans-Rubió 2012, 185.

turn implies that the relative share of people among the population requiring vaccination in order to achieve immunity increases. The development of vaccines is possible for a multitude of pathogens causing banal infections, e.g. adenoviruses, but the natural course of an infection through a wild virus is usually without consequence in these cases, so there is no need for a vaccine. Given the harmfulness of measles, it is not acceptable to tolerate such "natural", but by no means harmless infections in the context of preventive medicine.

Even if community immunity exists in one's own country, it is possible through mobility due to migration or tourism that pathogens are "exported" from populations with prevalent infections to regions where this contagious disease is not or no longer endemic. Such epidemics are particularly dangerous because they catch the health systems of the "receiving countries" by surprise. This is why they might not immediately be recognised, fought and curbed. For example, a measles epidemic raged in Bulgaria from 2008 until 2011, with over 24,000 diseased people and 24 deaths.<sup>58</sup> Its origin was a local measles outbreak in Hamburg.<sup>59</sup> In 2018, measles viruses were "exported" from Germany to Guatemala on the occasion of a students' exchange. Guatemala had previously been measles-free for 20 years.<sup>60</sup>

# 2.3 Preventive medicine targets of vaccinations and vaccination programmes

Vaccinations serve several purposes: Firstly, they protect the vaccinated person him- or herself, who acquires immunity through the vaccine. Secondly, they serve the common good in

<sup>58</sup> Cf. Muscat et al. 2016.

<sup>59</sup> Cf. Mankertz et al. 2011.

<sup>60</sup> Cf. Pan American Health Organization/World Health Organization 2018, 2.

solidarity, because they help to build up community immunity in one's own country and prevent that the disease is exported into other populations. Thirdly, for suitable diseases, they enable the global eradication and therefore protection of future generations.

Vaccinations therefore pursue four aims, which are not competing with each other, but which complement or are mutually dependent on one another in several ways:

#### Individual prevention

Carrying out or receiving a vaccination in order to avoid the individual risks due to an infection and the threat of suffering secondary health damages for the vaccinated person him- or herself. The practical requirement to do so is an effective, available and affordable vaccine. From a medical perspective it is necessary that, depending on the harmfulness of the disease, the relation between protective effect and risks is positive.

A special form of individual prevention are vaccinations that are not generally recommended, but are provided as an "indication vaccination" for a specific reason, e.g. in case of risk exposure in one's profession, before journeys to regions where a particular disease is endemic, or if the person belongs to a specifically vulnerable group (e.g. vaccination against yellow fever or rabies).

#### Population prevention

Vaccination with the aim of building up or maintaining community immunity. Primary objective is the well-being of people with a reduced or yet non-existent immunity (e.g. infants before their first dose of vaccine or transplant recipients undergoing immunosuppressive therapy). The location or identity of people benefiting from such protection might be clearly defined (e.g. other children in the day-care centre; patients of a doctor) or indefinite (e.g. unvaccinated pregnant women by means of rubella vaccination in men and women in their childbearing years).<sup>61</sup> The aim is to achieve the largest possible population immunity and the reduction or stoppage of pathogen circulation.

For contagious diseases that are transmissible not only from person to person, but also via other paths, like tetanus or TBE, the aim of the vaccination can only be individual prevention, and not community immunity.

#### Global prevention

Vaccination with the – usually implicit – aim of avoiding the export of pathogens into regions where the disease is not endemic. "Imported" infections may have a particularly severe course in regions where they are not endemic. Moreover, they can turn into quickly expanding epidemics in these areas because community immunity is non-existent there. Measles are exemplary for this scenario (see section 2.2.2).

Special cases of global prevention are the comprehensive immunisation of staff in development aid or of people serving in military or ecological deployments overseas, but also vice versa: when refugees or migrants come from world regions with endemic contagious diseases that are not endemic in the receiving country. Tuberculosis prevention has the same target, but since there is no effective vaccine it is achieved by means of medication.

#### Eradication/intergenerational prevention

Vaccination with the aim of globally eradicating those contagious diseases caused by pathogens with an exclusively human reservoir. For this purpose, vaccination strategies apply that have been devised and are co-ordinated by the WHO at the supranational level, but must be implemented at the national

<sup>61</sup> A special case in the parent-child-relationship are vaccinations in the context of pregnancy, birth and newborns (rubella, varicella, hepatitis-B viruses, influenza, pertussis, measles etc.). They help to avoid a vertical transmission from mother to child, in order to avoid congenital infections (rubella, varicella) and to improve maternal passive immunity.

level. The aim is to not only protect current human populations, but also their descendants in the indeterminate future. If a generation succeeds in eradicating a pathogen that can only be transmitted from person to person (like the smallpox virus), even unborn generations of human beings will not be exposed to the related dangers and are exempt from the corresponding prevention requirements.<sup>62</sup> Given their exclusively human pathogen reservoir and the availability of effective vaccines, measles are a disease that could be eradicated in the future.

#### 2.4 Psychosocial aspects

This section sums up current insights regarding the question which population groups in Germany are *not* vaccinated against measles, and for what reasons.

As can be seen from the second baseline survey of the representative "German Health Interview and Examination Survey for Children and Adolescents" (KiGGS Wave 2) carried out between 2014 and 2017, a coverage of 97.4 percent applies for the first dose of vaccine against measles in children and adolescents between 3 and 17 years of age.<sup>63</sup> The critical herd immunity threshold of approximately 95 percent is achieved in all age groups independent of sex, social status or migrant background. With regard to the second dose of vaccine against measles, this threshold is narrowly missed in almost all age groups as well as in the total cohort (93.6 percent).<sup>64</sup> Compared to the results of the first KiGGS study published in 2007, it is striking that the coverage for the second dose of vaccine against measles, which was low then, could be raised

<sup>62</sup> With regard to zoonoses transmitted by certain animal species, programmes for the sustainable elimination of pathogen reservoirs in these specific species serve the same purpose (e.g. vaccination-baits against rabies for foxes).

<sup>63</sup> Cf. Poethko-Müller et al. 2019, 416.

<sup>64</sup> Cf. ibid.

considerably, e.g. from 73.7 to 93.4 percent in the age group of the 3- to 10-year-olds.<sup>65</sup> However, the most recent data from school entry health examinations show that from 2015 until 2017 no further increase could be recorded for the coverage rates of the second measles vaccination.66

Moreover, there are still vaccination gaps in children and adolescents in specific regions, some of them substantial. With regard to the measles vaccination there are no longer significant differences between the coverage rates in Eastern and Western Germany.<sup>67</sup> Instead, the data of the "Versorgungsatlas" (Health Care Atlas) indicate that there are vaccination gaps in the more prosperous districts in Southern Germany.<sup>68</sup> For example, vaccination coverage in some regions of Bavaria and Baden-Wuerttemberg with a comparatively high household income, low unemployment rates and low health burden is distinctly lower than the German average: This is probably not due to a lack of vaccination offers, but rather to a fairly wide-spread critical attitude towards vaccination by parents and maybe also by doctors or staff in educational institutions. However, the exact reasons for these regional particularities are not known.

As there are no systematic surveys among adults, the data situation regarding the vaccination status of adults in Germany is less precise than that of children, whose status is recorded on the occasion of the school entry health examination. However, there can be no doubt that the vaccination coverage in adults is considerably lower than it is in children and adolescents. The DEGS1 survey of 2013 mentioned above showed that only 25.1 percent of the 40- to 49-year-olds had received at least one dose of vaccine against measles at the time.<sup>69</sup> In addition, it cannot be assumed that individuals born after

<sup>65</sup> Cf. ibid., 417.66 Cf. Robert Koch-Institut 2019, 152.

<sup>67</sup> Cf. Poethko-Müller 2019, 418.

<sup>68</sup> Cf. Goffrier/Schulz/Bätzing-Feigenbaum 2017.

<sup>69</sup> Cf. Poethko-Müller/Schmitz 2013, 849.

1970 are likely to have suffered from measles in their childhood and are therefore immune without vaccination. Also, an analysis of notified cases of measles leads to the conclusion that there are considerable vaccination gaps in adults. For years, a shift in the age distribution towards older age groups has been apparent in the notified cases.<sup>70</sup> In 2018 about half of the people suffering from measles in Germany were adults.<sup>71</sup> As a consequence, adults born after 1970 are referred to as a population group with a particular need for action in the "National Action Plan 2015-2020 to Eliminate Measles and Rubella in Germany".<sup>72</sup> Apparently there is little public awareness of this fact. In a 2016 survey, only a quarter of the respondents in this age group said that they had heard that since 2010 a single dose measles vaccination is recommended for people born after 1970.73

Particular need for action is recommended by the National Action Plan also for individuals who are part of "population groups with potentially insufficient access to health care or born in a foreign country (e.g. Romani people, refugees, asylum seekers)".74 There is evidence that vaccination coverage is lower among children and adolescents who were not born in Germany, which might be due to deficits in the provision of vaccination services in the respective countries of origin.75 However, data from the first KiGGS study have shown that a migrant background as such is *not* an indication that children and adolescents have lower vaccination coverage.<sup>76</sup> For example, according to the last survey carried out from 2014 until 2017, the vaccination coverage desired to achieve community immunity was found for the second dose of measles vaccine

<sup>70</sup> Cf. Bundesministerium für Gesundheit 2015, 17.

<sup>71</sup> Cf. https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ elimination\_04\_01.html [2019-05-13].

<sup>72</sup> Cf. Bundesministerium für Gesundheit 2015, 7.

<sup>73</sup> Cf. Horstkötter et al. 2017, 13.

<sup>74</sup> Bundesministerium für Gesundheit 2015, 24.

<sup>75</sup> Cf. Schenk et al. 2008, 116. 76 Cf. ibid.

only in the group of children and adolescents who have one parent with a migrant background, where this rate reached a level of 95.9 percent. Children and adolescents who have no parent with a migrant background, however, fail to reach the desired rate, as do children and adolescents whose parents both have a migrant background (93.6 resp. 93.2 percent).77 Culture-specific reservations of parents of children and adolescents with a migrant background have only been shown to exist with regard to specific vaccinations like the HPV-vaccination.<sup>78</sup> Across all social classes, parents with a migrant background less frequently raise objections against the vaccination of a child than do parents of children and adolescents without a migrant background.79

As far as the attitudes of the total population with regard to vaccinations are concerned, roughly three quarters of the population (77 percent) may be considered as generally being in favour of vaccinations, according to a representative survey by the Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education, BZgA) published in 2017; 18 percent have "at least some reservations towards vaccination", 3 percent "rather reject" vaccinations and 2 percent "reject" vaccinations.<sup>80</sup> Compared to previous studies from the years 2012 and 2014 the share of people supporting vaccination has increased significantly, whereas that of people opposing vaccination has decreased. The share of those who "rejected" or "rather rejected" vaccination was at 8 percent in 2012.81 Regarding the measles vaccination, 57 percent of parents in this survey said that immunisation of their child against measles was "particularly important" for them, 34 percent said it was "important". Merely 8 percent of the parents surveyed (4 percent of the women, compared to 15 percent of the men) stated

<sup>77</sup> Cf. Poethko-Müller 2019, 416.78 Cf. ibid., 419.

<sup>79</sup> Cf. Schenk et al. 2008, 117.

<sup>80</sup> Cf. Horstkötter et al. 2017, 31.

<sup>81</sup> Cf. ibid., 32.

that they considered immunisation against this disease "not so important" for their child.  $^{\mathtt{82}}$ 

If one intends to improve the acceptance of vaccinations and thus increase vaccination coverage, it is necessary to know in more detail the factors on which individual vaccination decisions depend. Psychologists analyse these factors and sum them up in models that help to understand, address and remove reservations and obstacles against vaccinations.<sup>83</sup> The so-called "5C model" is illustrated below, as it encompasses various older models and can therefore be considered as particularly comprehensive.<sup>84</sup> The five "C"s stand for five terms which are deemed to name the essential reasons for individual vaccination decisions: "Confidence (trust), Complacency (risk-awareness), Constraints (barriers to uptake), Calculation (extent of information seeking), and Collective Responsibility (sense of responsibility for the community)".<sup>85</sup>

In what way the fundamental question about confidence in the national authorities or the health system plays a role in every vaccination decision shall be elaborated in more detail in the section on ethics below. In the context of the 5C model, the "confidence" factor refers to effectiveness and safety of vaccines on the one hand, and to the trustworthiness of public vaccination recommendations on the other hand.<sup>86</sup> Two examples from the BZgA survey on infection protection showing a lack of trust are of particular importance in this context: In 2016, only 57 percent of the respondents "fully" or "rather" agreed to the statement that they trust "national authorities to always decide in the best interest of the public" as far as vaccination offers are concerned. Merely 56 percent "fully" or "rather" agreed to the statement that they have "complete

<sup>82</sup> Cf. ibid., 172.

<sup>83</sup> For a helpful overview of current psychological models for vaccination decisions see Betsch et al. 2018.

<sup>84</sup> Cf. Betsch et al. 2019, 400.

<sup>85</sup> Ibid. [Translator's note: Key words in English taken from the German original.]

<sup>86</sup> Cf. ibid., 401.

confidence in the safety of vaccines".<sup>87</sup> If you focus exclusively on the group of those with a "(rather) adverse" attitude towards immunisation, only 19 percent state that they have confidence in national vaccination recommendations and a mere 9 percent trust that vaccinations are safe.<sup>88</sup>

The obvious reaction towards the distrust which can be inferred from these survey results is to launch information campaigns. Information offers on the topic of immunisation that are evidence-based and understandable for laypersons have been around for quite some time.<sup>89</sup> Especially in the internet, however, reputable sources of information compete with websites spreading wrong information about vaccinations with the aim of compromising their acceptance. This is why scientists demand that the education on immunisation itself should be complemented with information on the rhetoric used by anti-vaccinationists trying to make their view of the matter appear reasonable.90 Having said that, it should be mentioned that better knowledge does not automatically lead to greater confidence. This is evident in the fact that health care staff as the population group who should be most competent in judging vaccination safety and the appropriateness of public vaccination recommendations does not have greater confidence in the vaccination system than the average population. Only 55 resp. 52 percent of medical staff agree to the statements mentioned above.91

The factor "complacency" points towards a lack of risk-awareness. The awareness of the risks related to a specific

<sup>87</sup> Cf. Horstkötter et al. 2017, 33.

<sup>88</sup> Cf. ibid., 37.

<sup>89</sup> Cf. first and foremost the BZgA's Internet portal on vaccination: https://www.impfen-info.de [2019-05-13]. The information offered by the Robert Koch Institute, on the other hand, mainly targets medical professionals. Nevertheless, their answers to the 20 most frequently raised objections against immunisation, elaborated jointly with the Paul Ehrlich Institute, are very helpful: https://www.rki.de/DE/Content/Infekt/Impfen/ Bedeutung/Schutzimpfungen\_20\_Einwaende.html [2019-05-13].

<sup>90</sup> Cf. Betsch et al. 2019, 403 f.

<sup>91</sup> Cf. Horstkötter et al. 2017, 38.

contagious disease decreases if that disease only rarely occurs, because people lack the personal experience. Which means that a vaccination campaign can become the victim of its own success, because the motivation to get vaccinated against a certain disease keeps declining the closer one gets to the ultimate target of eliminating this disease.<sup>92</sup> Such an effect could also occur in the case of measles vaccination. In the BZgA survey of 2016 about 12 percent of the adult respondents said that they did not get vaccinated up until then because they did not consider measles to be a very severe disease.<sup>93</sup> At least it can be said that the share of adults holding this view has been cut by half since 2012.94 The awareness of a disease's seriousness and of its possible complications can generally be raised by means of corresponding information campaigns. However, it is important to take into account psychological insights on effective strategies to influence risk-awareness when designing such campaigns. For example, there are indications that "fear appeals, i.e. anxiety-producing pictures of children with measles, [can] trigger a boomerang effect and lead to a lower willingness to be vaccinated".95

Not all individuals whose immunisation falls short of the recommendations can be called vaccination sceptics. For some of them the actual intention to get vaccinated themselves or to have their children vaccinated fails because of practical barriers ("constraints" – other models refer to this factor as "convenience").<sup>96</sup> In the BZgA survey, 13 percent of the respondents either fully or rather agreed to the statement that everyday stress prevented them from getting vaccinated, and 9 percent said that it would be a great effort to get vaccinated.<sup>97</sup> With regard to the vaccination of children, 9 percent of the parents said they

95 Cf. Betsch et al. 2019, 405.

<sup>92</sup> Cf. Betsch et al. 2019, 405.

<sup>93</sup> Cf. Horstkötter et al. 2017, 108.

<sup>94</sup> Cf. ibid., 109.

<sup>96</sup> Cf. ibid., 401.

<sup>97</sup> Cf. Horstkötter et al. 2017, 33.

had missed the vaccination of a child because they had simply forgotten about it in the hustle and bustle of everyday life; 3 percent claimed that it was not possible for them to see a doctor with the child for lack of time or for organisational reasons.<sup>98</sup>

People with a distinct "calculation" factor are actively and extensively looking for information in order to be able to exactly assess the benefits and risks of vaccinations. In the BZgA survey, 51 percent of the respondents fully agreed to the statement "When I consider being vaccinated, I carefully weigh the benefits and risks", and another 17 percent said they "rather agreed" to this statement.<sup>99</sup> As a rule, people with a great need for information but without ideological reservations can be reached by means of information and education campaigns. However, they, too, run the risk of stumbling across dubious sources of information, leading them to rather overestimate the risks of vaccinations and show a lower willingness to be vaccinated than the average population.<sup>100</sup>

The fifth factor is "collective responsibility". It refers to the sense of responsibility for the community and the willingness to be vaccinated oneself and to have one's children vaccinated in order to contribute to the protection from infection of others.<sup>101</sup> This attitude presupposes that the concept of community immunity is familiar in the first place. According to the BZgA survey of 2016, this is true for 71 percent of the respondents.<sup>102</sup> Two further questions were intended to assess the participants' sense of responsibility for the community. 4 percent of the respondents fully agreed and another 2 percent rather agreed to the statement: "When everybody is vaccinated there is no need for me to get vaccinated, too." On the other hand, 78 percent did not agree to this statement.<sup>103</sup> The second statement read

<sup>98</sup> Cf. ibid., 150.

<sup>99</sup> Cf. ibid., 33.

<sup>100</sup> Cf. Betsch et al. 2019, 406.

<sup>101</sup> Cf. ibid., 401.

<sup>102</sup> Cf. Horstkötter et al. 2017, 64.

<sup>103</sup> Cf. ibid., 66.

as follows: "I get vaccinated to also protect others who cannot or do not want to get vaccinated." Of the respondents, 36 percent fully agreed and another 16 percent rather agreed to this statement. 24 percent were undecided with regard to this statement, 7 percent did rather not agree and 17 percent did not agree.<sup>104</sup> Psychological research findings on this factor point out that learning about community immunity increases the willingness to be vaccinated, provided that the risks to which you are exposed are considered low. Moreover, it does seem to play a role whether the others, for whose protection one is getting vaccinated, *cannot* be vaccinated (e.g. for health reasons) or whether they do not want to get vaccinated (e.g. because they shy away from the risks of vaccination). When campaigns are designed to appeal to the collective sense of responsibility, it is therefore important to highlight that by means of a high vaccination coverage "involuntarily unvaccinated individuals can also be protected"105.

To conclude, the role of doctors must be addressed. In the surveys on infection protection by the BZgA in the years 2012, 2014 and 2016, those adults born after 1970, who said they were not yet vaccinated against measles, were asked why this was so. The most common answer by far was that the necessity of a vaccination had not been pointed out to them. However, since it is not known whether the respondents had seen a doctor at all, this fact does not allow to conclude that this is a failure on the part of doctors.

It is very rare for doctors to discourage adults from getting vaccinated. In 2016, only 1 percent of the respondents said that their doctor had discouraged them to get vaccinated, compared to 3 percent in 2012.<sup>106</sup> For children, this seems to be the case more frequently. Parents who had been asked for the reasons why their child was not vaccinated said in 19 percent of

<sup>104</sup> Cf. ibid., 67.

<sup>105</sup> Betsch et al. 2019, 406.

<sup>106</sup> Cf. Horstkötter et al. 2017, 108.

the cases that their doctor had discouraged them from having their child vaccinated.<sup>107</sup> The survey does not reveal whether medical contraindications were present in these cases.

<sup>107</sup> Cf. ibid., 149.

#### **3 NORMATIVE ANALYSIS**

The following normative considerations on an adequate way to deal with existing deficits in the field of measles immunisation take up the current (health) political debate focussing on the question whether a duty to vaccinate against measles should be introduced, and if so, for whom, under what conditions and how it should be implemented. However, they go beyond the current state of debate by elaborating legal and ethical arguments on the basis of a clarification of the ambiguous term "duty to vaccinate". These arguments must be taken into account when regulations with the aim of increasing vaccination coverage for measles are meant to be introduced.

# 3.1 Dimensions of the term "duty to vaccinate"

The ambiguous term "duty to vaccinate" can be understood either in the *moral* or in the *legal* sense. A duty to vaccinate in the narrow sense, meaning a mandatory vaccination policy imposed by the state, requires that two conditions are met: Firstly, the group(s) of persons who are obliged to mandatory vaccination must be clearly defined. Secondly, the tools to sanction possible violations of regulations need to be determined.

With regard to the obliged group of persons and therefore the *addressees of a regulation*, at least three distinctions must be made: First of all it must be clarified whether all people shall be vaccinated, or only specific groups of persons (e.g. children attending school or day-care, employees of hospitals or day-care centres etc.). Secondly, due regard must be given to the age-related decision-making competency of the persons concerned. For example, there is a difference between mandatory vaccination for adults on the one hand and for children and adolescents on the other hand, because the latter cannot decide whether they should be vaccinated, at least not alone. Rather, it is the person who has custody of the child (usually the parents). Thirdly, a distinction must be made between the primary duty of individuals to get vaccinated themselves and the secondary duty of third persons to guarantee that certain persons are immunised. In the latter sense, the management of a hospital or day-care centre for children can be obliged to ensure that its employees have sufficient immunisation.

Since the violation of a regulation usually has legal consequences, the call for a mandatory vaccination policy requires that the tools for regulation must be precisely defined. They can be categorised as follows: The legal consequences of non-compliance might lead, for instance, to legal disadvantages (e.g. in the form of a bonus-malus system in health insurance or by excluding the disease from health insurance coverage if the insured person is not vaccinated and contracts this disease), to a liability for the damage of third persons (in case they get infected by an unvaccinated person), to the prohibition to attend certain institutions (e.g. child-care centres or schools, for both unvaccinated children and unvaccinated adults), or to work bans (e.g. for unvaccinated teachers or hospital staff). Specific tools for sanctioning cases of violation of a legally enforced mandatory vaccination policy might be fines (administrative offence) or punishments (criminal offence). In order to impose mandatory vaccination, it would be possible to use the means of administrative enforcement, if necessary, up to giving the vaccination by coercive means ("forced vaccination"). Since the parents have custody of the child, they can generally decide to have their child vaccinated or not. However, the parents' autonomy ends where there is a legal duty to vaccinate in conformity with the constitution. In this case, the family court can intervene if the well-being of the child is threatened (Section 1666 BGB [Civil Code]).

In order to counteract a one-dimensional, i.e. purely legal usage of the term "duty to vaccinate", and to keep open the range of measures to increase vaccination coverage step
by step, the next section drafts the legal regulatory framework in order to identify possible leverage points for a constructive further development of the law. As a next step, the most important ethical arguments to justify a moral duty to vaccinate shall be elaborated.

## 3.2 The legal regulatory framework

#### 3.2.1 Applicable basic law

There is no provision for mandatory vaccination in the narrow sense in applicable law, apart from the special provision for soldiers in Section 17 (4) sentence 3 of the *Soldatengesetz* (Soldiers' Act)<sup>108</sup>. Section 28 (1) sentence 3 of the Protection against Infection Act (IfSG)<sup>109</sup> prohibits that a person is forced to submit to curative treatment. Nevertheless, the Federal Ministry of Health is empowered, pursuant to Section 20 (6) IfSG, to determine by means of an ordinance "that those segments of the population that are at risk have to undergo vaccinations or other measures of specific prophylaxis if a communicable disease occurs that takes a severe clinical course or can be expected to take on the proportions of an epidemic".<sup>110</sup> Quite apart from the question whether it does not have to be the legislator who can impose forced vaccination – and who may not delegate

<sup>108</sup> Gesetz über die Rechtsstellung der Soldaten (Legal Status of Military Personnel Act) of 30 May 2005 (BGBl. I, 1482), last amended by Article 10 of the Act of 11 December 2018 (BGBl. I, 2387).

<sup>109</sup> Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Act on the Prevention and Control of Infectious Diseases in Man) of 20 July 2000 (BGBI. I, 1045), last amended by Section 14b of the Act of 6 May 2019 (BGBI. I, 646). [Translator's note: English translation used for quotes throughout this document, taken from https://www.rki.de/ EN/Content/infections/inf\_dis\_down.pdf?\_\_blob=publicationFile (2020-04-14).]

<sup>110</sup> Where the Federal Ministry of Health does not avail itself of the powers conferred upon it, Section 20 (7) IfSG provides that the governments of the federal states shall be empowered to issue such ordinance, who in turn may delegate the power to act by means of an ordinance to the states' supreme health authorities.

these powers to the executive branch –, the power to issue statutory instruments mentioned above does probably not justify the establishment of a general forced vaccination. The criterion "segments of the population that are at risk" shall have to be understood as a reference to groups of persons with a likely risk of infection in case of an actual outbreak of a disease. Section 20 IfSG clearly follows a tiered approach: As a rule, vaccinations are explained (1) and recommended (3). Only in the event of an actual outbreak, the option of imposing vaccinations exists as a means of last resort (6). Such an order must be limited to the purpose of preventing a disease from spreading further. It is not intended to bring about community immunity.<sup>m</sup>

Current applicable law does not provide regulations to impose mandatory vaccinations that are aimed at prevention and can be sanctioned in case of violations. Instead, the government largely relies on counselling that provides information and recommendations, but may also be binding. In 2015, an instrument has been introduced that provides for slightly stricter regulations, namely the so-called Präventionsgesetz (Prevention Act)<sup>112</sup>. Pursuant to Section 34 (10a) IfSG, when a child is registered to attend a day-care centre, proof must be submitted that a doctor has previously given advice on immunisation. If no such proof is provided, the health authorities can - but do not have to - summon the persons who have custody of the child to a consultation. Pursuant to Section 35 sentence 1 IfSG, persons who exercise any teaching, educational, caring, supervisory or other regular activities in facilities in which predominantly infants, children and young people are cared for ("community facilities")<sup>113</sup>, and have contact with the persons

<sup>111</sup> Cf. Höfling/Stöckle 2018, 293 f.

<sup>112</sup> Gesetz zur Stärkung der Gesundheitsförderung und der Prävention (Act to Strengthen Health Promotion and Prevention) of 17 July 2015 (BGBI. I, 1368).

<sup>113</sup> In Section 33 IfSG, community facilities within the meaning of Section 35 are defined as "facilities in which predominantly infants, children and young people are cared for, particularly day nurseries, kindergartens, infant day-care centres, day-care centres for school-age children, schools or other educational facilities, homes, holiday camps and similar facilities".

taken care of there, must be instructed by their employer about the health requirements and obligations to co-operate under Section 34 IfSG before they first take up their duties, and subsequently at a maximum interval of two years. In Section 34 IfSG work bans, among other measures, are formulated with regard to persons who are "household contacts" of any individual whom medical opinion deems to be a case or suspect case of measles (Section 34 (3) no. 7 IfSG).

Moreover, the Protection against Infection Act as a "specialized act of applied epidemiology"<sup>114</sup> is intended to detect and interrupt infection chains on the basis of tiered possibilities of intervention. It provides a structure for different processes of surveillance, e.g. by defining notifiable facts and cases and by granting authority to collect data.<sup>115</sup>

In this informational action system, the Standing Committee on Vaccination (STIKO) is the crucial stakeholder where external specialist knowledge is pooled (Section 20 (2) IfSG). The STIKO's recommendations, although they come in the form of recommendations<sup>116</sup>, have some far-reaching normative consequences. They are the foundation for the recommendations to be issued by the supreme health authorities of the federal states with regard to vaccinations, among others (Section 20 (3) IfSG), which in turn are the prerequisites for compensation claims (Section 60 (1) sentence 1 no. 1 IfSG)<sup>117</sup>. The STIKO's recommendations also serve as a basis for the decisions of the Federal Joint Committee pursuant to Section 20d (1) sentence 3 SGB V<sup>118</sup> regarding the requirements, type

<sup>114</sup> Rixen 2011, 70.

<sup>115</sup> As an overview ibid, 70 ff.; see also Pflug 2013, 123 ff.

<sup>116</sup> Cf. Zuck 2017.

<sup>117</sup> The Impfentschädigungsrecht (vaccination compensation law) is the specialist legal expression of the former traditional, so-called Aufopferungsanspruch: Compensation following infringement of non-property rights suffered in "sacrifice for the common good".

<sup>118</sup> Sozialgesetzbuch Fünftes Buch – Gesetzliche Krankenversicherung (Book V of the Social Code – Statutory Health Insurance) of 20 December 1988 (BGBI. I, 2477), last amended by Section 1, 2 of the Act of 6 May 2019 (BGBI. I, 646).

and scope of vaccinations as item in the statutory health insurances catalogue of required services. Moreover, they are acknowledged in the jurisdiction of the Bundesgerichtshof (Federal Court of Justice) as a medical standard.<sup>119</sup> In addition, the STIKO's recommendations may play an important role in the case of parental conflicts regarding the vaccination of a child. In 2017, the Federal Court of Justice confirmed that in the event of a conflict of opinions between parents, the decision-making power will be transferred to the parent who intends to follow the STIKO's recommendations.<sup>120</sup>

The governance structure of the German vaccination system builds on the infection protection law, which is interconnected with multiple regulations, e.g. in the laws of the federal states on public health care services. Moreover, there are regulatory instruments in private law (in particular in liability law and insurance law), as well as criminal penalties. The latter may, for example, be applicable in the case of so-called "measles parties", where unvaccinated children are purposely exposed to an infection with wild viruses.<sup>121</sup>

# 3.2.2 The constitutional justification of the empowerment of national authorities to take further-reaching measures

The introduction of a mandatory vaccination policy has become the subject of increasing debate in Germany and is being called for by the Federal Ministry of Health and the Bundesärztekammer (German Medical Association), among others. From the perspective of constitutional law, it must first

<sup>119</sup> Cf. the decision of the Federal Court of Justice of 3 May 2017 (XII ZB 157/16) in NZFam 2017, 561 (para. 25) with reference to the judgement of the Federal Court of Justice of 15 February 2000 (VI ZR 48/99) in BGHZ 144, 1; cf. also Makoski 2017, 224 f.

<sup>120</sup> Cf. the decision of the Federal Court of Justice of 3 May 2017 (XII ZB 157/16) in NZFam 2017, 561.

<sup>121</sup> Cf. Wedlich 2013.

of all be stated that the current legal regulations do not raise any fundamental concerns. It is true that the legislator has the duty to protect the population's health, which is conveyed to it by the constitution and welfare-state regulations. However, there is considerable scope for interpretation and action with regard to the design of the protection scheme, and especially the choice of particular measures. Against this background, there is no reason to object to the current regulations, at least not to those aimed at combating measles. However, this does not answer the question of whether the legislator *would be allowed* to introduce "strict" mandatory vaccination regulations that go beyond current law.

With particular regard to mandatory vaccination for (young) children, both the basic right of the child to life and physical integrity guaranteed under Article 2 (2) GG (Basic Law) and the rights of parents under Article 6 (2) sentence 1 GG have to be taken into account. The crucial benchmark for the assessment of this question is the right of parents pursuant to Article 6 (2) sentence 1 GG. As a fundamental fiduciary right, it obliges parents to orient their care and education efforts towards the child's well-being.<sup>122</sup> However, parents have a prerogative of interpretation and primary responsibility. They are in principle allowed to "decide free of state influence and according to their own ideas how they wish to live up to their responsibility as parents".<sup>123</sup> Fundamentally, parental right also includes the right to decide whether their children should get vaccinated against measles. This means that making vaccination mandatory constitutes an interference with parental rights. As such it would only be legitimate in the context of the state's supervisory function (Article 6 (2) sentence 2 GG) and would have to

<sup>122</sup> Cf. the judgement of the Federal Constitutional Court of 1 April 2008 (1 BvR 1620/04) in BVerfGE 121, 69 (92).

<sup>123</sup> Cf. the judgement of the Federal Constitutional Court of 16 January 2003 (2 BvR 716/01) in BVerfGE 107, 104 (117). [Translator's note: English translation taken from http://www.bverfg.de/e/rs20030116\_2bvr071601en.html (2020-09-29).]

adhere to the principle of proportionality in a broader sense. In other words, said interference must be suitable, necessary and appropriate in respect of the – indisputably legitimate – objectives of the vaccination, i.e. protecting public health, the health of children and the health of particularly vulnerable population groups. Firstly, the *suitability* of the introduction of mandatory vaccination must be questioned.<sup>124</sup> Although possible negative side effects that may go along with the introduction of mandatory vaccination must be taken into account, the legislator still has a large scope of interpretation. Its limits are only exceeded if the legislator's considerations are too faulty to offer a sensible basis for the measures it has taken.<sup>125</sup> In the present context, such a claim of unsuitability is not valid.

The assessment whether the introduction of a sanctionable mandatory vaccination policy is also necessary requires an answer from the perspective of constitutional law to the question whether there is a feasible regulation that interferes less drastically with concepts of basic law like physical intactness and parental rights than the introduction of mandatory vaccination, but provides an equally effective protection of physical integrity. With a view to information and education campaigns, the legislator again has some scope of interpretation and action, and can take into account - among other aspects - that a successful prevention programme may become the victim of its own success. This paradox of effective prevention<sup>126</sup> and the problem of a distorted risk-awareness, i.e. the risks of vaccination tend to be perceived as more severe than the risks of infection, do not allow for a reliable prediction that vaccination policies below the threshold of the introduction of mandatory vaccination achieve the same preventive effect.

<sup>124</sup> On the following point, cf. Höfling/Stöckle 2018.

<sup>125</sup> Cf. the judgements of the Federal Constitutional Court to that effect: judgement of 16 March 1971 (1 BvR 52/66, 1 BvR 665/66, 1 BvR 667/66, 1 BvR 754/66) in BVerfGE 30, 292 (317) and of 30 July 2008 (1 BvR 3262/07, 1 BvR 402/08, 1 BvR 906/08) in BVerfGE 121, 317 (350).

<sup>126</sup> Cf. Meyer/Reiter 2004, 1186 f.

This leads to the decisive question whether the introduction of mandatory vaccination is *appropriate*. It is not possible to answer this question without considering the normative design of such a duty, especially with regard to the instruments chosen to impose it.

Any interference with parental rights by the family court that strips parents of their right to decide about vaccinations and transfers it to a supplementary curator, or any vaccination being forcibly carried out on a child, does not seem justifiable under the present circumstances, especially since such a procedure might traumatise the child.<sup>127</sup> Accordingly, linking school attendance to a previous measles vaccination also appears questionable. However, a possible constitutionally permissible design for a "hard" mandatory vaccination policy could comprise a regulation that makes children's attendance at day-care facilities (child-care centres, childminders) or the operating licenses of such facilities contingent upon proof of sufficient immunisation against measles.<sup>128</sup>

Considering parental rights, it must be heeded that national authorities do not simply presume a right to overrule the parents' decision about the reasonableness of a protective vaccination. Rather, in the case of measles vaccination, the introduction of mandatory vaccination aims to bring about community immunity (herd immunity) as an important objective in the public interest (see section 2.2.2), and thus goes beyond the individual child (in contrast to vaccination against tetanus, for example).

Besides children, adults should also be considered as addressees of a mandatory vaccination policy. For example, it

<sup>127</sup> Differing appreciations of constitutional law regarding a (not further specified) mandatory vaccination policy: opposed, cf. Trapp 2015; in contrast cf. Höfling/Stöckle 2018; justification through constitutional law considered feasible: Deutscher Bundestag 2016a.

<sup>128</sup> In order to guarantee the equal treatment of the children, all child-care centres would have to be obliged to check the vaccination status, independent of their (ideological) orientation, and to pay a fine in case of non-compliance.

might be reasonable to prohibit persons without proof of immunity or vaccination from being employed in jobs where their daily work involves dealing with people for whom a measles infection would pose a particularly high risk of serious illness or even death. A mandatory vaccination policy of this kind does not appear to be constitutionally inadmissible from the outset. Depending on the design of such a policy, the restriction of the freedom of profession can be more or less severe. It can refuse access to a profession completely, or it can merely limit the specific activity of the person concerned. In any case, the interference must be proportionate to the intended purpose. For all scenarios where a mandatory vaccination policy is designed in a way that does not leave the obliged person an (acceptable) alternative, strictly limited and individually justified exception provisions - apart from documented and medically justified exemptions - should be provided for persons who base their (intersubjectively comprehensible) attitude on religious or ideological reasons.

### 3.3 Ethical assessment

An ethical analysis of the above-mentioned challenges regarding measles immunisation in Germany must fulfil at least the following four requirements: *Firstly*, it must precisely define the ambiguous term "duty to vaccinate" and clarify its argumentative preconditions in the knowledge that various regulatory instruments exist and that the interrelatedness of ethics and law is multi-faceted. *Secondly*, it must adequately take account of the particularities of those groups of persons who currently show the largest vaccination gaps. *Thirdly*, with regard to the factual accessibility of these groups, it must identify the most important barriers that have so far prevented an increase in vaccination coverage. *Fourthly* and finally, it must verify whether the recommended measures are actually suitable to achieve the desired objective.

#### 3.3.1 Ethos and law

The term "duty to vaccinate" is often associated with the idea that the state imposes this duty by law and in extreme cases enforces it by means of coercion. In cases where mandatory vaccination is not only justified by the health and well-being of the individual, but serves the purpose of establishing a common good, i.e. the desired community immunity, the only alternative to a legal duty to vaccinate is often considered to be individual discretion. However, human behaviour is subject to a variety of regulatory mechanisms, which cannot be adequately described by the common distinction between legal provisions or coercive measures imposed by the state on the one hand and individual discretion on the other hand. In everyday life, what is of crucial importance are first and foremost those social phenomena that have been summed up in the term "morals" (Greek *ethos*, Latin *moralis*, from \**mos*) since Aristotle. Morals are understood to be the "ensemble of conventionalities"<sup>129</sup> (within a group) linked to various rules of behaviour. These rules of behaviour are not only familiar to the individual actors, but it is mutually expected that all group members adhere to them. Such expectations may be disappointed if they are not complied with, but they will not be "refuted". This means that moral rules are still considered valid although someone contravened against them, and even if this is quite frequently the case. Violations of the rules are usually sanctioned by a more or less strong form of social disintegration, from reprimanding or avoiding someone up to completely giving up any social contact with them. In contrast to the regulation of human behaviour through ethos, law is an independent sphere of normative claims. As regards the history of its development, law is a secondary phenomenon which has evolved in a multi-stage process from morals,<sup>130</sup>

<sup>129</sup> Marquard 1986, 123.

<sup>130</sup> Cf. Gethmann1982, 130-135.

which in themselves are multi-faceted. Despite its increasing institutionally safeguarded autonomy, law remains permanently linked to certain forms of ethos. Regarding the relation between morals and law, which can be tense at times, it is often postulated that social regulation of behaviour by means of moral rules can be attributed to a primitive phase of cultural history, whereas it has been almost completely replaced by the rules of law in the process of modernisation. However, this position does not recognise that orientation for most lifeworld actions still comes from the sphere of morals, while law merely offers guidance for those dramatic marginal cases that, for various reasons, require specific regulation or sanctions. For example, the lifeworld rule of truthfulness is not generally subject to legal control, but only in specific contexts. Only a false statement (under oath or not) before court will be sanctioned. The same is true for the lifeworld promise, in contrast to an explicit contract.

This division of labour between *ethos* and *law* has consequences for the dazzling talk of "duty to vaccination", which can be either understood in the sense of a *duty of virtue*, attributable to the field of ethos, or in the sense of a strict *duty of right*, or legal duty.<sup>131</sup> If the demand for a general duty of vaccination was conceived as a strict legal duty (*duty of right*), then the constitutive attributes of inescapability, enforceability and unambiguity would apply,<sup>132</sup> which would lead to a number of highly problematic consequences: The simple fact that a vaccination can be medically contraindicated in specific cases makes a general *inescapability* appear inappropriate. If a mandatory vaccination would be laid down by means of rules of law, these cases would need to be exempted at the outset.

<sup>131</sup> In "The Metaphysics of Morals" Immanuel Kant refers to moral rules under the notion of "imperfect duties" (MS, AA VI, 388 ff.). The attribute "imperfect" hints at the fact that Kant sees the moral duties/rights as deficient modes of the rules of law. By contrast, it is assumed herein that morals are the *point de départ* and the intuitive control authority for assessing whether the law is adequate.

<sup>132</sup> According to Kant, loc. cit.

Moreover, in the event of a statutory mandatory vaccination policy, the police would have to take patients to the health authorities by force in extreme cases. Such enforceability appears disproportionate and therefore inappropriate, both for minors, whose parents are opposed to vaccination, and for adults, who for whatever reason refuse to be vaccinated. Finally, the prognosis on propagation paths and propagation speed of communicable diseases as well as the determination of the vaccination coverage rate required to ensure community immunity are based on the current state of research. Although revolutionary scientific insights on the measles pathogen are not likely, the development of new anti-viral therapies - currently not in sight – might change the situation, for example, and make it necessary to re-evaluate the justification of certain sanctions. A regulatory regime that is open for new scientific findings in the first place goes against the requirement of normative unambiguity. Overall, from an ethical point of view, priority should be given to a regulation within the framework of socially binding rules of ethos. This assessment could change if special situations of emergency arise. For example, it could be justified to turn duties of virtue into strict legal duties if an acute health hazard threatening large parts of the population required rigid interventions.

Ethos and law are mutually interrelated in many respects. For example, if in our context infection protection law requires parents upon the registration of their children in a child-care centre to submit proof that a doctor has given them advice on vaccination (Section 34 (10a) IfSG), this may be interpreted as a legal-technical corroboration of a moral duty to vaccinate, which links non-conforming behaviour to the onus of justification. Moreover, the different types of obligation can also co-exist, depending on the group of people concerned and the given context of action. For example, there is no contradiction in merely appealing to the parents' sense of moral responsibility in order to increase vaccination coverage in children, while calling for mandatory vaccination enforced by appropriate

sanctions for medical personnel who have contact with highly vulnerable people.

Members of some groups put forth religious or ideological reasons against a duty to vaccinate justified on moral grounds. They refer to human life as conforming with creation or to the naturalness of human life and its processes of maturation. In principle, every individual should be free to live their lives according to their own individual religious and ideological convictions. This freedom has its limits, however, when the consequences of their actions affect the legitimate interests of other people. This not only applies to the execution of actions, but also their omission. Anyone who fails to get vaccinated (or fails to have those for whom he or she is responsible vaccinated) against measles is very likely to cause harm to (possibly unknown) others. Thus, freedom of faith or conscience cannot be invoked to justify an avoidable threat to third parties.

On the basis of the considerations given above it is recommendable to interpret the claim to validity of mandatory vaccinations in the context of *moral rules*. To get one's children vaccinated or to ensure one's own immunisation should be an element of common preventive health care. Anyone who contravenes against this common standard must expect to be confronted about it. Having to justify oneself is the way by which a violation of moral duties is sanctioned. Independent of what has been said, there might be valid reasons under specific circumstances or for certain groups of persons to think about a stricter *legal duty to vaccinate*, which would require separate justification, however.

# 3.3.2 Deliberations concerning specific groups of persons

The groups of persons with currently the largest vaccination gaps in Germany differ significantly from one another, also with regard to ethically relevant characteristics. This is why - keeping in mind particular vulnerabilities – the following section will first deal with minors, who are not yet fully capable of self-determination, and then focus on the heterogeneous group of adults with insufficient immunisation.

It is important to pay careful attention to particular forms of vulnerability of the persons concerned. Vulnerable groups are groups of persons who are especially susceptible to violations of their rights and interests by third parties. Vulnerability can manifest itself in various relational structures. First of all, vulnerability can develop if the persons concerned are not able to defend their rights and interests themselves. This typically applies to children who must rely on third parties for their education and protection, but also for exercising their rights and interests. In addition, vulnerability can be caused by dependence or reliance on others that goes beyond the usual level. This includes persons with low income and low social status, for example, who depend on social support for their survival more than other people. Finally, there is a special type of vulnerability in socially marginalised groups, in particular in groups that run the risk of being stigmatised or discriminated against. This applies to people with an uncertain residence status, for example. The consequences of a mandatory vaccination policy for these persons and groups of persons must therefore be given due consideration from an ethical perspective.

#### 3.3.2.1 Minors with limited self-determination

For the ethical assessment of a mandatory vaccination policy for minors, it must first of all be clarified whether and if so under what conditions it can be morally justified to interfere with the constitutionally guaranteed parental right to exercise the rights and interests of their children, who are not yet capable of self-determination. This perspective reveals a fundamental conflict between the state with its supervisory function for the well-being of the child, respectively its role as guarantor of public health, and the parents, whose liberty rights shall be restricted.<sup>133</sup> Due to the special benefit profile of vaccinations, it is necessary to distinguish between arguments referring to the well-being of an individual and those referring to the common good.

#### Arguments referring to the well-being of individuals

Reference to the child's well-being is of central importance when answering the question of whether parents are morally obliged to have their children vaccinated against measles. In this vein, it could be argued that because of the factual contribution of the measles vaccination to the well-being of children there is not only a moral duty on the part of the parents to not withhold protection by vaccination from their children. Rather, one may even argue that the legislator is in principle legitimised to codify this parental duty in law. The reasons to justify such a law would be that children need to be protected from the consequences of their parents' failure to fulfil their moral duties. However, such a reasoning requires a clarification of the term "child's well-being" itself,134 as well as an identification of generally undisputed, beneficial conditions for the children's development, and it presupposes a number of further deliberations to specify this moral duty of parents in more detail.

The first prerequisite for a duty of parents to have their children vaccinated is that it is *reasonable* for them to fulfil this duty. In the case of mandatory measles vaccination, this includes on the one hand the accessibility of the vaccination offer, which certainly could be made easier in Germany, but

<sup>133</sup> By contrast, there are voices in the international ethical debate who make a case for putting the children in the centre of considerations. They portray vaccinations like measles vaccination as something that a fair society directly owes to the children growing up in it (cf. Bester 2018, 613). A similar line of argument is put forward to claim that vaccinations must be excluded from the parental authority to decide, and made mandatory, because parents must not be allowed to expose their children to the risks for life and well-being caused by contagious diseases like measles, which can be avoided by vaccination (cf. Pierik 2018, 395).

<sup>134</sup> Cf. Bormann 2008.

is sufficiently well organised overall. On the other hand, the issue of reasonableness also concerns the acceptability of possible side effects that the child might suffer because of the vaccination, even if such side effects are very rare. One must keep in mind here that vaccinations are preventive measures whose risks cannot be justified with the argument that they serve to fight an acute disease. Parents might hesitate because of the different time-frames for the respective risks linked to the decision for or against vaccination: While the risks of possible vaccine injuries in case of a decision in favour of vaccination are situated in the present time, the benefits for the health protection it brings about will only show in the future. The situation is exactly reversed in case of a parental decision against vaccination: Here, the present avoidance of possible harm caused by vaccination comes at the expense of increased health risks in the future. Quite apart from the unfounded tendency to give preference to the present instead of the future, it should be considered that the respective health risks at stake differ in terms of probability and severity, and that these differences cannot be realistically assessed on the basis of personal experience. When making their decision, parents, doctors and last but not least the state and its institutions must trust epidemiological experts who are able to make reliable benefit-risk analyses solely by comparing the data of millions of vaccinations and millions of disease courses. In addition to purely probabilistic considerations, also the seriousness of the threatening health impairments must be taken into account in order to weigh the benefits and harms. The benefit expected from a vaccination is of course the absence of the damages that can occur during and after suffering from a contagious disease. But is this relevant for the justification of a moral duty on the part of parents to have their children vaccinated against measles? The strongest case for a duty to vaccinate on the part of parents could be made by claiming that they unnecessarily cause avoidable and serious health damage to their children by deciding not to have them vaccinated against measles. The

obvious objection is that, quite simply because parents refrain from doing something, there can be no question of actively causing harm. However, this objection ignores the fact that also omissions through which someone fails to avert damage from someone else (like the failure to render assistance in an emergency) can be the object of duties. Accordingly, parents can indeed harm their children by refraining from vaccinating them against measles, because in doing so they fail to protect them against the risks of contracting measles in the future.

However, the real problem when referring to the harm inflicted upon children by their parents' decision not to have them vaccinated against measles is that this risk decreases as the willingness of all other individuals to be vaccinated increases, who might infect those children in the future. If parents and their children live in a society where measles are virtually eliminated, the risk of infection at a later point in time and thus the possible damage due to failure to get vaccinated are considerably reduced. Based on individual damage alone, the decision of parents not to have their children vaccinated does not seem to be per se ethically reprehensible in a society where an overwhelming majority opts for vaccination. Nevertheless, such a reasoning has two limitations: First of all, despite a high vaccination coverage among the total population, there might be exceptional situations at a regional level (e.g. in parts of Southern Germany, see section 2.4) that substantially increase the probability of an infection in certain regions. Secondly, the attitude of parents who acknowledge the reasonableness of vaccination in principle and want their children to benefit from the positive effect of the behaviour of a majority of society, but who refuse to make their own contribution to maintaining this protection, gives rise to the suspicion of moral free-riding. This suspicion might be less applicable to parents who reject vaccination because they doubt the validity of a positive benefit-risk analysis for their own child - either because they are not sufficiently informed or for other, maybe ideological reasons. Paradoxically, this attitude is even likelier to be adopted, if more parents decide in favour of vaccination, thus making it less probable that one's own child gets infected with measles. However, this is not a strong argument against a parental duty to have their children vaccinated.

There can be no doubt that the promotion of one's own children's well-being is the crucial parameter when parents have to make a decision. Having said that, it would be helpful to verify whether the individual well-being is the only relevant parameter to determine the moral duties of parents, or whether it needs to be complemented by arguments referring to the common good.

#### Arguments referring to the common good

As has been described in the introduction, immunisation against a highly contagious disease like measles is not a purely private matter, because each unvaccinated child attenuates the population's immunity, thus elevating the risk of measles outbreaks as well as putting at risk particularly vulnerable individuals (who themselves cannot be vaccinated). It is therefore necessary to explore whether parents are obliged, beside their obligation to care for the well-being of their individual child, not to jeopardise the common good of all children, and ultimately of all adults who are not sufficiently immunised.

In this context, two arguments are relevant that mutually reinforce each other. One of them is based on the general concepts of "solidarity" and "intergenerational justice", while the other refers to the status of infection protection as a "public good".

A general parental duty to contribute in an act of solidarity to the improvement of community immunity by having their child vaccinated could be justified not only by direct individual benefit, but also by an *indirect* individual benefit to the child. It is feasible that the individual child might belong to the very small group of persons who do not achieve sufficient protection against the infection even after the second dose of vaccine. In this case, the child will have to rely on the protection provided by the vaccinated persons in their vicinity. From the knowledge of the fact that with a certain probability every child – also one's own child – cannot be protected directly, but only indirectly via the protection of others, may follow a solidarity-based duty of parents to protect all children. This is where the well-being of the individual and the common good coincide. With a certain – albeit low – probability, every vaccination brings a specific benefit to the respective individual, for reasons of community immunity. This parental duty to contribute to community immunity can be justified in a particularly plausible manner with a view to the small circle of siblings in the family, if applicable, for whom the parents have the same duty of care.

In this context, the argument for solidarity and justice<sup>135</sup> can not only be based on the insight that the risk of infection by dangerous pathogens constitutes a joint hazardous situation for most individuals, but also on the morally relevant fact that it exceeds the power of the individual to effectively avert this hazard. From this perspective, vaccination as a societal practice is a prime example of solidarity where the well-being of the individual is closely intertwined with the common good. However, duties of solidarity generally have a higher burden of justification. For example, the general priority of negative duties of abstention over positive duties of support applies also in the area of community-oriented solidarity commitments, in order to avoid that the individual is under excessive strain. Even if there are many fields (e.g. in tax law or in quarantine regulations) where we assume that the state and its organs generally have rather far-reaching rights to intervene in the individual citizens' lives, a vaccination represents an intervention in the physical integrity of a person, which as a rule is subject to a higher burden of justification. Particular attention must be given to the fact that children who are not yet capable of self-determination are an especially vulnerable group

<sup>135</sup> Cf. the detailed statements in Deutscher Ethikrat 2017, 219 ff., 226 ff.

of persons.<sup>136</sup> In this context it would be necessary to submit the proposed measures to a critical verification with regard to their depth of intervention, duration and individual strain.

There is a second aspect which concerns the timeframe of the fight against certain pathogens, particularly since vaccination programmes are usually designed for the long term. This aspect predominantly pertains to transgenerational interactions, where the idea of intergenerational justice plays a role in the way that the current generation benefits from the efforts of its predecessors, and owes the same efforts to the subsequent generation. The ethical significance of any parental decision on vaccination therefore always goes far beyond the children who are directly concerned. It is always an expression of a national, global and even intergenerational dimension of responsibility, too. An argument in favour of the existence of such an obligation to solidarity and justice is that with every vaccination a small contribution is made to further curb the threat that a measles epidemic breaks out, and to eradicate measles as a contagious disease in the long term at a global level once and for all, as has been done with smallpox. This target can only be reached if exceptions from the rule of measles vaccination are limited to a few well-founded cases.

Closely linked to the idea of solidarity and justice is a second argument which refers to prevention at the population level or herd immunity as a *public good*.<sup>137</sup> Public goods are characterised by their indivisibility. Unlike private goods, public goods concern all members of a population and therefore cannot be

<sup>136</sup> It must be taken into account that the legislator accepts arguments referring to the common good only to a very limited extent when children are affected, e.g. in the area of drug research, where medical interventions for the benefit of the general public are only admissible if the research activity does not involve more than minimal risk and strain (e.g. if a small amount of blood is taken for research purposes in the context of a venipuncture that was necessary anyway). The fact that with regard to the risks of a vaccination, the probability of such an event is extremely low, but the damage – if it occurs – is not, means that the risk cannot be rated as minimal. Accordingly, this would be an argument *against* an obligation to maximise the common good.

<sup>137</sup> Cf. Marckmann 2008, 176 and passim.

exclusively assigned to one of its individual members. However, vaccination measures must be differentiated with a view to their mechanism, depending on the kind of pathogen and its propagation paths. While protective vaccinations for some diseases (e.g. tetanus) exclusively serve the purpose of protecting the individual health of the vaccinated person, vaccination measures for other diseases (like poliomyelitis, diphtheria and measles) aim beyond individual prevention to the establishment of community immunity, which also includes persons who cannot be vaccinated themselves for medical reasons. Given the fact that the measles pathogen is highly contagious, any improvement of prevention at the population level is therefore a reasonable and necessary aim of public health measures.

The considerations outlined here show that there are strong arguments for the existence of a moral duty on the part of parents to have their minor children vaccinated against measles.

#### 3.3.2.2 Persons with full self-determination

About half of the people suffering from measles in Germany are adults, who may in turn infect other adults or children.<sup>138</sup> This is why their moral duties must be mentioned in the context of a discussion on the ethics of mandatory vaccination, too. Given these data, it would not be fair to load the burden of improving community immunity exclusively onto children. However, the group of adults without sufficient immunisation is by no means homogeneous, neither with regard to the respective reasons for their non-existent or insufficient immunisation, nor with regard to the ensuing consequences for third parties. It is therefore necessary to distinguish various subgroups, categorised according to motives, mobility and function of the persons concerned. The topic of mandatory vaccination must be discussed especially in view of those persons without sufficient immunisation, who due to their

<sup>138</sup> Cf. https://www.rki.de/DE/Content/Infekt/Impfen/Praevention/ elimination\_04\_01.html [2019-05-13].

professional activity are considerably more likely to pass the infection on to third parties and could thus significantly contribute to the local or regional propagation of the disease.

#### Arguments referring to the well-being of individuals

In order to answer the question whether a moral or even legal duty to vaccinate would be justified for adults without sufficient immunisation and without medical contraindications, one could first of all mention the health impairments threatening the persons themselves in case of an infection (argument of harm). Consciously refraining from being vaccinated basically means unnecessarily jeopardising one's personal well-being. There are no plausible reasons for such a behaviour. Since measles can occasionally have a particularly severe course in adults, the argument of harm is – at least prima facie – especially reasonable for this group of persons.

Nevertheless, it should be considered that a liberal constitutional state must not force any mentally capable person into treatment or preventive measures solely for his or her own good. After all, the state does not oblige people to have a healthy diet or to get enough exercise, although these are the preventive measures known to have the most favourable opportunity-risk ratio, and their disregard regularly causes high costs to the community of insured people. Since our legal system in many fields also tolerates irrational behaviour of its citizens in the name of freedom, the argument alone that a person is likely to inflict harm upon him- or herself will probably not be sufficient to legitimise legal sanctions against persons who decide not to get vaccinated in spite of accessible vaccination offers and sufficient factual information.

#### Arguments referring to the common good

Whereas the free and conscious decision of a mentally capable person to unnecessarily increase their own risk of disease is usually not prohibited by law – although it is morally questionable –, the claim of third parties to protection from damage inflicted upon them by others can quite reasonably entitle an infringement of the right to self-determination. This entitlement may even include interferences with physical integrity, provided the danger is substantial and imminent and cannot be averted by other less invasive means (e.g. isolation or bans from staying in certain locations). This may be justified with a third party's claim to protection, since vaccination is intended to prevent further infections and therefore a spread of the respective disease. So far, German legislation reserves the right to force mentally capable persons to have preventive or diagnostic measures carried out or to impose quarantine measures upon them under the provisions of the Protection against Infection Act for exceptional cases only, i.e. if these persons present a particularly great threat to the population.

In the case of infectious diseases like measles that are transmitted from person to person, it is particularly important that some people cannot sufficiently protect themselves against this infection, even if they wanted to. This is true, among others, for sick people with compromised immune systems, for children and adults without sufficient immunisation despite two doses of vaccine, and for infants without adequate maternal passive immunity. They can only be protected from illness and possible death with the help of others who are willing to get vaccinated. Unvaccinated individuals travelling abroad can also endanger children and adults in other regions of the world who do not have satisfactory access to preventive vaccination. This aspect requires special ethical consideration, because in some countries measles have a lot more complications and lead to chronic illness or death much more frequently than in Germany.<sup>139</sup> The protection of such vulnerable population groups can be an ethical reason to justify the introduction of

<sup>139</sup> Compare, for example, the high incidence of deaths in the measles epidemic of 2019 in Madagascar (cf. https://www.who.int/csr/don/ 17-january-2019-measles-madagascar/en [2019-06-04]).

specific obligations for travellers from rich countries with access to a high-quality health care system.

It is also necessary to enquire into a moral duty to get vaccinated because, apart from implicating health risks for third parties, vaccination decisions have further consequences for the common good, e.g. those touching on the fundamental value of solidarity. If a person decides not to get vaccinated although a particular vaccination is efficient and low-risk, this behaviour may impose additional costs to the community of solidarity if the person concerned contracts the disease, because of treatment costs, absence from work, or death of a contributor to health insurance. The reference to the indirect long-term costs for the general public which a decision against measles vaccination might involve is clearly germane to the question whether state interference with individual vaccination decisions is legitimate.

In fact, the risk that measles is passed on to third parties among the adult population has been on the rise for some time now, because an increasing share does not have sufficient immunity. However, the risk is relatively low with regard to the general population if the number of annual infections (in a three-digit range) is put in relation to the roughly 70 million over-18-year-olds. Only a relatively weak moral duty to vaccinate can be derived from such a comparatively low risk of endangering third parties. It can be more significant if persons who are not sufficiently immunised travel more frequently to destinations where the risk of infection for third parties is considerably higher. In any case it seems morally advisable to ascertain one's own vaccination status in order not to falsely believe oneself safe. In addition, it must be assumed that many younger adults are not sufficiently informed about the problematic issue of their inadequate immunisation and that they would be prepared, at least for the sake of their own protection, to submit to a measles vaccination if they were properly informed and had easy access to vaccination offers.

# Individuals with specifically increased risk to get infected and to pass on an infection

Insufficient immunisation is a problem especially in the range of 20- to 50-year-old-adults (approximately 50 percent of measles patients), who cannot be reached by means of recommendations for schools and kindergartens. Due to their occupation, some of the adults without adequate immunisation are highly exposed to infection risks and therefore also at risk of passing their infection on to others. Among these are teachers, for example, who might contract the virus from unvaccinated pupils or students and then themselves contribute to the propagation of the infection. The problem is even more serious in the case of medical, nursing and midwifery staff without sufficient immunisation. It is not rare that they are in contact with people suffering from a disease or in need of assistance whose immune response is compromised. Because of that they are particularly susceptible to infections and often suffer from an exceptionally severe course of infection. This problem will become increasingly urgent in the near future, when more and more unvaccinated or insufficiently immunised people from the times when only one dose of vaccine was administered reach an age where hospitalisation becomes more likely.

Among the people working in the health sector, the small group of doctors must be explicitly mentioned in this context, who, against their better judgement, do not make sure that they have sufficient immunisation themselves. They thereby fail to fulfil their special responsibility towards patients as a professionally exposed group, nor do they live up to their function as role models. Despite overwhelming scientific evidence to the contrary, some of them even discourage parents from having their children vaccinated, thereby actively causing harm. Although they are rare exceptions within the medical profession, these anti-vaccinationist doctors can achieve a large dissemination, especially via the social media, of their harmful statements. Such a behaviour that deliberately neglects or even denies approved medical-scientific standards must be considered as a serious violation of all doctors' obligation to conscientiously provide their patients with suitable measures of examination and treatment (Section 11 (1) MBO-Ä [Professional Code]). It is the responsibility of the Landesärztekammern (state chambers of physicians) and other professional organisations to rigorously apply their existing rights to supervision and powers to impose sanctions, or to further develop them in case they are not sufficient.

Specifically with a view to the members of certain health care professions (like clinicians), it should be examined whether there are sufficient reasons for introducing an occupation-related mandatory vaccination policy – as yet not existent in Germany. So far, no mandatory vaccination has been imposed on people with a high risk of transmitting diseases, like medical staff in hospitals or nursing homes, not even for frequent and dangerous diseases like influenza, but it is possible to restrict the constitutionally guaranteed freedom of profession in order to protect important public goods. From an ethical perspective it can barely be justified that a doctor does not get vaccinated despite better knowledge about the importance of vaccinations and thus deliberately puts patients at risk - especially as far as particularly vulnerable patients are concerned. The same applies as a general rule for staff in child-care centres and in health care institutions where there is a higher probability to encounter people with a compromised immune system, e.g. on oncological, nephrological or infection wards, or in certain institutions for long-term care. Although some communicable diseases - in particular those that are not transmitted via droplet infection - can be prevented by appropriate hygienic measures, this does not apply to measles, which might even be transmitted over a distance of several meters. In the interest of community immunity, there is a strong moral imperative to make vaccination mandatory at least for people who by virtue of their occupation bear an increased risk of becoming infected and of transmitting

the infection to third parties, in particular to susceptible and especially vulnerable persons. This argument is all the more valid since these people have voluntarily assumed increased responsibility by their choice of profession. In addition, it must be considered that persons working in the health care sector should be role models with regard to vaccinations. It would barely be convincing to defend the case of a generally mandatory vaccination policy if even among medical staff no systematic provisions had been made to the effect that any person who has contact with patients is vaccinated.

#### 3.3.3 Enforcement of a mandatory vaccination policy: Accessibility of significant groups of persons and overcoming relevant barriers

So far, these considerations were intended to broaden and differentiate the common debate about a duty to vaccinate in two ways. On the one hand, it could be shown with regard to the manifold options of steering behaviour by means of morally-based and legal regulations, that there are different possibilities below the threshold of legal coercive measures to formulate morally well-founded expectations as well as disapproval in case these expectations are disappointed. On the other hand, it could be illustrated that the aim of a tiered increase in vaccination coverage can only be achieved if different groups of persons are brought into focus. With regard to children the situation is rather complex, because vaccination coverage for the first dose of measles vaccine is guite satisfactory on a federal average, but in some regions (e.g. in Bavaria and Baden-Wuerttemberg) values are alarmingly low. Moreover, the coverage rate for the second dose of vaccine is overall not sufficient. The picture is considerably worse for adults without adequate immunisation. According to a study from 2013, only 79.8 percent of the 18- to 29-year-olds were vaccinated against measles in Germany, and only 46.7 percent of the 30- to 39-year-olds.<sup>140</sup> Correspondingly, about half of all the people suffering from measles today are young and middle-aged adults. From an ethical perspective it is particularly relevant that also people working in teaching and education or in health care, who have an increased risk of infection for themselves but also for particularly vulnerable third parties, present a rather bad vaccination status.

Even if it could be demonstrated that, on the whole, there are sufficiently strong arguments in favour of a moral duty to be vaccinated oneself and to have one's children vaccinated against measles, the question remains as to how this duty should be implemented in practice. In doing so, it is necessary to face specific challenges, i.e. the currently regionally heterogeneous status quo, the different risk situations for relevant professional groups, the different receptiveness of significant target groups to rational arguments and ordinary medical offers, and the increasing (national and international) mobility. In view of the close ties between individual well-being and common good, answers to this question should not only do justice to the moral aspects put forward here, i.e. fair burden sharing, solidarity and intergenerational justice. Rather, they should also be committed to the fundamental ideas of liberalism and proportionality. As a matter of principle, statutory coercion should only be used as a last resort, namely where all other less intrusive measures come up against their limits. Constructive steps towards improving vaccination coverage should therefore initially address those everyday practical barriers that have been proven to significantly contribute to the fact that vaccination targets set by German health policy have not been met up until today. It is obvious that interference with parental law and with the individual right to self-determination of unvaccinated or insufficiently vaccinated adults should be as minimal as possible. This is all the more true since threats of coercion would probably lead to immediate

<sup>140</sup> Cf. Poethko-Müller/Schmitz 2013, 849.

counter-productive effects, as was demonstrated in an experiment in behavioural psychology.<sup>141</sup> The experiment showed that the mere threat of using coercion reduced the trust in vaccinations and the willingness to voluntary vaccination. In this context it also must be mentioned that single vaccines against measles have no longer been available in Germany since 2017. Accordingly, a legally mandatory measles vaccination could currently not be properly implemented for practical reasons, because vaccination would have to be carried out with one of the available combination vaccines (MMR, MMRV), including an involuntary "co-vaccination" against diseases for which no mandatory vaccination policy applies. Although combination vaccines are medically advisable, such an expansion of mandatory vaccination would without doubt be legally contestable, therefore making it necessary to re-introduce single vaccines against measles in the market. Finally, it must be feared that as a collateral damage of a mandatory measles vaccination policy that is strictly enforced, public acceptance of recommended, but not mandatory vaccinations against other contagious diseases declines, and that vaccination rates of rubella, for example, decrease.

With regard to the next steps it is therefore recommended to pursue a tiered strategy aiming to achieve clearly defined target values for relevant groups of persons within a given period of time and by means of subtle tools. Legal elements of coercion targeting specific addressees should only be employed in case it is foreseeable that these efforts will fail.

There is evidence to suggest that the vaccination coverage rate of 95 percent prescribed by the WHO for the second vaccination in children can in principle be achieved without coercion, since 97 percent of young children in Germany receive the first dose of vaccine today already.<sup>142</sup> Moreover, childhood vaccination rates for the first dose of vaccine have been on the

<sup>141</sup> Cf. Betsch/Böhm 2016.

<sup>142</sup> Cf. Robert Koch-Institut 2019, 150.

rise for several years now. This is probably due to the measures that have already been taken, which are mainly aimed at improving public information. This proves that the acceptance of measles vaccination is very large these days. In turn, the number of people who fundamentally oppose vaccinations and who are often perceived as the true cause of the problem (and whose children would only be accessible by means of forced vaccination) is extremely small and has been declining for several years now. The fact that rates for the second dose of vaccine are actually too low, and that vaccinations both with the first and the second dose are generally often given too late in infancy, is probably not due to radical opposition, but mainly to practical obstacles and to still insufficient information. For example, resident physicians apparently do not systematically use existing documentation and reminder modules for vaccination, although they are included in their practice's accounting programme. They therefore often fail to explicitly address the persons concerned. It would be possible to lower the threshold for seizing vaccination offers if there were regular patient-related queries, invitations to necessary vaccination deadlines, vaccination days in doctors' surgeries or in the public sphere etc. It is still comparatively time-consuming for parents to have their child vaccinated, especially in the country, where there are less paediatricians and where a few vaccination-sceptics among doctors are enough to cause vaccination rates to drop dramatically in certain regions. Low-threshold offers of information and vaccination close to people's residence, e.g. in child-care centres, schools or pharmacies, could generally grant relief, but require suitable prerequisites in (professional) law. This applies particularly, but not exclusively, to refugees who have come here from countries with a deficient public health care system, as well as to migrants, most of whom are willing to get vaccinated, but often have limited access to the German health system.

An especially vulnerable group are the probably several Hundreds of thousands – it is self-evident that no exact figures

are available – of people living in Germany with an uncertain residence status. Many of them fear to be identified and get deported if they get in touch with the public health system. This is why they are particularly difficult to reach with medical offers.<sup>143</sup> There are doctors' associations doing volunteer work and financed by donations, e.g. "Praxis ohne Grenzen" (Practice without Borders), who try to care for them. With their help it would be possible to improve vaccination coverage among people with uncertain residence status. In order to do so, it would be required to create legal certainty for their activities and to provide adequate material equipment, especially vaccines. Even if they work in an environment that is problematic in terms of aliens law, supporting the doctors' associations mentioned above in carrying out vaccination programmes with funds from the general health care system makes sense, because improved vaccination coverage within this particular group is in the general public interest.

Altogether, the *information of the target group of parents and potential parents* (i.e. adolescents and young adults) still offers room for improvement, in particular in view of the importance of the second dose of vaccine, which is often underestimated, and of the threat that insufficiently immunised people pose for especially vulnerable groups of persons (new-borns, children and adults with an immune deficiency, travellers from other countries, particularly susceptible people in other regions of the world). To this effect, one could appeal to the solidarity with vulnerable persons, for which there is in fact a large potential in German society.

Quite generally, the *information status of the population* and the access to vaccination offers can be further improved. This includes first of all low-threshold opportunities to find out about one's own vaccination status. Adolescents, who have not been vaccinated because of their parents' concerns, but have reached unrestricted self-determination in health issues,

<sup>143</sup> Cf. Zentrale Ethikkommission bei der Bundesärztekammer 2013.

should be given a chance to be educated about the importance of vaccinations and to decide themselves about the measure (for example by means of vaccination offers in schools or institutions of further education). Overall, it should be made known to the public more explicitly than has been the case so far that measles has meanwhile become a disease of adults of all ages, and that the course of the disease can be especially severe in adults. Information and education campaigns might also put particular emphasis on highlighting the protection of persons with an immune deficiency or vaccination failure, which is only possible through joint efforts. In this way it is possible to illustrate the immediate benefit of one's individual contribution to community immunity for particularly vulnerable persons and to appeal to people's human solidarity.

From a societal perspective it could be helpful to establish a structured national immunisation register, in order to base future decisions on the best possible database. The majority of EU member states already have set up national immunisation registers, sometimes on the basis of special legislation.<sup>144</sup> It is true that since 2011 billing data on vaccinations of the Kassenärztliche Vereinigungen (Associations of Statutory Health Insurance Physicians) have been analysed in Germany (KV-Impfsurveillance). However, this analysis only collects data on statutorily insured patients. Moreover, they cannot be used to remind people of due vaccination deadlines because the data are anonymised. Some of the other countries use immunisation information systems, however, that can even track the reasons for missed vaccinations, which allows to introduce more targeted measures to combat vaccination fatigue and vaccination scepticism.145

Persons who are more likely to pass on the infection because of their professional activity (like teachers in schools) and especially those who might transmit infections to ill people (like

<sup>144</sup> Cf. European Centre for Disease Prevention and Control 2017, 13.

<sup>145</sup> Cf. ibid., 27 f.

hospital staff) bear a special ethical responsibility. Not only can these persons and the institutions who employ them prevent infections with appropriate measures a lot more effectively than the average population could do, but – due to their position – they also have the responsibility to underline the importance of vaccinations by their own behaviour.

This is why health care staff in particular should set a positive example with regard to vaccination, and be made to live up to their special position-related responsibility. After all, every decision on vaccination is ultimately an answer to the question of the trustworthiness of medical science.<sup>146</sup> If laypersons do not simply want to rely on their gut feeling, they must believe in the promise of evidence-based medicine that a rational weighing of a vaccination's potential benefit and its potential damage requires some effort, but in principle is absolutely feasible and comprehensible for everybody. The task of empirically assessing the benefits of vaccination is just as impossible to solve for a layperson alone, as finding an answer to the normative question what benefit/risk ratio should be considered "adequate". Even people who are capable of reading and understanding epidemiological studies would probably fail in the tedious task of evaluating the studies published worldwide, because of their sheer multitude. For this reason, it would be important that the confidence in the benefits of vaccination, which is so important for the general public, is strengthened by the circumstance that those persons with a deeper understanding of the scientific justification of vaccination programmes confirm the appropriateness of this prevention system through their own behaviour, visible for everybody.

Various measures should be taken to promote such behaviour. On the one hand, the crucial role of health care staff, of employees of community facilities (pursuant to Section 33 IfSG) and of persons in educational contexts to improve vaccination coverage should be highlighted even more than has

<sup>146</sup> Cf. Verweij/Dawson 2004, 3125.

been the case so far. For example, the general value of vaccinations and especially the importance of being vaccinated oneself should be adequately discussed in vocational education and training of medical and teaching staff. The management of community facilities and of health care institutions should be obliged to find out about their employees' status regarding relevant vaccinations, and to point out to them the importance of prevention through individual vaccination measures. Correspondingly, they should also be authorised to take action against negligent conduct of employees, especially by imposing work bans for sensitive areas of activity. Low-threshold opportunities for vaccination should regularly be offered (e.g. by the organisations' medical services) and systematically verified with regard to their success. Last but not least, for their own safety, users of community facilities or health care institutions should get information on whether the management has established such programmes or not.

Only if all these improvements to promote education and to expand low-threshold accessibility of vaccination offers do not lead to the required increase in vaccination coverage rates within a reasonable, pre-defined period of time, or if the vaccination rate should even further decline in some regions for other reasons, does it seem appropriate from an ethical point of view to impose specific statutory measures of coercion. These can include an exclusion of unvaccinated children from the attendance of child-care centres, fines for parents of school-age children without sufficient immunisation, or targeted work bans for unvaccinated adults in teaching or health care professions. In all these measures, the proportionality of purpose and means must be kept in mind. In Germany, a total of 929 persons suffered from measles in 2017; about a third of them were children below the age of nine.<sup>147</sup> In the same year, 763,000 under-threeyear-olds were taken care of in 55,266 child-care centres and

<sup>147</sup> Cf. Matysiak-Klose/Santibanez 2018, 326.

by 43,951 child minders.<sup>148</sup> Monitoring a general mandatory vaccination policy for children at day-care facilities, enforced by means of appropriate sanctions, can be expected to cause a considerable bureaucratic effort. In addition, the children of socially or financially disadvantaged parents would suffer much more from the consequences of an exclusion from day-care centres or fines than children of wealthier parents. Considering that according to a study by the Sabin Vaccine Institute, the vaccination rates achieved in European countries with and without mandatory child vaccination do not differ significant-ly<sup>149</sup>, it would seem justified in this context to first exhaust all available less stringent means to increase vaccination coverage, in particular by having paediatricians or youth or health authorities directly approach tardy parents.

<sup>148</sup> Cf. https://www.destatis.de/DE/Presse/Pressemitteilungen/2017/07/ PD17\_255\_225.html [2019-06-04].

<sup>149</sup> Cf. Sabin Vaccine Institute 2018, 24.

## 4 EXECUTIVE SUMMARY

#### Introduction

- Many contagious diseases transmitted by viruses are only treatable symptomatically. To date, vaccinations against such viruses have been the most important measure to prevent serious health risks and to eradicate diseases. Measles are an objectively dangerous – albeit often underestimated – contagious disease that can be prevented by means of a well-tolerated and generally accessible vaccine. These facts make measles a prime example of a contagious disease whose global eradication is absolutely feasible. However, temporary successes notwithstanding, not even the elimination of measles has been sustainably achieved in many parts of the world. Also Germany has failed to meet its goal of eliminating measles to date.
- 2) There are several reasons why measles has not yet been successfully eliminated in Germany. On the one hand, both the first and second doses of the vaccine are given to children too late, whilst the critical second dose is given at an overall insufficient rate. On the other hand, there are actually far more serious vaccination gaps in the adult population than in children.
- 3) The limited success of previous strategies raises important ethical and legal questions concerning future vaccination programmes. Specifically, the question arises whether obligatory/binding measures like the introduction of a mandatory vaccination policy are justified, and if so, to what extent. The present opinion of the German Ethics Council addresses these issues. Although it focuses on measles, the Council aims to develop general ethical standards that are also applicable to other vaccine-preventable infectious diseases.

#### **Current situation**

- 4) Measles is among the most contagious diseases of all. In Germany, the vast majority of patients who contract measles recover within just a few weeks without any major sequelae. Nevertheless, there are some measles sufferers who have access to good health care and no prior health issues but still experience various complications even during the "normal" course of the disease. These may include middle ear infections, diarrhoea, pneumonia and post-infectious encephalitis. The usually fatal late complication of subacute sclerosing panencephalitis (SSPE) might not develop until many years after an apparent recovery.
- 5) Usually, measles vaccinations are given in combination with vaccines against mumps and rubella (MMR). (Nowadays, MMR vaccines are often combined with a vaccine to protect against chickenpox and/or shingles.) The rate of side effects for these vaccines is considered extremely low.
- 6) The aim of vaccinations is to reduce the prevalence of a disease, and the frequency of its complications, as well as to prevent deaths resulting from the disease, as both targets are interdependent. The double MMR vaccine recommended in Germany prevents measles-associated morbidity, complications and mortality with a very high probability.
- 7) The term "community immunity" describes a condition where also non-immune individuals in the population are protected because a sufficient number of other people are immune and therefore can no longer transmit the pathogen to unprotected individuals. It should be noted, however, that this mechanism of protection only pertains to contagious diseases like measles that are exclusively transmissible from person to person. Most importantly, this type of protection benefits vulnerable people who cannot be vaccinated for medical reasons or in whom the vaccination does not effectively induce immunity. However, it also protects individuals who have not been vaccinated
although there is no medical reason and who thus profit from other people's willingness to be vaccinated without contributing their share. Due to measles' high infectivity, about 95 percent of a population must be immune to achieve effective community immunity.

8) There are various reasons why people in Germany are not vaccinated against measles. Among the more important ones are a lack of knowledge about the significance of immunisation even in adulthood, distrust in the efficacy and safety of vaccines and in official vaccination recommendations, a lack of awareness about the severity of measles as a disease. Other reasons of equal importance are practical barriers such as everyday stress, misjudgements about vaccination risks due to dubious sources of information, and a lacking sense of responsibility towards the community as a whole or a lack of willingness to contribute to the protection of others by being vaccinated oneself.

#### Normative analysis

- 9) The ambiguous term "duty to vaccinate" can be understood either in the *moral* or in the *legal* sense. A genuine mandatory vaccination policy presupposes that, firstly, the group(s) of persons obliged by the duty to vaccinate must be clearly defined and, secondly, the legal consequences of violating this duty need to be precisely determined.
- 10) There is no provision for mandatory vaccination in the narrow sense in applicable German law, except for certain special regulations governing military personnel. In particular, there is no legal duty to vaccinate aimed at prevention or enforced by sanctions. Instead, the government largely relies on counselling that provides information and recommendations, but may also be binding.
- 11) The introduction of a mandatory vaccination policy has become the subject of increasing debate in Germany and is being called for by the Bundesministerium für Gesundheit (Federal Ministry of Health) and the Bundesärztekammer

(German Medical Association), among others. From the perspective of constitutional law, it must first of all be stated that the current legal regulations do not raise any fundamental concerns. However, this does not answer the question of whether the legislator *would be allowed* to introduce "strict" mandatory vaccination regulations that go beyond current law.

- 12) With particular regard to mandatory vaccination for (young) children, both the basic right of the child to life and physical integrity guaranteed under Article 2 (2) GG and the rights of parents under Article 6 (2) sentence 1 GG have to be taken into account. The Bundesverfassungsgericht (Federal Constitutional Court) interprets the parental right as a fiduciary basic right on the part of parents to focus on the well-being of their child in their care and education efforts. Nevertheless, parents are fundamentally allowed to decide "free of state influence and according to their own ideas how they wish to live up to their responsibility as parents". This means that mandatory vaccination constitutes an interference with parental rights. As such it would only be legitimate in the context of the state's supervisory function (Article 6 (2) sentence 2 GG) and would have to adhere to the principle of proportionality in a broader sense. In other words, said interference must be suitable, necessary and appropriate in respect of the - indisputably legitimate - objectives of the vaccination, i.e. protecting public health, the health of children or the health of particularly vulnerable population groups.
- 13) Any interference with parental rights by the family court that strips parents of their right to decide about vaccinations and transfers it to a supplementary curator, or any vaccination being forcibly carried out on a child, does not seem justifiable under the present circumstances, especially since such a procedure might traumatise the child. Accordingly, linking school attendance to a previous

measles vaccination also appears questionable. However, a possible constitutionally permissible design for a "hard" mandatory vaccination policy could comprise a regulation that makes children's attendance at day-care facilities (child-care centres, childminders) or the operating licenses of such facilities contingent upon proof of sufficient immunisation against measles.

- 14) Besides children, adults should also be considered as addressees of a mandatory vaccination policy. For example, it might be reasonable to prohibit persons without proof of immunity or vaccination from being employed in jobs where their daily work involves dealing with people for whom a measles infection would pose a particularly high risk of serious illness or even death. A mandatory vaccination policy of this kind does not appear to be constitutionally inadmissible from the outset. Depending on the design of such a policy the degree of restriction of the individual's professional freedom may vary and must be proportionate to the purpose of the restriction.
- 15) The term "duty to vaccinate" is often associated with the idea that the state imposes this duty by law and in extreme cases enforces it by means of coercion. The term can, however, be understood both in the sense of a strict legal duty and in the sense of an ethical "duty of virtue", i.e. a purely moral duty. If the demand for mandatory vaccination was conceived as a strict legal duty, then the constitutive attributes of inescapability, enforceability and unambiguity would apply, which would lead to a number of highly problematic consequences.
- 16) Overall, from an ethical point of view, priority should be given to a regulation within the framework of socially binding rules of ethos. This assessment could change if special situations of emergency arise. For example, it could be justified to turn duties of virtue into strict legal duties if an acute health hazard threatening large parts of the population required rigid interventions. Moreover,

the different types of obligation can also co-exist, depending on the group of people concerned and the given context of action. For example, there is no contradiction in merely appealing to the parents' sense of moral responsibility in order to increase vaccination coverage in children, while calling for mandatory vaccination enforced by appropriate sanctions for medical personnel who have contact with highly vulnerable people.

- 17) Members of some groups put forth religious or ideological reasons against a duty to vaccinate justified on moral grounds. In principle, every individual should be free to live their lives according to their own individual religious and ideological convictions. This freedom has its limits, however, when the consequences of their actions affect the legitimate interests of other people. This not only applies to the execution of actions, but also their omission. Anyone who fails to get vaccinated (or fails to have those for whom he or she is responsible vaccinated) against measles is very likely to cause harm to (possibly unknown) others. Thus, freedom of faith or conscience cannot be invoked to justify an avoidable threat to third parties.
- 18) Reference to the child's well-being is of central importance when answering the question of whether parents are morally obliged to have their children vaccinated against measles. In this vein, it could be argued that because of the factual contribution of the measles vaccination to the well-being of children there is not only a moral duty on the part of the parents to not withhold protection by vaccination from their children. Rather, one may even argue that the legislator is in principle legitimised to codify this parental duty in law.
- 19) The first prerequisite for a duty of parents to have their children vaccinated is that it is *reasonable* for them to fulfil this duty. In the case of a mandatory measles vaccination this includes, firstly, access to the vaccination; secondly, it must also be reasonable to accept the (very rare) side

effects associated with the vaccination for the child. When weighing the desired benefits against the possible harm of a vaccination, parents must trust epidemiological experts who are able to make reliable benefit-risk analyses solely by comparing the data of millions of vaccinations and millions of disease courses.

- 20) The strongest case for a duty to vaccinate on the part of parents could be made by claiming that they unnecessarily cause avoidable and serious health damage to their children by deciding not to have them vaccinated against measles. Parents can harm their children by refraining from vaccinating them against measles because in doing so they fail to protect them against the risks of contracting measles in the future. However, the real problem when referring to the harm inflicted upon children by their parents' decision not to have them vaccinated against measles is that this risk decreases as the willingness of all other individuals to be vaccinated increases, who might infect those children in the future.
- 21) Immunisation against a highly contagious disease like measles is not a purely private matter, because each unvaccinated child attenuates the population's immunity, thus elevating the risk of measles outbreaks as well as putting at risk particularly vulnerable individuals (who themselves cannot be vaccinated).
- 22) In this context, an argument for solidarity and justice can be based on, firstly, the insight that the risk of infection by dangerous pathogens constitutes a hazardous situation for most individuals, and, secondly, the morally relevant fact that it exceeds the power of the individual to effectively avert this hazard. For every child there is a certain probability that it cannot be protected directly, but only indirectly via the protection of others, e.g. in the event that it does not develop antibodies despite having received two doses of vaccine. From this perspective, vaccination as a societal practice is a prime example of solidarity where the

well-being of the individual is closely intertwined with the common good. However, it must be taken into account that a vaccination represents an intervention in the physical integrity of a person, which as a rule is subject to a higher burden of justification.

- 23) Closely linked to the idea of solidarity and justice is a second argument which refers to prevention at the population level or herd immunity as a *public good*. Unlike private goods, public goods concern all members of a population and therefore cannot be exclusively assigned to one of its individual members. Given the fact that the measles pathogen is highly contagious, any improvement of prevention at the population level is a reasonable and necessary aim of public health measures. The considerations outlined here show that there are strong arguments for the existence of a moral duty on the part of parents to have their minor children vaccinated against measles.
- 24) In order to establish a moral or even legal duty for adult vaccination, one could first of all develop an argument from harm by referring to the health impairments threatening for one's own health which an infection would pose and by which one's personal well-being would be unnecessarily jeopardised. It should, however, be considered that a liberal constitutional state must not force any mentally capable person into treatment or preventive measures solely for his or her own good.
- 25) The entitlement of third-parties to protection against harm from others may justify an infringement of the right to self-determination, where appropriate even including interference with an individual's physical integrity, provided that the danger is substantial and imminent and that it cannot be averted by other less invasive means.
- 26) In the case of infectious diseases like measles that are transmitted from person to person, it is particularly important that some people cannot sufficiently protect themselves against this infection, even if they wanted to. They can

only be protected from illness and possible death with the help of others who are willing to get vaccinated. This is true, among others, for sick people with compromised immune systems, for children and adults without sufficient immunisation despite two doses of vaccine, and for infants without adequate maternal passive immunity. Unvaccinated individuals travelling abroad can also endanger children and adults in other regions of the world who do not have satisfactory access to preventive vaccination.

- 27) Due to their occupation, some of the adults without adequate immunisation are especially exposed to infection risks and thereby also at risk of passing their infection on to others. This includes teachers and, in particular, medical, nursing and midwifery staff.
- 28) Specifically with a view to the members of certain health care professions, it should be examined whether there are sufficient reasons for introducing an *occupation-related mandatory vaccination policy* as yet not existent in Germany. In the interest of community immunity, there is a strong moral imperative to make vaccination mandatory at least for people who by virtue of their occupation bear an increased risk of becoming infected and of transmitting the infection to third parties, in particular to susceptible and especially vulnerable persons. This argument is all the more valid since these people have voluntarily assumed increased responsibility by their choice of profession.
- 29) Although it has been demonstrated that, on the whole, there are sufficiently strong arguments in favour of a moral duty to be vaccinated oneself and to have one's children vaccinated against measles, the question remains as to how this duty should be implemented in practice. In view of the close ties between individual well-being and common good, answers to this question should not only do justice to the moral aspects put forward here, i.e. fair burden sharing, solidarity and intergenerational justice. Rather, they should also be committed to the fundamental

ideas of liberalism and proportionality. As a matter of principle, statutory coercion should only be used as a last resort, namely where all other less intrusive measures come up against their limits. Constructive steps towards improving vaccination coverage should therefore initially address those everyday practical barriers that have been proven to significantly contribute to the fact that vaccination targets set by German health policy have not been met up until today.

- 30) There is evidence to suggest that the vaccination coverage rate of 95 percent prescribed by the World Health Organization for the second vaccination in children can in principle be achieved even without coercion, since 97 percent of young children in Germany already now receive a first dose of vaccine. Moreover, childhood vaccination rates have been on the rise for several years now due to the measures already taken, which are mainly aimed at improving public information. This proves that the acceptance of measles vaccinations is very large these days. The number of people who fundamentally oppose vaccinations and who are often perceived as the true cause of the problem (and whose children would only be accessible by means of forced vaccination) is extremely small and has been declining for several years now, although it is regionally heterogeneous.
- 31) Moreover, the proportionality of purpose and means must be kept in mind. For example, monitoring a general mandatory vaccination policy for children at day-care facilities, enforced by means of appropriate sanctions, can be anticipated to cause a considerable bureaucratic effort. In addition, the children of socially or financially disadvantaged parents would suffer much more from the consequences of an exclusion from day-care centres or fines than children of wealthier parents. Considering that according to a study by the Sabin Vaccine Institute, the vaccination rates achieved in European countries with

and without mandatory child vaccination do not differ significantly, it would seem justified in this context to first exhaust all available less stringent means to increase vaccination coverage, in particular by having paediatricians or youth or health authorities directly approach tardy parents.

### 5 **RECOMMENDATIONS**

The elimination of measles is an important ethical aim, both for the individual and for society as a whole. The following recommendations serve the purpose of increasing vaccination rates among all age brackets and population groups to the extent required for the elimination of measles. Apart from professions with a special responsibility, the preferred means to achieve this aim shall be information, advice and easier access to vaccination. In case these means are not successful, stricter regulatory measures and measures with a greater depth of intervention will be necessary. Although the recommendations provided in this document focus on measles, they might also be developed further to suit vaccinations against other diseases.

Regarding vaccination against measles, the German Ethics Council recommends the following:

- Attempts to further increase vaccination rates against measles shall be undertaken. The measures taken to achieve this aim must address not only children, but also adolescents and adults. Targeted information campaigns should be carried out in order to raise awareness

   amongst adults in particular – for the importance of vaccination to protect oneself against illnesses which many people mistake for children's diseases.
- 2. Low-threshold offers of information and vaccination (e.g. open vaccination consultation for working people, regular vaccination days in day-care centres, schools and universities or vaccination days carried out by the medical service of companies) should be established. Any obstacles of an administrative nature should be removed, especially those contained in rules governing the various professions. Particular attention must be devoted to language and cultural barriers.

- 3. GPs and paediatricians should be obliged to use automatic reminder systems for vaccinations. They should be paid an adequate compensation for their efforts to do so.
- 4. The management of community facilities (Section 33 IfSG) and health care institutions should be entitled and obliged to find out about their employees' status regarding relevant vaccinations, and to point out to them the importance of adequate disease prevention through individual vaccination measures.
- 5. Doctors of all medical specialties should be qualified and entitled to carry out vaccinations; vaccination qualification courses should be mandatory in medical studies. Greater importance should be attributed to the issue of vaccinations in vocational education and training, as well as in further training and development of medical staff, educators and teachers (including the importance of being vaccinated oneself).
- 6. People with uncertain residence status should be given access to protected vaccination opportunities; medical aid organisations offering such services should be granted support and legal security.
- 7. It is recommended to set up a structured national immunisation register, in order to base future measures on better data. When collecting and evaluating these data, attention should be paid to regional and social particularities, so that interventions can be ideally targeted.
- 8. Imposing mandatory vaccination by applying physical force ("forced vaccination") is not justifiable.
- 9. For justice and effectiveness considerations, the German Ethics Council does not deem it advisable to impose fines

or other financial sanctions in order to increase vaccination rates.

- 10. Given the statutory obligation for children to attend school, a general interdependence of school attendance and vaccination status must be rejected, except for a temporary exclusion from school to prevent imminent threats in specific situations.
- 11. The German Ethics Council also opposes a general exclusion of children who are not vaccinated from pre-school educational institutions (day-care nurseries, day-care centres for school-age children, child minders etc.). In specific individual cases it should be possible to exclude an unvaccinated child for risk prevention purposes.
- 12. The control and consulting programme introduced pursuant to Section 34 (10a) IfSG should be tightened (documentation of the vaccination status upon registering for an institution, annual checks of the vaccination status carried out by the institution, regular consulting visits including the offer to carry out vaccinations through local health authorities or doctors mandated by these).
- 13. Except for one of its members, the German Ethics Council favours a mandatory vaccination policy that can be sanctioned with a work ban for professions with a special responsibility. This applies especially to staff in health care, social welfare and education.
- 14. If a mandatory vaccination policy was introduced, the practical opportunity should be provided to restrict vaccination to the specific disease that the policy refers to. Accordingly, it must be guaranteed that the respective mono-preparations are available.

Sanctions pursuant to professional law must be considered against doctors who publicly (especially in social media) spread incorrect information on vaccination against measles.

### **DISSENTING VOTE**

#### Target

The Ethics Council pursues the undisputed target of protecting the population from measles. In order to achieve this target, 95 percent of the population must be immune to measles. Immunisation can be achieved by means of vaccination or by having suffered a measles infection.

Measles are highly contagious and can easily be prevented by vaccination. As has been illustrated in section 2, vaccines have been available since 1963. Before vaccination against measles became the rule, almost everybody suffered from measles, i.e. almost all people born before 1970. Depending on the source of data, the disease has a mortality of 0.01 to 0.1 percent.<sup>150</sup> Compared to other contagious diseases like smallpox with a mortality of 30 percent, this is a relatively low mortality rate. Such a relatively low mortality does not justify a mandatory vaccination policy to impose the target, including a de facto mandatory vaccination of particular professional groups or the exclusion of individual children from day-care centres. Therefore, in contrast to what has been recommended in section 4, it is never necessary to apply stricter measures that interfere profoundly with people's lives. Instead, measures should only be aimed at easier access, information and counselling, because individual freedom, the basic right to physical integrity and the primacy of parental custody are higher values than the elimination of measles, even if the latter is an individually and socially important ethical aim.

In contrast to what has been said in the introduction, unvaccinated persons therefore should not be banned from staying in certain places or excluded from certain occupational activities, not even as a last resort.

<sup>150</sup> Cf. World Health Organization 2017, 209.

Although it is claimed otherwise in section 3, also institutions like the STIKO are influenced by vaccine manufacturers causing conflicts of interest, as has been confirmed by Leitlinienwatch (GuidelineWatch), the transparency web portal for clinical practice guidelines: "Unfortunately, no companies are mentioned with regard to the fees for external expert papers. The abstention rule prescribed for votes is therefore not sufficiently verifiable."<sup>151</sup>

### Why mandatory vaccination is not a suitable means to achieve the target of protecting the population from measles:

The call for a mandatory vaccination policy is often the automatic response to any measles outbreak, not only those confined to Germany.<sup>152</sup>

A de facto mandatory vaccination leads to the situation that the members of certain professions, or almost the total population, must get vaccinated. Even a de facto mandatory vaccination for so-called risk groups in health care, education and training, or the social sector mentioned in recommendation 13, or the possible exclusion of individual unvaccinated children from child-care centres in the context of risk prevention as it is called for in recommendation 11, must be rejected. This is also expressed in recommendation 12 that asks for a stricter Protection against Infection Act (IfSG).

A (de facto) mandatory vaccination policy against measles should be analysed under four aspects, in order to make it clear

<sup>151</sup> https://www.leitlinienwatch.de/empfehlungen-der-staendigenimpfkommission [2019-06-04]; cf. also https://www.rki.de/DE/Content/ Kommissionen/STIKO/Mitgliedschaft/Interessenskonflikte/ interessenskonflikte\_node.html [2019-06-04].

<sup>152</sup> Cf. https://www.aerzteblatt.de/nachrichten/100521/Lauterbach-will-Impfpflicht-fuer-Masern-neu-debattieren [2019-06-04]; Heininger/Iseke 2019; https://www.bvkj.de/presse/pressemitteilungen/ansicht/article/ kinder-und-jugendaerzte-fordern-impfpflicht [2019-06-04] and the decisions of the political parties CDU (https://www.cdu.de/system/tdf/ media/dokumente/sonstige-beschluesse.pdf?file=1 [2019-06-04]) and FDP (https://www.fdp.de/sites/default/files/uploads/2017/05/08/2017-04-29-bpt-kindeswohl-schuetzen-recht-auf-impfung-fuer-alle-kinder.pdf [2019-06-04]).

why it is unsuited to achieve the target of protecting the population against measles:

### 1. Effectiveness

# Does mandatory vaccination lead to a higher vaccination coverage?

If one compares the vaccination coverage rates of the first and the second dose of vaccine in Germany with the mean values of those eight EU member states where mandatory vaccination has been in force for some time now (Bulgaria, Croatia, Latvia, Poland, Slovakia, Slovenia, Czech Republic and Hungary)<sup>153</sup>, a positive effect of mandatory vaccination on increasing vaccination coverage is questionable. This is the resulting picture:

Vaccination coverage rates for the first dose of measles vaccine (MCV1) since 2010 have sometimes been higher in Germany than the average rate in countries with mandatory vaccination; in 2017, it was two percent higher in Germany.<sup>154</sup>

This fact goes against the concern that the lack of a mandatory vaccination policy would lead to lower vaccination coverage, which would in turn prevent the eradication of measles: For years, 97 percent of parents in Germany have decided voluntarily to have their children vaccinated with the first dose of vaccine.<sup>155</sup>

The second dose of vaccine (MCV2) does not serve the purpose of improving the protection provided by the first dose of vaccine, as the introduction tries to make the reader believe, but of protecting those persons with primary vaccination failure. Its effect therefore merely is to provide protection

<sup>153</sup> In France and Italy, the comprehensive mandatory vaccination policy is yet too recent to expect epidemiological effects.

<sup>154</sup> Cf. http://apps.who.int/immunization\_monitoring/globalsummary/ timeseries/tswucoveragedtp3.html [2019-06-04] and https://vaccineschedule.ecdc.europa.eu [2019-06-04].

<sup>155</sup> Cf. https://www.aerztezeitung.de/medizin/krankheiten/ infektionskrankheiten/masern/article/943821/eher-kontraproduktivimpfpflicht-wuerde-masernproblem-nicht-loesen.html [2019-06-04].

for people where the first vaccination against measles was not effective.

The comparison is more complex and multi-faceted here than it is for the first measles vaccination: 95 percent of the children who have only received the first dose of vaccine are already reliably protected against measles.<sup>156</sup> Almost all European neighbour countries, both those working on the basis of recommendations only as well as those with a mandatory vaccination policy, but also the German federal state of Saxony, therefore recommend to give the second dose of vaccine at a later point in time than the STIKO does.<sup>157</sup> In spite of these different contexts, the difference in vaccination coverage between countries with mandatory vaccination and Germany was less than one percent in 2017 also for the second dose of vaccine.

This shows that there is no scientific evidence to establish a connection between mandatory vaccination and vaccination coverage, and this is also what current international studies by ASSET and the Sabin Vaccine Institute say.<sup>158</sup>

# Does mandatory vaccination lead to a lower measles frequency?

It is frequently claimed that a mandatory vaccination policy would lead to a decrease in the frequency of measles. However, even if individual protection is effective and even if herd community can be proved to exist for this contagious disease that is only transmissible from person to person, these results are not valid for the total population. This is apparent in the comparison of the measles outbreaks (incidence) over the past ten years. In the EU, there were considerable measles outbreaks also in countries with a mandatory vaccination policy in place.<sup>159</sup> At

<sup>156</sup> Cf. Strebel et al. 2018.

<sup>157</sup> Cf. https://vaccine-schedule.ecdc.europa.eu [2019-06-04].

<sup>158</sup> Cf. ASSET 2016 and https://www.sabin.org/updates/blog/legislativeapproaches-immunization-across-european-region [2019-06-04].

<sup>159</sup> Cf. https://atlas.ecdc.europa.eu/public/index.aspx?Instance=GeneralAtlas [2019-06-04].

the same time, the incidence of measles in Germany for that period was lower than the average measles incidence in countries with a mandatory vaccination policy.

This means that a connection between the second measles vaccination and the incidence of measles is only marginal, if there is a connection at all.

Therefore, it must be doubted that there is a correlation between a mandatory vaccination policy and the frequency of measles outbreaks. The measles vaccination, which is highly effective at the individual health care level and leads to herd immunity, does not necessarily have the desired effect at the population level.

### 2. Legal issues

### Would a mandatory vaccination policy be constitutional?

Every vaccination interferes with a crucial fundamental law: *the right to physical integrity*. Every vaccination of children in addition interferes with *the parental right to care and custody of their children*.

This is why the state is subject to strict limitations with regard to imposing mandatory vaccination against the will of the individual or of parents. In addition to what has been said in section 3.2.2, it is uncertain whether a mandatory vaccination policy would conform with constitutional law. This is also the opinion of the Wissenschaftliche Dienste (Research Services, WD) of the Bundestag, the German parliament.<sup>160</sup>

According to the WD, three conditions must be met if mandatory vaccination shall apply for a disease that can be prevented through vaccination:

- The risk of infection must be significant.
- There must be a more than low risk of a fatal course of the disease.
- The danger of an epidemic spread must exist.

<sup>160</sup> Cf. Deutscher Bundestag 2016b.

Mandatory vaccination in case of an epidemic outbreak: According to the WD, the IfSG does not provide an authorisation for a general mandatory vaccination policy, but only for the limited possibility of an obligation that "those segments of the population that are at risk have to undergo vaccinations [...] if a communicable disease occurs that takes a severe clinical course or can be expected to take on the proportions of an epidemic" (Section 20 (6) IfSG). This means that legislation requires that an epidemic spread "can be expected".

General mandatory vaccination policy: According to the WD, it is not possible to give a universal answer to the question whether a general mandatory vaccination policy is constitutional. "Deliberations must always take into account the various types of disease. If the deliberations come to the conclusion that only a low risk exists, a general mandatory vaccination policy would be an interference with the right to life and physical integrity guaranteed under Article 2 (2) GG that is not justified by the constitution."<sup>161</sup>

For measles, the WD considers the risk to be low: "For example, given a mortality rate of 30 percent in the case of an infection with smallpox, a mandatory vaccination policy against smallpox was regarded as constitutional by the BVerwG in 1959. [...] However, in the case of measles, the mortality rate in Germany is only at 0.1 percent according to the Robert Koch Institute."<sup>162</sup>

Mandatory vaccination for children: As a general rule, according to the WD, protective vaccinations of children fall under the "scope of protection of the parental right to direct education". This is why the state must be limited to a "minimum of intervention" – "[The state] may not by itself impose the optimal health care measures for children because the parents have a priority of decision in that regard. [...] It shall be

<sup>161</sup> Ibid., 5 f.

<sup>162</sup> https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/ Ratgeber\_Masern.html [2019-06-04].

the parents' responsibility to determine the extent of burden and risk-bearing intervention to which they want to expose their child, considering its opportunities in life. Concerning vaccinations, the state therefore generally must respect the parental right to weigh the advantages of vaccination against its possible disadvantages (side effects, 'vaccine injuries') for their children."<sup>163</sup>

The WD sums up: "As a result of weighing up the various interests, a mandatory vaccination for children seems to be constitutionally admissible only for those diseases that may have fatal consequences for the life or health of the child, and that – in the absence of individual vaccination or full vaccination coverage – bear a probability of infection that is not neglectable [...]. For all other protective vaccinations, it can be presumed that parental right takes precedence over the state's supervisory function."<sup>164</sup>

It is therefore at least questionable whether a potential (de facto) mandatory vaccination policy against measles is constitutional. Sooner or later, this issue will be examined by the Federal Constitutional Court and/or the Federal Administrative Court. In that case, the concerns of experts in constitutional law would be voiced, who might deny the state the right to impose mandatory vaccination as it is suggested in recommendations 11, 12 and 13, which they deem constitutionally inadmissible.<sup>165</sup>

# 3. Possible counter-productive effects of a mandatory vaccination policy

### What are the risks of a mandatory vaccination policy?

For good and historic reasons, coercive measures are rare in Germany. Obligations – and a de facto mandatory vaccination would be such an obligation – and sanctions are always liable

<sup>163</sup> Deutscher Bundestag 2016b, 5 f.

<sup>164</sup> Ibid., 7.

<sup>165</sup> Cf. Zuck 2017.

to provoke resistance, which is not necessarily substantiated by facts, but often arises for the sake of resistance alone. Assuming that, in the case of mandatory vaccination, legal instruments to sanction violations will stand up in court, and that thus the basic legal principle of proportionality is complied with, it would be very likely that parents consciously accept these sanctions and might even boast about active non-participation, or that they would no longer have other vaccinations carried out which they had previously accepted. These children would increase the number of the children who – for other reasons – have not or not completely been vaccinated so far. A de facto mandatory vaccination against measles could therefore even lead to an overall decrease in vaccination coverage as a negative consequence. This would not be the case with voluntary vaccination.<sup>166</sup>

The fear of compromising the general acceptance of protective vaccinations among the population, and the good vaccination coverage that has been achieved in Germany without sanctionable measures up until today have induced experts to oppose a mandatory vaccination policy in the case of measles for years.<sup>167</sup>

### Aspects concerning physicians

The occupational sanctions threatened with in recommendation 13 might induce doctors to work as private resident doctors only, and to return their accreditation with the public health insurance funds. This is another reason why it seems to be counter-productive to threaten with occupational sanctions for doctors. Moreover, this recommendation would have severe social consequences, because such a development would

<sup>166</sup> Cf. Betsch/Böhm 2016.

<sup>167</sup> Cf. https://www.aerztezeitung.de/medizin/krankheiten/ infektionskrankheiten/masern/article/943821/eher-kontraproduktivimpfpflicht-wuerde-masernproblem-nicht-loesen.html [2019-06-04] and https://www.apotheken-umschau.de/Infektion/Braucht-Deutschland-eine-Impfpflicht-548597.html [2019-06-04].

affect poor people in particular. The majority of general practitioners does not approve of a mandatory vaccination policy because they must rely on an untroubled, trustful relationship in order to be able to give evidence-based counsel.<sup>168</sup>

### 4. Social and gender aspects

Mandatory vaccination for so-called risk groups (health care, education and training, social sector) and/or a general de facto mandatory vaccination policy would be counter-productive for unvaccinated adults and children, too. As a result, children could not attend child-care centres or benefit from other educational offers.

Especially girls whose parents have religious reasons to look for an excuse not to send their daughters to voluntary school events might possibly be excluded. Not vaccinating their children might even be purposely used as a pretext for not having to send girls on school trips, for example.

Wealthy children and their parents have the option of attending private schools and private kindergartens, or of seeing private doctors as an alternative.

This is why considerations regarding social and gender policy should have priority over a de facto mandatory vaccination policy.

In conclusion, it must be noted that the introduction of a de facto mandatory vaccination policy in Germany would be medically ineffective, legally problematic and socially quite likely counter-productive, which means that such a profound interference with fundamental rights is not legitimate.

#### **Christiane Fischer**

<sup>168</sup> Cf. https://www.aerzteblatt.de/nachrichten/102283/Allgemeinmedizinerbefuerworten-Impfpflicht-fuer-Masern-nicht [2019-06-04] and Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin 2019.

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## **ABBREVIATIONS**

AA	Akademieausgabe (Academy edition)
ADR	adverse drug reaction
BGB	Bürgerliches Gesetzbuch (Civil Code)
BGBI.	Bundesgesetzblatt (Federal Law Gazette)
BGHZ	Entscheidungen des Bundesgerichtshofes in Zivilsachen (Decisions of the Federal Court of Justice in Civil Cases)
BVerfGE	Entscheidungen des Bundesverfassungsgerichts (Decisions of the Federal Constitutional Court)
BVerwG	Bundesverwaltungsgericht (Federal Administrative Court)
BZgA	Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education)
DEGS	Studie zur Gesundheit Erwachsener in Deutschland (German Health Interview and Examination Survey for Adults)
EU	European Union
GG	Grundgesetz (Basic Law)
HPV	human papillomavirus
IfSG	Infektionsschutzgesetz (Protection against Infection Act)
KiGGS	Studie zur Gesundheit von Kindern und Jugendlichen in Deutschland (German Health Interview and Examination Survey for Children and Adolescents)
KV	Kassenärztliche Vereinigungen (Associations of Statutory Health Insurance Physicians)
MBO-Ä	(Muster-)Berufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte ([Model] Professional Code for Physicians in Germany)
MMR	measles/mumps/rubella
MMRV	measles/mumps/rubella/varicella
NNH	number needed to harm
NNT	number needed to treat
NZFam	Neue Zeitschrift für Familienrecht
SGB	Sozialgesetzbuch (Social Code)
SSPE	subacute sclerosing panencephalitis
STIKO	Ständige Impfkommission (Standing Committee on Vaccination)
suppl.	supplement
TBE	tick-borne encephalitis
US	United States
VE	vaccine efficacy/effectiveness

- WD Wissenschaftliche Dienste (Scientific Services [of the German Bundestag])
- WHO World Health Organization

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