

## Effectively enforcing mandatory vaccination in Poland and worldwide

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**Summary** Vaccinations are a crucial preventative measure performed by primary care. Polish local self-governments should be praised for their independent determination in attempting to improve public health by requiring parents to fulfill their legal obligation to have their children receive mandatory vaccinations. However, there is an urgent need for similar general regulations encompassing the entire population of Poland if serious risks to its public health are to be avoided. The variety of approaches attempted thus far in different countries demonstrates that there is no single ideal solution for all – although, judging by the results, it seems that incentive-based solutions seem to be more efficient than the repressive ones. We thus advised that Poland implement an escalating approach: proper education of all citizens in human biology and the basics of medicine is a must, as is demonstrated by the experience of Scandinavia; this should begin even in preschool facilities. The “No Jab No Pay” approach used in Australia could easily be replicated in Poland by withdrawing the right to the relatively new child benefit from parents who do not have their children vaccinated – especially as this benefit is ultimately planned to include all children in the country. Following the examples of the Czech Republic, France, Italy, and the United States, unvaccinated children could be banned from entering sports facilities. In case of the most persistent violators, harsh measures – including financial penalties imposed by the state – should be kept in reserve, and these should be similar to the significant fines known from Italy and Germany.

**Key words:** vaccination refusal, mandatory programs, primary health care, medical legislation, public health, preventive medicine.

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Vaccinations are a crucial preventative measure performed by primary care. In Poland, avoidance of vaccination can be effectively prevented on the basis of laws and their current judicial interpretations [1]. According to Article 68 of the Constitution of Poland [2], it is the duty of institutions of the Polish state to mitigate and prevent epidemic diseases; this duty is fulfilled through obligatory vaccination and other means. In the Act on Healthcare Services Financed from State Resources [3], vaccinations are mentioned as services that aim to preserve health, prevent disease, and allow for early detection of disease. We here examine the legal, formal, and organizational regulations concerning vaccinations and their avoidance in Poland and selected countries in order to identify solutions that could be improved on and those that could be introduced to Poland with the aim of increasing compliance with obligatory vaccinations.

### Infectious diseases and vaccinations

Vaccinations are provided by the healthcare system and benefit not only individual patients, but also serve as a means of securing the health of the general population; this is one of the preventative goals of public health [4]. It should be recalled that the epidemic diseases that are at present preventable through mass vaccinations have killed and damaged a significant part of the human population throughout all of history. This state of affairs only came to an end with the so-called epidemiological transition, which even in economically developed countries took place as late as the second half of the twentieth century

[5]. Such diseases continue to pose a serious threat in other parts of the globe, as they result not only from the presence of a pathogen in the human population or its environment, but also from the population’s susceptibility. This latter is associated with a wide variety of factors, including genetics (of both the pathogen and humans), peoples’ current immunity status (which in turn depends on age, general health, and nutrition), sanitation, awareness of health matters, and the organization, integrity, and resources of healthcare systems. These are the crucial factors that affect the efficacy of detection, treatment, and prevention of disease, including vaccinations. It is consequently vital that attitudes, opinions, and actions that undermine the very successful vaccination program are countered decisively. Smallpox, the first infectious disease to be eradicated through vaccinations, nonetheless persisted until 1980, and was one of the most severe plagues in history. In eighteenth-century Europe, an average of 1,500,000 people died of this disease each year, and during epidemics the fatality rate rose above 30%. It is no wonder then that smallpox was considered unrivalled in its cruelty: Thomas Sydenham stated that it had taken a greater toll than any gun; Piotr Frank complained that the only thing capable of freeing him of smallpox was death; and a German saying of the time states that few manage to avoid love and smallpox [6].

The devastation caused by infectious diseases urged people to seek protection. From ancient times, there have been attempts to ward away evil powers by superstitious means, such as burning aromatic herbs, or by isolation (such as quarantine),



or simply by fleeing, which often resulted in the side effect of the diseases being carried to new regions [5].

Progress in medical science ultimately led to vaccines being introduced for an increasing number of the infectious diseases that had plagued humanity, allowing them to be effectively prevented for the first time. Even the invention of antibiotics did not have such a great effect on limiting mortality and improving general health as did vaccines. Vaccinology, the medical science of inventing, developing, and evaluating vaccines, has revolutionized the twentieth century's view of the health-illness balance, while saving millions of lives each year [7]. A further step was made by the methods of molecular biology, which improved existing vaccines and discovered new one, giving hope for incurable diseases, such as AIDS [8].

Vaccination, as a method of treatment recognized by medical science, was born on 14 May 1726 when the English physician Edward Jenner employed it as a means of preventing smallpox in an eight-year-old boy, James Phillips, in Gloucestershire. The experiment proved successful [6]. However, since then, debates have occurred about whether vaccinations are actually efficient and in fact harmless to patients [9]. Many physicians who now vaccinate children need to respond to the doubts of their parents or guardians. Even quite well-educated nonsuperstitious people sometimes think that, since the world is now largely free from the infectious diseases that vaccinations prevent, vaccinating may be just a habit – even one that is excessive and unjustified, but deeply rooted in medical tradition and for this reason still employed by physicians [6]. They fail to appreciate that if vaccinations were discontinued, the infectious diseases they prevent would inevitably reappear; only vaccinations keep them at bay.

## Objections to vaccination

In the recent decades, skeptical attitudes to vaccinations have increased in the public worldwide, including in Poland. This has resulted in a significant increase in objections to vaccination, not only among patients who are capable of deciding for themselves, but more so among parents who make health decisions for their children. In Poland in 2017, there were over 30,000 objections to the vaccination of under-eighteens – this represents a tenfold increase in just a decade [10]. In 2018, there were over 40,000 such objections, an increase of a third in merely one year; if this continues, 2019 could be expected to see around 50,000 objections [11]. This is an increasingly serious threat to the health of Polish society as, contrary to the public's false beliefs, the danger of infectious diseases persists. In Poland in 2015, such diseases caused around 1,900 deaths, including over 300 cases of type B viral hepatitis and over 500 cases of tuberculosis of the respiratory tract. Both of these diseases can be effectively prevented by currently available vaccinations [12]. The World Health Organization (WHO) estimates that, each year, between two and three million deaths are prevented by vaccinations [13]. Parents can be divided – into three main categories depending on the attitude towards vaccination themselves or their children: acceptors, refusers and partial acceptors. Acceptors are parents of children who received all vaccinations scheduled. Refusers are those whose children received none of the scheduled vaccinations. Partial refusers are parents who refuse or delay some scheduled vaccines of their children [14]. It is crucial to remember that hesitant attitudes towards vaccinations are likely to turn into refusal [15] especially in populations where the vaccinations are passively accepted (e.c. due to legal demands) rather than actively demanded (out of awareness of their benefits) [16].

Vaccinations are an effective life-saving tool, but one that remains mistrusted and underutilized. One of the causes of this may be the relative invisibility to the public of infectious diseases and of the deaths they cause. It is therefore of vital im-

portance to make as vivid as possible the relationship between the low prevalence of infectious diseases and the high rate of vaccination. Whooping cough (pertussis) can serve as a good example: at the beginning of the 1990s, when vaccination for this disease in Poland was comprehensive, there were as few as 300 cases registered per year; in 2016, with the increasing popularity of the antivaccination movement, the yearly incidence of whooping cough was almost 7,000, an increase of more than a factor of 20. This is consistent with data from the USA indicating that an increase of 0.1% in the population of newborns not vaccinated against pertussis leads to a significant increase in the incidence of whooping cough of 5 cases per 100,000 exposed. Another example of untapped prevention potential is influenza: in 2015 there were 3.8 million cases reported, of which 12,100 cases required hospital treatment; in 2016, these numbers were 4.3 million and 16,600. This enormous and overwhelmingly preventable burden on Polish society can be easily explained through the low incidence of annual flu vaccinations, which on average do not exceed 3% to 5% [12]. It is mandatory in Poland for all groups of people indicated by the Ministry of Health in the yearly updated Preventive Vaccinations Program (*Program Szczepień Ochronnych*) to receive crucial vaccinations; mandatory vaccinations are administered free of charge following a detailed official schedule that optimizes the positive effects to evoking immunity while minimizing the risk of possible interactions and side effects [17].

Vaccines are used on healthy people on a massive scale, and so they undergo particularly meticulous control aiming at high efficacy, low risk, and low intensity of both side effects and adverse reactions. However, no matter how strenuous these efforts are, it is still not possible to achieve full efficacy and to eliminate all risks. Paradoxically, these risks draw particularly high levels of public attention in societies where the prevalence of vaccine-prevented diseases is low. Consequently, the typically low risks associated with vaccinations seem (subjectively and erroneously) to be unjustifiable, seeming to ostensibly outweigh the objectively undeniable benefits of vaccinations. The mass media in particular tend to focus excessively on solitary cases of vaccination-related side effects and dramatic adverse reactions, thus building in the public a distorted picture of the issue. It is well known, especially in the aftermath of the numerous rigorous studies stemming from the early 1980's, that occasionally a side effect of vaccinations can be serious and lead even to death of the patient [18].

The term “adverse event following immunization” (AEFI; the equivalent Polish term is “niepożądany odczyn poszczepienny”, or NOP) refers to an unintended local or generalized reaction to an administered vaccine. This can result from many factors, and most often it is secondary to the individual pathological reaction of the person's body. Other causes include improper administration of the vaccine; administration of a vaccine that should not have been used, due to an error in production, storing, or transport; signs, symptoms, or disease that occur coincidentally and are not causally associated with the administration of the vaccine. AEFIs can be of mild, moderate, or serious severity [18].

The decree of the Polish Minister of Health concerning AEFIs and their diagnostic criteria [19] describes an AEFI case as being serious when it is life-threatening, and thus may require hospitalization, lead to a lasting deficit of physical or mental fitness, or to death. An AEFI of moderate severity is characterized by very intense symptoms and signs that may involve significant swelling or redness of the extremity into which the vaccine was administered, or high fever, but does not require hospitalization, leads to a lasting deficit of health or posing a threat to life. A mild AEFI is associated with moderate intensity of signs and symptoms, including some degree of local swelling or redness of the vaccine-exposed extremity, or fever.

The Polish agency Narodowy Instytut Zdrowia Publicznego – Państwowy Zakład Higieny (NIZP–PZH; *National Institutes of Public Health and Hygiene*) coordinates nationwide AEFI report-

ing and has provided data supporting the thesis that there is an increase in registered AEFI cases: 982 cases were reported in 2008, 1130 in 2011, and 2111 in 2015. However, this should be attributed in the first place to the continuous improvement of the AEFI reporting system, and not to an increase in the incidence and intensity of adverse reactions or side effects of vaccines. It needs to be stressed that cases of serious AEFIs are extremely rare and deaths are sporadic; for example, in 2015 there were only three serious cases of all 2111 AEFI cases (0.14%) [20].

Although there are differences in the incidence and intensity of AEFIs associated with particular vaccines, the average rate of incidence of AEFIs in Poland does not exceed 1 per 10,000 vaccinations [21]; it is clear that the risk resulting from vaccination is minimal and that benefits for both the individual and society as a whole outweigh it. The incidence rate of different AEFIs can be found for a given vaccine from its summary of product characteristics (*Charakterystyka Produktu Leczniczego*): these are divided into very common AEFIs (occurring in over 10% of administrations); common (occurring in over 1% of administrations); moderately common (occurring in over 0.1% of administrations); rare (occurring in over 0.01% of administrations); and very rare (occurring in less than 0.01% administrations). According to the NIZP-PZH, the measles, mumps and rubella (MMR) vaccine causes local reactions in 10% of administrations, but the serious AEFI incidence rate is as low as one to three cases per million administrations. The live weakened oral poliovirus vaccine (OPV) caused paralysis in one in a million administrations [20].

The AEFI monitoring system has existed since 1996 and meets the requirements defined in the World Health Organization's Drug Monitoring Program Expanded Program on Immunization. The Polish state covers all costs of medical services provided to patients with AEFIs, regardless of whether they are covered by the public medical insurance system [22]. However, although both the incidence and intensity of AEFIs in Poland is low, they are still reported as the leading cause of parents' vaccination-related concerns and refusal to vaccinate their children [23].

## Effectively enforcing the obligation to vaccinate

Mandatory vaccination policy, started as early as in 1807 in Bavaria, Germany [24], is the crucial factor in ensuring high levels of vaccination coverage [25]. For several recent years, the administrative and legal measures taken in Poland to enforce vaccination seemed to be of limited efficacy [1]. Since 2017, when the problem was widely acknowledged, Poland has followed other developed democratic countries in the quest to revert the current negative trends in vaccinations statistics.

According to the NIZP-PZH reports, since 2017 the percentage of the population vaccinated with MMR vaccine has dropped below the 95% threshold, considered a satisfactory level of immunization. In case of the MMR vaccine, the 94% of the population received the first dose and 93% received the second dose; in 2018, these values dropped further to 92.9% and 92.4%, respectively; these should be compared to the 2009 values of 98% and 94%. While the WHO expected measles to be eradicated in Europe by 2017, it has returned as a serious public health threat in many countries, including Romania, Italy, France, Greece, Serbia, Ukraine, the Czech Republic, and the United Kingdom [26]. Moreover, between January 2016 and October 2017, there were 43 deaths from measles registered in the European Union, 34 of which were in Romania, and mainly among unvaccinated children [27]. In 2017, the President of the European Commission (EC) made a personal appeal to increase the number of vaccinated people in the European Union and to make vaccinations available to everybody, as pathogens do not

respect borders and leaving a significant percentage of Europe's population unprotected against them poses a serious threat to the health of EU citizens. This issue has also drawn the attention of the Commission, which in April 2018 appealed to EU member states to tighten their cooperation in fighting communicable diseases that can be prevented by vaccinations [26].

The EC propositions include implementing regional and national plans concerning vaccinations by 2020, including reaching a 95% level of immunization against measles; improving the availability of vaccinations by creating opportunities to undergo vaccination at various ages and at different institutions, while at the same time introducing routine verifications of vaccination status; developing an electronic vaccination card as a common means for all EU countries of documenting a person's vaccination status; educating all health workers on vaccinations and ways of dealing with the refusal to vaccinate; creating a joint coalition of European medical workers societies and provaccination student organizations to provide information on vaccinations to the public, fighting the myths concerning them and exchanging experiences [26].

In countries where child vaccinations are most commonly avoided, an increasing trend in the incidence of preventable infectious diseases, including measles, pertussis, and tuberculosis, can already be seen. In 2016, the WHO estimated that there were about 10,400,000 people infected with tuberculosis worldwide, including about a million children younger than 14 years. In the same year, there were 58,994 new cases of tuberculosis in the European Union and the European Economic Area, 23% of which were cases from Romania [28]. The increasing influence of antivaccination movements, ignored for decades, has now been acknowledged by politicians in countries like Italy and France. In the latter, only 69% of respondents in 2016 considered vaccinations a trustworthy medical method; at the same time, measles became a statistically noticeable cause of death again, leading French doctors to request the government to actively fight vaccination-related fake news and misinformation [27].

Many countries have introduced severe measures to revert the disturbing trends in vaccinations [29]; in some, mandatory vaccinations are enforced; in others, proof of having received all required vaccinations is needed to take part in educational and sport activities. In Italy, since March 2018, only vaccinated children have been allowed in crèches and preschool facilities and parents of older children who avoid mandatory vaccinations are subject to fines up to €500. Children exempt from vaccinations because of medical contraindication enter classes containing only vaccinated pupils. Italian politicians have stated that those solutions are meant to act as "a shield protecting children from serious diseases" [27]. In Germany since 2017 the parents of preschool children are obliged to discuss mandatory vaccinations with a physician. Avoiding this is subject to fine of up to €2500. Kindergartens may refuse to accept children who do not possess evidence of having received vaccinations [30]. In Romania, politicians have not gone so far as to discipline parents financially for not vaccinating children, but have considered restricting access to preschool facilities and schools to those with a vaccination confirmation issued by a physician. In the Czech Republic and Canada, the access of unvaccinated children to preschool facilities and schools is also limited [29]. In the United States of America, children who have not received the mandatory vaccinations cannot be admitted to public educational facilities. Due to a measles epidemic, New York City has introduced a fine of \$1000 for avoiding the measles vaccination [31]. Some physicians in the USA discontinue their provider relationship with families who refuse vaccines, e.c. among pediatricians: 40% declared that they would stop providing care to families that refused all vaccines and 28% stated that they would dismiss families that refused some vaccines [32, 33]. In Australia, the approach of refusing child-related social security benefits, that amount up to 15,000 AUD yearly, to those avoiding man-



datory vaccinations without medical contraindication has been highly effective since 2015, thus popularizing the catchy slogan “No Jab No Pay” [34]. Some countries prefer the carrot to the stick: although in Norway and Finland vaccinations are optional, thanks to effective medical education the percentage of population that is vaccinated is among the highest in Europe. Similarly, in the United Kingdom, vaccinations are optional and it is the job of GPs to promote them; parents who avoid vaccinating their children are subject to overt criticism [29]. On the other hand, among all countries with mandatory vaccination systems, only in 19 countries there are programs providing no-fault compensation for an adverse effect following vaccination, including: Germany – where such a scheme started as early as in the 1961 [35] – France, Hungary, Italy, Republic of Korea, Slovenia, Taiwan and the USA [36].

In Poland, there is a currently available way to discipline parents who refuse to let their children receive mandatory vaccinations, in the form of fines; in practice, however, these have yet not proven to be an efficient preventive measure [1]. The Polish physicians’ organization has asked politicians to introduce a law requiring parents to confirm that they have given their child all mandatory vaccinations before admission to crèches, pre-school facilities and schools [37].

In Poland, the firmest action was taken by local authorities, who initially requested the government for a statute that would allow them to deal with nonvaccinating parents in their communities [38]. However, rather than waiting for the usually slow work of the national legislature to finish, on 4 July 2019, the city of Wrocław altered its bye-laws regulations on the admission of children to crèches to exclude those who have not received all mandatory vaccinations; those with medical contraindications to vaccination can be admitted with a statement from a pediatrician [39]. Only five days later, the city of Poznań introduced a similar policy [40]. Somewhat less categorical solutions were then introduced by numerous other local authorities in Poland,

including giving preference to properly vaccinated children in admission to public crèches in Warsaw, Bydgoszcz, Kraków, and Szczecin [41].

## Conclusions

The increasing scale of vaccination avoidance and the resulting recurrence of epidemiological threats represent significant public health problems in Poland. Polish local self-governments should be praised for their independent determination in attempting to improve public health by requiring parents to fulfill their legal obligation to have their children receive mandatory vaccinations. However, there is an urgent need for similar general regulations encompassing the entire population of Poland if serious risks to its public health are to be avoided. The variety of approaches attempted thus far in different countries demonstrates that there is no single ideal solution for all – although, judging by the results, it seems that incentive-based solutions seem to be more efficient than the repressive ones. We thus advised that Poland implement an escalating approach: proper education of all citizens in human biology and the basics of medicine is a must, as is demonstrated by the experience of Scandinavia; this should begin even in preschool facilities. The “No Jab No Pay” approach used in Australia could easily be replicated in Poland by withdrawing the right to the relatively new child benefit from parents who do not have their children vaccinated – especially as this benefit is ultimately planned to include all children in the country. Following the examples of the Czech Republic, France, Italy, and the United States, unvaccinated children could be banned from entering sports facilities. In case of the most persistent violators, harsh measures – including financial penalties imposed by the state – should be kept in reserve, and these should be similar to the significant fines known from Italy and Germany.

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