



Vaccination refusal. Autonomy and permitted coercion

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ABSTRACT

The article presents vaccination obligation in relation to the existing or newly enacted legislation. Mass vaccinations and a wave of criticism they cause, forces us to reflect on the limits of medical intervention in the human body and the boundaries granted to individual's freedom and autonomy. This problem is universal and exists mainly in countries without mandatory vaccinations. Analyzing recent years, it must be underlined that a process in some legislatures has been introduced to enforce various forms of vaccination coercion. Although, refusing vaccinations has been treated liberally, the last wave of epidemics in the United States and Europe forced the creation of a different approach. Gradually in the USA, a duty (not a 'coercion') of vaccination is being enforced. Occurring epidemics, (e.g. measles) and dangers resulting from them, force authorities to violate the principle of autonomy and restrict individuals' freedoms regarding their own body. The article presents legal solutions relating to vaccinations in the United States and Europe i.e. administrative decisions imposing vaccinations, solutions conditioning social existence and financial penalties for not complying with this obligation and proposes a solution based on financial liability that will balance out patients' autonomy and public security.

KEYWORDS

Vaccinations; rights; consent; autonomy; legislature

Introduction

A vaccine is a specific substance applied, usually through invasive means, into the human body. It is an immune preparation which, when introduced into the body is to immunize it to a possible pathogen infection. Medicine considers vaccination a universal method for collective security [1]. According to current medical knowledge, a person who has been vaccinated has far greater chances of not being infected with a particular disease entity than somebody who was not. That person may be an adult (who makes his/her own decision) a child (who is under parental authority) or somebody who, for one reason or another, has a legally appointed guardian. Increasing numbers of people who are not vaccinated (those refusing vaccinations, immigrants, tourists, those who did not get a particular type of vaccine) are potentially vulnerable to infection and simultaneously become the source of disease spread. Vaccinations against life-threatening diseases are one of the greatest achievements in the history of public health, thanks to which it is possible to prevent millions of premature deaths [2,3]. However, the existing epidemiological situation and the popularity of anti-vaccine movements force authorities to create specific methods, which will serve the health and safety of the community [4].

Contemporarily, there are various solutions as to the issue of vaccinations, from strictly mandatory (Poland) to discretionary (Germany). Due to epidemiological risks, vaccination obligation is slowly being reintroduced, and, in case of refusal, this obligation may be enforced through legal solutions beginning with financial and administrative penalties to freedom restrictions. An example of application of the most severe sanctions i.e. freedom restrictions can be found in Pakistan where last year approximately 500 parents were arrested for refusing to vaccinate their children against polio, and in over 1000 cases arrest warrants have been issued [5]. In 2016, Australia suspended subsidies for parents of unvaccinated children. At present, Australian parents can refuse to vaccinate their children based on medical exemptions keeping their financial benefits, however, if parents do not vaccinate their children for any other reason, the country will not support them financially [6].

Vaccination obligation in the USA

All states allow vaccination exemptions for medical reasons, additionally until 2015, almost all states allowed vaccine exemptions based on religious or philosophical grounds [7,8]. The increase in the number of parents

Table 1. Obligatory vaccinations in the EU (http://venice.cineca.org/Report_II_WP3.pdf) and the USA.

1	Belgium	Only Polio/OPV
2	Bulgaria	Adult/BCG/DTP/IPV/OPV/MMR/ DT/Td
3	Czech Republic	Adult/BCG/DTP/IPV/OPV/MMR/ DT/Td
4	France	BCG DT IPV
5	Hungary	BCG Hib DTaP IPV MMR HepB
6	Italy	DT/IPV/HepB
7	Latvia	BCG/DT/DTP/IPV/MMR//HepB/TBE/ Adults/Td
8	Poland	BCG/HepB/DT/IPV/OPV/MMR/PCV (since 2017)
9	Slovakia	DTwP/IPV/HiB/HepB/MMR/BCG/Td
10	Slovenia	DTaP/IPV/Hib/HepB/MMR/BCG
11	USA – vaccination against:	(1) Diphtheria (2) Haemophilus influenzae type b. (3) Measles (4) Mumps (5) Pertussis (6) Poliomyelitis (7) Rubella (8) Tetanus (9) Hepatitis B (10) Varicella

Notes: Adult – hepatitis A vaccine, BCG (Bacillus Calmette-Guérin) –vaccine against tuberculosis, DTP – vaccine against diphtheria, tetanus toxoids and pertussis, DT – Diphtheria-Tetanus Toxoids vaccine (for children), DTvP – vaccine against pertussis is combined with vaccine against diphtheria and tetanus, DTap – vaccine containing tetanus toxoid, reduced dose of diphtheria toxoid and acellular pertussis components (booster for adolescents and adults), HepB – conjugate vaccine for type b Haemophilus influenzae, Hib – Haemophilus influenzae type b vaccine, HPV –human papilloma virus vaccines, IPV – Inactivated polio vaccine, MCV – meningococcal vaccine (*Neisseria meningitidis*), MMR – vaccine against measles, mumps, and rubella, MPSV – Meningococcal Polysaccharide Vaccine, OPV – Oral polio vaccine, PCV – Pneumococcal conjugate vaccine (*Streptococcus pneumoniae*), PPSV – Pneumococcal polysaccharide vaccine, TBE – Tick-borne encephalitis vaccine, Td –tetanus and diphtheria vaccine for adolescents and adults, TIV – trivalent influenza vaccine.

refusing to vaccinate their children resulted in 20% of children not receiving the recommended vaccines for medical and non-medical reasons. The California Department of Public Health (DPH) revealed that, in California, the number of vaccination refusals has doubled since 2007 [9]. What is more, recent years proved that the outbreaks of diseases considered to be 'defeated' are beginning to re-occur [10,11]. It has been proven that many populations have a decreased herd immunity, which in the United States was the reason for an outbreak of measles in California (Disneyland measles). This in turn forced the implementation of more rigorous laws mandating vaccinations [12,13]. Since the beginning of 2015, the Centers for Disease Control and Prevention in Atlanta registered 127 cases of infection associated with the outbreak of this epidemic. In 2014, California became much more restrictive concerning personal exemptions, requiring parents seeking such exemptions to obtain a certificate from the doctor that they were informed on the diseases that could be prevented using vaccinations. Soon afterwards, this solution proved insufficient. In April 2015, California's legislature proposed removing personal beliefs (religious, philosophical) as reasons for refusing vaccinations, which in turn initiated a public,

wide-range debate on the limitations of freedoms and rights granted to an individual [13]. Additionally, in June 2015, Bill SB 277 was passed, markedly narrowing the exceptions relating to the possibility of refusing vaccinations of children. California became the third state, after West Virginia and Mississippi to prohibit exemptions from immunization based on religious and/or philosophical beliefs. In respecting autonomy, the introduced law forbids admitting children to private and public nurseries and primary and secondary schools (and other public social institutions) without being vaccinated according to the established vaccination schedule. This does not pertain to children who have a medical exemption or those who have home schooling [13]. Such a solution, put into practice, limits the availability of public and private education, simultaneously leaving parents with the freedom of choice (home schooling), however, it may also lead to practices aimed at obtaining the medical exemption from vaccinations [13]. Critics postulate a referendum where the public would comment on this issue.

Vaccination obligation in Europe

Currently in Europe there is no overall vaccination requirement. The majority of European countries have their own immunization policies based on public health care systems, financed from public funds. However, until 1989, the former German Democratic Republic had vaccination coercion, which was unfavorably seen by critics as a characteristic of totalitarian regimes [8]. In many European countries, the introduction of mass vaccination occurred in the 1980s e.g. in Denmark the requirement of being vaccinated against measles was introduced in 1986. In countries with a decentralized administrative structure, such as Germany, the prophylactics of infectious diseases is the domain of individual States (Lands) [14]. For example, measles vaccination is only recommended by the German Standing Committee on Vaccination (STIKO). However in 2013, health authorities in Berlin's Tempelhof-Schoeneberg decided that in order to be accepted to school, a child must have proof of measles vaccination or a doctor-certified history of measles [15]. After a wave of complaints, the Administrative Court of the State of Berlin has ruled that such a solution (aimed at protecting other children) is not against law. In 2014, a measles outbreak, and the death of a child, became an ignition point for discussion on the possibility of introducing compulsory vaccination against measles [15]. In comparison, the only mandatory vaccination in Belgium is that against polio [14]. On the other hand, the Croatia Constitutional tribunal upheld the obligation to vaccinate children, recognizing that the child's right to health means more than the right of parents to make decisions. Since mid-2014 all children will be mandatorily given a vaccine against diphtheria, pertussis, tetanus, polio, measles, mumps, rubella and tuberculosis

Table 2. Information on mass vaccination and common sanctions for non-compliance.

	USA	Europe (UE)
Vaccination obligation	<p>Until 2015, lack of universal vaccination requirement</p> <p>Currently only in three US states (West Virginia, Mississippi, California) it is possible to refuse vaccination only on medical grounds</p>	<p>Individual EU countries differently regulate the obligation of vaccination</p> <p>No widespread coercion of vaccination for the countries of the EU (e.g. In Belgium there is only 1 compulsory vaccination; against polio)</p> <p>In Poland there is an established legal way to fulfill this obligation</p>
Introduced sanctions	<p>The inability to admit a child to primary and secondary schools, public and private childcare facilities (adult day care homes, development centers) - without vaccination according to a list of specific diseases from the list below:</p> <ol style="list-style-type: none"> (1) Diphtheria (2) Haemophilus influenzae type b (3) Measles (4) Mumps (5) Pertussis (6) Poliomyelitis (7) Rubella (8) Tetanus (9) Hepatitis type B (10) Varicella <p>Any other disease deemed appropriate by the (State Department of Public Health), taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians</p>	<p>Individual European countries either have no penalties or predict the following sanctions:</p> <ol style="list-style-type: none"> (1) Financial penalties (fines), non-compliance is sanctioned as an offense (Poland) (2) Administrative decisions determining vaccination obligation, lack of compliance results in financial penalties (3) Solutions basing access to public education on being vaccinated (Berlin)

[16,17]. In Italy, where measles vaccination is only recommended, an increase in measles' incidence was observed in 2011 compared to 2010 [18]. In some Scandinavia (e.g. Denmark and Norway), almost half the parents do not vaccinate their children at all or chose only selected vaccines and give them at a chosen time [18–20]. In Poland numerous vaccinations (currently listed in the Ministry of Health regulation of August 18, 2011) are labeled as obligatory. The legislature and the immunization program, created on its basis, clearly underline the mandatory character of vaccinations [18,21]. The institution responsible for carrying out this obligation is the State Sanitary Inspection [22]. Vaccination requirements are implemented through a fine, the payment of which is not synonymous with the completion of the enforcement proceedings as they are aimed at fulfilling the vaccination obligation. This in turn suggests that a competent authority can re-impose the fine until a person is vaccinated. What is more, direct coercion (i.e. vaccinating a person against their will) in order to implement this obligation is listed as a possible enforcement measure; however, it has never been used [21,23]. Growing concerns about the ineffectiveness of vaccines and complications following their administration caused the European Council to adopt, in 2014, a recommendation that vaccines are an effective tool in the field of public health [18]. Currently, 15 European countries have no mandatory vaccinations. Other countries have 1 obligatory vaccination included in the immunization program (e.g. Belgium). Polio vaccination is mandatory in 12 countries, vaccination against diphtheria and tetanus in 11 and vaccination against hepatitis B is compulsory in 10 European countries (see Table 1) [18,19].

Discussion

The first reliable report on inoculation against smallpox originated in China at the turn of the fifteenth and sixteenth century [24]. Over time, with the development of institutional and mass medicine, vaccinations became a part of health protection and social prevention against infective threats. In opposition to this preventive procedure, various anti-vaccination movements emerged, which for diverse reasons question the legitimacy and purpose of mass vaccinations. Information on mass vaccination and common sanctions for non-compliance are presented in table 2 [8,25]. The wave of criticism and emerging actions against vaccination obligation was directly associated with Wakefield's publication, in which he described studies interpreting associations between vaccinations and the occurrence of autism and enteritis (which were found to be falsified and subsequently discredited), and Sinclair's publication 'Vaccinations-the hidden facts', which revealed that vaccines may cause a number of side effects and pose other health hazards [26–29]. Contemporarily, vaccination opponents provide various arguments against required vaccinations, which can be grouped into four categories.

- (1) Philosophical (worldview), which are based on a liberal conception of individual's rights to self-determine about his/her health, body and life. Therefore, no one, much less the government should interfere with the individual's right to undergo or abandon medical treatment. Medical decisions for children should be left to parents or guardians. Proponents of this viewpoint argue that society is incapacitated

and used for medical experiments. It is claimed that healthcare systems, supported by pharmaceutical corporations, knows better than parents what is good for their children. What is more, it demands for children to be vaccinated for diseases, which do not endanger health or are currently eradicated [8].

- (2) Naturalistic. Supporters of the naturalistic arguments argue that being vaccinated goes against nature, because combating diseases using vaccines causes the body to be insufficiently prepared to combat more severe diseases, even though the body is strong enough to handle those for which it is vaccinated [8].
- (3) Religious, which rely on the fact that mandatory vaccines violate the constitutionally protected freedom of religion. Some religions do not acknowledge the efficiency of vaccines, for instance, the Amish believe that vaccines are unnecessary because they weaken the immune system that acts as the body's natural protection. Various religious organizations claim that vaccines violate the teaching of the Bible as they contaminate blood and thus have an important influence on soul's regeneration [30] Christian Science does not recognize the use of any drugs, including vaccines, as it is believed that the 'the body is a temple that cannot be defiled'. This is contrasted with the very production of vaccines and immunoglobulin [30] because some of them may contain components, obtaining of which may be considered immoral e.g. aborted fetal cells (listed in 1960's leaflets as MRC-5 and WI-38). Combination vaccines, DTaP/IPV/Hib, Hep A/Hep B, HEPA, MMR and vaccines for varicella, were made using animal products (cells of African green monkeys and insect cells), which in the beliefs of Eastern religions, is a violation of the rule prohibiting instrumental killing [30]. Although the number of members of these religions e.g. in USA is small, compared to the whole population, countries where the number of vaccination refusals exceeds few percent have experienced local epidemics of infectious diseases. For instance, failure to vaccinate against measles resulted in an epidemic of this disease with thousands of people becoming ill. In 2011, there were 28,800 cases of the disease and in 2013 -, 10,271 (91% of them in Germany, Italy, the Netherlands, Romania and the United Kingdom) [30].
- (4) Medical, which are raised most often, evaluate vaccines through side effects and possible negative outcomes [8,27]. Vaccine opponents raise concerns about their composition

i.e. about mercury or aluminum contained therein. Because of the introduction of toxic chemicals and hazardous biological components into the body, it is believed that vaccines may cause a variety of adverse reactions (e.g. mercury as ethylene mercury is added as a preservative and an adjuvant). In February 2002, GlaxoSmithKline Company withdrew a vaccine for Lyme disease from the market attributing its withdrawal to poor sale [31]. In reality, those who received the vaccine reported severe symptoms, such as arthritis and neurological disorders [32].

The consequences of vaccination refusal may also be very serious. It can be assumed that vaccination opponents do not take into consideration the threats to the public health caused by an increased number of unvaccinated individuals, and thus the increased number of those susceptible to infection (especially in case of an epidemic). This manuscript presents various forms of vaccination 'encouragement' from the very extreme, which opt for strong legal coercion, through more lenient formed as a suggestion, to those which completely ignore this phenomenon. None of the current solutions, however, are effective in balancing out patients' autonomy and social security. Our proposition of a solution is based on financial liability of those refusing vaccinations. In case of infection, required treatment and hospitalization should be done at the expense of the unvaccinated person. The principle: 'Against vaccinations? – consider possible costs' should be widespread and applied as the consequence of not being vaccinated. In practice, this would require the person who is not vaccinated or refuses to vaccinate their child to sign a properly constructed, legally binding contract about covering hospitalization and treatment costs in case of infection. The refusal to cover the costs would result in strictly defined consequences (e.g. in the most severe cases, debt collector). The threat of being faced with infrequently large hospital charges should definitely appeal to the intuition of those undecided about vaccinations. Additionally, unlike any of the described solutions the 'punishment' would occur after a real infection and not in order to avoid a possible one. Such an approach is crucial for maintaining the balance between coercion and autonomy; the individual is not forced to foresee and prevent the infection, but is ultimately faced with consequences if infection occurs [33]. In the case of some individuals, the reluctance to be vaccinated is strong, and those individuals should not be forced to get vaccinated; others may be hesitating and, for them, the facing of a financial penalty may prove decisive. Summing up, it is only reasonable that nobody should be forced to any medical intervention; however, we all individually (and not the healthcare system) should face consequences of our choices.

Conclusions

- (1) Vaccination obligation is implemented through legal measures
- (2) Vaccination refusal is sanctioned through administrative and financial penalties and freedom restrictions
- (3) Health threat may justify vaccine coercion
- (4) Greater number of those vaccinated will increase herd immunity
- (5) There is a need of vaccination education
- (6) Voluntary vaccination may liberalize the currently existing law
- (7) Financial liability may prove crucial in maintaining vaccination requirement and patient autonomy

Summary

Required vaccinations and various approaches to this method of preventing diseases make it difficult to interpret existing laws and create new rational ones. The possibility of using a specific form of coercion in order to implement any vaccination law, and the concept of treating immunization as an individual human decision, clash constantly and any form of coercion can be interpreted as a restriction of freedom, autonomy or granted rights (e.g. to profess a particular religion). This area is defined on one hand by individual's autonomous decisions, on the other by possible health threats to the individual and the society. Current practices and laws depending on the countries' historical traditions and the established concept of individual's autonomy and freedoms, either do not directly refer to vaccination requirements (Western Europe), associate this requirement with possibilities such as public education (USA), tie avoiding vaccinations to financial penalties (Poland), or even try to impose vaccinations through freedom restrictions (Pakistan). Currently, a process has been initiated where legal norms are used to specify vaccination requirement or the methods used to evade this obligation are becoming limited. The problem of individual autonomy and freedoms, and the vaccination obligation is frequently interpreted with reference to the words of a representative of liberal thought, J.S. Mill. Namely that 'the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others' [34]. In this context, individual refusal (if allowed) should be confronted with possible consequences such as infection and the possible threat of financial liability.

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