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Informed Consent in Obligatory Vaccinations?

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Vaccinations cause controversies for numerous reasons: medical, religious, and even personal. The following paper focuses on one more, underestimated conflict between individual autonomy and public health in regard to obligatory childhood vaccinations. Every medical intervention should be preceded by informed consent; however, informed consent in the case of obligatory vaccinations cannot be voluntary and valid. Moreover, asking parents to sign an informed consent form is paradoxical in a situation where not signing it will lead to legal consequences. Our paper tries to accentuate the issue of involuntariness and invalidity of informed consent in the case of obligatory vaccination and tries to propose a solution that acknowledges requirements for vaccinations and makes parents feel safer coming in and out of a vaccination visit.

MeSH Keywords: **Ethics • Informed Consent • Mass Vaccination • Professional Autonomy • Public Health**

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Background

Currently over 100 million children are vaccinated each year against infectious diseases such as measles, hepatitis B, diphtheria, tuberculosis, or polio. According to the European Commission, vaccinations prevent approximately 2.5 million deaths worldwide annually and reduce disease-specific treatment costs [1]. Global vaccination coverage has stalled for the past few years at 86%; however, it varies by different diseases and regions. For example, hemophilus influenzae vaccine, introduced in 191 countries has a 70% global coverage of 3 doses (90% in Americas compared to only 28% in Western Pacific regions) [2]. Rubella vaccine was introduced in 152 countries by the end of 2016, and global coverage reached a rough estimate of 47%. Pneumococcal diseases were covered somewhere around 42% and rotaviruses only 25%. In 2016, 85% of infants around the world received 3 doses of polio vaccine. Regions where polio is still a threat include Nigeria, Pakistan, and Afghanistan, however, all countries are at risk of contracting polio until the disease is fully eradicated [2]. This risk of disease pertains to other diseases in case of vaccination coverage lower than 100% and underlines how important vaccinations are. Because some parents choose not to vaccinate their children, the problem of a vaccination obligation for children under parental or legal guardianship has become a global issue. With vaccination hesitancy, lower vaccination access, and growing anti-vaccine movements, there have been increases in the number of unvaccinated individuals and ultimately increases in the incidence of vaccine preventable diseases. The number of new cases of vaccine preventable diseases varies by country; however, this tendency is growing. In Europe, several disease outbreaks were observed recently with the highest incidence levels in Romania, Italy, and Germany [3]. Data from the Polish Central Statistical Office revealed that in 2016, the pertussis incidence increased by 40% in comparison to 2015 (which was equal to 6.8 new cases of the diseases). A similar situation was observed for cases of measles, where 2016 witnessed 133 cases whereas 2015 only reported 48 cases [4–7]. In 2017 alone, in the European Union there were over 14 000 cases of measles reported, which was more than 3 times the number noted in 2016 [8].

Examples of Vaccination Coercion

Because of this increase, various governments try to persuade citizens to undergo vaccinations and they do so through imposing fines or placing conditions on social benefits or school admission based on vaccination status. Slovenia is considered to have the strictest vaccine laws, and refusing vaccinations goes against the Infectious Disease Law, the Inspection Act, and the Administrative Procedure Act with noncompliance fines ranging from €41 for refusing to vaccinate to €500

for noncompliance in the case of an order [9]. However, the country allows for a medical exemption and provides compensation in cases of damage caused by mandatory vaccinations. This strategy is clearly working, as the national coverage amounts to 95%. Additionally, unvaccinated children are not allowed in nurseries, preschools, or kindergartens (if such a child is accepted, the kindergarten might pay a fine of up to €18 500) [10]. Slovakia imposes fines up to €330 per parent and no objection to vaccination is possible (including the objection to abortion cell cultures in MMR vaccine despite 70% citizens' declaration of being Catholic) [11]. In Poland, vaccination hesitancy is treated with a fine, which, even if paid, does not relieve parents of a vaccination obligation and no compensation is offered in case of adverse events [12,13]. In France, parents who refuse to vaccinate their children might face criminal charges (with up to 6 months in prison for child neglect/abuse) and might be fined €3750 [14]. Although individual countries introduce their own vaccine policies, disease spread is not confined to the borders of those countries and weakened herd immunity in one country affects the herd immunity of other countries. In 2018, Joint Action, coordinated by INSERM, was launched to address vaccination hesitancy and increase European Union coverage. The initiative involves 24 countries (21 of them from the European Union) as partners and aims at limiting the spread of vaccine preventable diseases [1]. As observed, the European Union (and others) face the immense problem of increasing incidences of vaccine preventable diseases. On one hand, vaccinations have been proven to be effective; on the other, it is a medical intervention that requires consent and preferably, as is common in medicine, informed consent. Countries which deny school administration to unvaccinated children, to some extent, combine parent autonomy and public security. However, countries that make vaccinations obligatory without the possibility of "going around" that obligation confined within legal boundaries, place parents who refuse to vaccinate their children in a difficult position.

"Coerced" Informed Consent?

In the case of a vaccination obligation (which will be the main focus of this paper), individual autonomy is faced off against the state rules and regulations and a clash between individual's rights and public safety becomes apparent. Here we consider 2 mechanisms. The first is protecting individual autonomy (i.e., informed consent); the second is protecting the common good of society (i.e., public health protection through obligatory vaccinations). Currently, a lot of pressure is placed on obtaining informed consent from patients prior to invasive procedures, including vaccinations. An ideal situation exists when parents, after being informed on the benefits/risks of vaccinations, provide a voluntary informed consent for the proposed intervention

and sign proper forms stating their willingness to undergo the procedure. However, the popularity of anti-vaccine movements, parents' reluctance to vaccinate children, and epidemic outbreaks have forced individual countries to introduce mechanisms that impose a vaccination obligation [15]. Although the first premise for initiating the vaccination procedure should be, and is, informed consent; for obligatory vaccinations, we come across a paradoxical situation where parents/guardians of children who are to be vaccinated need to sign an informed consent form despite a vaccination obligation [16]. Consent presupposes a consciousness and will of the person concerned to undergo a certain medical procedure. Parents (after obtaining necessary information) should express voluntary consent for the procedure, which in this scenario is an illusion because their refusal will lead to legal consequences. What is more, these legal consequences do not stop the vaccination obligation mechanism; e.g., in the USA if a child is not vaccinated, that child might not be allowed to attend public schools and the procedure ends, whereas in Poland, receiving a financial penalty for refusing to vaccinate does not relieve parents from the obligation to vaccinate children and the penalty may be imposed repeatedly. The World Health Organization (WHO) also emphasizes that one of the premises for informed consent is voluntariness [17]. Therefore, in the case of obligation, voluntariness might be lacking and thus from an ethical and legal perspective, the whole informed consent is invalid and, in reality, becomes a legal fiction. Depending on the legal culture and country location, vaccination coercion exists at various levels and is connected with a broad catalogue of sanctions for noncompliance: freedom restrictions, financial penalties, and others (e.g., not accepting unvaccinated children to public schools or being denied various benefits) [18–20]. With obligatory vaccination, providing consent is only an additional formality. The principle of autonomy and obligatory vaccination are in conflict. Therefore, with obligatory vaccination, the right to refuse or withdraw the consent is also ineffective and impossible to execute.

References:

1. Vaccination. European Commission. Public Health. <https://ec.europa.eu/health/vaccination/overview>
2. Immunization coverage.WHO. <http://www.who.int/news-room/fact-sheets/detail/immunization-coverage>
3. Coombes R: Europe steps up action against vaccine hesitancy as measles outbreaks continue. *BMJ*, 2017; 359: j4803
4. Pierik R: Mandatory vaccination: An unqualified defence. *Journal of Applied Philosophy*, 2015; 381–89
5. Haire B, Komesaroff P, Leontini R, MacIntyre CR: Raising rates of childhood vaccination: The trade-off between coercion and trust. *J Bioeth Inq*, 2018; 15(2): 199–209
6. Michael D: Doctor and MPs in Italy are assaulted after vaccination law is passed. *BMJ*, 2017; 358: j3721
7. Nadler J: Expressive law, social norms, and social groups. *Law & Society Inquiry*, 2017. <https://doi.org/10.1111/lsi.12279>
8. Proposal for a COUNCIL RECOMMENDATION on Strengthened Cooperation against Vaccine Preventable Diseases COM/2018/244 final – 2018/0115 (NLE) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:244:FIN>
9. Rules establishing a program of “vaccination and protection with drugs” for 2015 (Official Gazette of RS, no. 40/15) in Slovenia there are 9 (nine) mandatory vaccines plus more vaccines for some workers. <https://www.efvv.eu/slovenia-2/>
10. Czech Republic immunisation is mandatory against 9 (nine) diseases. <https://www.efvv.eu/cezech-2/>
11. In Slovakia immunisation is mandatory against 10 (ten) diseases. <https://www.efvv.eu/slovakia-2/>

Conclusions

Unlike in informed consent, there should be a responsibility transfer from parents to entities responsible for the vaccination obligation, such as the government or vaccine manufacturers, for any side effects of the vaccine (from the very mild side effects such as fever to the more extreme side effects) and parents should not worry that once they are forced to vaccinate their children, they are also automatically forced to foresee, prevent, or bare vaccination aftermaths. Not all countries with mandatory vaccinations have such a solution in place. What is more, when discussing vaccinations that are mandatory, we postulate that the informed consent shaped by medical sciences and required by law, should be replaced by a simple signature on an appropriate document confirming that vaccination occurred. This would not confuse the parents that they had a choice nor burden them with that difficult decision. This document should be accompanied by an information sheet similar to that found in the USA (the Vaccination Information Sheet). On such a document/sheet, addition information on the obligation to vaccinate and sanctions for failing to do so should be included, in addition to the usual information on possible post-vaccination complications and a way of dealing with the most common complications. In addition, information sheets should include addresses and phone numbers of the nearest medical entities that parents could contact if side effects occur. A document created in such a manner should be written in clear concise language and be a source of information that allows parents/guardians to know what they can expect and how to deal with side effects, thus making parents feel safer. The document should be designed so there are 2 copies: 1 copy for the institution and 1 copy for the parents. Taking into consideration the aforementioned, the authors believe that the model of informed consent is confusing, inappropriate, and out of place in obligatory vaccinations settings.

Conflict of interest

None.

12. Dziwisz S: Prawne aspekty przeprowadzania i egzekwowania szczepień. Obowiązek szczepień ochronnych. Państwo i społeczeństwo, 2015; (2): 143–53 [in Polish]
13. Grzybowski A, Patryn RK, Sak J, Zagaja A: Vaccination refusal. Autonomy and permitted coercion, Pathogens and Global Health, 111: 4, 200–5
14. Freedom to ignore French vaccination program – a court case <https://www.skepticalraptor.com/skepticalraptorblog.php/freedom-vaccinate-france-a-court-case/ion> program – a court case
15. Baxter D: Opposition to vaccination and immunisation the UK experience from smallpox to MMR. J Vaccines Vaccine, 2014; 5: 254
16. Consent form from private archives
17. Over 500 Pakistani parents arrested for children's failure to get polio vaccine. Available at: <http://edition.cnn.com/2015/03/03/asia/pakistan-polio-vaccine-arrests/> Last accessed: September 28, 2017
18. Naomi NG: No jab, no pay: Australia cuts benefits for parents who don't vaccinate kids by. CNN April 13. 2015. Available at: <http://edition.cnn.com/2015/04/13/asia/australia-anti-vaccination-welfare-cut/> Last accessed: September 28, 2017
19. Mello MM, Studdert DM, Wendy E: Parmit. Shifting Vaccination Politics — The End of Personal-Belief Exemptions in California. N Engl J Med, 2015; (373): 785–87
20. Cahana A, Hurst SA: Voluntary informed consent in research and clinical care: An update. Pain Pract, 2008; 8: 446–51