

Vaccination for children- when parents doubts are a challenge for doctors

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Introduction

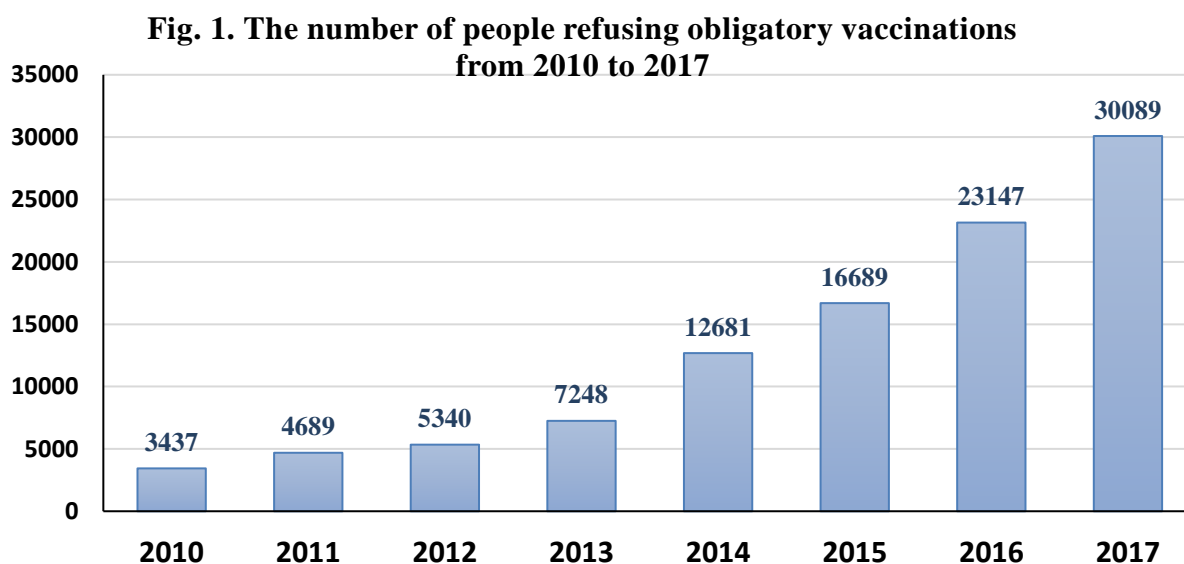
Most doctors strongly believe that vaccinations are one of the greatest goods in medicine. Obviously, vaccination is a procedure which, results like no other in a decrease in mortality. Vaccinations have significantly reduced the incidence of the infectious disease and even some of them, such as smallpox and polio, have been almost completely eliminated. The widespread implementation of vaccinations considerably improved the individual's health, regardless of gender and age. A question arises why every year a growing number of parents is choosing not to vaccinate their children, despite the obvious benefits from the procedure?

Key words: vaccinations, children, prophylaxis, infectious diseases

The scale of the problem

In Poland, vaccinations should be carried out in accordance with the current Vaccination Schedule, the so-called "Vaccination Calendar". The calendar is updated annually by the Chief Sanitary Inspector. The Vaccination Schedule is partly obligatory and that immunization is

performed free of charge for the all patients covered by the national health insurance. There are also recommended vaccinations available, which are bought by the parents on their own expense, yet prescribed by the doctor. The vast majority of vaccinations is carried out among children and in Poland the pediatricians are mainly responsible for ensuring the immunization of the child population. Meanwhile, the available data shows that more and more parents refuse to vaccinate their children. The information on the number of vaccinated and unvaccinated Polish children can be found on the National Institute of Public Health - National Institute of Hygiene (NIPH-NIH) website [1]. These are generally available data. NIPH-NIH collects information on the number of persons under the age of 19 years old who should be vaccinated according to the obligatory Vaccination Schedule, and were not vaccinated. Elaborated data are available on the NIPH-NIH website, in Epidemiological Reports section, and are published each year in annual newsletters "Vaccinations in Poland". Last complete bulletin assesses the situation in 2016 [2], the data from 2017 are preliminary. Available data shows that over the last few years, the number of refusals to vaccinate has increased almost tenfold. In 2010 there were 3437 refusals reported in the whole country, while in 2017 as much as 30089 (Figure 1). Table 1 depicts the population of children and young people avoiding vaccinations in 2016 in each voivodeship (province).



Data source: Annual newsletters "Vaccinations in Poland" (Eds: NIPH-NIH, GIS)

Table 1. Number of people avoiding vaccinations in 2016 by provinces. *Data source: Annual newsletters "Vaccinations in Poland in 2016" (Eds: NIPH-NIH, GIS) (Eds: NIPH-NIH, GIS)*

lp	Voivodeship (Provence)	Number of people	Indicator**
	Poland	23147	3.2
1.	Dolnośląskie	1412	2.8
2.	Kujawsko-Pomorskie	795	2.0
3.	Lubelskie	1130	2.8
4.	Lubuskie	702	3.6
5.	Łódzkie	795	1.8
6.	Małopolskie	1006	1.5
7.	Mazowieckie	4368	4.1
8.	Opolskie	489	2.9
9.	Podkarpackie	200	0.5
10.	Podlaskie	185	0.8
11.	Pomorskie	3074	6.5
12.	Śląskie	3949	4.8
13.	Świętokrzyskie	216	1.0
14.	Warmińsko-Mazurskie	961	3.5
15.	Wielkopolskie	3322	4.6
16.	Zachodniopomorskie	543	1.8

* Source: Quarterly reports on the supervision of immunization cards and people avoiding vaccinations.

** In 1000 people aged 0-19 years, included in the reports.

Every year NIPH-NIH also publishes a free newsletter entitled “Vaccinations in Poland”. It contains reliable information on the status of vaccinations against infectious diseases, recognized in the Vaccination Schedule as obligatory and recommended, the number and severity of side effects of vaccinations and the number of refusals of vaccinations. The publication is valuable and useful in the everyday practice of doctors who qualify children for vaccination. Although the number of children who are not vaccinated seems relatively small, it is worrying that the number of refusals increases yearly. Why do parents refuse to vaccinate their children? What are they afraid of? Supposedly they do not have adequate knowledge or derive it from an unreliable source? The Internet forums and parenting magazines are full of articles on vaccinology. It might be hard in this information overload, especially for a person not associated with medicine, to distinguish between the facts confirmed by reliable research and claims that are unfair or even harmful. The purpose of this article is to present the main concerns of parents who have to make decisions about vaccination and also to suggest some solutions aimed at improving vaccination rates of children. The matter is extremely important for the health of the whole population. Epidemiologists agree if the vaccination rate among children is below 95% , then epidemics of infectious diseases, such as measles and whooping cough, can return, in an unprecedented for the last few years manner. The most common

questions and concerns of parents and guardians (but also medical professionals) are about the relationship of vaccinations with autism, adverse post-vaccination reaction, the harmfulness of preservatives contained in vaccines (e.g. mercury) or combination vaccines. We will try to address those concerns with the use of reliable research and scientific literature.

1. Can autism be the consequence of a vaccination?

Global concern about the MMR vaccine and its relationship to autism in children was sparked by an article that appeared in 1998 in prestigious “The Lancet”. His first author was Andrew Wakefield from The Royal Free Medical School in London, who intended to prove a link between the MMR vaccine and Crohn’s disease. An organization associating parents intending to sue pharmaceutical companies for compensation for diseases allegedly caused by vaccines was the sponsor of his research. The thesis about the relationship of vaccination with the disease was ready even before the study was started, but the research took place. The researcher involved 12 children, 5 of whom had neurological problems in varying degrees before vaccination. As it turned out later he manipulated histopathological descriptions of intestinal slices, falsified evidence and bent the facts. As far as the autism is concerned, it was diagnosed only in one child and not in twelve as Wakefield and cooperators claimed [3,4]. Consistent proving that doctor Wakefield and his cooperators paper was a fraud took nearly a decade. A number of population studies have been carried out worldwide, none of which have shown that the use of MMR vaccine posed any danger [5,6,7]. Finally, after long court battles, the article that aroused extreme controversy was withdrawn from the journal twelve years after its publication [8]. In the justification, reference was made to the findings of the British General Medical Council that randomly applied patients were not eligible for the study, and the study was not approved by the bioethical committee [9]. Although the association between MMR vaccination and autism has never been proven, anxiety remains and parents are still asking about a “vaccine that causes autism” and doctors must patiently and convincingly explain that there is no such a risk.

2. Are the mercury compounds in vaccines dangerous?

Mercury content may seem dangerous. It is widely known that mercury is poisonous and none of the parents wants to poison their child. How the idea of harmful mercury in the vaccinations originated and is there any real danger connected with it? Vaccines contain preservatives to prevent the development of microorganisms, however, none of these additives is in a dose dangerous to health [10,11]. It is worth knowing that only a few of the vaccines in the Polish

Vaccination Schedule contain thimerosal as a preservative: One of them is a designed for children combination vaccine: diphtheria, tetanus and pertussis whole-cell - DTP manufactured by Biomed. It contains 50% ethyl mercury. This compound has a strong antibacterial and antifungal activity. It is added to the vaccines to prevent the contamination after the package is opened. The concentration of thiomersal is very low, allowed by registration offices and safe for health [12]. After inoculation, thiomersal is excreted from the body within a few days [13]. The reports of toxic effects of mercury are about non-ethylmercury compounds, mainly methylmercury found in the environment, for instance accumulated in predatory marine fish, such as tuna and swordfish. It is highly recommended both for the parents and for the doctors to get acquainted with the product's characteristics and the package leaflet about the vaccine that the child is going to be vaccinated. Additionally, before administering the vaccine, the parent with doubts should be thoroughly informed, among other, that before the product is approved for use it passes a series of reliable, credible research. Moreover, combination vaccines, for example, 5- and 6-valent are free of thiomersal.

3. Single or combination vaccine, payable or free?

As part of the general health insurance, according to the Polish Vaccination Schedule, single vaccines are used, which requires the making of many pricks (separate vaccination against DTP, Hib, Hepatitis B, IPV). There are also 5 or 6-valent combination vaccines available for an additional fee. One dose of hexa-vaccine contains diphtheria and tetanus toxoids, Bordetella pertussis and Hepatitis B surface antigens, inactivated Poliovirus and Haemophilus influenza type b polysaccharide, and protects the child from six diseases. The parents can expand compulsory free schedule with the other recommended payable vaccines like rotavirus vaccine, meningococcal vaccine, varicella zoster vaccine, hepatitis A vaccine or tick-borne encephalitis vaccine. As mentioned above, instead of refunded vaccines conjugate but payable vaccines may be used. The benefits of giving these vaccines are a smaller number of applications during one vaccination visit (eg 1 instead of 3). They have also different pertussis component, which is acellular and thus gives less disabling post-vaccination reactions and is safer for children with neurological problems [14]. Many parents who are considering to vaccinate their child with combination vaccines do not have enough knowledge about their use and are concerned about their effectiveness. They are often afraid that these more modern vaccinations have not been adequately tested and that their children constitute a group where the safety of such vaccinations is checked. Nothing could be further from the truth. Safety of all the vaccines is confirmed by tests, which take years to perform. There are procedures defined by law that every

pharmaceutical company must follow. The process is supervised by the domestic and international institutions [15,16,17]. Obviously, adverse post-vaccination reactions may occur, such as fever, rash, loss of appetite, drowsiness or anxiety and reaction at the injection site. These are phenomena associated with stimulation of the immune system [18]. They are temporary and resolve without leaving lasting consequences. Parents often think that payable additional vaccinations and conjugated vaccination are a huge source of income for pharmaceutical concerns, and suspect that even the doctor has also financial benefits. Although pharmaceutical companies are not charities, it is obvious that they want to benefit from their products. However, it must be taken into account that the long-term clinical trials of the vaccinations are very expensive. It sometimes happens that a vaccine over which the company works for several years does not enter the market, because it does not achieve the effectiveness required by the studies, and the costs are incurred without any chance for the future profits.

Another concern of parents is the idea of "excessive overloading of the immune system of the child" when a large number of vaccines is given at the same time. The position of experts in this matter is clear. They are purposefully designed for children, especially the youngest that have an immature immune system. Therefore the highest number of vaccination is recommended [18]. Thanks to scientific advances, simultaneous vaccination with multiple vaccines do not overload the regular healthy child immune system. Co-administration of up to 11 different vaccine antigens results in the involvement of only about 0.1% of the immune system [19]. On the other hand, in the case of infectious disease, the child's body is exposed to the impact of hundreds of thousands of proteins with antigenic properties [18].

4. Which one is better: disease or vaccination?

Physicians often hear the parents' opinion that the immunological system of an infected child produces natural immunity, not "artificial" as in the case of vaccination. Referring to the first part of such a statement, it should be clarified that after both vaccination and illness child produces antibody. In the case of vaccination, "artificial" is only a controlled way of contact with the pathogen [13]. Not all parents are aware of the fact that many infectious diseases can be very serious and some lead to permanent complications or death. Most of them are viral with limited treatment options. Some of the bacterial diseases can be so turbulent that treatment may not be effective. It is important to clearly indicate that immunization against infectious disease by vaccination is safer than that obtained as the result of the disease [18]. And what about post-vaccination reactions? Do not they tend to be dangerous? Most vaccine adverse events are temporary and minor. The most common are: fever, anxiety or apathy, rash, pain at the injection

site. These side effects are not a threat to the general health nor lethal. On the other hand, the symptoms and complications of infectious disease such as sepsis, meningitis, and encephalitis, myocardial infarction, dehydration, deafness or paralysis are life-threatening and in many cases irreversible. It is a merit of vaccination that some dangerous infectious diseases and their complications are no longer observed. Obviously, does not mean that they have completely disappeared and we do not need vaccinations. Parents have the right to know and should know the risks associated with the disease, but also must be forewarned about the possibility of an unexpected post-vaccination reaction. The increasing awareness of the danger resulting from contracting an infectious disease may stop parents from attending so-called "chicken pox parties", which have gained popularity recently. Maybe being aware of the danger resulting from contact with an infectious disease patient, they will not send their child to the so-called "chicken pox party", recently popular. It is worth emphasizing that the immune response of a previously unvaccinated child may be delayed or too weak to fight the infectious agent [20]. Meanwhile, in a vaccinated child, another contact with the antigen stimulates immune memory cells that lead to a secondary immune response - rapid production of antibodies and immune cells preventing the development of the disease.

5. Why also do doctors not vaccinate their children?

Information that also some doctors avoid vaccination of their children is spread especially among the parents engaged in so-called anti-vaccination movements. It is true that among the doctors there are some (fortunately a few) who are opponents of vaccination. Doctors' advice not to vaccinate - with the exception of special medical indications - usually results from ignorance, inexplicable fears or from a poor assessment of balance between the benefits and the possible risk of side effects [13]. Physicians should constantly study and get acquainted themselves with new prevention options, which are vaccinations and, what is more, with the summary of product characteristics. Wide access to medical information can sometimes cause the parent to surprise the doctor with the knowledge that the doctor has not been able to verify yet.

6. Does the parent/guardian bear the consequences of the vaccination refusal?

Internet forums are full of information about the possibility of punishing parents for refusal of the obligation to vaccinate a child. Currently valid Act of 5 December 2008 about the prevention and fight against infections and infectious diseases, raises extreme emotions and is interpreted differently in our society [21]. Doctor Kubiak explains this issue very clearly in his statement

for the Medycyna Praktyczna portal [22]. He writes that pursuant to Article 5 (2) of the above mentioned Act, a person who may be held criminally liable for non-compliance with the obligation to vaccinate a person without full legal capacity (among other, a child under 18 years of age) is his parent or legal guardian. Therefore, if the parents refuse to give the child a vaccination, the doctor supervising the child is obliged to inform the State Sanitary Inspector (in accordance with Annex 4 to the Ordinance of the Minister of Health of 18 August 2011 about obligatory preventive vaccinations). Inspector, in turn, may apply the appropriate sanctions. The previous Act on Infectious Diseases and Infections, from 2001, stated the possibility of a fine of up to PLN 5000 for the failure to comply with the obligation to vaccinate. The current law does not contain this type of criminal provision. However, the application of sanctions is possible on the basis of the Act of 17 June 1966 on executive proceedings in administration (consolidated text. Dz. U. z 2005, Nr 229, poz. 1954). Administrative enforcement is also permissible if these obligations result directly from the law and remain within the scope of government administration (Art. 3 § 1 of the law enforcement). Undoubtedly, the obligation of vaccination is clearly indicated in the Act of infections (art. 5 ust. 1 pkt 2). It can, therefore, be enforced in administrative mode. This thesis confirms the judgment of the Supreme Administrative Court of 06.04.2011 r. (Ref. Act II OSK 32/11), which states that: "The performance of this obligation [of vaccination] by law is secured by an administrative constraint and liability regulated by the provisions of the Act of May 20, 1971 - Code of Offenses." Pursuant to the aforementioned Act, it is possible to apply a fine of up to PLN 10000 (Article 119 et seq. Of the Act on enforcement proceedings in administration). The author also adds that if the administrative execution is not effective, the person who evades the obligation to vaccinate (in the case of children – e.g. their parent) may be subject to the liability provided for in the code of offenses. Pursuant to its article 115 § 1, punishment can be imposed on a person who despite the use of administrative enforcement measures does not undergo mandatory immunization vaccination against tuberculosis or other infectious disease or mandatory health, check aimed at the detection or treatment of tuberculosis, a venereal disease or another disease. In the analyzed case, however, § 2 of this article is more important, which stipulates that the responsibility may be borne by a person who, while administering a minor or helpless person, do not subject it to the protection or examination specified in §1. The perpetrator of the act in question may be fined from PLN 20 to PLN 1500 or a reprimand.

7. Where should we look for reliable information about vaccinations?

At the present time, our patients' parents can easily find information on any subject of their

interest. However, we must remember that anyone can speak on the internet, not necessarily an expert in a given field. The doctors' task is to explain to the patients which information is reliable and well checked and which is not worth paying attention. How to recognize reliable scientific publications? The reputation of the institution that published the information is a major factor and also the prestige of the magazine in which it was published [23]. Renowned research centers attach importance to the reliability of the information published by them, and reliable journals require the use of scientifically based research methods from the authors. Publications are reviewed and reviewers are experts in a given field of science. However, unfortunately most parents will not look for information about vaccinations in medical scientific journals or bulletins published by institutions dealing with vaccinology. It is worth explaining to them what they should pay attention to when viewing vaccination websites. First of all, you need to check who is the author of the information and whether he signed his name and surname and put affiliation [23]. It is also worth checking whether the author provides the source of information. If authors information is published on the site, you can easily reach them and check if they are indexed by recognized medical bases. The websites that are highly recommended are those run under the patronage of state institutions. An example of a reliable, trustworthy website for information vaccination, both for doctors and for parents, is the www.szczepienia.info website, launched the National Institute of Health-National Institute of Hygiene. One can find up-to-date news about available vaccines on the Polish market and the current vaccination calendar there. Moreover, it also answers many questions bothering parents. The website presents their editorial team and experts cooperating with the editors. What is more, this website provides reliable scientific information useful for physician and nurses.

Nearly everyone, doctors, parents, and politicians talk about vaccination. Information on this subject can be obtained from the radio and television programs and also the scientific and popular press. Unfortunately not only experts and propagators of vaccination are invited for lectures to many renowned universities, but also people working in anti-vaccine movements. It is no wonder that some parents have doubts - to vaccinate or not to vaccinate. The common thinking seems to be "It hurts and can cause a post-vaccination reaction and maybe something more." It is the health care workers to encourage to vaccination and it is possible to persuade those in doubt. The benefits of vaccination are undeniable. The ignorance or undecided attitude of health care professionals may cause distrust and parents will refuse the vaccination. Fortunately, most parents vaccinate their children. It seems that the committed opponents of vaccination, for example in STOP NOP movements, are in minority, but looking at the last 10

years, we note with concern that the problem of vaccination refusals is on the rise and we have to prevent it. Education is the solution. Education covering children and youth in schools, consultations for parents, competent conversations with those who hesitate, because they got lost in the information overload. It is necessary devote doubting parents the time to calmly and matter-of-factly answer their questions to dispel their doubts. In our opinion, the threat of legal consequences and financial penalties is not effective. It is better to convince the parent that without vaccinations, the child could suffer from the dangerous consequences of infectious disease. Additionally it puts other children at risk, as well as elderly people (usually less immune) from the child's family and surroundings.

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