

\*Iwona Wrześniewska-Wal, Anna Augustynowicz

## Obligatory vaccinations as a tool for public health

### Obowiązkowe szczepienia ochronne jako narzędzie zdrowia publicznego

Department of Economics, Law and Management, School of Public Health, Centre of Postgraduate Medical Education, Warsaw  
 Head of Department: Iwona Wrześniewska-Wal, MD, PhD

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#### Address/adres:

\*Iwona Wrześniewska-Wal  
 Department of Economics,  
 Law and Management  
 School of Public Health  
 Centre of Postgraduate Medical Education  
 ul. 61/63 Kleczewska, 01-826 Warszawa  
 tel. +48 (22) 560-11-31  
 idrwal@yahoo.com

#### Summary

The article presents the problem as of vaccination a tool for implementing one of the basic tasks of public health, which is the prevention of diseases. The obligation to undergo certain vaccines have been specified in the Act on the prevention and fighting infections and infectious diseases in humans. The list of diseases of compulsory vaccinations, as well as persons or groups of persons required to undergo mandatory protective vaccinations, defined in the Regulation of the Minister of Health on compulsory vaccinations. A detailed list of vaccines for that year announces Chief Sanitary Inspector in the form of a message. Vaccination protection is preceded by a medical examination of qualifying. It is also necessary to obtain the consent of the authorized entity: the patient or his legal representative.

#### Streszczenie

W artykule przedstawiono problematykę szczepień ochronnych jako narzędzia realizacji jednego z podstawowych zadań zdrowia publicznego, jakim jest profilaktyka chorób. Obowiązek poddawania się określonym szczepieniom ochronnym określa ustawa o zapobieganiu oraz zwalczaniu zakażeń i chorób zakaźnych u ludzi. Wykaz chorób zakaźnych objętych obowiązkiem szczepień ochronnych, a także osoby lub grupy osób obowiązane do poddania się obowiązkowym szczepieniom ochronnym, określa rozporządzenie Ministra Zdrowia w sprawie obowiązkowych szczepień ochronnych. Szczegółowy wykaz szczepionek na dany rok ogłasza Główny Inspektor Sanitarny w formie komunikatu. Wykonanie szczepienia ochronnego poprzedzone jest lekarskim badaniem kwalifikacyjnym. Niezbędne jest także uzyskanie zgody uprawnionego podmiotu: pacjenta lub jego przedstawiciela ustawowego.

#### INTRODUCTION

Intensive development of medicine offers great opportunities not only for diagnosis and treatment of many diseases, but also to prevent getting sick. The basic condition that determines the legality of medical action of a prophylactic or therapeutic agent is the patient's consent. However, in certain statutorily defined cases, introduced legal solutions which might affect the autonomy of the patient. In these cases, the dilemma between the values of the protection of community health patient autonomy is resolved in favor of the first one (1). Examples of such solutions are the provisions of the law on the prevention and combating of infections and infectious diseases in humans (2), including those that relate to mandatory vaccinations. In art. 1 of this Act states that it specifies "the rules and procedures of preventing and combating infections and

infectious diseases in humans" and "the rights and obligations of service providers and persons residing in the territory of the Polish Republic in the prevention and combating of infections and infectious diseases in humans". The obligations referred to in that provision include undergo sanitary treatment, preventive vaccination, after-exposure prophylactic medicines, sanitary-epidemiological studies, disease surveillance, quarantine, treatment, hospitalization, isolation (art. 5, paragraph. 1, item 1 of the Act).

Vaccinations, both compulsory and recommended pursue one of the basic tasks of public health, which is the prevention of diseases (3). The current decline in the incidence of severe, often fatal infectious disease is the result of 200 years of work of researchers (4). It is worth to add some historical statistics of the epidemiology of some infectious diseases. In 1963, Wrocław

there was an epidemic of smallpox (5). There have been 99 cases, including 7 deaths. In the twentieth century. Smallpox was responsible for 300-500 million deaths. The World Health Organization (WHO) estimated that in the 1967. 15 million people infected with the disease, of which 2 million died. Thanks to vaccinations, the disease was until 1980. Completely eliminated (4). WHO announced the eradication of smallpox. The germ is stored only in the laboratory WHO w Moscow and Atlanta (6). Another example is the diphtheria. In 1952, Poland had as many as 40 562 cases, including 782 deaths. After the introduction of vaccination in 1955 and the public vaccination program in 1960 there has been a rapid decline in incidence. Currently, since 2001 Poland was not a single disease (7). In 1973 it was recorded in Poland, 184 308 cases of measles and 109 deaths from the disease. Since the 90s. the number of cases is usually below 100 and they occur most frequently among unvaccinated. In Poland after 2000 deaths from measles are not present (4). Data from recent years show that measles fell ill in 2012 – 70 people, 2013 – 84 people and in 2014 – 110 people. In the case of rubella in 2009-2011 were recorded respectively 7856 cases, 4197 and 4292 cases of infection. In the last year of rubella fell ill 5891 people (7). These data indicate that the resignation of the immunization carries the risk of serious consequences not only for the individual non-vaccinated people, but above all for the whole population (8).

The effective implementation of vaccination, especially those with compulsory important role played by the legal provisions governing this issue. It is a clear indication of the list of infectious diseases, of persons obliged to fulfill the obligation of vaccination, as well as the means to enforce this obligation.

### **THE LEGAL BASIS OF PROTECTIVE VACCINATION**

The Law on prevention and fighting infections and infectious diseases in humans in art. 5 paragraph. 1 point. 1 point b in the compound of the art. 17 paragraph. 1 imposes on the persons on the territory of the Polish obligation to subject to specific protective vaccinations. Regulation of the Minister of Health on compulsory immunization (9) defines: the list of communicable diseases covered by the obligation of vaccination, as well as persons or groups of persons obliged to undergo mandatory preventive vaccination, specifying their age and other circumstances which are prerequisite to the possible exercise vaccination defined in the Regulation of the Minister health on compulsory vaccinations. Additionally, pursuant to art. 17 paragraph. 11 above Act detailed list of vaccines for that year announces the Chief Sanitary Inspector, in the form of an announcement in the official gazette of the Ministry of Health. This is the Immunization Program for the year, with specific indications regarding the use of individual vaccines. The program for 2016 was published in the Communication Chief Sanitary Inspector of 16 October 2015 on Immunization Program

for 2016 (10). In the previous year there were changes concerning, among others guidelines for vaccination against acute poliomyelitis (Polio) and pertussis, as well as changes in the group of persons to whom it is recommended that some vaccinations. Allowed to use 5-component vaccine (DTaP-IPV-Hib). Still does not include vaccination of all infants against pneumococcal or public vaccination formulations of acellular pertussis component (11). However, the vaccination kit intended for use in Poland does not differ significantly from those in force in other European Union countries. It is worth mentioning two different approaches to vaccination in EU countries. They may be exercised within the framework of the mandatory vaccination schedule and recommended. The differences arise, among others, used approaches the conditions of cultural, historical, the organization of health care, the level of economic development, and public awareness (12).

At this point it is worth noting that the nature issued by the Chief Sanitary Inspector statement, although it has its statutory authorization may raise doubts as to the compatibility with Article. 87 paragraph. 1 of the Constitution (13). Neither the law on the prevention and combating of infections and infectious diseases in humans or above. Regulation – i.e. the provisions of current law – do not define the requirements for vaccination in sufficient detail (14). This obligation concrete mentioned above message that is not a source of universally binding law. We are therefore faced with a reference to the legal regulation which is outside the constitutional catalog of sources of law (15). From a legal point of view, such a rule may be grounds to invoke subjecting the compulsory vaccination protective concretized in the document is not located in the directory of sources of law. And that may raise doubts as to the compatibility with the Constitution of the Republic of Poland. However, from a medical point of view, the legislative procedure is understandable and convenient because it allows relatively easy, from a regulatory point of view, the way to take into account the dynamically changing epidemiological situation (1).

It is worth noting that since 2017 change the rules of financing vaccines. The purchase of vaccines for the insured to finance the payer, currently the National Health Fund, and the vaccine for people not covered by insurance will pay the Ministry of Health (16).

### **PROCEDURES RELATED TO THE PERFORMANCE OF PROTECTIVE VACCINATION**

Procedures associated with the implementation of mandatory vaccination defines art. 17 of the Law on preventing and fighting infections and infectious diseases in humans and the regulation on compulsory vaccinations. Vaccination protection is preceded by a medical examination qualifying. Research qualifying performs a doctor who has the necessary knowledge in the field of immunization, knowledge of indications and contraindications to vaccination, as well as the side effects of vaccination and the rules of conduct and

documentation of vaccination. After the survey qualifying physician shall issue a certificate indicating the date and time of the audit. Preventive vaccination cannot be performed if 24 hours have passed from the date and time indicated in the certificate. Pursuant to § 7 of the mandatory vaccinations, medical examination qualification and mandatory vaccinations a person who has not attained the age of 6 are carried out in the presence of a person who in the legal custody of that person or the actual guardian within the meaning of the Act on the Rights of patient and patient Ombudsman (17). The presence of a person having permanent custody of the minor or the actual guardian is not required if the minor completed six years of age and obtained the written consent of these persons and information on the determinants of health which may constitute a contraindication to vaccination. If your doctor determines that there is a basis for long-term postponement of the protective vaccination directs the child to consult a specialist. Pediatrician should medical records, i.e., immunization record card of the consultation specialist, with emphasis on the period contraindications to perform the vaccination, kind of vaccine contraindicated for use or individual vaccination program indicating the type of vaccine used and the date of the next consultation. Important is the fact that undergo mandatory preventive vaccination may be exempt only those who have the specialist sees steady contraindications to the vaccination or specific vaccinations. Individual calendar vaccination program (mandatory and recommended) laid by a doctor for the child, taking into account the delays in the implementation of vaccination in relation to the Programme of Immunization.

The Law on prevention and combating of infectious diseases and infections in humans in the art. 17 paragraph. 9 requires the physician responsible for preventive health care for the patient to inform the immunization. At the same time in the medical record the fact inform the person obliged to undergo mandatory preventive vaccination or a person who in the legal custody of that person or the actual guardian. In practice such information. Parents about vaccinations mandatory may take place while in the case of illness of the child, visit. Your doctor may also notify parents while qualifying for the vaccination of the next mandatory vaccinations. It is possible to notice about vaccinations and presentation or prepared to send written information in this regard. If the medical records of a lack of information about the notification of vaccinations mandatory, and such. Parents within a reasonable time not come forward with a minor vaccination Administrators should not suffer the negative consequences associated with the failure to achieve the statutory obligation imposed. It should be remembered that holds legal custody of the minor and must have knowledge of the calendar vaccinations, and not informed can not have awareness of the need to undergo vaccination (1).

Since the law imposes an obligation to undergo certain preventive vaccination, then doubts may raise the

question of a possible receive approval for its achievement. The Act on Patients 'Rights and the Ombudsman for Patients' Rights in the art. 15 states that requires the consent of the patient or other authorized entity to provide health benefits, if the provisions of other laws provide otherwise. The Law on prevention and combating of infectious diseases and infections in humans is silent on obtaining consent for vaccination. The legal doctrine is assumed, even though it is worded statutory obligation to undergo preventive vaccination does not mean that your doctor can operate without the consent of (18).

In addition to the effectiveness consent to a health services it is that consent was expressed in an adequate discernment of all the facts relating to the performance of the health services (19). As for the coverage of the use of information under the general rules concerning the information obligation, which falls on the doctor granting health benefits (Art. 9-12 of the Act on Patients 'Rights and the Ombudsman for Patients' Rights). Considering the fact that vaccination is always preceded by a qualifying examination, specify the scope and purpose of this study, and after the results, give them the probationer, making used explanations. It should also provide details on the procedure itself, which is what the vaccine will be used, in which the dose (20). If they are available in different types of vaccines, the doctor should indicate these preparations give the arguments for and against the choice of one of these products. The person authorized to consent the doctor should inform about the consequences of the use of preventive vaccination, or its abandonment. So health benefits used prophylaxis, or describe a disease related possible complications. It should also indicate risk of suffering from side effects of vaccination, as well as informed of the proceedings as they occur (21). The doctor does not have to communicate the impact of improbable, for the case difficult to predict (22).

Only the person authorized to consent to the execution of the protective vaccination is a patient, provided that it is of legal age, he was not incapacitated and is capable of informed consent. In the case of a minor patient's consent shall legal representative (19), and in the absence of a legal representative consent, but only to study the qualification can give the actual guardian. Taking into account the provision of Article. 32 paragraph. 2 of the Act on professions of physician and dentist by the lack of legal representative refers a situation in which the patient does not have a legal representative or when the agreement with him is not possible. The legal representative may be a parent, adoptive parent, guardian or curator. Parents are the legal representatives of the child, provided that they are not deprived of parental authority, they are not minors or incapacitated. If the parental authority is entitled to both parents, each of them is obliged and entitled to its execution, that each of them can make decisions on the child (art. 97 paragraph. 1 The Family and Guardianship Code). In the important issues of the

child, and these are matters relating to the provision of health, parents decide together. If parents cannot agree on a decision taken guardianship court (art. 97, paragraph. 2 The Family and Guardianship Code). The doctor is not required to obtain a separate consent of both parents for the execution of the protective vaccination. Parents should pre-arrange their position. Therefore, the consent of one parent is a manifestation of the common will. If one of the parents agree on the execution of the protective vaccination, secondly, e.g. in the presence of a doctor opposes, then the basis for the conflict settlement will be the decision of the guardianship court (22). The legal representative of the minor is not only the parents, it may also be the adopter and his activities, the rules the same as in the case of parents. Guardian appointed by the court must obtain permission guardianship court in all important matters that relate to the person or property of a minor. A requirement for authorization of the guardianship court does not apply to ordinary operations and medical treatments posing a higher risk, and these should include vaccinations (23, 24). If the guardian suffered a transient obstacles in the care of minors, guardianship court may appoint a guardian. The powers of the superintendent determined by the court in its order. Curator has the right to rule on the provision of health services when authorized him to court (25).

Patient juvenile who has completed 16 years of age has the right to consent. So in this case consent is required cumulative legal representative of the minor and the patient. The consent of the minor is required in both the normal medical procedures and operations posing an increased risk to the patient.

It is worth noting that the medical qualification for a particular vaccination always carried a doctor, and the nurse responsible for the proper implementation of the physician. The legislator in art. 67 Section 3 of the Act introduced until 31 December 2015. Transitional period in terms of the necessary qualifications for vaccination. In the light of that provision vaccinations able to perform that day doctors or medics, nurses, midwives and hygienist school, who do not have the necessary qualifications, where they have 2.5 years of experience in carrying out vaccinations. Since January 1, 2016 compulsory vaccinations carried out I could only doctors, nurses and midwives who have completed the course (training) in this field or have a specialization including its scope this issue. If any, previous practical experience in this regard will not make any difference (26).

### ADMINISTRATIVE MEASURES

The legislature responsible for fulfilling the obligations set out in article 5 paragraph. 1 of the Act, which is also required to undergo preventive vaccination, if people do not have full legal capacity, order the person having legal custody of a minor or helpless or actual guardian. In medical practice, there are some situations where statutory representatives of minor refuse to perform an obligation arising directly from the pro-

visions of the above Act. It entitles the State District Sanitary Inspector to issue a warning calling for the obligation vaccinations within 7 days (27). The execution of this obligation is secured by compulsion and administrative responsibility adjustable Act Code offenses (28). On the basis of art. 115 paragraph. 2 of the Code offenses who, having custody of a minor or helpless, despite the use of administrative enforcement, does not give her a specific compulsory vaccination protective punishable by a fine up to 1500 PLN penalty or reprimand.

As for the administrative enforcement measures, which must precede the imposition of a fine or reprimand they are specified in the Act on administrative enforcement proceedings (29). The Act provides for five enforcement measures in the proceedings concerning the obligations of non-monetary: the fine in order to compel, the execution of replacement, receiving movable property, receive property, empty premises and other premises and direct coercion. The authority enforcement in the field of administrative enforcement responsibilities of non-pecuniary jurisdiction sanitary inspector (Art. 20 § 1, item 3 and 4 of the Act on enforcement proceedings in administration). In this case, the application may be fine in order to compel (Art. 119-126 of the Act on enforcement proceedings in administration). A fine in order to compel applied when enforcement involves the fulfillment by the debtor, among others, the obligation to perform the operations, especially operations, which because of its nature cannot meet another person. In the case of a natural person acting for the legal representative fine is applied to the same or to the person to whom you should direct monitoring the performance of certain obligations. Fine in order to compel it is exceptional in nature and may be used if it is not advisable to use another means of execution of duties. If a single application of a fine not effective it can be applied again in the same or a higher amount. Each time a fine cannot exceed PLN 10 000, while the fines imposed repeatedly cannot exceed a total amount of PLN 50 000.

### CONCLUSIONS

Currently there is a discussion of the merits of mandatory vaccinations. According to data published by the National Institute of Public Health – National Institute of Hygiene vaccination rates in Poland it is at a high, because more than 90% level. At the same time every year, the number of conscientious objectors from vaccination. In the case of children in 2012 it was a number from 5 to 5.5 thousand (8), while according to the latest data NIPH-PZH on September 30, 2015. This is already the number of 14 612 people (30). Reversing this trend is one of the important tasks faced by the organizers of the healthcare system and providers.

In the face of emerging anti-vaccination movements in raising awareness of patients regarding vaccination it is very important the role of doctors,

especially pediatricians and family doctors. It is not only the obligation to inform about vaccinations mandatory and recommended vaccinations, but also the duty to co-participation in the shaping of social attitudes. The task of the physician is to develop among patients view that health is a shared value, which means that the health of each of us depends on the others (31). Seronegative face serious risks to their own health and at the same time

pose a serious threat to the other members of the community.

Using the health of entire communities requires specific individual behaviors. Hence, the provisions on vaccination, because of their preventive nature can be found described in the operating limitations constitutionally guaranteed values, even if voluntary surrender to benefits health. They concern primarily the obligation to undergo preventive vaccination and penalties for evading them.

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