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Legal and ethical principles of informed consent to vaccination in Russia: the need to change approach

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The article analyzes the international experience in the regulation of procedures for obtaining voluntary informed consent to immunization as well as voluntary refusal of it. The authors set up the necessity of changing the approach to certain aspects of the obtaining voluntary consent to vaccination or refusal of it procedure regulation in the Russian Federation.
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Introduction

The necessity and order of conducting vaccination arouse fierce debates around the world [1]. Some countries are liberalizing the vaccination legislation and are abolishing mandatory vaccines, while others, on the opposite, are toughening the requirements and the responsibility for refusing prophylactic vaccination [2]. The decision of which vector of statutory and regulatory to choose should be based foremost upon the analysis of the real epidemiological situation in the country or one of its regions, as well as on the presence of resources possessed by the concrete state enough to support vaccination activities [3]. At the same time the principle of voluntary consent or refusal to medical intervention should remain unchanged [4, 5].

Statutory and regulatory provisions for conducting vaccination in Russia

According to point 5, article 2, Federal Law "Concerning the foundations for protecting the health of citizens in the Russian Federation" from 21.11.2011 Number 323-FL (Federal Law), medical intervention is defined as: "… medical examinations and/or medical manipulations of a prophylactic, research, diagnostic, therapeutic, or rehabilitating directivity, performed by a medical worker towards a patient and affecting the human physical or psychic state" [4]. It is clear from the definition, that vaccination should be considered as a medical intervention with a prophylactic goal, and, thus, all the regulating legal mechanisms should be adhered to during its performance. "A necessary precondition for medical intervention is a citizen's informed voluntary consent, based on the full information given by a medical worker in a comprehensive form, concerning the goals and methods of the rendered medical help, the corresponding risks, possible ways of medical intervention, their consequences, as well as the supposed results of medical help" (article 20, paragraphs 1, 2). In cases when the patients' condition makes it impossible for him to express his will, but medical intervention is urgent, the issue is solved on behalf of the patient by a council, and if a council is impossible – by the attending (on-duty) doctor, who then should inform the officials of the medical institution. On behalf of "persons aged under 15 years and citizens, who were declared legally incapable", consent is given by their legal representatives. "A citizen or his legal representative has the right to refuse medical intervention… however the possible outcomes of such

a refusal should be communicated to him in an accessible form" (article 20, paragraphs 3, 4). Both the informed voluntary consent and the refusal to medical intervention should be formalized in writing, signed by the citizen or one of his legal representatives and contained within the patient's medical documentation (art. 20, par. 7).

Immunoprophlaxis in Russia is conducted according to the Russian immunoprophlaxis legislation, namely the Federal Law "Concerning the immunoprophlaxis of infectious diseases" from 17.09.1998 No 157-FL (Federal Law) (with amendments from 14.12.2015) [5]. According to Art. 1 of this law, "prophylactic vaccinations are – the introduction of immunobiological medical preparations into a human organism, for the purpose of creating a specific immunity towards infectious diseases". The National calendar of vaccination is determined according to par. 2 art. 9 and is ratified by the government. It includes the terms of vaccination and the categories of citizens subject to mandatory vaccination. Par 2 of art. 11 of the above mentioned Federal Law secures the mandatory condition for vaccination – the presence of a voluntary informed consent to medical intervention. The legislation covering the state policy towards vaccination denotes the possibility of refusing prophylactic vaccination (art. 5 par. 1). In such a case, the citizen "should confirm in written form the refusal to conduct vaccination" (art. 5 par. 3). At the same time, a number of limitations accompanying such a refusal are denoted. According to par. 2 art. 5 the absence of vaccinations "to leads to: a ban for citizens to travel to countries, the presence in which according to international medical and sanitary regulations or international treaties of the Russian Federation requires specific vaccination; temporary refusal of acceptance to educational organizations and wellness institutions in cases of mass infectious diseases or an epidemic threat; refusal to employ citizens on, or their dismissal from jobs which are connected with a high risk of infectious diseases". According to art. 18 of the Federal Law №157-FL, in cases of post-vaccine complications citizens are guaranteed the right to social support in the form of one-time state payments, monthly monetary compensations and temporary disability benefits.

In order to find out whether the norms of international law concerned with the acquiring of voluntary informed consent to vaccination are adhered to in Russia, we have analyzed foreign experience in this area, which is set out in the corresponding normative documents and publications, including the publications by WHO experts, and compared it to the Russian regulations.

Recommendations of WHO experts concerning the procedure of acquiring informed consent

According to the WHO experts' recommendations, in order for the national immunization programs to be in correspondence with international principles of human rights and the Convention of Child Rights, the regulatory medical organs should develop a procedure of acquiring informed consent for vaccination [6, 7]. The procedure should be adapted to national peculiarities (the consent of a "third party" in cases when it is legal for an older sibling or a school executive to give consent for vaccination) and to the capabilities of the health care system (financial, human, infrastructural). It is offered to develop methodological guidelines, conduct educational seminars for medical workers concerning the procedure of acquiring informed consent to vaccination, and to make sure any special situations are managed accordingly [6]. The procedure of acquiring consent to vaccination should be regarded as an important element of medical ethics and international law. The informed consent form should contain all the information necessary for decision making, the offered information should be comprehensible for the parents or the legal representative of the child, the procedure of signing informed consent should be voluntary, and the person giving the consent should possess the ability to make decisions [6].

Some countries see vaccination as a most important and irreplaceable activity aimed at the liquidation of infectious diseases and the prevention of their spreading. In such countries, vaccination against the most socially important diseases is legally defined as mandatory [1]. At the same time, different regulating and/or restricting mechanisms of influence are used. For example, vaccination can be a necessary condition of joining an organized child collective. In this case the

necessity of acquiring consent to preventive vaccination depends upon the legal status of active normative documents [6]. In countries where vaccination is mandatory according to the law, consent might not be required [1]. In cases when the voluntary character of vaccination is based upon legal principles, informed consent is necessary for introducing both mandatory and any other vaccines [1]. In some countries, citizens are allowed to express "refusal to vaccination", however this can lead to certain infringements of rights, for example prohibition for unvaccinated children to attend school during outbreaks of infectious diseases [1].

The methods of acquiring informed consent to vaccination differ in the world practice; however, 3 main ones can be distinguished [6].

- Acquisition of a written consent: is used mainly in countries with moderate or high levels of income among the population with a higher proportion of literate people and a longer history of vaccination.
- Verbal affirmation of consent: is used only when parents can be present during the actual vaccination. This is the form of consent traditionally occurring in most developing countries, since an invitation to written consent is associated by many with participation in trials, which leads to an increased number of refusals to vaccination [6].
- Implied consent to vaccination: parents are informed beforehand about a vaccination being planned in a child collective, and thus the physical presence of a child is considered as evidence for consent. Parents who do not agree with the vaccination do not bring their child to the child collective.

In their recommendations on the legal basics of immunization, the WHO experts also point out that the older a child becomes, the more capable he becomes of making decisions by himself, and eventually can express his own will concerning immunization [6]. This principle of "developing abilities", noted in the Convention of Child Rights (art. 5), supplemented by the obligation to "respect views" (art. 12) and provide for the "child's best interests" (art. 3), supposes that children of older ages and teenagers should take part in the process of expressing consent for the upcoming vaccination [7]. This is the reason why in many developed countries the leaflets containing information about the planned vaccination are written in a language accessible and comprehensible by a child of an older age [6].

Experience of foreign countries

AUSTRALIA

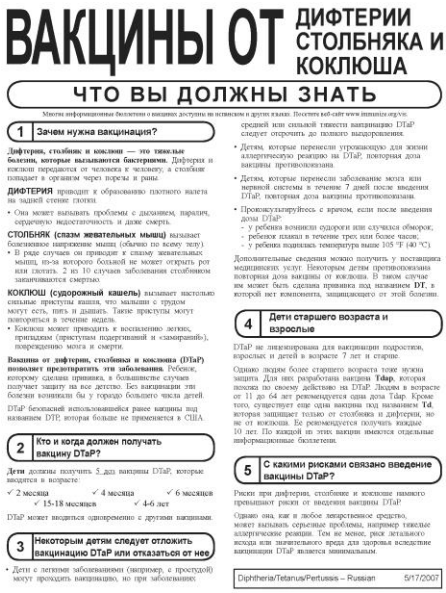
From our point of view, the Australian legislation demonstrates one of the most progressive approaches to regulating vaccination. Vaccination in this country is voluntary, however the vaccines recommended by the state are offered free of charge [8]. Prophylactic vaccines are conducted with the patient's consent (individual forms of consent exist for every disease included into the national vaccination calendar) [8]. The Australian legislation directly assumes the possibility of refusal to vaccination for any reasons. A special written form is affirmed for such a refusal [8]. However, in case of adverse epidemiological conditions in the kindergarten or school in regard to a disease prevented by vaccination, the child should stay at home during all the quarantine period imposed by 2the child organization [8]. At the same time, the state encourages timely vaccination by offering social benefits and payments [8]. However, since 2016 Australia plans to exclude such benefits if the refusal to vaccinate is due to any reasons different from medical contraindications and religious beliefs [8].

UNITED STATES OF AMERICA

Vaccination is de iure mandatory in the US, since having all the vaccines done is a condition for entering educational and nursery institutions [9]. However, de facto vaccination is voluntary, since most states allow the refusal of vaccination due to medical prescriptions, philosophical and/or religious beliefs [9]. At the same time there are significant limitations in the states of Mississippi and West Virginia concerning voluntary refusal to vaccination due to philosophical and/or religious

beliefs, which increases the mandatory character of vaccinations recommended by the legislation of such states [9]. In February 2015, California also took into consideration a law imposing mandatory vaccination. According to this law, it will only be possible to refuse vaccination if you have a medical contraindication. In some states, where there is a mandatory vaccination campaign, punishment is prescribed for non-vaccinated persons who are infecting others [9]. There are no requirements on the federal level for the formalization of the written informed consent to vaccination in the USA. Instead, the US system of vaccination and prevention uses such an instrument as the Vaccine Information Statement. Being accustomed with the Statement is necessary before every vaccination [10]. The state informs patients through special brochures about the benefits and risks of vaccination, as well as the risks of refusing it. Nevertheless, a common form of consent to vaccination can be used additionally to such statements.

Fig. 1. Informed consent to DTaP- and inactivated poliomyelitis vaccination (multiconsent), USA.



ВАКЦИНЫ ОТ ДИФТЕРИИ СТОЛБНЯКА И КОКЛЮША

ЧТО ВЫ ДОЛЖНЫ ЗНАТЬ

Многие информационные бюллетени о вакцинах доступны на испанском и других языках. Посетите веб-сайт www.immunize.org/vis.

1 Зачем нужна вакцинация?

Дифтерия, столбняк и коклюш — это тяжелые болезни, которые вызываются бактериями. Дифтерия и коклюш передаются от человека к человеку; а столбняк попадает в организм через порезы и раны.

ДИФТЕРИЯ приводит к образованию плотного налета на задней стенке глотки.

- Она может вызывать проблемы с дыханием, паралич, сердечную недостаточность и даже смерть.

СТОЛБНЯК (спазм жевательных мышц) вызывает болезненное напряжение мышц (обычно по всему телу).

- В ряде случаев он приводит к спазму жевательных мышц, из-за которого больной не может открыть рот или глотать. 2 из 10 случаев заболевания столбняком заканчиваются смертью.

КОКЛЮШ (судорожный кашель) вызывает настолько сильные приступы кашля, что малыши с трудом могут есть, пить и дышать. Такие приступы могут повторяться в течение недель.

- Коклюш может приводить к воспалению легких, припадкам (приступам подергиваний и «замираний»), повреждению мозга и смерти.

Вакцина от дифтерии, столбняка и коклюша (DTaP) позволяет предотвратить эти заболевания. Ребенок, которому сделана прививка, в большинстве случаев получает защиту на все детство. Без вакцинации эти болезни возникали бы у гораздо большего числа детей.

DTaP безопасней использовавшейся ранее вакцины под названием DTP, которая больше не применяется в США.

2 Кто и когда должен получать вакцину DTaP?

Дети должны получить 5 доз вакцины DTaP, которые вводятся в возрасте:

✓ 2 месяца ✓ 4 месяца ✓ 6 месяцев ✓ 15-18 месяцев ✓ 4-6 лет

DTaP может вводиться одновременно с другими вакцинами.

3 Некоторым детям следует отложить вакцинацию DTaP или отказаться от нее

- Дети с легкими заболеваниями (например, с простудой) могут проходить вакцинацию, но при заболевании средней или сильной тяжести вакцинацию DTaP следует отсрочить до полного выздоровления.
- Детям, которые перенесли угрожающую для жизни аллергическую реакцию на DTaP, повторная доза вакцины противопоказана.
- Детям, которые перенесли заболевание мозга или первичной системы в течение 7 дней после введения DTaP, повторная доза вакцины противопоказана.
- Проконсультируйтесь с врачом, если после введения дозы DTaP:
  - у ребенка возникли судороги или случился обморок;
  - ребенок плакал в течение трех или более часов;
  - у ребенка поднялась температура выше 105 °F (40 °C).

Дополнительные сведения можно получить у поставщика медицинских услуг. Некоторым детям противопоказана повторная доза вакцины от коклюша. В таком случае им может быть сделана прививка под названием **DT**, в которой нет компонента, защищающего от этой болезни.

4 Дети старшего возраста и взрослые

DTaP не лицензирована для вакцинации подростков, взрослых и детей в возрасте 7 лет и старше.

Однако людям более старшего возраста тоже нужна защита. Для них разработана вакцина **Tdap**, которая похожа по своему действию на DTaP. Людям в возрасте от 11 до 64 лет рекомендуется одна доза Tdap. Кроме того, существует еще одна вакцина под названием **Td**, которая защищает только от столбняка и дифтерии, но не от коклюша. Ее рекомендуется получать каждые 10 лет. По каждой из этих вакцин имеются отдельные информационные бюллетени.

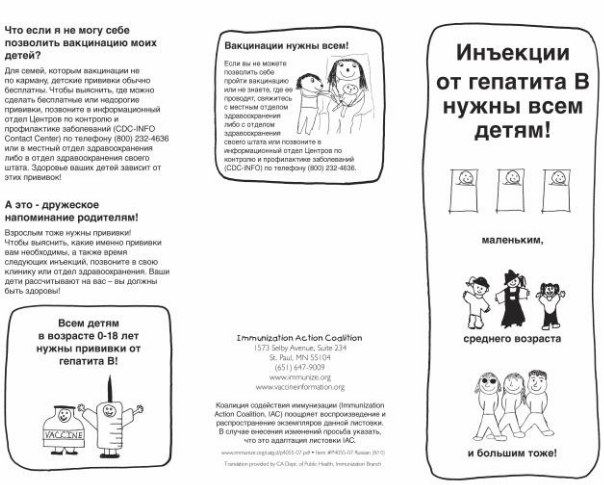
5 С какими рисками связано введение вакцины DTaP?

Риски при дифтерии, столбняке и коклюше намного превышают риски от введения вакцины DTaP.

Однако она, как и любое лекарственное средство, может вызывать серьезные проблемы, например тяжелые аллергические реакции. Тем не менее, риск летального исхода или значительного вреда для здоровья вследствие вакцинации DTaP является минимальным.

Diphtheria/Tetanus/Pertussis – Russian 5/17/2007

Fig. 2. Informational leaflet for parents about the necessity of vaccinating against hepatitis B, USA.



Что если я не могу себе позволить вакцинацию моих детей?

Для семей, которым вакцинации не по карману, детские прививки обычно бесплатны. Чтобы выяснить, где можно сделать бесплатные или недорогие прививки, позвоните в информационный отдел Центров по контролю и профилактике заболеваний (CDC-INFO Contact Center) по телефону (800) 232-4636 или в местный отдел здравоохранения либо в отдел здравоохранения своего штата. Здоровье ваших детей зависит от этих прививок!

А это - дружеское напоминание родителям!

Взрослым тоже нужны прививки! Чтобы выяснить, какие именно прививки вам необходимы, а также время следующих инъекций, позвоните в свою клинику или отдел здравоохранения. Ваши дети рассчитывают на вас – вы должны быть здоровы!

Всем детям в возрасте 0-18 лет нужны прививки от гепатита В!

Вакцинации нужны всем!

Если вы не можете позволить себе пройти вакцинацию или не знаете, где ее проводят, свяжитесь с местным отделом здравоохранения либо с отделом здравоохранения своего штата или позвоните в информационный отдел Центров по контролю и профилактике заболеваний (CDC-INFO) по телефону (800) 232-4636.

Immunization Action Coalition
1573 Selby Avenue, Suite 234
St. Paul, MN 55104
(651) 647-9009
www.immunize.org
www.vaccineinformation.org

Коалиция содействия иммунизации (Immunization Action Coalition, IAC) поощряет воспроизведение и распространение экземпляров данной листовки. В случае внесения изменений просьба указать, что это адаптация листовки IAC.

www.immunize.org/catg.d/p4055-07.pdf • Item #P4055-07 Russian (8/11)

Translation provided by CA Dept. of Public Health, Immunization Branch

Инъекции от гепатита В нужны всем детям!

маленьким,

среднего возраста

и большим тоже!

The vaccine information statement (VIS) is a legislatively regulated document, necessarily given to the patient before every vaccination [11]. Created by the Center for Disease Control and Prevention of the US, the VIS communicates the benefits and risks of vaccination. According to national child vaccination law [11], the medical organization (private or municipal) responsible for the child's immunization is obliged to provide the parent or other legal representative of the child with the corresponding document and to acquire his/her confirmation. According to the law, the VIS is given before the vaccination is carried out, and a separate signature should be received for every vaccine used. Also, this form should be filled out by adult patients, no matter what the patient's age is. For every vaccine, special VIS forms are created. These forms clarify the hazard posed by the disease against which immunization is carried out, as well as how it would be conducted and what possible adverse effects can develop during the post vaccination period [12]. Presumably, this allows to save the time of the medical personnel, decreases the parents' suspicion before an unknown procedure and, as a result, leads to a high level of vaccination coverage. In order to confirm the patient's familiarization with the VIS and his/her consent, the doctor should make a corresponding record in the individual medical documentation. Such informed consent forms are filled in once – before the start of a series of continuing pediatric vaccination, for example three-fold preventive vaccinations against whooping cough, diphtheria, tetanus and polio (fig. 1) [13].

The so-called multiconsents are quite justified, since there is no necessity to clarify the same information about the same vaccines again to the same parents.

The law (42 U.S.C. §300aa-26) mentions the VIS requirements ("the information should be accessible to the patient and should be presented in comprehensive terms"), including the requirements to its content: the presence of a brief description of the vaccination benefits and risks, information concerning the National program of postvaccinal complications compensation [11].

The development of electronic means of mass information has led to more ways of acquiring VIS, and today parents can make themselves familiar with it in advance over the Internet, print out, sign and bring the document with themselves to the clinic, where the immunization is going to take place. There is a practice of presenting the patient with the VIS in advance, for example at pre-birth appointments and childbirth [13, 14]. The main goal is to give the form before the vaccination. At the same time, clarification work is being done through websites – providing for transparency, accessibility and significance of vaccination and prevention (fig 2) [15].

In separate cases, private medical centers put together a form of written vaccine administration record. This includes, together with the possible vaccination risks, a section covering the patient's state of health, which he/she fills in by him/herself [16].

For example, whether he/she feels ill at the day of vaccination, is allergic to any of the vaccine components, had any pronounced reaction to vaccination previously etc. Apart from that, such a form may contain questions about the presence of an accompanying chronic disease and drugs being used at the present moment. The form also contains parts about the vaccination procedure that are filled in by the medical workers.

An excerpt from the legal part, which is included into the written vaccination consent form: "I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the Vaccine Information Statements on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering healthcare provider. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless the applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that the applicable Provider may disclose my immunization information to the State Registry. I acknowledge that I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider: (a) the disclosure of my immunization information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my immunization information with any of my other healthcare providers enrolled in the State Registry and/or State HIE." [17].

CANADA

Vaccinal prevention is recognized a voluntary procedure in Canada, since mandatory vaccination violates the Canadian constitution [18]. The acquisition of informed consent (written or verbal) is recognized as the ethical and legal responsibility of the physician carrying out the vaccination. Only 2 provinces – Ontario and New-Brunswick – have the right to demand a document proving a child's immunization to certain infections (diphtheria, tetanus, polio, measles, rubella, parotitis) before entering school [18]. Previously this list also included the province of Manitoba, where vaccination against measles was mandatory for entering school, however since 2014 the voluntary character of this procedure has also been recognized here [18]. Exceptions concerning refusal to vaccination due to medical contraindications and religious beliefs are acceptable, special forms for refusal to vaccination have been designed [18]. Information brochures about vaccines which are prepared by the Canadian pediatric society are accessible to the population and make the process of acquiring informed consent easier, as well as being helpful in answering the patients' and their parents' immunization questions [19]. Consent can be acquired both in verbal and written form. In the first

case, the medical workers should record in the medical documentation the fact of verbal consent to vaccination and that the patient was given all the information he/she was interested in and all the questions were answered. The information brochure may be included in the "written consent" which the patient or his/her parent are asked to sign immediately before the vaccination [20].

COUNTRIES OF THE EUROPEAN UNION

European countries have different approaches to regulating vaccination. For example, vaccination against certain diseases (diphtheria, polio, tetanus) is mandatory in France. Refusal is being punished: a fine of 3750 Euro or imprisonment for up to 6 months for those who did not pass the mandatory vaccination or those (including parents) who hindered the mandatory vaccination of those whose legal representatives they are [21]. In cases of serious post-vaccinal complications, the Health Ministry guarantees a substantial monetary compensation [21]. In the presence of contraindications to vaccination, confirmed by a doctor, the management of child institutions has no right to refuse a child [21].

Latvia has a policy of mandatory vaccination, however there is a possibility to refuse preventive vaccination. The refusal should be necessarily authenticated by medical specialists [22].

A different approach exists in Germany: vaccination is voluntary, the requirements for informed consent are the most liberal [23]. Still, the population is being informed about the necessity of preventive vaccination through information leaflets, which, in turn, can contain special paragraphs on consent to vaccination [23].

In Great Britain the attitude towards vaccination is a citizen's personal issue. It is not customary in the British society to be interested in other people's views towards vaccination – just as their political views [24]. In 2001 the administration of the Health Ministry demanded that all NHS funds accept a unified policy of acquiring informed consent to medical manipulations, specify the consent forms and information leaflets for the main procedures in order to provide the citizens with full information [24]. In Great Britain, the patient's consent is recognized as the key element in all aspects of medical service, care, and treatment, including specific immunization [24]. The necessity to acquire informed consent prior to immunization is based upon the principle of free choice, meaning that the citizen has the right to determine what is going to happen to him/her and what – not. The accessibility of information its understanding by the patient and voluntariness are the fundamental basics of informed consent that is to be acquired before vaccination. It is stressed, that the consent to vaccination should be free of any coercion [24]. During the discussion between the physician and the patient, a lot of time is used for clarifying issues concerning the infection against which vaccination is performed, the risks and benefits of every vaccine, including possible adverse effects, how often they appear and what should be done in case they manifest themselves. A broad range of visual means, including leaflets, posters, videos, information packages and web sites are used in order to clarify information on vaccination and to support all aspects of the immunization program [25]. The language used to communicate the information on vaccination is comprehensible to the patient. Moreover, patients are eligible to confidentiality concerning the data on vaccination, they also should be informed about which services are able to access this information. In this case it is necessary to clarify to the patient that the immunization data is used in order to control the safety and effectiveness of the current vaccination programs. However, there is no strictly specified form of consent to vaccination in the UK. A person can express such consent both in written and in verbal form. At the same time, it is illegal for the medical personnel to demand a formalized written consent [24], since a signature under the consent to vaccination is not supposed to be proof of the patient's intention, but together with a verbal consent makes it possible for the doctor to affirm the patient's decision to perform immunization and create a corresponding record in the personal medical documentation. There are arbitrary forms of informed consent for certain vaccines, for example before vaccinating teenage girls at school against the human papillomavirus the parents are offered informations in the form of a leaflet about the papillomavirus infection and the rules of conducting the vaccination, discuss it with the child and leave their signature on the consent or refusal line (fig. 3) [26].

Fig. 3. Informed consent form for vaccinating a teenage girl against papillomavirus infection at school, UK.

Vaccine Administration Record (VAR) Informed Consent for Vaccination for All Healthcare Providers*

Walgreens healthcare clinic

PATIENT: COMPLETE SECTIONS A, B, C

SECTION A *(Please print clearly.)*

Store Number: _____ Encounter ID: _____
Store Address: _____

First Name: _____ Last Name: _____ Date of Birth: _____ Age: _____

Gender: ☐ Female ☐ Male Home Phone: _____ Mobile Phone: _____

Race/Ethnicity (select one or more)
☐ Native American or Alaska Native ☐ Asian ☐ Black or African-American ☐ White ☐ Hispanic or Latino ☐ Native Hawaiian or other Pacific Islander ☐ Other

Home Address: _____ City: _____ State: _____ ZIP Code: _____

Email Address: _____ Medicare Part B Number (if applicable): _____

Primary Care Physician/Provider Name: _____ Phone Number: _____

Address: _____ City: _____ State: _____ ☐ I do not have a Primary Care Physician/Provider

I want to receive the following immunization(s): _____

SECTION B *The following questions will help us determine your eligibility to be vaccinated today. For all vaccines: Please answer questions 1-8. For live vaccines (e.g., MMR or Shingles): Please answer questions 1-14. For Flu nasal spray: Please answer questions 1-17.*

All Vaccines				
1.	Are you currently sick with a moderate to high fever, vomiting/diarrhea?	☐ Yes	☐ No	☐ Don't Know
2.	Have you ever fainted or felt dizzy when receiving an immunization?	☐ Yes	☐ No	☐ Don't Know
3.	Have you ever had a serious reaction after receiving an immunization?	☐ Yes	☐ No	☐ Don't Know
4.	Are you 19 years of age or older with an immunocompromising condition, functional or anatomic asplenia, CSF leak, or cochlear implant?	☐ Yes	☐ No	☐ Don't Know
5.	Do you have allergies to medications, food or vaccines? (Examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal) a. If yes, please list: _____	☐ Yes	☐ No	☐ Don't Know
6.	Have you received any vaccinations or skin tests in the past four weeks? a. If yes, please list: _____	☐ Yes	☐ No	☐ Don't Know
7.	Have you ever had a seizure disorder for which you are on seizure medication(s), a brain disorder, Guillain-Barré syndrome or other nervous system problems?	☐ Yes	☐ No	☐ Don't Know
8.	**For women:** Are you pregnant or considering becoming pregnant in the next month?	☐ Yes	☐ No	☐ Don't Know
Live Vaccines (Chicken pox, Flu nasal spray, MMR, Oral typhoid, Shingles, Yellow fever) **Only answer these questions if you are receiving any immunization listed above**				
9.	Are you currently on home infusions, weekly injections (such as adalimumab, infliximab and etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?	☐ Yes	☐ No	☐ Don't Know
10.	Do you have cancer, leukemia, lymphoma, HIV/AIDS or any other immune system disorder?	☐ Yes	☐ No	☐ Don't Know
11.	Have you received a transfusion of blood or blood products or been given a medicine called immune (gamma) globulin in the past year?	☐ Yes	☐ No	☐ Don't Know
12.	Are you currently taking high-dose steroid therapy (prednisone >20mg/day) for longer than two weeks?	☐ Yes	☐ No	☐ Don't Know
13	Do you have a history of thymus disease (including myasthenia gravis), thymoma or prior thymectomy? (Yellow fever only)	☐ Yes	☐ No	☐ Don't Know
14.	Are you currently taking any antibiotics or antimalarial medications? (Oral typhoid only)	☐ Yes	☐ No	☐ Don't Know
Flu Nasal Spray (FluMist®)				
15.	For patients 18 years of age and younger only: Are you receiving aspirin therapy or aspirin-containing therapy?	☐ Yes	☐ No	☐ Don't Know
16.	For patients 5 years of age and younger only: Is there a history of asthma or wheezing?	☐ Yes	☐ No	☐ Don't Know
17.	Do you have a nasal condition serious enough to make breathing difficult, such as a very stuffy nose?	☐ Yes	☐ No	☐ Don't Know

SECTION C

I certify that I am: (i) the Patient and at least 18 years of age; (ii) the parent or legal guardian of the minor Patient; or (iii) the legal guardian of the Patient. Further, I hereby give my consent to the healthcare provider of Walgreens or Take Care Health Services, as applicable, to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read/had explained to me the Vaccine Information Statements on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering healthcare provider. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless Walgreens or Take Care Health Services, as applicable, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of my state's immunization registry ("Registry"); (b) I may, if my state permits, object to Walgreens disclosing my immunization information to the Registry by providing Walgreens with a state approved Registry disclosure opt out form (which I may request and obtain from Walgreens, if permitted by my state); and (c) Unless I provide Walgreens with an approved opt out form, I have elected to participate in the Registry and consented to Walgreens reporting my immunization information. I authorize Walgreens or Take Care Health Services, as applicable, to (i) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to my healthcare professionals, Medicare, Medicaid, or other third party payer as necessary to effectuate care or payment, (ii) submit a claim to my insurer for the above requested items and services, and (iii) request payment of authorized benefits be made on my behalf to Walgreens or Take Care Health Services, as applicable, with respect to the above requested items and services. **I further agree to be fully financially responsible for any co-sharing amounts, including copays, coinsurance, and deductibles, for the requested items and services as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if Walgreens or Take Care Health Services invoices me after the time of service, upon receipt of such invoice.**

Signature: _____ Date: _____
(Parent or Guardian, if minor)

*Healthcare providers can be an immunization certified pharmacist or a registered nurse, licensed practical nurse, licensed vocational nurse, nurse practitioner or physician's assistant.
†Patient care services at Take Care Clinics are provided by Take Care Health Services℠, an independently owned professional corporation whose licensed healthcare professionals are not employed by or agents of Walgreen Co. or its subsidiaries, including Take Care Health Systems℠, LLC.

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SECTION D — **HEALTHCARE PROVIDER ONLY**

Complete BEFORE vaccine administration

Vaccine	Route	Dosage	Lot #	Expiration Date
Influenza (MDV)	Intramuscular	0.5mL		
Influenza (Intradermal)	Intradermal	Prefilled		
Influenza (Nasal)	Intranasal	0.1mL each nostril		
Influenza (High dose)	Intramuscular	Prefilled		
Chicken pox (Varicella)	Subcutaneous	0.5mL		
Hepatitis A	Intramuscular	1mL: Adults ≥19 years 0.5mL: Adolescents ≤ 18 years		
Hepatitis B	Intramuscular	1mL: Adults ≥20 years 0.5mL: Adolescents ≤ 19 years		
Hepatitis A/B (Twinrix®)	Intramuscular	1mL: Adults ≥18 years		
Human papillomavirus	Intramuscular	0.5mL		
Japanese encephalitis	Subcutaneous	0.5mL		
Meningococcal (Meningitis)	Intramuscular (Subcutaneous – Menomune Only)	0.5mL		
MMR (Measles, Mumps, Rubella)	Subcutaneous	0.5mL		
Pneumococcal (Pneumonia)	Intramuscular	0.5mL		
Polio	Intramuscular	0.5mL		
Shingles (Herpes Zoster)	Subcutaneous	0.65mL		
Td (Tetanus and diphtheria)	Intramuscular	0.5mL		
Tdap (Tetanus, diphtheria and pertussis)	Intramuscular	0.5mL		
Typhoid (Live Oral)	Orally			
Typhoid (Inactive injectable)	Intramuscular	0.5mL		
Yellow fever	Subcutaneous	0.5mL		

Needle size	Age
Intramuscular injection is in the deltoid	
⅝ to 1¼ inch needle	3-18 y/o (**⅝** inch needle for patients weighing less than 130 lbs)
1 to 1½ inch needle	19 y/o and older (Female 130-200 lbs; Male 130-260 lbs)
1½ inch needle	19 y/o and older (Female 200+ lbs; Male 260+ lbs)
Subcutaneous injection is in the upper arm (postero-lateral)	
⅝ inch needle	All ages
Intradermal injection is in the deltoid	
Prefilled Syringe	All ages

I have verified the immunization(s) that the patient requested meets state, age and vaccine restrictions.	Initial here: _____
I have verified the requested immunization(s) is the same as the product prepared.	Initial here: _____
I have verified the expiration date of the product is greater than today's date.	Initial here: _____
For Zostavax®, MMR II®, Varivax®, YF-Vax®, Menveo®, I have reconstituted the vaccine following the package insert's instructions.	Initial here: _____
For patients younger than 9 years of age requesting the influenza vaccine:	
Did you verify if a second dose is needed?	☐ Yes ☐ No
If this is the second dose, have 28 days elapsed since the first dose?	☐ Yes ☐ No

Complete AFTER vaccine administration

Rx #	Vaccine	NDC	Dosage	Site of Injection (circle site)	VIS Published Date

Immunizer Name (print): _____ **Immunizer Signature:** _____ **RPh/PharmD/RN/LPN/LVN/NP/PA** (circle one)

If Applicable, Intern Name (print): _____ **Administration Date:** _____ **Date VIS Given to Patient:** _____

Notes

13FL0002

In Italy, vaccination is obligatory since the second half of the XX century, but only for a number of the most socially significant infectious diseases, which include diphtheria, tetanus, polio and hepatitis B [27]. However, because every Italian district is autonomous, the voluntariness of vaccination varies around the country. For example, in the Veneto region vaccination is not mandatory [27]. Special forms for informed consent to vaccination are being designed in every Italian district by healthcare institutions and are affirmed by local ethics committees [27]. Informed consent is a document which the parents are offered to read and sign before the vaccination takes place. Before 2008 there were various forms of limitations in case of refusal to mandatory vaccinations: for example, children would not be accepted to school. At the moment it is rare for administrative sanctions to be applied against unvaccinated children. In case of refusal the parents face only an explanatory conversation at the local health ministry.

Table 1 contains characteristics of the above mentioned approaches adopted in different foreign countries.

Table 1. Main regulatory approaches to vaccination practice in certain countries

Countries	Character of Vaccination	Presence of a special consent form	Presence of a special refusal form	Ways of ensuring timely vaccination
Australia	Voluntary	Special form for every disease	Yes	Stimulating measures, requirements for entering educational/child facilities
USA	de iure mandatory, de facto voluntary (taking into consideration the legislation of every state)	Common practice: using the Vaccination Information Statement (in some cases together with a consent form)	Yes	Requirements for entering educational/child facilities
Canada	Voluntary (mandatory for entering school in 2 provinces)	No special form	A special refusal procedure exists (in provinces with mandatory vaccination)	Informational work
Germany	Mandatory	No special form, but a special line in informational leaflets	No	Informational work
France	Mandatory for a number of diseases	N/a	No	Responsibility for refusal
Latvia	Mandatory, but with a possibility to refuse	N/a	A special refusal procedure exists	Policy of mandatory vaccination
Great Britain	Voluntary	N/a (in some cases there are consent forms)	No	Informational work
Italy	Mandatory for a number of diseases (except the Veneto district)	Special form	No	Mandatory vaccination policy, informational work

The procedure of acquiring informed consent in Russia

All around the world, vaccination is considered to be a type of medical help, while the vaccines themselves are forms of medical intervention, which, by general rules, requires the patient's consent [6].

In most cases (except those when preventive vaccines are mandatory) such a consent should fit with the following criteria:

- consent should be voluntary;
- consent should be informed;
- the information should be accessible to the patient and delivered in a language comprehensive for the patient;
- the person giving consent should possess the ability to make decisions.

Part of the above mentioned principles are present in the Russian legislation. For example, p. 2 art. 11 of the Federal Law from 17.09.1998 №153-FL «Concerning the immunoprophilaxis of infectious diseases» states that preventive vaccination is conducted in the presence of an informed voluntary consent to medical intervention [5]. The form of such consent was approved by the Order of the Ministry for Health and Social Development from 26 Jan 2009 №19n (hereinafter - Order 19n) [28]. Apart from that, voluntary informed consent in Russia not only protects the patient's personal choice, but also the doctor's rights - by being one of the forms of medical documentation, which is used for the expert evaluation of medical help quality [29]. Nevertheless, the question still remains - whether this form really makes it possible to acquire informed consent from the patient or his/her

legal representative. Is it clear to the patient (or parents/guardians)? Does the form contain all the information the patient needs in order to understand the importance / necessity of preventive vaccination, the consequences of refusal to vaccination and the potential risks connected both with vaccination (unpredictable body reactions) and with refusal to it (severe complications from the disease)?

For example, the form, which is approved by Order 19n, is at the same time a consent form and a form of written refusal. Because of that a confusion can arise in practice, when the patient fills in the form incorrectly - with the document loosing legal validity as a result. Such a situation is described in the decision of the Oktyabrsky district court of Stavropol city from 26 March 2012 № 2-243/12 [30], according to which the patient's legal representative stroked out both the consent and the refusal in the form, as a result of which the document became invalid. At the same time, in the examined foreign experience examples, the written refusal form and the written consent form are two different documents, which differ both by their content and by the procedure of filling them in. Moreover, in the case when vaccination presumes the acquisition of informed content from the patient, the information about the diseases, against which the vaccination is done, as well as about the available vaccines and their effects, is given to the patient in full volume and is included in the consent form or the vaccine information statement text. Due to this, the content of the consent to vaccination against flue and the content of the consent to vaccination against pneumococcal infection are different in Australia [8]. Also, the VIS which are used individually for every vaccine in the USA [11, 17]. In Germany, information leaflets are used. These leaflets describe the diseases, their symptoms and complications - the studying of which helps the patient make and informed decision whether to express consent or refusal to preventive vaccinations [22, 23].

The form, which is affirmed by the 19n Order contains only general statements about the disease itself, the vaccine against it and the order of its usage, as well as about the real risks and consequences which might arise in case of refusal to preventive vaccination [28]. Because of this, it becomes obvious that there is a risk that the refusal or consent expressed by signing such a form can not be considered really «informed» from the standpoint of the principles that had been associated with these concepts at the federal law level. These risks increase if the form is signed without a thorough prior consultation with a doctor (for example, if the child is being vaccinated at school).

However, in 2007, the Russian Federal Medical and Biological Agency designed a medical consent form, which was approved by the Agency's order №88 from 30 Mar 2007. This form is from our point of view quite successful and corresponds with the main characteristics (fig. 4) [31].

Moreover, the same Order regulates the form of refusal to medical intervention, which also contains clarifications concerning the refusal to preventive vaccinations (fig. 5). Both forms bear a significant amount of information [31].

In particular, the informed voluntary consent to vaccination clarifies the characteristics of possible post-vaccinal complications, the patient is advised to warn the doctor about the state of his/her health and intolerance of specific substances; the vaccinated person is informed about the measures of social protection in case of post-vaccinal complications. The refusal form reminds of possible eligibility limitations the citizen can be subject to in case of a decision not to vaccinate. Table 2 shows a comparison between the international experience and the regulatory approach existing in Russia.

Table 2. Comparative characteristic of international experience and the Russian regulatory approach towards vaccination

Norms	International experience	Russian Federation
General requirements of consent to vaccination	In most legislations (expect for cases when vaccination is mandatory)	Corresponds with the international approach
Permissibility of refusal to vaccination	In most legislations (expect for cases when vaccination is mandatory, which is strengthened by sanctions)	Corresponds with the international approach

Special forms for consent / refusal, containing simple and understandable statements	In most legislations with a developed system of informing about vaccination	Does not correspond to the international approach: de iure a special single consent / refusal form is affirmed; de facto the document is hard to perceive and arouses usage difficulties in practice

Fig. 4. Voluntary informed consent to vaccination, FMBA of Russia (appendix 4, Order 88 from 30.03.2007).

Appendix № 4
Form approved by Russian FMBA
30.03.2007 № 88

FEDERAL MEDICAL AND BIOLOGICAL AGENCY
Central Medical-Sanitation Unit/Medical-Sanitation Unit/Hospital/Institute_____

Информированное добровольное согласие на вакцинацию

I, _____
(full name and surname)

born in _____ residential address _____

This section must be completed for persons under 15 years or legally incapable persons only:
I _____ passport № _____, issued: _____
the legal representative **(mother, father, adoptive parent, tutor, committee)** of the child or incapable person
_____
(full name and date of birth of the child or incapable person)

Give my voluntary consent to the vaccination of myself / the person of whom I am the legal representative with the following vaccines:
_____ from _____
(name the vaccine and the disease)
and ask the personnel of the medical institution to conduct it.

- I understand the reasons for vaccination and its goals.
- By the time of vaccination I (the vaccinated person) have (has) no acute complaints concerning my (his/her) health (fever, pains, chills, severe weakness).
- I understand that vaccination is a preventive medical activity which decreases the risks of developing certain diseases over a certain period of time after the vaccination.
- I understand and accept the fact that body reactions are rarely possible after vaccination. These reactions can be local (reddening, compactions, pain, burning, itching at the injection place and others) and general (fever, malaise, chills and others). I understand, that post-vaccinal complications can occur **very rarely** (shock, allergic reactions and others), but the probability of such reactions is much lower than the probability of developing unfavorable outcomes of the diseases, against which vaccination is done.
- I am conscious of the fact, the under the Federal Law from 17th Sept 1998 №153-FL "Concerning immunoprophilaxis of infectious diseases" the absence of preventive vaccinations leads to: a travel ban to countries, the traveling to which requires certain preventive vaccinations according to international medical rules or international treaties of Russia; a temporary refusal to accept citizens to educational and health institutions in cases of mass infectious diseases or epidemic hazard; refusal to accept citizens for works or removing citizens from works, which are connected with a high risk of infectious disease.
- I am warned of all the risk factors and contra-indications to vaccination.
- I have made myself familiar with the social defense measures aimed at protecting citizens in cases of post-vaccinal complications development.
- I have informed my medical worker about previous vaccinations, about all the health problems that I have, including any forms of allergy and personal intolerance to medicines, about all the diseases I (the represented person) have had, about the ecological and industrial factors of physical, chemical and biological nature that are affecting me (the represented person) during my life, about all medicines that I (the represented person) am (is) receiving, about complications and reactions to previous vaccinations in myself (the represented person) and my (his/her)closest relatives. I have given true information concerning heredity, as well as of consuming alcohol, narcotic and toxic substances.
- I am informed and agree with all the clauses of this document, the theses of which are clarified to me, are understood by me and I voluntarily give my consent to the vaccination.

"___" _____ 20___. Signed (patient / legal representative) X

Signed in my presence by:
Docto
r _____ (signature) X
(Position, full name, surname)

SEE REVERSE SIDE

REMARK:

For persons under the age of 15 years and citizens who were recognized as legally incapable the consent to medical intervention (vaccination) is given by their legal representatives (parents, foster parents, guardians and trustees) – with the indication of their full name, surname, passport information, kindred relationship after giving information about the examination results, the presence of a disease, its diagnosis and prognosis, methods of treatment, the associated risk, possible options of medical intervention, their consequences and the results of the conducted treatment

In the absence of legal representatives the decision regarding medical intervention (vaccination) is made by the council, and if a council is impossible to assemble – the actual treating doctor (doctor on duty) with a subsequent informing of the head doctor / director of the Central Medical-Sanitation Unit/Medical-Sanitation Unit/Hospital/Institute, and during holidays, evening and night time – the responsible doctor on duty and the legal representatives.

In cases when the citizen's state makes it impossible for him to express his/her will and the medical intervention (vaccination) is urgent, the question of conducting it in the interests of the citizen is resolved by the council, and if the council is impossible to assemble – the actual treating doctor (doctor on duty) with a subsequent informing of the head doctor / director of the Central Medical-Sanitation Unit/Medical-Sanitation Unit/Hospital/Institute, and during holidays, evening and night time – the responsible doctor on duty.

If the parents or other legal representatives of a person under the age of 15, or the legal representatives of a person that had been recognized legally incapable, refuse medical help necessary for the salvation of the mentioned persons' life, the hospital institution is eligible to go to court in order to protect the interests of the mentioned persons.

Under the articles 5, 18, 19, 20, 21 Of the Federal Law from 17th Sept 1998 №153-FL citizens have the following rights :

- To refuse preventive vaccination, at the same time they are obliged to confirm their refusal in written form (appendix 4 form)

- In case of a post-vaccinal complication – to receive a one-time allowance of 10 000 Rubles **at the organs of social protection**. In case of a citizen's death as a result of a post-vaccinal complication, members of his/her family are eligible to a one-time allowance of 30 000 rubles. A citizen recognized as disabled as a result of a post-vaccinal complication, is eligible to a monthly compensation of 1000 rubles. A citizen who has acquired temporary incapacitation as a result of post-vaccinal complications, is eligible to an allowance the size of 100 percent of his/her average wage no matter who long the length of work has been

Additional information: _____

"___" _____ 20___. Signature of the patient (legal representative) | X |

Signed in my presence:

Doctor _____ (signature) | X |

(Position, full name and surname)

Council:

Position, full name, signature _____

Position, full name, signature _____

Position, full name, signature _____

"___" _____ 20___

Fig. 5. Refusal to medical intervention, FMBA of Russia (Appendix 5, Order 88 from 30.03.2007).

Appendix № 4
Form approved by Russian FMBA
30.03.2007 № 88

FEDERAL MEDICAL AND BIOLOGICAL AGENCY
Central Medical-Sanitation Unit/Medical-Sanitation Unit/Hospital/Institute _____

Informed refusal to medical intervention

I, _____
(full name)

born in _____ residential address _____

_____

This section must be completed for persons under 15 years or legally incapable persons only:
I _____ passport № _____, issued: _____
the legal representative **(mother, father, adoptive parent, tutor, committee)** of the child or incapable person
_____
(full name and date of birth of the child or incapable person)

while being treated (examinated, having labour) at the

_____
(name of the department, ward number)

_____ department,

refuse to medical intervention on my behalf (on the behalf of the represented person).

- According to my own will, I was given complete and comprehensive information concerning the nature, severity and possible complications of my disease (disease of the represented person), including diagnostic findings, disease existence, its diagnosis and prognosis, ways of treatment and risks associated with them, information about possible types of medical interventions, their consequences and results of treatment;

- Possible consequences of my refusal (refusal on behalf of the represented person) were explained to me in detail and in an accessible form. I realize that the refusal to medical intervention (treatment) may negatively affect my health (health of the represented person) and even lead to death.

Possible consequences of refusal to medical intervention: _____

_____

_____

_____

_____

(must be filled by physician)

Additional information: _____

_____

_____

_____

_____

- I have reviewed and accepted all the points of this document, the propositions of which were explained to me and understood by me. I refuse to accept medical intervention (treatment) of my own free will, exercising my right provided by article 33 of "The basics of Russian legislation concerning citizen health protection".

" __ " _____ year 20__ . Patient's/legal representative's signature | X

Signed in my presence:
Physician _____ (signature) | X
(Position, full name)

SEE THE REVERSE SIDE

REMARK:

The citizen or his/her legal representative has the right to refuse medical intervention or to claim its termination.

Persons affected by the diseases which pose danger for the wider public, persons with severe mental disorders or persons who had committed socially dangerous acts are **NOT ALLOWED** to refuse medical intervention or treatment according to Russian legislation.

Based on sub-section 3 article 17 of the Federal Law from 09.01.1996 № 3-FL "Concerning the population's radiation safety", the citizen (patient) has the right to refuse radiology and nuclear medicine procedures with the exception of preventive examinations, which are held to detect epidemiologically dangerous diseases.

Based on sub-section 2 article 9 of the Federal Law from 18.06.2011 № 77-FL "Concerning the prevention of tuberculosis spreading in Russia", persons affected by tuberculosis are dispensary observed regardless of their own or their representatives' consent.

Based on sub-section 1 article 5 of the Federal Law from Sept 17th 1998 № 157-FL, citizens have the right to refuse preventive vaccinations. The absence of preventive vaccinations may lead to: a travel ban to countries, the traveling to which requires certain preventive vaccinations according to international medical rules or international treaties of Russia; a temporary refusal to accept citizens to educational and health institutions in cases of mass infectious diseases or epidemic hazard; refusal to accept citizens for works or removing citizens from works, which are connected with a high risk of infectious disease.

When a citizen or his/her legal representative refuses medical intervention, he/she should be informed about possible consequences in a form accessible for him/her. Refusal to medical intervention, together with the indication of possible consequences is formulated through a record in the medical documentation and is signed by the citizen or his/her legal representative, as well as by a medical worker.

If the parents or other legal representatives of a person under the age of 15, or the legal representatives of a person that had been recognized legally incapable, refuse medical help necessary for the salvation of the mentioned persons' life, the hospital institution is eligible to go to court in order to protect the interests of the mentioned persons.

Refused to sign the form of voluntary informed consent to refusal to medical intervention:

Physician's council :

Position, full name, signature _____

Position, full name, signature _____

Position, full name, signature _____

"___" _____ 20___

In general, in is possible to state that in Russia the regulation of vaccination-concerned issues corresponds to the international principles and approaches concerning voluntariness, human rights and the Child Rights Convention [4, 5, 7]. Nevertheless, the informed consent / refusal to vaccination form itself needs re-working in order to boraden the informative function and avoid any misunderstandings of its content or invalid filling in by patients. We believe that it is necessary to change the existing Russian approach to the procedure of consent / refusal to vaccination. First, we believe that its is necessary to divide the mentioned forms and affirm a separate consent form and a separate refusal form. The content of these forms should become more informative and detailed. Second, the consent to vaccination form can be both general and individual (for each vaccine). If the consent form is general, then the state or the professional medical community should produce informative leaflets fo patients. The latter should contain information about each infectious disease, about the complications which can follow the disease and the procedure of vaccination (the terms of vaccination, counter indications, possible body reactions to certain vaccines). If individual forms for every vaccine are affirmed, the corresponding information will be included in every form separately.

Conclusion

The current Russian regulations concerning the acquisition of consent to vaccination are generally in line with international principles and approaches. However, the informed consent / refusal requires re-working in order to broaden the informational function of the mentioned documents and eliminate situations when patients misunderstand the form or fill it in incorrectly. The most effective and realizable way of improving the vaccination practice is, to our mind, splitting the consent to

vaccination and refusal forms, changing the informed consent form using statements that are clear and understandable for parents in order to persuade them that preventive vaccination is necessary. It is also possible to realize a pilot project concerned with creating individual informed consent forms for certain vaccine-preventable infectious diseases - the so-called multi-consents, which are signed once for a series of repeating vaccinations (for example, the primary series of DTP and polio vaccinations).

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Conflict of interests

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REFERENCES

1. Мац А. Н. Врачам об антипрививочном движении и его вымыслах в СМИ // *Педиатрическая фармакология*. — 2009. — Т.6. — №6 — С. 12−35. [Mats AN. Information for physicians on the anti-vaccination movement and its myths in mass media. *Pediatric pharmacology*. 2009;6(6):12−35. (In Russ).]
2. ВОЗ. От паникерства вакцины нет. [WHO. No vaccine for the scaremongers. (In Russ).] Доступно по: http://www.who.int/bulletin/volumes/86/6/08-030608/ru. Ссылка активна на 23.03.2016.
3. ВОЗ. Положение в мире относительно вакцин и иммунизации. Изд. 3-е. ВОЗ; 2009. 11 с. [WHO. State of the world's vaccines and immunization: executive summary. 3rd ed. WHO; 2009. 11 p. (In Russ).] Доступно по: http://www.who.int/publications/list/WHO_IVB_09.10/ru. Ссылка активна на 23.03.2016.
4. Федеральный закон № 323-ФЗ от 01.11.2011 «Об основах охраны здоровья граждан РФ». [Federal law № 323-FZ dated November 01, 2011 «Ob osnovakh okhrany zdorov'ya grazhdan Rossiiskoi Federatsii». (In Russ).] Доступно по: http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=181698. Ссылка активна на 08.04.2016.
5. Федеральный закон № 157-ФЗ от 17.09.1998 «Об иммунопрофилактике инфекционных болезней». [Federal law № 157-FZ dated September 17, 1998 «Ob immunoprofilaktike infektsionnykh boleznei». (In Russ).] Доступно по: http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=173265. Ссылка активна на 08.04.2016.
6. *Соображения относительно согласия при проведении вакцинации детей и подростков в возрасте от 6 до 17 лет*. — Женева: ВОЗ; 2014. [*Soobrazheniya otnositel'no soglasiya pri provedenii vaktsinatsii detei i podrostkov v vozraste ot 6 do 17 let*. Geneva: WHO; 2014. (In Russ).]
7. Конвенция о правах ребенка. [Convention on the rights of the child (In Russ).] Доступно по: http://www.un.org/ru/documents/decl_conv/conventions/childcon.shtml. Ссылка активна на 12.01.2016.
8. Australian Government. Department of Health. The Australian immunization handbook [Internet]. 10th ed. 575 p. Canberra: Australian Government Department of Health; 2015 [updated June 2015]. Available from: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home.
9. Hurst D. Parents who refuse to vaccinate children to be denied childcare rebates. The Guardian [Internet]. 2015 April 11 [cited 2016 Jan 01]:[about 1 page]. Available from: http://www.theguardian.com/society/2015/apr/12/parents-who-refuseto-vaccinate-children-to-be-denied-childcare-rebates-reports. Available from: http://www.theguardian.com/society/2015/apr/12/parents-who-refuse-to-vaccinate-children-to-be-denied-childcarerebates-reports.

10. Cole JP, Swendiman KS. Mandatory vaccinations: precedent and current laws. Congressional research service report [Internet]. Washington: Congressional Research Service; 2014. Available from: http://fas.org/sgp/crs/misc/RS21414.pdf.
11. cdc.gov [Internet] Vaccine Information Statements (VIS) [updated 2014]. Available from: http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html.
12. Government Printing Office, GPO. United States Cord [Internet]. Title 42 - The Public Health and Welfare; Chapter 6A; Subchapter XIX; Part 2; Subpart C; Section 300AA-26 - Vaccine information. Washington: United States Code Government Printing Office, GPO FindLaw; 1989 [cited 2016 Jan 01]. Available from: http://codes.lp.findlaw.com/uscode/42/6A/XIX/2/C/300aa-26#sthash.CHbB1om9.dpuf
13. Министерство здравоохранения США. Центры контроля и профилактики заболеваний. Информационный бюллетень вакцины. [U. S. department of health & human services. Centers for disease control and prevention. Vaccine information statement (In Russ).] Доступно по: http://www.immunize.org/vis/russian_dtap.pdf. Ссылка активна на 08.04.2016.
14. Министерство здравоохранения США. Центры контроля и профилактики заболеваний. Вакцинация против гепатита В рекомендована всем новорожденным. [Hepatitis B shots are recommended for all new babies. (In Russ).] Доступно по: http://www.immunize.org/catg.d/p4110.pdf. Ссылка активна на 08.04.2016.
15. Министерство здравоохранения США. Центры контроля и профилактики заболеваний. Информационный бюллетень вакцины против гепатита В. [U. S. department of health & human services. Centers for disease control and prevention. Hepatitis B VIS. (In Russ).] Доступно по: http://www.immunize.org/vis/russian_hepatitis_b.pdf. Ссылка активна на 08.04.2016.
16. walgreens.com [Internet]. Vaccine Administration Record (VAR) Informed Consent for Vaccination for All Healthcare Providers [cited 2016 Apr 08]. Available from: http://www.walgreens.com/images/IN2097/13FL0002_2013_VAR_form_InStore.pdf.
17. walgreens.com [Internet]. Vaccine administration record (VAR) informed consent for vaccination [updated 2015; cited 2016 Apr 08]. Available from: http://www.walgreens.com/images/IN2097/13FL0002_2013_VAR_form_InStore.pdf.
18. Public Health Agency of Canada. Canadian Immunization Guide [Internet]. [updated 2014 Oct; cited 2016 Apr 08]. Available from: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php.
19. Government of Canada. A Parent's Guide to vaccination [Internet]. [updated 2014 Dec 24; cited 2016 Apr 08]. Available from: http://healthycanadians.gc.ca/publications/healthy-livingvie-saine/parent-guide-vaccination/index-eng.php?_ga=1.167605182.1274827017.1457722374.
20. Public Health Agency of Canada, Novartis, Sanofi Pasteur Ltd. Product Monograph, CPS. Rabies vaccine fact sheet and consent [Internet]. [updated 2012 Aug; cited 2016 Apr 08]. Available from: http://www.sheridancollege.ca/~/media/Files/Sheridan%20College/Life%20At%20Sheridan/Student%20Services/Health/Immunization/Rabies%20consent%20webite.pdf.
21. Le service public de la diffusion du droit. Code de la sante publique [Internet]. [updated 2016 Apr 07; cited 2016 Apr 08]. Available from: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=1F16B3770400D01D4008CDDC1F98B464.tpdila21v_2?cidTexte=LEGITEXT000006072665&dateTexte=20080314.
22. Walkinshaw E. Mandatory vaccinations: The international landscape. Canadian Medical Association Journal. 2011;183(16):1167-1168. doi: 10.1503/cmaj.109-3993.
23. Robert Koch-Institut. Epidemiologisches Bulletin Nr. 38 [Internet]. Available from: https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2014/Ausgaben/38_14.pdf?__blob=publicationFile.
24. Public Health England. Green Book. Immunization against infectious disease [Internet]. [updated 2014 Sept 02; cited 2016 Apr 08]. Available from: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.
25. Lancashire Care NHS Foundation trust. Immunization Consent Form [Internet]. Available from: http://docviewer.yandex.ru/?url=https%3A%2F%2Fwww.lancashirecare.nhs.uk%2Fmedia%2FPublications%2FImmunisation%2520Team%2FHPV%2520Consent%2520Form%2520-%25202%2520doses.doc&name=HPV%20Consent%20Form%20-%202%20doses.doc&lang=en&c=56e2db81e150.
26. Lancashire Care NHS Foundation trust. Human papillomavirus (HPV) Vaccination consent form [Internet]. [cited 2016 Apr 08] Available from:

http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318706/8874-HPV-consentform_04.pdf.
27. Attena F, Abuadili AV, Marino S. The informed consent in Southern Italy does not adequately inform parents about infant vaccination. *BMC Public Health*. 2014;14:211. doi: 10.1186/1471-2458-14-211.
28. Приказ Минздравсоцразвития РФ № 19 н от 26.01.2009 «О рекомендуемом образце добровольного информированного согласия на проведение профилактических прививок детям или отказа от них» // *Российская газета*. 13 мая, 2009:4908 (84). [Decree of the Ministry of Health of the Russian Federation № 19n dated January 26, 2009 «O rekomenduemom obraztse dobrovol'nogo informirovannogo soglasiya na provedenie profilakticheskikh privivok detyam ili otkaza ot nikh». *Rossiiskaya gazeta*. 2009 may 13:4908(84). (In Russ).]
29. Бажанов Н.О., Иваненко Н.С. Информированное добровольное согласие в практике врача-педиатра // *Вопросы современной педиатрии*. — 2012. — Т.11. — №2 — С. 11−13. [Bazhanov NO, Ivanenko NS. Informed voluntary consent in pediatrician practice. Original article. *Current pediatrics*. 2012;11(2):11−13. (In Russ).] doi: 10.15690/vsp.v11i2.205.
30. Решение Октябрьского районного суда г. Ставрополя от 26 марта 2012 года № 2-243/12. [Decision of the Oktyabr'skii Regional Court of Stavropol dated March 26, 2012 № 2-243/12. (In Russ).] Доступно по: http://sudact.ru/regular/doc/dG9UxLHeSa5w. Ссылка активна на 08.04.2016.
31. Приказ ФМБА № 88 от 30 марта 2007 г. «О добровольном информированном согласии на медицинское вмешательство». [Decree of the Federal Bio-Medical Agency № 88 dated March 30, 2007 «O dobrovol'nom informirovannom soglasii na meditsinskoe vmeshatel'stvo». (In Russ).] Доступно по: http://www.consultant.ru/document/cons_doc_LAW_87721. Ссылка активна на: 08.04.2016.