

Ethical and healthcare considerations in relation to mandatory vaccination - Bulgarian perspective

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Abstract

Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The right to health includes access to health services and also involves prevention as part of maintaining public health.

Despite the European Union framework, cases of children being unvaccinated and remaining vulnerable to potentially life-threatening diseases have been observed in Europe. Some of the reasons for this may be the multiple ethical factors to consider in the case of childhood vaccination.

Main aspects of ethical conflict are the rights of a child to protection from illnesses and poor health versus the rights of a parent to make choices for their child.

Some countries have adopted national policy of mandatory immunization, others liberalize their national legislation, after recognizing that mandatory immunization to some infectious diseases is not being enforced. In Bulgarian national legislation, since 2005 has been adopted Ordinance No.15 for the immunizations in the Republic of Bulgaria, issued by the Ministry of Health.

Ethical and healthcare considerations in relation to mandatory vaccination should be examined when establishing effective health policies both on national and international level.

Keywords: Vaccination, ethical conflict, public healthcare, right to health

Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The right to health includes access to health services and also involves prevention as part of maintaining public health.

The realization of the right to health could be pursued through complementary approaches, including the formulation of health policies, or the implementation of health programmes, or the adoption of specific legal instruments (1).

The human right to health is recognized in numerous international instruments, such as the Universal Declaration of Human Rights, The International Covenant on Economic, Social and Cultural Rights, etc. The European Union framework regulation (2) in relation to vaccines is based on Article 168 of the Treaty on the Functioning of the European Union (TFEU), where European Union action complement national policies. Fight against major health scourges includes promoting research into their causes, their transmission and their prevention. Health information, education, monitoring, early warning are crucial in combating serious cross-border threats to health.

Vaccines cause the immune system to develop antibodies (a blood protein that combats infection) against a specific pathogen (disease-causing virus or bacteria) without infecting the individual with that disease. If a person encounters the disease after having been vaccinated, his/her body will be able to develop antibodies as a response in order to combat it. The vaccine triggers an immune response without infecting the individual with the disease itself, because vaccines are developed by, in some way, altering the pathogen. That is why, if a significant percentage of the population is vaccinated, it is difficult for the disease to spread.

In relation to childhood immunization, all European Union countries have a “vaccination schedule” recommending the vaccines to be given at various ages during childhood. Childhood immunisation is the responsibility of individual Member States. Vaccination schemes exist as regards to the professional content, mandatory or voluntary character or financing issues.

However, despite the European Union framework, cases of children being unvaccinated and remaining vulnerable to potentially life-threatening diseases have been observed in Europe. Some of the reasons for this may be the multiple ethical factors to consider in the case of childhood vaccination.

Main aspects of ethical conflict are the rights of a child to protection from illnesses and poor health versus the rights of a parent to make choices for their child. Ethical conflict also appears in the rights of a community or society to be protected from illnesses and poor health versus the right of an individual to personal autonomy. The United Nations Convention on the Rights of the Child is an international human rights treaty regulating the right to health and health services and setting children right to good quality health care – the best health care possible. In article 24 of the Convention is regulated the child’s right to “the highest attainable standard of health”, including access to ‘preventative healthcare’.

The rights of a parent to make choices for their child is regulated in the United Nations Convention on the Rights of the Child, where in article 5 is set the responsibility of the of governments to “respect the rights and responsibilities of families to direct and guide their children so that, as they grow, they learn to use their rights properly”.

When considering the ethical conflict of both rights, it is important to keep in mind that immunisation does not simply benefit the individual by protecting them from disease, but it also provides benefit to the whole population by conferring “herd immunity”. This is a situation where in case of measles, where if 95% of the population is vaccinated against this infection, everyone is protected, including those who are not

vaccinated. The decision of parents not to vaccinate their children poses risk for the entire society, because in that case herd immunity is no longer guaranteed.

Parents objecting to vaccines often claim the right to informed consent, however consent should not override the rights of others to live safely in their communities. Unvaccinated children put the wider public at risk, violating a basic ethical principle of not imposing harms on others.

Despite the coordinated actions on international level for promoting vaccination and preventing the spread of diseases, between 2007 and 2013, the World Health Organization recorded a 348 per cent increase in measles cases in Europe (3).

In 1998 under a Decision No. 2119/98/EC of the European Parliament and of the Council, a network for the epidemiological surveillance and control of communicable diseases in the Community was set up. In 2004, under a EU Regulation(4) was established the European Centre for Disease Prevention and Control (ECDC), which supports activities for the prevention and control of communicable diseases.

In 2011 a Council Conclusion (5) was adopted on childhood immunisation (2011/C 202/02), in which the Member States and the Commission are invited, inter alia, to share experiences and best practices to improve the vaccination coverage of children against vaccine-preventable diseases.

In 2013 the European Parliament and the Council of EU adopted a Decision No. 1082 on serious cross-border threats to health. It repeals Decision No. 2119/98/CE, providing that Member States shall consult each other in liaison with the Commission through the Health Security Committee with a view to coordinating their response to serious cross-border threats to health, including communicable diseases.

In 2014, a third Programme for the Union action in the field of health was established by Regulation (EU) No 282/2014. The Programme, covering the time framework until 2020, aims to support capacity-building against major cross-border health threats and, to develop preparedness and response planning, taking into account complementarity with the work programme of the ECDC in the fight against communicable diseases.

Vaccines are medicinal products subject to the rules and procedures adopted at European Union level. They are authorized by national authorities or by the Commission on basis of assessment carried out by the European Medicines Agency. They are also subject to post-marketing monitoring.

Vaccines have to obtain a marketing authorization, granted after an evaluation of the risk-benefit ratio of the vaccine, before being released on the market. The evaluation of the risk-benefit ratio of the vaccine is based on a dossier presenting the data collected during the development and clinical trials of the product. The evaluation refers to various properties of the product such as safety, efficacy and quality, as well as compliance with good practices in the areas of clinical or laboratory testing and manufacturing.

Some countries have adopted national policy of mandatory immunization, others liberalize their national legislation, after recognizing that mandatory immunization to some infectious diseases is not being enforced, while other countries without a policy of mandatory immunisation encourage families with offers of financial incentives.

In Bulgarian national legislation, since 2005 has been adopted Ordinance No.15 for the immunizations in the Republic of Bulgaria (6), issued by the Ministry of Health. This act outlines the persons who are subject to mandatory target and recommended immunizations and booster vaccination, the procedure, method and timing of immunizations and booster vaccination, as well as the specific requirements and the application of certain serums, immunoglobulins and other biological products for prophylactic purposes. Ordinance No.15 of 2005 also refers to medical contraindications for vaccinations included in the Immunization calendar of the Republic of Bulgaria. In that way adverse reactions following vaccination could be prevented.

On national level, in relation to the pharmacovigilance system, the Bulgarian Drug Agency receives reports on adverse drug reactions. Healthcare professionals are a key source of information about medicines safety, but patients also have the opportunity to report an adverse reaction by filing an electronic report form available on the website of the Bulgarian Drug Agency.

Multiple-choice and open questions are provided to patients in the electronic report form, including a free text box that allows the patient to provide a description of the reaction. When filling in the form, the patient is asked to provide a permission to the Bulgarian Drug Agency to contact the patient's doctor if necessary. Patients are encouraged prior to making a report on adverse drug reaction, to share their experiences with their medical doctor and, if the healthcare professional suspects a direct link between the drug and the observed reaction, then to make a report.

Obligatory planned immunizations and booster vaccinations, according to Ordinance No.15 of 2005, are those against Tuberculosis, Diphtheria, Tetanus, Pertussis, Poliomyelitis, Measles, Mumps, Rubella, Hepatitis type B, Haemophilus influenza type B and Pneumococcal diseases.

The Ministry of Health of the Republic of Bulgaria has the obligation to provide the necessary quantities of vaccines for the implementation of the National immunization calendar. The necessary quantities are being calculated base on estimated birth rate, amount of population by age group according to National Statistics Institute data, the number of doses for each type of vaccine and expected incidence of infectious diseases.

Recommended immunizations and booster vaccinations are performed at the National Immunization and Consultation Center, in the National Center of Infectious and Parasitic Diseases, or in Regional Health Inspections or in medical institutions, where every patient has to pay on his own the price and this activity is fully covered by the national budget. Recommended immunizations and booster vaccinations are carried out at the request of the patient. These include immunizations against Hepatitis A, Hepatitis B, Diphtheria, Tetanus, Pertussis, Poliomyelitis, Measles, Mumps, Rubella, Influenza, Meningococcal, Pneumococcal, Haemophilus type B, Rotavirus infections, Typhoid, Rabies, Yellow fever and Infection with human papilloma virus in individuals out of the immunization age range and those at risk of a different nature (individuals with additional illnesses, individuals traveling to endemic regions, etc.).

The supervision of the of immunotherapy is performed by Regional Health Inspections and includes activities such as: guidance of medical specialists in the process of planning, implementation and monitoring for adverse reactions after vaccination; control over planning, storage and reporting of bio-products, compliance schemes immunization calendar and the level of immunization coverage; analysis of morbidity vaccination diseases, etc.

Based on Decision No. 538 of 12.09.2013, the Council of Ministers of the Republic of Bulgaria adopted a National Program for Prevention of Chronic Non-communicable Diseases, covering the period from 2014 until 2020.

The main objective of the program is to improve public health and enhance the quality of life by reducing premature mortality, morbidity and disability, as the expansion of the epidemic of chronic non-communicable diseases has increased their negative impact on the socio-economic development of the society.

Immunization protects against long-term effects of a disease on a person's health and has significant economic impact in relation to savings on cost of treatment. The protection provided by immunization offers personal benefits as well as benefits for the society in terms of earning capacity, productivity and growth. That is why ethical and healthcare considerations in relation to mandatory vaccination should be examined when establishing effective health policies both on national and international level.

References

1. Economic and social Council, Committee on economic, social and cultural rights, Substantive issues arising in the implementation of the international covenant on economic, social and cultural rights, General Comment No. 14, 2000.
2. Council of the European union, Conclusion on vaccinations as an effective tool in public health, 2014
3. Decision No. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, OJ L 268/1; 03.10.1998
4. Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, OJ L 142, 30.4.2004, p. 1-11
5. Council Conclusion on childhood immunization: Success and challenges of European childhood immunization and the way forward, OJ C 202, 8.7.2011, p. 4-6.
6. Ministry of Health of the Republic of Bulgaria, Ordinance No. 15 of 2005 for the immunizations in the Republic of Bulgaria, State Gazette issue 45 of 31 May 2005.

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