

Medicine and Law

World Association for Medical Law

Volume

39



Number 4

December 2020

Published by William S. Hein & Co., Inc.
Getzville, New York

International Center for Health, Law and Ethics
University of Haifa, Law Faculty, P.O.Box 6451
Haifa 31063, Israel

ISSN 0723-1393



An international publication dealing with medicolegal issues. Articles, court decisions, and legislation on: **Medical law, forensic medicine, sexology and law, psychiatry and law, psychology and law, dentistry and law, nursing law, pharmaceutical law, medical ethics, clinical criminology, drugs, alcohol, child abuse, medical experimentation, genetic engineering, organ transplantation, abortion, contraception, sterilization, euthanasia, religion, AIDS, etc.**

World Association for Medical Law

Manuscripts should be submitted to the Editorial Office:

The International Center for Health, Law and Ethics, University of Haifa, Haifa 31905, Israel

E-Mail: jmedlaw@research.haifa.ac.il

Founder and Editor-in-Chief (1980-2010): Amnon Carmi

Executive Editorial Committee:

Roy G Beran (Australia) (**Editor-in-Chief**)

David Townend (Netherlands) (**Law & Ethics**)

Richard Wilbur (USA) (**Legal Medicine**)

Professor Albert Lee (Hong Kong) (**Medicine, Law and Bioethics**)

Barry Solaiman (Qatar)

Nicola Glover-Thomas (United Kingdom)

(**Interim Editors-in-Chief**)

Administrative Officer: Ava Van Dam;

English Editor: Barry Solaiman;

Graphic Designer: Raul Vergara;

Indexing: Barry Solaiman;

WAML Administrative Officer and Publisher Liaison: Denise McNally;

Previous Editors in Chief: Amnon Carmi

(Founder) (Israel); Mohammed Wattad (Israel)

Editorial Board

Abu Ramadan, Moussa

Adlan, Abdallah

Aguiar-Guevara, Rafael

Bal, Sonny

Beran, Roy

Berger, Ken

Beyleveld, Deryck

Blum, John

Cotler, Miriam

Dangata, Yohanna

Dantas, Eduardo

Den Exter, Andre

Dickens, Bernard

DuMont, Janice

Dute, Joseph

Dutra Caue

Efron, Yael

Ferris, Lorraine

Fimate, Lallukhum

Frenkel, David

Hrevtsova, Radmila

Kassim, Puteri N. J.

Kegley, Jacquelyn

Keidar, Daniella

Khalaila, Rabei

Le Blang, Theodore

Lee, Albert

Lupton, Michael

Martens, Willem

Mester, Roberto

Nissim, Sara

Noguchi, Thomas

Pereira, André G. D.

Piga, Antonio

Rudnick Abraham

Shalata, Abed

Tabak, Nili

Talib, Norchaya

Townend, Prof. David

Van Wyk, Christa

Montanari Vergallo, Gianluca

Weedn, Prof. Victor

Wilbur, Richard

Wolfman, Samuel

Zaremski, Mr. Miles

Subscription Information:

Volume 39: 4 issues will appear in 2020

Worldwide annual subscription rate:

Online only: USD \$155.00

Online and Bound Archive: USD \$285.00

Bound Archive only: USD \$165.00

Place subscriptions with a recognized bookseller or directly with:

William S. Hein & Co., Inc.

2350 North Forest Road, Getzville, New York 14068

1-800-828-7571 * 716/882-2600 * FAX 716/883-8100

mail@wshein.com

www.wshein.com

Advertisement inquiries:

World Association for Medical Law, Denise McNally at worldassocmedlaw@gmail.com

Civil Law

**THE MECHANISM OF THE CIVIL LAW REGULATION OF
MANDATORY VACCINATION POLICIES**

Yurii M. Yurkevych*, Ivan V. Krasnytskyi, Khrystyna B. Romaniv*,
Oksana M. Bronevytska***, Vasyl M. Parasiuk******

Abstract: The main task of any state is to provide everyone, including the child, with the opportunity for a healthy and fulfilling life. Processes of immunisation through vaccination are considered most appropriate for the prevention of infectious diseases. The purpose of this article is to study the civil law regulation of immunisation of the population and to undertake a legal assessment. The authors reviewed legislation on vaccination in different countries. Also, this article identifies and evaluates the judicial approach adopted for resolving conflicts in the field of vaccination in Ukraine. The authors of the study conclude by considering the introduction of mandatory vaccination of children in Ukraine.

Keywords: Prevention of Infectious Diseases; Immunisation Process of the Population; Preventive Vaccinations; World Experience of Vaccination

Introduction

Immunisation among medical interventions in the epidemic process is considered to be one of the most effective and economically feasible strategies

* Department of Civil Law Disciplines, Lviv State University of Internal Affairs, 79000, 26 Gorodotska Str., Lviv, Ukraine.

** Department of Criminal Law and Criminology, Lviv State University of Internal Affairs, 79000, 26 Gorodotska Str., Lviv, Ukraine.

*** Department of Criminal Law Disciplines, Lviv State University of Internal Affairs, 79000, 26 Gorodotska Str., Lviv, Ukraine.

**** Department of Civil Law and Process, Lviv State University of Internal Affairs, 79000, 26 Gorodotska Str., Lviv, Ukraine.

(Fedyak et al., 2018). Timely and high-quality immunisation ensures the right of every child to a healthy and fulfilling life and is one of the main tasks of the state (Gorbachenko, 2016). Vaccination is the most effective method for preventing the development of infectious diseases. Vaccines stimulate the body's immune system to protect it from an infectious disease. A vaccine is a drug made from microorganisms with a weakened infectious agent, which does not cause disease, but leads to the appearance of lymphocytes of immunological memory to this antigen. Many researchers state that vaccinations are one of the most economically justified medical and social achievements of mankind. (Bertoncello et al., 2020; Bianco et al., 2019; Tavoschi et al., 2019). Vaccinations are the result of the evolution of medical science and the consciousness of civil society and the international community (Hendel, 2014). Consequently, the terms "immunisation" and "vaccination" are different because immunisation is the process by which a person acquires immunity, usually by vaccination (Demchenko & Dubitska, 2017).

Increasingly, clinicians, traditional and online media discuss vaccinations, population immunisation to create collective immunity, and the obligation to vaccinate new-borns (Ferdinands et al., 2017). These discussions sometimes divide opinion. Citizens and professional doctors may coalesce into two camps: some advocating vaccinations and their benefit, and others warning against complications that may arise from their use (Demicheli et al., 2018). Thus, in the field of legal regulation of preventive vaccinations in Ukraine, a serious problem is that the health authorities conducting vaccinations and the authorities mandating them do not simultaneously regulate their responsibility for health damage, caused to a particular citizen (Mykytenko & Gomlya, 2018).

In this article, the authors evaluate the legal regulations concerning immunisation in response to growing concerns surrounding parents abandoning compulsory vaccinations for their children.

Statistics and Global Trends in Vaccine Prevention

Undoubtedly, one can argue for international, political and national advocacy in favour of vaccination. This is evidenced by many factors. In particular, the World Health Organisation (WHO) insists on the vaccination of 95% of children (100% coverage cannot be achieved due to contraindications for various reasons, such as immunodeficiency, anaphylactic post-vaccination reactions, neurological disorders, etc.). In 2019, the WHO included the refusal of vaccination in the list of global threats to humanity. This list states that

vaccination is one of the most cost-effective ways to prevent disease, as it currently prevents 2-3 million deaths a year, and another 1.5 million could be avoided if global vaccination coverage is improved (Ten threats to global..., 2019).

According to the General Director of the WHO, Dr. Margaret Chen, “Immunisation is a cornerstone of global health security in an interconnected world where diseases do not adhere to national borders” (Chan et al., 2017). Legislation in countries such as the Netherlands, Estonia, and Latvia gives citizens the right to decide for themselves whether to vaccinate or refuse. (How vaccinations are done..., 2017). President Trump has also been liberal about vaccination issues. With the clear goal of banning mandatory vaccinations across the country, President Trump created a new unit in the administration of health and social services for civil rights and the right of citizens to choose their own health care (Trump Lays Groundwork..., 2018). An example of countries with a different, cardinal position is, in particular, Italy, which, as a result of an imperative health policy, adopted Decree Law No 73 of 7 June 2017 “On Urgent Provisions on Vaccine Prevention”, which provided that vaccination is compulsory for children between the ages of 16 and under the National Vaccination Prevention Plan. As a result of non-compliance with state guidelines, parents will incur substantial penalties. Moreover, the state government has tried to hold parents responsible for refusing to vaccinate their children (Figueroa, 2017).

The WHO recommends continuing routine vaccinations in the context of pandemics and other emergencies. According to the recommendations of the WHO, any interruption of routine immunization, even for a short period, will increase the likelihood of outbreaks of vaccine-controlled infections or increase the number of cases that can be prevented by vaccination.

Legal Regulation and Vaccination Jurisprudence in Ukraine

Ukraine had the lowest vaccination rate in the world in 2016 (Demchenko et al., 2017). This low rate was the impetus needed for the state to take decisive steps away from the existing passive vaccination policy. These moves have also been reinforced by case law seeking to uphold certain constitutional rights, such as the right to education. In particular, the Beryslavsky District Court of the Kherson region concludes in its sentence No 1-124/10 of 12.07.2010 that PERSON_2 is guilty of the crime under Art. 166 of the Criminal Code of Ukraine – the malicious failure of parents to fulfil their legal obligations to care for a child, which has caused grave consequences. The court also included

that in violating their childcare obligations, PERSON_2 was obliged to take care of the health of their child, his physical, spiritual and moral development, to provide him with complete secondary education, to prepare him for an independent life. However, during 2004-2009, PERSON_2, having refused compulsory vaccinations, did not grant their son the right to education by taking sick leave due to the school's refusal to take an unvaccinated child (The judgment of the Beryslavsky..., 2010).

Today, it is common practice for schools to prohibit unvaccinated children from attending kindergartens or schools. For example, on December 28, 2017, at an extraordinary meeting, the Commission on Technogenic and Environmental Safety and Emergencies of the Executive Committee of the Odessa City Council adopted a decision prohibiting children who are unvaccinated against measles from attending schools and kindergartens (The official site..., 2020). Zhytomyr City Council decided to ban non-vaccinated children from attending school (The decision to ban..., 2019). As a consequence, these numerous cases have led to citizens filing petitions and undertaking litigation. If a child has medical contraindications, he is provided with an appropriate certificate based on the data of the obligatory medical preventive examination of the child with the participation of a pediatrician and other specialists. The decision on the admission of such children to educational institutions is made by the commission of doctors of the relevant treatment and prevention institution (List of medical contraindications..., 2019). In the field of health care, the most important policy area is the prevention and treatment of infectious diseases because they are widespread. Without proper legal regulation, it is impossible to ensure the prevention and treatment of infectious diseases. Therefore, an important condition and an integral part of an effective state policy is the formation of a proper legislative framework. The legal field defines the basic parameters and factors, and legal regulation is provided (Kotvitska et al., 2014).

The first regulatory act that regulates vaccination in Ukraine is the Law of Ukraine "On the Protection of the People against Infectious Diseases" (On Protection of the Population..., 2000). According to Part 6 of Art. 12 of this law, preventive vaccinations shall be carried out on adult able-bodied citizens with their consent after providing objective information on vaccinations, the consequences of refusing them and possible post-vaccination complications. Persons who are under fifteen years of age or are recognised as incompetent by law, get preventive vaccinations with the consent of their objectively informed parents or other legal representatives. Persons from the age of fifteen to eighteen years old or recognised by the court, may receive vaccinations

with their consent after being provided with objective information and with the consent of objectively informed parents or other legal representatives of these persons.

According to Art. 16 of the United Nations Convention on the Rights of the Child (1989), no child may be subjected to arbitrary or unlawful interference with the exercise of his or her right to privacy and family life, privacy, correspondence or unlawful encroachment on her honour and dignity. In addition, State Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child (Article 5, 12). According to Art. 5 of the Convention for the Protection of Human Rights and Fundamental Freedoms (1950), everyone has the right to liberty and security of person. However, an exception to this rule may be the lawful detention of persons to prevent the spread of infectious diseases. According to Art. 8 of the Convention, everyone has the right to respect for his private life. Except where the intervention is performed *inter alia*, to protect health. Thus, it is a question of the admissibility of the restriction of individual rights.

According to A. Kasumova (2015), considering the limitations of citizens' rights related to their state of health, they should be defined as "statutory exemptions from the legal status of citizens established for the protection and defence of others, society and the state", and therefore, as scientists argue, compulsory vaccination is the basis for the legitimate restriction of citizens' rights related to their state of health. In the case of post-vaccination complications, every citizen of Ukraine has the right to free treatment, emergency care in health care facilities of state and communal ownership. He must also: undergo a mandatory examination in medical institutions; adhere to the rules of conduct and treatment regimens set by the treating physicians; do not evade rehabilitation measures and follow the instructions aimed at restoring health as soon as possible (Law of Ukraine "On..., 2009).

In the field of infectious disease, Ukraine has encountered a number of problems caused by the imperfection of national legislation regarding compulsory vaccination. In particular, questions regarding infectious diseases to prevent vaccinations, medical support for these procedures, and monitoring of potential complications due to vaccination are needed. In the field of infectious disease prevention, including through vaccination and quarantine measures, the major conflict that has to be eliminated both at the theoretical and the legal enforcement level is how the limits of state intervention in the

private sphere of citizens for the purpose of securing public interest should be achieved (Mykytenko & Gomlya, 2018; Khadzhyradieva et al., 2020).

One can agree with the conclusions of V.M. Pashkov (2018), that the analysis of certain aspects of human rights in the field of health care and the correlation of these rights with other fundamental rights and freedoms, in particular with the right to education, work, as well as freedom of religion and belief, proves that in the establishment of these rights and freedoms the policy is haphazard and chaotic. Therefore, mainly political interests and populist decisions outweigh the interests of citizens, and the right decisions are not always made on the priority of securing fundamental rights and freedoms.

Case Law of the European Court of Human Rights in Vaccination Cases

A citizen has the opportunity to pursue the lifestyle he chooses of his own volition and to pursue an activity that is perceived as harmful or dangerous to the health (physical condition) of that citizen. For the principles of self-determination and personal autonomy, freedom of choice and self-determination are themselves fundamental components of life. Therefore, the freedom to agree or refuse a particular treatment or to choose an alternative treatment is of primary importance and in the absence of any indication of the need to protect third parties. For example, by compulsory vaccination of the population during an epidemic, the state should refrain from interfering with the freedom of choice of citizens in health matters, since such interference can only reduce, not increase life values (The judgment of the Beryslavsky..., 2010).

The most relevant to the vaccination issue are two European Court of Human Rights (ECHR) decisions: the “Jehovah’s Witnesses Religious Community in Moscow v. Russia” of June 10, 2010 and “Solomakhin v. Ukraine” of March 15, 2011. According to the decision of the ECHR in the case:

“Religious Community of Jehovah’s Witnesses in Moscow v. Russia” of June 10, 2010, “the freedom to agree or refuse a specific method of treatment or to choose an alternative method of treatment is of paramount importance to the principles of self-determination and personal autonomy... However, to preserve the meaning of this freedom it is necessary the patient to have the right to make decisions in accordance with their own views and values, no matter how irrational, unreasonable and short-sighted they may seem to others... freedom of choice and self-determination are themselves fundamental components of life and in the absence of any signs of the need to

protect third parties, such as through forced vaccination during an epidemic, the state should refrain from interfering with the freedom of choice of citizens in health matters, as such it can only devalue, not elevate, the value of life” (Jehovah’s Witnesses Religious..., 2010).

In its ECHR judgment in the case “Solomakhin v. Ukraine” of March 15, 2011, the court stated that “in accordance with its practice, the physical inviolability of a person is covered by the concept of “private life” that is protected by Article 8 of the Convention (see the judgment of 26 March 1985 in the case “X and Y v. the Netherlands” (par. 22, Series A, No 91). The Court emphasised that a person’s physical integrity concerns the most intimate aspects of privacy and that mandatory medical intervention, even minor, constitutes an interference with that right (see Y.F. v. Turkey, claim No 24209/94, paragraph 33, ECHR 2003 IX, with further references). Compulsory vaccination, as a compulsory medical measure, is an interference with the right to respect for a person’s privacy, which includes the physical and psychological inviolability of the individual, guaranteed by Article 8. However, “the violation of the applicant’s physical integrity may be considered justified by the public health considerations and the need to control the spread of infectious disease in the area... necessary precautions have been taken to ensure that the medical intervention does not harm the applicant to the extent that this would violate the balance of the applicant’s personal integrity and public health interests”.

In authors’ opinion, taking into account the other ECHR’s decisions mentioned above and the words “the need to control the spread of infectious disease in the area”, the decision nevertheless refers to the exception that follows from Art. 8 of the United Nations Convention on the Rights of the Child (1989) “except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country ... for the protection of health or morals, or for the protection of the rights and freedoms of others”. Therefore, it is not the case that the vaccination should be compulsory, but that in the event of a critical epidemiological situation, the state has the right to oblige individuals to be vaccinated.

Conclusion

The issue of mandatory vaccination in Ukraine should be resolved not by the legal positions of the Supreme Court, but by the laws, which are determined in accordance with the Constitution and international obligations. Such a step is also necessary to ensure that the state’s criminal law policy in the research

field is clear.

Today, the existence of diametrically opposed positions in the jurisprudence regarding the resolution of the obligation to vaccinate people imposes its mark on criminal law regulation in this field. To begin with, if vaccination is not compulsory, then all cases of obstruction to “non-vaccinated” persons from accessing the exercise of their rights should receive a criminal law evaluation. We can say that the legislation in the field of legal relations of responsibility for refusal of vaccination and (or) consent to its implementation needs to be revised because there is a need for new approaches to these and other ways to solve problems in their enforcement. At the same time, a prerequisite for ensuring a clear and transparent state policy in Ukraine, and therefore unity in law enforcement, is the adoption in accordance with the Constitution of Ukraine and taking into account the international obligations that have been undertaken, which would clearly regulate the obligatory nature (or non-obligatory) of vaccination procedures.

Bibliography

Bertoncello, C., Ferro, A., Fonzo, M., Zanovello, S., Napoletano, G., Russo, F., Baldo, V., & Cocchio, S. (2020). Socioeconomic determinants in vaccine hesitancy and vaccine refusal in Italy. *Vaccines*, 8(2), Article number 276, 1-9

Bianco, A., Mascaro, V., Zucco, R., & Pavia, M. (2019). Parent perspectives on childhood vaccination: How to deal with vaccine hesitancy and refusal? *Vaccine*, 37(7), 984-990.

Chan, M., Elias, C., Fauci, A., Lake, A., & Berkley, S. (2017). Reaching everyone, everywhere with life-saving vaccines. *The Lancet*, 389(10071), 777-779.

Convention for the Protection of Human Rights and Fundamental Freedoms. (1950). Retrieved from https://www.echr.coe.int/Documents/Convention_UKR.pdf

Demchenko, I., Kozhan, N., Goltsas, L., & Fenchak, A. (2017). *Factors influencing parents' commitment to vaccination: Results of a study*. Socio Consulting Analytical Centre.

Demchenko, I.S., & Dubitska, N.T. (2017). Compulsory vaccination regulations: *Pros and cons*. *Journal of Kiev University of Law*, 4, 133-138.

Demicheli, V., Jefferson, T., Ferroni, E., Rivetti, A., & Di Pietrantonj, C. (2018). Vaccines for preventing influenza in healthy adults. *Cochrane Database of Systematic Reviews*, 2, Article number CD001269.

Fedyak, I.O., Bilyk, I.P., & Mateiko, G.B. (2018). Focus on vaccination: The view of doctors and parents and an analysis of its pharmaceutical provision for managed pediatric bacterial infections. *Pharmaceutical Journal*, 1, 139-151.

Ferdinands, J.M., Fry, A.M., Reynolds, S., Petrie, J.G., Flannery, B., Jackson, M.L., & Belongia, E.A. (2017). Intraseason waning of influenza vaccine protection: Evidence from the US influenza vaccine effectiveness network, 2011-2012 through 2014-2015. *Clinical Infectious Diseases*, 64(5), 544-550.

Figueroa, D. (2017). Italy: Vaccinations for children made mandatory. *Library of Congress*. Retrieved from <http://www.loc.gov/law/foreignnews/article/italy-vaccinations-for-children-made-mandatory>

Gorbachenko, O. (2016). Immunisation as a pledge of epidemic well-being of the population. *Library of Family Doctor and Family Nurse*, 5, 43-45.

Hendel, N.V. (2014). *International legal regulation of state cooperation in the field of health care*. National University "Odessa Law Academy".

How vaccinations are done to children in 25 countries: vaccination waivers and penalties. (2017). *UkrMedia*. Retrieved from <https://en.media/medicine/325630/>

Jehovah's Witnesses Religious Community in Moscow v. Russian Federation: The decision of the European Court of Human Rights. (2010). Retrieved from <https://www.portal-credo.ru/site/?act=lib&id=2743>

Kasumova, A. (2015). Restrictions on citizens' rights related to their health status. *Law & Society*, 4(4), 73-79.

Khadzhyradieva, S., Slukhai, S., & Rachynskyi, A. (2020). Public administration in Ukraine: adjusting to European standards. *NISPAcee Journal of Public Administration and Policy*, 13(1), 81-108.

Kotvitska, A.A., Kubareva, I.V., & Kononenko, O.V. (2014). *Investigation of legal aspects of planned childhood vaccination in Ukraine*. Publishing House of the National University of Pharmacy.

Law of Ukraine “On Vaccine Prevention of Infectious Diseases”. (2009). Retrieved from http://search.ligazakon.ua/l_doc2.nsf/link1/JF3OQ00A.html

List of medical contraindications and warnings for preventive vaccinations. (2019). Retrieved from <https://zakon.rada.gov.ua/laws/show/z1161-11#Text>

Mykytenko, D., & Gomlya, I. (2018). Problematic issues of liability for damage caused by vaccination. Scientific Journal “*ΛΟΓΟΣ. The Art of Scientific Mind*”, 1, 134-138.

On Protection of the Population Against Infectious Diseases: Law of Ukraine No 1645-III. (2000). Retrieved from <https://zakon.rada.gov.ua/laws/show/1645-14>

Pashkov, V.M. (2018). Vaccination history: Legal nihilism and medical. *Pharmacy*, 12(1133). Retrieved from <https://www.apteka.ua/article/451216>

Tavoschi, L., Quattrone, F., Agodi, A., & Lopalco, P.L. (2019). Risk of transmission of vaccine-preventable diseases in healthcare settings. *Future Microbiology*, 14(9s), 9-14.

Ten threats to global health in 2019. (2019). *World Health Organisation*. Retrieved from <https://www.who.int/emergencies/ten-threats-to-global-health-in-2019>

The decision to ban children from school without discrimination – discrimination against children – parents. (2019). *Aloud*. Retrieved from <https://www.vgolos.zt.ua/rishennya-pro-zaboronu-vidviduvaty-shkolu-bez-pryvyvok-dyskryminatsiya-ditey-batky/>

The judgment of the Beryslavsky District Court of Kherson region No 1-124/2010. (2010). Retrieved from <http://reyestr.court.gov.ua/Review/10495981>

The official site of the Department of Civil Protection, Defence Work and Cooperation with Law Enforcement Agencies of the Odessa Regional State Administration. (2020). Retrieved from <http://guns.odessa.gov.ua/en/>

Trump Lays Groundwork to Ban Mandatory Vaccinations Across U.S. (2018). NewsPunch. Retrieved from <https://newspunch.com/trump-ban-mandatory-vaccinations/>

United Nations Convention on the Rights of the Child. (1989). https://zakon.rada.gov.ua/laws/show/995_021